

Historical Control Data in Minipig

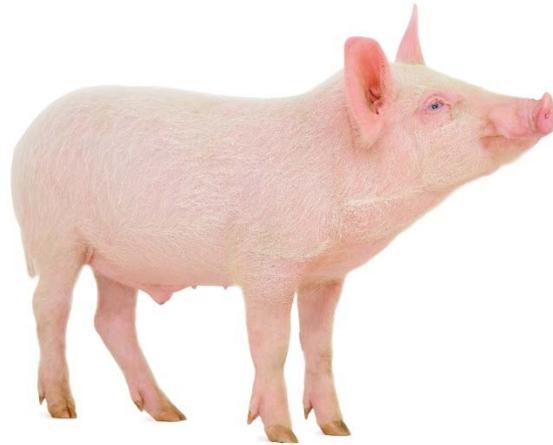


TABLE OF CONTENTS

<u>HCD</u> ¹	<u>Study Range</u>	<u>Page</u>
MINIPIG – Göttingen	2004-2018	3

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¹ Additional HCD endpoints and years are available upon request.

HISTORICAL CONTROL DATA

Print Date: 10/02/2019 21:17

Göttingen Minipig**Maternal body weight gain (kg) during gestation**

Study	Year	Dams with live fetuses	Gestation days															
			0 to 7		7 to 11		11 to 15		15 to 18		18 to 22		22 to 25		25 to 29		29 to 32	
			Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD
A12-1	2012	2	0.5	1.3	0.4	0.1	0.5	0.2	0.5	0.2	0.7	0.0	0.5	0.0	0.8	0.1	0.2	0.5
A12-2	2012	2	1.2	0.1	0.6	0.1	0.8	0.0	0.3	0.0	0.5	0.2	0.9	0.0	0.8	0.1	0.4	0.1
A11	2011	5			1.5	0.7	0.8	0.5	0.3	0.4	0.3	0.3	0.3	0.5	1.0	0.6	0.2	0.4
A10	2010	16	-0.1	0.8	0.9	0.5	0.6	0.3	0.2	0.4	0.6	0.5	0.6	0.5	0.8	0.7	0.2	0.6
A9	2009	4	0.0	0.4	0.7	0.6	0.5	1.3	0.0	0.7	0.9	0.9	0.5	0.6	0.9	0.4	0.0	0.8
A8	2008	13	1.0	0.4	0.4	0.4	0.5	0.5	0.5	0.5	0.4	0.4	0.9	0.4	0.5	0.5	0.2	0.4
A7	2007	6	0.6	0.2	0.5	0.1	0.1	0.3	0.2	0.2	0.4	0.1	1.4	0.2	0.8	0.1	0.3	0.3
A4	2004	18	0.7	0.5	0.4	0.5	0.1	0.8	0.5	0.7	0.4	0.4	0.4	0.3	0.6	0.4	0.2	0.4
A3	2003	5	1.1	0.4	-0.4	0.6	0.4	0.6	0.1	0.3	0.0	0.4	0.6	0.3	0.4	0.6	0.5	0.7
B3	2003	6	0.1	0.4	0.8	1.1	0.0	0.8	0.2	0.2	0.6	0.4	0.0	0.5	1.0	0.7	0.2	0.8
<i>Total</i>		<i>77</i>																
<i>Mean</i>			<i>0.5</i>		<i>0.6</i>		<i>0.4</i>		<i>0.3</i>		<i>0.5</i>		<i>0.6</i>		<i>0.7</i>		<i>0.2</i>	
<i>SD</i>				<i>0.7</i>		<i>0.7</i>		<i>0.6</i>		<i>0.5</i>		<i>0.4</i>		<i>0.5</i>		<i>0.5</i>		<i>0.5</i>

Study no. A3 was recorded on days 14, 21, 28, 35, 39, 46, 53, 60, 67, 74, 81, 88, 95, 102 and 109.

Study no. A8 was recorded on day 8 instead of day 7.

File name: I.7.1-MINIPIG_G110_G60_2018_OK.xls

HISTORICAL CONTROL DATA

Print Date: 10/02/2019 21:17

Göttingen Minipig**Maternal body weight gain (kg) during gestation**

Study	Year	Dams with live fetuses	Gestation days															
			32 to 36		36 to 39		39 to 45		45 to 52		52 to 59		59 to 66		66 to 73		73 to 80	
			Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD
A12-1	2012	2	0.0	0.1	0.7	0.2	1.0	0.5	1.5	0.5	0.1	0.8						
A12-2	2012	2	0.3	0.5	0.1	0.9	1.1	0.5	1.6	0.1	0.3	0.0	0.8	0.4	0.9	0.2	1.2	0.3
A11	2011	5	0.7	0.4	-0.3	0.6	0.7	0.2	1.1	0.2	1.3	0.3	0.6	0.3	0.1	0.5	1.0	0.3
A10	2010	16	0.4	0.4	0.3	0.5	1.0	0.8	1.1	0.6	0.9	0.5	0.9	0.3	0.8	0.4	0.7	0.4
A9	2009	4	-0.2	0.9	0.6	0.3												
A8	2008	13	0.3	0.4	0.4	0.5	0.5	0.6	1.0	0.5	1.1	0.5	0.8	0.4	0.6	0.6	0.8	0.4
A7	2007	6	0.4	0.3	0.6	0.3	1.3	0.4	0.9	0.6								
A4	2004	18	0.0	0.3	0.5	0.4	0.4	0.4	0.8	0.3	0.9	0.3	0.7	0.3	0.6	0.5	0.6	0.3
A3	2003	5	0.0	0.3	0.2	0.3	1.0	0.3	1.0	0.3	1.0	0.4	1.4	0.5	0.6	1.9	0.9	1.5
B3	2003	6	-0.1	0.4	0.5	0.9	0.2	1.2	1.5	1.5								
<i>Total Mean</i>		<i>77</i>	<i>0.2</i>		<i>0.4</i>		<i>0.7</i>		<i>1.0</i>		<i>0.9</i>		<i>1.0</i>		<i>0.7</i>		<i>0.9</i>	
<i>SD</i>				<i>0.4</i>		<i>0.5</i>		<i>0.7</i>		<i>0.7</i>		<i>0.5</i>		<i>0.1</i>		<i>0.7</i>		<i>0.5</i>

Study no. A3 was recorded on days 14, 21, 28, 35, 39, 46, 53, 60, 67, 74, 81, 88, 95, 102 and 109.

Study no. A7 was recorded on days 42, 49 and 54.

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HISTORICAL CONTROL DATA

Print Date: 10/02/2019 21:17

Göttingen Minipig**Maternal body weight gain (kg) during gestation**

Study	Year	Dams with live fetuses	Gestation days								Gestation periods							
			80 to 87		87 to 94		94 to 101		101 to 108		0 to 11		11 to 36		36 to 52		36 to 108	
			Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD
A12-1	2012	2									0.9	1.2	2.9	1.1	3.2	0.8		
A12-2	2012	2	1.5	0.1	1.9	0.2	1.6	0.0	1.8	0.0	1.8	0.3	3.9	0.8	2.8	0.4	12.8	0.1
A11	2011	5	1.8	0.5	1.2	0.3	1.6	0.4	1.3	0.2			3.5	0.5				
A10	2010	8	1.8	0.8	1.3	0.9							3.4	0.8				
A9	2009	4											2.6	0.8				
A8	2008	13	1.5	0.9	2.0	0.9	1.4	0.4	1.4	0.8	1.4	0.5	3.3	0.8	1.9	0.7	11.5	1.7
A7	2007	6											3.5	0.4	2.8	0.6		
A4	2004	18	0.9	0.6	2.0	0.5	1.4	0.3	1.1	0.7	1.1	0.6	2.3	0.7			9.8	1.0
A3	2003	5	0.7	1.5	2.3	0.9	1.8	1.3	0.4	1.2	0.9	0.4	2.1	0.6			9.1	2.3
B3	2003	6											2.0	1.0	1.8	0.4		
<i>Total Mean</i>		<i>69</i>	<i>1.0</i>		<i>1.7</i>		<i>1.5</i>		<i>1.2</i>		<i>1.1</i>		<i>2.9</i>		<i>1.8</i>		<i>9.8</i>	
<i>SD</i>			<i>0.9</i>		<i>0.9</i>		<i>0.5</i>		<i>0.8</i>		<i>0.6</i>		<i>0.9</i>		<i>1.0</i>		<i>2.9</i>	

Study no. A3 was recorded on days 14, 21, 28, 35, 39, 46, 53, 60, 67, 74, 81, 88, 95, 102 and 109.

File name: I.7.1-MINIPIG_G110_G60_2018_OK.xls

HISTORICAL CONTROL DATA

Print Date: 10/02/2019 21:17

Göttingen Minipig**Caesarean data collected on or close to day 60 or 110 of gestation**

Study	Year	Number of females			Number of uterine implants		Early resorptions per dam		Late resorptions per dam		Post-implantation loss %		Live litter size		Dead fetuses
		Mated	Pregnant	With live fetuses	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Total
		A12-1	2012	3	2	2	8.5	0.7	2.0	0.0	1.5	0.7	41.0	4.9	5.0
A12-1	2012	2	2	2	6.0	0.0	1.5	0.7	0.5	0.7	33.3	23.6	4.0	1.4	0
A11-1	2011	2	1	1	5.0	0.0	2.0	0.0	0.0	0.0	40.0	0.0	3.0	0.0	0
A11-2	2011	4	4	4	4.3	1.5	0.0	0.0	0.0	0.0	0.0	0.0	4.3	1.5	0
A10	2010	9	8	8	7.0	1.3	*	*	*	*	*	*	6.5	1.1	0
B10	2010	9	8	8	6.8	0.9	1.0	0.8	0.4	0.7	20.9	14.4	5.4	1.3	0
A9	2009	4	4	4	7.0	0.8	*	*	*	*	*	*	6.0	0.8	0
A8	2008	18	13	13	13.3	4.2	2.5	1.9	5.3	2.4	60.2	9.6	5.5	2.5	0
A7	2007	6	6	6	13.8	1.0	0.5	0.8	7.7	1.0	59.4	7.4	5.7	1.4	0
A4	2004	18	18	18	10.8	2.2	1.4	1.6	4.2	1.8	51.5	10.9	5.2	1.4	0
A3	2003	5	5	5	12.4	4.3	0.4	0.5	7.0	3.3	56.8	10.6	5.2	1.7	0
B3	2003	6	6	6	13.7	2.5	2.2	1.3	6.5	2.1	63.9	5.3	4.8	1.3	0
<i>Total</i>		86	77 90%	77 90%											0
<i>Mean</i>					10.2		1.4		4.2		47.5		5.3		
<i>SD</i>						3.9		1.5		3.1		20.4		1.6	

* Excluded, not submitted to luteinizing hormone.

File name: I.7.1-MINIPIG_G110_G60_2018_OK.xls

HISTORICAL CONTROL DATA

Print Date: 10/02/2019 21:17

Göttingen Minipig**Caesarean data collected on or close to day 60 or 110 of gestation**

Study	Year	Number of females			Fetal weight (g) on or close to day 60		Fetal weight (g) on or close to day 110		Gravid uterus weight (g) on or close to day 60		Gravid uterus weight (g) on or close to day 110		Sex ratio % males
		Mated	Pregnant	With live fetuses	Mean	SD	Mean	SD	Mean	SD	Mean	SD	
		A12-1	2012	3	2	2	46.2	9.0			2342	201	
A12-1	2012	2	2	2			346.8	7.7			3243	965	40.0
A11-1	2011	2	1	1	61.0	0.0			1680	0.0			33.3
A11-2	2011	4	4	4			387.1	43.5			3166	1201	65.0
A10	2010	9	8	8	52.9	3.7			2560	1138			53.0
B10	2010	9	8	8			329.2	62.3			3392	1091	46.5
A9	2009	4	4	4	34.0	3.3			2084	719			
A8	2008	18	13	13			349.0	59.8			3962	1543	49.2
A7	2007	6	6	6	36.5	4.1			1667	458			16.7
A4	2004	18	18	18			340.3	75.2					49.0
A3	2003	5	5	5			327.0	53.9					50.0
B3	2003	6	6	6	31.0	5.2							48.3
<i>Total</i>		86	77 90%	77 90%									
<i>Mean</i>					41.4		343.5		2152		3622		47.0
<i>SD</i>					10.6		63.0		859		1319		

File name: I.7.1-MINIPIG_G110_G60_2018_OK.xls

HISTORICAL CONTROL DATA

Print Date: 10/02/2019 21:17

Göttingen Minipig**Malformations (external, internal & skeletal)**

Study	Year	Number of litters examined	Number of fetuses examined	Number of litters with malformed fetuses	Litter Incidence %	Number of malformed fetuses	Fetal Incidence %	Type of malformation by fetus
A12-1	2012	2	10	1	50.00	1	10.00	1: Open eye
A12-2	2012	2	8	0	-	0	-	
A11-1	2011	1	3	0	-	0	-	
A11-2	2011	4	17	1	25.00	1	5.88	1: Open eye
A10	2010	8	52	0	-	0	-	
B10	2010	8	43	0	-	0	-	
A9	2009	4	24	0	-	0	-	
A8	2008	13	72	0	-	0	-	
A7	2007	6	34	0	-	0	-	
A4	2004	18	93	3	16.67	3	3.23	1: Pulmonary trunk atresia 2: Gall bladder absent 3: Malformed lumbar vertebrae
A3	2003	5	26	2	40.00	3	11.54	1: Cleft Palate 2: Diaphragmatic hernia, rudimentary lung 3: Diaphragmatic hernia, malrotated and flexed limbs, spina bifida, anal atresia, rudimentary tail, malformed vertebrae (thoracic, lumbar, sacral and caudal)
B3	2003	6	29	0	-	0	-	
2003 to 2018		73	393	6	8.22%	7	1.78%	

File name: I.7.1-MINIPIG_G110_G60_2018_OK.xls

HISTORICAL CONTROL DATA

Print Date: 10/02/2019 21:17

Göttingen Minipig

FETAL EXAMINATION - EXTERNAL (G60)

PERIOD	2009-2018	
Number of studies included	4	
Number of fetuses examined	89	
OBSERVATION	N	%
Eye: open	1	1.1
Nipples: number<6	9	10.1
Nipples: number>6	47	52.8
Nipples: touching	3	3.4
Pentadactyly	3	3.4

File name: I.7.1-MINIPIG_G110_G60_2018_OK.xls

HISTORICAL CONTROL DATA

Print Date: 10/02/2019 21:17

Göttingen Minipig

FETAL EXAMINATION - FRESH VISCERAL EXAMINATION (G60)

PERIOD	2010 - 2018	
Number of studies included	3	
Number of fetuses examined	65	
OBSERVATION	N	%
Lung: azygos lobe absent	2	3.1

File name: I.7.1-MINIPIG_G110_G60_2018_OK.xls

HISTORICAL CONTROL DATA

Print Date: 10/02/2019 21:17

Göttingen Minipig

FETAL EXAMINATION - FIXED VISCERAL EXAMINATION OF HEAD (G60)

PERIOD	2010 - 2018	
Number of studies included	3	
Number of fetuses examined	36	
OBSERVATION	N	%
No abnormalities detected	-	-

File name: I.7.1-MINIPIG_G110_G60_2018_OK.xls

HISTORICAL CONTROL DATA

Print Date: 10/02/2019 21:17

Göttingen Minipig**FETAL EXAMINATION - SKELETAL (G60) - page 1/2**

PERIOD	2010 - 2018	
Number of studies included	3	
Number of fetuses examined	65	
OBSERVATION	N	%
Spinous process: incomplete ossification	1	1.5
Spinous process: unossified	9	13.8
Vertebrae, cervical: C7 spinous process unossified	47	72.3
Vertebrae, thoracic: malformed	1	1.5
Vertebrae, thoracic: spinous process unossified	52	80.0
Vertebrae, thoracic: number = 13	7	10.8
Vertebrae, lumbar: number = 6	30	46.2
Vertebrae, sacral: malformed	2	3.1
Vertebrae, caudal: damaged	3	4.6
Vertebrae, caudal: number = 12	2	3.1
Vertebrae, caudal: number = 13	1	1.5
Vertebrae, caudal: number = 14	1	1.5
Vertebrae, caudal: number = 15	3	4.6
Vertebrae, caudal: number < 21	55	84.6
Tarsals: only 1 tarsal ossified	62	95.4
Carpals: unossified	64	98.5
Phalanx: incomplete ossification, hindpaw	33	50.8
Phalanx: incomplete ossification, forepaw	23	35.4
Phalanx, forepaw: unossified (1st or 4th digit)	6	9.2
Phalanx, hindpaw: unossified (1st or 4th digit)	9	13.8
Paw: pentadactyly	1	1.5

File name: I.7.1-MINIPIG_G110_G60_2018_OK.xls

HISTORICAL CONTROL DATA

Print Date: 10/02/2019 21:17

Göttingen Minipig**FETAL EXAMINATION - SKELETAL (G60) - page 2/2**

PERIOD	2010 - 2018	
Number of studies included	2	
Number of fetuses examined	55	
OBSERVATION	N	%
Sternebrae: number = 0	2	3.1
Sternebrae: number = 1	1	1.5
Sternebrae: number = 2	12	18.5
Sternebrae: number = 3	28	43.1
Sternebrae: number = 4	11	16.9
Sternebrae: number > or = 2	3	4.6
Sternebrae: bipartite ossification	7	10.8
Ribs: number of full ribs = 13/13	7	10.8
Ribs: number of full ribs = 13/14	2	3.1
Rib: lumbar	1	1.5
Rib: 7th cervical fused to 1st thoracic	13	20.0
Rib: cervical	38	58.5
Rib: cervical interrupted	2	3.1
Rib: short	6	9.2
Rib: unossified area	1	1.5
Rib: detached	2	3.1
Pelvis: incomplete ossification of pubis (bilateral)	49	75.4
Pelvis: unossified pubis (bilateral)	20	30.8
Pelvis: incomplete ossification of pubis (unilateral)	1	1.5
Pelvis: unossified pubis (unilateral)	1	1.5

File name: I.7.1-MINIPIG_G110_G60_2018_OK.xls

HISTORICAL CONTROL DATA

Print Date: 10/02/2019 21:17

Göttingen Minipig

FETAL EXAMINATION - SKELETAL EXAMINATION OF HEAD (G60)

PERIOD	2010 - 2018	
Number of studies included	3	
Number of fetuses examined	39	
OBSERVATION	N	%
Cranium: increased ossification	1	2.6
Cranium: sutural bone	1	2.56
Temporal: incomplete ossification	37	94.9
Occipital: bipartite ossification	1	2.6
Occipital: extra ossification	6	15.4
Hyoid: incomplete ossification	35	89.7
Hyoid: unossified	2	5.1
Hyoid: damaged	2	5.1

File name: I.7.1-MINIPIG_G110_G60_2018_OK.xls

HISTORICAL CONTROL DATA

Print Date: 10/02/2019 21:17

Göttingen Minipig

FETAL EXAMINATION - EXTERNAL (G110)

PERIOD	2003-2018	
Number of studies included	8	
Number of fetuses examined	322	
OBSERVATION	N	%
Cleft palate	1	0.3
Eye: open	1	0.3
Nipples: number<6	46	14.3
Nipples: number>6	184	57.1
Nipples: touching	58	18.0
Placental twin	1	0.3
Limb: malrotated	1	0.3
Limb: flexed	1	0.3
Pentadactyly	3	0.9
Spina bifida	1	0.3
Anal atresia	1	0.3
Tail: short	3	0.9
Tail: bent	2	0.6
Tail: rudimentary	1	0.3

File name: I.7.1-MINIPIG_G110_G60_2018_OK.xls

HISTORICAL CONTROL DATA

Print Date: 10/02/2019 21:17

Göttingen Minipig

FETAL EXAMINATION - FRESH VISCERAL EXAMINATION (G110)

PERIOD	2003-2018	
Number of studies included	6	
Number of fetuses examined	259	
OBSERVATION	N	%
Pulmonary trunk: atresia	1	0.4
Lung: azygos lobe absent	3	1.2
Lung: rudimentary	1	0.4
Diaphragmatic hernia	2	0.8
Gall bladder: absent	1	0.4
Gall bladder: malpositioned	1	0.4
Kidney: dilated renal pelvis	1	0.4
Testis: intra-abdominal	2	0.8

File name: I.7.1-MINIPIG_G110_G60_2018_OK.xls

HISTORICAL CONTROL DATA

Print Date: 10/02/2019 21:17

Göttingen Minipig

FETAL EXAMINATION - FIXED VISCERAL EXAMINATION OF HEAD (G110)

PERIOD	2003-2018	
Number of studies included	5	
Number of fetuses examined	113	
OBSERVATION	N	%
Brain: dilated cerebral ventricle(s)	11	9.7
Brain: dilated lateral cerebral ventricle(s)	14	12.4

File name: I.7.1-MINIPIG_G110_G60_2018_OK.xls

HISTORICAL CONTROL DATA

Print Date: 10/02/2019 21:17

Göttingen Minipig

FETAL EXAMINATION - SKELETAL (G110) - page 1/3

PERIOD	2004-2018	
Number of studies included	4	
Number of fetuses examined	225	
OBSERVATION	N	%
Vertebrae, cervical: incomplete ossification	4	1.8
Vertebrae, cervical: incomplete ossification C7 spinous process	16	7.1
Vertebrae, cervical: C7 spinous process unossified	1	0.4
Vertebrae, thoracic: incomplete ossification spinous process	5	2.2
Vertebrae, thoracic: number = 13	57	25.3
Vertebrae, thoracic: number = 15	1	0.4
Vertebrae, lumbar: number = 6	80	35.6
Vertebrae, lumbar: malformed	1	0.4
Vertebrae, lumbar: fused arch	1	0.4
Vertebrae, lumbar: incomplete ossification of arches	3	1.3
Vertebrae, sacral: incomplete ossification of arches	2	0.9
Vertebrae, sacral: unossified centrum	3	1.3
Vertebrae, sacral: unossified	4	1.8
Vertebrae, sacral: incomplete ossification of centrum	5	2.2
Vertebrae, caudal: malpositioned	1	0.4
Vertebrae, caudal: number < 21	11	4.9
Vertebrae, caudal: fused	14	6.2

File name: I.7.1-MINIPIG_G110_G60_2018_OK.xls

HISTORICAL CONTROL DATA

Print Date: 10/02/2019 21:17

Göttingen Minipig

FETAL EXAMINATION - SKELETAL (G110) - page 2/3

PERIOD	2004-2018	
Number of studies included	4	
Number of fetuses examined	225	
OBSERVATION	N	%
Tarsals: incomplete ossification	26	11.6
Tarsals: only 5 tarsals ossified	29	12.9
Tarsals: only 4 tarsals ossified	21	9.3
Tarsals: only 3 tarsals ossified	3	1.3
Carpals: only 5 carpals ossified	13	5.8
Carpals: only 4 carpals ossified	3	1.3
Carpals: only 3 carpals ossified	2	0.9
Tarsals: number < or = 4	3	1.3
Phalanx: absent	1	0.4
Paw: pentadactyly	4	1.8
Sternebrae: number = 6	48	21.3
Sternebrae: number = 4	7	3.1
Sternebrae: incomplete ossification	13	5.8
Sternebrae: bipartite ossification	4	1.8
Sternebrae: minor fusion	26	11.6
Sternebrae: misshapen	1	0.4
Sternebrae: misaligned	1	0.4
Sternebrae: extra ossification site	1	0.4
Sternebrae: small	6	2.7

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HISTORICAL CONTROL DATA

Print Date: 10/02/2019 21:17

Göttingen Minipig

FETAL EXAMINATION - SKELETAL (G110) - page 3/3

PERIOD	2004-2018	
Number of studies included	4	
Number of fetuses examined	225	
OBSERVATION	N	%
Ribs: number of full ribs = 13/13	83	36.9
Ribs: number of full ribs = 13/14	1	0.4
Ribs: number of full ribs = 15/15	1	0.4
Ribs: number of full ribs = 14/15	1	0.4
Rib: lumbar	38	16.9
Rib: 7th cervical fused to 1st thoracic	64	28.4
Rib: cervical	110	48.9
Rib: short	24	10.7
Rib: rudimentary	15	6.7
Rib: unossified area	4	1.8
Rib: detached	9	4.0
Pelvis: ischium and ilium fused	64	28.4
Pelvis: incomplete ossification of pubis	1	0.4
Pelvis: incomplete ossification of ischium	1	0.4
Pelvis: ischium and pubis fused	12	5.3
Pelvis: extra ossification site between pubis and ischium	6	2.7

File name: I.7.1-MINIPIG_G110_G60_2018_OK.xls

HISTORICAL CONTROL DATA

Print Date: 10/02/2019 21:17

Göttingen Minipig

FETAL EXAMINATION - SKELETAL EXAMINATION OF HEAD (G110)

PERIOD	2004-2018	
Number of studies included	4	
Number of fetuses examined	124	
OBSERVATION	N	%
Frontal: incomplete ossification	11	8.9
Temporal: incomplete ossification	15	12.1
Parietal: unossified area	1	0.8
Parietal: incomplete ossification	18	14.5
Occipital: incomplete ossification	20	16.1
Hyoid: incomplete ossification	27	21.8
Hyoid: point of ossification anterior to cornu	1	0.8
Hyoid: unossified	1	0.8

File name: I.7.1-MINIPIG_G110_G60_2018_OK.xls