

FINAL REPORT

Test Facility Study No. 20256434

Sponsor Reference [REDACTED]

A Combined Fertility and Developmental Study (Including Teratogenicity and Postnatal Investigations) of [REDACTED], BNT162b2 and [REDACTED] by Intramuscular Administration in the Wistar Rat

GLP Study

SPONSOR:

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PPD

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QUALITY ASSURANCE STATEMENT

This study has been audited by Quality Assurance in accordance with the applicable Good Laboratory Practice regulations. Reports were submitted in accordance with Standard Operating Procedures as follows:

QA INSPECTION DATES

Date(s) of Audit	Phase(s) Audited	Dates Findings Submitted to:	
		Study Director	Study Director Management
29-Jun-2020 – 30-Jun-2020	Final Study Plan	30-Jun-2020	30-Jun-2020
23-Jul-2020	Study Plan Amendment 01	23-Jul-2020	23-Jul-2020
02-Oct-2020	Study Plan Amendment 02	02-Oct-2020	02-Oct-2020
14-Sep-2020	Physical development	14-Sep-2020	14-Sep-2020
23-Nov-2020 – 04-Dec-2020	Report Tables	04-Dec-2020	04-Dec-2020
23-Nov-2020 – 04-Dec-2020	Report – Materials and Methods	04-Dec-2020	04-Dec-2020
23-Nov-2020 – 04-Dec-2020	Data Review – Formulations	04-Dec-2020	04-Dec-2020
23-Nov-2020 – 04-Dec-2020	Data Review – Technical Operations	04-Dec-2020	04-Dec-2020
23-Nov-2020 – 04-Dec-2020	Data Review – Clinical Pathology	04-Dec-2020	04-Dec-2020
23-Nov-2020 – 04-Dec-2020	Data Review – Necropsy	04-Dec-2020	04-Dec-2020
23-Nov-2020 – 04-Dec-2020	Report	04-Dec-2020	04-Dec-2020
07-Dec-2020 - 10-Dec-2020	Report - Results	10-Dec-2020	10-Dec-2020

In addition to the above-mentioned audits, process-based and routine facility inspections were also conducted during the course of this study. Inspection findings, if any, specific to this study were reported by Quality Assurance to the Study Director and Management and listed as a Phase Audit on this Quality Assurance Statement.

The Final Report has been reviewed to assure that it accurately describes the materials and methods, and that the reported results accurately reflect the raw data.

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Quality Assurance Auditor

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GLP COMPLIANCE STATEMENT AND REPORT APPROVAL

The study was performed in accordance with OECD Principles of Good Laboratory Practice as required in Directive 2004/10/EC of the European Parliament and of the Council of 11 February 2004, Bonnes Pratiques de Laboratoire, Ministère de l'Emploi et de la Solidarité Française, No. 2000/5bis, arrêté du 14/03/2000.

OECD Principles of Good Laboratory Practice are accepted by Regulatory Authorities throughout the European Union, United States of America (FDA and EPA), and Japan (MHLW, MAFF, and METI) and other countries that are signatories to the OECD Mutual Acceptance of Data Agreement.

Exceptions from the above regulations are listed below.

- Antibody analysis (Appendix 26) was not conducted in compliance with GLP but in accordance with the Good Clinical Laboratory Practice (GCLP). This Test site was selected by the Sponsor because it has the most appropriate experience concerning the measurement of neutralizing antibody titres against the SARS-CoV-2 live virus by Microneutralization CPE-based method. The delegated phase for antibody analysis was fit for purpose, performed in adherence to the facilities SOPs and working instructions, by a research facility with proper expertise, and adequate history and by individuals specially trained in this technique (according to VisMederi management of personnel procedure). This exception did not adversely affect the outcome or interpretation of this study because the methods included appropriate controls to provide reliable data and analyses according to data integrity principles and local QA Report review will ensure compliance to internal procedures.

PPD



PPD PhD
Study Director

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1. RESPONSI PERSONNEL

Role/Phase	A	Name	Contact Information
Study Director		PPD, PhD	Address as cited for Test Facility
Test Facility Management		PPD, General Director	Address as cited for Test Facility
Test Facility QAU		PPD, MSc, Chemical Engineer	Address as cited for Test Facility
Principal Investigator (PI)			
Role/Phase	Compliance	Name	Contact Information
Serum Antibody Analysis ^a	No (compliance with the GCLP)	PPD	VisMederi Srl Strada del Petriccio e Belriguardo, 35 53100 Siena, Italy

^a: Test Site selected by the Study Sponsor in agreement with the Study Director.

2. ABSTRACT

The objective of this study was to assess the potential effects of [REDACTED] CCI [REDACTED], BNT162b2 and [REDACTED] CCI [REDACTED], vaccine development candidates to prevent Covid-19, and the concomitant immune response, on fertility and pre and postnatal development in the female Wistar (CRL:WI[Han]) rat.

[REDACTED] CCI [REDACTED], BNT162b2 and [REDACTED] CCI [REDACTED] were administered intramuscularly (IM) to F0 female Wistar rats 21 and 14 days before the start of mating (M-21 and M-14, respectively) and then on Gestation Day (GD) 9 and GD20, for a total of 4 dose days. A separate control group was administered saline by the same route and regimen. Each dose group consisted of 44 F0 females, 22 rats assigned to the caesarean subgroup, and 22 rats assigned to the littering subgroup. Each dose consisted of 30 µg mRNA /dosing day (0.06 mL/dose) IM injection in alternating quadriceps muscles.

Following completion of a mating phase with untreated males, 22 rats per group (nominally) underwent caesarean section on GD21 and were submitted to routine embryo-fetal development evaluations (caesarean subgroup). The remaining 22 rats per group (nominally) were allowed to litter and development of the offspring was observed up to weaning on Postnatal Day (PND) 21 (littering subgroup).

The following parameters and end points were evaluated in all F0 animals: Survival, clinical signs, body weights, body weight gains, food consumption, estrous cycles, mating performance, fertility and macroscopic observations. F0 females assigned to the caesarean subgroup were further examined for ovarian and uterine contents, gravid uterine weights and fetuses were evaluated for viability, sex, body weights, and external, visceral, and skeletal morphology. F0 females assigned to the littering subgroup were allowed to deliver naturally, and were further assessed for parturition, lactation, and maternal behavior, and were monitored to the day of euthanasia on Lactation Day (LD) 21. F1 offspring were assessed for survival, clinical signs, body weights, physical development (pinna unfolding and eye opening), preweaning auditory and visual function tests to screen for normal neurodevelopment, and macroscopic observations.

Blood samples were collected before administration of the first dose (baseline) and on the first day of cohabitation for each F0 female (both subgroups), on GD21 (caesarean subgroup), and on LD21 (littering subgroup females). Blood samples were also collected on GD21 from viable fetuses in each available litter (caesarean subgroup) and on PND21 from pups from each available litter (littering subgroup). Blood samples were evaluated for neutralizing antibody titres against SARS-CoV-2 live virus.

There were no deaths throughout the study related to any of the 3 vaccine candidates.

Intramuscular administration of [REDACTED] CCI [REDACTED], BNT162b2 and [REDACTED] CCI [REDACTED], before and during gestation to female Wistar rats resulted in non-adverse clinical signs and macroscopic findings localized to the injection site as well as transient, non-adverse body weight and food consumption effects after each dose administration. These maternal findings are all consistent with administration of a vaccine and an inflammatory/immune response.

There were no effects on estrous cycles, pre-coital interval, mating, fertility and pregnancy index, or on any ovarian, uterine, or litter parameters, including F1 pre and postnatal survival, growth, external, visceral, and skeletal morphology, or effects on pre-weaning physical and functional development of the F1 pups related to any of the 3 vaccine candidates.

Administration of 4 doses (2 prior to mating and 2 during gestation) of [CCI], BNT162b2, or [CCI] elicited SARS-CoV-2 neutralizing antibody responses in the majority of females just prior to mating (M-14), at the end of gestation (GD21), and at the end of lactation (LD21). SARS-CoV-2 neutralizing titers were detected in most offspring (fetuses on GD21 and pups on PND21). SARS-CoV-2 neutralizing antibody titers were not observed in animals prior to vaccine administration or in saline-administered control animals.

In conclusion, intramuscular administration of [CCI], BNT162b2 and [CCI] before and during gestation to female Wistar (CRL:WI[Han]) rats was associated with non-adverse effects (body weight, food consumption and effects localized to the injection site) after each dose administration. There were no effects of any of the 3 vaccine candidates on mating performance or fertility in F0 female rats or on embryo-fetal or postnatal survival, growth, or development of the F1 offspring. An immune response was confirmed in F0 female rats following administration of each vaccine candidate and these responses were also detectable in the F1 offspring (fetuses and pups).

3. INTRODUCTION

The objective of this study was to assess the potential effects of [REDACTED], BNT162b2 and [REDACTED], vaccine development candidates to prevent Covid-19, and the concomitant immune response, on fertility and pre and postnatal development in the female Wistar (CRL:WI[Han]) rat.

The design of this study was based on Guidelines from the International Conference on Harmonization, S5(R3) Detection of Reproductive and Developmental Toxicity for Human Pharmaceuticals; Department of Health and Human Services, Food and Drug Administration (FDA), 2006 Guidance on Developmental Toxicity Studies in Vaccines for Infectious Disease Indications; WHO guidelines on nonclinical evaluation of vaccines.

The Study Plan, the last Study Plan amendment, and deviations are presented in Appendix 1.

Study Initiation Date

(Study Plan signed by the Study Director): 26 Jun 2020.

Experimental Starting Date

(First date of study-specific data collection):

29 Jun 2020.

Postnatal Development - Littering Subgroup:

Animal Arrivals: Females: 29 Jun 2020.

Males: 10 Aug 2020.

Initiation of Predose Estrous Cycle Monitoring:

13 Jul 2020.

First Injection (Day 1 = M-21):

27 Jul 2020.

Start of Mating (M1):

From 17 Aug 2020.

Littering (LD0):

From 09 Sep 2020.

Necropsy of Dams and Pups (LD21/PND21):

From 30 Sep 2020.

Embryo-Fetal Development - Cesarean Subgroup:

Animal Arrivals:

Females: 13 Jul 2020.

Males: 10 Aug 2020.

Initiation of Predose Estrous Cycle Monitoring:

27 Jul 2020.

First Injection (Day 1 = M-21)

10 Aug 2020.

Start of Mating (M1):

From 31 Aug 2020.

Cesarean Sections (GD21):

From 22 Sep 2020.

Experimental Completion Date (Last necropsy):

12 Oct 2020.

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4. MATERIALS AND METHODS

4.1. Test Materials

4.1.1. Test Items Characterization

The Sponsor provided to the Test Facility documentation of the identity, strength, purity, composition, and stability for the test items. Certificates of analysis were provided to the Test Facility and are presented in Appendix 2.

The characterization of the test items was conducted in a GMP environment (information provided by the Study Sponsor on 30 Nov 2020).

The Sponsor has appropriate documentation on file concerning the method of synthesis, fabrication or derivation of the test items, and this information is available to the appropriate regulatory agencies should it be requested.

4.1.2. Test Material Identification

Text Table 1
Test Item Identification

	Test Item 1	Test Item 2	Test Item 3
Identification:	CCI	BNT162b2	CCI
Alternate Identification:	CCI	CoVAC	CCI
Batch No.:	CCI	RBP020.2 LNP	CCI
Lot No.:	CCI	CoVAC/270320	CCI
Physical Description:	White to off-white suspension	White to off-white suspension	White to off-white suspension
Expiry Date:	10 Jan 2021	27 Nov 2020	04 Dec 2020
Correction Factor:	None	None	None
Concentration (RNA Content):	508 µg/mL	508 µg/mL	531 µg/mL
Storage Conditions:	Temperature set to maintain -80°C		
Provided by:	Sponsor		

Text Table 2
Control Item Identification

	Control Item
Identification:	Sterile physiological saline (0.9% NaCl)
Alternate Identification:	N/A
Batch/Lot Nos.:	905098 and 912642
Expiry Dates:	30 Apr 2022 and 30 Nov 2022 respectively
Storage Conditions:	Ambient temperature
Provided by:	Test Facility

N/A: Not Applicable.

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4.2. Reserve Samples

For each batch (lot) of test items supplied by the Sponsor, a reserve sample (1 unit) was collected and maintained under the appropriate storage conditions by the Test Facility.

4.3. Test Items Inventory and Disposition

The test materials (e.g., test items) were received by the Test Facility for distribution as needed. Records of the receipt, distribution, storage, and disposition of test materials are maintained. All unused Sponsor supplied bulk test materials, with the exception of the reserve samples, were returned to the Sponsor after the in-life period.

4.4. Dose Dispensing and Analysis

4.4.1. Preparation of Formulations

The test items and control item were supplied as a ready-to-use formulations and were dispensed as needed to the animal facility.

Text Table 3
Formulation Frequency of Preparation

Dose Formulation	Administration Dose Form	Frequency of Preparation	Storage Conditions
Control item	Solution	On each day of administration	Immediately dispensed at ambient temperature
Test item	Suspension	On each day of administration	Immediately dispensed at ambient temperature

Any residual volumes from each dosing occasion were discarded. Fresh vials were thawed for each administration.

4.4.2. Sample Collection and Analysis

The test items were used as received from the Sponsor; therefore, samples for dose formulation analysis were not collected by the Test Facility.

4.4.2.1. Stability and Homogeneity

The Sponsor has provided data that demonstrate that the test items formulations are stable and homogenous when stored under the same conditions as those used in the present study, as follows:

- Stable at a concentration of 0.5 mg/mL for 12 weeks at -80°C.
- Stable at a concentration of 0.5 mg/mL for at least 1 month at room temperature (information provided by the Study Sponsor on 03 Dec 2020).
- Homogenous for at least 6 hours following gentle inversion.

Homogeneity data provided by the Sponsor are retained in the study records (Study No. VR-VTR-10681). The Homogeneity Report is presented in Appendix 3.

4.5. Test System

4.5.1. Receipt

On 29 Jun 2020 and 13 Jul 2020 (females) and 10 Aug 2020 (males), Wistar rats CRL:WI(Han) were received from Charles River Laboratories France, PPD. Virgin females were 11 weeks old and weighed between 179.3 and 265.4 g at the initiation of dosing and virgin males (untreated) were 11 weeks old and weighed between 328.4 g and 415.9 g at arrival.

4.5.2. Justification for Test System and Number of Animals

At this time, studies in laboratory animals provide the best available basis for extrapolation to humans and are required to support regulatory submissions. Acceptable models which do not use live animals currently do not exist.

The rat was chosen as the animal model for this study as it is an accepted rodent species for preclinical toxicity testing by regulatory agencies. It mounts an immune response to the vaccines tested that is similar to the expected human response after vaccination.

The total number of animals to be used in this study is considered to be the minimum required to properly characterize the effects of the test item and its immune response. This study has been designed such that it does not require an unnecessary number of animals to accomplish its objectives.

4.5.3. Animal Identification (F0 Males and F0 Females)

Subcutaneously implanted electronic identification chip.

4.5.4. Environmental Acclimation

All animals received a clinical inspection for ill-health on arrival. Acclimation period was 28 days before the start of dosing for females and 7 days before the start of mating for males.

4.5.5. Selection, Assignment, Replacement, and Disposition of Animals

After arrival, animals were randomly assigned to groups.

The disposition of all animals was documented in the study records.

4.5.6. Husbandry

4.5.6.1. Housing

Housing: Single or group housed.

Caging: Plastic cages containing appropriate bedding.

The animals were caged as follows (see Appendix 1):

Phase	Number of Animals per Cage	
	Males	Females
Pre-mating	up to 4	up to 5
Mating	1 male + 1 female housed together	
Gestation of F0 generation	up to 4	1
Lactation of F0 generation	-	1 + litter

-: Not applicable.

Cage Identification: Color-coded cage card indicating study, group, animal number(s), and sex.

Animals were separated during designated procedures/activities or were separated as required for monitoring and/or health purposes, as deemed appropriate by Study Director and/or clinical veterinarian. Cages were arranged on the racks in group order. Where possible, control group animals were housed on a separate rack from the test item-treated animals.

4.5.6.2. Animal Enrichment

For environmental enrichment, animals were provided with items such as a wooden gnaw block and shredded paper, except when interrupted by study procedures/activities. It is considered that there are no known contaminants in the enrichment that could interfere with the outcome of the study.

4.5.6.3. Environmental Conditions

The targeted conditions for animal room environment were as follows:

Temperature: 19°C to 25°C.

Humidity: $\geq 35\%$.

Light Cycle: 12 hours light and 12 hours dark (except during any designated procedures).

Dimmed lighting appeared 15 minutes before the lights were switched on and disappeared 15 minutes after the lights were switched off.

Ventilation: 10 or more air changes per hour.

Environmental conditions were within the targets throughout the study.

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4.5.6.4. Food

Diet: Complete rodent diet (Reference No. A04C-10, Safe), sterilized by irradiation.

Type: Pellets.

Frequency: *Ad libitum*, except during designated procedures.

Analysis: Each batch of diet is supplied with a certificate of analysis which is verified and authorized for release by a veterinarian. Certificates of analysis are maintained in the archives of the Test Facility. It is considered that there are no known contaminants in the feed that would interfere with the objectives of the study.

4.5.6.5. Water

Type: Softened and filtered (0.2 µm) municipal drinking water.

Frequency/Ration: Freely available to each animal (except during designated procedures) (see Appendix 1).

Analysis: Analysed at least twice a year for chemical and bacterial contaminants by Laboratoire Santé Environnement Hygiène de Lyon, France. Certificates of analysis for the drinking water are maintained in the archives of the Test Facility. It is considered that there are no known contaminants in the water that could interfere with the outcome of the study.

4.5.6.6. Veterinary Care

Veterinary care was available throughout the course of the study, and animals were examined by the veterinary staff as warranted by clinical signs or other changes. All veterinary examinations were documented in the study records and reviewed by the Study Director (details are kept in the raw data).

4.6. Experimental Design

Text Table 4
Experimental Design of the F0 Generation

Group No.	Test Material	Dose (µg mRNA)	Dose Volume (mL)	Dose Concentration (mg/mL)	Number and Identification of Animals	
					Caesarean Subgroup	Littering Subgroup
1	Control item	0	0.06	0	22 (1 to 22)	22 (201 to 222)
2	CCI	30	0.06	0.5	22 (23 to 44)	22 (223 to 244)
3	BNT162b2	30	0.06	0.5	22 (45 to 66)	22 (245 to 266)
4	CCI	30 ^a	0.06	0.5	22 (67 to 88)	22 (267 to 288)

^a: 30 µg RNA/dosing day was the targeted dose level. However, based on the actual RNA concentration, this group received 32 µg RNA/dosing day.
Identification of untreated males: 301 to 388.

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4.6.1. Administration of Test Materials

Only F0 females were treated, males were not treated.

Dose Route:	Intramuscular injection into the quadriceps alternating on each dosing occasion.
Frequency (4 occasions):	21 days (M-21) and 14 days (M-14) before the start of the mating phase, and on GD9 and GD20.
Method:	<p>The hair of the animals on the injection area was clipped prior to the first injection and then as necessary during the dosing period. The animals were temporarily restrained for dose administration. The test item was administered under light isoflurane anaesthesia. The total volume for each dose was administered at 1 injection site in the quadriceps using an appropriate syringe and needle (BD Microfine Syringes). The right and left quadriceps were used in rotation.</p> <p>Each vial was gently inverted 3 times before the first dosing to ensure homogeneity according to the Study Sponsor (see Appendix 3).</p>

4.6.2. Justification of Route and Dose

The intramuscular route of exposure was selected because this is the route of human exposure. The dose administered was the highest absolute dose considered for Women of Childbearing Potential.

4.7. In-Life Procedures, Observations, and Measurements

The in-life procedures, observations, and measurements listed below were performed as specified. Untreated males were weighed, observed for morbidity and mortality and any abnormal clinical observations were recorded. These data are retained in the raw data but are not reported.

4.7.1. Mortality/Moribundity Checks

Throughout the study, all F0 females were observed for general health/mortality and moribundity at least twice daily, except on days of receipt and study termination where frequency was at least once daily. Animals were not removed from the cage during observation, unless necessary for identification or confirmation of possible findings.

F1 pups were counted daily during the preweaning phase.

4.7.2. Clinical Observations

4.7.2.1. Cage Side Observations

Cage side observations were performed at least once daily on non-dosing days for F0 females.

During the dosing period, cage side observations were performed before and at least once after dosing for F0 females. Animals were not removed from the cage during observation, unless necessary for identification or confirmation of possible findings.

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4.7.2.2. Detailed Clinical Observations

All F0 females were removed from the cage and a detailed clinical observation was performed weekly during the pre-mating period then on each weighing day during the gestation and lactation periods.

4.7.3. Body Weights

Individual body weights for F0 females were recorded as follows:

- At least weekly pretest, and twice weekly during the pre-mating and mating periods (only pre-mating data are reported).
- On GD0, GD6, GD9, GD12, GD15, GD18, GD21.
- On LD1¹, LD4, LD7, LD10, LD14, LD17 and LD21 (littering subgroup only).

During the lactation phase, offspring were weighed on PND1, PND4, PND7, PND10, PND14, PND17 and PND21.

4.7.4. Food Consumption

Food consumption of F0 females was recorded for the periods (days):

- Once weekly from Day 1 during pre-mating period.
- From GD0 to GD6, GD6 to GD9, GD9 to GD12, GD12 to GD15, GD15 to GD18, GD18 to GD21.
- From LD1 to LD4, LD4 to LD7, LD7 to LD10, LD10 to LD14, LD14 to LD17 and LD17 to LD21 (littering subgroup only).

4.7.5. Estrous Cycles

Vaginal smears were taken daily and used to determine the cycle stage for each F0 female throughout a 14-day pre-dosing period, then for 2 weeks before mating and during cohabitation until confirmation of GD0.

4.7.6. Mating

Animals were paired on the basis of 1 male and 1 F0 female from the same group (not siblings) for a maximum of 14 days.

The day of mating was confirmed by the presence of sperm in a vaginal smear or a vaginal plug and was recorded as GD0.

Mated females were separated from the males once mating had been confirmed and smearing ceased or when the appearance of the female suggested pregnancy from an undetected mating.

The same untreated males were used to mate both subgroups.

¹: F208 (Control, 0 µg) and F263 (BNT162b2, 30 µg) were additionally weighed on LD0.

4.8. Pregnancy and Parturition (Littering Subgroup Females)

For each littering subgroup female, the following data were recorded:

- Date of mating (GD0).
- Date of parturition (LD0).
- Duration of gestation.
- Abnormalities of nesting or nursing behaviour.
- Number of implantation sites (at necropsy after staining with ammonium sulphide solution).

4.9. Litter Data (Littering Subgroup Females)

For each littering subgroup litter, the following data were recorded pre-weaning:

- Number of pups born (live and dead).
- External abnormalities of the pups.
- Number, weight and sex of pups on PND1, PND4, PND7, PND10, PND14, PND17 and PND21.
- Physical development of the offspring, as assessed by the intra-litter onset and duration of pinna unfolding from PND1 and eye opening from PND12.
- Behavioural and functional tests in all pups as follows:
 - Pupillary reflex and auditory reflex on PND21.
- External and necropsy findings of dead pups.

On PND4, the size of each litter was adjusted (culling) to 8 pups, where possible, by eliminating extra pups by random selection to yield where possible 4 males and 4 females per litter. Extra pups were euthanized by an intraperitoneal injection of sodium pentobarbitone.

Justification of the culling procedure: The culling of litters to a standard size is given as an optional procedure in the ICH SR(R3) regulatory guideline. Scientific opinion remains divided regarding the justification of culling (see Section 11). It was therefore decided to use culling in this study in order to be consistent with the historical data compiled by the Test Facility.

4.10. Antibody Evaluation

4.10.1. Antibody Sample Collection

Samples were collected according to Text Table 5.

Text Table 5
Antibody Sample Collection

Group Nos.	Number of Females	Predose on Days of Dosing		Necropsy (GD21 or LD21/PND21) ^b
		Pretest	M0 ^a	
1 to 4	All F0 females	X	X	X
1 to 4	Selected fetuses from all litters of caesarean subgroup	-	-	X
1 to 4	Selected pups (1 male and 1 female if possible) from all litters of the lactation subgroup	-	-	X
Unscheduled euthanasia (dams only, done in the animal facility)		X		

X: Sample collected; -: Not collected.

M0: First day of pairing; GD: Gestation Day; LD: Lactation Day; PND: Post Natal Day.

^a: Sample collected just before pairing.

^b: The day of necropsy (i.e., Day 43 for failed to mate F43 (CCI) and for mistimed pregnancy F277 (CCI); on GD26 for not pregnant F254 (BNT162b2, 30 µg); on GD27 for not pregnant F226 (CCI); on LD1 for euthanized moribund post-partum F276 (CCI), for total litter death F236 (CCI) and F279 (CCI).

Method/Comments:	F0 females: Jugular vein Fetuses: Small incision after anaesthesia Pups: Intracardiac
Target Volume (mL):	Target 0.5 mL for F0 females Target 0.3 mL pooled per litter for fetuses Targeted 0.5 mL pooled per litter from 2 pups (ideally 1 male and 1 female)
Anticoagulant:	None
Special Requirements:	None
Processing	Serum

4.10.2. Antibody Sample Processing

Samples were processed according to Text Table 6.

Text Table 6
Antibody Sample Processing

Centrifugation	Volume Aliquot 1	Volume Aliquot 2	Freezing	Specific Request
1800 g 10 minutes Approximately +4°C	At least 120 µL (dams and pups) or 60 µL (fetuses) of serum	Remaining (serum)	-80°C	None

The exact time of sampling with respect to dosing was recorded for each animal (details are retained in the raw data).

4.10.3. Antibody Analysis by Microneutralization CPE-Based

Each serum sample was tested in duplicate for serological detection of SARS-CoV-2 specific neutralizing antibodies. The test was carried out at Vismederi, according to Vismederi Standard Operating Procedures and dedicated working instruction "Microneutralization CPE-based assay for SARS-COV-2" (WI-MNSARS-CoV-2).

The methods and results are presented in Appendix 26.

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4.11. Terminal Procedures

4.11.1. Unscheduled Deaths

A moribund female showing signs of parturition difficulties and 2 females with total litter death were euthanized by carbon dioxide inhalation and exsanguination.

The female euthanized moribund due to parturition difficulties was subject to full macroscopic examination of the thoracic and abdominal cavities, including the injection sites, to confirm pregnancy status, number of corpora lutea and numbers and types of uterine implantations. Any abnormalities observed were sampled and preserved. Retained fetuses and dead pups from this female were not examined and were discarded.

The females with total litter death were euthanized and subject to full macroscopic examination of the thoracic and abdominal cavities, including the injection sites, and number of uterine implantations. Any abnormalities observed were sampled and preserved.

One dead breeder male was discarded without further examinations.

4.11.2. Scheduled Euthanasia

Surviving animals were euthanized by carbon dioxide inhalation and exsanguination (with the exception of the PND4 extra pups - see Section 4.9) and then necropsied according to the following schedule:

F0 females:

Caesarean subgroup: On GD21.

F43 that failed to mate was euthanized after the mating period (on Day 43).

Littering subgroup: On LD21, after weaning of the F1 pups.

F226 and F254 that failed to produce a viable litter by GD26 or GD27 were euthanized and necropsied; F277 with a mistimed pregnancy (mating not detected) was euthanized and necropsied after the end of the mating period on Day 43).

Culled F1 pups:

On PND4.

Euthanized F1 pups:

On PND21.

The first 30 surviving untreated males were retained at the disposal of the Test Facility and the 57 remaining untreated males were euthanized without further examinations following completion of the majority of caesarean sections.

Selected fetuses (caesarean subgroup) and pups (littering subgroup) were sampled for blood (antibody analysis) at necropsy (see Section 4.10.1).

4.11.3. Necropsy

All adult animals and pups (including those culled on PND4) were submitted to a full macroscopic examination of the abdominal and thoracic cavities including the injection sites (for F0 females). Any abnormalities observed were recorded and preserved.

4.11.3.1. Subgroup 1 (Caesarean-Section)

For each female euthanized on GD21, the ovaries and uterus were removed and examined, including examination of the placentae. The following data were recorded:

Text Table 7
Necropsy Data

Parameters	Comments
Pregnancy status	-
Gravid uterus weight	The uterus of apparently non-pregnant females was placed in ammonium sulphide solution in order to stain any previously undetected implantation sites
Number and distribution of intrauterine implantations	Classified as: Live fetuses, dead fetuses, early resorptions and late resorptions
Number of corpora lutea	-
Fetal weights	Individual weights were recorded
Fetal sex	-

-: No comment.

4.11.3.2. Subgroup 2 (Natural Delivery)

The carcasses of PND21 pups were preserved for possible skeletal examinations. No further examination was performed.

For all F0 females, the number of implantation sites were recorded.

4.11.4. Fetal Examination (Caesarean-Section)

Each fetus was examined for external defects and euthanized by oral administration of sodium pentobarbitone. Approximately one half of each litter was submitted to fresh visceral examination of the body (abdominal and thoracic cavities). The head was fixed in Harrison's fluid for subsequent examination by serial sectioning. The remaining carcass was retained fixed in ethanol.

The remaining half of the fetuses in each litter was eviscerated and then processed for skeletal examination. The skeletal examinations were performed following maceration of the soft tissues with aqueous potassium hydroxide, staining of the skeleton with Alizarin red then passage into glycerol.

Soft tissue and skeletal examinations were performed using a binocular microscope.

5. STATISTICAL ANALYSIS

All results presented in the tables of the report are calculated using non-rounded values.

All statistical analyses were performed within the respective study phase, unless otherwise noted. Numerical data collected on scheduled occasions from all animals were summarized by occasion or by litter and statistically analyzed as indicated below according to the occasion or by litter.

5.1. Constructed Variables

Body weight gains (F0 generation): Calculated between each scheduled interval as well as between the following intervals: Day 1 to Day 22 (both subgroups), GD0 to GD21 (both subgroups) and LD1 to LD21 (littering subgroup).

Food consumption: Calculated between each scheduled interval as well as between the following intervals: Day 1 to Day 22 (both subgroups), GD0 to GD21 (both subgroups) and LD1 to LD21 (littering subgroup).

For both subgroups combined where applicable (caesarean and littering subgroups):

Pre-coital interval (in days):
$$\frac{\text{Sum of days until successful insemination}}{\text{Number of inseminated females}}$$

Copulation (mating) index (in %):
$$\frac{\text{Number of inseminated females}}{\text{Number of paired animals}} \times 100$$

Pregnancy rate (in %):
$$\frac{\text{Number of pregnant females}}{\text{Number of paired animals}} \times 100$$

Fertility index (in %):
$$\frac{\text{Number of pregnant females}}{\text{Number of inseminated females}} \times 100$$

For the caesarean subgroup:

Pre-implantation loss (in %):
$$\frac{\text{Number of corpora lutea} - \text{Number of implantations}}{\text{Number of corpora lutea}} \times 100$$

Post-implantation loss (in %):
$$\frac{\text{Number of Implantations} - \text{Number of Viable Fetuses}}{\text{Number of implantations}} \times 100$$

Sex ratio (proportion of male fetuses):
$$\frac{\text{Number of males}}{\text{Number of fetuses}} \times 100$$

% of Fetuses with Abnormalities:
$$\frac{\text{Number of fetuses in litter with a given finding}}{\text{Number of fetuses in litter examined}} \times 100$$

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For the littering subgroup:

$$\text{Gestation index (in \%):} \quad \frac{\text{Number of pups alive at birth}}{\text{Number of pregnant females}} \times 100$$

$$\text{Live birth index (in \%):} \quad \frac{\text{Number of pups born alive}}{\text{Number of pups born}} \times 100$$

$$\text{Pre-birth loss (in \%):} \quad \frac{\text{Number of pups born}}{\text{Number of implantation sites (scars)}} \times 100$$

$$\text{Viability index (in \%):} \quad \frac{\text{Number of pups alive on PND 4}}{\text{Number of pups alive at birth}} \times 100$$

$$\text{Weaning index (in \%):} \quad \frac{\text{Number of pups alive on PND21}}{\text{Number of pups alive on PND4*}} \times 100$$

*: Number of pups alive on Day 4 post-partum after adjustment of litter size.

$$\text{Sex ratio (proportion of male pups):} \quad \frac{\text{Number of male pups}}{\text{Number of pups}} \times 100$$

5.2. Descriptive Statistical Analyses

Means, standard deviations (or % coefficient of variation or standard error, when deemed appropriate), percentages, numbers, and/or incidences were reported as appropriate by dataset.

5.3. Inferential Statistical Methods

All statistical tests were conducted at the 5% significance level. All pairwise comparisons were conducted using two-sided tests and were reported at the 1% and 5% levels, unless otherwise noted.

The pairwise comparisons of interest are listed below:

Group 2	vs.	Group 1
Group 3	vs.	Group 1
Group 4	vs.	Group 1

Analyses were performed according to the matrix below when possible but excluded any group with less than 3 observations.

Text Table 8
Statistical Matrix

Variables for Inferential Analysis	Statistical Method		
	Parametric/ Non-Parametric	Non-Parametric	Incidence
Body weight ^a	X	-	-
Body weight gains ^a	X	-	-
Food consumption ^a	X	-	-
Delivery and litter data	X	-	-
Reflex and physical development	-	-	X
Mating performance and fertility indices	-	-	X
Parental indices and mortality	-	-	X
Gravid uterine weight and corrected maternal body weights	X	-	-
Ovarian and uterine data	X	-	-
Litter observations (litter means) ^c	X	-	-
Litter % of fetuses with gross/external/visceral/skeletal abnormalities ^b	-	X	-

X: Statistical analysis performed; -: Statistical analysis not performed.

^a: Excludes animals not pregnant from the gestation and lactation phases summarization and statistical analysis.

^b: Presented for sexes combined; live fetuses only.

^c: Presented for males, females and sexes combined; live fetuses only.

5.4. Parametric/Non-Parametric

Levene's test was used to assess the homogeneity of group variances. The groups were compared using a Dunnett's test if Levene's test was not significant or Dunn's test if it was significant.

Pre-coital interval, estrous cycle and F1 offspring functional tests data were analysed using a SAS software package. Levene's test was used to test the equality of variance across groups and Shapiro-Wilk's test was used to assess the normality of the data distribution in each group. Data with homogeneous variances and normal distribution in all groups was analysed using ANOVA followed by Dunnett's test. Data showing non-homogeneous variances or a non-normal distribution in at least 1 group was analysed using Kruskal-Wallis test followed by Wilcoxon's rank sum test.

5.5. Non-Parametric

Datasets were compared using a Dunn's test.

5.6. Incidence

A Fisher's exact test was used to conduct pairwise group comparisons of interest.

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6. COMPUTERIZED SYSTEMS

Critical computerized systems used in the study are listed below or presented in the appropriate Phase Report. All computerized systems used in the conduct of this study have been validated; when a particular system has not satisfied all requirements, appropriate administrative and procedural controls were implemented to assure the quality and integrity of data.

Text Table 9
Critical Computerized Systems

System Name	Version No.	Description of Data Collected and/or Analyzed
GTC Mozart 21	3.1	Environmental data recording
Vaisala	4.1.0	Environmental data recording
Provantis®	9 and 10	Test material receipt, accountability and/or formulation activities; in-life; postmortem; statistical analysis
Devil	2.1.148	Deviation information library
STATSAS	STATSAS 2.00	Statistical analysis
Share Document Management System	1.0	Reporting
DocuSign™	11	Collection of 21 CFR Part 11 compliant signature

Microsoft Excel® (version 2003 or higher) was employed to present certain results and perform associated calculations.

7. RETENTION AND DISPOSITION OF RECORDS, SAMPLES, AND SPECIMENS

All study-specific raw data, electronic data, documentation, Study Plan, retained samples and specimens, and the Final Report will be archived at the Final Report issue. All materials generated by Charles River Laboratories from this study will be transferred to a Charles River Laboratories archive and kept for a period of 2 years following the date of issue of the Final Report.

Disposition of residual/retained analytical samples was as described in the table below.

Text Table 10
Disposition of Residual/Retained Samples

Sample Type	Disposition
Serum for Antibody analysis	Return to the Sponsor

Records to be maintained included, but were not limited to, documentation and data for the following:

- Study Plan, Study Plan amendments, and deviations.
- Study schedule.
- Study-related correspondence.
- Test system receipt, health, and husbandry.
- Test materials receipt, identification and preparation.
- In-life measurements and observations.
- Reserve sample.
- Antibody sample collection and evaluation.
- Gross observations and related data.
- Organ weight measurement.
- Statistical analysis results.
- Original signed Final Report.

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Original signed Study Plan and amendments signed by the Sponsor (e-signed documents) are archived at the sponsor under his responsibility. The regulatory compliance to applicable regulations of electronic signature system developed and used by the Sponsor is under his responsibility.

Study deviations were archived electronically at the Charles River Laboratories facility located in Wilmington, Massachusetts.

8. RESULTS

8.1. Serum Antibody Analysis

(Appendix 26)

Administration of 4 doses (2 prior to mating and 2 during gestation) of CCI, BNT162b2, or CCI elicited SARS-CoV-2 neutralizing antibody responses in the majority of females just prior to mating (M-14), at the end of gestation (GD21), and at the end of lactation (LD21). SARS-CoV-2 neutralizing titers were detected in most offspring (fetuses on GD21 and pups on PND21). SARS-CoV-2 neutralizing antibody titers were not observed in animals prior to vaccine administration or in saline-administered control animals.

8.2. Mortality

(Appendix 4, Appendix 7 and Appendix 29)

There was no unscheduled death related to any of the 3 vaccine candidates.

CCI

The presence of the isolated case in each of the CCI and CCI groups, with no similar finding in the BNT162b2 group, suggested that they were incidental and not related to any of the 3 vaccine candidates.

8.3. Clinical Observations

(Table 1, Table 2, Table 3, Appendix 5, Appendix 6, Appendix 7 and Appendix 8)

There were no adverse clinical signs during the premating and gestations periods related to any of the 3 vaccine candidates.

Following administrations (M-21, M-14, GD9 and GD20), swelling (associated or not with limping and/or piloerection for 1 or 2 days after the second dose only) was noted at the injection site for animals in the CCI, BNT162b2 and CCI groups. Complete recovery was noted between each of the dose administrations. The overall health of the animals was not impacted by these transient clinical signs localized to the injection site; therefore, these observations were not considered adverse.

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There were no clinical signs during the lactation period related to any of the 3 vaccine candidates.

Other clinical signs such as abnormal vocalization, chromodacryorrhea, desquamation, erythema, localized hairloss, malocclusion, long or missing teeth, red vaginal discharge, red stained fur, scab(s), sore(s) noted sporadically across the groups were considered to be incidental, related to the method of dose administration or to the pregnancy status of the females.

8.4. Body Weight

(Figure 1, Figure 2, Figure 3, Table 4, Table 5, Table 6, Table 7, Table 8, Table 9, Appendix 9, Appendix 10 and Appendix 11)

There were no adverse effects on mean body weight change related to any of the 3 vaccine candidates.

Slight body weight loss or reduced body weight gain was noted after each dose administration (M-21, M-14, GD9 and GD20) in the [REDACTED], BNT162b2 and [REDACTED] groups compared with continuous body weight gain in the control group.

Complete recovery was noted between each of the dose administrations such that absolute mean body weight was comparable with the control group at the end of the pre-mating and gestation periods, therefore none of the transient differences from control were considered adverse.



8.5. Food Consumption

(Figure 4, Figure 5, Figure 6, Table 10, Table 11, Table 12, Appendix 12, Appendix 13 and Appendix 14)

There were no adverse effects on mean food consumption related to any of the 3 vaccine candidates.

Reduced mean food consumption was noted after the first 3 dose administrations (M-21, M-14 and GD9) in the [REDACTED], BNT162b2 and [REDACTED] groups compared with the control group (up to -14, -16 and -17% on GD9, respectively). Complete recovery was noted between each of the dose administrations such that mean food consumption was comparable with the control group during the pre-mating and gestation periods, therefore none of the transient differences from control were considered adverse.

There was no vaccine-related effect on mean food consumption during the lactation period.

8.6. Estrous Cycle Data

(Table 13, Appendix 15 and Appendix 29)

There were no effects on estrous cyclicity related to any of the 3 vaccine candidates.

Mean length and regularity of the estrous cycles were comparable in all groups during the acclimatization and pre-mating periods. Mean values were within the historical control range, and no effects on pre-coital interval and copulation index are consistent with normal cycling.

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8.7. Maternal Mating Performance and Fertility

(Table 14 and Appendix 16)

There were no effects on mating performance or fertility related to any of the 3 vaccine candidates.

In total (caesarean and littering subgroups combined), 44, 44 and 44 (out of 44) females mated in the control, CCI, BNT162b2 and CCI groups, respectively (including F277, from the CCI group, not detected at the time of mating) after completion of the 14-day cohabitation period.

The copulation index was therefore 100, CCI 100 and % in the control, CCI, BNT162b2 and CCI groups, respectively.

The majority of mated females were inseminated within the first 4 days of pairing (approximate duration of a normal estrous cycle). The mean pre-coital interval was consequently 3.0, CCI, 2.8 and CCI days in the control, CCI, BNT162b2 and CCI groups, respectively.

In total, there were 43, CCI, 42 and CCI pregnant females out of 44 per group paired in the control, CCI, BNT162b2 and CCI groups, respectively. The pregnancy rate was therefore 98%, CCI, 95% and CCI% in the control, CCI, BNT162b2 and CCI groups, respectively.

In total, there were 43/44, CCI, 42/44 and CCI pregnant/mated females in control, CCI, BNT162b2 and CCI groups, respectively. The fertility index was therefore 98%, CCI, 95% and CCI% in the control, CCI, BNT162b2 and CCI groups, respectively.

8.8. Caesarean Data

8.8.1. Gravid Uterus Weight

(Table 15 and Appendix 17)

There were no effects on mean gravid uterus weight related to any of the 3 vaccine candidates.

8.8.2. Pregnancy Incidence

(Table 16 and Appendix 18)

There were no effects on pregnancy incidence related to any of the 3 vaccine candidates.

There were 21/22, CCI, 21/22, and CCI pregnant/mated females in the control, CCI, BNT162b2 and CCI groups, respectively, at the terminal caesarean examinations, all of which had viable fetuses.

8.8.3. Pre-Implantation Data

(Table 16, Appendix 18 and Appendix 29)

There were no effects on the pre-implantation data related to any of the 3 vaccine candidates.

The mean numbers of corpora lutea and implantation sites were comparable in all groups.

The mean percentage pre-implantation loss was higher in the BNT162b2 and CCI groups (9.77% and CCI%, respectively) compared with the control group (4.09%). However, the differences were not biologically meaningful and the values remained within the historical control data range (5.1% to 11.5%) for pivotal studies (see Explanation Page), so the difference was considered to be incidental.

8.8.4. Post-Implantation Data

(Table 16, Appendix 18 and Appendix 29)

There were no effects on embryo-fetal survival related to any of the 3 vaccine candidates.

The mean percentage post-implantation loss and the mean live litter size were comparable in all groups and consistent with the historical control data.

8.8.5. Fetal Data

(Table 16, Appendix 18 and Appendix 29)

There were no effects on mean fetal weight or fetal sex ratio related to any of the 3 vaccine candidates.

8.9. Fetal Examinations

The numbers of fetuses (litters) submitted to the different examinations were as follows:

Group No.	1	2	3	4
External examination	277 (21)	CCI	276 (21)	CCI
Internal (visceral) examination (body)	133 (21)	CCI	132 (21)	CCI
Fixed head examination	133 (21)	CCI	132 (21)	CCI
Skeletal examination (head and body)	144 (21)	CCI	144 (21)	CCI

There were no effects on fetal morphology related to any of the 3 vaccine candidates. This is consistent with no corresponding malformations in pups described in Sections 8.10.4 and 8.10.7.

8.9.1. External Observations

(Table 17, Appendix 20 and Appendix 29)

There were no effects on fetal external morphology related to any of the 3 vaccine candidates.



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In the BNT162b2 group, there was Fetus 14 (F58) had gastroschisis and Fetus 14 (F64) had a small mouth and agnathia. These malformations are part of the background data for this strain of rat (CRL:WI(Han)) and were considered incidental in view of their isolated and sporadic nature.

8.9.2. Visceral Observations

(Table 17, Appendix 21 and Appendix 29)

There were no effects on fetal soft tissue morphology related to any of the 3 vaccine candidates.

CCI

CCI

Fetus 6 (F53) from the BNT162b2 group was observed with a right-sided aortic arch and

CCI

These findings are also part of the background of findings for this strain of rat (CRL:WI(Han)) and were considered incidental in view of their isolated incidences.

The other less severe soft tissue anomalies and variations are part of the background data for this strain of rat and were also incidental.

8.9.3. Skeletal Observations

(Table 17 and Appendix 22)

There were no effects on fetal skeletal morphology related to any of the 3 vaccine candidates.

CCI

and the Fetus 14 (F64) from the BNT162b2 group had short and fused mandibles. These malformations associated with the abnormalities noted externally were considered incidental in view of their isolated incidences.

The other less severe skeletal anomalies and variations, such as supernumerary lumbar ribs, 7 lumbar vertebrae or incomplete ossification of thoracic centrum are part of the background data for this strain of rat and were also incidental.

8.10. Delivery and Litter Data

8.10.1. Parturition and Gestation Length

(Table 18, Appendix 23 and Appendix 29)

There were no effects on parturition and gestation length related to any of the 3 vaccine candidates.

There were 22, 21 and females in the control, CCI, BNT162b2 and CCI groups that completed delivery and had liveborn pups giving a gestation index of 100%, 100% and %, respectively. This was consistent with the background data for this strain of rat.

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The mean duration of gestation (approximately 22 days) was comparable in all groups. CCI

[REDACTED]

8.10.2. Pre-Birth Loss

(Table 18, Appendix 23 and Appendix 29)

There was no effect on pre-birth loss related to any of the 3 vaccine candidates.

CCI

[REDACTED]

CCI

[REDACTED]

8.10.3. Pup Viability and Litter Sizes

(Table 18, Appendix 23 and Appendix 29)

There were no effects on pup viability and litter size related to any of the 3 vaccine candidates.

CCI

[REDACTED]

[REDACTED]

[REDACTED]

The viability index (PND0 through to PND4) and weaning index (PND4 through to PND21) were comparable in all groups and consistent with the historical control data.

8.10.4. Pup Clinical Observations

(Table 3 and Appendix 7)

There was no pattern in the incidence or type of pup clinical observations or external abnormalities that suggested a relationship to any of the 3 vaccine candidates.

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8.10.5. Pup Weights

(Figure 7a, Figure 7b, Table 19 and Appendix 24)

There was no effect on mean pup weight throughout the pre-weaning period related to any of the 3 vaccine candidates.

8.10.6. Pup Physical and Functional Development

(Table 20 and Appendix 25)

There were no effects on pre-weaning physical (pinna unfolding and eye opening) and functional (pupil and auditory reflexes) development related to any of the 3 vaccine candidates.

8.10.7. Pup Necropsy Findings

(Appendix 28)

There was no pattern in the incidence or type of pup macroscopic observations or malformations that suggested a relationship to any of the 3 vaccine candidates.

8.11. Necropsy Findings of Adult Females

(Table 21 and Appendix 27)

There were no adverse maternal macroscopic findings related to any of the 3 vaccine candidates.


Macroscopic findings were noted at the injection sites (firm area, enlarged, edematous area and/or pale) in the **CCI**, BNT162b2 and **CCI** groups. These findings were considered non-adverse as they had no impact on the overall health of the animals and are consistent with administration of a vaccine and an inflammatory/immune response localized to the injection site.

Abnormalities of the liver (diaphragmatic hernia, mottled surface, abnormal shape or adherent mass) were occasionally noted for isolated females across all groups (including controls) and were considered incidental.

Alopecia and/or sores/crusts were also noted for isolated females across the groups (including controls) and were incidental (related to the pregnancy status of the females).

9. INTEGRATED SUMMARY AND DISCUSSION OF RESULTS

The purpose of this study was to assess the potential effects of [REDACTED], BNT162b2 and [REDACTED], vaccine development candidates to prevent Covid-19, and the concomitant immune response, on fertility and pre and postnatal development in the pregnant and lactating female Wistar (CRL:WI[Han]) rat and on the in utero and postnatal development of their offspring.

There were no deaths throughout the study related to any of the vaccine candidates. 

Intramuscular administration of [REDACTED], BNT162b2 and [REDACTED], before and during gestation to female Wistar rats resulted in non-adverse clinical signs and macroscopic findings localized to the injection site as well as transient, non-adverse body weight and food consumption effects after each dose administration. These maternal effects were considered non-adverse as they had no impact on the overall health of the animals. These maternal findings are all consistent with administration of a vaccine and an inflammatory/immune response.

There were no effects on estrous cycles, pre-coital interval, mating, fertility and pregnancy index, or on any ovarian, uterine, or litter parameters, including F1 survival, growth, external, visceral, and skeletal morphology, or effects on pre-weaning physical and functional development of the F1 pups related to any of the 3 vaccine candidates.

Administration of 4 doses (2 prior to mating and 2 during gestation) of [REDACTED], BNT162b2, or [REDACTED] elicited SARS-CoV-2 neutralizing antibody responses in the majority of females just prior to mating (M-14), at the end of gestation (GD21), and at the end of lactation (LD21). SARS-CoV-2 neutralizing titers were detected in most offspring (fetuses on GD21 and pups on PND21). SARS-CoV-2 neutralizing antibody titers were not observed in animals prior to vaccine administration or in saline-administered control animals.

10. CONCLUSION

Intramuscular administration of CCI, BNT162b2 and CCI before and during gestation to female Wistar (CRL:WI[Han]) rats was associated with non-adverse effects (body weight, food consumption and effects localized to the injection site) after each dose administration. There were no effects of any of the 3 vaccine candidates on mating performance or fertility in F0 female rats or on embryo-fetal or postnatal survival, growth, or development of the F1 offspring.

An immune response was confirmed in F0 female rats following administration of each vaccine candidate and these responses were also detectable in the F1 offspring (fetuses and pups).

11. REFERENCES

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2. Agnish ND and Keller KA. The rationale for culling of rodent litters. Fundam. Appl. Toxicol. 1997 38, 2-6.
3. Palmer AK and Ulbrich BC. The cult of culling. Fundam. Appl. Toxicol. 1997 38, 7-22.
4. Kuwagata et al. Historical control data on developmental toxicity studies in rats. Congenital Anomalies. 2018 59, 125-131.

EXPLANATION PAGE

All day(s) referenced throughout the outputs generated are study days beginning with Study Day 1, the first day of dosing.

Abbreviations consistent throughout the Summary and Individual Tables.

Note: All of the abbreviations listed on these pages may not be applicable to this report.

The footnote "*" = result to left has an associated comment or marker" was printed on the following table without values marked with an asterisk due to data acquisition constraints.

Statistical significances arise from automatic comparisons with the principal control.

Principal Control Group: 1.

*: 5% significance level

**: 1% significance level

***: 0.1% significance level

Statistical significance is represented by "x", "xx" or "xxx", where "x" is a letter indicating which statistical test has been performed and where "x" corresponds to 0.05, "xx" corresponds to 0.01 and "xxx" corresponds to "0.001". On some occasions, the statistical significance does not appear on the tables due to system constraints.

GENERAL

Abbreviation	Description
< or >	Out of range
% Diff	% Difference from control group
DC	Died post-coitum
DP or MDPP	Moribund/died post-partum
EP	Euthanized preterminally
FM	Failed to mate
FME	Failed to mate excluded
G or GD	Gestation day
LD	Lactation day
mcg	µg
Mean	Arithmetic mean
m or M, f or F	Male, Female
MT, MTP	Mistimed pregnancy
N	Number of values included in analysis
NA	Not applicable
NC	Not calculable
NF, NVF	No viable fetuses
No.	Animal number
no.	Number
NP	Not pregnant
NPE	Not pregnant excluded
NV	No viable embryos/fetuses
P	Pregnant
RC	Result comment
S.D. or SD	Standard deviation
SpCMSD	Mean SD
tCtrl	Mean treated group versus control group ratio
TD or Total LDeath	Total litter death
TR	Total resorption
UD	Unable to deliver, sacrificed
Wx	Week x

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MORTALITY

Abbreviation	Description	Abbreviation	Description
ACCD	Accidental death	REL	Released
AD	Accidental death	TTP2	Pup transfer
AI	Interim euthanasia	TE	Terminal euthanasia
AM SIR	Mortality recorded in the morning	TERM	Terminal euthanasia
FD	Found dead	TLD	Total litter death
FL	Failed to litter	TS	Terminal euthanasia
HS	Moribund euthanasia	UE	Unscheduled euthanasia
INTM	Interim euthanasia	UNSC	Unscheduled euthanasia
PUE	Pup unscheduled euthanasia	UT	Unplanned terminal euthanasia
REC	Recovery euthanasia	VE	Removed from study alive

CLINICAL OBSERVATIONS

Abbreviation	Description	Abbreviation	Description
xM	Clinical observations performed x minutes postdosing. Target times are presented. Actual times are kept in the raw data.	P2DS	Observation performed before the second dosing
xH or x	Clinical observations performed x hour(s) postdosing. Target times are presented. Actual times are kept in the raw data.	Part	Particulates
+xh	Clinical observations performed x hour(s) postdosing. Target times are presented. Actual times are kept in the raw data.	PM_S	Observation performed in the afternoon
AM_S	Observation performed in the morning	PR	Observation predosing
BEF	Before dosing	PT	Permanent
Daily x	Clinical observations on days without dosing	Rx	Observation during dosing
DuRx	Observation during dosing	Sev Not App	Severity not applicable
DT	Observation during dosing	UDu	Unscheduled observation during dosing
EOD	Observation performed at the end of day	Un	Unscheduled observation
no TT area	Non treated area	Unsc or NS	Unscheduled observation
OTHR	Other	VET or Veto x	Veterinary observation
P	Observation postdosing	w/	With

Notes:

Injection site 1: left quadriceps

Injection site 2: right quadriceps

Clinical signs from all females with mating date (including not pregnant females) were presented in table "Summary Gestation Clinical Observations" and appendix "Individual Gestation Clinical Observations".

Only mistimed pregnancy female and failed to mate female were presented in appendix "Individual Clinical Observations of Excluded Females".

On 05 September 2020, sore on right forelimb was recorded for several females from littering subgroup. The females number was not recorded.

On GD18, teeth were cut from F202 (Control group). Information "lower teeth" or "upper teeth" were not recorded.

On several occasions on non-dosing days during lactation period, detailed clinical observations were recorded on timeslot BEF (before dosing).

Only animals and occasions with findings are presented.

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BODY WEIGHT/BODY WEIGHT GAIN**Notes:**

Pre-mating body weights on Days -26, -25, -21 and -20 were not represented in Figure 2 as only half animals were weighed.

F245 (BNT162b2 group) delivered on GD20, the body weight recorded on GD21 corresponds to LD1 due to system constraints.

F208 (Control group) and F263 (BNT162b2 group) were additionally weighed on LD0.

FOOD CONSUMPTION**Note:**

The quantity of remaining food was not weighed on GD21 for F245 (BNT162b2 group) because this female littered on GD20. Therefore, no food consumption was calculated for GD18 to 21 and GD0 to GD21.

ESTROUS CYCLE**Note:**

For each female, the day after which a last stage of cycle was recorded corresponds to the day where it was declared positive for the presence of sperm. This day was determined as the mating day and was recorded as Gestation Day (GD0). No mating day was determined for any female with a stage of cycle recorded on Day 36.

GRAVID UTERINE WEIGHTS AND MATERNAL BODY WEIGHT CHANGE

Abbreviation	Description	Abbreviation	Description
0-TBW	Weight calculation from G0 to terminal body weight (corrected)	Day X	Day X of gestation
6-TBW	Weight calculation from G6 to terminal body weight (corrected)	G	Gestation day
		NRQ	Not required
BW	Body weight	NSCH	Not scheduled to be performed
BWC	Body weight change	TBW	Terminal body weight
BWG	Body weight gain	Wt	Weight

Note:

CCI

CAESAREAN SECTION DATA

Abbreviation	Description	Abbreviation	Description
Post-Implant Loss	Post-Implantation Loss	Pre-Implant Loss or Pre-Impl.	Pre-Implant Loss
(B)	Both (males and females)	P-Implants	Post-implantation loss
both	Both (males and females)	Post-Implant Loss	Post-implantation loss
N+ve	Number positive	Wt	Weight

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FETAL DATA AND OBSERVATIONS

Abbreviation	Description	Abbreviation	Description
!	Preparation artefact	L	Left
(%)	Mean % of litters with the abnormality	Litters(%) N	Group litter incidence
A	Anomalie	L or LF	Live fetus
A	Alive	LR	Late resorption
Abbr	Abbreviation	M	Malformation
DE	Dead embryo	PLWT	Placental weight
DF	Dead fetus – not examined	R	Right
DFE	Dead fetus - examined	S	Scar
EI	Empty implantation site	SkeletalBody	Skeletal examination of body
E or ER	Early resorption	SkeletalHead	Skeletal examination of head
FPOS	Fetal position	TR	Total resorption
FreshVisBody	Visceral examination of body on fresh tissue	U	Unsexed
FreshVisEye	Visceral examination of eye on fresh tissue	V	Variation
H	Hermaphrodite	VisBody	Visceral body
Implant ID	Implantation identification	VisHead	Visceral head
		Wt	Weight

DELIVERY AND LITTER DATA

Abbreviation	Description	Abbreviation	Description
Cannib.	Cannibalized	N+ve	Number of positive
Implantat	Implantation	PND	Postnatal day
Miss.	Missing		

PUP BODY WEIGHT

Abbreviation	Description	Abbreviation	Description
BW	Body weight	P4pr	Postnatal Day 4 preculling
dX	Postnatal day x	P4po	Postnatal Day 4 postculling
Meas.	Measurement	Px or PND	Postnatal Day x

INDIVIDUAL PHYSICAL AND FUNCTIONAL DEVELOPMENT**Notes:**

Due to culling on PND4, observation of pinna unfolding for one unselected pup (weak pup) from F251 (BNT162b2 group) was not recorded on PND5.

Due to the technical error, observation of eyes opening for pups from F264 (BNT162b2 group) was recorded "0" on PND14. It was considered that number positive pups on PND15 was the same as PND14 for % calculation.

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MACROSCOPIC OBSERVATION

Abbreviation	Description	Abbreviation	Description
?	Questionable	M	Mass
Animal Ref.	Animal number	ML	Macroscopic lesion (impossible to weight)
C	Clinical observation	MPF	Major pathological finding
E	Excluded	NBF	Neutral buffered formalin
G	Gross pathology	TGL	Trackable gross lesion
H	Histopathology		

Notes:

In the summary table, if no abnormality was detected for a given removal reason, no data are presented.

Only pups and occasions with findings are presented.

HISTORICAL CONTROL DATA

Abbreviation	Description
GD	Gestation day

Notes:

Values compiled from undosed and control Wistar and Sprague Dawley rats in previous studies.

Pivotal studies include those with a comparable group size as in the present study.

The historical control data presented in the Appendix are not subject to Quality Assurance audit.

FIGURES

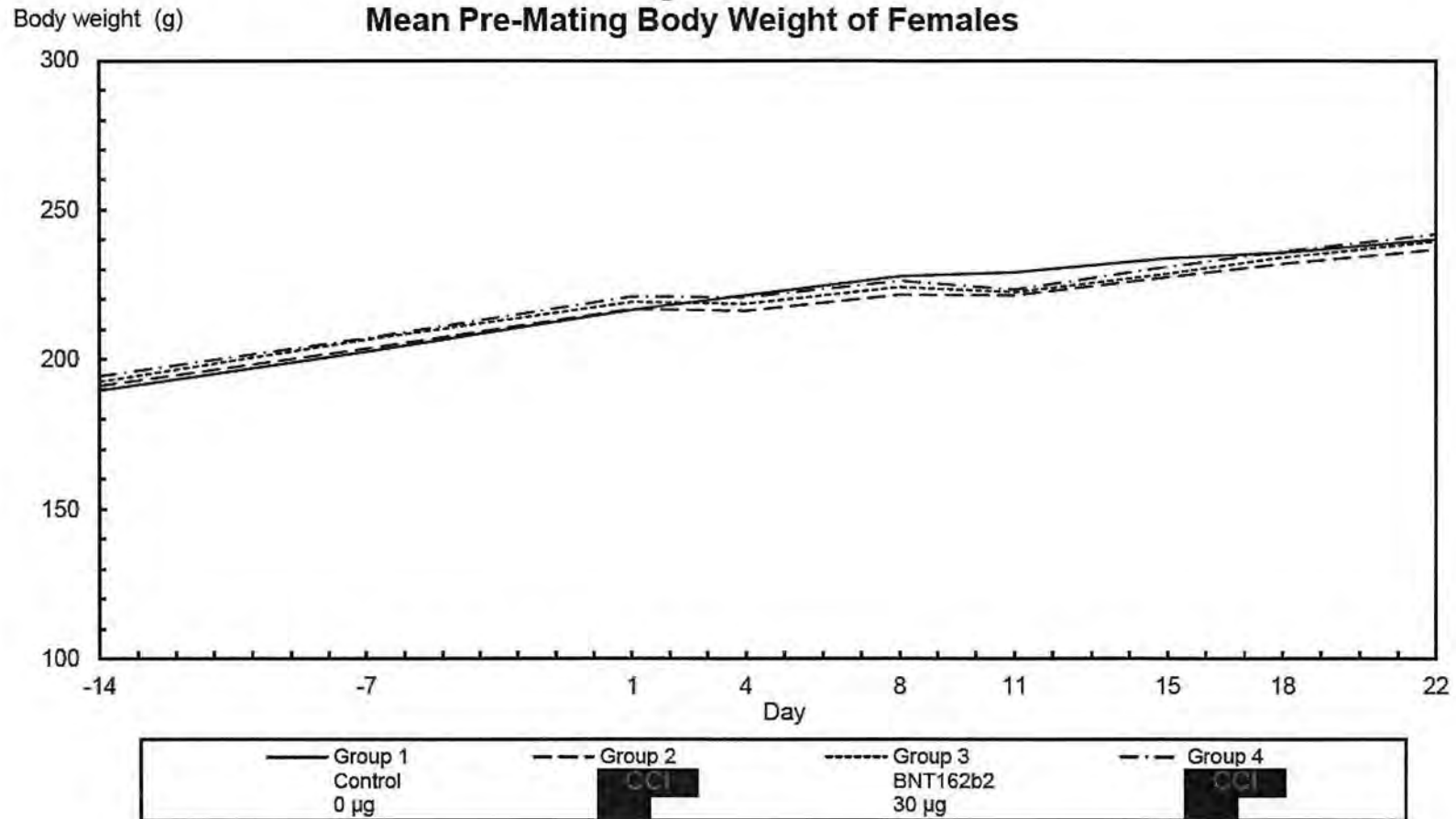
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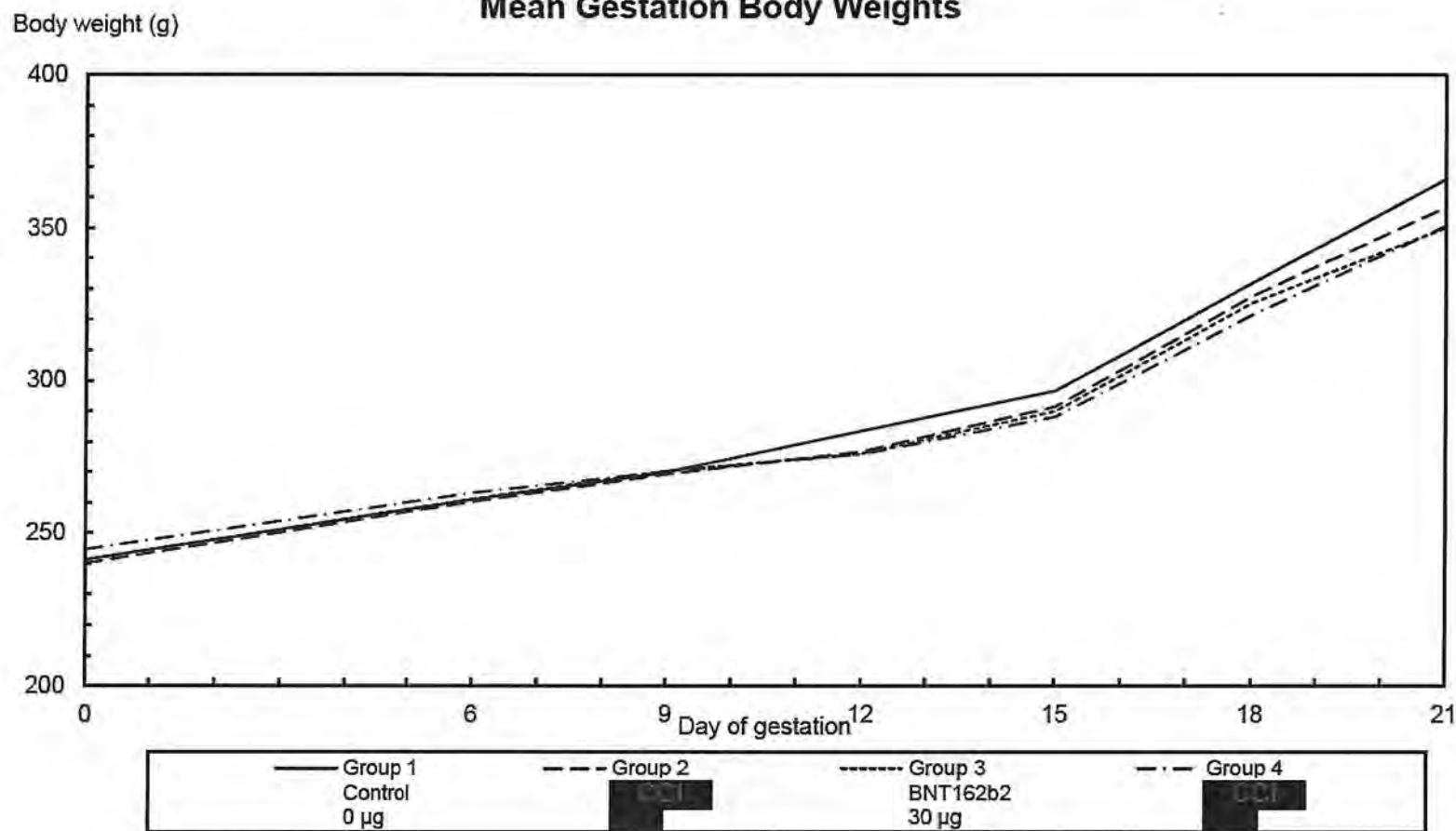
Figure 1

Mean Pre-Mating Body Weight of Females



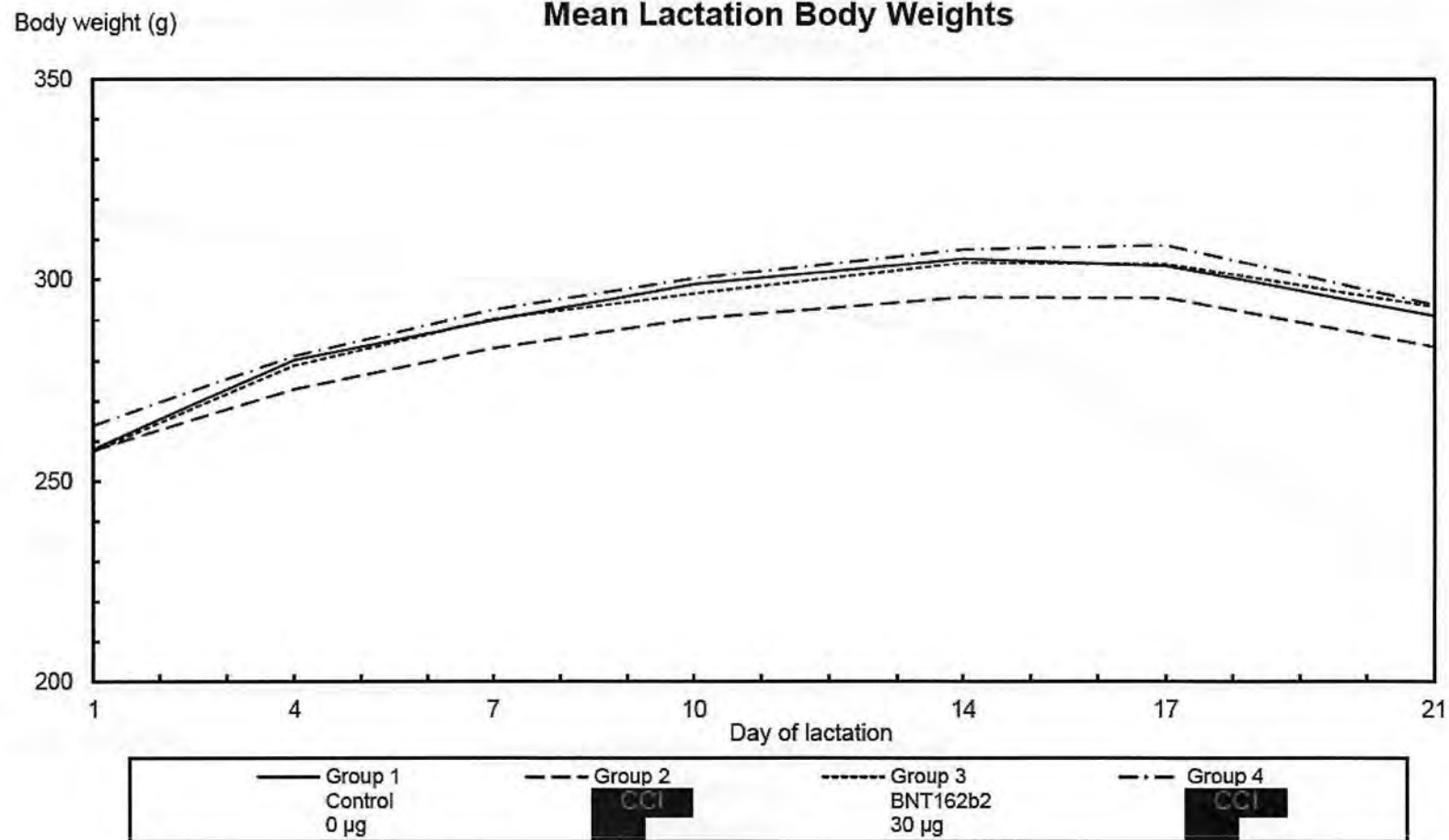
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Figure 2
Mean Gestation Body Weights



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Figure 3
Mean Lactation Body Weights

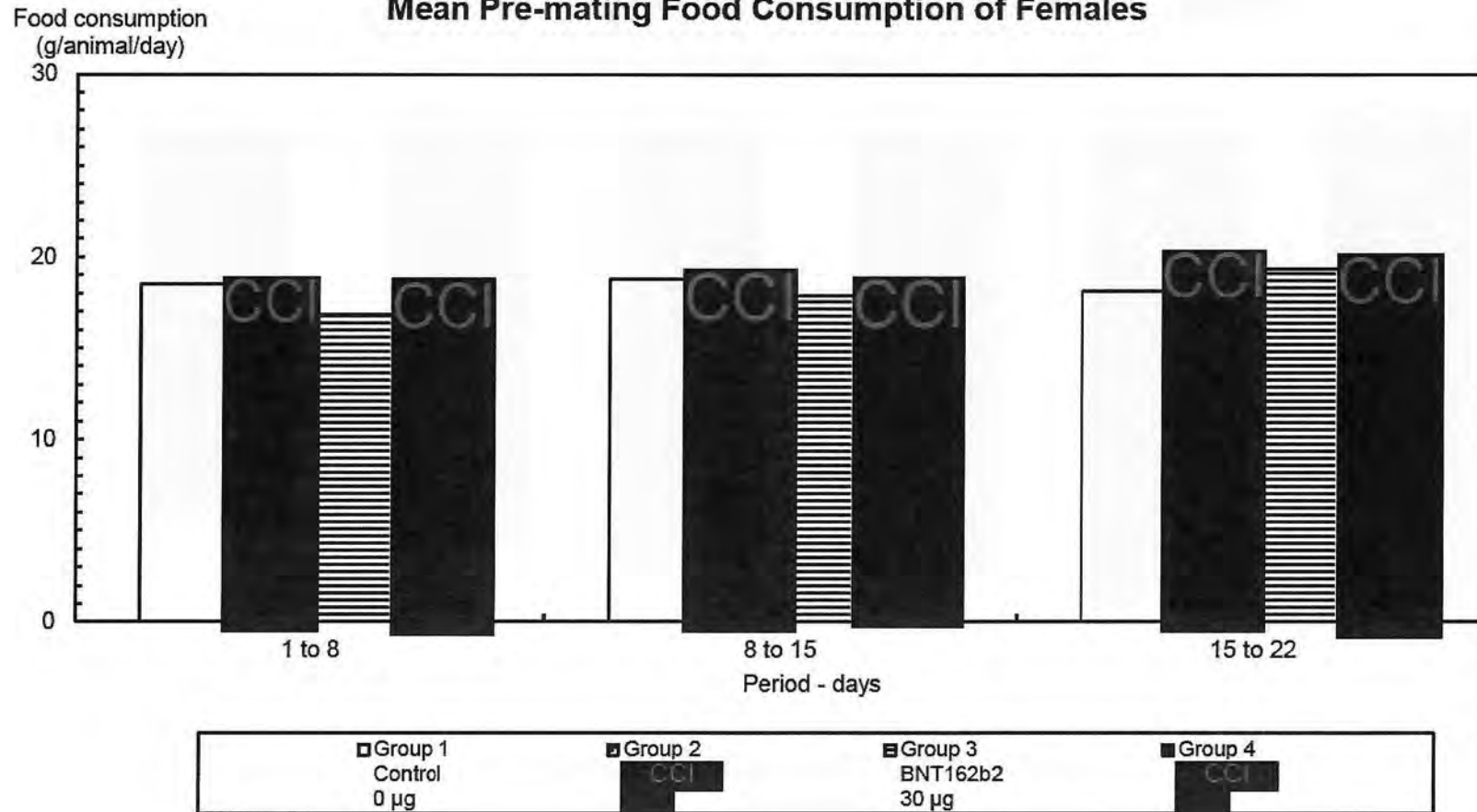


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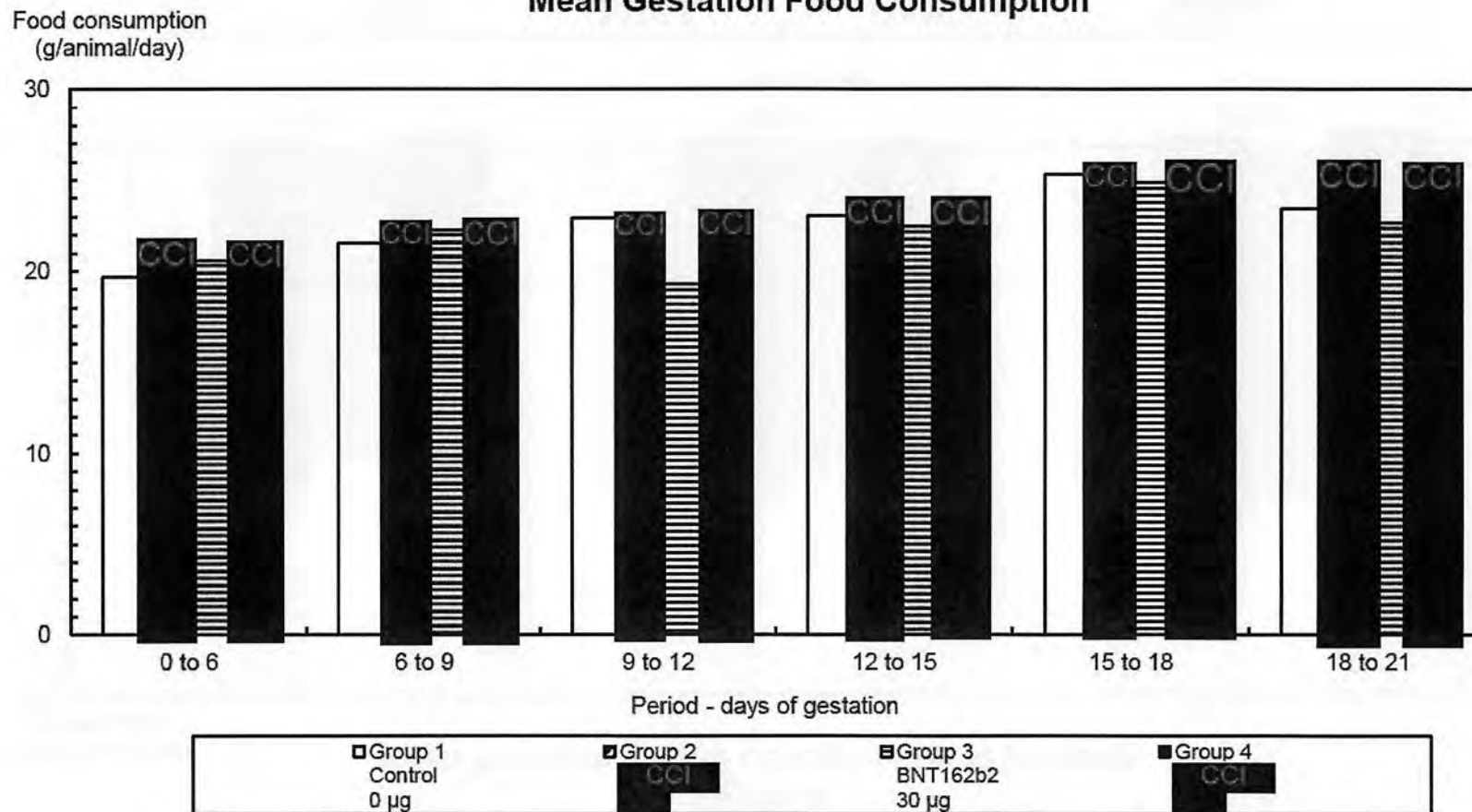
Figure 4

Mean Pre-mating Food Consumption of Females



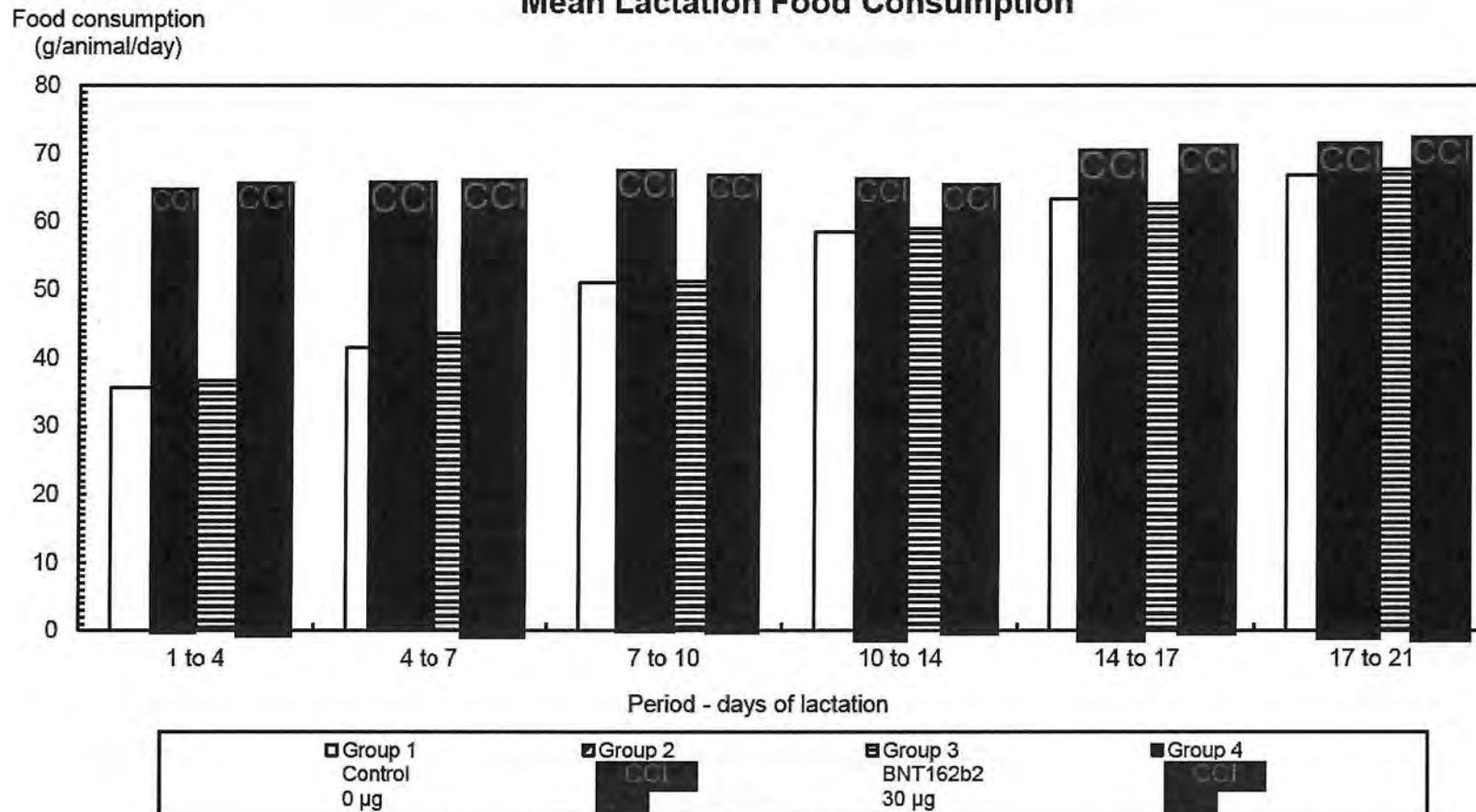
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Figure 5
Mean Gestation Food Consumption



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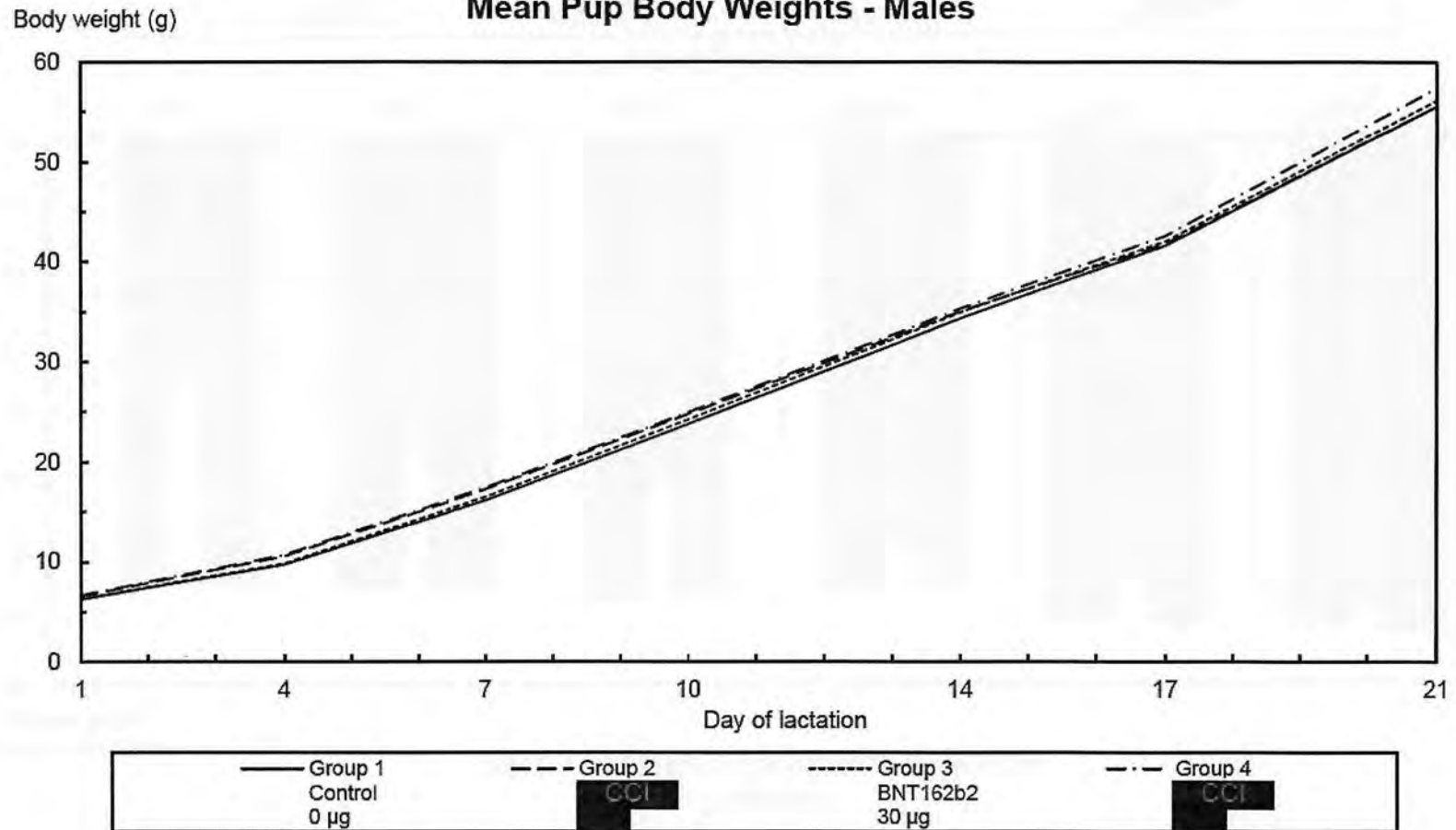
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Figure 6
Mean Lactation Food Consumption



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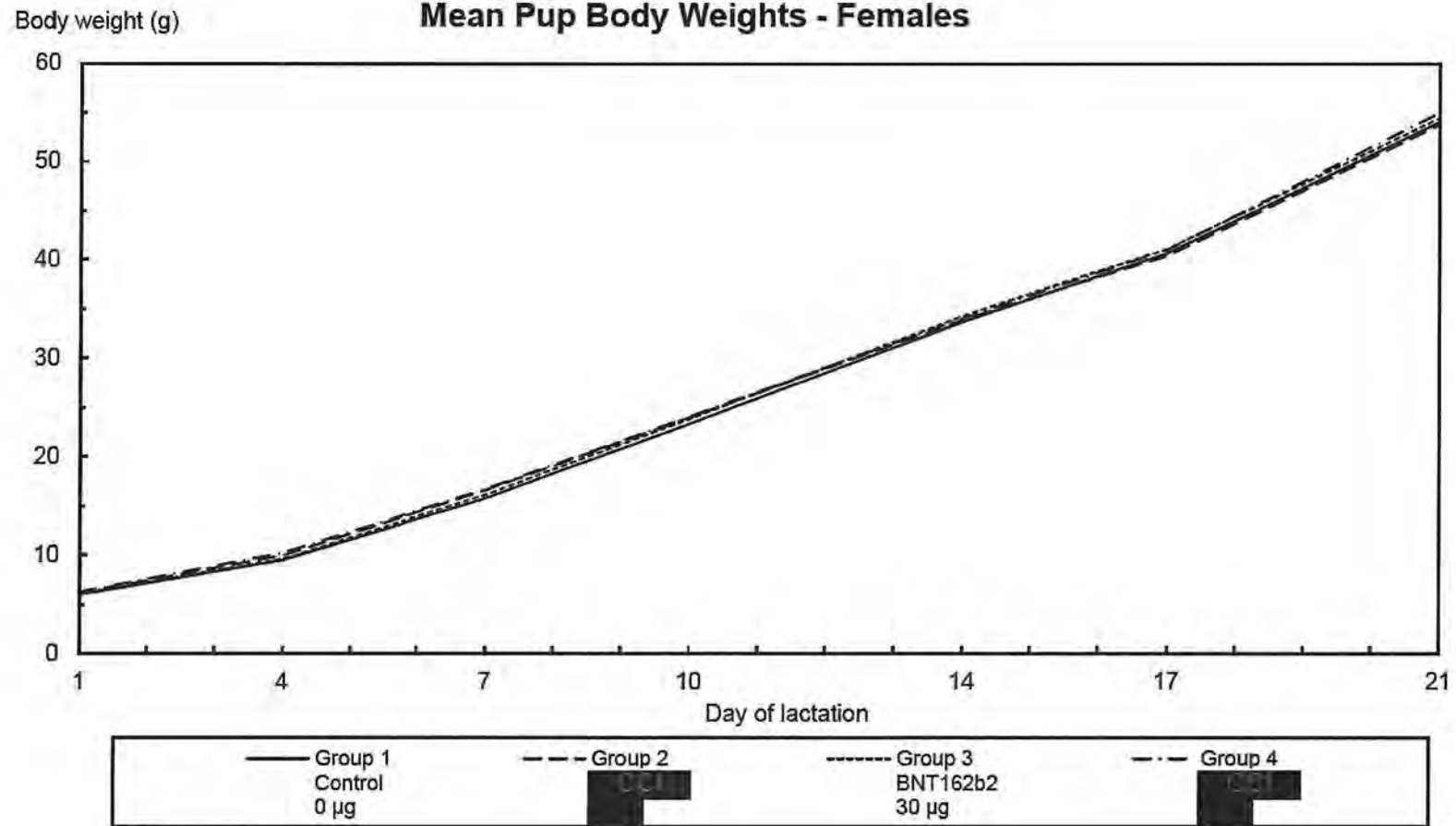
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Figure 7a
Mean Pup Body Weights - Males



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Figure 7b
Mean Pup Body Weights - Females



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TABLES

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Summary Pre-Mating Clinical Observations of Females

20256434

Day numbers relative to Start Date				
Sex: Female				
	Control 0mcg	CCI	BNT162b2 30mcg	CCI
Abnormal vocalisation				
Number of Observations	.		.	
Number of Animals	.		.	
Days from - to	.		.	
Chromodacryorrhea				
Number of Observations	.		1	
Number of Animals	.		1	
Days from - to	.		17 17	
Desquamation				
Number of Observations	7		1	
Number of Animals	5		1	
Days from - to	2 8		2 2	
Erythema.				
Number of Observations	5		6	
Number of Animals	3		3	
Days from - to	1 2		1 2	
Limping				
Number of Observations	.		26	
Number of Animals	.		13	
Days from - to	.		9 10	
Localised hairloss				
Number of Observations	10		1	
Number of Animals	4		1	
Days from - to	-26 15		-25 -25	

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Date: 07-Dec-2020 12:36 Page: 2

Summary Pre-Mating Clinical Observations of Females

20256434

		Day numbers relative to Start Date			
Sex: Female		Control 0mcg	CCI	BNT162b2 30mcg	CCI
Missing tooth					
	Number of Observations	2		.	
	Number of Animals	1		.	
	Days from - to	-3 1		.	
Piloerection					
	Number of Observations	.		2	
	Number of Animals	.		1	
	Days from - to	.		9 10	
Red vaginal discharge					
	Number of Observations	.		.	
	Number of Animals	.		.	
	Days from - to	.		.	
Scab(s).					
	Number of Observations	5		.	
	Number of Animals	5		.	
	Days from - to	-26 15		.	
Swelling.					
	Number of Observations	.		92	
	Number of Animals	.		44	
	Days from - to	.		2 15	
Teeth long					
	Number of Observations	1		.	
	Number of Animals	1		.	
	Days from - to	15 15		.	

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Summary Gestation Clinical Observations
20256434

Date: 19-Oct-2020 17:57 Page: 1

Day numbers relative to Mating Date				
Sex: Female				
	Control 0mcg	CCI	BNT162b2 30mcg	CCI
Localised hairloss				
Number of Observations	20		33	
Number of Animals	6		11	
Days from - to	6 21		0 21	
Malocclusion				
Number of Observations	5		.	
Number of Animals	1		.	
Days from - to	9 21		.	
Piloerection				
Number of Observations	.		.	
Number of Animals	.		.	
Days from - to	.		.	
Red stained fur				
Number of Observations	.		3	
Number of Animals	.		1	
Days from - to	.		6 12	
Scab(s).				
Number of Observations	1		2	
Number of Animals	1		2	
Days from - to	0 0		9 21	
Sore(s).				
Number of Observations	1		.	
Number of Animals	1		.	
Days from - to	15 15		.	

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Date: 19-Oct-2020 17:57 Page: 2

Summary Gestation Clinical Observations

20256434

Day numbers relative to Mating Date				
Sex: Female				
	Control 0mcg	CCI	BNT162b2 30mcg	CCI
Swelling.				
Number of Observations	.		12	
Number of Animals	.		10	
Days from - to	.		12 21	
Teeth long				
Number of Observations	1		.	
Number of Animals	1		.	
Days from - to	0 0		.	
Pup(s) - Cold to touch				
Number of Observations	.		1	
Number of Animals	.		1	
Days from - to	.		21 21	

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Date: 19-Oct-2020 17:58 Page: 1

Summary Lactation Clinical Observations

20256434

Day numbers relative to Litter Date				
Sex: Female				
	Control 0mcg		BNT162b2 30mcg	
Bleeding				
Number of Observations	.		.	
Number of Animals	.		.	
Days from - to	.		.	
Coloured skin				
Number of Observations	-		-	
Number of Animals	.		.	
Days from - to	.		.	
Hunched				
Number of Observations	.		.	
Number of Animals	.		.	
Days from - to	.		.	
Hunched gait				
Number of Observations	.		.	
Number of Animals	.		.	
Days from - to	.		.	
Localised hairloss				
Number of Observations	26		18	
Number of Animals	5		3	
Days from - to	1 21		1 21	
Malocclusion				
Number of Observations	7		.	
Number of Animals	1		.	
Days from - to	1 21		.	

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Summary Lactation Clinical Observations

20256434

Day numbers relative to Litter Date				
Sex: Female				
	Control 0mcg	CCI	BNT162b2 30mcg	CCI

Nodule(s) .				
Number of Observations	1		.	
Number of Animals	1		.	
Days from - to	21 21		.	
Pale				
Number of Observations	.		.	
Number of Animals	.		.	
Days from - to	.		.	
Partly closed eye(s)				
Number of Observations	.		.	
Number of Animals	.		.	
Days from - to	.		.	
Piloerection				
Number of Observations	.		.	
Number of Animals	.		.	
Days from - to	.		.	
Purple area(s)				
Number of Observations	.		.	
Number of Animals	.		.	
Days from - to	.		.	
Red vaginal discharge				
Number of Observations	.		.	
Number of Animals	.		.	
Days from - to	.		.	

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Summary Lactation Clinical Observations
20256434

Date: 19-Oct-2020 17:58 Page: 3

Day numbers relative to Litter Date				
Sex: Female				
	Control 0mcg		BNT162b2 30mcg	
Scab(s).				
Number of Observations	6		5	
Number of Animals	2		2	
Days from - to	4 21		4 21	
Soft distended abdomen				
Number of Observations	.		.	
Number of Animals	.		.	
Days from - to	.		.	
Sore(s)				
Number of Observations	3		.	
Number of Animals	1		.	
Days from - to	13 20		.	
Swelling.				
Number of Observations	2		3	
Number of Animals	1		3	
Days from - to	9 10		1 1	
Teeth cut				
Number of Observations	1		.	
Number of Animals	1		.	
Days from - to	1 1		.	
Total litter death				
Number of Observations	.		.	
Number of Animals	.		.	
Days from - to	.		.	

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Summary Lactation Clinical Observations

20256434

Day numbers relative to Litter Date				
Sex: Female				
	Control 0mcg	CCI	BNT162b2 30mcg	CCI
Pup(s) - Weak				
Number of Observations	.		6	
Number of Animals	.		2	
Days from - to	.		0 4	
Pup(s) - Thin				
Number of Observations	.		1	
Number of Animals	.		1	
Days from - to	.		3 3	
Pup(s) - Pale				
Number of Observations	.		2	
Number of Animals	.		2	
Days from - to	.		0 3	
Pup(s) - Cold to touch				
Number of Observations	.		3	
Number of Animals	.		3	
Days from - to	.		0 3	
Pup(s) - Cyanotic				
Number of Observations	.		1	
Number of Animals	.		1	
Days from - to	.		3 3	
Pup(s) - Incomplete hair growth				
Number of Observations	17		18	
Number of Animals	2		2	
Days from - to	9 20		10 21	

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Summary Lactation Clinical Observations

20256434

Day numbers relative to Litter Date				
Sex: Female				
	Control 0mcg	CCI	BNT162b2 30mcg	CCI
Pup(s) - Haematoma(s)				
Number of Observations	6		3	
Number of Animals	2		2	
Days from - to	1 11		0 1	
Pup(s) - Chromodacryorrhea				
Number of Observations	.		.	
Number of Animals	.		.	
Days from - to	.		.	
Pup(s) - Lacrimation				
Number of Observations	.		.	
Number of Animals	.		.	
Days from - to	.		.	
MORIBUND SACRIFICE				
Number of Observations	.		.	
Number of Animals	.		.	
Days from - to	.		.	
UNPLANNED TERMINAL SACRIFICE				
Number of Observations	.		.	
Number of Animals	.		.	
Days from - to	.		.	
Pup(s) - Red ocular mucous mem				
Number of Observations	.		.	
Number of Animals	.		.	
Days from - to	.		.	

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Page: 1

Mean Pre-Mating Body Weight of Females

20256434

Body Weight (g)		Control 0mcg		BNT162b2 30mcg	
Sex: Female					
Day(s) Relative to Start Date					
-26	Mean	160.99	R ¹	163.60	
	SD	13.11		17.64	
	N	22		22	
	%Diff	-		1.63	
-25	Mean	163.98	L ²	165.56	
	SD	14.48		14.15	
	N	22		22	
	%Diff	-		0.97	
-21	Mean	173.80	L ²	176.97	
	SD	13.45		17.45	
	N	22		22	
	%Diff	-		1.82	
-20	Mean	177.46	I ³	179.14	
	SD	14.57		16.54	
	N	22		22	
	%Diff	-		0.95	

Statistical Test: Generalised Anova/Ancova Test Transformation: Automatic

1 [R - Automatic Transformation: Rank]

3 [I - Automatic Transformation: Identity (No Transformation)]

2 [L - Automatic Transformation: Log]

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Page: 2

Mean Pre-Mating Body Weight of Females

20256434

Body Weight (g)		Control 0mcg		BNT162b2 30mcg	
Sex: Female					
Day(s) Relative to Start Date					
-14	Mean	189.68	L ¹	192.61	
	SD	15.40		16.69	
	N	44		44	
	%Diff	-		1.55	
-7	Mean	202.55	R ²	206.60	
	SD	16.23		16.39	
	N	44		44	
	%Diff	-		2.00	
1	Mean	216.49	I ³	219.15	
	SD	17.85		17.75	
	N	44		44	
	%Diff	-		1.23	
4	Mean	221.34	L ¹	218.51	
	SD	17.81		18.10	
	N	44		44	
	%Diff	-		-1.28	

Statistical Test: Generalised Anova/Ancova Test Transformation: Automatic

1 [L - Automatic Transformation: Log]

3 [I - Automatic Transformation: Identity (No Transformation)]

2 [R - Automatic Transformation: Rank]

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06-Nov-2020 15:44:50

Page: 3

Mean Pre-Mating Body Weight of Females

20256434

Body Weight (g)		Control 0mcg		BNT162b2 30mcg	
Sex: Female					
Day(s) Relative to Start Date					
8	Mean	227.71	L ¹	224.13	
	SD	18.80		19.18	
	N	44		44	
	%Diff	-		-1.57	
11	Mean	229.02	L ¹	222.45	
	SD	18.42		18.60	
	N	44		44	
	%Diff	-		-2.87	
15	Mean	233.81	L ¹	228.58	
	SD	17.24		18.32	
	N	44		44	
	%Diff	-		-2.23	
18	Mean	235.81	L ¹	234.09	
	SD	16.08		18.89	
	N	44		44	
	%Diff	-		-0.73	

Statistical Test: Generalised Anova/Ancova Test Transformation: Automatic

1 [L - Automatic Transformation: Log]

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Provantis

06-Nov-2020 15:44:50

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Mean Pre-Mating Body Weight of Females

20256434

Body Weight (g)		Control 0mcg		BNT162b2 30mcg	
Sex: Female					
Day(s) Relative to Start Date					
22	Mean	240.13	L ¹	239.54	
	SD	18.13		19.41	
	N	44		44	
	%Diff	-		-0.25	

Statistical Test: Generalised Anova/Ancova Test Transformation: Automatic

¹ [L - Automatic Transformation: Log]

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Mean Pre-Mating Body Weight Change of Females

20256434

Body Weight Change (g)							
Sex: Female		Control		CCI		BNT162b2	
		0mcg				30mcg	
Day(s) Relative to Start Date							
-26-21	Mean	12.82	R ¹			13.36	
	SD	4.35				3.59	
	N	22				22	
	%Diff	-				4.26	
-25-20	Mean	13.48	I ²			13.57	
	SD	5.15				4.99	
	N	22				22	
	%Diff	-				0.67	
-20-14	Mean	13.00	R ¹			13.76	
	SD	5.23				6.67	
	N	22				22	
	%Diff	-				5.84	
-21-14	Mean	15.08	I ²			15.36	
	SD	3.94				4.71	
	N	22				22	
	%Diff	-				1.84	

Statistical Test: Generalised Anova/Ancova Test Transformation: Automatic

1 [R - Automatic Transformation: Rank]

2 [I - Automatic Transformation: Identity (No Transformation)]

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Mean Pre-Mating Body Weight Change of Females

20256434

Body Weight Change (g)		Control 0mcg		BNT162b2 30mcg	
Sex: Female					
Day(s) Relative to Start Date					
-14-7	Mean	12.88 R ¹		13.98	
	SD	5.50		6.82	
	N	44		44	
	%Diff			8.60	
-7-1	Mean	13.94 R ¹		12.55	
	SD	7.32		9.13	
	N	44		44	
	%Diff			-9.96	
1-4	Mean	4.85 ²		-0.64ddd ³	
	SD	4.74		4.73	
	N	44		44	
	%Diff			-113.13	
4-8	Mean	6.37 R ¹		5.62	
	SD	4.25		4.16	
	N	44		44	
	%Diff			-11.81	

Statistical Test: Generalised Anova/Ancova Test Transformation:

1 [R - Automatic Transformation: Rank]
3 [ddd - Test: Dunnett 2 Sided p < 0.001]

2 [I,aaa - Automatic Transformation: Identity (No Transformation), (All Groups) Test: Analysis of Variance p < 0.001]

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Mean Pre-Mating Body Weight Change of Females

20256434

Body Weight Change (g)							
Sex: Female		Control		CCI	BNT162b2		CCI
		0mcg			30mcg		
Day(s) Relative to Start Date							
8-11	Mean	1.31 ¹			-1.69		
	SD	6.07			5.67		
	N	44			44		
	%Diff	-			-229.04		
11-15	Mean	4.79 ^{R²}			6.14		
	SD	6.17			5.49		
	N	44			44		
	%Diff	-			28.13		
15-18	Mean	2.00 ^{R,k³}			5.50 ^{dd*}		
	SD	5.69			4.64		
	N	44			44		
	%Diff	-			175.11		
18-22	Mean	4.32 ^{R²}			5.45		
	SD	4.23			3.97		
	N	44			44		
	%Diff	-			26.25		

Statistical Test: Generalised Anova/Ancova Test Transformation: Automatic

1 [R,kk - Automatic Transformation: Rank, (All Groups) Test: Kruskal-Wallis p < 0.01]
3 [R,k - Automatic Transformation: Rank, (All Groups) Test: Kruskal-Wallis p < 0.05]
5 [ddd - Test: Dunnett Non-Parametric 2 Sided p < 0.001]

2 [R - Automatic Transformation: Rank]
4 [dd - Test: Dunnett Non-Parametric 2 Sided p < 0.01]
6 [d - Test: Dunnett Non-Parametric 2 Sided p < 0.05]

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Mean Pre-Mating Body Weight Change of Females

20256434

Body Weight Change (g)					
Sex: Female		Control		BNT162b2	
		0mcg		30mcg	
Day(s) Relative to Start Date					
1-22	Mean	23.64	R ¹	20.39	
	SD	9.93		9.45	
	N	44		44	
	%Diff			-13.73	

Statistical Test: Generalised Anova/Ancova Test Transformation: Automatic

1 [R - Automatic Transformation: Rank]

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Mean Gestation Body Weight

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20256434

Body Weight (g)		Control 0mcg		BNT162b2 30mcg	
Sex: Female					
Day(s) Relative to Mating (Litter:)					
0	Mean	241.30	L ¹	241.23	
	SD	20.73		19.34	
	N	43		42	
	%Diff	-		-0.03	
6	Mean	261.04	L ¹	261.16	
	SD	22.34		18.67	
	N	43		42	
	%Diff	-		0.05	
9	Mean	269.97	L ¹	270.42	
	SD	22.98		19.10	
	N	43		42	
	%Diff	-		0.17	
12	Mean	283.52	L ¹	276.13	
	SD	24.24		18.87	
	N	43		42	
	%Diff	-		-2.61	

Statistical Test: Generalised Anova/Ancova Test Transformation: Automatic

¹ [L - Automatic Transformation: Log]

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Mean Gestation Body Weight

20256434

Body Weight (g)		Control 0mcg		BNT162b2 30mcg	
Sex: Female					
Day(s) Relative to Mating (Litter: /					
15	Mean	296.72 L ¹		290.04	
	SD	24.44		21.19	
	N	43		42	
	%Diff	-		-2.25	
18	Mean	331.88 L ¹		325.33	
	SD	27.03		25.07	
	N	43		42	
	%Diff	-		-1.97	
21	Mean	365.981, a ²		350.15 d ³	
	SD	29.55		31.12	
	N	43		42	
	%Diff	-		-4.32	

Statistical Test: Generalised Anova/Ancova Test Transformation: Automatic

¹ [L - Automatic Transformation: Log]

³ [d - Test: Dunnett 2 Sided p < 0.05]

² [I, a - Automatic Transformation: Identity (No Transformation), (All Groups) Test: Analysis of Variance p < 0

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Mean Gestation Body Weight Change

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20256434

Body Weight Change (g)					
Sex: Female		Control 0mcg		BNT162b2 30mcg	
Day(s) Relative to Mating (Litter:)					
0-6	Mean	19.75 I ¹		19.94	
	SD	6.20		5.40	
	N	43		42	
	%Diff	-		0.95	
6-9	Mean	8.93I,a ²		9.26	
	SD	3.82		4.37	
	N	43		42	
	%Diff	-		3.71	
9-12	Mean	13.55 ³		5.70ddd ⁵	
	SD	3.77		4.16	
	N	43		42	
	%Diff	-		-57.89	
12-15	Mean	13.20 R ⁴		13.91	
	SD	3.24		6.22	
	N	43		42	
	%Diff	-		5.37	

Statistical Test: Generalised Anova/Ancova Test Transformation: Automatic

1 [I - Automatic Transformation: Identity (No Transformation)]

2 [I,a - Automatic Transformation: Identity (No Transformation), (All Groups) Test: Analysis of Variance p < 0

3 [I,aaa - Automatic Transformation: Identity (No Transformation), (All Groups) Test: Analysis of Variance p < 4 [R - Automatic Transformation: Rank]

5 [ddd - Test: Dunnett 2 Sided p < 0.001]

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Mean Gestation Body Weight Change

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Body Weight Change (g)		Control 0mcg		BNT162b2 30mcg	
Sex: Female					
Day(s) Relative to Mating (Litter:)					
15-18	Mean	35.16 ¹		35.29	
	SD	5.81		7.81	
	N	43		42	
	%Diff	-		0.38	
18-21	Mean	34.10 ²		24.82ddd ³	
	SD	5.64		22.27	
	N	43		42	
	%Diff	-		-27.20	
0-21	Mean	124.68 ²		108.93ddd ³	
	SD	14.14		22.08	
	N	43		42	
	%Diff	-		-12.64	

Statistical Test: Generalised Anova/Ancova Test Transformation: Automatic

¹ [I - Automatic Transformation: Identity (No Transformation)]
³ [ddd - Test: Dunnett Non-Parametric 2 Sided p < 0.001]

² [R, kkk - Automatic Transformation: Rank, (All Groups) Test: Kruskal-Wallis p < 0.001]
⁴ [d - Test: Dunnett Non-Parametric 2 Sided p < 0.05]

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Mean Lactation Body Weight

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20256434

Body Weight (g)		Control 0mcg		BNT162b2 30mcg	
Sex: Female					
Day(s) Relative to Littering (Litter:					
1	Mean	257.97 R ¹		257.36	
	SD	29.31		19.91	
	N	22		21	
	%Diff	-		-0.24	
4	Mean	280.10 R ¹		278.83	
	SD	26.24		17.71	
	N	22		21	
	%Diff	-		-0.45	
7	Mean	289.97 L ²		290.31	
	SD	24.89		17.19	
	N	22		21	
	%Diff	-		0.12	
10	Mean	298.86 L ²		296.55	
	SD	23.50		17.47	
	N	22		21	
	%Diff	-		-0.77	

Statistical Test: Generalised Anova/Ancova Test Transformation: Automatic

1 [R - Automatic Transformation: Rank]

2 [L - Automatic Transformation: Log]

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Mean Lactation Body Weight

20256434

Body Weight (g)					
Sex: Female		Control 0mcg		BNT162b2 30mcg	
Day(s) Relative to Littering (Litter:					
14	Mean	305.30 ¹		304.29	
	SD	23.50		18.86	
	N	22		21	
	%Diff	-		-0.33	
17	Mean	303.55 ¹		303.92	
	SD	22.84		17.88	
	N	22		21	
	%Diff	-		0.12	
21	Mean	291.04 ¹		293.30	
	SD	21.86		15.56	
	N	22		21	
	%Diff	-		0.78	

Statistical Test: Generalised Anova/Ancova Test Transformation: Automatic

¹ [I - Automatic Transformation: Identity (No Transformation)]

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Mean Lactation Body Weight Change

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20256434

Body Weight Change (g)							
Sex: Female		Control			BNT162b2		
		0mcg			30mcg		
Day(s) Relative to Littering (Litter:							
1-4	Mean	22.13	R ¹		21.47		
	SD	9.92			10.49		
	N	22			21		
	%Diff	.			-2.99		
4-7	Mean	9.88	I ²		11.48		
	SD	4.27			4.88		
	N	22			21		
	%Diff	.			16.24		
7-10	Mean	8.89	I ²		6.24		
	SD	5.32			6.01		
	N	22			21		
	%Diff	.			-29.75		
10-14	Mean	6.44	I ²		7.74		
	SD	5.28			7.51		
	N	22			21		
	%Diff	.			20.22		

Statistical Test: Generalised Anova/Ancova Test Transformation: Automatic

1 [R - Automatic Transformation: Rank]

2 [I - Automatic Transformation: Identity (No Transformation)]

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Mean Lactation Body Weight Change

20256434

Body Weight Change (g)		Control 0mcg		BNT162b2 30mcg	
Sex: Female					
Day(s) Relative to Littering (Litter:					
14-17	Mean	-1.75 ¹		-0.37	
	SD	6.22		7.06	
	N	22		21	
	%Diff	.		-79.05	
17-21	Mean	-12.50 ¹		-10.62	
	SD	7.56		6.62	
	N	22		21	
	%Diff	.		-15.08	
1-21	Mean	33.07 ¹		35.94	
	SD	16.53		11.57	
	N	22		21	
	%Diff	.		8.68	

Statistical Test: Generalised Anova/Ancova Test Transformation: Automatic

1 [I - Automatic Transformation: Identity (No Transformation)]

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Mean Pre-Mating Food Consumption of Females

20256434FC

Food Consumption (g/animal/day)		Control 0mcg		BNT162b2 30mcg	
Sex: Female					
Day(s) Relative to Start Date					
1-8	Mean	18.49 ¹		16.79ddd ⁴	
	SD	1.44		1.15	
	N	44		44	
	%Diff			-9.17	
8-15	Mean	18.73R,k ²		17.87 d ⁵	
	SD	1.71		1.32	
	N	44		44	
	%Diff			-4.57	
15-22	Mean	18.09 ¹		19.34ddd ⁴	
	SD	1.03		0.86	
	N	44		44	
	%Diff			6.94	
1-22	Mean	18.43 ³		18.00	
	SD	1.08		0.82	
	N	44		44	
	%Diff			-2.34	

Statistical Test: Generalised Anova/Ancova Test Transformation: Automatic

1 [R,kkk - Automatic Transformation: Rank, (All Groups) Test: Kruskal-Wallis p < 0.001]
3 [R,kk - Automatic Transformation: Rank, (All Groups) Test: Kruskal-Wallis p < 0.01]
5 [d - Test: Dunnett Non-Parametric 2 Sided p < 0.05]

2 [R,k - Automatic Transformation: Rank, (All Groups) Test: Kruskal-Wallis p < 0.05]
4 [ddd - Test: Dunnett Non-Parametric 2 Sided p < 0.001]

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Mean Gestation Food Consumption

20256434

Food Consumption (g/animal/day)							
Sex: Female		Control 0mcg		BNT162b2 30mcg			
Day(s) Relative to Mating (Litter: /							
0-6	Mean	19.69 L ¹		20.59			
	SD	2.59		1.99			
	N	43		42			
	%Diff	.		4.61			
6-9	Mean	21.56 I ²		22.29			
	SD	2.64		2.23			
	N	43		42			
	%Diff	.		3.38			
9-12	Mean	22.95 ³		19.26 ddd ⁴			
	SD	2.63		2.22			
	N	43		42			
	%Diff	.		-16.08			
12-15	Mean	23.06 L ¹		22.46			
	SD	2.19		2.22			
	N	43		42			
	%Diff	.		-2.59			

Statistical Test: Generalised Anova/Ancova Test Transformation:

1 [L - Automatic Transformation: Log]

2 [I - Automatic Transformation: Identity (No Transformation)]

3 [I,aaa - Automatic Transformation: Identity (No Transformation), (All Groups) Test: Analysis of Variance p = 4 [ddd - Test: Dunnett 2 Sided p < 0.001]

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Mean Gestation Food Consumption

20256434

Food Consumption (g/animal/day)							
Sex: Female		Control 0mcg		CCI		BNT162b2 30mcg	
Day(s) Relative to Mating (Litter:)							
15-18	Mean	25.33	R ¹			24.84	
	SD	3.58				2.77	
	N	43				42	
	%Diff	.				-1.94	
18-21	Mean	23.41	I ²			22.66	
	SD	2.71				2.17	
	N	43				41	
	%Diff	.				-3.21	
0-21	Mean	22.24	I ²			21.80	
	SD	2.21				1.75	
	N	43				41	
	%Diff	.				-1.98	

Statistical Test: Generalised Anova/Ancova Test Transformation: Automatic

1 [R - Automatic Transformation: Rank]

2 [I - Automatic Transformation: Identity (No Transformation)]

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Mean Lactation Food Consumption

20256434

Food Consumption (g/animal/day)		Control 0mcg		BNT162b2 30mcg	
Sex: Female					
Day(s) Relative to Littering (Litter:					
1-4	Mean	35.64	¹	36.72	
	SD	4.25		5.72	
	N	22		21	
	%Diff	-		3.02	
4-7	Mean	41.48	²	43.65	
	SD	3.84		4.93	
	N	22		21	
	%Diff	-		5.22	
7-10	Mean	51.06	²	51.31	
	SD	3.96		6.20	
	N	22		21	
	%Diff	-		0.49	
10-14	Mean	58.48	³	59.12	
	SD	5.13		7.17	
	N	22		21	
	%Diff	-		1.09	

Statistical Test: Generalised Anova/Ancova Test Transformation: Automatic

¹ [I - Automatic Transformation: Identity (No Transformation)]

² [R - Automatic Transformation: Rank]

³ [R,kk - Automatic Transformation: Rank, (All Groups) Test: Kruskal-Wallis p < 0.01]

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Mean Lactation Food Consumption

20256434

Food Consumption (g/animal/day)							
Sex: Female		Control 0mcg		CCI	BNT162b2 30mcg		CCI
Day(s) Relative to Littering (Litter:							
14-17	Mean	63.35R,k ¹			62.73		
	SD	4.74			7.84		
	N	22			21		
	%Diff	-			-0.97		
17-21	Mean	66.81 ²			67.71		
	SD	6.05			8.32		
	N	22			21		
	%Diff	-			1.34		
1-21	Mean	53.79R,k ¹			54.53		
	SD	4.26			6.18		
	N	22			21		
	%Diff	-			1.37		

Statistical Test: Generalised Anova/Ancova Test Transformation: Automatic

1 [R,k - Automatic Transformation: Rank, (All Groups) Test: Kruskal-Wallis p < 0.05]

3 [d - Test: Dunnett Non-Parametric 2 Sided p < 0.05]

2 [R,kk - Automatic Transformation: Rank, (All Groups) Test: Kruskal-Wallis p < 0.01]

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20256434
Mean Estrous Cycle Data - Before Dosing

Parameter	Cycle length (days)	Irregularity index	Percentage of estrus days	Percentage of females acyclic or with acyclic period
Group 1, Control, 0 µg				
MEAN	4.02	0.19	26.95	
SD	0.19	0.30	6.14	0
N	44	44	44	
CCI				
Group 3, BNT162b2, 30 µg				
MEAN	4.00	0.18	26.70	
SD	0.11	0.30	5.00	4.5
N	42	42	42	
CCI				

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20256434
Mean Estrous Cycle Data - Pre-Mating Period

Parameter	Cycle length (days)	Irregularity index	Percentage of estrus days	Percentage of females acyclic or with acyclic period
Group 1, Control, 0 µg				
MEAN	4.00	0.03	25.19	
SD	0.00	0.14	3.94	18.2
N	36	36	36	
CCI				
Group 3, BNT162b2, 30 µg				
MEAN	4.02	0.05	24.07	
SD	0.13	0.12	3.66	18.2
N	36	36	36	
CCI				

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20256434
Summary of Cohabitation Data and Maternal Performance
Littering and Caesarean Subsets

GROUP	1	3
DOSING	Control 0 µg	BNT162b2 30 µg
<u>LITTERING AND CAESAREAN SUBSETS:</u>		
NUMBER OF FEMALES:		
Paired	44	44
Failed to mate	0	0
Inseminated	44	44
Not pregnant	1C	1C+1L
Mistimed pregnancy	0	0
Pregnant	43	42
PRE - COITAL INTERVAL - DAYS		
MEAN	3.0	2.8
SD	2.2	1.7
N	44	44
COPULATION INDEX (%)	100	100
PREGNANCY RATE (%)	98	95
FERTILITY INDEX (%)	98	95
Caesarean phase (inseminated females)		
- With viable fetuses	21	21
Lactation phase (inseminated females)		
- Females with live pups ⁽²⁾	22	21
- Euthanized moribund post-partum	0	0
- Total litter death post-partum	0	0
- Reared pups to weaning	22	21
GESTATION INDEX (%)	100	100

C: Caesarean phase

L: Lactation phase

⁽¹⁾ mistimed pregnancy for one pair of rats

⁽²⁾ including one euthanized moribund post-partum female from group 4

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Mean Gravid Uterus Weight and Maternal Body Weight Change

20256434

Sex: Female		Control 0mcg	CCI	BNT162b2 30mcg	CCI
Gravid Uterus (g)	Mean	86.32 R,k ¹		87.65	
	SD	7.69		13.48	
	N	21		21	
	%Diff	-		1.53	
Necropsy BW (g)	Mean	366.51 I,a ³		351.47	
	SD	24.72		26.24	
	N	21		21	
	%Diff	-		-4.11	
Adjusted BW (g)	Mean	280.19 L ⁴		263.82	
	SD	22.08		15.75	
	N	21		21	
	%Diff	-		-5.84	
Net BWC from G6 (g)	Mean	104.25 ⁵		93.20 dd ⁶	
	SD	7.27		15.12	
	N	21		21	
	%Diff	-		-10.61	
Net BWC - Uterine Wt (g)	Mean	17.93 ⁸		5.55 ddd ⁹	
	SD	7.54		8.56	
	N	21		21	
	%Diff	-		-69.06	
Mean Foetal Wt (Both) (g)	Mean	4.89 I ⁺		4.90	
	SD	0.23		0.30	
	N	21		21	
	%Diff	-		0.25	
No. Live Foetuses	Mean	13.2 R,k ¹		13.1	
	SD	1.6		2.1	
	%Diff	-		-0.4	

+ [Footnote is displayed in the Comments and Markers page]

1 [R,k - Automatic Transformation: Rank, (All Groups) Test: Kruskal-Wallis p < 0.05]

2 [d - Test: Dunnett Non-Parametric 2 Sided p < 0.05]

3 [I,a - Automatic Transformation: Identity (No Transformation), (All Groups) Test: Analysis of Variance p < 0.05]

4 [L - Automatic Transformation: Log]

5 [R,kkk - Automatic Transformation: Rank, (All Groups) Test: Kruskal-Wallis p < 0.001]

6 [dd - Test: Dunnett Non-Parametric 2 Sided p < 0.01]

7 [ddd - Test: Dunnett Non-Parametric 2 Sided p < 0.001]

8 [I,aaa - Automatic Transformation: Identity (No Transformation), (All Groups) Test: Analysis of Variance p < 0.001]

9 [ddd - Test: Dunnett 2 Sided p < 0.001]

0 [d - Test: Dunnett 2 Sided p < 0.05]

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Mean Caesarean Section Data

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20256434		20256434	
Sex: Female	Control 0mcg		BNT162b2 30mcg
Day(s) Relative to Mating (Litter: A)			
Females Pregnant [CHSQFS]	N+ve	21	21
Dams with Viable Foetuses		21	21
No. of Corpora Lutea [GEN AN]	Mean	14.7 I ¹	15.5
	SD	1.6	2.1
	Sum	309 I ¹	326
No. of Implantations [GEN AN]	Mean	14.1 R ²	14.0
	SD	1.6	2.2
	Sum	296 R ²	294
Pre-Implantation Loss [GEN AN]	Mean	0.6 R,k ³	1.5 d ⁴
	SD	1.0	1.3
	Sum	13 R,k ³	32 d ⁴
Pre-Implantation Loss (%) [KWLWCX]	Mean	4.09 k ⁵	9.77 d ⁴
	SD	6.56	8.09
No. of Early Resorptions [GEN AN]	Mean	0.8 R ²	0.7
	SD	1.2	1.0
	Sum	16 R ²	14
Early Resorptions (%) [KWLWCX]	Mean	5.04	4.62
	SD	7.23	6.12
No. of Late Resorptions [GEN AN]	Mean	0.1 R ²	0.2
	SD	0.4	0.5
	Sum	3 R ²	4
Late Resorptions (%) [KWLWCX]	Mean	1.05	1.23
	SD	2.66	3.27
No. of Dead Foetuses [GEN AN]	Mean	0.0 R ²	0.0
	SD	0.0	0.0
	Sum	0 R ²	0
Post-Implantation Loss [GEN AN]	Mean	0.9 R ²	0.9
	SD	1.2	1.2
	Sum	19 R ²	18

[CHSQFS] - Chi-Squared & Fisher's Exact

[GEN AN] - Generalised Anova/Ancova Test

[KWLWCX] - Kruskal Wallis & Wilcoxon

1 [I] - Automatic Transformation: Identity (No Transformation)]

2 [R] - Automatic Transformation: Rank]

3 [R,k] - Automatic Transformation: Rank, (All Groups) Test: Kruskal-Wallis p < 0.05]

4 [d] - Test: Dunnett Non-Parametric 2 Sided p < 0.05]

5 [k] - (All Groups) Test: Kruskal-Wallis p < 0.05]

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Mean Caesarean Section Data

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20256434		Control 0mcg		BNT162b2 30mcg	
Sex: Female					
Day(s) Relative to Mating (Litter: A)					
Post-Implantation Loss (%) [KWLWCX]	Mean	6.10		5.85	
	SD	7.64		7.28	
No. of Live Foetuses [GEN AN]	Mean	13.2 R,k ¹		13.1	
	SD	1.6		2.1	
	Sum	277 R,k ¹		276	
No. of Male Foetuses [GEN AN]	Mean	6.1 I ²		6.7	
	SD	1.7		2.0	
	Sum	129 I ²		141	
No. of Female Foetuses [GEN AN]	Mean	7.0 I ²		6.4	
	SD	2.1		1.5	
	Sum	148 I ²		135	
Male Foetuses (%) [KWLWCX]	Mean	46.96		50.66	
	SD	14.27		10.69	
Total Litter Weight (g) [GEN AN]	Mean	64.23 ³		64.32	
	SD	5.91		10.53	
	N	21		21	
	%Diff			0.14	
Mean Foetal Weight (both) (g) [GEN AN]	Mean	4.89 I ²		4.90	
	SD	0.23		0.30	
	N	21		21	
	%Diff			0.25	
Mean Foetal Weight (M) (g) [GEN AN]	Mean	5.00 I ²		5.02	
	SD	0.21		0.30	
Mean Foetal Weight (F) (g) [GEN AN]	Mean	4.79 I ²		4.77	
	SD	0.24		0.32	

[KWLWCX] - Kruskal Wallis & Wilcoxon

[GEN AN] - Generalised Anova/Ancova Test

1 [R,k - Automatic Transformation: Rank, (All Groups) Test: Kruskal-Wallis p < 0.05]

2 [I - Automatic Transformation: Identity (No Transformation)]

3 [R,kk - Automatic Transformation: Rank, (All Groups) Test: Kruskal-Wallis p < 0.01]

4 [d - Test: Dunnett Non-Parametric 2 Sided p < 0.05]

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Summary of Foetal External, Visceral and Skeletal Observations

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20256434		CC		CCI	
Exam Type: External		Control 0mcg		BNT162b2 30mcg	
Number of Fetuses Examined:		277		276	
Number of Litters Examined:		21		21	
Head/neck					
Head/neck, Exencephaly - (M)	Fetuses N(%)	0(0.0)		0(0.0)	
	Litters N(%)	0(0.0)		0(0.0)	
Eye					
Eye, Open - (M)	Fetuses N(%)	0(0.0)		0(0.0)	
	Litters N(%)	0(0.0)		0(0.0)	
Mouth/Jaw					
Mouth, Misshapen - (M)	Fetuses N(%)	0(0.0)		1(0.4)	
	Litters N(%)	0(0.0)		1(4.8)	
Jaw, Agnathia - (M)	Fetuses N(%)	0(0.0)		1(0.4)	
	Litters N(%)	0(0.0)		1(4.8)	
Body					
Trunk, Gastroschisis - (M)	Fetuses N(%)	0(0.0)		1(0.4)	
	Litters N(%)	0(0.0)		1(4.8)	
Trunk, Spina bifida - (M)	Fetuses N(%)	0(0.0)		0(0.0)	
	Litters N(%)	0(0.0)		0(0.0)	

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Summary of Foetal External, Visceral and Skeletal Observations

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Exam Type: Visceral Body (Rat)		Control 0mcg	BNT162b2 30mcg
Number of Fetuses Examined:		133	132
Number of Litters Examined:		21	21
Heart			
Heart, Ventricular septum defect - (M)	Fetuses N(%)	0(0.0)	0(0.0)
	Litters N(%)	0(0.0)	0(0.0)
Liver			
Liver, Abnormal lobation - (A)	Fetuses N(%)	1(0.8)	0(0.0)
	Litters N(%)	1(4.8)	0(0.0)
Lung			
Lobe, Absent - (A)	Fetuses N(%)	0(0.0)	1(0.8)
	Litters N(%)	0(0.0)	1(4.8)
Lobe, Supernumerary - (A)	Fetuses N(%)	0(0.0)	0(0.0)
	Litters N(%)	0(0.0)	0(0.0)
Major blood vessel			
Aortic arch, Right-sided - (M)	Fetuses N(%)	0(0.0)	1(0.8)
	Litters N(%)	0(0.0)	1(4.8)
Ductus arteriosus, Narrowed - (M)	Fetuses N(%)	0(0.0)	0(0.0)
	Litters N(%)	0(0.0)	0(0.0)
Subclavian artery, Malpositioned - (A)	Fetuses N(%)	0(0.0)	0(0.0)
	Litters N(%)	0(0.0)	0(0.0)
Umbilical artery, Transposed - (V)	Fetuses N(%)	7(5.3)	13(9.8)
	Litters N(%)	6(28.6)	8(38.1)

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Summary of Foetal External, Visceral and Skeletal Observations

20256434

Exam Type: Visceral Body (Rat)		Control 0mcg	BNT162b2 30mcg
Number of Fetuses Examined:		133	132
Number of Litters Examined:		21	21
Vein			
Azygos vein, Transposed - (A)	Fetuses N(%)	1(0.8)	0(0.0)
	Litters N(%)	1(4.8)	0(0.0)

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Summary of Foetal External, Visceral and Skeletal Observations

20256434

Exam Type: Visceral Head (Rat)		Control 0mcg	CCI	BNT162b2 30mcg	CCI
Number of Fetuses Examined:		133		132	
Number of Litters Examined:		21		21	
Eye					
Retina, Fold - (M)	Fetuses N(%)	0(0.0)		0(0.0)	
	Litters N(%)	0(0.0)		0(0.0)	

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Summary of Foetal External, Visceral and Skeletal Observations

20256434

Exam Type: Skeletal Head (Rat-G21)		Control 0mcg	BNT162b2 30mcg
Number of Fetuses Examined:		144	144
Number of Litters Examined:		21	21
Skull			
Cranium, Acrania - (M)	Fetuses N(%)	0(0.0)	0(0.0)
	Litters N(%)	0(0.0)	0(0.0)
Hyoid, Incomplete ossification - (A)	Fetuses N(%)	0(0.0)	1(0.7)
	Litters N(%)	0(0.0)	1(4.8)
Interparietal, Incomplete ossification - (V)	Fetuses N(%)	3(2.1)	4(2.8)
	Litters N(%)	3(14.3)	3(14.3)
Mandible, Fused - (M)	Fetuses N(%)	0(0.0)	1(0.7)
	Litters N(%)	0(0.0)	1(4.8)
Mandible, Misshapen - (A)	Fetuses N(%)	0(0.0)	1(0.7)
	Litters N(%)	0(0.0)	1(4.8)
Mandible, Short - (M)	Fetuses N(%)	0(0.0)	1(0.7)
	Litters N(%)	0(0.0)	1(4.8)
Parietal, Incomplete ossification - (V)	Fetuses N(%)	0(0.0)	3(2.1)
	Litters N(%)	0(0.0) c ¹	3(14.3)
Presphenoid, Incomplete ossification - (A)	Fetuses N(%)	1(0.7)	0(0.0)
	Litters N(%)	1(4.8)	0(0.0)
Squamosal, Incomplete ossification - (V)	Fetuses N(%)	0(0.0)	1(0.7)
	Litters N(%)	0(0.0)	1(4.8)
Supraoccipital, Incomplete ossification - (V)	Fetuses N(%)	0(0.0)	2(1.4)
	Litters N(%)	0(0.0)	2(9.5)

1 [c - Group Factor Chi-Squared & Fisher's Exact Test: Chi-Squared p < 0.05]

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Summary of Foetal External, Visceral and Skeletal Observations

20256434

Exam Type: Skeletal Body (Ral-G21)		Control 0mcg	BNT162b2 30mcg
Number of Fetuses Examined:		144	144
Number of Litters Examined:		21	21
General			
Vertebra, Presacral vertebral arches = 27 - (A)	Fetuses N(%)	0(0.0)	1(0.7)
	Litters N(%)	0(0.0)	1(4.8)
Forepaw			
Phalanx, Unossified - (A)	Fetuses N(%)	9(6.3)	6(4.2)
	Litters N(%)	7(33.3)	3(14.3)
Hindpaw			
Metatarsal, Unossified, 1st digit - (V)	Fetuses N(%)	3(2.1)	3(2.1)
	Litters N(%)	3(14.3)	3(14.3)
Phalanx, Unossified, proximal 2nd to 5th digits - (V)	Fetuses N(%)	46(31.9)	22(15.3)
	Litters N(%)	11(52.4)	7(33.3)
Ribs			
Ribs, Supernumerary cervical - (A)	Fetuses N(%)	3(2.1)	0(0.0)
	Litters N(%)	3(14.3)	0(0.0)
Ribs, Supernumerary lumbar - (A)	Fetuses N(%)	3(2.1)	12(8.3)
	Litters N(%)	3(14.3)	6(28.6)
Ribs, Thick - (A)	Fetuses N(%)	2(1.4)	4(2.8)
	Litters N(%)	1(4.8)	3(14.3)
Ribs, Wavy - (A)	Fetuses N(%)	0(0.0)	1(0.7)
	Litters N(%)	0(0.0)	1(4.8)
Ribs, Supernumerary lumbar, short - (V)	Fetuses N(%)	57(39.6)	71(49.3)

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Summary of Foetal External, Visceral and Skeletal Observations

20256434

Exam Type: Skeletal Body (Rat-G21)		Control 0mcg	BNT162b2 30mcg
Number of Fetuses Examined:		144	144
Number of Litters Examined:		21	21
Ribs (Continued...)	Litters N(%)	17(81.0)	18(85.7)
Ribs, Supernumerary lumbar, short - (V)			
Sternebra	Fetuses N(%)	1(0.7)	0(0.0)
Sternebra, Asymmetric - (A)	Litters N(%)	1(4.8)	0(0.0)
Sternebra, Extra ossification site - (A)	Fetuses N(%)	0(0.0)	0(0.0)
	Litters N(%)	0(0.0)	0(0.0)
Sternebra, Incomplete ossification, 1st/3rd - (A)	Fetuses N(%)	1(0.7)	1(0.7)
	Litters N(%)	1(4.8)	1(4.8)
Sternebra, Incomplete ossification, 2nd/4th - (V)	Fetuses N(%)	1(0.7)	2(1.4)
	Litters N(%)	1(4.8)	2(9.5)
Sternebra, Incomplete ossification, 6th - (V)	Fetuses N(%)	0(0.0)	0(0.0)
	Litters N(%)	0(0.0)	0(0.0)
Sternebra, Minor fusion - (A)	Fetuses N(%)	1(0.7)	0(0.0)
	Litters N(%)	1(4.8)	0(0.0)
Sternebra, Misshapen - (A)	Fetuses N(%)	0(0.0)	0(0.0)
	Litters N(%)	0(0.0)	0(0.0)
Sternebra, Unossified, 5th - (A)	Fetuses N(%)	0(0.0)	0(0.0)
	Litters N(%)	0(0.0)	0(0.0)
Vertebra			
Caudal, Number < 5 - (A)	Fetuses N(%)	0(0.0)	2(1.4)

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Summary of Foetal External, Visceral and Skeletal Observations

20256434

Exam Type: Skeletal Body (Rat-G21)		Control 0mcg	BNT162b2 30mcg
Number of Fetuses Examined:		144	144
Number of Litters Examined:		21	21
Vertebra (Continued...)			
Caudal, Number < 5 - (A)	Litters N(%)	0(0.0)	2(9.5)
Cervical, Fused arch - (A)	Fetuses N(%)	0(0.0)	0(0.0)
	Litters N(%)	0(0.0)	0(0.0)
Cervical, Incomplete ossification of arch - (A)	Fetuses N(%)	0(0.0)	2(1.4)
	Litters N(%)	0(0.0)	2(9.5)
Cervical, Multiple abnormalities - (M)	Fetuses N(%)	0(0.0)	0(0.0)
	Litters N(%)	0(0.0)	0(0.0)
Cervical, Odontoid process unossified - (V)	Fetuses N(%)	9(6.3)	6(4.2)
	Litters N(%)	7(33.3)	4(19.0)
Cervical, Unossified centrum - (V)	Fetuses N(%)	3(2.1)	2(1.4)
	Litters N(%)	3(14.3)	2(9.5)
Lumbar, Number = 7 - (A)	Fetuses N(%)	1(0.7)	3(2.1)
	Litters N(%)	1(4.8)	2(9.5)
Sacral, Misshapen arch - (A)	Fetuses N(%)	0(0.0)	0(0.0)
	Litters N(%)	0(0.0)	0(0.0)
Thoracic, Bipartite ossification of centrum - (A)	Fetuses N(%)	0(0.0)	0(0.0)
	Litters N(%)	0(0.0)	0(0.0)
Thoracic, Incomplete ossification of centrum, 1st to 9th - (A)	Fetuses N(%)	1(0.7)	3(2.1)
	Litters N(%)	1(4.8)	3(14.3)
Thoracic, Incomplete ossification of centrum, 10th to 13th - (A)	Fetuses N(%)	6(4.2)	9(6.3)

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Summary of Foetal External, Visceral and Skeletal Observations

20256434

Exam Type: Skeletal Body (Rat-G21)		Control 0mcg		BNT162b2 30mcg	
Number of Fetuses Examined:		144		144	
Number of Litters Examined:		21		21	
Vertebra (Continued...)					
Thoracic, Incomplete ossification of centrum, 10th to 13th. - (A)	Litters N(%)	5(23.8)	C ¹	9(42.9)	
Thoracic, Multiple abnormalities - (M)	Fetuses N(%)	0(0.0)		0(0.0)	
	Litters N(%)	0(0.0)		0(0.0)	
Thoracic, Number = 14 - (A)	Fetuses N(%)	0(0.0)		0(0.0)	
	Litters N(%)	0(0.0)		0(0.0)	

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Summary of Delivery and Litter Data

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20256434

Sex: Female		Control 0mcg	CCI	BNT162b2 30mcg	CCI
Day(s) Relative to Littering (Litter: A)					
Females Completing Delivery [CHSQFS]	N+ve	22		21	
with Liveborn Pups [CHSQFS]	N+ve	22		21	
with Stillborn Pups [CHSQFS]	N+ve	3		2	
with all Stillborn Pups [CHSQFS]	N+ve	0		0	
with all Dead PND 21 [CHSQFS]	N+ve	0		0	
Gestation Length (Days) [GEN AN]	Mean	22.1 ¹		22.0	
	SD	0.4		0.7	
	N	22		21	
Number of Implantation Sites [GEN AN]	Mean	14.3 ¹³		14.2	
	SD	2.2		2.2	
	N	22		21	
	Sum	314 ¹³		298	
Pre-Birth Loss (%) [GEN AN]	Mean	6.80 R,k ⁴		8.22	
	SD	8.75		15.51	
	N	22		21	
Pups Delivered/Litter [GEN AN]	Mean	13.3 R,k ⁴		13.1	
	SD	2.5		3.1	
	N	22		21	
	Sum	293 R,k ⁴		276	

[CHSQFS] - Chi-Squared & Fisher's Exact

1 [R,kk - Automatic Transformation: Rank, (All Groups) Test: Kruskal-Wallis p < 0.01]

3 [I - Automatic Transformation: Identity (No Transformation)]

5 [d - Test: Dunnett Non-Parametric 2 Sided p < 0.05]

[GEN AN] - Generalised Anova/Ancova Test

2 [dd - Test: Dunnett Non-Parametric 2 Sided p < 0.01]

4 [R,k - Automatic Transformation: Rank, (All Groups) Test: Kruskal-Wallis p < 0.05]

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Summary of Delivery and Litter Data

20256434

Sex: Female		Control 0mcg	CCI	BNT162b2 30mcg	CCI
Day(s) Relative to Littering (Litter: A)					
Live Pups PND 0 [GEN AN]	Mean	13.0 R,k ¹		13.0	
	SD	2.5		3.1	
	N	22		21	
	Sum	287 R,k ¹		274	
Live Pups PND 1 [GEN AN]	Mean	13.0 R,k ¹		13.0	
	SD	2.4		3.0	
	N	22		21	
	Sum	285 R,k ¹		273	
Live Pups Precull [GEN AN]	Mean	12.9 R,k ¹		12.9	
	SD	2.3		2.9	
	N	22		21	
	Sum	284 R,k ¹		271	
Live Pups Postcull [GEN AN]	Mean	8.0 R ³		7.8	
	SD	0.0		1.1	
	N	22		21	
	Sum	176 R ³		163	
Live Pups PND 7 [GEN AN]	Mean	8.0 R ³		7.8	
	SD	0.0		1.1	
	N	22		21	
	Sum	176 R ³		163	

[GEN AN] - Generalised Anova/Ancova Test
2 [d - Test: Dunnett Non-Parametric 2 Sided p < 0.05]

1 [R,k - Automatic Transformation: Rank, (All Groups) Test: Kruskal-Wallis p < 0.05]
3 [R - Automatic Transformation: Rank]

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Summary of Delivery and Litter Data

20256434

Sex: Female		Control 0mcg		BNT162b2 30mcg	
Day(s) Relative to Littering (Litter: A)					
Live Pups PND 10 [GEN AN]	Mean	8.0	R ¹	7.8	
	SD	0.0		1.1	
	N	22		21	
	Sum	176	R ¹	163	
Live Pups PND 14 [GEN AN]	Mean	8.0	R ¹	7.8	
	SD	0.0		1.1	
	N	22		21	
	Sum	176	R ¹	163	
Live Pups PND 17 [GEN AN]	Mean	8.0	R ¹	7.8	
	SD	0.0		1.1	
	N	22		21	
	Sum	176	R ¹	163	
Live Pups PND 21 [GEN AN]	Mean	8.0	R ¹	7.8	
	SD	0.2		1.1	
	N	22		21	
	Sum	175	R ¹	163	
Dead, Miss., Cannib. PND 0 [CHSQFS]		Sum	6	2	
Dead, Miss., Cannib. PND 1-4 [CHSQFS]		Sum	3	3	
Dead, Miss., Cannib. PND 5-21 [CHSQFS]		Sum	1	0	
Dead, Miss., Cannib. PND 0-21 [CHSQFS]		Sum	10	5	

[GEN AN] - Generalised Anova/Ancova Test
1 [R - Automatic Transformation: Rank]

[CHSQFS] - Chi-Squared & Fisher's Exact

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Summary of Delivery and Litter Data

20256434

Sex: Female		Control 0mcg		BNT162b2 30mcg	
Day(s) Relative to Littering (Litter: A)					
Live Birth Index (%)		98.0		99.3	
Viability Index (PND 0-4) (%)		99.0		98.9	
Weaning Index (PND 4-21) (%)		99.4		100.0	
Sex Ratio PND 1 - % Males [CHSQFS]	Mean	51.0		48.0	
Sex Ratio PND 21 - % Males [CHSQFS]	Mean	49.7		47.6	

[CHSQFS] - Chi-Squared & Fisher's Exact

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Mean Pup Body Weight (grams)

20256434

Sex: Female		Control 0mcg	CCI	BNT162b2 30mcg	CCI
Day(s) Relative to Littering (Litter: A)					
Mean Pup BW - Males d1 [GEN AN]	Mean	6.25 R ¹		6.27	
	SD	0.82		0.73	
	N	22		20	
	%Diff	-		0.23	
Mean Pup BW - Males d4 [GEN AN]	Mean	9.71 I ²		9.81	
	SD	1.26		1.21	
	N	22		20	
	%Diff	-		1.00	
Mean Pup BW - Males d7 [GEN AN]	Mean	16.14 R ¹		16.47	
	SD	1.76		1.74	
	N	22		20	
	%Diff	-		2.07	
Mean Pup BW - Males d10 [GEN AN]	Mean	23.79 R ¹		24.24	
	SD	2.17		1.87	
	N	22		20	
	%Diff	-		1.87	
Mean Pup BW - Males d14 [GEN AN]	Mean	34.35 I ²		34.93	
	SD	2.76		2.13	
	N	22		20	
	%Diff	-		1.69	

[GEN AN] - Generalised Anova/Ancova Test
2 [I - Automatic Transformation: Identity (No Transformation)]
4 [S - Test: Shirley 2 Sided p < 0.05]

1 [R - Automatic Transformation: Rank]
3 [w - Test: Williams 2 Sided p < 0.05]

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Mean Pup Body Weight (grams)

20256434

Sex: Female		Control 0mcg	CCI	BNT162b2 30mcg	CCI
Day(s) Relative to Littering (Litter: A)					
Mean Pup BW - Males d17 [GEN AN]	Mean	41.64 ¹		42.07	
	SD	3.10		2.36	
	N	22		20	
	%Diff	-		1.04	
Mean Pup BW - Males d21 [GEN AN]	Mean	55.53 ¹		56.10	
	SD	4.02		3.22	
	N	22		20	
	%Diff	-		1.03	
Mean Pup BW - Males d4 Postculling [GEN AN]	Mean	9.71 ¹		9.78	
	SD	1.31		1.24	
	N	22		20	
	%Diff	-		0.66	
Mean Pup BW - Females d1 [GEN AN]	Mean	6.00 ¹		6.06	
	SD	0.82		0.73	
	N	22		21	
	%Diff	-		0.97	
Mean Pup BW - Females d4 [GEN AN]	Mean	9.47 ¹		9.58	
	SD	1.25		1.33	
	N	22		21	
	%Diff	-		1.25	

[GEN AN] - Generalised Anova/Ancova Test
2 [w - Test: Williams 2 Sided p < 0.05]

1 [I - Automatic Transformation: Identity (No Transformation)]

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Mean Pup Body Weight (grams)

20256434

Sex: Female		Control 0mcg	CCI	BNT162b2 30mcg	CCI
Day(s) Relative to Littering (Litter: A)					
Mean Pup BW - Females d7 [GEN AN]	Mean	15.77 R ¹		16.10	
	SD	1.72		1.75	
	N	22		21	
	%Diff	-		2.14	
Mean Pup BW - Females d10 [GEN AN]	Mean	23.35 R ¹		23.82	
	SD	2.21		1.85	
	N	22		21	
	%Diff	-		1.99	
Mean Pup BW - Females d14 [GEN AN]	Mean	33.71 I ²		34.28	
	SD	2.88		2.04	
	N	22		21	
	%Diff	-		1.70	
Mean Pup BW - Females d17 [GEN AN]	Mean	40.69 I ²		41.10	
	SD	3.16		2.26	
	N	22		21	
	%Diff	-		1.00	
Mean Pup BW - Females d21 [GEN AN]	Mean	54.02 I ²		54.42	
	SD	4.18		2.66	
	N	22		21	
	%Diff	-		0.73	

[GEN AN] - Generalised Anova/Ancova Test

2 [I - Automatic Transformation: Identity (No Transformation)]

1 [R - Automatic Transformation: Rank]

3 [S - Test: Shirley 2 Sided p < 0.05]

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Mean Pup Body Weight (grams)

20256434

Sex: Female		Control 0mcg	CCI	BNT162b2 30mcg	CCI
Day(s) Relative to Littering (Litter: A)					
Mean Pup BW - Females d4 Postculling [GEN AN]	Mean	9.49 I ¹		9.59	
	SD	1.25		1.37	
	N	22		21	
	%Diff			1.09	
Mean Pup Body Weight d1 [GEN AN]	Mean	6.13 R ²		6.19	
	SD	0.82		0.74	
	N	22		21	
	%Diff			1.06	
Mean Pup Body Weight d4 [GEN AN]	Mean	9.60 I ¹		9.75	
	SD	1.25		1.31	
	N	22		21	
	%Diff			1.65	
Mean Pup Body Weight d7 [GEN AN]	Mean	15.95 R ²		16.34 S ³	
	SD	1.71		1.73	
	N	22		21	
	%Diff			2.46	
Mean Pup Body Weight d10 [GEN AN]	Mean	23.57 R ²		24.07	
	SD	2.15		1.81	
	N	22		21	
	%Diff			2.10	

[GEN AN] - Generalised Anova/Ancova Test
2 [R - Automatic Transformation: Rank]

1 [I - Automatic Transformation: Identity (No Transformation)]
3 [S - Test: Shirley 2 Sided p < 0.05]

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Mean Pup Body Weight (grams)

20256434

Sex: Female		Control 0mcg	CCI	BNT162b2 30mcg	CCI
Day(s) Relative to Littering (Litter: A)					
Mean Pup Body Weight d14 [GEN AN]	Mean	34.03 ¹		34.63	
	SD	2.78		2.00	
	N	22		21	
	%Diff	.		1.77	
Mean Pup Body Weight d17 [GEN AN]	Mean	41.16 ¹		41.59	
	SD	3.11		2.19	
	N	22		21	
	%Diff	.		1.06	
Mean Pup Body Weight d21 [GEN AN]	Mean	54.75 ¹		55.23	
	SD	4.07		2.71	
	N	22		21	
	%Diff	.		0.87	
Mean Pup BW d4 Postculling [GEN AN]	Mean	9.60 ¹		9.75	
	SD	1.26		1.34	
	N	22		21	
	%Diff	.		1.51	

[GEN AN] - Generalised Anova/Ancova Test

1 [I - Automatic Transformation: Identity (No Transformation)]

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		20256434	
		Summary of Reflex and Physi	
Group		1	3
Dose level		Control 0 µg	BNT162b2 30µg
PINNA UNFOLDING			
- % of pups positive:			
day 1	<i>post-partum</i>	5	6
day 2	<i>post-partum</i>	51	51
day 3	<i>post-partum</i>	98	99
day 4	<i>post-partum</i>	100	100 ⁽³⁾
EYE OPENING			
- % of pups positive:			
day 12	<i>post-partum</i>	0	3
day 13	<i>post-partum</i>	19	9
day 14	<i>post-partum</i>	83	79
day 15	<i>post-partum</i>	99	96
day 16	<i>post-partum</i>	100	100
day 17	<i>post-partum</i>		
PUPILLARY REFLEX - day 21 <i>post-partum</i>			
- % of pups positive:			
		100	100
AUDITORY REFLEX - day 21 <i>post-partum</i>			
- % of pups positive:			
		100	100

(1): 99.6%

(2): values excluded for three pups that were not observed after PND14 in error

(3): 99.7%, one unselected pup for culling was not observed after PND4

*: $p \leq 0.05$; *** $p \leq 0.001$

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Summary of Maternal Macroscopic Observations

20256434

		FEMALES	
Removal Reason: TERMINAL SACRIFICE		Control 0mcg	BNT162b2 30mcg
Number of Animals on Study :		44	43
Number of Animals Completed:		(44)	(43)
LIVER;			
Submitted.....	(2)	(1)	
No Visible Lesions.....	0	0	
Hernia; diaphragm; between right and left median lobes	2	0	
Mottled surface; all lobes	0	0	
Abnormal shape; left median lobe	0	0	
Small; left median lobe	0	0	
Mass a; adherent to surrounding tissue; papillary process; solid; dark; heterogeneous	0	1	
IDENTIFICATION;			
Submitted.....	(3)	(12)	
No Visible Lesions.....	3	12	
SKIN/SUBCUTIS;			
Submitted.....	(2)	(6)	
No Visible Lesions.....	0	0	
Alopecia; single; forelimb; right; left	0	3	
Alopecia; single; forelimb; left	1	0	
Alopecia; single; abdominal region; thoracic region	0	0	
Alopecia; single; thoracic region	0	1	
Alopecia; single; thoracic region; abdominal	0	1	
Alopecia; right; forepaw; abdominal; left	0	0	
Sore/crust; many; back; head	0	1	
Sore/crust; many; forelimb; left	0	0	
Sore/crust; single; right	0	0	
Sore/crust; single; forelimb; right	0	1	
Sore/crust; single; hindlimb; left	1	0	
Sore/crust; single; abdominal region	2	0	
NO CORRELATE;			
Submitted.....	(9)	(5)	

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Summary of Maternal Macroscopic Observations

20256434

		FEMALES	
Removal Reason: TERMINAL SACRIFICE		Control 0mcg	BNT162b2 30mcg
		44	43
		(44)	(43)
NO CORRELATE; (continued)			
No Visible Lesions.....		0	0
No correlate		9	6
INJECTION SITE 1;			
Submitted.....		(0)	(9)
No Visible Lesions.....		0	9
Pale		0	0
INJECTION SITE 2;			
Submitted.....		(0)	(10)
No Visible Lesions.....		0	0
Firm area		0	9
Enlarged		0	8
Oedematous area		0	1
Pale		0	4

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Summary of Maternal Macroscopic Observations

20256434

Removal Reason: MORIBUND SACRIFICE

		FEMALES	
		Control 0mcg	BNT162b2 30mcg
Number of Animals on Study :		0	0
Number of Animals Completed:		(0)	(0)
NO CORRELATE;			
Submitted.....		(0)	(0)
No Visible Lesions.....		0	0
No correlate		0	0

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Summary of Maternal Macroscopic Observations

20256434

		FEMALES	
Removal Reason: UNPLANNED TERMINAL SACRIFICE		Control 0mcg	BNT162b2 30mcg
Number of Animals on Study :		0	1
Number of Animals Completed:		(0)	(1)
LIVER;			
Submitted.....	(0)		(0)
No Visible Lesions.....	0		0
Pale; all lobes	0		0
SPLEEN;			
Submitted.....	(0)		(0)
No Visible Lesions.....	0		0
Enlarged	0		0
IDENTIFICATION;			
Submitted.....	(0)		(0)
No Visible Lesions.....	0		0
SKIN/SUBCUTIS;			
Submitted.....	(0)		(0)
No Visible Lesions.....	0		0
Alopecia; single; forelimb; abdominal region; left	0		0

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APPENDICES



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FINAL STUDY PLAN

Test Facility Study No. 20256434

Sponsor Reference No. RN9391R58

**Combined Fertility and Developmental Study (Including Teratogenicity
and Postnatal Investigations) of CCI, BNT162b2 and CCI by
the Intramuscular Route in the Wistar Rat
GLP Study**

SPONSOR:
BioNtech SE
12 An der Goldgrube
Mainz, 55131
Germany

TEST FACILITY:
Charles River Laboratories France Safety Assessment SAS
329 Impasse du Domaine Rozier
Les Oncins
69210 Saint-Germain-Nuelles
France

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1. OBJECTIVE(S)

The objective of this study is to assess the potential effects of CCI, BNT162b2 and CCI vaccine development candidates to prevent Covid-19, and the concomitant immune response, on fertility and pre and postnatal development in the pregnant and lactating female Wistar rat.

2. PROPOSED STUDY SCHEDULE

Proposed study dates are listed below. Actual dates will be included in the Final Report.

Experimental Starting Date: 29 Jun 2020
(first date of study-specific data collection).

Postnatal Development - Littering Subgroup:

Animal Arrivals: Females: 29 Jun 2020.
Males: 10 Aug 2020.

Initiation of Predose Estrous Cycle Monitoring: 13 Jul 2020.

First Injection (Day 1 = M-21): 27 Jul 2020.

Start of Mating (M1): From 17 Aug 2020.

Littering (LD0): From 09 Sep 2020.

Necropsy of Dams and Pups (LD21/PND21): From 30 Sep 2020.

Embryo-Fetal Development – Caesarean Subgroup:

Animal Arrivals: Females: 13 Jul 2020.
Males: 10 Aug 2020.

Initiation of Predose Estrous Cycle Monitoring: 27 Jul 2020.

First Injection (Day 1 = M-21) 10 Aug 2020.

Start of Mating (M1): From 31 Aug 2020.

Caesarean Sections (GD21): From 22 Sep 2020.

Experimental Completion Date: 16 Oct 2020
(last possible necropsy).

Preliminary Information: Week of 02 Nov 2020.

Data Review Meeting: Week of 16 Nov 2020.

Draft Report and CTD Table: 23 Dec 2020.

Consolidated Sponsor Comments: *Will be defined by Study Plan amendment.*

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Final Draft Report: *Will be defined by Study Plan amendment.*
This date is dependent on the date of receipt of Sponsor comments and final contributing Phase Reports. Any delay may have repercussions on the issue date of the Final Draft Report.

Proposed Final Study Report: *Will be defined by Study Plan amendment*
(expected date of Study Director signature of report).

The contributions from Principal Investigator(s) to Study Director are proposed at the dates indicated below to allow inclusion in Draft Report.

Antibody Assessment
Draft Phase Report: *Will be defined by Study Plan amendment.*

Antibody Assessment
Final Phase Report: *Will be defined by Study Plan amendment.*

3. SPONSOR

Role	Name	Contact Information
Sponsor Representative	Dr. PPD	Address as cited for Study Sponsor Tel: +49 6131 - 9084 - PPD E-mail: PPD

4. RESPONSIBLE PERSONNEL

Role/Phase	Quality Assurance Unit	Name	Contact Information
Study Director	Charles River	PPD, PhD	Address as cited for Test Facility Tel: +33 (0)4 74 01 PPD E-mail: PPD
Alternative Contact	Charles River	PPD, PharmD, ERT	Address as cited for Test Facility Tel: +33 (0)4 74 01 PPD E-mail: PPD
Test Facility Management	Charles River	PPD, General Director	Address as cited for Test Facility Tel: +33 (0)4 74 01 PPD E-mail: PPD
Test Facility QAU/Lead QA	Charles River	PPD, MSc, Chemical Engineer	Address as cited for Test Facility E-mail: PPD

Delegated Phases - Principal Investigators (PI)			
Role/Phase	GLP Compliance	Name	Contact Information
Serum Antibody Analysis ^{a)}		<i>Will be defined by Study Plan amendment</i>	

^{a)}: Test Site selected by the Study Sponsor in agreement with the Study Director

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Each PI is required to report any deviations or other circumstances that could affect the quality or integrity of the study to the Study Director in a timely manner. Each PI will provide a report addressing their assigned phase of the study, which will be included as an appendix to the Final Report. The Phase Report will include the following:

- A Statement of GLP Compliance.
- A QA Statement.
- The archive site for all records, samples, specimens and reports generated from the phase and their disposal at the end of the retention period.
- A listing of critical computerized systems used in the conduct and/or interpretation of the assigned Study Phase.

5. TEST MATERIALS

5.1. Test and Control Item Characterization

The Sponsor will provide to the Test Facility documentation of the identity, strength, purity, composition, and stability for the test material(s) provided. A certificate of analysis or equivalent documentation will be provided for inclusion in the Final Report. The Sponsor will also provide information concerning the regulatory standard (GLP, GMP, or other) followed for these evaluations.

The Sponsor has appropriate documentation on file concerning the method of synthesis, fabrication or derivation of the test material(s) provided, and this information is available to the appropriate regulatory agencies should it be requested.

5.2. Test Item Identification

Test Item Identification

	Test Item 1	Test Item 2	Test Item 3
Identification:	CCI	BNT162b2	CCI
Batch:	RBP020 3 LNP	RBP020 2 LNP	Will be defined by Study Plan amendment
Lot No.:	CoVAC/100320	CoVAC/270320	
Expiration/Retest Date*:	Will be defined by Study Plan amendment	Will be defined by Study Plan amendment	
Physical Description:	White to off-white suspension	White to off-white suspension	
Concentration (RNA Content):	508 µg/mL	508 µg/mL	
Correction Factor:	None	None	
Storage Conditions:	Temperature set to maintain -80°C		
Provided by:	Sponsor		

*: In the case that the Study Sponsor has updated information (e.g., retest or stability data) that could affect the validity of the study, during or after its completion, then the Study Director should be informed

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5.3. Control Item Identification

Control Item Identification

	Control Item
Identification:	Sterile physiological saline (0.9% NaCl)
Alternate Identification:	-
Batch/Lot No.:	Details will be documented in the raw data and specified in the Study Report
Expiration/Retest Date:	
Storage Conditions:	Room or ambient temperature
Provided by:	Test Facility

-: Not applicable

5.4. Reserve Samples

For each batch (lot) of any test and control material supplied by the Sponsor, reserve sample will be collected and maintained under the appropriate storage conditions by the Test Facility.

5.5. Test Materials Inventory and Disposition

Records of the receipt, distribution, storage, and disposition of test materials will be maintained. All unused Sponsor-supplied bulk test materials, with the exception of reserve samples, will be returned to the Sponsor after the end of use unless otherwise requested (documentation will be retained in the study record).

5.6. Safety

The following safety instructions apply to this study: Standard laboratory handling precautions.

6. DOSE FORMULATION AND ANALYSIS

6.1. Preparation of Formulations

Dose formulations will be dispensed on the morning of each administration to the animal facility.

Dose Formulation	Administration Dose Form	Frequency of Preparation	Storage Conditions
Control item	Solution	Daily	Immediately dispensed at ambient temperature
Test item	Suspension	Daily	Immediately dispensed at ambient temperature (it is recommended to use the formulations within 6 hours)

Any residual volumes from each dosing occasion will be discarded unless otherwise requested by the Study Director. **Fresh vials will be thaw for each administration.**

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Stability and homogeneity of dose formulations: The Sponsor has provided data that demonstrate that the test items formulations are stable when prepared and stored under the same conditions as those used in the present study, as follows:

- At a concentration of 0.5 mg/mL for 12 weeks at -80°C.
- In a concentration range of 0.002 - 0.5 mg/mL for 24 hours at room temperature.

Stability data provided by the Sponsor have been retained in the study records (Study No. R-20-0094).

6.2. Sample Collection and Analysis

The test items will be used as received from the Sponsor; therefore, samples for dose formulation analysis will not be collected by the Test Facility.

7. TEST SYSTEM

Species: Rat.
Strain: CRL:WI(Han) Wistar rat
Condition: Purpose-bred, naïve.
Source: Charles River Laboratories France, 329 Impasse du Domaine Rozier, Les Oncins, 69210 Saint-Germain-Nuelles, France
Number of Females: Caesarean subgroup: 88 virgin mated females.
Littering subgroup: 88 virgin mated females.
Number of Males: 88.
Approximate Age at Arrival: Females: Approximately 7 weeks old.
Males: 10 to 12 weeks old.
Estimated Body Weight Range at Mating: Females: 200 g to 250 g.
Males: 350 g to 400 g.

The actual age and weight of the animals will be listed in the Final Report.

7.1. Animal Identification

Method: Subcutaneously implanted electronic identification chip.

7.2. Selection, Assignment, Replacement, and Disposition of Animals

Mating: Animals will be acclimatized to the study housing conditions for at least 14 days before the start of dosing.
Selection: After arrival, animals will be randomly assigned to groups.
Disposition: The disposition of all animals will be documented in the study records.

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8. HUSBANDRY

8.1. Housing

Housing: Single or group housed.

Caging: Plastic cage containing appropriate bedding.

The animals will be caged as follows:

Phase	Number of Animals per Cage	
	Males	Females
Pre-mating	Up to 4	Up to 5
Mating	1 male + 1 female (housed together)	
Gestation of F0 Generation	Up to 4	1
Lactation of F0 Generation (littering subset only)	-	1 + litter

:- Not applicable

Cage Identification: Color-coded cage card indicating study, group, animal number(s), and sex.

Animals will be separated during designated procedures/activities or will be separated as required for monitoring and/or health purposes, as deemed appropriate by Study Director and/or Clinical Veterinarian. Cages will be arranged on the racks in group order. Where possible, control group animals will be housed on a separate rack from the test item-treated animals.

8.2. Animal Enrichment

For psychological/environmental enrichment, animals will be provided with items such as a wooden gnaw block and shredded paper, except when interrupted by study procedures/activities. It is considered that there are no known contaminants in the enrichment that could interfere with the outcome of the study

8.3. Environmental Conditions

The targeted conditions for animal room environment will be as follows:

Temperature: 19°C to 25°C.

Humidity: ≥ 35%.

Light Cycle: 12 hours light and 12 hours dark (except during designated procedures).

Ventilation: 10 or more air changes per hour.

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8.4. Food

Diet:	Pelleted complete diet ad (diet Reference No. A04C-10), sterilized by irradiation.
Type:	Pellets (alternate diet may be provided on individual animal basis as warranted as approved by the Study Director).
Frequency:	<i>Ad libitum</i> , except during designated procedures.
Analysis:	Each batch of diet is supplied with a certificate of analysis which is verified and authorized for release by a veterinarian. Certificates of analysis will be maintained in the archives of the Test Facility. It is considered that there are no known contaminants in the feed that would interfere with the objectives of the study.

8.5. Water

Type:	Softened and filtered (0.2 µm) mains drinking water.
Frequency/Ration:	Freely available to each animal (except during designated procedures).
Analysis:	Analysed at least twice a year for chemical and bacterial contaminants by Laboratoire Santé Environnement Hygiène de Lyon, France. Certificates of analysis for the drinking water will be maintained in the archives of the Test Facility. It is considered that there are no known contaminants in the water that could interfere with the outcome of the study.

8.6. Veterinary Care

Veterinary care will be available throughout the course of the study and animals will be examined by the veterinary staff as warranted by clinical signs or other changes. In the event that animals show signs of illness or distress, the Responsible Veterinarian may make initial recommendations about treatment of the animal(s) and/or alteration of study procedures, which must be approved by the Study Director. Treatment of the animal(s) for minor injuries or ailments may be approved without prior consultation with the Sponsor Representative when such treatment does not impact fulfilment of the study objectives. If the condition of the animal(s) warrants significant therapeutic intervention or alterations in study procedures, the Sponsor Representative will be contacted, when possible, to discuss appropriate action. If the condition of the animal(s) is such that emergency measures must be taken, the Study Director and/or attending Veterinarian will attempt to consult with the Sponsor Representative prior to responding to the medical crisis, but the Study Director and/or Veterinarian has authority to act immediately at his/her discretion to alleviate suffering. The Sponsor Representative will be fully informed of any such events.

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9. EXPERIMENTAL DESIGN

Experimental Design of the F0 Generation

Group No.	Test Material	Dose Level (µg mRNA)	Dose Volume (mL)	Dose Concentration (mg/mL)	Number and Identification of Animals	
					Caesarean Subgroup	Littering Subgroup
1	Control item	0	0.06	0	22 (1 to 22)	22 (201 to 222)
2						
3	BNT162b2	30	0.06	0.5	22 (45 to 66)	22 (245 to 266)
4						

Identification of untreated males: 301 to 388.

9.1. Administration of the Test and Control Items

Dose Route: Intramuscular injection into the quadriceps alternating on each dosing occasion.

Frequency: 4 dose days (2 pre-mating and 2 during gestation).

Dose Days: Pre-mating period: Study Day 1 (21 days before mating, M-21) and Day 8 (14 days before mating, M-14).
Gestation Days 9 and 20.

Method: The hair of the animals on the injection area will be clipped prior to the first injection and then as necessary during the treatment period. The animals will be temporarily restrained for dose administration. **The test item will be administered under light isoflurane anaesthesia.** The volume for each dose will be administered over 1 injection site in the quadriceps using appropriate syringe and needle (BD Microfine Syringes). The right and left quadriceps will be used in rotation for the administrations.

Each vial will be gently inverted 3 times before dosing. Each vial will be inverted once (not inverted between each dosing).

Only F0 females will be treated. Males will not be treated.

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10. IN-LIFE PROCEDURES, OBSERVATIONS, AND MEASUREMENTS

General In-Life Assessments – Untreated Males and F0 Females

Parameter	Population(s)	Frequency (Minimum required)	Comments
Mortality	All animals	At least twice daily* (at beginning and end of working day) F1 pups will be counted daily during the preweaning phase	Animals will be observed within their cage unless necessary for identification or confirmation of possible findings
Cageside Observations	All animals	Before and at least once on dosing days For males, at least 1 observation will be recorded before mating At least once daily on non-dosing days	Animals will be observed within their cage unless necessary for identification or confirmation of possible findings
Detailed Clinical Observations	All animals	A full clinical examination will be performed weekly during the pre-mating period then on each weighing day during the gestation and lactation periods	Animals will be removed from the cage
Individual Body Weights	All F0 females	Each F0 female will be weighed at least weekly during pretest, twice weekly before mating and for the periods: GD0, GD6, GD9, GD12, GD15, GD18 and GD21 LD1, LD4, LD7, LD10, LD14, LD17 and LD21	Animals may be weighed more often if necessary in order to monitor health status
	All F0 males	Each F0 male will be weighed at least weekly	
Food Consumption	All F0 females	Food consumption of each animal will be recorded at least once weekly from Day 1 and for the periods: GD0 to GD6, GD6 to GD9, GD9 to GD12, GD12 to GD15, GD15 to GD18 and GD18 to GD21 LD1 to LD4, LD4 to LD7, LD7 to LD10, LD10 to LD14, LD14 to LD17 and LD17 to LD21	Quantitatively measured

*: Except on days of receipt and necropsy where frequency will be at least once daily

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Parameter	Population(s)	Frequency (Minimum required)	Comments
Estrous Cycles	All F0 Females	Estrous cycles will be monitored pre-dosing (2 weeks), then for 2 weeks before mating and during cohabitation until confirmation of GD0	Animals are removed from the cage
Mating	Males and all F0 Females	Animals will be paired on the basis of 1 male and 1 female for a maximum of 14 days The day of mating will be confirmed by the presence of sperm in a vaginal smear or a vaginal plug and will be recorded and taken as Day 0 of gestation (GD0) The same untreated males will be used to mate both subgroups	Mated females will be separated from the male once mating has been confirmed and smearing will cease or when the appearance of the female suggests pregnancy from an undetected mating

10.1. Pregnancy and Parturition (Littering Subset Only)

For each F0 female, the following will be recorded:

- Date of mating.
- Date of parturition.
- Duration of gestation.
- Abnormalities of nesting or nursing behaviour.
- Number of implantation sites (at necropsy after staining with ammonium sulphide solution).

10.2. Litter Data (Littering Subset Only)

Litter Data

Population(s)	Frequency/Comments
Each Litter	Number of pups born (live and dead)
	External abnormalities of the pups
	Number and sex of pups alive on PND1, PND4, PND7, PND10, PND14, PND17 and PND21
	Physical development of the offspring, as assessed by the intra-litter onset and duration of pinna unfolding and eye opening Pupillary reflex and auditory reflex on PND21
	External and necropsy findings of dead pups

The size of each litter will be adjusted to 8 pups on PND4 by eliminating extra pups by random selection to yield where possible 4 male and 4 female pups per litter. Extra pups will be euthanized by an intraperitoneal injection of sodium pentobarbitone.

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11. ANTIBODY EVALUATION

11.1. Antibody Sample Collection

Bioanalytical Sample Collection

Group Nos.	Number of Females	Predose on Days of Dosing		Necropsy (GD21 or LD21/PND21) ^b
		Pretest	M0 ^a	
1 to 4	All F0 females	X	X	X
1 to 4	Selected fetuses from all litters of caesarean subset	-	-	X
1 to 4	Selected pups (1 male and 1 female if possible) from all litters of the lactation subset	-	-	X
Unscheduled euthanasia (when possible, done in the animal facility)		X		

X: Sample to be collected (on toxicokinetic females, where applicable); -: Not collected;

GD: Gestation Day; LD: Lactation Day; PND: Post Natal Day.

^a: Sample to be collected just before mating.^b: The day of necropsy will be mentioned in the Study Report for any apparently unmated females.

Method/Comments:	F0 female: Jugular vein (or other site as deemed necessary) Fetuses: Small incision after anesthesia (or other site as deemed necessary) Pups: Intracardiac (or other site as deemed necessary)
Target Volume (mL):	Target 0.5 mL for F0 females Target 0.3 mL pooled per litter for foetuses Targeted 0.5 mL pooled per litter from 2 pups (ideally 1 male and 1 female) Additional blood samples may be obtained (e.g., due to sample quality) if permissible sampling frequency and blood volume are not exceeded
Anticoagulant:	None
Special Requirements:	None
Processing	Serum

11.2. Antibody Sample Processing

Bioanalytical Sample Processing

Centrifugation	Volume Aliquot 1	Volume Aliquot 2	Freezing	Specific Request
1800 g 10 minutes Approximately +4°C	At least 120 µL (dams and pups) or 60 µL (fetuses) of serum	Remaining (serum)	-80°C	None

Theoretical number of samples:

- Dams: 528 samples x 2 aliquots.
- Fetuses: 88 samples x 2 aliquots.
- Pups: 88 samples x 2 aliquots.

The first set of samples (1 aliquot/occasion) will be shipped on dry ice to the Test Site for antibody Analysis, see Attachment A after the sample or the end of the treatment period.

The Test Site for bioanalysis will be notified before shipment of the samples. Samples will be stored at the bioanalytical laboratory in a freezer set to maintain -80°C until analysis.

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The duplicate samples will be sent only if requested by the Test Site. Any unused duplicate samples will be destroyed after issue of the Final Study Report unless requested otherwise by the Study Director and/or the Study Sponsor.

11.3. Antibody Analysis

Will be defined by Study Plan amendment.

12. TERMINAL PROCEDURES**12.1. Unscheduled Deaths**

Moribund animals and females (including toxicokinetic female from the caesarean subset) showing signs of parturition difficulties or total litter death will be euthanized by carbon dioxide inhalation and exsanguination. Any abnormalities observed will be recorded and preserved but not examined further in first instance.

Any such female found dead or moribund will be necropsied as follows:

Unscheduled Necropsy

Animals	Examination
Not Mated Females	Full macroscopic examination of the thoracic and abdominal cavities, including the injection sites . Any abnormalities observed will be sampled and preserved
Mated Females	Full macroscopic examination of the thoracic and abdominal cavities, including the injection sites , to determine their pregnancy status, number of corpora lutea and numbers and types of uterine implantations Any abnormalities observed will be sampled and preserved. Any fetuses from these females will not be examined and discarded

Moribund pups will be euthanized by intraperitoneal injection of sodium pentobarbitone.

Dead animals and pups (including toxicokinetic animals) will also be necropsied.

Dead or moribund males will be discarded without further examinations.

12.2. Scheduled Euthanasia

Surviving animals will euthanized by carbon dioxide inhalation and exsanguination (with the exception of the PND4 extra pups – see Section 10.2) and then necropsied according to the following schedule:

F0 Females:

Caesarean subset: On GD21.

Littering subset: After weaning of the F1 pups (females that fail to produce a viable litter by GD26 will be euthanized and necropsied).

Unmated Females:

After completion of the mating period.

Pups:

On PND4 (unselected pups) or on PND21.

Untreated males will be retained at the disposal of the Test Facility following completion of the majority of caesarean sections.

Selected fetuses (caesarean subset) and pups (littering subset) will be sampled for antibody analysis at necropsy (see Section 11.1).

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12.3. Necropsy

12.3.1. Caesarean Subset

All animals will be submitted to a full macroscopic examination of the abdominal and thoracic cavities including the injection sites. Any abnormalities observed will be recorded and preserved but not examined further in first instance.

For each female euthanized on GD21, the ovaries and uterus will be removed and examined including examination of the placentae. The following data will be recorded:

Necropsy Data

Parameters	Comments
Pregnancy Status	-
Gravid Uterus Weight	The uterus of apparently non-pregnant females will be placed in ammonium sulphide solution in order to stain any previously undetected implantation sites
Number and Distribution of Intrauterine Implantations	Will be classified as: live fetuses, dead fetuses, early resorptions and late resorptions
Number of Corpora Lutea	-
Fetal Weights	Individual weights will be recorded
Fetal Sex	-

-: No comment

12.3.2. Littering Subset

All adult animals and pups (including those culled on PND4) will be submitted to a full macroscopic examination of the abdominal and thoracic cavities **including the injection sites (for adult animals)**. Any abnormalities observed will be recorded and preserved but not examined further in first instance.

For all F0 females, the number of implantation sites will be recorded.

Any remaining tissues not required for retention may be harvested from the carcass of vehicle control animals before disposal. These tissues, if collected, may be used for validation or investigational purposes and as such are not part of this study and will not interfere with the study objectives.

13. FETAL EXAMINATION

Each fetus will be examined for external defects and all live fetuses will be euthanized by oral administration of sodium pentobarbitone. Approximately one half of each litter will be submitted to fresh visceral examination of the body (abdominal and thoracic cavities).

The head will be fixed in Harrison's fluid for subsequent examination by serial sectioning. The remaining carcass will be retained fixed in ethanol but not examined further in the first instance.

The remaining half of the fetuses in each litter will be eviscerated and then processed for skeletal examination. The skeletal examinations will be performed following maceration of the soft tissues with aqueous potassium hydroxide, staining of the skeleton with Alizarin red then passage into glycerol.

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Dead fetuses will be examined externally and discarded without further examination. Soft tissue and skeletal examinations will be performed using a binocular microscope. Photographs of any representative morphological abnormalities will be taken at the discretion of the Study Director (not considered as raw data or reported - kept under the responsibility of the Study Director).

14. STATISTICAL ANALYSIS

Numerical data collected on scheduled occasions (with the exception of data from toxicokinetic animals) will be summarized and statistically analyzed as indicated below according to the occasion or by litter.

Body Weight Gains (F0 Generation): Calculated between each scheduled interval (see Section 0) as well as between Day 1 to Day 22, GD0 to GD21 and LD1 to LD21 (where applicable).

Body Weight Gains (F1 Generation): Calculated between each scheduled interval (see Section 0).

Food Consumption: Calculated between each scheduled interval (see Section 0) as well as between Day 1 to Day 22, GD0 to GD21 and LD1 to LD21 (where applicable).

Additional or alternative body weight or food consumption intervals may be evaluated to elucidate study results at the discretion of the Study Director.

The following reproductive indices will be calculated:

For both subgroups combined where applicable (caesarean and littering):

Pre-coital interval (in days):	$\frac{\text{Sum of days until successful insemination}}{\text{Number of inseminated females}}$
Copulation (mating) index (in %):	$\frac{\text{Number of inseminated females}}{\text{Number of paired animals}} \times 100$
Pregnancy rate (in %):	$\frac{\text{Number of pregnant females}}{\text{Number of paired animals}} \times 100$
Fertility index (in %):	$\frac{\text{Number of pregnant females}}{\text{Number of inseminated females}} \times 100$

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For the caesarean subset:

Pre-Implantation Loss (in %):	$\frac{\text{Number of corpora lutea} - \text{Number of implants}}{\text{Number of corpora lutea}} \times 100$
Post-Implantation Loss (in %):	$\frac{\text{Number of implants} - \text{Number of live fetuses}}{\text{Number of implants}} \times 100$
Sex Ratio (% males):	$\frac{\text{Number male fetuses}}{\text{Total Number of fetuses}} \times 100$
Litter % of Fetuses with Abnormalities:	$\frac{\text{Number of fetuses in litter with a given finding}}{\text{Number of fetuses in litter examined}} \times 100$

For the littering subset:

Gestation index (in %):	$\frac{\text{Number of females with live pups}}{\text{Number of pregnant females}} \times 100$
Live Birth Index (in %):	$\frac{\text{Number of pups born alive}}{\text{Number of pups born}} \times 100$
Pre-Birth Loss (in %):	$\frac{\text{Number of implantations} - \text{Number of pups born}}{\text{Number of implantations}} \times 100$
Viability Index (in %):	$\frac{\text{Number of pups alive on PND4}}{\text{Number of pups alive at birth}} \times 100$
Weaning Index (in %):	$\frac{\text{Number of pups alive on PND21}}{\text{Number of pups alive on PND4}^*} \times 100$
Sex ratio (proportion of male pups):	$\frac{\text{Number of male pups}}{\text{Number of pups}} \times 100$

*: Number of pups alive on PND4 after adjustment of litter size, if applicable

Additional or alternative indices may be calculated to elucidate study results at the discretion of the Study Director.

The best transformation for the data (none, log or rank) will be determined depending upon:

- The normality of the data distribution tested by the Shapiro-Wilk's test.
- The homogeneity of the variances across groups tested by the Bartlett's test.

Non- or log-transformed data will be analysed by parametric methods.

Rank transformed data will be analysed using non-parametric methods.

The data from the treated groups will be analyzed by parametric or non-parametric Dunnett's test to look for significant differences from the control group.

All litter-based percentages will be analyzed using non-parametric methods, i.e., Kruskal Wallis test followed by non-parametric Dunnett's test if the Kruskal-Wallis was significant.

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Selected incidence data will be analysed using a χ^2 test for all groups followed by Fisher's two-tailed test with Bonferroni correction for each treated group versus the control if the χ^2 was significant.

Pre-coital interval, estrous cycle and F1 offspring functional tests will be analysed using a SAS software package. Levene's test will be used to test the equality of variance across groups and Shapiro-Wilk's test will be used to assess the normality of the data distribution in each group. Data with homogenous variances and normal distribution in all groups will be analysed using Anova followed by Dunnett's test. Data showing non-homogenous variances or a non-normal distribution in at least one group will be analysed using Kruskal-Wallis test followed by Wilcoxon's rank sum test.

15. COMPUTERIZED SYSTEMS

The following computerized systems may be used in the study. The actual computerized systems will be documented in the study data.

Computerized Systems

System Name	Description of Data Collected and/or Analyzed
GTC Mozart 21	Environmental data recording
Vaisala	Environmental data recording
Provantis	Test material receipt, accountability and/or formulation activities; in-life; postmortem; statistical analysis
Share Document Management System	Reporting
DocuSign	Collection of 21 CFR Part 11 compliant signature
Devil	Deviation information library
STATSAS	Statistical analysis

Microsoft Excel® (version 2003 or higher) may be employed to present certain results and perform associated calculations.

Data for parameters not required by the Study Plan, which are automatically generated by analytical devices used will be retained on file but not reported. Statistical analysis results that are generated by the program but are not required by the Study Plan and/or are not scientifically relevant will be retained on file but will not be included in the tabulations.

16. REGULATORY COMPLIANCE

The study will be performed in accordance with OECD Principles of Good Laboratory Practice as required in Directive 2004/10/EC of the European Parliament and of the Council of 11 February 2004, Bonnes Pratiques de Laboratoire, Ministère de l'Emploi et de la Solidarité Française, No. 2000/5bis, arrêté du 14/03/2000.

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17. QUALITY ASSURANCE

17.1. Test Facility

The Test Facility Quality Assurance Unit (QAU) will monitor the study to assure the facilities, equipment, personnel, methods, practices, records, and controls are in conformance with Good Laboratory Practice regulations. The QAU will review the Study Plan (and any amendments), conduct inspections at intervals adequate to assure the integrity of the study, and audit the Final Report to assure that it accurately describes the methods and Standard Operating Procedures and that the reported results accurately reflect the raw data of the study.

All Quality Assurance documents will be retained by the Test Facility as their property and will not be returned to the Study Sponsor.

17.2. Test Site(s)

For all study phases inspected by Test Site QAU(s), copies of each inspection report will be made available to the Study Director, Test Facility Management, and the Test Facility Lead QA.

18. AMENDMENT(S) AND DEVIATIONS

Changes to the approved Study Plan shall be made in the form of an amendment, which will be signed and dated by the Study Director. Every reasonable effort will be made to discuss any necessary Study Plan changes in advance with the Sponsor.

All Study Plan and SOP deviations will be documented in the study records.

The Study Director will notify the Sponsor of deviations that may result in a significant impact on the study as soon as possible.

Deviations from the Study Plan and/or SOP related to the phase(s) of the study conducted at a Test Site shall be documented, acknowledged by the Principal Investigator, and reported to the Study Director for authorization/acknowledgement.

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19. RETENTION AND DISPOSITION OF RECORDS, SAMPLES, AND SPECIMENS

All study-specific raw data, electronic data, documentation, Study Plan, retained samples and specimens, and the Final Report will be archived at the Final Report issue. All materials generated by Charles River Laboratories from this study will be transferred to a Charles River Laboratories archive and kept for a period of 2 years following the date of issue of the Final Report.

Disposition of residual/retained analytical samples will be as described in the table below.

Disposition of Residual/Retained Samples

Sample Type	Disposition	Schedule
Serum for antibody analysis	Return to the Sponsor	Samples will be maintained for a minimum of 6 months following issuance of the Draft Report or at an alternate time point prior to finalization as requested and authorized by the Study Director

Records to be maintained will include, but will not be limited to, documentation and data for the following:

- Study Plan, Study Plan amendments, and deviations.
- Study schedule.
- Study-related correspondence.
- Test system receipt, health, and husbandry.
- Test materials receipt, identification and preparation.
- Reserve sample.
- In-life measurements and observations.
- Antibody sample collection and evaluation.
- Gross observations and related data.
- Organ weight measurements.
- Statistical analysis results.
- Original signed Final Report.

20. STUDY CLASSIFICATION

Study Category: Reproductive and developmental toxicology.
Study Type: Combined fertility and developmental study (including teratogenicity and postnatal investigations).
Study Design: Parallel.
Primary Treatment Unique Ingredient ID: BNT162.
Class of Compound: Vaccine.

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21. REPORTING

The Study Sponsor will be informed promptly of any significant findings at any time during the study.

A study update with all available data will be provided after termination of the in-life phase.

A comprehensive Draft Report will be prepared following completion of the study and will be finalized following consultation with the Sponsor. The report will include all information necessary to provide a complete and accurate description of the experimental methods and results and any circumstances that may have affected the quality or integrity of the study.

The report will be issued in the Test Facility house style.

The Sponsor will receive an electronic version of the Final Report provided in Adobe Acrobat PDF format (hyperlinked and searchable at final). The PDF document will be created from native electronic files to the extent possible, including text and tables generated by the Test Facility. Report components not available in native electronic files and/or original signature pages will be scanned and converted to PDF image files for incorporation.

Reports should be finalized within 6 months of issue of the Draft Report. If the Sponsor has not provided comments to the report within 6 months of draft issue, the report will be finalized by the Test Facility unless other arrangements are made by the Sponsor.

A tabulated data summary will be provided in a format as outlined in the ICH Harmonized Tripartite Guideline, *The Common Technical Document for the Registration of Pharmaceuticals for Human Use: Safety – M4S (R2), Non-Clinical Overview and Non-Clinical Summaries of Module 2, Organisation of Module 4*.

22. JUSTIFICATION AND GUIDELINES

22.1. Justification of Test System and Number of Animals

At this time, studies in laboratory animals provide the best available basis for extrapolation to humans and are required to support regulatory submissions. Acceptable models which do not use live animals currently do not exist.

The rat was chosen as the animal model for this study as it is an accepted rodent species for preclinical toxicity testing by regulatory agencies. It mounts an immune response to the vaccines tested that is similar to the expected human response after vaccination.

The total number of animals to be used in this study is considered to be the minimum required to properly characterize the effects of the test item. This study has been designed such that it does not require an unnecessary number of animals to accomplish its objectives.

22.2. Justification of Route and Dose Levels

The intramuscular route of exposure was selected because this is the intended route of human exposure. The dose administered will be the highest absolute dose considered for Women of Childbearing Potential.

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22.3. Guidelines for Study

The study will be conducted in general compliance with the following:

- International Conference on Harmonization, Detection of Toxicity to Reproduction for Medicinal Products; Department of Health and Human Services, Food and Drug Administration; Federal Register 1994, Part IX. Vol. 59. No. 183, 48746 - 48752.
- ICH guideline S5(R3): Detection of Reproductive and Developmental Toxicity for Human Pharmaceuticals; February 2020.
- Food and Drug Administration (FDA). Guidance for Industry: Considerations for developmental toxicity studies for preventive and therapeutic vaccines for infectious disease indications, CBER Division of Vaccines and related products (February 2006).
- European Medicines Agency (EMA), CPMP/SWP/465/95 June 1998. Note for guidance on preclinical pharmacological and toxicological testing of vaccines.
- WHO guidelines on nonclinical evaluation of vaccines, Technical Report Series, No. 927, 2005

23. ANIMAL WELFARE

The study design was reviewed and approved by the ethical committee of the Test Facility as per the Standard Project Authorization No. 2017072617402851.

The study design, animal housing and associated procedures are in general compliance with the following animal health and welfare guidelines:

- Guide for the care and use of laboratory animals, 2011.
- Decree No. 2013-118 relating to the protection of animals used in scientific experiments described in the Journal Officiel de la République Française on 01 February 2013.
- Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes.


The Test Facility is AAALAC accredited.

By approving this Study Plan, the Sponsor affirms that there were no other alternative experimental methods other than the use of live animals to achieve the required objectives, that the harm-benefit analysis of the project was performed and that this study does not unnecessarily duplicate any previous experiments.

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TEST FACILITY APPROVAL

The signature below indicates that Test Facility Management approves the Study Director identified in this Study Plan and management's responsibility to the study as defined by the relevant GLP regulations.

DocuSigned by:

Signing Reason: I approve this document
Signing Time: 26-Jun-2020 | 10:38:19 EDT
DDC8F3F01E5748E899002A5866498F8E

Test Facility Management

The signature below indicates that the Study Director approves the Study Plan.

DocuSigned by:

Signing Reason: I approve this document
Signing Time: 26-Jun-2020 | 07:58:15 EDT
6A473C2E153B40C6AB924DFD8F0A3EC5

 , PhD
Study Director

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SPONSOR APPROVAL

The signature of the Sponsor Representative below indicates approval of this Study Plan.


Date: 11 Dec 20
D: 
Sponsor Representative

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ATTACHMENT A
Shipment of Samples and Study Records

Matrix	Purpose	Day/ Week/ Aliquot	Proposed Shipment Date	Conditions for Shipment	Recipient/Address
Serum	Antibody analysis	Pretest and M0	<i>Will be defined by Study Plan amendment</i>	Dry ice	<div>PPD</div> <div>VisMederi Srl Strada del Petriccio e Belignuardo, 35 53100 Siena, Italy E-mail: <div>PPD</div> and <i>Will be defined by Study Plan amendment</i></div>
Serum	Antibody analysis	GD21 or LD21	<i>Will be defined by Study Plan amendment</i>	Dry ice	<div>PPD</div> <div>VisMederi Srl Strada del Petriccio e Belignuardo, 35 53100 Siena, Italy E-mail: <div>PPD</div> and <i>Will be defined by Study Plan amendment</i></div>

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STUDY PLAN AMENDMENT No. 02

Test Facility Study No. 20256434

Sponsor Reference No. RN9391R58

**Combined Fertility and Developmental Study (Including Teratogenicity
and Postnatal Investigations) of CCI, BNT162b2 and CCI by
the Intramuscular Route in the Wistar Rat
GLP Study**

SPONSOR:
BioNtech SE
12 An der Goldgrube
Mainz, 55131
Germany

TEST FACILITY:
Charles River Laboratories France Safety Assessment SAS
329 Impasse du Domaine Rozier
Les Oncins
69210 Saint-Germain-Nuelles
France

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SUMMARY OF CHANGES AND JUSTIFICATIONS

Note: when applicable, additions are indicated in **bold underlined** and deletions are indicated in ~~strike through~~ text in the concerned sections.

Item / Section(s)	Reason for amendment
Final Study Plan	Date: 26 Jun 2020
Amendment 1	
2. PROPOSED STUDY SCHEDULE	To update the study schedule
5.2 Test Item Identification	To clarify the expiration/retest dates To add information on <u>CCI</u>
6.1. Preparation of Formulations 9. EXPERIMENTAL DESIGN	To clarify that test items should not be vortexed. Homogeneity is considered achieved following gentle inversion. Testing of homogeneity will be performed in parallel by the Sponsor.
4. RESPONSIBLE PERSONNEL 11.1. Antibody Sample Collection 11.3 Antibody Evaluation 16. REGULATORY COMPLIANCE 147.2 Test Site(s) ATTACHMENT A	To update the information for antibody collection and analysis
12.1. Unscheduled Deaths 14. STATISTICAL ANALYSIS	To correct typographical errors
Amendment 2	
12.3.2. Littering Subset	To clarify that carcass of PND21 pups will be preserved for possible skeletal examinations.

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Study Plan Amendment No 02

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1. OBJECTIVE(S)

The objective of this study is to assess the potential effects of CCI, BNT162b2 and CCI vaccine development candidates to prevent Covid-19, and the concomitant immune response, on fertility and pre and postnatal development in the pregnant and lactating female Wistar rat.

2. PROPOSED STUDY SCHEDULE

Proposed study dates are listed below. Actual dates will be included in the Final Report.

Experimental Starting Date: 29 Jun 2020
(first date of study-specific data collection).

Postnatal Development - Littering Subgroup:

Animal Arrivals: Females: 29 Jun 2020.
Males: 10 Aug 2020.

Initiation of Predose Estrous Cycle
Monitoring: 13 Jul 2020.

First Injection (Day 1 = M-21): 27 Jul 2020.

Start of Mating (M1): From 17 Aug 2020.

Littering (LD0): From 09 Sep 2020.

Necropsy of Dams and Pups
(LD21/PND21): From 30 Sep 2020.

Embryo-Fetal Development – Caesarean Subgroup:

Animal Arrivals: Females: 13 Jul 2020.
Males: 10 Aug 2020.

Initiation of Predose Estrous Cycle
Monitoring: 27 Jul 2020.

First Injection (Day 1 = M-21) 10 Aug 2020.

Start of Mating (M1): From 31 Aug 2020.

Caesarean Sections (GD21): From 22 Sep 2020.

Experimental Completion Date: 16 Oct 2020
(last possible necropsy).

Preliminary Information: Week of 02 Nov 2020.

Data Review Meeting: Week of 09 Nov 2020.

Draft Report and CTD Table: 16 Dec 2020.

Consolidated Sponsor Comments: 30 Dec 2020.

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Final Draft Report: 20 Jan 2021.

This date is dependent on the date of receipt of Sponsor comments and final contributing Phase Reports. Any delay may have repercussions on the issue date of the Final Draft Report.

Sponsor Approval for Signature: 25 Jan 2021.

Proposed Final Study Report: 29 Jan 2021.

(expected date of Study Director signature of report).

The contributions from Principal Investigator(s) to Study Director are proposed at the dates indicated below to allow inclusion in Draft Report.

Antibody Assessment

Draft Phase Report: 18 Nov 2020.

Antibody Assessment

Final Phase Report: 16 Dec 2020.

3. SPONSOR

Role	Name	Contact Information
Sponsor Representative	Dr [REDACTED]	Address as cited for Study Sponsor Tel: +49 6131 - 9084 - [REDACTED] E-mail: [REDACTED]

4. RESPONSIBLE PERSONNEL

Role/Phase	Quality Assurance Unit	Name	Contact Information
Study Director	Charles River	[REDACTED], PhD	Address as cited for Test Facility Tel: +33 (0)4 74 01 [REDACTED] E-mail: [REDACTED]
Alternative Contact	Charles River	[REDACTED], PharmD, ERT	Address as cited for Test Facility Tel: +33 (0)4 74 01 [REDACTED] E-mail: [REDACTED]
Test Facility Management	Charles River	[REDACTED], General Director	Address as cited for Test Facility Tel: +33 (0)4 74 01 [REDACTED] E-mail: [REDACTED]
Test Facility QAU/Lead QA	Charles River	[REDACTED], MSc, Chemical Engineer	Address as cited for Test Facility E-mail: [REDACTED]

Delegated Phases - Principal Investigator (PI)

Role/Phase	GLP Compliance	Name	Contact Information
Serum Antibody Analysis ^{a)}	No (Compliance with the GCLP, see Section 16)	[REDACTED]	Address: VisMederi Srl Strada del Petriccio e Belriguardo, 35 53100 Siena, Italy Tel: +39 0577 38 [REDACTED] E-mail: [REDACTED]

^{a)} Test Site selected by the Study Sponsor in agreement with the Study Director.

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Each PI is required to report any deviations or other circumstances that could affect the quality or integrity of the study to the Study Director in a timely manner. Each PI will provide a report addressing their assigned phase of the study, which will be included as an appendix to the Final Report. The Phase Report will include the following:

- A Statement of GLP Compliance.
- A QA Statement.
- The archive site for all records, samples, specimens and reports generated from the phase and their disposal at the end of the retention period.
- A listing of critical computerized systems used in the conduct and/or interpretation of the assigned Study Phase.

5. TEST MATERIALS

5.1. Test and Control Item Characterization

The Sponsor will provide to the Test Facility documentation of the identity, strength, purity, composition, and stability for the test material(s) provided. A certificate of analysis or equivalent documentation will be provided for inclusion in the Final Report. The Sponsor will also provide information concerning the regulatory standard (GLP, GMP, or other) followed for these evaluations.

The Sponsor has appropriate documentation on file concerning the method of synthesis, fabrication or derivation of the test material(s) provided, and this information is available to the appropriate regulatory agencies should it be requested.

5.2. Test Item Identification

Test Item Identification			
	Test Item 1	Test Item 2	Test Item 3
Identification:	CCI	BNT162b2	CCI
Batch:	RBP020 3 LNP	RBP020 2 LNP	RB020 8 LNP
Lot No.:	CoVAC/100320	CoVAC/270320	BCV/040620
Expiration/Retest Date ^a :	10 Sep 2020 ^b	25 Sep 2020 ^b	04 Dec 2020 ^b
Physical Description:	White to off-white suspension	White to off-white suspension	White to off-white suspension
Concentration (RNA Content):	508 µg/mL	508 µg/mL	531 µg/mL
Correction Factor:	None	None	None
Storage Conditions:	Temperature set to maintain -80°C		
Provided by:	Sponsor		

^a: In the case that the Study Sponsor has updated information (e.g., retest or stability data) that could affect the validity of the study, during or after its completion, then the Study Director should be informed

^b: Sponsor information on 05 Jul 2020

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5.3. Control Item Identification

Control Item Identification

	Control Item
Identification:	Sterile physiological saline (0.9% NaCl)
Alternate Identification:	-
Batch/Lot No.:	Details will be documented in the raw data and specified in the Study Report
Expiration/Retest Date:	
Storage Conditions:	Room or ambient temperature
Provided by:	Test Facility

-. Not applicable

5.4. Reserve Samples

For each batch (lot) of any test and control material supplied by the Sponsor, reserve sample will be collected and maintained under the appropriate storage conditions by the Test Facility.

5.5. Test Materials Inventory and Disposition

Records of the receipt, distribution, storage, and disposition of test materials will be maintained. All unused Sponsor-supplied bulk test materials, with the exception of reserve samples, will be returned to the Sponsor after the end of use unless otherwise requested (documentation will be retained in the study record).

5.6. Safety

The following safety instructions apply to this study: Standard laboratory handling precautions.

6. DOSE FORMULATION AND ANALYSIS

6.1. Preparation of Formulations

Dose formulations will be dispensed on the morning of each administration to the animal facility.

Dose Formulation	Administration Dose Form	Frequency of Preparation	Storage Conditions
Control item	Solution	Daily	Immediately dispensed at ambient temperature
Test item	Suspension	Daily	Immediately dispensed at ambient temperature (it is recommended to use the formulations within 6 hours)

Any residual volumes from each dosing occasion will be discarded unless otherwise requested by the Study Director. **Fresh vials will be thaw for each administration.**

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Stability of dose formulations: The Sponsor has provided data that demonstrate that the test items formulations are stable when prepared and stored under the same conditions as those used in the present study, as follows:

- At a concentration of 0.5 mg/mL for 12 weeks at -80°C.
- In a concentration range of 0.002 - 0.5 mg/mL for 24 hours at room temperature.

Stability data provided by the Sponsor have been retained in the study records (Study No. R-20-0094).

6.2. Sample Collection and Analysis

The test items will be used as received from the Sponsor; therefore, samples for dose formulation analysis will not be collected by the Test Facility.

7. TEST SYSTEM

Species: Rat.
Strain: CRL:WI(Han) Wistar rat
Condition: Purpose-bred, naïve.
Source: Charles River Laboratories France, 329 Impasse du Domaine Rozier, Les Oncins, 69210 Saint-Germain-Nuelles, France
Number of Females: Caesarean subgroup: 88 virgin mated females.
Littering subgroup: 88 virgin mated females.
Number of Males: 88.
Approximate Age at Arrival: Females: Approximately 7 weeks old.
Males: 10 to 12 weeks old.
Estimated Body Weight Range at Mating: Females: 200 g to 250 g.
Males: 350 g to 400 g.

The actual age and weight of the animals will be listed in the Final Report.

7.1. Animal Identification

Method: Subcutaneously implanted electronic identification chip.

7.2. Selection, Assignment, Replacement, and Disposition of Animals

Mating: Animals will be acclimatized to the study housing conditions for at least 14 days before the start of dosing.
Selection: After arrival, animals will be randomly assigned to groups.
Disposition: The disposition of all animals will be documented in the study records.

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8. HUSBANDRY

8.1. Housing

Housing: Single or group housed.

Caging: Plastic cage containing appropriate bedding.

The animals will be caged as follows:

Phase	Number of Animals per Cage	
	Males	Females
Pre-mating	Up to 4	Up to 5
Mating	1 male + 1 female (housed together)	
Gestation of F0 Generation	Up to 4	1
Lactation of F0 Generation (littering subset only)	-	1 + litter

∴ Not applicable

Cage Identification: Color-coded cage card indicating study, group, animal number(s), and sex.

Animals will be separated during designated procedures/activities or will be separated as required for monitoring and/or health purposes, as deemed appropriate by Study Director and/or Clinical Veterinarian. Cages will be arranged on the racks in group order. Where possible, control group animals will be housed on a separate rack from the test item-treated animals.

8.2. Animal Enrichment

For psychological/environmental enrichment, animals will be provided with items such as a wooden gnaw block and shredded paper, except when interrupted by study procedures/activities. It is considered that there are no known contaminants in the enrichment that could interfere with the outcome of the study

8.3. Environmental Conditions

The targeted conditions for animal room environment will be as follows:

Temperature: 19°C to 25°C.

Humidity: ≥ 35%.

Light Cycle: 12 hours light and 12 hours dark (except during designated procedures).

Ventilation: 10 or more air changes per hour.

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8.4. Food

Diet: Pelleted complete diet ad (diet Reference No. A04C-10), sterilized by irradiation.

Type: Pellets (alternate diet may be provided on individual animal basis as warranted as approved by the Study Director).

Frequency: *Ad libitum*, except during designated procedures.

Analysis: Each batch of diet is supplied with a certificate of analysis which is verified and authorized for release by a veterinarian. Certificates of analysis will be maintained in the archives of the Test Facility. It is considered that there are no known contaminants in the feed that would interfere with the objectives of the study.

8.5. Water

Type: Softened and filtered (0.2 µm) mains drinking water.

Frequency/Ration: Freely available to each animal (except during designated procedures).

Analysis: Analysed at least twice a year for chemical and bacterial contaminants by Laboratoire Santé Environnement Hygiène de Lyon, France. Certificates of analysis for the drinking water will be maintained in the archives of the Test Facility. It is considered that there are no known contaminants in the water that could interfere with the outcome of the study.

8.6. Veterinary Care

Veterinary care will be available throughout the course of the study and animals will be examined by the veterinary staff as warranted by clinical signs or other changes. In the event that animals show signs of illness or distress, the Responsible Veterinarian may make initial recommendations about treatment of the animal(s) and/or alteration of study procedures, which must be approved by the Study Director. Treatment of the animal(s) for minor injuries or ailments may be approved without prior consultation with the Sponsor Representative when such treatment does not impact fulfilment of the study objectives. If the condition of the animal(s) warrants significant therapeutic intervention or alterations in study procedures, the Sponsor Representative will be contacted, when possible, to discuss appropriate action. If the condition of the animal(s) is such that emergency measures must be taken, the Study Director and/or attending Veterinarian will attempt to consult with the Sponsor Representative prior to responding to the medical crisis, but the Study Director and/or Veterinarian has authority to act immediately at his/her discretion to alleviate suffering. The Sponsor Representative will be fully informed of any such events.

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9. EXPERIMENTAL DESIGN

Experimental Design of the F0 Generation

Group No.	Test Material	Dose Level (µg mRNA)	Dose Volume (mL)	Dose Concentration (mg/mL)	Number and Identification of Animals	
					Caesarean Subgroup	Littering Subgroup
1	Control item	0	0.06	0	22 (1 to 22)	22 (201 to 222)
2						
3	BNT162b2	30	0.06	0.5	22 (45 to 66)	22 (245 to 266)
4						

Identification of untreated males: 301 to 388.

9.1. Administration of the Test and Control Items

Dose Route: Intramuscular injection into the quadriceps alternating on each dosing occasion.

Frequency: 4 dose days (2 pre-mating and 2 during gestation).

Dose Days: Pre-mating period: Study Day 1 (21 days before mating, M-21) and Day 8 (14 days before mating, M-14).
Gestation Days 9 and 20.

Method: The hair of the animals on the injection area will be clipped prior to the first injection and then as necessary during the treatment period. The animals will be temporarily restrained for dose administration. **The test item will be administered under light isoflurane anaesthesia.** The volume for each dose will be administered over 1 injection site in the quadriceps using appropriate syringe and needle (BD Microfine Syringes). The right and left quadriceps will be used in rotation for the administrations.

Each vial will be gently inverted 3 times before dosing. Each vial will be inverted once (not inverted between each dosing). The vials should not be vortexed. Homogeneity was considered achieved following gentle inversion (information provided by the Sponsor). Testing of homogeneity will be performed in parallel by the Sponsor.

Only F0 females will be treated. Males will not be treated.

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10. IN-LIFE PROCEDURES, OBSERVATIONS, AND MEASUREMENTS

General In-Life Assessments – Untreated Males and F0 Females

Parameter	Population(s)	Frequency (Minimum required)	Comments
Mortality	All animals	At least twice daily* (at beginning and end of working day) F1 pups will be counted daily during the preweaning phase	Animals will be observed within their cage unless necessary for identification or confirmation of possible findings
Cageside Observations	All animals	Before and at least once on dosing days For males, at least 1 observation will be recorded before mating At least once daily on non-dosing days	Animals will be observed within their cage unless necessary for identification or confirmation of possible findings
Detailed Clinical Observations	All animals	A full clinical examination will be performed weekly during the pre-mating period then on each weighing day during the gestation and lactation periods	Animals will be removed from the cage
Individual Body Weights	All F0 females	Each F0 female will be weighed at least weekly during pretest, twice weekly before mating and for the periods: GD0, GD6, GD9, GD12, GD15, GD18 and GD21 LD1, LD4, LD7, LD10, LD14, LD17 and LD21	Animals may be weighed more often if necessary in order to monitor health status
	All F0 males	Each F0 male will be weighed at least weekly	
Food Consumption	All F0 females	Food consumption of each animal will be recorded at least once weekly from Day 1 and for the periods: GD0 to GD6, GD6 to GD9, GD9 to GD12, GD12 to GD15, GD15 to GD18 and GD18 to GD21 LD1 to LD4, LD4 to LD7, LD7 to LD10, LD10 to LD14, LD14 to LD17 and LD17 to LD21	Quantitatively measured

*: Except on days of receipt and necropsy where frequency will be at least once daily

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Parameter	Population(s)	Frequency (Minimum required)	Comments
Estrous Cycles	All F0 Females	Estrous cycles will be monitored pre-dosing (2 weeks), then for 2 weeks before mating and during cohabitation until confirmation of GD0	Animals are removed from the cage
Mating	Males and all F0 Females	Animals will be paired on the basis of 1 male and 1 female for a maximum of 14 days The day of mating will be confirmed by the presence of sperm in a vaginal smear or a vaginal plug and will be recorded and taken as Day 0 of gestation (GD0) The same untreated males will be used to mate both subgroups	Mated females will be separated from the male once mating has been confirmed and smearing will cease or when the appearance of the female suggests pregnancy from an undetected mating

10.1. Pregnancy and Parturition (Littering Subset Only)

For each F0 female, the following will be recorded:

- Date of mating.
- Date of parturition.
- Duration of gestation.
- Abnormalities of nesting or nursing behaviour.
- Number of implantation sites (at necropsy after staining with ammonium sulphide solution).

10.2. Litter Data (Littering Subset Only)

Litter Data

Population(s)	Frequency/Comments
Each Litter	Number of pups born (live and dead)
	External abnormalities of the pups
	Number and sex of pups alive on PND1, PND4, PND7, PND10, PND14, PND17 and PND21
	Physical development of the offspring, as assessed by the intra-litter onset and duration of pinna unfolding and eye opening Pupillary reflex and auditory reflex on PND21
	External and necropsy findings of dead pups

The size of each litter will be adjusted to 8 pups on PND4 by eliminating extra pups by random selection to yield where possible 4 male and 4 female pups per litter. Extra pups will be euthanized by an intraperitoneal injection of sodium pentobarbitone.

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11. ANTIBODY EVALUATION

11.1. Antibody Sample Collection

Bioanalytical Sample Collection

Group Nos.	Number of Females	Predose on Days of Dosing		Necropsy (GD21 or LD21/PND21) ^b
		Pretest	M0 ^a	
1 to 4	All F0 females	X	X	X
1 to 4	Selected fetuses from all litters of caesarean subset	-	-	X
1 to 4	Selected pups (1 male and 1 female if possible) from all litters of the lactation subset	-	-	X
Unscheduled euthanasia (dams only when possible, done in the animal facility)		X		

X: Sample to be collected (on toxicokinetic females, where applicable); -: Not collected;
GD: Gestation Day; LD: Lactation Day; PND: Post Natal Day.

^a: Sample to be collected just before mating.

^b: The day of necropsy will be mentioned in the Study Report for any apparently unmated females.

Method/Comments:	F0 female: Jugular vein (or other site as deemed necessary) Fetuses: Small incision after anesthesia (or other site as deemed necessary) Pups: Intracardiac (or other site as deemed necessary)
Target Volume (mL):	Target 0.5 mL for F0 females Target 0.3 mL pooled per litter for foetuses Targeted 0.5 mL pooled per litter from 2 pups (ideally 1 male and 1 female) Additional blood samples may be obtained (e.g., due to sample quality) if permissible sampling frequency and blood volume are not exceeded
Anticoagulant:	None
Special Requirements:	None
Processing	Serum

11.2. Antibody Sample Processing

Bioanalytical Sample Processing

Centrifugation	Volume Aliquot 1	Volume Aliquot 2	Freezing	Specific Request
1800 g 10 minutes Approximately +4°C	At least 120 µL (dams and pups) or 60 µL (fetuses) of serum	Remaining (serum)	-80°C	None

Theoretical number of samples:

- Dams: 528 samples x 2 aliquots.
- Fetuses: 88 samples x 2 aliquots.
- Pups: 88 samples x 2 aliquots.

The first set of samples (1 aliquot/occasion) will be shipped on dry ice to the Test Site for antibody Analysis, see Attachment A after the sample or the end of the treatment period.

The Test Site for bioanalysis will be notified before shipment of the samples. Samples will be stored at the bioanalytical laboratory in a freezer set to maintain -80°C until analysis.

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The duplicate samples will be sent only if requested by the Test Site. Any unused duplicate samples will be destroyed after issue of the Final Study Report unless requested otherwise by the Study Director and/or the Study Sponsor.

11.3. Antibody Analysis by Microneutralization CPE-Based

Each serum sample will be tested in duplicate for neutralizing antibody titre against Sars-CoV-2 live virus. The test will be carried out at Vismederi, according to Vismederi standard operating procedures and dedicated working instruction "microneutralization cpe-based assay for sars-cov-2" (wi-mnsars-cov-2).

12. TERMINAL PROCEDURES**12.1. Unscheduled Deaths**

Moribund animals and females showing signs of parturition difficulties or total litter death will be euthanized by carbon dioxide inhalation and exsanguination. Any abnormalities observed will be recorded and preserved but not examined further in first instance.

Any such female found dead or moribund will be necropsied as follows:

Unscheduled Necropsy

Animals	Examination
Not Mated Females	Full macroscopic examination of the thoracic and abdominal cavities, including the injection sites . Any abnormalities observed will be sampled and preserved
Mated Females	Full macroscopic examination of the thoracic and abdominal cavities, including the injection sites , to determine their pregnancy status, number of corpora lutea and numbers and types of uterine implantations. Any abnormalities observed will be sampled and preserved. Any fetuses from these females will not be examined and discarded

Moribund pups will be euthanized by intraperitoneal injection of sodium pentobarbitone.

Dead animals and pups will also be necropsied.

Dead or moribund males will be discarded without further examinations.

12.2. Scheduled Euthanasia

Surviving animals will be euthanized by carbon dioxide inhalation and exsanguination (with the exception of the PND4 extra pups – see Section 10.2) and then necropsied according to the following schedule:

F0 Females:	Caesarean subset: On GD21. Littering subset: After weaning of the F1 pups (females that fail to produce a viable litter by GD26 will be euthanized and necropsied).
Unmated Females:	After completion of the mating period.
Pups:	On PND4 (unselected pups) or on PND21.

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Untreated males will be retained at the disposal of the Test Facility following completion of the majority of caesarean sections.

Selected fetuses (caesarean subset) and pups (littering subset) will be sampled for antibody analysis at necropsy (see Section 11.1).

12.3. Necropsy**12.3.1. Caesarean Subset**

All animals will be submitted to a full macroscopic examination of the abdominal and thoracic cavities including the injection sites. Any abnormalities observed will be recorded and preserved but not examined further in first instance.

For each female euthanized on GD21, the ovaries and uterus will be removed and examined including examination of the placentae. The following data will be recorded:

Necropsy Data

Parameters	Comments
Pregnancy Status	-
Gravid Uterus Weight	The uterus of apparently non-pregnant females will be placed in ammonium sulphide solution in order to stain any previously undetected implantation sites
Number and Distribution of Intrauterine Implantations	Will be classified as: live fetuses, dead fetuses, early resorptions and late resorptions
Number of Corpora Lutea	-
Fetal Weights	Individual weights will be recorded
Fetal Sex	-

∴ No comment.

12.3.2. Littering Subset

All adult animals and pups (including those culled on PND4) will be submitted to a full macroscopic examination of the abdominal and thoracic cavities **including the injection sites (for adult animals)**. Any abnormalities observed will be recorded and preserved but not examined further in first instance.

Carcass of PND21 pups will be preserved for possible skeletal examinations.

For all F0 females, the number of implantation sites will be recorded.

Any remaining tissues not required for retention may be harvested from the carcass of vehicle control animals before disposal. These tissues, if collected, may be used for validation or investigational purposes and as such are not part of this study and will not interfere with the study objectives.

13. FETAL EXAMINATION

Each fetus will be examined for external defects and all live fetuses will be euthanized by oral administration of sodium pentobarbitone. Approximately one half of each litter will be submitted to fresh visceral examination of the body (abdominal and thoracic cavities). The head will be fixed in Harrison's fluid for subsequent examination by serial sectioning. The remaining carcass will be retained fixed in ethanol but not examined further in the first instance.

The remaining half of the fetuses in each litter will be eviscerated and then processed for skeletal examination. The skeletal examinations will be performed following maceration of the soft tissues with aqueous potassium hydroxide, staining of the skeleton with Alizarin red then passage into glycerol.

Dead fetuses will be examined externally and discarded without further examination.

Soft tissue and skeletal examinations will be performed using a binocular microscope.

Photographs of any representative morphological abnormalities will be taken at the discretion of the Study Director (not considered as raw data or reported - kept under the responsibility of the Study Director).

14. STATISTICAL ANALYSIS

Numerical data collected on scheduled occasions will be summarized and statistically analyzed as indicated below according to the occasion or by litter.

Body Weight Gains (F0 Generation): Calculated between each scheduled interval (see Section 10) as well as between Day 1 to Day 22, GD0 to GD21 and LD1 to LD21 (where applicable).

Body Weight Gains (F1 Generation): Calculated between each scheduled interval (see Section 10).

Food Consumption: Calculated between each scheduled interval (see Section 10) as well as between Day 1 to Day 22, GD0 to GD21 and LD1 to LD21 (where applicable).

Additional or alternative body weight or food consumption intervals may be evaluated to elucidate study results at the discretion of the Study Director.

The following reproductive indices will be calculated:

For both subgroups combined where applicable (caesarean and littering):

Pre-coital interval (in days):	$\frac{\text{Sum of days until successful insemination}}{\text{Number of inseminated females}}$
Copulation (mating) index (in %):	$\frac{\text{Number of inseminated females}}{\text{Number of paired animals}} \times 100$
Pregnancy rate (in %):	$\frac{\text{Number of pregnant females}}{\text{Number of paired animals}} \times 100$

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Fertility index (in %):	$\frac{\text{Number of pregnant females}}{\text{Number of inseminated females}} \times 100$
For the caesarean subset:	
Pre-Implantation Loss (in %):	$\frac{\text{Number of corpora lutea} - \text{Number of implants}}{\text{Number of corpora lutea}} \times 100$
Post-Implantation Loss (in %):	$\frac{\text{Number of implants} - \text{Number of live fetuses}}{\text{Number of implants}} \times 100$
Sex Ratio (% males):	$\frac{\text{Number male fetuses}}{\text{Total Number of fetuses}} \times 100$
Litter % of Fetuses with Abnormalities:	$\frac{\text{Number of fetuses in litter with a given finding}}{\text{Number of fetuses in litter examined}} \times 100$
For the littering subset:	
Gestation index (in %):	$\frac{\text{Number of females with live pups}}{\text{Number of pregnant females}} \times 100$
Live Birth Index (in %):	$\frac{\text{Number of pups born alive}}{\text{Number of pups born}} \times 100$
Pre-Birth Loss (in %):	$\frac{\text{Number of implantations} - \text{Number of pups born}}{\text{Number of implantations}} \times 100$
Viability Index (in %):	$\frac{\text{Number of pups alive on PND4}}{\text{Number of pups alive at birth}} \times 100$
Weaning Index (in %):	$\frac{\text{Number of pups alive on PND21}}{\text{Number of pups alive on PND4}^*} \times 100$
Sex ratio (proportion of male pups):	$\frac{\text{Number of male pups}}{\text{Number of pups}} \times 100$

*: Number of pups alive on PND4 after adjustment of litter size, if applicable

Additional or alternative indices may be calculated to elucidate study results at the discretion of the Study Director.

The best transformation for the data (none, log or rank) will be determined depending upon:

- The normality of the data distribution tested by the Shapiro-Wilk's test.
- The homogeneity of the variances across groups tested by the Bartlett's test.

Non- or log-transformed data will be analysed by parametric methods.

Rank transformed data will be analysed using non-parametric methods.

The data from the treated groups will be analyzed by parametric or non-parametric Dunnett's test to look for significant differences from the control group.

All litter-based percentages will be analyzed using non-parametric methods, i.e., Kruskal Wallis test followed by non-parametric Dunnett's test if the Kruskal-Wallis was significant.

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Selected incidence data will be analysed using a χ^2 test for all groups followed by Fisher's two-tailed test with Bonferroni correction for each treated group versus the control if the χ^2 was significant.

Pre-coital interval, estrous cycle and F1 offspring functional tests will be analysed using a SAS software package. Levene's test will be used to test the equality of variance across groups and Shapiro-Wilk's test will be used to assess the normality of the data distribution in each group. Data with homogenous variances and normal distribution in all groups will be analysed using Anova followed by Dunnett's test. Data showing non-homogenous variances or a non-normal distribution in at least one group will be analysed using Kruskal-Wallis test followed by Wilcoxon's rank sum test.

15. COMPUTERIZED SYSTEMS

The following computerized systems may be used in the study. The actual computerized systems will be documented in the study data.

Computerized Systems

System Name	Description of Data Collected and/or Analyzed
GTC Mozart 21	Environmental data recording
Vaisala	Environmental data recording
Provantis	Test material receipt, accountability and/or formulation activities; in-life; postmortem; statistical analysis
Share Document Management System	Reporting
DocuSign	Collection of 21 CFR Part 11 compliant signature
Devil	Deviation information library
STATSAS	Statistical analysis

Microsoft Excel[®] (version 2003 or higher) may be employed to present certain results and perform associated calculations.

Data for parameters not required by the Study Plan, which are automatically generated by analytical devices used will be retained on file but not reported. Statistical analysis results that are generated by the program but are not required by the Study Plan and/or are not scientifically relevant will be retained on file but will not be included in the tabulations.

Appendix 1

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16. REGULATORY COMPLIANCE

The study will be performed in accordance with OECD Principles of Good Laboratory Practice as required in Directive 2004/10/EC of the European Parliament and of the Council of 11 February 2004, Bonnes Pratiques de Laboratoire, Ministère de l'Emploi et de la Solidarité Française, No. 2000/5bis, arrêté du 14/03/2000.

Exceptions to GLPs include the following study elements:

- Antibody analysis will be performed in accordance with the Good Clinical Laboratory Practice (GCLP) and not the GLP (not applicable). The Test Site for antibody analysis (VisMederi Srl) is non-GLP compliant.
This Test site was selected by the Sponsor because it has the most appropriate experience concerning the measurement of neutralizing antibody titres against the Sars-CoV-2 live virus by Microneutralization CPE-based method.
The delegated phase for antibody analysis is fit for purpose, will be performed in adherence to local SOPs and working instructions, by a research facility with proper expertise, and adequate history and by individuals specially trained in this technique (according to VisMederi management of personnel procedure). This exception will not adversely affect the outcome or interpretation of this study because the methods will include appropriate controls to provide reliable data and analyses according to data integrity principles and local QA report review will ensure compliance to internal procedures. The measurement will be conducted according SOP described in Section 11.3.

17. QUALITY ASSURANCE**17.1. Test Facility**

The Test Facility Quality Assurance Unit (QAU) will monitor the study to assure the facilities, equipment, personnel, methods, practices, records, and controls are in conformance with Good Laboratory Practice regulations. The QAU will review the Study Plan (and any amendments), conduct inspections at intervals adequate to assure the integrity of the study, and audit the Final Report to assure that it accurately describes the methods and Standard Operating Procedures and that the reported results accurately reflect the raw data of the study.

All Quality Assurance documents will be retained by the Test Facility as their property and will not be returned to the Study Sponsor.

17.2. Test Site(s)

Not applicable (non-GLP phase – see Section 16).

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18. AMENDMENT(S) AND DEVIATIONS

Changes to the approved Study Plan shall be made in the form of an amendment, which will be signed and dated by the Study Director. Every reasonable effort will be made to discuss any necessary Study Plan changes in advance with the Sponsor.

All Study Plan and SOP deviations will be documented in the study records.

The Study Director will notify the Sponsor of deviations that may result in a significant impact on the study as soon as possible.

Deviations from the Study Plan and/or SOP related to the phase(s) of the study conducted at a Test Site shall be documented, acknowledged by the Principal Investigator, and reported to the Study Director for authorization/acknowledgement.

19. RETENTION AND DISPOSITION OF RECORDS, SAMPLES, AND SPECIMENS

All study-specific raw data, electronic data, documentation, Study Plan, retained samples and specimens, and the Final Report will be archived at the Final Report issue. All materials generated by Charles River Laboratories from this study will be transferred to a Charles River Laboratories archive and kept for a period of 2 years following the date of issue of the Final Report.

Disposition of residual/retained analytical samples will be as described in the table below.

Disposition of Residual/Retained Samples

Sample Type	Disposition	Schedule
Serum for antibody analysis	Return to the Sponsor	Samples will be maintained for a minimum of 6 months following issuance of the Draft Report or at an alternate time point prior to finalization as requested and authorized by the Study Director

Records to be maintained will include, but will not be limited to, documentation and data for the following:

- Study Plan, Study Plan amendments, and deviations.
- Study schedule.
- Study-related correspondence.
- Test system receipt, health, and husbandry.
- Test materials receipt, identification and preparation.
- Reserve sample.
- In-life measurements and observations.
- Antibody sample collection and evaluation.
- Gross observations and related data.
- Organ weight measurements.
- Statistical analysis results.
- Original signed Final Report.

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20. STUDY CLASSIFICATION

Study Category: Reproductive and developmental toxicology,
Study Type: Combined fertility and developmental study
(including teratogenicity and
postnatal investigations).
Study Design: Parallel.
Primary Treatment Unique Ingredient ID: BNT162.
Class of Compound: Vaccine.

21. REPORTING

The Study Sponsor will be informed promptly of any significant findings at any time during the study.

A study update with all available data will be provided after termination of the in-life phase.

A comprehensive Draft Report will be prepared following completion of the study and will be finalized following consultation with the Sponsor. The report will include all information necessary to provide a complete and accurate description of the experimental methods and results and any circumstances that may have affected the quality or integrity of the study.

The report will be issued in the Test Facility house style.

The Sponsor will receive an electronic version of the Final Report provided in Adobe Acrobat PDF format (hyperlinked and searchable at final). The PDF document will be created from native electronic files to the extent possible, including text and tables generated by the Test Facility. Report components not available in native electronic files and/or original signature pages will be scanned and converted to PDF image files for incorporation.

Reports should be finalized within 6 months of issue of the Draft Report. If the Sponsor has not provided comments to the report within 6 months of draft issue, the report will be finalized by the Test Facility unless other arrangements are made by the Sponsor.

A tabulated data summary will be provided in a format as outlined in the ICH Harmonized Tripartite Guideline, *The Common Technical Document for the Registration of Pharmaceuticals for Human Use: Safety – M4S (R2), Non-Clinical Overview and Non-Clinical Summaries of Module 2, Organisation of Module 4.*

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22. JUSTIFICATION AND GUIDELINES

22.1. Justification of Test System and Number of Animals

At this time, studies in laboratory animals provide the best available basis for extrapolation to humans and are required to support regulatory submissions. Acceptable models which do not use live animals currently do not exist.

The rat was chosen as the animal model for this study as it is an accepted rodent species for preclinical toxicity testing by regulatory agencies. It mounts an immune response to the vaccines tested that is similar to the expected human response after vaccination.

The total number of animals to be used in this study is considered to be the minimum required to properly characterize the effects of the test item. This study has been designed such that it does not require an unnecessary number of animals to accomplish its objectives.

22.2. Justification of Route and Dose Levels

The intramuscular route of exposure was selected because this is the intended route of human exposure. The dose administered will be the highest absolute dose considered for Women of Childbearing Potential.

22.3. Guidelines for Study

The study will be conducted in general compliance with the following:

- International Conference on Harmonization, Detection of Toxicity to Reproduction for Medicinal Products; Department of Health and Human Services, Food and Drug Administration; Federal Register 1994, Part IX. Vol. 59. No. 183, 48746 - 48752.
- ICH guideline S5(R3): Detection of Reproductive and Developmental Toxicity for Human Pharmaceuticals; February 2020.
- Food and Drug Administration (FDA). Guidance for Industry: Considerations for developmental toxicity studies for preventive and therapeutic vaccines for infectious disease indications, CBER Division of Vaccines and related products (February 2006).
- European Medicines Agency (EMA), CPMP/SWP/465/95 June 1998. Note for guidance on preclinical pharmacological and toxicological testing of vaccines.
- WHO guidelines on nonclinical evaluation of vaccines, Technical Report Series, No. 927, 2005

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23. ANIMAL WELFARE

The study design was reviewed and approved by the ethical committee of the Test Facility as per the Standard Project Authorization No. 2017072617402851.

The study design, animal housing and associated procedures are in general compliance with the following animal health and welfare guidelines:

- Guide for the care and use of laboratory animals, 2011.
- Decree No. 2013-118 relating to the protection of animals used in scientific experiments described in the Journal Officiel de la République Française on 01 February 2013.
- Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes.

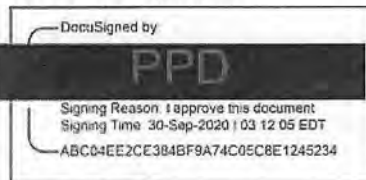
The Test Facility is AAALAC accredited.

By approving this Study Plan, the Sponsor affirms that there were no other alternative experimental methods other than the use of live animals to achieve the required objectives, that the harm-benefit analysis of the project was performed and that this study does not unnecessarily duplicate any previous experiments.

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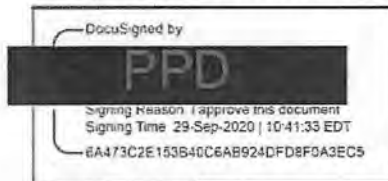
TEST FACILITY AMENDMENT APPROVAL

The signature below indicates that Test Facility Management approves the Study Director identified in this document and management's responsibility to the study as defined by the relevant GLP regulations.



Test Facility Management

The signature below indicates that the Study Director approves the document.



PPD PhD
Study Director

Sponsor Reference No. RN9391R58
Study Plan Amendment No. 02

Test Facility Study No. 20256434
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SPONSOR AMENDMENT APPROVAL

The signature of the Sponsor Representative below indicates approval of this document.

Dr. [Redacted] PPD Date: 11 Dec 20
Sponsor Representative

Sponsor Reference No. RN9391R58
Study Plan Amendment No. 02

Test Facility Study No. 20256434
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ATTACHMENT A
Shipment of Samples and Study Records

Matrix	Purpose	Day/ Week/ Aliquot	Proposed Shipment Date	Conditions for Shipment	Recipient/Address
Serum	Antibody analysis	Pretest and M0	02 Sep 2020	Dry ice	PPD VisMederi Srl Strada del Petriccio e Belriguardo, 35 53100 Siena, Italy E-mail: PPD and PPD
Serum	Antibody analysis	GD21 or LD21	21 Oct 2020	Dry ice	PPD VisMederi Srl Strada del Petriccio e Belriguardo, 35 53100 Siena, Italy E-mail: PPD and PPD

Sponsor Reference No RN9391R58
Study Plan Amendment No 02

Test Facility Study No 20256434
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Deviations

All deviations that occurred during the study have been authorized/acknowledged by the Study Director, assessed for impact, and documented in the study records. All Study Plan deviations and those SOP deviations that could have impacted the quality or integrity of the study are listed below. Minor SOP deviations that did not impact the quality or integrity of the study have been included at the discretion of the Study Director.

Husbandry

- On Day -19, F23 from the BNT162b2 group (caesarean subgroup) was found in the cage of F28 to F32 (BNT162b2 group) during blood sampling. The female was placed in the wrong cage after the estrous cycle smear that same day (i.e., for approximately 2h45). This animal was replaced in its cage as soon as noted. This did not noticeably affect the clinical condition of the animals or the outcome of the study.
- CC1
- On GD18, Female No. 54 (BNT162b2, 30 µg) was found with no access to water probably for approximately 23 hours due to a defective bottle. This did not noticeably affect the clinical condition of the animal or the outcome of the study.

Individual Physical and Functional Development

- PPD

Postmortem and Pathology

- One dead pup of F212 from the control group was necropsied on PND1. The results of the necropsy was not recorded in the raw data in error. This isolated incident for a single pup had no impact on the study validity or outcome.
- PPD



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A-3400 Klosterneuburg, Austria
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Fax: +43-2243-25060-399
E-Mail: office@polymer.com
http://www.polymer.com

Non-GMP CoA

Material not for human use
Version 3

Product: **CCI**
Batch: RBP020.3 LNP
Lot: CoVVAC/100320

Test	Method	Result
Appearance	Visual Inspection (224/SOP/011)	White to off-white suspension
RNA identity	CE (223/SOP/016)	CCI
RNA integrity	CE (223/SOP/016)	CCI
RNA content	Ribogreen Assay (221/SOP/018)	CCI
RNA encapsulation	Ribogreen assay +/- LNP disruption (221/SOP/018)	CCI
ALC-0315 content	HPLC-CAD (222/SOP/044)	CCI
ALC-0159 content	HPLC-CAD (222/SOP/044)	CCI
DSPC content	HPLC-CAD (222/SOP/044)	CCI
Cholesterol content	HPLC-CAD (222/SOP/044)	CCI
Particle size (Z_{avg})	Dynamic light scattering (224/SOP/002)	CCI
Polydispersity Index (PDI)	Dynamic light scattering (224/SOP/002)	CCI
pH	pH (224/SOP/016)	CCI
Osmolality	Freezing point depression (224/SOP/009)	CCI
Endotoxins/Pyrogens	Turbidimetric, kinetic LAL assay (Ph.Eur. 2.6.14/ USP<85>)	CCI
Bioburden	Membrane filtration method (225/SOP/001)	CCI

Store at: -70°C

Date: 26.03.2020

Dr. PPD (Quality Control)

Date: 26.03.2020

Dr. PPD (Head Liposome Technology)

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Shelf Life Extension SOP-070-003- V. 04 Anlage
FOR-070-003A SOP-070-003-AL-1- 31.07.2020 30.07.2022 BIO-TECH
Order_Clin_Rel_Mat V. 04

PSL number: PSL-20-0012

Part 1	To be filled in by staff member of the technical department responsible for the clinical relevant material	
Batch number	CoVAC100320	
Product/Material name	CCI	
SLR Number	CCI	
Manufacturer of the product/material	Polymun Scientific Donaustraße 99, 3400 Klosterneuburg, Austria	
Date of manufacturing	10.MAR.2020	
Test Point	5 months	
Shelf life up to now	Date	Months
	10.SEPT.2020	6
Document code of stability report	R-20-0229	
New shelf life	Date	Months
	10.JAN.2021	10
Sponsor's approval required (if not BNT)	<input type="checkbox"/> yes	<input checked="" type="checkbox"/> no
Evaluation	Evaluation according to ICH	<input checked="" type="checkbox"/> yes <input type="checkbox"/> no, justification below
	No movement of the CQAs of the DP is observed for any of the oldest DP batches either at the main temperature of $-70 \pm 10^{\circ}\text{C}$ or at the satellite storage temperature of $-40 \pm 5^{\circ}\text{C}$ which is at or below the glass transition temperature of the cryoprotectant, sucrose, ($T_g'1$: $-51.8 \pm 0.8^{\circ}\text{C}$ and $T_g'2$: $-38.8 \pm 0.1^{\circ}\text{C}$ may also be treated as indicative to long term stability CCI CCI	

Druckdatum: 01.06.2020

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Gedruckt am 01.06.2020 10:00:00

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Shelf Life Extension	SOP-070-003- V. 04	Anlage		
FOR-070-003A	SOP-070-003-AL-1-	31.07.2020	30.07.2022	BIO TECH
Order_Clin_Rel_Mat	V. 04			

PSL number:	236.10.0012
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Evaluation		
	Prepared	17. SEP 2020
	Approved	17. Sep. 2020

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Shelf Life Extension SOP-070-003- V. 04 Anlage
FOR-070-003A SOP-070-003-AL-1- 31.07.2020 30.07.2022
Order_Clin_Rel_Mat V. 04

	n.a. 17.09.2020 PPD
--	---------------------

PSL number: Psl-20-0012

Sponsor Approval

Sponsor	
Name	
Date	

Herewith I confirm that I have received the request to extend shelf life.

Approval granted	<input type="checkbox"/> yes n.a. <input type="checkbox"/> no
Comments	

Date

Signature

Seal of contractor


Please return the completed form per E-Mail to the sender and to PPD and other recipients if agreed (e.g in QAA).

PPD

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Shelf Life Extension	SOP-070-003- V. 04	Anlage
FOR-070-003A	SOP-070-003-AL-1-	31.07.2020 30.07.2022
Order_Clin_Rel_Mat	V. 04	

PSL number:

Part 2	To be filled in by QA	
The form is complete and correct	<input checked="" type="checkbox"/> yes	<input type="checkbox"/> no
Information was forwarded to the relevant functions according to SLR number	Function/Name:	
	Regulatory Affairs CMC	
	IMP Management	
	Pfizer CMC / Regulatory / PM	
	Project Management	
Comments	n a	
Date, Signature	17.09.2020	

PPD

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A-3400 Klosterneuburg, Austria
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Fax: +43-2243-25060-399
E-Mail: office@polymun.com
http://www.polymun.com

Non-GMP CoA

Material not for human use
Version 3

Product: 
Batch: RBP020.2LNP
Lot: CoVVAC/270320

Test	Method	Result
Appearance	Visual Inspection (224/SOP/011)	White to off-white suspension
RNA identity	CE (223/SOP/016)	
RNA integrity	CE (223/SOP/016)	
RNA content	Ribogreen Assay (221/SOP/018)	
RNA encapsulation	Ribogreen assay +/- LNP disruption (221/SOP/018)	
ALC-0315 content	HPLC-CAD (222/SOP/044)	
ALC-0159 content	HPLC-CAD (222/SOP/044)	
DSPC content	HPLC-CAD (222/SOP/044)	
Cholesterol content	HPLC-CAD (222/SOP/044)	
Particle size (Z_{avg})	Dynamic light scattering (224/SOP/002)	
Polydispersity index (PDI)	Dynamic light scattering (224/SOP/002)	
pH	pH (224/SOP/016)	
Osmolality	Freezing point depression (224/SOP/009)	
Endotoxins/Pyrogens	Turbidimetric, kinetic LAL assay (Ph.Eur. 2.6.14/ USP<85>)	
Bioburden	Membrane filtration method 225/SOP/001	

Store at: -70°C

Date: 09.04.20

Dr.

Date: 09.04.20

Dr.

ome Technology)

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Appendix 2

Hauptdokument Shelf Life Extension	Code SOP-070-003- V. 04	Dokumenttyp Anlage	BIONTECH
Anlage FOR-070-003A Order Clin Rel Mat	Code SOP-070-003-AL-1- V. 04	Gültig von 31.07.2020 Gültig bis 30.07.2022	

PSL number:	PSL-20-0014
-------------	-------------

Part 1	To be filled in by staff member of the technical department responsible for the clinical relevant material	
Batch number	COVVAC270320	
Product/Material name	BNT162b2	
SLR Number	SLR-20-0009	
Manufacturer of the product/material	Polymun Scientific Donaustaße 99, 3400 Klosterneuburg, Austria	
Date of manufacturing	27.MAR.2020	
Test Point	4 months	
Shelf life up to now	Date	Months
	27.SEP.2020	6
Document code of stability report	R-20-0229	
New shelf life	Date	Months
	27.NOV.2020	8
Sponsor's approval required (if not BNT)	<input type="checkbox"/> yes	<input checked="" type="checkbox"/> no
Evaluation	Evaluation according to ICH	<input checked="" type="checkbox"/> yes <input type="checkbox"/> no, justification below
	No movement of the CQAs of the DP is observed for any of the oldest DP batches either at the main temperature of $-70\pm 10^{\circ}\text{C}$ or at the satellite storage temperature of $-40\pm 5^{\circ}\text{C}$ which is at or below the glass transition temperature of the cryoprotectant, sucrose, ($T_g'1$: $-51.8\pm 0.8^{\circ}\text{C}$ and $T_g'2$: $-38.8\pm 0.1^{\circ}\text{C}$ may also be treated as indicative to long term stability. CCI [REDACTED] [REDACTED] [REDACTED] CCI [REDACTED]	

Shelf Life Extension SOP-070-003- V. 04 Anlage BIO ECH
FOR-070-003A SOP-070-003-AL-1- 31.07.2020 30.07.2022
Order_Clin_Rel_Mat V. 04

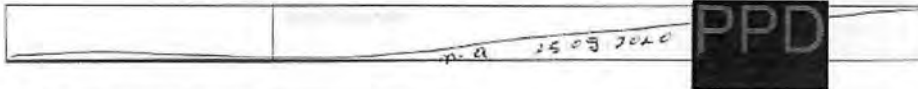
PSL number:	
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Evaluation	
Prepared	24. Sep. 2020
Approved	Sep 24 th , 2020



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Shelf Life Extension SOP-070-003- V. 04 Anlage
FOR-070-003A SOP-070-003-AL-1- 31.07.2020 30.07.2022
Order_Clin_Rel_Mat V. 04



PSL number: PSL-20-0014

Sponsor Approval

Sponsor	
Name	
Date	

Herewith I confirm that I have received the request to extend shelf life.

Approval granted	<input checked="" type="checkbox"/> yes
Comments	<p>25.09.2020</p> <p>PPD</p>

Date Signature Seal of contractor


Please return the completed form per E-Mail to the sender and to PPD and other recipients if agreed (e.g. in QAA).

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Shelf Life Extension SOP-070-003- V. 04 Anlage
FOR-070-003A SOP-070-003-AL-1- 31.07.2020 30.07.2022
Order_Clin_Rel_Mat V. 04

PSL number:

Part 2	To be filled in by QA	
The form is complete and correct	<input checked="checked" type="checkbox"/> yes	<input type="checkbox"/> no
Information was forwarded to the relevant functions according to SLR number	Function/Name: Regulatory Affairs CMC IMP management Pfizer CMC / Regulatory / PM 	
Comments	n.a.	
Date, Signature	25.09.2020 	

PPD

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Fax: +43-2243-25060-399
E-Mail: office@polymun.com
http://www.polymun.com

Non-GMP CoA
Material not for human use
Version 2

Product: **CCI**
Batch: RBP020.8 LNP
Lot: BCV/040620

Test	Method	Result
Appearance	Visual Inspection (224/SOP/011)	White to off-white suspension
RNA Identity	CE (223/SOP/015)	CCI
RNA Integrity	CE (223/SOP/015)	
RNA content	Ribogreen Assay (221/SOP/018)	
RNA encapsulation	Ribogreen assay +/- LNP disruption (221/SOP/018)	
ALC-0315 identification and content	HPLC-CAD (222/SOP/044)	
ALC-0159 identification and content	HPLC-CAD (222/SOP/044)	
DSPC identification and content	HPLC-CAD (222/SOP/044)	
Cholesterol identification and content	HPLC-CAD (222/SOP/044)	
Particle size (Z_{avg})	Dynamic light scattering (224/SOP/002)	
Polydispersity index (PDI)	Dynamic light scattering (224/SOP/002)	
pH	pH (224/SOP/016)	
Osmolality	Freezing point depression (224/SOP/009)	
Endotoxins/Pyrogens	Turbidimetric, kinetic LAL assay (Ph.Eur. 2.6.14/ USP<85>)	
Bioburden	Membrane filtration method 225/SOP/001	

Store at: -70°C

Date: 03.07.2020

Date: 03.07.2020

PPD
PPD
Dr.
Dr.
(Lead Liposome Technology)

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PF-07302048: Sample Homogeneity for COVID-19 mRNA LNP DP Used in GLP Toxicology Studies
VR-VTR-10681, Ver. 1.0



Title: Sample Homogeneity for COVID-19 mRNA LNP DP Used in GLP Toxicology Studies

Study Number: N/A

Parent Compound Number(s): PF-07302048

Alternative Compound Identifiers: N/A

**Pfizer Vaccine Research and Development
401 N. Middletown Rd.
Pearl River, NY**

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PF-07302048: Sample Homogeneity for COVID-19 mRNA LNP DP Used in GLP Toxicology Studies
VR-VTR-10681, Ver. 1.0

Title: Sample Homogeneity for COVID-19 mRNA LNP DP Used in GLP Toxicology Studies

PRINCIPAL INVESTIGATOR: PPD, Principal Scientist

CONTRIBUTING SCIENTIST(S): NA

PREPARED BY:

PPD, PhD
Associate Director, Early Bioprocess Development

APPROVED BY:

PPD, PhD
Senior Director, Early Bioprocess Development

PPD, PhD
Senior Manager, Quality and Compliant Operations

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090177e194f2f6a0\Approved\Approved On: 22-Sep-2020 12:37 (GMT)

PF-07302048: Sample Homogeneity for COVID-19 mRNA LNP DP Used in GLP Toxicology Studies
VR-VTR-10681, Ver. 1.0

Title: Sample Homogeneity for COVID-19 mRNA LNP DP Used in GLP Toxicology Studies

SYNOPSIS

This report provides the data to support the sample homogeneity assessment for COVID-19 mRNA drug product used in GLP Toxicity and GLP DART studies. The homogeneity is supported by evaluating the RNA concentration for multiple sample pulls from a single vial by Ribogreen. This is applicable to formulations of vaccines (test articles) containing RNA lipid nanoparticles (LNPs) that are used in GLP toxicology studies.

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090177e194f2f6a0\Approved\Approved On: 22-Sep-2020 12:37 (GMT)

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PF-07302048: Sample Homogeneity for COVID-19 mRNA LNP DP Used in GLP Toxicology Studies
VR-VTR-10681, Ver. 1.0

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PF-07302048: Sample Homogeneity for COVID-19 mRNA LNP DP Used in GLP Toxicology Studies
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1. OBJECTIVES

The objective of this report is to document the sample homogeneity of COVID-19 mRNA drug product (DP) as dosed in separate GLP Toxicity and DART studies over the expected dosing window.

2. INTRODUCTION

The COVID-19 messenger RNA Lipid Nanoparticle vaccine (mRNA LNP) is currently under development by Pfizer and BioNTech as a vaccine for COVID-19. The LNP drug product (DP) is composed of modRNA (modified nucleoside RNA) formulated in lipid nanoparticles consisting of ALC-0315, ALC-0159, DSPC, and cholesterol in a matrix of 300 mM sucrose, 0.75x PBS (103 mM NaCl, 2 mM KCl, 6 mM Na₂HPO₄, and 1.0 mM KH₂PO₄), pH 7.4.

3. STUDIES IN SUPPORT OF SAMPLE HOMOGENEITY

The LNP DP is presented in multi-dose vials stored frozen at -70°C. Prior to dosing, the DP vial is thawed and gently mixed by inversion. For the GLP Toxicity study, the vial is gently mixed by inversion before each of the nine 60-μL doses is withdrawn. For the DART study, the DP vial is gently mixed by inversion only prior to the first of the ten 60-μL doses being withdrawn. To ensure uniformity of LNP formulation throughout dosing using a multi-dose vial (from thawing the vial (initial dose) through the last dose), the RNA concentration was determined N=5 times over a 6-hour window to represent the Toxicity study vial handling and N=5 times over a 120-minute window to represent the DART study vial handling using the Ribogreen assay (VR-TM-10308).¹ The materials used in this evaluation are shown in Table 1.

Table 1. Samples Used in Content Uniformity Assessment

Material	Lot Number	Concentration	Reference
[REDACTED]	BCV/040620	531 μg/mL	132355-047

This homogeneity study supports the toxicity studies shown in Table 2. [REDACTED] DP lot BCV/040620 was evaluated in both toxicity studies (20GR142 and 20256434) and will serve as a representative of modRNA DP. The other construct formulations are similar in composition and are expected to behave the same.

Table 2. Toxicity Studies Being Supported

Study	Study (Sponsor) Number
17-Day IM Toxicity Study of BNT162B2 (V9) and [REDACTED] in Wistar Han Rats with a 3-Week Recovery	20GR142
Combined Fertility and Developmental Study (Including Teratogenicity and Postnatal Investigations) of [REDACTED] BNT162b2 and [REDACTED] by the IM Route in the Wistar Rat GLP Study	20256434

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The testing plan to represent the DP vial handling in study 20256434 is shown in Table 3.

Table 3. Testing Plan for DART DP Vial (Study Number 20256434)

Time point, hours	Dose volume, μ L	Testing	Dose treatment
0	60	TBT ^a	Gentle inversion prior to withdraw, 3X
0.5	60	NT ^b	None
1.0	60	TBT	None
1.5	60	NT	None
2.0	60	TBT	None
2.5	60	NT	None
3.0	60	NT	None
4.0	60	TBT	None
5.0	60	NT	None
6.0	60	TBT	None

- a. TBT = to be tested.
b. NT = not tested.

The testing plan to represent the DP vial handling in Toxicity Study 20GR142 is shown in Table 4.

Table 4. Testing Plan for Toxicity DP Vial (Study Number 20GR142)

Time point, minutes	Dose volume, μ L	Testing	Dose treatment
0	60	TBT ^a	Gentle inversion prior to withdraw, 3X
15	60	NT ^b	Gentle inversion prior to withdraw, 3X
30	60	TBT	Gentle inversion prior to withdraw, 3X
45	60	NT	Gentle inversion prior to withdraw, 3X
60	60	TBT	Gentle inversion prior to withdraw, 3X
75	60	NT	Gentle inversion prior to withdraw, 3X
90	60	TBT	Gentle inversion prior to withdraw, 3X
105	60	NT	Gentle inversion prior to withdraw, 3X
120	60	TBT	Gentle inversion prior to withdraw, 3X

- a. TBT = to be tested.
b. NT = not tested.

4. STUDY RESULTS

4.1. Homogeneity for DART Study Number 20256434

The concentration of mRNA measured over 6 hours was 585 μ g/mL on average with an %RSD of 4.3 as shown in Table 5. This supports that the sample is homogeneous over this time frame used which represents the dosing window for this study.

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Table 5. Homogeneity Results in Support of DART Study Number 20256434

Time point, hours	Dose volume, μ L	RNA concentration, μ g/mL
0	60	
1.0	60	
2.0	60	
4.0	60	
6.0	60	
Average RNA concentration, μ g/mL		
%RSD		

4.2. Homogeneity for Toxicity Study 20GR142

The concentration of mRNA measured over 2 hours was 571 μ g/mL on average with an %RSD of 4.2% as shown in Table 6. This supports that the sample is homogeneous over this time frame which represents the dosing window for this study.

Table 6. Homogeneity Results in Support of Toxicity Study Number 20GR142

Time point, minutes	Dose volume, μ L	RNA concentration, μ g/mL
0	60	
30	60	
60	60	
90	60	
120	60	
Average RNA concentration, μ g/mL		
%RSD		

5. CONCLUSION

The data in this report supports that the content of a DP vial is homogeneous during the dosing windows regardless of whether a vial is shaken once upon thawing or prior to withdrawing of each of the doses over the timeframes indicated.

6. DEVIATIONS

Not applicable.

7. REFERENCES

- VR-TM-10308, "Quantification of Total RNA in COVID-19 mRNA LNP DP by RiboGreen Fluorescence".

Document Approval Record

Document Name:	VR-VTR-10681	
Document Title:	Sample Homogeneity for COVID-19 mRNA LNP DP Used in GLP Toxicology	
Signed By:	Date(GMT)	Signing Capacity
PPD	18-Sep-2020 13:44:36	Author Approval
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Individual Mortality

20256434

Group	Dose Level	Sex	Animal	Cage	Removal Day	Removal Week	Removal Date	Removal Time	Time Slot	Removal Symptom	Pathology Reason
1	Control 0mcg	Female	201	201	69	10	03OCT2020	9:27	.	.	TS
			202	202	68	10	02OCT2020	12:03	.	.	TS
			203	203	68	10	02OCT2020	13:22	.	.	TS
			204	204	67	10	01OCT2020	14:27	.	.	TS
			205	205	68	10	02OCT2020	13:28	.	.	TS
			206	206	67	10	01OCT2020	14:33	.	.	TS
			207	207	67	10	01OCT2020	15:01	.	.	TS
			208	208	66	10	30SEP2020	15:15	.	.	TS
			209	209	66	10	30SEP2020	15:42	.	.	TS
			210	210	67	10	01OCT2020	15:01	.	.	TS
			211	211	66	10	30SEP2020	15:39	.	.	TS
			212	212	67	10	01OCT2020	15:30	.	.	TS
			213	213	69	10	03OCT2020	9:32	.	.	TS
			214	214	66	10	30SEP2020	15:54	.	.	TS
			215	215	66	10	30SEP2020	16:00	.	.	TS
			216	216	69	10	03OCT2020	9:38	.	.	TS
			217	217	69	10	03OCT2020	9:59	.	.	TS
			218	218	67	10	01OCT2020	15:37	.	.	TS
			219	219	67	10	01OCT2020	15:50	.	.	TS
			220	220	67	10	01OCT2020	15:53	.	.	TS
			221	221	69	10	03OCT2020	9:43	.	.	TS
			222	222	68	10	02OCT2020	13:39	.	.	TS
			1	1	47	7	25SEP2020	9:04	.	.	TS
			2	2	46	7	24SEP2020	9:12	.	.	TS
			3	3	47	7	25SEP2020	9:05	.	.	TS
			4	4	45	7	23SEP2020	9:15	.	.	TS
			5	5	44	7	22SEP2020	9:15	.	.	TS
			6	6	47	7	25SEP2020	9:06	.	.	TS
			7	7	45	7	23SEP2020	9:16	.	.	TS
			8	8	46	7	24SEP2020	9:12	.	.	TS
			9	9	47	7	25SEP2020	9:07	.	.	TS

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Individual Mortality
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Group	Dose Level	Sex	Animal	Cage	Removal Day	Removal Week	Removal Date	Removal Time	Time Slot	Removal Symptom	Pathology Reason
1	Control Omcg	Female	10	10	45	7	23SEP2020	10:02	.	.	TS
			11	11	47	7	25SEP2020	9:08	.	.	TS
			12	12	46	7	24SEP2020	9:18	.	.	TS
			13	13	47	7	25SEP2020	9:21	.	.	TS
			14	14	44	7	22SEP2020	9:16	.	.	TS
			15	15	53	8	01OCT2020	10:39	.	.	TS
			16	16	44	7	22SEP2020	9:19	.	.	TS
			17	17	56	8	04OCT2020	9:10	.	.	TS
			18	18	47	7	25SEP2020	9:25	.	.	TS
			19	19	44	7	22SEP2020	9:21	.	.	TS
			20	20	46	7	24SEP2020	9:34	.	.	TS
			21	21	47	7	25SEP2020	9:33	.	.	TS
			22	22	46	7	24SEP2020	9:45	.	.	TS

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Individual Mortality
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Group	Dose Level	Sex	Animal	Cage	Removal Day	Removal Week	Removal Date	Removal Time	Time Slot	Removal Symptom	Pathology Reason
3	BNT162b2 30mcg	Female	245	245	68	10	02OCT2020	13:35	.	.	TS
			246	246	68	10	02OCT2020	13:22	.	.	TS
			247	247	66	10	30SEP2020	15:23	.	.	TS

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Individual Mortality

20256434

Group	Dose Level	Sex	Animal	Cage	Removal Day	Removal Week	Removal Date	Removal Time	Time Slot	Removal Symptom	Pathology Reason
3	BNT162b2 30mcg	Female	248	248	66	10	30SEP2020	15:34	.	.	TS
			249	249	69	10	03OCT2020	10:38	.	.	TS
			250	250	69	10	03OCT2020	10:44	.	.	TS
			251	251	68	10	02OCT2020	13:14	.	.	TS
			252	252	69	10	03OCT2020	10:49	.	.	TS
			253	253	66	10	30SEP2020	15:47	.	.	TS
			254	254	52	8	16SEP2020	10:27	.	FL	UT
			255	255	68	10	02OCT2020	13:41	.	.	TS
			256	256	68	10	02OCT2020	13:31	.	.	TS
			257	257	67	10	01OCT2020	14:54	.	.	TS
			258	258	69	10	03OCT2020	11:00	.	.	TS
			259	259	69	10	03OCT2020	10:54	.	.	TS
			260	260	69	10	03OCT2020	11:06	.	.	TS
			261	261	67	10	01OCT2020	14:42	.	.	TS
			262	262	68	10	02OCT2020	13:50	.	.	TS
			263	263	68	10	02OCT2020	13:51	.	.	TS
			264	264	66	10	30SEP2020	15:49	.	.	TS
			265	265	67	10	01OCT2020	15:06	.	.	TS
			266	266	68	10	02OCT2020	13:45	.	.	TS
			45	45	44	7	22SEP2020	10:12	.	.	TS
			46	46	53	8	01OCT2020	11:26	.	.	TS
			47	47	44	7	22SEP2020	11:09	.	.	TS
			48	48	45	7	23SEP2020	11:18	.	.	TS
			49	49	47	7	25SEP2020	10:46	.	.	TS
			50	50	46	7	24SEP2020	11:05	.	.	TS
			51	51	47	7	25SEP2020	10:48	.	.	TS
			52	52	46	7	24SEP2020	11:16	.	.	TS
			53	53	47	7	25SEP2020	10:49	.	.	TS
			54	54	47	7	25SEP2020	10:51	.	.	TS
			55	55	46	7	24SEP2020	11:31	.	.	TS
			56	56	44	7	22SEP2020	11:09	.	.	TS

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Individual Mortality

20256434

Group	Dose Level	Sex	Animal	Cage	Removal		Removal Date	Removal Time	Time Slot	Removal Symptom	Pathology Reason
					Day	Week					
3	BNT162b2 30mcg	Female	57	57	46	7	24SEP2020	11:34	.	.	TS
			58	58	46	7	24SEP2020	11:43	.	.	TS
			59	59	46	7	24SEP2020	11:43	.	.	TS
			60	60	44	7	22SEP2020	11:11	.	.	TS
			61	61	44	7	22SEP2020	11:12	.	.	TS
			62	62	44	7	22SEP2020	11:17	.	.	TS
			63	63	44	7	22SEP2020	11:51	.	.	TS
			64	64	46	7	24SEP2020	11:45	.	.	TS
			65	65	47	7	25SEP2020	10:52	.	.	TS
			66	66	47	7	25SEP2020	10:53	.	.	TS

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Individual Mortality

20256434

Group	Dose Level	Sex	Animal	Cage	Removal Day	Removal Week	Removal Date	Removal Time	Time Slot	Removal Symptom	Pathology Reason
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Individual Pre-Mating Clinical Observations of Females

20256434

				Day numbers relative to Start Date							
Group	Sex	Animal	Clinical Sign	Site	-26 Daily 1	-21	-14	-7	-3	1	
1	f	201	Desquamation	Right hindlimb	
			Localised hairloss	Head	X	X	
				Scab(s).	Injection site(s)	X
		202	Teeth long	Lower tooth/teeth
		203	Missing tooth	Upper tooth/teeth	X	X
		204	Desquamation	Left and right hindlimbs
			Scab(s).	Injection site(s)	X
		205	Desquamation	Left and right hindlimbs
			Scab(s).	Injection site(s)	X
		212	Desquamation	Left hindlimb
			Erythema.	Injection site(s)	X
		220	Desquamation	Right hindlimb
			Erythema.	Right hindlimb
			Erythema.	Injection site(s)	X
		221	Erythema.	Left hindlimb
			Erythema.	Injection site(s)	X
			Localised hairloss	Dorsal neck region	X	X	X	X	.	.	
			Scab(s).	Back	X	
			Scab(s).	Dorsal neck region	X
		7	Localised hairloss	Left forelimb
		9	Localised hairloss	Dorsal neck region
			Scab(s).	Dorsal neck region

Severity Codes: X = Present; 1 = Slight

Group 1 - Control Omcg

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Individual Pre-Mating Clinical Observations of Females

20256434

Day numbers relative to Start Date

Group	Sex	Animal	Clinical Sign	Site	2	8 BEF	9	15
1	f	201	Desquamation	Right hindlimb	1	1	.	.
			Localised hairloss	Head
			Scab(s) .	Injection site(s)
		202	Teeth long	Lower tooth/teeth	.	.	.	X
		203	Missing tooth	Upper tooth/teeth
		204	Desquamation	Left and right hindlimbs	1	.	.	.
			Scab(s) .	Injection site(s)
		205	Desquamation	Left and right hindlimbs	1	1	.	.
			Scab(s) .	Injection site(s)
		212	Desquamation	Left hindlimb	1	.	.	.
			Erythema.	Injection site(s)
		220	Desquamation	Right hindlimb	1	.	.	.
			Erythema.	Right hindlimb	X	.	.	.
			Erythema.	Injection site(s)
		221	Erythema.	Left hindlimb	X	.	.	.
			Erythema.	Injection site(s)
			Localised hairloss	Dorsal neck region
			Scab(s) .	Back
			Scab(s) .	Dorsal neck region
		7	Localised hairloss	Left forelimb	.	X	X	X
		9	Localised hairloss	Dorsal neck region	.	.	.	X
			Scab(s) .	Dorsal neck region	.	.	.	X

Severity Codes: X = Present; 1 = Slight

Group 1 - Control 0mcg

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Individual Pre-Mating Clinical Observations of Females

20256434

Day numbers relative to Start Date										
Group	Sex	Animal	Clinical Sign	Site	-26	-13	1	2	8	9
					Daily 1	Daily 1			BEF	
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Individual Pre-Mating Clinical Observations of Females

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Day numbers relative to Start Date

Group	Sex	Animal	Clinical Sign	Site	9 Daily 1	10 Daily 1	15
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Individual Pre-Mating Clinical Observations of Females

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Day numbers relative to Start Date									
Group Sex	Animal	Clinical Sign	Site	-26 Daily 1	-13 Daily 1	1	2	8 BEF	9
[REDACTED]									

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Individual Pre-Mating Clinical Observations of Females

20256434

Day numbers relative to Start Date

Group Sex	Animal	Clinical Sign	Site	9 Daily 1	10 Daily 1	15
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Individual Pre-Mating Clinical Observations of Females

20256434

Day numbers relative to Start Date									
Group Sex	Animal	Clinical Sign	Site	-26 Daily 1	-13 Daily 1	1	2	8 BEF	9
[REDACTED]									

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Individual Pre-Mating Clinical Observations of Females

20256434

Day numbers relative to Start Date

Group	Sex	Animal	Clinical Sign	Site	9 Daily 1	10 Daily 1	15
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Individual Pre-Mating Clinical Observations of Females

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Day numbers relative to Start Date									
Group Sex	Animal	Clinical Sign	Site	-26 Daily 1	-13 Daily 1	1	2	8 BEF	9
[REDACTED]									

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Individual Pre-Mating Clinical Observations of Females

20256434

Day numbers relative to Start Date

Group	Sex	Animal	Clinical Sign	Site	9 Daily 1	10 Daily 1	15
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Individual Pre-Mating Clinical Observations of Females

20256434

Day numbers relative to Start Date

Group Sex	Animal	Clinical Sign	Site	-26 Daily 1	-13 Daily 1	1	2	8 BEF	9
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Individual Pre-Mating Clinical Observations of Females

20256434

Day numbers relative to Start Date

Group	Sex	Animal	Clinical Sign	Site	9 Daily 1	10 Daily 1	15
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Individual Pre-Mating Clinical Observations of Females

20256434

					Day numbers relative to Start Date						
Group	Sex	Animal	Clinical Sign	Site	-25	1	2	8 BEF	9	9 Daily 1	10 Daily 1
3	f	245	Limping	Right hindlimb	X	X
			Swelling.	Injection site 1	.	.	X
		246	Swelling.	Injection site 2	X	.	.
			Limping	Right hindlimb	X	X
		247	Swelling.	Injection site 1	.	.	X
			Swelling.	Injection site 2	X	.	.
		248	Desquamation	Left hindlimb	.	.	1
			Limping	Right hindlimb	X	X
		249	Swelling.	Injection site 1	.	.	X
			Swelling.	Injection site 2	X	.	.
		250	Swelling.	Injection site 1	.	.	X
			Swelling.	Injection site 2	X	.	.
		251	Erythema.	Left hindlimb	.	.	X
			Erythema.	Injection site(s)	.	X
		252	Swelling.	Injection site 1	.	.	X
			Swelling.	Injection site 2	X	.	.
		253	Limping	Right hindlimb	X	X
			Swelling.	Injection site 1	.	.	X
		254	Swelling.	Injection site 2	X	.	.
			Swelling.	Injection site 1	.	.	X
		255	Swelling.	Injection site 2	X	.	.
			Swelling.	Injection site 1	.	.	X

Severity Codes: X = Present; 1 = Slight

Group 3 - BNT162b2 30mcg

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Individual Pre-Mating Clinical Observations of Females

20256434

Day numbers relative to Start Date					
Group	Sex	Animal	Clinical Sign	Site	15 17 Daily 1
3	f	245	Limping	Right hindlimb	.
			Swelling.	Injection site 1	.
			Swelling.	Injection site 2	.
		246	Limping	Right hindlimb	.
			Swelling.	Injection site 1	.
			Swelling.	Injection site 2	.
		247	Desquamation	Left hindlimb	.
			Limping	Right hindlimb	.
			Swelling.	Injection site 1	.
		248	Swelling.	Injection site 2	.
			Swelling.	Injection site 1	.
			Swelling.	Injection site 2	.
		249	Limping	Right hindlimb	.
			Swelling.	Injection site 1	.
			Swelling.	Injection site 2	.
		250	Erythema.	Left hindlimb	.
			Erythema.	Injection site(s)	.
			Swelling.	Injection site 1	.
		251	Swelling.	Injection site 2	.
			Limping	Right hindlimb	.
			Swelling.	Injection site 1	.
		252	Swelling.	Injection site 2	.
			Limping	Right hindlimb	.
			Swelling.	Injection site 1	.
		253	Swelling.	Injection site 2	.
			Swelling.	Injection site 1	.
			Swelling.	Injection site 2	.

Severity Codes: X = Present; 1 = Slight

Group 3 - BNT162b2 30mcg

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Individual Pre-Mating Clinical Observations of Females

20256434

					Day numbers relative to Start Date						
Group	Sex	Animal	Clinical Sign	Site	-25	1	2	8 BEF	9	9 Daily 1	10 Daily 1
3	f	254	Swelling.	Injection site 1	.	.	X
			Swelling.	Injection site 2	X	.	.
		255	Swelling.	Injection site 1	.	.	X
			Swelling.	Injection site 2	X	.	.
		256	Limping	Right hindlimb	X	X
			Swelling.	Injection site 1	.	.	X
		257	Swelling.	Injection site 2	X	.	.
			Swelling.	Injection site 1	.	.	X
		258	Swelling.	Injection site 2	X	.	.
			Limping	Right hindlimb	X	X
		259	Swelling.	Injection site 1	.	.	X
			Swelling.	Injection site 2	X	.	.
		260	Swelling.	Injection site 1	.	.	X
			Swelling.	Injection site 2	X	.	.
		261	Swelling.	Injection site 1	.	.	X
			Swelling.	Injection site 2	X	.	.
		262	Limping	Right hindlimb	X	X
			Swelling.	Injection site 1	.	.	X
		263	Swelling.	Injection site 2	X	.	.
			Limping	Right hindlimb	X	X
			Swelling.	Injection site 1	.	.	X
			Swelling.	Injection site 2	X	.	.

Severity Codes: X = Present; 1 = Slight

Group 3 - BNT162b2 30mcg

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Individual Pre-Mating Clinical Observations of Females

20256434

Day numbers relative to Start Date					
Group	Sex	Animal	Clinical Sign	Site	15 17 Daily 1
3	f	254	Swelling.	Injection site 1	.
			Swelling.	Injection site 2	.
		255	Swelling.	Injection site 1	.
			Swelling.	Injection site 2	.
		256	Limping	Right hindlimb	.
			Swelling.	Injection site 1	.
		257	Swelling.	Injection site 2	.
			Swelling.	Injection site 1	.
		258	Swelling.	Injection site 2	.
			Limping	Right hindlimb	.
		259	Swelling.	Injection site 1	.
			Swelling.	Injection site 2	.
		260	Swelling.	Injection site 1	.
			Swelling.	Injection site 2	.
		261	Swelling.	Injection site 1	.
			Swelling.	Injection site 2	.
		262	Limping	Right hindlimb	.
			Swelling.	Injection site 1	.
		263	Swelling.	Injection site 2	.
			Limping	Right hindlimb	.
			Swelling.	Injection site 1	.
			Swelling.	Injection site 2	.

Severity Codes: X = Present; 1 = Slight

Group 3 - BNT162b2 30mcg

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Individual Pre-Mating Clinical Observations of Females

20256434

					Day numbers relative to Start Date						
Group	Sex	Animal	Clinical Sign	Site	-25	1	2	8 BEF	9	9 Daily 1	10 Daily 1
3	f	264	Erythema.	Right hindlimb	.	.	X
			Erythema.	Injection site(s)	.	X
			Limping	Right hindlimb	X	X
			Piloerection		1	1
		265	Swelling.	Injection site 1	.	.	X
			Swelling.	Injection site 2	X	.	.
			Erythema.	Left hindlimb	.	.	X
			Erythema.	Right hindlimb	.	.	X
		266	Erythema.	Injection site(s)	.	X
			Limping	Right hindlimb	X	X
			Swelling.	Injection site 1	.	.	X
			Swelling.	Injection site 2	X	.	.
		45	Limping	Right hindlimb	X	X
			Swelling.	Injection site 1	.	.	X
			Swelling.	Injection site 2	X	.	.
		46	Swelling.	Injection site 1	.	.	X
			Swelling.	Injection site 2	X	.	.
		47	Swelling.	Injection site 1	.	.	X
			Swelling.	Injection site 2	X	.	.
		48	Swelling.	Injection site 1	.	.	X
			Swelling.	Injection site 2	X	.	.
		49	Swelling.	Injection site 1	.	.	X
			Swelling.	Injection site 2	X	.	.
		50	Swelling.	Injection site 1	.	.	X
			Swelling.	Injection site 2	X	.	.

Severity Codes: X = Present; 1 = Slight

Group 3 - BNT162b2 30mcg

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Individual Pre-Mating Clinical Observations of Females

20256434

Day numbers relative to Start Date					
Group	Sex	Animal	Clinical Sign	Site	15 17 Daily 1
3	f	264	Erythema.	Right hindlimb	.
			Erythema.	Injection site(s)	.
			Limping	Right hindlimb	.
			Piloerection		.
		265	Swelling.	Injection site 1	.
			Swelling.	Injection site 2	.
			Erythema.	Left hindlimb	.
			Erythema.	Right hindlimb	.
		266	Erythema.	Injection site(s)	.
			Limping	Right hindlimb	.
			Swelling.	Injection site 1	.
			Swelling.	Injection site 2	.
		45	Limping	Right hindlimb	.
			Swelling.	Injection site 1	.
			Swelling.	Injection site 2	.
		46	Swelling.	Injection site 1	.
			Swelling.	Injection site 2	.
		47	Swelling.	Injection site 1	.
			Swelling.	Injection site 2	.
		48	Swelling.	Injection site 1	.
			Swelling.	Injection site 2	.
		49	Swelling.	Injection site 1	.
			Swelling.	Injection site 2	.
		50	Swelling.	Injection site 1	.
			Swelling.	Injection site 2	.

Severity Codes: X = Present; 1 = Slight

Group 3 - BNT162b2 30mcg

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Individual Pre-Mating Clinical Observations of Females
20256434

					Day numbers relative to Start Date						
Group	Sex	Animal	Clinical Sign	Site	-25	1	2	8 BEF	9	9 Daily 1	10 Daily 1
3	f	51	Swelling.	Injection site 1	.	.	X
			Swelling.	Injection site 2	X	.	.
		52	Swelling.	Injection site 1	.	.	X
			Swelling.	Injection site 2	X	.	.
		53	Swelling.	Injection site 1	.	.	X
			Swelling.	Injection site 2	X	.	.
		54	Swelling.	Injection site 1	.	.	X
			Swelling.	Injection site 2	X	.	.
		55	Swelling.	Injection site 1	.	.	X
			Swelling.	Injection site 2	X	.	.
		56	Localised hairloss	Head	X
			Swelling.	Injection site 1	.	.	X
		57	Swelling.	Injection site 2	X	.	.
			Swelling.	Injection site 1	.	.	X
		58	Swelling.	Injection site 2	X	.	.
			Swelling.	Injection site 1	.	.	X
		59	Swelling.	Injection site 2	X	.	.
			Swelling.	Injection site 1	.	.	X
		60	Swelling.	Injection site 2	X	.	.
			Swelling.	Injection site 1	.	.	X
		61	Swelling.	Injection site 2	X	.	.
			Swelling.	Injection site 1	.	.	X
		62	Swelling.	Injection site 2	X	.	.
			Swelling.	Injection site 1	.	.	X
		63	Swelling.	Injection site 2	X	.	.
			Swelling.	Injection site 1	.	.	X	X	.	.	.
			Swelling.	Injection site 2	X	.	.
			Swelling.	Injection site 1

Severity Codes: X = Present; 1 = Slight

Group 3 - BNT162b2 30mcg

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Individual Pre-Mating Clinical Observations of Females

20256434

Day numbers relative to Start Date					15	17
Group	Sex	Animal	Clinical Sign	Site		Daily 1
3	f	51	Swelling.	Injection site 1	.	.
			Swelling.	Injection site 2	.	.
		52	Swelling.	Injection site 1	.	.
			Swelling.	Injection site 2	.	.
		53	Swelling.	Injection site 1	.	.
			Swelling.	Injection site 2	.	.
		54	Swelling.	Injection site 1	.	.
			Swelling.	Injection site 2	.	.
		55	Swelling.	Injection site 1	.	.
			Swelling.	Injection site 2	.	.
		56	Localised hairloss	Head	.	.
			Swelling.	Injection site 1	.	.
		57	Swelling.	Injection site 2	.	.
			Swelling.	Injection site 1	.	.
		58	Swelling.	Injection site 2	.	.
			Swelling.	Injection site 1	.	.
		59	Swelling.	Injection site 2	.	.
			Swelling.	Injection site 1	.	.
		60	Swelling.	Injection site 2	.	.
			Swelling.	Injection site 1	.	.
		61	Swelling.	Injection site 2	.	.
			Swelling.	Injection site 1	.	.
		62	Swelling.	Injection site 2	.	.
			Swelling.	Injection site 1	.	.
		63	Swelling.	Injection site 2	.	.
			Swelling.	Injection site 1	.	.

Severity Codes: X = Present; 1 = Slight

Group 3 - BNT162b2 30mcg

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Individual Pre-Mating Clinical Observations of Females

20256434

					Day numbers relative to Start Date						
Group	Sex	Animal	Clinical Sign	Site	-25	1	2	8 BEF	9	9 Daily 1	10 Daily 1
3	f	64	Swelling.	Injection site 1	.	.	X	X	.	.	.
			Swelling.	Injection site 2	X	.	.
		65	Chromodacryorrhea	Left eye
			Swelling.	Injection site 1	.	.	X
		66	Swelling.	Injection site 2	X	.	.
			Swelling.	Injection site 1	.	.	X
			Swelling.	Injection site 2	X	.	.
			Swelling.	Injection site 2	X	.	.

Severity Codes: X = Present; 1 = Slight

Group 3 - BNT162b2 30mcg

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Individual Pre-Mating Clinical Observations of Females

20256434

Day numbers relative to Start Date						
Group	Sex	Animal	Clinical Sign	Site	15	17 Daily 1
3	f	64	Swelling.	Injection site 1	.	.
			Swelling.	Injection site 2	X	.
		65	Chromodacryorrhea	Left eye	.	X
			Swelling.	Injection site 1	.	.
		66	Swelling.	Injection site 2	X	.
			Swelling.	Injection site 1	.	.
			Swelling.	Injection site 2	.	.
			Swelling.	Injection site 2	.	.

Severity Codes: X = Present; 1 = Slight

Group 3 - BNT162b2 30mcg

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Individual Pre-Mating Clinical Observations of Females

20256434

Day numbers relative to Start Date

Group	Sex	Animal	Clinical Sign	Site	-7	-2	-1	1	1	1
						Daily 1	Daily 1		BEF	+3h

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Individual Pre-Mating Clinical Observations of Females

20256434

				Day numbers relative to Start Date						
Group	Sex	Animal	Clinical Sign	Site	2	8	9	9	10	15
						BEF		Daily 1	Daily 1	



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Individual Pre-Mating Clinical Observations of Females

20256434

Day numbers relative to Start Date

Group	Sex	Animal	Clinical Sign	Site	-7	-2	-1	1	1	1
						Daily 1	Daily 1		BEF	+3h

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Individual Pre-Mating Clinical Observations of Females

20256434

Day numbers relative to Start Date										
Group	Sex	Animal	Clinical Sign	Site	2	8	9	9	10	15
						BEF		Daily 1	Daily 1	
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Individual Pre-Mating Clinical Observations of Females

20256434

Day numbers relative to Start Date

Group	Sex	Animal	Clinical Sign	Site	-7	-2	-1	1	1	1
						Daily 1	Daily 1		BEF	+3h

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Individual Pre-Mating Clinical Observations of Females

20256434

Day numbers relative to Start Date

Group Sex	Animal	Clinical Sign	Site	2	8	9	9	10	15
					BEF		Daily 1	Daily 1	

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Individual Pre-Mating Clinical Observations of Females

20256434

Day numbers relative to Start Date

Group	Sex	Animal	Clinical Sign	Site	-7	-2	-1	1	1	1
						Daily 1	Daily 1		BEF	+3h

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Individual Pre-Mating Clinical Observations of Females

20256434

Day numbers relative to Start Date

Group	Sex	Animal	Clinical Sign	Site	2	8	9	9	10	15
						BEF		Daily 1	Daily 1	

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Individual Pre-Mating Clinical Observations of Females

20256434

Day numbers relative to Start Date

Group Sex	Animal	Clinical Sign	Site	-7	-2	-1	1	1	1
					Daily 1	Daily 1		BEF	+3h

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Individual Pre-Mating Clinical Observations of Females

20256434

Day numbers relative to Start Date

Group	Sex	Animal	Clinical Sign	Site	2	8	9	9	10	15
						BEF		Daily 1	Daily 1	

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Individual Gestation Clinical Observations

20256434

Day numbers relative to Mating Date										
Group	Sex	Animal	Clinical Sign	Site	0	0 Daily 1	6 BEF	9	9 BEF	12
1	F	202	Malocclusion		X	X
			Teeth long	Lower tooth/teeth	.	X
		215	Scab(s).	Right forelimb	X
		220	Localised hairloss	Thorax
			Localised hairloss	Left and right forelimbs
		221	Sore(s).	Left forelimb
		222	Localised hairloss	Left forelimb
			Localised hairloss	Right forelimb
		2	Localised hairloss	Left and right forelimbs
		7	Localised hairloss	Left forelimb	.	.	X	X	.	.
		13	Localised hairloss	Left and right forelimbs
		20	Localised hairloss	Left and right forelimbs

Severity Codes: X = Present

Group 1 - Control 0mcg

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Individual Gestation Clinical Observations

20256434

Day numbers relative to Mating Date										
Group	Sex	Animal	Clinical Sign	Site	12 Daily 1	15	15 Daily 1	18	18 BEF	18 Daily 1
1	f	202	Malocclusion		.	X	.	.	.	X
			Teeth long	Lower tooth/teeth
		215	Scab(s).	Right forelimb
		220	Localised hairloss	Thorax	.	.	X	X	.	.
			Localised hairloss	Left and right forelimbs	.	.	X	X	.	.
		221	Sore(s).	Left forelimb	.	X
		222	Localised hairloss	Left forelimb	X
			Localised hairloss	Right forelimb	.	X	.	.	.	X
		2	Localised hairloss	Left and right forelimbs	.	.	X	.	X	.
		7	Localised hairloss	Left forelimb	X	X	.	X	.	.
		13	Localised hairloss	Left and right forelimbs	.	.	.	X	.	.
		20	Localised hairloss	Left and right forelimbs	.	.	X	.	X	.

Severity Codes: X = Present

Group 1 - Control Omcg

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Individual Gestation Clinical Observations

20256434

Day numbers relative to Mating Date

Group	Sex	Animal	Clinical Sign	Site	21	21 BEF
1	f	202	Malocclusion		X	.
			Teeth long	Lower tooth/teeth	.	.
		215	Scab(s).	Right forelimb	.	.
		220	Localised hairloss	Thorax	X	.
			Localised hairloss	Left and right forelimbs	X	.
		221	Sore(s).	Left forelimb	.	.
		222	Localised hairloss	Left forelimb	X	.
			Localised hairloss	Right forelimb	X	.
		2	Localised hairloss	Left and right forelimbs	X	.
		7	Localised hairloss	Left forelimb	.	X
		13	Localised hairloss	Left and right forelimbs	X	.
		20	Localised hairloss	Left and right forelimbs	X	.

Severity Codes: X = Present

Group 1 - Control 0mcg

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Individual Gestation Clinical Observations

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Day numbers relative to Mating Date

Group	Sex	Animal	Clinical Sign	Site	0	0	6	6	9	9
						Daily 1		Daily 1		BEF



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Individual Gestation Clinical Observations

20256434

Day numbers relative to Mating Date

Group Sex	Animal	Clinical Sign	Site	9 Daily 1	12	12 Daily 1	15	15 Daily 1	18
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Individual Gestation Clinical Observations

20256434

Day numbers relative to Mating Date

Group	Sex	Animal	Clinical Sign	Site	18 BEF	21
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Individual Gestation Clinical Observations

20256434

Day numbers relative to Mating Date										
Group	Sex	Animal	Clinical Sign	Site	0	6	9	9 BEF	12	12 BEF
3	f	251	Red stained fur	Dorsal neck region	.	X	.	X	X	.
		253	Swelling.	Left hindlimb	X
			Swelling.	Injection site 2
		255	Swelling.	Injection site 2
		256	Localised hairloss	Back
			Localised hairloss	Left and right forelimbs	.	X	.	X	X	.
			Swelling.	Injection site 2
		259	Swelling.	Left hindlimb	X	.
		260	Localised hairloss	Thorax
			Localised hairloss	Left and right forelimbs
		261	Swelling.	Left hindlimb	X
			Swelling.	Injection site 2
		263	Pup(s) - Cold to touch	1 Pup
		264	Swelling.	Injection site 2
		265	Swelling.	Injection site 1
		47	Swelling.	Injection site 2
		49	Swelling.	Injection site 2
		53	Localised hairloss	Dorsal neck region	X	X	X	.	.	.
			Scab(s).	Clipped area
		54	Localised hairloss	Left and right forelimbs
		55	Localised hairloss	Left and right hindlimbs	.	X	X	.	X	.
		57	Localised hairloss	Left and right hindlimbs	.	X
		58	Localised hairloss	Left and right hindlimbs	.	X
		61	Localised hairloss	Left and right forelimbs
		62	Localised hairloss	Left and right forelimbs
		63	Swelling.	Injection site 2
		64	Localised hairloss	Left and right hindlimbs	.	X

Severity Codes: X = Present

Group 3 - BNT162b2 30mcg

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Individual Gestation Clinical Observations

20256434

					Day numbers relative to Mating Date					
Group	Sex	Animal	Clinical Sign	Site	12 Daily 1	15	15 Daily 1	18 BEF	18 Daily 1	21
3	f	251	Red stained fur	Dorsal neck region
		253	Swelling.	Left hindlimb
			Swelling.	Injection site 2
		255	Swelling.	Injection site 2
		256	Localised hairloss	Back	X
			Localised hairloss	Left and right forelimbs	.	X	.	.	X	X
			Swelling.	Injection site 2	X
		259	Swelling.	Left hindlimb
		260	Localised hairloss	Thorax	.	X	.	.	X	X
			Localised hairloss	Left and right forelimbs	.	X	.	.	X	X
		261	Swelling.	Left hindlimb
			Swelling.	Injection site 2
		263	Pup(s) - Cold to touch	1 Pup	X
		264	Swelling.	Injection site 2
		265	Swelling.	Injection site 1	X
		47	Swelling.	Injection site 2	X
		49	Swelling.	Injection site 2	X
		53	Localised hairloss	Dorsal neck region	X	X	.	X	.	X
			Scab(s).	Clipped area	X
		54	Localised hairloss	Left and right forelimbs	.	.	.	X	.	X
		55	Localised hairloss	Left and right hindlimbs	.	.	X	.	.	.
		57	Localised hairloss	Left and right hindlimbs
		58	Localised hairloss	Left and right hindlimbs
		61	Localised hairloss	Left and right forelimbs	X
		62	Localised hairloss	Left and right forelimbs	X
		63	Swelling.	Injection site 2	X
		64	Localised hairloss	Left and right hindlimbs

Severity Codes: X = Present

Group 3 - BNT162b2 30mcg

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Individual Gestation Clinical Observations

20256434

Day numbers relative to Mating Date

Group	Sex	Animal	Clinical Sign	Site	21 BEF
3	f	251	Red stained fur	Dorsal neck region	.
		253	Swelling.	Left hindlimb	.
			Swelling.	Injection site 2	X
		255	Swelling.	Injection site 2	X
		256	Localised hairloss	Back	.
			Localised hairloss	Left and right forelimbs	.
			Swelling.	Injection site 2	.
		259	Swelling.	Left hindlimb	.
		260	Localised hairloss	Thorax	.
			Localised hairloss	Left and right forelimbs	.
		261	Swelling.	Left hindlimb	.
			Swelling.	Injection site 2	X
		263	Pup(s) - Cold to touch	1 Pup	.
		264	Swelling.	Injection site 2	X
		265	Swelling.	Injection site 1	.
		47	Swelling.	Injection site 2	.
		49	Swelling.	Injection site 2	.
		53	Localised hairloss	Dorsal neck region	.
			Scab(s).	Clipped area	.
		54	Localised hairloss	Left and right forelimbs	.
		55	Localised hairloss	Left and right hindlimbs	.
		57	Localised hairloss	Left and right hindlimbs	.
		58	Localised hairloss	Left and right hindlimbs	.
		61	Localised hairloss	Left and right forelimbs	.
		62	Localised hairloss	Left and right forelimbs	.
		63	Swelling.	Injection site 2	.
		64	Localised hairloss	Left and right hindlimbs	.

Severity Codes: X = Present

Group 3 - BNT162b2 30mcg

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Individual Gestation Clinical Observations

20256434

					Day numbers relative to Mating Date					
Group	Sex	Animal	Clinical Sign	Site	0	6	9	9 BEF	12	12 BEF
3	f	65	Localised hairloss	Thorax	.	X	X	.	.	.
			Localised hairloss	Abdomen	.	X	X	.	.	.
			Localised hairloss	Left and right forelimbs	.	X	X	.	.	.
			Scab(s) .	Right hindlimb	.	.	X	.	.	.

Severity Codes: X = Present

Group 3 - BNT162b2 30mcg

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Individual Gestation Clinical Observations

20256434

Day numbers relative to Mating Date										
Group	Sex	Animal	Clinical Sign	Site	12 Daily 1	15	15 Daily 1	18 BEF	18 Daily 1	21
3	f	65	Localised hairloss	Thorax	X	X	.	X	.	X
			Localised hairloss	Abdomen	X	X	.	X	.	X
			Localised hairloss	Left and right forelimbs	X	X	.	X	.	X
			Scab(s) .	Right hindlimb

Severity Codes: X = Present

Group 3 - BNT162b2 30mcg

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Individual Gestation Clinical Observations

20256434

Day numbers relative to Mating Date

Group	Sex	Animal	Clinical Sign	Site	21 BEF
3	f	65	Localised hairloss	Thorax	.
			Localised hairloss	Abdomen	.
			Localised hairloss	Left and right forelimbs	.
			Scab(s) .	Right hindlimb	.

Severity Codes: X = Present

Group 3 - BNT162b2 30mcg

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Individual Gestation Clinical Observations

20256434

Day numbers relative to Mating Date

Group	Sex	Animal	Clinical Sign	Site	0	0	6	9	9	12
						Daily 1		BEF	Daily 1	

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Individual Gestation Clinical Observations

20256434

Day numbers relative to Mating Date									
Group Sex	Animal	Clinical Sign	Site	12 BEF	12 Daily 1	15	15 Daily 1	18 BEF	18 Daily 1
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Individual Gestation Clinical Observations

20256434

Day numbers relative to Mating Date

Group	Sex	Animal	Clinical Sign	Site	21	21	21
						BEF	Daily 1

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Individual Gestation Clinical Observations

20256434

Day numbers relative to Mating Date									
Group	Sex	Animal	Clinical Sign	Site	0	0	6	9	9
						Daily 1		BEF	Daily 1
									12
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Individual Gestation Clinical Observations

20256434

Day numbers relative to Mating Date

Group	Sex	Animal	Clinical Sign	Site	12 BEF	12 Daily 1	15	15 Daily 1	18 BEF	18 Daily 1
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Individual Gestation Clinical Observations

20256434

Day numbers relative to Mating Date

Group	Sex	Animal	Clinical Sign	Site	21	21	21
						BEF	Daily 1

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Individual Lactation Clinical Observations

20256434

Day numbers relative to Litter Date

Group	Sex	Animal	Clinical Sign	Site	1	4	4 Daily 1	7 Daily 1	8 Daily 1
I	f	202	Malocclusion		X	.	X	X	.
			Teeth cut	Lower tooth/teeth	X
		204	Localised hairloss	Left forelimb	.	X	.	X	.
		206	Pup(s) - Haematoma(s)	1 Male	.	.	.	T	T
		208	Pup(s) - Haematoma(s)	1 Male	H
		210	Scab(s).	Abdomen	.	X	.	.	.
		214	Localised hairloss	Left and right forelimbs
		215	Localised hairloss	Left and right forelimbs
			Nodule(s).	Nose
			Swelling.	Muzzle
		220	Localised hairloss	Thorax	X	X	.	X	.
			Localised hairloss	Left and right forelimbs	X	X	.	X	.
			Pup(s) -Incomplete hair growth	2 Males
			Pup(s) -Incomplete hair growth	2 Females
			Pup(s) -Incomplete hair growth	All Pups
		221	Scab(s).	Abdomen
			Scab(s).	Left hindlimb
			Scab(s).	Clipped area	.	.	.	X	.
			Sore(s)	Abdomen
		222	Localised hairloss	Left forelimb	X	X	.	X	.
			Localised hairloss	Right forelimb	X	X	.	X	.
			Localised hairloss	Whole body
			Pup(s) -Incomplete hair growth	All Pups

Severity Codes: X = Present; 1 = Slight; H = Head; T = Thorax/Abdomen

Group 1 - Control Omcg

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Individual Lactation Clinical Observations

20256434

Day numbers relative to Litter Date									
Group	Sex	Animal	Clinical Sign	Site	9 Daily 1	10 BEF	10 Daily 1	11 BEF	
1	f	202	Malocclusion		.	.	X	.	
			Teeth cut	Lower tooth/teeth	
		204	Localised hairloss	Left forelimb	.	X	.	.	
		206	Pup(s) - Haematoma(s)	1 Male	T	T	.	.	T
		208	Pup(s) - Haematoma(s)	1 Male
		210	Scab(s).	Abdomen
		214	Localised hairloss	Left and right forelimbs
		215	Localised hairloss	Left and right forelimbs	X	.	.	X	.
			Nodule(s).	Nose
			Swelling.	Muzzle	X	.	.	X	.
		220	Localised hairloss	Thorax	.	X	.	.	.
			Localised hairloss	Left and right forelimbs	.	X	.	.	.
			Pup(s) -Incomplete hair growth	2 Males	X	X	.	.	X
			Pup(s) -Incomplete hair growth	2 Females	X	X	.	.	X
			Pup(s) -Incomplete hair growth	All Pups
		221	Scab(s).	Abdomen
			Scab(s).	Left hindlimb
			Scab(s).	Clipped area	.	.	X	.	.
			Sore(s)	Abdomen
		222	Localised hairloss	Left forelimb
			Localised hairloss	Right forelimb
			Localised hairloss	Whole body	.	.	X	.	.
			Pup(s) -Incomplete hair growth	All Pups

Severity Codes: X = Present; 1 = Slight; H = Head; T = Thorax/Abdomen

Group 1 - Control Omcg

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Individual Lactation Clinical Observations

20256434

Day numbers relative to Litter Date

Group	Sex	Animal	Clinical Sign	Site	12 BEF	13	13 BEF	13 Veto 1	14
1	f	202	Malocclusion	
			Teeth cut	Lower tooth/teeth
		204	Localised hairloss	Left forelimb	X
		206	Pup(s) - Haematoma(s)	1 Male
		208	Pup(s) - Haematoma(s)	1 Male
		210	Scab(s).	Abdomen
		214	Localised hairloss	Left and right forelimbs
		215	Localised hairloss	Left and right forelimbs
			Nodule(s).	Nose
			Swelling.	Muzzle
		220	Localised hairloss	Thorax	X
			Localised hairloss	Left and right forelimbs	X
			Pup(s) -Incomplete hair growth	2 Males
			Pup(s) -Incomplete hair growth	2 Females
			Pup(s) -Incomplete hair growth	All Pups	X	.	X	.	X
		221	Scab(s).	Abdomen
			Scab(s).	Left hindlimb
			Scab(s).	Clipped area	X
			Sore(s)	Abdomen	.	.	.	1	.
		222	Localised hairloss	Left forelimb
			Localised hairloss	Right forelimb
			Localised hairloss	Whole body
			Pup(s) -Incomplete hair growth	All Pups	.	X	.	.	.

Severity Codes: X = Present; 1 = Slight; H = Head; T = Thorax/Abdomen

Group 1 - Control Omcg

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Individual Lactation Clinical Observations

20256434

Day numbers relative to Litter Date					
Group	Sex	Animal	Clinical Sign	Site	14 BEF
					14 Daily 1
					15
					15 Daily 1
					16
1	f	202	Malocclusion		.
			Teeth cut	Lower tooth/teeth	.
		204	Localised hairloss	Left forelimb	.
		206	Pup(s) - Haematoma(s)	1 Male	.
		208	Pup(s) - Haematoma(s)	1 Male	.
		210	Scab(s).	Abdomen	.
		214	Localised hairloss	Left and right forelimbs	.
		215	Localised hairloss	Left and right forelimbs	X
			Nodule(s).	Nose	.
			Swelling.	Muzzle	.
		220	Localised hairloss	Thorax	.
			Localised hairloss	Left and right forelimbs	.
			Pup(s) -Incomplete hair growth	2 Males	.
			Pup(s) -Incomplete hair growth	2 Females	.
			Pup(s) -Incomplete hair growth	All Pups	.
		221	Scab(s).	Abdomen	.
			Scab(s).	Left hindlimb	.
			Scab(s).	Clipped area	.
			Sore(s)	Abdomen	.
		222	Localised hairloss	Left forelimb	.
			Localised hairloss	Right forelimb	.
			Localised hairloss	Whole body	.
			Pup(s) -Incomplete hair growth	All Pups	.

Severity Codes: X = Present; 1 = Slight; H = Head; T = Thorax/Abdomen

Group 1 - Control Omcg

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Individual Lactation Clinical Observations

20256434

Day numbers relative to Litter Date									
Group	Sex	Animal	Clinical Sign	Site	16 Veto 1	17	17 Daily 1	18 Daily 1	19
1	f	202	Malocclusion		.	.	X	.	.
			Teeth cut	Lower tooth/teeth
		204	Localised hairloss	Left forelimb	.	X	.	.	.
		206	Pup(s) - Haematoma(s)	1 Male
		208	Pup(s) - Haematoma(s)	1 Male
		210	Scab(s).	Abdomen
		214	Localised hairloss	Left and right forelimbs
		215	Localised hairloss	Left and right forelimbs	.	X	.	.	.
			Nodule(s).	Nose
			Swelling.	Muzzle
		220	Localised hairloss	Thorax	.	X	.	.	.
			Localised hairloss	Left and right forelimbs	.	X	.	.	.
			Pup(s) -Incomplete hair growth	2 Males
			Pup(s) -Incomplete hair growth	2 Females
			Pup(s) -Incomplete hair growth	All Pups	.	X	.	.	.
		221	Scab(s).	Abdomen	.	.	X	.	.
			Scab(s).	Left hindlimb	.	.	X	.	.
			Scab(s).	Clipped area	.	.	X	.	.
			Sore(s)	Abdomen	1
		222	Localised hairloss	Left forelimb
			Localised hairloss	Right forelimb
			Localised hairloss	Whole body	.	.	X	.	.
			Pup(s) -Incomplete hair growth	All Pups	.	.	X	X	X

Severity Codes: X = Present; 1 = Slight; H = Head; T = Thorax/Abdomen

Group 1 - Control Omcg

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Individual Lactation Clinical Observations

20256434

Day numbers relative to Litter Date					20	20	21	21
Group	Sex	Animal	Clinical Sign	Site		Veto 1		Daily 1
1	f	202	Malocclusion		.	.	X	.
			Teeth cut	Lower tooth/teeth
		204	Localised hairloss	Left forelimb	.	.	X	.
		206	Pup(s) - Haematoma(s)	1 Male
		208	Pup(s) - Haematoma(s)	1 Male
		210	Scab(s).	Abdomen
		214	Localised hairloss	Left and right forelimbs	.	.	X	.
		215	Localised hairloss	Left and right forelimbs	.	.	X	.
			Nodule(s).	Nose	.	.	X	.
			Swelling.	Muzzle
		220	Localised hairloss	Thorax	.	.	X	.
			Localised hairloss	Left and right forelimbs	.	.	X	.
			Pup(s) -Incomplete hair growth	2 Males
			Pup(s) -Incomplete hair growth	2 Females
			Pup(s) -Incomplete hair growth	All Pups
		221	Scab(s).	Abdomen	.	.	.	X
			Scab(s).	Left hindlimb	.	.	.	X
			Scab(s).	Clipped area	.	.	.	X
			Sore(s)	Abdomen	.	1	.	.
		222	Localised hairloss	Left forelimb
			Localised hairloss	Right forelimb
			Localised hairloss	Whole body	.	.	X	.
			Pup(s) -Incomplete hair growth	All Pups	X	.	.	.

Severity Codes: X = Present; 1 = Slight; H = Head; T = Thorax/Abdomen

Group 1 - Control Omeg

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Individual Lactation Clinical Observations

20256434

Day numbers relative to Litter Date

Group	Sex	Animal	Clinical Sign	Site	0	1	2	3	3
								Daily 1	

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Individual Lactation Clinical Observations

20256434

Day numbers relative to Litter Date

Group	Sex	Animal	Clinical Sign	Site	4	4	5	7	10
						Daily 1	Daily 1	Daily 1	
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Individual Lactation Clinical Observations

20256434

Day numbers relative to Litter Date

Group	Sex	Animal	Clinical Sign	Site	10 BEF	11 BEF	12	12 BEF	13 BEF
[REDACTED]									

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Individual Lactation Clinical Observations

20256434

Day numbers relative to Litter Date

Group	Sex	Animal	Clinical Sign	Site	13 Daily 1	14	15	15 Daily 1	16
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Individual Lactation Clinical Observations

20256434

Day numbers relative to Litter Date

Group	Sex	Animal	Clinical Sign	Site	16 Daily 1	17 Daily 1	17 Daily 1	18 Daily 1	18 Daily 1
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Individual Lactation Clinical Observations

20256434

Day numbers relative to Litter Date

Group Sex Animal	Clinical Sign	Site	19	21	21 Daily 1
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Individual Lactation Clinical Observations

20256434

Day numbers relative to Litter Date					0	1	2	3	3
Group	Sex	Animal	Clinical Sign	Site					Daily 1
3	f	245	Localised hairloss	Left and right forelimbs
			Pup(s) -Incomplete hair growth	All Pups
		247	Pup(s) - Pale	1 Pup	X
		248	Pup(s) - Haematoma(s)	1 Pup	H
		251	Pup(s) - Weak	1 Female	.	X	X	.	X
			Pup(s) - Weak	1 Pup	X
		253	Scab(s).	Head
			Scab(s).	Back
		256	Localised hairloss	Back	.	X	.	.	.
			Localised hairloss	Left and right forelimbs	.	X	.	.	.
			Swelling.	Injection site 2	.	X	.	.	.
			Pup(s) - Cold to touch	1 Pup	X
		257	Pup(s) - Haematoma(s)	1 Pup	H	H	.	.	.
		260	Localised hairloss	Thorax	.	X	.	.	.
			Localised hairloss	Left and right forelimbs	.	X	.	.	.
			Pup(s) -Incomplete hair growth	All Pups
		261	Swelling.	Injection site 2	.	X	.	.	.
		262	Scab(s).	Clipped area
		263	Pup(s) - Cold to touch	1 Pup	X
		264	Swelling.	Injection site 2	.	X	.	.	.
		265	Pup(s) - Weak	1 Male	.	.	.	X	.
			Pup(s) - Thin	1 Male	.	.	.	X	.
			Pup(s) - Pale	1 Male	.	.	.	X	.
			Pup(s) - Cold to touch	1 Male	.	.	.	X	.
			Pup(s) - Cyanotic	1 Male	.	.	.	X	.

Severity Codes: X = Present; H = Head

Group 3 - BNT162b2 30mcg

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Individual Lactation Clinical Observations

20256434

Day numbers relative to Litter Date									
Group	Sex	Animal	Clinical Sign	Site	4	4 Daily 1	7 Daily 1	10 BEF	11
3	f	245	Localised hairloss	Left and right forelimbs	.	.	.	X	.
			Pup(s) -Incomplete hair growth	All Pups
		247	Pup(s) - Pale	1 Pup
		248	Pup(s) - Haematoma(s)	1 Pup
		251	Pup(s) - Weak	1 Female	.	X	.	.	.
			Pup(s) - Weak	1 Pup
		253	Scab(s).	Head
			Scab(s).	Back
		256	Localised hairloss	Back	.	X	X	X	.
			Localised hairloss	Left and right forelimbs	.	X	X	X	.
			Swelling.	Injection site 2
			Pup(s) - Cold to touch	1 Pup
		257	Pup(s) - Haematoma(s)	1 Pup
		260	Localised hairloss	Thorax	X	.	X	X	.
			Localised hairloss	Left and right forelimbs	X	.	X	X	.
			Pup(s) -Incomplete hair growth	All Pups	.	.	.	X	X
		261	Swelling.	Injection site 2
		262	Scab(s).	Clipped area	.	X	X	.	.
		263	Pup(s) - Cold to touch	1 Pup
		264	Swelling.	Injection site 2
		265	Pup(s) - Weak	1 Male
			Pup(s) - Thin	1 Male
			Pup(s) - Pale	1 Male
			Pup(s) - Cold to touch	1 Male
			Pup(s) - Cyanotic	1 Male

Severity Codes: X = Present; H = Head

Group 3 - BNT162b2 30mcg

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Individual Lactation Clinical Observations

20256434

Day numbers relative to Litter Date									
Group	Sex	Animal	Clinical Sign	Site	12	13	13 Daily 1	14	14 Daily 1
3	f	245	Localised hairloss	Left and right forelimbs	X
			Pup(s) -Incomplete hair growth	All Pups	X	X	.	.	X
		247	Pup(s) - Pale	1 Pup
		248	Pup(s) - Haematoma(s)	1 Pup
		251	Pup(s) - Weak	1 Female
			Pup(s) - Weak	1 Pup
		253	Scab(s).	Head	.	.	.	X	.
			Scab(s).	Back	.	.	.	X	.
		256	Localised hairloss	Back	X
			Localised hairloss	Left and right forelimbs	X
			Swelling.	Injection site 2
			Pup(s) - Cold to touch	1 Pup
		257	Pup(s) - Haematoma(s)	1 Pup
		260	Localised hairloss	Thorax	.	.	.	X	.
			Localised hairloss	Left and right forelimbs	.	.	.	X	.
			Pup(s) -Incomplete hair growth	All Pups	X	.	X	X	.
		261	Swelling.	Injection site 2
		262	Scab(s).	Clipped area
		263	Pup(s) - Cold to touch	1 Pup
		264	Swelling.	Injection site 2
		265	Pup(s) - Weak	1 Male
			Pup(s) - Thin	1 Male
			Pup(s) - Pale	1 Male
			Pup(s) - Cold to touch	1 Male
			Pup(s) - Cyanotic	1 Male

Severity Codes: X = Present; H = Head

Group 3 - BNT162b2 30mcg

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Individual Lactation Clinical Observations

20256434

Day numbers relative to Litter Date									
Group	Sex	Animal	Clinical Sign	Site	15	15 Daily 1	16 Daily 1	17	17 Daily 1
3	f	245	Localised hairloss	Left and right forelimbs	X
			Pup(s) -Incomplete hair growth	All Pups	X	.	X	.	X
		247	Pup(s) - Pale	1 Pup
		248	Pup(s) - Haematoma(s)	1 Pup
		251	Pup(s) - Weak	1 Female
			Pup(s) - Weak	1 Pup
		253	Scab(s) .	Head	.	.	.	X	.
			Scab(s) .	Back	.	.	.	X	.
		256	Localised hairloss	Back	X
			Localised hairloss	Left and right forelimbs	X
			Swelling.	Injection site 2
			Pup(s) - Cold to touch	1 Pup
		257	Pup(s) - Haematoma(s)	1 Pup
		260	Localised hairloss	Thorax	X
			Localised hairloss	Left and right forelimbs	X
			Pup(s) -Incomplete hair growth	All Pups	.	X	X	.	X
		261	Swelling.	Injection site 2
		262	Scab(s) .	Clipped area
		263	Pup(s) - Cold to touch	1 Pup
		264	Swelling.	Injection site 2
		265	Pup(s) - Weak	1 Male
			Pup(s) - Thin	1 Male
			Pup(s) - Pale	1 Male
			Pup(s) - Cold to touch	1 Male
			Pup(s) - Cyanotic	1 Male

Severity Codes: X = Present; H = Head

Group 3 - BNT162b2 30mcg

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Individual Lactation Clinical Observations

20256434

Day numbers relative to Litter Date					18	19	20	21	21
Group	Sex	Animal	Clinical Sign	Site			Daily 1		Daily 1
3	f	245	Localised hairloss	Left and right forelimbs	X
			Pup(s) -Incomplete hair growth	All Pups
		247	Pup(s) - Pale	1 Pup
		248	Pup(s) - Haematoma(s)	1 Pup
		251	Pup(s) - Weak	1 Female
			Pup(s) - Weak	1 Pup
		253	Scab(s).	Head	.	.	.	X	.
			Scab(s).	Back	.	.	.	X	.
		256	Localised hairloss	Back	X
			Localised hairloss	Left and right forelimbs	X
			Swelling.	Injection site 2
			Pup(s) - Cold to touch	1 Pup
		257	Pup(s) - Haematoma(s)	1 Pup
		260	Localised hairloss	Thorax	X
			Localised hairloss	Left and right forelimbs	X
			Pup(s) -Incomplete hair growth	All Pups	X	X	X	.	X
		261	Swelling.	Injection site 2
		262	Scab(s).	Clipped area
		263	Pup(s) - Cold to touch	1 Pup
		264	Swelling.	Injection site 2
		265	Pup(s) - Weak	1 Male
			Pup(s) - Thin	1 Male
			Pup(s) - Pale	1 Male
			Pup(s) - Cold to touch	1 Male
			Pup(s) - Cyanotic	1 Male

Severity Codes: X = Present; H = Head

Group 3 - BNT162b2 30mcg

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Individual Lactation Clinical Observations

20256434

Day numbers relative to Litter Date

Group	Sex	Animal	Clinical Sign	Site	0	0	0	1	1	1
						Veto	Daily		NS1	Veto



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Individual Lactation Clinical Observations

20256434

Day numbers relative to Litter Date

Group	Sex	Animal	Clinical Sign	Site	1 Daily 1	2 Daily 1	2 Daily 1	3 Daily 1	3 Daily 1	4 Daily 1
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Individual Lactation Clinical Observations

20256434

Day numbers relative to Litter Date

Group	Sex	Animal	Clinical Sign	Site	7 Daily 1	10 BEF	11 BEF	12	13	14 Daily 1
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Individual Lactation Clinical Observations

20256434

Day numbers relative to Litter Date

Group Sex	Animal	Clinical Sign	Site	15	16	17	18	19	20
					Daily 1	Daily 1	Daily 1		

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Individual Lactation Clinical Observations

20256434

Day numbers relative to Litter Date

Group Sex Animal

Clinical Sign

Site

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Individual Lactation Clinical Observations

20256434

Day numbers relative to Litter Date

Group Sex	Animal	Clinical Sign	Site	0	0	0	1	1	1
				Veto	Daily	NS	Veto		

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Individual Lactation Clinical Observations

20256434

Day numbers relative to Litter Date

Group	Sex	Animal	Clinical Sign	Site	1 Daily 1	2	2 Daily 1	3	3 Daily 1	4 Daily 1
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Individual Lactation Clinical Observations

20256434

Day numbers relative to Litter Date

Group Sex	Animal	Clinical Sign	Site	7 Daily 1	10 BEF	11 BEF	12	13	14 Daily 1
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Individual Lactation Clinical Observations

20256434

Day numbers relative to Litter Date

Group	Sex	Animal	Clinical Sign	Site	15	16	17	18	19	20
						Daily 1	Daily 1	Daily 1		

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Individual Lactation Clinical Observations

20256434

Day numbers relative to Litter Date

Group Sex Animal

Clinical Sign

Site

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Individual Clinical Observations of Excluded Females

20256434

Day numbers relative to Start Date

Group	Sex	Animal	Clinical Sign	Site	-26 Daily 1	-25 Daily 1	-24 Daily 1	-23 Daily 1	2	9	9 Daily 1
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Individual Clinical Observations of Excluded Females

20256434

Day numbers relative to Start Date

10 36 37 43

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Individual Clinical Observations of Excluded Females

20256434

Day numbers relative to Start Date

Group	Sex	Animal	Clinical Sign	Site	-26 Daily 1	-25 Daily 1	-24 Daily 1	-23 Daily 1	2	9	9 Daily 1
-------	-----	--------	---------------	------	----------------	----------------	----------------	----------------	---	---	--------------

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Individual Clinical Observations of Excluded Females

20256434

Day numbers relative to Start Date

Group	Sex	Animal	Clinical Sign	Site	10 Daily 1	36 Daily 1	37 Daily 1	43
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Individual Pre-Mating Body Weight and Body Weight Change of Females

20256434

Sex: Female Day(s) Relative to Start Date

Control Omcg							
	Body Weight (g)	Body Weight (g)	Body Weight (g)	Body Weight (g)	Body Weight (g)	Body Weight (g)	Body Weight (g)
	-26	-25	-21	-20	-14	-7	1
201	151.7	-	156.3	-	166.5	178.6	180.7
202	175.8	-	192.8	-	214.6	215.4	223.9
203	149.2	-	163.6	-	179.2	191.8	195.6
204	146.1	-	161.9	-	175.5	185.7	194.0
205	137.1	-	149.4	-	160.9	173.6	188.5
206	145.5	-	163.7	-	182.2	206.9	220.7
207	149.8	-	162.3	-	173.8	184.7	191.9
208	162.8	-	173.9	-	185.5	190.9	199.2
209	156.5	-	165.1	-	178.6	186.8	189.8
210	168.4	-	182.3	-	195.5	213.7	226.2
211	157.7	-	171.0	-	179.0	196.8	208.8
212	163.6	-	170.1	-	185.9	201.2	203.7
213	167.5	-	179.3	-	194.4	200.4	214.0
214	153.7	-	166.2	-	181.0	194.9	206.1
215	179.3	-	195.5	-	209.2	231.5	247.5
216	172.6	-	186.1	-	199.9	211.2	222.5
217	162.8	-	175.6	-	189.8	201.2	216.7
218	153.0	-	170.6	-	184.5	198.2	213.3

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Individual Pre-Mating Body Weight and Body Weight Change of Females

20256434

Sex: Female Day(s) Relative to Start Date

Control Omcg							Body Weight Change (g)
	Body Weight (g)	Body Weight (g)	Body Weight (g)	Body Weight (g)	Body Weight (g)	Body Weight (g)	
	4	8	11	15	18	22	
201	190.2	190.2	193.9	208.3	213.3	206.5	4.6
202	229.8	237.1	238.7	246.6	240.6	245.9	17.0
203	209.1	215.4	213.0	220.8	214.2	218.6	14.4
204	203.6	209.8	204.1	207.8	217.5	221.6	15.8
205	192.7	194.8	198.7	213.2	225.8	232.1	12.3
206	231.0	244.1	245.1	241.3	243.7	247.8	18.2
207	191.6	196.9	194.3	209.9	216.9	222.2	12.5
208	203.9	211.1	210.8	231.0	238.5	246.3	11.1
209	195.5	203.3	207.0	225.1	226.7	217.2	8.6
210	226.4	234.3	233.5	235.5	246.1	250.4	13.9
211	206.5	213.5	215.9	223.2	227.4	234.4	13.3
212	200.2	205.6	216.3	223.6	231.8	243.9	6.5
213	217.8	223.6	223.8	230.8	226.6	229.0	11.8
214	215.3	224.4	221.4	216.5 ¹	221.0	225.3	12.5
215	243.0	246.6	244.0	248.8	254.9	266.0	16.2
216	229.3	236.7	242.7	242.7	244.8	253.0	13.5
217	223.8	228.1	229.7	235.9	235.4	237.4	12.8
218	213.2	220.0	226.5	243.7	252.4	260.6	17.6

¹ [RC: Verified value]

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Individual Pre-Mating Body Weight and Body Weight Change of Females

20256434

Sex: Female Day(s) Relative to Start Date

Control Omcg							
	Body Weight Change (g)	Body Weight Change (g)	Body Weight Change (g)	Body Weight Change (g)	Body Weight Change (g)	Body Weight Change (g)	Body Weight Change (g)
	-25-20	-20-14	-21-14	-14-7	-7-1	1-4	4-8
201	.	.	10.2	12.1	2.1	9.5	0.0
202	.	.	21.8	0.8	8.5	5.9	7.3
203	.	.	15.6	12.6	3.8	13.5	6.3
204	.	.	13.6	10.2	8.3	9.6	6.2
205	.	.	11.5	12.7	14.9	4.2	2.1
206	.	.	18.5	24.7	13.8	10.3	13.1
207	.	.	11.5	10.9	7.2	-0.3	5.3
208	.	.	11.6	5.4	8.3	4.7	7.2
209	.	.	13.5	8.2	3.0	5.7	7.8
210	.	.	13.2	18.2	12.5	0.2	7.9
211	.	.	8.0	17.8	12.0	-2.3	7.0
212	.	.	15.8	15.3	2.5	-3.5	5.4
213	.	.	15.1	6.0	13.6	3.8	5.8
214	.	.	14.8	13.9	11.2	9.2	9.1
215	.	.	13.7	22.3	16.0	-4.5	3.6
216	.	.	13.8	11.3	11.3	6.8	7.4
217	.	.	14.2	11.4	15.5	7.1	4.3
218	.	.	13.9	13.7	15.1	-0.1	6.8

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Individual Pre-Mating Body Weight and Body Weight Change of Females

20256434

Sex: Female Day(s) Relative to Start Date

Control Omcg	Body Weight Change (g)				
	8-11	11-15	15-18	18-22	1-22
201	3.7	14.4	5.0	-6.8	25.8
202	1.6	7.9	-6.0	5.3	22.0
203	-2.4	7.8	-6.6	4.4	23.0
204	-5.7	3.7	9.7	4.1	27.6
205	3.9	14.5	12.6	6.3	43.6
206	1.0	-3.8	2.4	4.1	27.1
207	-2.6	15.6	7.0	5.3	30.3
208	-0.3	20.2	7.5	7.8	47.1
209	3.7	18.1	1.6	-9.5	27.4
210	-0.8	2.0	10.6	4.3	24.2
211	2.4	7.3	4.2	7.0	25.6
212	10.7	7.3	8.2	12.1	40.2
213	0.2	7.0	-4.2	2.4	15.0
214	-3.0	-4.9	4.5	4.3	19.2
215	-2.6	4.8	6.1	11.1	18.5
216	6.0	0.0	2.1	8.2	30.5
217	1.6	6.2	-0.5	2.0	20.7
218	6.5	17.2	8.7	8.2	47.3

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Individual Pre-Mating Body Weight and Body Weight Change of Females

20256434

Sex: Female Day(s) Relative to Start Date

Control Omcg							
	Body Weight (g)	Body Weight (g)	Body Weight (g)	Body Weight (g)	Body Weight (g)	Body Weight (g)	Body Weight (g)
	-26	-25	-21	-20	-14	-7	1
219	163.4	-	170.4	-	190.6	208.4	218.7
220	185.3	-	190.1	-	213.8 ¹	233.9	240.3
221	186.1	-	203.6	-	219.7	233.4	251.6
222	153.8	-	173.9	-	195.4	214.9	217.5
1	-	159.1	-	168.7	176.5	181.8	195.2
2	-	149.8	-	160.1	175.0	184.6	194.8
3	-	178.3	-	186.8	195.1	200.8	212.7
4	-	156.4	-	175.8	192.4	206.6	214.2
5	-	157.8	-	168.2	173.6	188.5	198.5
6	-	157.5	-	172.4	189.1	201.3	230.8
7	-	186.8	-	204.9	216.3	234.5	255.3
8	-	144.6	-	162.3	171.5	185.0	212.8
9	-	170.1	-	182.5	193.1	194.9	213.6
10	-	145.3	-	161.7	174.2	191.8	217.3
11	-	181.8	-	186.7	203.5	210.7	225.3
12	-	157.1	-	174.6	189.9	202.0	221.8
13	-	153.3	-	167.3	179.0	198.1	217.2
14	-	157.2	-	162.1	182.8	194.6	208.5

¹ [RC:Verified value]

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Individual Pre-Mating Body Weight and Body Weight Change of Females

20256434

Sex: Female Day(s) Relative to Start Date

Control Omcg							Body Weight Change (g)
	Body Weight (g)	Body Weight (g)	Body Weight (g)	Body Weight (g)	Body Weight (g)	Body Weight (g)	
	4	8	11	15	18	22	
219	216.5	220.9	235.3	235.5	240.6	245.9	7.0
220	236.7	243.7	254.9	265.6	270.7	281.9	4.8
221	256.9	261.5	267.3	273.7	269.6	276.7	17.5
222	231.6	234.2	240.8	246.6	244.9	254.9	20.1
1	200.2	201.8	207.4	210.2	210.4	209.3	.
2	198.8	205.6	210.7	213.3	218.0	220.6	.
3	222.9	224.4	226.8	229.9	223.8 ! ¹	229.1	.
4	211.5	219.7	230.4	231.3	230.6	234.9	.
5	200.5	208.0	202.2 ! ¹	201.5	208.5	212.4	.
6	238.9	255.7	247.6 ! ¹	246.3	242.4 ! ¹	248.4	.
7	262.6	265.9	267.6	272.0	272.7	279.0	.
8	221.1	235.6	229.9 ! ¹	229.8	228.1 ! ¹	235.1	.
9	221.5	226.7	232.1	237.9	232.7	239.0	.
10	226.7	223.6 ! ¹	226.2	230.4	235.9	241.5	.
11	227.5	230.0	232.9	235.3	232.6	230.8	.
12	230.8	234.5	236.3	245.3	244.7	246.1	.
13	223.8	227.2	224.0 ! ¹	230.7	227.8	230.6	.
14	216.3	228.1	221.0 ! ¹	217.2 ! ¹	220.8	222.4	.

! [RC:Verified value]

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Individual Pre-Mating Body Weight and Body Weight Change of Females

20256434

Sex: Female Day(s) Relative to Start Date

Control Omcg							
	Body Weight Change (g)	Body Weight Change (g)	Body Weight Change (g)	Body Weight Change (g)	Body Weight Change (g)	Body Weight Change (g)	Body Weight Change (g)
	-25-20	-20-14	-21-14	-14-7	-7-1	1-4	4-8
219	-	-	20.2	17.8	10.3	-2.2	4.4
220	-	-	23.7	20.1	6.4	-3.6	7.0
221	-	-	16.1	13.7	18.2	5.3	4.6
222	-	-	21.5	19.5	2.6	14.1	2.6
1	9.6	7.8	-	5.3	13.4	5.0	1.6
2	10.3	14.9	-	9.6	10.2	4.0	6.8
3	8.5	8.3	-	5.7	11.9	10.2	1.5
4	19.4	16.6	-	14.2	7.6	-2.7	8.2
5	10.4	5.4	-	14.9	10.0	2.0	7.5
6	14.9	16.7	-	12.2	29.5	8.1	16.8
7	18.1	11.4	-	18.2	20.8	7.3	3.3
8	17.7	9.2	-	13.5	27.8	8.3	14.5
9	12.4	10.6	-	1.8	18.7	7.9	5.2
10	16.4	12.5	-	17.6	25.5	9.4	-3.1
11	4.9	16.8	-	7.2	14.6	2.2	2.5
12	17.5	15.3	-	12.1	19.8	9.0	3.7
13	14.0	11.7	-	19.1	19.1	6.6	3.4
14	4.9	20.7	-	11.8	13.9	7.8	11.8

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Individual Pre-Mating Body Weight and Body Weight Change of Females

20256434

Sex: Female Day(s) Relative to Start Date

Control Omcg					
	Body Weight Change (g)	Body Weight Change (g)	Body Weight Change (g)	Body Weight Change (g)	Body Weight Change (g)
	8-11	11-15	15-18	18-22	1-22
219	14.4	0.2	5.1	5.3	27.2
220	11.2	10.7	5.1	11.2	41.6
221	5.8	6.4	-4.1	7.1	25.1
222	6.6	5.8	-1.7	10.0	37.4
1	5.6	2.8	0.2	-1.1	14.1
2	5.1	2.6	4.7	2.6	25.8
3	2.4	3.1	-6.1	5.3	16.4
4	10.7	0.9	-0.7	4.3	20.7
5	-5.8	-0.7	7.0	3.9	13.9
6	-8.1	-1.3	-3.9	6.0	17.6
7	1.7	4.4	0.7	6.3	23.7
8	-5.7	-0.1	-1.7	7.0	22.3
9	5.4	5.8	-5.2	6.3	25.4
10	2.6	4.2	5.5	5.6	24.2
11	2.9	2.4	-2.7	-1.8	5.5
12	1.8	9.0	-0.6	1.4	24.3
13	-3.2	6.7	-2.9	2.8	13.4
14	-7.1	-3.8	3.6	1.6	13.9

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Individual Pre-Mating Body Weight and Body Weight Change of Females

20256434

Sex: Female Day(s) Relative to Start Date

Control Omcg							
	Body Weight (g)	Body Weight (g)	Body Weight (g)	Body Weight (g)	Body Weight (g)	Body Weight (g)	Body Weight (g)
	-26	-25	-21	-20	-14	-7	1
15	-	154.8	-	173.0	175.8	194.2	224.1
16	-	158.2	-	178.9	187.6	211.2	221.1
17	-	169.1	-	190.5	208.4	221.7	233.5
18	-	195.1	-	204.2	226.3	236.7	254.5
19	-	151.8	-	158.1	173.1	182.4	209.7
20	-	164.4	-	181.6	199.7	205.6	226.3
21	-	167.5	-	176.4	194.2	203.5	228.8
22	-	191.5	-	207.3	213.1	227.7	238.5
Mean	160.99	163.98	173.80	177.46	189.68	202.55	216.49
SD	13.11	14.48	13.45	14.57	15.40	16.23	17.85
N	22	22	22	22	44	44	44

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Individual Pre-Mating Body Weight and Body Weight Change of Females

20256434

Sex: Female Day(s) Relative to Start Date

Control Omcg							Body Weight Change (g)
	Body Weight (g)	Body Weight (g)	Body Weight (g)	Body Weight (g)	Body Weight (g)	Body Weight (g)	
	4	8	11	15	18	22	
15	229.9	229.9	229.5 ¹	227.4	236.3	242.6	-
16	221.7	230.1	229.3 ¹	231.9	243.7	243.5	-
17	232.6	240.2	249.6	249.2	258.2	258.6	-
18	264.5	275.9	264.8 ¹	263.1 ¹	256.7 ¹	262.5	-
19	216.5	231.7	219.7 ¹	215.8 ¹	218.2	222.2	-
20	231.7	236.2	240.9	249.1	240.9 ¹	248.9	-
21	235.7	250.6	241.0 ¹	239.5 ¹	232.9 ¹	231.9 ¹	-
22	238.7	242.1	249.2	254.4	256.3	258.7	-
Mean	221.34	227.71	229.02	233.81	235.81	240.13	12.82
SD	17.81	18.80	18.42	17.24	16.08	18.13	4.35
N	44	44	44	44	44	44	22

¹ [RC:Verified value]

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Individual Pre-Mating Body Weight and Body Weight Change of Females

20256434

Sex: Female Day(s) Relative to Start Date

Control Omcg							
	Body Weight Change (g)	Body Weight Change (g)	Body Weight Change (g)	Body Weight Change (g)	Body Weight Change (g)	Body Weight Change (g)	Body Weight Change (g)
	-25-20	-20-14	-21-14	-14-7	-7-1	1-4	4-8
15	18.2	2.8	-	18.4	29.9	5.8	0.0
16	20.7	8.7	-	23.6	9.9	0.6	8.4
17	21.4	17.9	-	13.3	11.8	-0.9	7.6
18	9.1	22.1	-	10.4	17.8	10.0	11.4
19	6.3	15.0	-	9.3	27.3	6.8	15.2
20	17.2	18.1	-	5.9	20.7	5.4	4.5
21	8.9	17.8	-	9.3	25.3	6.9	14.9
22	15.8	5.8	-	14.6	10.8	0.2	3.4
Mean	13.48	13.00	15.08	12.88	13.94	4.85	6.37
SD	5.15	5.23	3.94	5.50	7.32	4.74	4.25
N	22	22	22	44	44	44	44

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Individual Pre-Mating Body Weight and Body Weight Change of Females

20256434

Sex: Female Day(s) Relative to Start Date

Control Omcg	Body Weight Change (g)				
	8-11	11-15	15-18	18-22	1-22
	Body Weight Change (g)	Body Weight Change (g)	Body Weight Change (g)	Body Weight Change (g)	Body Weight Change (g)
15	-0.4	-2.1	8.9	6.3	18.5
16	-0.8	2.6	11.8	-0.2	22.4
17	9.4	-0.4	9.0	0.4	25.1
18	-11.1	-1.7	-6.4	5.8	8.0
19	-12.0	-3.9	2.4	4.0	12.5
20	4.7	8.2	-8.2	8.0	22.6
21	-9.6	-1.5	-6.6	-1.0	3.1
22	7.1	5.2	1.9	2.4	20.2
Mean	1.31	4.79	2.00	4.32	23.64
SD	6.07	6.17	5.69	4.23	9.93
N	44	44	44	44	44

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Individual Pre-Mating Body Weight and Body Weight Change of Females

20256434

Sex: Female Day(s) Relative to Start Date



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Individual Pre-Mating Body Weight and Body Weight Change of Females

20256434

Sex: Female Day(s) Relative to Start Date



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Individual Pre-Mating Body Weight and Body Weight Change of Females

20256434

Sex: Female Day(s) Relative to Start Date



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Individual Pre-Mating Body Weight and Body Weight Change of Females

20256434

Sex: Female Day(s) Relative to Start Date



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Individual Pre-Mating Body Weight and Body Weight Change of Females

20256434

Sex: Female Day(s) Relative to Start Date



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Individual Pre-Mating Body Weight and Body Weight Change of Females

20256434

Sex: Female Day(s) Relative to Start Date



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Individual Pre-Mating Body Weight and Body Weight Change of Females

20256434

Sex: Female Day(s) Relative to Start Date



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Individual Pre-Mating Body Weight and Body Weight Change of Females

20256434

Sex: Female Day(s) Relative to Start Date



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Individual Pre-Mating Body Weight and Body Weight Change of Females

20256434

Sex: Female Day(s) Relative to Start Date



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Individual Pre-Mating Body Weight and Body Weight Change of Females

20256434

Sex: Female Day(s) Relative to Start Date



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Individual Pre-Mating Body Weight and Body Weight Change of Females

20256434

Sex: Female Day(s) Relative to Start Date



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Individual Pre-Mating Body Weight and Body Weight Change of Females

20256434

Sex: Female Day(s) Relative to Start Date



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Individual Pre-Mating Body Weight and Body Weight Change of Females

20256434

Sex: Female Day(s) Relative to Start Date

BNT162b2 30mcg							
	Body Weight (g)	Body Weight (g)	Body Weight (g)	Body Weight (g)	Body Weight (g)	Body Weight (g)	Body Weight (g)
	-26	-25	-21	-20	-14	-7	1
245	143.4	-	154.6	-	168.6	196.7	191.6 ¹
246	143.0	-	159.0	-	181.6	220.2	195.8
247	164.7	-	179.4	-	190.1	202.0	215.4
248	176.9	-	195.6	-	197.2	216.4	225.9
249	156.8	-	166.4	-	178.3	186.0	198.5
250	145.3	-	153.9	-	173.0	186.5	194.4
251	199.2	-	215.6	-	234.9	249.6	253.8
252	184.7	-	195.8	-	212.6	222.0	229.4
253	159.9	-	175.6	-	187.3	207.0	219.5
254	173.8	-	184.1	-	199.9	208.1	220.9
255	143.4	-	160.2	-	169.7	183.5	184.2
256	173.9	-	186.9	-	203.4	216.3	223.9
257	180.4	-	197.2	-	214.1	227.8	239.8
258	181.1	-	190.5	-	205.3	216.6	224.4
259	145.8	-	159.7	-	177.2	191.9	204.7
260	160.9	-	170.5	-	188.7	205.9	213.1
261	136.4	-	152.8	-	166.2	184.6	198.9
262	148.1	-	167.8	-	184.8	207.3	225.5

¹ [RC: Verified value]

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Individual Pre-Mating Body Weight and Body Weight Change of Females

20256434

Sex: Female Day(s) Relative to Start Date

BNT162b2 30mcg							Body Weight Change (g)
	Body Weight (g)	Body Weight (g)	Body Weight (g)	Body Weight (g)	Body Weight (g)	Body Weight (g)	
	4	8	11	15	18	22	
245	183.7	187.7	197.1	221.9	235.6	249.5	11.2
246	198.8	201.5	197.7	217.4	228.5	225.6	16.0
247	211.2	215.2	215.9	217.2	227.9	236.8	14.7
248	225.9	226.6	229.6	235.1	243.2	246.9	18.7
249	204.9	209.7	204.4	209.2	208.8	217.0	9.6
250	188.8	197.2	196.6	202.6	199.6	204.2	8.6
251	260.2	263.8	265.5	274.5	279.0	287.7	16.4
252	233.3	233.3	237.0	242.9	242.7	250.2	11.1
253	216.2	219.1	215.8	221.0	231.5	235.1	15.7
254	217.7	223.3	223.4	229.9	227.0	234.7	10.3
255	183.6	187.0	191.0	193.1	202.2	204.5	16.8
256	228.9	230.1	235.2	235.4	241.5	243.7	13.0
257	237.9	244.8	245.5	258.1	262.6	276.0	16.8
258	224.0	226.4	230.2	249.6	259.8	256.7	9.4
259	207.0	213.6	209.4	213.6	212.1	220.5	13.9
260	220.2	226.0	224.6	232.2	238.2	247.7	9.6
261	194.6	200.6	200.3	206.8	217.6	220.6	16.4
262	225.6	240.3	234.1	235.9	239.0	244.6	19.7

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Individual Pre-Mating Body Weight and Body Weight Change of Females

20256434

Sex: Female Day(s) Relative to Start Date

BNT162b2 30mcg							
	Body Weight Change (g)	Body Weight Change (g)	Body Weight Change (g)	Body Weight Change (g)	Body Weight Change (g)	Body Weight Change (g)	Body Weight Change (g)
	-25-20	-20-14	-21-14	-14-7	-7-1	1-4	4-8
245	.	.	14.0	28.1	-5.1	-7.9	4.0
246	.	.	22.6	38.6	-24.4	3.0	2.7
247	.	.	10.7	11.9	13.4	-4.2	4.0
248	.	.	1.6	19.2	9.5	0.0	0.7
249	.	.	11.9	7.7	12.5	6.4	4.8
250	.	.	19.1	13.5	7.9	-5.6	8.4
251	.	.	19.3	14.7	4.2	6.4	3.6
252	.	.	16.8	9.4	7.4	3.9	0.0
253	.	.	11.7	19.7	12.5	-3.3	2.9
254	.	.	15.8	8.2	12.8	-3.2	5.6
255	.	.	9.5	13.8	0.7	-0.6	3.4
256	.	.	16.5	12.9	7.6	5.0	1.2
257	.	.	16.9	13.7	12.0	-1.9	6.9
258	.	.	14.8	11.3	7.8	-0.4	2.4
259	.	.	17.5	14.7	12.8	2.3	6.6
260	.	.	18.2	17.2	7.2	7.1	5.8
261	.	.	13.4	18.4	14.3	-4.3	6.0
262	.	.	17.0	22.5	18.2	0.1	14.7

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Individual Pre-Mating Body Weight and Body Weight Change of Females

20256434

Sex: Female Day(s) Relative to Start Date

BNT162b2 30mcg	Body Weight Change (g)				
	8-11	11-15	15-18	18-22	1-22
245	9.4	24.8	13.7	13.9	57.9
246	-3.8	19.7	11.1	-2.9	29.8
247	0.7	1.3	10.7	8.9	21.4
248	3.0	5.5	8.1	3.7	21.0
249	-5.3	4.8	-0.4	8.2	18.5
250	-0.6	6.0	-3.0	4.6	9.8
251	1.7	9.0	4.5	8.7	33.9
252	3.7	5.9	-0.2	7.5	20.8
253	-3.3	5.2	10.5	3.6	15.6
254	0.1	6.5	-2.9	7.7	13.8
255	4.0	2.1	9.1	2.3	20.3
256	5.1	0.2	6.1	2.2	19.8
257	0.7	12.6	4.5	13.4	36.2
258	3.8	19.4	10.2	-3.1	32.3
259	-4.2	4.2	-1.5	8.4	15.8
260	-1.4	7.6	6.0	9.5	34.6
261	-0.3	6.5	10.8	3.0	21.7
262	-6.2	1.8	3.1	5.6	19.1

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Individual Pre-Mating Body Weight and Body Weight Change of Females

20256434

Sex: Female Day(s) Relative to Start Date

BNT162b2 30mcg							
	Body Weight (g)	Body Weight (g)	Body Weight (g)	Body Weight (g)	Body Weight (g)	Body Weight (g)	Body Weight (g)
	-26	-25	-21	-20	-14	-7	1
263	166.6	-	173.5	-	189.0	201.1	208.7
264	193.3	-	203.0	-	218.4	233.0	249.4
265	160.4	-	174.5	-	199.1	216.6	229.5
266	161.3	-	176.7	-	191.8	212.3	223.8
45	-	157.1	-	167.6	182.6	195.9	219.9
46	-	171.2	-	181.3	203.2	218.5	249.1
47	-	151.0	-	163.9	172.0	192.9	213.4
48	-	177.3	-	186.4	195.2	199.4	223.3
49	-	184.4	-	196.3	207.5	213.5	227.6
50	-	143.2	-	160.2	166.5	185.2	198.1
51	-	186.2	-	200.7	215.5	229.6	241.0
52	-	168.0	-	179.5	190.2	193.6	220.4
53	-	158.6	-	170.3	187.9	197.5	204.7
54	-	147.0	-	156.3	174.6	187.4	201.9
55	-	159.4	-	177.7	197.3	209.0	228.6
56	-	183.5	-	209.3	233.0	247.7	262.3
57	-	145.6	-	151.6	175.1	187.8	191.5
58	-	176.4	-	195.7	201.7	204.6	224.6

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Individual Pre-Mating Body Weight and Body Weight Change of Females

20256434

Sex: Female Day(s) Relative to Start Date

BNT162b2 30mcg							
	Body Weight (g)	Body Weight (g)	Body Weight (g)	Body Weight (g)	Body Weight (g)	Body Weight (g)	Body Weight Change (g)
	4	8	11	15	18	22	-26-21
263	203.2	206.4	212.2	219.9	221.5	226.5	6.9
264	246.9	253.4	246.1	252.8	262.2	273.1	9.7
265	221.4	229.8	237.2	239.3	247.6	257.6	14.1
266	233.0	246.9	242.7	242.1 ¹	242.6	249.0	15.4
45	223.5	238.2	219.4 ¹	220.2	228.7	235.8	-
46	249.5	263.8	250.0 ¹	251.0	259.8	272.1	-
47	204.5	212.3	204.2 ¹	211.7	220.1	228.9	-
48	213.1	220.7	225.1	235.0	241.2	238.6	-
49	222.2	232.6	223.9 ¹	227.6	230.5	233.4	-
50	193.8	200.6	195.4 ¹	201.4	214.4	220.3	-
51	237.6	242.8	245.7	244.7	249.5	253.6	-
52	216.3	220.4	217.0 ¹	230.5	233.8	236.1	-
53	206.0	210.3	209.9 ¹	213.5	211.4	218.6	-
54	208.4	215.6	216.1	221.7	223.7	227.3	-
55	229.1	236.4	231.6 ¹	239.4	240.3	244.0	-
56	257.9	269.1	271.8	272.8	283.1	283.9	-
57	200.3	205.4	208.5	212.0	218.6	222.1	-
58	223.0	230.5	227.9 ¹	233.9	236.0	239.5	-

¹ [RC:Verified value]

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Individual Pre-Mating Body Weight and Body Weight Change of Females

20256434

Sex: Female Day(s) Relative to Start Date

BNT162b2 30mcg	Day(s) Relative to Start Date						
	Body Weight Change (g)	Body Weight Change (g)	Body Weight Change (g)	Body Weight Change (g)	Body Weight Change (g)	Body Weight Change (g)	Body Weight Change (g)
	-25-20	-20-14	-21-14	-14-7	-7-1	1-4	4-8
263	-	-	15.5	12.1	7.6	-5.5	3.2
264	-	-	15.4	14.6	16.4	-2.5	6.5
265	-	-	24.6	17.5	12.9	-8.1	8.4
266	-	-	15.1	20.5	11.5	9.2	13.9
45	10.5	15.0	-	13.3	24.0	3.6	14.7
46	10.1	21.9	-	15.3	30.6	0.4	14.3
47	12.9	8.1	-	20.9	20.5	-8.9	7.8
48	9.1	8.8	-	4.2	23.9	-10.2	7.6
49	11.9	11.2	-	6.0	14.1	-5.4	10.4
50	17.0	6.3	-	18.7	12.9	-4.3	6.8
51	14.5	14.8	-	14.1	11.4	-3.4	5.2
52	11.5	10.7	-	3.4	26.8	-4.1	4.1
53	11.7	17.6	-	9.6	7.2	1.3	4.3
54	9.3	18.3	-	12.8	14.5	6.5	7.2
55	18.3	19.6	-	11.7	19.6	0.5	7.3
56	25.8	23.7	-	14.7	14.6	-4.4	11.2
57	6.0	23.5	-	12.7	3.7	8.8	5.1
58	19.3	6.0	-	2.9	20.0	-1.6	7.5

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Individual Pre-Mating Body Weight and Body Weight Change of Females

20256434

Sex: Female Day(s) Relative to Start Date

BNT162b2 30mcg					
	Body Weight Change (g)	Body Weight Change (g)	Body Weight Change (g)	Body Weight Change (g)	Body Weight Change (g)
	8-11	11-15	15-18	18-22	1-22
263	5.8	7.7	1.6	5.0	17.8
264	-7.3	6.7	9.4	10.9	23.7
265	7.4	2.1	8.3	10.0	28.1
266	-4.2	-0.6	0.5	6.4	25.2
45	-18.8	0.8	8.5	7.1	15.9
46	-13.8	1.0	8.8	12.3	23.0
47	-8.1	7.5	8.4	8.8	15.5
48	4.4	9.9	6.2	-2.6	15.3
49	-8.7	3.7	2.9	2.9	5.8
50	-5.2	6.0	13.0	5.9	22.2
51	2.9	-1.0	4.8	4.1	12.6
52	-3.4	13.5	3.3	2.3	15.7
53	-0.4	3.6	-2.1	7.2	13.9
54	0.5	5.6	2.0	3.6	25.4
55	-4.8	7.8	0.9	3.7	15.4
56	2.7	1.0	10.3	0.8	21.6
57	3.1	3.5	6.6	3.5	30.6
58	-2.6	6.0	2.1	3.5	14.9

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Individual Pre-Mating Body Weight and Body Weight Change of Females

20256434

Sex: Female Day(s) Relative to Start Date

BNT162b2 30mcg							
	Body Weight (g)	Body Weight (g)	Body Weight (g)	Body Weight (g)	Body Weight (g)	Body Weight (g)	Body Weight (g)
	-26	-25	-21	-20	-14	-7	1
59	-	183.1	-	198.1	200.9	220.5	227.7
60	-	166.6	-	182.9	193.3	200.5	223.4
61	-	161.1	-	177.6	199.7	216.3	238.2
62	-	157.9	-	176.5	188.5	206.8	217.6
63	-	166.0	-	184.3	188.5	204.9	219.3
64	-	166.1	-	175.9	196.6	206.2	214.8
65	-	186.4	-	198.9	205.7	205.5	228.2
66	-	146.3	-	150.0	168.3	175.6	195.9
Mean	163.60	165.56	176.97	179.14	192.61	206.60	219.15
SD	17.64	14.15	17.45	16.54	16.69	16.39	17.75
N	22	22	22	22	44	44	44
%Diff	1.63	0.97	1.82	0.95	1.55	2.00	1.23

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Individual Pre-Mating Body Weight and Body Weight Change of Females

20256434

Sex: Female Day(s) Relative to Start Date

BNT162b2 30mcg							Body Weight Change (g)
	Body Weight (g)	Body Weight (g)	Body Weight (g)	Body Weight (g)	Body Weight (g)	Body Weight (g)	
	4	8	11	15	18	22	
59	226.7	228.2	230.1	235.8	241.6	246.2	-
60	226.0	228.2	228.6	241.8	244.8	243.0	-
61	235.5	236.5	224.8 ¹	225.9	234.8	241.4	-
62	216.5	221.6	222.5	225.6	237.2	240.9	-
63	222.9	215.9	210.4 ¹	210.9	220.8	226.0	-
64	212.8	219.4	213.0 ¹	216.6	224.4	230.6	-
65	227.4	232.6	227.4 ¹	237.9	236.7	244.1	-
66	194.6	198.0	192.8 ¹	197.3	197.7	205.2	-
Mean	218.51	224.13	222.45	228.58	234.09	239.54	13.36
SD	18.10	19.18	18.60	18.32	18.89	19.41	3.59
N	44	44	44	44	44	44	22
%Diff	-1.28	-1.57	-2.87	-2.23	-0.73	-0.25	4.26

¹ [RC:Verified value]

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Individual Pre-Mating Body Weight and Body Weight Change of Females

20256434

Sex: Female Day(s) Relative to Start Date

BNT162b2 30mcg	Body Weight Change (g)						
	Body Weight Change (g)	Body Weight Change (g)	Body Weight Change (g)	Body Weight Change (g)	Body Weight Change (g)	Body Weight Change (g)	Body Weight Change (g)
	-25-20	-20-14	-21-14	-14-7	-7-1	1-4	4-8
59	15.0	2.8	.	19.6	7.2	-1.0	1.5
60	16.3	10.4	.	7.2	22.9	2.6	2.2
61	16.5	22.1	.	16.6	21.9	-2.7	1.0
62	18.6	12.0	.	18.3	10.8	-1.1	5.1
63	18.3	4.2	.	16.4	14.4	3.6	-7.0
64	9.8	20.7	.	9.6	8.6	-2.0	6.6
65	12.5	6.8	.	-0.2	22.7	-0.8	5.2
66	3.7	18.3	.	7.3	20.3	-1.3	3.4
Mean	13.57	13.76	15.36	13.98	12.55	-0.64	5.62
SD	4.99	6.67	4.71	6.82	9.13	4.73	4.16
N	22	22	22	44	44	44	44
%Diff	0.67	5.84	1.84	8.60	-9.96	-113.13	-11.81

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Individual Pre-Mating Body Weight and Body Weight Change of Females

20256434

Sex: Female Day(s) Relative to Start Date

BNT162b2 30mcg					
	Body Weight Change (g)	Body Weight Change (g)	Body Weight Change (g)	Body Weight Change (g)	Body Weight Change (g)
	8-11	11-15	15-18	18-22	1-22
59	1.9	5.7	5.8	4.6	18.5
60	0.4	13.2	3.0	-1.8	19.6
61	-11.7	1.1	8.9	6.6	3.2
62	0.9	3.1	11.6	3.7	23.3
63	-5.5	0.5	9.9	5.2	6.7
64	-6.4	3.6	7.8	6.2	15.8
65	-5.2	10.5	-1.2	7.4	15.9
66	-5.2	4.5	0.4	7.5	9.3
Mean	-1.69	6.14	5.50	5.45	20.39
SD	5.67	5.49	4.64	3.97	9.45
N	44	44	44	44	44
%Diff	-229.04	28.13	175.11	26.25	-13.73

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Individual Pre-Mating Body Weight and Body Weight Change of Females

20256434

Sex: Female Day(s) Relative to Start Date



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Individual Pre-Mating Body Weight and Body Weight Change of Females

20256434

Sex: Female Day(s) Relative to Start Date



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Individual Pre-Mating Body Weight and Body Weight Change of Females

20256434

Sex: Female Day(s) Relative to Start Date



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Individual Pre-Mating Body Weight and Body Weight Change of Females

20256434

Sex: Female Day(s) Relative to Start Date



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Individual Pre-Mating Body Weight and Body Weight Change of Females

20256434

Sex: Female Day(s) Relative to Start Date



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Individual Pre-Mating Body Weight and Body Weight Change of Females

20256434

Sex: Female Day(s) Relative to Start Date



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Individual Pre-Mating Body Weight and Body Weight Change of Females

20256434

Sex: Female Day(s) Relative to Start Date



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Individual Pre-Mating Body Weight and Body Weight Change of Females

20256434

Sex: Female Day(s) Relative to Start Date



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Individual Pre-Mating Body Weight and Body Weight Change of Females

20256434

Sex: Female Day(s) Relative to Start Date



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Individual Pre-Mating Body Weight and Body Weight Change of Females

20256434

Sex: Female Day(s) Relative to Start Date



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Individual Pre-Mating Body Weight and Body Weight Change of Females

20256434

Sex: Female Day(s) Relative to Start Date



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Individual Pre-Mating Body Weight and Body Weight Change of Females

20256434

Sex: Female Day(s) Relative to Start Date



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Page: 1

Individual Gestation Body Weight and Body Weight Change

20256434

Sex: Female Day(s) Relative to Mating (Litter: A)

Control Omcg							
	Body Weight (g)	Body Weight (g)	Body Weight (g)	Body Weight (g)	Body Weight (g)	Body Weight (g)	Body Weight (g)
	0	6	9	12	15	18	21
201	206.2	225.8	236.3	251.3	267.1	304.7	337.1
202	237.9 ¹	258.2	266.5	279.1	287.1	322.0	351.8
203	220.0	237.6	249.3	259.4	278.0	312.5	342.0
204	218.5	252.1	264.4	286.2	300.3	341.8	365.4
205	223.1	234.8	243.9	255.9	274.1	320.1	347.1
206	245.1	268.5	275.0	289.1	297.4	342.5	372.5
207	215.4	223.3	231.0	242.8	255.6	277.7	300.5
208	237.3	248.9	254.5	266.5	279.4	317.0	344.1
209	214.5	228.9	231.3	244.5	255.2	282.3	313.4
210	249.3	269.8	278.0	299.0	312.0	340.0	372.4
211	227.3	253.8	260.1	274.7	284.9	321.0	354.9
212	241.6	270.4	286.8	299.4	309.1	357.3	377.0
213	234.6	255.7	261.6	273.8	288.6	321.4	354.9
214	218.5	241.1	243.1	257.6	266.4	305.5	335.4
215	259.7	288.3	293.0	309.3	322.0	359.4	393.2
216	258.6	277.9	291.7	301.6	316.4	351.8	392.7
217	247.0	262.6	271.6	284.5	300.5	330.4	370.7
218	250.8	260.4	267.3	279.8	288.6	324.2	358.3

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Individual Gestation Body Weight and Body Weight Change

20256434

Sex: Female Day(s) Relative to Mating (Litter: A)

Control Omcg							
	Body Weight Change (g)	Body Weight Change (g)	Body Weight Change (g)	Body Weight Change (g)	Body Weight Change (g)	Body Weight Change (g)	Body Weight Change (g)
	0-6	6-9	9-12	12-15	15-18	18-21	0-21
201	19.6	10.5	15.0	15.8	37.6	32.4	130.9
202	20.3	8.3	12.6	8.0	34.9	29.8	113.9
203	17.6	11.7	10.1	18.6	34.5	29.5	122.0
204	33.6	12.3	21.8	14.1	41.5	23.6	146.9
205	11.7	9.1	12.0	18.2	46.0	27.0	124.0
206	23.4	6.5	14.1	8.3	45.1	30.0	127.4
207	7.9	7.7	11.8	12.8	22.1	22.8	85.1
208	11.6	5.6	12.0	12.9	37.6	27.1	106.8
209	14.4	2.4	13.2	10.7	27.1	31.1	98.9
210	20.5	8.2	21.0	13.0	28.0	32.4	123.1
211	26.5	6.3	14.6	10.2	36.1	33.9	127.6
212	28.8	16.4	12.6	9.7	48.2	19.7	135.4
213	21.1	5.9	12.2	14.8	32.8	33.5	120.3
214	22.6	2.0	14.5	8.8	39.1	29.9	116.9
215	28.6	4.7	16.3	12.7	37.4	33.8	133.5
216	19.3	13.8	9.9	14.8	35.4	40.9	134.1
217	15.6	9.0	12.9	16.0	29.9	40.3	123.7
218	9.6	6.9	12.5	8.8	35.6	34.1	107.5

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Individual Gestation Body Weight and Body Weight Change

20256434

Sex: Female Day(s) Relative to Mating (Litter: A)

Control Omcg							
	Body Weight (g)	Body Weight (g)	Body Weight (g)	Body Weight (g)	Body Weight (g)	Body Weight (g)	Body Weight (g)
	0	6	9	12	15	18	21
219	246.4	268.4	278.9	293.0	305.6	349.6	382.5
220	277.0	303.5	320.0	337.5	349.2	395.7	434.9
221	283.2	308.8	317.4	336.3	354.8	401.3	444.6
222	252.8	278.6	287.4	302.2	316.1	354.3	394.8
1	214.0	222.4	233.7	248.5	261.2	293.8	331.3
2	223.7	245.8	257.8	273.0	283.3	320.2	353.0
3	239.1	258.5	273.8	280.1	296.7	331.2	372.5
4	233.2	261.7	266.4	290.4	295.3	328.5	367.1
5	210.2	235.1	242.5	253.2	268.4	301.9	340.0
6	257.9	279.7	281.5	299.5	311.0	338.5	372.6
7	270.4	291.2	298.3	315.3	330.9	360.2	401.1
8	231.4	259.2	275.6	290.8	297.9	329.6	365.0
9	250.5	270.7	282.4	291.5	302.0	333.3	371.2
10	243.1	259.5	267.1	279.0	292.7	324.1	353.4
11	243.2	255.5	262.3	273.3	289.8	322.7	360.9
12	243.2	265.2	277.6	283.4	296.1	325.7	361.1
13	236.0	249.9	261.9	272.4	285.8	313.7	348.6
14	219.2	242.1	245.6	258.4	273.2	305.0	346.1

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Individual Gestation Body Weight and Body Weight Change

20256434

Sex: Female Day(s) Relative to Mating (Litter: A)

Control Omcg							
	Body Weight Change (g)	Body Weight Change (g)	Body Weight Change (g)	Body Weight Change (g)	Body Weight Change (g)	Body Weight Change (g)	Body Weight Change (g)
	0-6	6-9	9-12	12-15	15-18	18-21	0-21
219	22.0	10.5	14.1	12.6	44.0	32.9	136.1
220	26.5	16.5	17.5	11.7	46.5	39.2	157.9
221	25.6	8.6	18.9	18.5	46.5	43.3	161.4
222	25.8	8.8	14.8	13.9	38.2	40.5	142.0
1	8.4	11.3	14.8	12.7	32.6	37.5	117.3
2	22.1	12.0	15.2	10.3	36.9	32.8	129.3
3	19.4	15.3	6.3	16.6	34.5	41.3	133.4
4	28.5	4.7	24.0	4.9	33.2	38.6	133.9
5	24.9	7.4	10.7	15.2	33.5	38.1	129.8
6	21.8	1.8	18.0	11.5	27.5	34.1	114.7
7	20.8	7.1	17.0	15.6	29.3	40.9	130.7
8	27.8	16.4	15.2	7.1	31.7	35.4	133.6
9	20.2	11.7	9.1	10.5	31.3	37.9	120.7
10	16.4	7.6	11.9	13.7	31.4	29.3	110.3
11	12.3	6.8	11.0	16.5	32.9	38.2	117.7
12	22.0	12.4	5.8	12.7	29.6	35.4	117.9
13	13.9	12.0	10.5	13.4	27.9	34.9	112.6
14	22.9	3.5	12.8	14.8	31.8	41.1	126.9

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Individual Gestation Body Weight and Body Weight Change

20256434

Sex: Female Day(s) Relative to Mating (Litter: A)

Control Omcg							
	Body Weight (g)	Body Weight (g)	Body Weight (g)	Body Weight (g)	Body Weight (g)	Body Weight (g)	Body Weight (g)
	0	6	9	12	15	18	21
15	263.0	272.3	285.1	296.1	313.2	348.5	388.3
16	240.8	254.1	265.2	275.3	290.5	322.8	348.6
17	296.4	316.6	320.9	337.8	353.9	391.3	429.2
18	275.1	293.7	302.3	318.0	331.8	364.6	398.9
19	221.7	234.2	240.0	250.9	269.0	300.4	331.3
20 NP	258.6 E ¹	279.1 E ¹	276.2 E ¹	275.2 E ¹	272.6 E ¹²	270.7 E ¹²	272.7 E ¹
21	239.0	262.4	272.6	280.8	292.7	330.3	361.8
22	259.8	277.7	287.1	300.1	315.3	352.0	394.8
Mean	241.30	261.04	269.97	283.52	296.72	331.88	365.98
SD	20.73	22.34	22.98	24.24	24.44	27.03	29.55
N	43	43	43	43	43	43	43

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Individual Gestation Body Weight and Body Weight Change

20256434

Sex: Female Day(s) Relative to Mating (Litter: A)

Control Omeg							
	Body Weight Change (g)	Body Weight Change (g)	Body Weight Change (g)	Body Weight Change (g)	Body Weight Change (g)	Body Weight Change (g)	Body Weight Change (g)
	0-6	6-9	9-12	12-15	15-18	18-21	0-21
15	9.3	12.8	11.0	17.1	35.3	39.8	125.3
16	13.3	11.1	10.1	15.2	32.3	25.8	107.8
17	20.2	4.3	16.9	16.1	37.4	37.9	132.8
18	18.6	8.6	15.7	13.8	32.8	34.3	123.8
19	12.5	5.8	10.9	18.1	31.4	30.9	109.6
20 NP	20.5 E ¹	-2.9 E ¹	-1.0 E ¹	-2.6 E ¹	-1.9 E ¹	2.0 E ¹	14.1 E ¹
21	23.4	10.2	8.2	11.9	37.6	31.5	122.8
22	17.9	9.4	13.0	15.2	36.7	42.8	135.0
Mean	19.75	8.93	13.55	13.20	35.16	34.10	124.68
SD	6.20	3.82	3.77	3.24	5.81	5.64	14.14
N	43	43	43	43	43	43	43

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Individual Gestation Body Weight and Body Weight Change

20256434

Sex: Female Day(s) Relative to Mating (Litter: A)



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Individual Gestation Body Weight and Body Weight Change

20256434

Sex: Female Day(s) Relative to Mating (Litter: A)



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Individual Gestation Body Weight and Body Weight Change

20256434

Sex: Female Day(s) Relative to Mating (Litter: A)



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Individual Gestation Body Weight and Body Weight Change

20256434

Sex: Female Day(s) Relative to Mating (Litter: A)



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Individual Gestation Body Weight and Body Weight Change

20256434

Sex: Female Day(s) Relative to Mating (Litter: A)



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Individual Gestation Body Weight and Body Weight Change

20256434

Sex: Female Day(s) Relative to Mating (Litter: A)



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Individual Gestation Body Weight and Body Weight Change

20256434

Sex: Female Day(s) Relative to Mating (Litter: A)

BNT162b2 30mcg							
	Body Weight (g)	Body Weight (g)	Body Weight (g)	Body Weight (g)	Body Weight (g)	Body Weight (g)	Body Weight (g)
	0	6	9	12	15	18	21
245	248.2	260.6	274.7	284.4	323.6	364.0	255.3
246	224.3	244.3	250.9	252.2	266.6	299.1	321.1
247	235.8	263.2	269.3	279.4	293.4	327.6	360.2
248	245.1	265.5	263.2	275.3	284.9	313.8	335.8
249	223.4	249.3	257.6	265.1	279.9	327.0	350.6
250	213.9	237.0	246.2	251.7	263.9	293.6	321.0
251	292.4	310.0	321.8	329.4	346.2	385.3	412.1
252	250.3	279.2	288.2	290.6	301.1	337.5	369.7
253	236.7	270.4	271.2	272.9	292.6	328.9	352.1
254 NP	245.2 E ¹	267.8 E ¹	278.1 E ¹	274.6 E ¹	271.1 E ¹	266.4 E ¹³	259.6 E ¹³
255	206.4	237.1	237.5	252.9	257.9	274.2	280.5
256	248.0	268.5	284.1	289.7	308.0	345.7	378.2
257	271.0	282.4	285.3	291.7	310.2	347.2	379.5
258	258.3	277.0	287.2	294.4	315.2	351.4	381.3
259	227.4	246.3	256.4	263.6	275.7	318.2	348.5
260	244.3	272.7 ¹²	281.1	282.2	299.7	339.3	369.1
261	217.8	236.8	241.8	248.4	256.4	291.4	319.3
262	249.2	268.1	279.6	285.0	284.9	341.5	365.6

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Individual Gestation Body Weight and Body Weight Change

20256434

Sex: Female Day(s) Relative to Mating (Litter: A)

BNT162b2 30mcg	Body Weight Change (g)						
	0-6	6-9	9-12	12-15	15-18	18-21	0-21
245	12.4	14.1	9.7	39.2	40.4	-108.7	7.1
246	20.0	6.6	1.3	14.4	32.5	22.0	96.8
247	27.4	6.1	10.1	14.0	34.2	32.6	124.4
248	20.4	-2.3	12.1	9.6	28.9	22.0	90.7
249	25.9	8.3	7.5	14.8	47.1	23.6	127.2
250	23.1	9.2	5.5	12.2	29.7	27.4	107.1
251	17.6	11.8	7.6	16.8	39.1	26.8	119.7
252	28.9	9.0	2.4	10.5	36.4	32.2	119.4
253	33.7	0.8	1.7	19.7	36.3	23.2	115.4
254 NP	22.6 E ¹	10.3 E ¹	-3.5 E ¹	-3.5 E ¹	-4.7 E ¹	-6.8 E ¹	14.4 E ¹
255	30.7	0.4	15.4	5.0	16.3	6.3	74.1
256	20.5	15.6	5.6	18.3	37.7	32.5	130.2
257	11.4	2.9	6.4	18.5	37.0	32.3	108.5
258	18.7	10.2	7.2	20.8	36.2	29.9	123.0
259	18.9	10.1	7.2	12.1	42.5	30.3	121.1
260	28.4	8.4	1.1	17.5	39.6	29.8	124.8
261	19.0	5.0	6.6	8.0	35.0	27.9	101.5
262	18.9	11.5	5.4	-0.1	56.6	24.1	116.4

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Individual Gestation Body Weight and Body Weight Change

20256434

Sex: Female Day(s) Relative to Mating (Litter: A)

BNT162b2 30mcg							
	Body Weight (g)	Body Weight (g)	Body Weight (g)	Body Weight (g)	Body Weight (g)	Body Weight (g)	Body Weight (g)
	0	6	9	12	15	18	21
263	227.7	243.5	257.9	261.0	278.9	312.8	323.2
264	268.4	295.2	301.6	303.5	316.3	346.3	368.7
265	250.4	270.8	284.3	285.6	304.2	343.9	364.1
266	249.8	267.2	276.3	281.1	297.4	331.1	369.7
45	236.8	256.1	266.4	262.0	282.2	316.2	348.7
46	296.3	310.6	313.9	322.3	335.0	377.9	411.1
47	228.5	246.7	258.7	264.8	273.3	306.0	335.7
48	237.7	252.1	263.2	257.7 ¹²	270.0	284.9	311.4
49	243.4	265.3	281.6	283.2 ¹²	294.1	324.2	359.0
50	220.9	235.0	243.8	246.2	253.2	276.9	300.4
51	269.8	283.5	299.2	303.5	313.2	357.2	394.2
52	232.1	253.5	268.9	273.5	292.2	334.4	368.7
53	221.5	237.5	249.9	261.0	270.0	321.1	356.8
54	237.1	257.1	269.3	279.5	290.9	315.1	356.0
55	252.0	270.5	281.8	288.6	297.2	331.9	356.8
56 NP	283.8 ^{E1}	320.2 ^{E1}	333.6 ^{E1}	338.1 ^{E1}	322.7 ^{E13}	323.3 ^{E1}	310.2 ^{E1}
57	219.7	247.4	261.1	271.0	284.3	324.1	356.3
58	240.0	263.0	273.4	275.1	288.3	324.5	343.9

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Individual Gestation Body Weight and Body Weight Change

20256434

Sex: Female Day(s) Relative to Mating (Litter: A)

BNT162b2 30mcg							
	Body Weight Change (g)	Body Weight Change (g)	Body Weight Change (g)	Body Weight Change (g)	Body Weight Change (g)	Body Weight Change (g)	Body Weight Change (g)
	0-6	6-9	9-12	12-15	15-18	18-21	0-21
263	15.8	14.4	3.1	17.9	33.9	10.4	95.5
264	26.8	6.4	1.9	12.8	30.0	22.4	100.3
265	20.4	13.5	1.3	18.6	39.7	20.2	113.7
266	17.4	9.1	4.8	16.3	33.7	38.6	119.9
45	19.3	10.3	-4.4	20.2	34.0	32.5	111.9
46	14.3	3.3	8.4	12.7	42.9	33.2	114.8
47	18.2	12.0	6.1	8.5	32.7	29.7	107.2
48	14.4	11.1	-5.5	12.3	14.9	26.5	73.7
49	21.9	16.3	1.6	10.9	30.1	34.8	115.6
50	14.1	8.8	2.4	7.0	23.7	23.5	79.5
51	13.7	15.7	4.3	9.7	44.0	37.0	124.4
52	21.4	15.4	4.6	18.7	42.2	34.3	136.6
53	16.0	12.4	11.1	9.0	51.1	35.7	135.3
54	20.0	12.2	10.2	11.4	24.2	40.9	118.9
55	18.5	11.3	6.8	8.6	34.7	24.9	104.8
56 NP	36.4 E ¹	13.4 E ¹	4.5 E ¹	-15.4 E ¹	0.6 E ¹	-13.1 E ¹	26.4 E ¹
57	27.7	13.7	9.9	13.3	39.8	32.2	136.6
58	23.0	10.4	1.7	13.2	36.2	19.4	103.9

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Individual Gestation Body Weight and Body Weight Change

20256434

Sex: Female Day(s) Relative to Mating (Litter: A)

BNT162b2 30mcg							
	Body Weight (g)	Body Weight (g)	Body Weight (g)	Body Weight (g)	Body Weight (g)	Body Weight (g)	Body Weight (g)
	0	6	9	12	15	18	21
59	250.8	269.9	281.6	291.0	304.8	339.8	359.9
60	241.3	260.3	269.3	275.0	288.8	320.9	346.4
61	242.3	263.2	271.9	277.0	300.2	332.3	368.7
62	241.1	253.2	258.9	270.8	280.2	317.1	350.0
63	223.5	247.8	260.2	265.0	275.4	304.2	329.7
64	239.1	251.1	258.7	266.9	285.1	322.5	345.0
65	254.5	272.1	277.9	283.1	298.7	337.1	374.8
66	214.3	227.8	231.8	240.0	247.6	275.8	307.3
Mean	241.23	261.16	270.42	276.13	290.04	325.33	350.15
SD	19.34	18.67	19.10	18.87	21.19	25.07	31.12
N	42	42	42	42	42	42	42
%Diff	-0.03	0.05	0.17	-2.61	-2.25	-1.97	-4.32

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Individual Gestation Body Weight and Body Weight Change

20256434

Sex: Female Day(s) Relative to Mating (Litter: A)

BNT162b2 30mcg	Body Weight Change (g)						
	0-6	6-9	9-12	12-15	15-18	18-21	0-21
59	19.1	11.7	9.4	13.8	35.0	20.1	109.1
60	19.0	9.0	5.7	13.8	32.1	25.5	105.1
61	20.9	8.7	5.1	23.2	32.1	36.4	126.4
62	12.1	5.7	11.9	9.4	36.9	32.9	108.9
63	24.3	12.4	4.8	10.4	28.8	25.5	106.2
64	12.0	7.6	8.2	18.2	37.4	22.5	105.9
65	17.6	5.8	5.2	15.6	38.4	37.7	120.3
66	13.5	4.0	8.2	7.6	28.2	31.5	93.0
Mean	19.94	9.26	5.70	13.91	35.29	24.82	108.93
SD	5.40	4.37	4.16	6.22	7.81	22.27	22.08
N	42	42	42	42	42	42	42
%Diff	0.95	3.71	-57.89	5.37	0.38	-27.20	-12.64

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Individual Gestation Body Weight and Body Weight Change

20256434

Sex: Female Day(s) Relative to Mating (Litter: A)



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Individual Gestation Body Weight and Body Weight Change

20256434

Sex: Female Day(s) Relative to Mating (Litter: A)



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Individual Gestation Body Weight and Body Weight Change

20256434

Sex: Female Day(s) Relative to Mating (Litter: A)



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Individual Gestation Body Weight and Body Weight Change

20256434

Sex: Female Day(s) Relative to Mating (Litter: A)



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Individual Gestation Body Weight and Body Weight Change

20256434

Sex: Female Day(s) Relative to Mating (Litter: A)



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Individual Gestation Body Weight and Body Weight Change

20256434

Sex: Female Day(s) Relative to Mating (Litter: A)



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Individual Lactation Body Weight and Body Weight Change

20256434

Sex: Female Day(s) Relative to Littering (Litter: A)

Control Omcg							
	Body Weight (g)	Body Weight (g)	Body Weight (g)	Body Weight (g)	Body Weight (g)	Body Weight (g)	Body Weight (g)
	0	1	4	7	10	14	17
201	-	240.7	255.0	261.8	275.7	281.4	275.6
202	-	263.1	288.0	294.2	307.1	310.7	298.7
203	-	254.1	267.4	271.7	282.0	290.7	282.0
204	-	242.8	264.6	283.8	297.3	297.2	301.9
205	-	210.4	248.2	259.0	267.3	278.2	276.8
206	-	237.0	266.2	282.0	290.5	300.4	307.9
207	-	240.1	249.6	260.4	267.4	274.6	283.5
208	344.1	243.0 ¹	263.3	271.5	280.3	284.2	285.6
209	-	231.8	244.8	255.0	268.8	270.3	264.8
210	-	275.5	295.9	306.6	322.0	321.9	325.4
211	-	259.1	271.2	279.8	291.8	293.4	292.6
212	-	231.8	275.2	288.9	297.7	305.1	298.3
213	-	261.3	280.9	293.9	300.0	307.5	301.2
214	-	219.2	252.6	269.4	280.2	283.9	285.3
215	-	305.9	315.3	319.8	328.9	335.7	326.2 ¹
216	-	278.5	301.7	310.7	319.8	326.3	326.6
217	-	260.3	283.7	296.0	292.0	300.5	310.7
218	-	273.3	288.6	291.3	303.3	306.6	304.3

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Individual Lactation Body Weight and Body Weight Change

20256434

Sex: Female Day(s) Relative to Littering (Litter: A)

Control Omcg							
	Body Weight (g)	Body Weight Change (g)	Body Weight Change (g)	Body Weight Change (g)	Body Weight Change (g)	Body Weight Change (g)	Body Weight Change (g)
	21	1-4	4-7	7-10	10-14	14-17	17-21
201	264.8	14.3	6.8	13.9	5.7	-5.8	-10.8
202	296.3	24.9	6.2	12.9	3.6	-12.0	-2.4
203	272.3	13.3	4.3	10.3	8.7	-8.7	-9.7
204	277.5 ¹	21.8	19.2	13.5	-0.1	4.7	-24.4
205	264.8	37.8	10.8	8.3	10.9	-1.4	-12.0
206	300.5	29.2	15.8	8.5	9.9	7.5	-7.4
207	260.4	9.5	10.8	7.0	7.2	8.9	-23.1
208	279.7	20.3	8.2	8.8	3.9	1.4	-5.9
209	262.0	13.0	10.2	13.8	1.5	-5.5	-2.8
210	303.5 ¹	20.4	10.7	15.4	-0.1	3.5	-21.9
211	283.1	12.1	8.6	12.0	1.6	-0.8	-9.5
212	296.5	43.4	13.7	8.8	7.4	-6.8	-1.8
213	292.4	19.6	13.0	6.1	7.5	-6.3	-8.8
214	261.8 ¹	33.4	16.8	10.8	3.7	1.4	-23.5
215	302.9	9.4	4.5	9.1	6.8	-9.5	-23.3
216	308.6	23.2	9.0	9.1	6.5	0.3	-18.0
217	297.0	23.4	12.3	-4.0	8.5	10.2	-13.7
218	301.7	15.3	2.7	12.0	3.3	-2.3	-2.6

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Individual Lactation Body Weight and Body Weight Change

20256434

Sex: Female Day(s) Relative to Littering (Litter: A)

Control 0mcg		
	Body Weight Change (g)	
	1-21	
201	24.1	
202	33.2	
203	18.2	
204	34.7	
205	54.4	
206	63.5	
207	20.3	
208	36.7	
209	30.2	
210	28.0	
211	24.0	
212	64.7	
213	31.1	
214	42.6	
215	-3.0	
216	30.1	
217	36.7	
218	28.4	

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Individual Lactation Body Weight and Body Weight Change

20256434

Sex: Female Day(s) Relative to Littering (Litter: A)

Control Omcg							
	Body Weight (g)	Body Weight (g)	Body Weight (g)	Body Weight (g)	Body Weight (g)	Body Weight (g)	Body Weight (g)
	0	1	4	7	10	14	17
219	-	242.0	284.4	292.1	307.0	322.6	312.3
220	-	306.7	329.1	334.0	340.2	341.4	336.6
221	-	331.1	345.3	353.6	356.2	361.8	359.7
222	-	267.6	291.1	303.9	299.4	322.1	322.0
Mean	344.10	257.97	280.10	289.97	298.86	305.30	303.55
SD	-	29.31	26.24	24.89	23.50	23.50	22.84
N	1	22	22	22	22	22	22

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Individual Lactation Body Weight and Body Weight Change

20256434

Sex: Female Day(s) Relative to Littering (Litter: A)

Control Omcg							
	Body Weight (g)	Body Weight Change (g)	Body Weight Change (g)	Body Weight Change (g)	Body Weight Change (g)	Body Weight Change (g)	Body Weight Change (g)
	21	1-4	4-7	7-10	10-14	14-17	17-21
219	302.4	42.4	7.7	14.9	15.6	-10.3	-9.9
220	328.1	22.4	4.9	6.2	1.2	-4.8	-8.5
221	343.4	14.2	8.3	2.6	5.6	-2.1	-16.3
222	303.2	23.5	12.8	-4.5	22.7	-0.1	-18.8
Mean	291.04	22.13	9.88	8.89	6.44	-1.75	-12.50
SD	21.86	9.92	4.27	5.32	5.28	6.22	7.56
N	22	22	22	22	22	22	22

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Individual Lactation Body Weight and Body Weight Change

20256434

Sex: Female Day(s) Relative to Littering (Litter: A)

Control 0mcg	Body Weight Change (g)	
	1-21	
219	60.4	
220	21.4	
221	12.3	
222	35.6	
Mean	33.07	
SD	16.53	
N	22	

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Individual Lactation Body Weight and Body Weight Change

20256434

Sex: Female Day(s) Relative to Littering (Litter: A)



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Individual Lactation Body Weight and Body Weight Change

20256434

Sex: Female Day(s) Relative to Littering (Litter: A)



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Individual Lactation Body Weight and Body Weight Change

20256434

Sex: Female Day(s) Relative to Littering (Litter: A)



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Individual Lactation Body Weight and Body Weight Change

20256434

Sex: Female Day(s) Relative to Littering (Litter: A)



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Individual Lactation Body Weight and Body Weight Change

20256434

Sex: Female Day(s) Relative to Littering (Litter: A)



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Individual Lactation Body Weight and Body Weight Change

20256434

Sex: Female Day(s) Relative to Littering (Litter: A)



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Individual Lactation Body Weight and Body Weight Change

20256434

Sex: Female Day(s) Relative to Littering (Litter: A)

BNT162b2 30mcg							
	Body Weight (g)	Body Weight (g)	Body Weight (g)	Body Weight (g)	Body Weight (g)	Body Weight (g)	Body Weight (g)
	0	1	4	7	10	14	17
245	-	255.3	291.2	295.7	308.9	300.4	293.8
246	-	239.4	278.2	278.7	293.5	298.5	288.5
247	-	266.4	275.0	293.2	291.4	301.3	294.6
248	-	253.0	266.4	277.7	292.1	297.5	306.3
249	-	246.5	271.1	283.2	291.9	303.4	310.1
250	-	238.4	252.6	263.2	274.2	279.1	280.0
251	-	306.7	305.8	319.2	326.1	331.1	334.8
252	-	275.2	297.2	302.9	315.5	321.1	323.9
253	-	248.8	267.4	291.9	296.3	310.4	312.0
254 NP	- E ¹	- E ¹	- E ¹	- E ¹	- E ¹	- E ¹	- E ¹
255	-	241.8	256.1	265.3	267.1	264.5	270.1
256	-	261.3	290.4	304.5	305.7	317.5	327.5
257	-	276.1	299.2	309.6	312.0	327.7	313.7
258	-	272.5	297.1	310.6	320.5	325.8	323.5
259	-	233.9	249.9	262.3	277.3	272.9	281.7
260	-	266.3	284.3	297.0	295.1	311.0	299.3
261	-	237.9	264.4	277.2	277.2	280.4	278.9
262	-	261.1	276.4	290.4	288.0	306.8	311.8

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Individual Lactation Body Weight and Body Weight Change

20256434

Sex: Female Day(s) Relative to Littering (Litter: A)

BNT162b2 30mcg							
	Body Weight (g)	Body Weight Change (g)	Body Weight Change (g)	Body Weight Change (g)	Body Weight Change (g)	Body Weight Change (g)	Body Weight Change (g)
	21	1-4	4-7	7-10	10-14	14-17	17-21
245	281.7	35.9	4.5	13.2	-8.5	-6.6	-12.1
246	291.1	38.8	0.5	14.8	5.0	-10.0	2.6
247	287.2	8.6	18.2	-1.8	9.9	-6.7	-7.4
248	293.5	13.4	11.3	14.4	5.4	8.8	-12.8
249	291.7	24.6	12.1	8.7	11.5	6.7	-18.4
250	278.4	14.2	10.6	11.0	4.9	0.9	-1.6
251	329.9	-0.9	13.4	6.9	5.0	3.7	-4.9
252	303.5	22.0	5.7	12.6	5.6	2.8	-20.4
253	296.7 ¹	18.6	24.5	4.4	14.1	1.6	-15.3
254 NP	- ^{E2}	- ^{E2}	- ^{E2}	- ^{E2}	- ^{E2}	- ^{E2}	- ^{E2}
255	263.8	14.3	9.2	1.8	-2.6	5.6	-6.3
256	307.0	29.1	14.1	1.2	11.8	10.0	-20.5
257	310.8	23.1	10.4	2.4	15.7	-14.0	-2.9
258	303.9	24.6	13.5	9.9	5.3	-2.3	-19.6
259	270.9	16.0	12.4	15.0	-4.4	8.8	-10.8
260	287.2	18.0	12.7	-1.9	15.9	-11.7	-12.1
261	273.5	26.5	12.8	0.0	3.2	-1.5	-5.4
262	295.2	15.3	14.0	-2.4	18.8	5.0	-16.6

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Individual Lactation Body Weight and Body Weight Change

20256434

Sex: Female Day(s) Relative to Littering (Litter: A)

BNT162b2 30mcg	Body Weight Change (g)	
	1-21	
245		26.4
246		51.7
247		20.8
248		40.5
249		45.2
250		40.0
251		23.2
252		28.3
253		47.9
254 NP		E ¹
255		22.0
256		45.7
257		34.7
258		31.4
259		37.0
260		20.9
261		35.6
262		34.1

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Individual Lactation Body Weight and Body Weight Change

20256434

Sex: Female Day(s) Relative to Littering (Litter: A)

BNT162b2 30mcg							
	Body Weight (g)	Body Weight (g)	Body Weight (g)	Body Weight (g)	Body Weight (g)	Body Weight (g)	Body Weight (g)
	0	1	4	7	10	14	17
263	323.2	229.1	256.9	270.9	274.0	296.2	295.1
264	-	283.1	310.0	318.0	328.9	334.2	325.3
265	-	235.0	278.3	288.4	294.9	305.1	303.6
266	-	276.8	287.5	296.6	297.0	305.2	307.9
Mean	323.20	257.36	278.83	290.31	296.55	304.29	303.92
SD	-	19.91	17.71	17.19	17.47	18.86	17.88
N	1	21	21	21	21	21	21
%Diff	-6.07	-0.24	-0.45	0.12	-0.77	-0.33	0.12

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Individual Lactation Body Weight and Body Weight Change

20256434

Sex: Female Day(s) Relative to Littering (Litter: A)

BNT162b2 30mcg							
	Body Weight (g)	Body Weight Change (g)	Body Weight Change (g)	Body Weight Change (g)	Body Weight Change (g)	Body Weight Change (g)	Body Weight Change (g)
	21	1-4	4-7	7-10	10-14	14-17	17-21
263	290.2	27.8	14.0	3.1	22.2	-1.1	-4.9
264	315.2 ¹	26.9	8.0	10.9	5.3	-8.9	-10.1
265	287.6	43.3	10.1	6.5	10.2	-1.5	-16.0
266	300.4	10.7	9.1	0.4	8.2	2.7	-7.5
Mean	293.30	21.47	11.48	6.24	7.74	-0.37	-10.62
SD	15.56	10.49	4.88	6.01	7.51	7.06	6.62
N	21	21	21	21	21	21	21
%Diff	0.78	-2.99	16.24	-29.75	20.22	-79.05	-15.08

¹ [RC:Verified value]

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Individual Lactation Body Weight and Body Weight Change

20256434

Sex: Female Day(s) Relative to Littering (Litter: A)

BNT162b2 30mcg	Body Weight Change (g)
	1-21
263	61.1
264	32.1
265	52.6
266	23.6
Mean	35.94
SD	11.57
N	21
%Diff	8.68

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Individual Lactation Body Weight and Body Weight Change

20256434

Sex: Female Day(s) Relative to Littering (Litter: A)



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Individual Lactation Body Weight and Body Weight Change

20256434

Sex: Female Day(s) Relative to Littering (Litter: A)



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Individual Lactation Body Weight and Body Weight Change

20256434



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Individual Lactation Body Weight and Body Weight Change

20256434

Sex: Female Day(s) Relative to Littering (Litter: A)



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Individual Lactation Body Weight and Body Weight Change

20256434

Sex: Female Day(s) Relative to Littering (Litter: A)



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Individual Lactation Body Weight and Body Weight Change

20256434

Sex: Female Day(s) Relative to Littering (Litter: A)



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Individual Pre-Mating Food Consumption of Females

20256434FC

Sex: Female Day(s) Relative to Start Date

Control Omcg	Day(s) Relative to Start Date			
	Food Consumption (g/animal/day)	Food Consumption (g/animal/day)	Food Consumption (g/animal/day)	Food Consumption (g/animal/day)
	1-8	8-15	15-22	1-22
201	17.1	18.6	18.5	18.1
202	17.1	18.6	18.5	18.1
203	17.1	18.6	18.5	18.1
204	17.1	18.6	18.5	18.1
205	17.1	18.6	18.5	18.1
206	17.4	19.3	17.7	18.1
207	17.4	19.3	17.7	18.1
208	17.4	19.3	17.7	18.1
209	17.4	19.3	17.7	18.1
210	17.4	19.3	17.7	18.1
211	18.3	19.9	18.4	18.9
212	18.3	19.9	18.4	18.9
213	18.3	19.9	18.4	18.9
214	18.3	19.9	18.4	18.9
215	18.3	19.9	18.4	18.9
216	17.5	20.8	19.4	19.2
217	17.5	20.8	19.4	19.2
218	17.5	20.8	19.4	19.2

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Individual Pre-Mating Food Consumption of Females

20256434FC

Sex: Female Day(s) Relative to Start Date

Control Omcg	Food Consumption (g/animal/day)			
	Food Consumption (g/animal/day)	Food Consumption (g/animal/day)	Food Consumption (g/animal/day)	Food Consumption (g/animal/day)
	1-8	8-15	15-22	1-22
219	17.5	20.8	19.4	19.2
220	20.4	22.8	20.3	21.2
221	20.4	22.8	20.3	21.2
222	20.4	22.8	20.3	21.2
1	16.5	17.2	17.0	16.9
2	16.5	17.2	17.0	16.9
3	16.5	17.2	17.0	16.9
4	16.5	17.2	17.0	16.9
5	16.5	17.2	17.0	16.9
6	20.3	17.5	18.0	18.6
7	20.3	17.5	18.0	18.6
8	20.3	17.5	18.0	18.6
9	20.3	17.5	18.0	18.6
10	20.3	17.5	18.0	18.6
11	18.6	16.6	16.3	17.2
12	18.6	16.6	16.3	17.2
13	18.6	16.6	16.3	17.2
14	18.6	16.6	16.3	17.2

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Individual Pre-Mating Food Consumption of Females

20256434FC

Sex: Female Day(s) Relative to Start Date

Control Omcg	Food Consumption (g/animal/day)			
	Food Consumption (g/animal/day)	Food Consumption (g/animal/day)	Food Consumption (g/animal/day)	Food Consumption (g/animal/day)
	1-8	8-15	15-22	1-22
15	18.6	16.6	16.3	17.2
16	19.7	17.3	17.9	18.3
17	19.7	17.3	17.9	18.3
18	19.7	17.3	17.9	18.3
19	19.7	17.3	17.9	18.3
20	20.8	19.1	18.7	19.5
21	20.8	19.1	18.7	19.5
22	20.8	19.1	18.7	19.5
Mean	18.49	18.73	18.09	18.43
SD	1.44	1.71	1.03	1.08
N	44	44	44	44

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Individual Pre-Mating Food Consumption of Females

20256434FC

Sex: Female Day(s) Relative to Start Date



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Individual Pre-Mating Food Consumption of Females

20256434FC

Sex: Female Day(s) Relative to Start Date



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Individual Pre-Mating Food Consumption of Females

20256434FC

Sex: Female Day(s) Relative to Start Date



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Individual Pre-Mating Food Consumption of Females

20256434FC

Sex: Female Day(s) Relative to Start Date

BNT162b2 30mcg	Food Consumption (g/animal/day)			
	Food Consumption (g/animal/day)	Food Consumption (g/animal/day)	Food Consumption (g/animal/day)	Food Consumption (g/animal/day)
	1-8	8-15	15-22	1-22
245	15.5	19.3	21.2	18.7
246	15.5	19.3	21.2	18.7
247	15.5	19.3	21.2	18.7
248	15.5	19.3	21.2	18.7
249	15.5	19.3	21.2	18.7
250	16.0	18.0	19.0	17.7
251	16.0	18.0	19.0	17.7
252	16.0	18.0	19.0	17.7
253	16.0	18.0	19.0	17.7
254	16.0	18.0	19.0	17.7
255	16.3	18.9	19.1	18.1
256	16.3	18.9	19.1	18.1
257	16.3	18.9	19.1	18.1
258	16.3	18.9	19.1	18.1
259	16.3	18.9	19.1	18.1
260	16.9	18.0	18.3	17.7
261	16.9	18.0	18.3	17.7
262	16.9	18.0	18.3	17.7

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Individual Pre-Mating Food Consumption of Females

20256434FC

Sex: Female Day(s) Relative to Start Date

BNT162b2 30mcg	Food Consumption (g/animal/day)			
	Food Consumption (g/animal/day)	Food Consumption (g/animal/day)	Food Consumption (g/animal/day)	Food Consumption (g/animal/day)
	1-8	8-15	15-22	1-22
263	16.9	18.0	18.3	17.7
264	19.4	20.9	20.0	20.1
265	19.4	20.9	20.0	20.1
266	19.4	20.9	20.0	20.1
45	17.9	16.6	19.5	18.0
46	17.9	16.6	19.5	18.0
47	17.9	16.6	19.5	18.0
48	17.9	16.6	19.5	18.0
49	17.9	16.6	19.5	18.0
50	15.5	16.4	18.4	16.7
51	15.5	16.4	18.4	16.7
52	15.5	16.4	18.4	16.7
53	15.5	16.4	18.4	16.7
54	15.5	16.4	18.4	16.7
55	17.5	17.8	19.9	18.4
56	17.5	17.8	19.9	18.4
57	17.5	17.8	19.9	18.4
58	17.5	17.8	19.9	18.4

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Individual Pre-Mating Food Consumption of Females

20256434FC

Sex: Female Day(s) Relative to Start Date

BNT162b2 30mcg	Food Consumption (g/animal/day)			
	Food Consumption (g/animal/day)	Food Consumption (g/animal/day)	Food Consumption (g/animal/day)	Food Consumption (g/animal/day)
	1-8	8-15	15-22	1-22
59	17.5	17.8	19.9	18.4
60	17.9	17.1	19.3	18.1
61	17.9	17.1	19.3	18.1
62	17.9	17.1	19.3	18.1
63	17.9	17.1	19.3	18.1
64	16.2	16.1	18.6	17.0
65	16.2	16.1	18.6	17.0
66	16.2	16.1	18.6	17.0
Mean	16.79	17.87	19.34	18.00
SD	1.15	1.32	0.86	0.82
N	44	44	44	44
%Diff	-9.17	-4.57	6.94	-2.34

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Individual Pre-Mating Food Consumption of Females

20256434FC

Sex: Female Day(s) Relative to Start Date



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Individual Pre-Mating Food Consumption of Females

20256434FC

Sex: Female Day(s) Relative to Start Date



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Individual Pre-Mating Food Consumption of Females

20256434FC

Sex: Female Day(s) Relative to Start Date



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Individual Gestation Food Consumption

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20256434

Sex: Female Day(s) Relative to Mating (Litter: A)

Control Omcg	Food Consumption (g/animal/day)						
	Food Consumption (g/animal/day)	Food Consumption (g/animal/day)	Food Consumption (g/animal/day)	Food Consumption (g/animal/day)	Food Consumption (g/animal/day)	Food Consumption (g/animal/day)	Food Consumption (g/animal/day)
	0-6	6-9	9-12	12-15	15-18	18-21	0-21
201	17.2	20.0	22.3	24.0	40.1	20.2	23.0
202	17.9	20.1	22.5	21.6	25.6	25.0	21.5
203	18.0	22.1	23.2	24.1	24.7	23.2	21.9
204	19.4	24.4	25.4	25.1	27.4	19.7	23.0
205	17.4	19.6	20.4	22.9	26.2	19.1	20.4
206	21.0	21.7	22.7	21.7	25.5	22.4	22.3
207	13.4	15.7	18.7	18.2	19.3	19.0	16.8
208	16.6	17.7	19.5	19.4	22.9	19.4	18.9
209	17.4	18.6	19.7	20.3	22.0	21.2	19.5
210	19.6	21.5	23.3	22.7	24.4	23.6	22.1
211	20.9	22.3	21.4	23.4	25.2	23.1	22.4
212	24.1	26.7	25.4	23.5	27.9	16.5	24.0
213	19.2	20.1	22.5	22.7	23.2	24.2	21.6
214	17.7	20.9	21.1	21.9	23.5	21.4	20.6
215	22.4	23.7	24.9	25.1	29.7	25.3	24.8
216	21.4	23.1	23.5	24.9	26.8	24.0	23.6
217	20.2	20.8	20.4	23.0	22.8	23.5	21.5
218	19.4	19.8	22.5	21.9	27.6	26.2	22.4

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Individual Gestation Food Consumption

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20256434

Sex: Female Day(s) Relative to Mating (Litter: A)

Control Omcg	Food Consumption (g/animal/day)						
	Food Consumption (g/animal/day)	Food Consumption (g/animal/day)	Food Consumption (g/animal/day)	Food Consumption (g/animal/day)	Food Consumption (g/animal/day)	Food Consumption (g/animal/day)	Food Consumption (g/animal/day)
	0-6	6-9	9-12	12-15	15-18	18-21	0-21
219	20.2	21.2	24.4	23.6	28.0	22.1	22.8
220	25.1	26.5	30.0	27.7	33.5	28.9	28.1
221	23.0	25.4	27.2	30.1	32.4	30.0	27.3
222	21.7	23.5	26.2	22.9	25.9	25.2	23.9
1	15.5	19.3	20.4	19.6	21.6	22.2	19.2
2	20.2	21.9	22.7	22.7	23.5	21.6	21.8
3	21.8	25.5	23.8	23.4	22.9	25.4	23.5
4	21.6	22.2	27.8	22.1	25.5	26.0	23.8
5	20.3	21.4	22.2	23.1	24.0	22.7	22.0
6	18.7	19.8	22.4	22.3	23.5	25.4	21.5
7	21.6	21.8	26.3	23.0	25.7	26.5	23.8
8	20.2	24.4	24.6	24.5	24.0	24.8	23.2
9	23.2	23.0	23.5	24.0	25.6	25.8	24.0
10	21.7	21.5	23.8	22.1	24.4	23.9	22.7
11	16.7	17.3	19.7	20.9	24.6	24.5	20.1
12	20.7	22.4	21.6	24.2	24.3	24.7	22.6
13	16.5	18.2	19.4	19.4	21.2	20.8	18.9
14	17.0	17.6	18.2	20.3	20.2	21.4	18.8

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Individual Gestation Food Consumption

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20256434

Sex: Female Day(s) Relative to Mating (Litter: A)

Control 0mcg	Food Consumption (g/animal/day)						
	Food Consumption (g/animal/day)	Food Consumption (g/animal/day)	Food Consumption (g/animal/day)	Food Consumption (g/animal/day)	Food Consumption (g/animal/day)	Food Consumption (g/animal/day)	Food Consumption (g/animal/day)
	0-6	6-9	9-12	12-15	15-18	18-21	0-21
15	18.9	21.5	23.1	25.2	26.5	26.9	23.0
16	17.3	20.8	21.6	22.4	23.0	22.2	20.7
17	20.5	22.9	25.7	25.1	25.7	23.1	23.3
18	23.8	25.5	26.2	25.6	25.6	23.7	24.9
19	15.7	17.2	18.9	22.3	23.3	21.6	19.3
20 NP	23.0 E ¹	22.6 E ¹	18.1 E ¹	18.2 E ¹	18.6 E ¹	19.1 E ¹	20.4 E ¹
21	23.0	25.7	24.3	24.5	25.9	23.9	24.3
22	18.6	21.7	23.6	24.2	24.1	26.4	22.4
Mean	19.69	21.56	22.95	23.06	25.33	23.41	22.24
SD	2.59	2.64	2.63	2.19	3.58	2.71	2.21
N	43	43	43	43	43	43	43

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Individual Gestation Food Consumption

20256434

Sex: Female Day(s) Relative to Mating (Litter: A)



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Individual Gestation Food Consumption

20256434

Sex: Female Day(s) Relative to Mating (Litter: A)



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Individual Gestation Food Consumption

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20256434

Sex: Female Day(s) Relative to Mating (Litter: A)



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Individual Gestation Food Consumption

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20256434

Sex: Female Day(s) Relative to Mating (Litter: A)

BNT162b2 30mcg	Food Consumption (g/animal/day)						
	Food Consumption (g/animal/day)	Food Consumption (g/animal/day)	Food Consumption (g/animal/day)	Food Consumption (g/animal/day)	Food Consumption (g/animal/day)	Food Consumption (g/animal/day)	Food Consumption (g/animal/day)
	0-6	6-9	9-12	12-15	15-18	18-21	0-21
245	22.1	22.8	17.7	25.6	23.9	.	.
246	18.5	19.0	17.3	20.8	22.9	21.7	19.8
247	24.2	25.6	21.9	25.5	26.1	24.2	24.5
248	20.8	19.3	17.6	20.0	22.3	22.2	20.4
249	21.9	22.5	20.6	22.5	26.1	20.8	22.3
250	20.7	22.9	18.8	22.7	23.5	23.8	21.9
251	22.2	25.4	24.1	21.8	24.8	23.4	23.4
252	23.2	24.2	20.4	23.5	26.4	25.7	23.8
253	21.0	20.9	17.3	22.3	27.1	21.8	21.7
254 NP	23.7 E ¹	25.9 E ¹	20.7 E ¹	20.1 E ¹	16.8 E ¹	15.2 E ¹	20.9 E ¹
255	22.3	22.8	20.3	23.3	24.8	22.0	22.5
256	22.1	26.6	23.3	24.1	26.7	24.2	24.2
257	18.9	19.3	18.9	20.8	22.7	19.1	19.8
258	19.8	23.1	17.5	24.1	27.6	24.8	22.4
259	21.0	23.1	17.3	23.5	25.8	21.0	21.8
260	22.3	22.2	18.7	21.7	25.1	21.7	22.0
261	17.3	19.4	17.2	20.5	24.9	22.8	19.9
262	21.9	24.6	19.6	22.2	27.6	24.8	23.2

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Individual Gestation Food Consumption

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20256434

Sex: Female Day(s) Relative to Mating (Litter: A)

BNT162b2 30mcg	Food Consumption (g/animal/day)						
	Food Consumption (g/animal/day)	Food Consumption (g/animal/day)	Food Consumption (g/animal/day)	Food Consumption (g/animal/day)	Food Consumption (g/animal/day)	Food Consumption (g/animal/day)	Food Consumption (g/animal/day)
	0-6	6-9	9-12	12-15	15-18	18-21	0-21
263	18.3	20.0	16.0	20.2	22.5	16.6	18.8
264	25.9	26.8	22.0	25.1	26.7	21.6	24.9
265	21.9	24.5	20.9	24.8	26.4	18.0	22.6
266	19.1	21.8	19.8	20.1	22.6	23.3	20.9
45	21.9	23.1	16.0	23.1	26.3	25.6	22.5
46	21.2	21.1	21.4	22.8	27.1	24.9	22.8
47	19.1	21.0	17.0	20.7	23.4	24.6	20.7
48	17.0	20.0	14.4	17.6	12.4	21.6	17.1
49	22.3	25.5	21.4	21.2	27.4	24.1	23.5
50	20.0	20.0	18.2	20.0	20.7	19.6	19.8
51	21.8	24.5	23.1	19.5	24.4	26.2	23.0
52	19.6	22.7	18.8	26.4	28.2	26.6	23.1
53	18.4	21.3	18.9	22.8	28.1	23.7	21.6
54	19.5	22.2	19.3	22.6	25.6	22.9	21.6
55	20.4	20.9	19.5	23.3	25.0	22.4	21.7
56 NP	28.4 E ¹	33.3 E ¹	25.5 E ¹	23.4 E ¹	18.7 E ¹	16.5 E ¹	24.9 E ¹
57	18.4	22.1	20.7	23.6	25.8	21.8	21.5
58	22.0	23.0	18.5	23.0	25.5	22.5	22.4

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Individual Gestation Food Consumption

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20256434

Sex: Female Day(s) Relative to Mating (Litter: A)

BNT162b2 30mcg	Food Consumption (g/animal/day)						
	Food Consumption (g/animal/day)	Food Consumption (g/animal/day)	Food Consumption (g/animal/day)	Food Consumption (g/animal/day)	Food Consumption (g/animal/day)	Food Consumption (g/animal/day)	Food Consumption (g/animal/day)
	0-6	6-9	9-12	12-15	15-18	18-21	0-21
59	21.8	25.4	23.5	27.4	27.6	23.4	24.4
60	19.8	21.5	19.7	22.7	25.2	22.8	21.6
61	20.4	23.0	20.8	26.8	27.3	25.8	23.5
62	16.8	18.8	16.8	18.9	22.7	19.8	18.6
63	21.1	23.5	19.6	21.9	24.6	22.7	22.1
64	19.3	19.9	19.3	21.9	22.4	21.3	20.5
65	22.3	22.0	18.7	23.2	25.7	21.3	22.2
66	17.0	17.9	16.2	18.5	21.5	22.2	18.6
Mean	20.59	22.29	19.26	22.46	24.84	22.66	21.80
SD	1.99	2.23	2.22	2.22	2.77	2.17	1.75
N	42	42	42	42	42	41	41
%Diff	4.61	3.38	-16.08	-2.59	-1.94	-3.21	-1.98

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Individual Gestation Food Consumption

20256434

Sex: Female Day(s) Relative to Mating (Litter: A)



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Individual Gestation Food Consumption

20256434

Sex: Female Day(s) Relative to Mating (Litter: A)



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Individual Gestation Food Consumption

20256434

Sex: Female Day(s) Relative to Mating (Litter: A)



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Individual Lactation Food Consumption

20256434

Sex: Female Day(s) Relative to Littering (Litter: A)

Control Omcg							
	Food Consumption (g/animal/day)	Food Consumption (g/animal/day)	Food Consumption (g/animal/day)	Food Consumption (g/animal/day)	Food Consumption (g/animal/day)	Food Consumption (g/animal/day)	Food Consumption (g/animal/day)
	1-4	4-7	7-10	10-14	14-17	17-21	1-21
201	36.0	40.6	51.4	55.4	59.4	66.9	52.6
202	31.9	38.7	48.3	55.4	60.1	63.4	50.6
203	32.2	38.6	47.7	58.2	65.0	65.2	52.2
204	38.7	44.5	53.7	59.5	65.6	69.7	56.2
205	30.6	39.6	48.5	61.2	66.9	67.0	53.5
206	39.0	40.7	51.1	59.2	67.1	69.7	55.5
207	30.8	34.6	42.6	48.6	52.5	55.0	44.8
208	26.6	36.8	46.8	52.3	60.8	58.3	47.8
209	31.2	39.3	46.0	48.3	54.9	55.0	46.4
210	36.8	45.5	57.7	61.5	67.6	82.1	59.9
211	37.1	43.0	52.1	58.7	64.4	64.4	54.1
212	38.7	40.4	50.6	61.8	63.4	68.4	55.0
213	35.1	42.9	52.0	59.0	60.5	64.7	53.3
214	38.8	46.1	51.4	55.3	62.2	66.8	54.2
215	36.2	43.0	52.8	60.1	65.8	67.4	55.2
216	41.1	45.0	53.2	62.5	70.1	70.0	57.9
217	33.3	41.5	49.8	55.1	63.7	72.7	53.8
218	33.0	35.1	47.4	55.1	57.1	64.9	49.9

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Provantis
Individual Lactation Food Consumption

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20256434

Sex: Female Day(s) Relative to Littering (Litter: A)

Control Omcg							
	Food Consumption (g/animal/day)	Food Consumption (g/animal/day)	Food Consumption (g/animal/day)	Food Consumption (g/animal/day)	Food Consumption (g/animal/day)	Food Consumption (g/animal/day)	Food Consumption (g/animal/day)
	1-4	4-7	7-10	10-14	14-17	17-21	1-21
219	38.5	44.0	56.7	63.5	65.3	68.2	57.0
220	38.6	39.2	53.5	62.9	64.5	65.8	55.1
221	45.6	51.2	59.7	70.9	72.8	76.1	63.8
222	34.2	42.3	50.3	62.2	64.1	68.5	54.8
Mean	35.64	41.48	51.06	58.48	63.35	66.81	53.79
SD	4.25	3.84	3.96	5.13	4.74	6.05	4.26
N	22	22	22	22	22	22	22

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Individual Lactation Food Consumption

20256434

Sex: Female Day(s) Relative to Littering (Litter: A)



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Individual Lactation Food Consumption

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20256434

Sex: Female Day(s) Relative to Littering (Litter: A)



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Individual Lactation Food Consumption

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20256434

Sex: Female Day(s) Relative to Littering (Litter: A)

BNT162b2 30mcg							
	Food Consumption (g/animal/day)	Food Consumption (g/animal/day)	Food Consumption (g/animal/day)	Food Consumption (g/animal/day)	Food Consumption (g/animal/day)	Food Consumption (g/animal/day)	Food Consumption (g/animal/day)
	1-4	4-7	7-10	10-14	14-17	17-21	1-21
245	46.9	46.1	54.8	62.5	63.1	71.1	58.4
246	41.9	43.9	53.6	59.8	61.4	65.4	55.2
247	36.2	50.4	55.1	63.8	67.7	70.5	58.3
248	31.2	43.0	50.4	57.5	67.1	67.7	53.8
249	41.8	40.2	51.8	59.8	66.9	73.8	56.8
250	30.5	42.4	53.7	57.0	61.9	68.6	53.4
251	35.5	41.0	50.3	63.0	66.8	73.4	56.3
252	36.8	45.7	52.4	58.5	63.8	72.0	55.9
253	35.0	48.5	51.9	59.0	57.0	61.4	52.9
254 NP	E ¹	E ¹	E ¹	E ¹	E ¹	E ¹	E ¹
255	23.0	26.1	28.0	30.4	33.5	33.9	29.5
256	36.6	46.5	57.3	66.6	72.1	70.8	59.3
257	42.5	45.0	53.2	61.9	58.9	67.8	55.9
258	42.0	47.7	58.6	64.9	71.4	70.6	60.1
259	35.8	44.9	52.8	58.8	63.5	72.9	55.9
260	41.4	45.1	50.1	60.7	62.7	71.0	56.2
261	41.7	46.2	52.4	58.7	59.9	68.7	55.5
262	30.7	42.1	49.2	64.4	67.4	72.1	55.7

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Individual Lactation Food Consumption

20256434

Sex: Female Day(s) Relative to Littering (Litter: A)

BNT162b2 30mcg	Food Consumption (g/animal/day)						
	Food Consumption (g/animal/day)	Food Consumption (g/animal/day)	Food Consumption (g/animal/day)	Food Consumption (g/animal/day)	Food Consumption (g/animal/day)	Food Consumption (g/animal/day)	Food Consumption (g/animal/day)
	1-4	4-7	7-10	10-14	14-17	17-21	1-21
263	29.0	38.3	43.9	56.4	58.0	67.1	50.1
264	41.8	46.8	56.4	61.9	67.3	65.4	57.3
265	35.3	44.3	52.3	57.6	65.3	70.2	55.1
266	35.6	42.5	49.5	58.6	61.7	67.6	53.6
Mean	36.72	43.65	51.31	59.12	62.73	67.71	54.53
SD	5.72	4.93	6.20	7.17	7.84	8.32	6.18
N	21	21	21	21	21	21	21
%Diff	3.02	5.22	0.49	1.09	-0.97	1.34	1.37

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Individual Lactation Food Consumption

20256434

Sex: Female Day(s) Relative to Littering (Litter: A)



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Individual Lactation Food Consumption

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20256434

Sex: Female Day(s) Relative to Littering (Litter: A)



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20256434
Individual Estrous Cycle Data
Before Dosing

Group 1, Control, 0 µg

Female number	Stage of cycle on day of smearing:															Mean cycle length (days)	Irregularity index	% days in estrus
	-14	-13	-12	-11	-10	-9	-8	-7	-6	-5	-4	-3	-2	-1				
1	M	M	P	E	M	D	P	E	M	M	P	E	M	D	4.0	0.0	21.4	
2	D	D	E	M	D	P	E	M	D	P	E	M	D	P	4.0	0.0	21.4	
3	M	D	P	E	M	D	P	E	M	P	P	E	M	D	4.0	0.0	21.4	
4	P	E	M	D	E	E	M	D	P	E	M	M	D	P	4.0	0.7	28.6	
5	E	M	D	P	E	M	D	PE	E	M	M	P	E	M	4.0	0.7	35.7	
6	P	E	M	D	D	E	M	D	P	E	M	D	P	M	4.0	0.0	21.4	
7	P	E	M	D	P	E	M	D	P	E	M	M	D	D	4.0	0.0	21.4	
8	P	E	M	D	P	E	M	D	P	E	M	P	P	M	4.0	0.0	21.4	
9	M	D	P	E	M	D	P	E	M	P	P	E	M	D	4.0	0.0	21.4	
10	P	E	D	M	D	E	M	D	P	E	M	D	P	D	4.0	0.0	21.4	
11	D	P	E	M	D	P	E	M	D	P	E	M	D	D	4.0	0.0	21.4	
12	P	E	M	D	P	E	M	D	P	E	M	M	P	D	4.0	0.0	21.4	
13	E	M	D	P	E	M	D	P	E	M	M	P	D	D	4.0	0.0	21.4	
14	D	P	E	M	D	E	E	M	D	E	E	M	D	D	3.5	0.4	35.7	
15	E	M	D	P	E	M	D	P	E	M	D	P	P	D	4.0	0.0	21.4	
16	E	M	D	P	E	M	D	PE	E	M	D	P	E	M	4.0	0.7	35.7	
17	P	E	D	D	E	E	M	D	E	E	M	M	P	E	4.0	0.5	42.9	
18	M	P	E	M	D	P	E	D	D	P	E	M	D	D	4.0	0.0	21.4	
19	M	M	E	M	D	P	E	D	D	P	E	M	D	D	4.0	0.0	21.4	
20	M	D	P	E	M	D	P	E	E	M	P	E	M	D	4.0	0.0	28.6	
21	D	P	E	M	D	D	E	D	D	P	E	M	M	D	4.0	0.0	21.4	
22	E	M	D	P	E	M	D	PE	E	M	D	P	E	E	4.0	0.7	42.9	

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20256434
Individual Estrous Cycle Data
Before Dosing

Group 1, Control, 0 µg

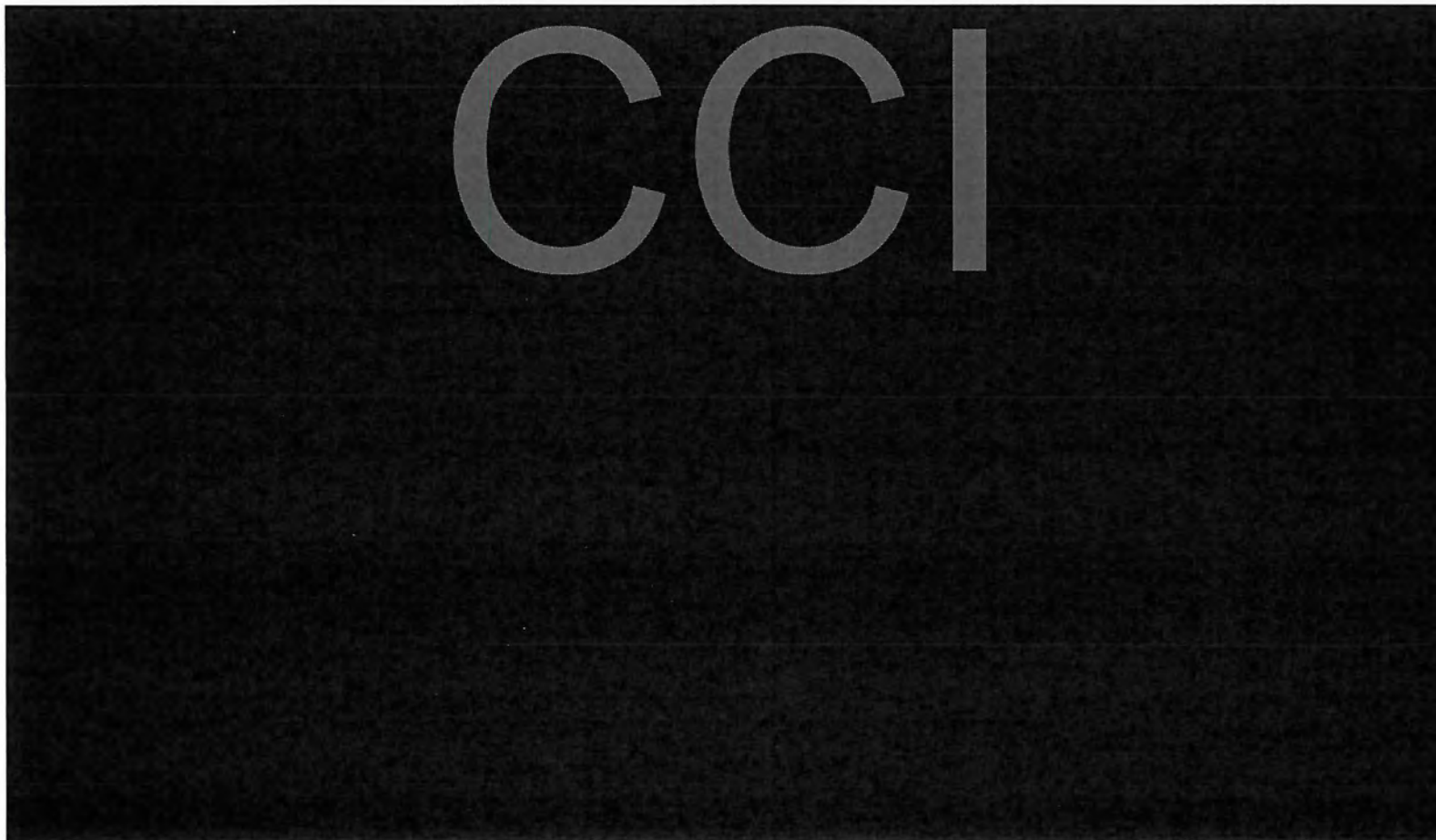
Female number	Stage of cycle on day of smearing:															Mean cycle length (days)	Irregularity index	% days in estrus
	-14	-13	-12	-11	-10	-9	-8	-7	-6	-5	-4	-3	-2	-1				
201	D	D	E	M	M	PE	E	M	M	P	E	M	M	P	4.0	0.7	28.6	
202	E	E	M	M	P	PE	E	M	D	P	E	M	M	P	5.0	0.0	35.7	
203	M	P	E	M	D	P	E	M	D	P	E	M	M	P	4.0	0.0	21.4	
204	E	M	D	P	E	M	D	P	E	M	D	P	E	M	4.0	0.0	28.6	
205	M	D	P	E	M	M	P	E	M	D	P	E	M	D	4.0	0.0	21.4	
206	E	M	D	P	E	M	D	P	E	M	D	P	E	M	4.0	0.0	28.6	
207	E	M	D	E	E	M	D	P	E	M	M	P	E	M	4.5	0.4	35.7	
208	M	M	P	E	M	D	PE	E	M	M	P	E	M	M	4.0	0.7	28.6	
209	D	P	E	M	M	PE	E	M	D	P	E	M	D	P	4.0	0.7	28.6	
210	E	M	D	P	E	M	D	P	E	M	M	P	E	M	4.0	0.0	28.6	
211	E	M	D	P	E	M	D	P	E	M	D	P	E	M	4.0	0.0	28.6	
212	P	E	M	D	P	E	M	D	P	E	M	D	P	E	4.0	0.0	28.6	
213	M	M	P	E	M	D	P	E	M	D	P	E	M	D	4.0	0.0	21.4	
214	E	M	D	P	E	M	D	P	E	M	D	P	E	M	4.0	0.0	28.6	
215	E	M	D	P	E	M	D	P	E	M	M	P	E	M	4.0	0.0	28.6	
216	M	M	P	E	M	D	P	E	M	D	P	E	M	D	4.0	0.0	21.4	
217	M	M	P	E	M	D	PE	E	M	M	P	E	M	M	4.0	0.7	28.6	
218	M	D	P	E	M	M	PE	E	M	D	P	E	M	M	4.0	0.7	28.6	
219	P	E	M	D	P	E	M	D	P	E	M	D	P	E	4.0	0.0	28.6	
220	P	E	M	D	P	E	M	D	P	E	M	D	E	E	3.7	0.3	35.7	
221	M	D	P	E	M	M	P	E	M	M	P	E	M	D	4.0	0.0	21.4	
222	D	D	E	M	M	PE	E	M	D	P	E	M	D	P	4.0	0.7	28.6	

D = di-estrus P = pro-estrus E = estrus M = met-estrus

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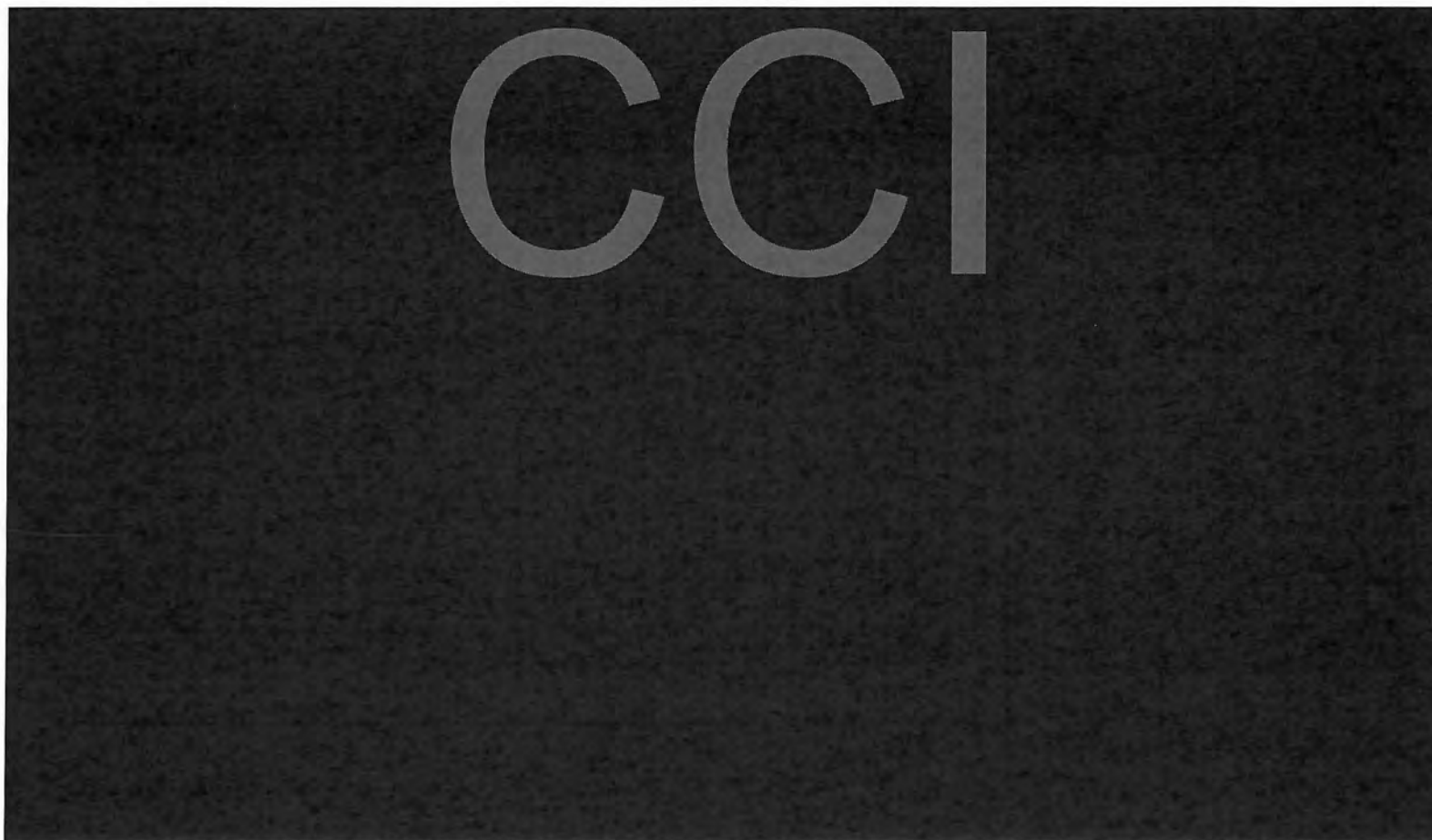
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20256434
Individual Estrous Cycle Data
Before Dosing



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20256434
Individual Estrous Cycle Data
Before Dosing



D = di-estrus P = pro-estrus E = estrus M = met-estrus

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20256434
Individual Estrous Cycle Data
Before Dosing

Group 3, BNT162b2, 30 µg

Female number	Stage of cycle on day of smearing:															Mean cycle length (days)	Irregularity index	% days in estrus
	-14	-13	-12	-11	-10	-9	-8	-7	-6	-5	-4	-3	-2	-1				
45	M	P	E	M	D	P	E	M	D	P	E	M	D	D	4.0	0.0	21.4	
46	M	P	E	M	D	E	E	M	M	P	E	M	D	D	4.0	0.7	28.6	
47	E	M	D	P	E	M	D	P	E	M	D	P	E	M	4.0	0.0	28.6	
48	M	M	P	E	M	D	P	E	M	M	P	E	M	D	4.0	0.0	21.4	
49	M	D	P	E	M	D	P	E	M	D	P	E	M	D	4.0	0.0	21.4	
50	E	M	D	P	E	M	D	D	E	M	D	D	E	M	4.0	0.0	28.6	
51	P	E	M	M	D	E	M	D	P	E	M	M	P	E	4.0	0.0	28.6	
52	M	D	P	E	M	D	P	E	M	D	P	E	M	D	4.0	0.0	21.4	
53	D	P	E	M	D	P	E	M	M	P	E	M	M	D	4.0	0.0	21.4	
54	M	P	E	M	D	E	E	M	M	P	E	M	D	D	4.0	0.7	28.6	
55	P	E	M	D	E	E	M	D	P	E	M	D	D	D	4.0	0.7	28.6	
56	P	E	M	D	E	E	M	D	P	E	M	M	D	E	4.0	0.5	35.7	
57	D	P	E	M	D	E	E	D	P	P	E	M	D	P	4.0	0.7	28.6	
58	M	D	P	E	M	D	P	E	M	D	P	E	M	D	4.0	0.0	21.4	
59	E	M	D	P	E	M	D	P	E	M	D	P	E	E	4.0	0.0	35.7	
60	P	E	M	D	D	E	M	D	P	E	M	M	D	M	4.0	0.0	21.4	
61	P	E	M	D	P	E	M	D	P	E	M	D	D	D	4.0	0.0	21.4	
62	E	M	D	P	E	M	D	P	E	M	D	P	E	M	4.0	0.0	28.6	
63	P	M	D	P	E	M	D	P	E	M	D	D	D	D	4.0	0.0	14.3	
64	D	P	E	M	D	D	P	D	D	P	E	M	D	E	Acyclic Period			
65	M	D	P	E	M	D	P	E	M	D	P	E	M	D	4.0	0.0	21.4	
66	D	P	E	M	D	P	E	M	M	P	E	M	D	D	4.0	0.0	21.4	

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20256434
Individual Estrous Cycle Data
Before Dosing

Group 3, BNT162b2, 30 µg

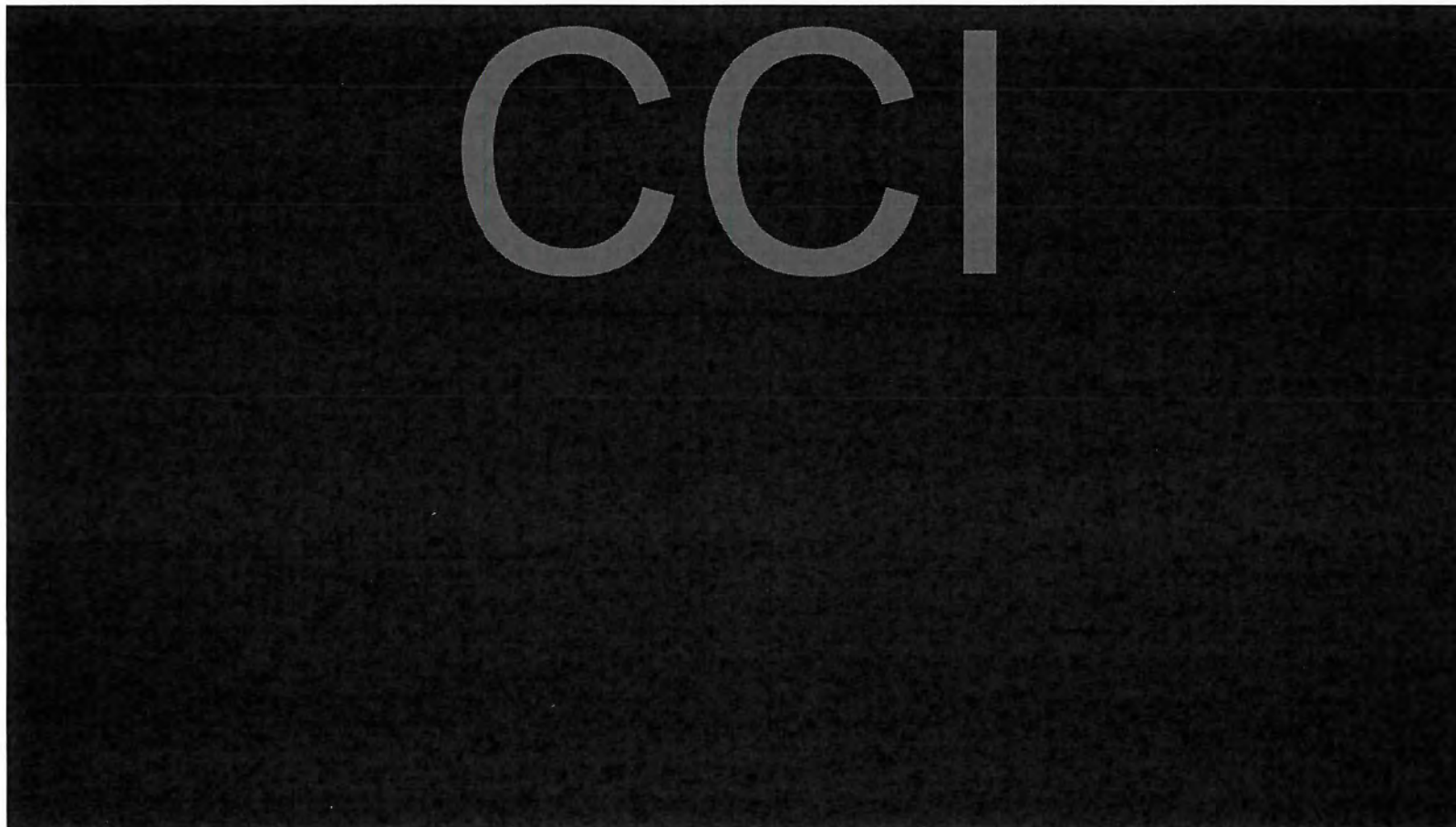
Female number	Stage of cycle on day of smearing:														Mean cycle length (days)	Irregularity index	% days in estrus
	-14	-13	-12	-11	-10	-9	-8	-7	-6	-5	-4	-3	-2	-1			
245	P	E	M	D	D	E	M	D	P	E	M	M	P	E	4.0	0.0	28.6
246	D	D	D	D	D	D	D	M	D	D	P	D	M	P	Acyclic		
247	E	M	D	E	E	M	D	P	E	M	M	P	E	M	4.5	0.4	35.7
248	E	M	D	P	E	M	D	P	E	M	D	P	E	M	4.0	0.0	28.6
249	M	M	P	E	M	D	P	E	M	D	P	E	M	D	4.0	0.0	21.4
250	P	E	M	D	P	E	M	D	P	E	M	D	E	E	3.7	0.3	35.7
251	M	P	E	M	D	PE	E	M	D	P	E	M	D	P	4.0	0.7	28.6
252	M	P	E	M	D	PE	E	M	D	P	E	M	M	P	4.0	0.7	28.6
253	E	M	D	P	E	M	D	P	E	M	M	P	E	M	4.0	0.0	28.6
254	M	M	P	E	D	D	PE	E	M	M	P	E	M	D	4.0	0.7	28.6
255	E	M	D	P	E	M	D	P	E	M	M	P	E	M	4.0	0.0	28.6
256	M	P	E	M	M	P	E	M	D	P	E	M	D	P	4.0	0.0	21.4
257	M	M	P	E	M	D	PE	E	M	D	P	E	M	D	4.0	0.7	28.6
258	M	P	E	M	M	P	E	M	D	P	E	M	D	P	4.0	0.0	21.4
259	M	M	P	E	M	M	PE	E	M	D	P	E	M	D	4.0	0.7	28.6
260	D	P	E	M	D	P	E	M	D	P	E	M	D	P	4.0	0.0	21.4
261	E	M	D	P	E	M	D	P	E	M	M	P	E	M	4.0	0.0	28.6
262	E	M	D	P	E	M	D	P	E	M	M	P	E	M	4.0	0.0	28.6
263	P	E	M	D	P	E	M	D	P	E	M	D	P	E	4.0	0.0	28.6
264	E	M	M	P	E	M	D	P	E	M	M	P	E	M	4.0	0.0	28.6
265	P	E	M	D	P	E	M	D	P	E	M	D	E	E	3.7	0.3	35.7
266	E	M	D	P	E	M	D	P	E	M	M	P	E	M	4.0	0.0	28.6

D = di-estrus P = pro-estrus E = estrus M = met-estrus

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20256434
Individual Estrous Cycle Data
Before Dosing



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20256434
Individual Estrous Cycle Data
Before Dosing



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20256434
Individual Estrous Cycle Data
Pre-Mating Period

Group 1, Control, 0 µg

Female number	Stage of cycle on day of smearing:															Mean cycle length (days)	Irregularity index	% days in estrus
	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22			
1	D	P	E	M	D	P	E	M	D	P	E	M	M	P	E	4.0	0.0	26.7
2	D	E	M	D	P	E	M	D	P	E	M	D	P	E	D	4.0	0.0	26.7
3	M	P	E	M	M	E	E	M	D	P	E	M	D	P	E	4.0	0.5	33.3
4	E	M	D	P	E	M	D	P	E	M	D	P	E	M	D	4.0	0.0	26.7
5	M	D	P	E	M	D	P	E	M	D	P	E	M	D	D	4.0	0.0	20.0
6	M	D	E	M	D	P	E	M	D	P	E	M	D	P	E	4.0	0.0	26.7
7	P	M	D	P	E	M	D	P	E	M	D	P	E	M	D	4.0	0.0	20.0
8	D	E	M	D	P	E	M	D	P	E	M	D	P	E	M	4.0	0.0	26.7
9	M	P	E	M	D	P	E	M	D	P	E	M	D	P	E	4.0	0.0	26.7
10	E	M	D	P	E	M	D	P	E	M	D	P	E	M	M	4.0	0.0	26.7
11	M	P	E	M	D	P	E	M	M	P	E	M	D	P	E	4.0	0.0	26.7
12	P	M	D	P	E	M	D	P	E	M	D	P	E	M	D	4.0	0.0	20.0
13	M	P	E	M	D	P	E	M	D	P	E	M	D	P	E	4.0	0.0	26.7
14	D	D	D	E	M	D	P	E	M	D	P	E	M	D	P	4.0	0.0	20.0
15	M	D	P	E	M	D	P	E	M	D	P	E	M	D	P	4.0	0.0	20.0
16	M	P	P	E	M	D	P	E	M	D	P	E	M	D	D	4.0	0.0	20.0
17	E	M	D	P	E	M	D	P	E	M	D	P	E	M	D	4.0	0.0	26.7
18	D	P	E	M	D	P	E	M	D	P	E	M	D	P	E	4.0	0.0	26.7
19	D	D	D	P	M	D	P	E	M	D	P	E	M	D	P	Acyclic Period		
20	M	P	E	M	D	P	E	M	D	P	E	M	D	P	E	4.0	0.0	26.7
21	D	P	P	M	D	P	E	M	D	D	E	M	D	P	E	4.0	0.0	20.0
22	E	M	D	P	E	M	D	P	E	M	D	P	E	M	D	4.0	0.0	26.7

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20256434
Individual Estrous Cycle Data
Pre-Mating Period

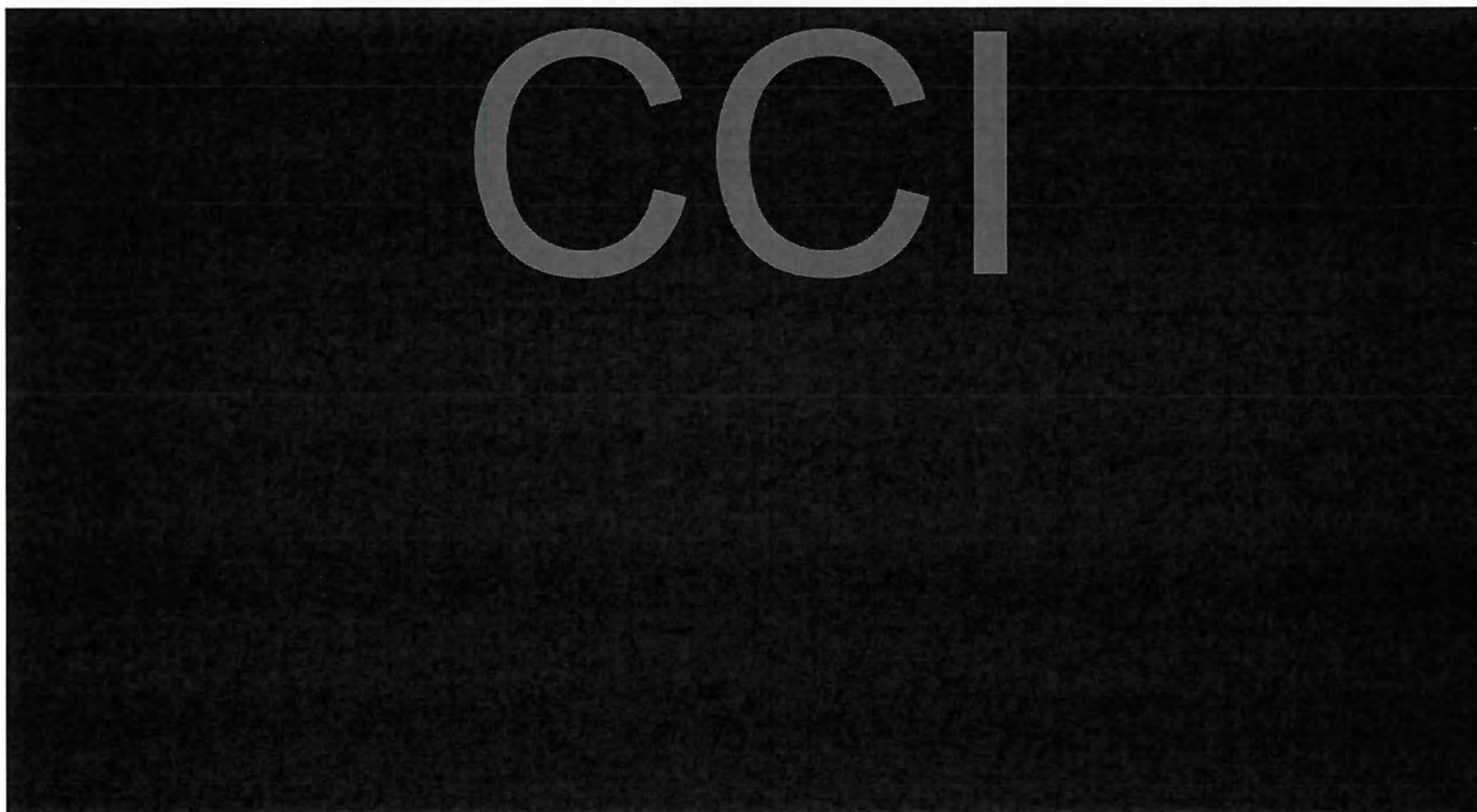
Group 1, Control, 0 µg

Female number	Stage of cycle on day of smearing:															Mean cycle length (days)	Irregularity index	% days in estrus
	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22			
201	D	E	M	D	D	D	D	D	D	D	D	D	D	D	E	Acyclic Period		
202	PE	E	M	D	P	E	M	M	P	E	M	D	P	E	M	4.0	0.0	33.3
203	P	E	M	D	P	E	M	D	P	E	M	D	P	E	M	4.0	0.0	26.7
204	D	D	P	E	M	D	P	E	M	P	P	E	M	D	P	4.0	0.0	20.0
205	D	P	E	M	D	D	M	D	D	D	D	D	D	D	D	Acyclic		
206	D	D	D	D	P	P	M	P	P	M	D	P	E	M	D	Acyclic		
207	D	D	P	E	M	D	D	D	D	D	D	D	D	D	D	Acyclic		
208	D	P	E	M	M	D	D	D	D	D	D	D	D	D	D	Acyclic		
209	PE	E	M	D	P	D	D	D	D	D	D	D	D	D	P	Acyclic		
210	PE	M	P	E	M	M	P	E	M	D	P	E	M	M	P	4.0	0.0	26.7
211	M	M	P	E	M	D	P	E	M	D	P	E	M	D	P	4.0	0.0	20.0
212	E	M	M	P	E	M	M	P	E	M	D	P	E	M	M	4.0	0.0	26.7
213	D	P	E	M	D	P	E	D	D	P	E	D	D	P	E	4.0	0.0	26.7
214	D	D	D	E	M	D	P	E	D	D	P	E	M	D	P	4.0	0.0	20.0
215	M	D	P	E	M	D	P	E	M	D	P	E	D	D	P	4.0	0.0	20.0
216	D	P	E	M	D	P	E	M	M	P	E	M	D	P	E	4.0	0.0	26.7
217	D	P	E	M	D	P	E	M	M	P	E	M	D	P	E	4.0	0.0	26.7
218	P	P	E	M	D	D	D	D	D	D	D	D	D	D	D	Acyclic		
219	E	M	D	P	E	D	D	P	E	M	D	P	E	M	M	4.0	0.0	26.7
220	E	M	M	P	E	D	D	E	E	M	D	P	E	M	D	4.0	0.7	33.3
221	D	P	E	M	D	P	E	M	D	P	E	D	D	P	E	4.0	0.0	26.7
222	P	E	M	D	P	E	M	D	P	E	M	D	P	E	M	4.0	0.0	26.7

D = di-estrus P = pro-estrus E = estrus M = met-estrus

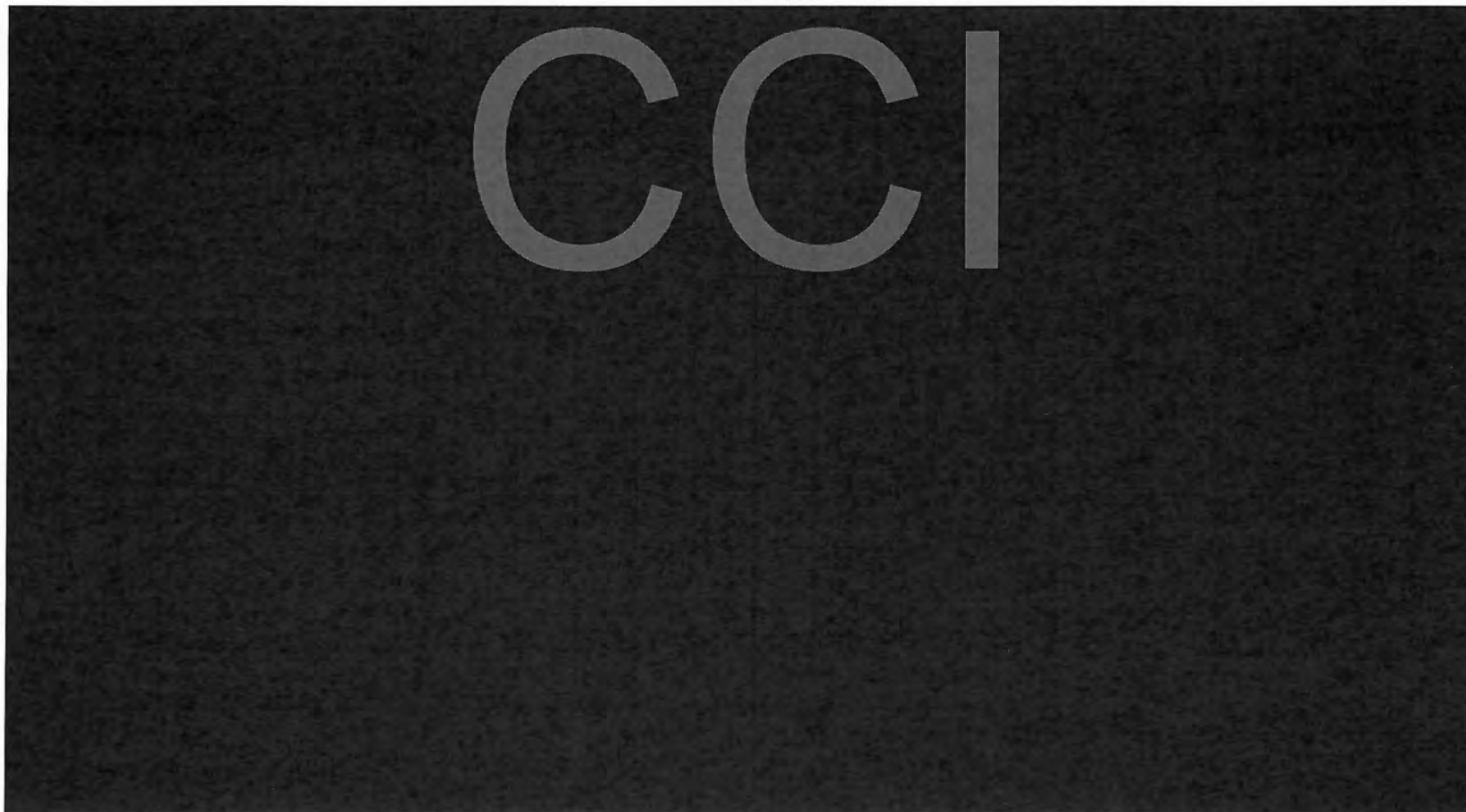
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20256434
Individual Estrous Cycle Data
Pre-Mating Period



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20256434
Individual Estrous Cycle Data
Pre-Mating Period



D = di-estrus P = pro-estrus E = estrus M = met-estrus

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20256434
Individual Estrous Cycle Data
Pre-Mating Period

Group 3, BNT162b2, 30 µg

Female number	Stage of cycle on day of smearing:															Mean cycle length (days)	Irregularity index	% days in estrus
	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22			
45	D	D	D	E	M	D	P	E	M	D	P	E	M	D	P	4.0	0.0	20.0
46	M	D	D	E	M	D	P	E	M	D	P	E	M	D	M	4.0	0.0	20.0
47	M	M	D	E	M	D	P	E	M	D	P	E	M	D	P	4.0	0.0	20.0
48	M	P	D	D	D	D	D	D	D	D	D	E	E	M	D	Acyclic		
49	M	P	E	M	M	P	E	M	D	P	E	M	D	P	E	4.0	0.0	26.7
50	M	D	P	E	M	D	P	E	M	D	P	E	M	D	M	4.0	0.0	20.0
51	E	M	D	D	D	P	E	M	D	P	E	M	D	P	E	4.0	0.0	26.7
52	M	D	D	P	E	M	D	P	E	M	D	P	E	M	D	4.0	0.0	20.0
53	P	E	M	D	D	P	E	D	D	P	E	M	D	P	E	4.3	0.3	26.7
54	M	P	E	M	D	P	E	M	D	P	E	M	D	P	E	4.0	0.0	26.7
55	P	E	M	D	P	E	M	D	P	E	M	D	P	E	M	4.0	0.0	26.7
56	P	E	M	D	P	E	E	E	E	E	M	D	P	E	E	Acyclic Period		
57	P	E	M	D	P	E	M	D	P	E	M	D	P	E	D		4.0	0.0
58	D	P	E	M	M	E	M	D	P	E	M	D	P	E	D	3.7	0.3	26.7
59	E	M	M	P	E	M	D	P	E	M	D	P	E	M	D	4.0	0.0	26.7
60	E	M	M	D	D	D	D	D	D	D	D	P	M	D	P	Acyclic		
61	D	P	P	E	M	D	P	E	M	D	P	E	M	D	P	4.0	0.0	20.0
62	M	D	D	E	M	D	P	E	M	D	D	E	M	D	D	4.0	0.0	20.0
63	M	D	P	E	M	D	P	E	M	D	P	E	M	D	P	4.0	0.0	20.0
64	P	M	D	P	E	M	D	P	E	M	D	D	E	M	D	4.0	0.0	20.0
65	P	P	E	M	D	P	E	M	D	P	E	M	D	P	E	4.0	0.0	26.7
66	D	P	M	D	D	P	E	M	D	P	E	M	D	P	E	4.0	0.0	20.0

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20256434
Individual Estrous Cycle Data
Pre-Mating Period

Group 3, BNT162b2, 30 µg

Female number	Stage of cycle on day of smearing:															Mean cycle length (days)	Irregularity index	% days in estrus
	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22			
245	E	M	D	D	P	M	D	D	D	D	D	D	D	D	M	Acyclic		
246	PE	E	M	D	D	D	D	D	D	D	D	D	D	M	D	Acyclic		
247	P	M	D	E	M	P	M	E	M	M	P	E	M	D	P	4.0	0.0	20.0
248	D	D	P	E	M	D	P	E	M	D	P	E	M	D	P	4.0	0.0	20.0
249	D	P	E	D	P	E	E	M	D	P	E	D	D	P	E	4.0	0.5	33.3
250	P	E	M	M	D	P	E	M	D	P	E	M	D	P	E	4.3	0.3	26.7
251	P	E	M	D	P	E	M	D	P	E	M	D	P	E	M	4.0	0.0	26.7
252	D	P	E	M	M	D	E	M	M	P	E	M	D	P	E	4.0	0.0	26.7
253	M	D	P	E	M	D	P	E	M	D	P	E	M	D	P	4.0	0.0	20.0
254	D	P	E	M	D	P	E	M	M	P	E	M	D	P	E	4.0	0.0	26.7
255	D	D	P	E	M	D	P	E	M	D	P	E	M	D	P	4.0	0.0	20.0
256	P	E	M	D	P	E	M	M	P	E	M	D	P	E	M	4.0	0.0	26.7
257	D	P	E	M	D	D	D	D	D	D	D	D	D	D	D	Acyclic		
258	P	E	M	D	D	D	D	D	D	D	D	D	D	D	E	Acyclic Period		
259	D	P	E	M	D	P	E	M	D	P	E	M	D	P	E	4.0	0.0	26.7
260	P	E	M	D	P	E	M	D	P	E	M	D	P	E	M	4.0	0.0	26.7
261	PE	M	P	E	M	D	P	E	M	M	D	E	D	D	P	4.0	0.0	26.7
262	D	D	D	D	E	E	M	D	P	E	M	D	P	E	M	4.5	0.4	26.7
263	E	M	D	D	P	E	M	D	P	E	M	D	P	E	M	4.0	0.0	26.7
264	D	P	P	E	M	D	P	E	M	M	P	E	M	D	P	4.0	0.0	20.0
265	E	M	D	P	E	M	D	P	E	M	M	P	E	M	D	4.0	0.0	26.7
266	D	D	D	D	D	P	M	D	P	E	M	D	P	E	D	Acyclic Period		

D = di-estrus P = pro-estrus E = estrus M = met-estrus

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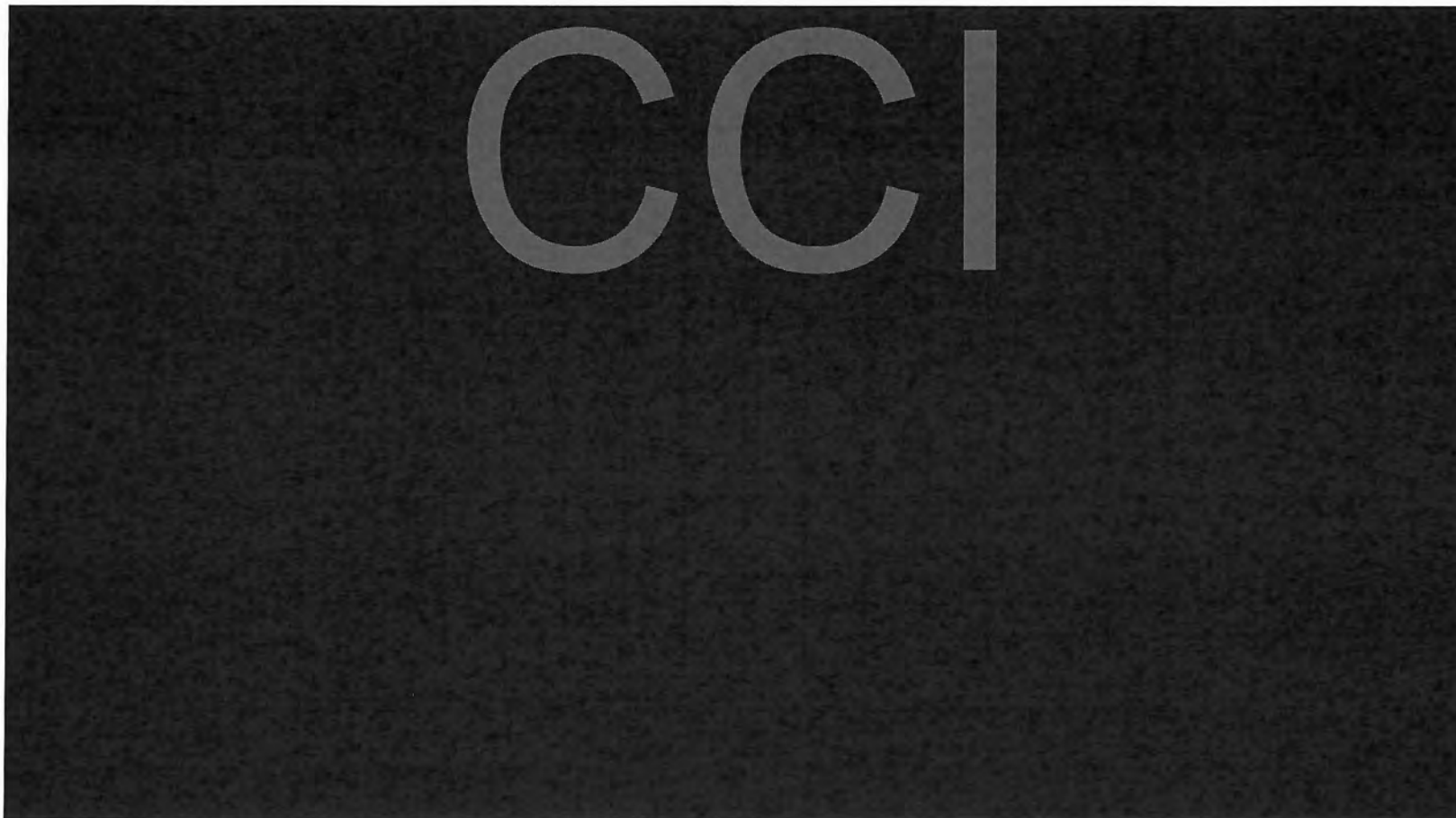
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Individual Estrous Cycle Data
Pre-Mating Period



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Individual Estrous Cycle Data
Pre-Mating Period



D = di-estrus P = pro-estrus E = estrus M = met-estrus

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Individual Estrous Cycle Data
From Mating

Group 1, Control, 0 µg

Female number	Stage of cycle on day of smearing:												
	23	24	25	26	27	28	29	30	31	32	33	34	35
1	M	D	P	E+									
2	D	P	E+										
3	M	D	P	E+									
4	P	E+											
5	E+												
6	M	D	P	E+									
7	P	E+											
8	D	P	E+										
9	M	D	P	E+									
10	P	E+											
11	M	D	P	E+									
12	D	P	E+										
13	M	D	P	E+									
14	D+												
15	D	D	D	D	D	D	D	D	D	E+			
16	E+												
17	D	D	D	D	D	D	D	D	D	D	D	P	E+
18	M	D	P	E+									
19	D+												
20	D	D	D+										
21	M	D	P	E+									
22	D	D	D+										

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Individual Estrous Cycle Data
From Mating

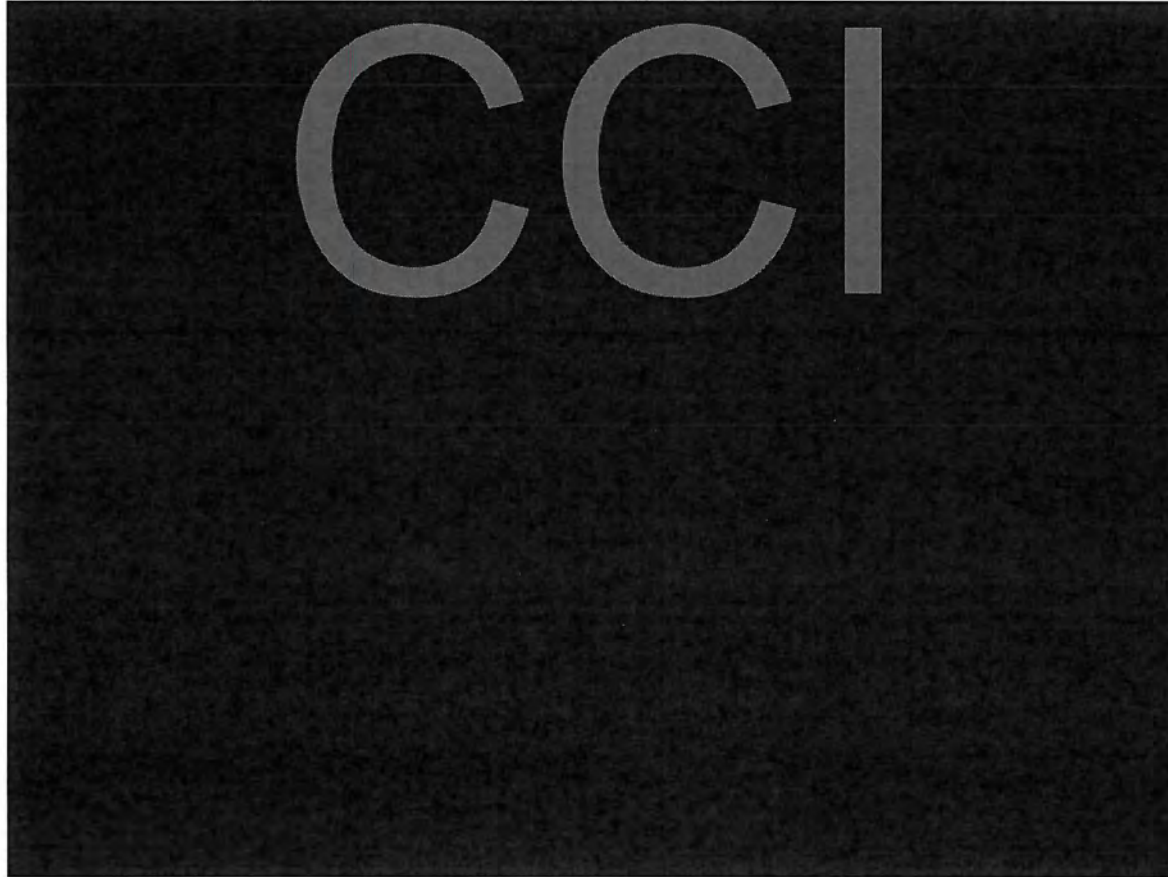
Group 1, Control, 0 µg

Female number	Stage of cycle on day of smearing:												
	23	24	25	26	27	28	29	30	31	32	33	34	35
201	M	D	P	E+									
202	D	P	E+										
203	D	P	E+										
204	E+												
205	D	E+											
206	P	E+											
207	D	D+											
208	D	D+											
209	E+												
210	E+												
211	BV+												
212	P	E+											
213	M	D	P	BV+									
214	E+												
215	E+												
216	M	D	P	E+									
217	M	D	P	E+									
218	D	D+											
219	P	E+											
220	P	E+											
221	M	D	P	E+									
222	D	P	E+										

D = di-estrus P = pro-estrus E = estrus M = met-estrus BV = vaginal plug
+: Positive

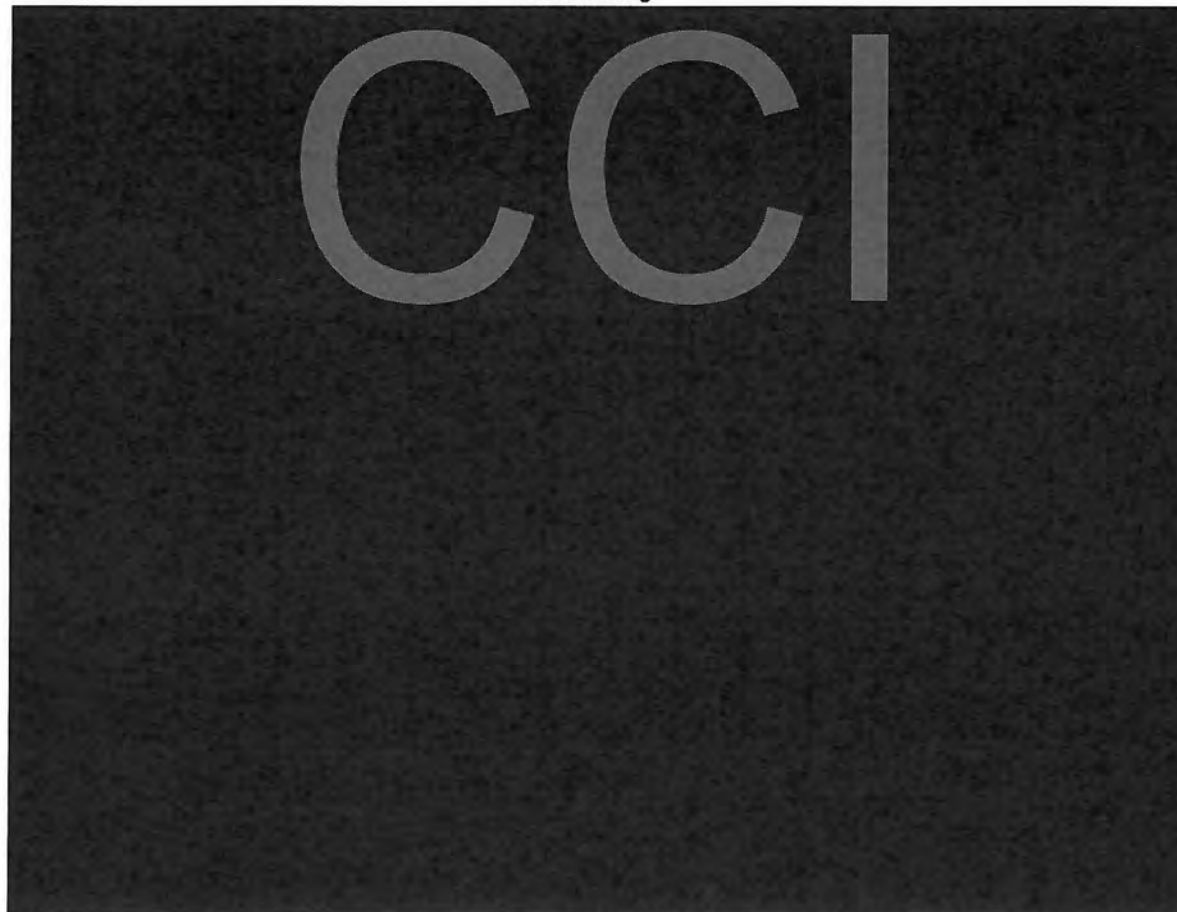
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Individual Estrous Cycle Data
From Mating



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20256434
Individual Estrous Cycle Data
From Mating



D = di-estrus P = pro-estrus E = estrus M = met-estrus BV = vaginal plug
+: Positive

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Individual Estrous Cycle Data
From Mating

Group 3, BNT162b2, 30 µg

Female number	Stage of cycle on day of smearing:									
	23	24	25	26	27	28	29	30	31	32
45	E+									
46	D	D	D	P	D	P	D	D	D	E+
47	E+									
48	P	E+								
49	M	D	P	E+						
50	D	D	BV+							
51	M	D	P	E+						
52	D	D	E+							
53	M	P	P	E+						
54	M	M	P	E+						
55	D	P	E+							
56	D+									
57	D	P	E+							
58	D	D	D+							
59	D	D	D+							
60	E+									
61	E+									
62	E+									
63	E+									
64	P	D	D+							
65	M	D	P	E+						
66	M	D	P	E+						

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Individual Estrous Cycle Data
From Mating

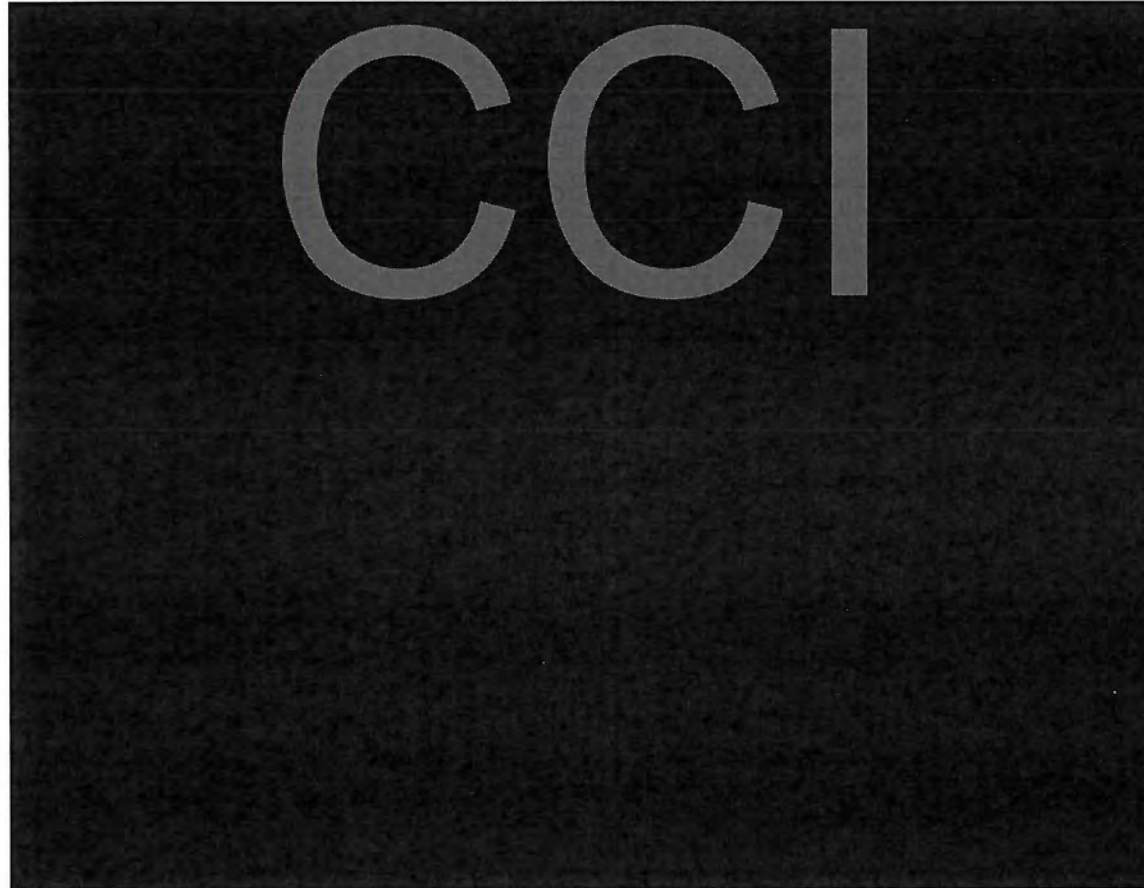
Group 3, BNT162b2, 30 µg

Female number	Stage of cycle on day of smearing:									
	23	24	25	26	27	28	29	30	31	32
245	D	D	D	D	D+					
246	P	P	E+							
247	E+									
248	E+									
249	M	D	P	E+						
250	M	D	P	E+						
251	M	P	E+							
252	M	D	P	BV+						
253	E+									
254	M	M	P	BV+						
255	E+									
256	M	P	E+							
257	D	D+								
258	M	D	P	E+						
259	M	D	P	E+						
260	D	P	E+							
261	E+									
262	D	P	E+							
263	P	P	P	M+						
264	E+									
265	D	E+								
266	D	P	E+							

D = di-estrus P = pro-estrus E = estrus M = met-estrus BV = vaginal plug
+: Positive

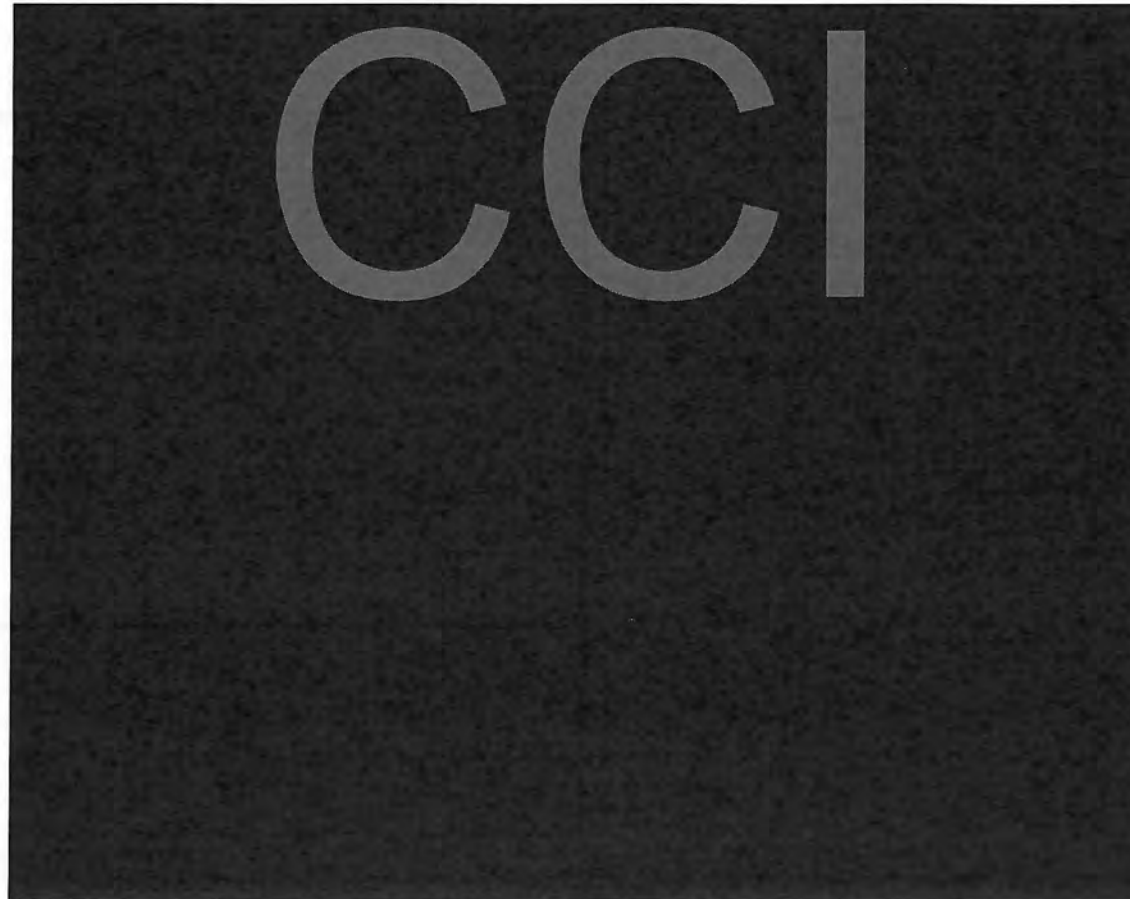
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Individual Estrous Cycle Data
From Mating



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Individual Estrous Cycle Data
From Mating



D = di-estrus P = pro-estrus E = estrus M = met-estrus BV = vaginal plug
+: Positive * Presence of blood

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Individual Mating Performance

20256434

Sex: Female Day(s) Relative to Pairing (Litter: A)

Control Omcg			
	Pairing Male	Pre-coital Interval (Days)	Pregnancy Type
	-	-	-
201	301	4	-
202	302	3	-
203	303	3	-
204	304	1	-
205	305	2	-
206	306	2	-
207	307	2	-
208	308	2	-
209	309	1	-
210	310	1	-
211	311	1	-
212	312	2	-
213	313	4	-
214	314	1	-
215	315	1	-
216	316	4	-
217	317	4	-
218	318	2	-

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Provantis
Individual Mating Performance

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Sex: Female Day(s) Relative to Pairing (Litter: A)

Control Omcg	Pairing Male	Pre-coital Interval (Days)	Pregnancy Type
	-	-	-
219	319	2	-
220	320	2	-
221	321	4	-
222	322	3	-
1	301	4	P
2	302	3	P
3	303	4	P
4	304	2	P
5	305	1	P
6	306	4	P
7	307	2	P
8	308	3	P
9	309	4	P
10	310	2	P
11	311	4	P
12	312	3	P
13	313	4	P
14	314	1	P

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Provantis
Individual Mating Performance

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Sex: Female Day(s) Relative to Pairing (Litter: A)

Control Omcg			
	Pairing Male	Pre-coital Interval (Days)	Pregnancy Type
	-	-	-
15	315	10	P
16	316	1	P
17	317	13	P
18	318	4	P
19	319	1	P
20	320	3	NP
21	321	4	P
22	322	3	P
Mean	-	3.0	-
SD	-	2.2	-
N	-	44	-

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Individual Mating Performance

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Sex: Female Day(s) Relative to Pairing (Litter: A)



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Individual Mating Performance

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Sex: Female Day(s) Relative to Pairing (Litter: A)



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Individual Mating Performance

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Sex: Female Day(s) Relative to Pairing (Litter: A)



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Individual Mating Performance

20256434

Sex: Female Day(s) Relative to Pairing (Litter: A)

BNT162b2 30mcg			
	Pairing Male	Pre-coital Interval (Days)	Pregnancy Type
	-	-	-
245	345	5	.
246	346	3	.
247	347	1	.
248	348	1	.
249	349	4	.
250	350	4	.
251	351	3	.
252	352	4	.
253	353	1	.
254	354	4	NP
255	355	1	.
256	356	3	.
257	357	2	.
258	358	4	.
259	359	4	.
260	360	3	.
261	361	1	.
262	362	3	.

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Individual Mating Performance

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Sex: Female Day(s) Relative to Pairing (Litter: A)

BNT162b2 30mcg	Pairing Male	Pre-coital Interval (Days)	Pregnancy Type
	-	-	-
263	363	4	-
264	364	1	-
265	365	2	-
266	366	3	-
45	345	1	P
46	346	10	P
47	347	1	P
48	348	2	P
49	349	4	P
50	350	3	P
51	351	4	P
52	352	3	P
53	353	4	P
54	354	4	P
55	355	3	P
56	356	1	NP
57	357	3	P
58	358	3	P

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Individual Mating Performance

20256434

Sex: Female Day(s) Relative to Pairing (Litter: A)

BNT162b2 30mcg			
	Pairing Male	Pre-coital Interval (Days)	Pregnancy Type
	-	-	-
59	359	3	P
60	360	1	P
61	361	1	P
62	362	1	P
63	363	1	P
64	364	3	P
65	365	4	P
66	366	4	P
Mean	-	2.8	-
SD	-	1.7	-
N	-	44	-

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Individual Mating Performance

20256434

Sex: Female Day(s) Relative to Pairing (Litter: A)



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Individual Mating Performance

20256434

Sex: Female Day(s) Relative to Pairing (Litter: A)



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Individual Mating Performance
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Sex: Female Day(s) Relative to Pairing (Litter: A)



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Individual Gravid Uterus Weight and Maternal Body Weight Change

20256434

Sex: Female Day(s) Relative to Mating (Litter: A)

Control Omcg							
	Gravid Uterus (g)	Necropsy BW (g)	Adjusted BW (g)	Net BWC from G6 (g)	Net BWC - Uterine Wt (g)	Mean Foetal Wt (Both) (g)	No. Live Foetuses
	G21	G21	-	G6-G21	G6-G21	G21	-
1	79.3	331.3	252.0	108.9	29.6	5.0	11
2	94.8	353.0	258.2	107.2	12.4	4.7	15
3	98.7	372.5	273.8	114.0	15.3	4.6	16
4	86.5	387.1	280.6	105.4	18.9	4.6	14
5	85.4	340.0	254.6	104.9	19.5	5.0	13
6	69.4	372.6	303.2	92.9	23.5	5.2	10
7	93.5	401.1	307.6	109.9	16.4	5.1	14
8	79.0	365.0	286.0	105.8	26.8	5.0	12
9	89.3	371.2	281.9	100.5	11.2	5.1	13
10	78.6	353.4	274.8	93.9	15.3	5.3	11
11	80.7	360.9	280.2	105.4	24.7	5.1	12
12	85.1	361.1	276.0	95.9	10.8	4.9	13
13	86.1	348.6	262.5	98.7	12.6	4.6	14
14	84.4	346.1	261.7	104.0	19.6	4.7	13
15	88.9	388.3	299.4	116.0	27.1	5.0	13
16	81.9	348.6	266.7	94.5	12.6	4.6	13
17	96.3	429.2	332.9	112.6	16.3	4.6	15
18	95.6	398.9	303.3	105.2	9.6	5.1	14

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Individual Gravid Uterus Weight and Maternal Body Weight Change

20256434

Sex: Female Day(s) Relative to Mating (Litter: A)

Control 0mg							
	Gravid Uterus (g)	Necropsy BW (g)	Adjusted BW (g)	Net BWC from G6 (g)	Net BWC - Uterine Wt (g)	Mean Foetal Wt (Both) (g)	No. Live Foetuses
	G21	G21	-	G6-G21	G6-G21	G21	-
19	77.8	331.3	253.5	97.1	19.3	5.0	12
20 NP	NRQ E ¹	272.7 E ¹	. E ¹	-6.4 E ¹	. E ¹	. E ¹	. E ¹
21	97.4	361.8	264.4	99.4	2.0	4.6	16
22	84.1	394.8	310.7	117.1	33.0	4.8	13
Mean	86.32	366.51	280.19	104.25	17.93	4.89	13.2
SD	7.69	24.72	22.08	7.27	7.54	0.23	1.6
N	21	21	21	21	21	21	21

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Individual Gravid Uterus Weight and Maternal Body Weight Change

20256434

Sex: Female Day(s) Relative to Mating (Litter: A)



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Individual Gravid Uterus Weight and Maternal Body Weight Change

20256434

Sex: Female Day(s) Relative to Mating (Litter: A)



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Individual Gravid Uterus Weight and Maternal Body Weight Change

20256434

Sex: Female Day(s) Relative to Mating (Litter: A)

BNT162b2 30mcg							
	Gravid Uterus (g)	Necropsy BW (g)	Adjusted BW (g)	Net BWC from G6 (g)	Net BWC - Uterine Wt (g)	Mean Foetal Wt (Both) (g)	No. Live Foetuses
	G21	G21	-	G6-G21	G6-G21	G21	-
45	85.1	348.7	263.6	92.6	7.5	4.7	13
46	111.3	411.1	299.8	100.5	-10.8	4.9	17
47	79.1	335.7	256.6	89.0	9.9	4.9	12
48	67.9	311.4	243.5	59.3	-8.6	4.8	10
49	80.6	359.0	278.4	93.7	13.1	4.5	13
50	60.9	300.4	239.5	65.4	4.5	4.7	9
51	104.3	394.2	289.9	110.7	6.4	5.2	15
52	94.2	368.7	274.5	115.2	21.0	5.3	13
53	99.6	356.8	257.2	119.3	19.7	4.5	16
54	90.5	356.0	265.5	98.9	8.4	5.3	13
55	88.1	356.8	268.7	86.3	-1.8	5.1	13
56 NP	NRQ E ¹	310.2 E ¹	E ¹	-10.0 E ¹	E ¹	E ¹	E ¹
57	104.5	356.3	251.8	108.9	4.4	5.0	15
58	83.2	343.9	260.7	80.9	-2.3	4.4	14
59	83.3	359.9	276.6	90.0	6.7	4.6	13
60	83.8	346.4	262.6	86.1	2.3	5.2	12
61	89.9	368.7	278.8	105.5	15.6	5.2	13
62	93.5	350.0	256.5	96.8	3.3	4.8	14

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Individual Gravid Uterus Weight and Maternal Body Weight Change

20256434

Sex: Female Day(s) Relative to Mating (Litter: A)

BNT162b2 30mcg	Gravid Uterus (g)	Necropsy BW (g)	Adjusted BW (g)	Net BWC from G6 (g)	Net BWC - Uterine Wt (g)	Mean Foetal Wt (Both) (g)	No. Live Foetuses
	G21	G21	-	G6-G21	G6-G21	G21	-
63	73.5	329.7	256.2	81.9	8.4	4.6	12
64	83.1	345.0	261.9	93.9	10.8	4.9	12
65	111.2	374.8	263.6	102.7	-8.5	4.9	17
66	73.0	307.3	234.3	79.5	6.5	5.5	10
Mean	87.65	351.47	263.82	93.20	5.55	4.90	13.1
SD	13.48	26.24	15.75	15.12	8.56	0.30	2.1
N	21	21	21	21	21	21	21
%Diff	-	-4.11	-	-	-	0.25	-

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Individual Gravid Uterus Weight and Maternal Body Weight Change

20256434

Sex: Female Day(s) Relative to Mating (Litter: A)



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Individual Gravid Uterus Weight and Maternal Body Weight Change

20256434

Sex: Female Day(s) Relative to Mating (Litter: A)



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Individual Caesarean Section Data

20256434

Sex: Female Day(s) Relative to Mating (Litter: A)

Control Omcg	No. Corpora Lutea	No. Implants	Pre- Implant Loss	Pre-Impl. Loss (%)	No. Early Resorptions	No. Late Resorptions	Dead Foetuses	Post- Implant Loss	Post- Implant Loss (%)	No. Live Foetuses	No. Male Foetuses	No. Female Foetuses	Male Foetuses (%)	Total Litter Weight (g)
	-	-	-	-	-	-	-	-	-	-	-	-	-	-
1	14	14	0	0.0	2	1	0	3	21.4	11	4	7	36.4	55.5
2	15	15	0	0.0	0	0	0	0	0.0	15	7	8	46.7	69.8
3	17	16	1	5.9	0	0	0	0	0.0	16	7	9	43.8	74.3
4	16	16	0	0.0	2	0	0	2	12.5	14	6	8	42.9	64.5
5	15	14	1	6.7	1	0	0	1	7.1	13	3	10	23.1	64.6
6	12	10	2	16.7	0	0	0	0	0.0	10	7	3	70.0	52.1
7	14	14	0	0.0	0	0	0	0	0.0	14	7	7	50.0	71.2
8	17	17	0	0.0	5	0	0	5	29.4	12	6	6	50.0	59.9
9	17	13	4	23.5	0	0	0	0	0.0	13	8	5	61.5	65.9
10	13	12	1	7.7	0	1	0	1	8.3	11	9	2	81.8	58.2
11	12	12	0	0.0	0	0	0	0	0.0	12	5	7	41.7	60.8
12	14	14	0	0.0	1	0	0	1	7.1	13	7	6	53.8	63.6
13	15	15	0	0.0	0	1	0	1	6.7	14	7	7	50.0	64.1
14	14	14	0	0.0	1	0	0	1	7.1	13	6	7	46.2	61.3
15	16	14	2	12.5	1	0	0	1	7.1	13	8	5	61.5	65.5
16	14	13	1	7.1	0	0	0	0	0.0	13	3	10	23.1	60.2
17	16	16	0	0.0	1	0	0	1	6.3	15	6	9	40.0	69.5
18	14	14	0	0.0	0	0	0	0	0.0	14	5	9	35.7	71.3

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Individual Caesarean Section Data

20256434

Sex: Female Day(s) Relative to Mating (Litter: A)

Control Omcg		Mean	Mean	Mean
		Foetal	Foetal	Foetal
		Wt (Both)	Wt (M)	Wt (F)
		(g)	(g)	(g)
		-	-	-
	1	5.0	5.1	5.0
	2	4.7	4.7	4.7
	3	4.6	4.9	4.5
	4	4.6	4.9	4.4
	5	5.0	5.1	4.9
	6	5.2	5.2	5.2
	7	5.1	5.2	5.0
	8	5.0	5.0	5.0
	9	5.1	5.2	4.9
	10	5.3	5.4	5.0
	11	5.1	5.2	5.0
	12	4.9	5.0	4.8
	13	4.6	4.5	4.6
	14	4.7	4.9	4.6
	15	5.0	5.1	5.0
	16	4.6	4.8	4.6
	17	4.6	4.8	4.5
	18	5.1	5.1	5.1

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Individual Caesarean Section Data

20256434

Sex: Female Day(s) Relative to Mating (Litter: A)

Control Omcg	No. Corpora Lutea	No. Implants	Pre- Implant Loss	Pre-Impl. Loss (%)	No. Early Resorptions	No. Late Resorptions	Dead Foetuses	Post- Implant Loss	Post- Implant Loss (%)	No. Live Foetuses	No. Male Foetuses	No. Female Foetuses	Male Foetuses (%)	Total Litter Weight (g)
	-	-	-	-	-	-	-	-	-	-	-	-	-	-
19	13	13	0	0.0	1	0	0	1	7.7	12	4	8	33.3	60.2
20 NP	0 E ¹	E ¹	E ¹	E ¹	E ¹	E ¹	E ¹	E ¹	E ¹	E ¹	E ¹	E ¹	E ¹	E ¹
21	17	16	1	5.9	0	0	0	0	0.0	16	9	7	56.3	74.2
22	14	14	0	0.0	1	0	0	1	7.1	13	5	8	38.5	62.2
Mean	14.7	14.1	0.6	4.09	0.8	0.1	0.0	0.9	6.10	13.2	6.1	7.0	46.96	64.23
SD	1.6	1.6	1.0	6.56	1.2	0.4	0.0	1.2	7.64	1.6	1.7	2.1	14.27	5.91
N	21	21	21	21	21	21	21	21	21	21	21	21	21	21
Sum	309	296	13	-	16	3	0	19	-	277	129	148	-	-

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Individual Caesarean Section Data

20256434

Sex: Female Day(s) Relative to Mating (Litter: A)

Control 0mcg			
	Mean Foetal Wt (Both) (g)	Mean Foetal Wt (M) (g)	Mean Foetal Wt (F) (g)
	-	-	-
19	5.0	5.2	4.9
20 NP	. E ¹	. E ¹	. E ¹
21	4.6	4.8	4.4
22	4.8	4.9	4.7
Mean	4.89	5.00	4.79
SD	0.23	0.21	0.24
N	21	21	21
Sum	.	.	.

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Individual Caesarean Section Data

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Sex: Female Day(s) Relative to Mating (Litter: A)



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Individual Caesarean Section Data

20256434

Sex: Female Day(s) Relative to Mating (Litter: A)



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Individual Caesarean Section Data

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Sex: Female Day(s) Relative to Mating (Litter: A)



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Individual Caesarean Section Data

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Sex: Female Day(s) Relative to Mating (Litter: A)



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Individual Caesarean Section Data

20256434

Sex: Female Day(s) Relative to Mating (Litter: A)

BNT162b2 30mcg	No. Corpora Lutea	No. Implants	Pre- Implant Loss	Pre-Impl. Loss (%)	No. Early Resorptions	No. Late Resorptions	Dead Foetuses	Post- Implant Loss	Post- Implant Loss (%)	No. Live Foetuses	No. Male Foetuses	No. Female Foetuses	Male Foetuses (%)	Total Litter Weight (g)
	-	-	-	-	-	-	-	-	-	-	-	-	-	-
45	16	14	2	12.5	1	0	0	1	7.1	13	6	7	46.2	61.3
46	18	17	1	5.6	0	0	0	0	0.0	17	10	7	58.8	82.7
47	16	12	4	25.0	0	0	0	0	0.0	12	6	6	50.0	59.1
48	12	10	2	16.7	0	0	0	0	0.0	10	5	5	50.0	48.5
49	20	17	3	15.0	4	0	0	4	23.5	13	7	6	53.8	58.0
50	14	10	4	28.6	1	0	0	1	10.0	9	5	4	55.6	42.3
51	16	15	1	6.3	0	0	0	0	0.0	15	10	5	66.7	78.2
52	16	15	1	6.3	2	0	0	2	13.3	13	6	7	46.2	68.4
53	20	16	4	20.0	0	0	0	0	0.0	16	9	7	56.3	71.2
54	15	14	1	6.7	1	0	0	1	7.1	13	9	4	69.2	68.5
55	15	14	1	6.7	1	0	0	1	7.1	13	5	8	38.5	66.8
56 NP	0 E ¹	E ¹	E ¹	E ¹	E ¹	E ¹	E ¹	E ¹	E ¹	E ¹	E ¹	E ¹	E ¹	E ¹
57	15	15	0	0.0	0	0	0	0	0.0	15	8	7	53.3	75.6
58	16	16	0	0.0	1	1	0	2	12.5	14	8	6	57.1	61.9
59	17	16	1	5.9	1	2	0	3	18.8	13	3	10	23.1	59.5
60	14	12	2	14.3	0	0	0	0	0.0	12	7	5	58.3	62.1
61	14	13	1	7.1	0	0	0	0	0.0	13	6	7	46.2	67.9
62	15	14	1	6.7	0	0	0	0	0.0	14	9	5	64.3	67.6

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Individual Caesarean Section Data

20256434

Sex: Female Day(s) Relative to Mating (Litter: A)

BNT162b2 30mcg			
	Mean Foetal Wt (Both) (g)	Mean Foetal Wt (M) (g)	Mean Foetal Wt (F) (g)
	-	-	-
45	4.7	4.8	4.6
46	4.9	4.9	4.8
47	4.9	5.1	4.8
48	4.8	4.9	4.8
49	4.5	4.5	4.4
50	4.7	5.0	4.4
51	5.2	5.3	5.1
52	5.3	5.4	5.2
53	4.5	4.6	4.2
54	5.3	5.3	5.2
55	5.1	5.4	5.0
56 NP	E ¹	E ¹	E ¹
57	5.0	5.1	5.0
58	4.4	4.5	4.3
59	4.6	4.7	4.6
60	5.2	5.3	5.0
61	5.2	5.4	5.1
62	4.8	4.9	4.7

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Individual Caesarean Section Data

20256434

Sex: Female Day(s) Relative to Mating (Litter: A)

BNT162b2 30mcg	No. Corpora Lutea	No. Implants	Pre- Implant Loss	Pre-Impl. Loss (%)	No. Early Resorptions	No. Late Resorptions	Dead Foetuses	Post- Implant Loss	Post- Implant Loss (%)	No. Live Foetuses	No. Male Foetuses	No. Female Foetuses	Male Foetuses (%)	Total Litter Weight (g)
	-	-	-	-	-	-	-	-	-	-	-	-	-	-
63	12	12	0	0.0	0	0	0	0	0.0	12	5	7	41.7	54.7
64	15	14	1	6.7	1	1	0	2	14.3	12	5	7	41.7	58.5
65	17	17	0	0.0	0	0	0	0	0.0	17	8	9	47.1	83.8
66	13	11	2	15.4	1	0	0	1	9.1	10	4	6	40.0	54.6
Mean	15.5	14.0	1.5	9.77	0.7	0.2	0.0	0.9	5.85	13.1	6.7	6.4	50.66	64.32
SD	2.1	2.2	1.3	8.09	1.0	0.5	0.0	1.2	7.28	2.1	2.0	1.5	10.69	10.53
N	21	21	21	21	21	21	21	21	21	21	21	21	21	21
Sum	326	294	32	-	14	4	0	18	-	276	141	135	-	-

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Individual Caesarean Section Data

20256434

Sex: Female Day(s) Relative to Mating (Litter: A)

BNT162b2 30mcg	Mean	Mean	Mean
	Foetal	Foetal	Foetal
	Wt (Both)	Wt (M)	Wt (F)
	(g)	(g)	(g)
	-	-	-
63	4.6	4.8	4.4
64	4.9	5.0	4.8
65	4.9	5.1	4.8
66	5.5	5.5	5.4
Mean	4.90	5.02	4.77
SD	0.30	0.30	0.32
N	21	21	21
Sum	.	.	.

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Individual Caesarean Section Data

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Sex: Female Day(s) Relative to Mating (Litter: A)



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Individual Caesarean Section Data
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Sex: Female Day(s) Relative to Mating (Litter: A)



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Individual Caesarean Section Data

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Sex: Female Day(s) Relative to Mating (Litter: A)



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Individual Caesarean Section Data

20256434

Sex: Female Day(s) Relative to Mating (Litter: A)



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Individual Foetal Weight and Status

20256434

Control Omeg

Dam	Meas.	Mean/ Count	← Left Horn — Cervix Indicator [I] — Right Horn →																	
			1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18
1	FPOS		L01	L02	L03	L04	L05	L06	L07	L08	/R06	R05	R04	R03	R02	R01	-	-	-	-
	Status		A	A	A	E	A	A	A	E	/A	L	A	A	A	A	-	-	-	-
	Sex		F	M	F	.	F	M	M	.	/F	.	F	M	F	F
	Wt (g)	5.04	4.82	5.23	5.03	-	5.05	5.25	5.14	-	/4.97	-	5.13	4.93	5.06	4.84	-	-	-	-
2	FPOS		L01	L02	L03	L04	L05	L06	L07	/R08	R07	R06	R05	R04	R03	R02	R01	-	-	-
	Status		A	A	A	A	A	A	A	/A	A	A	A	A	A	A	A	-	-	-
	Sex		M	F	F	F	F	F	M	/M	F	M	M	M	M	F	F	.	.	.
	Wt (g)	4.86	4.79	4.52	4.91	4.39	5.02	4.65	5.03	/4.70	4.79	4.79	4.32	4.91	4.05	4.67	4.30	-	-	-
3	FPOS		L01	L02	L03	L04	L05	L06	L07	/R09	R08	R07	R06	R05	R04	R03	R02	R01	-	-
	Status		A	A	A	A	A	A	A	/A	A	A	A	A	A	A	A	A	-	-
	Sex		M	M	F	F	M	M	F	/F	F	F	F	M	F	M	F	M	.	.
	Wt (g)	4.64	4.51	4.93	4.75	4.36	5.12	4.76	5.03	/4.80	4.48	4.63	4.22	5.13	3.36	4.64	4.64	4.90	-	-
4	FPOS		L01	L02	L03	L04	L05	L06	L07	/R09	R08	R07	R06	R05	R04	R03	R02	R01	-	-
	Status		A	A	A	A	A	A	A	/A	E	A	E	A	A	A	A	A	-	-
	Sex		M	M	F	F	F	M	F	/M	.	F	.	M	M	F	F	F	.	.
	Wt (g)	4.81	4.81	4.05	4.72	4.45	4.47	4.80	4.50	/5.12	-	3.60	-	4.90	5.67	3.33	5.39	4.71	-	-
5	FPOS		L01	L02	L03	L04	L05	L06	L07	L08	/R06	R05	R04	R03	R02	R01	-	-	-	-
	Status		E	A	A	A	A	A	A	A	/A	A	A	A	A	A	-	-	-	-
	Sex		.	F	F	F	F	F	M	F	/F	F	M	F	M	F	-	-	-	-
	Wt (g)	4.97	-	5.16	4.93	4.84	4.95	4.83	5.01	5.03	/4.96	4.97	4.82	5.18	5.41	4.53	-	-	-	-

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Dam	Meas.	Mean/ Count	← Left Horn — Cervix Indicator [/] — Right Horn →																	
			1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18
6	FPOS		L01	L02	L03	L04	L05	L06	/R04	R03	R02	R01	-	-	-	-	-	-	-	-
	Status		A	A	A	A	A	A	/A	A	A	A	-	-	-	-	-	-	-	-
	Sex		M	M	M	M	M	F	/M	F	M	F	-	-	-	-	-	-	-	-
	Wt (g)	5.21	3.42	5.09	5.45	5.58	5.64	5.61	/5.61	4.46	5.89	5.39	-	-	-	-	-	-	-	-
7	FPOS		L01	L02	L03	L04	L05	L06	L07	L08	L09	/R05	R04	R03	R02	R01	-	-	-	-
	Status		A	A	A	A	A	A	A	A	A	/A	A	A	A	A	-	-	-	-
	Sex		F	M	F	F	F	M	M	F	M	/F	M	M	M	F	-	-	-	-
	Wt (g)	5.09	5.23	5.04	4.76	4.85	5.14	5.12	4.84	4.95	5.44	/5.33	5.50	5.32	5.13	4.59	-	-	-	-
8	FPOS		L01	L02	L03	L04	L05	L06	L07	L08	L09	/R08	R07	R06	R05	R04	R03	R02	R01	-
	Status		A	A	E	A	A	E	A	A	A	/E	A	A	E	E	A	A	A	-
	Sex		M	M	-	F	F	-	M	M	F	-	/F	M	-	-	F	M	F	-
	Wt (g)	4.99	4.66	4.87	-	4.97	5.11	-	4.43	5.48	5.12	-	/4.96	5.20	-	-	4.91	5.53	4.64	-
9	FPOS		L01	L02	L03	L04	L05	L06	/R07	R06	R05	R04	R03	R02	R01	-	-	-	-	-
	Status		A	A	A	A	A	A	/A	A	A	A	A	A	A	-	-	-	-	-
	Sex		F	M	F	M	F	M	/M	M	M	M	M	F	F	-	-	-	-	-
	Wt (g)	5.07	4.75	4.92	4.39	5.25	5.24	5.42	/5.48	5.28	5.07	4.69	5.27	4.74	5.36	-	-	-	-	-
10	FPOS		L01	L02	L03	L04	L05	L06	L07	/R05	R04	R03	R02	R01	-	-	-	-	-	-
	Status		A	A	A	A	L	A	A	/A	A	A	A	A	-	-	-	-	-	-
	Sex		M	M	M	M	-	M	M	/M	M	M	F	F	-	-	-	-	-	-
	Wt (g)	5.29	5.27	5.14	5.45	5.43	-	5.74	5.65	/5.26	5.15	5.08	5.16	4.89	-	-	-	-	-	-

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Control Omcg																				
Dam	Meas.	Mean/ Count	← Left Horn — Cervix Indicator [I] — Right Horn →																	
			1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18
11	FPOS	5.07	L01	L02	L03	L04	L05	L06	L07	L08	/R04	R03	R02	R01	-	-	-	-	-	-
	Status		A	A	A	A	A	A	A	A	/A	A	A	A	-	-	-	-	-	-
	Sex		M	M	F	F	F	F	M	F	/M	F	F	M	-	-	-	-	-	-
	Wt (g)		4.88	4.89	4.29	4.96	5.27	4.88	5.44	5.27	/5.12	5.08	5.29	5.45	-	-	-	-	-	-
12	FPOS	4.90	L01	L02	L03	L04	L05	/R09	R08	R07	R06	R05	R04	R03	R02	R01	-	-	-	-
	Status		A	A	A	E	A	/A	A	A	A	A	A	A	A	A	-	-	-	-
	Sex		F	M	M	-	M	/F	F	M	M	F	M	F	M	F	-	-	-	-
	Wt (g)		4.95	5.12	4.78	-	5.25	/4.51	4.77	4.97	4.93	4.87	5.01	5.01	5.08	4.39	-	-	-	-
13	FPOS	4.58	L01	L02	L03	L04	L05	L06	L07	L08	L09	L10	L11	/R04	R03	R02	R01	-	-	-
	Status		A	A	A	A	A	A	L	A	A	A	A	/A	A	A	A	-	-	-
	Sex		F	F	M	M	F	M	-	M	F	M	F	/M	M	F	F	-	-	-
	Wt (g)		4.29	4.40	4.09	3.80	4.75	5.01	-	4.85	4.81	4.62	4.43	/4.21	5.03	5.10	4.66	-	-	-
14	FPOS	4.71	L01	L02	L03	L04	L05	L06	L07	/R07	R06	R05	R04	R03	R02	R01	-	-	-	-
	Status		A	A	A	A	A	E	A	/A	A	A	A	A	A	A	-	-	-	-
	Sex		M	F	M	M	F	-	M	/M	F	F	M	F	F	F	-	-	-	-
	Wt (g)		5.06	4.55	5.15	5.09	4.54	-	4.25	/4.93	4.54	4.92	4.80	4.44	4.69	4.30	-	-	-	-
15	FPOS	5.04	L01	L02	L03	L04	/R10	R09	R08	R07	R06	R05	R04	R03	R02	R01	-	-	-	-
	Status		A	A	A	A	/A	A	A	E	A	A	A	A	A	A	-	-	-	-
	Sex		M	F	M	F	/M	M	F	-	M	M	F	M	F	M	-	-	-	-
	Wt (g)		5.17	4.70	5.18	5.06	/5.16	5.22	5.00	-	5.30	5.09	5.14	4.91	4.87	4.73	-	-	-	-

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Dam	Meas.	Mean/ Count	← Left Horn — Cervix Indicator [I] — Right Horn →																	
			1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18
16	FPOS		L01	L02	L03	L04	L05	L06	/R07	R06	R05	R04	R03	R02	R01	-	-	-	-	-
	Status		A	A	A	A	A	A	/A	A	A	A	A	A	A	-	-	-	-	-
	Sex		M	M	M	F	F	F	/F	F	F	F	F	F	F	-	-	-	-	-
	Wt (g)	4.63	4.74	4.84	4.86	4.69	4.74	4.53	/4.84	4.92	4.97	4.42	4.61	4.10	3.91	-	-	-	-	-
17	FPOS		L01	L02	L03	L04	L05	L06	/R10	R09	R08	R07	R06	R05	R04	R03	R02	R01	-	-
	Status		A	A	A	A	E	A	/A	A	A	A	A	A	A	A	A	A	-	-
	Sex		M	M	F	F	-	M	/M	M	F	M	F	F	F	F	F	F	-	-
	Wt (g)	4.63	4.92	4.10	4.67	4.50	-	5.49	/5.08	4.78	4.80	4.56	4.76	4.25	4.84	4.37	4.29	4.10	-	-
18	FPOS		L01	L02	L03	L04	L05	L06	L07	/R07	R06	R05	R04	R03	R02	R01	-	-	-	-
	Status		A	A	A	A	A	A	A	/A	A	A	A	A	A	A	-	-	-	-
	Sex		F	M	F	F	M	F	F	/F	F	F	M	F	M	M	-	-	-	-
	Wt (g)	5.09	4.87	5.08	5.12	5.09	5.13	5.18	5.04	/5.19	5.07	4.83	5.80	5.17	5.21	4.50	-	-	-	-
19	FPOS		L01	L02	/R11	R10	R09	R08	R07	R06	R05	R04	R03	R02	R01	-	-	-	-	-
	Status		A	A	/E	A	A	A	A	A	A	A	A	A	A	-	-	-	-	-
	Sex		M	M	-	/M	F	F	F	F	F	F	F	F	M	-	-	-	-	-
	Wt (g)	5.02	5.36	5.26	-	/5.38	5.01	5.02	4.68	4.10	5.14	5.30	5.27	4.77	4.90	-	-	-	-	-
21	FPOS		L01	L02	L03	L04	L05	L06	L07	L08	L09	L10	/R06	R05	R04	R03	R02	R01	-	-
	Status		A	A	A	A	A	A	A	A	A	A	/A	A	A	A	A	A	-	-
	Sex		M	F	F	M	M	M	M	M	F	F	/F	F	M	F	M	M	-	-
	Wt (g)	4.64	4.80	4.18	3.84	4.75	4.75	5.07	4.57	4.66	4.49	4.61	/4.57	4.51	4.82	4.66	4.93	4.96	-	-

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Control Omcg																				
Dam	Meas.	Mean/ Count	← Left Horn — Cervix Indicator [I] — Right Horn →																	
			1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18
22	FPOS		L01	L02	L03	L04	L05	/R09	R08	R07	R06	R05	R04	R03	R02	R01	-	-	-	-
	Status		E	A	A	A	A	/A	A	A	A	A	A	A	A	A	-	-	-	-
	Sex		.	F	F	F	F	/F	F	M	M	M	F	F	M	M	-	-	-	-
	Wt (g)	4.79	-	4.46	5.04	4.81	4.65	/4.72	4.85	4.87	5.04	5.30	4.79	4.53	4.83	4.32	-	-	-	-

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Individual Foetal Weight and Status

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Dam	Meas.	Mean/ Count	← Left Horn — Cervix Indicator [I] — Right Horn →																	
			1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18
45	FPOS		L01	L02	L03	L04	L05	L06	L07	L08	L09	/R05	R04	R03	R02	R01	-	-	-	-
	Status		A	A	A	A	A	A	A	A	A	/A	A	A	E	A	-	-	-	-
	Sex		F	F	F	M	F	M	M	M	F	/M	F	M	-	F	-	-	-	-
	Wt (g)	4.71	4.30	3.69	4.84	4.84	4.90	3.87	4.91	5.13	5.27	/5.20	4.37	4.78	-	5.17	-	-	-	-
46	FPOS		L01	L02	L03	L04	L05	L06	L07	L08	/R09	R08	R07	R06	R05	R04	R03	R02	R01	-
	Status		A	A	A	A	A	A	A	A	/A	A	A	A	A	A	A	A	A	-
	Sex		M	M	M	F	F	M	F	M	/F	F	F	M	M	M	M	F	M	-
	Wt (g)	4.86	4.82	4.91	4.80	4.82	4.57	4.74	5.12	5.15	/5.00	4.49	4.95	4.85	5.04	4.84	4.99	4.73	4.85	-
47	FPOS		L01	L02	L03	L04	L05	L06	L07	/R05	R04	R03	R02	R01	-	-	-	-	-	-
	Status		A	A	A	A	A	A	A	/A	A	A	A	A	-	-	-	-	-	-
	Sex		F	F	M	F	F	M	M	/M	F	F	M	M	-	-	-	-	-	-
	Wt (g)	4.92	4.84	4.59	5.21	4.90	4.93	5.10	5.21	/4.67	4.42	4.95	5.18	5.06	-	-	-	-	-	-
48	FPOS		L01	L02	L03	L04	L05	/R05	R04	R03	R02	R01	-	-	-	-	-	-	-	-
	Status		A	A	A	A	A	/A	A	A	A	A	-	-	-	-	-	-	-	-
	Sex		F	M	F	M	M	/M	M	F	F	F	-	-	-	-	-	-	-	-
	Wt (g)	4.85	5.13	5.10	4.42	4.68	4.90	/4.89	5.14	4.90	4.82	4.51	-	-	-	-	-	-	-	-
49	FPOS		L01	L02	L03	L04	L05	L06	L07	/R10	R09	R08	R07	R06	R05	R04	R03	R02	R01	-
	Status		A	A	A	E	A	A	E	/A	A	A	E	A	A	A	A	E	A	-
	Sex		F	M	M	-	M	M	-	/M	M	F	-	F	F	F	F	-	M	-
	Wt (g)	4.46	4.20	4.73	4.50	-	4.83	3.56	-	/4.93	4.49	4.54	-	4.49	4.54	4.19	4.67	-	4.32	-

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Dam	Meas.	Mean/ Count	← Left Horn — Cervix Indicator [I] — Right Horn →																	
			1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18
50	FPOS	4.70	L01	L02	L03	L04	L05	L06	/R04	R03	R02	R01	-	-	-	-	-	-	-	-
	Status		A	A	A	A	E	A	/A	A	A	A	-	-	-	-	-	-	-	-
	Sex		F	M	M	F	-	F	/M	M	M	F	-	-	-	-	-	-	-	-
	Wt (g)		4.27	5.05	4.73	4.21	-	4.51	/4.64	5.16	5.25	4.45	-	-	-	-	-	-	-	-
51	FPOS	5.22	L01	L02	L03	L04	L05	L06	L07	L08	/R07	R06	R05	R04	R03	R02	R01	-	-	-
	Status		A	A	A	A	A	A	A	A	/A	A	A	A	A	A	A	-	-	-
	Sex		F	M	M	F	M	M	F	M	/M	M	F	M	M	F	M	-	-	-
	Wt (g)		5.07	5.37	5.56	5.11	5.43	5.42	5.18	4.54	/5.38	4.94	4.69	5.55	5.53	5.33	5.13	-	-	-
52	FPOS	5.26	L01	L02	L03	L04	L05	L06	L07	/R08	R07	R06	R05	R04	R03	R02	R01	-	-	-
	Status		A	A	A	A	E	A	A	/E	A	A	A	A	A	A	A	-	-	-
	Sex		F	F	M	F	-	F	F	-	/M	F	F	M	M	M	M	-	-	-
	Wt (g)		5.46	4.99	5.64	5.25	-	5.10	5.12	-	/5.31	5.21	4.96	5.01	5.74	5.45	5.14	-	-	-
53	FPOS	4.45	L01	L02	L03	L04	L05	L06	L07	L08	/R08	R07	R06	R05	R04	R03	R02	R01	-	-
	Status		A	A	A	A	A	A	A	A	/A	A	A	A	A	A	A	A	-	-
	Sex		M	M	F	M	F	M	F	M	/F	M	F	F	M	M	M	F	-	-
	Wt (g)		4.98	4.96	4.85	4.49	4.04	2.70	4.28	5.26	/4.86	5.10	3.10	4.65	4.03	4.98	5.11	3.84	-	-
54	FPOS	5.27	L01	L02	L03	L04	L05	/R09	R08	R07	R06	R05	R04	R03	R02	R01	-	-	-	-
	Status		A	A	A	A	A	/A	A	A	A	A	E	A	A	A	-	-	-	-
	Sex		M	M	M	M	F	/M	M	F	M	M	-	M	F	-	-	-	-	-
	Wt (g)		4.61	5.45	5.08	5.72	5.59	/5.38	5.28	4.92	5.46	5.16	-	5.64	5.49	4.71	-	-	-	-

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Dam	Meas.	Mean/ Count	← Left Horn — Cervix Indicator [I] — Right Horn →																	
			1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18
55	FPOS		L01	L02	L03	L04	L05	/R09	R08	R07	R06	R05	R04	R03	R02	R01	-	-	-	-
	Status		A	A	A	A	A	/A	E	A	A	A	A	A	A	A	-	-	-	-
	Sex		F	M	F	F	M	/F	-	M	F	F	F	M	F	M	-	-	-	-
	Wt (g)	5.14	5.00	5.64	5.24	5.13	5.36	/4.81	-	5.18	4.54	5.25	4.96	5.42	5.03	5.24	-	-	-	-
57	FPOS		L01	L02	L03	L04	L05	L06	L07	L08	L09	/R06	R05	R04	R03	R02	R01	-	-	-
	Status		A	A	A	A	A	A	A	A	A	/A	A	A	A	A	A	-	-	-
	Sex		M	F	F	F	F	M	M	M	F	/M	F	F	M	M	M	-	-	-
	Wt (g)	5.04	5.01	4.67	4.86	4.94	5.15	5.26	4.97	5.45	4.76	/4.20	5.34	5.00	5.39	5.40	5.16	-	-	-
58	FPOS		L01	L02	L03	L04	L05	L06	L07	L08	L09	/R07	R06	R05	R04	R03	R02	R01	-	-
	Status		A	A	A	A	A	E	A	A	A	/A	A	L	A	A	A	A	-	-
	Sex		M	M	F	M	F	-	M	F	M	/M	F	-	M	F	F	M	-	-
	Wt (g)	4.42	4.04	5.05	4.69	4.78	4.68	-	5.00	4.77	4.00	/3.77	4.36	-	4.83	2.50	4.59	4.79	-	-
59	FPOS		L01	L02	L03	L04	L05	L06	L07	/R09	R08	R07	R06	R05	R04	R03	R02	R01	-	-
	Status		A	A	L	A	A	L	A	/A	A	A	A	A	A	A	A	E	-	-
	Sex		F	F	-	F	F	-	F	/M	M	F	M	F	F	F	F	-	-	-
	Wt (g)	4.58	4.55	4.52	-	5.02	4.19	-	4.27	/4.61	5.04	4.63	4.35	4.66	4.54	4.36	4.79	-	-	-
60	FPOS		L01	L02	L03	L04	L05	L06	L07	/R05	R04	R03	R02	R01	-	-	-	-	-	-
	Status		A	A	A	A	A	A	A	/A	A	A	A	A	-	-	-	-	-	-
	Sex		F	M	F	M	M	F	M	/M	M	F	M	F	-	-	-	-	-	-
	Wt (g)	5.17	4.99	5.18	5.00	5.94	5.22	4.99	4.93	/5.25	5.30	4.80	5.41	5.04	-	-	-	-	-	-

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BNT162b2 30mcg

Dam	Meas.	Mean/ Count	← Left Horn — Cervix Indicator [I] — Right Horn →																	
			1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18
61	FPOS		L01	L02	L03	L04	L05	L06	/R07	R06	R05	R04	R03	R02	R01	-	-	-	-	-
	Status		A	A	A	A	A	A	/A	A	A	A	A	A	A	-	-	-	-	-
	Sex		F	M	M	F	M	F	/F	F	M	M	F	M	F	-	-	-	-	-
	Wt (g)	5.22	5.00	5.13	5.34	5.07	5.49	5.07	/5.24	5.09	5.37	5.34	5.02	5.63	5.07	-	-	-	-	-
62	FPOS		L01	L02	L03	L04	L05	L06	L07	L08	/R06	R05	R04	R03	R02	R01	-	-	-	-
	Status		A	A	A	A	A	A	A	A	/A	A	A	A	A	A	-	-	-	-
	Sex		F	M	M	F	M	F	M	M	/F	M	M	M	M	F	-	-	-	-
	Wt (g)	4.83	4.66	5.24	5.10	4.88	4.75	4.44	4.71	4.60	/4.71	4.73	4.91	4.84	5.11	4.88	-	-	-	-
63	FPOS		L01	L02	L03	L04	L05	/R07	R06	R05	R04	R03	R02	R01	-	-	-	-	-	-
	Status		A	A	A	A	A	/A	A	A	A	A	A	A	-	-	-	-	-	-
	Sex		F	F	M	F	M	/M	F	F	F	M	M	F	-	-	-	-	-	-
	Wt (g)	4.56	4.47	4.48	4.55	4.87	4.64	/5.37	4.80	4.71	4.51	4.51	5.00	2.79	-	-	-	-	-	-
64	FPOS		L01	L02	L03	L04	/R10	R09	R08	R07	R06	R05	R04	R03	R02	R01	-	-	-	-
	Status		A	A	A	A	/A	A	A	A	A	A	E	L	A	A	-	-	-	-
	Sex		F	F	F	M	/M	M	F	F	F	M	-	-	M	F	-	-	-	-
	Wt (g)	4.87	4.89	4.96	4.84	5.29	/5.19	4.65	4.70	4.89	5.03	5.23	-	-	4.84	3.95	-	-	-	-
65	FPOS		L01	L02	L03	L04	L05	L06	L07	L08	/R09	R08	R07	R06	R05	R04	R03	R02	R01	-
	Status		A	A	A	A	A	A	A	A	/A	A	A	A	A	A	A	A	A	-
	Sex		F	M	F	F	M	F	F	F	/F	M	M	M	F	M	M	F	M	-
	Wt (g)	4.93	4.64	5.21	4.81	4.80	5.12	4.55	4.69	5.17	/4.68	4.83	5.26	5.31	4.83	5.12	5.26	4.82	4.68	-

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BNT162b2 30mcg																				
Dam	Meas.	Mean/ Count	← Left Horn — Cervix Indicator [I] — Right Horn →																	
			1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18
66	FPOS	5.46	L01	L02	L03	L04	L05	/R06	R05	R04	R03	R02	R01	-	-	-	-	-	-	-
	Status		A	A	E	A	A	/A	A	A	A	A	A	-	-	-	-	-	-	-
	Sex		F	F	-	F	F	/M	M	F	F	M	M	-	-	-	-	-	-	-
	Wt (g)		5.18	5.62	-	5.49	5.38	/5.04	5.75	4.96	5.80	5.96	5.39	-	-	-	-	-	-	-

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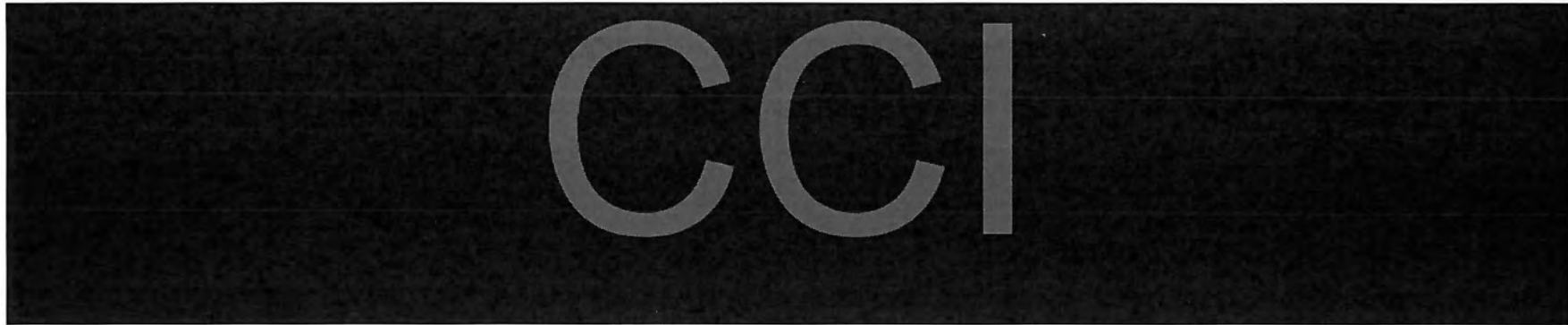
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Individual Foetal Weight and Status



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Individual Foetal External Observations

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Control 0mcg	Foetal Sex	Foetal Weight (g)	Findings
Dam: 1 Pregnancy Type: P			
1	F	4.82External, No abnormalities detected
2	M	5.23External, No abnormalities detected
3	F	5.03External, No abnormalities detected
5	F	5.05External, No abnormalities detected
6	M	5.25External, No abnormalities detected
7	M	5.14External, No abnormalities detected
9	F	4.97External, No abnormalities detected
11	F	5.13External, No abnormalities detected
12	M	4.93External, No abnormalities detected
13	F	5.06External, No abnormalities detected
14	F	4.84External, No abnormalities detected
Dam: 2 Pregnancy Type: P			
1	M	4.79External, No abnormalities detected
2	F	4.52External, No abnormalities detected
3	F	4.91External, No abnormalities detected
4	F	4.39External, No abnormalities detected
5	F	5.02External, No abnormalities detected
6	F	4.65External, No abnormalities detected
7	M	5.03External, No abnormalities detected
8	M	4.70External, No abnormalities detected
9	F	4.79External, No abnormalities detected

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Individual Foetal External Observations

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Control 0mcg	Foetal Sex	Foetal Weight (g)	Findings
Dam: 2 (Continued...)			
10	M	4.79External, No abnormalities detected
11	M	4.32External, No abnormalities detected
12	M	4.91External, No abnormalities detected
13	M	4.05External, No abnormalities detected
14	F	4.67External, No abnormalities detected
15	F	4.30External, No abnormalities detected
Dam: 3 Pregnancy Type: P			
1	M	4.51External, No abnormalities detected
2	M	4.93External, No abnormalities detected
3	F	4.75External, No abnormalities detected
4	F	4.36External, No abnormalities detected
5	M	5.12External, No abnormalities detected
6	M	4.76External, No abnormalities detected
7	F	5.03External, No abnormalities detected
8	F	4.80External, No abnormalities detected
9	F	4.48External, No abnormalities detected
10	F	4.63External, No abnormalities detected
11	F	4.22External, No abnormalities detected
12	M	5.13External, No abnormalities detected
13	F	3.36External, No abnormalities detected
14	M	4.64External, No abnormalities detected

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Individual Foetal External Observations

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Control Omcg	Foetal Sex	Foetal Weight (g)	Findings
Dam: 3 (Continued...)			
15	F	4.64External, No abnormalities detected
16	M	4.90External, No abnormalities detected
Dam: 4 Pregnancy Type: P			
1	M	4.81External, No abnormalities detected
2	M	4.05External, No abnormalities detected
3	F	4.72External, No abnormalities detected
4	F	4.45External, No abnormalities detected
5	F	4.47External, No abnormalities detected
6	M	4.80External, No abnormalities detected
7	F	4.50External, No abnormalities detected
8	M	5.12External, No abnormalities detected
10	F	3.60External, No abnormalities detected
12	M	4.90External, No abnormalities detected
13	M	5.67External, No abnormalities detected
14	F	3.33External, No abnormalities detected
15	F	5.39External, No abnormalities detected
16	F	4.71External, No abnormalities detected
Dam: 5 Pregnancy Type: P			
2	F	5.16External, No abnormalities detected
3	F	4.93External, No abnormalities detected
4	F	4.84External, No abnormalities detected

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Control Omcg	Foetal Sex	Foetal Weight (g)	Findings
Dam: 5 (Continued...)			
5	F	4.95External, No abnormalities detected
6	F	4.83External, No abnormalities detected
7	M	5.01External, No abnormalities detected
8	F	5.03External, No abnormalities detected
9	F	4.96External, No abnormalities detected
10	F	4.97External, No abnormalities detected
11	M	4.82External, No abnormalities detected
12	F	5.18External, No abnormalities detected
13	M	5.41External, No abnormalities detected
14	F	4.53External, No abnormalities detected
Dam: 6 Pregnancy Type: P			
1	M	3.42External, No abnormalities detected
2	M	5.09External, No abnormalities detected
3	M	5.45External, No abnormalities detected
4	M	5.58External, No abnormalities detected
5	M	5.64External, No abnormalities detected
6	F	5.61External, No abnormalities detected
7	M	5.61External, No abnormalities detected
8	F	4.46External, No abnormalities detected
9	M	5.89External, No abnormalities detected
10	F	5.39External, No abnormalities detected

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Individual Foetal External Observations

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Control Omcg	Foetal Sex	Foetal Weight (g)	Findings
Dam: 7 Pregnancy Type: P			
1	F	5.23External, No abnormalities detected
2	M	5.04External, No abnormalities detected
3	F	4.76External, No abnormalities detected
4	F	4.85External, No abnormalities detected
5	F	5.14External, No abnormalities detected
6	M	5.12External, No abnormalities detected
7	M	4.84External, No abnormalities detected
8	F	4.95External, No abnormalities detected
9	M	5.44External, No abnormalities detected
10	F	5.33External, No abnormalities detected
11	M	5.50External, No abnormalities detected
12	M	5.32External, No abnormalities detected
13	M	5.13External, No abnormalities detected
14	F	4.59External, No abnormalities detected
Dam: 8 Pregnancy Type: P			
1	M	4.66External, No abnormalities detected
2	M	4.87External, No abnormalities detected
4	F	4.97External, No abnormalities detected
5	F	5.11External, No abnormalities detected
7	M	4.43External, No abnormalities detected
8	M	5.48External, No abnormalities detected

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Individual Foetal External Observations

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Control Omcg	Foetal Sex	Foetal Weight (g)	Findings
Dam: 8 (Continued...)			
9	F	5.12External, No abnormalities detected
11	F	4.96External, No abnormalities detected
12	M	5.20External, No abnormalities detected
15	F	4.91External, No abnormalities detected
16	M	5.53External, No abnormalities detected
17	F	4.64External, No abnormalities detected
Dam: 9 Pregnancy Type: P			
1	F	4.75External, No abnormalities detected
2	M	4.92External, No abnormalities detected
3	F	4.39External, No abnormalities detected
4	M	5.25External, No abnormalities detected
5	F	5.24External, No abnormalities detected
6	M	5.42External, No abnormalities detected
7	M	5.48External, No abnormalities detected
8	M	5.28External, No abnormalities detected
9	M	5.07External, No abnormalities detected
10	M	4.69External, No abnormalities detected
11	M	5.27External, No abnormalities detected
12	F	4.74External, No abnormalities detected
13	F	5.36External, No abnormalities detected

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Individual Foetal External Observations

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Control Omcg	Foetal Sex	Foetal Weight (g)	Findings
Dam: 10- Pregnancy Type: P			
1	M	5.27External, No abnormalities detected
2	M	5.14External, No abnormalities detected
3	M	5.45External, No abnormalities detected
4	M	5.43External, No abnormalities detected
6	M	5.74External, No abnormalities detected
7	M	5.65External, No abnormalities detected
8	M	5.26External, No abnormalities detected
9	M	5.15External, No abnormalities detected
10	M	5.08External, No abnormalities detected
11	F	5.16External, No abnormalities detected
12	F	4.89External, No abnormalities detected
Dam: 11- Pregnancy Type: P			
1	M	4.88External, No abnormalities detected
2	M	4.89External, No abnormalities detected
3	F	4.29External, No abnormalities detected
4	F	4.96External, No abnormalities detected
5	F	5.27External, No abnormalities detected
6	F	4.88External, No abnormalities detected
7	M	5.44External, No abnormalities detected
8	F	5.27External, No abnormalities detected
9	M	5.12External, No abnormalities detected

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Individual Foetal External Observations

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Control Omcg	Foetal Sex	Foetal Weight (g)	Findings
Dam: 11 (Continued...)			
10	F	5.08External, No abnormalities detected
11	F	5.29External, No abnormalities detected
12	M	5.45External, No abnormalities detected
Dam: 12 Pregnancy Type: P			
1	F	4.95External, No abnormalities detected
2	M	5.12External, No abnormalities detected
3	M	4.78External, No abnormalities detected
5	M	5.25External, No abnormalities detected
6	F	4.51External, No abnormalities detected
7	F	4.77External, No abnormalities detected
8	M	4.97External, No abnormalities detected
9	M	4.93External, No abnormalities detected
10	F	4.87External, No abnormalities detected
11	M	5.01External, No abnormalities detected
12	F	5.01External, No abnormalities detected
13	M	5.08External, No abnormalities detected
14	F	4.39External, No abnormalities detected
Dam: 13 Pregnancy Type: P			
1	F	4.29External, No abnormalities detected
2	F	4.40External, No abnormalities detected
3	M	4.09External, No abnormalities detected

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Control Omeg	Foetal Sex	Foetal Weight (g)	Findings
Dam: 13 (Continued...)			
4	M	3.80External, No abnormalities detected
5	F	4.75External, No abnormalities detected
6	M	5.01External, No abnormalities detected
8	M	4.85External, No abnormalities detected
9	F	4.81External, No abnormalities detected
10	M	4.62External, No abnormalities detected
11	F	4.43External, No abnormalities detected
12	M	4.21External, No abnormalities detected
13	M	5.03External, No abnormalities detected
14	F	5.10External, No abnormalities detected
15	F	4.66External, No abnormalities detected
Dam: 14 Pregnancy Type: P			
1	M	5.06External, No abnormalities detected
2	F	4.55External, No abnormalities detected
3	M	5.15External, No abnormalities detected
4	M	5.09External, No abnormalities detected
5	F	4.54External, No abnormalities detected
7	M	4.25External, No abnormalities detected
8	M	4.93External, No abnormalities detected
9	F	4.54External, No abnormalities detected
10	F	4.92External, No abnormalities detected

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Individual Foetal External Observations

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Control Omcg	Foetal Sex	Foetal Weight (g)	Findings
Dam: 14 (Continued...)			
11	M	4.80External, No abnormalities detected
12	F	4.44External, No abnormalities detected
13	F	4.69External, No abnormalities detected
14	F	4.30External, No abnormalities detected
Dam: 15 Pregnancy Type: P			
1	M	5.17External, No abnormalities detected
2	F	4.70External, No abnormalities detected
3	M	5.18External, No abnormalities detected
4	F	5.06External, No abnormalities detected
5	M	5.16External, No abnormalities detected
6	M	5.22External, No abnormalities detected
7	F	5.00External, No abnormalities detected
9	M	5.30External, No abnormalities detected
10	M	5.09External, No abnormalities detected
11	F	5.14External, No abnormalities detected
12	M	4.91External, No abnormalities detected
13	F	4.87External, No abnormalities detected
14	M	4.73External, No abnormalities detected
Dam: 16 Pregnancy Type: P			
1	M	4.74External, No abnormalities detected
2	M	4.84External, No abnormalities detected

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Individual Foetal External Observations

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Control Omeg	Foetal Sex	Foetal Weight (g)	Findings
Dam: 16 (Continued...)			
3	M	4.86External, No abnormalities detected
4	F	4.69External, No abnormalities detected
5	F	4.74External, No abnormalities detected
6	F	4.53External, No abnormalities detected
7	F	4.84External, No abnormalities detected
8	F	4.92External, No abnormalities detected
9	F	4.97External, No abnormalities detected
10	F	4.42External, No abnormalities detected
11	F	4.61External, No abnormalities detected
12	F	4.10External, No abnormalities detected
13	F	3.91External, No abnormalities detected
Dam: 17 Pregnancy Type: P			
1	M	4.92External, No abnormalities detected
2	M	4.10External, No abnormalities detected
3	F	4.67External, No abnormalities detected
4	F	4.50External, No abnormalities detected
6	M	5.49External, No abnormalities detected
7	M	5.08External, No abnormalities detected
8	M	4.78External, No abnormalities detected
9	F	4.80External, No abnormalities detected
10	M	4.56External, No abnormalities detected

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Control Omcg	Foetal Sex	Foetal Weight (g)	Findings
Dam: 17 (Continued...)			
11	F	4.76External, No abnormalities detected
12	F	4.25External, No abnormalities detected
13	F	4.84External, No abnormalities detected
14	F	4.37External, No abnormalities detected
15	F	4.29External, No abnormalities detected
16	F	4.10External, No abnormalities detected
Dam: 18 Pregnancy Type: P			
1	F	4.87External, No abnormalities detected
2	M	5.08External, No abnormalities detected
3	F	5.12External, No abnormalities detected
4	F	5.09External, No abnormalities detected
5	M	5.13External, No abnormalities detected
6	F	5.18External, No abnormalities detected
7	F	5.04External, No abnormalities detected
8	F	5.19External, No abnormalities detected
9	F	5.07External, No abnormalities detected
10	F	4.83External, No abnormalities detected
11	M	5.80External, No abnormalities detected
12	F	5.17External, No abnormalities detected
13	M	5.21External, No abnormalities detected
14	M	4.50External, No abnormalities detected

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Control Omcg	Foetal Sex	Foetal Weight (g)	Findings
Dam: 19 Pregnancy Type: P			
1	M	5.36External, No abnormalities detected
2	M	5.26External, No abnormalities detected
4	M	5.38External, No abnormalities detected
5	F	5.01External, No abnormalities detected
6	F	5.02External, No abnormalities detected
7	F	4.68External, No abnormalities detected
8	F	4.10External, No abnormalities detected
9	F	5.14External, No abnormalities detected
10	F	5.30External, No abnormalities detected
11	F	5.27External, No abnormalities detected
12	F	4.77External, No abnormalities detected
13	M	4.90External, No abnormalities detected
Dam: 20 Pregnancy Type: NPE			
Dam: 21 Pregnancy Type: P			
1	M	4.80External, No abnormalities detected
2	F	4.18External, No abnormalities detected
3	F	3.84External, No abnormalities detected
4	M	4.75External, No abnormalities detected
5	M	4.75External, No abnormalities detected
6	M	5.07External, No abnormalities detected

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Control Omcg	Foetal Sex	Foetal Weight (g)	Findings
Dam: 21 (Continued...)			
7	M	4.57External, No abnormalities detected
8	M	4.66External, No abnormalities detected
9	F	4.49External, No abnormalities detected
10	F	4.61External, No abnormalities detected
11	F	4.57External, No abnormalities detected
12	F	4.51External, No abnormalities detected
13	M	4.82External, No abnormalities detected
14	F	4.66External, No abnormalities detected
15	M	4.93External, No abnormalities detected
16	M	4.96External, No abnormalities detected
Dam: 22 Pregnancy Type: P			
2	F	4.46External, No abnormalities detected
3	F	5.04External, No abnormalities detected
4	F	4.81External, No abnormalities detected
5	F	4.65External, No abnormalities detected
6	F	4.72External, No abnormalities detected
7!	F	4.85External, No abnormalities detected
8	M	4.87External, No abnormalities detected
9	M	5.04External, No abnormalities detected
10	M	5.30External, No abnormalities detected
11	F	4.79External, No abnormalities detected

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Control Omeg	Foetal Sex	Foetal Weight (g)	Findings
Dam: 22 (Continued...)			
12	F	4.53External, No abnormalities detected
13	M	4.83External, No abnormalities detected
14	M	4.32External, No abnormalities detected

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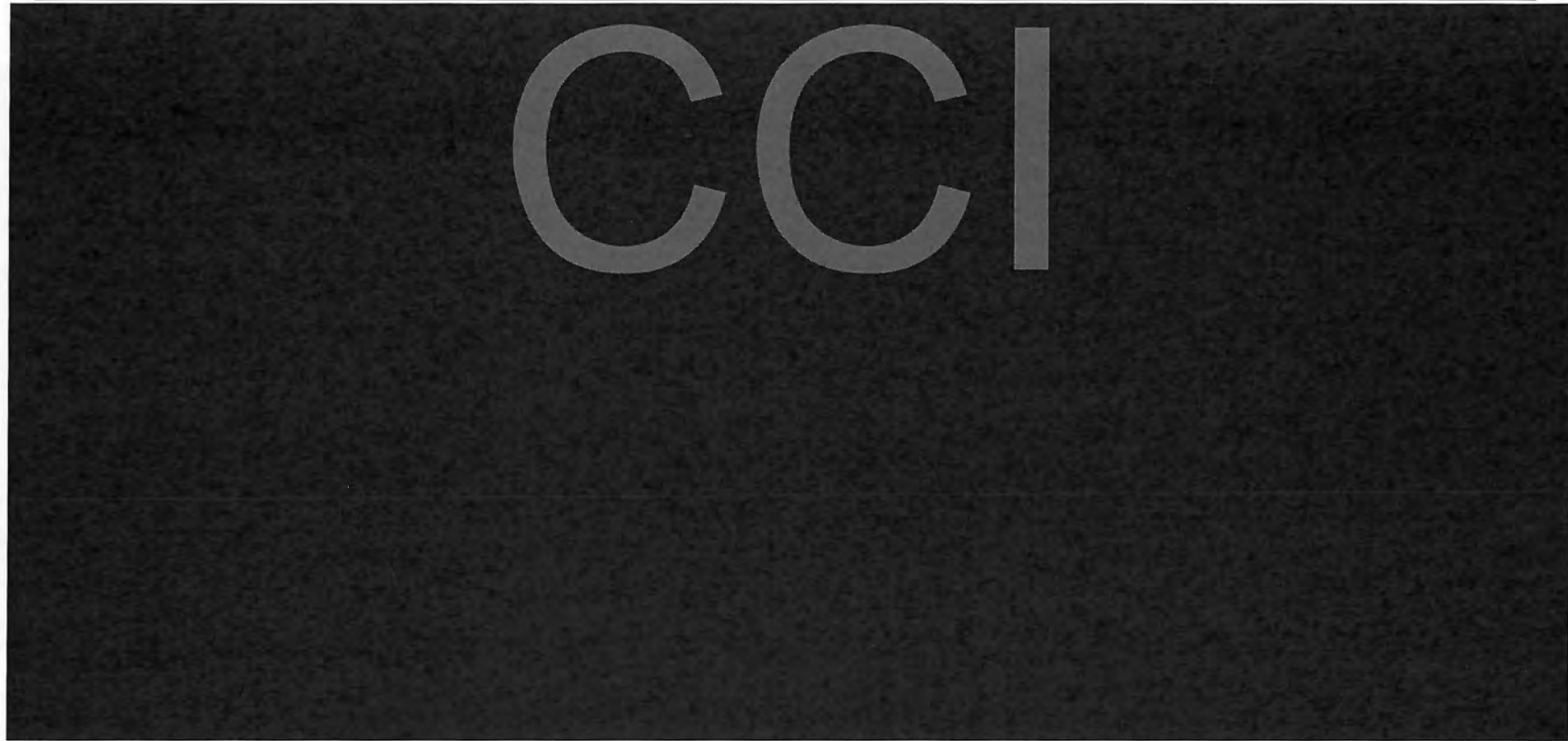
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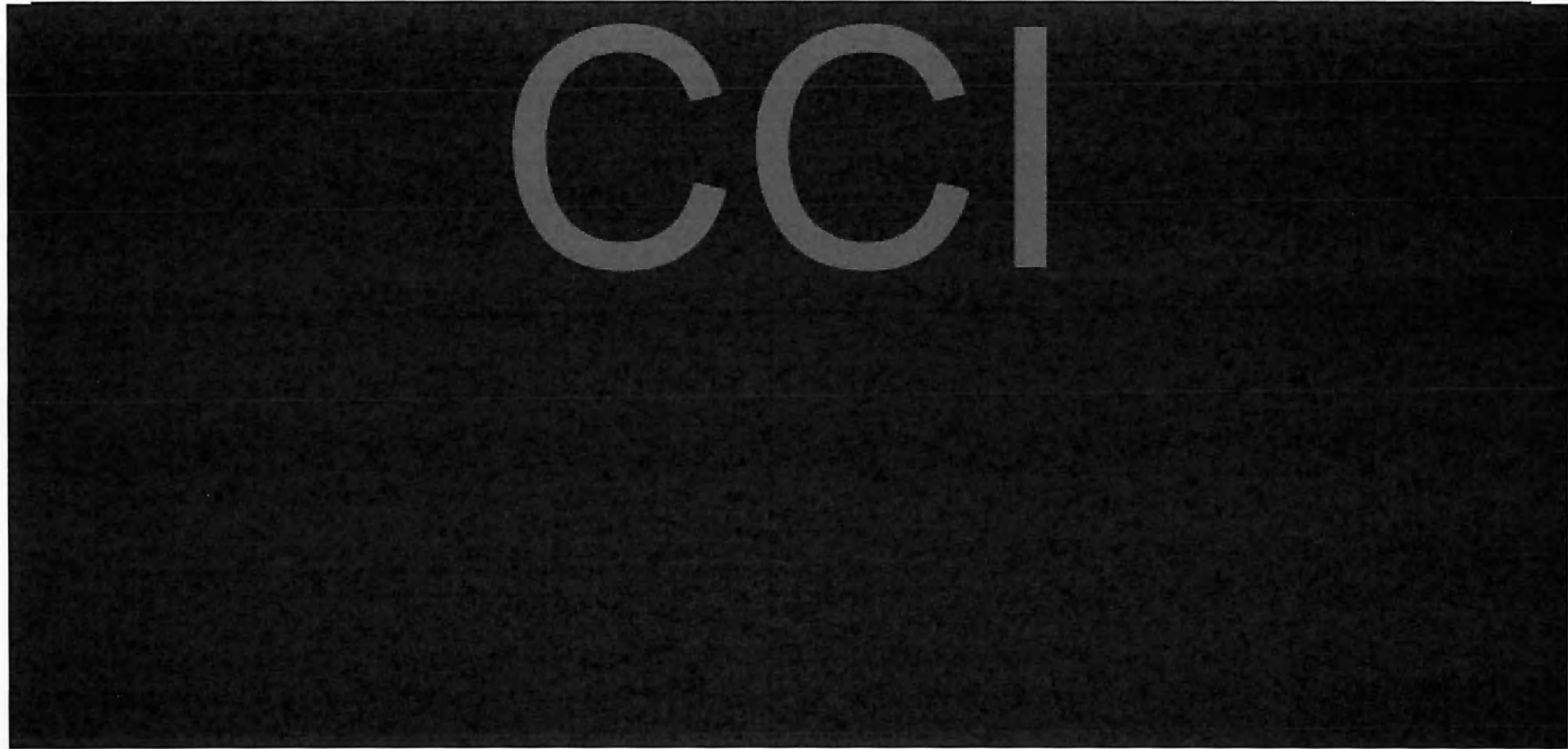
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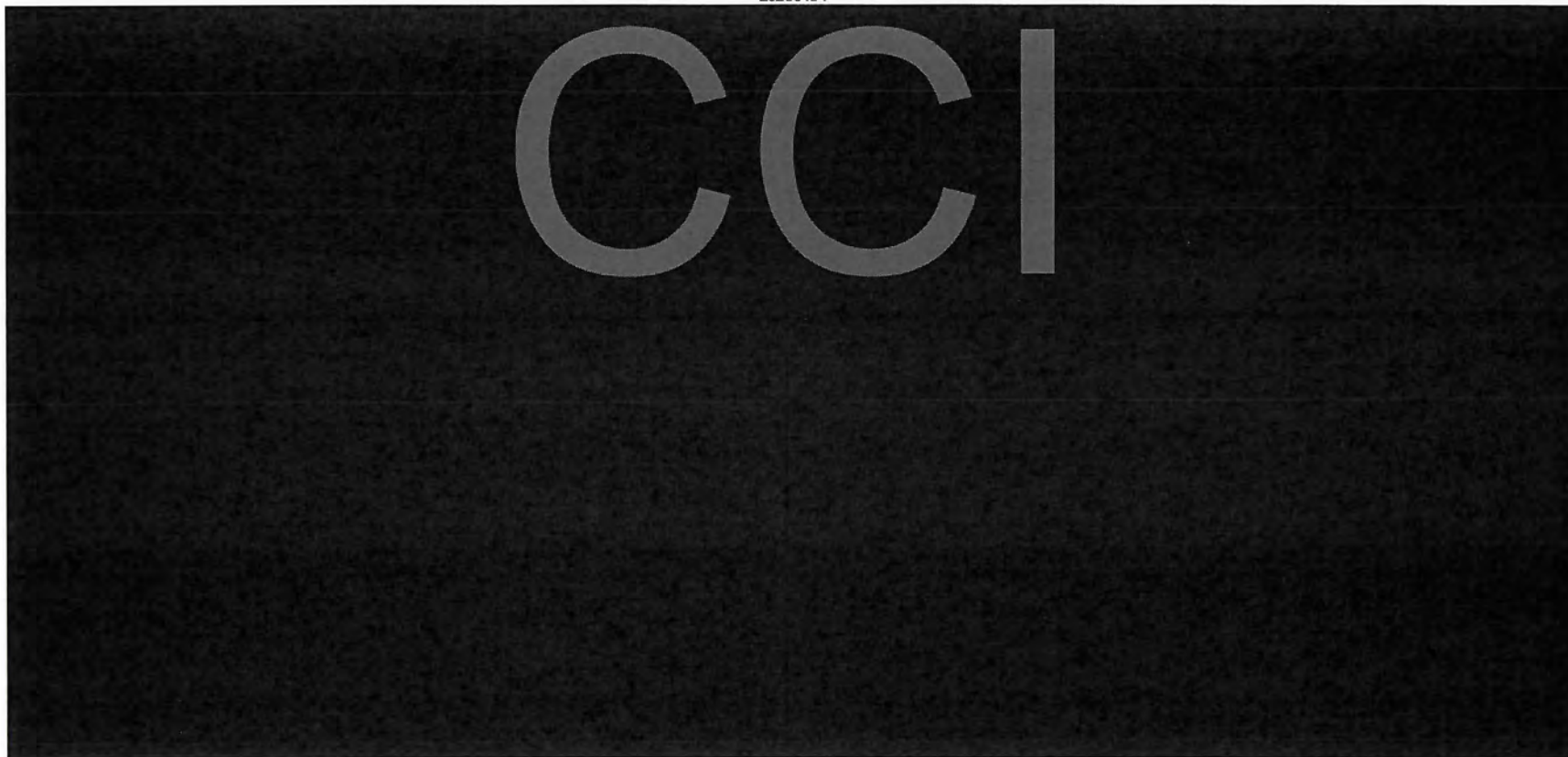
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Individual Foetal External Observations

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BNT162b2 30mcg	Foetal Sex	Foetal Weight (g)	Findings
Dam: 45 Pregnancy Type: P			
1	F	4.30External, No abnormalities detected
2	F	3.69External, No abnormalities detected
3	F	4.84External, No abnormalities detected
4	M	4.84External, No abnormalities detected
5	F	4.90External, No abnormalities detected
6	M	3.87External, No abnormalities detected
7	M	4.91External, No abnormalities detected
8	M	5.13External, No abnormalities detected
9	F	5.27External, No abnormalities detected
10	M	5.20External, No abnormalities detected
11	F	4.37External, No abnormalities detected
12	M	4.78External, No abnormalities detected
14	F	5.17External, No abnormalities detected
Dam: 46 Pregnancy Type: P			
1	M	4.82External, No abnormalities detected
2	M	4.91External, No abnormalities detected
3	M	4.80External, No abnormalities detected
4	F	4.82External, No abnormalities detected
5	F	4.57External, No abnormalities detected
6	M	4.74External, No abnormalities detected
7	F	5.12External, No abnormalities detected

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BNT162b2 30mcg	Foetal Sex	Foetal Weight (g)	Findings
Dam: 46 (Continued...)			
8	M	5.15External, No abnormalities detected
9	F	5.00External, No abnormalities detected
10	F	4.49External, No abnormalities detected
11	F	4.95External, No abnormalities detected
12	M	4.85External, No abnormalities detected
13	M	5.04External, No abnormalities detected
14	M	4.84External, No abnormalities detected
15	M	4.99External, No abnormalities detected
16	F	4.73External, No abnormalities detected
17	M	4.85External, No abnormalities detected
Dam: 47 Pregnancy Type: P			
1	F	4.84External, No abnormalities detected
2	F	4.59External, No abnormalities detected
3	M	5.21External, No abnormalities detected
4	F	4.90External, No abnormalities detected
5	F	4.93External, No abnormalities detected
6	M	5.10External, No abnormalities detected
7	M	5.21External, No abnormalities detected
8	M	4.67External, No abnormalities detected
9	F	4.42External, No abnormalities detected
10	F	4.95External, No abnormalities detected

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BNT162b2 30mcg	Foetal Sex	Foetal Weight (g)	Findings
Dam: 47 (Continued...)			
11	M	5.18External, No abnormalities detected
12	M	5.06External, No abnormalities detected
Dam: 48 Pregnancy Type: P			
1	F	5.13External, No abnormalities detected
2	M	5.10External, No abnormalities detected
3	F	4.42External, No abnormalities detected
4	M	4.68External, No abnormalities detected
5	M	4.90External, No abnormalities detected
6	M	4.89External, No abnormalities detected
7	M	5.14External, No abnormalities detected
8	F	4.90External, No abnormalities detected
9	F	4.82External, No abnormalities detected
10	F	4.51External, No abnormalities detected
Dam: 49 Pregnancy Type: P			
1	F	4.20External, No abnormalities detected
2	M	4.73External, No abnormalities detected
3	M	4.50External, No abnormalities detected
5	M	4.83External, No abnormalities detected
6	M	3.56External, No abnormalities detected
8	M	4.93External, No abnormalities detected
9	M	4.49External, No abnormalities detected

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BNT162b2 30mcg	Foetal Sex	Foetal Weight (g)	Findings
Dam: 49 (Continued...)			
10	F	4.54External, No abnormalities detected
12	F	4.49External, No abnormalities detected
13	F	4.54External, No abnormalities detected
14	F	4.19External, No abnormalities detected
15	F	4.67External, No abnormalities detected
17	M	4.32External, No abnormalities detected
Dam: 50 Pregnancy Type: P			
1	F	4.27External, No abnormalities detected
2	M	5.05External, No abnormalities detected
3	M	4.73External, No abnormalities detected
4	F	4.21External, No abnormalities detected
6	F	4.51External, No abnormalities detected
7	M	4.64External, No abnormalities detected
8	M	5.16External, No abnormalities detected
9	M	5.25External, No abnormalities detected
10	F	4.45External, No abnormalities detected
Dam: 51 Pregnancy Type: P			
1	F	5.07External, No abnormalities detected
2	M	5.37External, No abnormalities detected
3	M	5.56External, No abnormalities detected
4	F	5.11External, No abnormalities detected

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Individual Foetal External Observations

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BNT162b2 30mcg	Foetal Sex	Foetal Weight (g)	Findings
Dam: 51 (Continued...)			
5	M	5.43External, No abnormalities detected
6	M	5.42External, No abnormalities detected
7	F	5.18External, No abnormalities detected
8	M	4.54External, No abnormalities detected
9	M	5.38External, No abnormalities detected
10	M	4.94External, No abnormalities detected
11	F	4.69External, No abnormalities detected
12	M	5.55External, No abnormalities detected
13	M	5.53External, No abnormalities detected
14	F	5.33External, No abnormalities detected
15	M	5.13External, No abnormalities detected
Dam: 52 Pregnancy Type: P			
1	F	5.46External, No abnormalities detected
2	F	4.99External, No abnormalities detected
3	M	5.64External, No abnormalities detected
4	F	5.25External, No abnormalities detected
6	F	5.10External, No abnormalities detected
7	F	5.12External, No abnormalities detected
9	M	5.31External, No abnormalities detected
10	F	5.21External, No abnormalities detected
11	F	4.96External, No abnormalities detected

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Individual Foetal External Observations

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BNT162b2 30mcg	Foetal Sex	Foetal Weight (g)	Findings
Dam: 52 (Continued...)			
12	M	5.01External, No abnormalities detected
13	M	5.74External, No abnormalities detected
14	M	5.45External, No abnormalities detected
15	M	5.14External, No abnormalities detected
Dam: 53 Pregnancy Type: P			
1	M	4.98External, No abnormalities detected
2	M	4.96External, No abnormalities detected
3	F	4.85External, No abnormalities detected
4	M	4.49External, No abnormalities detected
5	F	4.04External, No abnormalities detected
6	M	2.70External, No abnormalities detected
7	F	4.28External, No abnormalities detected
8	M	5.26External, No abnormalities detected
9	F	4.86External, No abnormalities detected
10	M	5.10External, No abnormalities detected
11	F	3.10External, No abnormalities detected
12	F	4.65External, No abnormalities detected
13	M	4.03External, No abnormalities detected
14	M	4.98External, No abnormalities detected
15	M	5.11External, No abnormalities detected
16	F	3.84External, No abnormalities detected

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BNT162b2 30mcg	Foetal Sex	Foetal Weight (g)	Findings
Dam: 54 Pregnancy Type: P			
1	M	4.61External, No abnormalities detected
2	M	5.45External, No abnormalities detected
3	M	5.08External, No abnormalities detected
4	M	5.72External, No abnormalities detected
5	F	5.59External, No abnormalities detected
6	M	5.38External, No abnormalities detected
7	M	5.28External, No abnormalities detected
8	F	4.92External, No abnormalities detected
9	M	5.46External, No abnormalities detected
10	M	5.16External, No abnormalities detected
12	M	5.64External, No abnormalities detected
13	F	5.49External, No abnormalities detected
14	F	4.71External, No abnormalities detected
Dam: 55 Pregnancy Type: P			
1	F	5.00External, No abnormalities detected
2	M	5.64External, No abnormalities detected
3	F	5.24External, No abnormalities detected
4	F	5.13External, No abnormalities detected
5	M	5.36External, No abnormalities detected
6	F	4.81External, No abnormalities detected
8	M	5.18External, No abnormalities detected

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BNT162b2 30mcg	Foetal Sex	Foetal Weight (g)	Findings
Dam: 55 (Continued...)			
9	F	4.54External, No abnormalities detected
10	F	5.25External, No abnormalities detected
11	F	4.96External, No abnormalities detected
12	M	5.42External, No abnormalities detected
13	F	5.03External, No abnormalities detected
14	M	5.24External, No abnormalities detected
Dam: 56 Pregnancy Type: NPE			
Dam: 57 Pregnancy Type: P			
1	M	5.01External, No abnormalities detected
2	F	4.67External, No abnormalities detected
3	F	4.86External, No abnormalities detected
4	F	4.94External, No abnormalities detected
5	F	5.15External, No abnormalities detected
6	M	5.26External, No abnormalities detected
7	M	4.97External, No abnormalities detected
8	M	5.45External, No abnormalities detected
9	F	4.76External, No abnormalities detected
10	M	4.20External, No abnormalities detected
11	F	5.34External, No abnormalities detected
12	F	5.00External, No abnormalities detected

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BNT162b2 30mcg	Foetal Sex	Foetal Weight (g)	Findings
Dam: 57 (Continued...)			
13	M	5.39External, No abnormalities detected
14	M	5.40External, No abnormalities detected
15	M	5.16External, No abnormalities detected
Dam: 58 Pregnancy Type: P			
1	M	4.04External, No abnormalities detected
2	M	5.05External, No abnormalities detected
3	F	4.69External, No abnormalities detected
4	M	4.78External, No abnormalities detected
5	F	4.68External, No abnormalities detected
7	M	5.00External, No abnormalities detected
8	F	4.77External, No abnormalities detected
9	M	4.00External, No abnormalities detected
10	M	3.77External, No abnormalities detected
11	F	4.36External, No abnormalities detected
13	M	4.83External, No abnormalities detected
14	F	2.50External, Body Trunk, Gastroschisis - (M)
15	F	4.59External, No abnormalities detected
16	M	4.79External, No abnormalities detected
Dam: 59 Pregnancy Type: P			
1	F	4.55External, No abnormalities detected
2	F	4.52External, No abnormalities detected

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BNT162b2 30mcg	Foetal Sex	Foetal Weight (g)	Findings
Dam: 59 (Continued...)			
4	F	5.02External, No abnormalities detected
5	F	4.19External, No abnormalities detected
7	F	4.27External, No abnormalities detected
8	M	4.61External, No abnormalities detected
9	M	5.04External, No abnormalities detected
10	F	4.63External, No abnormalities detected
11	M	4.35External, No abnormalities detected
12	F	4.66External, No abnormalities detected
13	F	4.54External, No abnormalities detected
14	F	4.36External, No abnormalities detected
15	F	4.79External, No abnormalities detected
Dam: 60 Pregnancy Type: P			
1	F	4.99External, No abnormalities detected
2	M	5.18External, No abnormalities detected
3	F	5.00External, No abnormalities detected
4	M	5.94External, No abnormalities detected
5	M	5.22External, No abnormalities detected
6	F	4.99External, No abnormalities detected
7	M	4.93External, No abnormalities detected
8	M	5.25External, No abnormalities detected
9	M	5.30External, No abnormalities detected

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BNT162b2 30mcg	Foetal Sex	Foetal Weight (g)	Findings
Dam: 60 (Continued...)			
10	F	4.80External, No abnormalities detected
11	M	5.41External, No abnormalities detected
12	F	5.04External, No abnormalities detected
Dam: 61 Pregnancy Type: P			
1	F	5.00External, No abnormalities detected
2	M	5.13External, No abnormalities detected
3	M	5.34External, No abnormalities detected
4	F	5.07External, No abnormalities detected
5	M	5.49External, No abnormalities detected
6	F	5.07External, No abnormalities detected
7	F	5.24External, No abnormalities detected
8	F	5.09External, No abnormalities detected
9	M	5.37External, No abnormalities detected
10	M	5.34External, No abnormalities detected
11	F	5.02External, No abnormalities detected
12	M	5.63External, No abnormalities detected
13	F	5.07External, No abnormalities detected
Dam: 62 Pregnancy Type: P			
1	F	4.66External, No abnormalities detected
2	M	5.24External, No abnormalities detected
3	M	5.10External, No abnormalities detected

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BNT162b2 30mcg	Foetal Sex	Foetal Weight (g)	Findings
Dam: 62 (Continued...)			
4	F	4.88External, No abnormalities detected
5	M	4.75External, No abnormalities detected
6	F	4.44External, No abnormalities detected
7	M	4.71External, No abnormalities detected
8	M	4.60External, No abnormalities detected
9	F	4.71External, No abnormalities detected
10	M	4.73External, No abnormalities detected
11	M	4.91External, No abnormalities detected
12	M	4.84External, No abnormalities detected
13	M	5.11External, No abnormalities detected
14	F	4.88External, No abnormalities detected
Dam: 63 Pregnancy Type: P			
1	F	4.47External, No abnormalities detected
2	F	4.48External, No abnormalities detected
3	M	4.55External, No abnormalities detected
4	F	4.87External, No abnormalities detected
5	M	4.64External, No abnormalities detected
6	M	5.37External, No abnormalities detected
7	F	4.80External, No abnormalities detected
8	F	4.71External, No abnormalities detected
9	F	4.51External, No abnormalities detected

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BNT162b2 30mcg	Foetal Sex	Foetal Weight (g)	Findings
Dam: 63 (Continued...)			
10	M	4.51External, No abnormalities detected
11	M	5.00External, No abnormalities detected
12	F	2.79External, No abnormalities detected
Dam: 64 Pregnancy Type: P			
1	F	4.89External, No abnormalities detected
2	F	4.96External, No abnormalities detected
3	F	4.84External, No abnormalities detected
4	M	5.29External, No abnormalities detected
5	M	5.19External, No abnormalities detected
6	M	4.65External, No abnormalities detected
7	F	4.70External, No abnormalities detected
8	F	4.89External, No abnormalities detected
9	F	5.03External, No abnormalities detected
10	M	5.23External, No abnormalities detected
13	M	4.84External, No abnormalities detected
14	F	3.95External, Mouth/Jaw Mouth, Misshapen - (M), [small] Jaw, Agnathia - (M), [lower]
Dam: 65 Pregnancy Type: P			
1	F	4.64External, No abnormalities detected
2	M	5.21External, No abnormalities detected
3	F	4.81External, No abnormalities detected

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BNT162b2 30mcg	Foetal Sex	Foetal Weight (g)	Findings
Dam: 65 (Continued...)			
4	F	4.80External, No abnormalities detected
5	M	5.12External, No abnormalities detected
6	F	4.55External, No abnormalities detected
7	F	4.69External, No abnormalities detected
8	F	5.17External, No abnormalities detected
9	F	4.68External, No abnormalities detected
10	M	4.83External, No abnormalities detected
11	M	5.26External, No abnormalities detected
12	M	5.31External, No abnormalities detected
13	F	4.83External, No abnormalities detected
14	M	5.12External, No abnormalities detected
15	M	5.26External, No abnormalities detected
16	F	4.82External, No abnormalities detected
17	M	4.68External, No abnormalities detected
Dam: 66 Pregnancy Type: P			
1	F	5.18External, No abnormalities detected
2	F	5.62External, No abnormalities detected
4	F	5.49External, No abnormalities detected
5	F	5.38External, No abnormalities detected
6	M	5.04External, No abnormalities detected
7	M	5.75External, No abnormalities detected

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BNT162b2 30mcg	Foetal Sex	Foetal Weight (g)	Findings
Dam: 66 (Continued...)			
8	F	4.96External, No abnormalities detected
9	F	5.80External, No abnormalities detected
10	M	5.96External, No abnormalities detected
11	M	5.39External, No abnormalities detected

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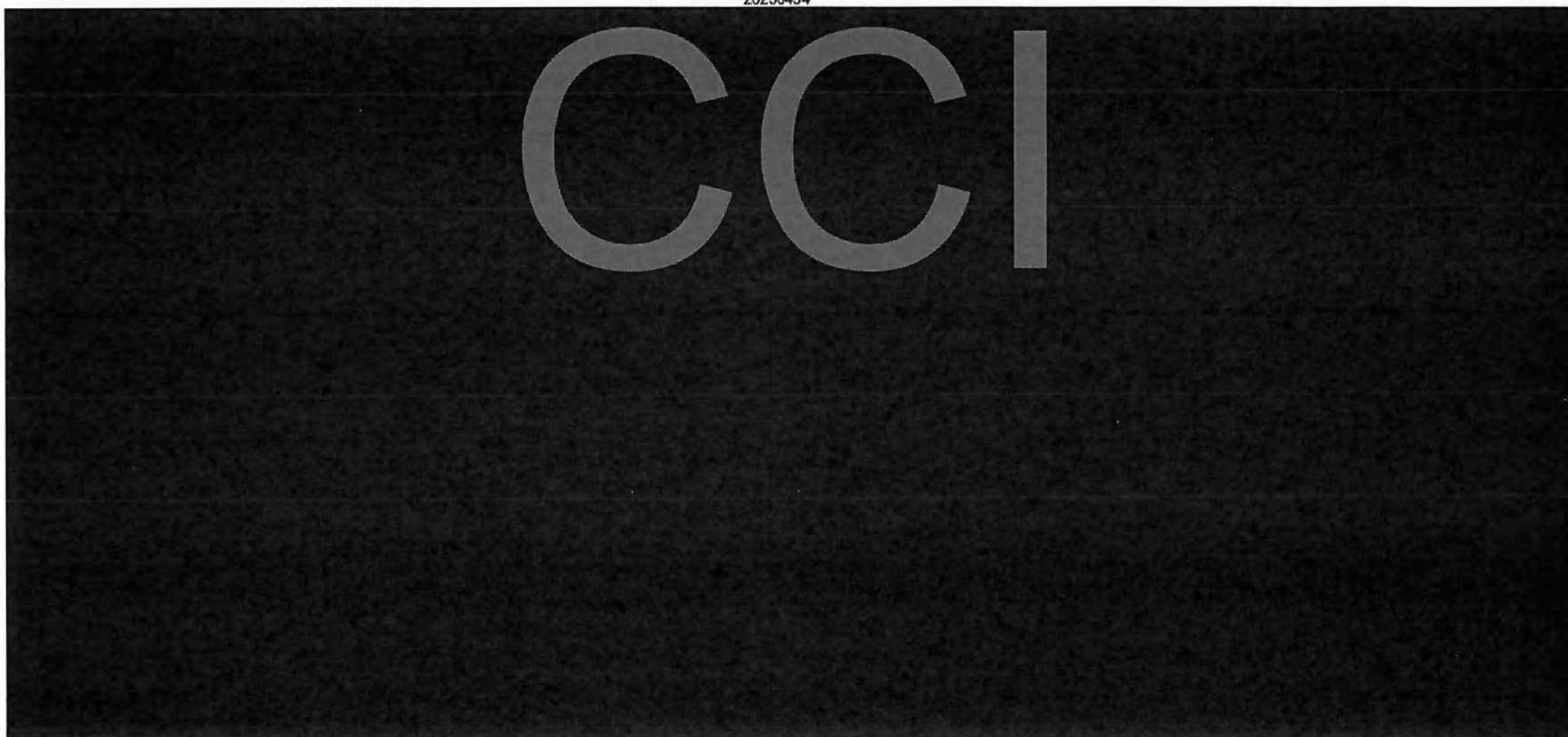
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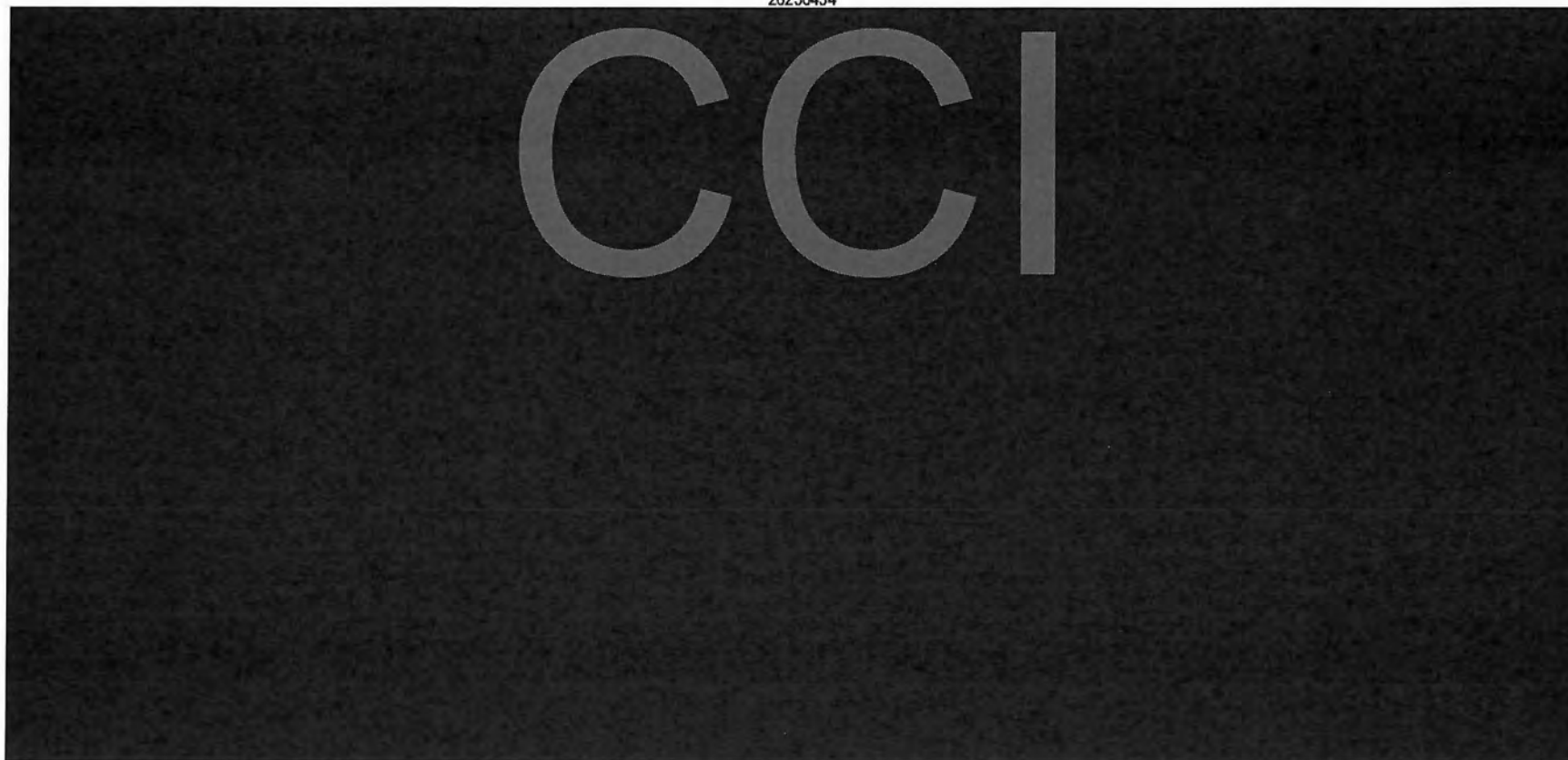
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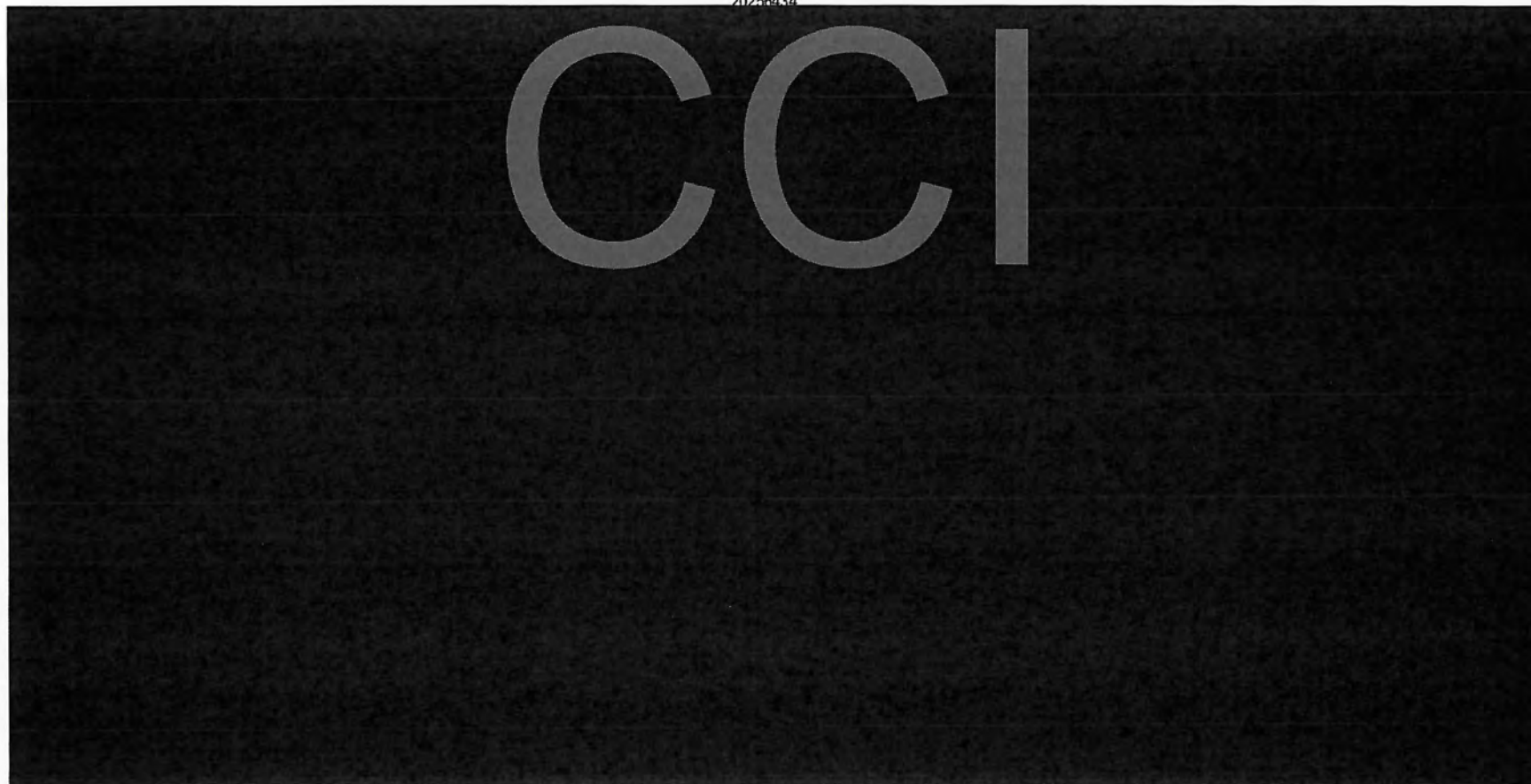
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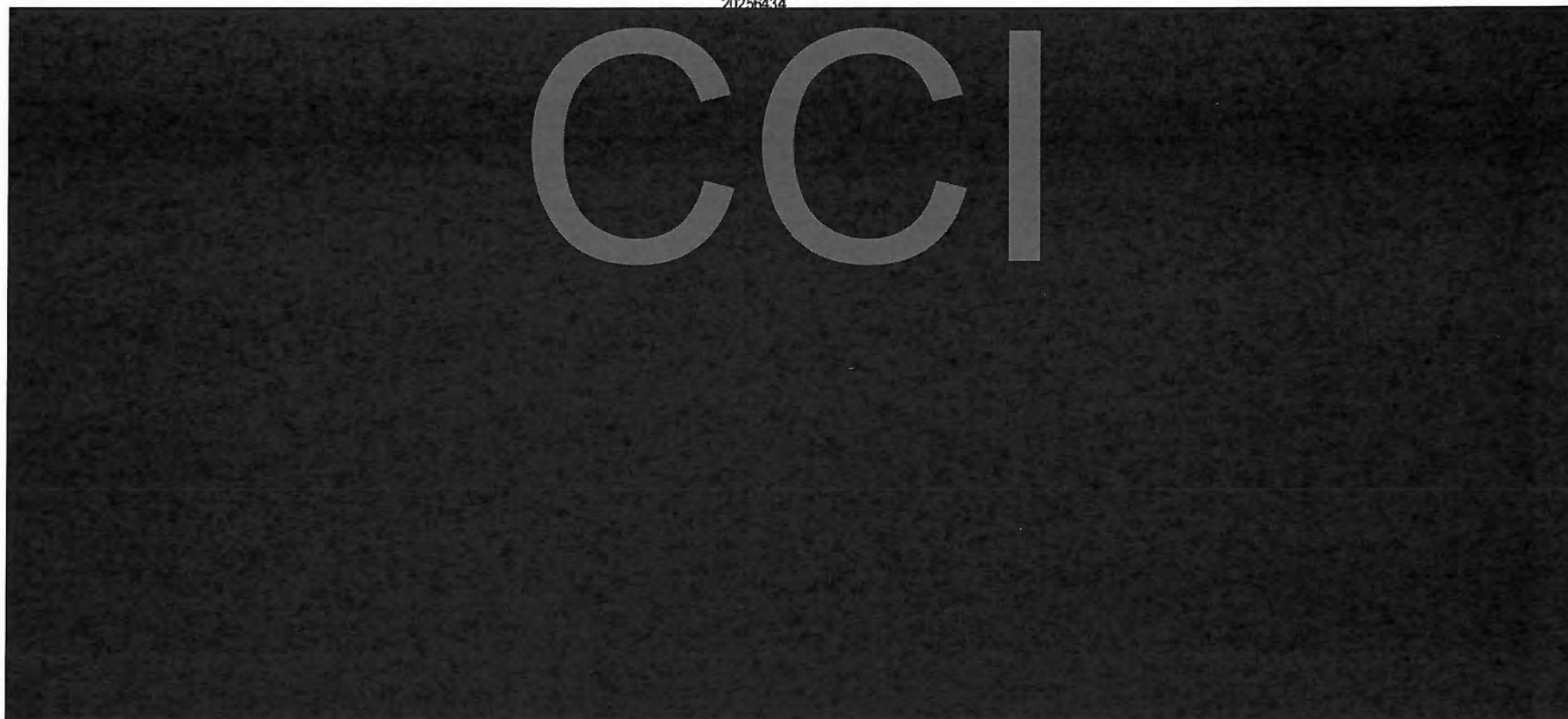
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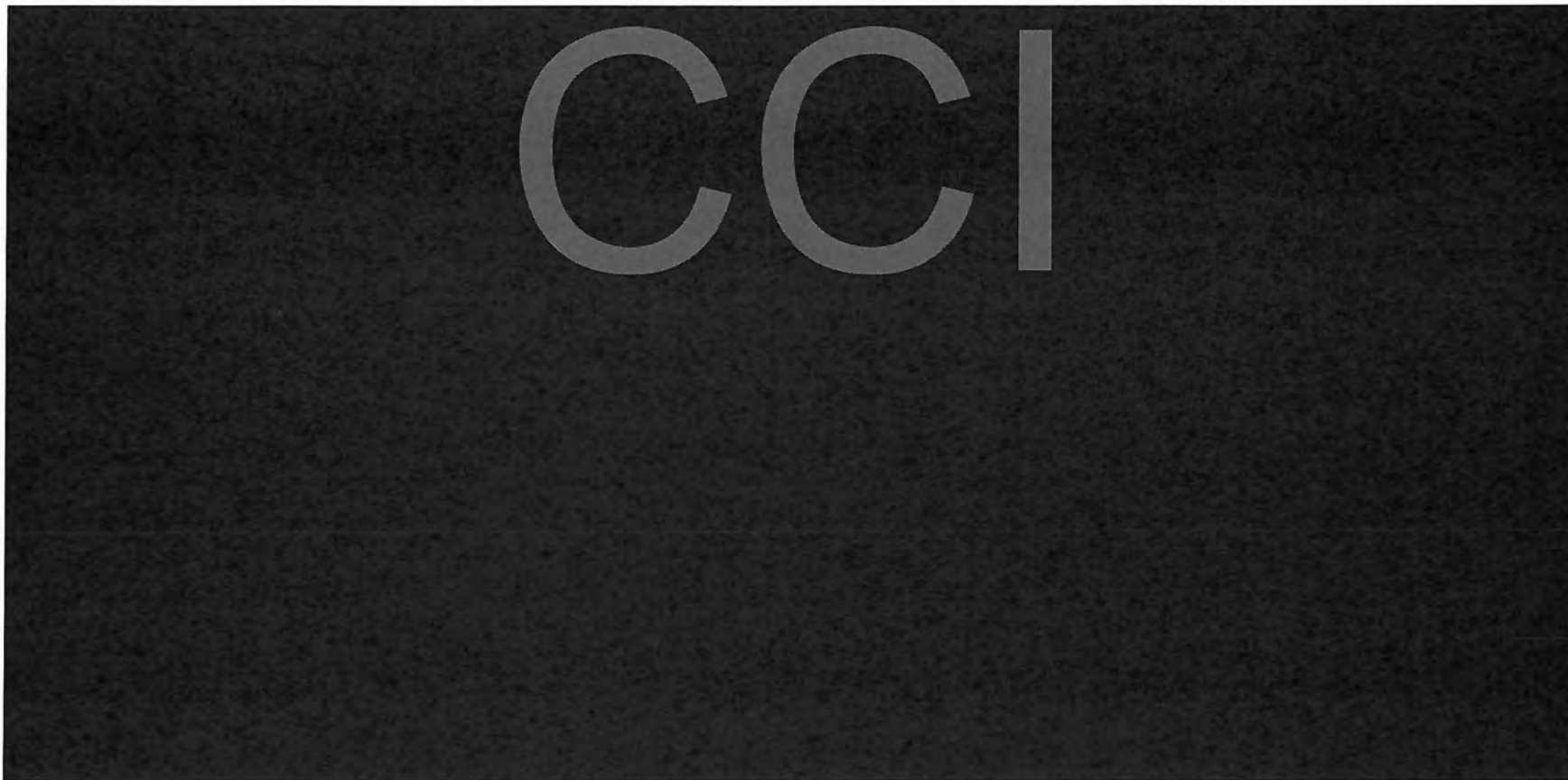
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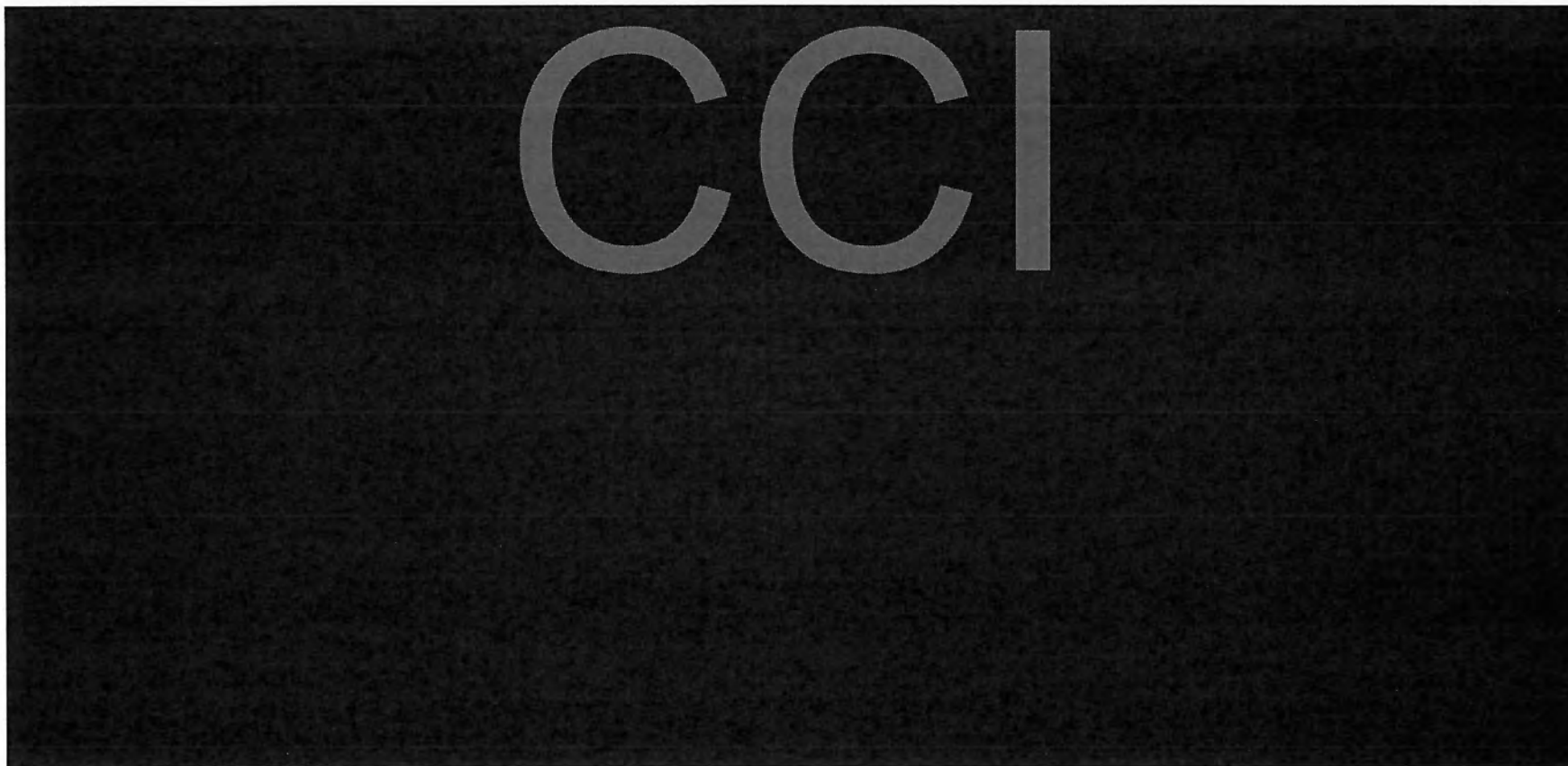
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Individual Foetal Visceral Observations

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Control Omcg	Foetal Sex	Foetal Weight (g)	Findings
Dam: 1 Pregnancy Type: P			
1	F	4.82	
2	M	5.23Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected
3	F	5.03	
5	F	5.05Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected
6	M	5.25	
7	M	5.14Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected
9	F	4.97	
11	F	5.13Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected
12	M	4.93	
13	F	5.06Visceral Body (Rat), Major blood vessel Umbilical artery, Transposed - (V)Visceral Head (Rat), No abnormalities detected
14	F	4.84	
Dam: 2 Pregnancy Type: P			
1	M	4.79	
2	F	4.52Visceral Body (Rat), Vein Azygos vein, Transposed - (A)Visceral Head (Rat), No abnormalities detected
3	F	4.91	
4	F	4.39Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected

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Individual Foetal Visceral Observations

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Control 0mcg	Foetal Sex	Foetal Weight (g)	Findings
Dam: 2 (Continued...)			
5	F	5.02	
6	F	4.65Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected
7	M	5.03	
8	M	4.70Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected
9	F	4.79	
10	M	4.79Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected
11	M	4.32	
12	M	4.91Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected
13	M	4.05	
14	F	4.67Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected
15	F	4.30	
Dam: 3 Pregnancy Type: P			
1	M	4.51	
2	M	4.93Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected
3	F	4.75	
4	F	4.36Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected
5	M	5.12	
6	M	4.76Visceral Body (Rat), No abnormalities detected

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Individual Foetal Visceral Observations

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Control Omcg	Foetal Sex	Foetal Weight (g)	Findings
Dam: 3 (Continued...)			
7	F	5.03Visceral Head (Rat), No abnormalities detected
8	F	4.80Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected
9	F	4.48	
10	F	4.63Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected
11	F	4.22	
12	M	5.13Visceral Body (Rat), Major blood vessel Umbilical artery, Transposed - (V)Visceral Head (Rat), No abnormalities detected
13	F	3.36	
14	M	4.64Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected
15	F	4.64	
16	M	4.90Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected
Dam: 4 Pregnancy Type: P			
1	M	4.81	
2	M	4.05Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected
3	F	4.72	
4	F	4.45Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected
5	F	4.47	

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Individual Foetal Visceral Observations

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Control Omcg	Foetal Sex	Foetal Weight (g)	Findings
Dam: 4 (Continued...)			
6	M	4.80Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected
7	F	4.50	
8	M	5.12Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected
10	F	3.60	
12	M	4.90Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected
13	M	5.67	
14	F	3.33Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected
15	F	5.39	
16	F	4.71Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected
Dam: 5 Pregnancy Type: P			
2	F	5.16	
3	F	4.93Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected
4	F	4.84	
5	F	4.95Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected
6	F	4.83	
7	M	5.01Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected
8	F	5.03	

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Individual Foetal Visceral Observations

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Control Omcg	Foetal Sex	Foetal Weight (g)	Findings
Dam: 5 (Continued...)			
9	F	4.96Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected
10	F	4.97	
11	M	4.82Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected
12	F	5.18	
13	M	5.41Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected
14	F	4.53	
Dam: 6 Pregnancy Type: P			
1	M	3.42	
2	M	5.09Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected
3	M	5.45	
4	M	5.58Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected
5	M	5.64	
6	F	5.61Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected
7	M	5.61	
8	F	4.46Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected
9	M	5.89	
10	F	5.39Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected

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Individual Foetal Visceral Observations

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Control Omcg	Foetal Sex	Foetal Weight (g)	Findings
Dam: 7 Pregnancy Type: P			
1	F	5.23	
2	M	5.04Visceral Body (Rat), No abnormalities detected
		Visceral Head (Rat), No abnormalities detected
3	F	4.76	
4	F	4.85Visceral Body (Rat), No abnormalities detected
		Visceral Head (Rat), No abnormalities detected
5	F	5.14	
6	M	5.12Visceral Body (Rat), No abnormalities detected
		Visceral Head (Rat), No abnormalities detected
7	M	4.84	
8	F	4.95Visceral Body (Rat), No abnormalities detected
		Visceral Head (Rat), No abnormalities detected
9	M	5.44	
10	F	5.33Visceral Body (Rat), No abnormalities detected
		Visceral Head (Rat), No abnormalities detected
11	M	5.50	
12	M	5.32Visceral Body (Rat), No abnormalities detected
		Visceral Head (Rat), No abnormalities detected
13	M	5.13	
14	F	4.59Visceral Body (Rat), No abnormalities detected
		Visceral Head (Rat), No abnormalities detected
Dam: 8 Pregnancy Type: P			
1	M	4.66	
2	M	4.87Visceral Body (Rat), No abnormalities detected
		Visceral Head (Rat), No abnormalities detected

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Individual Foetal Visceral Observations

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Control Omcg	Foetal Sex	Foetal Weight (g)	Findings
Dam: 8 (Continued...)			
4	F	4.97	
5	F	5.11Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected
7	M	4.43	
8	M	5.48Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected
9	F	5.12	
11	F	4.96Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected
12	M	5.20	
15	F	4.91Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected
16	M	5.53	
17	F	4.64Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected
Dam: 9 Pregnancy Type: P			
1	F	4.75	
2	M	4.92Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected
3	F	4.39	
4	M	5.25Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected
5	F	5.24	
6	M	5.42Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected

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Individual Foetal Visceral Observations

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Control Omcg	Foetal Sex	Foetal Weight (g)	Findings
Dam: 9 (Continued...)			
7	M	5.48	
8	M	5.28Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected
9	M	5.07	
10	M	4.69Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected
11	M	5.27	
12	F	4.74Visceral Body (Rat), Major blood vessel Umbilical artery, Transposed - (V)Visceral Head (Rat), No abnormalities detected
13	F	5.36	
Dam: 10 Pregnancy Type: P			
1	M	5.27	
2	M	5.14Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected
3	M	5.45	
4	M	5.43Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected
6	M	5.74	
7	M	5.65Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected
8	M	5.26	
9	M	5.15Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected
10	M	5.08	

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Individual Foetal Visceral Observations

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Control Omcg	Foetal Sex	Foetal Weight (g)	Findings
Dam: 10 (Continued...)			
11	F	5.16Visceral Body (Rat), No abnormalities detected
12	F	4.89Visceral Head (Rat), No abnormalities detected
Dam: 11 Pregnancy Type: P			
1	M	4.88	
2	M	4.89Visceral Body (Rat), No abnormalities detected
		Visceral Head (Rat), No abnormalities detected
3	F	4.29	
4	F	4.96Visceral Body (Rat), No abnormalities detected
		Visceral Head (Rat), No abnormalities detected
5	F	5.27	
6	F	4.88Visceral Body (Rat), Major blood vessel
			Umbilical artery, Transposed - (V)
		Visceral Head (Rat), No abnormalities detected
7	M	5.44	
8	F	5.27Visceral Body (Rat), Liver
			Liver, Abnormal lobation - (A), [pale, right median lobe]
		Visceral Head (Rat), No abnormalities detected
9	M	5.12	
10	F	5.08Visceral Body (Rat), No abnormalities detected
		Visceral Head (Rat), No abnormalities detected
11	F	5.29	
12	M	5.45Visceral Body (Rat), No abnormalities detected
		Visceral Head (Rat), No abnormalities detected

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Individual Foetal Visceral Observations

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Control Omcg	Foetal Sex	Foetal Weight (g)	Findings
Dam: 12 Pregnancy Type: P			
1	F	4.95	
2	M	5.12Visceral Body (Rat), No abnormalities detected
		Visceral Head (Rat), No abnormalities detected
3	M	4.78	
5	M	5.25Visceral Body (Rat), Major blood vessel Umbilical artery, Transposed - (V)
		Visceral Head (Rat), No abnormalities detected
6	F	4.51	
7	F	4.77Visceral Body (Rat), No abnormalities detected
		Visceral Head (Rat), No abnormalities detected
8	M	4.97	
9	M	4.93Visceral Body (Rat), No abnormalities detected
		Visceral Head (Rat), No abnormalities detected
10	F	4.87	
11	M	5.01Visceral Body (Rat), Major blood vessel Umbilical artery, Transposed - (V)
		Visceral Head (Rat), No abnormalities detected
12	F	5.01	
13	M	5.08Visceral Body (Rat), No abnormalities detected
		Visceral Head (Rat), No abnormalities detected
14	F	4.39	
Dam: 13 Pregnancy Type: P			
1	F	4.29	
2	F	4.40Visceral Body (Rat), No abnormalities detected
		Visceral Head (Rat), No abnormalities detected

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Individual Foetal Visceral Observations

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Control 0mcg	Foetal Sex	Foetal Weight (g)	Findings
Dam: 13 (Continued...)			
3	M	4.09	
4	M	3.80Visceral Body (Rat), No abnormalities detected
		Visceral Head (Rat), No abnormalities detected
5	F	4.75	
6	M	5.01Visceral Body (Rat), No abnormalities detected
		Visceral Head (Rat), No abnormalities detected
8	M	4.85	
9	F	4.81Visceral Body (Rat), No abnormalities detected
		Visceral Head (Rat), No abnormalities detected
10	M	4.62	
11	F	4.43Visceral Body (Rat), No abnormalities detected
		Visceral Head (Rat), No abnormalities detected
12	M	4.21	
13	M	5.03Visceral Body (Rat), No abnormalities detected
		Visceral Head (Rat), No abnormalities detected
14	F	5.10	
15	F	4.66Visceral Body (Rat), No abnormalities detected
		Visceral Head (Rat), No abnormalities detected
Dam: 14 Pregnancy Type: P			
1	M	5.06	
2	F	4.55Visceral Body (Rat), No abnormalities detected
		Visceral Head (Rat), No abnormalities detected
3	M	5.15	
4	M	5.09Visceral Body (Rat), No abnormalities detected
		Visceral Head (Rat), No abnormalities detected

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Individual Foetal Visceral Observations

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Control Omcg	Foetal Sex	Foetal Weight (g)	Findings
Dam: 14 (Continued...)			
5	F	4.54Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected
7	M	4.25	
8	M	4.93	
9	F	4.54	
10	F	4.92	
11	M	4.80	
12	F	4.44	
13	F	4.69	
14	F	4.30	
Dam: 15 Pregnancy Type: P			
1	M	5.17Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected
2	F	4.70	
3	M	5.18	
4	F	5.06	
5	M	5.16	
6	M	5.22	
7	F	5.00	
9	M	5.30	

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Control Omcg	Foetal Sex	Foetal Weight (g)	Findings
Dam: 15 (Continued...)			
10	M	5.09Visceral Head (Rat), No abnormalities detected
11	F	5.14Visceral Body (Rat), No abnormalities detected
		Visceral Head (Rat), No abnormalities detected
12	M	4.91	
13	F	4.87Visceral Body (Rat), No abnormalities detected
		Visceral Head (Rat), No abnormalities detected
14	M	4.73	
Dam: 16 Pregnancy Type: P			
1	M	4.74	
2	M	4.84Visceral Body (Rat), No abnormalities detected
		Visceral Head (Rat), No abnormalities detected
3	M	4.86	
4	F	4.69Visceral Body (Rat), No abnormalities detected
		Visceral Head (Rat), No abnormalities detected
5	F	4.74	
6	F	4.53Visceral Body (Rat), No abnormalities detected
		Visceral Head (Rat), No abnormalities detected
7	F	4.84	
8	F	4.92Visceral Body (Rat), No abnormalities detected
		Visceral Head (Rat), No abnormalities detected
9	F	4.97	
10	F	4.42Visceral Body (Rat), No abnormalities detected
		Visceral Head (Rat), No abnormalities detected
11	F	4.61	

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Control Omcg	Foetal Sex	Foetal Weight (g)	Findings
Dam: 16 (Continued...)			
12	F	4.10Visceral Body (Rat), No abnormalities detected
13	F	3.91Visceral Head (Rat), No abnormalities detected
Dam: 17 Pregnancy Type: P			
1	M	4.92	
2	M	4.10Visceral Body (Rat), No abnormalities detected
		Visceral Head (Rat), No abnormalities detected
3	F	4.67	
4	F	4.50Visceral Body (Rat), No abnormalities detected
		Visceral Head (Rat), No abnormalities detected
6	M	5.49	
7	M	5.08Visceral Body (Rat), No abnormalities detected
		Visceral Head (Rat), No abnormalities detected
8	M	4.78	
9	F	4.80Visceral Body (Rat), No abnormalities detected
		Visceral Head (Rat), No abnormalities detected
10	M	4.56	
11	F	4.76Visceral Body (Rat), No abnormalities detected
		Visceral Head (Rat), No abnormalities detected
12	F	4.25	
13	F	4.84Visceral Body (Rat), No abnormalities detected
		Visceral Head (Rat), No abnormalities detected
14	F	4.37	
15	F	4.29Visceral Body (Rat), No abnormalities detected
		Visceral Head (Rat), No abnormalities detected

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Control Omeg	Foetal Sex	Foetal Weight (g)	Findings
Dam: 17 (Continued...)			
16	F	4.10	
Dam: 18 Pregnancy Type: P			
1	F	4.87	
2	M	5.08Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected
3	F	5.12	
4	F	5.09Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected
5	M	5.13	
6	F	5.18Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected
7	F	5.04	
8	F	5.19Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected
9	F	5.07	
10	F	4.83Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected
11	M	5.80	
12	F	5.17Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected
13	M	5.21	
14	M	4.50Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected

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Individual Foetal Visceral Observations

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Control 0mcg	Foetal Sex	Foetal Weight (g)	Findings
Dam: 19 Pregnancy Type: P			
1	M	5.36	
2	M	5.26Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected
4	M	5.38	
5	F	5.01Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected
6	F	5.02	
7	F	4.68Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected
8	F	4.10	
9	F	5.14Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected
10	F	5.30	
11	F	5.27Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected
12	F	4.77	
13	M	4.90Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected
Dam: 20 Pregnancy Type: NPE			
Dam: 21 Pregnancy Type: P			
1	M	4.80	
2	F	4.18Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected

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Individual Foetal Visceral Observations

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Control Omcg	Foetal Sex	Foetal Weight (g)	Findings
Dam: 21 (Continued...)			
3	F	3.84	
4	M	4.75Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected
5	M	4.75	
6	M	5.07Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected
7	M	4.57	
8	M	4.66Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected
9	F	4.49	
10	F	4.61Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected
11	F	4.57	
12	F	4.51Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected
13	M	4.82	
14	F	4.66Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected
15	M	4.93	
16	M	4.96Visceral Body (Rat), Major blood vessel Umbilical artery, Transposed - (V)Visceral Head (Rat), No abnormalities detected
Dam: 22 Pregnancy Type: P			
2	F	4.46	
3	F	5.04Visceral Body (Rat), No abnormalities detected

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Control Omcg	Foetal Sex	Foetal Weight (g)	Findings
Dam: 22 (Continued...)			
4	F	4.81Visceral Head (Rat), No abnormalities detected
5	F	4.65Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected
6	F	4.72	
7	F	4.85Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected
8	M	4.87	
9	M	5.04Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected
10	M	5.30	
11	F	4.79Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected
12	F	4.53	
13	M	4.83Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected
14	M	4.32	

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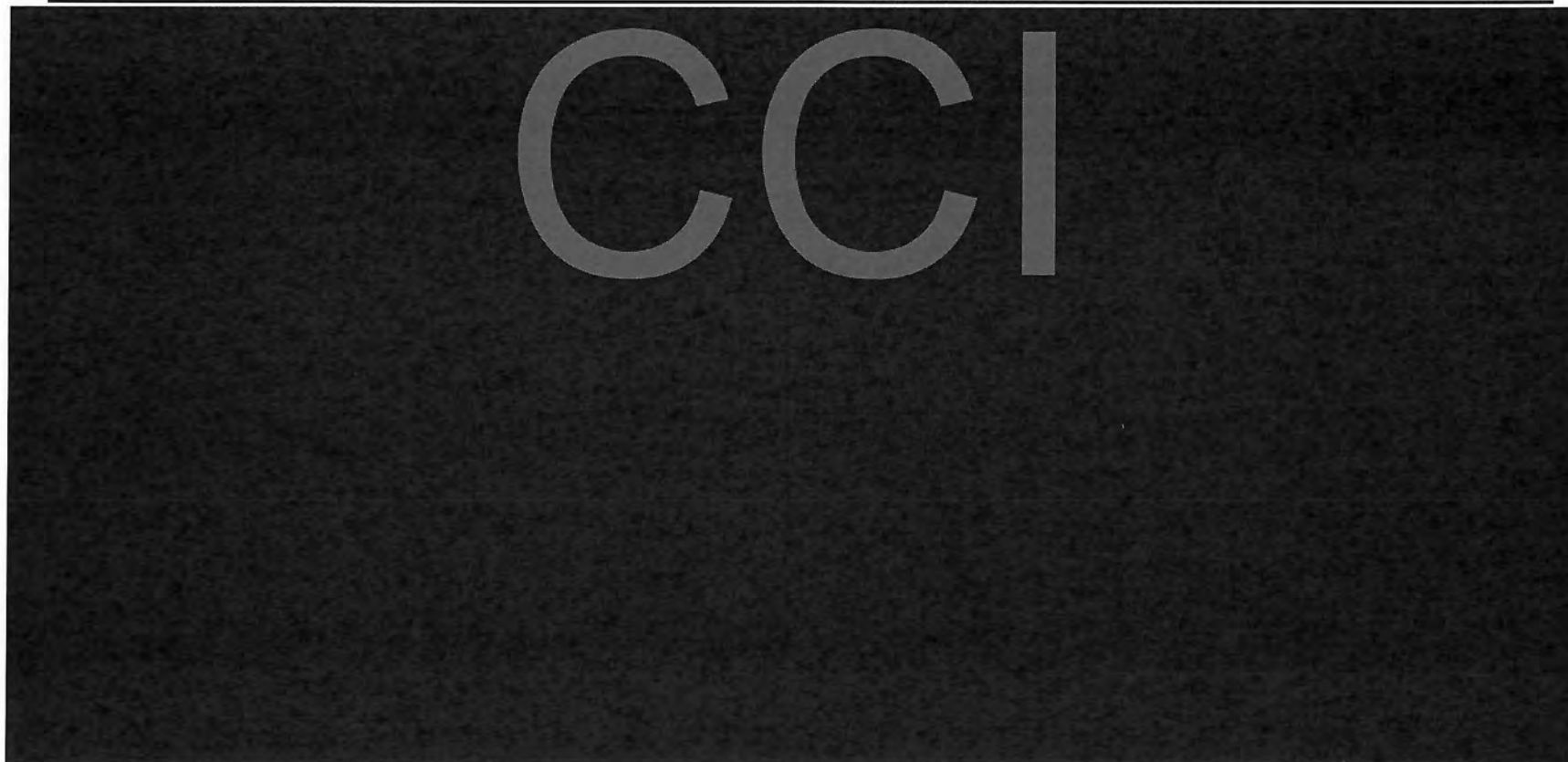
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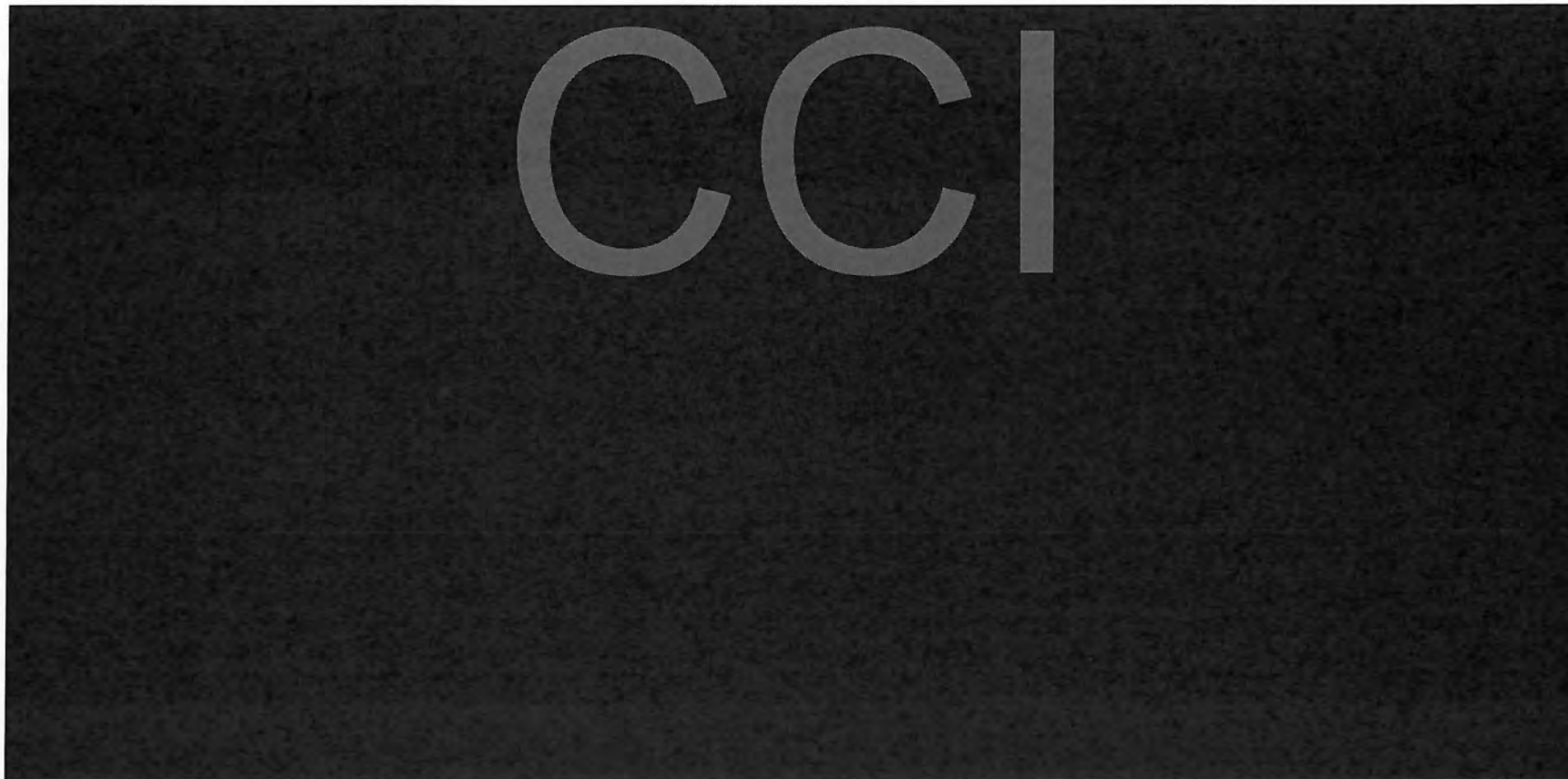
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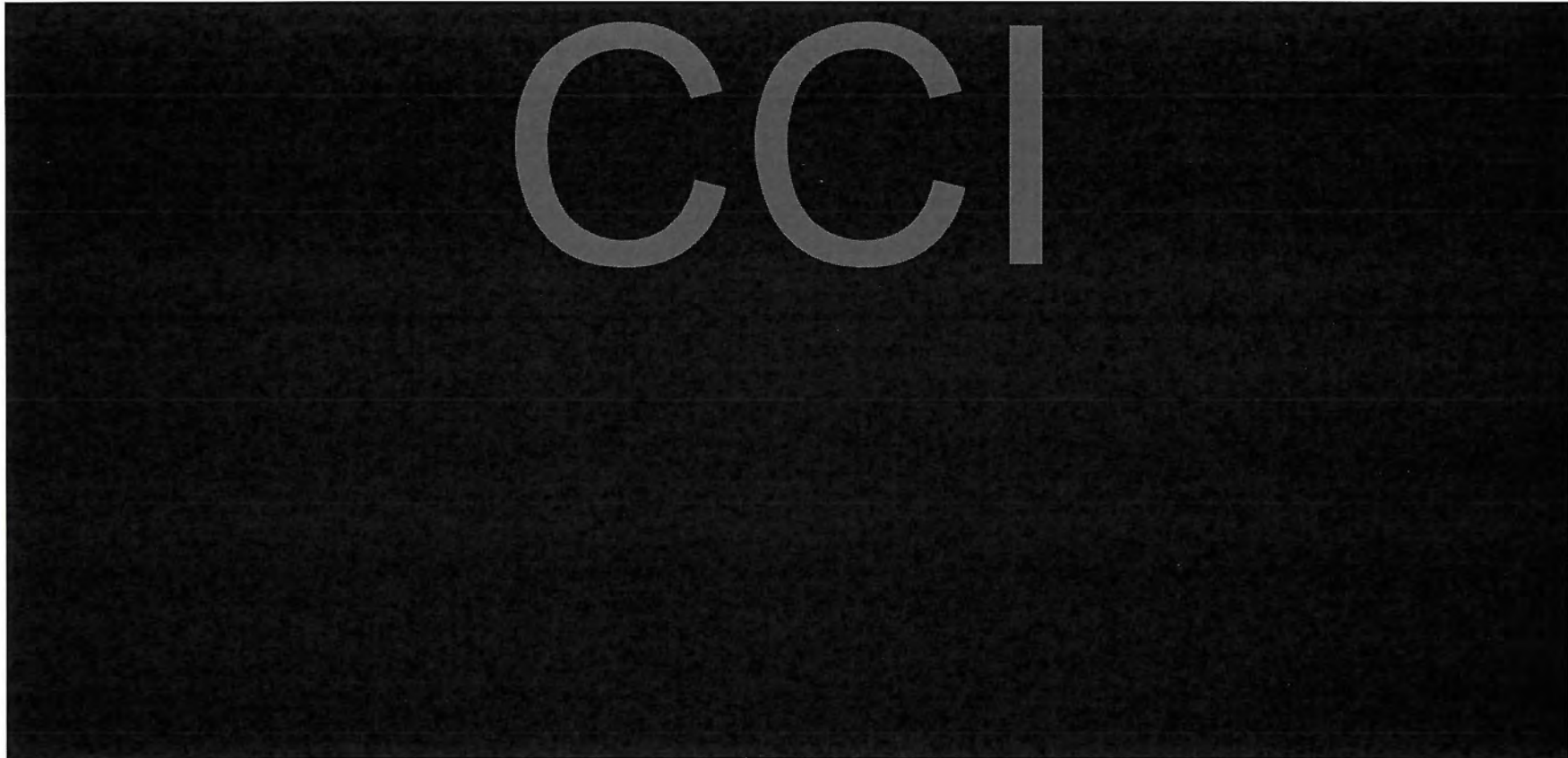
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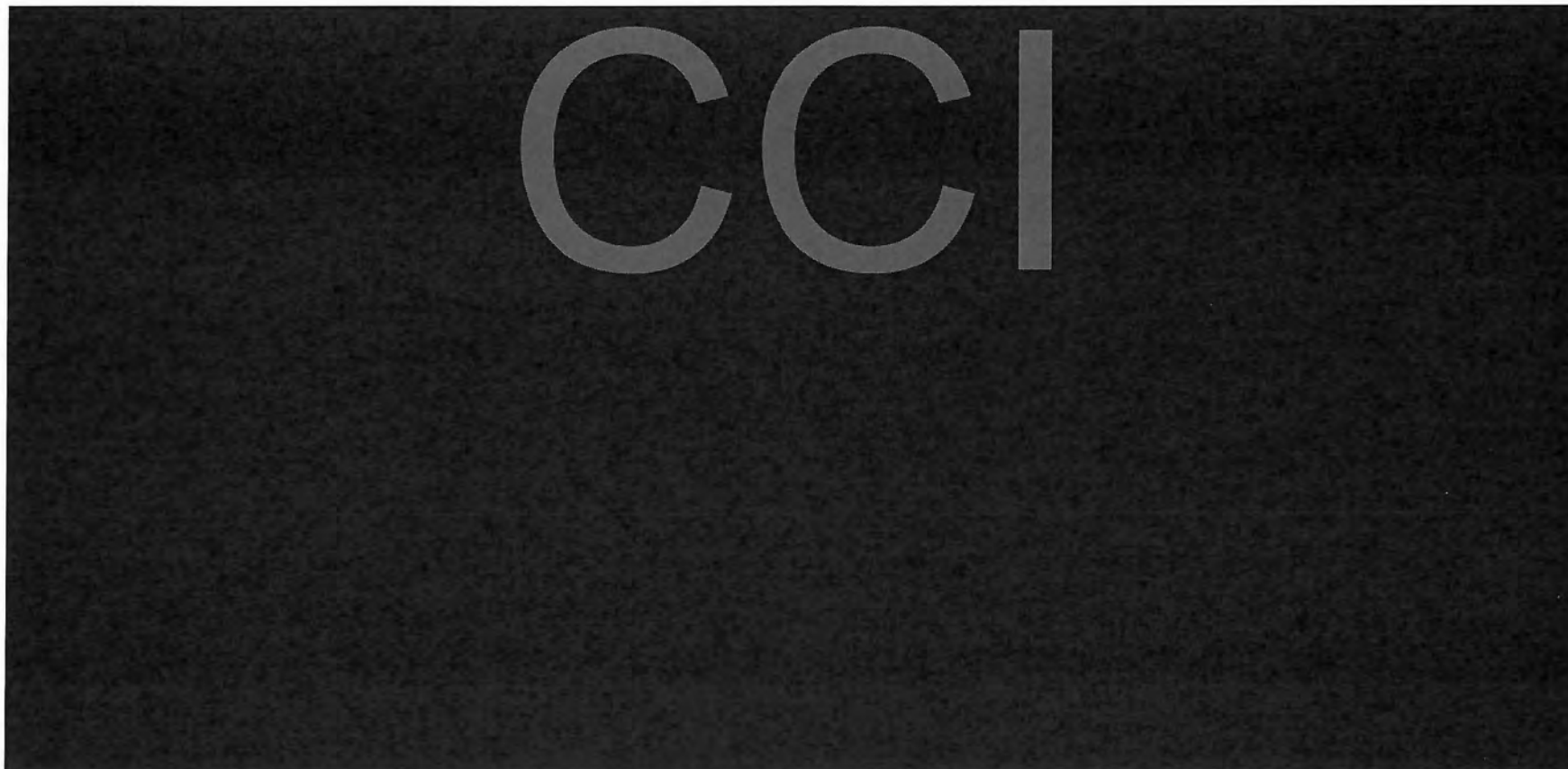
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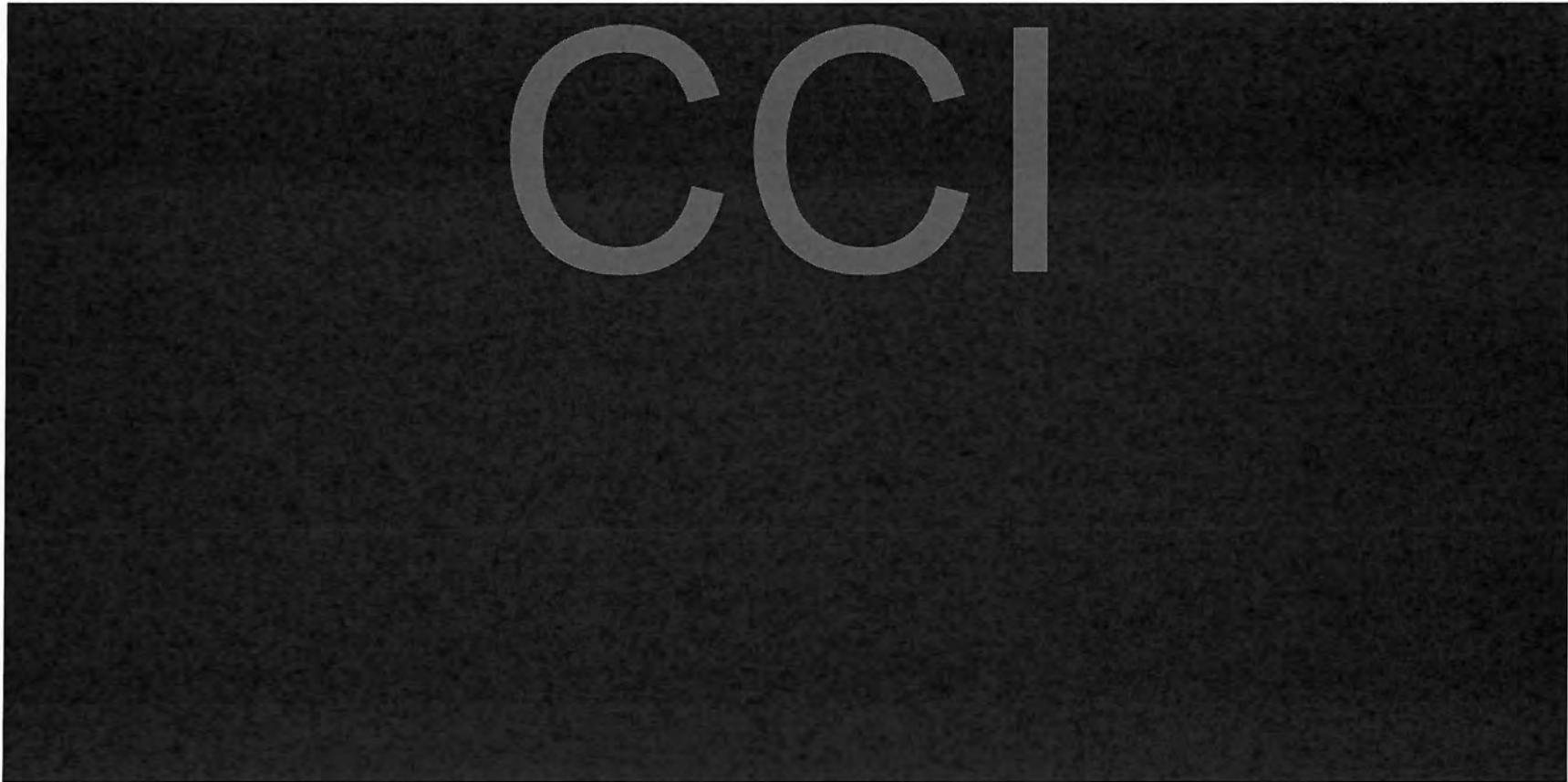
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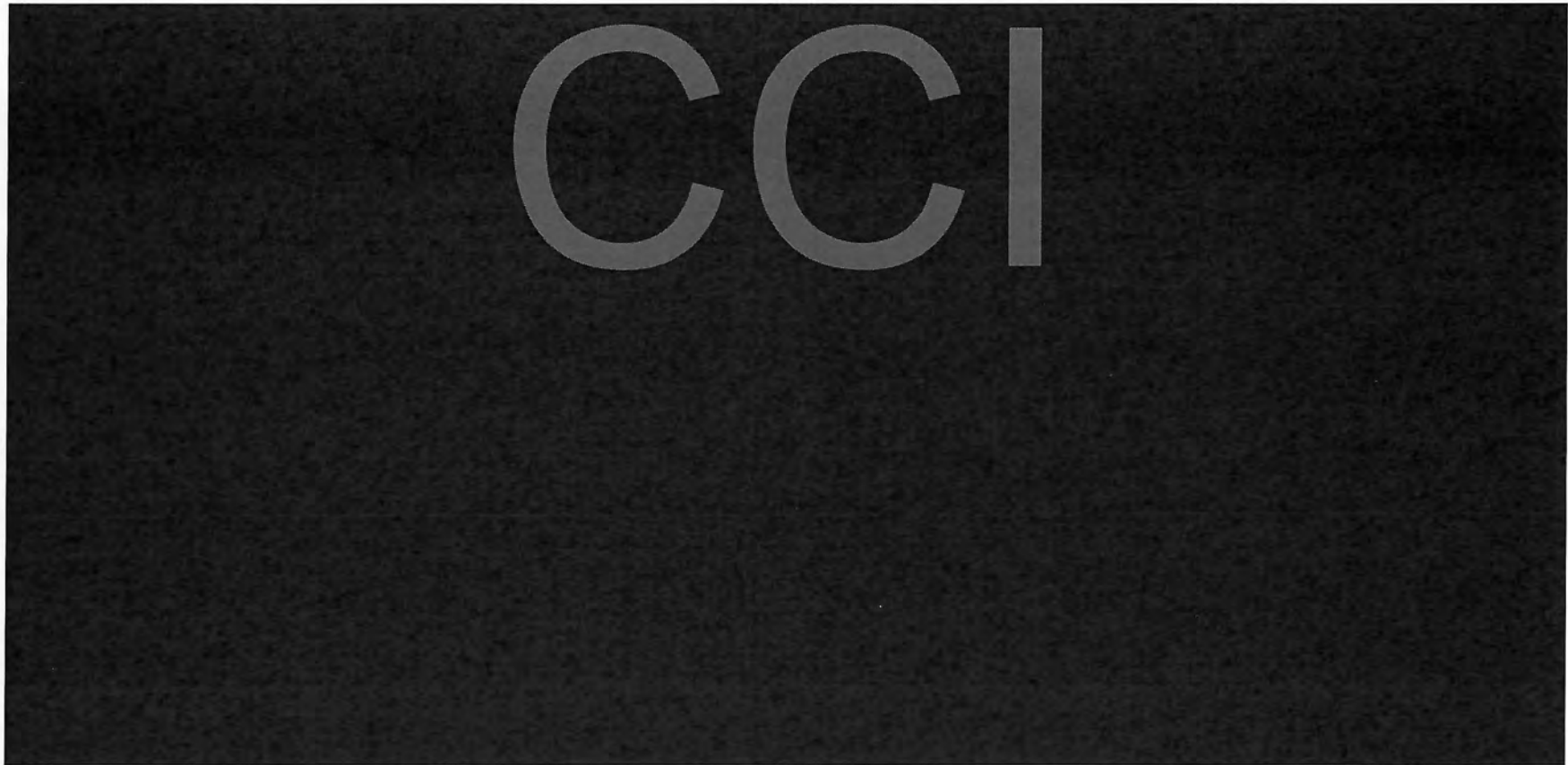
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Individual Foetal Visceral Observations

20256434

BNT162b2 30mcg	Foetal Sex	Foetal Weight (g)	Findings
Dam: 45 Pregnancy Type: P			
1	F	4.30	
2	F	3.69Visceral Body (Rat), No abnormalities detected
		Visceral Head (Rat), No abnormalities detected
3	F	4.84	
4	M	4.84Visceral Body (Rat), No abnormalities detected
		Visceral Head (Rat), No abnormalities detected
5	F	4.90	
6	M	3.87Visceral Body (Rat), No abnormalities detected
		Visceral Head (Rat), No abnormalities detected
7	M	4.91	
8	M	5.13Visceral Body (Rat), No abnormalities detected
		Visceral Head (Rat), No abnormalities detected
9	F	5.27	
10	M	5.20Visceral Body (Rat), No abnormalities detected
		Visceral Head (Rat), No abnormalities detected
11	F	4.37	
12	M	4.78Visceral Body (Rat), No abnormalities detected
		Visceral Head (Rat), No abnormalities detected
14	F	5.17	
Dam: 46 Pregnancy Type: P			
1	M	4.82	
2	M	4.91Visceral Body (Rat), No abnormalities detected
		Visceral Head (Rat), No abnormalities detected
3	M	4.80	

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Individual Foetal Visceral Observations

20256434

BNT162b2 30mcg	Foetal Sex	Foetal Weight (g)	Findings
Dam: 46 (Continued...)			
4	F	4.82Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected
5	F	4.57	
6	M	4.74Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected
7	F	5.12	
8	M	5.15Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected
9	F	5.00	
10	F	4.49Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected
11	F	4.95	
12	M	4.85Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected
13	M	5.04	
14	M	4.84Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected
15	M	4.99	
16	F	4.73Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected
17	M	4.85	
Dam: 47 Pregnancy Type: P			
1	F	4.84	
2	F	4.59Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected

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Individual Foetal Visceral Observations

20256434

BNT162b2 30mcg	Foetal Sex	Foetal Weight (g)	Findings
Dam: 47 (Continued...)			
3	M	5.21	
4	F	4.90Visceral Body (Rat), No abnormalities detected
		Visceral Head (Rat), No abnormalities detected
5	F	4.93	
6	M	5.10Visceral Body (Rat), No abnormalities detected
		Visceral Head (Rat), No abnormalities detected
7	M	5.21	
8	M	4.67Visceral Body (Rat), No abnormalities detected
		Visceral Head (Rat), No abnormalities detected
9	F	4.42	
10	F	4.95Visceral Body (Rat), No abnormalities detected
		Visceral Head (Rat), No abnormalities detected
11	M	5.18	
12	M	5.06Visceral Body (Rat), No abnormalities detected
		Visceral Head (Rat), No abnormalities detected
Dam: 48 Pregnancy Type: P			
1	F	5.13	
2	M	5.10Visceral Body (Rat), No abnormalities detected
		Visceral Head (Rat), No abnormalities detected
3	F	4.42	
4	M	4.68Visceral Body (Rat), No abnormalities detected
		Visceral Head (Rat), No abnormalities detected
5	M	4.90	
6	M	4.89Visceral Body (Rat), No abnormalities detected
		Visceral Head (Rat), No abnormalities detected

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Individual Foetal Visceral Observations

20256434

BNT162b2 30mcg	Foetal Sex	Foetal Weight (g)	Findings
Dam: 48 (Continued...)			
7	M	5.14	
8	F	4.90Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected
9	F	4.82	
10	F	4.51Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected
Dam: 49 Pregnancy Type: P			
1	F	4.20	
2	M	4.73Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected
3	M	4.50	
5	M	4.83Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected
6	M	3.56	
8	M	4.93Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected
9	M	4.49	
10	F	4.54Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected
12	F	4.49	
13	F	4.54Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected
14	F	4.19	
15	F	4.67Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected

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Individual Foetal Visceral Observations

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BNT162b2 30mcg	Foetal Sex	Foetal Weight (g)	Findings
Dam: 49 (Continued...)			
17	M	4.32	
Dam: 50 Pregnancy Type: P			
1	F	4.27	
2	M	5.05Visceral Body (Rat), Major blood vessel Umbilical artery, Transposed - (V)Visceral Head (Rat), No abnormalities detected
3	M	4.73	
4	F	4.21Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected
6	F	4.51	
7	M	4.64Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected
8	M	5.16	
9	M	5.25Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected
10	F	4.45	
Dam: 51 Pregnancy Type: P			
1	F	5.07	
2	M	5.37Visceral Body (Rat), Major blood vessel Umbilical artery, Transposed - (V)Visceral Head (Rat), No abnormalities detected
3	M	5.56	
4	F	5.11Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected

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Individual Foetal Visceral Observations

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BNT162b2 30mcg	Foetal Sex	Foetal Weight (g)	Findings
Dam: 51 (Continued...)			
5	M	5.43	
6	M	5.42Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected
7	F	5.18	
8	M	4.54Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected
9	M	5.38	
10	M	4.94Visceral Body (Rat), Major blood vessel Umbilical artery, Transposed - (V)Visceral Head (Rat), No abnormalities detected
11	F	4.69	
12	M	5.55Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected
13	M	5.53	
14	F	5.33Visceral Body (Rat), Major blood vessel Umbilical artery, Transposed - (V)Visceral Head (Rat), No abnormalities detected
15	M	5.13	
Dam: 52 Pregnancy Type: P			
1	F	5.46	
2	F	4.99Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected
3	M	5.64	
4	F	5.25Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected

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Individual Foetal Visceral Observations

20256434

BNT162b2 30mcg	Foetal Sex	Foetal Weight (g)	Findings
Dam: 52 (Continued...)			
6	F	5.10	
7	F	5.12Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected
9	M	5.31	
10	F	5.21Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected
11	F	4.96	
12	M	5.01Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected
13	M	5.74	
14	M	5.45Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected
15	M	5.14	
Dam: 53 Pregnancy Type: P			
1	M	4.98	
2	M	4.96Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected
3	F	4.85	
4	M	4.49Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected
5	F	4.04	
6	M	2.70Visceral Body (Rat), Lung Lobe, Absent - (A), [azygos]Visceral Body (Rat), Major blood vessel Aortic arch, Right-sided - (M)

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Individual Foetal Visceral Observations

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BNT162b2 30mcg	Foetal Sex	Foetal Weight (g)	Findings
Dam: 53 (Continued...)			
7	F	4.28	Umbilical artery, Transposed - (V)
8	M	5.26Visceral Head (Rat), No abnormalities detected
9	F	4.86Visceral Body (Rat), No abnormalities detected
10	M	5.10Visceral Head (Rat), No abnormalities detected
11	F	3.10Visceral Body (Rat), No abnormalities detected
12	F	4.65Visceral Head (Rat), No abnormalities detected
13	M	4.03Visceral Body (Rat), No abnormalities detected
14	M	4.98Visceral Head (Rat), No abnormalities detected
15	M	5.11Visceral Body (Rat), No abnormalities detected
16	F	3.84Visceral Head (Rat), No abnormalities detected
Dam: 54 Pregnancy Type: P			
1	M	4.61Visceral Body (Rat), No abnormalities detected
2	M	5.45Visceral Head (Rat), No abnormalities detected
3	M	5.08Visceral Body (Rat), No abnormalities detected
4	M	5.72Visceral Head (Rat), No abnormalities detected
5	F	5.59Visceral Body (Rat), No abnormalities detected

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Individual Foetal Visceral Observations

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BNT162b2 30mcg	Foetal Sex	Foetal Weight (g)	Findings
Dam: 54 (Continued...)			
6	M	5.38Visceral Body (Rat), No abnormalities detected
7	M	5.28Visceral Head (Rat), No abnormalities detected
8	F	4.92Visceral Body (Rat), No abnormalities detected
9	M	5.46Visceral Head (Rat), No abnormalities detected
10	M	5.16Visceral Body (Rat), No abnormalities detected
12	M	5.64Visceral Head (Rat), No abnormalities detected
13	F	5.49Visceral Body (Rat), No abnormalities detected
14	F	4.71Visceral Head (Rat), No abnormalities detected
Dam: 55 Pregnancy Type: P			
1	F	5.00Visceral Body (Rat), No abnormalities detected
2	M	5.64Visceral Head (Rat), No abnormalities detected
3	F	5.24Visceral Body (Rat), No abnormalities detected
4	F	5.13Visceral Head (Rat), No abnormalities detected
5	M	5.36Visceral Body (Rat), No abnormalities detected
6	F	4.81Visceral Head (Rat), No abnormalities detected
8	M	5.18Visceral Body (Rat), Major blood vessel
9	F	4.54	Umbilical artery, Transposed - (V)

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Individual Foetal Visceral Observations

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BNT162b2 30mcg	Foetal Sex	Foetal Weight (g)	Findings
Dam: 55 (Continued...)			
10	F	5.25Visceral Head (Rat), No abnormalities detected
11	F	4.96Visceral Body (Rat), No abnormalities detected
12	M	5.42Visceral Head (Rat), No abnormalities detected
13	F	5.03Visceral Body (Rat), Major blood vessel Umbilical artery, Transposed - (V)
14	M	5.24Visceral Head (Rat), No abnormalities detected
Dam: 56 Pregnancy Type: NPE			
Dam: 57 Pregnancy Type: P			
1	M	5.01Visceral Body (Rat), No abnormalities detected
2	F	4.67Visceral Head (Rat), No abnormalities detected
3	F	4.86Visceral Body (Rat), No abnormalities detected
4	F	4.94Visceral Head (Rat), No abnormalities detected
5	F	5.15Visceral Body (Rat), No abnormalities detected
6	M	5.26Visceral Head (Rat), No abnormalities detected
7	M	4.97Visceral Body (Rat), No abnormalities detected
8	M	5.45Visceral Head (Rat), No abnormalities detected

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Individual Foetal Visceral Observations

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BNT162b2 30mcg	Foetal Sex	Foetal Weight (g)	Findings
Dam: 57 (Continued...)			
9	F	4.76	
10	M	4.20Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected
11	F	5.34	
12	F	5.00Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected
13	M	5.39	
14	M	5.40Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected
15	M	5.16	
Dam: 58 Pregnancy Type: P			
1	M	4.04	
2	M	5.05Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected
3	F	4.69	
4	M	4.78Visceral Body (Rat), Major blood vessel Umbilical artery, Transposed - (V)Visceral Head (Rat), No abnormalities detected
5	F	4.68	
7	M	5.00Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected
8	F	4.77	
9	M	4.00Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected
10	M	3.77	

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Individual Foetal Visceral Observations

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BNT162b2 30mcg	Foetal Sex	Foetal Weight (g)	Findings
Dam: 58 (Continued...)			
11	F	4.36Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected
13	M	4.83	
14	F	2.50Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected
15	F	4.59	
16	M	4.79Visceral Body (Rat), Major blood vessel Umbilical artery, Transposed - (V)Visceral Head (Rat), No abnormalities detected
Dam: 59 Pregnancy Type: P			
1	F	4.55	
2	F	4.52Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected
4	F	5.02	
5	F	4.19Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected
7	F	4.27	
8	M	4.61Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected
9	M	5.04	
10	F	4.63Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected
11	M	4.35	
12	F	4.66Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected

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Individual Foetal Visceral Observations

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BNT162b2 30mcg	Foetal Sex	Foetal Weight (g)	Findings
Dam: 59 (Continued...)			
13	F	4.54	
14	F	4.36Visceral Body (Rat), No abnormalities detected
15	F	4.79Visceral Head (Rat), No abnormalities detected
Dam: 60 Pregnancy Type: P			
1	F	4.99	
2	M	5.18Visceral Body (Rat), Major blood vessel Umbilical artery, Transposed - (V)
3	F	5.00Visceral Head (Rat), No abnormalities detected
4	M	5.94Visceral Body (Rat), No abnormalities detected
5	M	5.22Visceral Head (Rat), No abnormalities detected
6	F	4.99Visceral Body (Rat), No abnormalities detected
7	M	4.93Visceral Head (Rat), No abnormalities detected
8	M	5.25Visceral Body (Rat), No abnormalities detected
9	M	5.30Visceral Head (Rat), No abnormalities detected
10	F	4.80Visceral Body (Rat), No abnormalities detected
11	M	5.41Visceral Head (Rat), No abnormalities detected
12	F	5.04Visceral Body (Rat), Major blood vessel Umbilical artery, Transposed - (V)
		Visceral Head (Rat), No abnormalities detected

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Individual Foetal Visceral Observations

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BNT162b2 30mcg	Foetal Sex	Foetal Weight (g)	Findings
Dam: 61 Pregnancy Type: P			
1	F	5.00	
2	M	5.13Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected
3	M	5.34	
4	F	5.07Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected
5	M	5.49	
6	F	5.07Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected
7	F	5.24	
8	F	5.09Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected
9	M	5.37	
10	M	5.34Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected
11	F	5.02	
12	M	5.63Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected
13	F	5.07	
Dam: 62 Pregnancy Type: P			
1	F	4.66	
2	M	5.24Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected
3	M	5.10	

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BNT162b2 30mcg	Foetal Sex	Foetal Weight (g)	Findings
Dam: 62 (Continued...)			
4	F	4.88Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected
5	M	4.75	
6	F	4.44Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected
7	M	4.71	
8	M	4.60Visceral Body (Rat), Major blood vessel Umbilical artery, Transposed - (V)Visceral Head (Rat), No abnormalities detected
9	F	4.71	
10	M	4.73Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected
11	M	4.91	
12	M	4.84Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected
13	M	5.11	
14	F	4.88Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected
Dam: 63 Pregnancy Type: P			
1	F	4.47	
2	F	4.48Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected
3	M	4.55	
4	F	4.87Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected

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Individual Foetal Visceral Observations

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BNT162b2 30mcg	Foetal Sex	Foetal Weight (g)	Findings
Dam: 63 (Continued...)			
5	M	4.64	
6	M	5.37Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected
7	F	4.80	
8	F	4.71Visceral Body (Rat), Major blood vessel Umbilical artery, Transposed - (V)Visceral Head (Rat), No abnormalities detected
9	F	4.51	
10	M	4.51Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected
11	M	5.00	
12	F	2.79Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected
Dam: 64 Pregnancy Type: P			
1	F	4.89	
2	F	4.96Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected
3	F	4.84	
4	M	5.29Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected
5	M	5.19	
6	M	4.65Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected
7	F	4.70	
8	F	4.89Visceral Body (Rat), No abnormalities detected

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Individual Foetal Visceral Observations

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BNT162b2 30mcg	Foetal Sex	Foetal Weight (g)	Findings
Dam: 64 (Continued...)			
9	F	5.03Visceral Head (Rat), No abnormalities detected
10	M	5.23Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected
13	M	4.84Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected
14	F	3.95Visceral Head (Rat), No abnormalities detected
Dam: 65 Pregnancy Type: P			
1	F	4.64	
2	M	5.21Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected
3	F	4.81	
4	F	4.80Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected
5	M	5.12	
6	F	4.55Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected
7	F	4.69	
8	F	5.17Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected
9	F	4.68	
10	M	4.83Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected
11	M	5.26	
12	M	5.31Visceral Body (Rat), No abnormalities detected

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Individual Foetal Visceral Observations

20256434

BNT162b2 30mcg	Foetal Sex	Foetal Weight (g)	Findings
Dam: 65 (Continued...)			
13	F	4.83Visceral Head (Rat), No abnormalities detected
14	M	5.12Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected
15	M	5.26	
16	F	4.82Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected
17	M	4.68	
Dam: 66 Pregnancy Type: P			
1	F	5.18	
2	F	5.62Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected
4	F	5.49	
5	F	5.38Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected
6	M	5.04	
7	M	5.75Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected
8	F	4.96	
9	F	5.80Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected
10	M	5.96	
11	M	5.39Visceral Body (Rat), No abnormalities detectedVisceral Head (Rat), No abnormalities detected

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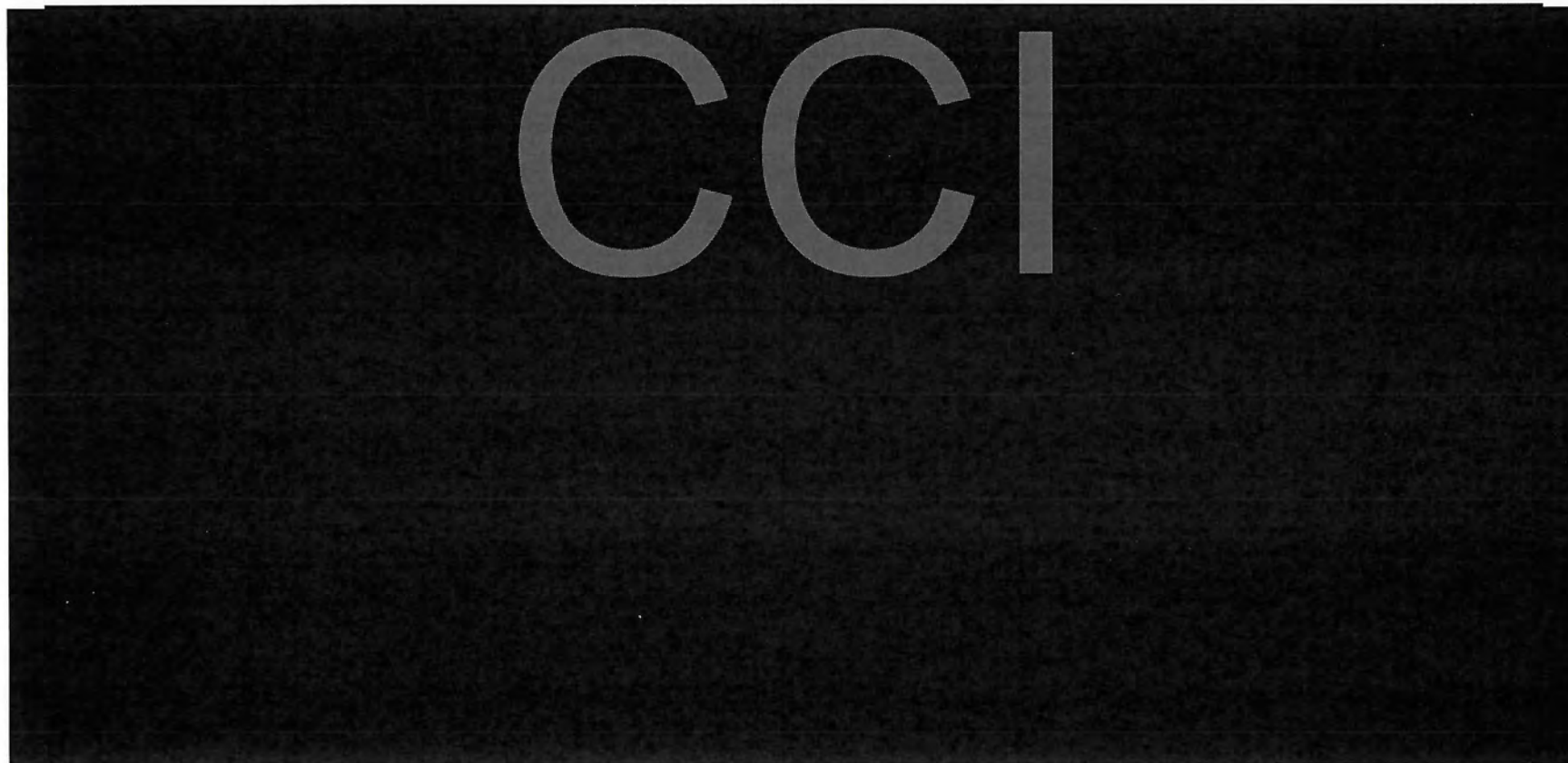
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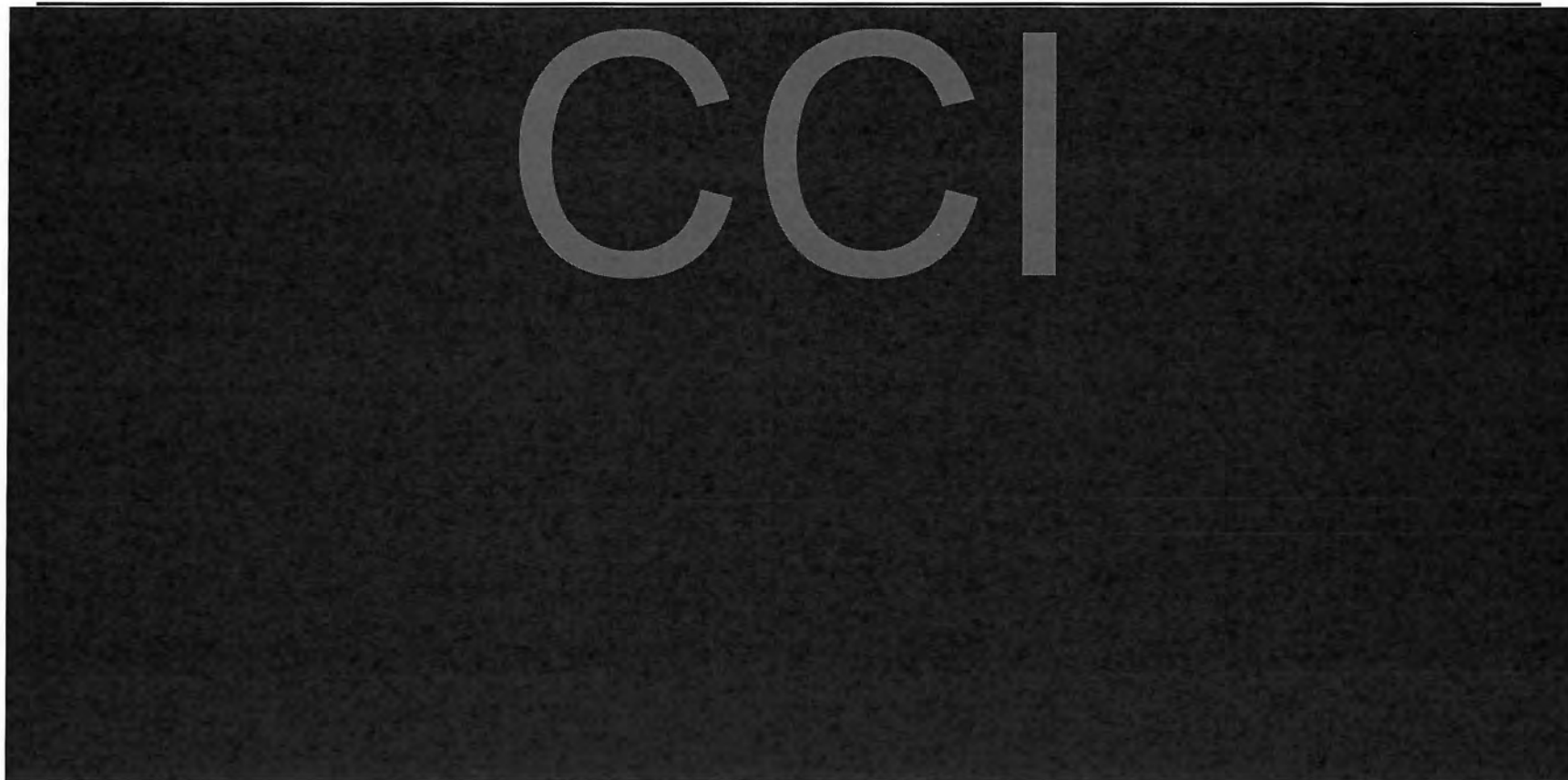
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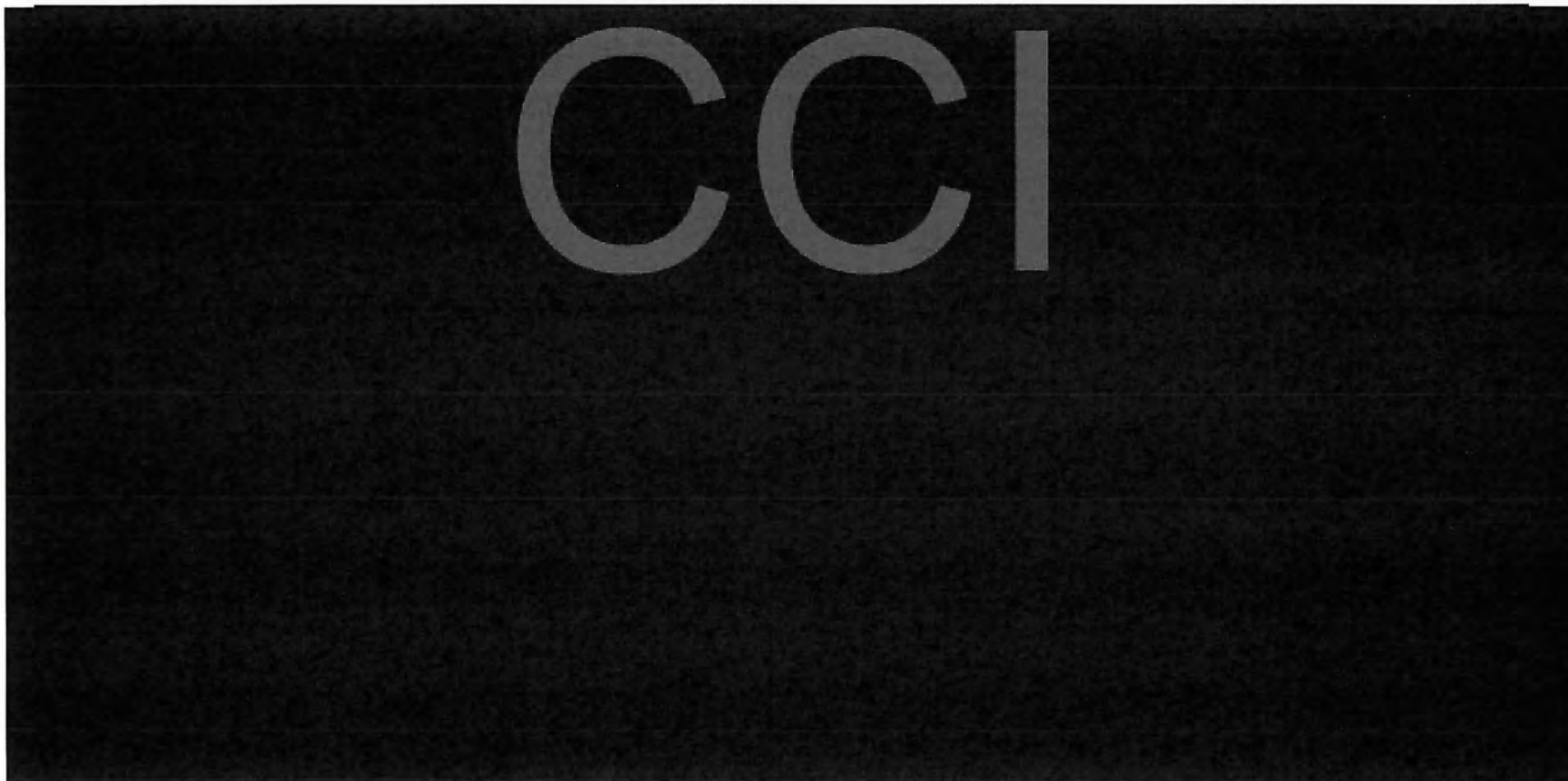
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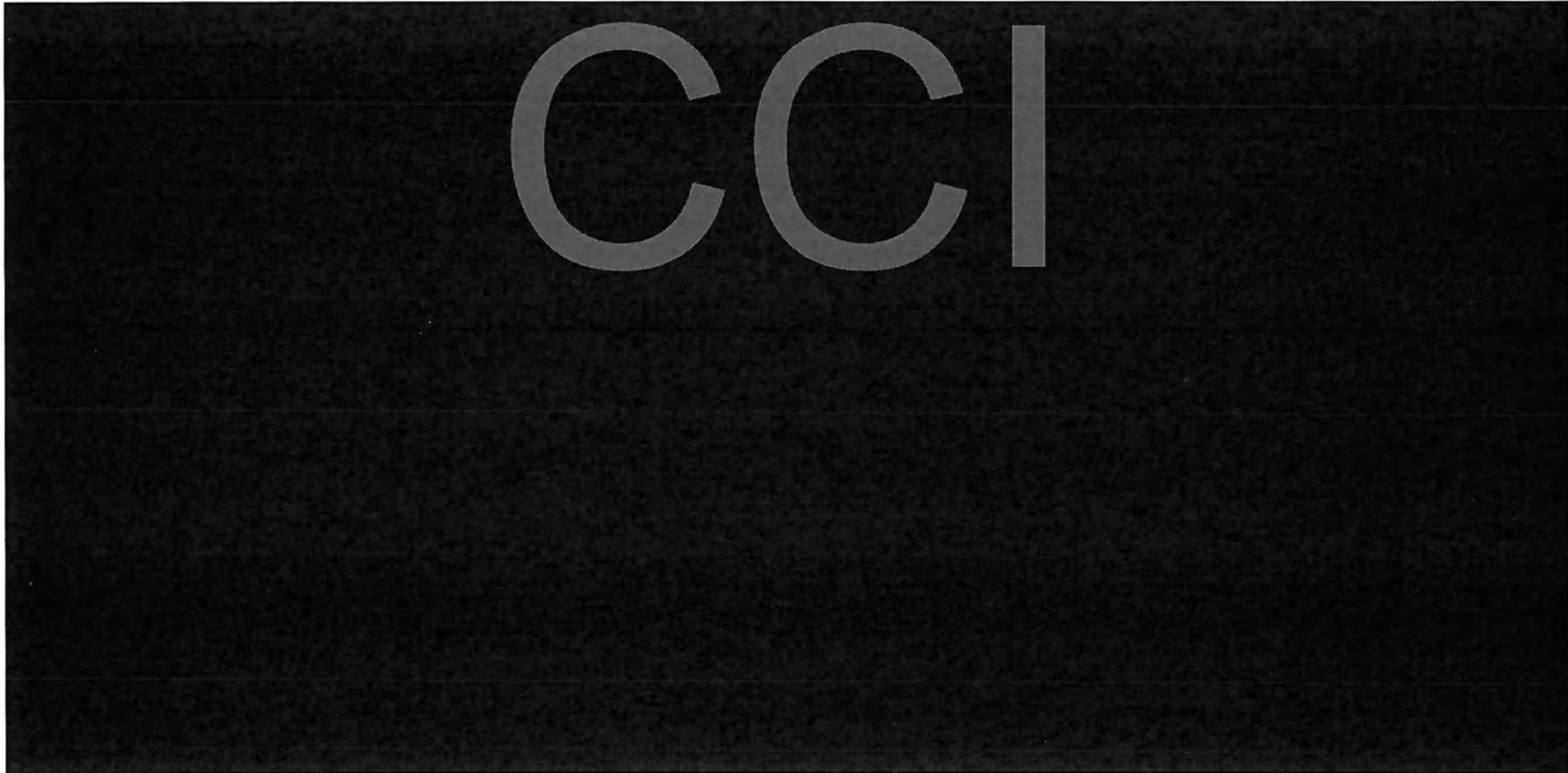
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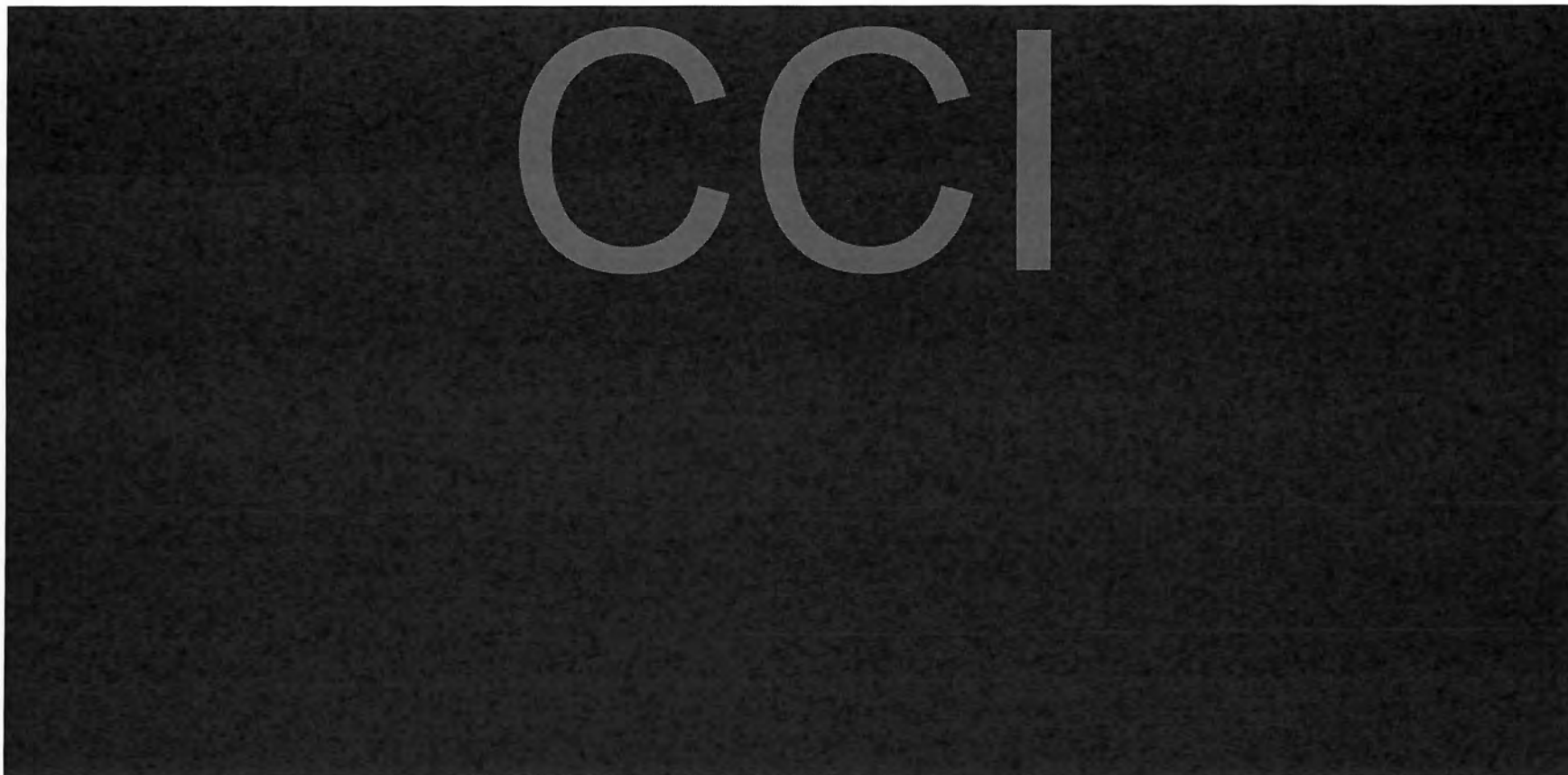
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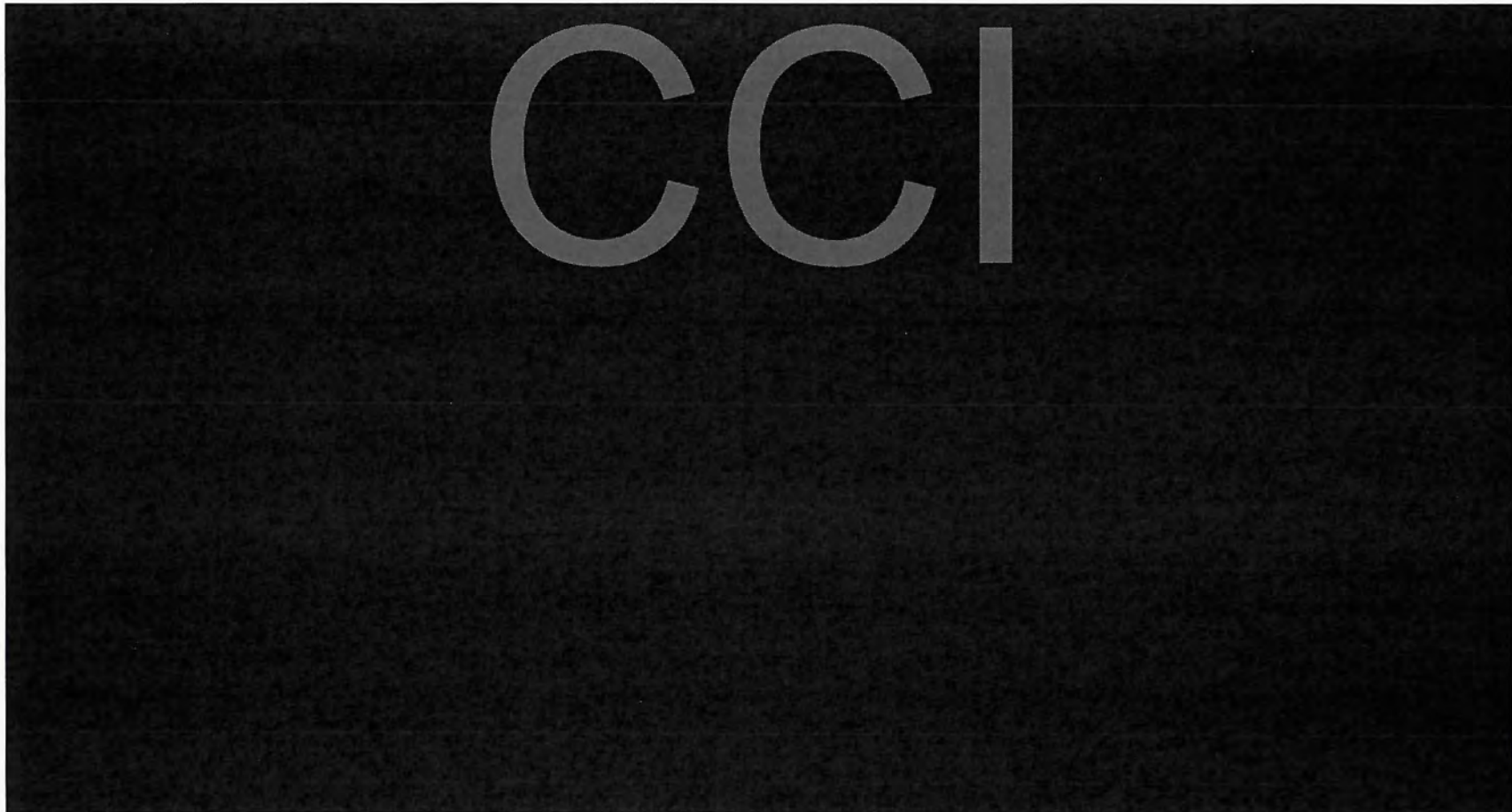
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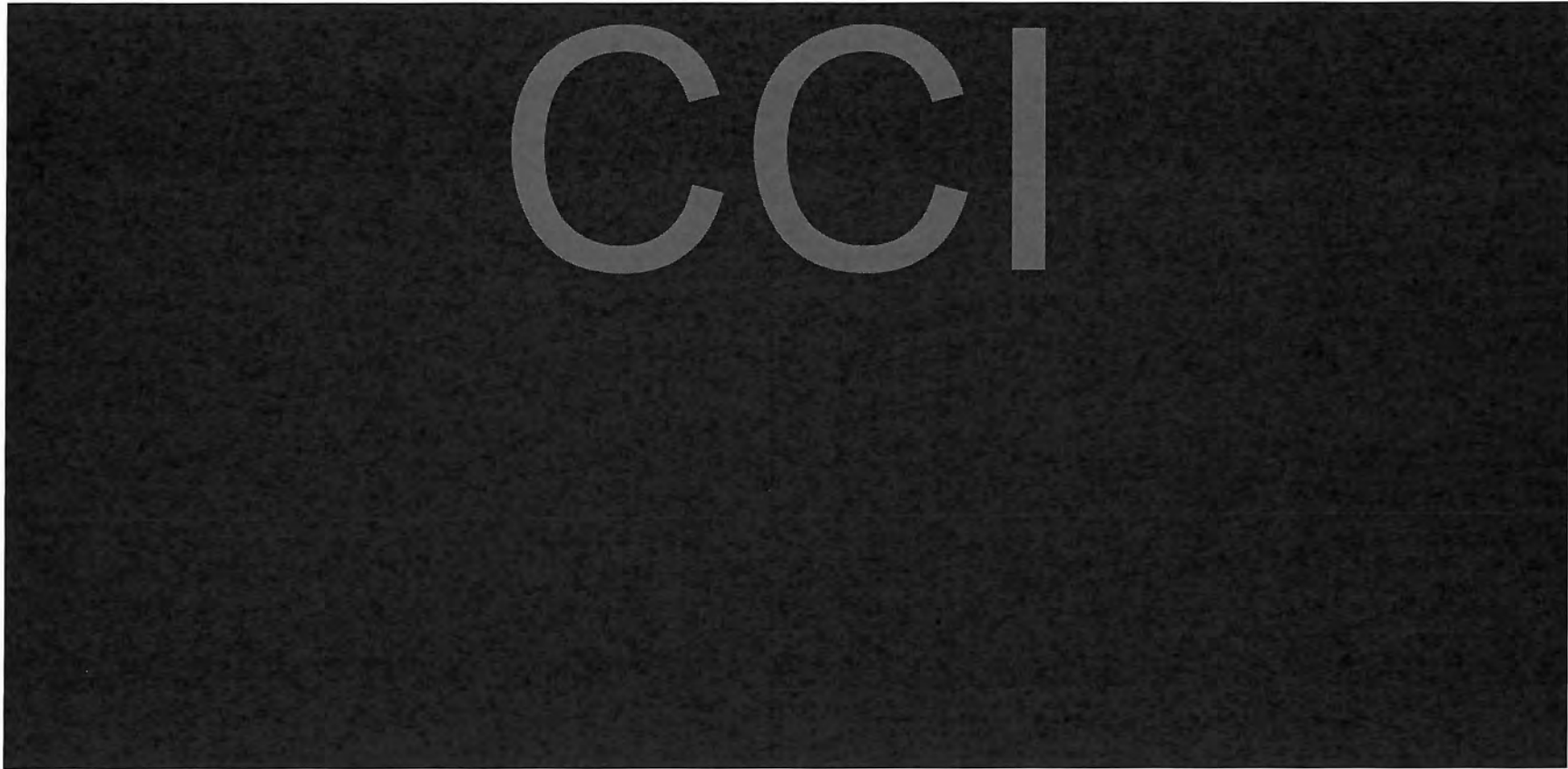
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Individual Foetal Visceral Observations



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Individual Foetal Skeletal Observations

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Control Omcg	Foetal Sex	Foetal Weight (g)	Findings
Dam: 1 Pregnancy Type: P			
1	F	4.82Skeletal Body (Rat-G21), Hindpaw Phalanx, Unossified, proximal 2nd to 5th digits - (V), [bilateral]Skeletal Body (Rat-G21), Vertebra Thoracic, Incomplete ossification of centrum, 10th to 13th. - (A)Skeletal Head (Rat-G21), No abnormalities detected
2	M	5.23	
3	F	5.03Skeletal Body (Rat-G21), Hindpaw Phalanx, Unossified, proximal 2nd to 5th digits - (V), [bilateral]Skeletal Body (Rat-G21), Sternebra Sternebra, Asymmetric - (A), [3rd to 5th]Skeletal Head (Rat-G21), No abnormalities detected
5	F	5.05	
6	M	5.25Skeletal Body (Rat-G21), Forepaw Phalanx, Unossified - (A), [bilateral]Skeletal Body (Rat-G21), Hindpaw Phalanx, Unossified, proximal 2nd to 5th digits - (V), [bilateral]Skeletal Head (Rat-G21), No abnormalities detected
7	M	5.14	
9	F	4.97Skeletal Body (Rat-G21), Hindpaw Phalanx, Unossified, proximal 2nd to 5th digits - (V), [bilateral]Skeletal Body (Rat-G21), Vertebra Thoracic, Incomplete ossification of centrum, 1st to 9th - (A), [3rd bipartite]Skeletal Head (Rat-G21), No abnormalities detected
11	F	5.13	
12	M	4.93Skeletal Body (Rat-G21), Hindpaw Phalanx, Unossified, proximal 2nd to 5th digits - (V), [bilateral]Skeletal Head (Rat-G21), No abnormalities detected

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Individual Foetal Skeletal Observations

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Control Omcg	Foetal Sex	Foetal Weight (g)	Findings
Dam: 1 (Continued...)			
13	F	5.06Skeletal Body (Rat-G21), Forepaw
14	F	4.84	Phalanx, Unossified - (A), [bilateral]Skeletal Body (Rat-G21), Hindpaw Phalanx, Unossified, proximal 2nd to 5th digits - (V), [bilateral]Skeletal Head (Rat-G21), No abnormalities detected
Dam: 2 Pregnancy Type: P			
1	M	4.79Skeletal Body (Rat-G21), Ribs Ribs, Supernumerary lumbar, short - (V), [bilateral]Skeletal Head (Rat-G21), No abnormalities detected
2	F	4.52Skeletal Body (Rat-G21), No abnormalities detected
3	F	4.91Skeletal Head (Rat-G21), No abnormalities detected
4	F	4.39Skeletal Body (Rat-G21), No abnormalities detected
5	F	5.02Skeletal Body (Rat-G21), Ribs Ribs, Supernumerary lumbar, short - (V), [right]Skeletal Head (Rat-G21), No abnormalities detected
6	F	4.65Skeletal Body (Rat-G21), No abnormalities detected
7	M	5.03Skeletal Head (Rat-G21), No abnormalities detected
8	M	4.70Skeletal Body (Rat-G21), No abnormalities detected
9	F	4.79Skeletal Body (Rat-G21), Ribs Ribs, Supernumerary lumbar - (A), [bilateral]Skeletal Head (Rat-G21), No abnormalities detected
10	M	4.79Skeletal Head (Rat-G21), No abnormalities detected

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Individual Foetal Skeletal Observations

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Control Omcg	Foetal Sex	Foetal Weight (g)	Findings
Dam: 2 (Continued...)			
11	M	4.32Skeletal Body (Rat-G21), No abnormalities detectedSkeletal Head (Rat-G21), No abnormalities detected
12	M	4.91	
13	M	4.05Skeletal Body (Rat-G21), No abnormalities detectedSkeletal Head (Rat-G21), No abnormalities detected
14	F	4.67	
15	F	4.30Skeletal Body (Rat-G21), Hindpaw Phalanx, Unossified, proximal 2nd to 5th digits - (V), [left]Skeletal Head (Rat-G21), No abnormalities detected
Dam: 3 Pregnancy Type: P			
1	M	4.51Skeletal Body (Rat-G21), Hindpaw Phalanx, Unossified, proximal 2nd to 5th digits - (V), [bilateral]Skeletal Head (Rat-G21), No abnormalities detected
2	M	4.93	
3	F	4.75Skeletal Body (Rat-G21), Hindpaw Phalanx, Unossified, proximal 2nd to 5th digits - (V), [bilateral]Skeletal Head (Rat-G21), No abnormalities detected
4	F	4.36	
5	M	5.12Skeletal Body (Rat-G21), Hindpaw Phalanx, Unossified, proximal 2nd to 5th digits - (V), [bilateral]Skeletal Head (Rat-G21), No abnormalities detected
6	M	4.76	
7	F	5.03Skeletal Body (Rat-G21), Ribs Ribs, Supernumerary cervical - (A), [right, short]Skeletal Head (Rat-G21), No abnormalities detected
8	F	4.80	

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Individual Foetal Skeletal Observations

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Control 0mcg	Foetal Sex	Foetal Weight (g)	Findings
Dam: 3 (Continued...)			
9	F	4.48Skeletal Body (Rat-G21), Hindpaw Phalanx, Unossified, proximal 2nd to 5th digits - (V), [bilateral]Skeletal Head (Rat-G21), No abnormalities detected
10	F	4.63	
11	F	4.22Skeletal Body (Rat-G21), Hindpaw Phalanx, Unossified, proximal 2nd to 5th digits - (V), [bilateral]Skeletal Body (Rat-G21), Vertebra Cervical, Odontoid process unossified - (V)Skeletal Head (Rat-G21), No abnormalities detected
12	M	5.13	
13	F	3.36Skeletal Body (Rat-G21), Forepaw Phalanx, Unossified - (A), [bilateral]Skeletal Body (Rat-G21), Hindpaw Metatarsal, Unossified, 1st digit - (V), [bilateral] Phalanx, Unossified, proximal 2nd to 5th digits - (V), [bilateral]Skeletal Body (Rat-G21), Vertebra Cervical, Odontoid process unossified - (V)Skeletal Head (Rat-G21), Skull Presphenoid, Incomplete ossification - (A)
14	M	4.64	
15	F	4.64Skeletal Body (Rat-G21), Hindpaw Phalanx, Unossified, proximal 2nd to 5th digits - (V), [bilateral]Skeletal Head (Rat-G21), No abnormalities detected
16	M	4.90	
Dam: 4 Pregnancy Type: P			
1	M	4.81Skeletal Body (Rat-G21), No abnormalities detected

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Control Omcg	Foetal Sex	Foetal Weight (g)	Findings
Dam: 4 (Continued...)			
2	M	4.05Skeletal Head (Rat-G21), No abnormalities detected
3	F	4.72Skeletal Body (Rat-G21), Vertebra Thoracic, Incomplete ossification of centrum, 10th to 13th. - (A), [12th bipartite]Skeletal Head (Rat-G21), No abnormalities detected
4	F	4.45Skeletal Head (Rat-G21), No abnormalities detected
5	F	4.47Skeletal Body (Rat-G21), No abnormalities detectedSkeletal Head (Rat-G21), No abnormalities detected
6	M	4.80Skeletal Head (Rat-G21), No abnormalities detected
7	F	4.50Skeletal Body (Rat-G21), Ribs Ribs, Supernumerary cervical - (A), [left, short] Ribs, Supernumerary lumbar, short - (V), [left]Skeletal Head (Rat-G21), No abnormalities detected
8	M	5.12Skeletal Head (Rat-G21), No abnormalities detected
10	F	3.60Skeletal Body (Rat-G21), Hindpaw Phalanx, Unossified, proximal 2nd to 5th digits - (V), [right]Skeletal Body (Rat-G21), Ribs Ribs, Supernumerary lumbar, short - (V), [bilateral]Skeletal Head (Rat-G21), No abnormalities detected
12	M	4.90Skeletal Head (Rat-G21), No abnormalities detected
13	M	5.67Skeletal Body (Rat-G21), Ribs Ribs, Supernumerary lumbar, short - (V), [right]Skeletal Head (Rat-G21), No abnormalities detected
14	F	3.33Skeletal Head (Rat-G21), No abnormalities detected
15	F	5.39Skeletal Body (Rat-G21), No abnormalities detectedSkeletal Head (Rat-G21), No abnormalities detected

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Control Omcg	Foetal Sex	Foetal Weight (g)	Findings
Dam: 4 (Continued...)			
16	F	4.71	
Dam: 5 Pregnancy Type: P			
2	F	5.16Skeletal Body (Rat-G21), Vertebra Thoracic, Incomplete ossification of centrum, 10th to 13th. - (A)Skeletal Head (Rat-G21), No abnormalities detected
3	F	4.93	
4	F	4.84Skeletal Body (Rat-G21), No abnormalities detectedSkeletal Head (Rat-G21), No abnormalities detected
5	F	4.95	
6	F	4.83Skeletal Body (Rat-G21), No abnormalities detectedSkeletal Head (Rat-G21), No abnormalities detected
7	M	5.01	
8	F	5.03Skeletal Body (Rat-G21), No abnormalities detectedSkeletal Head (Rat-G21), No abnormalities detected
9	F	4.96	
10	F	4.97Skeletal Body (Rat-G21), No abnormalities detectedSkeletal Head (Rat-G21), No abnormalities detected
11	M	4.82	
12	F	5.18Skeletal Body (Rat-G21), No abnormalities detectedSkeletal Head (Rat-G21), No abnormalities detected
13	M	5.41	
14	F	4.53Skeletal Body (Rat-G21), No abnormalities detectedSkeletal Head (Rat-G21), No abnormalities detected
Dam: 6 Pregnancy Type: P			
1	M	3.42Skeletal Body (Rat-G21), Forepaw

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Individual Foetal Skeletal Observations

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Control 0mcg	Foetal Sex	Foetal Weight (g)	Findings
Dam: 6 (Continued...)			
			Phalanx, Unossified - (A), [bilateral]Skeletal Body (Rat-G21), Hindpaw Metatarsal, Unossified, 1st digit - (V), [bilateral] Phalanx, Unossified, proximal 2nd to 5th digits - (V), [bilateral]Skeletal Body (Rat-G21), Ribs Ribs, Supernumerary lumbar, short - (V), [left]Skeletal Body (Rat-G21), Vertebra Cervical, Unossified centrum - (V)Skeletal Head (Rat-G21), No abnormalities detected
2	M	5.09	
3	M	5.45Skeletal Body (Rat-G21), Ribs Ribs, Supernumerary lumbar - (A), [right] Ribs, Supernumerary lumbar, short - (V), [left]Skeletal Head (Rat-G21), No abnormalities detected
4	M	5.58	
5	M	5.64Skeletal Body (Rat-G21), Ribs Ribs, Supernumerary lumbar, short - (V), [bilateral]Skeletal Head (Rat-G21), No abnormalities detected
6	F	5.61	
7	M	5.61Skeletal Body (Rat-G21), Ribs Ribs, Supernumerary lumbar, short - (V), [bilateral]Skeletal Head (Rat-G21), No abnormalities detected
8	F	4.46	
9	M	5.89Skeletal Body (Rat-G21), Ribs Ribs, Supernumerary lumbar, short - (V), [right]Skeletal Head (Rat-G21), No abnormalities detected

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Control Omcg	Foetal Sex	Foetal Weight (g)	Findings
Dam: 6 (Continued...)			
10	F	5.39	
Dam: 7 Pregnancy Type: P			
1	F	5.23Skeletal Body (Rat-G21), Ribs Ribs, Supernumerary lumbar, short - (V), [bilateral]Skeletal Head (Rat-G21), No abnormalities detected
2	M	5.04	
3	F	4.76Skeletal Body (Rat-G21), Ribs Ribs, Supernumerary lumbar, short - (V), [right]Skeletal Head (Rat-G21), No abnormalities detected
4	F	4.85	
5	F	5.14Skeletal Body (Rat-G21), No abnormalities detectedSkeletal Head (Rat-G21), No abnormalities detected
6	M	5.12	
7	M	4.84Skeletal Body (Rat-G21), No abnormalities detectedSkeletal Head (Rat-G21), No abnormalities detected
8	F	4.95	
9	M	5.44Skeletal Body (Rat-G21), Ribs Ribs, Supernumerary lumbar, short - (V), [bilateral]Skeletal Head (Rat-G21), No abnormalities detected
10	F	5.33	
11	M	5.50Skeletal Body (Rat-G21), No abnormalities detectedSkeletal Head (Rat-G21), No abnormalities detected
12	M	5.32	
13	M	5.13Skeletal Body (Rat-G21), Ribs Ribs, Supernumerary lumbar, short - (V), [left]

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Control Omcg	Foetal Sex	Foetal Weight (g)	Findings
Dam: 7 (Continued...)			
14	F	4.59Skeletal Head (Rat-G21), No abnormalities detected
Dam: 8 Pregnancy Type: P			
1	M	4.66Skeletal Body (Rat-G21), No abnormalities detectedSkeletal Head (Rat-G21), No abnormalities detected
2	M	4.87	
4	F	4.97Skeletal Body (Rat-G21), No abnormalities detectedSkeletal Head (Rat-G21), No abnormalities detected
5	F	5.11	
7	M	4.43Skeletal Body (Rat-G21), No abnormalities detectedSkeletal Head (Rat-G21), No abnormalities detected
8	M	5.48	
9	F	5.12Skeletal Body (Rat-G21), No abnormalities detectedSkeletal Head (Rat-G21), No abnormalities detected
11	F	4.96	
12	M	5.20Skeletal Body (Rat-G21), No abnormalities detectedSkeletal Head (Rat-G21), No abnormalities detected
15	F	4.91	
16	M	5.53Skeletal Body (Rat-G21), Ribs Ribs, Supernumerary lumbar, short - (V), [right]Skeletal Body (Rat-G21), Vertebra Thoracic, Incomplete ossification of centrum, 10th to 13th. - (A)Skeletal Head (Rat-G21), No abnormalities detected
17	F	4.64	

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Control Omco	Foetal Sex	Foetal Weight (g)	Findings
Dam: 9 Pregnancy Type: P			
1	F	4.75Skeletal Body (Rat-G21), Hindpaw Phalanx, Unossified, proximal 2nd to 5th digits - (V), [bilateral]Skeletal Body (Rat-G21), Ribs Ribs, Supernumerary lumbar, short - (V), [bilateral]Skeletal Head (Rat-G21), Skull Interparietal, Incomplete ossification - (V)
2	M	4.92	
3	F	4.39Skeletal Body (Rat-G21), Forepaw Phalanx, Unossified - (A), [bilateral]Skeletal Body (Rat-G21), Hindpaw Phalanx, Unossified, proximal 2nd to 5th digits - (V), [bilateral]Skeletal Body (Rat-G21), Ribs Ribs, Supernumerary lumbar, short - (V), [bilateral]Skeletal Head (Rat-G21), No abnormalities detected
4	M	5.25	
5	F	5.24Skeletal Body (Rat-G21), Hindpaw Phalanx, Unossified, proximal 2nd to 5th digits - (V), [bilateral]Skeletal Body (Rat-G21), Ribs Ribs, Supernumerary lumbar, short - (V), [left]Skeletal Head (Rat-G21), No abnormalities detected
6	M	5.42	
7	M	5.48Skeletal Body (Rat-G21), Ribs Ribs, Thick - (A), [bilateral] Ribs, Supernumerary lumbar, short - (V), [bilateral]Skeletal Head (Rat-G21), No abnormalities detected
8	M	5.28	

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Control Omcg	Foetal Sex	Foetal Weight (g)	Findings
Dam: 9 (Continued...)			
9	M	5.07Skeletal Body (Rat-G21), Hindpaw Phalanx, Unossified, proximal 2nd to 5th digits - (V), [bilateral]Skeletal Head (Rat-G21), No abnormalities detected
10	M	4.69Skeletal Body (Rat-G21), Hindpaw Phalanx, Unossified, proximal 2nd to 5th digits - (V), [bilateral]
11	M	5.27Skeletal Body (Rat-G21), Ribs Ribs, Supernumerary lumbar, short - (V), [left]Skeletal Head (Rat-G21), No abnormalities detected
12	F	4.74Skeletal Body (Rat-G21), Hindpaw Phalanx, Unossified, proximal 2nd to 5th digits - (V), [right]
13	F	5.36Skeletal Body (Rat-G21), Ribs Ribs, Thick - (A), [right] Ribs, Supernumerary lumbar, short - (V), [bilateral]Skeletal Head (Rat-G21), No abnormalities detected
Dam: 10 Pregnancy Type: P			
1	M	5.27Skeletal Body (Rat-G21), Ribs Ribs, Supernumerary lumbar, short - (V), [left]Skeletal Head (Rat-G21), Skull Interparietal, Incomplete ossification - (V)
2	M	5.14Skeletal Body (Rat-G21), Ribs Ribs, Supernumerary lumbar, short - (V), [bilateral]
3	M	5.45Skeletal Body (Rat-G21), Ribs Ribs, Supernumerary lumbar, short - (V), [bilateral]Skeletal Head (Rat-G21), No abnormalities detected
4	M	5.43Skeletal Body (Rat-G21), Ribs Ribs, Supernumerary lumbar, short - (V), [bilateral]Skeletal Head (Rat-G21), No abnormalities detected

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Individual Foetal Skeletal Observations

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Control 0mcg	Foetal Sex	Foetal Weight (g)	Findings
Dam: 10 (Continued...)			
6	M	5.74Skeletal Body (Rat-G21), Ribs Ribs, Supernumerary lumbar, short - (V), [left]Skeletal Head (Rat-G21), No abnormalities detected
7	M	5.65Skeletal Body (Rat-G21), Ribs Ribs, Supernumerary lumbar, short - (V), [bilateral]Skeletal Head (Rat-G21), No abnormalities detected
8	M	5.26Skeletal Body (Rat-G21), Ribs Ribs, Supernumerary lumbar, short - (V), [bilateral]Skeletal Head (Rat-G21), No abnormalities detected
9	M	5.15Skeletal Body (Rat-G21), Vertebra Cervical, Odontoid process unossified - (V)Skeletal Head (Rat-G21), No abnormalities detected
10	M	5.08Skeletal Body (Rat-G21), Vertebra Cervical, Odontoid process unossified - (V)Skeletal Head (Rat-G21), No abnormalities detected
11	F	5.16Skeletal Body (Rat-G21), No abnormalities detectedSkeletal Head (Rat-G21), No abnormalities detected
12	F	4.89Skeletal Body (Rat-G21), No abnormalities detectedSkeletal Head (Rat-G21), No abnormalities detected
Dam: 11 Pregnancy Type: P			
1	M	4.88Skeletal Body (Rat-G21), Hindpaw Phalanx, Unossified, proximal 2nd to 5th digits - (V), [bilateral]Skeletal Head (Rat-G21), No abnormalities detected
2	M	4.89Skeletal Body (Rat-G21), Hindpaw Phalanx, Unossified, proximal 2nd to 5th digits - (V), [bilateral]Skeletal Head (Rat-G21), No abnormalities detected
3	F	4.29Skeletal Body (Rat-G21), Forepaw Phalanx, Unossified - (A), [bilateral]Skeletal Body (Rat-G21), Hindpaw Phalanx, Unossified, proximal 2nd to 5th digits - (V), [bilateral]Skeletal Body (Rat-G21), Sternebra Sternebra, Incomplete ossification, 1st/3rd - (A), [3rd bipartite] Sternebra, Incomplete ossification, 2nd/4th - (V), [2nd and 4th bipartite]

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Individual Foetal Skeletal Observations

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Control Omcg	Foetal Sex	Foetal Weight (g)	Findings
Dam: 11 (Continued...)			
			Sterebra, Minor fusion - (A), [1st and 2nd]Skeletal Body (Rat-G21), Vertebra Cervical, Odontoid process unossified - (V) Cervical, Unossified centrum - (V)Skeletal Head (Rat-G21), No abnormalities detected
4	F	4.96	
5	F	5.27Skeletal Body (Rat-G21), Hindpaw Phalanx, Unossified, proximal 2nd to 5th digits - (V), [bilateral]Skeletal Head (Rat-G21), No abnormalities detected
6	F	4.88	
7	M	5.44Skeletal Body (Rat-G21), Hindpaw Phalanx, Unossified, proximal 2nd to 5th digits - (V), [left]Skeletal Body (Rat-G21), Ribs Ribs, Supernumerary lumbar, short - (V), [bilateral]Skeletal Head (Rat-G21), No abnormalities detected
8	F	5.27	
9	M	5.12Skeletal Body (Rat-G21), No abnormalities detectedSkeletal Head (Rat-G21), No abnormalities detected
10	F	5.08	
11	F	5.29Skeletal Body (Rat-G21), Hindpaw Phalanx, Unossified, proximal 2nd to 5th digits - (V), [bilateral]Skeletal Body (Rat-G21), Ribs Ribs, Supernumerary lumbar, short - (V), [bilateral]Skeletal Head (Rat-G21), No abnormalities detected
12	M	5.45	

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Control Omcg	Foetal Sex	Foetal Weight (g)	Findings
Dam: 12 Pregnancy Type: P			
1	F	4.95Skeletal Body (Rat-G21), No abnormalities detectedSkeletal Head (Rat-G21), No abnormalities detected
2	M	5.12	
3	M	4.78Skeletal Body (Rat-G21), Ribs Ribs, Supernumerary lumbar, short - (V), [bilateral]Skeletal Head (Rat-G21), No abnormalities detected
5	M	5.25	
6	F	4.51Skeletal Body (Rat-G21), No abnormalities detectedSkeletal Head (Rat-G21), No abnormalities detected
7	F	4.77	
8	M	4.97Skeletal Body (Rat-G21), Ribs Ribs, Supernumerary lumbar, short - (V), [bilateral]Skeletal Head (Rat-G21), No abnormalities detected
9	M	4.93	
10	F	4.87Skeletal Body (Rat-G21), No abnormalities detectedSkeletal Head (Rat-G21), No abnormalities detected
11	M	5.01	
12	F	5.01Skeletal Body (Rat-G21), Ribs Ribs, Supernumerary lumbar, short - (V), [left]Skeletal Head (Rat-G21), No abnormalities detected
13	M	5.08	
14	F	4.39Skeletal Body (Rat-G21), Ribs Ribs, Supernumerary lumbar, short - (V), [bilateral]Skeletal Head (Rat-G21), Skull Interparietal, Incomplete ossification - (V)

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Control 0mcg	Foetal Sex	Foetal Weight (g)	Findings
Dam: 13			Pregnancy Type: P
1	F	4.29Skeletal Body (Rat-G21), Hindpaw Phalanx, Unossified, proximal 2nd to 5th digits - (V), [bilateral]Skeletal Head (Rat-G21), No abnormalities detected
2	F	4.40	
3	M	4.09Skeletal Body (Rat-G21), Hindpaw Phalanx, Unossified, proximal 2nd to 5th digits - (V), [bilateral]Skeletal Head (Rat-G21), No abnormalities detected
4	M	3.80	
5	F	4.75Skeletal Body (Rat-G21), Hindpaw Phalanx, Unossified, proximal 2nd to 5th digits - (V), [left]Skeletal Head (Rat-G21), No abnormalities detected
6	M	5.01	
8	M	4.85Skeletal Body (Rat-G21), Hindpaw Phalanx, Unossified, proximal 2nd to 5th digits - (V), [bilateral]Skeletal Head (Rat-G21), No abnormalities detected
9	F	4.81	
10	M	4.62Skeletal Body (Rat-G21), Hindpaw Phalanx, Unossified, proximal 2nd to 5th digits - (V), [bilateral]Skeletal Head (Rat-G21), No abnormalities detected
11	F	4.43	
12	M	4.21Skeletal Body (Rat-G21), Hindpaw Phalanx, Unossified, proximal 2nd to 5th digits - (V), [bilateral]Skeletal Head (Rat-G21), No abnormalities detected
13	M	5.03	
14	F	5.10Skeletal Body (Rat-G21), Ribs Ribs, Supernumerary lumbar, short - (V), [bilateral]

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Control Omcg	Foetal Sex	Foetal Weight (g)	Findings
Dam: 13 (Continued...)			
15	F	4.66Skeletal Head (Rat-G21), No abnormalities detected
Dam: 14 Pregnancy Type: P			
1	M	5.06Skeletal Body (Rat-G21), Ribs Ribs, Supernumerary lumbar, short - (V), [bilateral]Skeletal Head (Rat-G21), No abnormalities detected
2	F	4.55Skeletal Body (Rat-G21), No abnormalities detected
3	M	5.15Skeletal Head (Rat-G21), No abnormalities detected
4	M	5.09Skeletal Body (Rat-G21), No abnormalities detected
5	F	4.54Skeletal Head (Rat-G21), No abnormalities detected
7	M	4.25Skeletal Body (Rat-G21), Ribs Ribs, Supernumerary lumbar, short - (V), [bilateral]Skeletal Head (Rat-G21), No abnormalities detected
8	M	4.93Skeletal Body (Rat-G21), No abnormalities detected
9	F	4.54Skeletal Head (Rat-G21), No abnormalities detected
10	F	4.92Skeletal Body (Rat-G21), Ribs Ribs, Supernumerary lumbar, short - (V), [bilateral]Skeletal Head (Rat-G21), No abnormalities detected
11	M	4.80Skeletal Body (Rat-G21), No abnormalities detected
12	F	4.44Skeletal Head (Rat-G21), No abnormalities detected
13	F	4.69Skeletal Body (Rat-G21), No abnormalities detected
14	F	4.30Skeletal Head (Rat-G21), No abnormalities detected

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Control Omcg	Foetal Sex	Foetal Weight (g)	Findings
Dam: 14 (Continued...)			
			Ribs, Supernumerary lumbar, short - (V), [right]Skeletal Head (Rat-G21), No abnormalities detected
Dam: 15 Pregnancy Type: P			
1	M	5.17Skeletal Body (Rat-G21), Vertebra Cervical, Odontoid process unossified - (V)Skeletal Head (Rat-G21), No abnormalities detected
2	F	4.70Skeletal Head (Rat-G21), No abnormalities detected
3	M	5.18Skeletal Body (Rat-G21), Ribs Ribs, Supernumerary lumbar, short - (V), [left]Skeletal Head (Rat-G21), No abnormalities detected
4	F	5.06Skeletal Body (Rat-G21), No abnormalities detected
5	M	5.16Skeletal Head (Rat-G21), No abnormalities detected
6	M	5.22Skeletal Body (Rat-G21), Ribs Ribs, Supernumerary lumbar, short - (V), [bilateral]Skeletal Head (Rat-G21), No abnormalities detected
7	F	5.00Skeletal Body (Rat-G21), Ribs Ribs, Supernumerary lumbar, short - (V), [bilateral]Skeletal Head (Rat-G21), No abnormalities detected
9	M	5.30Skeletal Body (Rat-G21), No abnormalities detected
10	M	5.09Skeletal Head (Rat-G21), No abnormalities detected
11	F	5.14Skeletal Body (Rat-G21), Ribs Ribs, Supernumerary lumbar, short - (V), [bilateral]Skeletal Head (Rat-G21), No abnormalities detected
12	M	4.91Skeletal Body (Rat-G21), Ribs Ribs, Supernumerary lumbar, short - (V), [bilateral]Skeletal Head (Rat-G21), No abnormalities detected
13	F	4.87Skeletal Body (Rat-G21), Ribs Ribs, Supernumerary lumbar, short - (V), [bilateral]Skeletal Head (Rat-G21), No abnormalities detected

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Individual Foetal Skeletal Observations

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Control Omcg	Foetal Sex	Foetal Weight (g)	Findings
Dam: 15 (Continued...)			
14	M	4.73Skeletal Body (Rat-G21), No abnormalities detectedSkeletal Head (Rat-G21), No abnormalities detected
Dam: 16 Pregnancy Type: P			
1	M	4.74Skeletal Body (Rat-G21), Ribs Ribs, Supernumerary lumbar, short - (V), [bilateral]Skeletal Head (Rat-G21), No abnormalities detected
2	M	4.84	
3	M	4.86Skeletal Body (Rat-G21), Ribs Ribs, Supernumerary lumbar, short - (V), [right]Skeletal Head (Rat-G21), No abnormalities detected
4	F	4.69	
5	F	4.74Skeletal Body (Rat-G21), Ribs Ribs, Supernumerary lumbar, short - (V), [left]Skeletal Head (Rat-G21), No abnormalities detected
6	F	4.53	
7	F	4.84Skeletal Body (Rat-G21), Ribs Ribs, Supernumerary lumbar, short - (V), [left]Skeletal Head (Rat-G21), No abnormalities detected
8	F	4.92	
9	F	4.97Skeletal Body (Rat-G21), Ribs Ribs, Supernumerary lumbar, short - (V), [left]Skeletal Head (Rat-G21), No abnormalities detected
10	F	4.42	
11	F	4.61Skeletal Body (Rat-G21), Ribs Ribs, Supernumerary lumbar - (A), [left] Ribs, Supernumerary lumbar, short - (V), [right]

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Individual Foetal Skeletal Observations

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Control 0mcg	Foetal Sex	Foetal Weight (g)	Findings
Dam: 16 (Continued...)			
12	F	4.10Skeletal Head (Rat-G21), No abnormalities detected
13	F	3.91Skeletal Body (Rat-G21), Ribs Ribs, Supernumerary lumbar, short - (V), [bilateral]Skeletal Head (Rat-G21), No abnormalities detected
Dam: 17 Pregnancy Type: P			
1	M	4.92Skeletal Body (Rat-G21), Hindpaw Phalanx, Unossified, proximal 2nd to 5th digits - (V), [bilateral]Skeletal Body (Rat-G21), Ribs Ribs, Supernumerary lumbar, short - (V), [bilateral]Skeletal Head (Rat-G21), No abnormalities detected
2	M	4.10	
3	F	4.67Skeletal Body (Rat-G21), Forepaw Phalanx, Unossified - (A), [left]Skeletal Body (Rat-G21), Hindpaw Phalanx, Unossified, proximal 2nd to 5th digits - (V), [bilateral]Skeletal Head (Rat-G21), No abnormalities detected
4	F	4.50	
6	M	5.49Skeletal Body (Rat-G21), Hindpaw Phalanx, Unossified, proximal 2nd to 5th digits - (V), [bilateral]Skeletal Body (Rat-G21), Vertebra Thoracic, Incomplete ossification of centrum, 10th to 13th. - (A)Skeletal Head (Rat-G21), No abnormalities detected
7	M	5.08	
8	M	4.78Skeletal Body (Rat-G21), Hindpaw Phalanx, Unossified, proximal 2nd to 5th digits - (V), [bilateral]

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Individual Foetal Skeletal Observations

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Control Omcg	Foetal Sex	Foetal Weight (g)	Findings
Dam: 17 (Continued...)			
9	F	4.80Skeletal Head (Rat-G21), No abnormalities detected
10	M	4.56Skeletal Body (Rat-G21), Forepaw Phalanx, Unossified - (A), [bilateral]Skeletal Body (Rat-G21), Hindpaw Phalanx, Unossified, proximal 2nd to 5th digits - (V), [bilateral]Skeletal Body (Rat-G21), Ribs Ribs, Supernumerary lumbar, short - (V), [bilateral]Skeletal Head (Rat-G21), No abnormalities detected
11	F	4.76Skeletal Head (Rat-G21), No abnormalities detected
12	F	4.25Skeletal Body (Rat-G21), Hindpaw Phalanx, Unossified, proximal 2nd to 5th digits - (V), [bilateral]Skeletal Body (Rat-G21), Vertebra Cervical, Odontoid process unossified - (V) Thoracic, Incomplete ossification of centrum, 10th to 13th. - (A), [11th bipartite]Skeletal Head (Rat-G21), No abnormalities detected
13	F	4.84Skeletal Head (Rat-G21), No abnormalities detected
14	F	4.37Skeletal Body (Rat-G21), Hindpaw Phalanx, Unossified, proximal 2nd to 5th digits - (V), [bilateral]Skeletal Head (Rat-G21), No abnormalities detected
15	F	4.29Skeletal Body (Rat-G21), No abnormalities detected
16	F	4.10Skeletal Body (Rat-G21), No abnormalities detectedSkeletal Head (Rat-G21), No abnormalities detected
Dam: 18 Pregnancy Type: P			
1	F	4.87Skeletal Body (Rat-G21), Ribs Ribs, Supernumerary lumbar, short - (V), [left]

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Control Omcg	Foetal Sex	Foetal Weight (g)	Findings
Dam: 18 (Continued...)			
2	M	5.08Skeletal Head (Rat-G21), No abnormalities detected
3	F	5.12Skeletal Body (Rat-G21), No abnormalities detectedSkeletal Head (Rat-G21), No abnormalities detected
4	F	5.09Skeletal Body (Rat-G21), No abnormalities detected
5	M	5.13Skeletal Head (Rat-G21), No abnormalities detected
6	F	5.18Skeletal Body (Rat-G21), No abnormalities detected
7	F	5.04Skeletal Head (Rat-G21), No abnormalities detected
8	F	5.19Skeletal Body (Rat-G21), No abnormalities detected
9	F	5.07Skeletal Head (Rat-G21), No abnormalities detected
10	F	4.83Skeletal Body (Rat-G21), No abnormalities detected
11	M	5.80Skeletal Head (Rat-G21), No abnormalities detected
12	F	5.17Skeletal Body (Rat-G21), Hindpaw Phalanx, Unossified, proximal 2nd to 5th digits - (V), [bilateral]
13	M	5.21Skeletal Head (Rat-G21), No abnormalities detected
14	M	4.50Skeletal Head (Rat-G21), No abnormalities detected
Dam: 19 Pregnancy Type: P			
1	M	5.36Skeletal Body (Rat-G21), Ribs Ribs, Supernumerary lumbar, short - (V), [right]Skeletal Head (Rat-G21), No abnormalities detected

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Control Omcg	Foetal Sex	Foetal Weight (g)	Findings
Dam: 19 (Continued...)			
2	M	5.26Skeletal Body (Rat-G21), No abnormalities detected
4	M	5.38Skeletal Head (Rat-G21), No abnormalities detected
5	F	5.01Skeletal Body (Rat-G21), Ribs
6	F	5.02	Ribs, Supernumerary lumbar, short - (V), [left]Skeletal Head (Rat-G21), No abnormalities detected
7	F	4.68Skeletal Body (Rat-G21), Ribs
8	F	4.10	Ribs, Supernumerary lumbar, short - (V), [left]Skeletal Body (Rat-G21), Vertebra Lumbar, Number = 7 - (A)Skeletal Head (Rat-G21), No abnormalities detected
9	F	5.14Skeletal Body (Rat-G21), Ribs
10	F	5.30	Ribs, Supernumerary cervical - (A), [left, short]Skeletal Head (Rat-G21), No abnormalities detected
11	F	5.27Skeletal Body (Rat-G21), No abnormalities detected
12	F	4.77Skeletal Head (Rat-G21), No abnormalities detected
13	M	4.90Skeletal Body (Rat-G21), No abnormalities detected
Dam: 20 Pregnancy Type: NPE			
Dam: 21 Pregnancy Type: P			
1	M	4.80Skeletal Body (Rat-G21), Hindpaw

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Control 0mcg	Foetal Sex	Foetal Weight (g)	Findings
Dam: 21 (Continued...)			
2	F	4.18	Phalanx, Unossified, proximal 2nd to 5th digits - (V), [bilateral]Skeletal Body (Rat-G21), Ribs Ribs, Supernumerary lumbar, short - (V), [bilateral]Skeletal Head (Rat-G21), No abnormalities detected
3	F	3.84Skeletal Body (Rat-G21), Forepaw Phalanx, Unossified - (A), [right]Skeletal Body (Rat-G21), Hindpaw Metatarsal, Unossified, 1st digit - (V), [right] Phalanx, Unossified, proximal 2nd to 5th digits - (V), [bilateral]Skeletal Head (Rat-G21), No abnormalities detected
4	M	4.75Skeletal Body (Rat-G21), No abnormalities detected
5	M	4.75Skeletal Head (Rat-G21), No abnormalities detected
6	M	5.07Skeletal Body (Rat-G21), Hindpaw
7	M	4.57	Phalanx, Unossified, proximal 2nd to 5th digits - (V), [bilateral]Skeletal Body (Rat-G21), Vertebra Cervical, Odontoid process unossified - (V) Cervical, Unossified centrum - (V)Skeletal Head (Rat-G21), No abnormalities detected
8	M	4.66Skeletal Body (Rat-G21), Ribs
9	F	4.49	Ribs, Supernumerary lumbar, short - (V), [bilateral]Skeletal Head (Rat-G21), No abnormalities detected
10	F	4.61	

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Control Omcg	Foetal Sex	Foetal Weight (g)	Findings
Dam: 21 (Continued...)			
11	F	4.57Skeletal Body (Rat-G21), Ribs Ribs, Supernumerary lumbar, short - (V), [bilateral]Skeletal Body (Rat-G21), Vertebra Cervical, Odontoid process unossified - (V)Skeletal Head (Rat-G21), No abnormalities detected
12	F	4.51Skeletal Body (Rat-G21), Hindpaw Phalanx, Unossified, proximal 2nd to 5th digits - (V), [bilateral]
13	M	4.82Skeletal Body (Rat-G21), Ribs Ribs, Supernumerary lumbar, short - (V), [bilateral]Skeletal Head (Rat-G21), No abnormalities detected
14	F	4.66Skeletal Body (Rat-G21), Hindpaw Phalanx, Unossified, proximal 2nd to 5th digits - (V), [bilateral]
15	M	4.93Skeletal Body (Rat-G21), Ribs Ribs, Supernumerary lumbar, short - (V), [right]Skeletal Head (Rat-G21), No abnormalities detected
16	M	4.96Skeletal Body (Rat-G21), No abnormalities detected
Dam: 22 Pregnancy Type: P			
2	F	4.46Skeletal Body (Rat-G21), No abnormalities detected
3	F	5.04Skeletal Head (Rat-G21), No abnormalities detected
4	F	4.81Skeletal Body (Rat-G21), No abnormalities detected
5	F	4.65Skeletal Head (Rat-G21), No abnormalities detected
6	F	4.72Skeletal Body (Rat-G21), No abnormalities detected

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Control Omcg	Foetal Sex	Foetal Weight (g)	Findings
Dam: 22 (Continued...)			
7 I	F	4.85Skeletal Head (Rat-G21), No abnormalities detected
8	M	4.87Skeletal Body (Rat-G21), No abnormalities detected
		Skeletal Head (Rat-G21), No abnormalities detected
9	M	5.04	
10	M	5.30Skeletal Body (Rat-G21), No abnormalities detected
		Skeletal Head (Rat-G21), No abnormalities detected
11	F	4.79	
12	F	4.53Skeletal Body (Rat-G21), Vertebra Cervical, Odontoid process unossified - (V)
		Skeletal Head (Rat-G21), No abnormalities detected
13	M	4.83	
14	M	4.32Skeletal Body (Rat-G21), No abnormalities detected
		Skeletal Head (Rat-G21), No abnormalities detected

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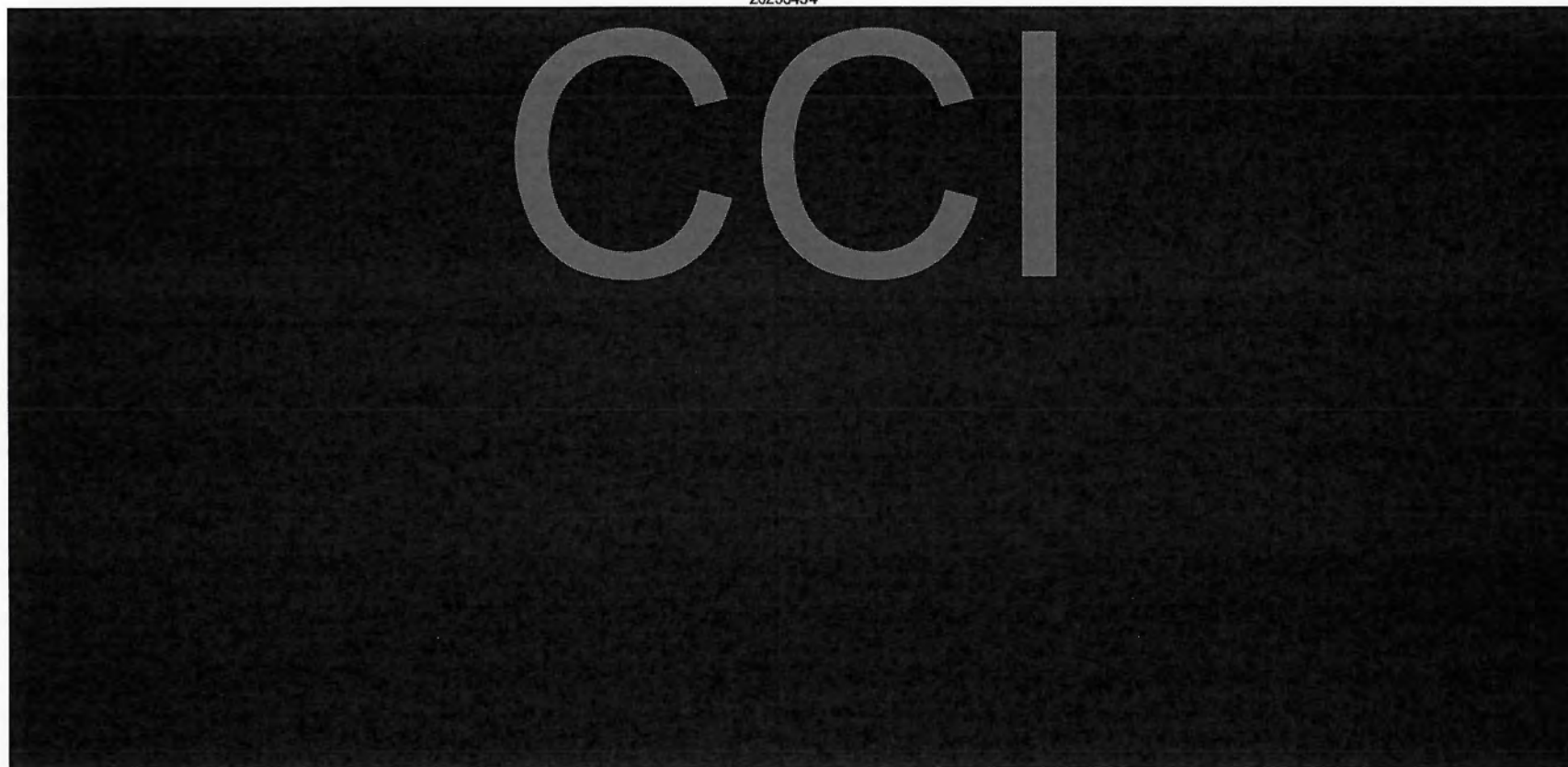
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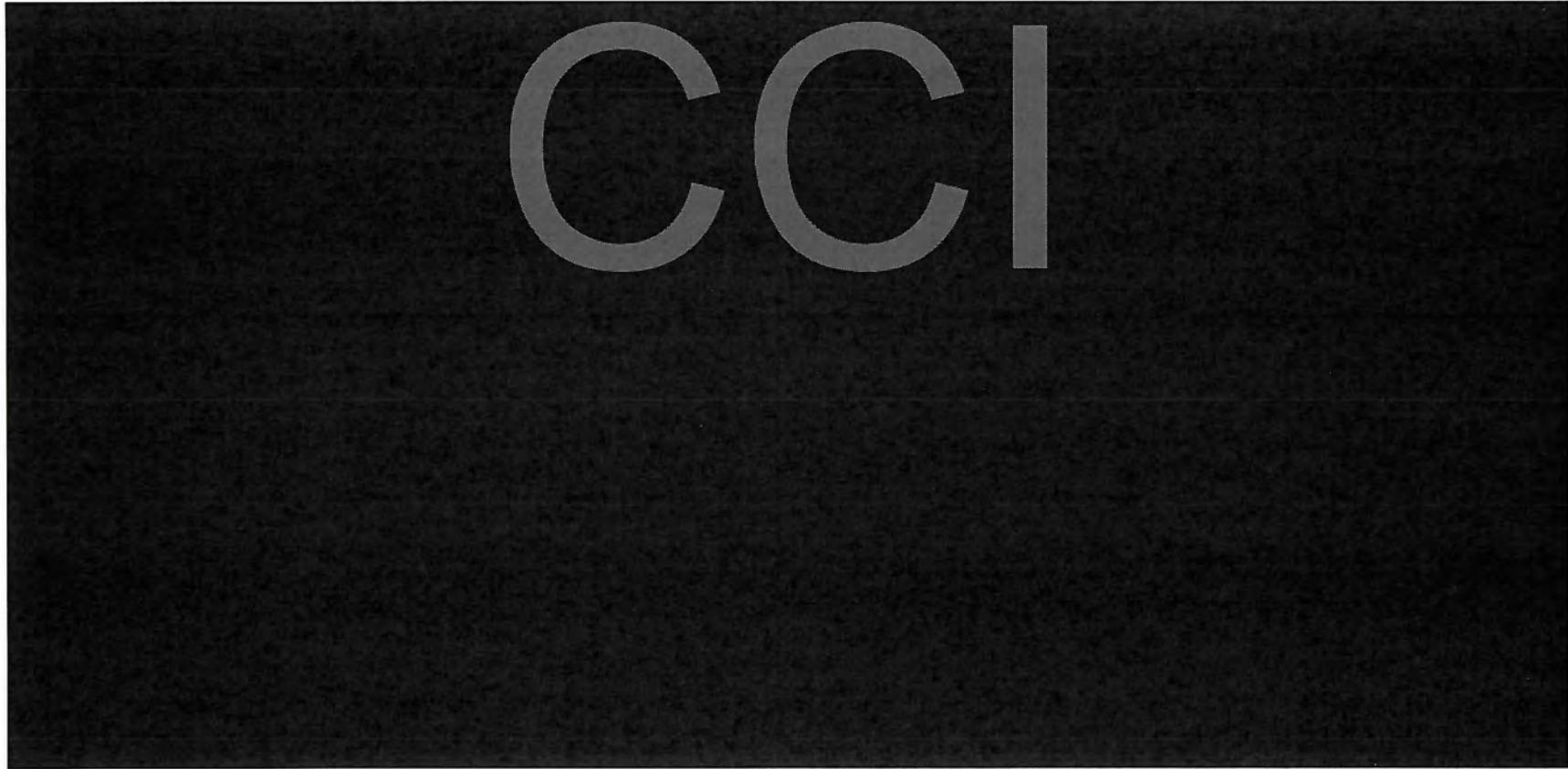
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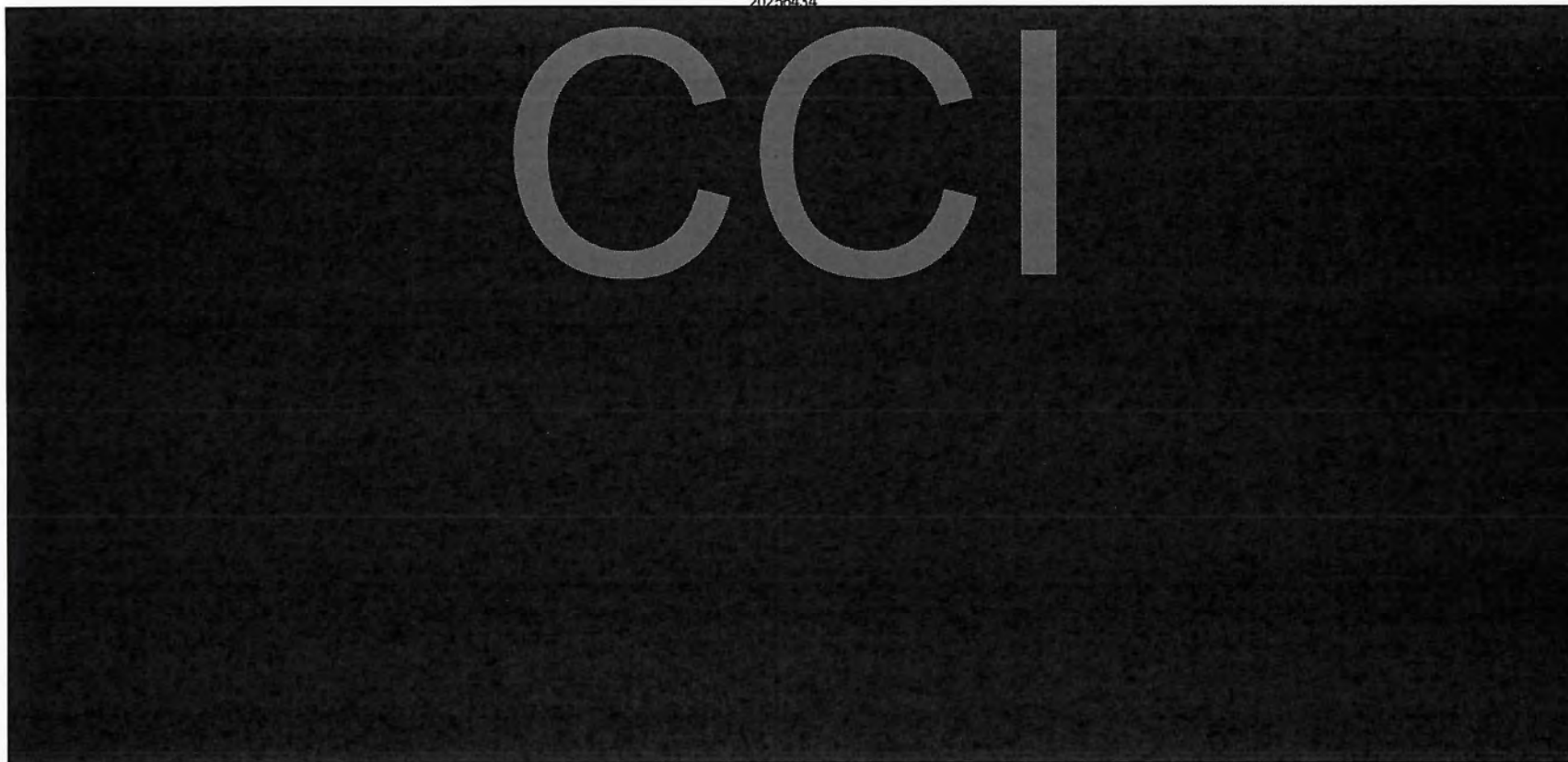
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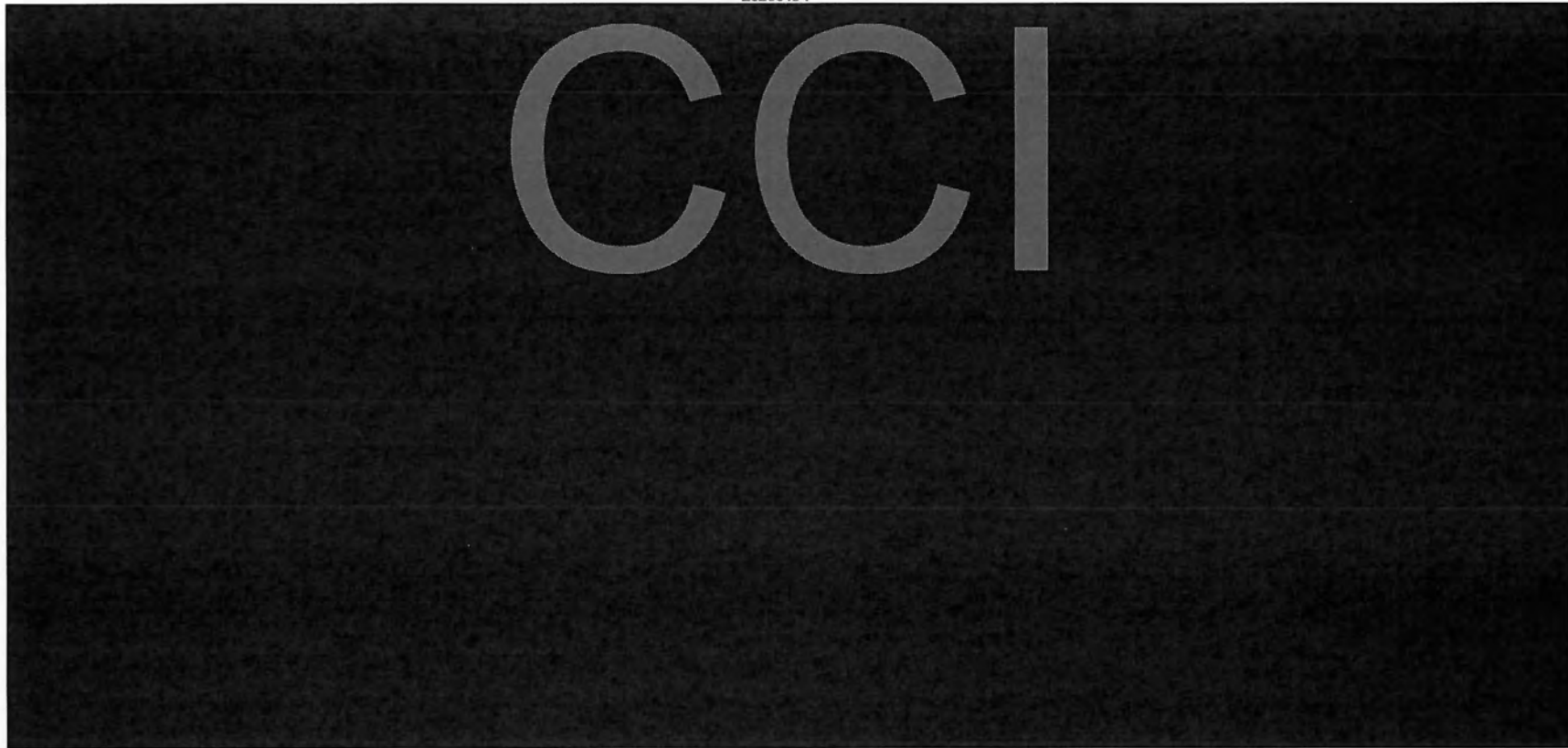
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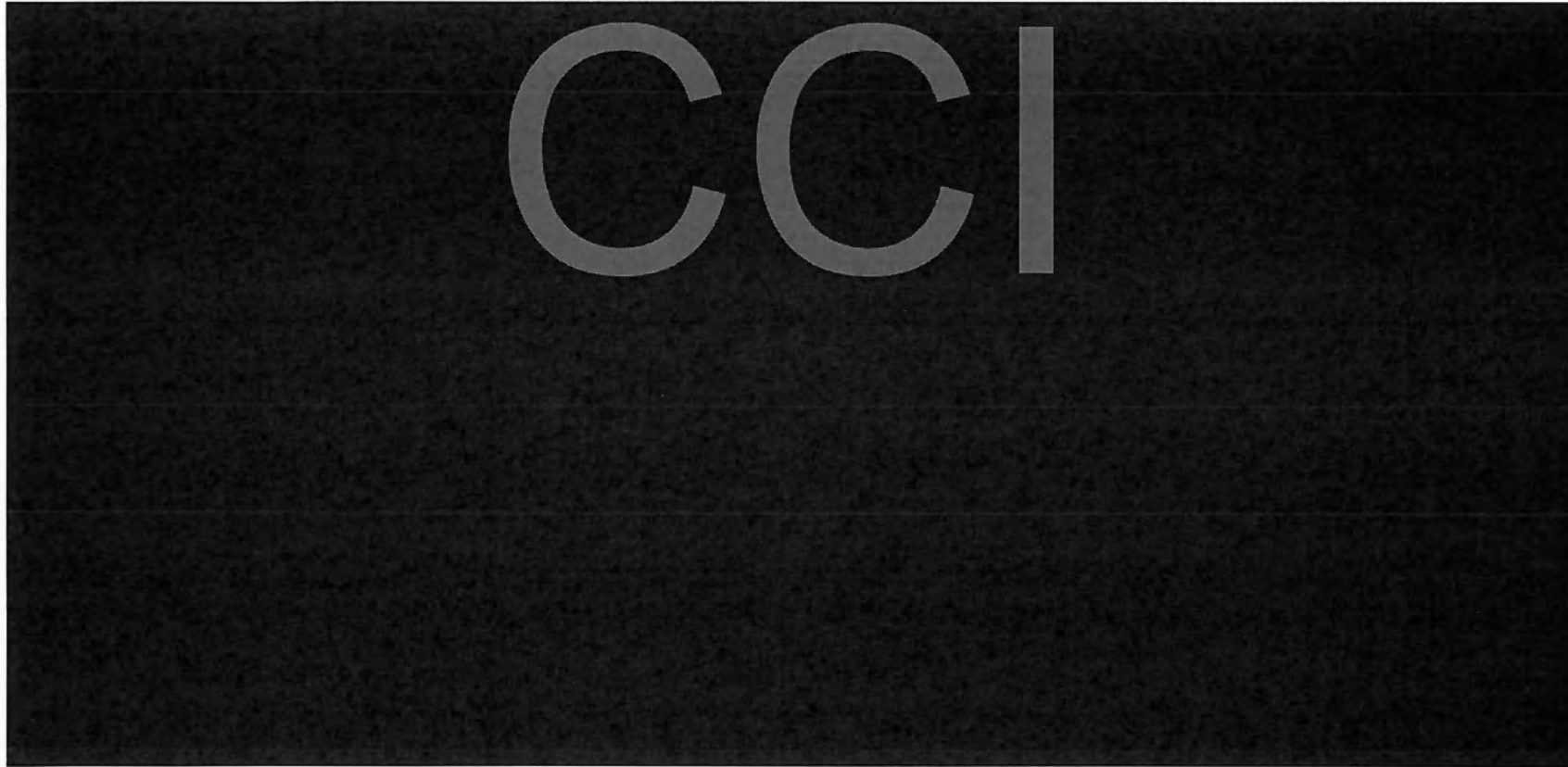
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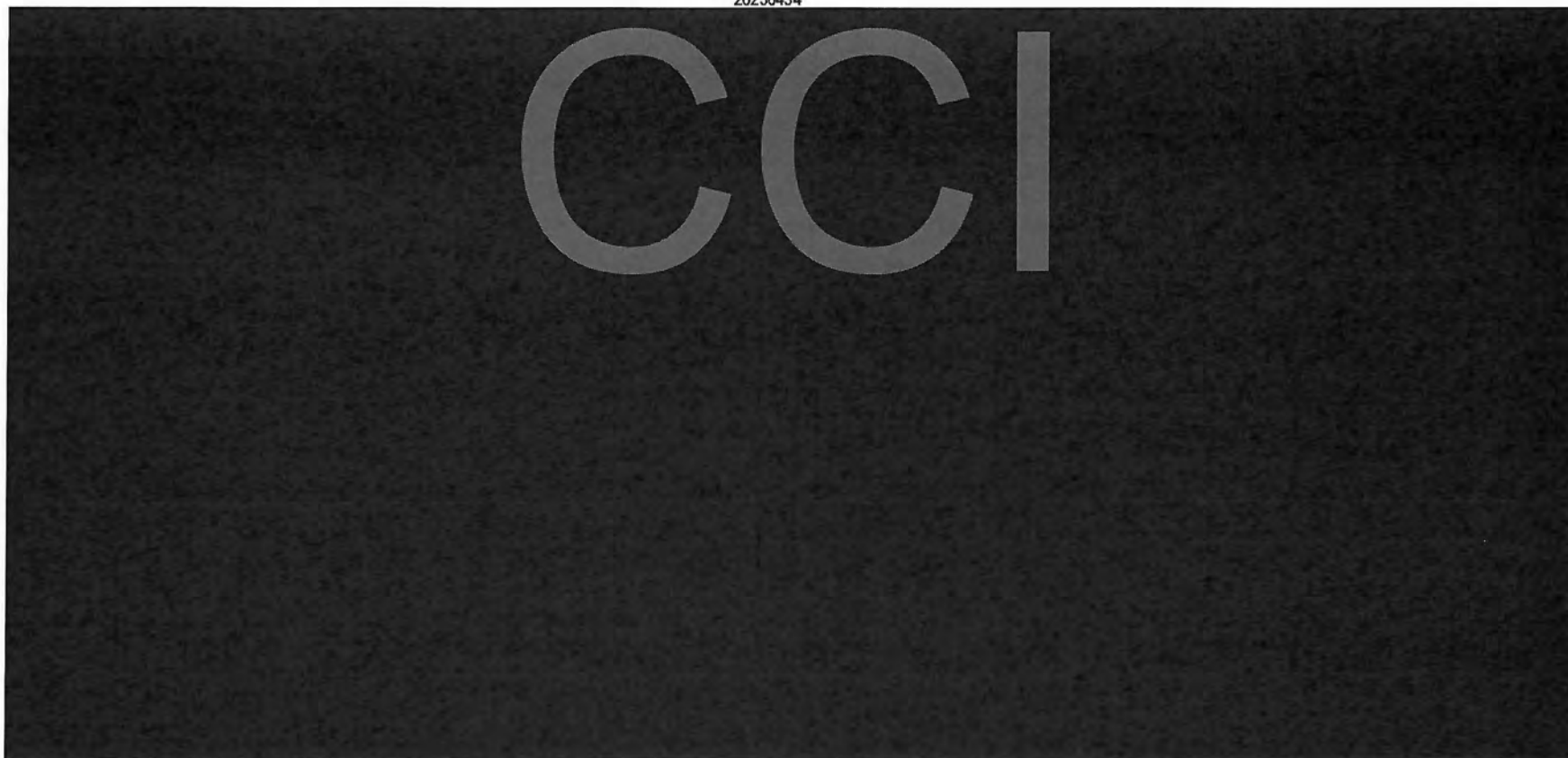
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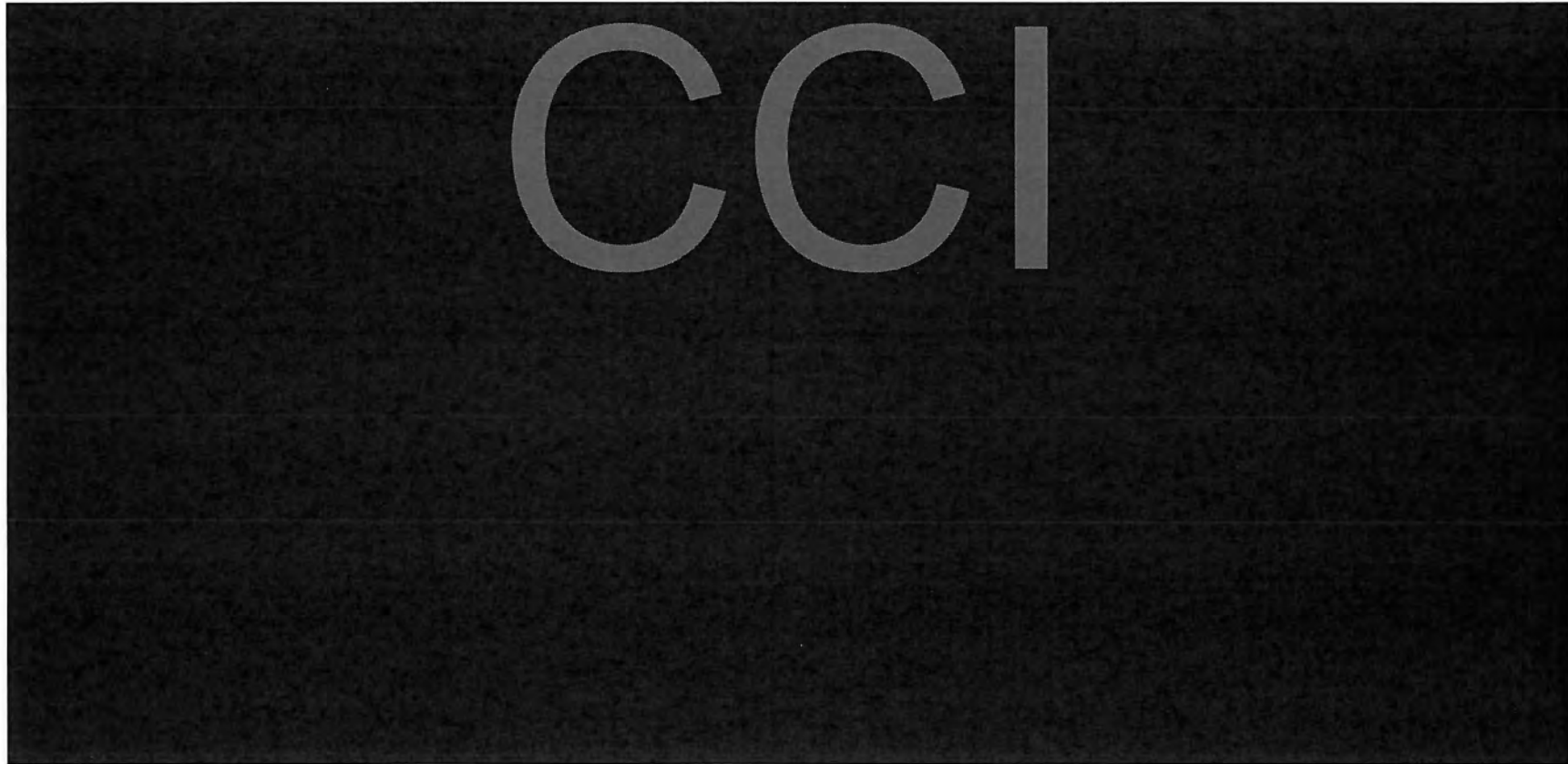
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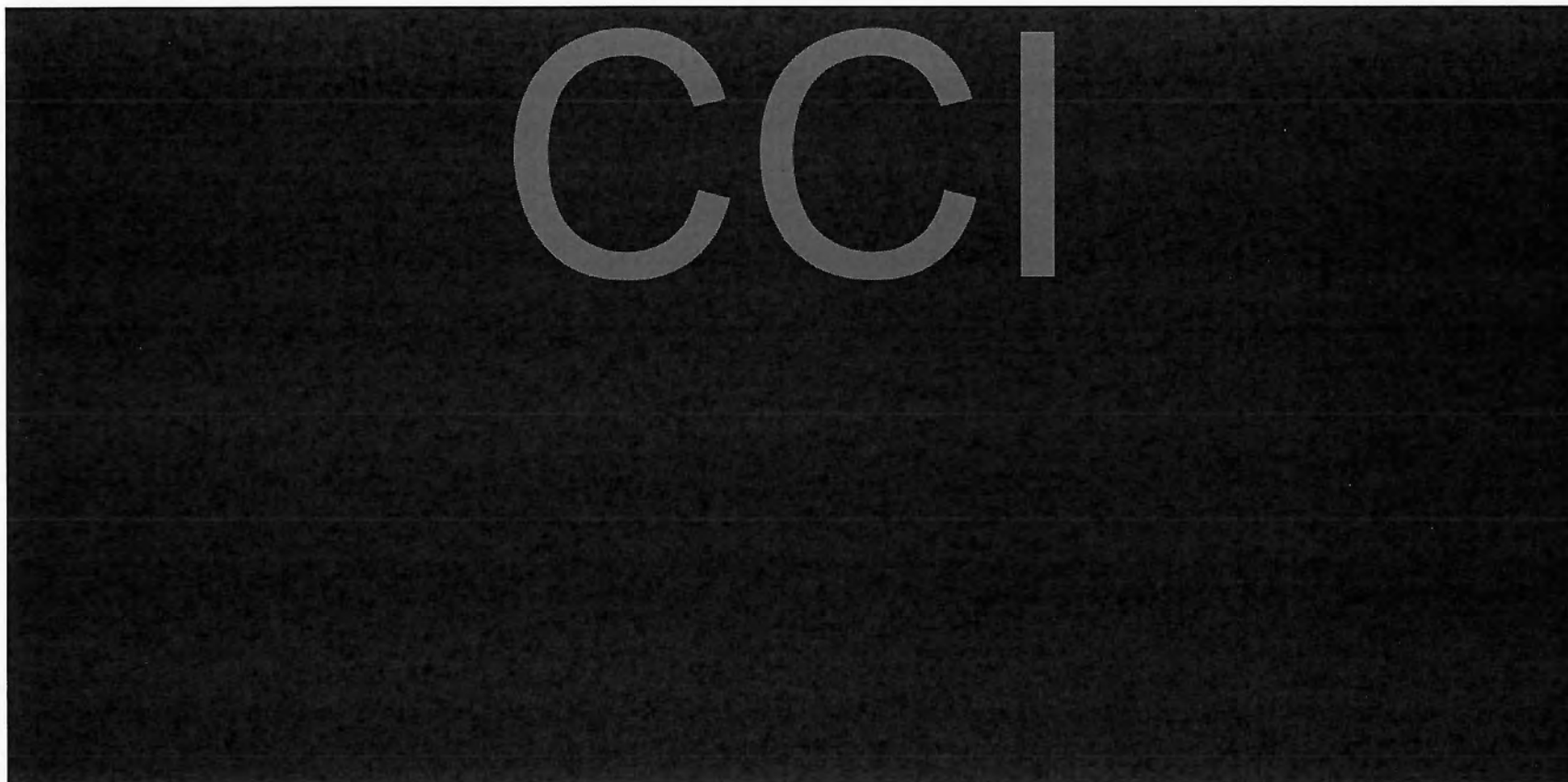
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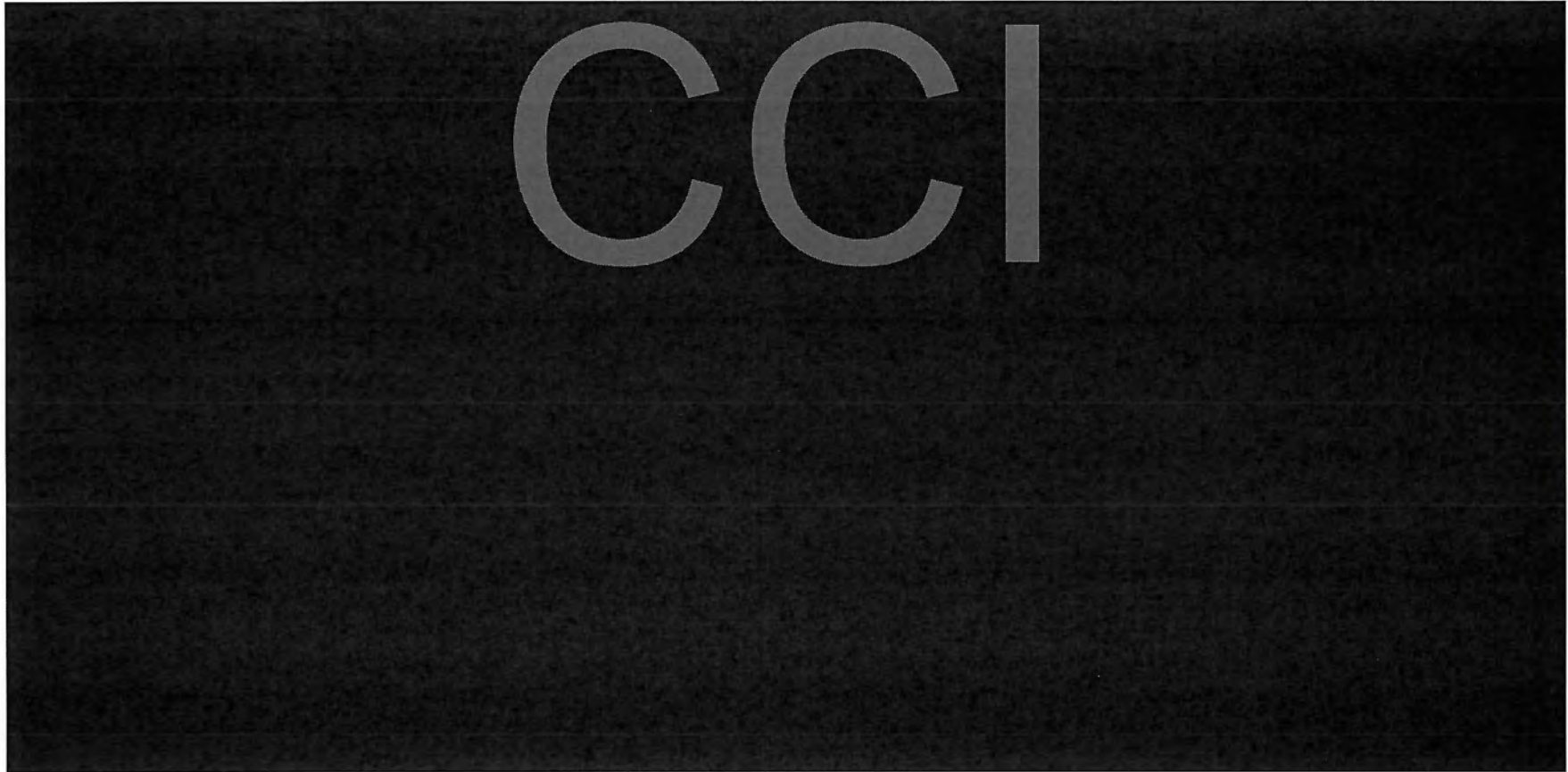
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BNT162b2 30mcg	Foetal Sex	Foetal Weight (g)	Findings
Dam: 45 Pregnancy Type: P			
1	F	4.30Skeletal Body (Rat-G21), Ribs Ribs, Supernumerary lumbar, short - (V), [bilateral]Skeletal Head (Rat-G21), No abnormalities detected
2	F	3.69Skeletal Body (Rat-G21), No abnormalities detected
3	F	4.84Skeletal Head (Rat-G21), No abnormalities detected
4	M	4.84Skeletal Body (Rat-G21), No abnormalities detected
5	F	4.90Skeletal Head (Rat-G21), No abnormalities detected
6	M	3.87Skeletal Body (Rat-G21), No abnormalities detected
7	M	4.91Skeletal Head (Rat-G21), No abnormalities detected
8	M	5.13Skeletal Body (Rat-G21), Ribs Ribs, Supernumerary lumbar, short - (V), [bilateral]Skeletal Head (Rat-G21), No abnormalities detected
9	F	5.27Skeletal Body (Rat-G21), No abnormalities detected
10	M	5.20Skeletal Head (Rat-G21), No abnormalities detected
11	F	4.37Skeletal Body (Rat-G21), No abnormalities detected
12	M	4.78Skeletal Head (Rat-G21), No abnormalities detected
14	F	5.17Skeletal Body (Rat-G21), No abnormalities detectedSkeletal Head (Rat-G21), No abnormalities detected
Dam: 46 Pregnancy Type: P			
1	M	4.82Skeletal Body (Rat-G21), Ribs Ribs, Supernumerary lumbar, short - (V), [bilateral]Skeletal Head (Rat-G21), No abnormalities detected

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BNT162b2 30mcg	Foetal Sex	Foetal Weight (g)	Findings
Dam: 46 (Continued...)			
2	M	4.91	
3	M	4.80Skeletal Body (Rat-G21), Ribs Ribs, Supernumerary lumbar - (A), [right] Ribs, Supernumerary lumbar, short - (V), [left]Skeletal Head (Rat-G21), No abnormalities detected
4	F	4.82	
5	F	4.57Skeletal Body (Rat-G21), Ribs Ribs, Supernumerary lumbar, short - (V), [bilateral]Skeletal Head (Rat-G21), No abnormalities detected
6	M	4.74	
7	F	5.12Skeletal Body (Rat-G21), Ribs Ribs, Supernumerary lumbar - (A), [left] Ribs, Supernumerary lumbar, short - (V), [right]Skeletal Head (Rat-G21), No abnormalities detected
8	M	5.15	
9	F	5.00Skeletal Body (Rat-G21), Ribs Ribs, Supernumerary lumbar - (A), [bilateral]Skeletal Head (Rat-G21), No abnormalities detected
10	F	4.49	
11	F	4.95Skeletal Body (Rat-G21), Ribs Ribs, Supernumerary lumbar, short - (V), [bilateral]Skeletal Head (Rat-G21), No abnormalities detected
12	M	4.85	
13	M	5.04Skeletal Body (Rat-G21), Ribs Ribs, Supernumerary lumbar, short - (V), [bilateral]Skeletal Head (Rat-G21), No abnormalities detected

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BNT162b2 30mcg	Foetal Sex	Foetal Weight (g)	Findings
Dam: 46 (Continued...)			
14	M	4.84Skeletal Body (Rat-G21), Ribs
15	M	4.99	Ribs, Supernumerary lumbar, short - (V), [bilateral]Skeletal Head (Rat-G21), No abnormalities detected
16	F	4.73Skeletal Body (Rat-G21), Ribs
17	M	4.85	Ribs, Supernumerary lumbar - (A), [bilateral]Skeletal Head (Rat-G21), No abnormalities detected
Dam: 47 Pregnancy Type: P			
1	F	4.84Skeletal Body (Rat-G21), Ribs Ribs, Supernumerary lumbar, short - (V), [bilateral]Skeletal Head (Rat-G21), No abnormalities detected
2	F	4.59Skeletal Body (Rat-G21), Ribs
3	M	5.21	Ribs, Supernumerary lumbar, short - (V), [right]Skeletal Head (Rat-G21), No abnormalities detected
4	F	4.90Skeletal Body (Rat-G21), Ribs
5	F	4.93	Ribs, Supernumerary lumbar, short - (V), [bilateral]Skeletal Head (Rat-G21), No abnormalities detected
6	M	5.10Skeletal Body (Rat-G21), Ribs
7	M	5.21	Ribs, Supernumerary lumbar, short - (V), [bilateral]Skeletal Body (Rat-G21), Vertebra Thoracic, Incomplete ossification of centrum, 10th to 13th. - (A), [12th bipartite]Skeletal Head (Rat-G21), No abnormalities detected

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BNT162b2 30mcg	Foetal Sex	Foetal Weight (g)	Findings
Dam: 47 (Continued...)			
8	M	4.67Skeletal Body (Rat-G21), Ribs
9	F	4.42	Ribs, Supernumerary lumbar, short - (V), [bilateral]Skeletal Head (Rat-G21), No abnormalities detected
10	F	4.95Skeletal Body (Rat-G21), Ribs
11	M	5.18	Ribs, Supernumerary lumbar, short - (V), [bilateral]Skeletal Head (Rat-G21), No abnormalities detected
12	M	5.06Skeletal Head (Rat-G21), No abnormalities detected
Dam: 48 Pregnancy Type: P			
1	F	5.13Skeletal Body (Rat-G21), No abnormalities detectedSkeletal Head (Rat-G21), No abnormalities detected
2	M	5.10Skeletal Body (Rat-G21), Ribs
3	F	4.42	Ribs, Supernumerary lumbar, short - (V), [right]Skeletal Head (Rat-G21), No abnormalities detected
4	M	4.68Skeletal Body (Rat-G21), No abnormalities detected
5	M	4.90Skeletal Head (Rat-G21), No abnormalities detected
6	M	4.89Skeletal Body (Rat-G21), Ribs
7	M	5.14	Ribs, Supernumerary lumbar, short - (V), [bilateral]Skeletal Head (Rat-G21), No abnormalities detected
8	F	4.90Skeletal Body (Rat-G21), Ribs
9	F	4.82Skeletal Head (Rat-G21), No abnormalities detected

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BNT162b2 30mcg	Foetal Sex	Foetal Weight (g)	Findings
Dam: 48 (Continued...)			
10	F	4.51	Ribs, Supernumerary lumbar, short - (V), [bilateral]Skeletal Head (Rat-G21), No abnormalities detected
Dam: 49 Pregnancy Type: P			
1	F	4.20Skeletal Body (Rat-G21), Ribs Ribs, Thick - (A), [bilateral] Ribs, Supernumerary lumbar, short - (V), [right]Skeletal Head (Rat-G21), No abnormalities detected
2	M	4.73	
3	M	4.50Skeletal Body (Rat-G21), Hindpaw Phalanx, Unossified, proximal 2nd to 5th digits - (V), [bilateral]Skeletal Body (Rat-G21), Ribs Ribs, Supernumerary lumbar, short - (V), [bilateral]Skeletal Body (Rat-G21), Vertebra Cervical, Odontoid process unossified - (V) Thoracic, Incomplete ossification of centrum, 10th to 13th. - (A)Skeletal Head (Rat-G21), No abnormalities detected
5	M	4.83	
6	M	3.56Skeletal Body (Rat-G21), Forepaw Phalanx, Unossified - (A), [bilateral]Skeletal Body (Rat-G21), Hindpaw Metatarsal, Unossified, 1st digit - (V), [bilateral] Phalanx, Unossified, proximal 2nd to 5th digits - (V), [bilateral]Skeletal Body (Rat-G21), Ribs Ribs, Supernumerary lumbar - (A), [left] Ribs, Supernumerary lumbar, short - (V), [right]Skeletal Head (Rat-G21), No abnormalities detected

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Individual Foetal Skeletal Observations

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BNT162b2 30mcg	Foetal Sex	Foetal Weight (g)	Findings
Dam: 49 (Continued...)			
8	M	4.93Skeletal Body (Rat-G21), Ribs
9	M	4.49	Ribs, Supernumerary lumbar, short - (V), [bilateral]Skeletal Head (Rat-G21), No abnormalities detected
10	F	4.54Skeletal Body (Rat-G21), Hindpaw
12	F	4.49	Phalanx, Unossified, proximal 2nd to 5th digits - (V), [left]Skeletal Head (Rat-G21), No abnormalities detected
13	F	4.54Skeletal Body (Rat-G21), Hindpaw
14	F	4.19	Phalanx, Unossified, proximal 2nd to 5th digits - (V), [bilateral]Skeletal Body (Rat-G21), Ribs Ribs, Supernumerary lumbar - (A), [bilateral]Skeletal Head (Rat-G21), No abnormalities detected
15	F	4.67Skeletal Body (Rat-G21), No abnormalities detected
17	M	4.32Skeletal Head (Rat-G21), No abnormalities detected
Dam: 50 Pregnancy Type: P			
1	F	4.27Skeletal Body (Rat-G21), No abnormalities detectedSkeletal Head (Rat-G21), No abnormalities detected
2	M	5.05Skeletal Body (Rat-G21), No abnormalities detected
3	M	4.73Skeletal Head (Rat-G21), No abnormalities detected
4	F	4.21Skeletal Body (Rat-G21), No abnormalities detected
6	F	4.51Skeletal Head (Rat-G21), No abnormalities detected

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Individual Foetal Skeletal Observations

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BNT162b2 30mcg	Foetal Sex	Foetal Weight (g)	Findings
Dam: 50 (Continued...)			
7	M	4.64Skeletal Body (Rat-G21), Ribs Ribs, Supernumerary lumbar, short - (V), [bilateral]Skeletal Body (Rat-G21), Vertebra Cervical, Odontoid process unossified - (V)Skeletal Head (Rat-G21), No abnormalities detected
8	M	5.16	
9	M	5.25	
10	F	4.45Skeletal Body (Rat-G21), Hindpaw Phalanx, Unossified, proximal 2nd to 5th digits - (V), [right]Skeletal Head (Rat-G21), No abnormalities detected
Dam: 51 Pregnancy Type: P			
1	F	5.07Skeletal Body (Rat-G21), Hindpaw Phalanx, Unossified, proximal 2nd to 5th digits - (V), [bilateral]Skeletal Head (Rat-G21), No abnormalities detected
2	M	5.37Skeletal Body (Rat-G21), Hindpaw Phalanx, Unossified, proximal 2nd to 5th digits - (V), [left]Skeletal Head (Rat-G21), No abnormalities detected
3	M	5.56	
4	F	5.11	
5	M	5.43Skeletal Body (Rat-G21), No abnormalities detectedSkeletal Head (Rat-G21), No abnormalities detected
6	M	5.42Skeletal Body (Rat-G21), Ribs Ribs, Supernumerary lumbar, short - (V), [bilateral]Skeletal Head (Rat-G21), No abnormalities detected
7	F	5.18	
8	M	4.54	

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Individual Foetal Skeletal Observations

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BNT162b2 30mcg	Foetal Sex	Foetal Weight (g)	Findings
Dam: 51 (Continued...)			
9	M	5.38Skeletal Body (Rat-G21), No abnormalities detectedSkeletal Head (Rat-G21), No abnormalities detected
10	M	4.94	
11	F	4.69Skeletal Body (Rat-G21), Hindpaw Phalanx, Unossified, proximal 2nd to 5th digits - (V), [bilateral]Skeletal Head (Rat-G21), No abnormalities detected
12	M	5.55	
13	M	5.53Skeletal Body (Rat-G21), Vertebra Thoracic, Incomplete ossification of centrum, 10th to 13th. - (A)Skeletal Head (Rat-G21), No abnormalities detected
14	F	5.33	
15	M	5.13Skeletal Body (Rat-G21), No abnormalities detectedSkeletal Head (Rat-G21), No abnormalities detected
Dam: 52 Pregnancy Type: P			
1	F	5.46Skeletal Body (Rat-G21), Ribs Ribs, Thick - (A), [right]Skeletal Head (Rat-G21), No abnormalities detected
2	F	4.99	
3	M	5.64Skeletal Body (Rat-G21), Ribs Ribs, Supernumerary lumbar, short - (V), [left]Skeletal Head (Rat-G21), No abnormalities detected
4	F	5.25	
6	F	5.10Skeletal Body (Rat-G21), No abnormalities detectedSkeletal Head (Rat-G21), No abnormalities detected
7	F	5.12	

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Individual Foetal Skeletal Observations

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BNT162b2 30mcg	Foetal Sex	Foetal Weight (g)	Findings
Dam: 52 (Continued...)			
9	M	5.31Skeletal Body (Rat-G21), Ribs Ribs, Supernumerary lumbar, short - (V), [left]Skeletal Head (Rat-G21), No abnormalities detected
10	F	5.21	
11	F	4.96Skeletal Body (Rat-G21), No abnormalities detectedSkeletal Head (Rat-G21), No abnormalities detected
12	M	5.01	
13	M	5.74Skeletal Body (Rat-G21), Ribs Ribs, Thick - (A), [bilateral] Ribs, Wavy - (A), [bilateral, 11th and 12th]Skeletal Head (Rat-G21), Skull Parietal, Incomplete ossification - (V) Squamosal, Incomplete ossification - (V)
14	M	5.45	
15	M	5.14Skeletal Body (Rat-G21), No abnormalities detectedSkeletal Head (Rat-G21), No abnormalities detected
Dam: 53 Pregnancy Type: P			
1	M	4.98Skeletal Body (Rat-G21), Hindpaw Phalanx, Unossified, proximal 2nd to 5th digits - (V), [right]Skeletal Body (Rat-G21), Ribs Ribs, Supernumerary lumbar, short - (V), [bilateral]Skeletal Head (Rat-G21), Skull Interparietal, Incomplete ossification - (V)
2	M	4.96	
3	F	4.85Skeletal Body (Rat-G21), Ribs Ribs, Supernumerary lumbar, short - (V), [bilateral]

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BNT162b2 30mcg	Foetal Sex	Foetal Weight (g)	Findings
Dam: 53 (Continued...)			
4	M	4.49Skeletal Head (Rat-G21), No abnormalities detected
5	F	4.04Skeletal Body (Rat-G21), Hindpaw Phalanx, Unossified, proximal 2nd to 5th digits - (V), [bilateral]Skeletal Body (Rat-G21), Ribs Ribs, Supernumerary lumbar, short - (V), [bilateral]Skeletal Head (Rat-G21), No abnormalities detected
6	M	2.70Skeletal Body (Rat-G21), Hindpaw Phalanx, Unossified, proximal 2nd to 5th digits - (V), [bilateral]Skeletal Body (Rat-G21), Ribs Ribs, Supernumerary lumbar, short - (V), [left]Skeletal Head (Rat-G21), No abnormalities detected
7	F	4.28Skeletal Body (Rat-G21), Ribs Ribs, Supernumerary lumbar, short - (V), [left]Skeletal Head (Rat-G21), No abnormalities detected
8	M	5.26Skeletal Body (Rat-G21), Ribs Ribs, Supernumerary lumbar, short - (V), [left]Skeletal Head (Rat-G21), No abnormalities detected
9	F	4.86Skeletal Body (Rat-G21), Forepaw Phalanx, Unossified - (A), [bilateral]Skeletal Body (Rat-G21), Hindpaw Metatarsal, Unossified, 1st digit - (V), [bilateral] Phalanx, Unossified, proximal 2nd to 5th digits - (V), [bilateral]Skeletal Body (Rat-G21), Ribs Ribs, Supernumerary lumbar, short - (V), [bilateral]Skeletal Body (Rat-G21), Sternebra Sternebra, Incomplete ossification, 2nd/4th - (V), [2nd bipartite]
10	M	5.10	
11	F	3.10	

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Individual Foetal Skeletal Observations

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BNT162b2 30mcg	Foetal Sex	Foetal Weight (g)	Findings
Dam: 53 (Continued...)			
12	F	4.65Skeletal Body (Rat-G21), Vertebra Caudal, Number < 5 - (A) Cervical, Odontoid process unossified - (V) Cervical, Unossified centrum - (V) Lumbar, Number = 7 - (A)Skeletal Head (Rat-G21), Skull Supraoccipital, Incomplete ossification - (V)
13	M	4.03Skeletal Body (Rat-G21), Hindpaw Phalanx, Unossified, proximal 2nd to 5th digits - (V), [bilateral]Skeletal Body (Rat-G21), Ribs Ribs, Supernumerary lumbar, short - (V), [bilateral]Skeletal Head (Rat-G21), No abnormalities detected
14	M	4.98Skeletal Body (Rat-G21), Ribs Ribs, Supernumerary lumbar, short - (V), [bilateral]Skeletal Head (Rat-G21), No abnormalities detected
15	M	5.11Skeletal Body (Rat-G21), Ribs Ribs, Supernumerary lumbar, short - (V), [bilateral]Skeletal Head (Rat-G21), No abnormalities detected
16	F	3.84Skeletal Body (Rat-G21), Ribs Ribs, Supernumerary lumbar, short - (V), [bilateral]Skeletal Head (Rat-G21), No abnormalities detected
Dam: 54 Pregnancy Type: P			
1	M	4.61Skeletal Body (Rat-G21), Hindpaw Phalanx, Unossified, proximal 2nd to 5th digits - (V), [bilateral]Skeletal Body (Rat-G21), Ribs Ribs, Supernumerary lumbar - (A), [right] Ribs, Supernumerary lumbar, short - (V), [left]Skeletal Head (Rat-G21), No abnormalities detected
2	M	5.45Skeletal Body (Rat-G21), Hindpaw Phalanx, Unossified, proximal 2nd to 5th digits - (V), [bilateral]Skeletal Body (Rat-G21), Ribs Ribs, Supernumerary lumbar - (A), [right] Ribs, Supernumerary lumbar, short - (V), [left]Skeletal Head (Rat-G21), No abnormalities detected

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BNT162b2 30mcg	Foetal Sex	Foetal Weight (g)	Findings
Dam: 54 (Continued...)			
3	M	5.08Skeletal Body (Rat-G21), Hindpaw Phalanx, Unossified, proximal 2nd to 5th digits - (V), [bilateral]Skeletal Body (Rat-G21), Ribs Ribs, Supernumerary lumbar, short - (V), [bilateral]Skeletal Head (Rat-G21), No abnormalities detected
4	M	5.72	
5	F	5.59Skeletal Body (Rat-G21), Ribs Ribs, Supernumerary lumbar - (A), [left] Ribs, Supernumerary lumbar, short - (V), [right]Skeletal Body (Rat-G21), Vertebra Lumbar, Number = 7 - (A)Skeletal Head (Rat-G21), No abnormalities detected
6	M	5.38	
7	M	5.28Skeletal Body (Rat-G21), Ribs Ribs, Supernumerary lumbar, short - (V), [left]Skeletal Head (Rat-G21), No abnormalities detected
8	F	4.92	
9	M	5.46Skeletal Body (Rat-G21), Ribs Ribs, Supernumerary lumbar, short - (V), [left]Skeletal Head (Rat-G21), No abnormalities detected
10	M	5.16	
12	M	5.64Skeletal Body (Rat-G21), Ribs Ribs, Supernumerary lumbar - (A), [bilateral]Skeletal Body (Rat-G21), Vertebra Lumbar, Number = 7 - (A)Skeletal Head (Rat-G21), No abnormalities detected

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Individual Foetal Skeletal Observations

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BNT162b2 30mcg	Foetal Sex	Foetal Weight (g)	Findings
Dam: 54 (Continued...)			
13	F	5.49Skeletal Body (Rat-G21), Ribs Ribs, Supernumerary lumbar, short - (V), [bilateral]Skeletal Head (Rat-G21), No abnormalities detected
14	F	4.71	
Dam: 55 Pregnancy Type: P			
1	F	5.00Skeletal Body (Rat-G21), Ribs Ribs, Supernumerary lumbar, short - (V), [left]Skeletal Head (Rat-G21), No abnormalities detected
2	M	5.64Skeletal Body (Rat-G21), No abnormalities detectedSkeletal Head (Rat-G21), No abnormalities detected
3	F	5.24	
4	F	5.13Skeletal Body (Rat-G21), Ribs Ribs, Supernumerary lumbar, short - (V), [right]Skeletal Head (Rat-G21), No abnormalities detected
5	M	5.36	
6	F	4.81Skeletal Body (Rat-G21), Ribs Ribs, Supernumerary lumbar, short - (V), [left]Skeletal Head (Rat-G21), No abnormalities detected
8	M	5.18	
9	F	4.54Skeletal Body (Rat-G21), No abnormalities detectedSkeletal Head (Rat-G21), No abnormalities detected
10	F	5.25	
11	F	4.96Skeletal Body (Rat-G21), No abnormalities detectedSkeletal Head (Rat-G21), No abnormalities detected
12	M	5.42	

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Individual Foetal Skeletal Observations

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BNT162b2 30mcg	Foetal Sex	Foetal Weight (g)	Findings
Dam: 55 (Continued...)			
13	F	5.03	
14	M	5.24Skeletal Body (Rat-G21), No abnormalities detectedSkeletal Head (Rat-G21), No abnormalities detected
Dam: 56 Pregnancy Type: NPE			
Dam: 57 Pregnancy Type: P			
1	M	5.01Skeletal Body (Rat-G21), No abnormalities detectedSkeletal Head (Rat-G21), No abnormalities detected
2	F	4.67	
3	F	4.86Skeletal Body (Rat-G21), Ribs Ribs, Supernumerary lumbar, short - (V), [bilateral]Skeletal Head (Rat-G21), No abnormalities detected
4	F	4.94	
5	F	5.15Skeletal Body (Rat-G21), No abnormalities detectedSkeletal Head (Rat-G21), No abnormalities detected
6	M	5.26	
7	M	4.97Skeletal Body (Rat-G21), Ribs Ribs, Supernumerary lumbar, short - (V), [bilateral]Skeletal Head (Rat-G21), No abnormalities detected
8	M	5.45	
9	F	4.76Skeletal Body (Rat-G21), Ribs Ribs, Supernumerary lumbar, short - (V), [left]Skeletal Head (Rat-G21), No abnormalities detected
10	M	4.20	
11	F	5.34Skeletal Body (Rat-G21), Ribs

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Individual Foetal Skeletal Observations

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BNT162b2 30mcg	Foetal Sex	Foetal Weight (g)	Findings
Dam: 57 (Continued...)			
12	F	5.00	Ribs, Supernumerary lumbar - (A), [right] Ribs, Supernumerary lumbar, short - (V), [left]Skeletal Head (Rat-G21), No abnormalities detected
13	M	5.39Skeletal Body (Rat-G21), Ribs Ribs, Supernumerary lumbar, short - (V), [bilateral]Skeletal Head (Rat-G21), No abnormalities detected
14	M	5.40Skeletal Body (Rat-G21), Ribs Ribs, Supernumerary lumbar, short - (V), [bilateral]Skeletal Head (Rat-G21), No abnormalities detected
15	M	5.16Skeletal Body (Rat-G21), Ribs Ribs, Supernumerary lumbar, short - (V), [bilateral]Skeletal Head (Rat-G21), No abnormalities detected
Dam: 58 Pregnancy Type: P			
1	M	4.04Skeletal Body (Rat-G21), General Vertebra, Presacral vertebral arches = 27 - (A), [left]Skeletal Body (Rat-G21), Ribs Ribs, Supernumerary lumbar - (A), [left] Ribs, Supernumerary lumbar, short - (V), [right]Skeletal Body (Rat-G21), Vertebra Cervical, Odontoid process unossified - (V) Cervical, Unossified centrum - (V) Thoracic, Incomplete ossification of centrum, 10th to 13th. - (A)Skeletal Head (Rat-G21), No abnormalities detected
2	M	5.05Skeletal Body (Rat-G21), No abnormalities detected
3	F	4.69Skeletal Head (Rat-G21), No abnormalities detected
4	M	4.78Skeletal Head (Rat-G21), No abnormalities detected

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Individual Foetal Skeletal Observations

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BNT162b2 30mcg	Foetal Sex	Foetal Weight (g)	Findings
Dam: 58 (Continued...)			
5	F	4.68Skeletal Body (Rat-G21), No abnormalities detectedSkeletal Head (Rat-G21), No abnormalities detected
7	M	5.00	
8	F	4.77Skeletal Body (Rat-G21), Ribs Ribs, Supernumerary lumbar, short - (V), [bilateral]Skeletal Body (Rat-G21), Vertebra Cervical, Odontoid process unossified - (V)Skeletal Head (Rat-G21), No abnormalities detected
9	M	4.00	
10	M	3.77Skeletal Body (Rat-G21), Ribs Ribs, Supernumerary lumbar, short - (V), [bilateral]Skeletal Body (Rat-G21), Sternebra Sternebra, Incomplete ossification, 1st/3rd - (A) Sternebra, Incomplete ossification, 2nd/4th - (V)Skeletal Body (Rat-G21), Vertebra Caudal, Number < 5 - (A) Cervical, Incomplete ossification of arch - (A), [5th and 6th] Cervical, Odontoid process unossified - (V) Thoracic, Incomplete ossification of centrum, 1st to 9th - (A)Skeletal Head (Rat-G21), No abnormalities detected
11	F	4.36	
13	M	4.83Skeletal Body (Rat-G21), Ribs Ribs, Supernumerary lumbar, short - (V), [bilateral]Skeletal Head (Rat-G21), No abnormalities detected
14	F	2.50	
15	F	4.59Skeletal Body (Rat-G21), Ribs Ribs, Supernumerary lumbar, short - (V), [bilateral]

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Individual Foetal Skeletal Observations

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BNT162b2 30mcg	Foetal Sex	Foetal Weight (g)	Findings
Dam: 58 (Continued...)			
16	M	4.79Skeletal Head (Rat-G21), No abnormalities detected
Dam: 59 Pregnancy Type: P			
1	F	4.55Skeletal Body (Rat-G21), Ribs Ribs, Supernumerary lumbar, short - (V), [left]Skeletal Head (Rat-G21), No abnormalities detected
2	F	4.52Skeletal Body (Rat-G21), Ribs Ribs, Supernumerary lumbar, short - (V), [left]Skeletal Head (Rat-G21), No abnormalities detected
4	F	5.02Skeletal Body (Rat-G21), Ribs Ribs, Supernumerary lumbar, short - (V), [left]Skeletal Head (Rat-G21), No abnormalities detected
5	F	4.19Skeletal Body (Rat-G21), Ribs Ribs, Supernumerary lumbar, short - (V), [left]Skeletal Head (Rat-G21), No abnormalities detected
7	F	4.27Skeletal Body (Rat-G21), Ribs Ribs, Supernumerary lumbar, short - (V), [left]Skeletal Head (Rat-G21), No abnormalities detected
8	M	4.61Skeletal Body (Rat-G21), Ribs Ribs, Supernumerary lumbar, short - (V), [left]Skeletal Head (Rat-G21), No abnormalities detected
9	M	5.04Skeletal Body (Rat-G21), Hindpaw Phalanx, Unossified, proximal 2nd to 5th digits - (V), [left]Skeletal Head (Rat-G21), No abnormalities detected
10	F	4.63Skeletal Body (Rat-G21), Ribs Ribs, Supernumerary lumbar, short - (V), [left]Skeletal Head (Rat-G21), No abnormalities detected
11	M	4.35Skeletal Body (Rat-G21), Ribs Ribs, Supernumerary lumbar, short - (V), [bilateral]Skeletal Head (Rat-G21), No abnormalities detected
12	F	4.68Skeletal Body (Rat-G21), Ribs Ribs, Supernumerary lumbar, short - (V), [left]Skeletal Head (Rat-G21), No abnormalities detected
13	F	4.54Skeletal Body (Rat-G21), Ribs Ribs, Supernumerary lumbar - (A), [right] Ribs, Supernumerary lumbar, short - (V), [left]Skeletal Head (Rat-G21), No abnormalities detected

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Individual Foetal Skeletal Observations

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BNT162b2 30mcg	Foetal Sex	Foetal Weight (g)	Findings
Dam: 59 (Continued...)			
14	F	4.36	
15	F	4.79Skeletal Body (Rat-G21), No abnormalities detectedSkeletal Head (Rat-G21), No abnormalities detected
Dam: 60 Pregnancy Type: P			
1	F	4.99Skeletal Body (Rat-G21), No abnormalities detectedSkeletal Head (Rat-G21), No abnormalities detected
2	M	5.18	
3	F	5.00Skeletal Body (Rat-G21), No abnormalities detectedSkeletal Head (Rat-G21), No abnormalities detected
4	M	5.94	
5	M	5.22Skeletal Body (Rat-G21), Ribs Ribs, Supernumerary lumbar, short - (V), [bilateral]Skeletal Head (Rat-G21), No abnormalities detected
6	F	4.99	
7	M	4.93Skeletal Body (Rat-G21), Ribs Ribs, Supernumerary lumbar, short - (V), [bilateral]Skeletal Head (Rat-G21), No abnormalities detected
8	M	5.25	
9	M	5.30Skeletal Body (Rat-G21), Ribs Ribs, Supernumerary lumbar, short - (V), [bilateral]Skeletal Body (Rat-G21), Vertebra Thoracic, Incomplete ossification of centrum, 1st to 9th - (A) Thoracic, Incomplete ossification of centrum, 10th to 13th - (A)Skeletal Head (Rat-G21), No abnormalities detected
10	F	4.80	

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Individual Foetal Skeletal Observations

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BNT162b2 30mcg	Foetal Sex	Foetal Weight (g)	Findings
Dam: 60 (Continued...)			
11	M	5.41Skeletal Body (Rat-G21), No abnormalities detectedSkeletal Head (Rat-G21), No abnormalities detected
12	F	5.04	
Dam: 61 Pregnancy Type: P			
1	F	5.00Skeletal Body (Rat-G21), No abnormalities detectedSkeletal Head (Rat-G21), No abnormalities detected
2	M	5.13	
3	M	5.34Skeletal Body (Rat-G21), No abnormalities detectedSkeletal Head (Rat-G21), No abnormalities detected
4	F	5.07	
5	M	5.49Skeletal Body (Rat-G21), No abnormalities detectedSkeletal Head (Rat-G21), Skull Interparietal, Incomplete ossification - (V)
6	F	5.07	
7	F	5.24Skeletal Body (Rat-G21), No abnormalities detectedSkeletal Head (Rat-G21), No abnormalities detected
8	F	5.09	
9	M	5.37Skeletal Body (Rat-G21), No abnormalities detectedSkeletal Head (Rat-G21), No abnormalities detected
10	M	5.34	
11	F	5.02Skeletal Body (Rat-G21), Ribs Ribs, Supernumerary lumbar, short - (V), [right]Skeletal Head (Rat-G21), No abnormalities detected
12	M	5.63	
13	F	5.07Skeletal Body (Rat-G21), No abnormalities detected

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Individual Foetal Skeletal Observations

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BNT162b2 30mcg	Foetal Sex	Foetal Weight (g)	Findings
Dam: 61 (Continued...)			
		Skeletal Head (Rat-G21), Skull Interparietal, Incomplete ossification - (V) Parietal, Incomplete ossification - (V)
Dam: 62 Pregnancy Type: P			
1	F	4.66Skeletal Body (Rat-G21), No abnormalities detectedSkeletal Head (Rat-G21), No abnormalities detected
2	M	5.24	
3	M	5.10Skeletal Body (Rat-G21), Ribs Ribs, Supernumerary lumbar, short - (V), [bilateral]Skeletal Head (Rat-G21), No abnormalities detected
4	F	4.88	
5	M	4.75Skeletal Body (Rat-G21), Ribs Ribs, Supernumerary lumbar, short - (V), [bilateral]Skeletal Body (Rat-G21), Vertebra Thoracic, Incomplete ossification of centrum, 10th to 13th. - (A)Skeletal Head (Rat-G21), No abnormalities detected
6	F	4.44	
7	M	4.71Skeletal Body (Rat-G21), Ribs Ribs, Supernumerary lumbar, short - (V), [bilateral]Skeletal Head (Rat-G21), No abnormalities detected
8	M	4.60	
9	F	4.71Skeletal Body (Rat-G21), Ribs Ribs, Supernumerary lumbar, short - (V), [bilateral]Skeletal Head (Rat-G21), No abnormalities detected
10	M	4.73	
11	M	4.91Skeletal Body (Rat-G21), No abnormalities detected

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BNT162b2 30mcg	Foetal Sex	Foetal Weight (g)	Findings
Dam: 62 (Continued...)			
12	M	4.84Skeletal Head (Rat-G21), No abnormalities detected
13	M	5.11Skeletal Body (Rat-G21), No abnormalities detected
14	F	4.88Skeletal Head (Rat-G21), No abnormalities detected
Dam: 63 Pregnancy Type: P			
1	F	4.47Skeletal Body (Rat-G21), Ribs Ribs, Thick - (A), [bilateral]Skeletal Head (Rat-G21), No abnormalities detected
2	F	4.48Skeletal Head (Rat-G21), No abnormalities detected
3	M	4.55Skeletal Body (Rat-G21), No abnormalities detected
4	F	4.87Skeletal Head (Rat-G21), No abnormalities detected
5	M	4.64Skeletal Body (Rat-G21), No abnormalities detected
6	M	5.37Skeletal Head (Rat-G21), No abnormalities detected
7	F	4.80Skeletal Body (Rat-G21), No abnormalities detected
8	F	4.71Skeletal Head (Rat-G21), No abnormalities detected
9	F	4.51Skeletal Body (Rat-G21), No abnormalities detected
10	M	4.51Skeletal Head (Rat-G21), No abnormalities detected
11	M	5.00Skeletal Body (Rat-G21), No abnormalities detected
12	F	2.79Skeletal Head (Rat-G21), No abnormalities detected

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Individual Foetal Skeletal Observations

20256434

BNT162b2 30mcg	Foetal Sex	Foetal Weight (g)	Findings
Dam: 64 Pregnancy Type: P			
1	F	4.89Skeletal Body (Rat-G21), No abnormalities detectedSkeletal Head (Rat-G21), No abnormalities detected
2	F	4.96	
3	F	4.84Skeletal Body (Rat-G21), No abnormalities detectedSkeletal Head (Rat-G21), No abnormalities detected
4	M	5.29	
5	M	5.19Skeletal Body (Rat-G21), No abnormalities detectedSkeletal Head (Rat-G21), No abnormalities detected
6	M	4.65	
7	F	4.70Skeletal Body (Rat-G21), No abnormalities detectedSkeletal Head (Rat-G21), No abnormalities detected
8	F	4.89	
9	F	5.03Skeletal Body (Rat-G21), No abnormalities detectedSkeletal Head (Rat-G21), No abnormalities detected
10	M	5.23	
13	M	4.84	
14	F	3.95Skeletal Body (Rat-G21), Vertebra Cervical, Incomplete ossification of arch - (A), [4th] Thoracic, Incomplete ossification of centrum, 1st to 9th - (A) Thoracic, Incomplete ossification of centrum, 10th to 13th. - (A)Skeletal Head (Rat-G21), Skull Mandible, Fused - (M) Mandible, Misshapen - (A) Mandible, Short - (M) Supraoccipital, Incomplete ossification - (V)

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Individual Foetal Skeletal Observations

20256434

BNT162b2 30mcg	Foetal Sex	Foetal Weight (g)	Findings
Dam: 65 Pregnancy Type: P			
1	F	4.64Skeletal Body (Rat-G21), Hindpaw Metatarsal, Unossified, 1st digit - (V), [bilateral]Skeletal Body (Rat-G21), Ribs Ribs, Supernumerary lumbar, short - (V), [right]Skeletal Head (Rat-G21), No abnormalities detected
2	M	5.21	
3	F	4.81Skeletal Body (Rat-G21), Forepaw Phalanx, Unossified - (A), [bilateral]Skeletal Body (Rat-G21), Hindpaw Phalanx, Unossified, proximal 2nd to 5th digits - (V), [bilateral]Skeletal Head (Rat-G21), Skull Hyoid, Incomplete ossification - (A)
4	F	4.80	
5	M	5.12Skeletal Body (Rat-G21), Forepaw Phalanx, Unossified - (A), [bilateral]Skeletal Body (Rat-G21), Hindpaw Phalanx, Unossified, proximal 2nd to 5th digits - (V), [bilateral]Skeletal Body (Rat-G21), Ribs Ribs, Supernumerary lumbar, short - (V), [bilateral]Skeletal Head (Rat-G21), No abnormalities detected
6	F	4.55	
7	F	4.69Skeletal Body (Rat-G21), No abnormalities detectedSkeletal Head (Rat-G21), No abnormalities detected
8	F	5.17	
9	F	4.68Skeletal Body (Rat-G21), Hindpaw Phalanx, Unossified, proximal 2nd to 5th digits - (V), [bilateral]Skeletal Body (Rat-G21), Ribs

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Individual Foetal Skeletal Observations

20256434

BNT162b2 30mcg	Foetal Sex	Foetal Weight (g)	Findings
Dam: 65 (Continued...)			
10	M	4.83	Ribs, Supernumerary lumbar, short - (V), [bilateral]Skeletal Body (Rat-G21), Vertebra Thoracic, Incomplete ossification of centrum, 10th to 13th. - (A)Skeletal Head (Rat-G21), No abnormalities detected
11	M	5.26Skeletal Body (Rat-G21), Hindpaw Phalanx, Unossified, proximal 2nd to 5th digits - (V), [bilateral]Skeletal Head (Rat-G21), No abnormalities detected
12	M	5.31	
13	F	4.83Skeletal Body (Rat-G21), Forepaw Phalanx, Unossified - (A), [left]Skeletal Body (Rat-G21), Hindpaw Phalanx, Unossified, proximal 2nd to 5th digits - (V), [bilateral]Skeletal Head (Rat-G21), No abnormalities detected
14	M	5.12	
15	M	5.26Skeletal Body (Rat-G21), Ribs Ribs, Supernumerary lumbar, short - (V), [bilateral]Skeletal Head (Rat-G21), No abnormalities detected
16	F	4.82	
17	M	4.68Skeletal Body (Rat-G21), Forepaw Phalanx, Unossified - (A), [left]Skeletal Body (Rat-G21), Hindpaw Phalanx, Unossified, proximal 2nd to 5th digits - (V), [bilateral]Skeletal Body (Rat-G21), Ribs Ribs, Supernumerary lumbar, short - (V), [bilateral]Skeletal Head (Rat-G21), Skull Interparietal, Incomplete ossification - (V)

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Individual Foetal Skeletal Observations

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BNT162b2 30mcg	Foetal Sex	Foetal Weight (g)	Findings
Dam: 65 (Continued...)			
			Parietal, Incomplete ossification - (V)
Dam: 66 Pregnancy Type: P			
1	F	5.18Skeletal Body (Rat-G21), No abnormalities detectedSkeletal Head (Rat-G21), No abnormalities detected
2	F	5.62	
4	F	5.49Skeletal Body (Rat-G21), No abnormalities detectedSkeletal Head (Rat-G21), No abnormalities detected
5	F	5.38	
6	M	5.04Skeletal Body (Rat-G21), Vertebra Thoracic, Incomplete ossification of centrum, 10th to 13th. - (A)Skeletal Head (Rat-G21), No abnormalities detected
7	M	5.75	
8	F	4.96Skeletal Body (Rat-G21), No abnormalities detectedSkeletal Head (Rat-G21), No abnormalities detected
9	F	5.80	
10	M	5.96Skeletal Body (Rat-G21), No abnormalities detectedSkeletal Head (Rat-G21), No abnormalities detected
11	M	5.39	

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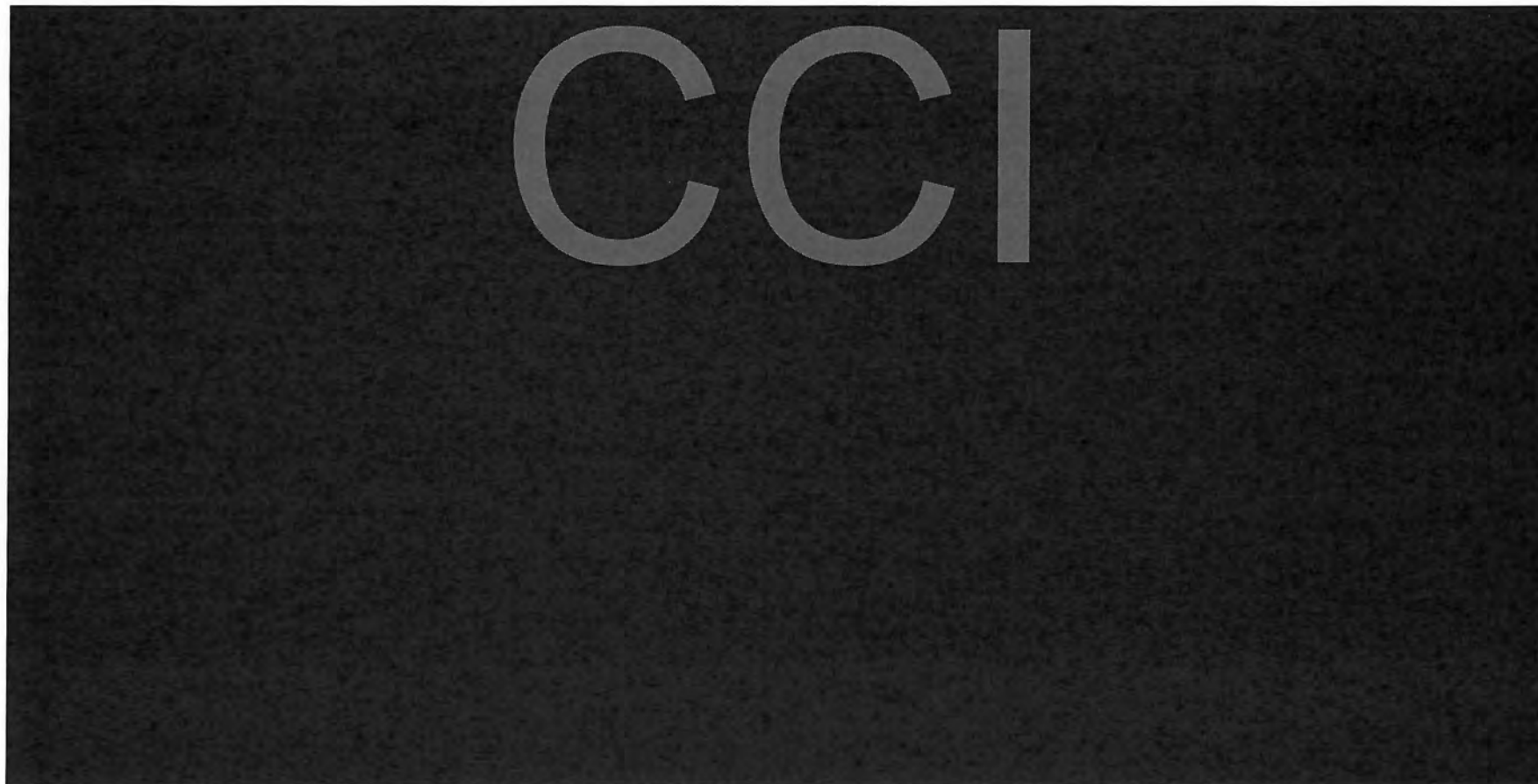
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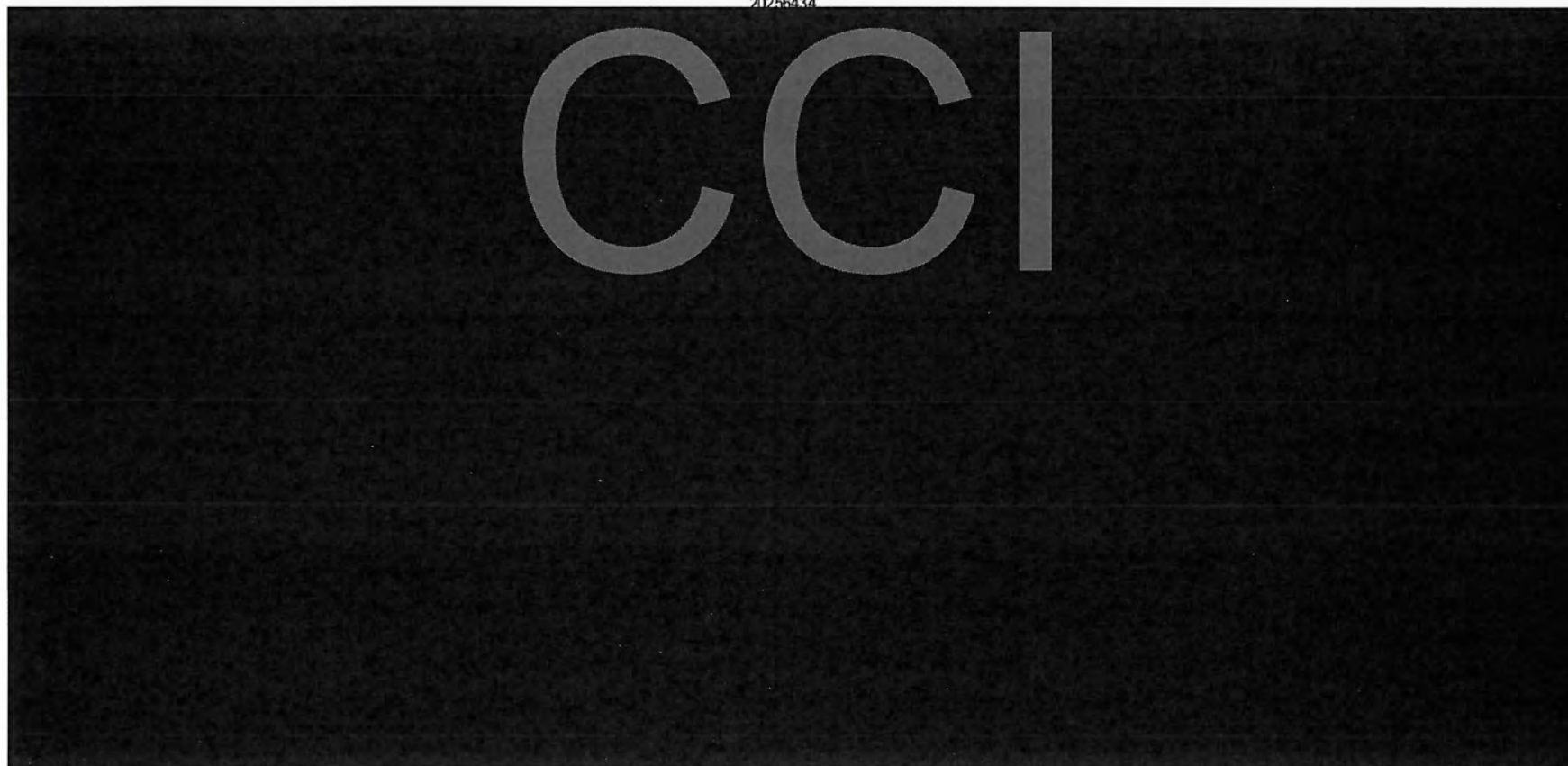
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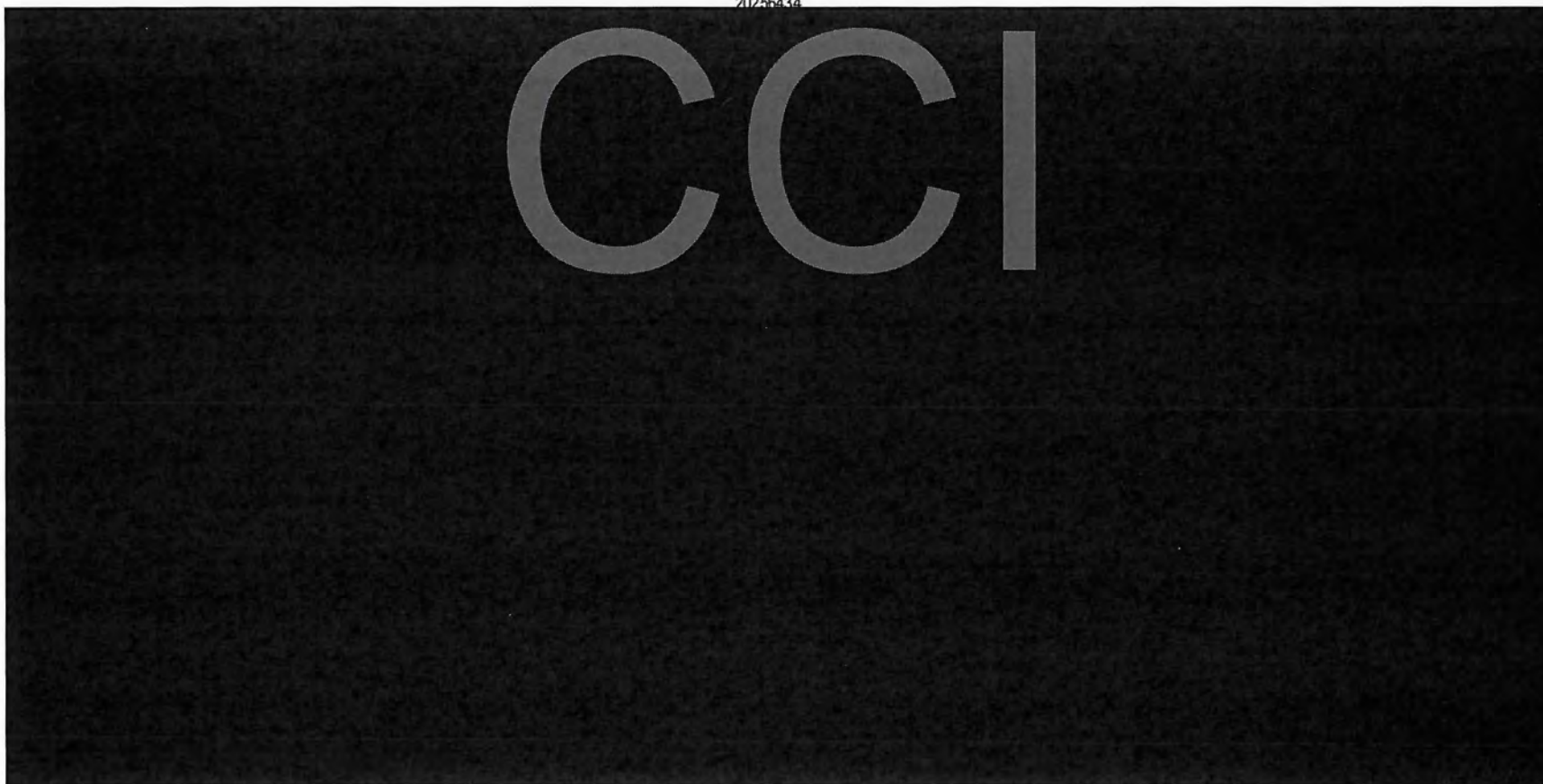
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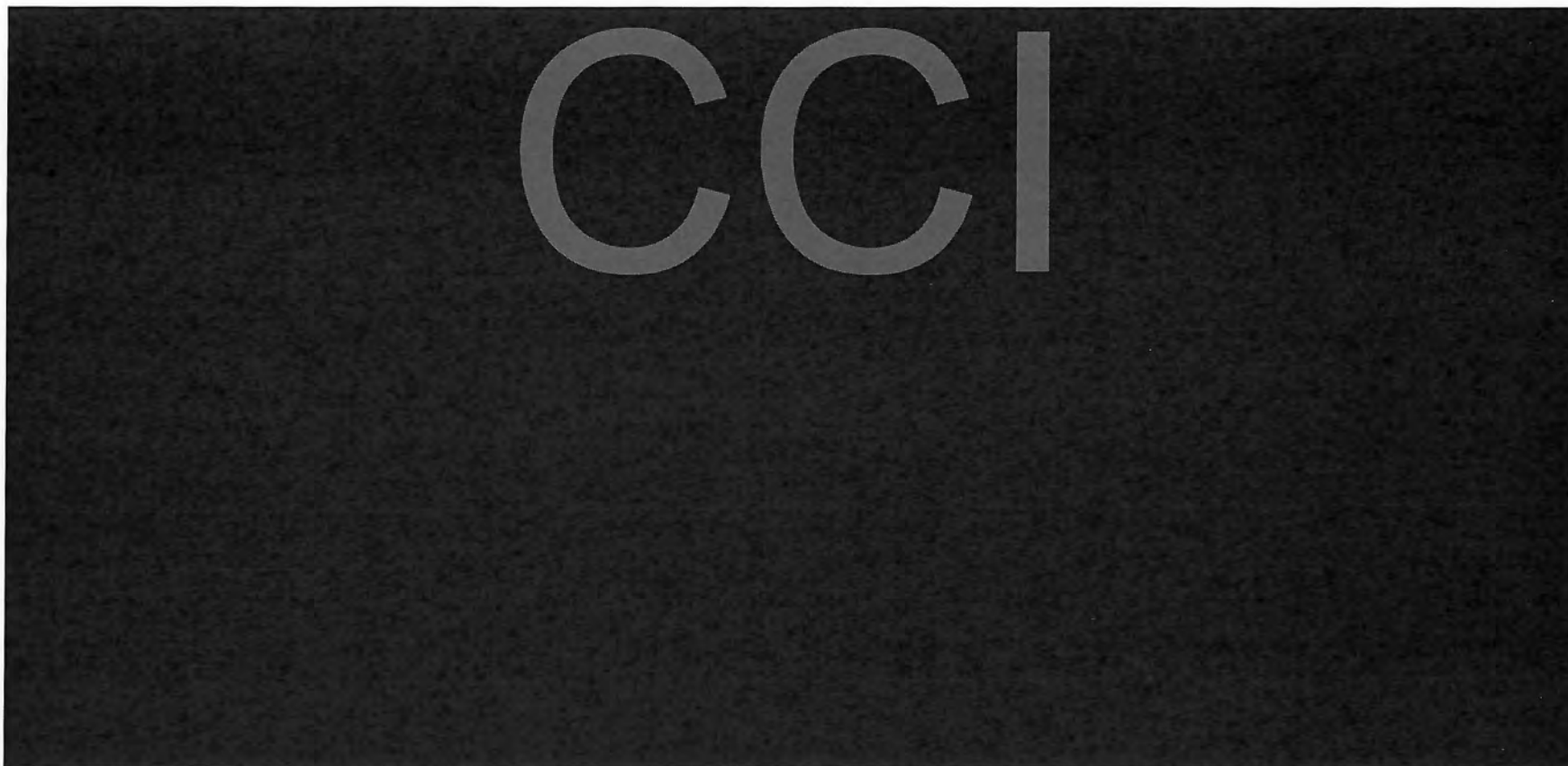
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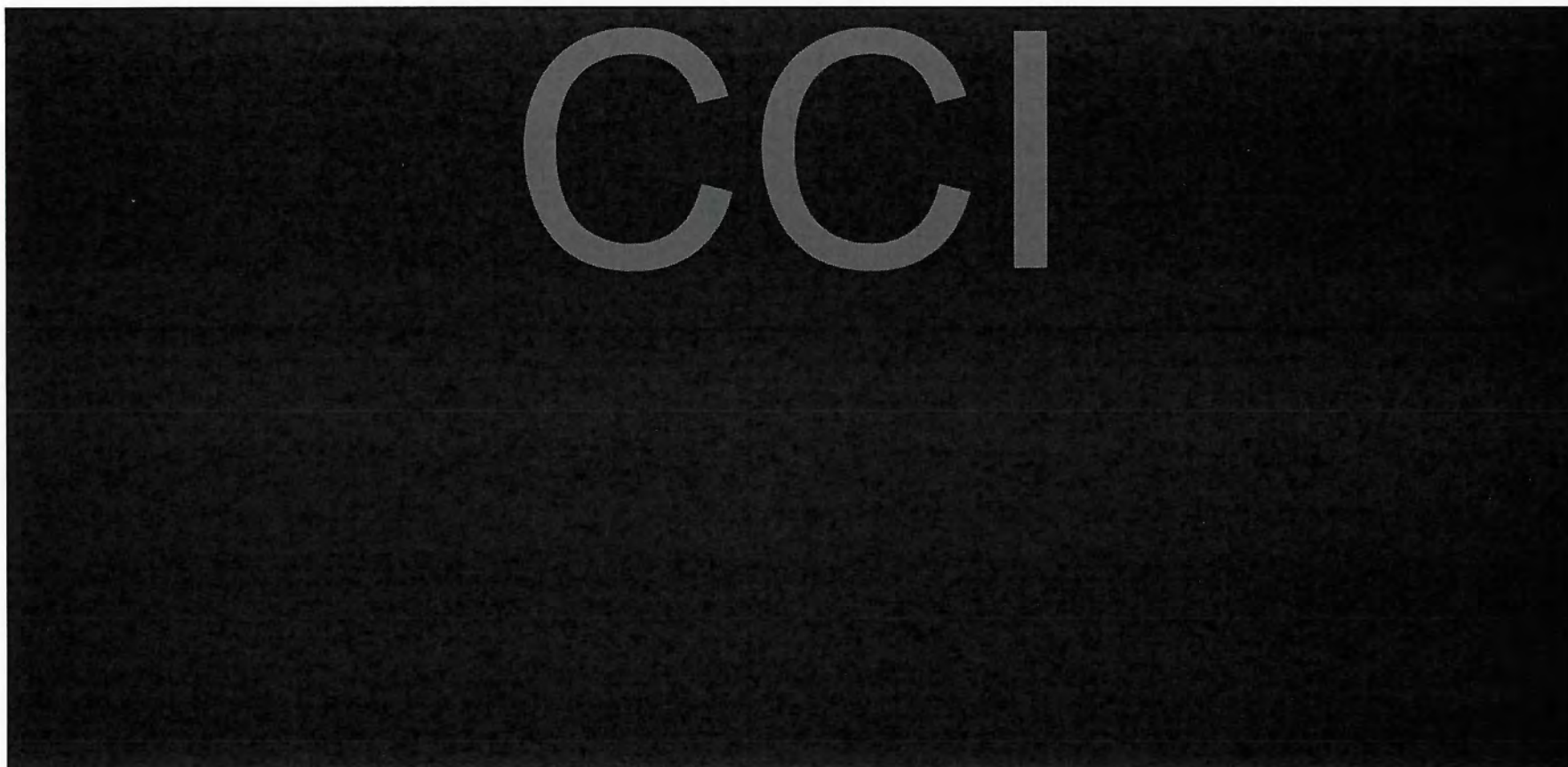
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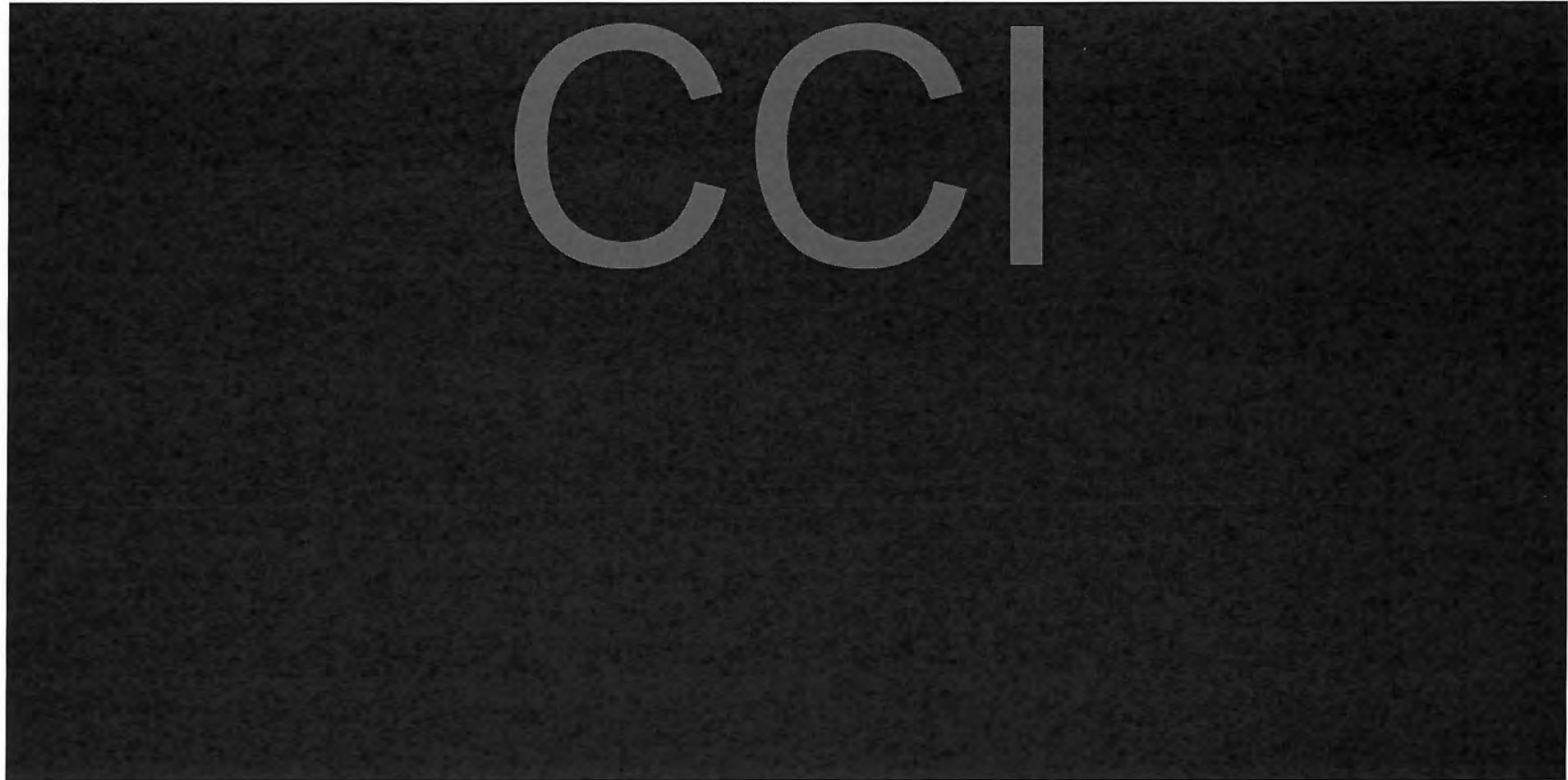
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Individual Foetal Skeletal Observations

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Individual Delivery and Litter Data

20256434

Sex: Female Day(s) Relative to Littering (Litter: A)

Control Omcg	Gestation Length (Days)	Implantat site(s)	Pups Delivered	Pre-Birth Loss (%)	Delivered Dead PND 0	Live Pups PND 0	Live Pups PND 1	Live Pups Precull	Live Pups Postcull	Live Pups PND 7	Live Pups PND 10	Live Pups PND 14	Live Pups PND 17	Live Pups PND 21
	-	-	-	-	-	-	-	PND 4	PND 4	-	-	-	-	-
201	22	14	14	0.0	0	14	14	14	8	8	8	8	8	8
202	22	12	10	16.7	0	10	10	10	8	8	8	8	8	8
203	22	14	13	7.1	0	13	13	13	8	8	8	8	8	8
204	23	16	16	0.0	2	14	13	13	8	8	8	8	8	8
205	23	15	14	6.7	3	11	11	11	8	8	8	8	8	8
206	22	16	16	0.0	0	16	16	16	8	8	8	8	8	8
207	22	10	9	10.0	0	9	9	9	8	8	8	8	8	7
208	21	14	13	7.1	0	13	13	13	8	8	8	8	8	8
209	22	13	10	23.1	0	10	10	10	8	8	8	8	8	8
210	23	15	10	33.3	0	10	10	10	8	8	8	8	8	8
211	22	15	13	13.3	0	13	13	13	8	8	8	8	8	8
212	22	20	20	0.0	0	20	19	19	8	8	8	8	8	8
213	22	12	12	0.0	0	12	12	12	8	8	8	8	8	8
214	22	14	13	7.1	0	13	13	13	8	8	8	8	8	8
215	22	13	13	0.0	0	13	13	13	8	8	8	8	8	8
216	22	15	14	6.7	0	14	14	14	8	8	8	8	8	8
217	22	14	14	0.0	1	13	13	13	8	8	8	8	8	8
218	22	10	10	0.0	0	10	10	10	8	8	8	8	8	8

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Individual Delivery and Litter Data

20256434

Sex: Female Day(s) Relative to Littering (Litter: A)

Control Omcg	Gestation Length (Days)	Implantat site(s)	Pups Delivered	Pre-Birth Loss (%)	Delivered Dead PND 0	Live Pups PND 0	Live Pups PND 1	Live Pups Precull	Live Pups Postcull	Live Pups PND 7	Live Pups PND 10	Live Pups PND 14	Live Pups PND 17	Live Pups PND 21
	-	-	-	-	-	-	-	PND 4	PND 4	-	-	-	-	-
219	22	15	14	6.7	0	14	14	14	8	8	8	8	8	8
220	22	15	15	0.0	0	15	15	15	8	8	8	8	8	8
221	22	17	15	11.8	0	15	15	15	8	8	8	8	8	8
222	22	15	15	0.0	0	15	15	14	8	8	8	8	8	8
Mean	22.1	14.3	13.3	6.80	0.3	13.0	13.0	12.9	8.0	8.0	8.0	8.0	8.0	8.0
SD	0.4	2.2	2.5	8.75	0.8	2.5	2.4	2.3	0.0	0.0	0.0	0.0	0.0	0.2
N	22	22	22	22	22	22	22	22	22	22	22	22	22	22
Sum	.	314	293	.	6	287	285	284	176	176	176	176	176	175

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Individual Delivery and Litter Data

20256434

Sex: Female Day(s) Relative to Littering (Litter A)



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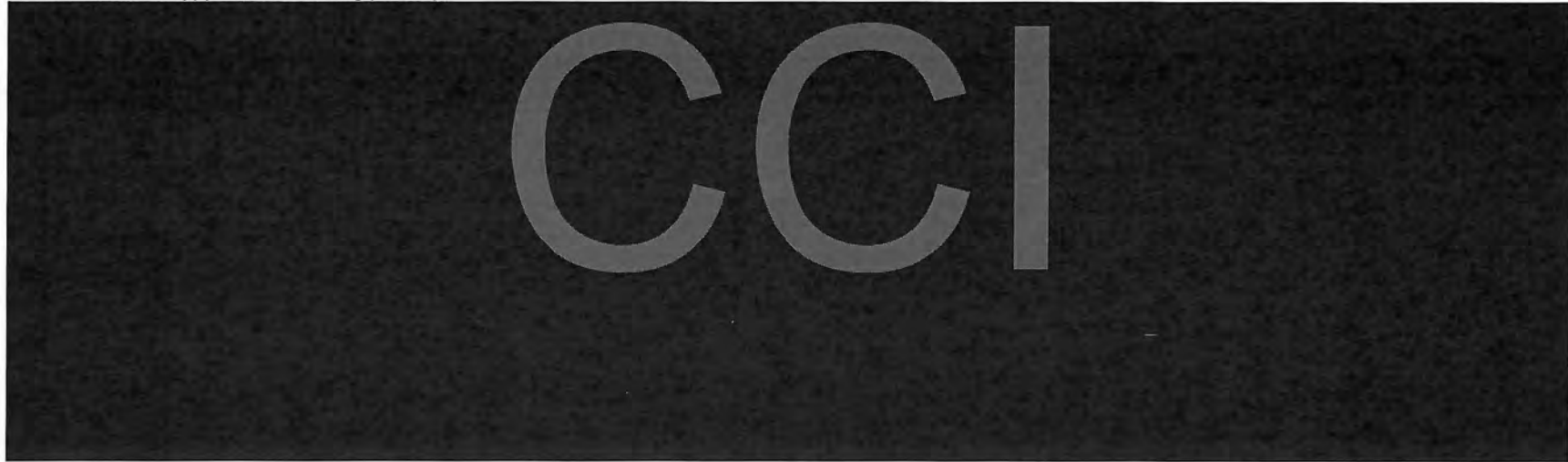
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Individual Delivery and Litter Data

20256434

Sex: Female Day(s) Relative to Littering (Litter: A)



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Individual Delivery and Litter Data

20256434

Sex: Female Day(s) Relative to Littering (Litter: A)

BNT162b2 30mcg														
	Gestation Length (Days)	Implantat site(s)	Pups Delivered	Pre-Birth Loss (%)	Delivered Dead PND 0	Live Pups PND 0	Live Pups PND 1	Live Pups Precull	Live Pups Postcull	Live Pups PND 7	Live Pups PND 10	Live Pups PND 14	Live Pups PND 17	Live Pups PND 21
	-	-	-	-	-	-	-	PND 4	PND 4	-	-	-	-	-
245	20	16	16	0.0	0	16	16	16	8	8	8	8	8	8
246	22	12	12	0.0	0	12	12	12	8	8	8	8	8	8
247	22	15	14	6.7	0	14	13	13	8	8	8	8	8	8
248	22	12	11	8.3	0	11	11	11	8	8	8	8	8	8
249	22	18	18	0.0	1	17	17	17	8	8	8	8	8	8
250	22	15	12	20.0	0	12	12	12	8	8	8	8	8	8
251	22	17	17	0.0	0	17	17	16	8	8	8	8	8	8
252	22	12	12	0.0	1	11	11	11	8	8	8	8	8	8
253	22	13	12	7.7	0	12	12	12	8	8	8	8	8	8
254 NP	E ¹	0 E ¹	E ¹	E ¹	E ¹	E ¹	E ¹	E ¹	E ¹	E ¹	E ¹	E ¹	E ¹	E ¹
255	24	10	3	70.0	0	3	3	3	3	3	3	3	3	3
256	22	16	15	6.3	0	15	15	15	8	8	8	8	8	8
257	22	16	15	6.3	0	15	15	15	8	8	8	8	8	8
258	22	15	15	0.0	0	15	15	15	8	8	8	8	8	8
259	22	16	15	6.3	0	15	15	15	8	8	8	8	8	8
260	23	14	13	7.1	0	13	13	13	8	8	8	8	8	8
261	23	11	11	0.0	0	11	11	11	8	8	8	8	8	8
262	22	13	13	0.0	0	13	13	13	8	8	8	8	8	8

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Individual Delivery and Litter Data

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20256434

Sex: Female Day(s) Relative to Littering (Litter: A)

BNT162b2 30mcg	Gestation Length (Days)	Implantat site(s)	Pups Delivered	Pre-Birth Loss (%)	Delivered Dead PND 0	Live Pups PND 0	Live Pups PND 1	Live Pups Precull	Live Pups Postcull	Live Pups PND 7	Live Pups PND 10	Live Pups PND 14	Live Pups PND 17	Live Pups PND 21
	-	-	-	-	-	-	-	PND 4	PND 4	-	-	-	-	-
263	21	12	12	0.0	0	12	12	12	8	8	8	8	8	8
264	22	16	13	18.8	0	13	13	13	8	8	8	8	8	8
265	22	16	16	0.0	0	16	16	15	8	8	8	8	8	8
266	22	13	11	15.4	0	11	11	11	8	8	8	8	8	8
Mean	22.0	14.2	13.1	8.22	0.1	13.0	13.0	12.9	7.8	7.8	7.8	7.8	7.8	7.8
SD	0.7	2.2	3.1	15.51	0.3	3.1	3.0	2.9	1.1	1.1	1.1	1.1	1.1	1.1
N	21	21	21	21	21	21	21	21	21	21	21	21	21	21
Sum	-	298	276	-	2	274	273	271	163	163	163	163	163	163

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Individual Delivery and Litter Data



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Individual Pup Body Weights (grams)

20256434

Day(s): - Relative to Littering (Litter: A)

Control 0mcg															
Dam	Pup Sex	Meas.	Mean/ Count	1	2	3	4	5	6	7	8	9	10	11	12
201	Male	P1	5.7	5.3	5.3	5.6	6.2	6.0	5.8
		P4pr	9.0	9.3	8.9	8.8	9.4	9.6	8.1
		P4po	9.3	9.3	.	8.8	9.4	9.6
		P7	15.6	15.6	.	15.9	15.2	15.7
		P10	22.7	22.6	.	23.0	22.5	22.6
		P14	32.0	32.2	.	32.0	32.2	31.7
		P17	39.1	39.0	.	39.5	38.7	39.2
	Female	P21	53.9	55.2	.	52.7	54.4	53.2
		P1	5.6	5.4	5.8	5.4	5.7	5.4	5.6	5.5	5.6
		P4pr	8.9	8.8	8.3	9.0	8.9	9.0	9.0	9.2	9.1
		P4po	9.1	.	.	.	8.9	9.0	.	9.2	9.1
		P7	15.1	.	.	.	15.1	15.7	.	14.8	14.7
		P10	22.2	.	.	.	22.8	21.7	.	22.2	21.9
		P14	31.4	.	.	.	32.2	31.5	.	30.7	31.2
		P17	38.0	.	.	.	38.0	36.8	.	39.4	37.6
		P21	52.5	.	.	.	51.4	52.9	.	53.5	52.2
202	Male	P1	7.8	7.8	7.9	7.8
		P4pr	10.4	10.6	10.4	10.3

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Individual Pup Body Weights (grams)

20256434

Day(s): - Relative to Littering (Litter: A)

Control 0mcg															
Dam	Pup Sex	Meas.	Mean/ Count	1	2	3	4	5	6	7	8	9	10	11	12
202	Male	P4po	10.4	10.6	10.4	10.3
		P7	16.4	16.4	16.0	16.7
		P10	23.3	23.4	22.7	23.9
		P14	33.7	33.0	34.1	33.9
		P17	41.2	40.7	41.6	41.4
	Female	P21	54.3	54.8	54.2	54.0
		P1	7.2	7.6	7.2	6.8	6.9	7.3	7.5	7.1
		P4pr	9.8	9.8	9.7	9.6	9.5	9.6	10.4	10.2
		P4po	9.9	.	9.7	9.6	.	9.6	10.4	10.2
		P7	15.6	.	16.2	15.0	.	15.8	15.8	15.0
		P10	22.4	.	23.2	22.8	.	21.5	22.5	21.9
		P14	32.2	.	33.1	31.1	.	32.7	31.1	32.8
		P17	39.3	.	38.4	39.7	.	39.2	40.5	38.5
		P21	51.6	.	51.3	49.5	.	52.4	53.2	51.5
203	Male	P1	6.1	6.3	5.8	6.9	6.0	5.9	5.7
		P4pr	9.6	9.2	10.1	9.8	9.3	9.8	9.5
		P4po	9.6	9.2	10.1	9.8	9.3
		P7	17.0	17.4	16.4	18.1	16.1

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Individual Pup Body Weights (grams)

20256434

Day(s): - Relative to Littering (Litter: A)

Control 0mcg															
Dam	Pup Sex	Meas.	Mean/ Count	1	2	3	4	5	6	7	8	9	10	11	12
203	Male	P10	24.0	24.5	23.2	25.0	23.1	-	-	-	-	-	-	-	-
		P14	34.5	35.7	33.8	35.2	33.3	-	-	-	-	-	-	-	-
		P17	42.2	40.8	43.5	43.8	40.6	-	-	-	-	-	-	-	-
		P21	57.0	59.9	53.7	59.4	54.8	-	-	-	-	-	-	-	-
	Female	P1	5.8	5.6	5.5	5.5	5.8	5.9	6.2	5.9	-	-	-	-	-
		P4pr	9.2	9.5	10.1	8.7	9.2	9.2	9.0	8.6	-	-	-	-	-
		P4po	9.0	9.5	-	8.7	9.2	-	-	8.6	-	-	-	-	-
		P7	15.8	15.2	-	15.8	15.8	-	-	16.3	-	-	-	-	-
		P10	22.7	22.7	-	22.0	22.7	-	-	23.4	-	-	-	-	-
		P14	32.8	32.7	-	32.5	32.6	-	-	33.2	-	-	-	-	-
204	Male	P17	40.2	41.2	-	40.1	40.0	-	-	39.6	-	-	-	-	-
		P21	53.4	54.5	-	53.0	53.1	-	-	53.1	-	-	-	-	-
		P1	5.9	5.8	5.8	5.5	5.8	6.1	5.8	5.8	6.4	-	-	-	-
		P4pr	9.8	9.4	10.3	9.6	9.2	10.3	9.6	9.8	9.8	-	-	-	-
		P4po	9.5	9.4	-	9.6	9.2	-	-	-	9.8	-	-	-	-
		P7	15.8	15.5	-	15.3	16.3	-	-	-	16.0	-	-	-	-
		P10	23.8	23.2	-	23.9	24.3	-	-	-	23.7	-	-	-	-
		P14	35.1	34.4	-	35.3	35.2	-	-	-	35.4	-	-	-	-

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Individual Pup Body Weights (grams)

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Day(s): - Relative to Littering (Litter: A)

Control 0mcg															
Dam	Pup Sex	Meas.	Mean/ Count	1	2	3	4	5	6	7	8	9	10	11	12
204	Male	P17	42.1	42.3	-	42.5	42.4	-	-	-	41.3	-	-	-	-
		P21	58.4	57.3	-	58.3	57.0	-	-	-	60.8	-	-	-	-
	Female	P1	5.6	5.5	6.0	5.4	5.6	5.3	-	-	-	-	-	-	-
		P4pr	9.8	10.1	9.5	9.6	10.1	9.7	-	-	-	-	-	-	-
		P4po	9.8	10.1	9.5	9.6	10.1	-	-	-	-	-	-	-	-
		P7	16.1	16.3	15.9	15.9	16.2	-	-	-	-	-	-	-	-
		P10	24.4	25.1	24.0	24.3	24.2	-	-	-	-	-	-	-	-
		P14	36.0	35.3	35.5	35.9	37.1	-	-	-	-	-	-	-	-
		P17	43.0	42.2	43.3	42.5	44.1	-	-	-	-	-	-	-	-
		P21	57.9	57.0	58.6	58.0	58.0	-	-	-	-	-	-	-	-
205	Male	P1	5.1	5.3	5.0	5.0	5.0	-	-	-	-	-	-	-	-
		P4pr	8.5	8.6	8.4	9.0	8.0	-	-	-	-	-	-	-	-
		P4po	8.5	8.6	8.4	9.0	8.0	-	-	-	-	-	-	-	-
		P7	14.6	13.7	14.6	15.5	14.4	-	-	-	-	-	-	-	-
		P10	21.6	23.0	21.5	21.4	20.6	-	-	-	-	-	-	-	-
		P14	32.2	31.8	34.3	30.6	32.2	-	-	-	-	-	-	-	-
		P17	39.3	41.1	39.0	37.7	39.3	-	-	-	-	-	-	-	-
		P21	53.9	51.5	56.9	54.2	53.0	-	-	-	-	-	-	-	-

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Individual Pup Body Weights (grams)

20256434

Day(s): - Relative to Littering (Litter: A)

Control 0mcg															
Dam	Pup Sex	Meas.	Mean/ Count	1	2	3	4	5	6	7	8	9	10	11	12
205	Female	P1	4.4	4.5	4.5	4.7	4.0	4.3	4.7	4.3	-	-	-	-	-
		P4pr	8.0	7.9	8.0	8.7	8.0	7.1	8.1	7.9	-	-	-	-	-
		P4po	8.0	-	8.0	8.7	-	7.1	8.1	-	-	-	-	-	-
		P7	13.5	-	13.2	13.6	-	15.0	12.2	-	-	-	-	-	-
		P10	20.3	-	19.9	22.2	-	19.9	19.1	-	-	-	-	-	-
		P14	30.6	-	30.7	29.9	-	29.5	32.3	-	-	-	-	-	-
		P17	37.6	-	36.9	36.7	-	36.9	40.0	-	-	-	-	-	-
		P21	52.1	-	51.2	49.3	-	55.1	52.6	-	-	-	-	-	-
206	Male	P1	5.6	5.5	5.9	5.8	5.6	5.5	6.1	5.8	6.0	5.7	4.9	5.2	-
		P4pr	8.3	8.0	8.6	7.7	8.9	8.0	8.8	9.0	8.6	8.3	6.9	8.1	-
		P4po	8.5	8.0	-	-	8.9	-	8.8	-	-	-	-	8.1	-
		P7	14.9	15.3	-	-	15.2	-	14.5	-	-	-	-	14.6	-
		P10	22.4	21.9	-	-	23.2	-	22.4	-	-	-	-	22.0	-
		P14	32.6	32.7	-	-	33.5	-	32.3	-	-	-	-	31.8	-
		P17	40.1	39.7	-	-	40.4	-	40.9	-	-	-	-	39.2	-
		P21	53.2	53.5	-	-	54.4	-	51.6	-	-	-	-	53.1	-
	Female	P1	5.7	5.8	6.0	5.9	5.1	5.5	-	-	-	-	-	-	-
		P4pr	8.3	7.7	8.2	8.5	8.8	8.2	-	-	-	-	-	-	-

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Individual Pup Body Weights (grams)

20256434

Day(s): - Relative to Littering (Litter: A)

Control 0mcg															
Dam	Pup Sex	Meas.	Mean/ Count	1	2	3	4	5	6	7	8	9	10	11	12
206	Female	P4po	8.4	-	8.2	8.5	8.8	8.2	-	-	-	-	-	-	-
		P7	15.0	-	14.5	14.3	16.1	15.1	-	-	-	-	-	-	-
		P10	22.6	-	23.3	22.1	22.0	23.0	-	-	-	-	-	-	-
		P14	32.5	-	31.9	32.7	33.3	32.2	-	-	-	-	-	-	-
		P17	39.2	-	38.9	38.9	38.9	39.9	-	-	-	-	-	-	-
207	Male	P21	52.2	-	53.0	51.3	51.9	52.6	-	-	-	-	-	-	-
		P1	6.7	6.3	6.6	6.5	7.4	-	-	-	-	-	-	-	-
		P4pr	10.8	10.8	10.4	10.5	11.3	-	-	-	-	-	-	-	-
		P4po	10.8	10.8	10.4	10.5	11.3	-	-	-	-	-	-	-	-
		P7	16.0	15.7	16.0	16.7	15.5	-	-	-	-	-	-	-	-
	Female	P10	22.3	21.8	22.1	22.8	22.4	-	-	-	-	-	-	-	-
		P14	31.4	31.8	31.0	31.7	31.1	-	-	-	-	-	-	-	-
		P17	36.9	37.1	37.5	36.1	36.7	-	-	-	-	-	-	-	-
		P21	50.5	50.6	50.6	50.4	-	-	-	-	-	-	-	-	-
		P1	6.4	6.6	6.6	6.7	5.6	6.6	-	-	-	-	-	-	-
		P4pr	10.3	10.6	10.8	9.2	10.2	10.7	-	-	-	-	-	-	-
		P4po	10.3	10.6	10.8	9.2	-	10.7	-	-	-	-	-	-	-
		P7	15.5	13.8	16.0	15.9	-	16.1	-	-	-	-	-	-	-

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Individual Pup Body Weights (grams)

20256434

Day(s): - Relative to Littering (Litter: A)

Control 0mcg															
Dam	Pup Sex	Meas.	Mean/ Count	1	2	3	4	5	6	7	8	9	10	11	12
207	Female	P10	21.3	21.6	19.8	21.4	.	22.4
		P14	30.1	30.8	31.1	30.3	.	28.2
		P17	35.4	35.9	35.5	36.0	.	34.0
		P21	47.3	48.1	46.1	46.7	.	48.1
208	Male	P1	5.8	5.8	5.9	6.2	6.3	5.9	5.8	4.7	6.0
		P4pr	8.2	6.7	8.4	8.2	8.6	9.0	8.3	8.0	8.4
		P4po	8.0	6.7	8.4	.	8.6	.	.	.	8.4
		P7	14.0	15.0	14.7	.	11.8	.	.	.	14.5
	Female	P10	21.1	22.1	22.3	.	21.7	.	.	.	18.1
		P14	31.7	32.7	29.4	.	32.3	.	.	.	32.2
		P17	38.6	37.9	36.4	.	39.6	.	.	.	40.5
		P21	51.4	48.4	52.5	.	51.4	.	.	.	53.3
		P1	5.5	5.3	5.6	5.4	5.6	5.5
		P4pr	7.6	7.7	7.8	7.2	7.5	7.6
		P4po	7.6	7.7	7.8	7.2	.	7.6
		P7	13.2	13.6	13.7	13.1	.	12.3
		P10	19.7	20.0	18.5	20.3	.	20.0
		P14	29.5	29.9	28.2	29.1	.	30.7

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Individual Pup Body Weights (grams)

20256434

Day(s): - Relative to Littering (Litter: A)

Control 0mcg															
Dam	Pup Sex	Meas.	Mean/ Count	1	2	3	4	5	6	7	8	9	10	11	12
208	Female	P17	36.9	36.8	35.4	39.9	-	35.3	-	-	-	-	-	-	-
		P21	48.3	46.0	47.2	48.4	-	51.4	-	-	-	-	-	-	-
209	Male	P1	6.3	6.3	6.8	6.4	6.6	5.3	-	-	-	-	-	-	-
		P4pr	9.9	9.9	10.4	10.1	10.3	8.8	-	-	-	-	-	-	-
		P4po	9.8	9.9	10.4	10.1	-	8.8	-	-	-	-	-	-	-
		P7	15.9	16.7	14.6	16.4	-	15.8	-	-	-	-	-	-	-
	Female	P10	21.9	22.1	21.9	20.7	-	22.9	-	-	-	-	-	-	-
		P14	30.1	31.4	28.7	30.2	-	30.2	-	-	-	-	-	-	-
		P17	36.6	37.0	36.3	37.3	-	35.6	-	-	-	-	-	-	-
		P21	46.2	44.8	46.7	47.4	-	46.0	-	-	-	-	-	-	-
		P1	6.2	6.4	6.3	5.8	6.2	6.5	-	-	-	-	-	-	-
		P4pr	9.9	9.3	9.7	10.3	10.1	9.9	-	-	-	-	-	-	-
		P4po	9.8	9.3	9.7	10.3	-	9.9	-	-	-	-	-	-	-
		P7	15.6	15.1	15.6	16.5	-	15.3	-	-	-	-	-	-	-
		P10	21.6	22.0	22.6	21.3	-	20.6	-	-	-	-	-	-	-
		P14	29.9	29.4	29.7	31.0	-	29.5	-	-	-	-	-	-	-
		P17	35.7	35.6	37.0	35.3	-	34.8	-	-	-	-	-	-	-
		P21	45.8	45.0	44.5	47.0	-	46.7	-	-	-	-	-	-	-

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Individual Pup Body Weights (grams)

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Day(s): - Relative to Littering (Litter: A)

Control 0mcg															
Dam	Pup Sex	Meas.	Mean/ Count	1	2	3	4	5	6	7	8	9	10	11	12
210	Male	P1	8.2	8.3	8.3	7.6	8.0	8.6	8.2	-	-	-	-	-	-
		P4pr	13.0	12.9	13.3	13.2	13.6	12.9	12.0	-	-	-	-	-	-
		P4po	13.3	12.9	13.3	13.2	13.6	-	-	-	-	-	-	-	-
		P7	20.3	20.5	19.8	20.2	20.6	-	-	-	-	-	-	-	-
		P10	28.8	28.6	28.5	28.8	29.3	-	-	-	-	-	-	-	-
		P14	39.8	39.8	40.1	39.7	39.4	-	-	-	-	-	-	-	-
		P17	47.4	46.9	47.1	48.2	47.2	-	-	-	-	-	-	-	-
	Female	P21	65.1	63.9	65.8	66.4	64.4	-	-	-	-	-	-	-	-
		P1	7.9	8.0	7.8	8.4	7.5	-	-	-	-	-	-	-	-
		P4pr	12.7	12.8	12.5	13.0	12.5	-	-	-	-	-	-	-	-
		P4po	12.7	12.8	12.5	13.0	12.5	-	-	-	-	-	-	-	-
		P7	19.7	19.8	19.5	20.2	19.2	-	-	-	-	-	-	-	-
		P10	27.7	28.4	27.0	27.9	27.5	-	-	-	-	-	-	-	-
		P14	38.7	39.0	38.3	39.9	37.7	-	-	-	-	-	-	-	-
		P17	45.9	45.2	45.4	46.1	46.7	-	-	-	-	-	-	-	-
		P21	63.7	63.5	65.1	63.2	62.8	-	-	-	-	-	-	-	-
211	Male	P1	6.4	6.3	6.4	6.6	6.6	6.7	6.0	6.2	6.2	-	-	-	-
		P4pr	10.1	10.2	10.2	9.4	10.4	10.1	10.0	10.5	9.9	-	-	-	-

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Individual Pup Body Weights (grams)

20256434

Day(s): - Relative to Littering (Litter: A)

Control Omcg															
Dam	Pup Sex	Meas.	Mean/ Count	1	2	3	4	5	6	7	8	9	10	11	12
211	Male	P4po	10.2	10.2	10.2	-	10.4	-	-	-	9.9	-	-	-	-
		P7	17.0	17.1	16.5	-	17.2	-	-	-	17.2	-	-	-	-
		P10	24.9	24.7	25.1	-	25.1	-	-	-	24.6	-	-	-	-
		P14	36.1	35.7	35.3	-	36.8	-	-	-	36.5	-	-	-	-
		P17	43.1	44.0	42.8	-	42.6	-	-	-	43.1	-	-	-	-
		P21	56.6	57.3	56.1	-	54.7	-	-	-	58.2	-	-	-	-
	Female	P1	6.1	5.9	6.1	5.9	5.8	6.6	-	-	-	-	-	-	-
		P4pr	9.8	9.9	9.1	10.3	10.1	9.6	-	-	-	-	-	-	-
		P4po	9.7	9.9	9.1	10.3	-	9.6	-	-	-	-	-	-	-
		P7	16.2	16.4	16.5	15.3	-	16.4	-	-	-	-	-	-	-
		P10	24.0	25.0	24.0	24.2	-	22.7	-	-	-	-	-	-	-
		P14	34.9	33.9	35.7	34.9	-	35.0	-	-	-	-	-	-	-
		P17	41.7	39.5	42.4	41.6	-	43.1	-	-	-	-	-	-	-
		P21	54.1	51.9	54.3	55.8	-	54.2	-	-	-	-	-	-	-
212	Male	P1	4.4	4.3	4.4	4.2	4.8	4.5	4.4	4.1	4.6	4.4	-	-	-
		P4pr	7.1	7.8	7.2	6.5	7.2	7.4	6.7	7.9	6.5	6.3	-	-	-
		P4po	7.0	-	7.2	6.5	-	7.4	6.7	-	-	-	-	-	-
		P7	11.6	-	12.7	11.9	-	11.0	10.8	-	-	-	-	-	-

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Individual Pup Body Weights (grams)

20256434

Day(s): - Relative to Littering (Litter: A)

Control 0mcg															
Dam	Pup Sex	Meas.	Mean/ Count	1	2	3	4	5	6	7	8	9	10	11	12
212	Male	P10	19.7	-	21.0	20.3	-	18.9	18.5	-	-	-	-	-	-
		P14	31.4	-	33.1	32.1	-	30.6	29.7	-	-	-	-	-	-
		P17	38.7	-	40.3	38.3	-	39.5	36.7	-	-	-	-	-	-
		P21	52.3	-	53.0	53.9	-	53.4	48.7	-	-	-	-	-	-
	Female	P1	4.2	4.5	4.2	4.4	3.2	4.6	4.4	4.7	4.1	3.5	4.6	-	-
		P4pr	7.2	6.3	6.6	6.0	7.9	7.4	7.6	7.9	7.6	8.0	7.0	-	-
		P4po	7.1	-	-	6.0	7.9	7.4	-	-	-	-	7.0	-	-
		P7	12.2	-	-	13.6	12.5	10.0	-	-	-	-	12.8	-	-
		P10	20.6	-	-	21.0	17.8	21.3	-	-	-	-	22.2	-	-
		P14	32.3	-	-	33.4	28.8	34.0	-	-	-	-	33.0	-	-
		P17	38.9	-	-	40.6	40.1	35.3	-	-	-	-	39.7	-	-
		P21	52.5	-	-	55.2	54.1	53.7	-	-	-	-	46.8	-	-
213	Male	P1	6.3	6.6	6.3	6.8	5.8	6.5	6.1	6.3	6.3	-	-	-	-
		P4pr	9.9	9.6	9.4	9.9	10.3	10.7	10.4	8.8	10.0	-	-	-	-
		P4po	10.3	-	-	9.9	-	10.7	10.4	-	10.0	-	-	-	-
		P7	16.6	-	-	16.1	-	17.5	16.9	-	15.9	-	-	-	-
		P10	24.6	-	-	26.0	-	23.7	24.9	-	23.7	-	-	-	-
		P14	34.7	-	-	33.4	-	36.4	33.4	-	35.4	-	-	-	-

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Individual Pup Body Weights (grams)

20256434

Day(s): - Relative to Littering (Litter: A)

Control 0mcg															
Dam	Pup Sex	Meas.	Mean/ Count	1	2	3	4	5	6	7	8	9	10	11	12
213	Male	P17	42.0	-	-	43.2	-	40.6	44.4	-	39.7	-	-	-	-
		P21	56.2	-	-	58.5	-	53.4	57.2	-	55.5	-	-	-	-
	Female	P1	6.2	6.2	5.8	6.2	6.7	-	-	-	-	-	-	-	-
		P4pr	9.8	9.8	9.9	9.8	9.6	-	-	-	-	-	-	-	-
		P4po	9.8	9.8	9.9	9.8	9.6	-	-	-	-	-	-	-	-
		P7	15.8	15.8	15.6	16.6	15.3	-	-	-	-	-	-	-	-
		P10	23.7	23.1	23.2	25.1	23.4	-	-	-	-	-	-	-	-
		P14	33.5	33.2	32.7	34.6	33.6	-	-	-	-	-	-	-	-
		P17	40.6	40.7	41.4	40.2	40.0	-	-	-	-	-	-	-	-
		P21	53.2	51.4	53.2	52.2	55.8	-	-	-	-	-	-	-	-
214	Male	P1	5.7	5.8	5.4	5.9	5.7	-	-	-	-	-	-	-	-
		P4pr	8.7	8.8	8.5	8.5	8.9	-	-	-	-	-	-	-	-
		P4po	8.7	8.8	8.5	8.5	8.9	-	-	-	-	-	-	-	-
		P7	15.1	14.3	15.6	15.2	15.1	-	-	-	-	-	-	-	-
		P10	22.9	23.8	21.7	22.9	23.2	-	-	-	-	-	-	-	-
		P14	32.9	33.5	32.4	31.7	34.0	-	-	-	-	-	-	-	-
		P17	40.5	39.3	41.5	39.6	41.4	-	-	-	-	-	-	-	-
		P21	55.2	55.1	56.1	53.8	55.7	-	-	-	-	-	-	-	-

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Individual Pup Body Weights (grams)

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Day(s): - Relative to Littering (Litter: A)

Control 0mcg															
Dam	Pup Sex	Meas.	Mean/ Count	1	2	3	4	5	6	7	8	9	10	11	12
214	Female	P1	5.6	5.3	5.6	5.8	5.7	5.4	5.7	5.7	5.7	5.5	-	-	-
		P4pr	8.6	8.8	8.7	8.7	8.1	8.5	8.3	8.5	8.9	8.6	-	-	-
		P4po	8.7	8.8	-	8.7	-	8.5	-	-	-	8.6	-	-	-
		P7	14.6	14.6	-	14.6	-	14.6	-	-	-	14.4	-	-	-
		P10	22.3	22.5	-	22.1	-	21.8	-	-	-	22.7	-	-	-
		P14	32.5	32.9	-	31.5	-	32.5	-	-	-	32.9	-	-	-
		P17	39.2	38.0	-	40.7	-	39.3	-	-	-	38.9	-	-	-
		P21	53.1	54.8	-	51.6	-	53.4	-	-	-	52.6	-	-	-
215	Male	P1	7.0	7.3	7.7	6.7	6.5	6.1	7.3	6.9	7.1	-	-	-	-
		P4pr	10.9	10.4	10.9	11.5	9.8	11.3	11.9	11.1	10.4	-	-	-	-
		P4po	10.4	10.4	10.9	-	9.8	-	-	-	10.4	-	-	-	-
		P7	17.7	17.5	17.2	-	18.3	-	-	-	17.6	-	-	-	-
		P10	25.8	25.8	26.0	-	25.1	-	-	-	26.1	-	-	-	-
		P14	36.7	37.5	37.2	-	35.8	-	-	-	36.4	-	-	-	-
		P17	44.6	45.9	44.5	-	45.4	-	-	-	42.7	-	-	-	-
		P21	58.4	57.4	60.0	-	55.2	-	-	-	61.1	-	-	-	-
	Female	P1	6.5	6.3	6.5	6.4	7.2	6.2	-	-	-	-	-	-	-
		P4pr	10.1	9.6	10.3	10.0	10.1	10.7	-	-	-	-	-	-	-

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Individual Pup Body Weights (grams)

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Day(s): - Relative to Littering (Litter: A)

Control 0mcg															
Dam	Pup Sex	Meas.	Mean/ Count	1	2	3	4	5	6	7	8	9	10	11	12
215	Female	P4po	10.2	9.6	10.3	10.0	.	10.7
		P7	17.9	19.0	17.7	17.1	.	17.8
		P10	25.9	25.3	25.1	25.8	.	27.5
		P14	36.3	38.3	36.5	34.8	.	35.4
		P17	43.7	43.9	42.1	42.4	.	46.5
216	Male	P21	56.2	55.2	60.1	54.2	.	55.4
		P1	6.5	5.0	6.6	6.4	6.2	6.7	7.1	6.8	6.9
		P4pr	10.3	10.7	11.0	10.1	9.7	10.8	8.9	10.4	11.0
		P4po	10.7	10.7	11.0	10.1	.	10.8
		P7	17.8	18.6	18.4	16.5	.	17.8
	Female	P10	25.7	23.8	25.9	26.7	.	26.4
		P14	36.3	38.2	36.5	36.3	.	34.2
		P17	44.9	47.6	44.9	45.3	.	41.9
		P21	58.8	59.1	55.1	62.3	.	58.7
		P1	6.5	6.5	6.6	6.5	6.1	6.3	6.8
		P4pr	10.3	11.0	10.4	9.7	10.6	9.8	10.0
		P4po	10.2	.	10.4	.	10.6	9.8	10.0
		P7	17.2	.	17.2	.	16.4	16.8	18.4

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Individual Pup Body Weights (grams)

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Day(s): - Relative to Littering (Litter: A)

Control 0mcg															
Dam	Pup Sex	Meas.	Mean/ Count	1	2	3	4	5	6	7	8	9	10	11	12
216	Female	P10	25.2	.	24.8	.	25.1	27.1	23.6
		P14	36.0	.	35.5	.	37.5	35.6	35.4
		P17	43.8	.	43.2	.	43.5	43.3	45.3
		P21	57.2	.	60.3	.	54.1	57.3	57.1
217	Male	P1	5.9	5.6	5.6	5.7	6.6	6.0
		P4pr	9.0	8.7	9.5	10.0	7.7	9.0
		P4po	8.9	8.7	.	10.0	7.7	9.0
		P7	15.1	17.2	.	14.9	13.2	15.2
		P10	22.7	23.0	.	25.4	19.8	22.4
		P14	32.2	32.9	.	28.5	35.8	31.4
		P17	39.6	40.1	.	39.1	43.5	35.7
	Female	P21	53.9	60.1	.	53.2	54.8	47.6
		P1	5.6	5.4	5.9	4.9	5.9	6.1	5.7	5.9	4.9
		P4pr	9.0	9.1	8.6	8.5	8.7	9.4	9.3	9.1	9.5
		P4po	9.1	.	.	.	8.7	9.4	9.3	9.1
		P7	16.3	.	.	.	15.9	16.7	16.5	16.2
		P10	23.9	.	.	.	24.3	23.9	23.4	24.1
		P14	33.3	.	.	.	32.8	33.0	34.3	33.2

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Individual Pup Body Weights (grams)

20256434

Day(s): - Relative to Littering (Litter: A)

Control 0mcg															
Dam	Pup Sex	Meas.	Mean/ Count	1	2	3	4	5	6	7	8	9	10	11	12
217	Female	P17	40.8	-	-	-	41.8	40.7	40.2	40.3	-	-	-	-	-
		P21	54.8	-	-	-	54.8	55.6	54.3	54.6	-	-	-	-	-
218	Male	P1	6.9	6.8	6.9	6.9	6.9	-	-	-	-	-	-	-	-
		P4pr	11.0	11.2	11.1	10.6	11.1	-	-	-	-	-	-	-	-
		P4po	11.0	11.2	11.1	10.6	11.1	-	-	-	-	-	-	-	-
		P7	17.7	18.1	17.2	17.5	17.8	-	-	-	-	-	-	-	-
		P10	24.6	24.6	24.4	24.5	24.8	-	-	-	-	-	-	-	-
		P14	34.7	34.7	34.3	35.2	34.4	-	-	-	-	-	-	-	-
	Female	P17	41.5	41.2	41.5	41.0	42.4	-	-	-	-	-	-	-	-
		P21	54.5	56.7	54.3	52.0	54.8	-	-	-	-	-	-	-	-
		P1	7.0	7.1	6.4	7.0	6.9	7.0	7.4	-	-	-	-	-	-
		P4pr	11.0	11.1	10.9	9.8	11.4	11.5	11.1	-	-	-	-	-	-
		P4po	10.7	11.1	10.9	9.8	-	-	11.1	-	-	-	-	-	-
		P7	17.1	17.8	17.5	17.4	-	-	15.5	-	-	-	-	-	-
		P10	24.2	24.9	25.0	24.5	-	-	22.5	-	-	-	-	-	-
		P14	34.6	35.0	34.9	33.0	-	-	35.6	-	-	-	-	-	-
		P17	41.6	41.6	41.7	40.3	-	-	42.9	-	-	-	-	-	-
		P21	55.0	52.6	54.7	57.0	-	-	55.7	-	-	-	-	-	-

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Individual Pup Body Weights (grams)

20256434

Day(s): - Relative to Littering (Litter: A)

Control 0mcg															
Dam	Pup Sex	Meas.	Mean/ Count	1	2	3	4	5	6	7	8	9	10	11	12
219	Male	P1	5.8	5.9	5.8	6.2	5.5	6.2	5.2	5.6	-	-	-	-	-
		P4pr	9.0	8.6	9.8	9.8	9.0	8.0	8.4	9.4	-	-	-	-	-
		P4po	8.6	8.6	-	-	-	8.0	8.4	9.4	-	-	-	-	-
		P7	14.9	15.0	-	-	-	15.1	13.6	15.8	-	-	-	-	-
		P10	23.3	24.8	-	-	-	20.9	23.8	23.5	-	-	-	-	-
		P14	35.2	37.0	-	-	-	34.4	36.7	32.8	-	-	-	-	-
		P17	43.4	45.6	-	-	-	44.8	42.9	40.2	-	-	-	-	-
	Female	P21	57.0	57.2	-	-	-	59.8	53.1	57.9	-	-	-	-	-
		P1	5.7	6.1	5.7	5.6	5.6	5.7	5.9	5.1	-	-	-	-	-
		P4pr	8.8	9.0	9.7	8.5	9.2	7.3	8.5	9.2	-	-	-	-	-
		P4po	9.0	-	9.7	8.5	9.2	-	8.5	-	-	-	-	-	-
		P7	15.5	-	16.1	15.9	15.3	-	14.5	-	-	-	-	-	-
		P10	24.0	-	24.3	25.3	22.7	-	23.6	-	-	-	-	-	-
		P14	35.1	-	35.1	37.0	35.1	-	33.1	-	-	-	-	-	-
		P17	43.1	-	43.0	43.2	44.5	-	41.8	-	-	-	-	-	-
220	Male	P21	56.6	-	56.2	54.4	56.5	-	59.3	-	-	-	-	-	-
		P1	6.3	6.5	6.4	6.7	6.3	6.0	6.2	6.2	6.3	-	-	-	-
		P4pr	9.9	9.8	9.6	11.1	9.2	9.2	10.6	10.0	9.9	-	-	-	-

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Individual Pup Body Weights (grams)

20256434

Day(s): - Relative to Littering (Litter: A)

Control 0mcg															
Dam	Pup Sex	Meas.	Mean/ Count	1	2	3	4	5	6	7	8	9	10	11	12
220	Male	P4po	10.4	-	-	11.1	-	-	10.6	10.0	9.9	-	-	-	-
		P7	16.7	-	-	17.2	-	-	16.6	17.3	15.7	-	-	-	-
		P10	25.3	-	-	25.8	-	-	26.2	23.6	25.4	-	-	-	-
		P14	37.2	-	-	35.6	-	-	37.9	37.4	38.0	-	-	-	-
		P17	44.8	-	-	46.4	-	-	43.7	45.1	44.1	-	-	-	-
		P21	57.6	-	-	55.0	-	-	58.8	56.7	60.0	-	-	-	-
	Female	P1	6.1	6.5	5.8	6.1	6.2	6.1	6.5	5.6	-	-	-	-	-
		P4pr	9.4	10.1	9.9	9.1	9.0	8.0	9.7	9.8	-	-	-	-	-
		P4po	9.5	10.1	-	9.1	9.0	-	-	9.8	-	-	-	-	-
		P7	15.1	14.5	-	15.4	15.7	-	-	14.8	-	-	-	-	-
		P10	23.5	23.8	-	24.5	22.9	-	-	22.9	-	-	-	-	-
		P14	35.3	34.6	-	34.4	35.0	-	-	37.1	-	-	-	-	-
		P17	42.6	41.5	-	45.5	41.5	-	-	41.7	-	-	-	-	-
		P21	54.9	54.1	-	58.8	52.9	-	-	53.9	-	-	-	-	-
221	Male	P1	6.7	6.4	7.7	6.3	6.7	6.5	6.3	-	-	-	-	-	-
		P4pr	11.0	10.5	10.0	11.2	10.9	11.8	11.6	-	-	-	-	-	-
		P4po	10.8	10.5	10.0	-	10.9	11.8	-	-	-	-	-	-	-
		P7	18.4	18.7	17.8	-	19.4	17.8	-	-	-	-	-	-	-

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Individual Pup Body Weights (grams)

20256434

Day(s): - Relative to Littering (Litter: A)

Control 0mcg															
Dam	Pup Sex	Meas.	Mean/ Count	1	2	3	4	5	6	7	8	9	10	11	12
221	Male	P10	28.3	27.6	29.5	-	27.7	28.5	-	-	-	-	-	-	-
		P14	41.1	42.4	40.5	-	41.0	40.4	-	-	-	-	-	-	-
		P17	48.5	47.9	48.4	-	47.6	50.0	-	-	-	-	-	-	-
		P21	62.8	62.5	64.5	-	63.5	60.8	-	-	-	-	-	-	-
	Female	P1	6.5	6.7	6.6	6.1	6.7	6.7	6.6	6.4	6.0	6.6	-	-	-
		P4pr	11.2	10.9	11.5	11.7	12.0	10.8	10.8	11.9	10.3	11.2	-	-	-
		P4po	11.5	-	-	11.7	12.0	-	-	11.9	10.3	-	-	-	-
		P7	19.0	-	-	19.5	19.7	-	-	19.1	17.5	-	-	-	-
		P10	28.7	-	-	29.4	28.7	-	-	29.5	27.0	-	-	-	-
		P14	41.2	-	-	42.3	41.7	-	-	41.5	39.4	-	-	-	-
		P17	48.0	-	-	46.5	48.0	-	-	47.9	49.4	-	-	-	-
		P21	62.3	-	-	60.6	63.4	-	-	61.4	63.7	-	-	-	-
222	Male	P1	6.6	6.7	7.0	5.8	6.8	6.9	5.9	6.0	7.2	6.6	7.1	6.7	-
		P4pr	9.3	9.8	9.5	9.8	9.5	9.4	8.8	9.7	8.2	8.6	10.0	9.4	-
		P4po	9.4	9.8	-	9.8	9.5	9.4	-	-	-	8.6	-	-	-
		P7	16.2	16.6	-	16.0	16.8	14.3	-	-	-	17.2	-	-	-
		P10	24.2	24.7	-	25.5	25.1	21.3	-	-	-	24.3	-	-	-
		P14	34.3	31.2	-	35.0	34.6	34.6	-	-	-	36.0	-	-	-

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Individual Pup Body Weights (grams)

20256434

Day(s): - Relative to Littering (Litter: A)

Control 0mcg															
Dam	Pup Sex	Meas.	Mean/ Count	1	2	3	4	5	6	7	8	9	10	11	12
222	Male	P17	41.2	43.3	.	41.7	40.6	38.1	.	.	.	42.3	.	.	.
		P21	54.6	55.7	.	54.2	55.1	50.6	.	.	.	57.2	.	.	.
	Female	P1	5.8	5.9	6.3	4.9	6.2
		P4pr	8.7	9.1	8.3	8.8
		P4po	8.7	9.1	8.3	8.8
		P7	15.2	14.9	15.4	15.4
		P10	23.0	23.3	23.2	22.6
		P14	33.1	33.9	32.2	33.2
		P17	40.3	40.8	40.1	40.1
		P21	54.0	53.1	55.5	53.5

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Individual Pup Body Weights (grams)

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Day(s): - Relative to Littering (Litter: A)



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Individual Pup Body Weights (grams)

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Day(s): - Relative to Littering (Litter: A)



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Individual Pup Body Weights (grams)

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Day(s): - Relative to Littering (Litter: A)



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Individual Pup Body Weights (grams)

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Day(s): - Relative to Littering (Litter: A)



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Individual Pup Body Weights (grams)

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Day(s): - Relative to Littering (Litter: A)



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Individual Pup Body Weights (grams)

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Day(s): - Relative to Littering (Litter: A)



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Individual Pup Body Weights (grams)

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Individual Pup Body Weights (grams)

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Day(s): - Relative to Littering (Litter: A)



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Individual Pup Body Weights (grams)

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Day(s): - Relative to Littering (Litter: A)



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Individual Pup Body Weights (grams)

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Day(s): - Relative to Littering (Litter: A)



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Individual Pup Body Weights (grams)

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Day(s): - Relative to Littering (Litter: A)



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Individual Pup Body Weights (grams)

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Individual Pup Body Weights (grams)

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Day(s): - Relative to Littering (Litter: A)



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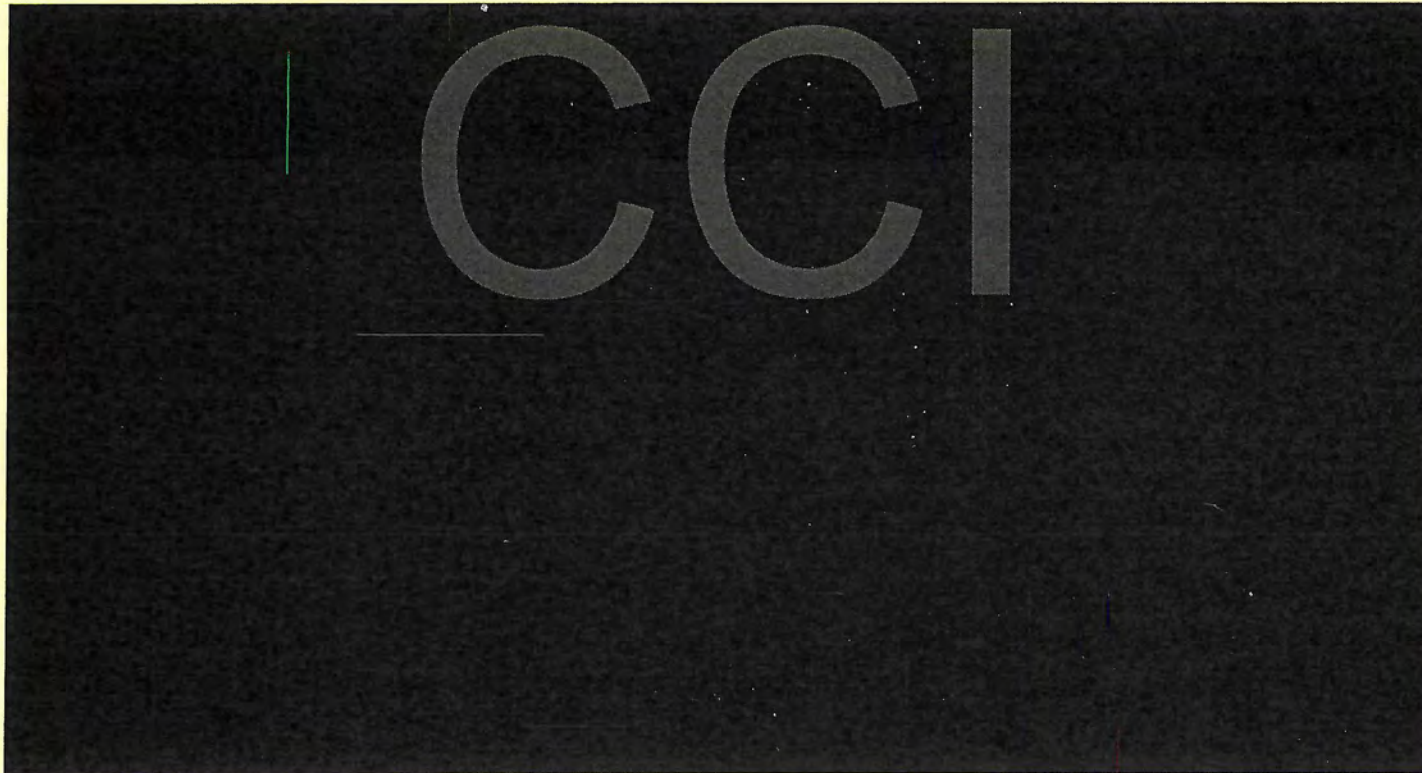
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Individual Pup Body Weights (grams)

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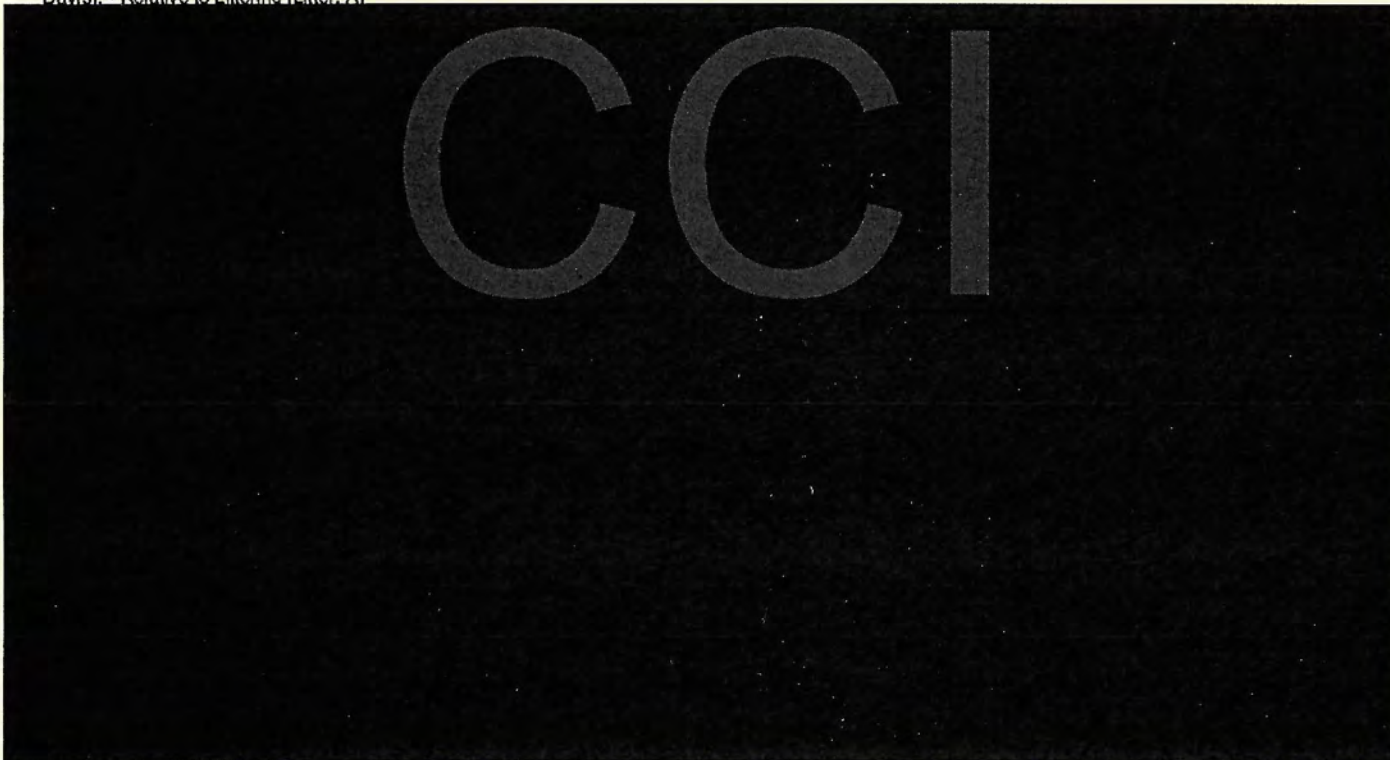
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Individual Pup Body Weights (grams)

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Day(s): - Relative to Littering (Litter: A)



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Individual Pup Body Weights (grams)

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Day(s): - Relative to Littering (Litter: A)



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Individual Pup Body Weights (grams)

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Day(s) - Relative to Littering (Litter: A)



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Individual Pup Body Weights (grams)

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Individual Pup Body Weights (grams)

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Day(s): - Relative to Littering (Litter: A)

BNT162b2 30mcg															
Dam	Pup Sex	Meas.	Mean/ Count	1	2	3	4	5	6	7	8	9	10	11	12
245	Male	P1	6.8	7.3	7.4	5.3	7.2	6.1	7.1	6.9	7.3	7.4	7.2	5.9	-
		P4pr	10.0	11.0	11.2	10.1	10.9	10.5	9.2	10.8	7.2	10.4	10.4	8.6	-
		P4po	10.5	-	-	10.1	10.9	10.5	-	-	-	10.4	-	-	-
		P7	17.4	-	-	17.5	16.7	18.4	-	-	-	16.8	-	-	-
		P10	24.8	-	-	23.4	25.4	26.3	-	-	-	24.0	-	-	-
		P14	36.2	-	-	37.2	35.3	37.1	-	-	-	35.3	-	-	-
		P17	42.9	-	-	42.7	42.0	42.9	-	-	-	44.0	-	-	-
	Female	P21	59.1	-	-	58.2	62.4	58.6	-	-	-	57.0	-	-	-
		P1	6.4	6.1	6.3	7.1	6.0	6.6	-	-	-	-	-	-	-
		P4pr	9.7	9.0	8.6	10.8	10.2	10.0	-	-	-	-	-	-	-
		P4po	9.7	9.0	8.6	10.8	10.2	-	-	-	-	-	-	-	-
		P7	16.5	18.0	15.1	17.6	15.3	-	-	-	-	-	-	-	-
		P10	24.1	25.0	25.7	22.6	22.9	-	-	-	-	-	-	-	-
		P14	35.0	35.8	36.9	34.2	33.0	-	-	-	-	-	-	-	-
		P17	41.6	42.0	40.9	43.4	40.0	-	-	-	-	-	-	-	-
		P21	55.4	54.2	54.8	57.8	54.9	-	-	-	-	-	-	-	-
246	Male	P1	5.9	6.0	5.9	6.2	5.7	6.1	6.0	5.7	-	-	-	-	-
		P4pr	9.5	9.3	9.3	9.3	9.8	9.4	10.0	9.6	-	-	-	-	-

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Individual Pup Body Weights (grams)

20256434

Day(s): - Relative to Littering (Litter: A)

BNT162b2 30mcg															
Dam	Pup Sex	Meas.	Mean/ Count	1	2	3	4	5	6	7	8	9	10	11	12
246	Male	P4po	9.6	-	9.3	-	-	9.4	10.0	9.6	-	-	-	-	-
		P7	16.3	-	16.1	-	-	15.8	16.7	16.7	-	-	-	-	-
		P10	22.9	-	23.2	-	-	22.6	22.5	23.4	-	-	-	-	-
		P14	32.8	-	33.3	-	-	32.4	33.0	32.5	-	-	-	-	-
		P17	39.4	-	39.7	-	-	39.5	39.5	38.7	-	-	-	-	-
	Female	P21	52.1	-	54.2	-	-	51.9	50.6	51.7	-	-	-	-	-
		P1	5.8	6.1	6.2	5.5	5.9	5.5	-	-	-	-	-	-	-
		P4pr	9.3	9.4	9.1	9.9	8.7	9.5	-	-	-	-	-	-	-
		P4po	9.2	9.4	9.1	-	8.7	9.5	-	-	-	-	-	-	-
		P7	15.8	15.7	16.2	-	15.9	15.4	-	-	-	-	-	-	-
		P10	22.2	22.9	22.3	-	21.9	21.6	-	-	-	-	-	-	-
		P14	31.8	31.9	31.8	-	31.5	32.1	-	-	-	-	-	-	-
		P17	38.1	38.2	37.9	-	38.3	37.8	-	-	-	-	-	-	-
		P21	50.6	51.4	52.1	-	49.2	49.7	-	-	-	-	-	-	-
247	Male	P1	6.3	6.0	6.8	6.2	6.2	-	-	-	-	-	-	-	-
		P4pr	9.7	10.0	10.4	9.3	9.2	-	-	-	-	-	-	-	-
		P4po	9.7	10.0	10.4	9.3	9.2	-	-	-	-	-	-	-	-
		P7	16.4	16.7	17.3	15.6	16.1	-	-	-	-	-	-	-	-

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Individual Pup Body Weights (grams)

20256434

Day(s): - Relative to Littering (Litter: A)															
BNT162b2 30mcg															
Dam	Pup Sex	Meas.	Mean/ Count	1	2	3	4	5	6	7	8	9	10	11	12
247	Male	P10	25.0	25.4	24.2	25.8	24.5	-	-	-	-	-	-	-	-
		P14	36.3	37.1	36.8	35.9	35.2	-	-	-	-	-	-	-	-
		P17	44.0	43.7	45.1	42.6	44.5	-	-	-	-	-	-	-	-
		P21	57.6	57.9	58.4	56.1	58.1	-	-	-	-	-	-	-	-
	Female	P1	6.1	6.0	6.2	6.2	6.0	5.6	5.8	6.4	6.7	6.4	-	-	-
		P4pr	9.7	10.1	9.5	9.8	10.1	9.9	8.5	9.4	9.3	10.3	-	-	-
		P4po	10.0	10.1	-	9.8	-	9.9	-	-	-	10.3	-	-	-
		P7	16.7	17.1	-	16.1	-	16.6	-	-	-	17.0	-	-	-
		P10	25.4	24.8	-	25.6	-	25.3	-	-	-	25.9	-	-	-
		P14	36.4	36.2	-	36.7	-	36.3	-	-	-	36.2	-	-	-
		P17	43.8	43.9	-	43.3	-	43.8	-	-	-	44.2	-	-	-
		P21	56.2	57.2	-	56.8	-	56.0	-	-	-	54.9	-	-	-
248	Male	P1	6.5	6.1	7.2	5.9	6.0	6.7	6.3	7.4	6.3	-	-	-	-
		P4pr	10.6	10.4	11.4	9.9	10.2	11.6	10.0	10.4	10.6	-	-	-	-
		P4po	10.5	10.4	11.4	9.9	10.2	-	-	-	10.6	-	-	-	-
		P7	17.0	18.2	17.2	16.1	17.5	-	-	-	15.8	-	-	-	-
		P10	24.5	24.6	23.2	25.2	26.0	-	-	-	23.7	-	-	-	-
		P14	35.0	35.4	34.6	33.8	37.0	-	-	-	34.1	-	-	-	-

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Individual Pup Body Weights (grams)

20256434

Day(s): - Relative to Littering (Litter: A)

BNT162b2 30mcg															
Dam	Pup Sex	Meas.	Mean/ Count	1	2	3	4	5	6	7	8	9	10	11	12
248	Male	P17	42.1	40.7	41.6	44.7	42.8	-	-	-	40.5	-	-	-	-
		P21	54.0	54.4	55.0	58.1	50.2	-	-	-	52.2	-	-	-	-
	Female	P1	6.4	6.7	6.1	6.3	-	-	-	-	-	-	-	-	-
		P4pr	10.2	9.9	11.0	9.8	-	-	-	-	-	-	-	-	-
		P4po	10.2	9.9	11.0	9.8	-	-	-	-	-	-	-	-	-
		P7	16.5	17.4	16.0	16.1	-	-	-	-	-	-	-	-	-
		P10	23.9	23.7	23.4	24.5	-	-	-	-	-	-	-	-	-
		P14	34.0	33.3	35.1	33.6	-	-	-	-	-	-	-	-	-
		P17	40.3	40.7	39.2	41.0	-	-	-	-	-	-	-	-	-
		P21	51.7	53.0	52.7	49.4	-	-	-	-	-	-	-	-	-
249	Male	P1	4.7	5.2	3.9	4.8	4.8	4.9	4.0	4.6	4.8	5.2	-	-	-
		P4pr	7.4	7.7	6.8	8.3	5.7	7.8	7.6	7.1	8.3	7.2	-	-	-
		P4po	7.0	-	6.8	-	5.7	7.8	7.6	-	-	-	-	-	-
		P7	12.0	-	9.8	-	12.8	13.9	11.4	-	-	-	-	-	-
		P10	19.4	-	22.0	-	15.8	21.0	18.7	-	-	-	-	-	-
		P14	29.3	-	28.7	-	30.5	25.3	32.5	-	-	-	-	-	-
		P17	36.8	-	33.4	-	40.6	37.5	35.8	-	-	-	-	-	-
		P21	50.7	-	52.5	-	49.3	54.6	46.4	-	-	-	-	-	-

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Individual Pup Body Weights (grams)

20256434

Day(s): - Relative to Littering (Litter: A)

BNT162b2 30mcg															
Dam	Pup Sex	Meas.	Mean/ Count	1	2	3	4	5	6	7	8	9	10	11	12
249	Female	P1	4.4	4.0	4.6	4.9	4.6	4.2	4.5	4.1	4.0	-	-	-	-
		P4pr	6.9	6.9	7.1	8.3	5.9	6.4	7.7	6.7	6.1	-	-	-	-
		P4po	7.0	6.9	7.1	-	-	-	7.7	-	6.1	-	-	-	-
		P7	12.3	10.7	11.8	-	-	-	12.7	-	13.8	-	-	-	-
		P10	19.8	21.4	18.0	-	-	-	19.3	-	20.5	-	-	-	-
		P14	29.8	31.2	27.7	-	-	-	30.5	-	29.7	-	-	-	-
		P17	37.4	37.5	34.6	-	-	-	38.5	-	38.8	-	-	-	-
250	Male	P21	51.9	53.5	50.7	-	-	-	49.4	-	53.8	-	-	-	-
		P1	6.4	7.0	6.2	6.4	6.3	5.9	6.3	6.4	6.5	6.4	-	-	-
		P4pr	9.6	9.8	9.7	10.2	9.1	9.1	9.5	9.7	9.5	9.8	-	-	-
		P4po	9.7	9.8	-	-	-	-	9.5	9.7	9.5	9.8	-	-	-
		P7	16.6	16.6	-	-	-	-	16.9	16.9	16.3	16.5	-	-	-
		P10	23.9	23.9	-	-	-	-	23.6	23.9	24.2	23.9	-	-	-
		P14	34.0	34.2	-	-	-	-	33.8	34.0	34.2	34.0	-	-	-
		P17	40.9	41.5	-	-	-	-	40.9	40.1	41.1	40.9	-	-	-
	Female	P21	53.6	55.0	-	-	-	-	52.7	54.0	53.9	52.5	-	-	-
		P1	5.9	5.8	5.8	6.2	-	-	-	-	-	-	-	-	-
		P4pr	9.3	9.4	9.5	9.0	-	-	-	-	-	-	-	-	-

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Individual Pup Body Weights (grams)

20256434

Day(s): - Relative to Littering (Litter: A)

BNT162b2 30mcg															
Dam	Pup Sex	Meas.	Mean/ Count	1	2	3	4	5	6	7	8	9	10	11	12
250	Female	P4po	9.3	9.4	9.5	9.0	-	-	-	-	-	-	-	-	-
		P7	15.9	16.0	15.6	16.1	-	-	-	-	-	-	-	-	-
		P10	23.2	23.5	23.7	22.3	-	-	-	-	-	-	-	-	-
		P14	33.0	33.8	31.7	33.6	-	-	-	-	-	-	-	-	-
		P17	39.3	39.6	40.3	38.1	-	-	-	-	-	-	-	-	-
		P21	52.2	53.1	52.6	50.8	-	-	-	-	-	-	-	-	-
251	Male	P1	5.8	6.4	5.8	6.1	6.1	5.9	5.6	5.3	5.4	-	-	-	-
		P4pr	9.4	9.6	9.8	10.0	8.9	9.0	9.4	9.2	-	-	-	-	-
		P4po	9.6	9.6	9.8	10.0	8.9	-	-	-	-	-	-	-	-
		P7	15.9	15.2	16.3	15.9	16.1	-	-	-	-	-	-	-	-
		P10	23.9	23.6	23.1	24.5	24.3	-	-	-	-	-	-	-	-
		P14	36.0	36.8	36.7	35.8	34.7	-	-	-	-	-	-	-	-
	Female	P17	42.8	42.3	41.9	44.3	42.8	-	-	-	-	-	-	-	-
		P21	57.6	59.4	56.7	57.1	57.2	-	-	-	-	-	-	-	-
		P1	5.7	5.2	6.1	6.3	5.6	5.7	3.9	5.9	6.1	6.2	-	-	-
		P4pr	8.8	9.7	8.9	9.4	9.4	7.5	9.5	9.7	5.2	9.9	-	-	-
		P4po	9.0	9.7	-	9.4	-	7.5	9.5	-	-	-	-	-	-
		P7	15.7	16.6	-	13.7	-	16.8	15.8	-	-	-	-	-	-

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Individual Pup Body Weights (grams)

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Day(s): - Relative to Littering (Litter: A)

BNT162b2 30mcg															
Dam	Pup Sex	Meas.	Mean/ Count	1	2	3	4	5	6	7	8	9	10	11	12
251	Female	P10	23.8	21.1	-	24.9	-	25.2	24.1	-	-	-	-	-	-
		P14	35.8	36.3	-	35.3	-	37.5	34.1	-	-	-	-	-	-
		P17	42.6	40.5	-	42.0	-	44.8	43.2	-	-	-	-	-	-
		P21	56.9	59.8	-	57.6	-	56.4	53.7	-	-	-	-	-	-
252	Male	P1	7.6	7.5	7.9	7.4	-	-	-	-	-	-	-	-	-
		P4pr	11.9	11.8	12.6	11.4	-	-	-	-	-	-	-	-	-
		P4po	11.9	11.8	12.6	11.4	-	-	-	-	-	-	-	-	-
		P7	19.6	19.3	18.4	21.1	-	-	-	-	-	-	-	-	-
		P10	27.3	27.3	28.6	26.0	-	-	-	-	-	-	-	-	-
		P14	37.7	38.9	37.4	36.7	-	-	-	-	-	-	-	-	-
		P17	45.2	45.5	44.1	46.0	-	-	-	-	-	-	-	-	-
	Female	P21	61.8	60.3	61.6	63.5	-	-	-	-	-	-	-	-	-
		P1	6.8	6.7	6.9	5.8	6.9	6.7	6.7	7.5	7.1	-	-	-	-
		P4pr	10.8	11.3	10.8	9.8	11.8	10.9	10.5	10.8	10.6	-	-	-	-
		P4po	10.9	11.3	-	9.8	11.8	10.9	10.5	-	-	-	-	-	-
		P7	18.1	17.8	-	17.3	18.2	19.5	17.9	-	-	-	-	-	-
		P10	25.7	25.6	-	24.9	25.8	27.6	24.7	-	-	-	-	-	-
		P14	35.7	34.7	-	37.3	35.6	36.1	34.6	-	-	-	-	-	-

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Individual Pup Body Weights (grams)

20256434

Day(s): - Relative to Littering (Litter: A)

BNT162b2 30mcg															
Dam	Pup Sex	Meas.	Mean/ Count	1	2	3	4	5	6	7	8	9	10	11	12
252	Female	P17	42.2	41.9	.	44.8	40.0	41.0	43.4
		P21	57.2	54.2	.	55.5	58.0	59.2	59.1
253	Male	P1	6.5	6.7	6.6	6.3	6.7	6.4	6.8	6.3	6.2
		P4pr	10.1	10.5	9.7	10.2	9.7	9.7	10.0	10.2	10.7
		P4po	10.2	10.5	9.7	.	9.7	.	.	.	10.7
		P7	16.8	16.1	17.5	.	17.2	.	.	.	16.3
		P10	24.4	25.1	23.0	.	24.2	.	.	.	25.4
	Female	P14	34.4	34.0	35.4	.	33.2	.	.	.	34.9
		P17	40.2	40.1	40.3	.	39.3	.	.	.	41.2
		P21	52.6	53.0	51.9	.	52.6	.	.	.	52.9
		P1	6.2	5.8	6.1	6.4	6.5
		P4pr	10.0	9.8	10.2	10.1	9.8
		P4po	10.0	9.8	10.2	10.1	9.8
		P7	16.8	16.2	16.6	17.5	16.9
		P10	24.5	24.5	24.1	25.3	23.9
		P14	33.8	34.7	33.1	33.4	33.9
		P17	38.7	39.7	38.3	38.1	38.5
		P21	50.9	52.5	49.1	51.1	51.0

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Individual Pup Body Weights (grams)

20256434

Day(s): - Relative to Littering (Litter: A)

BNT162b2 30mcg															
Dam	Pup Sex	Meas.	Mean/ Count	1	2	3	4	5	6	7	8	9	10	11	12
255	Female	P1	7.5	8.4	6.9	7.2	-	-	-	-	-	-	-	-	-
		P4pr	12.5	12.5	14.0	11.1	-	-	-	-	-	-	-	-	-
		P4po	12.5	12.5	14.0	11.1	-	-	-	-	-	-	-	-	-
		P7	19.0	19.2	20.6	17.3	-	-	-	-	-	-	-	-	-
		P10	26.1	27.9	26.1	24.4	-	-	-	-	-	-	-	-	-
		P14	36.0	33.9	37.9	36.1	-	-	-	-	-	-	-	-	-
		P17	42.7	40.7	44.5	42.8	-	-	-	-	-	-	-	-	-
		P21	55.8	57.1	58.0	52.3	-	-	-	-	-	-	-	-	-
256	Male	P1	6.0	6.5	5.7	6.4	5.1	6.3	-	-	-	-	-	-	-
		P4pr	8.8	7.8	9.3	8.4	9.5	8.8	-	-	-	-	-	-	-
		P4po	8.8	7.8	9.3	8.4	9.5	-	-	-	-	-	-	-	-
		P7	15.4	14.7	16.6	13.8	16.5	-	-	-	-	-	-	-	-
		P10	23.7	22.7	22.2	25.3	24.7	-	-	-	-	-	-	-	-
		P14	36.2	37.5	34.7	34.3	38.4	-	-	-	-	-	-	-	-
		P17	44.3	45.4	42.5	42.7	46.7	-	-	-	-	-	-	-	-
		P21	57.3	57.9	55.6	60.4	55.2	-	-	-	-	-	-	-	-
	Female	P1	6.0	6.1	6.1	5.9	5.6	6.1	5.6	6.2	6.4	6.1	6.3	-	-
		P4pr	8.8	8.4	8.6	8.3	9.9	8.7	9.0	8.4	9.8	8.8	8.2	-	-

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Individual Pup Body Weights (grams)

20256434

Day(s): - Relative to Littering (Litter: A)

BNT162b2 30mcg															
Dam	Pup Sex	Meas.	Mean/ Count	1	2	3	4	5	6	7	8	9	10	11	12
256	Female	P4po	8.6	8.4	9.0	.	.	8.8	8.2	.	.
		P7	15.6	15.7	14.3	.	.	16.6	15.6	.	.
		P10	24.1	25.6	24.4	.	.	22.4	24.1	.	.
		P14	35.8	34.1	36.5	.	.	37.7	34.9	.	.
		P17	43.8	42.2	42.1	.	.	45.0	45.7	.	.
		P21	56.6	58.4	54.6	.	.	54.3	59.0	.	.
257	Male	P1	6.0	5.9	6.4	6.4	5.7	6.0	6.1	5.3
		P4pr	10.0	9.7	10.8	9.0	10.3	10.1	8.9	11.0
		P4po	9.7	.	10.8	9.0	.	10.1	8.9
		P7	16.2	.	14.8	17.4	.	17.1	15.3
		P10	23.9	.	25.5	25.0	.	21.8	23.1
		P14	34.2	.	37.1	34.1	.	28.6	36.9
	Female	P17	40.6	.	45.2	44.6	.	30.5	41.9
		P21	54.1	.	58.1	59.8	.	59.6	38.7
		P1	5.6	5.5	6.2	5.3	6.0	5.6	5.5	5.0	5.9
		P4pr	9.1	8.1	8.8	9.1	8.5	9.0	9.4	10.5	9.5
		P4po	8.9	8.1	8.8	9.1	.	.	9.4
		P7	14.5	14.1	12.5	16.1	.	.	15.1

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Individual Pup Body Weights (grams)

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Day(s): - Relative to Littering (Litter: A)

BNT162b2 30mcg															
Dam	Pup Sex	Meas.	Mean/ Count	1	2	3	4	5	6	7	8	9	10	11	12
257	Female	P10	22.2	22.1	19.4	23.3	.	.	24.0
		P14	33.7	32.2	33.6	35.7	.	.	33.1
		P17	40.8	41.0	38.9	40.3	.	.	42.9
		P21	55.0	52.2	53.9	57.7	.	.	56.0
258	Male	P1	6.0	5.6	5.6	6.3	6.3	5.5	6.1	6.0	6.3
		P4pr	9.5	9.3	8.2	9.7	9.8	10.4	10.2	9.5	8.8
		P4po	9.4	9.3	8.2	9.7	.	10.4
		P7	16.1	17.7	15.5	16.9	.	14.4
		P10	24.4	21.9	26.4	23.9	.	25.2
		P14	36.5	38.6	34.4	37.1	.	35.9
		P17	44.7	47.7	45.2	43.4	.	42.6
		P21	59.6	57.1	60.5	57.1	.	63.5
	Female	P1	5.7	5.8	6.1	5.8	5.3	5.3	5.9	5.9
		P4pr	9.5	10.1	9.7	9.3	9.7	8.2	9.7	9.8
		P4po	9.8	10.1	.	.	9.7	.	9.7	9.8
		P7	15.6	17.2	.	.	16.8	.	14.3	14.2
		P10	24.6	22.2	.	.	25.9	.	24.7	25.5
		P14	36.6	36.6	.	.	37.4	.	34.1	38.2

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Individual Pup Body Weights (grams)

20256434

Day(s): - Relative to Littering (Litter: A)

BNT162b2 30mcg															
Dam	Pup Sex	Meas.	Mean/ Count												
				1	2	3	4	5	6	7	8	9	10	11	12
258	Female	P17	44.2	44.0	.	.	42.2	.	45.4	45.1
		P21	58.0	59.0	.	.	55.3	.	59.7	58.0
259	Male	P1	5.6	5.6	5.7	5.7	5.6	5.8	5.4
		P4pr	9.2	9.5	8.9	9.2	9.1	9.6	9.1
		P4po	9.2	.	8.9	9.2	9.1	9.6
		P7	15.9	.	15.7	16.3	15.3	16.2
	Female	P10	24.1	.	24.9	23.4	23.9	24.1
		P14	35.3	.	37.0	35.6	34.0	34.7
		P17	42.4	.	41.2	41.5	42.2	44.5
		P21	57.6	.	58.8	59.1	58.0	54.6
		P1	5.5	5.6	5.2	5.3	5.6	5.2	5.5	5.3	5.7	5.9	.	.	.
		P4pr	9.1	9.7	9.3	8.8	8.2	9.3	8.1	9.7	8.9	9.7	.	.	.
		P4po	9.2	9.7	9.3	.	8.2	.	.	9.7
		P7	15.9	15.8	15.9	.	14.6	.	.	17.2
		P10	24.1	24.3	25.5	.	22.8	.	.	23.8
		P14	34.8	33.0	34.5	.	35.3	.	.	36.3
		P17	41.7	42.5	40.7	.	43.2	.	.	40.2
		P21	55.6	56.4	58.5	.	54.5	.	.	53.0

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Individual Pup Body Weights (grams)

20256434

Day(s): - Relative to Littering (Litter: A)

BNT162b2 30mcg															
Dam	Pup Sex	Meas.	Mean/ Count	1	2	3	4	5	6	7	8	9	10	11	12
260	Male	P1	7.0	7.0	7.5	6.8	6.7	7.6	6.8	7.1	6.1	-	-	-	-
		P4pr	11.0	11.3	11.3	11.7	10.5	10.6	11.0	11.7	9.8	-	-	-	-
		P4po	10.8	-	11.3	11.7	10.5	-	-	-	9.8	-	-	-	-
		P7	17.8	-	16.7	16.4	18.8	-	-	-	19.4	-	-	-	-
		P10	26.0	-	24.8	24.2	28.1	-	-	-	27.0	-	-	-	-
		P14	35.9	-	34.2	38.0	33.9	-	-	-	37.4	-	-	-	-
		P17	43.1	-	44.8	40.9	45.3	-	-	-	41.2	-	-	-	-
	Female	P21	58.4	-	60.7	55.9	56.0	-	-	-	60.8	-	-	-	-
		P1	6.9	6.9	7.1	7.0	6.7	6.6	-	-	-	-	-	-	-
		P4pr	10.6	10.9	10.0	10.5	10.9	10.9	-	-	-	-	-	-	-
		P4po	10.6	-	10.0	10.5	10.9	10.9	-	-	-	-	-	-	-
		P7	17.4	-	17.4	18.1	16.1	18.1	-	-	-	-	-	-	-
		P10	25.5	-	26.4	25.4	23.7	26.4	-	-	-	-	-	-	-
		P14	35.3	-	35.9	33.3	36.5	35.5	-	-	-	-	-	-	-
		P17	42.5	-	43.1	40.2	43.2	43.5	-	-	-	-	-	-	-
		P21	57.3	-	54.5	58.8	58.1	57.9	-	-	-	-	-	-	-
261	Male	P1	7.3	7.2	7.1	7.5	7.1	7.7	6.9	7.8	-	-	-	-	-
		P4pr	11.7	12.4	11.3	12.6	11.4	11.1	11.4	11.5	-	-	-	-	-

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Individual Pup Body Weights (grams)

20256434

Day(s): - Relative to Littering (Litter: A)

BNT162b2 30mcg															
Dam	Pup Sex	Meas.	Mean/ Count	1	2	3	4	5	6	7	8	9	10	11	12
261	Male	P4po	11.6	12.4	11.3	.	11.4	11.1
		P7	18.2	19.1	17.9	.	17.8	17.8
		P10	26.4	28.0	24.9	.	26.2	26.6
		P14	36.7	38.7	36.0	.	35.8	36.3
		P17	43.3	41.8	42.3	.	43.4	45.8
	Female	P21	57.4	55.8	58.4	.	61.1	54.4
		P1	7.0	7.1	7.0	7.0	6.7
		P4pr	11.4	10.8	11.6	11.6	11.5
		P4po	11.4	10.8	11.6	11.6	11.5
		P7	17.9	18.5	18.0	18.3	16.9
		P10	25.8	26.7	23.4	27.1	26.0
		P14	36.3	33.9	36.9	37.1	37.3
		P17	43.0	43.5	44.5	40.2	43.8
		P21	56.7	57.3	58.2	52.3	59.1
262	Male	P1	6.7	6.7	6.6	6.8	7.2	6.8	6.6	6.5
		P4pr	10.2	11.1	9.4	10.2	10.3	10.2	10.2	9.9
		P4po	10.0	.	9.4	.	10.3	10.2	10.2
		P7	17.7	.	17.5	.	18.3	18.3	16.6

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Individual Pup Body Weights (grams)

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Day(s): - Relative to Littering (Litter: A)

BNT162b2 30mcg															
Dam	Pup Sex	Meas.	Mean/ Count	1	2	3	4	5	6	7	8	9	10	11	12
262	Male	P10	25.5	-	24.0	-	26.2	26.0	25.6	-	-	-	-	-	-
		P14	36.9	-	35.6	-	36.9	36.7	38.5	-	-	-	-	-	-
		P17	44.8	-	44.3	-	45.3	42.6	46.8	-	-	-	-	-	-
		P21	59.8	-	59.5	-	60.9	55.5	63.1	-	-	-	-	-	-
	Female	P1	6.1	5.6	6.1	6.2	6.4	6.0	6.5	-	-	-	-	-	-
		P4pr	9.4	8.1	9.8	9.5	9.2	10.1	9.7	-	-	-	-	-	-
		P4po	9.2	8.1	9.8	-	9.2	-	9.7	-	-	-	-	-	-
		P7	16.1	17.4	17.1	-	15.8	-	14.2	-	-	-	-	-	-
		P10	23.4	22.8	24.9	-	25.0	-	20.8	-	-	-	-	-	-
		P14	33.5	35.5	34.0	-	35.3	-	29.2	-	-	-	-	-	-
		P17	41.2	43.9	43.7	-	40.8	-	36.4	-	-	-	-	-	-
		P21	54.1	57.0	58.3	-	54.5	-	46.6	-	-	-	-	-	-
263	Male	P1	5.5	5.3	6.1	5.3	5.9	5.1	5.6	5.2	-	-	-	-	-
		P4pr	8.3	8.6	8.1	9.1	7.7	8.6	8.2	8.1	-	-	-	-	-
		P4po	8.4	8.6	8.1	9.1	7.7	-	-	-	-	-	-	-	-
		P7	14.0	15.1	12.9	14.6	13.5	-	-	-	-	-	-	-	-
		P10	21.3	19.6	22.1	22.8	20.6	-	-	-	-	-	-	-	-
		P14	31.1	30.5	29.3	32.0	32.7	-	-	-	-	-	-	-	-

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Individual Pup Body Weights (grams)

20256434

Day(s): - Relative to Littering (Litter: A)

BNT162b2 30mcg															
Dam	Pup Sex	Meas.	Mean/ Count	1	2	3	4	5	6	7	8	9	10	11	12
263	Male	P17	37.8	39.6	36.4	39.3	35.8	-	-	-	-	-	-	-	-
		P21	51.3	53.0	55.8	47.8	48.5	-	-	-	-	-	-	-	-
	Female	P1	5.2	5.3	4.6	5.5	5.1	5.4	-	-	-	-	-	-	-
		P4pr	8.0	8.5	7.2	8.6	8.1	7.8	-	-	-	-	-	-	-
		P4po	7.9	-	7.2	8.6	8.1	7.8	-	-	-	-	-	-	-
		P7	13.4	-	13.9	14.4	13.2	11.9	-	-	-	-	-	-	-
		P10	20.4	-	19.9	22.2	20.7	18.6	-	-	-	-	-	-	-
		P14	30.2	-	28.5	29.5	32.3	30.4	-	-	-	-	-	-	-
		P17	36.3	-	35.3	38.7	34.0	37.0	-	-	-	-	-	-	-
		P21	48.7	-	43.9	47.7	52.5	50.6	-	-	-	-	-	-	-
264	Male	P1	6.2	6.0	6.2	6.4	6.2	6.1	6.2	-	-	-	-	-	-
		P4pr	9.8	9.4	10.1	9.6	9.9	9.9	9.7	-	-	-	-	-	-
		P4po	9.8	9.4	10.1	9.6	9.9	-	-	-	-	-	-	-	-
		P7	16.8	16.8	17.0	16.4	16.8	-	-	-	-	-	-	-	-
		P10	24.2	24.2	24.2	24.4	23.9	-	-	-	-	-	-	-	-
		P14	33.7	33.6	33.4	34.2	33.5	-	-	-	-	-	-	-	-
		P17	41.4	42.3	41.0	41.0	41.1	-	-	-	-	-	-	-	-
		P21	53.9	53.5	54.5	52.4	55.1	-	-	-	-	-	-	-	-

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Individual Pup Body Weights (grams)

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Day(s): - Relative to Littering (Litter: A)

BNT162b2 30mcg															
Dam	Pup Sex	Meas.	Mean/ Count	1	2	3	4	5	6	7	8	9	10	11	12
264	Female	P1	5.9	6.0	5.7	6.2	5.9	5.5	6.3	5.7	-	-	-	-	-
		P4pr	9.3	9.5	9.6	8.7	9.1	9.2	9.3	9.8	-	-	-	-	-
		P4po	9.4	9.5	9.6	8.7	-	-	-	9.8	-	-	-	-	-
		P7	16.5	16.9	16.9	15.6	-	-	-	16.6	-	-	-	-	-
		P10	23.9	24.6	24.0	24.3	-	-	-	22.6	-	-	-	-	-
		P14	34.2	34.9	32.8	35.2	-	-	-	34.0	-	-	-	-	-
		P17	41.4	42.3	39.8	42.4	-	-	-	41.2	-	-	-	-	-
		P21	53.8	54.1	53.7	52.7	-	-	-	54.6	-	-	-	-	-
265	Male	P1	5.2	5.7	4.9	5.2	5.1	-	-	-	-	-	-	-	-
		P4pr	7.8	8.0	7.2	7.4	8.5	-	-	-	-	-	-	-	-
		P4po	7.8	8.0	7.2	7.4	8.5	-	-	-	-	-	-	-	-
		P7	14.3	16.1	12.9	14.7	13.5	-	-	-	-	-	-	-	-
		P10	22.3	22.6	24.4	21.0	21.1	-	-	-	-	-	-	-	-
		P14	33.4	31.6	33.9	32.4	35.5	-	-	-	-	-	-	-	-
		P17	40.6	39.1	41.2	42.5	39.5	-	-	-	-	-	-	-	-
		P21	54.2	56.5	51.7	55.2	53.4	-	-	-	-	-	-	-	-
	Female	P1	5.1	5.6	5.5	4.9	4.7	5.0	5.0	5.2	5.1	5.4	5.1	4.3	5.0
		P4pr	7.3	7.5	7.3	7.5	6.3	7.7	7.1	7.8	7.3	7.6	7.2	6.9	-

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Individual Pup Body Weights (grams)

20256434

Day(s): - Relative to Littering (Litter: A)

BNT162b2 30mcg															
Dam	Pup Sex	Meas.	Mean/ Count	1	2	3	4	5	6	7	8	9	10	11	12
265	Female	P4po	7.1	-	7.3	-	6.3	-	-	-	-	7.6	7.2	-	-
		P7	13.2	-	14.0	-	14.0	-	-	-	-	13.2	11.6	-	-
		P10	21.1	-	21.3	-	22.2	-	-	-	-	19.5	21.4	-	-
		P14	31.7	-	31.9	-	32.1	-	-	-	-	30.0	32.9	-	-
		P17	38.7	-	39.2	-	39.7	-	-	-	-	37.4	38.5	-	-
		P21	52.0	-	52.1	-	51.0	-	-	-	-	53.4	51.4	-	-
266	Male	P1	7.3	7.2	7.4	7.3	-	-	-	-	-	-	-	-	-
		P4pr	11.7	11.7	11.2	12.1	-	-	-	-	-	-	-	-	-
		P4po	11.7	11.7	11.2	12.1	-	-	-	-	-	-	-	-	-
		P7	19.2	19.4	19.2	19.0	-	-	-	-	-	-	-	-	-
		P10	27.1	27.4	26.5	27.3	-	-	-	-	-	-	-	-	-
		P14	37.1	36.9	37.0	37.4	-	-	-	-	-	-	-	-	-
	Female	P17	44.4	44.0	44.7	44.6	-	-	-	-	-	-	-	-	-
		P21	59.5	59.8	60.9	57.9	-	-	-	-	-	-	-	-	-
		P1	7.0	7.2	6.6	7.1	7.3	7.2	6.8	7.4	6.6	-	-	-	-
		P4pr	11.5	11.8	11.3	11.6	11.5	10.9	11.6	12.2	10.9	-	-	-	-
		P4po	11.6	11.8	11.3	-	-	-	11.6	12.2	10.9	-	-	-	-
		P7	18.8	18.7	18.6	-	-	-	18.8	19.8	18.2	-	-	-	-

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Individual Pup Body Weights (grams)

20256434

Day(s): - Relative to Littering (Litter: A)

BNT162b2 30mcg															
Dam	Pup Sex	Meas.	Mean/ Count	1	2	3	4	5	6	7	8	9	10	11	12
266	Female	P10	26.6	26.6	28.0	-	-	-	25.6	26.7	26.2	-	-	-	-
		P14	36.7	36.6	37.0	-	-	-	38.1	36.8	35.2	-	-	-	-
		P17	43.1	41.6	43.7	-	-	-	43.1	42.3	44.8	-	-	-	-
		P21	56.3	53.3	58.4	-	-	-	57.8	54.8	57.1	-	-	-	-

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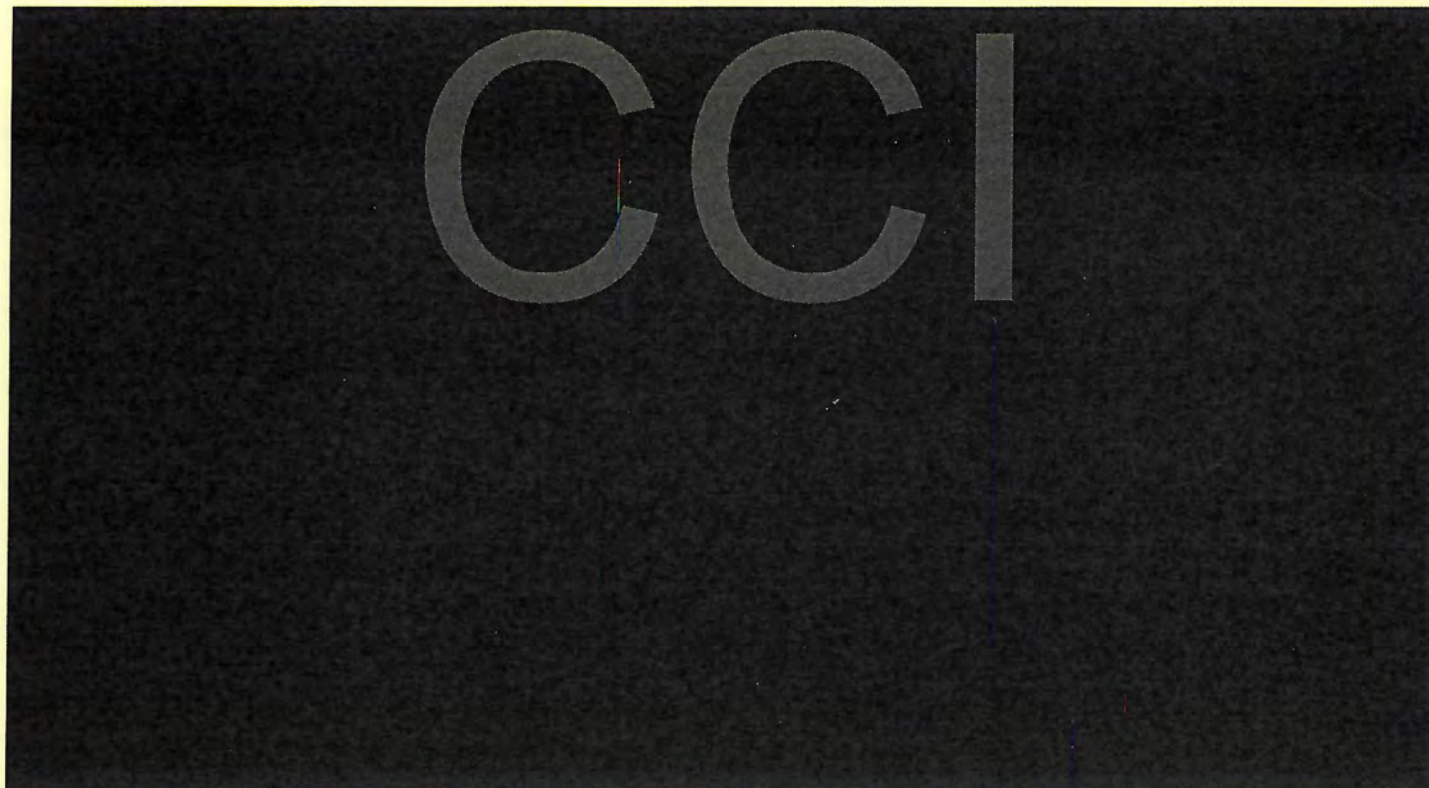
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Individual Pup Body Weights (grams)

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Individual Pup Body Weights (grams)

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Individual Pup Body Weights (grams)

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Day(s): - Relative to Littering (Litter: A)



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Individual Pup Body Weights (grams)

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Individual Pup Body Weights (grams)

20256434

Day(s): - Relative to Littering (Litter: A)



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Individual Pup Body Weights (grams)

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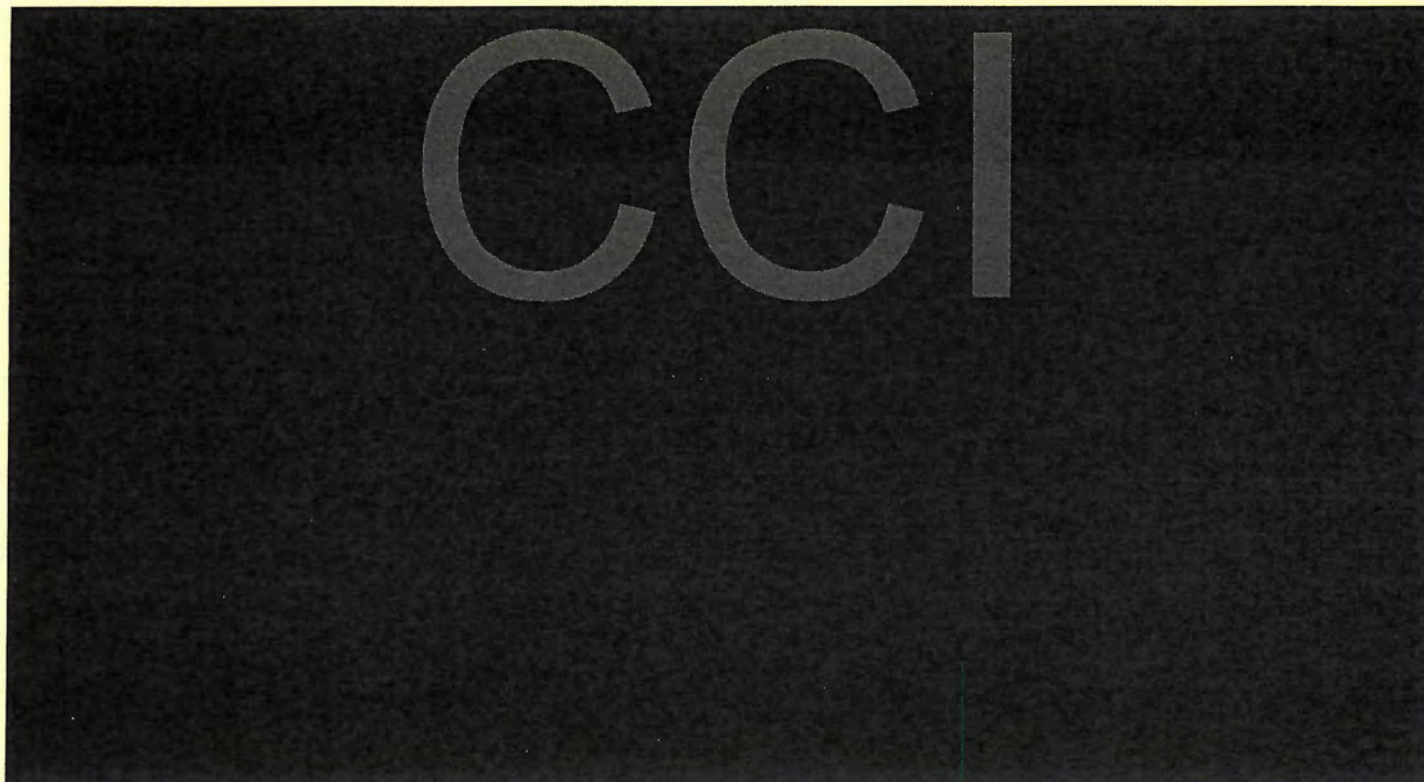
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Individual Pup Body Weights (grams)

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Individual Pup Body Weights (grams)

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Day(s): - Relative to Littering (Litter: A)



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Individual Pup Body Weights (grams)

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Individual Pup Body Weights (grams)

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Individual Pup Body Weights (grams)

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Individual Pup Body Weights (grams)

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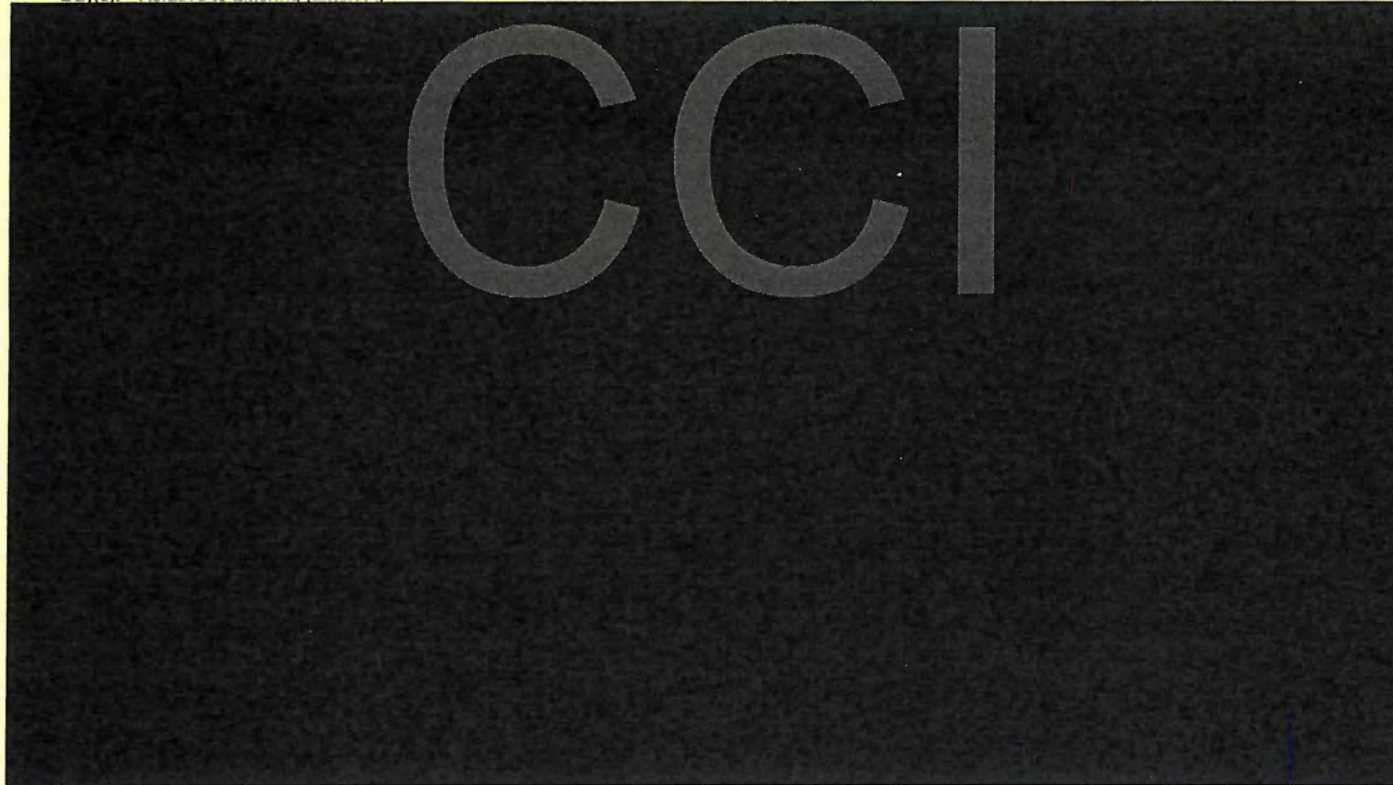
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Individual Pup Body Weights (grams)

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Day(s): - Relative to Littering (Litter: A)



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Individual Pup Body Weights (grams)

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Individual Pup Body Weights (grams)

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Day(s): - Relative to Littering (Litter: A)



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Individual Pup Body Weights (grams)

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Individual Pup Body Weights (grams)

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Individual Physical and Functional Development - Pinna Unfolding

20256434

Sex: Female Day(s) Relative to Littering (Litter: A)

Control Omcg				
	Pinna Unfolding	Pinna Unfolding	Pinna Unfolding	Pinna Unfolding
	1	2	3	4
201	0/14	1/14	14/14	.
202	0/10	3/10	10/10	.
203	0/13	12/13	13/13	.
204	0/13	13/13	.	.
205	0/11	11/11	.	.
206	0/16	3/16	16/16	.
207	0/9	7/9	9/9	.
208	0/13	0/13	7/13	13/13
209	0/10	7/10	10/10	.
210	10/10	.	.	.
211	0/13	4/13	13/13	.
212	0/19	8/19	19/19	.
213	0/12	6/12	12/12	.
214	0/13	1/13	13/13	.
215	0/13	11/13	13/13	.
216	0/14	1/14	14/14	.
217	0/13	8/13	13/13	.
218	0/10	9/10	10/10	.

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Individual Physical and Functional Development - Pinna Unfolding

20256434

Sex: Female Day(s) Relative to Littering (Litter: A)

Control 0mcg	Pinna Unfolding			
	Pinna Unfolding	Pinna Unfolding	Pinna Unfolding	Pinna Unfolding
	1	2	3	4
219	0/14	6/14	14/14	.
220	0/15	1/15	15/15	.
221	0/15	13/15	15/15	.
222	0/15	4/15	14/14	.

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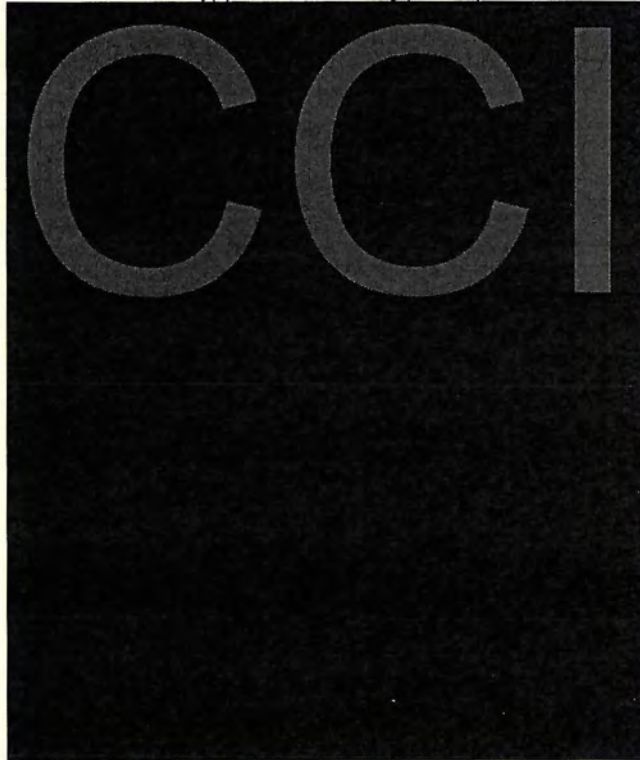
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Individual Physical and Functional Development - Pinna Unfolding

20256434

Sex: Female Day(s) Relative to Littering (Litter: A)



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Individual Physical and Functional Development - Pinna Unfolding

20256434

Sex: Female Day(s) Relative to Littering (Litter: A)



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Individual Physical and Functional Development - Pinna Unfolding

20256434

Sex: Female Day(s) Relative to Littering (Litter: A)

BNT162b2 30mcg	Pinna Unfolding			
	Pinna Unfolding	Pinna Unfolding	Pinna Unfolding	Pinna Unfolding
	1	2	3	4
245	0/16	16/16	.	.
246	0/12	0/12	12/12	.
247	0/13	4/13	13/13	.
248	0/11	7/11	11/11	.
249	0/17	1/17	17/17	.
250	0/12	7/12	12/12	.
251	0/17	2/17	14/16	15/16
252	0/11	9/11	11/11	.
253	0/12	1/12	12/12	.
255	3/3	.	.	.
256	0/15	7/15	15/15	.
257	0/15	6/15	15/15	.
258	0/15	14/15	15/15	.
259	0/15	11/15	15/15	.
260	3/13	13/13	.	.
261	0/11	11/11	.	.
262	0/13	8/13	13/13	.
263	0/12	0/12	12/12	.

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Individual Physical and Functional Development - Pinna Unfolding

20256434

Sex: Female Day(s) Relative to Littering (Litter: A)

BNT162b2 30mcg	Pinna Unfolding	Pinna Unfolding	Pinna Unfolding	Pinna Unfolding
	1	2	3	4
	264	0/13	2/13	13/13
265	0/16	1/16	15/16	15/15
266	0/11	7/11	11/11	.

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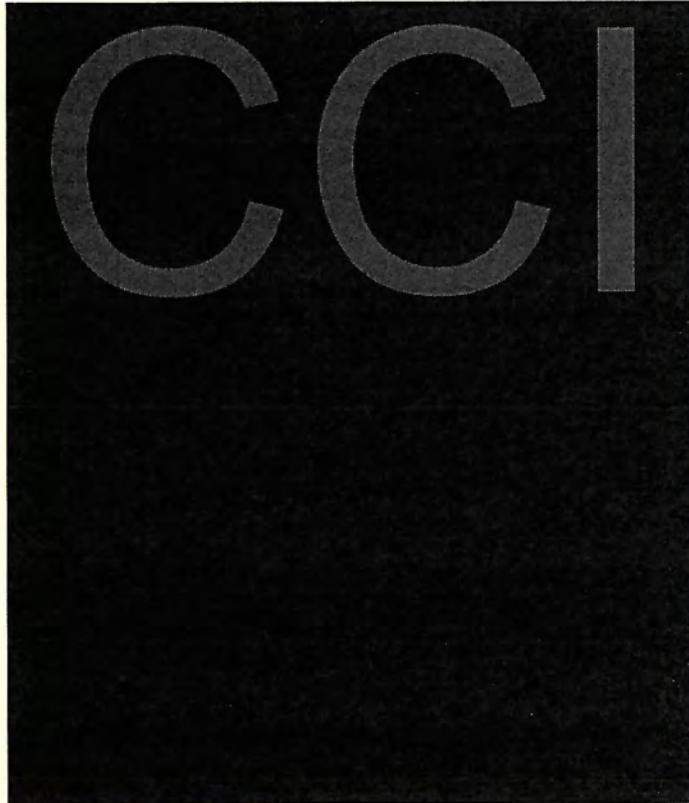
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Individual Physical and Functional Development - Pinna Unfolding

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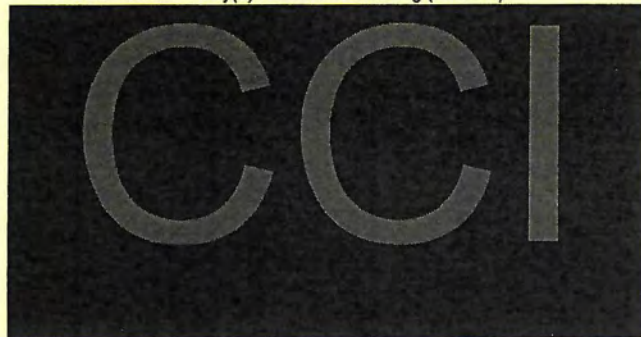
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Individual Physical and Functional Development - Pinna Unfolding

20256434

Sex: Female Day(s) Relative to Littering (Litter: A)



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Individual Physical and Functional Development - Eye Opening

20256434

Sex: Female Day(s) Relative to Littering (Litter: A)

Control Omcg	Eyes Opening				
	Eyes Opening	Eyes Opening	Eyes Opening	Eyes Opening	Eyes Opening
	12	13	14	15	16
201	0/8	2/8	7/8	8/8	-
202	0/8	0/8	4/8	8/8	-
203	0/8	1/8	8/8	.	-
204	0/8	6/8	8/8	.	-
205	0/8	5/8	8/8	.	-
206	0/8	0/8	3/8	8/8	-
207	0/8	0/8	8/8	.	-
208	0/8	0/8	1/8	8/8	-
209	0/8	0/8	8/8	.	-
210	0/8	7/8	8/8	.	-
211	0/8	0/8	6/8	7/8	8/8
212	0/8	1/8	8/8	.	-
213	0/8	5/8	8/8	.	-
214	0/8	0/8	5/8	8/8	-
215	0/8	2/8	8/8	.	-
216	0/8	1/8	6/8	8/8	-
217	0/8	1/8	8/8	.	-
218	0/8	0/8	5/8	8/8	-

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Individual Physical and Functional Development - Eye Opening

20256434

Sex: Female Day(s) Relative to Littering (Litter: A)

Control 0mcg					
	Eyes Opening	Eyes Opening	Eyes Opening	Eyes Opening	Eyes Opening
	12	13	14	15	16
219	0/8	0/8	7/8	8/8	-
220	0/8	1/8	7/8	8/8	-
221	0/8	2/8	8/8	-	-
222	0/8	0/8	7/8	8/8	-

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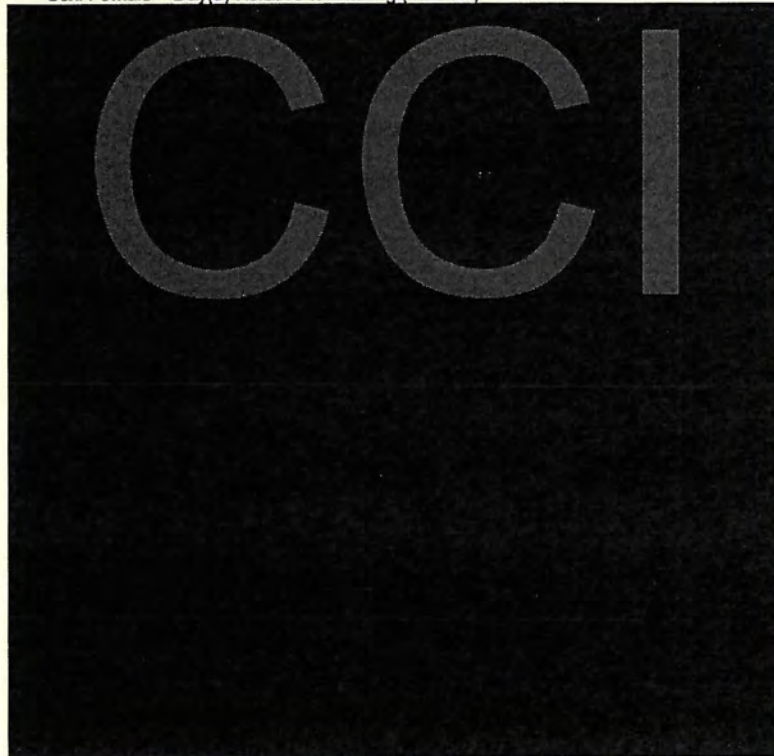
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Individual Physical and Functional Development - Eye Opening

20256434

Sex: Female Day(s) Relative to Littering (Litter: A)



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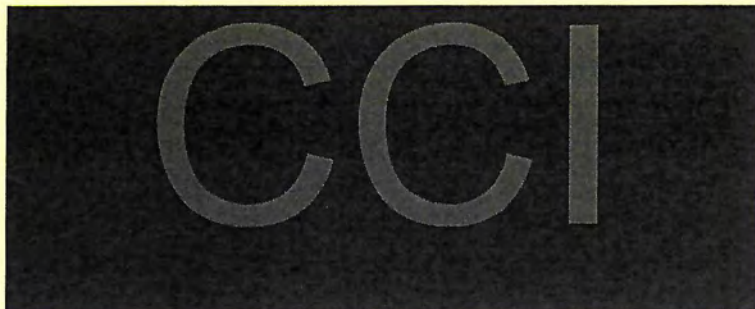
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Individual Physical and Functional Development - Eye Opening

20256434



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Individual Physical and Functional Development - Eye Opening

20256434

Sex: Female Day(s) Relative to Littering (Litter: A)

BNT162b2 30mcg					
	Eyes Opening	Eyes Opening	Eyes Opening	Eyes Opening	Eyes Opening
	12	13	14	15	16
245	0/8	2/8	8/8	-	-
246	0/8	0/8	5/8	8/8	-
247	0/8	0/8	2/8	4/8	8/8
248	0/8	0/8	7/8	8/8	-
249	0/8	0/8	4/8	8/8	-
250	0/8	0/8	8/8	-	-
251	0/8	0/8	4/8	8/8	-
252	0/8	0/8	7/8	8/8	-
253	0/8	2/8	5/8	8/8	-
255	2/3	2/3	3/3	-	-
256	0/8	0/8	8/8	-	-
257	0/8	1/8	8/8	-	-
258	0/8	0/8	5/8	8/8	-
259	0/8	0/8	7/8	8/8	-
260	0/8	4/8	7/8	8/8	-
261	0/8	1/8	8/8	-	-
262	0/8	0/8	7/8	8/8	-
263	0/8	0/8	4/8	8/8	-

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Individual Physical and Functional Development - Eye Opening

20256434

Sex: Female Day(s) Relative to Littering (Litter: A)

BNT162b2 30mcg					
	Eyes Opening	Eyes Opening	Eyes Opening	Eyes Opening	Eyes Opening
	12	13	14	15	16
264	0/8	0/8	6/8	0/8	8/8
265	0/8	0/8	7/8	8/8	-
266	0/8	0/8	8/8	-	-

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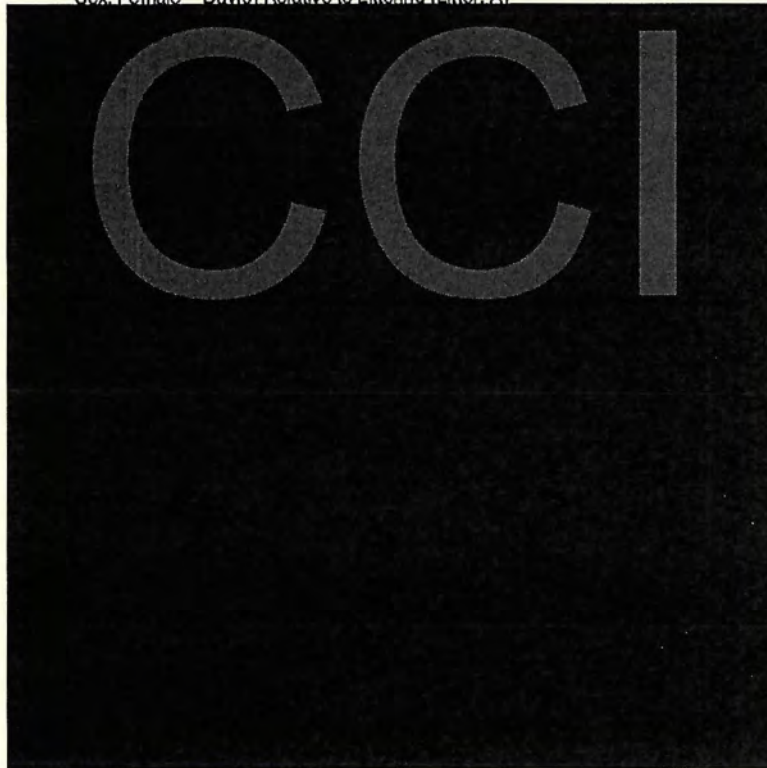
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Individual Physical and Functional Development - Eye Opening

20256434

Sex: Female Day(s) Relative to Littering (Litter: A)



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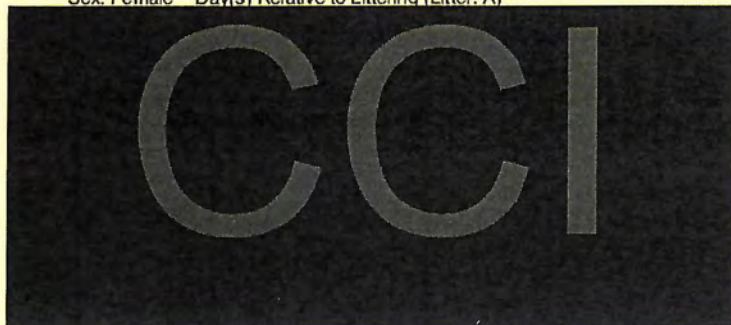
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Individual Physical and Functional Development - Eye Opening

20256434

Sex: Female Day(s) Relative to Littering (Litter: A)



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Individual Reflex and Functional Tests

20256434

Sex: Female Day(s) Relative to Littering (Litter: A)

Control 0mcg		
	Pupillary Reflex	Auditory Reflex
	21	21
201	8/8	8/8
202	8/8	8/8
203	8/8	8/8
204	8/8	8/8
205	8/8	8/8
206	8/8	8/8
207	7/7	7/7
208	8/8	8/8
209	8/8	8/8
210	8/8	8/8
211	8/8	8/8
212	8/8	8/8
213	8/8	8/8
214	8/8	8/8
215	8/8	8/8
216	8/8	8/8
217	8/8	8/8
218	8/8	8/8

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Individual Reflex and Functional Tests

20256434

Sex: Female Day(s) Relative to Littering (Litter: A)

Control 0mcg		
	Pupillary Reflex	Auditory Reflex
	21	21
219	8/8	8/8
220	8/8	8/8
221	8/8	8/8
222	8/8	8/8

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Individual Reflex and Functional Tests

20256434

Sex: Female Day(s) Relative to Littering (Litter: A)



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Individual Reflex and Functional Tests

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Individual Reflex and Functional Tests

20256434

Sex: Female Day(s) Relative to Littering (Litter: A)

BNT162b2 30mcg	Pupillary Reflex	Auditory Reflex
	21	21
245	8/8	8/8
246	8/8	8/8
247	8/8	8/8
248	8/8	8/8
249	8/8	8/8
250	8/8	8/8
251	8/8	8/8
252	8/8	8/8
253	8/8	8/8
255	3/3	3/3
256	8/8	8/8
257	8/8	8/8
258	8/8	8/8
259	8/8	8/8
260	8/8	8/8
261	8/8	8/8
262	8/8	8/8
263	8/8	8/8

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Individual Reflex and Functional Tests

20256434

Sex: Female Day(s) Relative to Littering (Litter: A)

BNT162b2 30mcg	Pupillary Reflex	Auditory Reflex
	21	21
264	8/8	8/8
265	8/8	8/8
266	8/8	8/8

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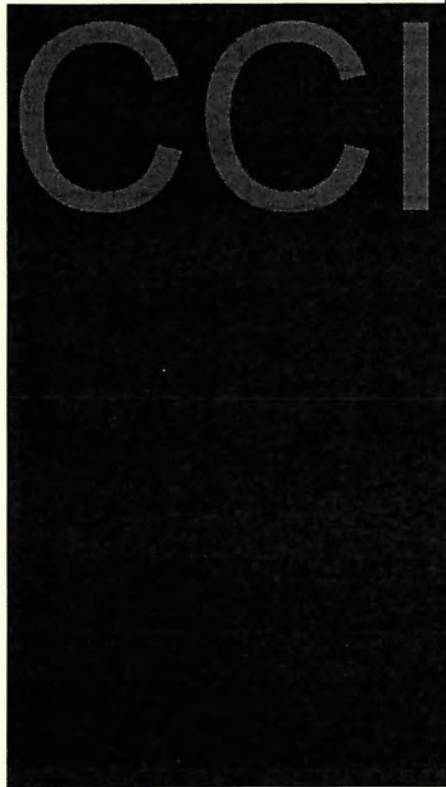
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Individual Reflex and Functional Tests

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Individual Reflex and Functional Tests

20256434

Sex: Female Day(s) Relative to Littering (Litter: A)



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Phase Report
Study No. 20256434 (BNT_Work Order 3)
Version 1.0 of 10 Dec 2020

PHASE REPORT

**Combined Fertility and Developmental Study
(Including Teratogenicity and Postnatal Investigations)
of BNT162b1, BNT162b2 and BNT162b3
by the Intramuscular Route in the Wistar Rat
GLP Study (BNT_WO 3)**

SERVICE PERFORMED BY:

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Principal Investigator

PPD [REDACTED], Project Leader, VisMederi srl

Date: *December 10th, 2020*

Signature: PPD [REDACTED]

PPD [REDACTED], HQD VisMederi srl

Date: *December 10th, 2020*

[REDACTED]
[REDACTED]

SPONSOR:

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CRL STUDY NUMBER 20256434

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Phase Report
Study No. 20256434 (BNT_Work Order 3)
Version 1.0 of 10 Dec 2020

Version summary:

VERSION	ISSUE DATE	CHANGE
1.0	10 Dec 2020	First issue

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Phase Report
Study No. 20256434 (BNT_Work Order 3)
Version 1.0 of 10 Dec 2020

1. PURPOSE

This Phase Report describes the activities completed by VisMederi applying the Microneutralization (MN) assay for serological detection of SARS-CoV-2 specific neutralizing titers in animal sera relative to the "Work order 3" agreed between VisMederi Srl and BioNTech RNA Pharmaceuticals GmbH.

2. STUDY MANAGEMENT

The CCI, BNT162b2 and CCI vaccine development candidates to prevent Covid-19 are based on an RNA platform and target the SARS-CoV-2 spike protein. They were evaluated through the 20256434 (Charles River Laboratories) study to assess potential effect of the vaccine product and the concomitant immune response on fertility and pre- and postnatal development in the Wistar Han rat.

30 µg of CCI, BNT162b2 and CCI vaccine candidates were administered by intramuscular (IM) injection, once on each of 4 dosing days (60 µL per dose) into the quadriceps muscle:

- Pre-mating: Study Day 1 (21 days before mating, M-21) and Day 8 (14 days before mating, M-14).
- Gestation Days 9 and 20.

Animals received saline (Control item) or test article at doses of 30 µg mRNA/Dose Day. Table below shows group designations, vaccine dose, and subgroups identification.

Experimental Design of the F0 Generation				
Group Number	Test Material	Dose Level (µg/mRNA)	Number and Identification of Animals	
			Caesarean Subgroup	Littering Subgroup
1	Control Item	0	22 (1 to 22)	22 (201 to 222)
2	CCI	30	22 (23 to 44)	22 (223 to 244)
3	BNT162b2	30	22 (45 to 66)	22 (245 to 266)
4	CCI	30	22 (67 to 88)	22 (267 to 288)



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Samples for antibody analyses were collected prior to first vaccine dose (Pretest) and just before the mating (M-0) for all F0 females.

The Caesarean subset was subjected to caesarean section on Gestation Day 21 (GD-21) and serum samples from Caesarean Dams and Foetuses in each litter were collected.

The sample collections from Littering Dams were performed at Lactation Day 21 (LD-21) and from pups in each litter on Postnatal Day 21 (PND-21).

VisMederi performed immunogenicity tests on rat samples for detection of neutralizing titers to wild type live SARS-CoV-2 virus.

The assay was performed according to VisMederi internal working instruction "Microneutralization CPE-based assay for SARS-COV-2" (WI-MNSARS-CoV-2), in accordance with the Good Clinical Laboratory Practice 2009/2013 (GCLP).

VisMederi received a first shipment of serum samples on September 3rd 2020, 352 rat serum samples, from Charles River Laboratories, which contained "Pretest" time-point and "M0" (collected just before mating) samples.

A second shipment of 342 serum samples was received on October 20th 2020 from Charles River Laboratories, which contained GD-21, LD-21, and PND-21 occasions. Upon arrival, all samples passed a visual check of the physical characteristics and correspondence with material shipping inventory, according to the SOP-HBM of VisMederi, and samples were stored in a -80 °C freezer (VM-F-008).

Each serum sample was tested in duplicate for serological detection of SARS-CoV-2 specific neutralizing antibodies.

The SARS-CoV-2 2019 live wild type virus 2019-nCoV strain 2019-nCov/Italy-INMI1 was obtained by VisMederi Srl from the European Virus Archive Global (EVAg).

Detailed strain information are available at the following link:



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<https://www.european-virus-archive.com/virus/human-2019-ncov-strain-2019-ncovitaly-inmi1-clade-v>

The virus growth was carried out by VisMederi Research Srl, according to VisMederi Research procedure "Virus Growth in cell culture" (SOP-VGC) in an epithelial cell line, VERO E6 cells (from kidney of a normal monkey Cercopithecus aethiops), provided by the American Type Culture Collection (ATCC - CRL 1586).

The internal virus batch applied for MN analyses was VMR_SARSCOV2VEROE6_280420_C1.

SARS-CoV-2 Microneutralization assay testing of the first shipment samples was performed on 15th – 25th September 2020 in the VisMederi BSL3 laboratories in accordance to the SOP-HSAL of VisMederi.

The second panel of samples was analyzed on 4th – 12th November 2020.

QA Statement and Regulatory Statement

The work was conducted in accordance with the procedures in force and following the GCLP guidelines and under ISO 9001:2015.

All laboratory staff involved were trained in recording the raw data of the study in a timely and accurate manner, and aware of the responsibility of the quality of the data produced.

Independent laboratory audits are conducted periodically to ensure the quality of work and data integrity.

Equipment used are periodically maintained, calibrated and qualified as appropriate.

All documentation related to the study are archived in a secure place in compliance with the ISO 27001 (both in electronic and paper format).



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No significant laboratory events or deviations occurred during the study that could have impacted the results.

3. TEST PROCEDURE

The MN-CPE (Microneutralization based on Cytopathic effect) method is a specific technique used for the detection of virus-specific neutralizing antibodies against live viruses that block virus infection. This assay is a fundamental test in virology, immunology, vaccine assessment and epidemiology studies.

The assay was performed following the VisMederi procedure "WI-MNSARS-CoV-2", and the main phases are described as follows:

- Virus Titration
- Back titration
- Microneutralization

Virus titration

The virus, ten-fold serially diluted in suitable MN medium, was transferred to a plate containing confluent VERO E6 cell monolayers.

After a 3 day incubation the plate was observed under an inverted microscope and the wells were scored as positive/negative for Cytopathic effect (CPE), the presence of CPE in a well monolayer makes it positive for the purpose of calculating the virus titer.

The titer was calculated using the Reed-Muench method, obtaining $10^{7.59}$ TCID₅₀/mL as result. The stock virus was then applied in the MN assay at a proper dilution in order to contain 2000 TCID₅₀/mL in the working virus solution.



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MN assay

Serum samples were heat-inactivated for 30 minutes at 56 °C, then two-fold serially diluted starting from 1:10 up to 1:5120 and were mixed with an equal volume of viral solution.

Duplicate runs for each sample were performed in two different plates.

The serum-virus mixture was incubated for 1 hour at 37 °C, in a humidified atmosphere with 5% CO₂. After the incubation time, 100 µl of the mixture for each dilution was added in duplicate to a cell plate containing a healthy and sub confluent-to confluent VERO E6 cell lawn and incubated for 3 days in the CO₂ incubator at 37 °C and 5% CO₂. The readout was achieved through inverted optical microscopy in order to discriminate wells as positive/negative for Cytopathic effect (CPE). The CPE negativity of a well is provided by at least 50% of cell monolayer intact.

The Microneutralization titer (MNT) of each titrated sample corresponded to the reciprocal of the highest sample dilution able to protect from CPE at least 50% of the cell monolayer. If no neutralization was observed (MNT <10) an arbitrary value of 5 was reported.

Back titration and reference samples

To verify the quantity of virus in the solution applied in the assay, the virus working solution was titrated in each MN session. The back titrations performed in both sessions for this study confirmed virus titers within the defined acceptance range of $10^{2.75} - 10^{3.75}$ TCID₅₀/mL.

In addition, each test session included runs of specific reference sera: a positive and a negative serum.

The positive control (PCS) used in every test run, is a human plasma sample collected from a COVID-19 convalescent patient, it was kindly provided by Toscana Life Science (vAMRes/MAD laboratories) on 13th May 2020, and it is identified by code "TLS-CoV-



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8" or "TLS-8". This sample was previously tested by MN and by ELISA for SARS-CoV-2 antibody titer, providing high positive response confirmed by multiple repetitions. The negative control sample (NCS) used was a human serum depleted of IgA, IgM and IgG, provided by Sigma Aldrich, cod. S5393 batch 108M4791V.

4. ACCEPTANCE CRITERIA

In agreement with WI-MNSARS-CoV-2, the following internal quality controls were met in each session of analysis for the Study samples, therefore results were considered reliable and acceptable.

Virus titer evaluation:

- The back titration of the working viral solution lies within the defined target range of $10^{2.75}$ - $10^{3.75}$ TCID₅₀/mL.

MN results acceptability of each MN plate:

- The cell control (CC) showed a healthy cell monolayer and no evidence of CPE.
- The virus control (VC) wells showed 100% cytopathic effect.

MN results acceptability of each sample:

- The duplicate neutralization titers of each serum sample were within a range of ± 1 titer step (2-fold).

MN results acceptability of each analysis session:

- The positive control sample (PCS) showed a positive titer, in agreement with previous data (expected titer range: 320-640),
- The negative control sample (NCS) with absent antibody titer showed a negative response.

Since all the acceptability criteria were met, no retest was necessary.



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5. DATA RELEASE

Test results were recorded through dedicated forms, attachments of the VisMederi WI "WI-MNSARS-CoV-2", and transferred to Excel data entry sheets:

- BNT_WO3_MNSARSCOV2_V1_20200930.xlsx for the first set of samples,
- BNT_WO3_MNSARSCOV2_V2_20201118.xlsx for cumulative data.

This report shows the full set of data in Appendix 1 (cumulative data).

Data entry description

The cumulative data table presents three sections:

- Sample Identification
- Raw Data (end-point titers)
- Derived values as geometric mean of duplicate tests

Each subject is identified in a row of table by Group, Animal number, Interval/ Occasion, Barcode number and Study Phase.

Raw data are shown in the following columns as duplicate titers "T1A" and "T1B", obtained in the same analysis session, from duplicate run of the same sample.

The last column shows the geometric mean titer (GMT) calculated on the two replicate titers for each sample.



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6. RESULTS AND CONCLUSIONS

The following table shows geometric mean titers (GMT) by time-point (Interval/Occasion) and by group of females or offspring (fetuses and pups).

Interval/Occasion	Saline	CCI	BNT162b2	CCI
Pretest	5.0		5.3	
MO	5.0		3886.4	
GD21 (Dams)	5.0		3445.5	
LD21	5.0		3620.4	
Fetuses (GD21)	5.0		640.0	
Pups (PND21)	5.0		4561.4	

Time-point legend:

MO= just prior to mating

GD21 = gestation day 21

LD21= lactation day 21

PND21= post-natal days

These GMTs exclude values from no pregnant females and other intermittent sample time points. See Appendix 1 footnotes for list of all excluded samples, in data table they are marked (*).

Administration of 4 doses (2 prior to mating and 2 during gestation) of CCI, BNT162b2, or CCI elicited SARS-CoV-2 neutralizing antibody responses in the majority of females just prior to mating (Day 22), at the end of gestation (GD21), and at the end of lactation (LD21). SARS-CoV-2 neutralizing titers were detected in most offspring (fetuses on GD21 and pups on PND21). SARS-CoV-2 neutralizing antibody titers were not observed in animals prior to vaccine administration or in saline-administered control animals.



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7. REFERENCES

- Manenti A, Maggetti M, Casa E, et al (2020). Evaluation of SARS-CoV-2 neutralizing antibodies using of a CPE-based Colorimetric live virus micro-neutralization assay in human serum samples. Journal of Medical Virology. doi: 10.1002/jmv.25986.
- Reed, L.J.; Muench, H. (1938). "A simple method of estimating fifty percent endpoints". The American Journal of Hygiene. 27: 493–497.
- Algaissi A, Hashem AM. (2020). Evaluation of MERS-CoV Neutralizing Antibodies in Sera Using Live Virus Microneutralization Assay. Methods in molecular biology (Clifton, N.J.) vol. 2099: 107-116.
- Good Clinical Laboratory Practice GCLP – 2009/2013
- OECD Principles on Good Laboratory Practice (ENV/MC/CHEM(98)17)
- UNI EN ISO 9001:2015
- UNI EN ISO 27001:2017
- "WI-MNSARS-CoV-2" Working Instruction "Microneutralization CPE-based assay for Sars-Cov-2"
- "HSAL" Handling and safety for activities in BSL2 and BSL3 Laboratories – VisMederi procedure
- "HBM" Handling Of Biological Material – VisMederi procedure
- "HCC" Handling Cell Cultures – VisMederi Research procedure
- "MRR" Management and Release of Results – VisMederi procedure
- "VGC" Virus Growth in Cell culture – VisMederi Research procedure
- Rat Matrix Effect report for "Combined Fertility and Developmental Study (Including Teratogenicity and Postnatal Investigations) of CCI [REDACTED], BNT162b2 and CCI [REDACTED] by the Intramuscular Route in the Wistar Rat"

8. APPENDICES

Appendix 1: cumulative data table

Group	Animal number	Interval/ Occasion	Barcode number	Study Phase	T1A	T1B	Geometric Mean Titer
1	1	Pret	485765Ab1	caesarean	5	5	5.0
1	1	M0	489037-1	caesarean	5	5	5.0
1	2	Pret	485766Ab1	caesarean	5	5	5.0
1	2	M0	489038-1	caesarean	5	5	5.0

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Group	Animal number	Interval/ Occasion	Barcode number	Study Phase	T1A	T1B	Geometric Mean Titer
1	3	Pret	485767Ab1	caesarean	5	5	5.0
1	3	M0	489039-1	caesarean	5	5	5.0
1	4	Pret	485768Ab1	caesarean	5	5	5.0
1	4	M0	489040-1	caesarean	5	5	5.0
1	5	Pret	485769Ab1	caesarean	5	5	5.0
1	5	M0	489041-1	caesarean	5	5	5.0
1	6	Pret	485770Ab1	caesarean	5	5	5.0
1	6	M0	489042-1	caesarean	5	5	5.0
1	7	Pret	485771Ab1	caesarean	5	5	5.0
1	7	M0	489043-1	caesarean	5	5	5.0
1	8	Pret	485772Ab1	caesarean	5	5	5.0
1	8	M0	489044-1	caesarean	5	5	5.0
1	9	Pret	485773Ab1	caesarean	5	5	5.0
1	9	M0	489045-1	caesarean	5	5	5.0
1	10	Pret	485774Ab1	caesarean	5	5	5.0
1	10	M0	489046-1	caesarean	5	5	5.0
1	11	Pret	485775Ab1	caesarean	5	5	5.0
1	11	M0	489047-1	caesarean	5	5	5.0
1	12	Pret	485776Ab1	caesarean	5	5	5.0
1	12	M0	489048-1	caesarean	5	5	5.0
1	13	Pret	485777Ab1	caesarean	5	5	5.0
1	13	M0	489049-1	caesarean	5	5	5.0
1	14	Pret	485778Ab1	caesarean	5	5	5.0
1	14	M0	489050-1	caesarean	5	5	5.0
1	15	Pret	485779Ab1	caesarean	5	5	5.0
1	15	M0	489051-1	caesarean	5	5	5.0
1	16	Pret	485780Ab1	caesarean	5	5	5.0
1	16	M0	489052-1	caesarean	5	5	5.0
1	17	Pret	485781Ab1	caesarean	5	5	5.0
1	17	M0	489053-1	caesarean	5	5	5.0
1	18	Pret	485782Ab1	caesarean	5	5	5.0
1	18	M0	489054-1	caesarean	5	5	5.0
1	19	Pret	485783Ab1	caesarean	5	5	5.0
1	19	M0	489055-1	caesarean	5	5	5.0
1	20	Pret	485784Ab1	caesarean	5	5	5.0
1	20	M0	489056-1	caesarean	5	5	5.0
1	21	Pret	485785Ab1	caesarean	5	5	5.0
1	21	M0	489057-1	caesarean	5	5	5.0
1	22	Pret	485786Ab1	caesarean	5	5	5.0

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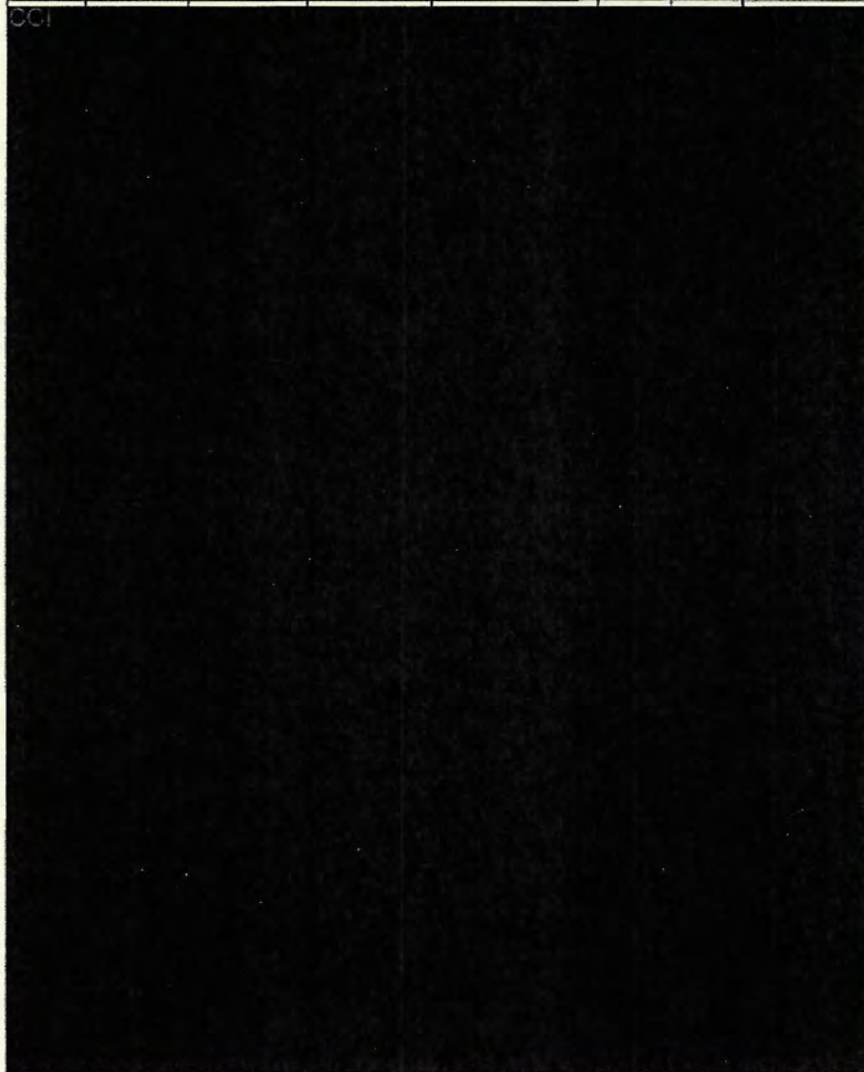
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Group	Animal number	Interval/ Occasion	Barcode number	Study Phase	T1A	T1B	Geometric Mean Titer
1	22	M0	489058-1	caesarean	5	5	5.0



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Group	Animal number	Interval/ Occasion	Barcode number	Study Phase	T1A	T1B	Geometric Mean Titer
CCI							
3	45	Pret	485809Ab1	caesarean	5	5	5.0
3	45	M0	489081-1	caesarean	5120	2560	3620.4
3	46	Pret	485810Ab1	caesarean	5	5	5.0
3	46	M0	489082-1	caesarean	5120	5120	5120.0
3	47	Pret	485811Ab1	caesarean	5	5	5.0
3	47	M0	489083-1	caesarean	2560	2560	2560.0
3	48	Pret	485812Ab1	caesarean	5	5	5.0
3	48	M0	489084-1	caesarean	5120	5120	5120.0
3	49	Pret	485813Ab1	caesarean	5	5	5.0
3	49	M0	489085-1	caesarean	5120	2560	3620.4
3	50	Pret	485814Ab1	caesarean	5	5	5.0
3	50	M0	489086-1	caesarean	2560	5120	3620.4
3	51	Pret	485815Ab1	caesarean	5	5	5.0
3	51	M0	489087-1	caesarean	2560	2560	2560.0
3	52	Pret	485816Ab1	caesarean	5	5	5.0
3	52	M0	489088-1	caesarean	5120	5120	5120.0
3	53	Pret	485817Ab1	caesarean	10	5	7.1
3	53	M0	489089-1	caesarean	640	640	640.0
3	54	Pret	485818Ab1	caesarean	5	5	5.0
3	54	M0	489090-1	caesarean	5120	2560	3620.4
3	55	Pret	485819Ab1	caesarean	5	5	5.0
3	55	M0	489091-1	caesarean	5120	5120	5120.0
3	56	Pret	485820Ab1	caesarean	5	10	7.1
3	56	M0	489092-1	caesarean	5120	5120	5120.0
3	57	Pret	485821Ab1	caesarean	5	10	7.1
3	57	M0	489093-1	caesarean	5120	5120	5120.0
3	58	Pret	485822Ab1	caesarean	10	10	10.0
3	58	M0	489094-1	caesarean	5120	5120	5120.0
3	59	Pret	485823Ab1	caesarean	5	10	7.1
3	59	M0	489095-1	caesarean	5120	5120	5120.0
3	60	Pret	485824Ab1	caesarean	5	10	7.1
3	60	M0	489096-1	caesarean	2560	5120	3620.4
3	61	Pret	485825Ab1	caesarean	5	5	5.0

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Group	Animal number	Interval/ Occasion	Barcode number	Study Phase	T1A	T1B	Geometric Mean Titer
3	61	M0	489097-1	caesarean	1280	1280	1280.0
3	62	Pret	485826Ab1	caesarean	5	5	5.0
3	62	M0	489098-1	caesarean	5120	5120	5120.0
3	63	Pret	485827Ab1	caesarean	5	5	5.0
3	63	M0	489099-1	caesarean	5120	5120	5120.0
3	64	Pret	485828Ab1	caesarean	5	5	5.0
3	64	M0	489100-1	caesarean	1280	2560	1810.2
3	65	Pret	485829Ab1	caesarean	5	5	5.0
3	65	M0	489101-1	caesarean	5120	5120	5120.0
3	66	Pret	485830Ab1	caesarean	5	5	5.0
3	66	M0	489102-1	caesarean	5120	5120	5120.0

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Group	Animal number	Interval/ Occasion	Barcode number	Study Phase	T1A	T1B	Geometric Mean Titer
CCI							
1	201	Pret	485857Ab1	Littering	5	5	5.0
1	201	M0	488949-1	Littering	5	5	5.0
1	202	Pret	485858Ab1	Littering	5	5	5.0
1	202	M0	488950-1	Littering	5	5	5.0
1	203	Pret	485859Ab1	Littering	5	5	5.0
1	203	M0	488951-1	Littering	5	5	5.0
1	204	Pret	485860Ab1	Littering	5	5	5.0
1	204	M0	488952-1	Littering	5	5	5.0
1	205	Pret	485861Ab1	Littering	5	5	5.0
1	205	M0	488953-1	Littering	5	5	5.0
1	206	Pret	485862Ab1	Littering	5	5	5.0
1	206	M0	488954-1	Littering	5	5	5.0
1	207	Pret	485863Ab1	Littering	5	5	5.0
1	207	M0	488955-1	Littering	5	5	5.0
1	208	Pret	485864Ab1	Littering	5	5	5.0
1	208	M0	488956-1	Littering	5	5	5.0
1	209	Pret	485865Ab1	Littering	5	5	5.0
1	209	M0	488957-1	Littering	5	5	5.0
1	210	Pret	485866Ab1	Littering	5	5	5.0
1	210	M0	488958-1	Littering	5	5	5.0
1	211	Pret	485867Ab1	Littering	5	5	5.0
1	211	M0	488959-1	Littering	5	5	5.0
1	212	Pret	485868Ab1	Littering	5	5	5.0

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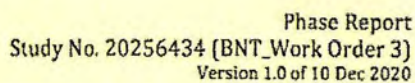
Group	Animal number	Interval/ Occasion	Barcode number	Study Phase	T1A	T1B	Geometric Mean Titer
1	212	M0	488960-1	Littering	5	5	5.0
1	213	Pret	485869Ab1	Littering	5	5	5.0
1	213	M0	488961-1	Littering	5	5	5.0
1	214	Pret	485870Ab1	Littering	5	5	5.0
1	214	M0	488962-1	Littering	5	5	5.0
1	215	Pret	485871Ab1	Littering	5	5	5.0
1	215	M0	488963-1	Littering	5	5	5.0
1	216	Pret	485872Ab1	Littering	5	5	5.0
1	216	M0	488964-1	Littering	5	5	5.0
1	217	Pret	485873Ab1	Littering	5	5	5.0
1	217	M0	488965-1	Littering	5	5	5.0
1	218	Pret	485874Ab1	Littering	5	5	5.0
1	218	M0	488966-1	Littering	5	5	5.0
1	219	Pret	485875Ab1	Littering	5	5	5.0
1	219	M0	488967-1	Littering	5	5	5.0
1	220	Pret	485876Ab1	Littering	5	5	5.0
1	220	M0	488968-1	Littering	5	5	5.0
1	221	Pret	485877Ab1	Littering	5	5	5.0
1	221	M0	488969-1	Littering	5	5	5.0
1	222	Pret	485878Ab1	Littering	5	5	5.0
1	222	M0	488970-1	Littering	5	5	5.0

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Group	Animal number	Interval/ Occasion	Barcode number	Study Phase	T1A	T1B	Geometric Mean Titer
CCI							
3	245	Pret	485901Ab1	Littering	5	5	5.0
3	245	M0	488993-1	Littering	5120	5120	5120.0
3	246	Pret	485902Ab1	Littering	5	5	5.0
3	246	M0	488994-1	Littering	5120	5120	5120.0
3	247	Pret	485903Ab1	Littering	5	5	5.0
3	247	M0	488995-1	Littering	1280	2560	1810.2
3	248	Pret	485904Ab1	Littering	5	5	5.0
3	248	M0	488996-1	Littering	2560	2560	2560.0
3	249	Pret	485905Ab1	Littering	5	5	5.0
3	249	M0	488997-1	Littering	5120	5120	5120.0
3	250	Pret	485906Ab1	Littering	5	5	5.0
3	250	M0	488998-1	Littering	5120	5120	5120.0
3	251	Pret	485907Ab1	Littering	5	5	5.0

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Group	Animal number	Interval/ Occasion	Barcode number	Study Phase	T1A	T1B	Geometric Mean Titer
3	251	M0	488999-1	Littering	5120	5120	5120.0
3	252	Pret	485908Ab1	Littering	5	5	5.0
3	252	M0	489000-1	Littering	5120	5120	5120.0
3	253	Pret	485909Ab1	Littering	5	5	5.0
3	253	M0	489001-1	Littering	320	320	320.0
3	254	Pret	485910Ab1	Littering	5	5	5.0
3	254	M0	489002-1	Littering	5120	5120	5120.0
3	255	Pret	485911Ab1	Littering	5	5	5.0
3	255	M0	489003-1	Littering	5120	5120	5120.0
3	256	Pret	485912Ab1	Littering	5	5	5.0
3	256	M0	489004-1	Littering	5120	5120	5120.0
3	257	Pret	485913Ab1	Littering	5	5	5.0
3	257	M0	489005-1	Littering	5120	5120	5120.0
3	258	Pret	485914Ab1	Littering	5	5	5.0
3	258	M0	489006-1	Littering	5120	5120	5120.0
3	259	Pret	485915Ab1	Littering	5	5	5.0
3	259	M0	489007-1	Littering	5120	5120	5120.0
3	260	Pret	485916Ab1	Littering	5	5	5.0
3	260	M0	489008-1	Littering	5120	5120	5120.0
3	261	Pret	485917Ab1	Littering	5	5	5.0
3	261	M0	489009-1	Littering	5120	5120	5120.0
3	262	Pret	485918Ab1	Littering	5	5	5.0
3	262	M0	489010-1	Littering	5120	5120	5120.0
3	263	Pret	485919Ab1	Littering	5	5	5.0
3	263	M0	489011-1	Littering	5120	5120	5120.0
3	264	Pret	485920Ab1	Littering	5	5	5.0
3	264	M0	489012-1	Littering	5120	5120	5120.0
3	265	Pret	485921Ab1	Littering	5	5	5.0
3	265	M0	489013-1	Littering	5120	5120	5120.0
3	266	Pret	485922Ab1	Littering	5	5	5.0
3	266	M0	489014-1	Littering	5120	5120	5120.0
CC							

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Group	Animal number	Interval/ Occasion	Barcode number	Study Phase	T1A	T1B	Geometric Mean Titer
CCI							
1	1	GD21	489623Ab1	caesarean Dams	5	5	5.0
1	1	GD21	489711Ab1	fetuses	5	5	5.0
1	2	GD21	489624Ab1	caesarean Dams	5	5	5.0

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Group	Animal number	Interval/ Occasion	Barcode number	Study Phase	T1A	T1B	Geometric Mean Titer
1	2	GD21	489712Ab1	fetuses	5	5	5.0
1	3	GD21	489625Ab1	caesarean Dams	5	5	5.0
1	3	GD21	489713Ab1	fetuses	5	5	5.0
1	4	GD21	489626Ab1	caesarean Dams	5	5	5.0
1	4	GD21	489714Ab1	fetuses	5	5	5.0
1	5	GD21	489627Ab1	caesarean Dams	5	5	5.0
1	5	GD21	489715Ab1	fetuses	5	5	5.0
1	6	GD21	489628Ab1	caesarean Dams	5	5	5.0
1	6	GD21	489716Ab1	fetuses	5	5	5.0
1	7	GD21	489629Ab1	caesarean Dams	5	5	5.0
1	7	GD21	489717Ab1	fetuses	5	5	5.0
1	8	GD21	489630Ab1	caesarean Dams	5	5	5.0
1	8	GD21	489718Ab1	fetuses	5	5	5.0
1	9	GD21	489631Ab1	caesarean Dams	5	5	5.0
1	9	GD21	489719Ab1	fetuses	5	5	5.0
1	10	GD21	489632Ab1	caesarean Dams	5	5	5.0
1	10	GD21	489720Ab1	fetuses	5	5	5.0
1	11	GD21	489633Ab1	caesarean Dams	5	5	5.0
1	11	GD21	489721Ab1	fetuses	5	5	5.0
1	12	GD21	489634Ab1	caesarean Dams	5	5	5.0
1	12	GD21	489722Ab1	fetuses	5	5	5.0
1	13	GD21	489635Ab1	caesarean Dams	5	5	5.0
1	13	GD21	489723Ab1	fetuses	5	5	5.0
1	14	GD21	489636Ab1	caesarean Dams	5	5	5.0
1	14	GD21	489724Ab1	fetuses	5	5	5.0
1	15	GD21	489637Ab1	caesarean Dams	5	5	5.0
1	15	GD21	489725Ab1	fetuses	5	5	5.0
1	16	GD21	489638Ab1	caesarean Dams	5	5	5.0
1	16	GD21	489726Ab1	fetuses	5	5	5.0
1	17	GD21	489639Ab1	caesarean Dams	5	5	5.0
1	17	GD21	489727Ab1	fetuses	5	5	5.0
1	18	GD21	489640Ab1	caesarean Dams	5	5	5.0
1	18	GD21	489728Ab1	fetuses	5	5	5.0
1	19	GD21	489641Ab1	caesarean Dams	5	5	5.0
1	19	GD21	489729Ab1	fetuses	5	5	5.0
1	20 (*)	GD21	489642Ab1	caesarean Dams	5	5	5.0
1	21	GD21	489643Ab1	caesarean Dams	5	5	5.0
1	21	GD21	489731Ab1	fetuses	5	5	5.0
1	22	GD21	489644Ab1	caesarean Dams	5	5	5.0

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Group	Animal number	Interval/ Occasion	Barcode number	Study Phase	T1A	T1B	Geometric Mean Titer
1	22	GD21	489732Ab1	fetuses	5	5	5.0
CCI							

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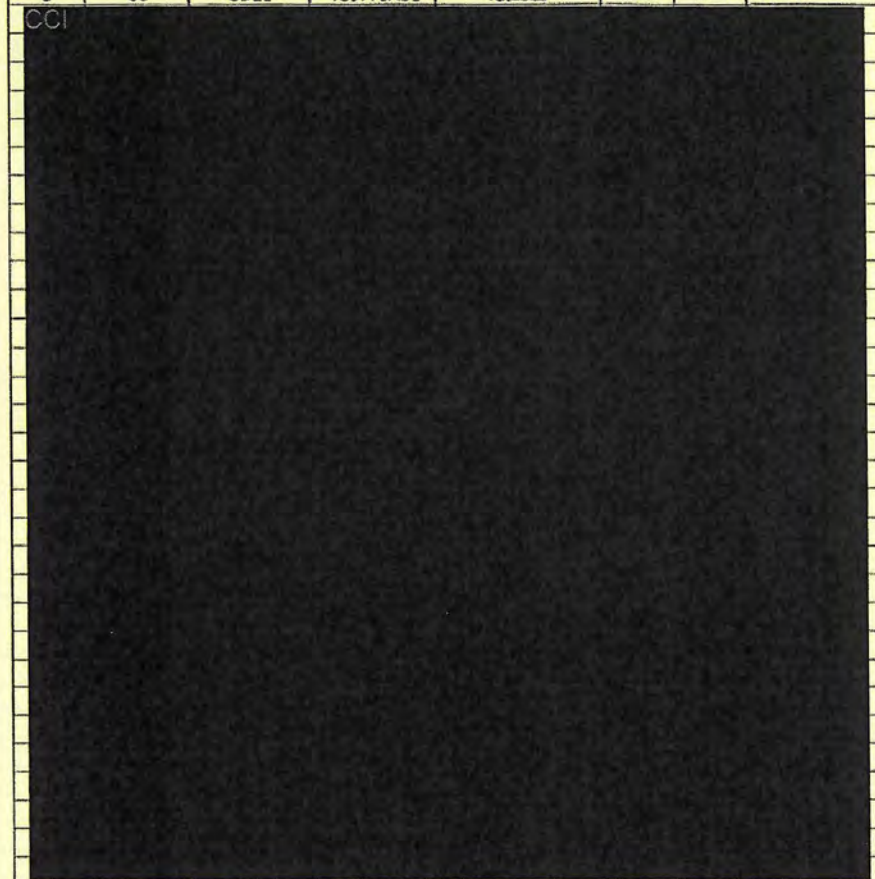
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Group	Animal number	Interval/ Occasion	Barcode number	Study Phase	T1A	T1B	Geometric Mean Titer
CCI							
3	45	GD21	489667Ab1	caesarean Dams	5120	5120	5120.0
3	45	GD21	489755Ab1	fetuses	320	640	452.5
3	46	GD21	489668Ab1	caesarean Dams	5120	2560	3620.4
3	46	GD21	489756Ab1	fetuses	640	320	452.5
3	47	GD21	489669Ab1	caesarean Dams	2560	2560	2560.0
3	47	GD21	489757Ab1	fetuses	1280	640	905.1
3	48	GD21	489670Ab1	caesarean Dams	5120	5120	5120.0
3	48	GD21	489758Ab1	fetuses	1280	1280	1280.0
3	49	GD21	489671Ab1	caesarean Dams	5120	2560	3620.4
3	49	GD21	489759Ab1	fetuses	640	640	640.0
3	50	GD21	489672Ab1	caesarean Dams	2560	5120	3620.4
3	50	GD21	489760Ab1	fetuses	640	640	640.0
3	51	GD21	489673Ab1	caesarean Dams	5120	5120	5120.0
3	51	GD21	489761Ab1	fetuses	640	1280	905.1
3	52	GD21	489674Ab1	caesarean Dams	5120	5120	5120.0
3	52	GD21	489762Ab1	fetuses	640	640	640.0
3	53	GD21	489675Ab1	caesarean Dams	1280	1280	1280.0
3	53	GD21	489763Ab1	fetuses	640	1280	905.1
3	54	GD21	489676Ab1	caesarean Dams	5120	5120	5120.0
3	54	GD21	489764Ab1	fetuses	640	640	640.0
3	55	GD21	489677Ab1	caesarean Dams	5120	5120	5120.0
3	55	GD21	489765Ab1	fetuses	1280	1280	1280.0
3	56 (*)	GD21	489678Ab1	caesarean Dams	5120	5120	5120.0
3	57	GD21	489679Ab1	caesarean Dams	5120	5120	5120.0
3	57	GD21	489767Ab1	fetuses	1280	640	905.1
3	58	GD21	489680Ab1	caesarean Dams	5120	5120	5120.0
3	58	GD21	489768Ab1	fetuses	1280	1280	1280.0
3	59	GD21	489681Ab1	caesarean Dams	5120	5120	5120.0
3	59	GD21	489769Ab1	fetuses	640	640	640.0
3	60	GD21	489682Ab1	caesarean Dams	5120	5120	5120.0
3	60	GD21	489770Ab1	fetuses	640	1280	905.1
3	61	GD21	489683Ab1	caesarean Dams	640	640	640.0
3	61	GD21	489771Ab1	fetuses	160	160	160.0
3	62	GD21	489684Ab1	caesarean Dams	2560	2560	2560.0
3	62	GD21	489772Ab1	fetuses	320	320	320.0



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Group	Animal number	Interval/ Occasion	Barcode number	Study Phase	T1A	T1B	Geometric Mean Titer
3	63	GD21	489685Ab1	caesarean Dams	2560	2560	2560.0
3	63	GD21	489773Ab1	fetuses	320	640	452.5
3	64	GD21	489686Ab1	caesarean Dams	1280	2560	1810.2
3	64	GD21	489774Ab1	fetuses	320	160	226.3
3	65	GD21	489687Ab1	caesarean Dams	2560	5120	3620.4
3	65	GD21	489775Ab1	fetuses	640	640	640.0
3	66	GD21	489688Ab1	caesarean Dams	5120	2560	3620.4
3	66	GD21	489776Ab1	fetuses	1280	640	905.1



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Group	Animal number	Interval/ Occasion	Barcode number	Study Phase	T1A	T1B	Geometric Mean Titer
CCI							
1	201	LD21	489799Ab1	Littering Dams	5	5	5.0
1	201	PND21	489441Ab1	pups	5	5	5.0
1	202	LD21	489800Ab1	Littering Dams	5	5	5.0
1	202	PND21	489442Ab1	pups	5	5	5.0
1	203	LD21	489801Ab1	Littering Dams	5	5	5.0
1	203	PND21	489443Ab1	pups	5	5	5.0
1	204	LD21	489802Ab1	Littering Dams	5	5	5.0
1	204	PND21	489444Ab1	pups	5	5	5.0
1	205	LD21	489803Ab1	Littering Dams	5	5	5.0
1	205	PND21	489445Ab1	pups	5	5	5.0
1	206	LD21	489804Ab1	Littering Dams	5	5	5.0
1	206	PND21	489446Ab1	pups	5	5	5.0
1	207	LD21	489805Ab1	Littering Dams	5	5	5.0
1	207	PND21	489447Ab1	pups	5	5	5.0
1	208	LD21	489806Ab1	Littering Dams	5	5	5.0
1	208	PND21	489448Ab1	pups	5	5	5.0
1	209	LD21	489807Ab1	Littering Dams	5	5	5.0
1	209	PND21	489449Ab1	pups	5	5	5.0
1	210	LD21	489808Ab1	Littering Dams	5	5	5.0
1	210	PND21	489450Ab1	pups	5	5	5.0
1	211	LD21	489809Ab1	Littering Dams	5	5	5.0
1	211	PND21	489451Ab1	pups	5	5	5.0
1	212	LD21	489810Ab1	Littering Dams	5	5	5.0
1	212	PND21	489452Ab1	pups	5	5	5.0
1	213	LD21	489811Ab1	Littering Dams	5	5	5.0
1	213	PND21	489453Ab1	pups	5	5	5.0

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Group	Animal number	Interval/ Occasion	Barcode number	Study Phase	T1A	T1B	Geometric Mean Titer
1	214	LD21	489812Ab1	Littering Dams	5	5	5.0
1	214	PND21	489454Ab1	pups	5	5	5.0
1	215	LD21	489813Ab1	Littering Dams	5	5	5.0
1	215	PND21	489455Ab1	pups	5	5	5.0
1	216	LD21	489814Ab1	Littering Dams	5	5	5.0
1	216	PND21	489456Ab1	pups	5	5	5.0
1	217	LD21	489815Ab1	Littering Dams	5	5	5.0
1	217	PND21	489457Ab1	pups	5	5	5.0
1	218	LD21	489816Ab1	Littering Dams	5	5	5.0
1	218	PND21	489458Ab1	pups	5	5	5.0
1	219	LD21	489817Ab1	Littering Dams	5	5	5.0
1	219	PND21	489459Ab1	pups	5	5	5.0
1	220	LD21	489818Ab1	Littering Dams	5	5	5.0
1	220	PND21	489460Ab1	pups	5	5	5.0
1	221	LD21	489819Ab1	Littering Dams	5	5	5.0
1	221	PND21	489461Ab1	pups	5	5	5.0
1	222	LD21	489820Ab1	Littering Dams	5	5	5.0
1	222	PND21	489462Ab1	pups	5	5	5.0
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Group	Animal number	Interval/ Occasion	Barcode number	Study Phase	T1A	T1B	Geometric Mean Titer
CCI							
3	245	LD21	489843Ab1	Littering Dams	5120	5120	5120.0
3	245	PND21	489485Ab1	pups	5120	5120	5120.0
3	246	LD21	489844Ab1	Littering Dams	5120	5120	5120.0
3	246	PND21	489486Ab1	pups	5120	5120	5120.0
3	247	LD21	489845Ab1	Littering Dams	640	640	640.0
3	247	PND21	489487Ab1	pups	2560	5120	3620.4
3	248	LD21	489846Ab1	Littering Dams	5120	5120	5120.0
3	248	PND21	489488Ab1	pups	5120	5120	5120.0
3	249	LD21	489847Ab1	Littering Dams	5120	5120	5120.0
3	249	PND21	489489Ab1	pups	5120	5120	5120.0
3	250	LD21	489848Ab1	Littering Dams	5120	5120	5120.0
3	250	PND21	489490Ab1	pups	5120	5120	5120.0
3	251	LD21	489849Ab1	Littering Dams	5120	5120	5120.0
3	251	PND21	489491Ab1	pups	5120	5120	5120.0
3	252	LD21	489850Ab1	Littering Dams	5120	5120	5120.0
3	252	PND21	489492Ab1	pups	5120	5120	5120.0
3	253	LD21	489851Ab1	Littering Dams	160	320	226.3
3	253	PND21	489493Ab1	pups	640	640	640.0

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Group	Animal number	Interval/ Occasion	Barcode number	Study Phase	T1A	T1B	Geometric Mean Titer
3	254 (*)	NEC	489534Ab1	Littering Dams	5120	5120	5120.0
3	255	LD21	489853Ab1	Littering Dams	5120	5120	5120.0
3	255	PND21	489495Ab1	pups	5120	5120	5120.0
3	256	LD21	489854Ab1	Littering Dams	1280	2560	1810.2
3	256	PND21	489496Ab1	pups	5120	5120	5120.0
3	257	LD21	489855Ab1	Littering Dams	5120	5120	5120.0
3	257	PND21	489497Ab1	pups	5120	5120	5120.0
3	258	LD21	489856Ab1	Littering Dams	5120	5120	5120.0
3	258	PND21	489498Ab1	pups	5120	5120	5120.0
3	259	LD21	489857Ab1	Littering Dams	5120	5120	5120.0
3	259	PND21	489499Ab1	pups	5120	5120	5120.0
3	260	LD21	489858Ab1	Littering Dams	5120	5120	5120.0
3	260	PND21	489500Ab1	pups	5120	5120	5120.0
3	261	LD21	489859Ab1	Littering Dams	5120	5120	5120.0
3	261	PND21	489501Ab1	pups	5120	5120	5120.0
3	262	LD21	489860Ab1	Littering Dams	2560	2560	2560.0
3	262	PND21	489502Ab1	pups	5120	5120	5120.0
3	263	LD21	489861Ab1	Littering Dams	5120	5120	5120.0
3	263	PND21	489503Ab1	pups	5120	5120	5120.0
3	264	LD21	489862Ab1	Littering Dams	5120	5120	5120.0
3	264	PND21	489504Ab1	pups	5120	5120	5120.0
3	265	LD21	489863Ab1	Littering Dams	5120	5120	5120.0
3	265	PND21	489505Ab1	pups	5120	5120	5120.0
3	266	LD21	489864Ab1	Littering Dams	5120	2560	3620.4
3	266	PND21	489506Ab1	pups	5120	5120	5120.0



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Group	Animal number	Interval/ Occasion	Barcode number	Study Phase	T1A	T1B	Geometric Mean Titer
CCI							

The results of samples marked with (*) have been excluded from the calculation of GMT shown in table at paragraph 6. RESULTS AND CONCLUSIONS, for following reasons:

- Animal-Occasion 20-GD21, 39-GD21, 56-GD21, 226-NEC and 254-NEC samples data excluded as animal "Not pregnant"
- Animal-Occasion 236-NEC and 279-NEC samples data excluded as animal "Euthanized due to total litter death"
- Animal-Occasion 43-NEC sample data excluded as animal "Not mated"
- Animal-Occasion 276-LD1 sample data excluded as animal "Euthanized due to clinical signs on LD1/PND1"
- Animal-Occasion 277-NEC sample data excluded as animal "Mistimed pregnancy"

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Individual Maternal Macroscopic Observations

20256434

Animal Ref.: 201 Group: 1 Sex: Female Species: Rat Strain: Wistar: Crl: WI (Han)
Test Material: See Protocol Dose: Control 0mcg Route: Intramuscular Study Type: Reproduction
Date of Death : 03OCT2020 Study Day No. (Week): 69 (10) Mode of Death: TERMINAL SACRIFICE
Date of Necropsy: 03OCT2020 ** NECROPSY COMPLETE **

Terminal Body Weight: None

Gross Pathology Observations: None

Probable cause of death: None

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Individual Maternal Macroscopic Observations

20256434

Animal Ref.: 202 Group: 1 Sex: Female Species: Rat Strain: Wistar: Crl: WI (Han)
Test Material: See Protocol Dose: Control 0mcg Route: Intramuscular Study Type: Reproduction
Date of Death : 02OCT2020 Study Day No. (Week): 68 (10) Mode of Death: TERMINAL SACRIFICE
Date of Necropsy: 02OCT2020 ** NECROPSY COMPLETE **

Terminal Body Weight: None

Gross Pathology Observations:

Correlated with:

NO CORRELATE;

No correlate Malocclusion (C)

Probable cause of death: None

Codes Used: (C) = Clinical Observation

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Individual Maternal Macroscopic Observations

20256434

Animal Ref.: 203 Group: 1 Sex: Female Species: Rat Strain: Wistar: Crl: WI (Han)
Test Material: See Protocol Dose: Control 0mcg Route: Intramuscular Study Type: Reproduction
Date of Death : 02OCT2020 Study Day No. (Week): 68 (10) Mode of Death: TERMINAL SACRIFICE
Date of Necropsy: 02OCT2020 ** NECROPSY COMPLETE **

Terminal Body Weight: None

Gross Pathology Observations: None

Probable cause of death: None

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Individual Maternal Macroscopic Observations

20256434

Animal Ref.: 204 Group: 1 Sex: Female Species: Rat Strain: Wistar: Crl: WI (Han)
Test Material: See Protocol Dose: Control 0mcg Route: Intramuscular Study Type: Reproduction
Date of Death : 01OCT2020 Study Day No. (Week): 67 (10) Mode of Death: TERMINAL SACRIFICE
Date of Necropsy: 01OCT2020 ** NECROPSY COMPLETE **

Terminal Body Weight: None

Gross Pathology Observations:

Correlated with:

NO CORRELATE;

No correlate Localised hairloss; Left forelimb (C)

Probable cause of death: None

Codes Used: (C) = Clinical Observation

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Individual Maternal Macroscopic Observations

20256434

Animal Ref.: 205 Group: 1 Sex: Female Species: Rat Strain: Wistar: Crl: WI (Han)
Test Material: See Protocol Dose: Control 0mcg Route: Intramuscular Study Type: Reproduction
Date of Death : 02OCT2020 Study Day No. (Week): 68 (10) Mode of Death: TERMINAL SACRIFICE
Date of Necropsy: 02OCT2020 ** NECROPSY COMPLETE **

Terminal Body Weight: None

Gross Pathology Observations: None

Probable cause of death: None

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Individual Maternal Macroscopic Observations

20256434

Animal Ref.: 206 Group: 1 Sex: Female Species: Rat Strain: Wistar: Crl: WI (Han)
Test Material: See Protocol Dose: Control Omcg Route: Intramuscular Study Type: Reproduction
Date of Death : 01OCT2020 Study Day No. (Week): 67 (10) Mode of Death: TERMINAL SACRIFICE
Date of Necropsy: 01OCT2020 ** NECROPSY COMPLETE **

Terminal Body Weight: None

Gross Pathology Observations: None

Probable cause of death: None

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Individual Maternal Macroscopic Observations

20256434

Animal Ref.: 207 Group: 1 Sex: Female Species: Rat Strain: Wistar: Crl: WI (Han)
Test Material: See Protocol Dose: Control 0mcg Route: Intramuscular Study Type: Reproduction
Date of Death : 01OCT2020 Study Day No. (Week): 67 (10) Mode of Death: TERMINAL SACRIFICE
Date of Necropsy: 01OCT2020 ** NECROPSY COMPLETE **

Terminal Body Weight: None

Gross Pathology Observations: None

Probable cause of death: None

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Individual Maternal Macroscopic Observations

20256434

Animal Ref.: 208 Group: 1 Sex: Female Species: Rat Strain: Wistar: Crl: WI (Han)
Test Material: See Protocol Dose: Control 0mcg Route: Intramuscular Study Type: Reproduction
Date of Death : 30SEP2020 Study Day No. (Week): 66 (10) Mode of Death: TERMINAL SACRIFICE
Date of Necropsy: 30SEP2020 ** NECROPSY COMPLETE **

Terminal Body Weight: None

Gross Pathology Observations: None

Probable cause of death: None

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Individual Maternal Macroscopic Observations

20256434

Animal Ref.: 209 Group: 1 Sex: Female Species: Rat Strain: Wistar: Crl: WI (Han)
Test Material: See Protocol Dose: Control 0mcg Route: Intramuscular Study Type: Reproduction
Date of Death : 30SEP2020 Study Day No. (Week): 66 (10) Mode of Death: TERMINAL SACRIFICE
Date of Necropsy: 30SEP2020 ** NECROPSY COMPLETE **

Terminal Body Weight: None

Gross Pathology Observations: None

Probable cause of death: None

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Individual Maternal Macroscopic Observations

20256434

Animal Ref.: 210 Group: 1 Sex: Female Species: Rat Strain: Wistar: Crl: WI (Han)
Test Material: See Protocol Dose: Control 0mcg Route: Intramuscular Study Type: Reproduction
Date of Death : 01OCT2020 Study Day No. (Week): 67 (10) Mode of Death: TERMINAL SACRIFICE
Date of Necropsy: 01OCT2020 ** NECROPSY COMPLETE **

Terminal Body Weight: None

Gross Pathology Observations: None

Probable cause of death: None

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Individual Maternal Macroscopic Observations

20256434

Animal Ref.: 211 Group: 1 Sex: Female Species: Rat Strain: Wistar: Crl: WI (Han)
Test Material: See Protocol Dose: Control 0mcg Route: Intramuscular Study Type: Reproduction
Date of Death : 30SEP2020 Study Day No. (Week): 66 (10) Mode of Death: TERMINAL SACRIFICE
Date of Necropsy: 30SEP2020 ** NECROPSY COMPLETE **

Terminal Body Weight: None

Gross Pathology Observations: None

Probable cause of death: None

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Individual Maternal Macroscopic Observations

20256434

Animal Ref.: 212 Group: 1 Sex: Female Species: Rat Strain: Wistar: Crl: WI (Han)
Test Material: See Protocol Dose: Control 0mcg Route: Intramuscular Study Type: Reproduction
Date of Death : 01OCT2020 Study Day No. (Week): 67 (10) Mode of Death: TERMINAL SACRIFICE
Date of Necropsy: 01OCT2020 ** NECROPSY COMPLETE **

Terminal Body Weight: None

Gross Pathology Observations: None

Probable cause of death: None

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Individual Maternal Macroscopic Observations

20256434

Animal Ref.: 213 Group: 1 Sex: Female Species: Rat Strain: Wistar: Crl: WI (Han)
Test Material: See Protocol Dose: Control 0mcg Route: Intramuscular Study Type: Reproduction
Date of Death : 03OCT2020 Study Day No. (Week): 69 (10) Mode of Death: TERMINAL SACRIFICE
Date of Necropsy: 03OCT2020 ** NECROPSY COMPLETE **

Terminal Body Weight: None

Gross Pathology Observations: None

Probable cause of death: None

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Individual Maternal Macroscopic Observations

20256434

Animal Ref.: 214 Group: 1 Sex: Female Species: Rat Strain: Wistar: Crl: WI (Han)
Test Material: See Protocol Dose: Control 0mcg Route: Intramuscular Study Type: Reproduction
Date of Death : 30SEP2020 Study Day No. (Week): 66 (10) Mode of Death: TERMINAL SACRIFICE
Date of Necropsy: 30SEP2020 ** NECROPSY COMPLETE **

Terminal Body Weight: None

Gross Pathology Observations:

Correlated with:

NO CORRELATE;

No correlate Localised hairloss; Left and right forelimbs (C)

Probable cause of death: None

Codes Used: (C) = Clinical Observation

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Individual Maternal Macroscopic Observations

20256434

Animal Ref.: 215 Group: 1 Sex: Female Species: Rat Strain: Wistar: Crl: WI (Han)
Test Material: See Protocol Dose: Control 0mcg Route: Intramuscular Study Type: Reproduction
Date of Death : 30SEP2020 Study Day No. (Week): 66 (10) Mode of Death: TERMINAL SACRIFICE
Date of Necropsy: 30SEP2020 ** NECROPSY COMPLETE **

Terminal Body Weight: None

Gross Pathology Observations:

Correlated with:

NO CORRELATE;

No correlate Localised hairloss; Left and right forelimbs (C)
Nodule(s).; Nose (C)

Probable cause of death: None

Codes Used: (C) = Clinical Observation

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Individual Maternal Macroscopic Observations

20256434

Animal Ref.: 216 Group: 1 Sex: Female Species: Rat Strain: Wistar: Crl: WI (Han)

Test Material: See Protocol Dose: Control 0mcg Route: Intramuscular Study Type: Reproduction
Date of Death : 03OCT2020 Study Day No. (Week): 69 (10) Mode of Death: TERMINAL SACRIFICE
Date of Necropsy: 03OCT2020 ** NECROPSY COMPLETE **

Terminal Body Weight: None

Gross Pathology Observations: None

Probable cause of death: None

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Individual Maternal Macroscopic Observations

20256434

Animal Ref.: 217 Group: 1 Sex: Female Species: Rat Strain: Wistar: Crl: WI (Han)
Test Material: See Protocol Dose: Control 0mcg Route: Intramuscular Study Type: Reproduction
Date of Death : 03OCT2020 Study Day No. (Week): 69 (10) Mode of Death: TERMINAL SACRIFICE
Date of Necropsy: 03OCT2020 ** NECROPSY COMPLETE **

Terminal Body Weight: None

Gross Pathology Observations: None

Probable cause of death: None

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Individual Maternal Macroscopic Observations

20256434

Animal Ref.: 218 Group: 1 Sex: Female Species: Rat Strain: Wistar: Crl: WI (Han)
Test Material: See Protocol Dose: Control 0mcg Route: Intramuscular Study Type: Reproduction
Date of Death : 01OCT2020 Study Day No. (Week): 67 (10) Mode of Death: TERMINAL SACRIFICE
Date of Necropsy: 01OCT2020 ** NECROPSY COMPLETE **

Terminal Body Weight: None

Gross Pathology Observations: None

Probable cause of death: None

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Individual Maternal Macroscopic Observations

20256434

Animal Ref.: 219 Group: 1 Sex: Female Species: Rat Strain: Wistar: Crl: WI (Han)
Test Material: See Protocol Dose: Control 0mcg Route: Intramuscular Study Type: Reproduction
Date of Death : 01OCT2020 Study Day No. (Week): 67 (10) Mode of Death: TERMINAL SACRIFICE
Date of Necropsy: 01OCT2020 ** NECROPSY COMPLETE **

Terminal Body Weight: None

Gross Pathology Observations: None

Probable cause of death: None

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Individual Maternal Macroscopic Observations

20256434

Animal Ref.: 220 Group: 1 Sex: Female Species: Rat Strain: Wistar: Crl: WI (Han)
Test Material: See Protocol Dose: Control 0mcg Route: Intramuscular Study Type: Reproduction
Date of Death : 01OCT2020 Study Day No. (Week): 67 (10) Mode of Death: TERMINAL SACRIFICE
Date of Necropsy: 01OCT2020 ** NECROPSY COMPLETE **

Terminal Body Weight: None

Gross Pathology Observations:

Correlated with:

NO CORRELATE;

No correlate

Localised hairloss; Thorax (C)

Localised hairloss; Left and right forelimbs (C)

Probable cause of death: None

Codes Used: (C) = Clinical Observation

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Individual Maternal Macroscopic Observations

20256434

Animal Ref.: 221 Group: 1 Sex: Female Species: Rat Strain: Wistar: Crl: WI (Han)
Test Material: See Protocol Dose: Control 0mcg Route: Intramuscular Study Type: Reproduction
Date of Death : 03OCT2020 Study Day No. (Week): 69 (10) Mode of Death: TERMINAL SACRIFICE
Date of Necropsy: 03OCT2020 ** NECROPSY COMPLETE **

Terminal Body Weight: None

Gross Pathology Observations:

Correlated with:

SKIN/SUBCUTIS;

Sore/crust; hindlimb; single; left (TGL)	Scab(s).; Left hindlimb (C)
Sore/crust; abdominal region; single (TGL)	Scab(s).; Clipped area (C)
Sore/crust; abdominal region; single (TGL)	Scab(s).; Abdomen (C)
	Sore(s); Abdomen; Slight (C)

Probable cause of death: None

Codes Used: (TGL) = Trackable Gross Lesion, (C) = Clinical Observation

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Individual Maternal Macroscopic Observations

20256434

Animal Ref.: 222 Group: 1 Sex: Female Species: Rat Strain: Wistar: Crl: WI (Han)
Test Material: See Protocol Dose: Control Omcg Route: Intramuscular Study Type: Reproduction
Date of Death : 02OCT2020 Study Day No. (Week): 68 (10) Mode of Death: TERMINAL SACRIFICE
Date of Necropsy: 02OCT2020 ** NECROPSY COMPLETE **

Terminal Body Weight: None

Gross Pathology Observations:

Correlated with:

NO CORRELATE;

No correlate Localised hairloss; Whole body (C)

Probable cause of death: None

Codes Used: (C) = Clinical Observation

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Individual Maternal Macroscopic Observations

20256434

Animal Ref.: 1 Group: 1 Sex: Female Species: Rat Strain: Wistar: Crl: WI (Han)
Test Material: See Protocol Dose: Control 0mcg Route: Intramuscular Study Type: Reproduction
Date of Death : 25SEP2020 Study Day No. (Week): 47 (7) Mode of Death: TERMINAL SACRIFICE
Date of Necropsy: 25SEP2020 ** NECROPSY COMPLETE **

Terminal Body Weight: None

Organ Weights:

NECROPSY BODYWEIGHT : 331.3g GRAVID UTERUS : 79.3g

Gross Pathology Observations: None

Probable cause of death: None

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Individual Maternal Macroscopic Observations

20256434

Animal Ref.: 2 Group: 1 Sex: Female Species: Rat Strain: Wistar: Crl: WI (Han)
Test Material: See Protocol Dose: Control 0mcg Route: Intramuscular Study Type: Reproduction
Date of Death : 24SEP2020 Study Day No. (Week): 46 (7) Mode of Death: TERMINAL SACRIFICE
Date of Necropsy: 24SEP2020 ** NECROPSY COMPLETE **

Terminal Body Weight: None

Organ Weights:

NECROPSY BODYWEIGHT : 353.0g GRAVID UTERUS : 94.8g

Gross Pathology Observations:

Correlated with:

NO CORRELATE;

No correlate Localised hairloss; Left and right forelimbs (C)

Probable cause of death: None

Codes Used: (C) = Clinical Observation

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Individual Maternal Macroscopic Observations

20256434

Animal Ref.: 3 Group: 1 Sex: Female Species: Rat Strain: Wistar: Crl: WI (Han)
Test Material: See Protocol Dose: Control 0mcg Route: Intramuscular Study Type: Reproduction
Date of Death : 25SEP2020 Study Day No. (Week): 47 (7) Mode of Death: TERMINAL SACRIFICE
Date of Necropsy: 25SEP2020 ** NECROPSY COMPLETE **

Terminal Body Weight: None

Organ Weights:

NECROPSY BODYWEIGHT : 372.5g GRAVID UTERUS : 98.7g

Gross Pathology Observations: None

Probable cause of death: None

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Individual Maternal Macroscopic Observations

20256434

Animal Ref.: 4 Group: 1 Sex: Female Species: Rat Strain: Wistar: Crl: WI (Han)
Test Material: See Protocol Dose: Control 0mcg Route: Intramuscular Study Type: Reproduction
Date of Death : 23SEP2020 Study Day No. (Week): 45 (7) Mode of Death: TERMINAL SACRIFICE
Date of Necropsy: 23SEP2020 ** NECROPSY COMPLETE **

Terminal Body Weight: None

Organ Weights:

NECROPSY BODYWEIGHT : 367.1g GRAVID UTERUS : 86.5g

Gross Pathology Observations: None

Probable cause of death: None

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Individual Maternal Macroscopic Observations

20256434

Animal Ref.: 5 Group: 1 Sex: Female Species: Rat Strain: Wistar: Crl: WI (Han)
Test Material: See Protocol Dose: Control 0mcg Route: Intramuscular Study Type: Reproduction
Date of Death : 22SEP2020 Study Day No. (Week): 44 (7) Mode of Death: TERMINAL SACRIFICE
Date of Necropsy: 22SEP2020 ** NECROPSY COMPLETE **

Terminal Body Weight: None

Organ Weights:

NECROPSY BODYWEIGHT : 340.0g GRAVID UTERUS : 85.4g

Gross Pathology Observations: None

Probable cause of death: None

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Individual Maternal Macroscopic Observations

20256434

Animal Ref.: 6 Group: 1 Sex: Female Species: Rat Strain: Wistar: Crl: WI (Han)
Test Material: See Protocol Dose: Control Omcg Route: Intramuscular Study Type: Reproduction
Date of Death : 25SEP2020 Study Day No. (Week): 47 (7) Mode of Death: TERMINAL SACRIFICE
Date of Necropsy: 25SEP2020 ** NECROPSY COMPLETE **

Terminal Body Weight: None

Organ Weights:

NECROPSY BODYWEIGHT : 372.6g GRAVID UTERUS : 69.4g

Gross Pathology Observations: None

Probable cause of death: None

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Individual Maternal Macroscopic Observations

20256434

Animal Ref.: 7 Group: 1 Sex: Female Species: Rat Strain: Wistar: Crl: WI (Han)
Test Material: See Protocol Dose: Control 0mcg Route: Intramuscular Study Type: Reproduction
Date of Death : 23SEP2020 Study Day No. (Week): 45 (7) Mode of Death: TERMINAL SACRIFICE
Date of Necropsy: 23SEP2020 ** NECROPSY COMPLETE **

Terminal Body Weight: None

Organ Weights:

NECROPSY BODYWEIGHT : 401.1g GRAVID UTERUS : 93.5g

Gross Pathology Observations:

Correlated with:

SKIN/SUBCUTIS;

Alopecia; forelimb; single; left (TGL) Localised hairloss; Left forelimb (C)

Any remaining protocol required tissues, which have been examined, have no visible lesions

Probable cause of death: None

Codes Used: (TGL) = Trackable Gross Lesion, (C) = Clinical Observation

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Individual Maternal Macroscopic Observations

20256434

Animal Ref.: 8 Group: 1 Sex: Female Species: Rat Strain: Wistar: Crl: WI (Han)
Test Material: See Protocol Dose: Control 0mcg Route: Intramuscular Study Type: Reproduction
Date of Death : 24SEP2020 Study Day No. (Week): 46 (7) Mode of Death: TERMINAL SACRIFICE
Date of Necropsy: 24SEP2020 ** NECROPSY COMPLETE **

Terminal Body Weight: None

Organ Weights:

NECROPSY BODYWEIGHT : 365.0g GRAVID UTERUS : 79.0g

Gross Pathology Observations: None

Probable cause of death: None

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Individual Maternal Macroscopic Observations

20256434

Animal Ref.: 9 Group: 1 Sex: Female Species: Rat Strain: Wistar: Crl: WI (Han)
Test Material: See Protocol Dose: Control 0mcg Route: Intramuscular Study Type: Reproduction
Date of Death : 25SEP2020 Study Day No. (Week): 47 (7) Mode of Death: TERMINAL SACRIFICE
Date of Necropsy: 25SEP2020 ** NECROPSY COMPLETE **

Terminal Body Weight: None

Organ Weights:

NECROPSY BODYWEIGHT : 371.2g GRAVID UTERUS : 89.3g

Gross Pathology Observations: None

Probable cause of death: None

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Individual Maternal Macroscopic Observations

20256434

Animal Ref.: 10 Group: 1 Sex: Female Species: Rat Strain: Wistar: Crl: WI (Han)
Test Material: See Protocol Dose: Control 0mcg Route: Intramuscular Study Type: Reproduction
Date of Death : 23SEP2020 Study Day No. (Week): 45 (7) Mode of Death: TERMINAL SACRIFICE
Date of Necropsy: 23SEP2020 ** NECROPSY COMPLETE **

Terminal Body Weight: None

Organ Weights:

NECROPSY BODYWEIGHT : 353.4g GRAVID UTERUS : 78.6g

Gross Pathology Observations:

LIVER;

Hernia; between right and left median lobes; diaphragm (TGL)

Any remaining protocol required tissues, which have been examined, have no visible lesions

Probable cause of death: None

Codes Used: (TGL) = Trackable Gross Lesion

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Individual Maternal Macroscopic Observations

20256434

Animal Ref.: 11 Group: 1 Sex: Female Species: Rat Strain: Wistar: Crl: WI (Han)
Test Material: See Protocol Dose: Control 0mcg Route: Intramuscular Study Type: Reproduction
Date of Death : 25SEP2020 Study Day No. (Week): 47 (7) Mode of Death: TERMINAL SACRIFICE
Date of Necropsy: 25SEP2020 ** NECROPSY COMPLETE **

Terminal Body Weight: None

Organ Weights:

NECROPSY BODYWEIGHT : 360.9g GRAVID UTERUS : 80.7g

Gross Pathology Observations: None

Probable cause of death: None

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Individual Maternal Macroscopic Observations

20256434

Animal Ref.: 12 Group: 1 Sex: Female Species: Rat Strain: Wistar: Crl: WI (Han)
Test Material: See Protocol Dose: Control 0mcg Route: Intramuscular Study Type: Reproduction
Date of Death : 24SEP2020 Study Day No. (Week): 46 (7) Mode of Death: TERMINAL SACRIFICE
Date of Necropsy: 24SEP2020 ** NECROPSY COMPLETE **

Terminal Body Weight: None

Organ Weights:

NECROPSY BODYWEIGHT : 361.1g GRAVID UTERUS : 85.1g

Gross Pathology Observations: None

Probable cause of death: None

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Individual Maternal Macroscopic Observations

20256434

Animal Ref.: 13 Group: 1 Sex: Female Species: Rat Strain: Wistar: Crl: WI (Han)
Test Material: See Protocol Dose: Control 0mcg Route: Intramuscular Study Type: Reproduction
Date of Death : 25SEP2020 Study Day No. (Week): 47 (7) Mode of Death: TERMINAL SACRIFICE
Date of Necropsy: 25SEP2020 ** NECROPSY COMPLETE **

Terminal Body Weight: None

Organ Weights:

NECROPSY BODYWEIGHT : 348.6g GRAVID UTERUS : 86.1g

Gross Pathology Observations:

Correlated with:

NO CORRELATE;

No correlate Localised hairloss; Left and right forelimbs (C)

Probable cause of death: None

Codes Used: (C) = Clinical Observation

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Individual Maternal Macroscopic Observations

20256434

Animal Ref.: 14 Group: 1 Sex: Female Species: Rat Strain: Wistar: Crl: WI (Han)
Test Material: See Protocol Dose: Control 0mcg Route: Intramuscular Study Type: Reproduction
Date of Death : 22SEP2020 Study Day No. (Week): 44 (7) Mode of Death: TERMINAL SACRIFICE
Date of Necropsy: 22SEP2020 ** NECROPSY COMPLETE **

Terminal Body Weight: None

Organ Weights:

NECROPSY BODYWEIGHT : 346.1g GRAVID UTERUS : 84.4g

Gross Pathology Observations: None

Probable cause of death: None

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Individual Maternal Macroscopic Observations

20256434

Animal Ref.: 15 Group: 1 Sex: Female Species: Rat Strain: Wistar: Crl: WI (Han)
Test Material: See Protocol Dose: Control 0mcg Route: Intramuscular Study Type: Reproduction
Date of Death : 01OCT2020 Study Day No. (Week): 53 (8) Mode of Death: TERMINAL SACRIFICE
Date of Necropsy: 01OCT2020 ** NECROPSY COMPLETE **

Terminal Body Weight: None

Organ Weights:

NECROPSY BODYWEIGHT : 388.3g GRAVID UTERUS : 88.9g

Gross Pathology Observations: None

Probable cause of death: None

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Individual Maternal Macroscopic Observations

20256434

Animal Ref.: 16 Group: 1 Sex: Female Species: Rat Strain: Wistar: Crl: WI (Han)
Test Material: See Protocol Dose: Control 0mcg Route: Intramuscular Study Type: Reproduction
Date of Death : 22SEP2020 Study Day No. (Week): 44 (7) Mode of Death: TERMINAL SACRIFICE
Date of Necropsy: 22SEP2020 ** NECROPSY COMPLETE **

Terminal Body Weight: None

Organ Weights:

NECROPSY BODYWEIGHT : 348.6g GRAVID UTERUS : 81.9g

Gross Pathology Observations: None

Probable cause of death: None

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Individual Maternal Macroscopic Observations

20256434

Animal Ref.: 17 Group: 1 Sex: Female Species: Rat Strain: Wistar: Crl: WI (Han)

Test Material: See Protocol Dose: Control 0mcg Route: Intramuscular Study Type: Reproduction
Date of Death : 04OCT2020 Study Day No. (Week): 56 (8) Mode of Death: TERMINAL SACRIFICE
Date of Necropsy: 04OCT2020 ** NECROPSY COMPLETE **

Terminal Body Weight: None

Organ Weights:

NECROPSY BODYWEIGHT : 429.2g GRAVID UTERUS : 96.3g

Gross Pathology Observations: None

Probable cause of death: None

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Individual Maternal Macroscopic Observations

20256434

Animal Ref.: 18 Group: 1 Sex: Female Species: Rat Strain: Wistar: Crl: WI (Han)

Test Material: See Protocol Dose: Control 0mcg Route: Intramuscular Study Type: Reproduction
Date of Death : 25SEP2020 Study Day No. (Week): 47 (7) Mode of Death: TERMINAL SACRIFICE
Date of Necropsy: 25SEP2020 ** NECROPSY COMPLETE **

Terminal Body Weight: 398.9g

Organ Weights:

NECROPSY BODYWEIGHT : 398.9g GRAVID UTERUS : 95.6g

Gross Pathology Observations: None

Probable cause of death: None

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Individual Maternal Macroscopic Observations

20256434

Animal Ref.: 19 Group: 1 Sex: Female Species: Rat Strain: Wistar: Crl: WI (Han)
Test Material: See Protocol Dose: Control 0mcg Route: Intramuscular Study Type: Reproduction
Date of Death : 22SEP2020 Study Day No. (Week): 44 (7) Mode of Death: TERMINAL SACRIFICE
Date of Necropsy: 22SEP2020 ** NECROPSY COMPLETE **

Terminal Body Weight: None

Organ Weights:

NECROPSY BODYWEIGHT : 331.3g GRAVID UTERUS : 77.8g

Gross Pathology Observations:

LIVER;

Hernia; between right and left median lobes; diaphragm (TGL)

Any remaining protocol required tissues, which have been examined, have no visible lesions

Probable cause of death: None

Codes Used: (TGL) = Trackable Gross Lesion

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Individual Maternal Macroscopic Observations

20256434

Animal Ref.: 20 Group: 1 Sex: Female Species: Rat Strain: Wistar: Crl: WI (Han)
Test Material: See Protocol Dose: Control 0mcg Route: Intramuscular Study Type: Reproduction
Date of Death : 24SEP2020 Study Day No. (Week): 46 (7) Mode of Death: TERMINAL SACRIFICE
Date of Necropsy: 24SEP2020 ** NECROPSY COMPLETE **

Terminal Body Weight: None

Organ Weights:

NECROPSY BODYWEIGHT : 272.7g GRAVID UTERUS : NRQ

Gross Pathology Observations:

Correlated with:

NO CORRELATE;

No correlate Localised hairloss; Left and right forelimbs (C)

Probable cause of death: None

Codes Used: (C) = Clinical Observation, NRQ = Not required

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Individual Maternal Macroscopic Observations

20256434

Animal Ref.: 21 Group: 1 Sex: Female Species: Rat Strain: Wistar: Crl: WI (Han)
Test Material: See Protocol Dose: Control 0mcg Route: Intramuscular Study Type: Reproduction
Date of Death : 25SEP2020 Study Day No. (Week): 47 (7) Mode of Death: TERMINAL SACRIFICE
Date of Necropsy: 25SEP2020 ** NECROPSY COMPLETE **

Terminal Body Weight: None

Organ Weights:

NECROPSY BODYWEIGHT : 361.8g GRAVID UTERUS : 97.4g

Gross Pathology Observations: None

Probable cause of death: None

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Individual Maternal Macroscopic Observations

20256434

Animal Ref.: 22 Group: 1 Sex: Female Species: Rat Strain: Wistar: Crl: WI (Han)
Test Material: See Protocol Dose: Control 0mcg Route: Intramuscular Study Type: Reproduction
Date of Death : 24SEP2020 Study Day No. (Week): 46 (7) Mode of Death: TERMINAL SACRIFICE
Date of Necropsy: 24SEP2020 ** NECROPSY COMPLETE **

Terminal Body Weight: None

Organ Weights:

NECROPSY BODYWEIGHT : 394.8g GRAVID UTERUS : 84.1g

Gross Pathology Observations: None

Probable cause of death: None

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Individual Maternal Macroscopic Observations

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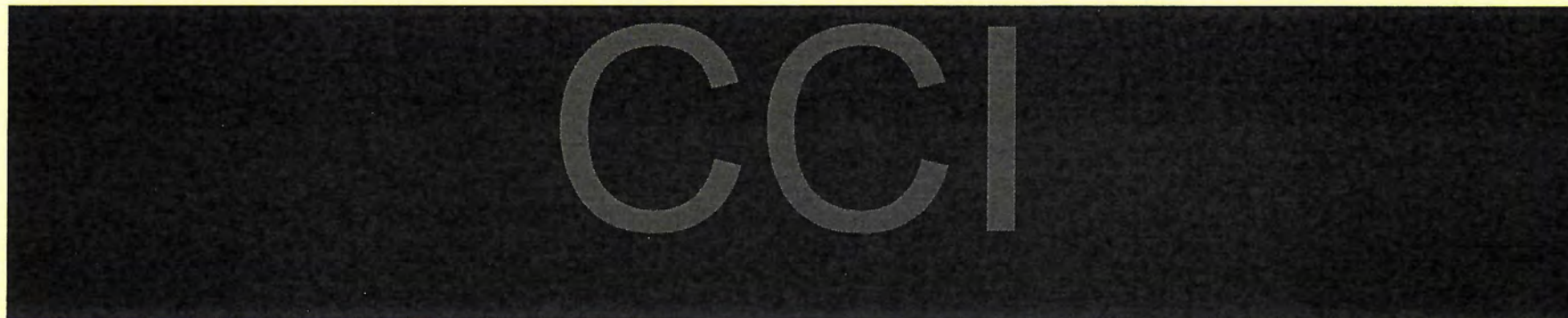
Animal Ref.: 223

Group: 2

Sex: Female

Species: Rat

Strain: Wistar: Crl: WI (Han)



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Individual Maternal Macroscopic Observations

20256434

Animal Ref.: 224

Group: 2

Sex: Female

Species: Rat

Strain: Wistar: Crl: WI (Han)



Codes Used: (C) = Clinical Observation

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Individual Maternal Macroscopic Observations

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Animal Ref.: 225

Group: 2

Sex: Female

Species: Rat

Strain: Wistar: Crl: WI (Han)



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Individual Maternal Macroscopic Observations

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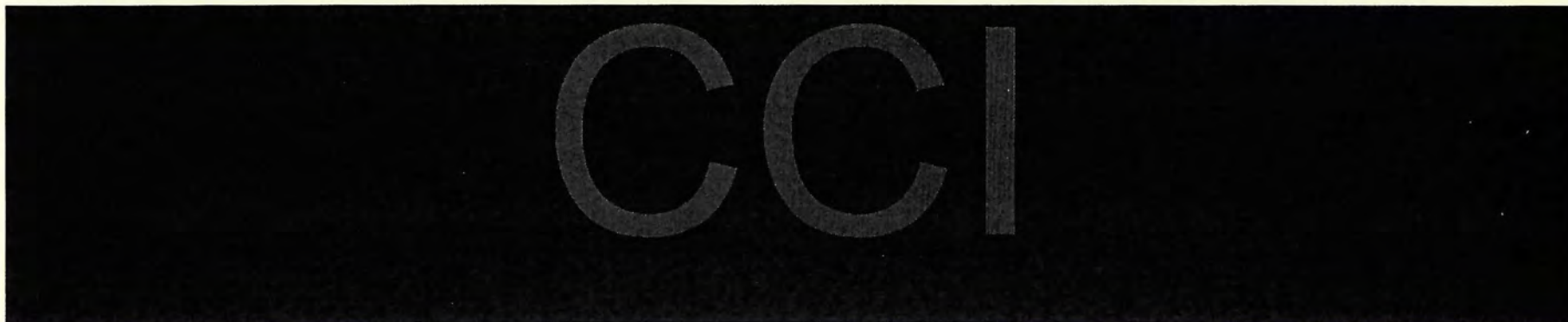
Animal Ref.: 226

Group: 2

Sex: Female

Species: Rat

Strain: Wistar: Crl: WI (Han)



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Individual Maternal Macroscopic Observations

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Animal Ref.: 227

Group: 2

Sex: Female

Species: Rat

Strain: Wistar: Crl: WI (Han)



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Individual Maternal Macroscopic Observations

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Animal Ref.: 228

Group: 2

Sex: Female

Species: Rat

Strain: Wistar: Crl: WI (Han)



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Individual Maternal Macroscopic Observations

20256434

Animal Ref.: 229

Group: 2

Sex: Female

Species: Rat

Strain: Wistar: Crl: WI (Han)



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Individual Maternal Macroscopic Observations

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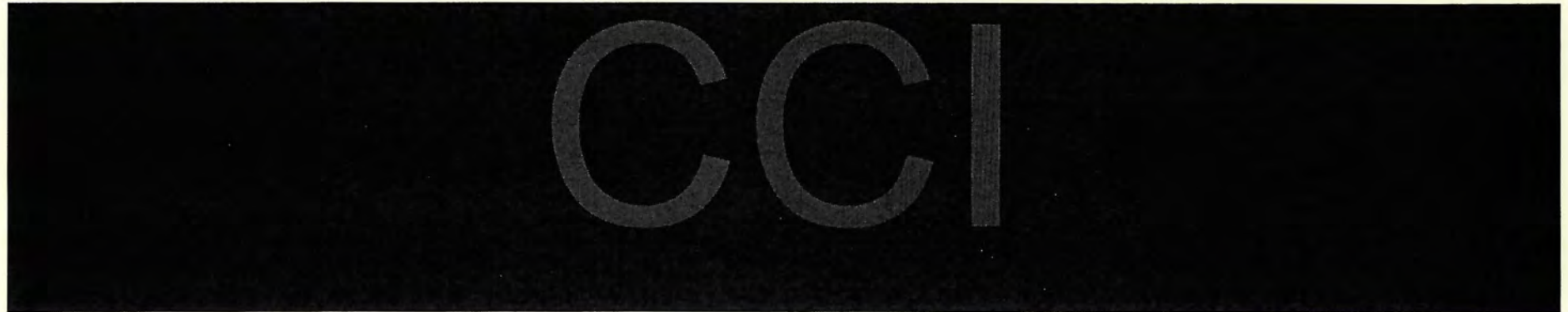
Animal Ref.: 230

Group: 2

Sex: Female

Species: Rat

Strain: Wistar: Crl: WI (Han)



Codes Used: (C) = Clinical Observation

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Individual Maternal Macroscopic Observations

20256434

Animal Ref.: 231

Group: 2

Sex: Female

Species: Rat

Strain: Wistar: Crl: WI (Han)



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Individual Maternal Macroscopic Observations

20256434

Animal Ref.: 232

Group: 2

Sex: Female

Species: Rat

Strain: Wistar: Crl: WI (Han)



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Individual Maternal Macroscopic Observations

20256434

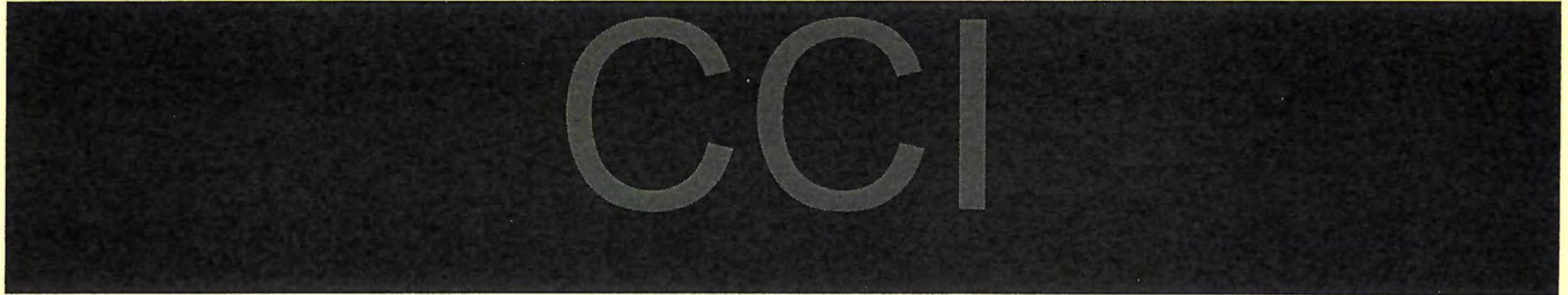
Animal Ref.: 233

Group: 2

Sex: Female

Species: Rat

Strain: Wistar: Crl: WI (Han)



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Individual Maternal Macroscopic Observations

20256434

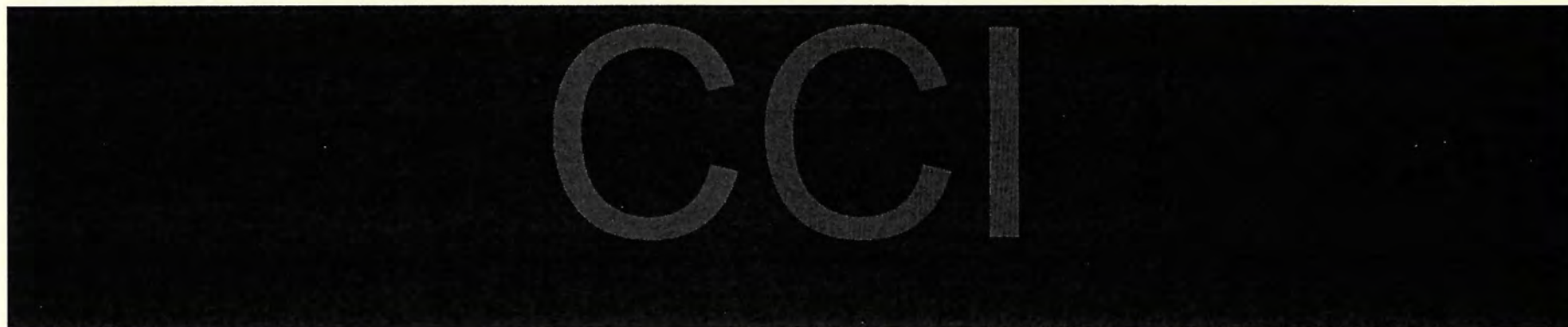
Animal Ref.: 234

Group: 2

Sex: Female

Species: Rat

Strain: Wistar: Crl: WI (Han)



Codes Used: (C) = Clinical Observation

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Individual Maternal Macroscopic Observations

20256434

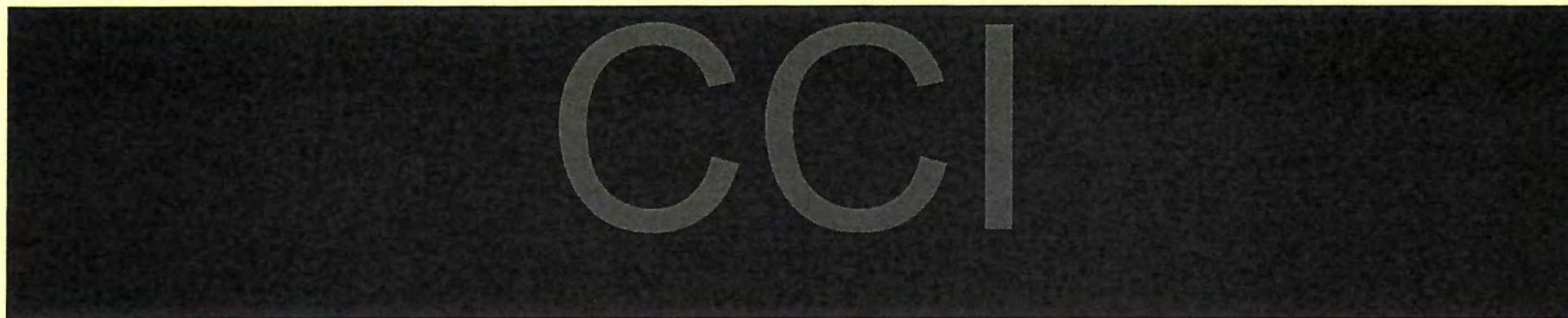
Animal Ref.: 235

Group: 2

Sex: Female

Species: Rat

Strain: Wistar: Crl: WI (Han)



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Individual Maternal Macroscopic Observations

20256434

Animal Ref.: 236

Group: 2

Sex: Female

Species: Rat

Strain: Wistar: Crl: WI (Han)



Codes Used: (TGL) = Trackable Gross Lesion, (C) = Clinical Observation

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Individual Maternal Macroscopic Observations

20256434

Animal Ref.: 237

Group: 2

Sex: Female

Species: Rat

Strain: Wistar: Crl: WI (Han)



Codes Used: (C) = Clinical Observation

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Individual Maternal Macroscopic Observations

20256434

Animal Ref.: 238

Group: 2

Sex: Female

Species: Rat

Strain: Wistar: Crl: WI (Han)



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Individual Maternal Macroscopic Observations

20256434

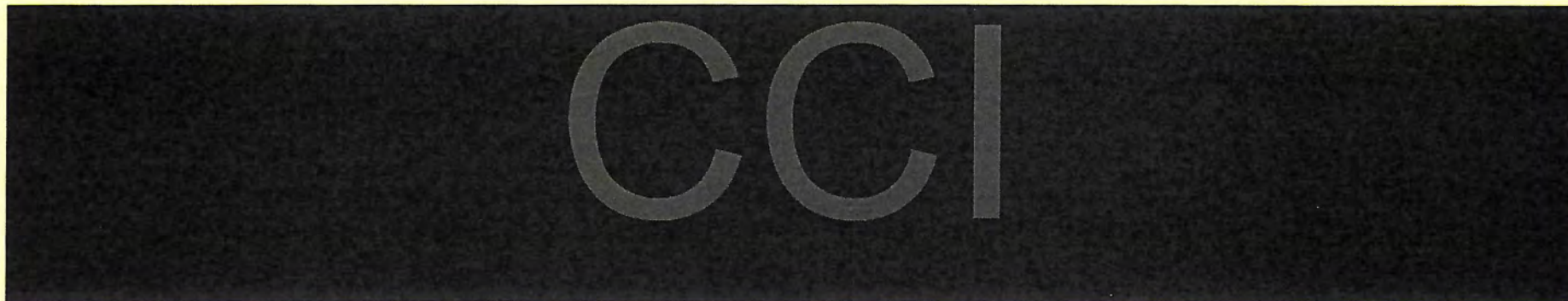
Animal Ref.: 239

Group: 2

Sex: Female

Species: Rat

Strain: Wistar: Crl: WI (Han)



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Individual Maternal Macroscopic Observations

20256434

Animal Ref.: 240

Group: 2

Sex: Female

Species: Rat

Strain: Wistar: Crl: WI (Han)



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Individual Maternal Macroscopic Observations

20256434

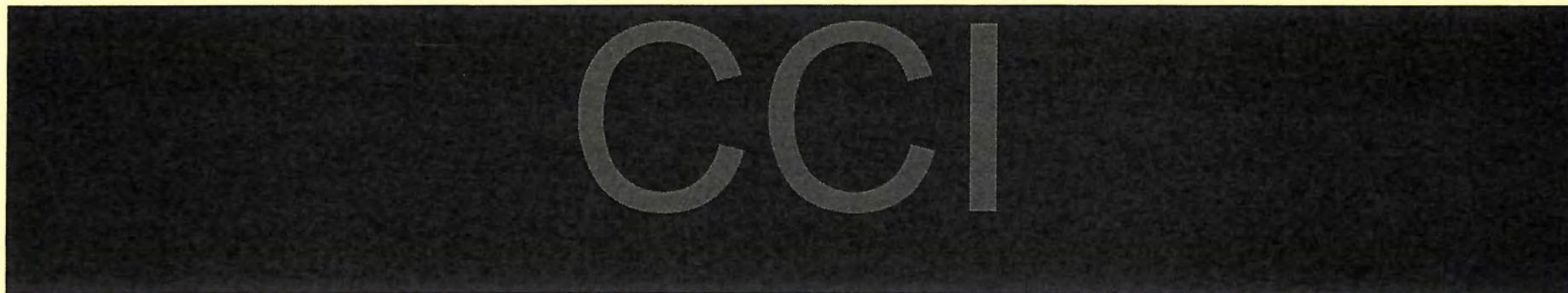
Animal Ref.: 241

Group: 2

Sex: Female

Species: Rat

Strain: Wistar: Crl: WI (Han)



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Individual Maternal Macroscopic Observations
20256434

Animal Ref.: 242

Group: 2

Sex: Female

Species: Rat

Strain: Wistar: Crl: WI (Han)



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Individual Maternal Macroscopic Observations

20256434

Animal Ref.: 243

Group: 2

Sex: Female

Species: Rat

Strain: Wistar: Crl: WI (Han)



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Individual Maternal Macroscopic Observations

20256434

Animal Ref.: 244

Group: 2

Sex: Female

Species: Rat

Strain: Wistar: Crl: WI (Han)



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Individual Maternal Macroscopic Observations

20256434

Animal Ref.: 23

Group: 2

Sex: Female

Species: Rat

Strain: Wistar: Crl: WI (Han)



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Individual Maternal Macroscopic Observations

20256434

Animal Ref.: 24

Group: 2

Sex: Female

Species: Rat

Strain: Wistar: Crl: WI (Han)



Codes Used: (TGL) = Trackable Gross Lesion

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Individual Maternal Macroscopic Observations

20256434

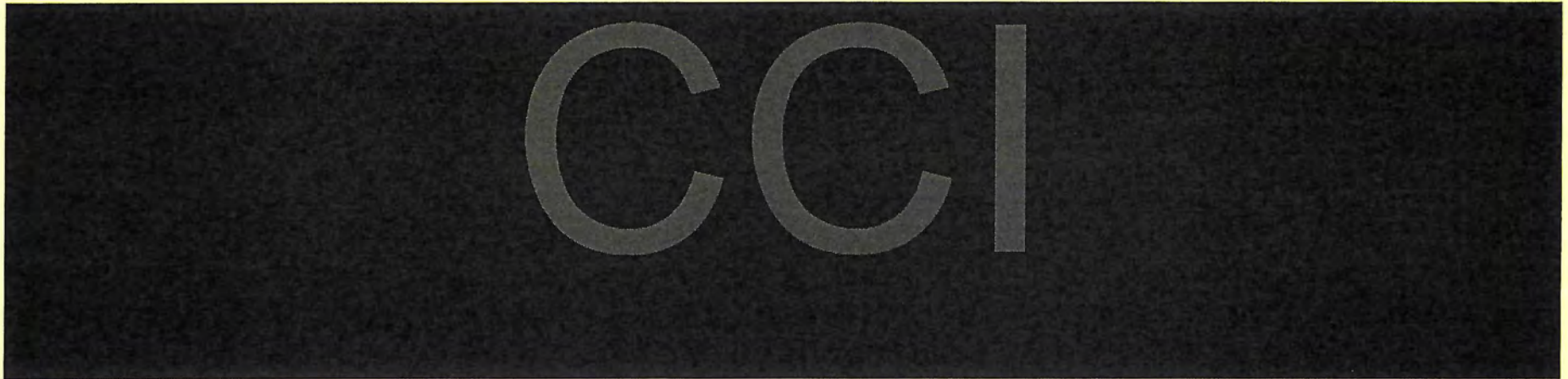
Animal Ref.: 25

Group: 2

Sex: Female

Species: Rat

Strain: Wistar: Crl: WI (Han)



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Individual Maternal Macroscopic Observations

20256434

Animal Ref.: 26

Group: 2

Sex: Female

Species: Rat

Strain: Wistar: Crl: WI (Han)



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Individual Maternal Macroscopic Observations

20256434

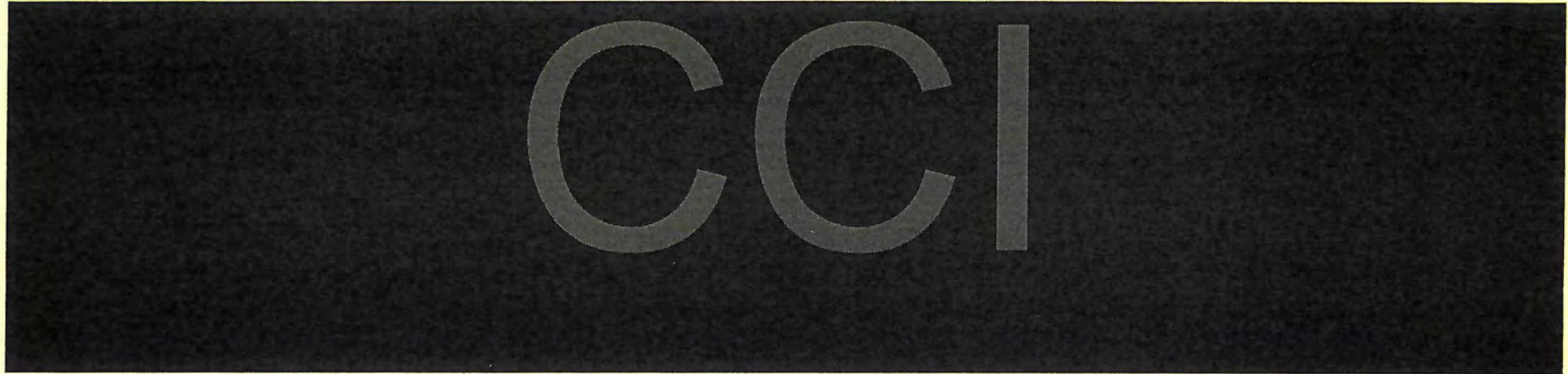
Animal Ref.: 27

Group: 2

Sex: Female

Species: Rat

Strain: Wistar: Crl: WI (Han)



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Individual Maternal Macroscopic Observations

20256434

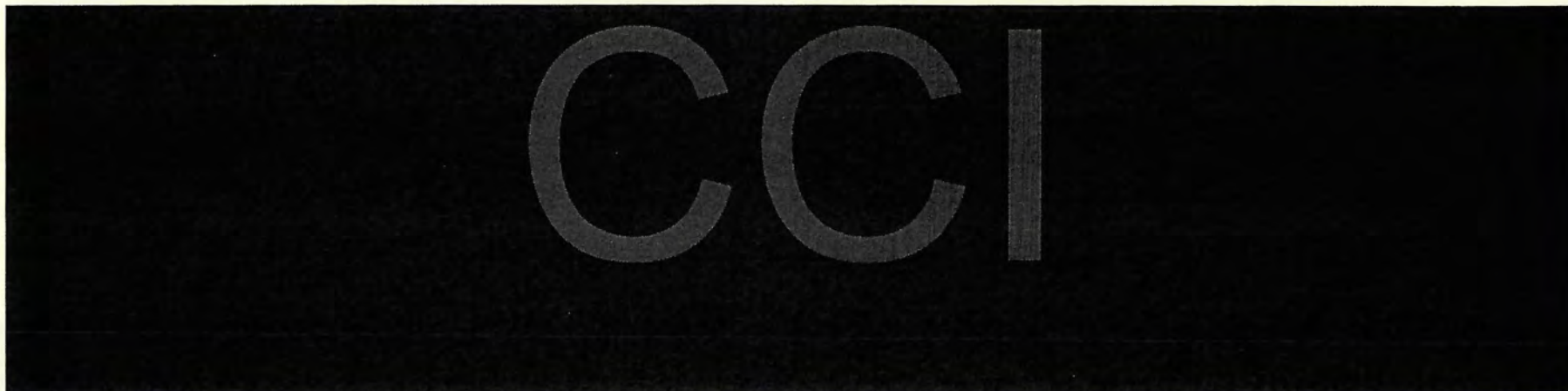
Animal Ref.: 28

Group: 2

Sex: Female

Species: Rat

Strain: Wistar: Crl: WI (Han)



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Individual Maternal Macroscopic Observations

20256434

Animal Ref.: 29

Group: 2

Sex: Female

Species: Rat

Strain: Wistar: Crl: WI (Han)



Codes Used: (C) = Clinical Observation

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Individual Maternal Macroscopic Observations

20256434

Animal Ref.: 30

Group: 2

Sex: Female

Species: Rat

Strain: Wistar: Crl: WI (Han)



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Individual Maternal Macroscopic Observations

20256434

Animal Ref.: 31

Group: 2

Sex: Female

Species: Rat

Strain: Wistar: Crl: WI (Han)



Codes Used: (TGL) = Trackable Gross Lesion, (C) = Clinical Observation

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Individual Maternal Macroscopic Observations

20256434

Animal Ref.: 32

Group: 2

Sex: Female

Species: Rat

Strain: Wistar: Crl: WI (Han)



Codes Used: (TGL) = Trackable Gross Lesion

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Individual Maternal Macroscopic Observations

20256434

Animal Ref.: 33

Group: 2

Sex: Female

Species: Rat

Strain: Wistar: Crl: WI (Han)



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Individual Maternal Macroscopic Observations

20256434

Animal Ref.: 34

Group: 2

Sex: Female

Species: Rat

Strain: Wistar: Crl: WI (Han)



Codes Used: (TGL) = Trackable Gross Lesion

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Individual Maternal Macroscopic Observations

20256434

Animal Ref.: 35

Group: 2

Sex: Female

Species: Rat

Strain: Wistar: Crl: WI (Han)



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Individual Maternal Macroscopic Observations

20256434

Animal Ref.: 36

Group: 2

Sex: Female

Species: Rat

Strain: Wistar: Crl: WI (Han)



Codes Used: (TGL) = Trackable Gross Lesion, (C) = Clinical Observation

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Individual Maternal Macroscopic Observations

20256434

Animal Ref.: 37

Group: 2

Sex: Female

Species: Rat

Strain: Wistar: Crl: WI (Han)



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Individual Maternal Macroscopic Observations

20256434

Animal Ref.: 38

Group: 2

Sex: Female

Species: Rat

Strain: Wistar: Crl: WI (Han)



Codes Used: (TGL) = Trackable Gross Lesion, (C) = Clinical Observation

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Individual Maternal Macroscopic Observations

20256434

Animal Ref.: 39

Group: 2

Sex: Female

Species: Rat

Strain: Wistar: Crl: WI (Han)



Codes Used: (TGL) = Trackable Gross Lesion, NRQ = Not required

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Individual Maternal Macroscopic Observations

20256434

Animal Ref.: 40

Group: 2

Sex: Female

Species: Rat

Strain: Wistar: Crl: WI (Han)

CCI

Codes Used: (TGL) = Trackable Gross Lesion, (C) = Clinical Observation

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Individual Maternal Macroscopic Observations

20256434

Animal Ref.: 41

Group: 2

Sex: Female

Species: Rat

Strain: Wistar: Crl: WI (Han)



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Individual Maternal Macroscopic Observations

20256434

Animal Ref.: 42

Group: 2

Sex: Female

Species: Rat

Strain: Wistar: Crl: WI (Han)



Codes Used: (TGL) = Trackable Gross Lesion

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Individual Maternal Macroscopic Observations

20256434

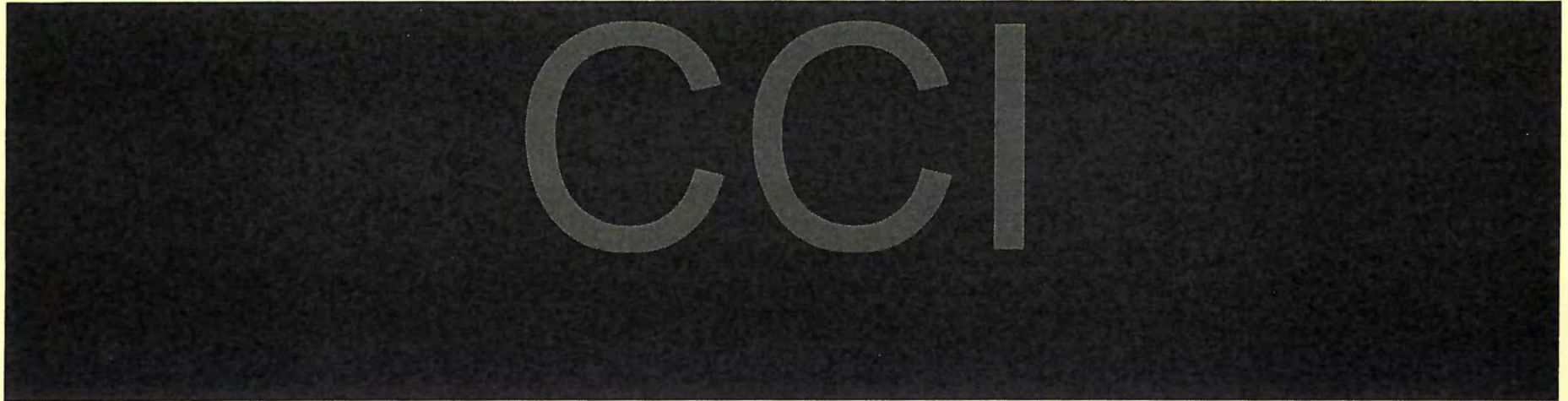
Animal Ref.: 43

Group: 2

Sex: Female

Species: Rat

Strain: Wistar: Crl: WI (Han)



Codes Used: NRQ = Not required

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Individual Maternal Macroscopic Observations

20256434

Animal Ref.: 44

Group: 2

Sex: Female

Species: Rat

Strain: Wistar: Crl: WI (Han)



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Individual Maternal Macroscopic Observations

20256434

Animal Ref.: 245 Group: 3 Sex: Female Species: Rat Strain: Wistar: Crl: WI (Han)
Test Material: See Protocol Dose: BNT162b2 30mcg Route: Intramuscular Study Type: Reproduction
Date of Death : 02OCT2020 Study Day No. (Week): 68 (10) Mode of Death: TERMINAL SACRIFICE
Date of Necropsy: 02OCT2020 ** NECROPSY COMPLETE **

Terminal Body Weight: None

Gross Pathology Observations:

Correlated with:

NO CORRELATE;

No correlate Localised hairloss; Left and right forelimbs (C)

Probable cause of death: None

Codes Used: (C) = Clinical Observation

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Individual Maternal Macroscopic Observations

20256434

Animal Ref.: 246 Group: 3 Sex: Female Species: Rat Strain: Wistar: Crl: WI (Han)

Test Material: See Protocol Dose: BNT162b2 30mcg Route: Intramuscular Study Type: Reproduction
Date of Death : 02OCT2020 Study Day No. (Week): 68 (10) Mode of Death: TERMINAL SACRIFICE
Date of Necropsy: 02OCT2020 ** NECROPSY COMPLETE **

Terminal Body Weight: None

Gross Pathology Observations: None

Probable cause of death: None

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Individual Maternal Macroscopic Observations

20256434

Animal Ref.: 247 Group: 3 Sex: Female Species: Rat Strain: Wistar: Crl: WI (Han)
Test Material: See Protocol Dose: BNT162b2 30mcg Route: Intramuscular Study Type: Reproduction
Date of Death : 30SEP2020 Study Day No. (Week): 66 (10) Mode of Death: TERMINAL SACRIFICE
Date of Necropsy: 30SEP2020 ** NECROPSY COMPLETE **

Terminal Body Weight: None

Gross Pathology Observations: None

Probable cause of death: None

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Individual Maternal Macroscopic Observations

20256434

Animal Ref.: 248 Group: 3 Sex: Female Species: Rat Strain: Wistar: Crl: WI (Han)

Test Material: See Protocol Dose: BNT162b2 30mcg Route: Intramuscular Study Type: Reproduction
Date of Death : 30SEP2020 Study Day No. (Week): 66 (10) Mode of Death: TERMINAL SACRIFICE
Date of Necropsy: 30SEP2020 ** NECROPSY COMPLETE **

Terminal Body Weight: None

Gross Pathology Observations: None

Probable cause of death: None

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Individual Maternal Macroscopic Observations

20256434

Animal Ref.: 249 Group: 3 Sex: Female Species: Rat Strain: Wistar: Crl: WI (Han)
Test Material: See Protocol Dose: BNT162b2 30mcg Route: Intramuscular Study Type: Reproduction
Date of Death : 03OCT2020 Study Day No. (Week): 69 (10) Mode of Death: TERMINAL SACRIFICE
Date of Necropsy: 03OCT2020 ** NECROPSY COMPLETE **

Terminal Body Weight: None

Gross Pathology Observations: None

Probable cause of death: None

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Individual Maternal Macroscopic Observations

20256434

Animal Ref.: 250 Group: 3 Sex: Female Species: Rat Strain: Wistar: Crl: WI (Han)
Test Material: See Protocol Dose: BNT162b2 30mcg Route: Intramuscular Study Type: Reproduction
Date of Death : 03OCT2020 Study Day No. (Week): 69 (10) Mode of Death: TERMINAL SACRIFICE
Date of Necropsy: 03OCT2020 ** NECROPSY COMPLETE **

Terminal Body Weight: None

Gross Pathology Observations: None

Probable cause of death: None

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Individual Maternal Macroscopic Observations

20256434

Animal Ref.: 251 Group: 3 Sex: Female Species: Rat Strain: Wistar: Crl: WI (Han)
Test Material: See Protocol Dose: BNT162b2 30mcg Route: Intramuscular Study Type: Reproduction
Date of Death : 02OCT2020 Study Day No. (Week): 68 (10) Mode of Death: TERMINAL SACRIFICE
Date of Necropsy: 02OCT2020 ** NECROPSY COMPLETE **

Terminal Body Weight: None

Gross Pathology Observations: None

Probable cause of death: None

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Individual Maternal Macroscopic Observations

20256434

Animal Ref.: 252 Group: 3 Sex: Female Species: Rat Strain: Wistar: Crl: WI (Han)
Test Material: See Protocol Dose: BNT162b2 30mcg Route: Intramuscular Study Type: Reproduction
Date of Death : 03OCT2020 Study Day No. (Week): 69 (10) Mode of Death: TERMINAL SACRIFICE
Date of Necropsy: 03OCT2020 ** NECROPSY COMPLETE **

Terminal Body Weight: None

Gross Pathology Observations: None

Probable cause of death: None

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Individual Maternal Macroscopic Observations

20256434

Animal Ref.: 253 Group: 3 Sex: Female Species: Rat Strain: Wistar: Crl: WI (Han)
Test Material: See Protocol Dose: BNT162b2 30mcg Route: Intramuscular Study Type: Reproduction
Date of Death : 30SEP2020 Study Day No. (Week): 66 (10) Mode of Death: TERMINAL SACRIFICE
Date of Necropsy: 30SEP2020 ** NECROPSY COMPLETE **

Terminal Body Weight: None

Gross Pathology Observations:

Correlated with:

LIVER;

Mass a; papillary process; adherent to surrounding tissue;
solid; dark; heterogeneous (TGL): 2.0x2.0x1.2cm

SKIN/SUBCUTIS;

Sore/crust; back; head; many (TGL) Scab(s).; Head (C)
Scab(s).; Back (C)

Any remaining protocol required tissues, which have been examined, have no visible lesions

Probable cause of death: None

Codes Used: (TGL) = Trackable Gross Lesion, (C) = Clinical Observation

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Individual Maternal Macroscopic Observations

20256434

Animal Ref.: 254 Group: 3 Sex: Female Species: Rat Strain: Wistar: Crl: WI (Han)

Test Material: See Protocol Dose: BNT162b2 30mcg Route: Intramuscular Study Type: Reproduction
Date of Death : 16SEP2020 Study Day No. (Week): 52 (8) Mode of Death: UNPLANNED TERMINAL SACRIFICE
Date of Necropsy: 16SEP2020 ** NECROPSY COMPLETE **

Terminal Body Weight: None

Gross Pathology Observations: None

Probable cause of death: None

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Individual Maternal Macroscopic Observations

20256434

Animal Ref.: 255 Group: 3 Sex: Female Species: Rat Strain: Wistar: Crl: WI (Han)
Test Material: See Protocol Dose: BNT162b2 30mcg Route: Intramuscular Study Type: Reproduction
Date of Death : 02OCT2020 Study Day No. (Week): 68 (10) Mode of Death: TERMINAL SACRIFICE
Date of Necropsy: 02OCT2020 ** NECROPSY COMPLETE **

Terminal Body Weight: None

Gross Pathology Observations: None

Probable cause of death: None

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Individual Maternal Macroscopic Observations

20256434

Animal Ref.: 256 Group: 3 Sex: Female Species: Rat Strain: Wistar: Crl: WI (Han)
Test Material: See Protocol Dose: BNT162b2 30mcg Route: Intramuscular Study Type: Reproduction
Date of Death : 02OCT2020 Study Day No. (Week): 68 (10) Mode of Death: TERMINAL SACRIFICE
Date of Necropsy: 02OCT2020 ** NECROPSY COMPLETE **

Terminal Body Weight: None

Gross Pathology Observations:

NO CORRELATE;

No correlate

Correlated with:

Localised hairloss; Back (C)

Localised hairloss; Left and right forelimbs (C)

Probable cause of death: None

Codes Used: (C) = Clinical Observation

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Individual Maternal Macroscopic Observations

20256434

Animal Ref.: 257 Group: 3 Sex: Female Species: Rat Strain: Wistar: Crl: WI (Han)
Test Material: See Protocol Dose: BNT162b2 30mcg Route: Intramuscular Study Type: Reproduction
Date of Death : 01OCT2020 Study Day No. (Week): 67 (10) Mode of Death: TERMINAL SACRIFICE
Date of Necropsy: 01OCT2020 ** NECROPSY COMPLETE **

Terminal Body Weight: None

Gross Pathology Observations: None

Probable cause of death: None

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Individual Maternal Macroscopic Observations

20256434

Animal Ref.: 258 Group: 3 Sex: Female Species: Rat Strain: Wistar: Crl: WI (Han)
Test Material: See Protocol Dose: BNT162b2 30mcg Route: Intramuscular Study Type: Reproduction
Date of Death : 03OCT2020 Study Day No. (Week): 69 (10) Mode of Death: TERMINAL SACRIFICE
Date of Necropsy: 03OCT2020 ** NECROPSY COMPLETE **

Terminal Body Weight: None

Gross Pathology Observations: None

Probable cause of death: None

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Individual Maternal Macroscopic Observations

20256434

Animal Ref.: 259 Group: 3 Sex: Female Species: Rat Strain: Wistar: Crl: WI (Han)
Test Material: See Protocol Dose: BNT162b2 30mcg Route: Intramuscular Study Type: Reproduction
Date of Death : 03OCT2020 Study Day No. (Week): 69 (10) Mode of Death: TERMINAL SACRIFICE
Date of Necropsy: 03OCT2020 ** NECROPSY COMPLETE **

Terminal Body Weight: None

Gross Pathology Observations: None

Probable cause of death: None

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Individual Maternal Macroscopic Observations

20256434

Animal Ref.: 260 Group: 3 Sex: Female Species: Rat Strain: Wistar: Crl: WI (Han)

Test Material: See Protocol Dose: BNT162b2 30mcg Route: Intramuscular Study Type: Reproduction
Date of Death : 03OCT2020 Study Day No. (Week): 69 (10) Mode of Death: TERMINAL SACRIFICE
Date of Necropsy: 03OCT2020 ** NECROPSY COMPLETE **

Terminal Body Weight: None

Gross Pathology Observations:

Correlated with:

SKIN/SUBCUTIS;

Alopecia; thoracic region; single (TGL) Localised hairloss; Thorax (C)

NO CORRELATE;

No correlate Localised hairloss; Left and right forelimbs (C)

Any remaining protocol required tissues, which have been examined, have no visible lesions

Probable cause of death: None

Codes Used: (TGL) = Trackable Gross Lesion, (C) = Clinical Observation

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Individual Maternal Macroscopic Observations

20256434

Animal Ref.: 261	Group: 3	Sex: Female	Species: Rat	Strain: Wistar: Crl: WI (Han)
Test Material: See Protocol	Dose: BNT162b2 30mcg	Route: Intramuscular	Study Type: Reproduction	
Date of Death : 01OCT2020	Study Day No. (Week): 67 (10)	Mode of Death: TERMINAL SACRIFICE		
Date of Necropsy: 01OCT2020	** NECROPSY COMPLETE **			

Terminal Body Weight: None

Gross Pathology Observations: None

Probable cause of death: None

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Individual Maternal Macroscopic Observations

20256434

Animal Ref.: 262 Group: 3 Sex: Female Species: Rat Strain: Wistar: Crl: WI (Han)
Test Material: See Protocol Dose: BNT162b2 30mcg Route: Intramuscular Study Type: Reproduction
Date of Death : 02OCT2020 Study Day No. (Week): 68 (10) Mode of Death: TERMINAL SACRIFICE
Date of Necropsy: 02OCT2020 ** NECROPSY COMPLETE **

Terminal Body Weight: None

Gross Pathology Observations: None

Probable cause of death: None

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Individual Maternal Macroscopic Observations

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Animal Ref.: 263 Group: 3 Sex: Female Species: Rat Strain: Wistar: Crl: WI (Han)
Test Material: See Protocol Dose: ENT162b2 30mcg Route: Intramuscular Study Type: Reproduction
Date of Death : 02OCT2020 Study Day No. (Week): 68 (10) Mode of Death: TERMINAL SACRIFICE
Date of Necropsy: 02OCT2020 ** NECROPSY COMPLETE **

Terminal Body Weight: None

Gross Pathology Observations: None

Probable cause of death: None

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Individual Maternal Macroscopic Observations

20256434

Animal Ref.: 264 Group: 3 Sex: Female Species: Rat Strain: Wistar: Crl: WI (Han)
Test Material: See Protocol Dose: BNT162b2 30mcg Route: Intramuscular Study Type: Reproduction
Date of Death : 30SEP2020 Study Day No. (Week): 66 (10) Mode of Death: TERMINAL SACRIFICE
Date of Necropsy: 30SEP2020 ** NECROPSY COMPLETE **

Terminal Body Weight: None

Gross Pathology Observations: None

Probable cause of death: None

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Individual Maternal Macroscopic Observations

20256434

Animal Ref.: 265 Group: 3 Sex: Female Species: Rat Strain: Wistar: Crl: WI (Han)
Test Material: See Protocol Dose: BNT162b2 30mcg Route: Intramuscular Study Type: Reproduction
Date of Death : 01OCT2020 Study Day No. (Week): 67 (10) Mode of Death: TERMINAL SACRIFICE
Date of Necropsy: 01OCT2020 ** NECROPSY COMPLETE **

Terminal Body Weight: None

Gross Pathology Observations: None

Probable cause of death: None

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Individual Maternal Macroscopic Observations

20256434

Animal Ref.: 266 Group: 3 Sex: Female Species: Rat Strain: Wistar: Crl: WI (Han)
Test Material: See Protocol Dose: BNT162b2 30mcg Route: Intramuscular Study Type: Reproduction
Date of Death : 02OCT2020 Study Day No. (Week): 68 (10) Mode of Death: TERMINAL SACRIFICE
Date of Necropsy: 02OCT2020 ** NECROPSY COMPLETE **

Terminal Body Weight: None

Gross Pathology Observations: None

Probable cause of death: None

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Individual Maternal Macroscopic Observations

20256434

Animal Ref.: 45 Group: 3 Sex: Female Species: Rat Strain: Wistar: Crl: WI (Han)

Test Material: See Protocol Dose: BNT162b2 30mcg Route: Intramuscular Study Type: Reproduction
Date of Death : 22SEP2020 Study Day No. (Week): 44 (7) Mode of Death: TERMINAL SACRIFICE
Date of Necropsy: 22SEP2020 ** NECROPSY COMPLETE **

Terminal Body Weight: None

Organ Weights:

NECROPSY BODYWEIGHT : 348.7g GRAVID UTERUS : 85.1g

Gross Pathology Observations: None

Probable cause of death: None

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Individual Maternal Macroscopic Observations

20256434

Animal Ref.: 46 Group: 3 Sex: Female Species: Rat Strain: Wistar: Crl: WI (Han)
Test Material: See Protocol Dose: BNT162b2 30mcg Route: Intramuscular Study Type: Reproduction
Date of Death : 01OCT2020 Study Day No. (Week): 53 (8) Mode of Death: TERMINAL SACRIFICE
Date of Necropsy: 01OCT2020 ** NECROPSY COMPLETE **

Terminal Body Weight: None

Organ Weights:

NECROPSY BODYWEIGHT : 411.1g GRAVID UTERUS : 111.3g

Gross Pathology Observations: None

Probable cause of death: None

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Individual Maternal Macroscopic Observations

20256434

Animal Ref.: 47 Group: 3 Sex: Female Species: Rat Strain: Wistar: Crl: WI (Han)
Test Material: See Protocol Dose: BNT162b2 30mcg Route: Intramuscular Study Type: Reproduction
Date of Death : 22SEP2020 Study Day No. (Week): 44 (7) Mode of Death: TERMINAL SACRIFICE
Date of Necropsy: 22SEP2020 ** NECROPSY COMPLETE **

Terminal Body Weight: None

Organ Weights:

NECROPSY BODYWEIGHT : 335.7g GRAVID UTERUS : 79.1g

Gross Pathology Observations:

Correlated with:

NO CORRELATE;

No correlate Swelling.; Injection site 2 (C)

Probable cause of death: None

Codes Used: (C) = Clinical Observation

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Individual Maternal Macroscopic Observations

20256434

Animal Ref.: 48 Group: 3 Sex: Female Species: Rat Strain: Wistar: Crl: WI (Han)
Test Material: See Protocol Dose: BNT162b2 30mcg Route: Intramuscular Study Type: Reproduction
Date of Death : 23SEP2020 Study Day No. (Week): 45 (7) Mode of Death: TERMINAL SACRIFICE
Date of Necropsy: 23SEP2020 ** NECROPSY COMPLETE **

Terminal Body Weight: None

Organ Weights:

NECROPSY BODYWEIGHT : 311.4g GRAVID UTERUS : 67.9g

Gross Pathology Observations: None

Probable cause of death: None

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Individual Maternal Macroscopic Observations

20256434

Animal Ref.: 49 Group: 3 Sex: Female Species: Rat Strain: Wistar: Crl: WI (Han)
Test Material: See Protocol Dose: BNT162b2 30mcg Route: Intramuscular Study Type: Reproduction
Date of Death : 25SEP2020 Study Day No. (Week): 47 (7) Mode of Death: TERMINAL SACRIFICE
Date of Necropsy: 25SEP2020 ** NECROPSY COMPLETE **

Terminal Body Weight: None

Organ Weights:

NECROPSY BODYWEIGHT : 359.0g GRAVID UTERUS : 80.6g

Gross Pathology Observations:

Correlated with:

INJECTION SITE 2;

Firm area (TGL)

Enlarged (TGL) Swelling.; Injection site 2 (C)

Oedematous area (TGL)

Pale (TGL)

Any remaining protocol required tissues, which have been examined, have no visible lesions

Probable cause of death: None

Codes Used: (TGL) = Trackable Gross Lesion, (C) = Clinical Observation

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Individual Maternal Macroscopic Observations

20256434

Animal Ref.: 50 Group: 3 Sex: Female Species: Rat Strain: Wistar: Crl: WI (Han)
Test Material: See Protocol Dose: BNT162b2 30mcg Route: Intramuscular Study Type: Reproduction
Date of Death : 24SEP2020 Study Day No. (Week): 46 (7) Mode of Death: TERMINAL SACRIFICE
Date of Necropsy: 24SEP2020 ** NECROPSY COMPLETE **

Terminal Body Weight: None

Organ Weights:

NECROPSY BODYWEIGHT : 300.4g GRAVID UTERUS : 60.9g

Gross Pathology Observations: None

Probable cause of death: None

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Individual Maternal Macroscopic Observations

20256434

Animal Ref.: 51 Group: 3 Sex: Female Species: Rat Strain: Wistar: Crl: WI (Han)

Test Material: See Protocol Dose: BNT162b2 30mcg Route: Intramuscular Study Type: Reproduction
Date of Death : 25SEP2020 Study Day No. (Week): 47 (7) Mode of Death: TERMINAL SACRIFICE
Date of Necropsy: 25SEP2020 ** NECROPSY COMPLETE **

Terminal Body Weight: None

Organ Weights:

NECROPSY BODYWEIGHT : 394.2g GRAVID UTERUS : 104.3g

Gross Pathology Observations: None

Probable cause of death: None

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Individual Maternal Macroscopic Observations

20256434

Animal Ref.: 52 Group: 3 Sex: Female Species: Rat Strain: Wistar: Crl: WI (Han)
Test Material: See Protocol Dose: BNT162b2 30mcg Route: Intramuscular Study Type: Reproduction
Date of Death : 24SEP2020 Study Day No. (Week): 46 (7) Mode of Death: TERMINAL SACRIFICE
Date of Necropsy: 24SEP2020 ** NECROPSY COMPLETE **

Terminal Body Weight: None

Organ Weights:

NECROPSY BODYWEIGHT : 368.7g GRAVID UTERUS : 94.2g

Gross Pathology Observations: None

Probable cause of death: None

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Individual Maternal Macroscopic Observations

20256434

Animal Ref.: 53 Group: 3 Sex: Female Species: Rat Strain: Wistar: Crl: WI (Han)
Test Material: See Protocol Dose: BNT162b2 30mcg Route: Intramuscular Study Type: Reproduction
Date of Death : 25SEP2020 Study Day No. (Week): 47 (7) Mode of Death: TERMINAL SACRIFICE
Date of Necropsy: 25SEP2020 ** NECROPSY COMPLETE **

Terminal Body Weight: None

Organ Weights:

NECROPSY BODYWEIGHT : 356.8g GRAVID UTERUS : 99.6g

Gross Pathology Observations:

Correlated with:

SKIN/SUBCUTIS;

Sore/crust; forelimb; single; right (TGL) Scab(s).; Clipped area (C)

NO CORRELATE;

No correlate Localised hairloss; Dorsal neck region (C)

INJECTION SITE 2;

Firm area (TGL)

Enlarged (TGL)

Any remaining protocol required tissues, which have been examined, have no visible lesions

Probable cause of death: None

Codes Used: (TGL) = Trackable Gross Lesion, (C) = Clinical Observation

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Individual Maternal Macroscopic Observations

20256434

Animal Ref.: 54 Group: 3 Sex: Female Species: Rat Strain: Wistar: Crl: WI (Han)
Test Material: See Protocol Dose: BNT162b2 30mcg Route: Intramuscular Study Type: Reproduction
Date of Death : 25SEP2020 Study Day No. (Week): 47 (7) Mode of Death: TERMINAL SACRIFICE
Date of Necropsy: 25SEP2020 ** NECROPSY COMPLETE **

Terminal Body Weight: None

Organ Weights:

NECROPSY BODYWEIGHT : 356.0g GRAVID UTERUS : 90.5g

Gross Pathology Observations:

Correlated with:

SKIN/SUBCUTIS;

Alopecia; forelimb; single; right; left (TGL): take on right Localised hairloss; Left and right forelimbs (C)
forelimb

INJECTION SITE 2;

Enlarged (TGL)
Pale (TGL)

Any remaining protocol required tissues, which have been examined, have no visible lesions

Probable cause of death: None

Codes Used: (TGL) = Trackable Gross Lesion, (C) = Clinical Observation

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Individual Maternal Macroscopic Observations

20256434

Animal Ref.: 55 Group: 3 Sex: Female Species: Rat Strain: Wistar: Crl: WI (Han)
Test Material: See Protocol Dose: BNT162b2 30mcg Route: Intramuscular Study Type: Reproduction
Date of Death : 24SEP2020 Study Day No. (Week): 46 (7) Mode of Death: TERMINAL SACRIFICE
Date of Necropsy: 24SEP2020 ** NECROPSY COMPLETE **

Terminal Body Weight: None

Organ Weights:

NECROPSY BODYWEIGHT : 356.8g GRAVID UTERUS : 88.1g

Gross Pathology Observations:

INJECTION SITE 2;
Firm area (TGL)
Enlarged (TGL)

Any remaining protocol required tissues, which have been examined, have no visible lesions

Probable cause of death: None

Codes Used: (TGL) = Trackable Gross Lesion

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Individual Maternal Macroscopic Observations

20256434

Animal Ref.: 56 Group: 3 Sex: Female Species: Rat Strain: Wistar: Crl: WI (Han)
Test Material: See Protocol Dose: BNT162b2 30mcg Route: Intramuscular Study Type: Reproduction
Date of Death : 22SEP2020 Study Day No. (Week): 44 (7) Mode of Death: TERMINAL SACRIFICE
Date of Necropsy: 22SEP2020 ** NECROPSY COMPLETE **

Terminal Body Weight: None

Organ Weights:

NECROPSY BODYWEIGHT : 310.2g GRAVID UTERUS : NRQ

Gross Pathology Observations: None

Probable cause of death: None

Codes Used: NRQ = Not required

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Individual Maternal Macroscopic Observations

20256434

Animal Ref.: 57 Group: 3 Sex: Female Species: Rat Strain: Wistar: Crl: WI (Han)
Test Material: See Protocol Dose: BNT162b2 30mcg Route: Intramuscular Study Type: Reproduction
Date of Death : 24SEP2020 Study Day No. (Week): 46 (7) Mode of Death: TERMINAL SACRIFICE
Date of Necropsy: 24SEP2020 ** NECROPSY COMPLETE **

Terminal Body Weight: None

Organ Weights:

NECROPSY BODYWEIGHT : 356.3g GRAVID UTERUS : 104.5g

Gross Pathology Observations:

INJECTION SITE 2;
 Firm area (TGL)
 Enlarged (TGL)

Any remaining protocol required tissues, which have been examined, have no visible lesions

Probable cause of death: None

Codes Used: (TGL) = Trackable Gross Lesion

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Individual Maternal Macroscopic Observations

20256434

Animal Ref.: 58 Group: 3 Sex: Female Species: Rat Strain: Wistar: Crl: WI (Han)
Test Material: See Protocol Dose: BNT162b2 30mcg Route: Intramuscular Study Type: Reproduction
Date of Death : 24SEP2020 Study Day No. (Week): 46 (7) Mode of Death: TERMINAL SACRIFICE
Date of Necropsy: 24SEP2020 ** NECROPSY COMPLETE **

Terminal Body Weight: None

Organ Weights:

NECROPSY BODYWEIGHT : 343.9g GRAVID UTERUS : 83.2g

Gross Pathology Observations:

INJECTION SITE 2;
Firm area (TGL)
Enlarged (TGL)

Any remaining protocol required tissues, which have been examined, have no visible lesions

Probable cause of death: None

Codes Used: (TGL) = Trackable Gross Lesion

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Individual Maternal Macroscopic Observations

20256434

Animal Ref.: 59 Group: 3 Sex: Female Species: Rat Strain: Wistar: Crl: WI (Han)
Test Material: See Protocol Dose: BNT162b2 30mcg Route: Intramuscular Study Type: Reproduction
Date of Death : 24SEP2020 Study Day No. (Week): 46 (7) Mode of Death: TERMINAL SACRIFICE
Date of Necropsy: 24SEP2020 ** NECROPSY COMPLETE **

Terminal Body Weight: None

Organ Weights:

NECROPSY BODYWEIGHT : 359.9g GRAVID UTERUS : 83.3g

Gross Pathology Observations:

INJECTION SITE 2;

Firm area (TGL)

Enlarged (TGL)

Any remaining protocol required tissues, which have been examined, have no visible lesions

Probable cause of death: None

Codes Used: (TGL) = Trackable Gross Lesion

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Individual Maternal Macroscopic Observations

20256434

Animal Ref.: 60 Group: 3 Sex: Female Species: Rat Strain: Wistar: Crl: WI (Han)
Test Material: See Protocol Dose: BNT162b2 30mcg Route: Intramuscular Study Type: Reproduction
Date of Death : 22SEP2020 Study Day No. (Week): 44 (7) Mode of Death: TERMINAL SACRIFICE
Date of Necropsy: 22SEP2020 ** NECROPSY COMPLETE **

Terminal Body Weight: None

Organ Weights:

NECROPSY BODYWEIGHT : 346.4g GRAVID UTERUS : 83.8g

Gross Pathology Observations: None

Probable cause of death: None

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Individual Maternal Macroscopic Observations

20256434

Animal Ref.: 61 Group: 3 Sex: Female Species: Rat Strain: Wistar: Crl: WI (Han)
Test Material: See Protocol Dose: BNT162b2 30mcg Route: Intramuscular Study Type: Reproduction
Date of Death : 22SEP2020 Study Day No. (Week): 44 (7) Mode of Death: TERMINAL SACRIFICE
Date of Necropsy: 22SEP2020 ** NECROPSY COMPLETE **

Terminal Body Weight: None

Organ Weights:

NECROPSY BODYWEIGHT : 368.7g GRAVID UTERUS : 89.9g

Gross Pathology Observations:

Correlated with:

NO CORRELATE;

No correlate Localised hairloss; Left and right forelimbs (C)

Probable cause of death: None

Codes Used: (C) = Clinical Observation

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Individual Maternal Macroscopic Observations

20256434

Animal Ref.: 62 Group: 3 Sex: Female Species: Rat Strain: Wistar: Crl: WI (Han)
Test Material: See Protocol Dose: BNT162b2 30mcg Route: Intramuscular Study Type: Reproduction
Date of Death : 22SEP2020 Study Day No. (Week): 44 (7) Mode of Death: TERMINAL SACRIFICE
Date of Necropsy: 22SEP2020 ** NECROPSY COMPLETE **

Terminal Body Weight: None

Organ Weights:

NECROPSY BODYWEIGHT : 350.0g GRAVID UTERUS : 93.5g

Gross Pathology Observations: Correlated with:

SKIN/SUBCUTIS;
collected on right forelimb
Alopecia; forelimb; single; right; left (TGL) Localised hairloss; Left and right forelimbs (C)

Probable cause of death: None

Codes Used: (TGL) = Trackable Gross Lesion, (C) = Clinical Observation

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Individual Maternal Macroscopic Observations

20256434

Animal Ref.: 63 Group: 3 Sex: Female Species: Rat Strain: Wistar: Crl: WI (Han)
Test Material: See Protocol Dose: BNT162b2 30mcg Route: Intramuscular Study Type: Reproduction
Date of Death : 22SEP2020 Study Day No. (Week): 44 (7) Mode of Death: TERMINAL SACRIFICE
Date of Necropsy: 22SEP2020 ** NECROPSY COMPLETE **

Terminal Body Weight: None

Organ Weights:

NECROPSY BODYWEIGHT : 329.7g GRAVID UTERUS : 73.5g

Gross Pathology Observations:

Correlated with:

INJECTION SITE 2;

Firm area (TGL) Swelling.; Injection site 2 (C)

Any remaining protocol required tissues, which have been examined, have no visible lesions

Probable cause of death: None

Codes Used: (TGL) = Trackable Gross Lesion, (C) = Clinical Observation

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Individual Maternal Macroscopic Observations

20256434

Animal Ref.: 64 Group: 3 Sex: Female Species: Rat Strain: Wistar: Crl: WI (Han)
Test Material: See Protocol Dose: BNT162b2 30mcg Route: Intramuscular Study Type: Reproduction
Date of Death : 24SEP2020 Study Day No. (Week): 46 (7) Mode of Death: TERMINAL SACRIFICE
Date of Necropsy: 24SEP2020 ** NECROPSY COMPLETE **

Terminal Body Weight: None

Organ Weights:

NECROPSY BODYWEIGHT : 345.0g GRAVID UTERUS : 83.1g

Gross Pathology Observations: None

Probable cause of death: None

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Individual Maternal Macroscopic Observations

20256434

Animal Ref.: 65 Group: 3 Sex: Female Species: Rat Strain: Wistar: Crl: WI (Han)
Test Material: See Protocol Dose: BNT162b2 30mcg Route: Intramuscular Study Type: Reproduction
Date of Death : 25SEP2020 Study Day No. (Week): 47 (7) Mode of Death: TERMINAL SACRIFICE
Date of Necropsy: 25SEP2020 ** NECROPSY COMPLETE **

Terminal Body Weight: None

Organ Weights:

NECROPSY BODYWEIGHT : 374.8g GRAVID UTERUS : 111.2g

Gross Pathology Observations:

Correlated with:

SKIN/SUBCUTIS;

Alopecia; forelimb; single; right; left (TGL): take thoracic Localised hairloss; Left and right forelimbs (C)
region
Alopecia; thoracic region; abdominal; single (TGL): take Localised hairloss; Thorax (C)
thoracic region Localised hairloss; Abdomen (C)

INJECTION SITE 2;

Firm area (TGL)
Pale (TGL)

Any remaining protocol required tissues, which have been examined, have no visible lesions

Probable cause of death: None

Codes Used: (TGL) = Trackable Gross Lesion, (C) = Clinical Observation

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Individual Maternal Macroscopic Observations

20256434

Animal Ref.: 66 Group: 3 Sex: Female Species: Rat Strain: Wistar: Crl: WI (Han)
Test Material: See Protocol Dose: BNT162b2 30mcg Route: Intramuscular Study Type: Reproduction
Date of Death : 25SEP2020 Study Day No. (Week): 47 (7) Mode of Death: TERMINAL SACRIFICE
Date of Necropsy: 25SEP2020 ** NECROPSY COMPLETE **

Terminal Body Weight: None

Organ Weights:

NECROPSY BODYWEIGHT : 307.3g GRAVID UTERUS : 73.0g

Gross Pathology Observations:

INJECTION SITE 2;
 Firm area (TGL)
 Enlarged (TGL)
 Pale (TGL)

Any remaining protocol required tissues, which have been examined, have no visible lesions

Probable cause of death: None

Codes Used: (TGL) = Trackable Gross Lesion

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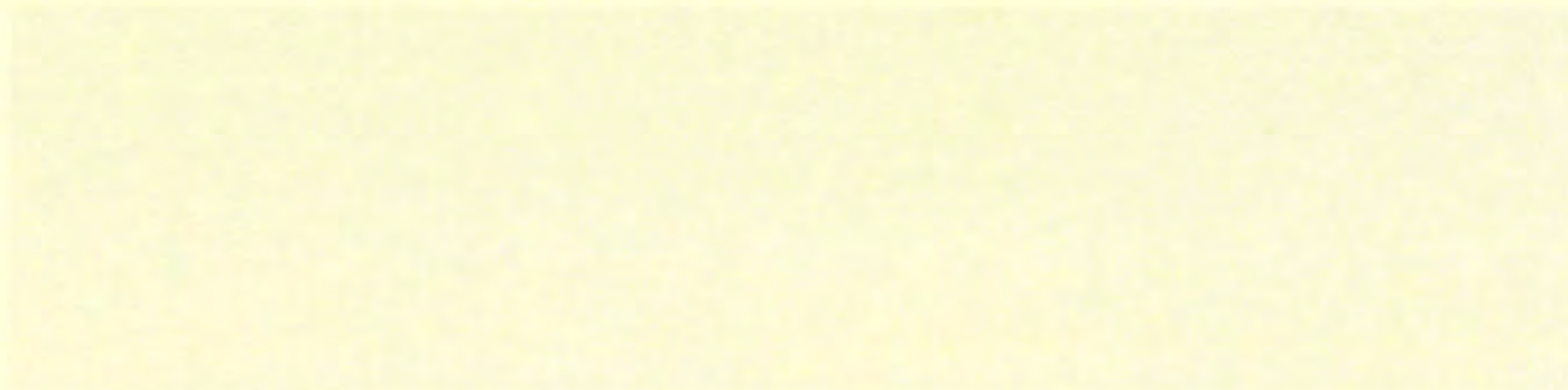
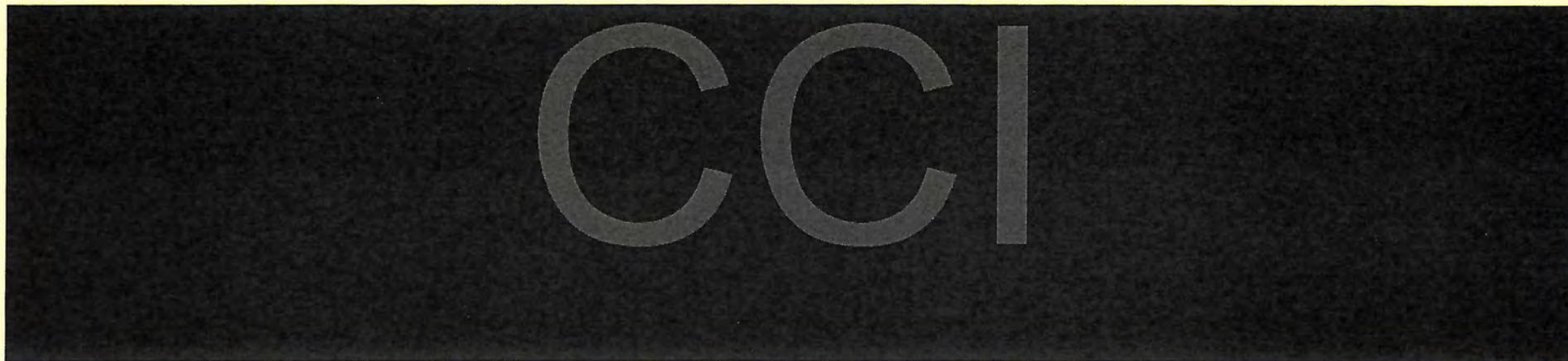
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Individual Maternal Macroscopic Observations

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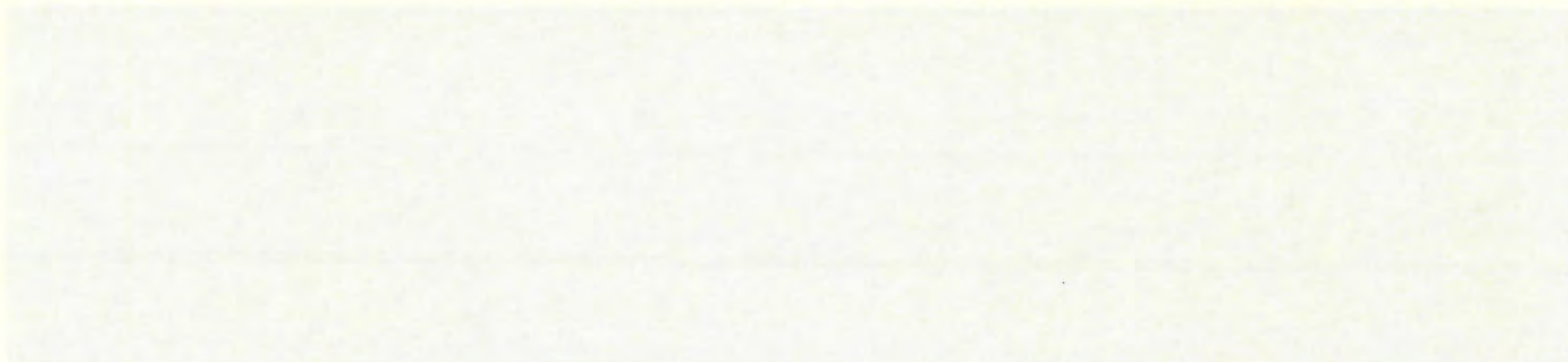
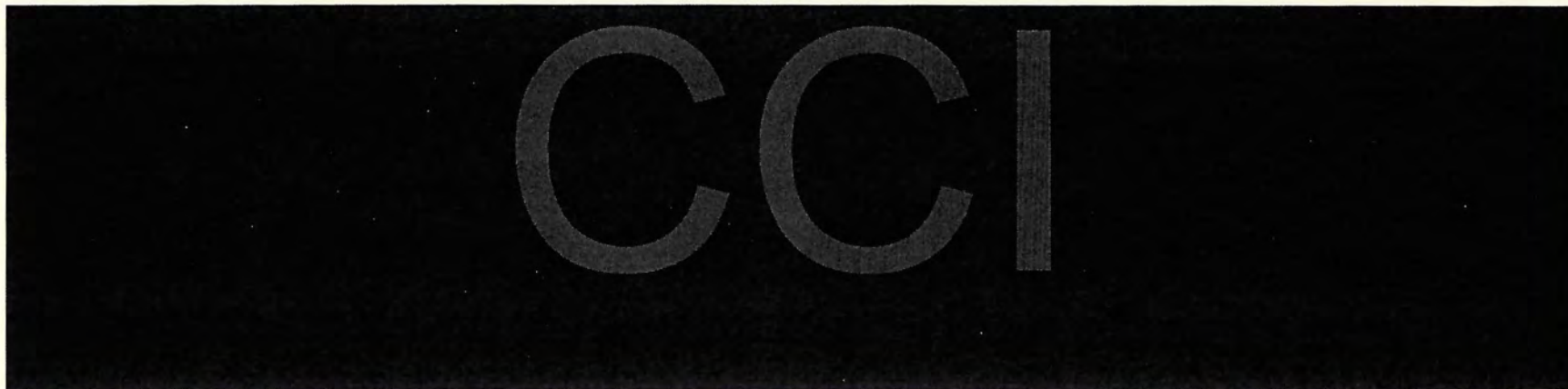
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Individual Maternal Macroscopic Observations

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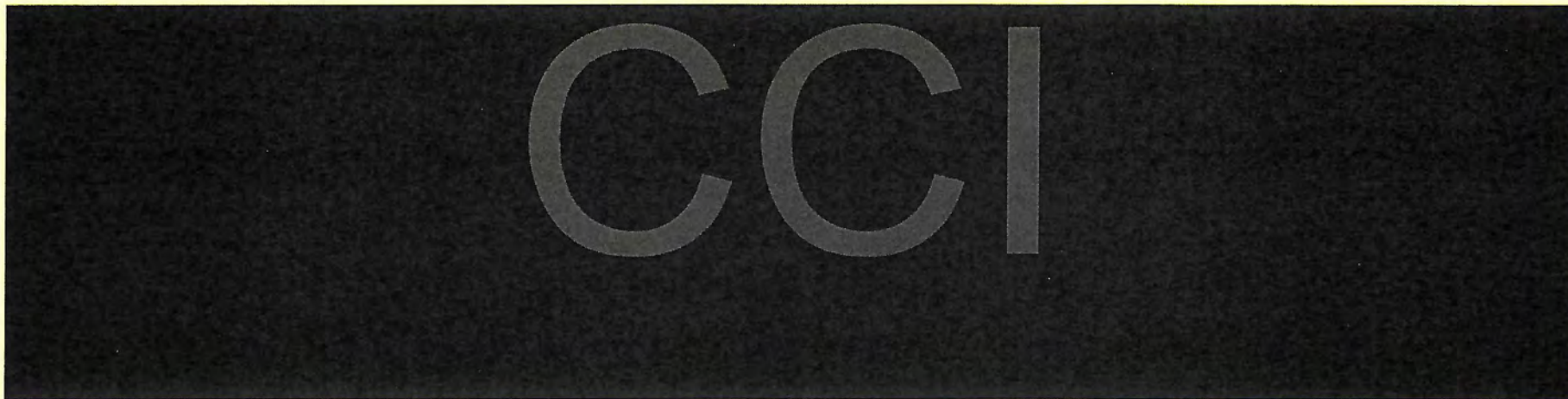
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Individual Maternal Macroscopic Observations

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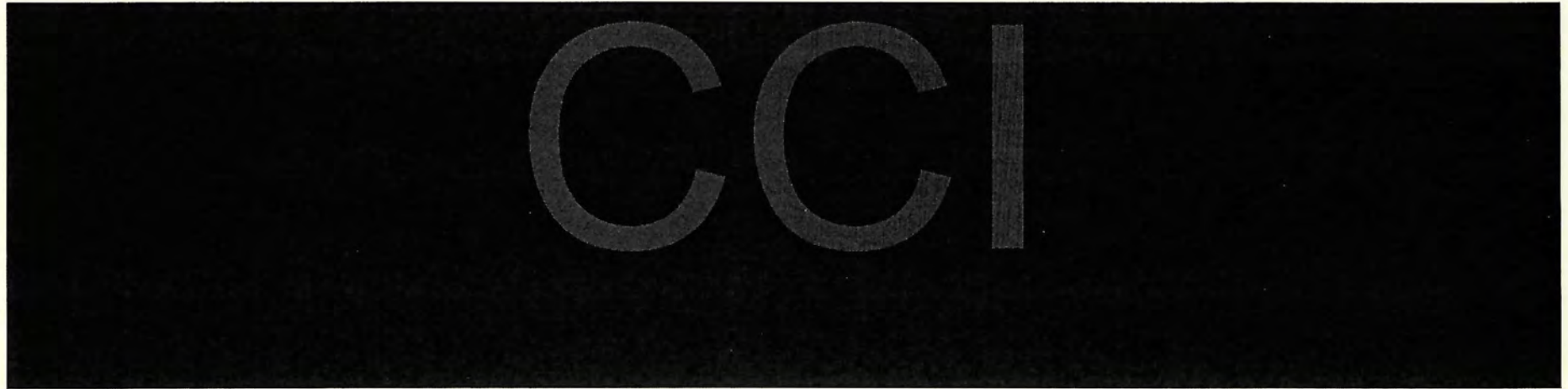
Codes Used: (C) = Clinical Observation

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Individual Maternal Macroscopic Observations



Codes Used: (C) = Clinical Observation

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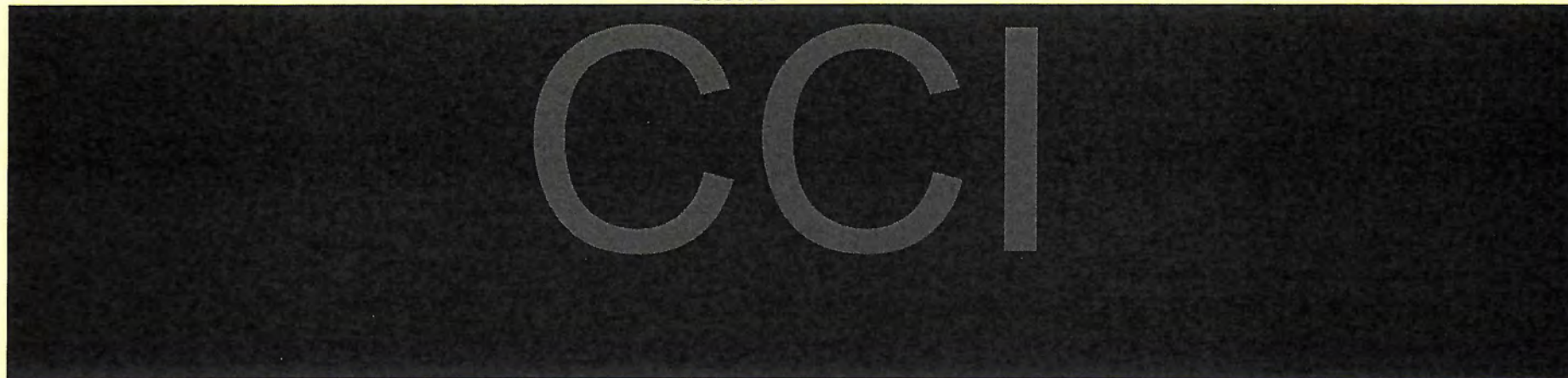
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Individual Maternal Macroscopic Observations

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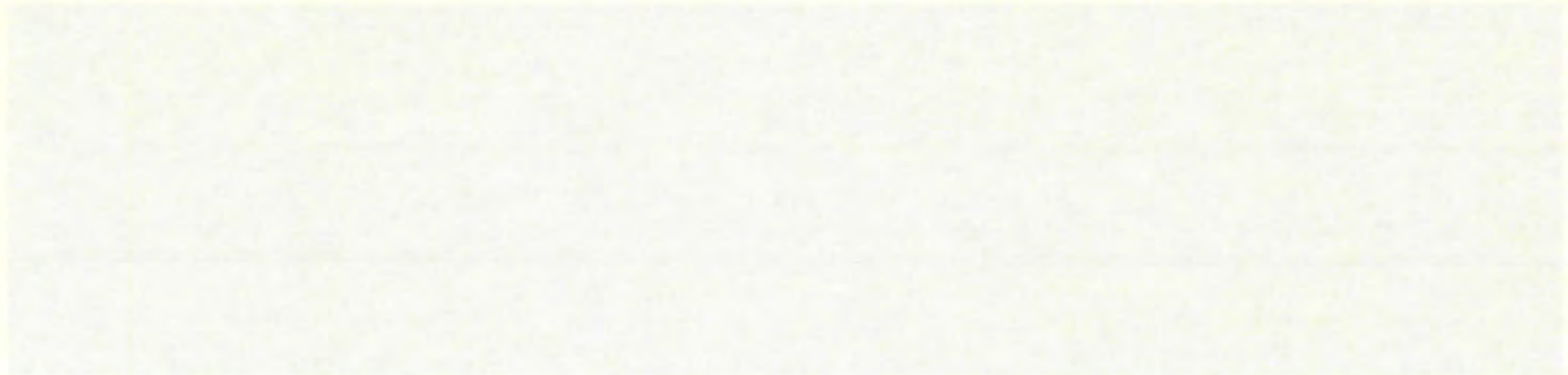
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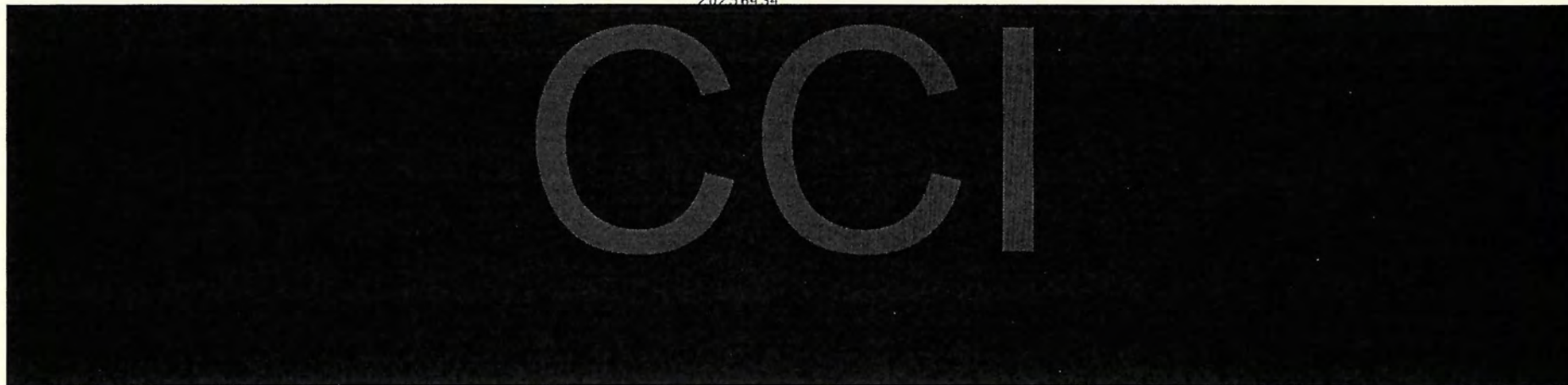
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Codes Used: (C) = Clinical Observation

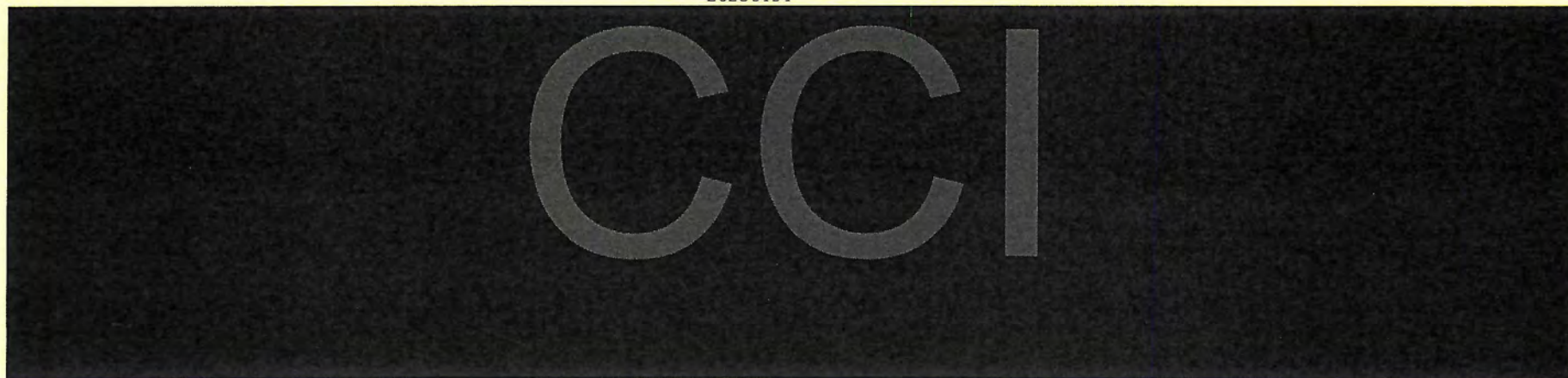
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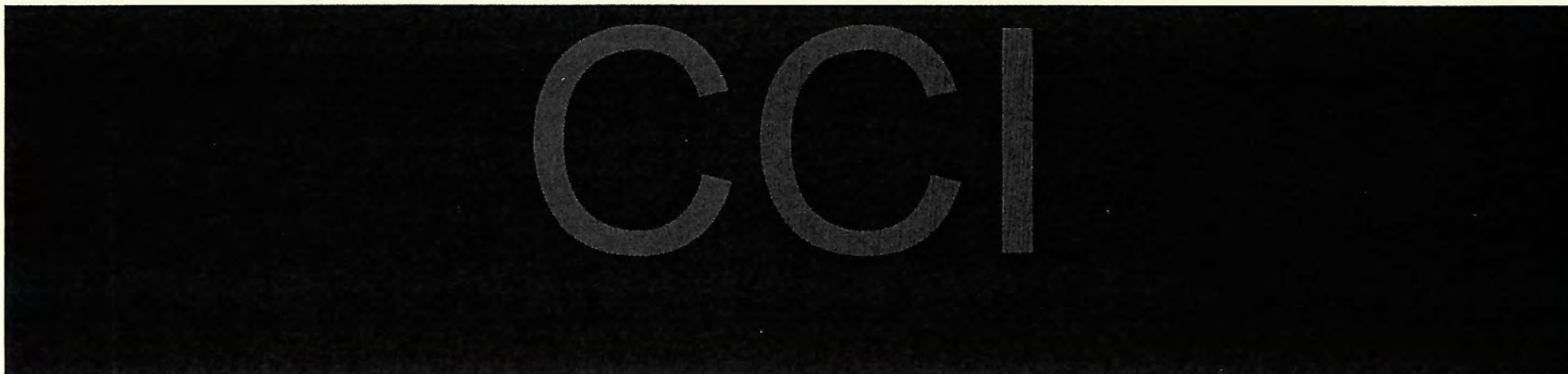
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Codes Used: (TGL) = Trackable Gross Lesion

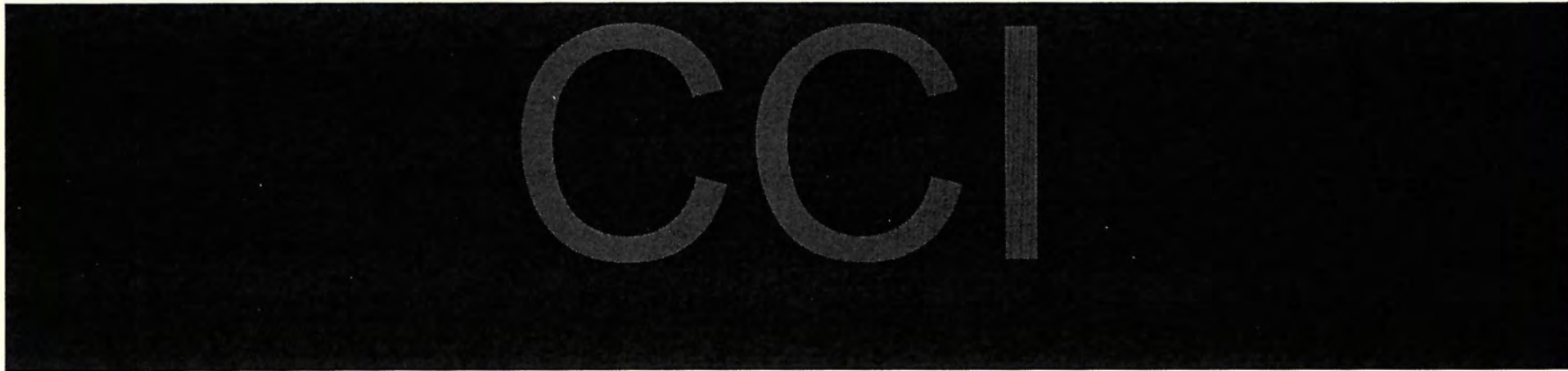
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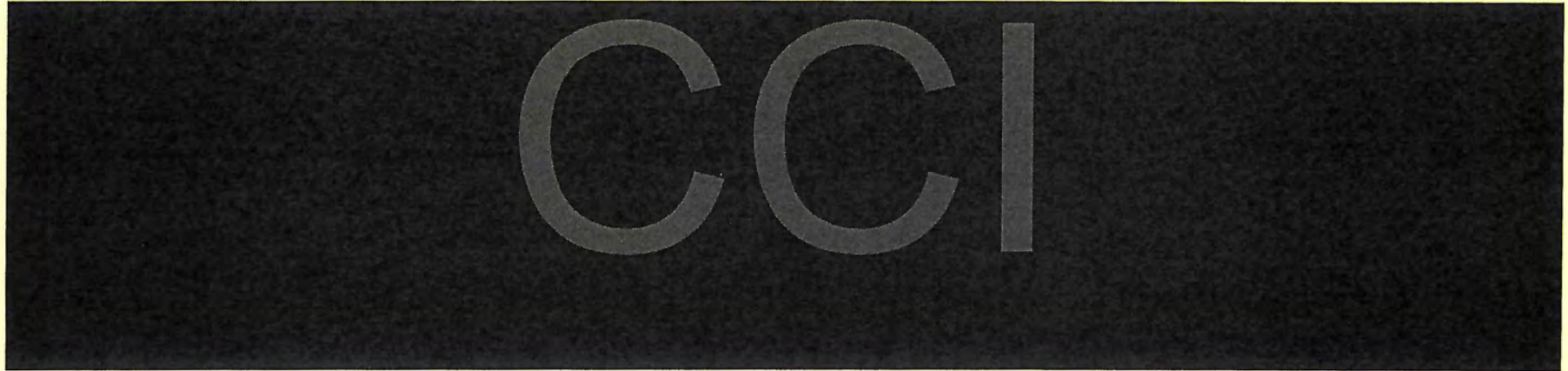
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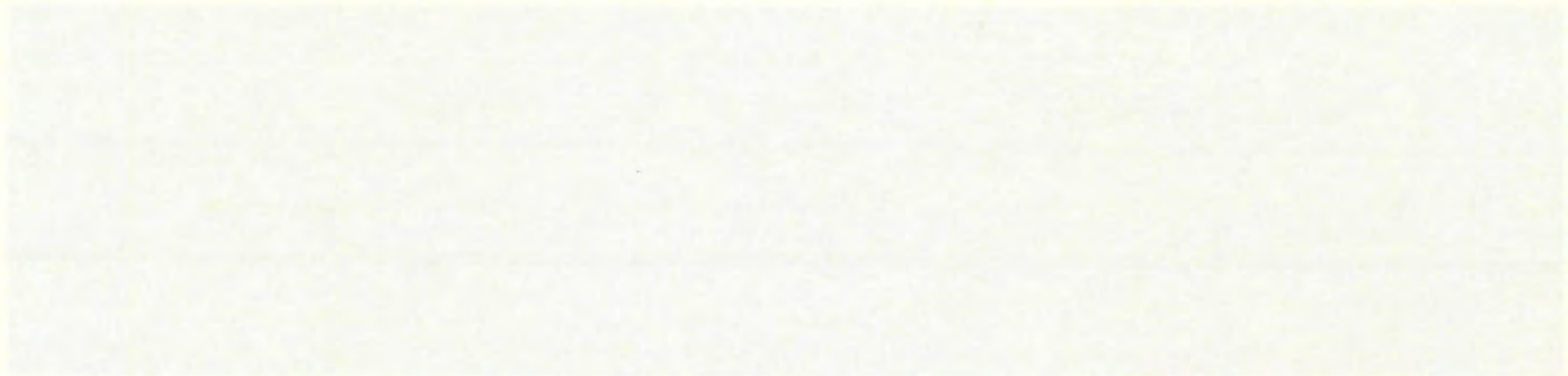
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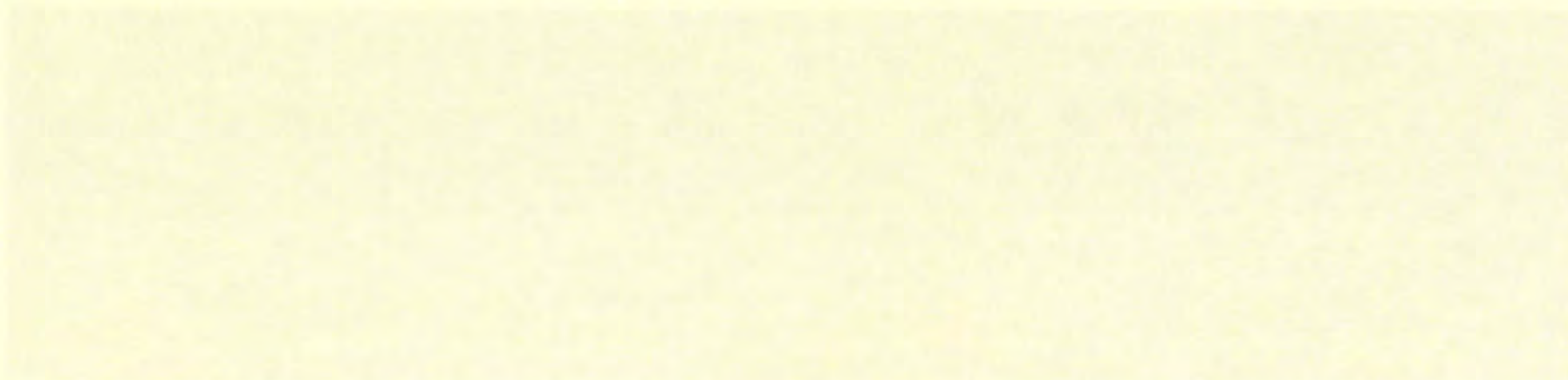
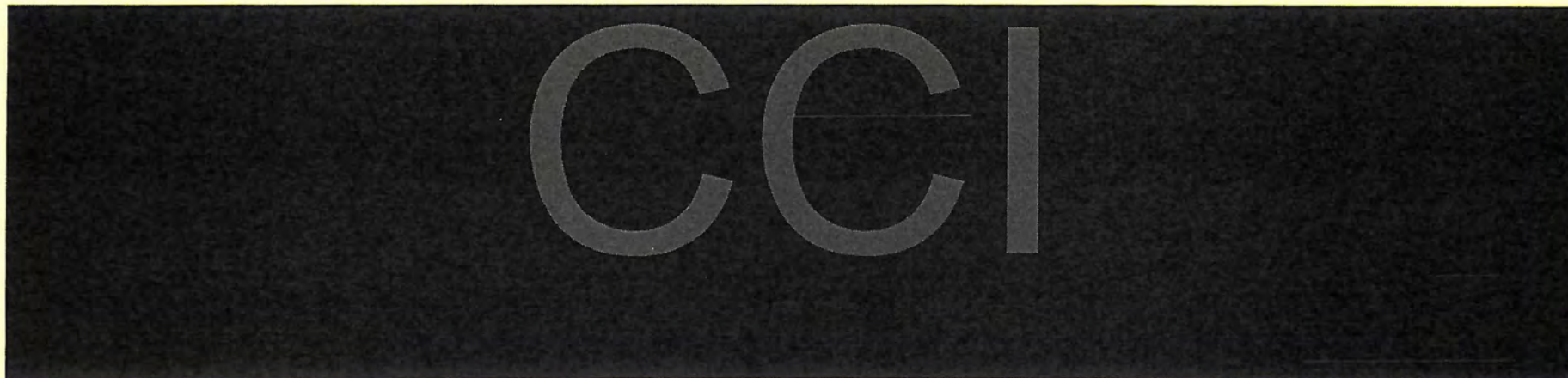
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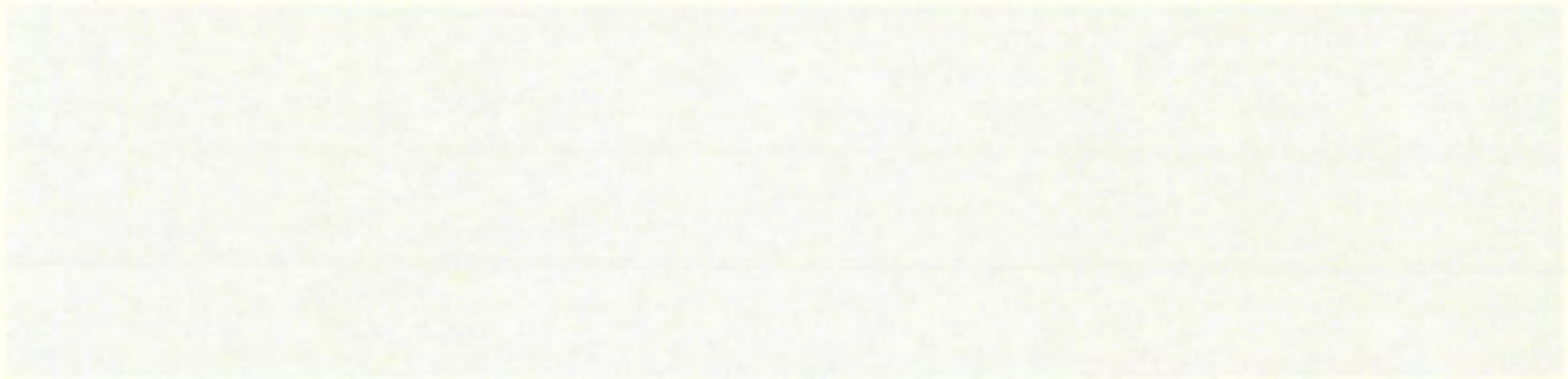
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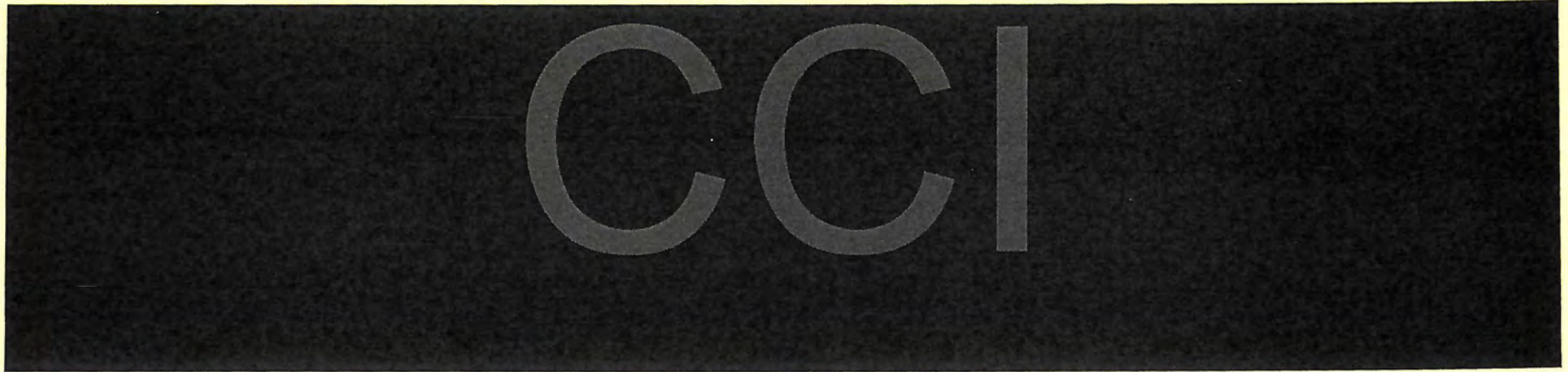
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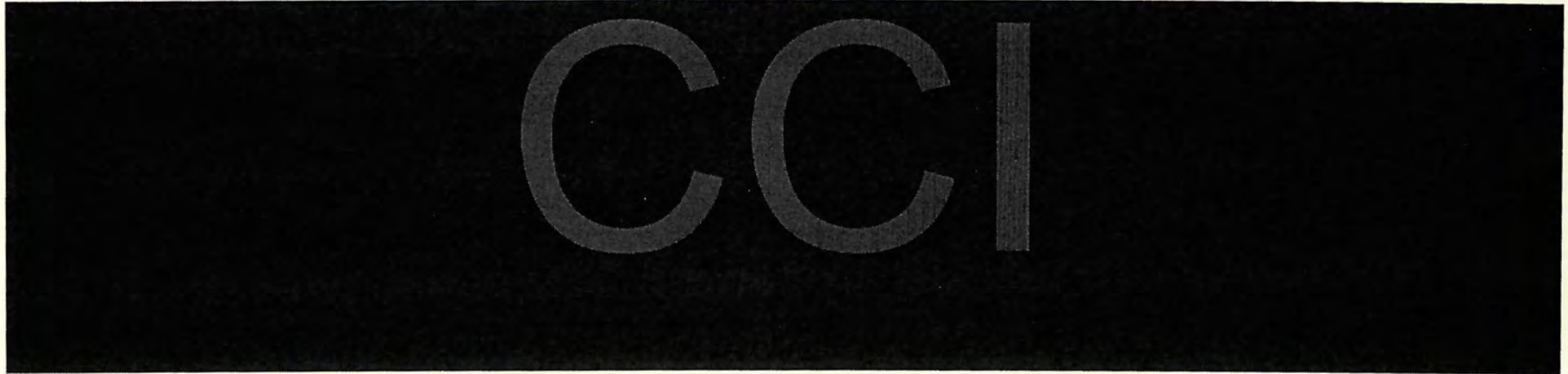
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Codes Used: (TGL) = Trackable Gross Lesion

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Codes Used: (TGL) = Trackable Gross Lesion, (C) = Clinical Observation

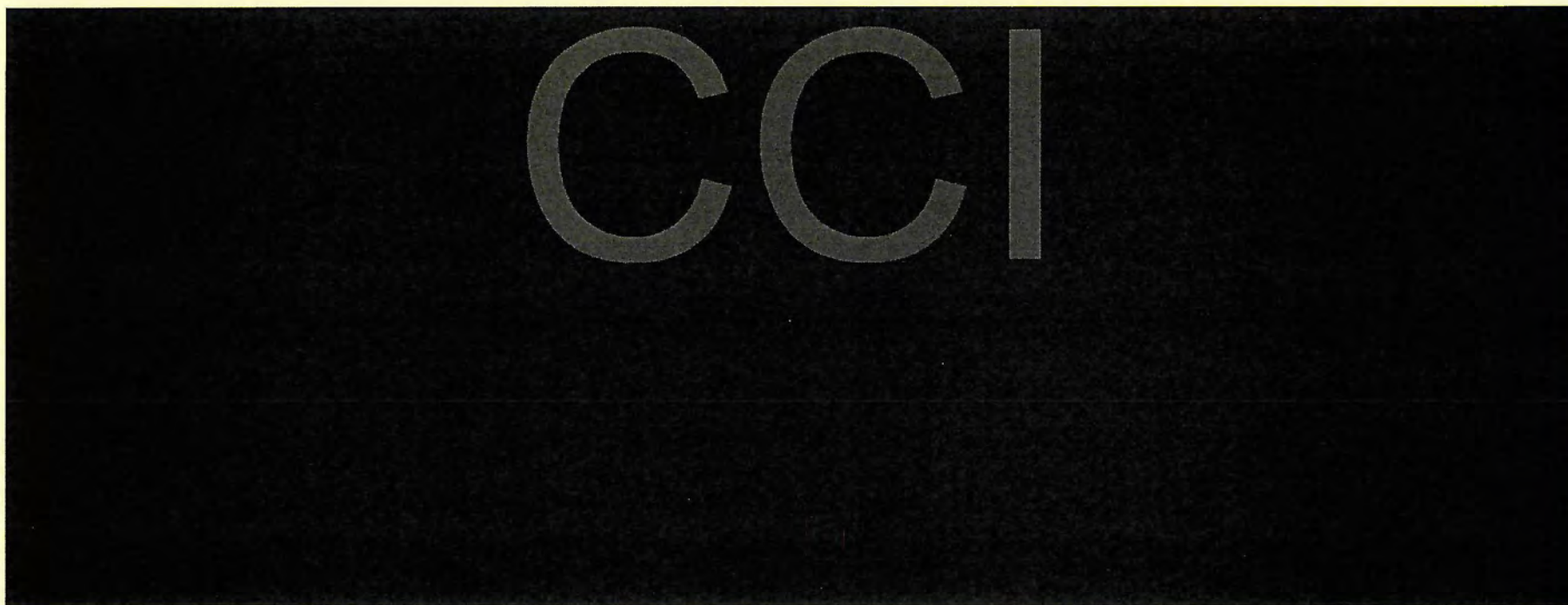
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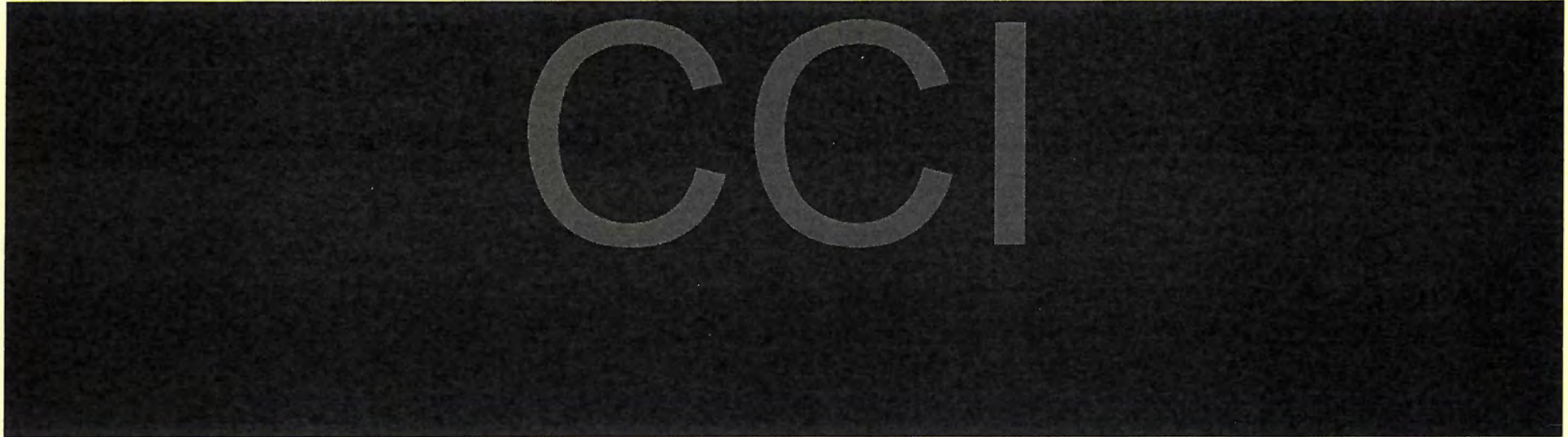
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Codes Used: (TGL) = Trackable Gross Lesion

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Codes Used: (TGL) = Trackable Gross Lesion

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Codes Used: (TGL) = Trackable Gross Lesion

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Control Omcg	Findings
Dam: 201	
	1Observations, No abnormalities detected
	2Observations, No abnormalities detected
	3Observations, No abnormalities detected
	4Observations, No abnormalities detected
	5Observations, No abnormalities detected
	6Observations, No abnormalities detected
	7Observations, No abnormalities detected
	8Observations, No abnormalities detected
	9Observations, No abnormalities detected
	10Observations, No abnormalities detected
	11Observations, No abnormalities detected
	12Observations, No abnormalities detected
	13Observations, No abnormalities detected
	14Observations, No abnormalities detected
Dam: 202	
	1Observations, No abnormalities detected
	2Observations, No abnormalities detected
	3Observations, No abnormalities detected
	4Observations, No abnormalities detected
	5Observations, No abnormalities detected
	6Observations, No abnormalities detected

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Control Omcg	Findings
Dam: 202	(Continued...)
7Observations, No abnormalities detected
8Observations, No abnormalities detected
9Observations, No abnormalities detected
10Observations, No abnormalities detected
Dam: 203	
1Observations, No abnormalities detected
2Observations, No abnormalities detected
3Observations, No abnormalities detected
4Observations, No abnormalities detected
5Observations, No abnormalities detected
6Observations, No abnormalities detected
7Observations, No abnormalities detected
8Observations, No abnormalities detected
9Observations, No abnormalities detected
10Observations, No abnormalities detected
11Observations, No abnormalities detected
12Observations, No abnormalities detected
13Observations, No abnormalities detected
Dam: 204	
1Observations, No abnormalities detected
2Observations, No abnormalities detected

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Control 0mcg	Findings
Dam: 204	(Continued...)
3Observations, No abnormalities detected
4Observations, No abnormalities detected
5Observations, No abnormalities detected
6Observations, No abnormalities detected
7Observations, No abnormalities detected
8Observations, No abnormalities detected
9Observations, No abnormalities detected
10Observations, No abnormalities detected
11Observations, No abnormalities detected
12Observations, No abnormalities detected
13Observations, No abnormalities detected
14Observations, Abdomen Stomach, Milk
15Observations, Abdomen Stomach, No milk
16Observations, Abdomen Stomach, No milk
Dam: 205	
1Observations, No abnormalities detected
2Observations, No abnormalities detected
3Observations, No abnormalities detected
4Observations, No abnormalities detected

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Control 0mcg	Findings
Dam: 205	(Continued...)
5Observations, No abnormalities detected
6Observations, No abnormalities detected
7Observations, No abnormalities detected
8Observations, No abnormalities detected
9Observations, No abnormalities detected
10Observations, No abnormalities detected
11Observations, No abnormalities detected
12Observations, Abdomen Abdomen, AutolysisObservations, Thorax Thoracic, Autolysis
13Observations, Abdomen Abdomen, AutolysisObservations, Thorax Thoracic, Autolysis
14Observations, General General, Cannibalized
Dam: 206	
1Observations, No abnormalities detected
2Observations, No abnormalities detected
3Observations, No abnormalities detected
4Observations, No abnormalities detected
5Observations, No abnormalities detected

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Control 0mcg	Findings
Dam: 206	(Continued...)
6Observations, No abnormalities detected
7Observations, No abnormalities detected
8Observations, No abnormalities detected
9Observations, No abnormalities detected
10Observations, No abnormalities detected
11Observations, No abnormalities detected
12Observations, No abnormalities detected
13Observations, No abnormalities detected
14Observations, No abnormalities detected
15Observations, No abnormalities detected
16Observations, No abnormalities detected
Dam: 207	
1Observations, No abnormalities detected
2Observations, No abnormalities detected
3Observations, No abnormalities detected
4Observations, Abdomen Stomach, No milk
5Observations, No abnormalities detected
6Observations, No abnormalities detected
7Observations, No abnormalities detected
8Observations, No abnormalities detected
9Observations, No abnormalities detected

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Control 0mcg	Findings
Dam: 208	
1Observations, No abnormalities detected
2Observations, No abnormalities detected
3Observations, No abnormalities detected
4Observations, No abnormalities detected
5Observations, No abnormalities detected
6Observations, No abnormalities detected
7Observations, No abnormalities detected
8Observations, No abnormalities detected
9Observations, No abnormalities detected
10Observations, No abnormalities detected
11Observations, No abnormalities detected
12Observations, No abnormalities detected
13Observations, No abnormalities detected
Dam: 209	
1Observations, No abnormalities detected
2Observations, No abnormalities detected
3Observations, No abnormalities detected
4Observations, No abnormalities detected
5Observations, No abnormalities detected
6Observations, No abnormalities detected
7Observations, No abnormalities detected

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Control Omcg	Findings
Dam: 209	(Continued...)
8Observations, No abnormalities detected
9Observations, No abnormalities detected
10Observations, No abnormalities detected
Dam: 210	
1Observations, No abnormalities detected
2Observations, No abnormalities detected
3Observations, No abnormalities detected
4Observations, No abnormalities detected
5Observations, No abnormalities detected
6Observations, No abnormalities detected
7Observations, No abnormalities detected
8Observations, No abnormalities detected
9Observations, No abnormalities detected
10Observations, No abnormalities detected
Dam: 211	
1Observations, No abnormalities detected
2Observations, No abnormalities detected
3Observations, No abnormalities detected
4Observations, No abnormalities detected
5Observations, No abnormalities detected
6Observations, No abnormalities detected

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Control 0mcg	Findings
Dam: 211	(Continued...)
7Observations, No abnormalities detected
8Observations, No abnormalities detected
9Observations, No abnormalities detected
10Observations, No abnormalities detected
11Observations, No abnormalities detected
12Observations, No abnormalities detected
13Observations, No abnormalities detected
Dam: 212	
1Observations, No abnormalities detected
2Observations, No abnormalities detected
3Observations, No abnormalities detected
4Observations, No abnormalities detected
5Observations, No abnormalities detected
6Observations, No abnormalities detected
7Observations, No abnormalities detected
8Observations, No abnormalities detected
9Observations, No abnormalities detected
10Observations, No abnormalities detected
11Observations, No abnormalities detected
12Observations, No abnormalities detected
13Observations, No abnormalities detected

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Control Omeg	Findings
Dam: 212	(Continued...)
14Observations, No abnormalities detected
15Observations, No abnormalities detected
16Observations, No abnormalities detected
17Observations, No abnormalities detected
18Observations, No abnormalities detected
19Observations, No abnormalities detected
Dam: 213	
1Observations, No abnormalities detected
2Observations, No abnormalities detected
3Observations, No abnormalities detected
4Observations, No abnormalities detected
5Observations, No abnormalities detected
6Observations, No abnormalities detected
7Observations, No abnormalities detected
8Observations, No abnormalities detected
9Observations, No abnormalities detected
10Observations, No abnormalities detected
11Observations, No abnormalities detected
12Observations, No abnormalities detected
Dam: 214	
1Observations, No abnormalities detected

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Control 0mcg	Findings
Dam: 214	(Continued...)
2Observations, No abnormalities detected
3Observations, No abnormalities detected
4Observations, No abnormalities detected
5Observations, No abnormalities detected
6Observations, No abnormalities detected
7Observations, No abnormalities detected
8Observations, No abnormalities detected
9Observations, No abnormalities detected
10Observations, No abnormalities detected
11Observations, No abnormalities detected
12Observations, No abnormalities detected
13Observations, No abnormalities detected
Dam: 215	
1Observations, No abnormalities detected
2Observations, No abnormalities detected
3Observations, No abnormalities detected
4Observations, No abnormalities detected
5Observations, No abnormalities detected
6Observations, No abnormalities detected
7Observations, No abnormalities detected
8Observations, No abnormalities detected

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Control Omcg	Findings
Dam: 215	(Continued...)
9Observations, No abnormalities detected
10Observations, No abnormalities detected
11Observations, No abnormalities detected
12Observations, No abnormalities detected
13Observations, No abnormalities detected
Dam: 216	
1Observations, No abnormalities detected
2Observations, No abnormalities detected
3Observations, No abnormalities detected
4Observations, No abnormalities detected
5Observations, No abnormalities detected
6Observations, No abnormalities detected
7Observations, No abnormalities detected
8Observations, No abnormalities detected
9Observations, No abnormalities detected
10Observations, No abnormalities detected
11Observations, No abnormalities detected
12Observations, No abnormalities detected
13Observations, No abnormalities detected
14Observations, No abnormalities detected

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Control 0mcg	Findings
Dam: 217	
1Observations, No abnormalities detected
2Observations, No abnormalities detected
3Observations, No abnormalities detected
4Observations, No abnormalities detected
5Observations, No abnormalities detected
6Observations, No abnormalities detected
7Observations, No abnormalities detected
8Observations, No abnormalities detected
9Observations, No abnormalities detected
10Observations, No abnormalities detected
11Observations, No abnormalities detected
12Observations, No abnormalities detected
13Observations, No abnormalities detected
14Observations, Abdomen Abdomen, Autolysis Stomach, No milkObservations, Thorax Thoracic, Autolysis
Dam: 218	
1Observations, No abnormalities detected
2Observations, No abnormalities detected
3Observations, No abnormalities detected

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Control 0mcg	Findings
Dam: 218	(Continued...)
4Observations, No abnormalities detected
5Observations, No abnormalities detected
6Observations, No abnormalities detected
7Observations, No abnormalities detected
8Observations, No abnormalities detected
9Observations, No abnormalities detected
10Observations, No abnormalities detected
Dam: 219	
1Observations, No abnormalities detected
2Observations, No abnormalities detected
3Observations, No abnormalities detected
4Observations, No abnormalities detected
5Observations, No abnormalities detected
6Observations, No abnormalities detected
7Observations, No abnormalities detected
8Observations, No abnormalities detected
9Observations, No abnormalities detected
10Observations, No abnormalities detected
11Observations, No abnormalities detected
12Observations, No abnormalities detected
13Observations, No abnormalities detected

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Control 0mcg	Findings
Dam: 219	(Continued...)
14Observations, No abnormalities detected
Dam: 220	
1Observations, No abnormalities detected
2Observations, No abnormalities detected
3Observations, No abnormalities detected
4Observations, No abnormalities detected
5Observations, No abnormalities detected
6Observations, No abnormalities detected
7Observations, No abnormalities detected
8Observations, No abnormalities detected
9Observations, No abnormalities detected
10Observations, No abnormalities detected
11Observations, No abnormalities detected
12Observations, No abnormalities detected
13Observations, No abnormalities detected
14Observations, No abnormalities detected
15Observations, No abnormalities detected
Dam: 221	
1Observations, No abnormalities detected
2Observations, No abnormalities detected
3Observations, No abnormalities detected

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Control Omcg	Findings
Dam: 221	(Continued...)
4Observations, No abnormalities detected
5Observations, No abnormalities detected
6Observations, No abnormalities detected
7Observations, No abnormalities detected
8Observations, No abnormalities detected
9Observations, No abnormalities detected
10Observations, No abnormalities detected
11Observations, No abnormalities detected
12Observations, No abnormalities detected
13Observations, No abnormalities detected
14Observations, No abnormalities detected
15Observations, No abnormalities detected
Dam: 222	
1Observations, No abnormalities detected
2Observations, No abnormalities detected
3Observations, No abnormalities detected
4Observations, No abnormalities detected
5Observations, No abnormalities detected
6Observations, No abnormalities detected
7Observations, No abnormalities detected
8Observations, No abnormalities detected

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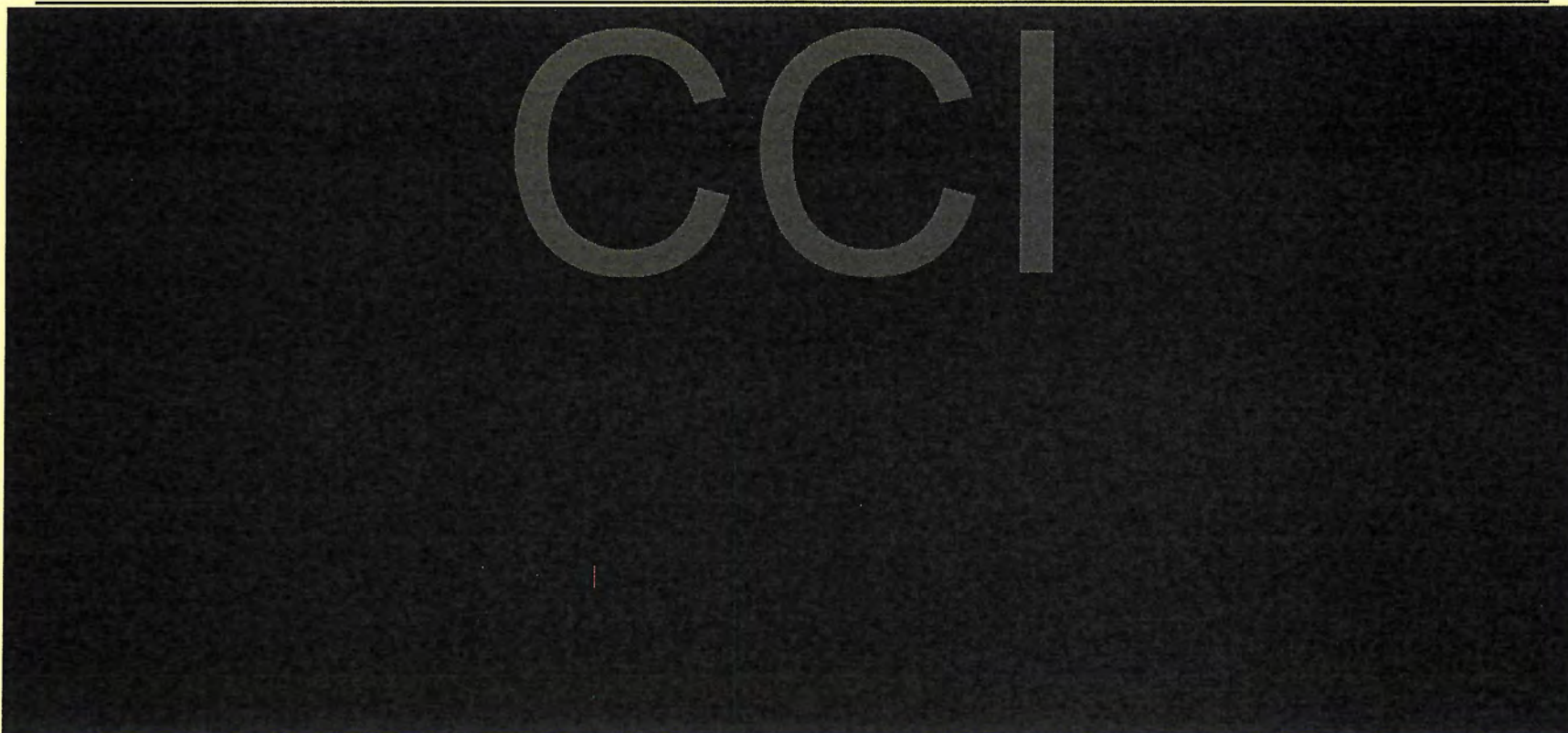
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Control Omcg	Findings
Dam: 222	(Continued...)
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10Observations, No abnormalities detected
11Observations, No abnormalities detected
12Observations, No abnormalities detected
13Observations, No abnormalities detected
14Observations, No abnormalities detected

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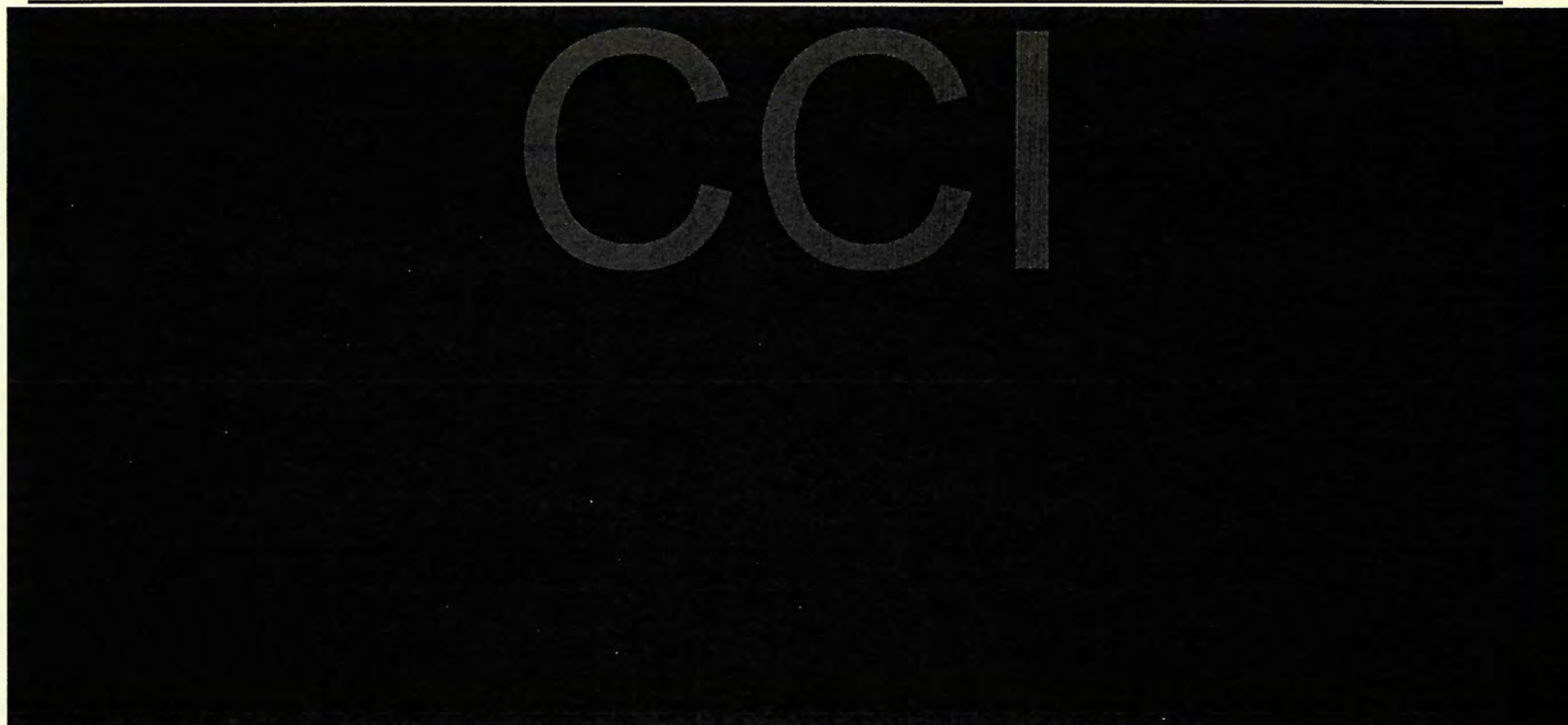
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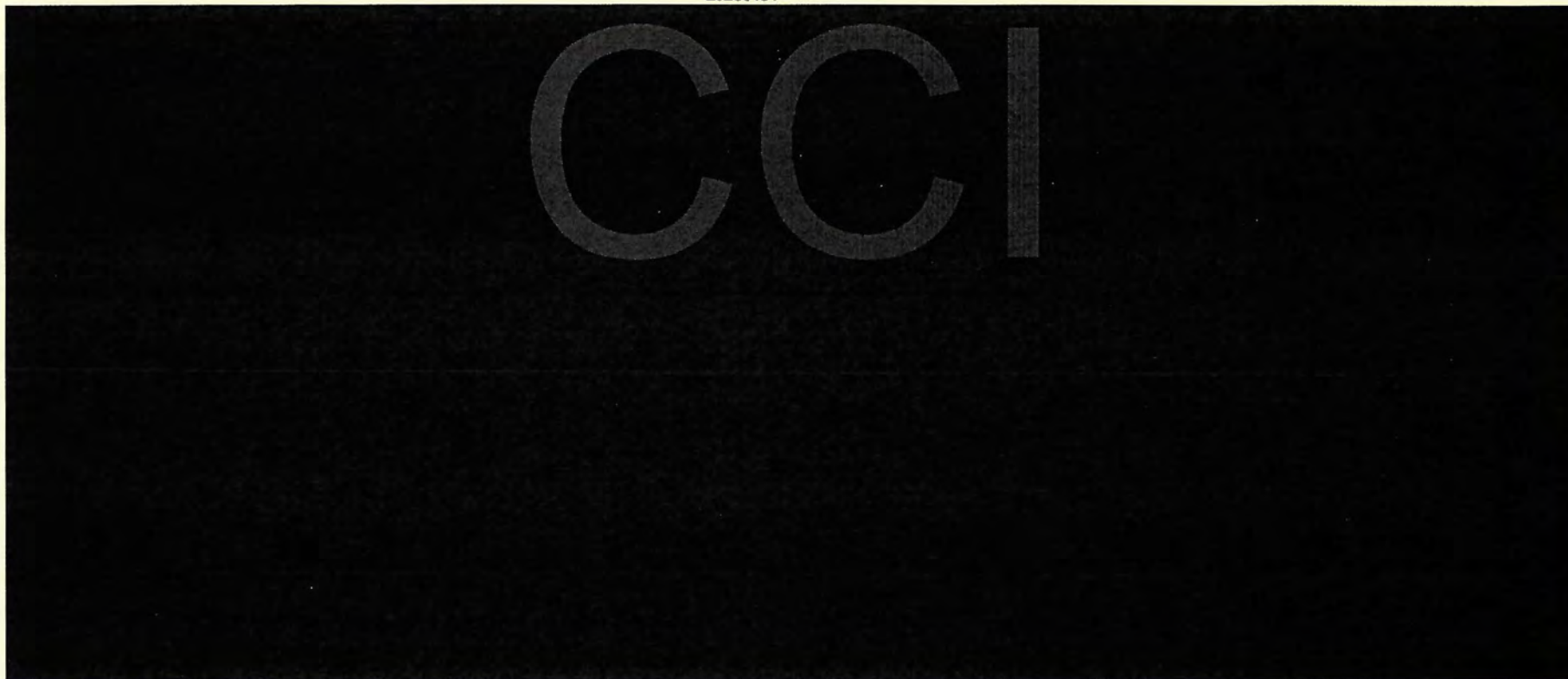
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BNT162b2 30mcg	Findings
Dam: 245	
1Observations, No abnormalities detected
2Observations, No abnormalities detected
3Observations, No abnormalities detected
4Observations, No abnormalities detected
5Observations, No abnormalities detected
6Observations, No abnormalities detected
7Observations, No abnormalities detected
8Observations, No abnormalities detected
9Observations, No abnormalities detected
10Observations, No abnormalities detected
11Observations, No abnormalities detected
12Observations, No abnormalities detected
13Observations, No abnormalities detected
14Observations, No abnormalities detected
15Observations, No abnormalities detected
16Observations, No abnormalities detected
Dam: 246	
1Observations, No abnormalities detected
2Observations, No abnormalities detected
3Observations, No abnormalities detected
4Observations, No abnormalities detected

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Individual Pup Macroscopic Observations

20256434

BNT162b2 30mcg	Findings
Dam: 246	(Continued...)
5Observations, No abnormalities detected
6Observations, No abnormalities detected
7Observations, No abnormalities detected
8Observations, No abnormalities detected
9Observations, No abnormalities detected
10Observations, No abnormalities detected
11Observations, No abnormalities detected
12Observations, No abnormalities detected
Dam: 247	
1Observations, No abnormalities detected
2Observations, No abnormalities detected
3Observations, No abnormalities detected
4Observations, No abnormalities detected
5Observations, No abnormalities detected
6Observations, No abnormalities detected
7Observations, No abnormalities detected
8Observations, No abnormalities detected
9Observations, No abnormalities detected
10Observations, No abnormalities detected
11Observations, No abnormalities detected
12Observations, No abnormalities detected

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Individual Pup Macroscopic Observations

20256434

BNT162b2 30mcg	Findings
Dam: 247	(Continued...)
13Observations, No abnormalities detected
Dam: 248	
1Observations, No abnormalities detected
2Observations, No abnormalities detected
3Observations, No abnormalities detected
4Observations, No abnormalities detected
5Observations, No abnormalities detected
6Observations, No abnormalities detected
7Observations, No abnormalities detected
8Observations, No abnormalities detected
9Observations, No abnormalities detected
10Observations, No abnormalities detected
11Observations, No abnormalities detected
Dam: 249	
1Observations, No abnormalities detected
2Observations, No abnormalities detected
3Observations, No abnormalities detected
4Observations, No abnormalities detected
5Observations, No abnormalities detected
6Observations, No abnormalities detected
7Observations, No abnormalities detected

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Individual Pup Macroscopic Observations

20256434

BNT162b2 30mcg	Findings
Dam: 249	(Continued...)
8Observations, No abnormalities detected
9Observations, No abnormalities detected
10Observations, No abnormalities detected
11Observations, No abnormalities detected
12Observations, No abnormalities detected
13Observations, No abnormalities detected
14Observations, No abnormalities detected
15Observations, No abnormalities detected
16Observations, No abnormalities detected
17Observations, No abnormalities detected
18Observations, Abdomen Abdomen, Autolysis Stomach, No milkObservations, Thorax Thoracic, Autolysis
Dam: 250	
1Observations, No abnormalities detected
2Observations, No abnormalities detected
3Observations, No abnormalities detected
4Observations, No abnormalities detected
5Observations, No abnormalities detected
6Observations, No abnormalities detected

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Individual Pup Macroscopic Observations

20256434

BNT162b2 30mcg	Findings
Dam: 250	(Continued...)
7Observations, No abnormalities detected
8Observations, No abnormalities detected
9Observations, No abnormalities detected
10Observations, No abnormalities detected
11Observations, No abnormalities detected
12Observations, No abnormalities detected
Dam: 251	
1Observations, No abnormalities detected
2Observations, No abnormalities detected
3Observations, No abnormalities detected
4Observations, No abnormalities detected
5Observations, No abnormalities detected
6Observations, No abnormalities detected
7Observations, No abnormalities detected
9Observations, No abnormalities detected
10Observations, No abnormalities detected
11Observations, No abnormalities detected
12Observations, No abnormalities detected
13Observations, No abnormalities detected
14Observations, No abnormalities detected
15Observations, No abnormalities detected

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Individual Pup Macroscopic Observations

20256434

BNT162b2 30mcg	Findings
Dam: 251	(Continued...)
16Observations, No abnormalities detected
17Observations, No abnormalities detected
Dam: 252	
1Observations, No abnormalities detected
2Observations, No abnormalities detected
3Observations, No abnormalities detected
4Observations, No abnormalities detected
5Observations, No abnormalities detected
6Observations, No abnormalities detected
7Observations, No abnormalities detected
8Observations, No abnormalities detected
9Observations, No abnormalities detected
10Observations, No abnormalities detected
11Observations, No abnormalities detected
12Observations, Abdomen Stomach, No milk
Dam: 253	
1Observations, No abnormalities detected
2Observations, No abnormalities detected
3Observations, No abnormalities detected
4Observations, No abnormalities detected

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Individual Pup Macroscopic Observations

20256434

BNT162b2 30mcg	Findings
Dam: 253	(Continued...)
5Observations, No abnormalities detected
6Observations, No abnormalities detected
7Observations, No abnormalities detected
8Observations, No abnormalities detected
9Observations, No abnormalities detected
10Observations, No abnormalities detected
11Observations, No abnormalities detected
12Observations, Thorax Thoracic, Dark, [thymus]
Dam: 254	
Dam: 255	
1Observations, Abdomen Liver, Hernia, [left medial lobe]Observations, General General, Situs inversus - (M), [thoracic and abdominal cavities]
2Observations, No abnormalities detected
3Observations, No abnormalities detected
Dam: 256	
1Observations, No abnormalities detected
2Observations, No abnormalities detected
3Observations, No abnormalities detected

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20256434

BNT162b2 30mcg	Findings
Dam: 256	(Continued...)
4Observations, No abnormalities detected
5Observations, No abnormalities detected
6Observations, No abnormalities detected
7Observations, No abnormalities detected
8Observations, No abnormalities detected
9Observations, No abnormalities detected
10Observations, No abnormalities detected
11Observations, No abnormalities detected
12Observations, No abnormalities detected
13Observations, No abnormalities detected
14Observations, No abnormalities detected
15Observations, No abnormalities detected
Dam: 257	
1Observations, No abnormalities detected
2Observations, No abnormalities detected
3Observations, No abnormalities detected
4Observations, No abnormalities detected
5Observations, No abnormalities detected
6Observations, No abnormalities detected
7Observations, No abnormalities detected
8Observations, No abnormalities detected

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20256434

BNT162b2 30mcg	Findings
Dam: 257	(Continued...)
9Observations, No abnormalities detected
10Observations, No abnormalities detected
11Observations, No abnormalities detected
12Observations, No abnormalities detected
13Observations, No abnormalities detected
14Observations, No abnormalities detected
15Observations, No abnormalities detected
Dam: 258	
1Observations, No abnormalities detected
2Observations, No abnormalities detected
3Observations, No abnormalities detected
4Observations, No abnormalities detected
5Observations, No abnormalities detected
6Observations, No abnormalities detected
7Observations, No abnormalities detected
8Observations, No abnormalities detected
9Observations, No abnormalities detected
10Observations, No abnormalities detected
11Observations, No abnormalities detected
12Observations, No abnormalities detected
13Observations, No abnormalities detected

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Individual Pup Macroscopic Observations

20256434

BNT162b2 30mcg	Findings
Dam: 258	(Continued...)
14Observations, No abnormalities detected
15Observations, No abnormalities detected
Dam: 259	
1Observations, No abnormalities detected
2Observations, No abnormalities detected
3Observations, No abnormalities detected
4Observations, No abnormalities detected
5Observations, No abnormalities detected
6Observations, No abnormalities detected
7Observations, No abnormalities detected
8Observations, No abnormalities detected
9Observations, No abnormalities detected
10Observations, No abnormalities detected
11Observations, No abnormalities detected
12Observations, No abnormalities detected
13Observations, No abnormalities detected
14Observations, No abnormalities detected
15Observations, No abnormalities detected
Dam: 260	
1Observations, No abnormalities detected
2Observations, No abnormalities detected

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Individual Pup Macroscopic Observations

20256434

BNT162b2 30mcg	Findings
Dam: 260	(Continued...)
3Observations, No abnormalities detected
4Observations, No abnormalities detected
5Observations, No abnormalities detected
6Observations, No abnormalities detected
7Observations, No abnormalities detected
8Observations, No abnormalities detected
9Observations, No abnormalities detected
10Observations, No abnormalities detected
11Observations, No abnormalities detected
12Observations, No abnormalities detected
13Observations, No abnormalities detected
Dam: 261	
1Observations, No abnormalities detected
2Observations, No abnormalities detected
3Observations, No abnormalities detected
4Observations, No abnormalities detected
5Observations, No abnormalities detected
6Observations, No abnormalities detected
7Observations, No abnormalities detected
8Observations, No abnormalities detected
9Observations, No abnormalities detected

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Individual Pup Macroscopic Observations

20256434

BNT162b2 30mcg	Findings
Dam: 261	(Continued...)
10Observations, No abnormalities detected
11Observations, No abnormalities detected
Dam: 262	
1Observations, No abnormalities detected
2Observations, No abnormalities detected
3Observations, No abnormalities detected
4Observations, No abnormalities detected
5Observations, No abnormalities detected
6Observations, No abnormalities detected
7Observations, No abnormalities detected
8Observations, No abnormalities detected
9Observations, No abnormalities detected
10Observations, No abnormalities detected
11Observations, No abnormalities detected
12Observations, No abnormalities detected
13Observations, No abnormalities detected
Dam: 263	
1Observations, No abnormalities detected
2Observations, No abnormalities detected
3Observations, No abnormalities detected
4Observations, No abnormalities detected

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20256434

BNT162b2 30mcg	Findings
Dam: 263	(Continued...)
5Observations, No abnormalities detected
6Observations, No abnormalities detected
7Observations, No abnormalities detected
8Observations, No abnormalities detected
9Observations, No abnormalities detected
10Observations, No abnormalities detected
11Observations, No abnormalities detected
12Observations, No abnormalities detected
Dam: 264	
1Observations, No abnormalities detected
2Observations, No abnormalities detected
3Observations, No abnormalities detected
4Observations, No abnormalities detected
5Observations, No abnormalities detected
6Observations, No abnormalities detected
7Observations, No abnormalities detected
8Observations, No abnormalities detected
9Observations, No abnormalities detected
10Observations, No abnormalities detected
11Observations, No abnormalities detected
12Observations, No abnormalities detected

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20256434

BNT162b2 30mcg	Findings
Dam: 264	(Continued...)
13Observations, No abnormalities detected
Dam: 265	
1Observations, No abnormalities detected
2Observations, No abnormalities detected
3Observations, No abnormalities detected
4Observations, No abnormalities detected
5Observations, No abnormalities detected
6Observations, No abnormalities detected
7Observations, No abnormalities detected
8Observations, No abnormalities detected
9Observations, No abnormalities detected
10Observations, No abnormalities detected
11Observations, No abnormalities detected
12Observations, No abnormalities detected
13Observations, No abnormalities detected
14Observations, No abnormalities detected
15Observations, No abnormalities detected
Dam: 266	
1Observations, No abnormalities detected
2Observations, No abnormalities detected
3Observations, No abnormalities detected

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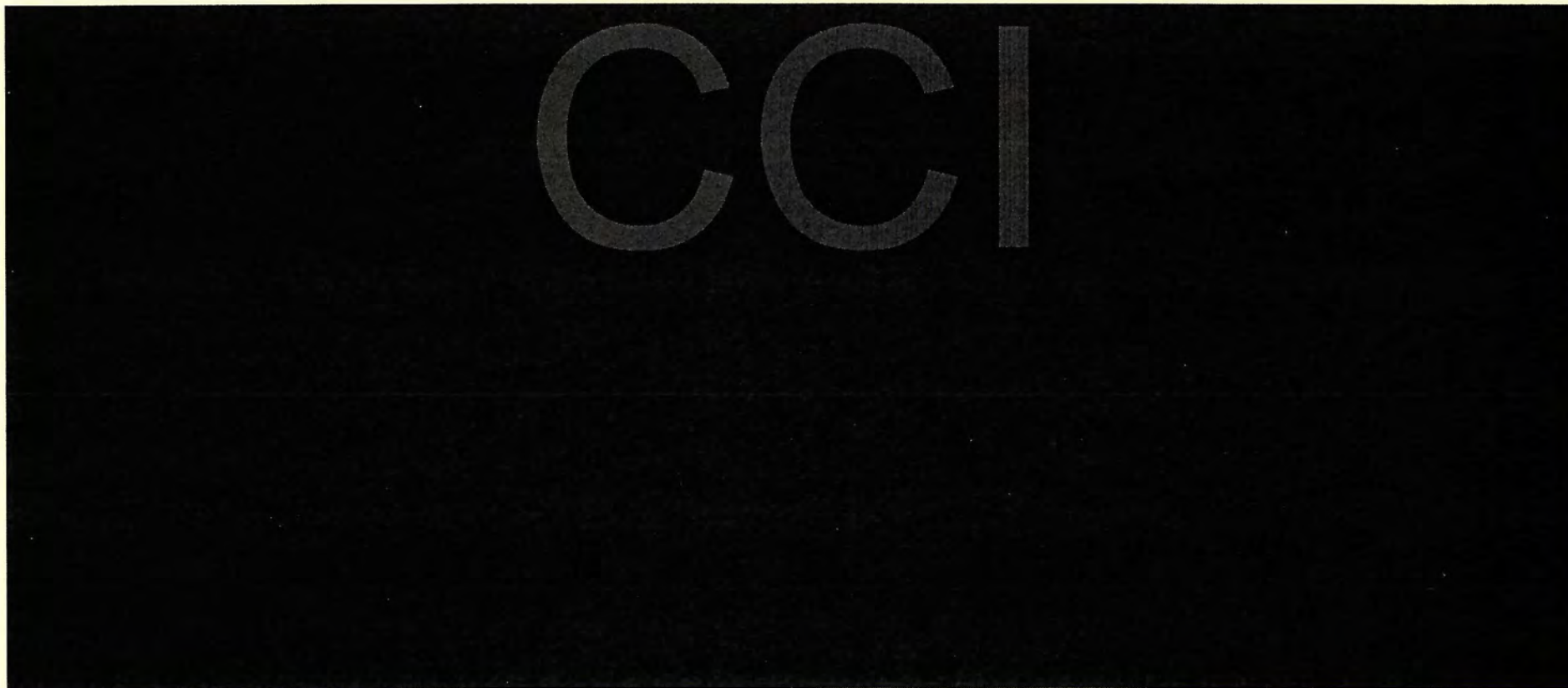
Individual Pup Macroscopic Observations

20256434

BNT162b2 30mcg	Findings
Dam: 266	(Continued...)
4Observations, No abnormalities detected
5Observations, No abnormalities detected
6Observations, No abnormalities detected
7Observations, No abnormalities detected
8Observations, No abnormalities detected
9Observations, No abnormalities detected
10Observations, No abnormalities detected
11Observations, No abnormalities detected

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Individual Pup Macroscopic Observations



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Individual Pup Macroscopic Observations



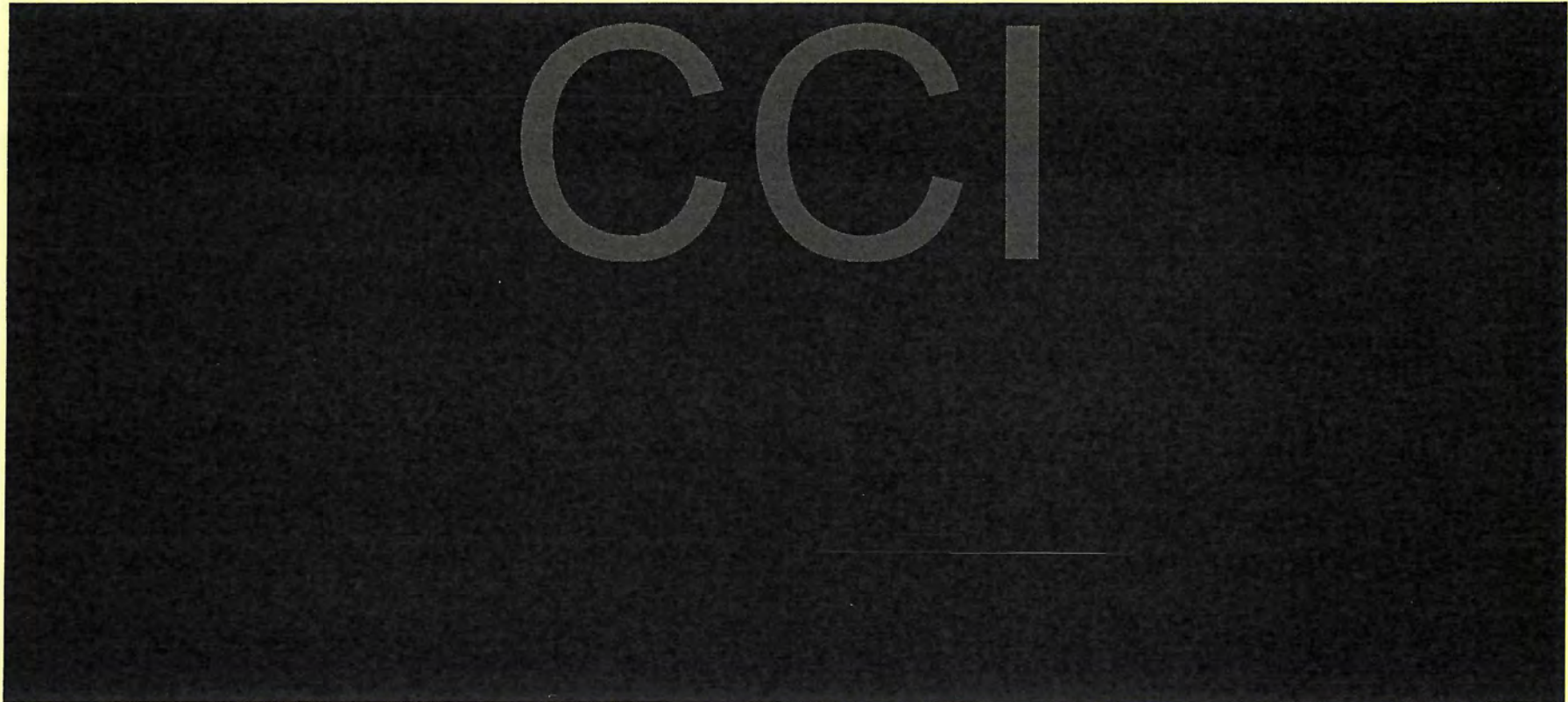
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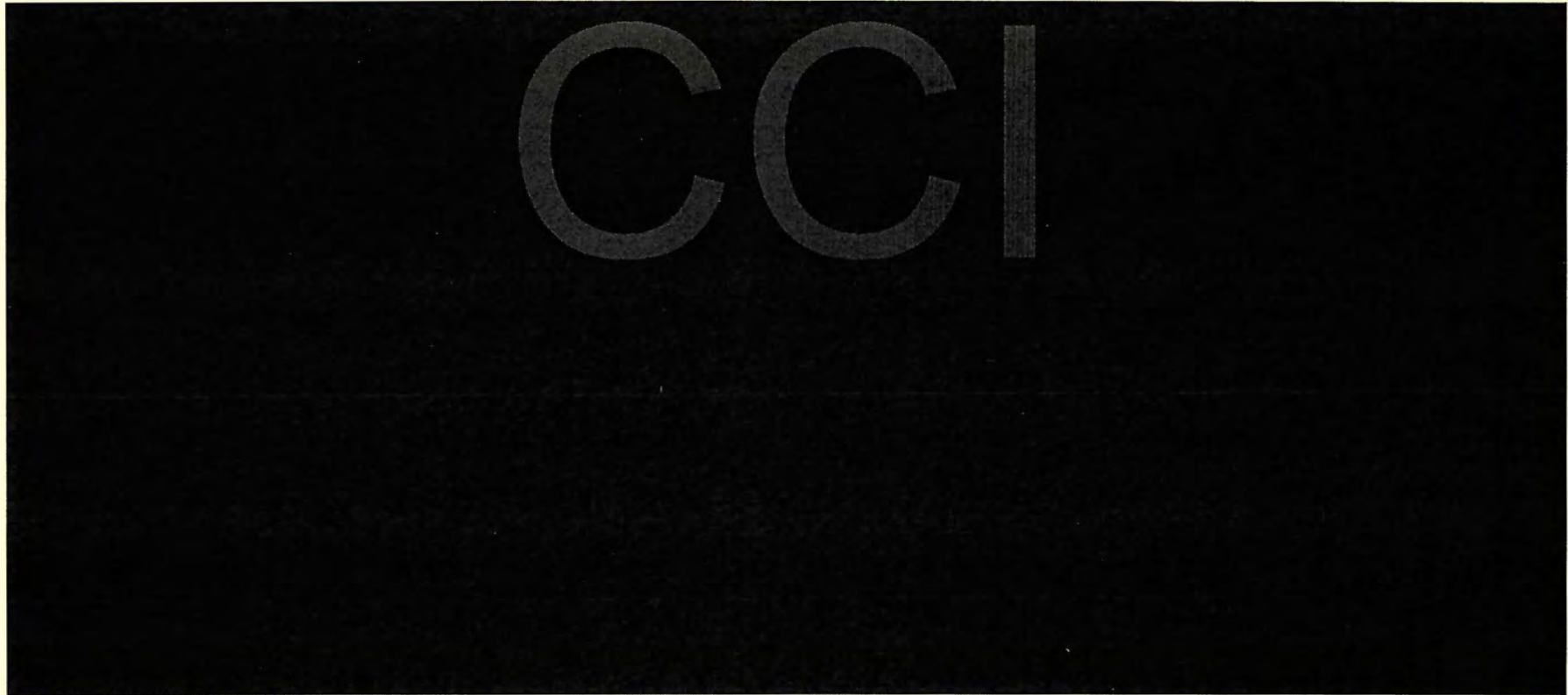
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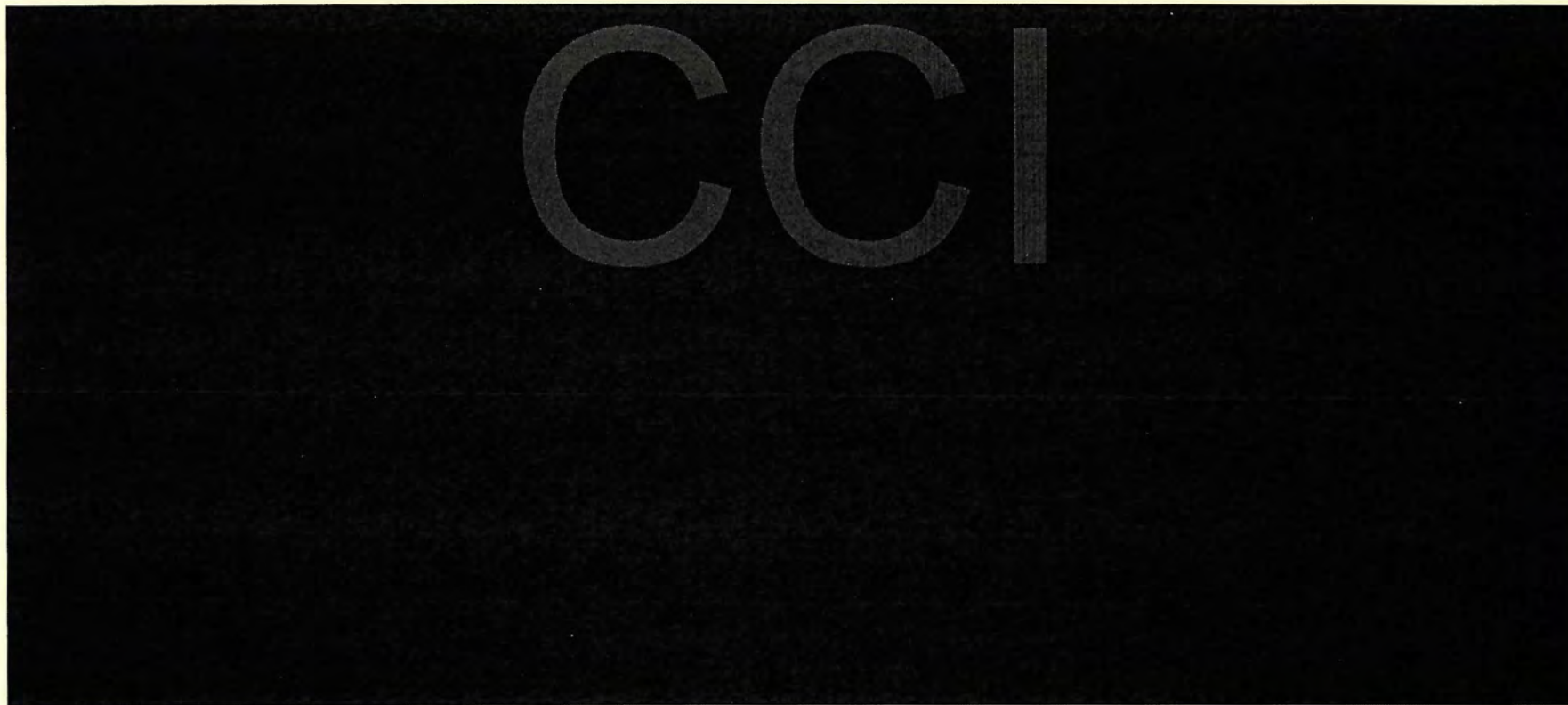
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Individual Pup Macroscopic Observations



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Historical Control Data from Wistar Rat (CRL Lyon)



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Historical Control Data

Rat Wistar : CrI-WI

Oestrous cycle - before treatment

Study	Year	Females evaluated	Cycle length (days)		Irregularity index		Oestrous days (%)		Females acyclic or with acyclic period
		N	Mean	SD	Mean	SD	Mean	SD	%
Q17	2017	20	3.8	0.3	0.2	0.2	31.8	6.3	0
U17	2017	19	3.9	0.2	0.3	0.2	30.5	4.0	5
I13	2013	17	3.9	0.3	0.3	0.2	31.4	7.4	15
J13	2013	20	4.1	0.3	0.2	0.3	29.3	8.5	0
<i>Total</i>		76							
<i>Mean</i>			3.9		0.2		30.7		5
<i>SD</i>				0.3		0.2		6.7	

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Historical Control Data

Rat Wistar : Crl-WI

Oestrous cycle - during treatment (pre-mating period)

Study	Year	Females evaluated	Cycle length (days)		Irregularity index		Oestrous days (%)		Females acyclic or with acyclic period
		N	Mean	SD	Mean	SD	Mean	SD	%
J18	2017	16	4.0	0.2	0.1	0.2	28.7	5.8	20
Q17	2017	17	4.2	0.23	0.3	0.28	30.7	6.1	15
U17	2017	20	4.1	0.5	0.3	0.3	32.1	6.8	0
A16	2016	20	4	0.3	0.3	0.2	32.0	5.6	9
B16	2016	19	3.8	0.3	0.2	0.2	27.4	6.2	5
F16	2016	21	3.9	0.2	0.2	0.3	28.6	5.1	5
Y16	2016	16	3.9	0.5	0.3	0.3	32.1	5.6	24
A15	2015	20	3.8	0.3	0.3	0.2	32.7	4.3	0
K15-1	2015	16	4.1	0.2	0.2	0.2	31.3	4.7	33
K15-2	2015	23	3.9	0.2	0.2	0.2	31.4	3.9	4
Total		188							
Mean			4.0		0.2		30.7		10
SD				0.3		0.2		5.6	
2009-2014		92	3.9	0.3	0.2	0.2	32.5	7.5	7

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Historical Control Data

Rat Wistar : Crl-WI

Maternal body weight gain (g) during gestation

Study	Year	Dams with live fetuses	GD 0 to 6		GD 6 to 9		GD 9 to 12		GD 12 to 15		GD 15 to 18		GD 18 to 20		GD 20 to 21		GD 21 to 24	
			Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD
A18	2018	21	31.7	7.2	6.5	3.9	13.6	3.7	14.6	3.3	32.2	6.6	66.8	9.5	24.5	4.4		
B18	2018	9	31.4	6.5	10.1	3.1	15.7	4.1	15.0	4.4	29.1	8.3	69.9	5.6			38.0	5.9
C18	2018	21	35.3	7.9	12.6	5.4	15.4	4.5	13.9	11.5	35.2	10.4	77.1	8.0	26.2	6.2		
D18	2018	6	32.5	5.3	8.9	4.2	14.2	4.2	14.9	3.6	28.6	6.4	66.5	13.0			34.4	8.0
E18	2018	22	30.5	8.8	12.4	5.4	16.1	3.8	17.5	5.4	31.1	4.4	77.1	11.3			38.7	6.1
F18	2018	6	30.1	8.0	12.0	4.1	12.8	2.3	19.6	4.4	29.5	6.9	73.9	10.2	26.0	6.1		
G18	2018	18	28.2	6.3	12.5	3.5	12.5	5.0	14.7	4.5	32.8	6.5	72.5	9.2			31.5	8.3
H18	2018	5	29.2	6.9	9.2	4.9	17.8	4.4	12.5	3.7	33.0	6.6	72.5	18.6			31.3	9.8
K18	2018	6	30.8	6.9	13.9	3.7	15.4	2.0	14.3	3.0	35.5	6.6			20.4	6.0		
L18	2018	21	31.1	5.9	11.8	3.2	18.2	2.9	15.5	5.2	31.8	5.4			22.7	7.1		
M18	2018	5	29.4	5.2	10.7	4.5	13.5	10.0	19.2	4.8	27.2	2.5			28.1	2.8		
N18	2018	6			2.3	6.5	15.7	2.6	18.0	2.5	33.6	4.0			26.8	4.4		
A17	2017	22	31.9	6.2	11.4	4.8	15.9	3.4	16.1	3.7	32.0	6.7	75.5	11.3			112.6	18.2
B17	2017	5	32.9	8.4	14.1	2.6	14.1	4.8	18.4	3.9	29.4	11.9	76.0	17.0	110.0	24.9	37.1	7.9
C17	2017	22	25.3	5.2	9.9	4.1	15.3	3.6	16.7	4.5	31.7	5.9	73.7	11.6			34.1	8.2
D17	2017	6	27.9	6.8	13.8	5.8	12.9	3.5	15.4	3.3	34.7	5.7	76.7	10.6	24.2	5.5		
E17	2017	9	27.6	8.8	13.1	4.2	16.3	4.5	14.4	5.0	34.8	2.9	78.5	6.5	25.2	2.8		
F17	2017	21	32.4	6.7	9.3	4.2	14.9	3.8	18.0	4.0	31.6	3.7	73.8	9.2	24.9	4.1		
H17	2017	6	30.1	8.0	12.0	4.1	12.8	2.3	19.6	4.4	29.5	6.9	73.9	10.2	25.0	4.5		
I17	2017	24	33.9	6.9	18.1	3.2	15.4	3.3	20.1	3.9	32.0	5.3	85.7	9.0	26.0	6.1	40.9	7.0
J17	2017	24	33.5	5.8	17.8	5.0	14.2	3.7	23.6	4.0	30.9	5.8	86.5	11.5	26.8	4.7		
K17	2017	6	27.0	7.4	11.1	3.4	17.5	3.7	12.8	2.1	35.4	5.3					116.4	7.8
L17	2017	22	32.1	6.4	11.3	3.9	16.2	4.6	16.9	4.0	33.5	4.9					116.6	10.9
M17	2017	6	34.2	4.4	10.8	3.4	11.9	24.7	26.5	22.4	35.9	3.2					124.6	9.9
N17	2017	22	31.3	6.2	10.1	3.0	15.9	3.9	17.2	5.7	32.7	7.0					107.5	14.2
O17	2017	6	40.2	7.5	10.0	2.2	23.5	3.4	12.6	6.3	34.7	4.3					120.0	11.4
P17	2017	22	29.6	6.7	13.0	4.7	17.6	4.0	17.0	3.7	32.7	4.6					113.7	13.0
V17	2017	24	33.5	7.4	12.0	5.3	15.7	4.0	15.3	4.6	31.4	4.2			26.3	5.8		
Total Mean		393	31.4		11.9		15.5		16.9		32.2		76.2		25.2		113.7	
SD			7.1		5.1		5.0		6.1		6.1		11.6		5.4		14.5	
2014 to 2016		627	29.4	13.5	11.3	4.5	15.6	4.6	16.0	4.8	31.7	6.7	75.5	11.7	24.6	5.9	111.9	17.1
																	35.6	8.1

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Historical Control Data

Rat Wistar : Crl-WI

Maternal food consumption (g/day) during gestation

Study	Year	Dams with live foetuses	GD 0 to 6		GD 6 to 9		GD 9 to 12		GD 12 to 15		GD 15 to 18		GD 6 to 18		GD 18 to 20		GD 6 to 21		GD 18 to 21	
			Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD
A18	2018	21	18.9	2.3	21.2	2.9	22.3	2.6	24.0	2.6	25.0	2.7	23.1	2.5	25.8	2.6				
B18	2018	9	20.8	2.6	25.8	6.4	24.5	2.9	26.3	3.3	27.2	2.4	26.0	3.1					26.3	2.5
C18	2018	21	19.7	2.9	23.1	2.8	24.5	3.1	24.9	3.3	27.6	2.4	25.0	2.3	28.1	3.3				
D18	2018	6	19.1	1.6	22.0	3.5	25.0	2.9	25.1	2.8	26.3	2.6	24.6	2.7					26.0	2.6
E18	2018	22	18.3	2.8	22.5	3.1	23.0	3.3	24.9	3.3	25.5	2.7	24.0	3.0					25.5	2.7
F18	2018	6	18.2	2.0	21.0	2.2	22.8	1.8	24.3	1.9	25.7	2.1	23.5	1.9	28.4	2.5				
G18	2018	18	18.6	2.6	20.0	2.3	21.8	2.9	24.3	2.2	25.1	2.5	22.8	2.3					25.0	3.3
H18	2018	5	16.0	1.9	21.0	4.2	21.2	4.4	24.0	4.0	25.2	2.5	22.8	3.6					24.9	2.8
K18	2018	6	18.3	1.9	21.1	4.6	20.9	3.3	23.2	3.3	26.0	3.5			25.8	3.2				
L18	2018	21	17.8	2.3	19.7	1.9	20.5	2.4	23.1	2.0	24.1	2.6			24.9	2.8				
M18	2018	5	18.6	3.3	17.8	4.9	25.3	1.7	23.2	3.7	28.0	3.8			28.4	4.2				
N18	2018	6			22.4	1.6	22.9	0.9	25.0	1.6	25.8	0.9			27.5	1.0				
A17	2017	22	20.3	2.6	24.6	2.7	25.6	3.1	26.6	2.8	27.8	2.9	26.2	2.7			26.4	2.7	27.5	2.8
B17	2017	5	21.3	2.2	25.5	2.0	25.9	3.7	26.8	2.5	29.0	1.4	26.8	2.1			26.6	2.0	25.7	1.9
C17	2017	22	19.2	2.0	23.0	2.1	24.4	2.3	26.2	2.1	27.2	2.8	25.2	2.0	26.8	2.9				
D17	2017	6	18.5	2.6	20.7	2.4	21.4	1.5	22.5	1.5	24.5	1.9	22.3	1.7	25.4	1.5				
E17	2017	9	18.8	2.8	21.8	3.3	23.0	3.4	24.1	3.2	25.6	3.1	23.6	3.2	25.7	3.5				
F17	2017	21	19.9	2.6	22.8	2.9	23.6	2.9	26.1	2.5	25.8	2.4	24.6	2.5	26.3	3.0				
G17	2017	8	21.3	1.3	23.1	1.6	23.8	2.2	24.3	2.2	25.8	2.5	24.3	2.0	26.0	1.8				
H17	2017	6	18.2	2.0	21.0	2.2	22.8	1.8	24.3	1.9	25.7	2.1	23.5	1.9	28.4	2.5				
I17	2017	24	19.7	2.7	24.5	2.3	26.2	2.5	26.8	2.6	28.8	2.7	26.6	2.3					26.6	2.7
J17	2017	24	20.6	2.7	23.8	2.5	26.3	3.1	26.3	3.0	28.8	3.2	26.3	2.8	27.8	3.5				
K17	2017	6	17.8	2.3	21.1	1.6	21.9	2.1	23.2	2.0	24.6	1.9					23.3	1.4	25.6	1.7
L17	2017	22	19.6	2.2	22.8	2.3	22.7	2.4	25.0	2.1	26.5	2.5					24.6	2.0	26.0	2.2
M17	2017	6	20.5	1.5	21.6	1.0	20.1	6.0	25.1	2.0	26.5	1.4					23.8	1.3	25.9	1.3
N17	2017	22	19.9	2.7	20.2	2.6	20.4	2.9	23.5	2.5	25.7	2.8					23.0	2.2	25.0	3.0
O17	2017	6	20.1	2.1	19.8	0.8	21.4	1.2	23.7	1.5	23.4	1.9					22.5	1.0	23.9	0.6
P17	2017	22	18.7	2.6	20.1	2.2	21.4	2.2	23.1	2.1	23.9	2.2					22.5	1.8	24.0	2.3
V17	2017	24	19.6	2.2	23.3	2.4	23.5	2.8	25.0	2.8	26.5	3.1			26.8	3.6				
Total Mean		401	19.3		22.2		23.3		24.9		26.3		24.8		26.7		24.1		25.7	
SD			2.6		3.1		3.3		2.8		2.9		2.8		3.1		2.5		2.7	
2014 to 2016		627	19.0	2.4	21.9	2.9	22.9	3.1	24.5	2.9	25.6	3.0	24.0	2.6	26.1	3.2	23.5	2.5	25.0	2.8

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Historical Control Data

Rat Wistar : Crl-WI

Caesarean data collected on day 21 of gestation - page 1/2

Study	Year	Number of females			Number of corpora lutea		Number of uterine implants		Pre-implantation loss %		Early resorptions per dam		Late resorptions per dam		Post-implantation loss %	
		Mated	Pregnant	With live fetuses	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD
A18	2018	22	21	21	13.2	1.6	12.1	1.6	8.5	8.5	1.0	1.2	0.0	0.0	9.0	10.1
B18	2018	9	9	9	13.0	1.5	12.1	1.9	7.0	7.2	1.4	1.3	0.0	0.0	12.8	13.0
C18	2018	22	21	21	13.4	1.6	12.7	1.9	5.5	8.6	1.2	1.1	0.0	0.0	9.5	8.6
D18	2018	6	6	6	12.8	2.7	11.3	1.9	10.5	13.0	1.8	1.3	0.2	0.4	17.3	12.8
E18	2018	22	22	22	13.0	1.1	12.2	1.6	6.8	7.2	0.9	0.7	0.0	0.2	7.7	5.7
F18	2018	6	6	6	13.2	2.8	11.5	2.8	13.1	10.3	1.0	0.9	0.5	0.5	15.7	15.0
G18	2018	20	18	18	12.9	1.3	11.5	1.7	10.8	9.6	0.6	0.8	0.0	0.0	5.2	7.3
H18	2018	6	5	5	11.6	2.3	10.4	3.9	13.3	21.7	1.0	1.0	0.0	0.0	7.9	7.5
A17	2017	22	22	22	13.1	2.1	11.8	2.9	10.8	16.4	0.9	1.0	0.1	0.3	8.2	9.7
B17	2017	6	5	5	12.4	2.1	10.8	4.4	16.2	28.4	0.8	0.8	0.2	0.4	7.7	7.7
C17	2017	22	22	22	13.3	1.9	12.2	2.7	8.1	15.8	0.8	0.9	0.0	0.2	6.3	7.3
D17	2017	6	6	6	13.2	1.9	12.8	1.7	2.3	3.6	0.3	0.8	0.2	0.4	4.0	6.5
E17	2017	9	9	9	13.4	1.2	12.4	1.2	7.2	7.2	0.6	1.0	0.0	0.0	4.1	7.0
F17	2017	22	21	21	13.8	1.5	12.2	1.5	11.0	9.8	1.0	1.3	0.1	0.4	9.9	11.8
G17	2017	8	8	8	12.9	4.0	12.1	4.7	9.1	17.0	1.4	1.1	0.0	0.0	14.1	11.8
H17	2017	6	6	6	13.2	2.8	11.5	2.8	13.1	10.3	1.0	0.9	0.5	0.5	15.7	15.0
I17	2017	24	24	24	13.0	1.7	11.8	1.8	8.6	9.0	1.1	1.1	0.0	0.2	9.9	9.8
J17	2017	24	24	24	13.3	2.2	12.6	1.7	5.1	6.8	1.1	1.2	0.0	0.2	8.7	8.6
K17	2017	6	6	6	13.7	1.0	13.0	1.3	5.0	3.9	0.3	0.8	0.0	0.0	2.4	5.8
L17	2017	22	22	22	13.6	1.8	12.5	1.6	8.2	9.4	1.0	1.6	0.0	0.0	8.1	12.3
M17	2017	6	6	6	13.5	1.4	13.3	1.6	1.4	3.4	0.8	1.2	0.0	0.0	6.5	9.0
N17	2017	22	22	22	12.3	1.8	10.9	2.1	11.5	11.9	0.8	1.0	0.0	0.2	8.2	9.4
O17	2017	6	6	6	14.3	1.9	13.8	0.8	2.8	6.8	1.2	1.0	0.0	0.0	8.5	7.3
P17	2017	22	22	22	13.2	1.6	12.3	2.0	7.0	8.9	1.2	1.0	0.1	0.4	11.0	9.7
Total		346	339	339												
Mean			98%	98%	13.2		12.1		8.4		1.0		0.0		8.8	
SD						1.8		2.2		11.0		1.1		0.3		9.7
2014 to 2016		536	514	508	12.8	1.9	11.7	2.6	7.8	12.5	0.9	1.2	0.1	0.5	9.0	13.4
			96%	95%												

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Historical Control Data

Rat Wistar : Crl-WI

Caesarean data collected on day 21 of gestation - page 2/2

Study	Year	Number of females			Dead foetuses Total	Live litter size		Litter weight (g) on GD 21		Foetal weight (g) on GD 21		Uterus weight (g) on GD 21		Sex ratio % males
		Mated	Pregnant	With live foetuses		Mean	SD	Mean	SD	Mean	SD	Mean	SD	
A18	2018	22	21	21	0	11.0	2.1							53.2
B18	2018	9	9	9	0	10.7	2.7	52.6	12.9	4.94	0.31	72.9	16.2	42.7
C18	2018	22	21	21	0	11.4	1.9							47.1
D18	2018	6	6	6	0	9.3	2.0	46.5	10.3	4.98	0.23	64.6	13.0	52.1
E18	2018	22	22	22	0	11.2	1.5	57.2	6.5	5.11	0.24	77.1	8.6	45.0
F18	2018	6	6	6	0	10.0	3.6							58.9
G18	2018	20	18	18	0	10.9	1.7	54.8	8.8	5.04	0.19	74.9	10.7	51.1
H18	2018	6	5	5	0	9.4	3.2	48.2	17.5	5.08	0.27	65.0	22.1	45.7
A17	2017	22	22	22	0	10.8	3.1	54.0	14.8	5.03	0.31	74.4	19.3	48.5
B17	2017	6	5	5	0	9.8	3.8	50.7	21.0	5.07	0.38	70.4	27.5	55.0
C17	2017	22	22	22	0	11.4	2.6							52.5
D17	2017	6	6	6	0	12.3	2.0							48.0
E17	2017	9	9	9	0	11.9	0.9							43.5
F17	2017	22	21	21	0	11.0	2.0							47.5
G17	2017	8	8	8	0	10.8	4.8							40.6
H17	2017	6	6	6	0	10.0	3.6							58.9
I17	2017	24	24	24	0	10.7	2.0	55.8	10.4	5.24	0.25	77.1	13.2	53.8
J17	2017	24	24	24	0	11.5	1.7							45.6
K17	2017	6	6	6	0	12.7	1.2	64.4	5.6	5.09	0.33	86.8	7.4	49.5
L17	2017	22	22	22	0	11.4	1.9	58.7	8.8	5.17	0.24	79.4	11.0	49.2
M17	2017	6	6	6	0	12.5	2.2	60.9	10.7	4.87	0.35	82.2	13.3	52.9
N17	2017	22	22	22	0	10.0	2.2	51.5	10.9	5.15	0.32	71.4	14.2	48.8
O17	2017	6	6	6	0	12.7	1.4	64.5	6.1	5.10	0.13	85.7	7.9	56.1
P17	2017	22	22	22	0	11.0	2.4	55.1	11.0	5.03	0.30	75.0	14.3	54.4
Total		346	339 98%	339 98%	0									
Mean						11.0		55.3		5.09		75.6		49.6
SD							2.3		11.2		0.28		14.3	
2014 to 2016		536	514 96%	508 95%	0	10.8	2.5	54.4	11.4	5.02	0.25	74.9	15.1	51.2

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Historical Control Data

Rat Wistar : CrI-WI

Malformations (external, internal and skeletal)

Study	Year	Number of litters examined	Number of foetuses examined	Number of litters with malformed foetuses	Litter incidence %	Number of malformed foetuses	Foetal incidence %	Type of malformation by foetus
A18	2018	21	232	1	4.76	1	0.43	Malformed cervical and thoracic vertebrae, and ribs
B18	2018	9	96	1	11.11	1	1.04	Narrowed aortic arch
C18	2018	21	240	0	-	0	-	
D18	2018	6	56	0	-	0	-	
E18	2018	22	247	0	-	0	-	
F18	2018	6	60	0	-	0	-	
G18	2018	18	196	0	-	0	-	
H18	2018	5	47	0	-	0	-	
A17	2017	22	238	2	9.09	2	0.84	1st: Situs inversus, abnormal lobation of lung 2nd: Situs inversus, abnormal lobation of lung, transposed great vessels
B17	2017	5	49	0	-	0	-	
C17	2017	22	251	2	9.09	2	0.80	1st: Cleft lip and palate; 2nd: Malformed thoracic vertebrae
D17	2017	6	74	1	16.67	1	1.35	Agnathia
E17	2017	9	107	0	-	0	-	
F17	2017	21	231	0	-	0	-	
G17	2017	8	86	0	-	0	-	
H17	2017	6	60	0	-	0	-	
I17	2017	24	256	0	-	0	-	
J17	2017	24	275	2	8.33	2	0.73	1st: Microphthalmia; 2nd: Proboscis (malformed skull)
K17	2017	6	76	0	-	0	-	
L17	2017	22	251	1	4.55	1	0.40	Proboscis
M17	2017	6	75	0	-	0	-	
N17	2017	22	221	0	-	0	-	
O17	2017	6	76	0	-	0	-	
P17	2017	22	242	0	-	0	-	
Total 2017 and 2018		339	3742	10	2.95%	10	0.27%	
Total 2014 to 2016		508	5539	25	4.92%	25	0.45%	

Study nos. B17, D17, H17, Q17, S17, U17, D18, F18 and H18: Dose Range Finding studies with external examination only

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Historical Control Data

Rat Wistar : Crl-WI

FOETAL EXAMINATION - EXTERNAL EXAMINATION ON DAY 20 OR 21 OF GESTATION

PERIOD	2013-2015		2016-2018	
Number of studies included	30		39	
Number of fetuses examined	4672		6077	
OBSERVATION	N	%	N	%
Anasarca	1	0.02	0	0.00
Exencephaly	2	0.04	0	0.00
Head/neck: malformed	1	0.02	0	0.00
Eye(s): malformed	0	0.00	1	0.02
Eye(s): absent bulge	0	0.00	1	0.02
Agnathia	0	0.00	2	0.03
Astomia	0	0.00	1	0.02
Micrognathia	2	0.04	2	0.03
Cleft palate	0	0.00	1	0.02
Cleft lip	0	0.00	1	0.02
Nose: single naris	1	0.02	0	0.00
Proboscis	0	0.00	3	0.05
Limbs: malrotated	1	0.02	0	0.00
Trunk: omphalocele	1	0.02	0	0.00
Umbilicus: hernia	1	0.02	0	0.00
Gastroschisis	1	0.02	0	0.00
Anal atresia	2	0.04	0	0.00
Tail: thread-like	1	0.02	0	0.00

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Historical Control Data

Rat Wistar : CrI-WI

FOETAL EXAMINATION - FRESH VISCERAL EXAMINATION OF BODY ON DAY 20 OR 21 OF GESTATION

PERIOD	2013-2015		2016-2018	
Number of studies included	17		23	
Number of fetuses examined	1857		2716	
OBSERVATION	N	%	N	%
Situs inversus	4	0.22	1	0.04
Great blood vessels: malformed	1	0.05	2	0.07
Great blood vessels: transposition	0	0.00	1	0.04
Carotid artery: narrowed	1	0.05	0	0.00
Pulmonary artery: malpositioned	1	0.05	0	0.00
Subclavian artery: retroesophageal	1	0.05	0	0.00
Umbilical artery: transposed	239	12.87	345	12.70
Azygos vein: transposed	0	0.00	1	0.04
Aortic arch: narrowed	0	0.00	1	0.04
Lungs: abnormal lobation	0	0.00	2	0.07
Lungs: lobe absent	1	0.05	1	0.04
Thyroid gland: small	0	0.00	1	0.04
Thorax: tissue-mass	0	0.00	1	0.04
Diaphragm: absent	1	0.05	0	0.00
Intestine: distended	0	0.00	1	0.04
Stomach: narrowed	0	0.00	1	0.04
Pancreas: large	0	0.00	1	0.04
Pancreas: malpositioned	0	0.00	1	0.04
Spleen: small	0	0.00	1	0.04
Spleen: discolored	0	0.00	1	0.04
Liver: discolored lobe	1	0.05	4	0.15
Liver: abnormal lobation	1	0.05	1	0.04
Adrenal gland(s): discolored	1	0.05	0	0.00
Kidney(s): renal pelvic dilatation	0	0.00	1	0.04
Kidney(s): malpositioned	1	0.05	0	0.00
Kidney(s): large	2	0.11	0	0.00
Kidney: absent	1	0.05	0	0.00
Ureter(s): dilated	59	3.18	24	0.88
Ureter(s): convoluted	20	1.08	9	0.33
Testis: malpositioned	2	0.11	0	0.00
Testis: cyst	1	0.05	9	0.33

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Historical Control Data

Rat Wistar : Cri-WI

FOETAL EXAMINATION - FIXED VISCERAL EXAMINATION OF HEAD ON DAY 20 OR 21 OF GESTATION

PERIOD	2013-2015		2016-2018	
Number of studies included	18		23	
Number of foetuses examined	1664		2407	
OBSERVATION	N	%	N	%
Head: multiple visceral abnormalities	0	0.00	1	0.04
Microphthalmia	0	0.00	1	0.04
Anophthalmia	2	0.12	0	0.00
Aphakia	0	0.00	1	0.04
Retinal fold	0	0.00	1	0.04
Brain: dilated lateral ventricles	6	0.36	6	0.25

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Historical Control Data

Rat Wistar : CrI-WI

FOETAL EXAMINATION - SKELETAL EXAMINATION OF BODY ON DAY 21 OF GESTATION - Page 1/2

PERIOD	2013-2015		2016-2018	
Number of studies included	2		9	
Number of foetuses examined	233		1096	
OBSERVATION	N	%	N	%
Metacarpals: incomplete ossification (5th digit)	1	0.43	7	0.64
Metatarsals: unossified, 1st digit	7	3.00	11	1.00
Phalanx: unossified (2nd to 5th digits), forepaws	21	9.01	0	0.00
Phalanx: unossified, forepaws	0	0.00	110	10.04
Phalanx: unossified, hindpaws	0	0.00	30	2.74
Phalanx: unossified (2nd to 5th digits), hindpaws	54	23.18	236	21.53
Rib: supernumerary cervical	4	1.72	21	1.92
Rib: supernumerary lumbar	2	0.86	39	3.56
Rib: supernumerary lumbar (short)	121	51.93	491	44.80
Rib: short	0	0.00	1	0.09
Rib: wavy	17	7.30	11	1.00
Rib: thick	8	3.43	39	3.56
Sternebrae: incomplete ossification of 1st/3rd	1	0.43	2	0.18
Sternebrae: incomplete ossification of 2nd/4th	2	0.86	12	1.09
Sternebrae: incomplete ossification of 6th	2	0.86	2	0.18
Sternebrae: unossified 5th	1	0.43	1	0.09
Sternebrae: unossified 6th	1	0.43	0	0.00
Sternebrae: extra ossification site	0	0.00	2	0.18
Sternebrae: asymmetric	5	2.15	7	0.64
Sternebrae: split	1	0.43	0	0.00
Sternebrae: misshapen	0	0.00	1	0.09

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Historical Control Data

Rat Wistar : CrI-WI

FOETAL EXAMINATION - SKELETAL EXAMINATION OF BODY ON DAY 21 OF GESTATION - page 2/2

PERIOD	2013-2015		2016-2018	
Number of studies included	2		9	
Number of fetuses examined	233		1096	
OBSERVATION	N	%	N	%
Vertebrae, presacral arches = 27	2	0.86	3	0.27
Vertebrae, cervical: incomplete ossification of arch	0	0.00	2	0.18
Vertebrae, cervical: unossified odontoid process	21	9.01	153	13.96
Vertebrae, cervical: unossified centrum	57	24.46	344	31.39
Vertebrae, cervical: bipartite centrum	0	0.00	27	2.46
Vertebrae, thoracic: incomplete ossification of centrum	0	0.00	3	0.27
Vertebrae, thoracic: incomplete ossification of 1-9th centrum	3	1.29	7	0.64
Vertebrae, thoracic: incomplete ossification of 10-13th centrum	14	6.01	24	2.19
Vertebrae, thoracic: fused arch	0	0.00	1	0.09
Vertebrae, thoracic: bipartite ossification of centrum	6	2.58	3	0.27
Vertebrae, thoracic: centrum hemicentric	0	0.00	1	0.09
Vertebrae, thoracic: misaligned centrum	0	0.00	1	0.09
Vertebrae, thoracic: absent centrum	0	0.00	1	0.09
Vertebrae, thoracic: small centrum	0	0.00	1	0.09
Vertebrae, lumbar: number = 5	0	0.00	1	0.09
Vertebrae, lumbar: number = 7	2	0.86	9	0.82
Vertebrae, lumbar: incomplete ossification of centrum	0	0.00	1	0.09
Vertebrae, sacral: incomplete ossification of arches	1	0.43	0	0.00
Vertebrae, caudal number < 5	7	3.00	39	3.56

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Historical Control Data

Rat Wistar : Crl-WI

FOETAL EXAMINATION - SKELETAL EXAMINATION OF HEAD ON DAY 21 OF GESTATION

PERIOD	2013-2015		2016-2018	
Number of studies included	2		9	
Number of foetuses examined	233		1050	
OBSERVATION	N	%	N	%
Parietal: incomplete ossification	9	3.86	38	3.62
Interparietal: incomplete ossification	23	9.87	80	7.62
Supraoccipital: incomplete ossification	6	2.58	8	0.76
Cranium: Sutural bone	2	0.86	2	0.19
Squamosal: incomplete ossification	4	1.72	7	0.67
Zygomatic arch: incomplete ossification	2	0.86	9	0.86
Hyoid: incomplete ossification	0	0.00	7	0.67
Mandible: incomplete ossification	0	0.00	15	1.43

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Han Wistar Rat

Route of Adm.: Not Infusion

Study Type: Main

Skeletal examination

Studies included: 17

Litters included: 275

Fetuses included: 1721

Fetal Obs Location	Fetal Obs Morphology	Level	Count	Average %	Min %	Max %	Average	Min	Max
Basisphenoid	Incomplete ossification	Litters	1	0.28	0.00	4.76	0.06	0	1
		Fetuses	1	0.05	0.00	0.79	0.00	0	1
Caudal	Number < 5	Litters	4	6.53	0.00	55.56	0.94	0	5
		Fetuses	19	1.12	0.00	6.25	0.08	0	2
Caudal	Unossified	Litters	3	1.92	0.00	14.29	0.41	0	3
		Fetuses	8	0.41	0.00	2.65	0.02	0	2
Caudal	Unossified arch, 1st and 2nd	Litters	15	27.63	0.00	90.48	4.65	0	19
		Fetuses	248	12.81	0.00	42.09	0.90	0	10
Caudal vertebra	Unossified	Litters	2	4.15	0.00	22.22	0.59	0	4
		Fetuses	14	1.00	0.00	5.61	0.06	0	2
Cervical	Absent arch	Litters	1	0.28	0.00	4.76	0.06	0	1
		Fetuses	1	0.07	0.00	1.19	0.00	0	1
Cervical	Incomplete ossification of arch	Litters	1	2.79	0.00	19.05	0.59	0	4
		Fetuses	12	0.67	0.00	5.84	0.03	0	3
Cervical	Increased ossification 1st	Litters	13	21.99	0.00	66.67	3.71	0	14
		Fetuses	145	7.40	0.00	26.86	0.49	0	6
Cervical	Odontoid process unossified	Litters	11	13.73	0.00	61.11	2.41	0	11
		Fetuses	65	3.30	0.00	12.96	0.21	0	7
Cervical	Short	Litters	2	7.23	0.00	44.44	0.71	0	4
		Fetuses	15	1.25	0.00	5.60	0.08	0	2
Cervical	Unossified centrum	Litters	2	15.92	0.00	100.00	2.71	0	18
		Fetuses	111	5.45	0.00	32.75	0.40	0	6
Cervical centrum	Unossified	Litters	2	3.51	0.00	16.67	0.47	0	3
		Fetuses	10	0.73	0.00	3.68	0.05	0	2
Cranium	Sutural bone	Litters	2	0.53	0.00	9.09	0.12	0	2
		Fetuses	2	0.08	0.00	1.41	0.01	0	1
Femur	Bent	Litters	1	0.65	0.00	11.11	0.06	0	1
		Fetuses	1	0.06	0.00	1.01	0.01	0	1
Forepaw phalanges	Unossified	Litters	6	8.86	0.00	44.44	1.29	0	6
		Fetuses	51	3.27	0.00	15.71	0.19	0	6
Frontal	Incomplete ossification	Litters	1	1.76	0.00	11.11	0.29	0	1
		Fetuses	6	0.31	0.00	1.82	0.02	0	2
General	Generalised incomplete	Litters	1	0.28	0.00	4.76	0.06	0	1
		Fetuses	1	0.06	0.00	0.95	0.00	0	1
General	Multiple skeletal abnormalities	Litters	1	0.27	0.00	4.55	0.06	0	1
		Fetuses	1	0.04	0.00	0.76	0.00	0	1
Hindpaw phalanges	Unossified	Litters	8	17.00	0.00	100.00	2.24	0	10
		Fetuses	133	8.74	0.00	34.54	0.58	0	8
Humerus	Thick	Litters	1	0.28	0.00	4.76	0.06	0	1
		Fetuses	1	0.04	0.00	0.68	0.00	0	1
Hyoid	Incomplete ossification	Litters	1	0.83	0.00	5.00	0.18	0	1
		Fetuses	4	0.21	0.00	2.00	0.01	0	2
Hyoid	Unossified	Litters	1	1.58	0.00	12.50	0.24	0	2
		Fetuses	4	0.25	0.00	1.79	0.02	0	1
Hyoid body	Incomplete ossification	Litters	1	0.90	0.00	5.26	0.18	0	1
		Fetuses	4	0.25	0.00	1.75	0.01	0	2
Hyoid body	Unossified	Litters	1	0.98	0.00	16.67	0.06	0	1
		Fetuses	1	0.16	0.00	2.78	0.01	0	1

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Han Wistar Rat

Route of Adm.: Not infusion

Study Type: Main

Skeletal examination (cont'd)

Studies included: 17

Litters included: 275

Fetuses included: 1721

Fetal Obs Location	Fetal Obs Morphology	Level	Count	Average %	Min %	Max %	Average	Min	Max
Ilium	Malpositioned	Litters	2	0.56	0.00	9.52	0.12	0	2
		Fetuses	3	0.14	0.00	2.38	0.01	0	2
Interparietal	Incomplete ossification	Litters	1	25.60	0.00	44.44	4.12	0	9
		Fetuses	113	6.42	0.00	15.05	0.41	0	5
Ischium	Unossified	Litters	1	0.28	0.00	4.76	0.06	0	1
		Fetuses	1	0.06	0.00	0.95	0.00	0	1
Lumbar	Incomplete ossification of arch	Litters	1	0.28	0.00	4.76	0.06	0	1
		Fetuses	1	0.04	0.00	0.68	0.00	0	1
Lumbar	Incomplete ossification of	Litters	1	1.09	0.00	9.52	0.24	0	2
		Fetuses	4	0.26	0.00	2.27	0.01	0	1
Lumbar	Number = 7	Litters	1	3.08	0.00	13.64	0.65	0	3
		Fetuses	12	0.67	0.00	3.17	0.03	0	2
Lumbar	Unossified centrum	Litters	1	0.28	0.00	4.76	0.06	0	1
		Fetuses	1	0.06	0.00	0.95	0.00	0	1
Lumbar vertebra	Supernumerary	Litters	2	0.56	0.00	9.52	0.12	0	2
		Fetuses	2	0.09	0.00	1.59	0.01	0	1
Mandible	Fused	Litters	1	0.28	0.00	4.76	0.06	0	1
		Fetuses	1	0.06	0.00	0.95	0.00	0	1
Mandible	Incomplete ossification	Litters	6	28.01	0.00	88.89	3.76	0	16
		Fetuses	162	12.13	0.00	46.92	0.77	0	6
Metacarpal	Incomplete ossif., 2nd to 4th digit	Litters	1	0.27	0.00	4.55	0.06	0	1
		Fetuses	1	0.07	0.00	1.14	0.00	0	1
Metacarpal	Incomplete ossif., 2nd to 4th digit	Litters	1	0.27	0.00	4.55	0.06	0	1
		Fetuses	1	0.07	0.00	1.14	0.00	0	1
Metacarpal	Incomplete ossification, 5th digit.	Litters	2	2.16	0.00	22.22	0.29	0	2
		Fetuses	6	0.35	0.00	2.25	0.02	0	2
Metacarpal	Unossified, 2nd to 4th digits	Litters	1	0.28	0.00	4.76	0.06	0	1
		Fetuses	1	0.06	0.00	0.95	0.00	0	1
Metacarpal	Unossified, 5th digit	Litters	4	14.51	0.00	88.89	2.35	0	11
		Fetuses	72	3.99	0.00	18.72	0.28	0	6
Metatarsal	Incomplete ossification	Litters	1	0.84	0.00	4.76	0.18	0	1
		Fetuses	3	0.15	0.00	0.95	0.01	0	1
Metatarsal	Unossified	Litters	1	0.81	0.00	9.09	0.18	0	2
		Fetuses	3	0.17	0.00	1.89	0.01	0	1
Metatarsal	Unossified, 1st digit	Litters	1	3.08	0.00	22.22	0.47	0	4
		Fetuses	10	0.57	0.00	4.33	0.04	0	2
Nasal	Incomplete ossification	Litters	2	0.56	0.00	9.52	0.12	0	2
		Fetuses	3	0.19	0.00	3.17	0.01	0	2
Parietal	Incomplete ossification	Litters	1	21.92	0.00	52.38	3.76	0	11
		Fetuses	107	5.81	0.00	16.20	0.34	0	5
Parietal	Supernumerary site	Litters	2	0.62	0.00	10.53	0.12	0	2
		Fetuses	2	0.10	0.00	1.75	0.01	0	1
Phalanx	Unossified	Litters	5	5.60	0.00	33.33	0.88	0	5
		Fetuses	36	2.13	0.00	16.87	0.13	0	6
Phalanx	Unossified, proximal 2nd to 5th digits	Litters	6	11.23	0.00	66.67	1.82	0	10
		Fetuses	84	4.96	0.00	29.08	0.31	0	7
Presphenoid	Incomplete ossification	Litters	1	0.27	0.00	4.55	0.06	0	1
		Fetuses	1	0.07	0.00	1.14	0.00	0	1

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Han Wistar Rat

Route of Adm.: Not infusion

Studies included: 17

Study Type: Main

Litters included: 275

Skeletal examination (cont'd)

Fetuses included: 1721

Fetal Obs Location	Fetal Obs Morphology	Level	Count	Average %	Min %	Max %	Average	Min	Max
Presphenoid	Unossified	Litters	1	0.28	0.00	4.76	0.06	0	1
		Fetuses	1	0.06	0.00	0.95	0.00	0	1
Pubis	Incomplete ossification	Litters	1	1.20	0.00	11.11	0.18	0	1
		Fetuses	3	0.15	0.00	1.01	0.01	0	1
Pubis	Unossified	Litters	1	0.28	0.00	4.76	0.06	0	1
		Fetuses	1	0.06	0.00	0.95	0.00	0	1
Rib	Thick	Litters	5	4.48	0.00	26.32	0.71	0	5
		Fetuses	19	1.16	0.00	9.26	0.07	0	4
Rib	Wavy rib	Litters	1	1.63	0.00	12.50	0.24	0	2
		Fetuses	5	0.34	0.00	2.50	0.02	0	2
Ribs	Branched	Litters	1	0.28	0.00	4.76	0.06	0	1
		Fetuses	1	0.06	0.00	0.95	0.00	0	1
Ribs	Incomplete ossification	Litters	1	0.56	0.00	5.00	0.12	0	1
		Fetuses	2	0.11	0.00	1.00	0.01	0	1
Ribs	Intercostal	Litters	1	0.28	0.00	4.76	0.06	0	1
		Fetuses	1	0.06	0.00	0.95	0.00	0	1
Ribs	Number of full ribs = 12/12	Litters	1	0.28	0.00	4.76	0.06	0	1
		Fetuses	1	0.06	0.00	0.95	0.00	0	1
Ribs	Supernumerary cervical	Litters	2	3.08	0.00	11.11	0.47	0	2
		Fetuses	11	0.62	0.00	4.50	0.04	0	4
Ribs	Supernumerary lumbar	Litters	3	8.01	0.00	22.73	1.41	0	5
		Fetuses	29	1.62	0.00	5.27	0.09	0	2
Ribs	Supernumerary lumbar, short	Litters	15	59.64	0.00	100.00	10.41	0	22
		Fetuses	500	27.11	0.00	56.09	1.74	0	8
Ribs	Thick	Litters	2	11.17	0.00	36.36	1.94	0	8
		Fetuses	57	3.08	0.00	11.19	0.20	0	5
Ribs	Wavy	Litters	1	3.70	0.00	12.50	0.53	0	2
		Fetuses	13	0.85	0.00	3.38	0.05	0	3
Sacral	Incomplete ossification of arch	Litters	1	6.18	0.00	27.27	1.06	0	6
		Fetuses	22	1.11	0.00	5.88	0.07	0	3
Sacral	Incomplete ossification of	Litters	1	0.27	0.00	4.55	0.06	0	1
		Fetuses	1	0.04	0.00	0.76	0.00	0	1
Sacral	Unossified	Litters	1	0.28	0.00	4.76	0.06	0	1
		Fetuses	1	0.06	0.00	0.95	0.00	0	1
Sacral	Unossified arch	Litters	1	0.28	0.00	4.76	0.06	0	1
		Fetuses	1	0.05	0.00	0.79	0.00	0	1
Sacral arch	Incomplete ossification	Litters	1	0.65	0.00	11.11	0.06	0	1
		Fetuses	1	0.06	0.00	1.01	0.01	0	1
Sacral arch	Misshapen	Litters	2	0.56	0.00	9.52	0.12	0	2
		Fetuses	2	0.09	0.00	1.59	0.01	0	1
Scapula	Bent	Litters	1	0.93	0.00	11.11	0.12	0	1
		Fetuses	2	0.10	0.00	1.01	0.01	0	1
Skull	Multiple Malformations	Litters	1	0.98	0.00	16.67	0.06	0	1
		Fetuses	1	0.16	0.00	2.78	0.01	0	1
Squamosal	Incomplete ossification	Litters	1	8.86	0.00	31.82	1.47	0	7
		Fetuses	36	2.01	0.00	11.18	0.12	0	5
Sternebra	Asymetri	Litters	1	3.37	0.00	18.18	0.71	0	4
		Fetuses	12	0.58	0.00	2.84	0.03	0	1

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Han Wistar Rat

Route of Adm.: Not infusion
Study Type: Main
Skeletal examination (cont'd)

Studies included: 17
Litters included: 275
Fetuses included: 1721

Fetal Obs Location	Fetal Obs Morphology	Level	Count	Average %	Min %	Max %	Average	Min	Max
Sternebra	Asymmetric	Litters	1	3.37	0.00	18.18	0.71	0	4
		Fetuses	12	0.58	0.00	2.84	0.03	0	1
Sternebra	Extra ossification site	Litters	1	0.33	0.00	5.56	0.06	0	1
		Fetuses	1	0.05	0.00	0.93	0.00	0	1
Sternebra	Incomplete ossification	Litters	1	1.21	0.00	10.53	0.24	0	2
		Fetuses	4	0.23	0.00	1.75	0.01	0	1
Sternebra	Incomplete ossification, 1st/3rd	Litters	2	3.06	0.00	10.00	0.65	0	2
		Fetuses	11	0.59	0.00	2.08	0.03	0	1
Sternebra	Incomplete ossification, 2nd/4th	Litters	3	6.87	0.00	23.81	1.35	0	5
		Fetuses	34	1.76	0.00	6.90	0.10	0	3
Sternebra	Incomplete ossification, 6th	Litters	2	22.28	0.00	77.78	3.88	0	16
		Fetuses	147	7.92	0.00	36.99	0.50	0	6
Sternebra	Incomplete ossification of	Litters	3	6.87	0.00	23.81	1.35	0	5
		Fetuses	34	1.76	0.00	6.90	0.10	0	3
Sternebra	Misshapen	Litters	1	1.50	0.00	15.79	0.29	0	3
		Fetuses	5	0.28	0.00	2.94	0.02	0	1
Sternebra	Sternoschisis	Litters	1	0.28	0.00	4.76	0.06	0	1
		Fetuses	1	0.05	0.00	0.79	0.00	0	1
Sternebra	Supernumerary site	Litters	1	0.31	0.00	5.26	0.06	0	1
		Fetuses	1	0.06	0.00	1.05	0.00	0	1
Sternebra	Unossified	Litters	2	1.21	0.00	11.11	0.18	0	2
		Fetuses	3	0.15	0.00	1.59	0.01	0	1
Sternebra	Unossified, 1st/3rd	Litters	1	0.81	0.00	9.09	0.18	0	2
		Fetuses	3	0.17	0.00	1.89	0.01	0	1
Sternebra	Unossified, 2nd/4th	Litters	1	1.38	0.00	9.09	0.29	0	2
		Fetuses	5	0.26	0.00	1.89	0.01	0	1
Sternebra	Unossified, 5th	Litters	5	7.65	0.00	31.82	1.47	0	7
		Fetuses	37	1.85	0.00	9.39	0.11	0	4
Sternebra	Unossified, 6th	Litters	4	3.86	0.00	22.73	0.82	0	5
		Fetuses	16	0.80	0.00	4.25	0.04	0	2
Supraoccipital	Incomplete ossification	Litters	1	11.62	0.00	37.50	2.00	0	7
		Fetuses	44	2.49	0.00	8.90	0.15	0	3
Supraoccipital	Unossified	Litters	1	0.28	0.00	4.76	0.06	0	1
		Fetuses	1	0.06	0.00	0.95	0.00	0	1
Thoracic	Bipartite ossification of centrum	Litters	1	1.49	0.00	11.11	0.24	0	2
		Fetuses	4	0.21	0.00	1.75	0.01	0	1
Thoracic	Fused centrum	Litters	1	0.29	0.00	5.00	0.06	0	1
		Fetuses	1	0.06	0.00	1.00	0.00	0	1
Thoracic	Incomplete ossification, 10th to	Litters	3	3.12	0.00	22.73	0.65	0	5
		Fetuses	12	0.59	0.00	5.00	0.03	0	2
Thoracic	Incomplete ossification of arch	Litters	1	0.29	0.00	5.00	0.06	0	1
		Fetuses	1	0.06	0.00	1.00	0.00	0	1
Thoracic	Incomplete ossification of	Litters	3	3.12	0.00	22.73	0.65	0	5
		Fetuses	12	0.59	0.00	5.00	0.03	0	2
Thoracic	Incomplete ossification of	Litters	1	2.18	0.00	14.29	0.47	0	3
		Fetuses	8	0.40	0.00	2.78	0.02	0	1
Thoracic	Misaligned centrum	Litters	1	0.29	0.00	5.00	0.06	0	1
		Fetuses	1	0.04	0.00	0.71	0.00	0	1

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Han Wistar Rat

Route of Adm.: Not infusion

Studies included: 17

Study Type: Main

Litters included: 275

Skeletal examination (cont'd)

Fetuses included: 1721

Fetal Obs Location	Fetal Obs Morphology	Level	Count	Average %	Min %	Max %	Average	Min	Max
Thoracic	Multiple abnormalities	Litters	1	0.55	0.00	4.76	0.12	0	1
		Fetuses	2	0.11	0.00	1.19	0.01	0	1
Thoracic	Number = 12	Litters	1	0.28	0.00	4.76	0.06	0	1
		Fetuses	1	0.06	0.00	0.95	0.00	0	1
Thoracic	Small centrum	Litters	1	0.29	0.00	5.00	0.06	0	1
		Fetuses	1	0.04	0.00	0.71	0.00	0	1
Thoracic	Unossified centrum, 1st to 9th	Litters	1	0.28	0.00	4.76	0.06	0	1
		Fetuses	1	0.06	0.00	0.95	0.00	0	1
Thoracic centrum	Incomplete ossification	Litters	5	8.39	0.00	37.50	1.06	0	5
		Fetuses	22	1.77	0.00	9.60	0.11	0	3
Thoracolumbar	Full	Litters	4	7.80	0.00	50.00	0.76	0	4
		Fetuses	17	1.43	0.00	9.72	0.11	0	2
Thoracolumbar	Short	Litters	15	29.06	0.00	100.00	3.94	0	19
		Fetuses	203	14.30	0.00	48.05	0.96	0	9
Vertebra	Presacral vertebral arches = 27	Litters	1	1.54	0.00	11.11	0.24	0	2
		Fetuses	4	0.21	0.00	1.47	0.02	0	1
Zygomatic arch	Incomplete ossification	Litters	1	4.31	0.00	16.67	0.65	0	2
		Fetuses	17	1.02	0.00	4.25	0.06	0	3

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Historical Control Data

Rat Wistar: Crl-WI

Maternal body weight gain (g) during lactation

Study	Year	Dams with litters	Lactation days 1 to 4		Lactation days 4 to 7		Lactation days 7 to 10		Lactation days 10 to 14		Lactation days 14 to 17		Lactation days 17 to 21	
			Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD
A19	2019	21	8.4	8.0	6.9	4.7	3.5	7.7	11.4	6.2	3.5	6.4	-13.3	8.3
B19	2019	19	14.8	8.2	9.6	8.1	2.7	6.4	4.2	6.1	-0.2	6.1	-10.6	7.3
C19	2019	18	16.2	8.7	11.1	5.0	6.6	8.1	5.4	6.9	-0.8	4.6	-11.1	5.3
K18	2018	6	14.9	5.7	3.8	6.0	16.3	7.0	0.1	3.6				
L18	2018	21	13.3	6.3	6.3	8.8	7.2	5.8	10.2	6.7	0.2	7.2	-14.0	6.1
M18	2018	5	12.4	8.5	7.1	3.1								
N18	2018	6	15.5	9.3	13.2	9.9								
V17	2017	23	10.2	10.0	8.7	6.1	2.7	5.6	7.8	6.5	-1.2	8.3	-17.2	9.9
U16	2016	5	6.6	2.5	1.2	5.3								
V16	2016	21	9.1	6.4	10.2	3.8	8.0	5.4	6.6	7.1	4.5	7.3	-12.8	6.4
W16	2016	21	17.6	10.4	9.1	4.9	8.5	5.5	6.5	5.8	1.6	5.7	-10.7	7.5
X16	2016	7	2.6	7.2										
I15	2015	22	13.9	9.9	5.2	6.8	8.1	6.4	2.5	7.1	-4.1	7.4	-10.4	6.2
J15	2015	24	10.5	7.0	8.3	6.4	8.8	5.8	4.5	4.3	2.8	6.3	-12.8	7.6
K15-1	2015	22	12.9	6.8	7.4	5.6								
K15-2	2015	22	11.2	6.0	10.0	5.9								
L15	2015	10	21.2	11.3										
M15	2015	9	18.8	5.3										
Total		282												
Mean			12.7		8.2		6.6		6.4		0.7		-12.6	
SD				8.7		6.4		6.9		6.8		7.1		7.5

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Historical Control Data

Rat Wistar: Crl-WI

Maternal food consumption (g/day) during lactation

Study	Year	Dams with litters	Lactation days 1 to 4		Lactation days 4 to 7		Lactation days 7 to 10		Lactation days 10 to 14		Lactation days 14 to 17		Lactation days 17 to 21	
			Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD
A19	2019	21	31.7	4.8	40.0	4.1	47.8	4.4	54.8	5.3	59.7	6.6	64.9	5.4
B19	2019	19	33.0	4.5	42.9	4.0	50.2	5.1	56.0	5.2	58.7	5.3	65.4	5.7
C19	2019	18	35.3	3.6	44.3	3.1	50.9	3.5	56.0	2.8	60.5	3.7	66.6	3.9
K18	2018	6	32.0	6.7	39.1	4.5	49.3	3.4	53.2	4.3				
L18	2018	21	31.5	4.9	38.1	6.4	45.4	6.4	55.7	8.9	54.8	5.5	62.7	6.2
M18	2018	5	37.8	5.8	45.5	6.5								
N18	2018	6	37.1	3.7	50.7	4.4								
V17	2017	23	35.2	4.7	43.3	3.8	50.3	4.5	57.5	4.1	62.3	5.0	68.0	6.2
U16	2016	5	24.4	4.0	31.5	5.2								
V16	2016	21	28.5	4.8	39.5	5.7	45.4	6.6	52.1	9.4	56.2	9.3	65.2	11.3
W16	2016	21	31.2	5.5	43.0	6.2	48.4	7.4	57.0	9.1	58.0	10.3	66.6	10.9
X16	2016	7	24.5	2.8										
I15	2015	22	34.4	5.2	44.0	4.4	51.7	4.0	55.3	5.1	58.4	4.5	65.1	5.5
J15	2015	24	30.8	4.0	40.6	3.9	48.4	4.5	53.8	4.6	59.2	4.6	64.0	4.5
K15-1	2015	22	30.6	3.9	40.1	2.8								
K15-2	2015	22	27.6	4.5	38.4	3.8								
L15	2015	10	38.2	5.3										
M15	2015	9	36.1	4.5										
Total		282												
Mean			32.0		41.3		48.7		55.3		58.7		65.4	
SD				5.5		5.3		5.6		6.5		6.6		7.1

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Historical Control Data

Rat Wistar: Crl-WI

Post-partum litter data

Study	Year	Number of females				Gestation length (days)		Number of uterine implants		Number of pups born		Pre-birth loss index %	Live birth index %	Pup viability index %	Pup weaning index %	Live Litter size %
		Mated	Pregnant	With liveborn	With pups at weaning	Mean	SD	Mean	SD	Mean	SD					
A19	2019	22	22	21	21	22.3	0.6	11.4	2.7	10.3	3.1	11.7	97.4	100.0	98.2	10.5
B19	2019	22	19	19	19	22.5	0.5	11.9	1.7	10.9	2.2	8.6	98.6	98.5	99.3	10.8
C19	2019	20	18	18	18	22.5	0.5	11.9	2.3	10.9	2.4	7.8	100.0	99.5	98.6	10.9
K18	2018	6	6	6	NA	22.5	0.5	11.5	1.9	10.7	2.4	7.2	100.0	98.4	NA	NC
L18	2018	22	21	21	21	22.3	0.5	11.7	2.5	10.7	2.2	8.3	99.1	97.7	100.0	10.6
M18	2018	6	5	5	NA	22.2	0.4	11.6	1.5	10.8	1.6	6.7	100.0	100.0	NA	NC
N18	2018	6	6	6	NA	22.2	0.4	13.3	1.4	12.8	1.2	3.3	100.0	98.7	NA	NC
V17	2017	24	24	23	23	22.4	0.5	12.6	1.5	11.0	2.1	12.3	96.2	98.8	99.4	11.1
U16	2016	6	5	5	NA	22.8	0.8	10.2	3.6	8.0	3.4	18.7	100	100	NA	NC
V16	2016	21	21	21	21	22.5	0.6	11.3	2.1	9.9	2.3	13.6	99.5	97.1	100	9.8
W16	2016	22	22	21	21	22.4	0.5	11.0	4.0	10.3	3.5	10.7	99.1	99.5	100	10.2
X16	2016	10	9	7	NA	22.6	0.8	11.9	5.3	10.6	3.6	20.7	100	100	NA	NC
I15	2015	24	22	22	22	22.2	0.4	12.8	1.5	11.5	1.3	10.1	98.4	99.6	100	11.3
J15	2015	24	24	24	24	22.4	0.5	11.9	1.8	10.6	1.7	10.4	99.6	98.0	100	10.6
K15-1	2015	24	22	22	22	22.2	0.4	12.8	1.6	11.8	1.4	7.8	98.8	98.8	100	11.6
K15-2	2015	24	24	22	22	22.2	0.4	11.9	2.1	11.3	2.2	5.1	96.0	96.2	100	10.9
L15	2015	10	10	10	NA	22.3	0.5	15.0	1.5	13.6	1.6	9.1	97.1	100	NA	NC
M15	2015	9	9	9	NA	22.0	0.0	14.2	3.6	13.9	3.3	2.0	100	100	NA	NC
Total %		302	289	282	234											
Mean			96%	93%	94%	22.3		12.1		11.0		9.9	98.5	98.7	99.6	10.8
SD						0.5		2.5		2.5						

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Historical Control Data

Rat Wistar: CrI-WI

Post-partum data - pup weights (g)

Page 1/2

Study	Year	Number of litters	Postnatal day 1				Postnatal day 4				Postnatal day 7				Postnatal day 14			
			Males		Females		Males		Females		Males		Females		Males		Females	
			Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD
A19	2019	21	7.0	0.6	6.8	0.8	10.9	1.3	10.7	1.5	16.9	1.4	16.7	2.1	32.1	2.5	31.4	3.2
B19	2019	19	7.2	0.9	6.7	0.8	11.2	1.9	10.7	1.6	17.7	2.3	17.0	2.0	34.7	2.9	33.6	2.4
C19	2019	18	7.3	1.1	7.1	1.1	11.4	2.0	11.1	1.9	18.0	2.4	17.6	2.1	34.9	2.6	33.9	2.2
K18	2018	6	7.3	0.6	6.8	0.7	11.3	1.2	10.8	1.4	17.6	1.9	17.0	2.0	34.1	2.2	33.3	2.7
L18	2018	21	7.1	0.9	6.8	0.8	11.1	1.2	10.7	1.3	17.3	1.8	16.9	1.7	33.7	3.2	32.9	3.1
M18	2018	5	7.1	1.1	6.7	0.9	10.9	2.1	10.5	1.9	17.6	3.4	17.1	3.0				
N18	2018	6	6.8	0.2	6.6	0.3	10.8	0.6	10.5	0.6	15.9	0.5	15.4	0.5				
V17	2017	23	7.2	0.9	6.9	0.8	11.3	1.4	11.1	1.4	18.3	1.5	17.7	1.6	35.6	2.3	34.8	2.5
U16	2016	5	7.4	1.3	7.0	1.3	11.5	2.3	11.2	2.5	17.5	2.6	17.0	2.9				
V16	2016	21	7.4	0.8	7.0	0.6	11.4	1.0	10.9	0.9	17.4	1.1	16.5	1.5	33.3	2.0	31.9	3.0
X16	2016	7	7.0	1.4	6.6	1.1	10.5	2.3	10.2	2.3								
W16	2016	21	6.7	1.0	6.4	1.0	10.5	1.9	10.1	2.0	16.9	2.2	16.4	2.3	34.1	2.5	33.1	2.6
I15	2015	22	7.0	0.7	6.8	0.7	11.1	1.0	10.9	1.1	17.9	1.4	17.4	1.5	34.2	2.4	33.3	2.1
J15	2015	24	7.3	0.9	6.9	0.9	11.2	1.1	10.8	1.2	17.3	1.5	16.7	1.5	33.4	2.4	32.6	2.5
K15-1	2015	22	6.6	0.5	6.4	0.5	10.3	1.0	10.0	1.0	16.8	1.1	16.1	1.1	33.5	1.6	32.6	1.8
K15-2	2015	22	6.8	0.9	6.5	0.8	10.2	1.5	9.9	1.5	15.8	1.8	15.4	1.8	31.1	3.0	30.7	2.9
L15	2015	10	6.7	0.5	6.4	0.6	10.2	1.0	9.7	1.0								
M15	2015	9	6.4	0.6	6.0	0.5	9.8	1.2	9.4	1.1								
Total		282																
Mean			7.0		6.7		10.9		10.5		17.3		16.7		33.7		32.8	
SD				0.9		0.8		1.5		1.5		1.8		1.9		2.7		2.8

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Historical Control Data

Rat Wistar: Crl-WI

Post-partum data - pup weights (g) Page 2/2

Study	Year	Number of litters	Postnatal day 21			
			Males		Females	
			Mean	SD	Mean	SD
A19	2019	21	52.1	4.5	51.5	4.7
B19	2019	19	55.3	4.7	53.5	3.9
C19	2019	18	55.9	3.5	54.1	2.6
K18	2018	6				
L18	2018	21	53.6	5.5	52.2	4.9
M18	2018	5				
N18	2018	6				
V17	2017	23	57.6	3.8	56.0	4.4
U16	2016	5				
V16	2016	21	55.1	3.3	52.5	5.0
X16	2016	7				
W16	2016	21	56.0	3.8	53.9	3.8
I15	2015	22	54.2	4.1	52.8	3.7
J15	2015	24	53.8	3.5	52.3	3.7
K15-1	2015	22	53.5	2.7	51.5	3.0
K15-2	2015	22	49.7	4.5	48.8	4.1
L15	2015	10				
M15	2015	9				
Total		282				
Mean			54.2		52.6	
SD				4.5		4.3

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Historical Control Data

Rat Wistar: Crl-WI

Pre-weaning development - % of pups positive

Study	Year	Number of litters	Pinna unfolding					Incisor eruption								Eye opening					
			PND1	PND2	PND3	PND4	PND5	PND7	PND8	PND9	PND10	PND11	PND12	PND13	PND14	PND12	PND13	PND14	PND15	PND16	PND17
B19	2019	19	12	79	100	100	100	0	0	8	36	74	100	100	100	6	45	94	100	100	100
C19	2019	18	31	73	100	100	100	0	0	1	15	44	85	98	100	2	41	86	100	100	100
L18	2018	21	10	48	100	100	100	0	3	10	39	66	99	100	100	1	15	77	100	100	100
V17	2017	23	18	73	100	100	100	0	0	2	43	81	98	100	100	1	20	84	99	100	100
V16	2016	21	25	79	100	100	100	0	1	8	23	61	93	99	100	1	14	73	97	100	100
W16	2016	21	7	59	99	100	100	1	2	16	46	84	97	99	100	3	11	56	94	100	100
I15	2015	22	4	43	98	100	100	0	4	11	50	89	99	100	100	0	25	85	99	100	100
J15	2015	24	9	71	99	100	100	0	1	7	47	87	100	100	100	1	18	83	100	100	100
Total Mean %		169	14	65	99	100	100	0	1	8	38	74	97	100	100	2	23	80	99	100	100

PND: postnatal day

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Historical Control Data from Wistar Rat (CRL Den Bosch)

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Historical Control Data Rat: Cri:WI(Han) (outbred, SPF-Quality)
Gestation Day 21

No. of Studies	49	
Total No. Fetuses/Litters Examined Externally	11515	1072
Total No. Fetuses/Litters Examined Viscerally	6234	1071
Total No. Fetuses/Litters Examined Skeletally	6219	1070

MALFORMATIONS	Mean of Study Means (% Per Litter Basis)							Summary Incidence (Total No. Affected)	
	Mean	SD	Median	Min	Max	P5	P95	Fetuses	Litters
Total External Malformations								14	14
Total Visceral Malformations								28	28
Total Skeletal Malformations								66	59
Total Malformations								101	92
EXTERNAL									
Anogenital- Fissure	0.0	0.06	0.0	0.0	0.4	0.0	0.0	1	1
Anus- Atresia	0.0	0.06	0.0	0.0	0.4	0.0	0.0	1	1
Exencephaly	0.0	0.09	0.0	0.0	0.5	0.0	0.2	2	2
Eye(s)- Bulge Absent and/or Small	0.0	0.09	0.0	0.0	0.6	0.0	0.0	1	1
Eye(s)- Open	0.0	0.09	0.0	0.0	0.5	0.0	0.2	2	2
General- Anasarca	0.0	0.07	0.0	0.0	0.5	0.0	0.0	1	1
Limb(s)- Malrotated	0.0	0.06	0.0	0.0	0.4	0.0	0.0	1	1
Lip- Cleft	0.0	0.09	0.0	0.0	0.6	0.0	0.0	1	1
Lower Jaw- Absent or small	0.0	0.10	0.0	0.0	0.5	0.0	0.4	3	3
Meningocele	0.0	0.10	0.0	0.0	0.5	0.0	0.3	2	2
Palate- Cleft	0.0	0.09	0.0	0.0	0.6	0.0	0.0	1	1
Snout- Proboscis	0.0	0.06	0.0	0.0	0.4	0.0	0.0	1	1
Tail- Absent	0.0	0.06	0.0	0.0	0.4	0.0	0.0	1	1
Trunk- Omphalocele	0.1	0.16	0.0	0.0	0.6	0.0	0.6	5	5
VISCERAL									
Aorta- Overriding	0.0	0.14	0.0	0.0	1.0	0.0	0.0	1	1
Aorta- Dilated	0.0	0.14	0.0	0.0	1.0	0.0	0.0	1	1
Aortic Arch- Right-sided	0.0	0.14	0.0	0.0	0.8	0.0	0.3	2	2
Diaphragmatic Hernia	0.0	0.12	0.0	0.0	0.8	0.0	0.2	2	2
Eye(s)- Absent and/or Small	0.2	0.81	0.0	0.0	5.3	0.0	1.5	7	7
Heart- Large	0.0	0.09	0.0	0.0	0.6	0.0	0.0	1	1

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Historical Control Data Rat: Crl:WI(Han) (outbred, SPF-Quality)
Gestation Day 21

MALFORMATIONS	Mean of Study Means (% Per Litter Basis)							Summary Incidence (Total No. Affected)	
	Mean	SD	Median	Min	Max	P5	P95	Fetuses	Litters
VISCERAL (continued)									
Hydrocephaly- External	0.0	0.13	0.0	0.0	0.9	0.0	0.0	1	1
Hydrocephaly- Internal	0.0	0.17	0.0	0.0	0.9	0.0	0.4	2	2
Lung- Abnormal Lobation	0.1	0.20	0.0	0.0	0.8	0.0	0.8	4	4
Situs Inversus	0.2	0.38	0.0	0.0	1.1	0.0	1.1	14	14
Ventricular Septum Defect	0.0	0.09	0.0	0.0	0.6	0.0	0.0	1	1
SKELETAL									
Costal Catilage Anomaly	0.1	0.27	0.0	0.0	1.7	0.0	0.5	3	3
Jaw- Upper Jaw Small	0.0	0.11	0.0	0.0	0.8	0.0	0.0	1	1
Jaw- Lower Jaw Absent or Small	0.0	0.11	0.0	0.0	0.8	0.0	0.0	1	1
Limb Bone(s)- Bent ¹	0.3	0.71	0.0	0.0	2.3	@	@	5	3
Rib Anomaly	0.1	0.34	0.0	0.0	1.6	0.0	1.0	6	5
Skull Anomaly	0.1	0.34	0.0	0.0	2.3	0.0	0.3	2	2
Skull Bones- Fused	0.0	0.19	0.0	0.0	1.1	0.0	0.4	2	2
Sternoschisis	0.1	0.22	0.0	0.0	1.1	0.0	0.8	3	3
Vertebral Anomaly With or Without Associated Rib Anomaly	0.3	0.52	0.0	0.0	1.9	0.0	1.6	16	16
Vertebral Centra Anomaly	0.0	0.18	0.0	0.0	1.0	0.0	0.4	2	2

@ Insufficient number of data for calculation. ¹ Based on 12 datasets.

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Historical Control Data Rat: Crl:WI(Han) (outbred, SPF-Quality)
Gestation Day 21

VARIATIONS	Mean of Study Means (% Per Litter Basis)							Summary Incidence (Total No. Affected)	
	Mean	SD	Median	Min	Max	P5	P95	Fetuses	Litters
EXTERNAL									
None Observed									
VISCERAL									
Adrenal Gland- Discolored	0.0	0.13	0.0	0.0	0.9	0.0	0.0	1	1
Kidney(s)- Renal Papilla(e) Absent and/or Small	0.1	0.24	0.0	0.0	1.1	0.0	0.9	4	4
Liver- Discolored	0.1	0.25	0.0	0.0	1.0	0.0	0.9	6	6
Liver- Small Supernumerary Lobe(s)	4.6	2.80	4.8	0.0	9.6	0.0	9.1	266	221
Lung- Abnormal Lobation	0.0	0.11	0.0	0.0	0.8	0.0	0.0	1	1
Spleen- Supernumerary	0.0	0.07	0.0	0.0	0.5	0.0	0.0	1	1
Subclavian (Right)- Originating from the Aortic Arch	0.0	0.10	0.0	0.0	0.7	0.0	0.0	1	1
Subclavian (Right)- Retroesophageal	0.0	0.27	0.0	0.0	1.9	0.0	0.0	2	2
Thymus- Partially Undescended Horn(s)	0.4	0.97	0.0	0.0	4.3	0.0	3.5	37	26
Thyroid- Discolored	0.0	0.19	0.0	0.0	1.3	0.0	0.0	1	1
Ureter(s)- Convoluted	0.9	1.58	0.0	0.0	8.7	0.0	4.2	73	54
Ureter(s)- Dilated	0.5	1.32	0.0	0.0	8.5	0.0	2.3	57	32
SKELETAL									
7th Cervical Rudimentary Rib(s) / Ossification Site(s)	3,8	2,65	3,6	0,0	9,9	0,0	8,7	215	174
7th Cervical Full Rib(s)	0,4	0,58	0,0	0,0	2,4	0,0	1,7	18	16
14th Full Rib(s)	6,3	3,65	6,8	0,0	13,1	0,7	12,1	365	254
14th Rudimentary Rib(s)	51,2	11,98	53,2	19,0	72,0	23,1	71,8	3033	970
Metacarpal(s) and/or Metatarsal(s) Malpositioned	0,0	0,09	0,0	0,0	0,6	0,0	0,0	1	1
Metacarpal(s) and/or Metatarsal(s) Unossified	3,3	3,57	2,2	0,0	17,6	0,0	12,4	186	122
Pelvic Girdle- Caudal Shift	5,9	2,87	5,0	1,7	13,0	1,9	12,3	360	230
Pubis- Unossified / Reduced Ossification	0,0	0,23	0,0	0,0	1,6	0,0	0,0	1	1
Rib(s)- Bent	13,7	6,37	12,8	0,8	27,4	2,1	25,8	757	401
Rib(s)- reduced ossification	0,0	0,13	0,0	0,0	0,9	0,0	0,0	1	1
Rib(s)- Short	0,0	0,03	0,0	0,0	0,2	0,0	0,0	1	1
Scapula(e)- Bent ¹	0,3	0,72	0,0	0,0	2,4	@	@	4	3

@ Insufficient number of data for calculation. ¹ Based on 12 datasets.

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Historical Control Data Rat: Cri:WI(Han) (outbred, SPF-Quality)
Gestation Day 21

VARIATIONS	Mean of Study Means (% Per Litter Basis)							Summary Incidence (Total No. Affected)	
	Mean	SD	Median	Min	Max	P5	P95	Fetuses	Litters
SKELETAL (continued)									
Skull Bone- Unossified Line	0.0	0.07	0.0	0.0	0.5	0.0	0.0	1	1
Skull- Reduced Ossification	8.5	5.22	7.1	0.0	20.0	0.4	18.8	483	282
Skull- Supernumerary Site	0.0	0.14	0.0	0.0	1.0	0.0	0.0	1	1
Sternebra- Supernumerary	0.0	0.26	0.0	0.0	1.8	0.0	0.0	2	1
Sternebra(e) #1, #2, #3 and/or #4 Unossified	0.1	0.28	0.0	0.0	1.6	0.0	0.8	4	4
Sternebra(e) #5 and/or #6 Unossified	0.4	0.84	0.0	0.0	4.1	0.0	2.5	44	30
Sternebra(e)- Branched	0.2	0.41	0.0	0.0	1.5	0.0	1.3	11	10
Sternebra(e)- Fused	0.0	0.15	0.0	0.0	1.0	0.0	0.2	2	2
Sternebrae- Malaligned ¹	7.9	2.49	8.2	3.0	11.7	@	@	123	99
Sternebra(e) Malaligned (Severe) ²	0.0	0.14	0.0	0.0	0.8	0.0	0.4	2	2
Sternebrae- Malaligned (Slight or Moderate) ²	17.7	9.07	18.6	4.4	43.8	5.1	33.9	748	447
Sternum- Supernumerary Ossification Site	0.1	0.25	0.0	0.0	1.1	0.0	1.0	3	3
Vertebral Arches- Reduced Ossification	0.1	0.42	0.0	0.0	2.3	0.0	1.1	6	6
Vertebral Centra- Reduced Ossification	0.8	1.01	0.6	0.0	3.5	0.0	3.2	48	45
Vertebral Centra- Unossified	0.0	0.13	0.0	0.0	0.9	0.0	0.0	1	1

@ Insufficient number of data for calculation. ¹ Based on 13 dataset. ² Based on 36 datasets.

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FETAL EXTERNAL ABNORMALITIES
WISTAR RATS (CrI:WI[Han])
GESTATION DAY 20 CAESAREAN-SECTION
FULL STUDIES

NO. OF STUDIES INCLUDED	3				
NO. LITTERS EXAMINED	70				
NO. LIVE FETUSES EXAMINED	812				
	ABNORMALITIES		N	RANGE/STUDY N %	
EYE(S)					
	: Bulge, depressed	L	1	0-1	(0-4.8)
		F	1	0-1	(0-0.4)
MOUTH					
	: Oral opening, small	L	1	0-1	(0-4.8)
		F	1	0-1	(0-0.4)
	: Tongue, absent	L	1	0-1	(0-4.8)
		F	1	0-1	(0-0.4)
BODY					
	: Umbilical hernia	L	1	0-1	(0-3.7)
		F	1	0-1	(0-0.3)
JAW					
	: Agnathia	L	1	0-1	(0-4.8)
		F	1	0-1	(0-0.4)
FORELIMB(S)/PAW(S)					
	: Digit, absent	L	1	0-1	(0-4.5)
		F	1	0-1	(0-0.4)
L: LITTER INCIDENCE					
F: FETAL INCIDENCE					

Note: All summary values are based on studies with fetal findings

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FETAL SOFT TISSUE ABNORMALITIES
WISTAR RATS (CrI:WI[Han])
GESTATION DAY 20 CAESAREAN-SECTION
FULL STUDIES

NO. OF STUDIES INCLUDED		2			
NO. LITTERS EXAMINED		45			
NO. FETUSES EXAMINED		262			
		ABNORMALITIES	RANGE/STUDY		
			N	N	%
BRAIN	: Lateral ventricle, slight	L	2	0-2	(0-8.0)
	dilation	F	2	0-2	(0-1.2)
VESSELS	: Umbilical artery descends	L	1	0-1	(0-5.0)
	to left of urinary bladder	F	1	0-1	(0-1.0)

L: LITTER INCIDENCE
F: FETAL INCIDENCE

Note: All summary values are based on studies with fetal findings

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FETAL SKELETAL ABNORMALITIES
WISTAR RATS (CrI:WI[Han])
GESTATION DAY 20 CAESAREAN-SECTION
FULL STUDIES

NO. OF STUDIES INCLUDED 2
NO. LITTERS EXAMINED 46
NO. FETUSES EXAMINED 289

SKULL	ABNORMALITIES			RANGE/STUDY		
				N	N	%
	Nasal	: Nasal-frontal, suture, large	L	1	0-1	(0-4.0)
			F	1	0-1	(0-0.6)
	Parietals	: Incompletely ossified	L	1	0-1	(0-4.8)
			F	1	0-1	(0-0.9)
	Supraoccipitals	: Incompletely ossified	L	1	0-1	(0-4.0)
			F	1	0-1	(0-0.6)
VERTEBRAE	Cervical	: Arch, reduced ventral process, 6th	L	7	0-7	(0-28.0)
			F	9	0-9	(0-5.1)
		: Arch, incompletely ossified	L	4	0-4	(0-16.0)
			F	5	0-5	(0-2.8)
	Thoracic	: Cervical rib(s), present	L	1	0-1	(0-4.0)
			F	1	0-1	(0-0.6)
		: Centrum, bifid	L	1	0-1	(0-4.0)
			F	1	0-1	(0-0.6)
RIBS	Ribs	: One or more, wavy	L	8	0-4	(0-19.0)
			F	12	0-12	(0-5.3)
		: Incompletely ossified	L	2	0-2	(0-8.0)
			F	2	0-2	(0-1.1)
STERNEBRAE	Sternebra	: Incompletely ossified	L	12	0-12	(0-44.0)
			F	14	0-14	(0-7.4)
		: Not ossified	L	4	0-4	(0-16.0)
			F	5	0-5	(0-2.8)

L: LITTER INCIDENCE
F: FETAL INCIDENCE

Note: All summary values are based on studies with fetal findings

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FETAL OSSIFICATION SITES
WISTAR RATS (CrI:WI[Han])
GESTATION DAY 20 CAESAREAN-SECTION

NO. OF STUDIES INCLUDED	2
NO. LITTERS EXAMINED	46
NO. FETUSES EXAMINED	289

	MEAN	MINIMUM	MAXIMUM
HYOID	0.97	0.94	1.00
VERTEBRAE			
CERVICAL	7.00	7.00	7.00
THORACIC	13.20	13.20	13.20
LUMBAR	5.80	5.79	5.80
SACRAL	3.00	3.00	3.00
CAUDAL	4.90	4.72	5.07
RIBS (pairs)	13.18	13.17	13.18
STERNUM			
MANUBRIUM	1.00	1.00	1.00
STERNAL CENTERS	3.85	3.82	3.88
XIPHOID	0.99	0.97	1.00
FOREPAWS ^a			
CARPALS	0.00	0.00	0.00
METACARPALS	3.80	3.77	3.82
DIGITS	5.00	5.00	5.00
PHALANGES	5.48	5.38	5.57
HINDPAWS ^a			
TARSALS	0.00	0.00	0.00
METATARSALS	4.01	4.00	4.01
DIGITS	5.00	5.00	5.00
PHALANGES	5.00	5.00	5.00

a. Calculated as mean per limb

Note: All summary values are based on studies with fetal findings

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REPRODUCTIVE INDICES
WISTAR RATS (CrI:WI[Han])
GESTATION DAY 21 CAESAREAN-SECTION

	FULL STUDIES			DOSE RANGE STUDIES		
NO. OF STUDIES INCLUDED	27			12		
NO. OF RATS TESTED	600			78		
NO. OF RATS PREGNANT	568			74		
NO. FOUND DEAD	2			0		
NO. ABORTED	0			0		
NO. DELIVERED	4			1		
CAESAREAN-SECTIONED ON GD 20	562			73		
NO. OF RATS WITH SINGLE CONCEPTUS LITTER						
LIVE:	0			0		
RESORBED:	1			0		
ABORTED:	0			0		
	MEAN	MIN	MAX	MEAN	MIN	MAX
PREGNANT (%)	94.9	81.8	100.0	94.6	83.3	100.0
CORPORA LUTEA	11.2	9.6	16.0	11.3	8.8	15.0
IMPLANTATIONS	10.3	8.4	15.2	10.6	6.7	14.2
PREIMPLANTATION LOSS (%)	8.2	2.6	13.8	6.2	0.0	25.9
LITTER SIZES						
LIVE FETUSES	9.8	8.0	14.6	10.2	6.3	13.8
DEAD FETUSES	0.0	0.0	0.0	0.0	0.0	0.0
TOTAL RESORPTIONS	0.4	0.1	1.2	0.4	0.0	0.9
EARLY RESORPTIONS	0.4	0.1	1.1	0.4	0.0	0.8
LATE RESORPTIONS	0.0	0.0	0.1	0.1	0.0	0.5
POSTIMPLANTATION LOSS (%)	5.1	1.2	11.4	3.2	0.0	8.0
DAMS WITH ANY RESORPTIONS (%)	31.0	15.8	54.5	29.5	0.0	50.0
DAMS WITH ALL CONCEPTUSES RESORBED (%)	0.2	0.0	5.6	0.0	0.0	0.0
DAMS WITH ONE OR MORE VIABLE FETUSES (%)	98.7	90.0	100.0	100.0	100.0	100.0

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REPRODUCTIVE INDICES
WISTAR RATS (CrI:WI[Han])
GESTATION DAY 21 CAESAREAN-SECTION

NO. OF STUDIES INCLUDED	FULL STUDIES 27			DOSE RANGE STUDIES 12		
	MEAN	MIN	MAX	MEAN	MIN	MAX
SEX RATIO (% MALES/LITTER)	50.3	41.1	56.9	48.9	39.4	57.4
LIVE FETAL BODY WEIGHTS GRAMS/LITTER:	5.26	4.94	5.52	5.43	5.27	5.68
MALE FETUSES:	5.41	5.06	5.66	5.54	5.26	5.91
FEMALE FETUSES:	5.14	4.80	5.55	5.27	4.98	5.57

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FETAL EXTERNAL ABNORMALITIES
WISTAR RATS (CrI:WI[Han])
GESTATION DAY 21 CAESAREAN-SECTION
FULL STUDIES

NO. OF STUDIES INCLUDED 7
NO. LITTERS EXAMINED 148
NO. LIVE FETUSES EXAMINED 1618

		RANGE/STUDY		
ABNORMALITIES		N	N	%
EYE(S)	: Bulge depressed	L	3	0-1 (0-5.0)
		F	3	0-1 (0-0.5)
MOUTH	: Oral opening absent	L	1	0-1 (0-4.5)
		F	1	0-1 (0-0.3)
JAWS	: Micrognathia	L	1	0-1 (0-4.5)
		F	1	0-1 (0-0.3)
BODY	: Umbilical hernia	L	4	0-2 (0-10.0)
		F	4	0-2 (0-1.0)
	: No anal opening	L	1	0-1 (0-4.5)
		F	1	0-1 (0-0.3)
	: Gastroschisis	L	1	0-1 (0-5.0)
		F	1	0-1 (0-0.5)
	: Subcutaneous edema, generalized	L	1	0-1 (0-5.0)
		F	1	0-1 (0-0.5)
HINDLIMB(S)	: Genital tubercle, absent	L	1	0-1 (0-5.0)
		F	1	0-1 (0-0.5)
	: Rotated	L	3	0-1 (0-5.6)
		F	3	0-1 (0-0.6)
	: Absent	L	1	0-1 (0-5.0)
		F	1	0-1 (0-0.5)
	: Short	L	1	0-1 (0-5.0)
		F	1	0-1 (0-0.5)
PAW/DIGIT	: Forepaw, short	L	1	0-1 (0-5.0)
		F	1	0-1 (0-0.5)
TAIL	: Thread-like	L	1	0-1 (0-4.5)
		F	1	0-1 (0-0.3)
	: Pedunculated	L	1	0-1 (0-4.5)
		F	1	0-1 (0-0.3)
	: Short	L	1	0-1 (0-4.3)
		F	1	0-1 (0-0.4)
	: Constricted	L	1	0-1 (0-4.3)
		F	1	0-1 (0-0.4)

L: LITTER INCIDENCE
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FETAL SOFT TISSUE ABNORMALITIES
WISTAR RATS (CrI:WI[Han])
GESTATION DAY 21 CAESAREAN-SECTION
FULL STUDIES

NO. OF STUDIES INCLUDED		15			
NO. LITTERS EXAMINED		271			
NO. FETUSES EXAMINED		1663			
ABNORMALITIES					
EYE(S)			RANGE/STUDY		
			N	N	%
	: Retina, folded	L	2	0-1	(0-5.0)
		F	2	0-1	(0-1.1)
	: Microphthalmia	L	1	0-1	(0-5.0)
		F	1	0-1	(0-1.0)
	: Lens, malpositioned	L	1	0-1	(0-4.5)
		F	1	0-1	(0-1.0)
SINUS		L	1	0-1	(0-5.0)
		F	1	0-1	(0-0.9)
HEART	: Interventricular septal defect	L	1	0-1	(0-5.0)
		F	1	0-1	(0-1.0)
VESSELS	: Umbilical artery descends to left of urinary bladder	L	27	0-9	(0-44.4)
		F	39	0-16	(0-10.0)
	: Persistent truncus arteriosus	L	1	0-1	(0-5.0)
		F	1	0-1	(0-1.0)
	: Aorta descends to the right, vessels arise in incorrect order, left subclavian branches from left carotid and innominate artery absent	L	1	0-1	(0-5.0)
		F	1	0-1	(0-1.0)
INTESTINES	: Protrudes through umbilicus	L	1	0-1	(0-4.2)
		F	1	0-1	(0-0.8)
	: Malpositioned	L	2	0-1	(0-4.8)
		F	2	0-1	(0-1.0)
LIVER	: Discoloration	L	5	0-3	(0-15.0)
		F	6	0-4	(0-3.8)
	: Misshapen	L	4	0-1	(0-16.7)
		F	5	0-2	(0-2.5)
STOMACH	: Contents discolored	L	1	0-1	(0-4.8)
		F	1	0-1	(0-0.6)
KIDNEY	: Renal pelvis, dilated, minimal	L	1	0-1	(0-5.0)
		F	1	0-1	(0-0.9)
GONAD	: Malpositioned	L	1	0-1	(0-5.0)
		F	1	0-1	(0-0.9)
URETER	: Dilated, severe	L	1	0-1	(0-5.0)
		F	1	0-1	(0-0.9)

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FETAL SKELETAL ABNORMALITIES
WISTAR RATS (Ctrl:WI[Han])
GESTATION DAY 21 CAESAREAN-SECTION
DOSE-RANGE FINDING STUDIES

NO. OF STUDIES INCLUDED 1
NO. LITTERS EXAMINED 6
NO. FETUSES EXAMINED 35

SKULL	ABNORMALITIES	RANGE/STUDY		
		N	N	%
Parietal	: Incompletely ossified	L 1	0-1	(0-16.7)
		F 2	0-2	(0-5.6)
	Interparietal	L 1	0-1	(0-16.7)
		F 1	0-1	(0-2.8)
	Squamosal	L 1	0-1	(0-16.7)
		F 1	0-1	(0-2.8)
	Zygomatic arch	L 2	0-2	(0-33.3)
		F 3	0-3	(0-7.9)
		L 2	0-2	(0-33.3)
		F 2	0-2	(0-5.2)
Vertebrae	Cervical	: Cervical rib, short	L 3	0-3 (0-50.0)
			F 4	0-4 (0-12.5)
		: Arch, fused	L 1	0-1 (0-16.7)
			F 1	0-1 (0-2.4)
		: Centrum, bipartite ossification (previously reported as centrum, bifid)	L 1	0-1 (0-16.7)
			F 1	0-1 (0-2.4)
RIBS	Ribs	: Nodulated	L 3	0-3 (0-50.0)
			F 7	0-7 (0-18.0)
		: One or more, wavy	L 1	0-1 (0-16.7)
			F 1	0-1 (0-2.8)
STERNEBRAE	Sternebra	: Incompletely ossified	L 1	0-1 (0-16.7)
			F 1	0-1 (0-3.3)

L: LITTER INCIDENCE
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FETAL SKELETAL ABNORMALITIES
WISTAR RATS (CrI:WI[Han])
GESTATION DAY 21 CAESAREAN-SECTION
FULL STUDIES

NO. OF STUDIES INCLUDED 24
NO. LITTERS EXAMINED 493
NO. FETUSES EXAMINED 2623

SKULL	ABNORMALITIES	N		RANGE/STUDY	
				N	%
Parietal	: Incompletely ossified	L	105	0-11	(0-52.4)
		F	165	0-22	(0-15.7)
Interparietal	: Incompletely ossified	L	47	0-8	(0-38.1)
		F	67	0-18	(0-11.1)
Squamosal	: Incompletely ossified	L	71	0-8	(0-36.4)
		F	92	0-12	(0-11.9)
Zygomatic arch	: Incompletely ossified	L	74	0-10	(0-47.6)
		F	92	0-20	(0-10.8)
	: Fused	L	5	0-2	(0-9.1)
		F	6	0-2	(0-2)
Frontal	: Incompletely ossified	L	22	0-4	(0-18.2)
		F	29	0-6	(0-5.9)
	: Holes	L	1	0-1	(0-5)
		F	1	0-1	(0-1.1)
Supraoccipital	: Incompletely ossified	L	16	0-5	(0-22.7)
		F	20	0-7	(0-6.9)
Hyoid	: Incompletely ossified	L	2	0-1	(0-4.8)
		F	2	0-1	(0-1)
Mandible	: Thickened	L	1	0-1	(0-5.6)
		F	1	0-1	(0-1.1)
	: Misshapen	L	1	0-1	(0-5.3)
		F	2	0-2	(0-2.2)
	: Contains a hole	L	2	0-1	(0-5)
		F	2	0-1	(0-1.1)
Suture	: Large	L	3	0-1	(0-5)
		F	10	0-8	(0-8.6)
Premaxilla	: Incomplete ossification	L	1	0-1	(0-5.3)
		F	2	0-2	(0-2.2)

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FETAL SKELETAL ABNORMALITIES
WISTAR RATS (CrI:WI[Han])
GESTATION DAY 21 CAESAREAN-SECTION
FULL STUDIES

	ABNORMALITIES	RANGE/STUDY		
		N	N	%
SKULL (CONT.)				
	Tympanic			
	: Annulus, incomplete ossification	L 2	0-2	(0-10.5)
		F 3	0-3	(0-3.3)
	: Annulus, misshapen	L 1	0-1	(0-5.3)
		F 1	0-1	(0-1.1)
VERTEBRAE				
	Cervical			
	: Arch, incompletely ossified	L 4	0-2	(0-10.5)
		F 5	0-3	(0-3.3)
	: Arch, misshapen	L 3	0-3	(0-15.0)
		F 4	0-4	(0-4.1)
	: Lateral ossification site present at 7th cervical vertebrae	L 16	0-9	(0-42.8)
		F 26	0-16	(0-8.9)
	: Arch fused	L 1	0-1	(0-5.3)
		F 1	0-1	(0-1.1)
	: Cervical rib present at 7th cervical	L 13	0-4	(0-21)
		F 16	0-5	(0-5.6)
	: Cervical rib(s) present	L 27	0-10	(0-43.5)
		F 37	0-15	(0-10.9)
	: Cervical rib, short	L 32	0-5	(0-26.3)
		F 39	0-5	(0-5.8)
	: Cervical rib, full	L 7	0-4	(0-21.1)
		F 7	0-4	(0-4.7)
	Thoracic			
	: 12 present	L 1	0-1	(0-4.3)
		F 1	0-1	(0-0.7)
	: Arch, incompletely ossified	L 1	0-1	(0-5.6)
		F 1	0-1	(0-0.7)
	: Arch, fused	L 1	0-1	(0-5.6)
		F 1	0-1	(0-0.7)
	: Centrum, bipartite ossification (previously reported as centrum, bifid)	L 11	0-3	(0-14.3)
		F 11	0-3	(0-1.7)
	: Centrum, irregularly shaped	L 1	0-1	(0-5.0)
		F 1	0-1	(0-1.1)
	: Centrum, fused	L 1	0-1	(0-5.3)
		F 1	0-1	(0-1.1)
	: Centrum, incomplete ossification	L 2	0-2	(0-10.5)
		F 2	0-2	(0-2.2)
	: Centrum, unilateral ossification	L 1	0-1	(0-5.3)
		F 1	0-1	(0-1.1)
	Lumbar			
	: 5 present	L 2	0-2	(0-8.7)
		F 2	0-2	(0-1.4)
	: Centrum, unilateral ossification	L 1	0-1	(0-5.6)
		F 1	0-1	(0-0.7)
	: Arch and centrum, fused	L 1	0-1	(0-5.6)
		F 1	0-1	(0-0.7)
	: Vertebra, supernumerary	L 2	0-1	(0-5.3)
		F 2	0-1	(0-1.2)
	: Vertebra, absent	L 1	0-1	(0-5.3)
		F 1	0-1	(0-1.1)

L: LITTER INCIDENCE
F: FETAL INCIDENCE

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FETAL SKELETAL ABNORMALITIES
WISTAR RATS (Crl:WI[Han])
GESTATION DAY 21 CAESAREAN-SECTION
FULL STUDIES

		ABNORMALITIES	N		RANGE/STUDY	
					N	%
VERTEBRAE (CONT.)	Sacral	: Arch, small	L	1	0-1	(0-4.3)
			F	1	0-1	(0-0.7)
		: Centrum, unilateral ossification	L	1	0-1	(0-4.3)
			F	1	0-1	(0-0.7)
		: Arch, irregularly shaped	L	4	0-1	(0-5.9)
			F	4	0-1	(0-1.3)
	Caudal	: 0 present	L	1	0-1	(0-4.3)
			F	1	0-1	(0-0.7)
		: Unossified	L	1	0-1	(0-4.3)
			F	2	0-2	(0-2.2)
	Vertebra	: Supernumerary	L	1	0-1	(0-4.5)
			F	1	0-1	(0-1)
RIBS	Ribs	: Incomplete ossification	L	1	0-1	(0-5.0)
			F	1	0-1	(0-0.9)
		: Nodulated	L	84	0-8	(0-42.1)
		(previously reported as thickened)	F	129	0-14	(0-15.1)
		: One or more, wavy	L	29	0-5	(0-22.7)
			F	36	0-9	(0-8.9)
		: 12 present	L	1	0-1	(0-4.3)
			F	1	0-1	(0-0.7)
		: Bowed	L	1	0-1	(0-5.0)
			F	1	0-1	(0-0.9)
		: Short	L	4	0-1	(0-5.3)
			F	4	0-1	(0-1.1)
	Thoracolumbar	: Thoracolumbar, full	L	31	0-8	(0-36.4)
		(previously reported as T14, supernumerary)	F	37	0-9	(0-8.5)
		: Thoracolumbar, short	L	159	0-21	(0-100)
		(previously reported as T14, less than 1/2 of the preceding rib)	F	513	0-103	(0-57.2)
STERNEBRAE	Sternebra	: Asymmetric	L	10	0-2	(0-10.5)
			F	10	0-2	(0-2.3)
		: Fused	L	3	0-1	(0-5.3)
			F	3	0-1	(0-1.2)
		: Duplicated	L	1	0-1	(0-5.0)
			F	1	0-1	(0-0.9)
		: Incompletely ossified	L	8	0-2	(0-10.5)
			F	9	0-3	(0-3.3)
		: Misshappen	L	4	0-1	(0-5.3)
			F	4	0-1	(0-1.2)
		: Small	L	1	0-1	(0-5.6)
			F	1	0-1	(0-0.7)
		: Extra point of ossification	L	3	0-1	(0-5.0)
			F	3	0-1	(0-0.9)

L: LITTER INCIDENCE
F: FETAL INCIDENCE

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FETAL SKELETAL ABNORMALITIES
WISTAR RATS (CrI:WI(Han))
GESTATION DAY 21 CAESAREAN-SECTION
FULL STUDIES

		ABNORMALITIES	N		RANGE/STUDY N %	
STERNEBRAE (CONT.)	Claviculae	: Extra point of ossification	L	1	0-1	(0-4.8)
			F	1	0-1	(0-0.6)
FORELIMB	Phalanges	: Less than the expected number are ossified	L	33	0-14	(0-63.6)
			F	65	0-37	(0-36.6)
		: Unossified	L	12	0-11	(0-50.0)
			F	20	0-19	(0-17.9)
		: Absent	L	1	0-1	(0-5.0)
			F	1	0-1	(0-1.0)
	Humerus	: Misshapen	L	1	0-1	(0-5.3)
			F	1	0-1	(0-1.1)
	Metacarpal	: Unossified	L	3	0-2	(0-10.5)
			F	4	0-3	(0-3.3)
HINDLIMB	Phalanges	: Less than the expected number are ossified	L	27	0-13	(0-72.2)
			F	52	0-28	(0-19.8)
		: Absent	L	1	0-1	(0-5.0)
			F	1	0-1	(0-1.0)
		: Small	L	1	0-1	(0-5.0)
			F	1	0-1	(0-1.0)
	Femur	: Short	L	2	0-1	(0-5.3)
			F	2	0-1	(0-1.1)
	Fibula	: Short	L	2	0-1	(0-5.3)
			F	2	0-1	(0-1.1)
	Metatarsal	: Unossified	L	1	0-1	(0-5.3)
			F	1	0-1	(0-1.1)
	Tibia	: Short	L	2	0-1	(0-5.3)
			F	2	0-1	(0-1.1)

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FETAL EXTERNAL ABNORMALITIES
CrI:CD(SD) RATS
GESTATION DAY 21 CAESAREAN-SECTION
DOSE-RANGE STUDIES

NO. OF STUDIES INCLUDED	9				
NO. LITTERS EXAMINED	53				
NO. LIVE FETUSES EXAMINED	674				
	ABNORMALITIES			RANGE/STUDY	
			N	N	%
FACE					
	: Naris, Absent	L	1	0-1	(0-16.7)
		F	1	0-1	(0-1.2)
	: Snout, Cleft	L	1	0-1	(0-16.7)
		F	1	0-1	(0-1.2)
MOUTH					
	: Small oral opening	L	2	0-1	(0-25.0)
		F	2	0-1	(0-1.9)
PALATE					
	: Cleft	L	2	0-1	(0-33.3)
		F	3	0-2	(0-4.2)
JAW					
	: Agnathia	L	1	0-1	(0-25.0)
		F	1	0-1	(0-1.9)
	: Micrognathia	L	1	0-1	(0-16.7)
		F	1	0-1	(0-1.4)
EYES					
	: Bulge depressed	L	1	0-1	(0-25.0)
		F	1	0-1	(0-1.9)
	: Open	L	1	0-1	(0-16.7)
		F	2	0-2	(0-2.7)
EARS					
	: Low set	L	1	0-1	(0-25.0)
		F	1	0-1	(0-1.9)
BODY					
	: Abdominal distension	L	1	0-1	(0-10.0)
		F	1	0-1	(0-0.6)
	: Trunk, short	L	1	0-1	(0-16.7)
		F	1	0-1	(0-1.5)
FORE AND/OR HINDLIMB(S)					
	: Limb(s), short	L	1	0-1	(0-10.0)
		F	1	0-1	(0-0.6)
	: Forepaw, hyperflexion	L	1	0-1	(0-16.7)
		F	1	0-1	(0-1.4)
	: Hindlimb, malrotated	L	1	0-1	(0-16.7)
		F	1	0-1	(0-1.5)

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Updated on 02 Mar 2019

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FETAL EXTERNAL ABNORMALITIES
Cr:CD(SD) RATS
GESTATION DAY 21 CAESAREAN-SECTION
DOSE-RANGE STUDIES

	ABNORMALITIES		RANGE/STUDY		
			N	N	%
TAIL	: Absent	L	1	0-1	(0-16.7)
		F	1	0-1	(0-1.5)
	: Short	L	1	0-1	(0-16.7)
		F	1	0-1	(0-1.5)
	: Curled	L	1	0-1	(0-16.7)
		F	4	0-4	(0-5.3)
	: Thread-like	L	1	0-1	(0-16.7)
		F	1	0-1	(0-1.5)
ANUS	: No opening present	L	0	0-1	(0-16.7)
		F	1	0-1	(0-1.5)

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Updated on 02 Mar 2019

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FETAL EXTERNAL ABNORMALITIES
Cr:CD(SD) RATS
GESTATION DAY 21 CAESAREAN-SECTION
FULL STUDIES

NO OF STUDIES INCLUDED			21		
NO LITTERS EXAMINED			468		
NO LIVE FETUSES EXAMINED			5994		
	ABNORMALITIES	N	RANGE/STUDY N %		
HEAD	: Exencephaly	L 3	0-1	(0-5	0)
		F 3	0-1	(0-0	4)
	: Fleishy protrusion	L 1	0-1	(0-4	3)
		F 1	0-1	(0-0	3)
	: Irregularly shaped	L 1	0-1	(0-4	3)
		F 1	0-1	(0-0	3)
	: Domed	L 2	0-1	(0-5	0)
		F 2	0-1	(0-0	3)
	: Meningocele	L 3	0-1	(0-4	5)
		F 3	0-1	(0-0	4)
EAR	: Pinna, absent	L 1	0-1	(0-5	0)
		F 1	0-1	(0-0	4)
EYE	: One or both eye bulges depressed	L 8	0-1	(0-5	6)
		F 8	0-1	(0-0	4)
	: One or both eye lids open	L 2	0-1	(0-5	6)
		F 2	0-1	(0-0	4)
	: Absent	L 1	0-1	(0-4	2)
		F 1	0-1	(0-0	8)
	: Protruding	L 1	0-1	(0-4	5)
		F 1	0-1	(0-0	4)
SNOUT	: Short	L 1	0-1	(0-5	6)
		F 1	0-1	(0-0	4)
	: Cleft	L 1	0-1	(0-4	3)
		F 1	0-1	(0-0	3)
	: Misshapen	L 2	0-1	(0-5	0)
		F 2	0-1	(0-0	4)
PALATE	: Cleft	L 1	0-1	(0-4	2)
		F 1	0-1	(0-0	3)
TONGUE	: Protruded	L 2	0-1	(0-5	6)
		F 2	0-1	(0-0	4)
	: Absent	L 1	0-1	(0-4	2)
		F 1	0-1	(0-0	3)
NOSE	: Nares, fused	L 2	0-1	(0-4	5)
		F 2	0-1	(0-0	4)

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FETAL EXTERNAL ABNORMALITIES
Cr:CD(SD) RATS
GESTATION DAY 21 CAESAREAN-SECTION
FULL STUDIES

	ABNORMALITIES		RANGE/STUDY		
			N	N	%
MOUTH	: Small oral opening	L	2	0-1	(0-5 0)
		F	2	0-1	(0-0 4)
	: Absent	L	2	0-1	(0-4 5)
		F	2	0-1	(0-0 4)
JAW	: Micrognathia	L	2	0-1	(0-4 2)
		F	2	0-1	(0-0 3)
	: Agnathia	L	1	0-1	(0-4 2)
		F	1	0-1	(0-0 3)
	: Mandible, absent	L	2	0-1	(0-4 5)
		F	2	0-1	(0-0 4)
BODY	: Umbilical hernia	L	2	0-1	(0-4 5)
		F	2	0-1	(0-0 4)
	: Edema	L	2	0-1	(0-5 0)
		F	2	0-1	(0-0 4)
	: Trunk short	L	4	0-1	(0-5 6)
		F	4	0-1	(0-0 4)
	: Gastroschisis	L	1	0-1	(0-4 8)
		F	1	0-1	(0-0 4)
	: Craniorachischisis	L	2	0-1	(0-5 6)
		F	2	0-1	(0-0 4)
	: Spina bifida	L	1	0-1	(0-5 0)
		F	1	0-1	(0-0 3)
	: Trunk, thoracogastroschisis	L	1	0-1	(0-5 0)
		F	1	0-1	(0-0 4)
FORE AND/OR HINDLIMBS(S)	: Digit(s), extra	L	1	0-1	(0-4 0)
		F	1	0-1	(0-0 3)
	: Paw(s), flexed	L	3	0-1	(0-5 0)
		F	3	0-1	(0-0 4)
	: Limb(s), rotated	L	2	0-1	(0-4 5)
		F	2	0-1	(0-0 3)
	: Limb(s), flexed	L	1	0-1	(0-4 2)
		F	1	0-1	(0-0 3)
	: Malrotated	L	1	0-1	(0-5 0)
		F	1	0-1	(0-0 4)
ANUS	: No opening present	L	2	0-1	(0-5 0)
		F	2	0-1	(0-0 4)
TAIL	: Short	L	1	0-1	(0-4 2)
		F	1	0-1	(0-0 3)
	: Absent	L	1	0-1	(0-4 8)
		F	1	0-1	(0-0 3)
	: Misshapen	L	1	0-1	(0-5 0)
		F	1	0-1	(0-0 4)

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Updated 02 March 2019

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FETAL SOFT TISSUE ABNORMALITIES
CrI:CD(SD) RATS
GESTATION DAY 21 CAESAREAN-SECTION
DOSE RANGE FINDING STUDIES

NO. OF STUDIES INCLUDED	6				
NO. LITTERS EXAMINED	44				
NO. FETUSES EXAMINED	403				
		ABNORMALITIES		RANGE/STUDY	
			N	N	%
BRAIN	: Lateral ventricles, dilation, moderate	L	1	0-1	(0-10.0)
		F	1	0-1	(0-1.4)
EYE(S)	: Retina(s) folded	L	2	0-1	(0-16.7)
		F	3	0-2	(0-2.7)
	: Microphthalmia	L	2	0-1	(0-16.7)
		F	2	0-1	(0-1.4)
GENERAL	: Total, situs inversus	L	2	0-1	(0-16.7)
		F	2	0-1	(0-2.8)
TONGUE	: Small	L	1	0-1	(0-16.7)
		F	1	0-1	(0-1.4)
VESSELS	: Innominate artery, absent	L	1	0-1	(0-10.0)
		F	1	0-1	(0-1.3)
KIDNEY(S)	: Small	L	1	0-1	(0-16.7)
		F	4	0-4	(0-5.3)
	: Absent	L	1	0-1	(0-16.7)
		F	1	0-1	(0-1.3)
	: Malpositioned	L	1	0-1	(0-16.7)
		F	1	0-1	(0-1.3)

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Updated 03 March 2019

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FETAL SOFT TISSUE ABNORMALITIES
CrI:CD(SD) RATS
GESTATION DAY 21 CAESAREAN-SECTION
FULL STUDIES

NO. OF STUDIES INCLUDED	31
NO. LITTERS EXAMINED	693
NO. FETUSES EXAMINED	4864
NO. HEADS ONLY EXAMINED	149
NO. BODIES ONLY EXAMINED	162

ABNORMALITIES		RANGE/STUDY		
		N	N	%
BRAIN				
	: Lateral ventricles, dilation, slight	L 3	0-1	(0-5.3)
		F 3	0-1	(0-0.8)
	: Lateral ventricles, dilation, moderate	L 3	0-1	(0-4.5)
EYE(S)		F 3	0-1	(0-0.6)
	: Retina(s) folded	L 6	0-1	(0-5.3)
		F 6	0-1	(0-0.8)
	: Malpositioned	L 1	0-1	(0-4.2)
		F 1	0-1	(0-0.6)
	: Cup irregular	L 1	0-1	(0-4.2)
		F 1	0-1	(0-0.6)
	: Microphthalmia	L 8	0-3	(0-12.5)
		F 8	0-3	(0-1.9)
	: Absent	L 1	0-1	(0-4.8)
		F 1	0-1	(0-0.8)
TONGUE				
	: Small	L 1	0-1	(0-4.2)
		F 1	0-1	(0-0.6)
	: Absent	L 1	0-1	(0-4.2)
		F 1	0-1	(0-0.6)
PALATE				
	: Irregularly shaped	L 1	0-1	(0-4.2)
		F 1	0-1	(0-0.6)
NASOPHARYNX				
	: Misshapen	L 1	0-1	(0-4.2)
		F 1	0-1	(0-0.6)

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FETAL SOFT TISSUE ABNORMALITIES
CrI:CD(SD) RATS
GESTATION DAY 21 CAESAREAN-SECTION
FULL STUDIES

	ABNORMALITIES		RANGE/STUDY		
			N	N	%
HEART	: Interventricular septal defect	L	4	0-1	(0-4.8)
		F	4	0-1	(0-0.7)
	: Bicuspid valve, misshapen	L	1	0-1	(0-4.8)
		F	1	0-1	(0-0.7)
	: Lobe, misshapened	L	3	0-3	(0-14.3)
		F	3	0-3	(0-2.4)
VESSELS	: Innominate artery, absent	L	6	0-1	(0-5.0)
		F	6	0-1	(0-0.7)
	: Aorta passes dorsal to the trachea and esophagus	L	2	0-1	(0-5.0)
		F	2	0-1	(0-0.6)
	: Aortic arch, absent	L	1	0-1	(0-4.5)
		F	1	0-1	(0-0.8)
	: Aortic arch, interrupted	L	1	0-1	(0-4.8)
		F	1	0-1	(0-0.8)
	: Caroid artery, malpositioned	L	1	0-1	(0-4.5)
		F	1	0-1	(0-0.8)
	: Ductus arteriosus, patent	L	1	0-1	(0-5.0)
		F	3	0-3	(0-2.1)

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FETAL SOFT TISSUE ABNORMALITIES
CrI:CD(SD) RATS
GESTATION DAY 21 CAESAREAN-SECTION
FULL STUDIES

VESSELS (CONT'D)	ABNORMALITIES		N	RANGE/STUDY	
				N	%
VESSELS (CONT'D)	: Subclavian artery, malpositioned	L	1	0-1	(0-4.5)
		F	1	0-1	(0-0.8)
	: Vessels arise in incorrect order	L	1	0-1	(0-4.0)
		F	1	0-1	(0-0.6)
	: Right subclavian passes dorsal to trachea and esophagus	L	1	0-1	(0-4.3)
		F	1	0-1	(0-0.6)
	: Right subclavian arises to the left of left subclavian	L	1	0-1	(0-4.3)
		F	1	0-1	(0-0.6)
	: Pulmonary artery constricted	L	1	0-1	(0-4.3)
		F	1	0-1	(0-0.6)
	: Transposed	L	2	0-1	(0-4.0)
		F	2	0-1	(0-0.7)
	: Major vessels, malpositioned	L	1	0-1	(0-5.0)
		F	1	0-1	(0-0.6)
INTESTINES	: Portion protrudes through umbilicus	L	1	0-1	(0-4.0)
		F	1	0-1	(0-0.6)
KIDNEYS	: Small	L	1	0-1	(0-4.5)
		F	1	0-1	(0-0.8)
URETER	: Dilated, slight	L	1	0-1	(0-5.0)
		F	1	0-1	(0-0.6)

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FETAL SKELETAL ABNORMALITIES
CrI:CD(SD) RATS
GESTATION DAY 21 CAESAREAN-SECTION
DOSE RANGE FINDING STUDIES

NO. OF STUDIES INCLUDED		6	
NO. LITTERS EXAMINED		52	
NO. FETUSES EXAMINED		357	
		RANGE STUDY	
		N	N %
ABNORMALITIES			
SKULL	Zygomatic	: Arch, incomplete ossification	L 4 0-1 (0-16.7)
			F 4 0-1 (0-3.3)
	Squamosal	: Incomplete ossification	L 1 0-1 (0-10.0)
			F 1 0-1 (0-1.6)
	Skull	: Suture, large	L 1 0-1 (0-10.0)
			F 1 0-1 (0-1.6)
VERTEBRAE	Cervical	: Cervical rib(s) present	L 3 0-2 (0-20.0)
			F 4 0-2 (0-3.0)
		: Cervical arch, misshapen	L 1 0-1 (0-16.7)
			F 1 0-1 (0-2.8)
		: Supernumerary, short	L 1 0-1 (0-16.7)
			F 1 0-1 (0-2.6)
	Thoracic	: Centrum, bifid	L 4 0-2 (0-20.0)
			F 5 0-3 (0-4.8)
		: Centrum, bipartite ossification	L 1 0-1 (0-16.7)
			F 2 0-2 (0-6.7)
	Lumbar	: Centrum, small	L 1 0-1 (0-10.0)
			F 1 0-1 (0-1.2)
		: Arches and centrum, fused	L 1 0-1 (0-10.0)
			F 1 0-1 (0-1.2)
		: 1 present	L 1 0-1 (0-10.0)
			F 1 0-1 (0-1.2)
	Sacral	: 0 present	L 1 0-1 (0-10.0)
			F 1 0-1 (0-1.2)
	Caudal	: Space	L 1 0-1 (0-10.0)
			F 1 0-1 (0-1.2)
		: Small	L 1 0-1 (0-10.0)
			F 1 0-1 (0-1.2)

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FETAL SKELETAL ABNORMALITIES
Cr:CD(SD) RATS
GESTATION DAY 21 CAESAREAN-SECTION
DOSE RANGE FINDING STUDIES

		RANGESTUDY			
		N	N	%	
ABNORMALITIES					
RIBS					
	: Incomplete ossification	L	1	0-1	(0-10.0)
		F	1	0-1	(0-1.6)
STERNEBRAE					
	: One or more incompletely ossified or not ossified	L	1	0-1	(0-10.0)
		F	1	0-1	(0-1.5)
	: Asymmetric	L	1	0-1	(0-10.0)
		F	1	0-1	(0-1.5)
	: Misshapen	L	1	0-1	(0-16.7)
		F	1	0-1	(0-2.6)
PELVIS	Ilium				
	: Close set	L	1	0-1	(0-10.0)
		F	1	0-1	(0-1.2)
	Pubis				
	: Incomplete ossification	L	1	0-1	(0-10.0)
		F	1	0-1	(0-1.6)

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FETAL SKELETAL ABNORMALITIES
Cd:CD(SD) RATS
GESTATION DAY 21 CAESAREAN-SECTION
FULL STUDIES

NO OF STUDIES INCLUDED 76
NO LITTERS EXAMINED 1680
NO FETUSES EXAMINED 11630

SKULL	ABNORMALITIES	RANGE/STUDY		
		N	N	%
SKULL	Frontals			
	: Contain an interfrontal	L 4	0-1	(0-5 0)
		F 4	0-1	(0-0 8)
	: Incompletely ossified	L 20	0-2	(0-10 5)
		F 24	0-5	(0-3 3)
	: Misshapen	L 1	0-1	(0-5 0)
		F 1	0-1	(0-0 7)
	Nasal			
	: Short	L 1	0-1	(0-4 2)
		F 1	0-1	(0-0 6)
	: Misshapen	L 3	0-1	(0-5 0)
		F 3	0-1	(0-0 8)
	Nasal-Frontal			
	: Suture, large	L 5	0-1	(0-5 9)
		F 5	0-1	(0-0 9)
	Parietal			
	: Incompletely ossified	L 49	0-6	(0-30 0)
		F 63	0-8	(0-6 3)
	: Hole	L 2	0-1	(0-5 3)
		F 2	0-1	(0-0 7)
	: Misshapen	L 1	0-1	(0-5 0)
		F 1	0-1	(0-0 7)
	Interparietals			
	: Unossified	L 2	0-1	(0-5 0)
		F 2	0-1	(0-0 7)
	: Incompletely ossified	L 14	0-6	(0-28 6)
		F 17	0-6	(0-4 5)
	: Absent	L 2	0-1	(0-5 0)
		F 2	0-1	(0-0 8)
	Eye Socket			
	: Small	L 4	0-1	(0-4 8)
		F 4	0-1	(0-0 6)
	Palate			
	: Incompletely ossified	L 2	0-1	(0-4 2)
		F 2	0-1	(0-0 6)
	: Irregularly shaped	L 2	0-1	(0-5 0)
		F 2	0-1	(0-0 7)
	: Absent	L 2	0-1	(0-4 5)
		F 2	0-1	(0-0 7)
	Premaxilla			
	: Short	L 1	0-1	(0-4 2)
		F 1	0-1	(0-0 6)
	: Misshapen	L 2	0-1	(0-5 0)
		F 2	0-1	(0-0 7)

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SKULL (CONT)	ABNORMALITIES	RANGE/STUDY		
		N	N	%
SKULL (CONT)	Maxilla			
	: Short	L 1	0-1	(0-4 2)
		F 1	0-1	(0-0 6)
	: Split	L 1	0-1	(0-4 2)
		F 1	0-1	(0-0 5)
	: Incompletely ossified	L 1	0-1	(0-4 8)
		F 2	0-2	(0-1 3)
	: Misshapen	L 3	0-1	(0-5 0)
		F 3	0-1	(0-0 8)
	Mandible			
	: Short	L 1	0-1	(0-4 2)
		F 1	0-1	(0-0 6)
	: Misshapen	L 1	0-1	(0-5 0)
		F 1	0-1	(0-0 7)
	: Absent	L 2	0-1	(0-4 5)
		F 2	0-1	(0-0 8)
	Squamosal			
	: Misshapen	L 4	0-1	(0-5 0)
		F 4	0-1	(0-0 8)
	: Incompletely ossified	L 91	0-7	(0-35 0)
		F 124	0-10	(0-8 3)
	Supraoccipital			
	: Incompletely ossified	L 4	0-1	(0-4 8)
		F 5	0-2	(0-1 3)
	: Hole	L 1	0-1	(0-5 3)
		F 1	0-1	(0-0 7)
	: Absent	L 1	0-1	(0-5 0)
		F 1	0-1	(0-0 7)
	Suture			
	: Large	L 2	0-1	(0-5 6)
		F 2	0-1	(0-0 8)
	Zygomatic Arch			
	: Incompletely ossified	L 131	0-11	(0-55 0)
		F 201	0-21	(0-19 0)
	: Fused	L 2	0-2	(0-9 5)
		F 2	0-2	(0-1 8)
	: Misshapen	L 4	0-1	(0-5 0)
		F 4	0-1	(0-0 8)
	Tympanic Rings			
	: Incompletely ossified	L 4	0-3	(0-13 6)
		F 5	0-4	(0-1 4)
	: Close set	L 1	0-1	(0-4 2)
		F 1	0-1	(0-0 5)
	: Absent	L 1	0-1	(0-5 0)
		F 1	0-1	(0-0 7)
	: Fused	L 2	0-1	(0-4 5)
		F 2	0-1	(0-0 8)
	Exoccipital			
	: Fused	L 1	0-1	(0-4 5)
		F 1	0-1	(0-0 7)
	: Absent	L 2	0-1	(0-5 0)
		F 2	0-1	(0-0 7)

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SKULL (CONT)	ABNORMALITIES	RANGE/STUDY		
		N	N	%
Sphenoid	: Incompletely ossified	L	1	0-1 (0-4 2)
		F	1	0-1 (0-0 6)
Basisphenoid	: Irregularly shaped	L	4	0-1 (0-5 0)
		F	4	0-1 (0-0 8)
Basioccipital	: Irregularly shaped	L	2	0-1 (0-5 0)
		F	2	0-1 (0-0 7)
Skull	: Unossified	L	1	0-1 (0-4 2)
		F	1	0-1 (0-0 5)
	: Short	L	1	0-1 (0-4 2)
		F	1	0-1 (0-0 5)
Hyoid	: Unossified	L	4	0-2 (0-9 1)
		F	4	0-2 (0-1 6)
	: Body, incomplete ossification	L	6	0-4 (0-20 0)
		F	8	0-6 (0-3 9)
VERTEBRAE				
Canal	: Absent	L	1	0-1 (0-5 0)
		F	1	0-1 (0-0 8)
Cervical	: Arch, incompletely ossified	L	28	0-3 (0-14 3)
		F	33	0-4 (0-2 2)
	: Arch, reduced ventral process, 6th	L	29	0-3 (0-13 6)
		F	32	0-5 (0-3 0)
	: Arch, 7th cervical arch had the appearance of the 6th arch	L	6	0-2 (0-8 0)
		F	6	0-2 (0-1 1)
	: Arch, fused	L	3	0-1 (0-4 2)
		F	3	0-1 (0-0 6)
	: Arch, open	L	1	0-1 (0-4 2)
		F	1	0-1 (0-0 5)
	: Arch, irregularly shaped	L	24	0-3 (0-13 6)
		F	24	0-3 (0-2 2)
	: Lateral ossification site	L	9	0-6 (0-27 3)
		F	9	0-6 (0-3 7)
	: Cervical rib present at 7th vertebra	L	64	0-4 (0-18 2)
		F	73	0-5 (0-4 0)
	: Hemivertebra	L	1	0-1 (0-4 0)
		F	1	0-1 (0-0 7)
	: Arch, small	L	1	0-1 (0-4 0)
		F	1	0-1 (0-0 7)
	: Supernumerary, short	L	17	0-3 (0-15 0)
		F	19	0-4 (0-3 2)
	: Supernumerary, full	L	1	0-1 (0-5 0)
		F	1	0-1 (0-0 8)

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VERTEBRAE (CONT)	ABNORMALITIES	RANGE/STUDY		
		N	N	%
Thoracic	: Centrum, bifid	L 166	0-8	(0-34 8)
		F 186	0-10	(0-5 7)
	: Centrum, unilateral ossification	L 5	0-1	(0-5 0)
		F 5	0-1	(0-0 8)
	: Centrum, not ossified	L 2	0-1	(0-5 0)
		F 2	0-1	(0-0 6)
	: Arch, fused	L 4	0-1	(0-4 8)
		F 4	0-1	(0-0 8)
	: Arch, open	L 1	0-1	(0-4 2)
		F 1	0-1	(0-0 5)
	: Arch, misshapen	L 1	0-1	(0-4 8)
		F 1	0-1	(0-0 8)
	: Centrum, misshapen	L 1	0-1	(0-4 5)
		F 1	0-1	(0-0 7)
	: 7 present	L 1	0-1	(0-4 2)
		F 1	0-1	(0-0 6)
	: 11 present	L 1	0-1	(0-4 0)
		F 1	0-1	(0-0 6)
	: Arch, small	L 1	0-1	(0-4 0)
		F 1	0-1	(0-0 6)
Lumbar	: Centrum, bifid	L 11	0-4	(0-18 2)
		F 11	0-4	(0-2 8)
	: Centrum, unilateral ossification	L 1	0-1	(0-4 2)
		F 1	0-1	(0-0 6)
	: Centrum, not ossified	L 1	0-1	(0-5 0)
		F 1	0-1	(0-0 8)
	: Centrum, irregularly shaped	L 1	0-1	(0-5 0)
		F 1	0-1	(0-0 8)
	: Centra, fused	L 1	0-1	(0-4 2)
		F 1	0-1	(0-0 6)
	: Arch, fused	L 1	0-1	(0-5 0)
		F 1	0-1	(0-0 8)
	: Arch, open	L 2	0-1	(0-5 0)
		F 2	0-1	(0-0 7)
	: Arch, irregularly shaped	L 1	0-1	(0-5 0)
		F 1	0-1	(0-0 8)
	: 10 present	L 1	0-1	(0-4 2)
		F 1	0-1	(0-0 6)
	: 5 present	L 1	0-1	(0-5 0)
		F 1	0-1	(0-0 8)
	: Supernumerary	L 1	0-1	(0-4 8)
		F 1	0-1	(0-0 7)
	: Arch, incompletely ossified	L 1	0-1	(0-5 0)
		F 1	0-1	(0-0 7)
Sacral	: Arch, open	L 2	0-1	(0-5 0)
		F 2	0-1	(0-0 7)
	: Arch, incompletely ossified	L 4	0-2	(0-10 0)
		F 4	0-2	(0-1 6)
	: 0 present	L 1	0-1	(0-5 0)
		F 1	0-1	(0-0 8)

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VERTEBRAE (CONT)	ABNORMALITIES	RANGE/STUDY		
		N	N	%
Caudal	: 4 present	L 1	0-1	(0-4 2)
		F 1	0-1	(0-0 6)
	: Arch, open	L 3	0-1	(0-5 0)
		F 3	0-1	(0-0 8)
	: Less than 26 pre-sacral vertebrae	L 1	0-1	(0-4 5)
		F 1	0-1	(0-0 8)
RIBS				
	: Wavy	L 37	0-3	(0-12 5)
		F 40	0-4	(0-2 4)
	: One or more incompletely ossified	L 44	0-3	(0-12 0)
	(hypoplastic) or not ossified	F 47	0-4	(0-2 4)
	: Fused	L 4	0-1	(0-4 5)
		F 4	0-1	(0-0 8)
	: Short	L 42	0-3	(0-12 5)
		F 45	0-3	(0-2 3)
	: Thickened	L 25	0-3	(0-12 5)
		F 29	0-4	(0-2 4)
	: 6 present	L 1	0-1	(0-4 2)
		F 1	0-1	(0-0 6)
	: 7 present	L 1	0-1	(0-4 2)
		F 1	0-1	(0-0 6)
	: Bent	L 1	0-1	(0-4 5)
		F 1	0-1	(0-0 6)
	: Broad	L 1	0-1	(0-4 5)
		F 1	0-1	(0-0 6)
	: Absent	L 2	0-1	(0-4 2)
		F 2	0-1	(0-0 5)
	: Nodulated	L 12	0-4	(0-20 0)
		F 14	0-5	(0-4 2)
	: Split	L 1	0-1	(0-4 0)
		F 1	0-1	(0-0 6)
	: 11 present	L 1	0-1	(0-4 0)
		F 1	0-1	(0-0 6)
	: T14, short	L 28	0-7	(0-31 8)
		F 49	0-15	(0-12 1)
	: T14, full	L 2	0-2	(0-9 5)
		F 2	0-2	(0-1 3)
	: Thoracolumbar, full	L 3	0-3	(0-14 3)
		F 3	0-3	(0-2 3)
	: Thoracolumbar, short	L 19	0-19	(0-90 5)
		F 66	0-66	(0-49 9)

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STERNUM	ABNORMALITIES	RANGE/STUDY		
		N	N	%
STERNUM	Sternbrae			
	: One or more incompletely ossified or not ossified	L 24	0-2	(0-9 1)
		F 26	0-3	(0-2 4)
	: Asymmetric	L 13	0-2	(0-8 3)
		F 13	0-2	(0-1 1)
	: Irregularly shaped	L 9	0-2	(0-10 0)
		F 11	0-4	(0-3 7)
	: Fused	L 5	0-2	(0-10 2)
		F 5	0-2	(0-2 0)
	: Duplicated	L 9	0-1	(0-5 0)
		F 11	0-1	(0-0 7)
	: Bipartite ossification	L 5	0-1	(0-5 0)
		F 5	0-1	(0-0 8)
	: Split	L 1	0-1	(0-5 0)
		F 1	0-1	(0-0 7)
	Centra			
	: Not ossified	L 3	0-1	(0-5 3)
		F 3	0-1	(0-0 7)
	: Incompletely ossified	L 1	0-1	(0-5 3)
		F 1	0-1	(0-0 7)
	: Asymmetric	L 2	0-1	(0-5 3)
		F 3	0-2	(0-1 4)
	: 7 present	L 1	0-1	(0-4 8)
		F 1	0-1	(0-0 7)
	: Irregularly shaped	L 1	0-1	(0-4 8)
		F 1	0-1	(0-0 7)
	: Bifid	L 1	0-1	(0-5 0)
		F 1	0-1	(0-0 6)
	Manubrium			
	: Fused	L 2	0-1	(0-4 2)
		F 2	0-1	(0-0 6)
	: Irregularly shaped	L 4	0-1	(0-4 0)
		F 4	0-1	(0-0 5)
	: Duplicated	L 2	0-1	(0-5 3)
		F 2	0-1	(0-0 7)
	: Incompletely ossified	L 1	0-1	(0-4 8)
		F 1	0-1	(0-0 7)
	Xiphoid			
	: Irregularly shaped	L 1	0-1	(0-4 5)
		F 1	0-1	(0-0 7)
	: Incompletely ossified	L 2	0-1	(0-4 8)
		F 2	0-1	(0-0 7)
SCAPULAE				
	Body and Ala			
	: Bent	L 1	0-1	(0-4 2)
		F 1	0-1	(0-0 6)

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	ABNORMALITIES	RANGE/STUDY		
		N	N	%
PELVIS	Pubis			
	: Incompletely ossified	L 17	0-2	(0-9 5)
		F 20	0-2	(0-2 6)
	Ishchium			
	: Incompletely ossified	L 12	0-2	(0-8 0)
		F 12	0-2	(0-1 1)
Pelvis	: Close-set	L 1	0-1	(0-5 0)
		F 1	0-1	(0-0 8)
	Ilium			
	: Malpositioned	L 1	0-1	(0-5 0)
		F 1	0-1	(0-0 7)
FORELIMB(S)	Phalanx			
		: Absent	L 1	0-1 (0-4 5)
			F 1	0-1 (0-0 6)
		: Less than the expected number ossified	L 13	0-9 (0-42 8)
			F 24	0-20 (0-13 9)
	: Unossified	L 63	0-17	(0-81 0)
		F 204	0-71	(0-47 0)
	Digit	: Absent	L 1	0-1 (0-4 5)
			F 1	0-1 (0-0 6)
		: Short	L 1	0-1 (0-4 5)
			F 1	0-1 (0-0 6)
	Metacarpal	: Fused	L 1	0-1 (0-4 2)
			F 1	0-1 (0-0 6)
		: Less than the expected number ossified	L 2	0-2 (0-9 1)
			F 2	0-2 (0-1 2)
		: Misaligned	L 1	0-1 (0-4 5)
			F 1	0-1 (0-0 6)
HINDLIMB(S)	Digit	: Extra	L 2	0-1 (0-4 2)
			F 2	0-1 (0-0 6)
	Phalanx	: Extra	L 2	0-1 (0-4 2)
			F 2	0-1 (0-0 6)
		: Less than the expected number ossified	L 37	0-20 (0-95 2)
			F 167	0-101 (0-70 1)
	Metatarsal	: Unossified	L 12	0-5 (0-22 7)
			F 16	0-7 (0-5 5)

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