表 2.7.4.8-付録-34　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（3008 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Calcium (mg/dL)

Visit / Statistics	TAK-385 40mg (N=33) Observed Value at Visit	TAK-385 40mg (N=33) Change from Baseline	Placebo (N=32) Observed Value at Visit	Placebo (N=32) Change from Baseline
Baseline				
N	33		32	
Mean	8.86		8.80	
SD	0.293		0.273	
Minimum	8.3		8.3	
Q1	8.70		8.60	
Median	8.80		8.80	
Q3	9.10		9.00	
Maximum	9.7		9.5	
Week 4				
N	33	33	32	32
Mean	9.13	0.27	8.79	0.00
SD	0.291	0.315	0.251	0.266
Minimum	8.3	-0.5	8.4	-0.5
Q1	9.00	0.10	8.60	-0.20
Median	9.10	0.30	8.75	0.05
Q3	9.30	0.50	9.05	0.20
Maximum	9.6	0.9	9.3	0.5
Week 8				
N	32	32	31	31
Mean	9.26	0.42	8.85	0.05
SD	0.258	0.314	0.280	0.322
Minimum	8.8	-0.2	8.4	-0.6
Q1	9.00	0.20	8.60	-0.20
Median	9.30	0.35	8.80	0.10
Q3	9.50	0.70	9.10	0.30
Maximum	9.8	1.2	9.4	0.7

治験総括報告書 Table 15.3.2.1.1（5.3.5.1-3）から引用

表 2.7.4.8-付録-34　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（3008 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Calcium (mg/dL)

Visit / Statistics	TAK-385 40mg (N=33) Observed Value at Visit	TAK-385 40mg (N=33) Change from Baseline	Placebo (N=32) Observed Value at Visit	Placebo (N=32) Change from Baseline
Week 12				
N	32	32	31	31
Mean	9.29	0.46	8.82	0.02
SD	0.335	0.332	0.326	0.374
Minimum	8.8	-0.2	8.2	-0.7
Q1	9.00	0.20	8.60	-0.20
Median	9.20	0.40	8.90	0.00
Q3	9.50	0.60	9.00	0.30
Maximum	10.2	1.2	9.6	0.9
Follow-up				
N	33	33	32	32
Mean	8.93	0.07	8.83	0.04
SD	0.259	0.372	0.306	0.337
Minimum	8.5	-0.8	8.2	-0.6
Q1	8.80	-0.20	8.70	-0.20
Median	8.90	0.10	8.80	0.00
Q3	9.10	0.30	9.05	0.20
Maximum	9.5	1.2	9.4	0.8

治験総括報告書 Table 15.3.2.1.1（5.3.5.1-3）から引用

表 2.7.4.8-付録-34　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（3008 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Phosphate (mg/dL)

Visit / Statistics	TAK-385 40mg (N=33) Observed Value at Visit	TAK-385 40mg (N=33) Change from Baseline	Placebo (N=32) Observed Value at Visit	Placebo (N=32) Change from Baseline
Baseline				
N	33		32	
Mean	3.39		3.37	
SD	0.598		0.360	
Minimum	1.9		2.5	
Q1	3.10		3.15	
Median	3.40		3.40	
Q3	3.60		3.60	
Maximum	5.0		4.0	
Week 4				
N	33	33	32	32
Mean	3.63	0.24	3.37	0.00
SD	0.486	0.530	0.367	0.425
Minimum	2.7	-0.7	2.7	-0.8
Q1	3.20	-0.10	3.05	-0.40
Median	3.60	0.20	3.40	0.00
Q3	4.00	0.40	3.60	0.45
Maximum	4.7	2.1	4.3	0.8
Week 8				
N	32	32	31	31
Mean	3.71	0.37	3.27	-0.08
SD	0.395	0.460	0.465	0.462
Minimum	3.0	-0.6	2.3	-1.1
Q1	3.50	0.00	2.90	-0.40
Median	3.60	0.35	3.30	0.00
Q3	3.90	0.70	3.70	0.30
Maximum	4.5	1.6	4.0	0.6

治験総括報告書 Table 15.3.2.1.1（5.3.5.1-3）から引用

表 2.7.4.8-付録-34　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（3008 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Phosphate (mg/dL)

Visit / Statistics	TAK-385 40mg (N=33) Observed Value at Visit	TAK-385 40mg (N=33) Change from Baseline	Placebo (N=32) Observed Value at Visit	Placebo (N=32) Change from Baseline
Week 12				
N	32	32	31	31
Mean	3.94	0.60	3.38	0.03
SD	0.458	0.566	0.364	0.440
Minimum	2.9	-0.3	2.9	-0.8
Q1	3.70	0.20	3.10	-0.30
Median	3.85	0.45	3.40	0.00
Q3	4.40	0.90	3.60	0.20
Maximum	4.8	2.3	4.5	1.1
Follow-up				
N	33	33	32	32
Mean	3.48	0.09	3.40	0.03
SD	0.564	0.624	0.440	0.376
Minimum	2.4	-1.1	2.4	-0.7
Q1	3.00	-0.40	3.15	-0.25
Median	3.40	0.10	3.40	0.00
Q3	3.80	0.30	3.70	0.30
Maximum	4.9	1.9	4.4	0.8

治験総括報告書 Table 15.3.2.1.1（5.3.5.1-3）から引用

表 2.7.4.8-付録-34　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（3008 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Magnesium (mg/dL)

Visit / Statistics	TAK-385 40mg (N=33) Observed Value at Visit	TAK-385 40mg (N=33) Change from Baseline	Placebo (N=32) Observed Value at Visit	Placebo (N=32) Change from Baseline
Baseline				
N	33		32	
Mean	2.17		2.17	
SD	0.151		0.146	
Minimum	1.9		1.8	
Q1	2.10		2.10	
Median	2.20		2.20	
Q3	2.20		2.30	
Maximum	2.6		2.5	
Week 4				
N	33	33	32	32
Mean	2.20	0.03	2.14	-0.03
SD	0.164	0.144	0.139	0.104
Minimum	1.7	-0.2	1.9	-0.2
Q1	2.10	-0.10	2.10	-0.10
Median	2.20	0.00	2.10	0.00
Q3	2.30	0.10	2.20	0.00
Maximum	2.5	0.3	2.4	0.1
Week 8				
N	32	32	31	31
Mean	2.14	-0.03	2.13	-0.04
SD	0.168	0.130	0.144	0.134
Minimum	1.9	-0.2	1.9	-0.3
Q1	2.00	-0.15	2.00	-0.10
Median	2.10	0.00	2.10	0.00
Q3	2.20	0.10	2.20	0.10
Maximum	2.7	0.2	2.4	0.2

治験総括報告書 Table 15.3.2.1.1（5.3.5.1-3）から引用

表 2.7.4.8-付録-34　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（3008 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Magnesium (mg/dL)

Visit / Statistics	TAK-385 40mg (N=33) Observed Value at Visit	TAK-385 40mg (N=33) Change from Baseline	Placebo (N=32) Observed Value at Visit	Placebo (N=32) Change from Baseline
Week 12				
N	32	32	31	31
Mean	2.16	-0.01	2.12	-0.05
SD	0.172	0.119	0.133	0.136
Minimum	1.9	-0.2	1.8	-0.3
Q1	2.00	-0.10	2.00	-0.20
Median	2.15	0.00	2.10	0.00
Q3	2.25	0.10	2.20	0.10
Maximum	2.5	0.3	2.4	0.2
Follow-up				
N	33	33	32	32
Mean	2.16	-0.02	2.16	-0.01
SD	0.146	0.128	0.141	0.128
Minimum	1.9	-0.3	1.9	-0.2
Q1	2.10	-0.10	2.10	-0.10
Median	2.10	0.00	2.20	0.00
Q3	2.20	0.10	2.25	0.10
Maximum	2.5	0.2	2.4	0.2

治験総括報告書 Table 15.3.2.1.1（5.3.5.1-3）から引用

表 2.7.4.8-付録-35　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-101 試験）

Laboratory Group: Serum Chemistry
Laboratory Test: ALT (GPT) (U/L)

Visit / Statistics	Placebo (N=97) Observed Value at Visit	Placebo (N=97) Change from Baseline	TAK-385 10mg (N=103) Observed Value at Visit	TAK-385 10mg (N=103) Change from Baseline	TAK-385 20mg (N=100) Observed Value at Visit	TAK-385 20mg (N=100) Change from Baseline	TAK-385 40mg (N=103) Observed Value at Visit	TAK-385 40mg (N=103) Change from Baseline	Leuprorelin (N=80) Observed Value at Visit	Leuprorelin (N=80) Change from Baseline
Baseline										
N	97		103		100		103		80	
Mean	12.5		13.6		12.2		12.6		14.3	
SD	4.68		6.25		3.98		4.31		5.79	
Minimum	6		6		7		7		6	
Q1	9.0		10.0		9.0		9.0		11.0	
Median	12.0		12.0		11.0		12.0		13.5	
Q3	14.0		15.0		14.0		14.0		17.0	
Maximum	35		40		24		29		48	
Week 4										
N	97	97	103	103	100	100	103	103	80	80
Mean	14.1	1.5	14.7	1.1	15.0	2.8	14.9	2.3	16.0	1.7
SD	5.86	4.55	7.41	5.79	6.86	5.51	6.52	5.01	7.55	5.85
Minimum	6	-11	8	-13	7	-8	7	-11	7	-9
Q1	10.0	-1.0	10.0	-1.0	11.0	0.0	11.0	-1.0	12.0	-1.0
Median	13.0	1.0	13.0	1.0	13.0	2.0	13.0	2.0	14.0	1.0
Q3	17.0	2.0	17.0	2.0	16.0	4.0	18.0	4.0	17.0	3.0
Maximum	37	18	58	34	48	32	58	29	56	38
Week 8										
N	95	95	103	103	96	96	101	101	78	78
Mean	13.3	0.9	13.9	0.3	24.6	12.4	16.9	4.3	18.5	4.1
SD	4.79	3.45	5.63	3.71	93.85	93.37	9.76	8.63	9.76	6.63
Minimum	7	-16	6	-13	5	-5	7	-8	8	-8
Q1	10.0	-1.0	11.0	-1.0	11.0	1.0	12.0	1.0	13.0	1.0
Median	12.0	1.0	12.0	0.0	14.0	3.0	14.0	2.0	15.5	2.0
Q3	16.0	3.0	16.0	2.0	18.0	4.0	19.0	5.0	19.0	5.0
Maximum	30	12	40	10	933	917	79	58	60	30
Week 12										
N	93	93	101	101	92	92	101	101	75	75
Mean	13.7	1.1	14.6	1.1	15.9	3.7	17.5	4.9	18.8	4.3
SD	6.17	5.13	6.90	4.46	9.08	7.41	10.47	9.56	9.57	6.15
Minimum	6	-12	5	-11	9	-4	8	-8	8	-9
Q1	9.0	-2.0	10.0	-1.0	11.0	0.0	12.0	1.0	12.0	1.0
Median	12.0	0.0	13.0	1.0	13.0	2.0	14.0	3.0	16.0	3.0
Q3	15.0	2.0	15.0	2.0	17.0	5.0	19.0	5.0	21.0	7.0
Maximum	45	28	48	18	73	55	82	61	56	26
Follow-up										
N	18	18	19	19	22	22	13	13	10	10
Mean	15.2	1.2	15.0	0.4	13.1	1.1	13.5	2.1	15.4	2.0
SD	8.57	5.44	6.30	4.59	4.67	2.36	3.73	4.15	3.41	5.91
Minimum	7	-8	8	-13	8	-3	8	-3	12	-11
Q1	9.0	-1.0	10.0	-2.0	11.0	-1.0	11.0	-2.0	12.0	-1.0
Median	12.0	1.0	14.0	1.0	11.5	1.0	13.0	3.0	14.5	2.5
Q3	19.0	2.0	16.0	3.0	14.0	2.0	17.0	4.0	18.0	6.0
Maximum	38	16	33	10	28	7	20	9	21	9

治験総括報告書 Table 3.3.1.1.1（Section 15.1）（5.3.5.4-1）から引用

表 2.7.4.8-付録-35　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-101 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: AST (GOT) (U/L)

Visit / Statistics	Placebo (N=97)		TAK-385 10mg (N=103)		TAK-385 20mg (N=100)		TAK-385 40mg (N=103)		Leuprorelin (N=80)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Baseline										
N	97		103		100		103		80	
Mean	15.8		16.8		16.0		16.5		17.1	
SD	3.64		4.30		2.91		3.52		4.17	
Minimum	8		12		10		11		11	
Q1	14.0		14.0		14.0		14.0		14.0	
Median	15.0		16.0		16.0		16.0		16.0	
Q3	18.0		18.0		18.0		19.0		19.0	
Maximum	33		37		26		31		38	
Week 4										
N	97	97	103	103	100	100	103	103	80	80
Mean	16.7	0.9	17.8	1.0	18.0	2.0	18.6	2.1	18.5	1.3
SD	4.72	3.83	4.39	4.45	3.89	3.20	4.72	3.88	4.22	3.23
Minimum	10	-7	10	-20	10	-6	10	-4	11	-9
Q1	14.0	-1.0	15.0	-1.0	15.0	0.0	16.0	0.0	16.0	-0.5
Median	16.0	0.0	17.0	1.0	18.0	2.0	18.0	2.0	17.0	1.0
Q3	18.0	2.0	20.0	3.0	20.0	3.0	20.0	4.0	21.0	3.0
Maximum	37	22	36	15	35	18	46	24	34	14
Week 8										
N	95	95	103	103	96	96	101	101	78	78
Mean	16.2	0.5	17.3	0.4	23.0	6.9	19.5	2.9	20.2	3.1
SD	3.76	2.91	3.66	3.20	49.86	49.28	7.09	6.29	6.15	4.30
Minimum	10	-9	11	-18	11	-3	11	-8	13	-7
Q1	14.0	-1.0	15.0	-1.0	15.0	0.0	16.0	0.0	16.0	0.0
Median	16.0	0.0	17.0	1.0	17.0	1.5	18.0	2.0	18.5	3.0
Q3	18.0	2.0	20.0	2.0	20.0	3.0	21.0	4.0	22.0	5.0
Maximum	29	11	29	6	505	484	77	53	42	17
Week 12										
N	93	93	100	100	92	92	101	101	75	75
Mean	17.3	1.5	17.5	0.7	18.5	2.5	19.8	3.3	20.3	3.1
SD	10.00	10.10	3.60	3.61	6.47	5.55	6.79	5.79	6.57	4.23
Minimum	10	-7	12	-20	11	-4	13	-6	13	-8
Q1	14.0	-1.0	15.0	-1.0	15.5	0.0	16.0	0.0	16.0	0.0
Median	16.0	0.0	17.0	1.0	17.0	1.0	18.0	2.0	18.0	2.0
Q3	19.0	2.0	20.0	3.0	20.0	4.0	21.0	4.0	23.0	5.0
Maximum	104	92	35	9	62	44	70	46	54	16
Follow-up										
N	18	18	19	19	22	22	13	13	10	10
Mean	17.4	0.3	17.5	0.5	16.7	0.5	16.5	0.9	17.8	0.9
SD	4.71	3.79	3.37	3.27	2.69	2.74	3.89	2.63	2.86	3.21
Minimum	11	-7	12	-10	13	-6	12	-3	14	-6
Q1	14.0	-1.0	15.0	-1.0	14.0	-1.0	14.0	0.0	16.0	-1.0
Median	17.0	0.5	17.0	1.0	16.0	1.0	15.0	1.0	18.0	2.0
Q3	23.0	2.0	20.0	2.0	19.0	2.0	19.0	2.0	19.0	3.0
Maximum	26	8	26	6	22	5	24	6	24	5

治験総括報告書 Table 3.3.1.1.1（Section 15.1）（5.3.5.4-1）から引用

表 2.7.4.8-付録-35　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-101 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: LDH (U/L)

Visit / Statistics	Placebo (N=97) Observed Value at Visit	Placebo (N=97) Change from Baseline	TAK-385 10mg (N=103) Observed Value at Visit	TAK-385 10mg (N=103) Change from Baseline	TAK-385 20mg (N=100) Observed Value at Visit	TAK-385 20mg (N=100) Change from Baseline	TAK-385 40mg (N=103) Observed Value at Visit	TAK-385 40mg (N=103) Change from Baseline	Leuprorelin (N=80) Observed Value at Visit	Leuprorelin (N=80) Change from Baseline
Baseline										
N	97		103		100		103		80	
Mean	154.1		153.7		147.7		150.0		153.9	
SD	30.16		25.85		23.61		23.05		24.49	
Minimum	91		103		102		100		103	
Q1	134.0		134.0		133.0		136.0		138.5	
Median	150.0		150.0		144.0		146.0		152.5	
Q3	170.0		170.0		160.0		163.0		171.0	
Maximum	299		233		254		249		257	
Week 4										
N	97	97	103	103	100	100	103	103	80	80
Mean	152.4	-1.7	155.0	1.2	153.7	6.0	161.5	11.6	158.7	4.8
SD	25.03	20.77	27.71	22.76	22.41	15.46	29.69	20.34	20.12	20.49
Minimum	104	-107	106	-86	101	-46	106	-29	108	-109
Q1	133.0	-12.0	137.0	-9.0	140.0	-4.0	144.0	-1.0	147.5	-3.5
Median	151.0	-1.0	152.0	1.0	152.0	5.5	157.0	10.0	161.5	5.0
Q3	166.0	8.0	171.0	13.0	169.0	16.0	175.0	19.0	171.0	15.0
Maximum	245	83	278	77	223	44	293	127	200	47
Week 8										
N	95	95	103	103	96	96	101	101	78	78
Mean	154.1	-0.1	152.8	-0.9	158.6	10.2	161.4	11.7	163.3	9.3
SD	33.16	21.29	23.81	19.91	37.19	29.74	29.16	17.56	20.38	21.86
Minimum	114	-82	102	-75	92	-24	93	-27	101	-114
Q1	136.0	-10.0	134.0	-14.0	139.0	-4.0	144.0	2.0	150.0	2.0
Median	146.0	1.0	154.0	1.0	150.5	5.0	159.0	10.0	165.5	10.0
Q3	170.0	9.0	172.0	11.0	170.0	17.0	176.0	21.0	178.0	19.0
Maximum	362	65	201	64	389	223	282	79	213	60
Week 12										
N	93	93	100	100	92	92	101	101	75	75
Mean	159.9	5.4	156.9	2.6	160.0	12.2	163.5	13.8	166.6	12.4
SD	43.38	42.42	25.22	18.87	26.40	20.36	28.61	18.22	24.66	24.05
Minimum	117	-98	110	-82	94	-25	114	-28	105	-140
Q1	134.0	-11.0	137.0	-9.0	139.5	-0.5	144.0	-1.0	149.0	3.0
Median	153.0	1.0	158.5	2.5	158.0	7.0	161.0	15.0	166.0	14.0
Q3	171.0	15.0	175.0	14.0	174.5	25.5	174.0	27.0	183.0	27.0
Maximum	481	354	216	56	231	61	272	59	230	58
Follow-up										
N	18	18	19	19	22	22	13	13	10	10
Mean	164.1	5.6	147.6	-3.1	145.6	1.5	153.2	5.6	151.8	5.5
SD	80.83	49.73	22.38	17.66	16.24	14.94	28.57	14.15	22.41	18.96
Minimum	112	-92	104	-49	116	-26	108	-14	109	-16
Q1	127.0	-16.0	129.0	-14.0	134.0	-6.0	134.0	-4.0	141.0	-8.0
Median	137.0	-2.5	146.0	0.0	144.0	3.5	145.0	0.0	147.5	-1.0
Q3	181.0	21.0	165.0	8.0	161.0	7.0	160.0	18.0	166.0	21.0
Maximum	464	165	191	22	175	41	208	29	187	32

治験総括報告書 Table 3.3.1.1.1（Section 15.1）（5.3.5.4-1）から引用

表 2.7.4.8-付録-35　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-101 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: GGT (U/L)

Visit / Statistics	Placebo (N=97)		TAK-385 10mg (N=103)		TAK-385 20mg (N=100)		TAK-385 40mg (N=103)		Leuprorelin (N=80)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Baseline										
N	97		103		100		103		80	
Mean	16.9		17.2		16.1		15.5		17.6	
SD	9.00		11.05		9.92		7.29		8.19	
Minimum	7		5		7		7		8	
Q1	12.0		12.0		12.0		11.0		12.0	
Median	15.0		14.0		14.0		14.0		15.0	
Q3	18.0		19.0		16.0		17.0		19.5	
Maximum	74		105		73		51		46	
Week 4										
N	97	97	103	103	100	100	103	103	80	80
Mean	18.9	2.1	17.8	0.6	17.4	1.3	17.0	1.5	19.2	1.6
SD	19.78	12.49	13.83	4.91	11.13	5.13	9.62	5.16	11.65	7.26
Minimum	6	-8	5	-13	8	-20	8	-13	8	-5
Q1	13.0	-1.0	12.0	-1.0	12.5	-0.5	12.0	-1.0	13.0	-1.0
Median	15.0	0.0	15.0	0.0	15.0	1.0	15.0	1.0	16.0	1.0
Q3	18.0	2.0	19.0	2.0	17.5	2.0	18.0	2.0	21.5	2.0
Maximum	194	120	132	29	92	35	77	31	94	61
Week 8										
N	95	95	103	103	96	96	101	101	78	78
Mean	18.8	2.0	17.4	0.2	18.8	2.6	19.5	4.0	22.4	4.6
SD	19.58	12.15	11.89	2.64	17.00	13.30	23.90	20.06	17.13	12.27
Minimum	9	-8	7	-7	8	-18	7	-17	9	-3
Q1	13.0	-1.0	12.0	-1.0	13.0	0.0	12.0	0.0	13.0	0.0
Median	15.0	1.0	15.0	0.0	15.0	1.0	15.0	1.0	16.0	1.5
Q3	19.0	2.0	18.0	1.0	19.0	2.0	20.0	4.0	24.0	3.0
Maximum	187	113	118	13	141	124	242	196	93	67
Week 12										
N	93	93	101	101	92	92	101	101	75	75
Mean	17.7	0.8	18.6	1.3	18.7	2.5	19.8	4.3	22.3	4.7
SD	11.60	4.51	14.87	6.03	16.25	8.62	23.44	19.40	14.53	9.29
Minimum	9	-10	5	-12	8	-24	8	-18	8	-5
Q1	13.0	-1.0	12.0	-1.0	12.5	-1.0	12.0	-1.0	13.0	1.0
Median	15.0	0.0	15.0	1.0	14.0	1.0	15.0	1.0	17.0	2.0
Q3	18.0	2.0	21.0	2.0	17.0	3.0	19.0	3.0	25.0	5.0
Maximum	88	22	136	31	130	57	229	183	86	60
Follow-up										
N	18	18	19	19	22	22	13	13	10	10
Mean	16.7	0.6	17.1	0.3	16.5	1.6	16.3	1.7	17.5	2.1
SD	5.55	3.78	7.32	2.65	9.09	6.66	6.66	4.64	8.72	3.07
Minimum	9	-5	8	-5	8	-5	9	-2	10	-3
Q1	13.0	-2.0	12.0	-1.0	12.0	-1.0	13.0	-1.0	11.0	1.0
Median	15.0	-1.0	15.0	0.0	14.0	0.5	15.0	1.0	14.5	2.0
Q3	18.0	3.0	20.0	2.0	18.0	1.0	16.0	1.0	21.0	3.0
Maximum	31	11	41	5	47	30	32	16	39	9

治験総括報告書 Table 3.3.1.1.1（Section 15.1）（5.3.5.4-1）から引用

表 2.7.4.8-付録-35　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-101 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Albumin (g/dL)

Visit / Statistics	Placebo (N=97)		TAK-385 10mg (N=103)		TAK-385 20mg (N=100)		TAK-385 40mg (N=103)		Leuprorelin (N=80)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Baseline										
N	97		103		100		103		80	
Mean	4.23		4.24		4.19		4.24		4.25	
SD	0.224		0.225		0.210		0.239		0.226	
Minimum	3.8		3.7		3.7		3.7		3.7	
Q1	4.10		4.10		4.10		4.10		4.10	
Median	4.20		4.20		4.20		4.20		4.20	
Q3	4.30		4.40		4.30		4.40		4.40	
Maximum	4.9		4.8		4.7		5.0		4.9	
Week 4										
N	97	97	103	103	100	100	103	103	80	80
Mean	4.25	0.01	4.34	0.10	4.37	0.18	4.49	0.24	4.39	0.14
SD	0.239	0.225	0.229	0.219	0.238	0.212	0.224	0.225	0.245	0.220
Minimum	3.6	-0.7	3.8	-0.4	3.9	-0.3	3.9	-0.2	3.8	-0.3
Q1	4.10	-0.10	4.20	0.00	4.20	0.10	4.30	0.10	4.20	0.00
Median	4.20	0.00	4.30	0.10	4.40	0.20	4.50	0.20	4.40	0.20
Q3	4.40	0.20	4.50	0.20	4.50	0.30	4.60	0.40	4.50	0.30
Maximum	4.8	0.6	5.0	0.6	4.9	0.7	4.9	0.8	5.1	0.9
Week 8										
N	95	95	103	103	96	96	101	101	78	78
Mean	4.29	0.06	4.33	0.10	4.38	0.19	4.45	0.21	4.41	0.17
SD	0.209	0.211	0.211	0.223	0.235	0.194	0.248	0.249	0.211	0.211
Minimum	3.8	-0.5	3.7	-0.4	3.7	-0.4	3.3	-0.5	3.9	-0.3
Q1	4.20	0.00	4.20	-0.10	4.20	0.05	4.30	0.10	4.30	0.10
Median	4.30	0.10	4.30	0.10	4.40	0.20	4.50	0.20	4.40	0.20
Q3	4.40	0.20	4.50	0.20	4.60	0.30	4.60	0.40	4.60	0.30
Maximum	4.9	0.5	4.8	0.6	4.9	0.7	5.1	0.9	4.9	0.7
Week 12										
N	93	93	101	101	92	92	101	101	75	75
Mean	4.26	0.02	4.35	0.11	4.35	0.16	4.43	0.18	4.38	0.14
SD	0.223	0.205	0.218	0.241	0.227	0.203	0.244	0.229	0.233	0.221
Minimum	3.7	-0.5	3.9	-0.4	3.8	-0.4	3.6	-0.3	3.7	-0.4
Q1	4.10	-0.10	4.20	0.00	4.20	0.00	4.30	0.00	4.20	0.00
Median	4.30	0.00	4.30	0.10	4.30	0.10	4.40	0.20	4.40	0.10
Q3	4.40	0.10	4.50	0.20	4.50	0.30	4.60	0.30	4.50	0.30
Maximum	4.9	0.6	5.0	1.1	5.0	0.8	5.0	0.8	5.0	0.7
Follow-up										
N	18	18	19	19	22	22	13	13	10	10
Mean	4.29	0.08	4.27	-0.01	4.21	0.06	4.24	0.05	4.36	0.17
SD	0.207	0.170	0.200	0.196	0.236	0.209	0.243	0.226	0.184	0.211
Minimum	3.8	-0.3	3.8	-0.3	3.7	-0.4	3.9	-0.3	4.0	-0.3
Q1	4.10	0.00	4.20	-0.20	4.00	0.00	4.00	-0.20	4.20	0.10
Median	4.35	0.10	4.30	0.00	4.25	0.05	4.20	0.10	4.40	0.20
Q3	4.40	0.20	4.40	0.20	4.40	0.20	4.40	0.10	4.40	0.20
Maximum	4.6	0.3	4.6	0.3	4.6	0.3	4.6	0.5	4.6	0.5

治験総括報告書 Table 3.3.1.1.1（Section 15.1）（5.3.5.4-1）から引用

表 2.7.4.8-付録-35　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-101 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Alkaline Phosphatase (U/L)

Visit / Statistics	Placebo (N=97)		TAK-385 10mg (N=103)		TAK-385 20mg (N=100)		TAK-385 40mg (N=103)		Leuprorelin (N=80)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Baseline										
N	97		103		100		103		80	
Mean	172.1		169.1		167.5		168.6		170.2	
SD	46.74		41.91		41.21		39.47		39.58	
Minimum	81		107		66		95		101	
Q1	137.0		138.0		139.0		138.0		140.0	
Median	168.0		162.0		166.0		163.0		162.5	
Q3	200.0		197.0		185.5		201.0		198.5	
Maximum	307		356		329		279		276	
Week 4										
N	97	97	103	103	100	100	103	103	80	80
Mean	172.9	0.8	175.5	6.4	170.7	3.2	174.7	6.1	174.8	4.6
SD	47.86	20.46	44.56	22.00	41.03	22.06	42.58	22.72	38.28	20.08
Minimum	76	-47	100	-49	75	-130	93	-92	111	-33
Q1	141.0	-11.0	140.0	-5.0	140.5	-7.0	136.0	-6.0	145.0	-7.0
Median	165.0	0.0	172.0	5.0	171.0	3.5	176.0	6.0	173.5	2.5
Q3	194.0	11.0	201.0	17.0	189.5	15.0	199.0	21.0	202.5	15.0
Maximum	337	72	339	122	349	65	294	95	271	82
Week 8										
N	95	95	103	103	96	96	101	101	78	78
Mean	170.5	0.6	174.3	5.2	178.7	11.8	180.7	12.6	181.2	10.7
SD	45.09	18.40	43.38	25.50	71.93	51.99	47.62	32.96	45.24	22.83
Minimum	71	-40	108	-51	72	-148	102	-49	109	-43
Q1	137.0	-11.0	139.0	-7.0	142.5	-4.0	142.0	-5.0	147.0	-2.0
Median	165.0	1.0	171.0	1.0	171.5	6.0	174.0	7.0	169.0	3.5
Q3	200.0	12.0	200.0	18.0	192.0	20.0	208.0	21.0	209.0	21.0
Maximum	335	70	356	128	718	421	334	183	297	105
Week 12										
N	93	93	100	100	92	92	101	101	75	75
Mean	169.4	-0.5	178.1	8.5	175.5	10.4	187.1	19.0	187.0	16.2
SD	45.25	19.22	44.30	29.64	41.53	26.25	50.51	34.41	42.29	21.61
Minimum	76	-46	112	-93	70	-107	109	-102	126	-40
Q1	136.0	-10.0	142.5	-7.0	148.5	-4.5	151.0	2.0	155.0	0.0
Median	166.0	-2.0	173.5	7.5	173.0	11.0	179.0	17.0	174.0	14.0
Q3	197.0	10.0	211.0	24.0	201.5	23.0	219.0	32.0	220.0	32.0
Maximum	294	53	343	115	301	143	394	144	303	73
Follow-up										
N	18	18	19	19	22	22	13	13	10	10
Mean	185.3	-0.9	167.8	0.8	189.6	14.6	176.2	7.4	185.1	28.4
SD	55.02	32.09	30.56	14.89	58.87	26.20	39.24	20.36	44.60	37.74
Minimum	103	-90	125	-20	115	-45	117	-18	124	-18
Q1	157.0	-14.0	142.0	-13.0	147.0	0.0	145.0	-3.0	151.0	4.0
Median	184.5	6.0	164.0	5.0	178.5	15.5	182.0	2.0	182.5	15.5
Q3	217.0	21.0	183.0	13.0	204.0	27.0	210.0	13.0	223.0	42.0
Maximum	282	38	226	29	341	76	223	54	270	101

治験総括報告書 Table 3.3.1.1.1（Section 15.1）（5.3.5.4-1）から引用

表 2.7.4.8-付録-35　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-101 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Total Bilirubin (mg/dL)

Visit / Statistics	Placebo (N=97) Observed Value at Visit	Placebo (N=97) Change from Baseline	TAK-385 10mg (N=103) Observed Value at Visit	TAK-385 10mg (N=103) Change from Baseline	TAK-385 20mg (N=100) Observed Value at Visit	TAK-385 20mg (N=100) Change from Baseline	TAK-385 40mg (N=103) Observed Value at Visit	TAK-385 40mg (N=103) Change from Baseline	Leuprorelin (N=80) Observed Value at Visit	Leuprorelin (N=80) Change from Baseline
Baseline										
N	97		103		100		103		80	
Mean	0.52		0.53		0.51		0.55		0.54	
SD	0.182		0.185		0.223		0.199		0.205	
Minimum	0.2		0.1		0.2		0.2		0.2	
Q1	0.40		0.40		0.40		0.40		0.40	
Median	0.50		0.50		0.40		0.50		0.50	
Q3	0.70		0.70		0.60		0.60		0.70	
Maximum	1.0		1.0		1.2		1.4		1.2	
Week 4										
N	97	97	103	103	100	100	103	103	80	80
Mean	0.53	0.01	0.57	0.04	0.59	0.08	0.60	0.05	0.59	0.05
SD	0.184	0.177	0.212	0.167	0.210	0.174	0.241	0.215	0.211	0.194
Minimum	0.2	-0.4	0.2	-0.4	0.3	-0.4	0.3	-0.6	0.2	-0.5
Q1	0.40	-0.10	0.40	-0.10	0.40	0.00	0.40	-0.10	0.40	-0.10
Median	0.50	0.00	0.50	0.00	0.60	0.10	0.50	0.00	0.60	0.00
Q3	0.60	0.10	0.70	0.10	0.70	0.20	0.70	0.10	0.70	0.20
Maximum	1.0	0.6	1.2	0.5	1.2	0.5	1.9	0.9	1.4	0.5
Week 8										
N	95	95	103	103	96	96	101	101	78	78
Mean	0.53	0.01	0.60	0.06	0.59	0.08	0.59	0.04	0.58	0.05
SD	0.177	0.160	0.223	0.187	0.227	0.224	0.234	0.235	0.226	0.225
Minimum	0.2	-0.5	0.2	-0.7	0.2	-0.4	0.2	-0.7	0.2	-0.6
Q1	0.40	-0.10	0.40	0.00	0.40	-0.10	0.40	-0.10	0.40	-0.10
Median	0.50	0.00	0.60	0.10	0.60	0.10	0.50	0.10	0.55	0.00
Q3	0.60	0.10	0.70	0.20	0.70	0.20	0.70	0.10	0.70	0.20
Maximum	1.0	0.3	1.3	0.7	1.3	0.8	1.8	0.8	1.3	0.8
Week 12										
N	93	93	101	101	92	92	101	101	75	75
Mean	0.55	0.03	0.60	0.07	0.57	0.06	0.58	0.03	0.59	0.06
SD	0.230	0.185	0.293	0.255	0.218	0.198	0.239	0.200	0.203	0.199
Minimum	0.2	-0.5	0.3	-0.5	0.2	-0.7	0.2	-0.4	0.2	-0.4
Q1	0.40	-0.10	0.40	-0.10	0.40	0.00	0.40	-0.10	0.40	-0.10
Median	0.50	0.00	0.60	0.00	0.50	0.10	0.50	0.00	0.50	0.10
Q3	0.70	0.10	0.70	0.20	0.65	0.20	0.70	0.20	0.70	0.20
Maximum	1.3	0.6	2.7	1.9	1.2	0.7	1.8	0.5	1.1	0.6
Follow-up										
N	18	18	19	19	22	22	13	13	10	10
Mean	0.50	0.00	0.49	-0.04	0.45	-0.07	0.58	0.02	0.54	0.05
SD	0.171	0.197	0.154	0.161	0.179	0.221	0.245	0.265	0.178	0.135
Minimum	0.2	-0.5	0.2	-0.4	0.2	-0.6	0.3	-0.3	0.4	-0.2
Q1	0.40	-0.10	0.40	-0.20	0.30	-0.20	0.40	-0.20	0.40	0.00
Median	0.50	0.00	0.50	0.00	0.50	-0.10	0.50	0.00	0.50	0.05
Q3	0.60	0.10	0.60	0.10	0.50	0.00	0.70	0.10	0.60	0.20
Maximum	0.9	0.4	0.7	0.3	0.9	0.6	1.1	0.6	0.9	0.2

治験総括報告書 Table 3.3.1.1.1（Section 15.1）（5.3.5.4-1）から引用

表 2.7.4.8-付録-35　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-101 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Total Protein (g/dL)

Visit / Statistics	Placebo (N=97)		TAK-385 10mg (N=103)		TAK-385 20mg (N=100)		TAK-385 40mg (N=103)		Leuprorelin (N=80)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Baseline										
N	97		103		100		103		80	
Mean	7.01		7.00		6.97		7.00		6.99	
SD	0.380		0.441		0.309		0.412		0.380	
Minimum	6.2		5.9		6.0		6.1		6.1	
Q1	6.80		6.70		6.80		6.70		6.70	
Median	7.00		7.00		7.00		7.00		7.00	
Q3	7.20		7.30		7.10		7.30		7.25	
Maximum	8.0		8.3		7.6		8.0		7.9	
Week 4										
N	97	97	103	103	100	100	103	103	80	80
Mean	7.01	0.00	7.17	0.17	7.22	0.25	7.35	0.35	7.19	0.20
SD	0.412	0.375	0.421	0.364	0.387	0.345	0.384	0.374	0.434	0.391
Minimum	6.0	-1.0	6.4	-0.8	6.4	-0.6	6.6	-0.5	6.0	-0.6
Q1	6.70	-0.20	6.90	-0.10	6.90	0.00	7.00	0.10	6.90	-0.10
Median	7.00	0.00	7.10	0.20	7.20	0.25	7.30	0.30	7.20	0.20
Q3	7.30	0.20	7.40	0.40	7.50	0.50	7.60	0.70	7.45	0.50
Maximum	8.1	1.1	8.2	1.0	8.1	1.0	8.3	1.2	8.6	1.4
Week 8										
N	95	95	103	103	96	96	101	101	78	78
Mean	7.10	0.08	7.14	0.14	7.22	0.25	7.34	0.33	7.20	0.22
SD	0.400	0.359	0.375	0.380	0.364	0.321	0.420	0.412	0.430	0.376
Minimum	6.1	-0.8	6.0	-1.0	6.4	-0.5	6.3	-0.7	6.3	-0.7
Q1	6.90	-0.10	6.90	-0.10	6.95	0.00	7.00	0.10	6.90	0.00
Median	7.10	0.10	7.10	0.10	7.30	0.30	7.30	0.40	7.20	0.20
Q3	7.30	0.30	7.40	0.50	7.40	0.50	7.60	0.60	7.50	0.40
Maximum	8.6	0.9	8.2	0.8	8.1	1.1	8.4	1.4	8.3	1.0
Week 12										
N	93	93	100	100	92	92	101	101	75	75
Mean	7.06	0.05	7.17	0.17	7.21	0.25	7.32	0.31	7.21	0.23
SD	0.404	0.356	0.448	0.425	0.371	0.365	0.409	0.388	0.428	0.408
Minimum	5.9	-0.8	6.3	-0.7	6.2	-0.5	6.5	-0.6	6.2	-0.8
Q1	6.80	-0.10	6.90	-0.10	7.00	0.00	7.00	0.10	6.90	0.00
Median	7.10	0.00	7.10	0.10	7.20	0.30	7.30	0.30	7.20	0.20
Q3	7.40	0.20	7.40	0.45	7.45	0.50	7.60	0.50	7.50	0.50
Maximum	8.2	0.9	8.7	1.5	8.2	1.3	8.2	1.4	8.3	1.5
Follow-up										
N	18	18	19	19	22	22	13	13	10	10
Mean	7.05	0.15	7.19	0.01	7.06	0.04	6.95	0.02	7.25	0.23
SD	0.449	0.309	0.422	0.363	0.363	0.340	0.240	0.329	0.448	0.490
Minimum	6.3	-0.3	6.3	-0.6	6.3	-0.7	6.5	-0.4	6.5	-0.6
Q1	6.90	0.00	6.90	-0.30	6.80	-0.20	6.80	-0.20	7.10	0.00
Median	7.00	0.10	7.00	0.00	7.10	0.05	6.90	0.00	7.20	0.20
Q3	7.30	0.30	7.50	0.20	7.40	0.30	7.10	0.30	7.50	0.50
Maximum	8.1	0.7	8.2	0.7	7.6	0.6	7.4	0.5	7.9	1.1

治験総括報告書 Table 3.3.1.1.1（Section 15.1）（5.3.5.4-1）から引用

表 2.7.4.8-付録-35　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-101 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Total Cholesterol (mg/dL)

Visit / Statistics	Placebo (N=97) Observed Value at Visit	Placebo (N=97) Change from Baseline	TAK-385 10mg (N=103) Observed Value at Visit	TAK-385 10mg (N=103) Change from Baseline	TAK-385 20mg (N=100) Observed Value at Visit	TAK-385 20mg (N=100) Change from Baseline	TAK-385 40mg (N=103) Observed Value at Visit	TAK-385 40mg (N=103) Change from Baseline	Leuprorelin (N=80) Observed Value at Visit	Leuprorelin (N=80) Change from Baseline
Baseline										
N	97		103		100		103		80	
Mean	183.5		178.4		179.1		179.1		186.1	
SD	28.57		24.91		28.02		29.73		28.74	
Minimum	136		128		121		112		128	
Q1	161.0		160.0		159.0		159.0		164.0	
Median	180.0		178.0		177.0		176.0		184.5	
Q3	203.0		196.0		199.5		200.0		204.0	
Maximum	276		240		260		308		273	
Week 4										
N	97	97	103	103	100	100	103	103	80	80
Mean	183.6	0.1	188.3	10.0	192.1	13.0	195.7	16.6	199.2	13.0
SD	27.86	15.61	27.82	16.60	30.89	16.84	34.12	19.50	29.17	17.08
Minimum	135	-65	118	-25	133	-45	129	-45	141	-25
Q1	163.0	-9.0	166.0	-2.0	168.5	2.5	177.0	6.0	180.0	2.0
Median	185.0	0.0	187.0	9.0	191.5	13.0	190.0	14.0	197.0	12.0
Q3	199.0	9.0	209.0	21.0	207.5	24.5	213.0	29.0	212.0	23.5
Maximum	291	37	258	51	280	61	386	78	293	61
Week 8										
N	95	95	103	103	96	96	101	101	78	78
Mean	188.3	4.8	188.3	9.9	192.4	12.1	197.1	17.8	197.5	11.1
SD	29.01	17.84	27.76	19.25	30.35	17.67	35.00	22.68	30.52	16.86
Minimum	120	-44	138	-37	133	-39	111	-43	135	-33
Q1	169.0	-6.0	166.0	-4.0	171.0	0.5	172.0	2.0	174.0	0.0
Median	183.0	6.0	188.0	11.0	192.5	9.5	193.0	20.0	198.5	10.0
Q3	204.0	16.0	207.0	25.0	213.0	25.5	220.0	30.0	216.0	24.0
Maximum	280	48	256	78	282	49	365	80	293	57
Week 12										
N	93	93	101	101	92	92	101	101	75	75
Mean	187.1	3.5	189.4	10.9	191.8	10.8	196.5	17.3	198.1	11.0
SD	33.13	20.84	29.10	19.46	29.61	20.81	34.51	21.99	31.01	16.86
Minimum	124	-34	140	-34	130	-53	120	-44	128	-50
Q1	164.0	-9.0	169.0	-1.0	173.5	-1.5	176.0	1.0	177.0	1.0
Median	184.0	3.0	187.0	10.0	190.5	12.0	193.0	17.0	195.0	10.0
Q3	201.0	13.0	205.0	19.0	207.0	25.0	211.0	30.0	218.0	21.0
Maximum	293	78	266	72	273	58	373	82	287	55
Follow-up										
N	18	18	19	19	22	22	13	13	10	10
Mean	197.0	8.6	185.4	5.4	169.5	4.6	176.6	1.8	181.9	18.5
SD	31.96	16.48	32.60	24.91	30.53	17.22	16.53	23.67	27.19	17.77
Minimum	132	-19	131	-47	124	-20	152	-58	146	-3
Q1	174.0	-4.0	157.0	-6.0	150.0	-10.0	168.0	-10.0	150.0	6.0
Median	202.0	8.0	186.0	0.0	158.5	2.0	178.0	3.0	187.5	12.5
Q3	217.0	20.0	197.0	32.0	181.0	17.0	186.0	19.0	207.0	26.0
Maximum	243	47	276	49	241	38	211	36	214	52

治験総括報告書 Table 3.3.1.1.1（Section 15.1）（5.3.5.4-1）から引用

表 2.7.4.8-付録-35　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-101 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: HDL Cholesterol (mg/dL)

Visit / Statistics	Placebo (N=97)		TAK-385 10mg (N=103)		TAK-385 20mg (N=100)		TAK-385 40mg (N=103)		Leuprorelin (N=80)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Baseline										
N	97		103		100		103		80	
Mean	64.0		62.9		64.6		63.0		61.7	
SD	12.37		12.77		12.45		10.69		13.17	
Minimum	38		33		30		37		38	
Q1	56.0		54.0		58.0		55.0		53.0	
Median	64.0		62.0		63.0		64.0		61.0	
Q3	72.0		71.0		73.0		71.0		68.0	
Maximum	96		101		97		89		107	
Week 4										
N	97	97	103	103	100	100	103	103	80	80
Mean	64.5	0.5	67.3	4.4	70.3	5.7	70.0	6.9	67.6	5.9
SD	12.32	6.34	14.81	7.07	15.19	7.42	13.46	8.66	14.88	6.99
Minimum	34	-16	34	-17	36	-13	44	-12	31	-12
Q1	56.0	-3.0	56.0	-1.0	60.0	1.0	58.0	1.0	59.0	2.0
Median	64.0	1.0	67.0	4.0	70.0	6.0	72.0	7.0	66.0	6.0
Q3	74.0	5.0	76.0	10.0	78.0	11.0	80.0	13.0	76.0	10.0
Maximum	94	15	113	22	118	28	105	36	112	25
Week 8										
N	95	95	103	103	96	96	101	101	78	78
Mean	65.9	2.0	67.1	4.2	70.1	5.4	69.3	6.2	65.6	4.1
SD	12.84	6.82	14.23	7.61	14.71	7.78	14.52	10.55	13.52	6.87
Minimum	33	-17	37	-17	36	-13	25	-26	36	-11
Q1	58.0	-2.0	58.0	0.0	60.0	0.0	59.0	0.0	57.0	0.0
Median	66.0	2.0	65.0	4.0	68.0	5.0	69.0	6.0	66.0	4.0
Q3	75.0	7.0	75.0	9.0	78.0	11.0	79.0	10.0	74.0	8.0
Maximum	97	16	105	29	113	22	108	39	106	24
Week 12										
N	93	93	101	101	92	92	101	101	75	75
Mean	65.9	2.0	67.4	4.4	69.6	4.8	68.8	5.6	65.9	4.8
SD	13.29	7.23	14.39	8.27	13.37	8.53	14.04	10.03	13.82	7.76
Minimum	37	-17	38	-23	35	-17	36	-18	38	-21
Q1	57.0	-2.0	58.0	0.0	60.5	-3.0	58.0	-1.0	56.0	-1.0
Median	67.0	1.0	66.0	3.0	69.0	6.0	68.0	6.0	67.0	5.0
Q3	75.0	5.0	77.0	10.0	79.0	11.0	78.0	11.0	75.0	9.0
Maximum	101	17	104	31	97	25	107	37	113	27
Follow-up										
N	18	18	19	19	22	22	13	13	10	10
Mean	68.3	2.3	59.1	1.3	63.9	0.5	64.6	2.7	62.7	2.8
SD	16.27	7.89	12.25	11.59	13.57	7.20	9.92	7.76	12.52	9.08
Minimum	41	-13	39	-25	46	-13	50	-12	36	-12
Q1	62.0	-4.0	52.0	-7.0	55.0	-5.0	58.0	-3.0	53.0	-4.0
Median	66.0	3.5	60.0	3.0	59.5	0.5	63.0	3.0	66.0	3.0
Q3	78.0	10.0	70.0	9.0	71.0	7.0	71.0	9.0	72.0	9.0
Maximum	104	14	77	23	91	13	83	13	77	18

治験総括報告書 Table 3.3.1.1.1（Section 15.1）（5.3.5.4-1）から引用

表 2.7.4.8-付録-35　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-101 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: LDL Cholesterol (mg/dL)

Visit / Statistics	Placebo (N=97) Observed Value at Visit	Placebo (N=97) Change from Baseline	TAK-385 10mg (N=103) Observed Value at Visit	TAK-385 10mg (N=103) Change from Baseline	TAK-385 20mg (N=100) Observed Value at Visit	TAK-385 20mg (N=100) Change from Baseline	TAK-385 40mg (N=103) Observed Value at Visit	TAK-385 40mg (N=103) Change from Baseline	Leuprorelin (N=80) Observed Value at Visit	Leuprorelin (N=80) Change from Baseline
Baseline										
N	97		103		100		103		80	
Mean	102.9		99.9		98.9		101.2		107.8	
SD	26.31		22.77		22.93		27.22		26.01	
Minimum	49		42		54		41		58	
Q1	85.0		83.0		84.5		83.0		90.0	
Median	101.0		97.0		98.0		97.0		105.0	
Q3	120.0		113.0		109.0		117.0		122.0	
Maximum	197		166		184		215		194	
Week 4										
N	97	97	103	103	100	100	103	103	80	80
Mean	104.0	1.1	105.2	5.3	105.5	6.6	109.1	7.9	113.9	6.1
SD	26.60	12.71	24.87	11.73	25.58	13.04	32.03	15.16	27.78	14.13
Minimum	48	-42	38	-20	54	-39	53	-28	67	-24
Q1	85.0	-6.0	88.0	-3.0	89.0	-2.5	89.0	-3.0	93.0	-3.5
Median	102.0	0.0	101.0	6.0	104.5	7.0	102.0	8.0	112.0	5.0
Q3	121.0	8.0	124.0	14.0	119.5	15.5	123.0	15.0	128.0	15.0
Maximum	202	39	162	33	199	40	273	58	198	46
Week 8										
N	95	95	103	103	96	96	101	101	78	78
Mean	106.9	3.7	105.7	5.8	105.6	5.8	111.4	10.1	114.0	6.0
SD	27.97	14.72	26.10	14.52	25.13	12.23	31.50	15.83	28.98	15.17
Minimum	67	-31	46	-31	51	-24	50	-23	46	-39
Q1	85.0	-6.0	87.0	-4.0	90.0	-1.5	90.0	-2.0	91.0	-3.0
Median	102.0	4.0	104.0	7.0	105.0	5.0	104.0	9.0	110.0	6.5
Q3	120.0	12.0	123.0	15.0	122.0	14.5	129.0	22.0	133.0	16.0
Maximum	192	40	173	71	203	38	269	54	205	49
Week 12										
N	93	93	101	101	92	92	101	101	75	75
Mean	106.6	3.4	106.3	6.4	107.1	6.9	111.8	10.5	116.0	7.0
SD	31.25	16.35	25.74	14.24	26.21	15.24	32.06	16.83	29.17	13.93
Minimum	48	-31	51	-23	51	-28	52	-23	51	-29
Q1	84.0	-8.0	84.0	-2.0	89.0	-3.5	94.0	-3.0	95.0	-1.0
Median	98.0	3.0	109.0	5.0	106.5	7.0	105.0	11.0	117.0	6.0
Q3	124.0	10.0	120.0	14.0	121.5	18.5	126.0	20.0	134.0	16.0
Maximum	213	67	171	67	193	39	259	59	201	35
Follow-up										
N	18	18	19	19	22	22	13	13	10	10
Mean	110.8	6.1	113.2	6.1	91.1	2.9	96.3	-4.2	100.9	12.7
SD	31.27	14.71	25.26	16.80	20.14	10.80	18.53	18.97	27.20	16.08
Minimum	51	-16	74	-36	54	-24	66	-52	66	-4
Q1	89.0	-3.0	100.0	-5.0	81.0	-5.0	85.0	-16.0	78.0	3.0
Median	105.5	4.5	108.0	5.0	85.5	2.0	91.0	1.0	102.5	8.5
Q3	136.0	17.0	124.0	21.0	107.0	11.0	101.0	8.0	125.0	20.0
Maximum	158	42	179	33	131	22	128	18	141	46

治験総括報告書 Table 3.3.1.1.1（Section 15.1）（5.3.5.4-1）から引用

表 2.7.4.8-付録-35　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-101 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Triglycerides (mg/dL)

Visit / Statistics	Placebo (N=97) Observed Value at Visit	Placebo (N=97) Change from Baseline	TAK-385 10mg (N=103) Observed Value at Visit	TAK-385 10mg (N=103) Change from Baseline	TAK-385 20mg (N=100) Observed Value at Visit	TAK-385 20mg (N=100) Change from Baseline	TAK-385 40mg (N=103) Observed Value at Visit	TAK-385 40mg (N=103) Change from Baseline	Leuprorelin (N=80) Observed Value at Visit	Leuprorelin (N=80) Change from Baseline
Baseline										
N	97		103		100		103		80	
Mean	79.5		73.9		73.6		73.9		86.0	
SD	49.15		47.14		43.62		35.08		79.47	
Minimum	30		27		27		25		33	
Q1	47.0		46.0		46.5		46.0		54.0	
Median	65.0		62.0		59.0		65.0		70.0	
Q3	87.0		87.0		83.5		92.0		98.0	
Maximum	318		345		272		188		720	
Week 4										
N	97	97	103	103	100	100	103	103	80	80
Mean	76.4	-3.2	79.3	5.4	74.0	0.4	85.0	11.0	89.3	3.3
SD	46.12	41.82	54.37	31.86	41.63	37.52	56.89	48.58	55.01	82.04
Minimum	29	-246	24	-81	31	-138	27	-128	26	-625
Q1	50.0	-18.0	50.0	-9.0	48.5	-13.5	50.0	-9.0	58.0	-5.5
Median	63.0	1.0	67.0	3.0	64.0	4.0	69.0	4.0	73.5	7.5
Q3	87.0	13.0	87.0	21.0	92.5	18.0	99.0	26.0	100.0	25.0
Maximum	323	120	404	140	329	151	369	196	358	251
Week 8										
N	95	95	103	103	96	96	101	101	78	78
Mean	79.0	-0.7	76.6	2.8	78.9	4.0	83.0	9.5	94.6	8.1
SD	54.29	34.93	44.18	35.87	57.27	55.60	47.50	37.51	58.56	81.65
Minimum	23	-109	30	-92	27	-135	29	-129	30	-608
Q1	47.0	-19.0	50.0	-14.0	46.0	-13.0	50.0	-10.0	56.0	-10.0
Median	62.0	-3.0	68.0	2.0	66.0	1.0	68.0	4.0	78.0	4.5
Q3	88.0	14.0	84.0	16.0	85.5	15.0	96.0	28.0	106.0	41.0
Maximum	362	159	267	169	408	345	272	120	353	198
Week 12										
N	93	93	101	101	92	92	101	101	75	75
Mean	76.1	-4.2	81.3	7.6	77.1	1.4	87.8	14.3	89.9	2.0
SD	42.92	38.09	56.14	37.95	38.11	43.97	52.51	46.04	48.91	79.60
Minimum	25	-137	30	-100	33	-186	31	-144	30	-606
Q1	47.0	-19.0	51.0	-11.0	47.0	-15.5	52.0	-8.0	53.0	-12.0
Median	66.0	0.0	63.0	4.0	68.0	3.0	75.0	11.0	76.0	7.0
Q3	90.0	13.0	90.0	20.0	92.0	20.0	107.0	36.0	114.0	27.0
Maximum	213	97	408	140	185	112	360	211	264	109
Follow-up										
N	18	18	19	19	22	22	13	13	10	10
Mean	90.3	8.8	76.4	-11.4	77.3	21.6	79.3	12.4	92.1	18.8
SD	59.72	39.93	29.87	30.48	44.80	43.19	37.67	31.61	46.07	40.02
Minimum	40	-64	36	-96	31	-25	30	-18	43	-28
Q1	55.0	-8.0	66.0	-18.0	45.0	-11.0	58.0	-2.0	55.0	-9.0
Median	67.0	-2.0	69.0	-5.0	62.0	7.0	68.0	2.0	83.5	9.5
Q3	103.0	29.0	83.0	8.0	98.0	50.0	86.0	9.0	132.0	34.0
Maximum	286	102	164	20	228	168	157	92	182	98

治験総括報告書 Table 3.3.1.1.1（Section 15.1）（5.3.5.4-1）から引用

表 2.7.4.8-付録-35　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-101 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Glucose (mg/dL)

Visit / Statistics	Placebo (N=97)		TAK-385 10mg (N=103)		TAK-385 20mg (N=100)		TAK-385 40mg (N=103)		Leuprorelin (N=80)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Baseline										
N	97		103		100		103		80	
Mean	93.5		93.7		93.0		92.1		91.8	
SD	11.91		21.02		13.90		12.46		10.12	
Minimum	69		75		74		73		63	
Q1	86.0		86.0		86.0		86.0		86.5	
Median	91.0		92.0		91.0		90.0		91.0	
Q3	99.0		96.0		95.0		94.0		97.0	
Maximum	130		282		183		181		125	
Week 4										
N	97	97	103	103	100	100	103	103	80	80
Mean	95.2	1.7	95.2	1.5	89.1	-3.9	92.2	0.1	93.1	1.3
SD	21.91	20.68	22.35	10.76	9.14	14.12	7.68	12.42	12.96	13.36
Minimum	56	-42	71	-22	59	-94	59	-87	57	-43
Q1	87.0	-5.0	87.0	-4.0	84.0	-6.5	88.0	-4.0	87.0	-4.0
Median	91.0	0.0	91.0	1.0	89.0	-1.0	92.0	2.0	92.0	1.0
Q3	98.0	5.0	98.0	4.0	94.0	3.0	97.0	5.0	97.5	6.5
Maximum	276	172	284	51	114	26	111	24	152	58
Week 8										
N	95	95	103	103	96	96	101	101	78	78
Mean	95.8	2.2	94.1	0.4	91.6	-1.8	91.6	-0.7	92.9	0.9
SD	19.67	18.58	18.59	11.90	9.80	15.36	8.45	12.19	8.71	11.07
Minimum	60	-37	63	-44	62	-79	69	-90	66	-42
Q1	87.0	-4.0	86.0	-5.0	86.0	-6.0	87.0	-4.0	87.0	-3.0
Median	94.0	0.0	91.0	0.0	91.0	0.5	91.0	1.0	91.5	2.0
Q3	99.0	7.0	99.0	6.0	96.5	6.0	96.0	5.0	97.0	6.0
Maximum	239	135	238	66	121	32	127	15	118	35
Week 12										
N	93	93	101	101	92	92	101	101	75	75
Mean	93.8	0.5	94.9	1.0	90.6	-2.8	91.7	-0.6	93.5	1.2
SD	16.79	15.66	18.18	13.88	11.71	16.47	7.74	13.43	9.76	11.91
Minimum	66	-38	64	-54	59	-92	72	-97	64	-41
Q1	86.0	-5.0	87.0	-5.0	84.0	-5.0	88.0	-3.0	88.0	-3.0
Median	90.0	0.0	92.0	0.0	90.0	-1.5	91.0	1.0	94.0	1.0
Q3	97.0	7.0	98.0	5.0	95.0	4.0	95.0	6.0	98.0	7.0
Maximum	213	109	228	57	134	36	120	32	137	41
Follow-up										
N	18	18	19	19	22	22	13	13	10	10
Mean	92.6	1.3	93.6	1.1	89.7	-0.4	91.7	2.8	92.8	4.0
SD	14.81	18.96	15.36	9.09	12.69	11.40	6.82	5.34	9.17	12.14
Minimum	75	-45	79	-14	68	-29	80	-10	81	-10
Q1	83.0	-7.0	85.0	-4.0	79.0	-10.0	90.0	0.0	87.0	-5.0
Median	90.5	0.0	92.0	1.0	89.5	1.0	92.0	4.0	91.0	2.0
Q3	100.0	8.0	94.0	4.0	99.0	8.0	96.0	7.0	97.0	10.0
Maximum	137	46	153	29	125	16	104	9	111	31

治験総括報告書 Table 3.3.1.1.1（Section 15.1）（5.3.5.4-1）から引用

表 2.7.4.8-付録-35　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-101 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Creatinine (mg/dL)

Visit / Statistics	Placebo (N=97)		TAK-385 10mg (N=103)		TAK-385 20mg (N=100)		TAK-385 40mg (N=103)		Leuprorelin (N=80)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Baseline										
N	97		103		100		103		80	
Mean	0.588		0.598		0.580		0.594		0.605	
SD	0.0769		0.0873		0.0781		0.0738		0.0881	
Minimum	0.41		0.43		0.41		0.43		0.43	
Q1	0.540		0.530		0.525		0.540		0.535	
Median	0.590		0.600		0.575		0.580		0.605	
Q3	0.630		0.660		0.635		0.640		0.670	
Maximum	0.87		0.82		0.75		0.90		0.83	
Week 4										
N	97	97	103	103	100	100	103	103	80	80
Mean	0.586	-0.002	0.614	0.015	0.597	0.018	0.618	0.023	0.619	0.014
SD	0.0823	0.0485	0.0890	0.0519	0.0821	0.0464	0.0769	0.0467	0.0829	0.0514
Minimum	0.39	-0.15	0.43	-0.15	0.42	-0.08	0.41	-0.10	0.46	-0.13
Q1	0.530	-0.020	0.550	-0.010	0.540	-0.015	0.570	-0.010	0.550	-0.020
Median	0.590	0.000	0.600	0.020	0.595	0.020	0.610	0.020	0.610	0.020
Q3	0.640	0.030	0.670	0.050	0.645	0.040	0.660	0.060	0.675	0.050
Maximum	0.86	0.10	0.89	0.15	0.82	0.18	0.82	0.14	0.82	0.15
Week 8										
N	95	95	103	103	96	96	101	101	78	78
Mean	0.590	0.001	0.612	0.013	0.600	0.020	0.612	0.016	0.618	0.015
SD	0.0771	0.0453	0.0843	0.0565	0.0897	0.0513	0.0802	0.0505	0.0832	0.0438
Minimum	0.44	-0.10	0.43	-0.19	0.44	-0.13	0.45	-0.09	0.45	-0.09
Q1	0.540	-0.030	0.560	-0.020	0.525	-0.015	0.560	-0.020	0.550	-0.010
Median	0.590	0.010	0.620	0.010	0.590	0.020	0.610	0.010	0.620	0.020
Q3	0.640	0.030	0.670	0.050	0.665	0.050	0.660	0.050	0.690	0.050
Maximum	0.86	0.11	0.83	0.13	0.85	0.16	0.88	0.15	0.84	0.10
Week 12										
N	93	93	101	101	92	92	101	101	75	75
Mean	0.590	0.000	0.613	0.015	0.600	0.019	0.610	0.014	0.616	0.014
SD	0.0796	0.0472	0.0819	0.0502	0.0862	0.0480	0.0740	0.0513	0.0853	0.0467
Minimum	0.43	-0.12	0.44	-0.10	0.42	-0.09	0.47	-0.09	0.41	-0.10
Q1	0.540	-0.030	0.550	-0.020	0.540	-0.010	0.560	-0.030	0.560	-0.020
Median	0.590	0.000	0.610	0.010	0.600	0.020	0.600	0.020	0.620	0.020
Q3	0.630	0.030	0.670	0.050	0.650	0.050	0.650	0.050	0.670	0.040
Maximum	0.91	0.15	0.85	0.14	0.81	0.15	0.86	0.21	0.85	0.15
Follow-up										
N	18	18	19	19	22	22	13	13	10	10
Mean	0.608	0.023	0.595	0.011	0.596	0.015	0.576	-0.022	0.662	0.033
SD	0.0552	0.0363	0.0710	0.0585	0.0965	0.0533	0.0481	0.0564	0.0875	0.0427
Minimum	0.51	-0.04	0.46	-0.09	0.43	-0.07	0.49	-0.17	0.54	-0.03
Q1	0.570	0.000	0.580	-0.040	0.530	-0.020	0.540	-0.030	0.580	0.010
Median	0.595	0.015	0.610	0.020	0.580	0.005	0.580	0.000	0.670	0.020
Q3	0.640	0.060	0.630	0.060	0.660	0.060	0.620	0.010	0.720	0.070
Maximum	0.72	0.07	0.73	0.12	0.80	0.13	0.64	0.04	0.79	0.11

治験総括報告書 Table 3.3.1.1.1（Section 15.1）（5.3.5.4-1）から引用

表 2.7.4.8-付録-35　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-101 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Blood Urea Nitrogen (mg/dL)

Visit / Statistics	Placebo (N=97)		TAK-385 10mg (N=103)		TAK-385 20mg (N=100)		TAK-385 40mg (N=103)		Leuprorelin (N=80)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Baseline										
N	97		103		100		103		80	
Mean	11.17		10.95		11.32		10.63		10.60	
SD	3.073		2.475		2.733		2.660		2.363	
Minimum	4.8		6.1		5.2		5.5		4.6	
Q1	9.10		9.10		9.45		8.70		8.85	
Median	11.00		10.40		11.05		10.50		10.55	
Q3	13.10		12.90		13.00		12.10		12.05	
Maximum	19.4		17.0		22.6		21.9		18.0	
Week 4										
N	97	97	103	103	100	100	103	103	80	80
Mean	11.06	-0.11	11.66	0.71	12.38	1.06	11.93	1.31	12.00	1.41
SD	2.978	2.525	2.447	2.516	2.909	2.739	2.750	2.504	2.934	2.573
Minimum	4.9	-6.5	6.2	-5.1	6.0	-6.1	4.7	-3.7	6.7	-4.5
Q1	8.80	-1.50	9.80	-0.80	10.10	-0.70	10.20	-0.60	9.95	-0.70
Median	10.50	0.00	11.70	0.90	12.10	1.05	11.60	1.20	11.80	1.40
Q3	12.60	1.50	13.40	2.50	14.05	2.60	13.50	3.00	14.20	3.30
Maximum	20.0	6.0	17.7	5.8	19.5	8.2	21.1	10.0	18.2	8.4
Week 8										
N	95	95	103	103	96	96	101	101	78	78
Mean	11.00	-0.12	11.83	0.89	11.99	0.67	12.09	1.46	12.16	1.53
SD	2.901	2.641	2.674	2.527	2.856	2.668	2.863	2.708	2.990	2.608
Minimum	5.6	-8.5	6.8	-4.1	6.2	-7.2	6.2	-4.9	5.4	-3.6
Q1	8.80	-1.90	9.80	-0.80	10.05	-1.25	10.30	-0.40	10.40	-0.40
Median	10.70	-0.20	11.60	1.00	11.85	0.85	11.80	1.50	11.80	1.80
Q3	13.00	1.30	13.70	2.30	13.30	2.20	14.00	3.30	13.80	3.40
Maximum	19.9	8.5	19.1	9.4	19.9	7.0	19.3	9.3	20.0	7.7
Week 12										
N	93	93	101	101	92	92	101	101	75	75
Mean	10.82	-0.30	11.82	0.91	12.23	0.84	11.88	1.26	12.03	1.34
SD	2.946	2.357	2.706	2.767	2.785	2.458	3.017	2.508	3.148	2.551
Minimum	4.8	-9.1	6.0	-5.7	6.6	-5.5	6.6	-4.0	6.0	-3.5
Q1	8.80	-1.80	10.00	-0.80	10.40	-0.65	9.50	-0.60	9.80	-0.60
Median	10.80	-0.20	11.50	0.90	12.05	0.70	11.50	1.20	11.30	0.90
Q3	12.40	1.30	13.60	2.60	13.80	2.40	13.70	3.00	13.70	2.90
Maximum	20.6	5.1	18.6	8.8	22.0	7.3	20.5	7.7	23.0	10.6
Follow-up										
N	18	18	19	19	22	22	13	13	10	10
Mean	12.01	-0.32	11.09	0.15	10.84	0.69	11.56	0.79	12.74	2.29
SD	3.179	2.270	3.298	2.602	2.687	2.252	2.340	2.515	3.313	4.327
Minimum	5.9	-4.2	7.0	-2.9	5.7	-4.2	8.5	-2.5	7.8	-4.8
Q1	9.30	-2.00	7.80	-1.70	8.90	-0.50	10.30	-1.10	9.50	-1.50
Median	13.30	-0.60	10.90	0.00	10.85	0.90	11.10	0.10	13.25	2.95
Q3	14.60	1.20	12.90	1.10	12.60	2.90	11.90	2.70	15.40	4.80
Maximum	16.4	4.5	19.3	7.5	15.9	3.6	16.6	5.8	17.4	9.2

治験総括報告書 Table 3.3.1.1.1（Section 15.1）（5.3.5.4-1）から引用

表 2.7.4.8-付録-35　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-101 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: CK (CPK) (U/L)

	Placebo (N=97)		TAK-385 10mg (N=103)		TAK-385 20mg (N=100)		TAK-385 40mg (N=103)		Leuprorelin (N=80)	
Visit / Statistics	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Baseline										
N	97		103		100		103		80	
Mean	82.8		80.6		75.7		73.0		78.0	
SD	53.59		29.23		26.39		27.80		27.39	
Minimum	33		34		28		26		25	
Q1	56.0		60.0		59.0		57.0		61.0	
Median	70.0		76.0		68.5		70.0		74.5	
Q3	89.0		96.0		90.5		83.0		90.0	
Maximum	500		164		173		258		208	
Week 4										
N	97	97	103	103	100	100	103	103	80	80
Mean	90.8	8.1	86.8	6.3	80.3	4.6	97.5	24.5	87.2	9.2
SD	137.04	135.92	46.18	38.54	35.26	24.26	89.80	88.76	37.00	27.10
Minimum	34	-299	36	-65	30	-109	35	-23	27	-24
Q1	58.0	-11.0	62.0	-9.0	60.0	-7.0	65.0	0.0	65.0	-5.5
Median	73.0	-2.0	78.0	-1.0	73.5	2.0	77.0	10.0	77.0	4.5
Q3	87.0	8.0	105.0	13.0	88.5	13.0	101.0	21.0	100.0	16.0
Maximum	1393	1287	395	279	245	125	844	792	267	191
Week 8										
N	95	95	103	103	96	96	101	101	78	78
Mean	78.7	-4.5	80.4	-0.1	80.1	3.8	85.3	12.1	86.2	8.4
SD	43.04	39.77	32.17	25.11	33.71	26.29	50.87	43.03	41.12	25.16
Minimum	32	-272	29	-79	27	-97	21	-104	26	-25
Q1	55.0	-15.0	60.0	-9.0	58.5	-6.5	63.0	-3.0	62.0	-7.0
Median	70.0	-1.0	74.0	0.0	73.5	2.0	75.0	6.0	74.0	4.0
Q3	85.0	8.0	94.0	10.0	89.0	12.0	94.0	18.0	100.0	13.0
Maximum	333	142	239	113	235	137	500	341	313	136
Week 12										
N	93	93	101	101	92	92	101	101	75	75
Mean	216.1	132.1	83.7	2.6	85.6	10.4	80.1	6.9	84.7	6.8
SD	1320.65	1323.71	33.08	27.89	67.73	55.76	34.36	20.56	38.01	19.82
Minimum	33	-326	26	-64	29	-51	28	-33	23	-27
Q1	57.0	-12.0	62.0	-9.0	62.0	-5.5	58.0	-8.0	61.0	-6.0
Median	67.0	-1.0	80.0	3.0	73.5	3.0	75.0	4.0	80.0	5.0
Q3	86.0	8.0	101.0	15.0	90.5	12.5	91.0	13.0	95.0	17.0
Maximum	12810	12754	250	168	654	496	266	80	293	85
Follow-up										
N	18	18	19	19	22	22	13	13	10	10
Mean	97.9	15.4	81.2	4.4	65.7	-12.6	60.8	-4.3	86.9	8.8
SD	82.89	89.06	34.23	12.13	24.62	31.24	23.16	16.30	61.81	51.58
Minimum	43	-118	38	-19	40	-122	30	-25	27	-34
Q1	59.0	-12.0	51.0	-4.0	51.0	-14.0	44.0	-14.0	60.0	-12.0
Median	79.0	2.5	80.0	4.0	55.5	-5.0	63.0	-5.0	79.0	-6.5
Q3	102.0	19.0	96.0	12.0	75.0	2.0	68.0	4.0	90.0	13.0
Maximum	410	340	157	24	130	23	113	37	249	149

治験総括報告書 Table 3.3.1.1.1（Section 15.1）（5.3.5.4-1）から引用

表 2.7.4.8-付録-35　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-101 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Uric Acid (mg/dL)

Visit / Statistics	Placebo (N=97)		TAK-385 10mg (N=103)		TAK-385 20mg (N=100)		TAK-385 40mg (N=103)		Leuprorelin (N=80)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Baseline										
N	97		103		100		103		80	
Mean	3.91		3.89		3.91		3.89		4.03	
SD	0.965		0.900		0.839		0.825		0.812	
Minimum	1.8		1.6		1.8		1.5		1.8	
Q1	3.20		3.30		3.45		3.30		3.55	
Median	3.90		3.80		3.80		4.00		4.05	
Q3	4.40		4.30		4.30		4.40		4.60	
Maximum	7.0		6.8		6.4		6.4		6.3	
Week 4										
N	97	97	103	103	100	100	103	103	80	80
Mean	3.94	0.03	4.11	0.22	4.22	0.31	4.28	0.39	4.23	0.20
SD	0.872	0.481	0.917	0.553	0.875	0.599	0.907	0.636	0.768	0.458
Minimum	2.0	-1.3	2.3	-1.2	1.7	-1.2	1.6	-1.0	2.5	-1.0
Q1	3.40	-0.30	3.50	-0.20	3.70	-0.05	3.60	0.00	3.80	-0.05
Median	3.90	0.10	3.90	0.20	4.10	0.20	4.30	0.30	4.20	0.20
Q3	4.50	0.30	4.50	0.50	4.55	0.70	4.80	0.80	4.80	0.50
Maximum	6.8	1.7	7.9	2.3	7.7	2.0	8.1	2.4	6.1	1.3
Week 8										
N	95	95	103	103	96	96	101	101	78	78
Mean	3.93	0.01	4.10	0.21	4.26	0.32	4.37	0.48	4.18	0.15
SD	0.974	0.563	0.972	0.687	0.880	0.567	0.904	0.607	0.697	0.514
Minimum	1.9	-1.5	2.2	-2.6	2.3	-1.0	2.0	-1.1	2.3	-0.9
Q1	3.30	-0.30	3.40	-0.20	3.70	-0.10	3.80	0.10	3.80	-0.20
Median	3.90	0.10	4.10	0.20	4.20	0.30	4.30	0.40	4.30	0.10
Q3	4.70	0.40	4.60	0.70	4.50	0.65	4.90	0.90	4.60	0.50
Maximum	5.8	1.2	6.9	1.7	8.7	2.4	7.0	2.4	5.7	1.6
Week 12										
N	93	93	101	101	92	92	101	101	75	75
Mean	3.89	-0.05	4.11	0.23	4.23	0.30	4.45	0.57	4.31	0.28
SD	0.918	0.486	0.972	0.619	0.809	0.582	0.916	0.650	0.762	0.591
Minimum	1.9	-1.2	1.9	-1.0	2.6	-1.1	1.6	-1.2	2.4	-1.3
Q1	3.40	-0.40	3.50	-0.20	3.75	-0.10	3.70	0.10	3.80	-0.10
Median	3.90	0.00	4.10	0.20	4.10	0.30	4.50	0.50	4.40	0.40
Q3	4.40	0.30	4.60	0.70	4.55	0.70	5.00	0.80	4.80	0.60
Maximum	6.6	1.0	7.3	1.9	7.5	1.8	7.7	2.7	5.9	2.3
Follow-up										
N	18	18	19	19	22	22	13	13	10	10
Mean	3.99	0.19	4.25	0.16	3.67	-0.01	4.05	0.15	4.38	0.56
SD	1.045	0.447	0.984	0.431	0.546	0.385	0.859	0.782	0.405	0.341
Minimum	2.1	-0.4	2.4	-0.5	2.2	-1.0	2.7	-0.7	3.4	0.1
Q1	3.70	-0.10	3.60	-0.10	3.40	-0.20	3.60	-0.20	4.30	0.30
Median	4.05	0.15	4.00	0.10	3.70	-0.05	4.10	0.00	4.50	0.55
Q3	4.50	0.40	4.90	0.40	4.00	0.20	4.50	0.30	4.50	0.70
Maximum	6.1	1.3	6.7	1.0	4.6	0.7	5.8	2.4	4.9	1.2

治験総括報告書 Table 3.3.1.1.1（Section 15.1）（5.3.5.4-1）から引用

表 2.7.4.8-付録-35　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-101 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Sodium (mEq/L)

Visit / Statistics	Placebo (N=97)		TAK-385 10mg (N=103)		TAK-385 20mg (N=100)		TAK-385 40mg (N=103)		Leuprorelin (N=80)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Baseline										
N	97		103		100		103		80	
Mean	141.3		141.3		141.2		141.4		141.2	
SD	1.39		1.21		1.25		1.40		1.41	
Minimum	138		138		138		138		137	
Q1	140.0		140.0		140.0		140.0		140.0	
Median	141.0		141.0		141.0		141.0		141.0	
Q3	142.0		142.0		142.0		142.0		142.0	
Maximum	145		144		144		146		145	
Week 4										
N	97	97	103	103	100	100	103	103	80	80
Mean	140.8	-0.5	141.0	-0.3	141.5	0.3	141.8	0.4	142.0	0.9
SD	1.40	1.77	1.49	1.60	1.53	1.56	1.47	1.62	1.51	1.69
Minimum	138	-5	136	-5	139	-4	139	-3	139	-3
Q1	140.0	-1.0	140.0	-2.0	140.0	-1.0	141.0	-1.0	141.0	0.0
Median	141.0	0.0	141.0	0.0	141.0	0.0	142.0	1.0	142.0	1.0
Q3	142.0	1.0	142.0	1.0	142.0	1.0	143.0	1.0	143.0	2.0
Maximum	144	4	144	3	145	4	146	6	147	6
Week 8										
N	95	95	103	103	96	96	101	101	78	78
Mean	140.4	-0.8	141.2	-0.1	141.6	0.4	142.0	0.6	142.1	1.0
SD	1.39	1.83	1.59	1.72	1.58	1.75	1.33	1.67	1.59	1.59
Minimum	137	-5	138	-5	137	-4	138	-4	138	-3
Q1	140.0	-2.0	140.0	-1.0	141.0	-1.0	141.0	0.0	141.0	0.0
Median	140.0	-1.0	141.0	0.0	141.0	0.0	142.0	1.0	142.0	1.0
Q3	141.0	0.0	142.0	1.0	142.0	1.5	143.0	2.0	143.0	2.0
Maximum	145	3	145	4	147	5	146	5	146	5
Week 12										
N	93	93	101	101	92	92	101	101	75	75
Mean	140.6	-0.7	141.1	-0.2	141.6	0.5	142.1	0.7	142.1	1.0
SD	1.48	1.70	1.50	1.53	1.45	1.58	1.49	1.67	1.34	1.56
Minimum	137	-4	137	-4	138	-4	139	-4	139	-2
Q1	140.0	-2.0	140.0	-1.0	141.0	0.0	141.0	0.0	141.0	0.0
Median	140.0	-1.0	141.0	0.0	142.0	1.0	142.0	1.0	142.0	1.0
Q3	141.0	0.0	142.0	1.0	143.0	2.0	143.0	2.0	143.0	2.0
Maximum	148	4	146	3	145	3	146	5	146	4
Follow-up										
N	18	18	19	19	22	22	13	13	10	10
Mean	140.7	-0.6	140.6	-0.8	140.7	-0.7	140.5	-0.9	141.1	-0.8
SD	1.23	1.75	1.50	1.74	1.49	1.81	1.51	2.10	1.73	1.75
Minimum	139	-4	138	-4	137	-5	139	-5	138	-4
Q1	140.0	-2.0	140.0	-2.0	140.0	-2.0	139.0	-2.0	140.0	-2.0
Median	141.0	-1.0	141.0	-1.0	141.0	-0.5	140.0	-1.0	142.0	-0.5
Q3	142.0	1.0	141.0	1.0	142.0	0.0	141.0	0.0	142.0	0.0
Maximum	142	2	144	2	143	3	144	3	143	2

治験総括報告書 Table 3.3.1.1.1（Section 15.1）（5.3.5.4-1）から引用

表 2.7.4.8-付録-35　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-101 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Potassium (mEq/L)

Visit / Statistics	Placebo (N=97)		TAK-385 10mg (N=103)		TAK-385 20mg (N=100)		TAK-385 40mg (N=103)		Leuprorelin (N=80)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Baseline										
N	97		103		100		103		80	
Mean	4.05		4.06		4.07		4.06		4.08	
SD	0.271		0.287		0.277		0.278		0.343	
Minimum	3.5		3.4		3.5		3.5		3.2	
Q1	3.90		3.90		3.90		3.90		3.80	
Median	4.00		4.00		4.00		4.00		4.10	
Q3	4.20		4.20		4.25		4.30		4.30	
Maximum	4.9		5.0		4.9		4.9		4.9	
Week 4										
N	97	97	103	103	100	100	103	103	80	80
Mean	4.03	-0.02	4.14	0.07	4.14	0.07	4.17	0.11	4.15	0.07
SD	0.283	0.344	0.274	0.307	0.278	0.247	0.293	0.308	0.299	0.325
Minimum	3.5	-1.0	3.5	-1.0	3.6	-0.5	3.5	-0.8	3.4	-0.7
Q1	3.80	-0.30	4.00	-0.10	3.90	-0.10	4.00	-0.10	3.95	-0.20
Median	4.00	0.00	4.10	0.10	4.10	0.10	4.10	0.10	4.20	0.10
Q3	4.20	0.20	4.30	0.30	4.30	0.20	4.30	0.30	4.30	0.30
Maximum	5.0	0.8	4.8	0.8	4.8	0.7	5.0	1.3	5.1	0.7
Week 8										
N	95	95	103	103	96	96	101	101	78	78
Mean	4.09	0.04	4.11	0.05	4.11	0.05	4.17	0.11	4.18	0.11
SD	0.317	0.344	0.279	0.274	0.293	0.321	0.307	0.292	0.291	0.371
Minimum	3.4	-1.1	3.6	-0.9	3.5	-0.8	3.6	-0.5	3.6	-1.0
Q1	3.90	-0.10	3.90	-0.10	3.90	-0.20	4.00	-0.10	4.00	-0.10
Median	4.10	0.10	4.10	0.10	4.10	0.00	4.10	0.10	4.10	0.10
Q3	4.30	0.20	4.30	0.20	4.20	0.25	4.30	0.30	4.30	0.30
Maximum	5.2	1.0	4.9	0.8	5.3	0.8	5.1	0.9	5.0	1.5
Week 12										
N	93	93	100	100	92	92	101	101	75	75
Mean	4.06	0.01	4.09	0.03	4.14	0.07	4.16	0.10	4.11	0.04
SD	0.289	0.307	0.275	0.244	0.313	0.273	0.283	0.279	0.252	0.285
Minimum	3.3	-0.7	3.6	-0.5	3.4	-0.7	3.5	-0.6	3.4	-0.7
Q1	3.90	-0.20	3.90	-0.10	4.00	-0.10	3.90	-0.10	3.90	-0.10
Median	4.00	0.00	4.10	0.00	4.10	0.05	4.10	0.10	4.10	0.10
Q3	4.20	0.20	4.30	0.20	4.30	0.20	4.30	0.20	4.30	0.20
Maximum	4.8	0.9	4.8	0.8	5.3	0.9	4.9	1.1	4.6	0.7
Follow-up										
N	18	18	19	19	22	22	13	13	10	10
Mean	4.11	-0.05	4.02	-0.05	4.09	0.04	4.37	0.10	4.10	-0.07
SD	0.286	0.349	0.288	0.334	0.272	0.303	0.287	0.332	0.170	0.400
Minimum	3.7	-0.9	3.4	-0.7	3.6	-0.4	3.9	-0.5	3.9	-0.7
Q1	3.90	-0.10	3.80	-0.30	3.80	-0.30	4.30	-0.10	4.00	-0.50
Median	4.05	-0.05	4.10	-0.10	4.10	0.10	4.40	0.10	4.00	0.05
Q3	4.20	0.20	4.30	0.20	4.30	0.30	4.50	0.30	4.30	0.20
Maximum	4.8	0.5	4.5	0.6	4.5	0.5	4.9	0.7	4.4	0.5

治験総括報告書 Table 3.3.1.1.1（Section 15.1）（5.3.5.4-1）から引用

表 2.7.4.8-付録-35　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-101 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Chloride (mEq/L)

	Placebo (N=97)		TAK-385 10mg (N=103)		TAK-385 20mg (N=100)		TAK-385 40mg (N=103)		Leuprorelin (N=80)	
Visit / Statistics	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Baseline										
N	97		103		100		103		80	
Mean	106.2		106.6		106.5		106.4		106.0	
SD	2.00		1.80		1.99		1.96		1.97	
Minimum	98		103		101		102		97	
Q1	105.0		105.0		105.0		105.0		105.0	
Median	106.0		107.0		106.5		107.0		106.0	
Q3	107.0		107.0		108.0		108.0		107.0	
Maximum	110		112		111		111		110	
Week 4										
N	97	97	103	103	100	100	103	103	80	80
Mean	106.1	-0.1	106.1	-0.5	106.0	-0.5	105.9	-0.5	105.7	-0.3
SD	1.93	2.35	1.97	2.05	1.94	2.20	1.65	2.20	2.02	2.30
Minimum	102	-5	99	-5	102	-6	101	-6	101	-4
Q1	105.0	-2.0	105.0	-2.0	104.0	-2.0	105.0	-2.0	104.5	-2.0
Median	106.0	0.0	106.0	-1.0	106.0	0.0	106.0	0.0	106.0	-1.0
Q3	107.0	1.0	107.0	1.0	107.0	1.0	107.0	1.0	107.0	1.0
Maximum	111	10	110	4	110	5	110	4	112	12
Week 8										
N	95	95	103	103	96	96	101	101	78	78
Mean	105.7	-0.4	106.1	-0.5	106.0	-0.5	105.8	-0.6	105.8	-0.2
SD	1.89	2.52	1.80	2.20	1.92	2.38	2.26	2.48	2.01	2.23
Minimum	101	-6	102	-6	100	-7	98	-9	100	-5
Q1	104.0	-2.0	105.0	-2.0	105.0	-2.0	105.0	-2.0	105.0	-1.0
Median	106.0	-1.0	106.0	0.0	106.0	0.0	106.0	-1.0	106.0	0.0
Q3	107.0	1.0	107.0	0.0	107.5	1.0	107.0	1.0	107.0	1.0
Maximum	110	10	111	6	110	5	111	7	111	9
Week 12										
N	93	93	101	101	92	92	101	101	75	75
Mean	104.0	-2.1	103.8	-2.7	103.8	-2.6	103.7	-2.7	103.8	-2.2
SD	1.84	2.18	1.71	2.01	1.89	2.30	2.02	2.22	1.98	2.31
Minimum	100	-7	101	-8	100	-9	98	-8	100	-7
Q1	103.0	-3.0	103.0	-4.0	102.0	-4.0	102.0	-4.0	102.0	-4.0
Median	104.0	-2.0	104.0	-3.0	104.0	-3.0	104.0	-3.0	104.0	-2.0
Q3	105.0	-1.0	105.0	-1.0	105.0	-1.0	105.0	-1.0	105.0	-1.0
Maximum	109	5	108	2	109	3	109	3	108	6
Follow-up										
N	18	18	19	19	22	22	13	13	10	10
Mean	105.9	-0.7	106.1	-0.4	106.3	-0.2	106.8	-0.2	105.2	-0.9
SD	1.75	1.78	1.82	1.95	2.12	1.59	1.88	2.58	2.10	3.00
Minimum	103	-4	102	-5	102	-3	104	-5	102	-7
Q1	105.0	-2.0	104.0	-1.0	105.0	-1.0	106.0	-2.0	104.0	-2.0
Median	105.0	-1.0	107.0	0.0	106.0	0.0	106.0	0.0	105.0	-1.0
Q3	107.0	1.0	107.0	1.0	108.0	1.0	109.0	2.0	107.0	1.0
Maximum	110	3	109	3	110	3	109	4	109	4

治験総括報告書 Table 3.3.1.1.1（Section 15.1）（5.3.5.4-1）から引用

表 2.7.4.8-付録-35　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-101 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Calcium (mg/dL)

Visit / Statistics	Placebo (N=97)		TAK-385 10mg (N=103)		TAK-385 20mg (N=100)		TAK-385 40mg (N=103)		Leuprorelin (N=80)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Baseline										
N	97		103		100		103		80	
Mean	8.93		8.94		8.95		8.93		9.00	
SD	0.346		0.263		0.322		0.344		0.331	
Minimum	8.1		8.3		8.0		8.2		8.4	
Q1	8.70		8.80		8.70		8.70		8.75	
Median	8.90		8.90		8.90		8.90		8.90	
Q3	9.10		9.10		9.20		9.10		9.20	
Maximum	9.8		9.6		9.8		10.2		9.9	
Week 4										
N	97	97	103	103	100	100	103	103	80	80
Mean	8.94	0.01	9.12	0.18	9.18	0.23	9.34	0.41	9.25	0.26
SD	0.319	0.332	0.309	0.334	0.364	0.335	0.329	0.337	0.326	0.346
Minimum	8.3	-0.8	8.3	-0.8	8.2	-0.7	8.4	-0.4	8.6	-0.9
Q1	8.70	-0.20	8.90	0.00	8.90	0.00	9.10	0.20	9.00	0.00
Median	8.90	0.00	9.20	0.20	9.20	0.20	9.30	0.40	9.20	0.25
Q3	9.20	0.20	9.30	0.40	9.40	0.50	9.60	0.70	9.40	0.50
Maximum	9.8	1.0	9.7	0.8	10.0	1.0	10.1	1.1	10.4	1.0
Week 8										
N	95	95	103	103	96	96	101	101	78	78
Mean	9.02	0.09	9.08	0.13	9.21	0.26	9.42	0.48	9.36	0.38
SD	0.326	0.339	0.304	0.314	0.350	0.305	0.304	0.359	0.322	0.358
Minimum	8.2	-0.6	8.3	-0.7	8.4	-0.4	8.7	-0.5	8.8	-0.4
Q1	8.80	-0.20	8.80	-0.10	9.00	0.05	9.20	0.30	9.20	0.10
Median	9.00	0.10	9.00	0.20	9.20	0.30	9.40	0.50	9.35	0.40
Q3	9.30	0.30	9.30	0.40	9.40	0.40	9.60	0.70	9.60	0.60
Maximum	9.7	0.9	9.9	0.8	10.1	1.5	10.2	1.3	10.7	1.3
Week 12										
N	93	93	100	100	92	92	101	101	75	75
Mean	8.97	0.03	9.09	0.15	9.22	0.27	9.43	0.50	9.36	0.38
SD	0.346	0.337	0.316	0.310	0.351	0.348	0.335	0.360	0.294	0.316
Minimum	8.2	-0.7	8.3	-0.6	8.4	-0.4	8.4	-0.4	8.6	-0.4
Q1	8.70	-0.20	8.90	-0.10	9.00	0.00	9.20	0.30	9.20	0.20
Median	8.90	0.00	9.10	0.20	9.20	0.30	9.50	0.50	9.30	0.30
Q3	9.20	0.30	9.35	0.40	9.50	0.50	9.60	0.70	9.50	0.70
Maximum	9.8	0.8	9.8	1.1	10.1	1.4	10.2	1.2	10.6	1.0
Follow-up										
N	18	18	19	19	22	22	13	13	10	10
Mean	8.97	0.09	8.99	0.04	8.93	0.06	9.06	0.18	9.24	0.26
SD	0.281	0.354	0.291	0.304	0.415	0.287	0.247	0.300	0.272	0.401
Minimum	8.4	-0.5	8.3	-0.5	8.3	-0.7	8.7	-0.4	8.6	-0.4
Q1	8.80	-0.20	8.80	-0.20	8.70	-0.20	8.80	0.10	9.20	0.00
Median	9.00	0.15	9.00	0.10	8.90	0.10	9.10	0.20	9.25	0.45
Q3	9.20	0.40	9.20	0.30	9.10	0.30	9.20	0.30	9.40	0.60
Maximum	9.4	0.8	9.6	0.5	10.0	0.5	9.5	0.6	9.6	0.7

治験総括報告書 Table 3.3.1.1.1（Section 15.1）（5.3.5.4-1）から引用

表 2.7.4.8-付録-35　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-101 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Phosphorus (mg/dL)

Visit / Statistics	Placebo (N=97) Observed Value at Visit	Placebo (N=97) Change from Baseline	TAK-385 10mg (N=103) Observed Value at Visit	TAK-385 10mg (N=103) Change from Baseline	TAK-385 20mg (N=100) Observed Value at Visit	TAK-385 20mg (N=100) Change from Baseline	TAK-385 40mg (N=103) Observed Value at Visit	TAK-385 40mg (N=103) Change from Baseline	Leuprorelin (N=80) Observed Value at Visit	Leuprorelin (N=80) Change from Baseline
Baseline										
N	97		103		100		103		80	
Mean	3.62		3.59		3.62		3.60		3.61	
SD	0.494		0.428		0.426		0.461		0.489	
Minimum	2.5		2.4		2.7		2.0		2.7	
Q1	3.30		3.30		3.40		3.30		3.30	
Median	3.60		3.60		3.60		3.70		3.60	
Q3	3.90		3.90		3.80		4.00		3.90	
Maximum	5.0		4.6		5.0		4.7		4.9	
Week 4										
N	97	97	103	103	100	100	103	103	80	80
Mean	3.62	-0.01	3.67	0.08	3.82	0.20	4.03	0.43	3.95	0.34
SD	0.474	0.473	0.413	0.450	0.513	0.538	0.436	0.460	0.434	0.409
Minimum	2.6	-1.4	2.8	-0.9	2.7	-1.2	2.7	-0.5	3.0	-1.0
Q1	3.30	-0.30	3.40	-0.20	3.50	-0.10	3.80	0.10	3.70	0.10
Median	3.60	0.00	3.70	0.10	3.80	0.25	4.00	0.40	3.90	0.30
Q3	3.90	0.30	4.00	0.40	4.10	0.50	4.30	0.80	4.20	0.60
Maximum	4.7	1.0	4.6	1.3	5.0	1.4	5.5	1.8	5.2	1.2
Week 8										
N	95	95	103	103	96	96	101	101	78	78
Mean	3.62	0.00	3.64	0.05	3.87	0.24	4.08	0.47	4.10	0.49
SD	0.504	0.494	0.438	0.471	0.529	0.548	0.436	0.507	0.508	0.501
Minimum	2.4	-1.2	2.5	-1.7	2.8	-1.6	2.8	-0.7	3.1	-0.8
Q1	3.30	-0.40	3.40	-0.30	3.45	-0.15	3.80	0.10	3.70	0.20
Median	3.70	0.00	3.60	0.10	3.80	0.25	4.10	0.50	4.20	0.50
Q3	3.90	0.40	4.00	0.30	4.20	0.60	4.40	0.80	4.40	0.80
Maximum	5.1	1.1	4.8	1.2	5.0	1.6	5.1	1.6	5.4	1.7
Week 12										
N	93	93	100	100	92	92	101	101	75	75
Mean	3.60	-0.03	3.75	0.17	3.97	0.34	4.22	0.62	4.22	0.63
SD	0.533	0.501	0.407	0.441	0.512	0.543	0.471	0.551	0.481	0.464
Minimum	2.4	-1.0	2.5	-0.7	2.8	-1.0	3.0	-0.7	3.3	-0.5
Q1	3.20	-0.30	3.50	-0.20	3.60	-0.10	3.90	0.20	3.90	0.30
Median	3.60	-0.10	3.80	0.20	3.85	0.30	4.30	0.60	4.30	0.60
Q3	3.90	0.20	4.00	0.50	4.30	0.70	4.50	0.90	4.60	0.90
Maximum	5.4	1.8	4.6	1.2	5.2	1.8	5.5	1.9	5.6	1.7
Follow-up										
N	18	18	19	19	22	22	13	13	10	10
Mean	3.57	0.01	3.49	-0.10	3.66	0.10	3.78	0.12	3.91	0.01
SD	0.437	0.562	0.442	0.450	0.508	0.457	0.490	0.474	0.612	0.714
Minimum	2.8	-1.1	2.5	-1.2	2.8	-0.7	3.2	-0.9	3.1	-0.8
Q1	3.30	-0.30	3.20	-0.30	3.20	-0.10	3.40	-0.10	3.60	-0.80
Median	3.50	0.15	3.50	-0.20	3.60	0.10	3.70	0.20	3.70	0.15
Q3	4.00	0.30	4.00	0.20	4.10	0.40	3.90	0.30	4.10	0.40
Maximum	4.2	1.0	4.2	0.7	4.8	0.9	5.0	1.0	5.1	1.2

治験総括報告書 Table 3.3.1.1.1（Section 15.1）（5.3.5.4-1）から引用

表 2.7.4.8-付録-36　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（OCT-101 試験）

Laboratory Group: Serum Chemistry
Laboratory Test: ALT (GPT) (U/L)

Visit / Statistics	Placebo (N=97) Observed Value at Visit	Placebo (N=97) Change from Baseline	TAK-385 10mg (N=103) Observed Value at Visit	TAK-385 10mg (N=103) Change from Baseline	TAK-385 20mg (N=100) Observed Value at Visit	TAK-385 20mg (N=100) Change from Baseline	TAK-385 40mg (N=103) Observed Value at Visit	TAK-385 40mg (N=103) Change from Baseline	Leuprorelin (N=80) Observed Value at Visit	Leuprorelin (N=80) Change from Baseline
Baseline										
N	97		103		100		103		80	
Mean	12.5		13.6		12.2		12.6		14.3	
SD	4.68		6.25		3.98		4.31		5.79	
Minimum	6		6		7		7		6	
Q1	9.0		10.0		9.0		9.0		11.0	
Median	12.0		12.0		11.0		12.0		13.5	
Q3	14.0		15.0		14.0		14.0		17.0	
Maximum	35		40		24		29		48	
Week 4										
N	97	97	103	103	100	100	103	103	80	80
Mean	14.1	1.5	14.7	1.1	15.0	2.8	14.9	2.3	16.0	1.7
SD	5.86	4.55	7.41	5.79	6.86	5.51	6.52	5.01	7.55	5.85
Minimum	6	-11	8	-13	7	-8	7	-11	7	-9
Q1	10.0	-1.0	10.0	-1.0	11.0	0.0	11.0	-1.0	12.0	-1.0
Median	13.0	1.0	13.0	1.0	13.0	2.0	13.0	2.0	14.0	1.0
Q3	17.0	2.0	17.0	2.0	16.0	4.0	18.0	4.0	17.0	3.0
Maximum	37	18	58	34	48	32	58	29	56	38
Week 8										
N	95	95	103	103	96	96	101	101	78	78
Mean	13.3	0.9	13.9	0.3	24.6	12.4	16.9	4.3	18.5	4.1
SD	4.79	3.45	5.63	3.71	93.85	93.37	9.76	8.63	9.76	6.63
Minimum	7	-16	6	-13	5	-5	7	-8	8	-8
Q1	10.0	-1.0	11.0	-1.0	11.0	1.0	12.0	1.0	13.0	1.0
Median	12.0	1.0	12.0	0.0	14.0	3.0	14.0	2.0	15.5	2.0
Q3	16.0	3.0	16.0	2.0	18.0	4.0	19.0	5.0	19.0	5.0
Maximum	30	12	40	10	933	917	79	58	60	30
Week 12										
N	93	93	101	101	92	92	101	101	75	75
Mean	13.7	1.1	14.6	1.1	15.9	3.7	17.5	4.9	18.8	4.3
SD	6.17	5.13	6.90	4.46	9.08	7.41	10.47	9.56	9.57	6.15
Minimum	6	-12	5	-11	9	-4	8	-8	8	-9
Q1	9.0	-2.0	10.0	-1.0	11.0	0.0	12.0	1.0	12.0	1.0
Median	12.0	0.0	13.0	1.0	13.0	2.0	14.0	3.0	16.0	3.0
Q3	15.0	2.0	15.0	2.0	17.0	5.0	19.0	5.0	21.0	7.0
Maximum	45	28	48	18	73	55	82	61	56	26
Week 16										
N	75	75	84	84	78	78	89	89	69	69
Mean	12.3	0.0	14.7	1.3	16.6	4.3	20.7	8.0	19.1	4.6
SD	4.42	2.97	6.83	5.07	11.28	10.44	23.77	22.87	11.01	8.34
Minimum	6	-10	7	-12	6	-11	8	-6	9	-6
Q1	9.0	-1.0	10.0	-2.0	11.0	0.0	12.0	1.0	12.0	0.0
Median	12.0	0.0	13.0	1.0	13.5	2.0	15.0	3.0	16.0	2.0
Q3	14.0	2.0	16.5	4.0	17.0	5.0	21.0	7.0	22.0	6.0
Maximum	32	11	42	21	89	75	209	198	74	56

治験総括報告書 Table 3.2.1.1.1（Section 15.1）（5.3.5.4-2）から引用

表 2.7.4.8-付録-36　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（OCT-101 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: ALT (GPT) (U/L)

Visit / Statistics	Placebo (N=97)		TAK-385 10mg (N=103)		TAK-385 20mg (N=100)		TAK-385 40mg (N=103)		Leuprorelin (N=80)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 20										
N	75	75	81	81	77	77	87	87	65	65
Mean	13.1	0.8	14.4	0.9	16.6	4.3	17.9	5.1	20.3	6.0
SD	6.11	4.98	6.13	6.31	10.26	8.81	10.52	9.77	11.13	7.26
Minimum	7	-10	7	-18	7	-8	8	-12	9	-5
Q1	9.0	-2.0	10.0	-2.0	11.0	0.0	12.0	1.0	13.0	2.0
Median	11.0	0.0	12.0	0.0	14.0	2.0	16.0	3.0	16.0	4.0
Q3	15.0	2.0	17.0	3.0	18.0	5.0	20.0	7.0	23.0	8.0
Maximum	45	32	32	21	70	56	81	60	69	41
Week 24										
N	68	68	79	79	76	76	88	88	62	62
Mean	12.3	0.2	14.8	1.3	16.9	4.7	18.6	5.8	20.7	6.4
SD	5.34	3.67	6.37	6.54	12.19	11.21	12.21	11.06	12.68	9.53
Minimum	6	-10	7	-18	7	-6	8	-6	7	-3
Q1	9.0	-2.0	10.0	-1.0	11.0	0.0	12.0	0.0	14.0	1.0
Median	11.0	0.0	13.0	1.0	13.0	2.0	15.0	3.0	18.0	4.5
Q3	14.0	2.0	17.0	4.0	18.0	5.0	19.5	6.0	24.0	7.0
Maximum	37	16	34	23	92	78	76	60	78	60
Follow-up										
N	77	77	83	83	77	77	89	89	69	69
Mean	12.9	0.6	13.8	0.4	13.8	1.5	16.5	3.7	19.5	5.0
SD	5.17	4.37	7.24	6.60	5.26	3.93	8.37	7.04	11.66	7.42
Minimum	6	-9	6	-18	7	-6	8	-9	7	-5
Q1	9.0	-2.0	9.0	-2.0	10.0	-1.0	11.0	0.0	12.0	1.0
Median	12.0	0.0	11.0	0.0	12.0	1.0	14.0	2.0	16.0	4.0
Q3	15.0	1.0	16.0	2.0	15.0	3.0	19.0	5.0	24.0	6.0
Maximum	28	19	47	28	34	15	57	33	86	38

治験総括報告書 Table 3.2.1.1.1（Section 15.1）（5.3.5.4-2）から引用

表 2.7.4.8-付録-36　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（OCT-101 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: AST (GOT) (U/L)

Visit / Statistics	Placebo (N=97) Observed Value at Visit	Placebo (N=97) Change from Baseline	TAK-385 10mg (N=103) Observed Value at Visit	TAK-385 10mg (N=103) Change from Baseline	TAK-385 20mg (N=100) Observed Value at Visit	TAK-385 20mg (N=100) Change from Baseline	TAK-385 40mg (N=103) Observed Value at Visit	TAK-385 40mg (N=103) Change from Baseline	Leuprorelin (N=80) Observed Value at Visit	Leuprorelin (N=80) Change from Baseline
Baseline										
N	97		103		100		103		80	
Mean	15.8		16.8		16.0		16.5		17.1	
SD	3.64		4.30		2.91		3.52		4.17	
Minimum	8		12		10		11		11	
Q1	14.0		14.0		14.0		14.0		14.0	
Median	15.0		16.0		16.0		16.0		16.0	
Q3	18.0		18.0		18.0		19.0		19.0	
Maximum	33		37		26		31		38	
Week 4										
N	97	97	103	103	100	100	103	103	80	80
Mean	16.7	0.9	17.8	1.0	18.0	2.0	18.6	2.1	18.5	1.3
SD	4.72	3.83	4.39	4.45	3.89	3.20	4.72	3.88	4.22	3.23
Minimum	10	-7	10	-20	10	-6	10	-4	11	-9
Q1	14.0	-1.0	15.0	-1.0	15.0	0.0	16.0	0.0	16.0	-0.5
Median	16.0	0.0	17.0	1.0	18.0	2.0	18.0	2.0	17.0	1.0
Q3	18.0	2.0	20.0	3.0	20.0	3.0	20.0	4.0	21.0	3.0
Maximum	37	22	36	15	35	18	46	24	34	14
Week 8										
N	95	95	103	103	96	96	101	101	78	78
Mean	16.2	0.5	17.3	0.4	23.0	6.9	19.5	2.9	20.2	3.1
SD	3.76	2.91	3.66	3.20	49.86	49.28	7.09	6.29	6.15	4.30
Minimum	10	-9	11	-18	11	-3	11	-8	13	-7
Q1	14.0	-1.0	15.0	-1.0	15.0	0.0	16.0	0.0	16.0	0.0
Median	16.0	0.0	17.0	1.0	17.0	1.5	18.0	2.0	18.5	3.0
Q3	18.0	2.0	20.0	2.0	20.0	3.0	21.0	4.0	22.0	5.0
Maximum	29	11	29	6	505	484	77	53	42	17
Week 12										
N	93	93	100	100	92	92	101	101	75	75
Mean	17.3	1.5	17.5	0.7	18.5	2.5	19.8	3.3	20.3	3.1
SD	10.00	10.10	3.60	3.61	6.47	5.55	6.79	5.79	6.57	4.23
Minimum	10	-7	12	-20	11	-4	13	-6	13	-8
Q1	14.0	-1.0	15.0	-1.0	15.5	0.0	16.0	0.0	16.0	0.0
Median	16.0	0.0	17.0	1.0	17.0	1.0	18.0	2.0	18.0	2.0
Q3	19.0	2.0	20.0	3.0	20.0	4.0	21.0	4.0	23.0	5.0
Maximum	104	92	35	9	62	44	70	46	54	16
Week 16										
N	75	75	84	84	78	78	89	89	69	69
Mean	15.8	0.2	17.9	1.1	18.9	2.9	21.6	4.9	20.3	3.0
SD	3.34	2.94	3.90	4.45	6.28	5.42	12.58	11.81	6.06	4.26
Minimum	10	-6	11	-17	11	-7	11	-5	12	-4
Q1	14.0	-1.0	15.0	-1.0	15.0	0.0	16.0	1.0	16.0	1.0
Median	15.0	0.0	17.5	1.0	18.0	2.0	18.0	3.0	18.0	3.0
Q3	17.0	2.0	20.0	3.0	20.0	4.0	22.0	5.0	21.0	4.0
Maximum	27	10	31	15	54	35	111	97	45	27

治験総括報告書 Table 3.2.1.1.1（Section 15.1）（5.3.5.4-2）から引用

表 2.7.4.8-付録-36　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（OCT-101 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: AST (GOT) (U/L)

Visit / Statistics	Placebo (N=97)		TAK-385 10mg (N=103)		TAK-385 20mg (N=100)		TAK-385 40mg (N=103)		Leuprorelin (N=80)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 20										
N	75	75	81	81	77	77	87	87	65	65
Mean	16.1	0.5	17.7	0.8	18.5	2.5	20.2	3.5	21.0	4.0
SD	4.38	3.69	3.55	4.64	5.56	4.44	7.20	6.54	7.19	4.77
Minimum	9	-6	12	-22	9	-2	12	-10	14	-6
Q1	14.0	-1.0	15.0	-1.0	15.0	0.0	16.0	0.0	17.0	2.0
Median	15.0	0.0	17.0	1.0	17.0	2.0	19.0	3.0	19.0	3.0
Q3	17.0	2.0	20.0	3.0	20.0	3.0	22.0	5.0	23.0	5.0
Maximum	36	18	31	14	45	21	67	43	60	22
Week 24										
N	68	68	79	79	76	76	88	88	62	62
Mean	15.3	0.0	17.7	0.7	18.7	2.8	20.6	3.9	21.3	4.4
SD	3.60	3.66	3.94	4.69	5.91	5.04	6.91	6.33	8.96	7.38
Minimum	9	-10	11	-20	12	-4	12	-8	10	-8
Q1	13.0	-2.0	15.0	-1.0	15.0	0.0	16.5	0.0	17.0	1.0
Median	14.5	0.0	17.0	1.0	17.0	2.0	19.0	3.0	18.0	3.0
Q3	17.0	1.0	20.0	2.0	21.0	4.0	22.0	5.0	23.0	6.0
Maximum	28	12	29	14	42	27	60	36	67	49
Follow-up										
N	77	77	83	83	77	77	89	89	69	69
Mean	15.8	0.3	17.2	0.4	16.9	0.9	18.5	1.8	21.4	4.2
SD	3.70	3.61	5.73	5.72	3.89	3.27	4.72	3.49	9.03	6.05
Minimum	9	-8	9	-19	10	-5	11	-5	13	-7
Q1	14.0	-2.0	14.0	-2.0	14.0	-1.0	15.0	0.0	17.0	1.0
Median	15.0	0.0	16.0	0.0	16.0	0.0	18.0	1.0	19.0	3.0
Q3	18.0	2.0	19.0	2.0	19.0	2.0	20.0	3.0	23.0	6.0
Maximum	31	18	47	30	29	11	35	12	78	40

治験総括報告書 Table 3.2.1.1.1（Section 15.1）（5.3.5.4-2）から引用

表 2.7.4.8-付録-36　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（OCT-101 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: LDH (U/L)

Visit / Statistics	Placebo (N=97)		TAK-385 10mg (N=103)		TAK-385 20mg (N=100)		TAK-385 40mg (N=103)		Leuprorelin (N=80)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Baseline										
N	97		103		100		103		80	
Mean	154.1		153.7		147.7		150.0		153.9	
SD	30.16		25.85		23.61		23.05		24.49	
Minimum	91		103		102		100		103	
Q1	134.0		134.0		133.0		136.0		138.5	
Median	150.0		150.0		144.0		146.0		152.5	
Q3	170.0		170.0		160.0		163.0		171.0	
Maximum	299		233		254		249		257	
Week 4										
N	97	97	103	103	100	100	103	103	80	80
Mean	152.4	-1.7	155.0	1.2	153.7	6.0	161.5	11.6	158.7	4.8
SD	25.03	20.77	27.71	22.76	22.41	15.46	29.69	20.34	20.12	20.49
Minimum	104	-107	106	-86	101	-46	106	-29	108	-109
Q1	133.0	-12.0	137.0	-9.0	140.0	-4.0	144.0	-1.0	147.5	-3.5
Median	151.0	-1.0	152.0	1.0	152.0	5.5	157.0	10.0	161.5	5.0
Q3	166.0	8.0	171.0	13.0	169.0	16.0	175.0	19.0	171.0	15.0
Maximum	245	83	278	77	223	44	293	127	200	47
Week 8										
N	95	95	103	103	96	96	101	101	78	78
Mean	154.1	-0.1	152.8	-0.9	158.6	10.2	161.4	11.7	163.3	9.3
SD	33.16	21.29	23.81	19.91	37.19	29.74	29.16	17.56	20.38	21.86
Minimum	114	-82	102	-75	92	-24	93	-27	101	-114
Q1	136.0	-10.0	134.0	-14.0	139.0	-4.0	144.0	2.0	150.0	2.0
Median	146.0	1.0	154.0	1.0	150.5	5.0	159.0	10.0	165.5	10.0
Q3	170.0	9.0	172.0	11.0	170.0	17.0	176.0	21.0	178.0	19.0
Maximum	362	65	201	64	389	223	282	79	213	60
Week 12										
N	93	93	100	100	92	92	101	101	75	75
Mean	159.9	5.4	156.9	2.6	160.0	12.2	163.5	13.8	166.6	12.4
SD	43.38	42.42	25.22	18.87	26.40	20.36	28.61	18.22	24.66	24.05
Minimum	117	-98	110	-82	94	-25	114	-28	105	-140
Q1	134.0	-11.0	137.0	-9.0	139.5	-0.5	144.0	-1.0	149.0	3.0
Median	153.0	1.0	158.5	2.5	158.0	7.0	161.0	15.0	166.0	14.0
Q3	171.0	15.0	175.0	14.0	174.5	25.5	174.0	27.0	183.0	27.0
Maximum	481	354	216	56	231	61	272	59	230	58
Week 16										
N	75	75	84	84	78	78	89	89	69	69
Mean	150.6	-2.7	156.3	1.9	157.5	8.8	164.4	14.1	164.5	9.2
SD	24.72	20.49	26.02	22.13	27.23	19.96	26.36	18.31	25.11	24.66
Minimum	109	-49	110	-74	95	-33	112	-29	102	-122
Q1	136.0	-17.0	139.0	-10.0	139.0	-3.0	149.0	2.0	147.0	-3.0
Median	147.0	-3.0	153.5	1.5	156.0	6.5	162.0	15.0	164.0	10.0
Q3	167.0	7.0	177.0	15.5	172.0	20.0	177.0	23.0	179.0	23.0
Maximum	213	82	220	78	223	66	257	58	235	60

治験総括報告書 Table 3.2.1.1.1（Section 15.1）（5.3.5.4-2）から引用

表 2.7.4.8-付録-36　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（OCT-101 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: LDH (U/L)

Visit / Statistics	Placebo (N=97)		TAK-385 10mg (N=103)		TAK-385 20mg (N=100)		TAK-385 40mg (N=103)		Leuprorelin (N=80)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 20										
N	75	75	81	81	77	77	87	87	65	65
Mean	151.9	-1.4	153.9	-1.0	153.5	4.9	163.9	13.4	167.5	12.2
SD	23.45	17.93	24.92	17.22	25.59	18.05	27.73	16.89	26.35	24.80
Minimum	105	-46	112	-60	85	-41	112	-26	111	-126
Q1	136.0	-14.0	135.0	-10.0	138.0	-5.0	148.0	3.0	153.0	3.0
Median	149.0	2.0	153.0	1.0	151.0	2.0	160.0	12.0	166.0	16.0
Q3	170.0	10.0	171.0	10.0	164.0	16.0	179.0	20.0	185.0	27.0
Maximum	216	44	226	32	255	45	256	76	266	63
Week 24										
N	68	68	79	79	76	76	88	88	62	62
Mean	151.6	-1.4	156.5	1.1	154.5	5.6	166.4	15.9	170.8	16.1
SD	21.87	17.25	23.34	18.46	25.26	20.22	30.74	18.80	25.95	23.12
Minimum	106	-52	109	-70	94	-38	108	-20	109	-104
Q1	136.5	-11.0	141.0	-11.0	136.0	-9.5	146.0	4.0	154.0	6.0
Median	151.0	-1.0	157.0	4.0	153.5	3.5	162.0	14.0	167.5	17.0
Q3	169.5	9.0	170.0	12.0	169.0	17.5	182.5	24.5	188.0	27.0
Maximum	211	42	224	42	252	63	265	85	257	58
Follow-up										
N	77	77	83	83	77	77	89	89	69	69
Mean	151.0	-2.6	149.3	-5.4	148.6	-0.3	156.3	5.9	167.2	12.0
SD	24.58	19.68	22.21	19.90	22.97	17.91	31.89	21.55	32.16	30.47
Minimum	103	-61	91	-68	98	-43	104	-31	108	-131
Q1	134.0	-15.0	132.0	-16.0	134.0	-11.0	138.0	-7.0	145.0	-2.0
Median	150.0	-2.0	149.0	-4.0	144.0	0.0	151.0	4.0	163.0	7.0
Q3	168.0	8.0	167.0	7.0	160.0	13.0	170.0	14.0	179.0	25.0
Maximum	220	57	198	35	219	62	300	150	309	106

治験総括報告書 Table 3.2.1.1.1（Section 15.1）（5.3.5.4-2）から引用

表 2.7.4.8-付録-36　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（OCT-101 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: GGT (U/L)

Visit / Statistics	Placebo (N=97)		TAK-385 10mg (N=103)		TAK-385 20mg (N=100)		TAK-385 40mg (N=103)		Leuprorelin (N=80)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Baseline										
N	97		103		100		103		80	
Mean	16.9		17.2		16.1		15.5		17.6	
SD	9.00		11.05		9.92		7.29		8.19	
Minimum	7		5		7		7		8	
Q1	12.0		12.0		12.0		11.0		12.0	
Median	15.0		14.0		14.0		14.0		15.0	
Q3	18.0		19.0		16.0		17.0		19.5	
Maximum	74		105		73		51		46	
Week 4										
N	97	97	103	103	100	100	103	103	80	80
Mean	18.9	2.1	17.8	0.6	17.4	1.3	17.0	1.5	19.2	1.6
SD	19.78	12.49	13.83	4.91	11.13	5.13	9.62	5.16	11.65	7.26
Minimum	6	-8	5	-13	8	-20	8	-13	8	-5
Q1	13.0	-1.0	12.0	-1.0	12.5	-0.5	12.0	-1.0	13.0	-1.0
Median	15.0	0.0	15.0	0.0	15.0	1.0	15.0	1.0	16.0	1.0
Q3	18.0	2.0	19.0	2.0	17.5	2.0	18.0	2.0	21.5	2.0
Maximum	194	120	132	29	92	35	77	31	94	61
Week 8										
N	95	95	103	103	96	96	101	101	78	78
Mean	18.8	2.0	17.4	0.2	18.8	2.6	19.5	4.0	22.4	4.6
SD	19.58	12.15	11.89	2.64	17.00	13.30	23.90	20.06	17.13	12.27
Minimum	9	-8	7	-7	8	-18	7	-17	9	-3
Q1	13.0	-1.0	12.0	-1.0	13.0	0.0	12.0	0.0	13.0	0.0
Median	15.0	1.0	15.0	0.0	15.0	1.0	15.0	1.0	16.0	1.5
Q3	19.0	2.0	18.0	1.0	19.0	2.0	20.0	4.0	24.0	3.0
Maximum	187	113	118	13	141	124	242	196	93	67
Week 12										
N	93	93	101	101	92	92	101	101	75	75
Mean	17.7	0.8	18.6	1.3	18.7	2.5	19.8	4.3	22.3	4.7
SD	11.60	4.51	14.87	6.03	16.25	8.62	23.44	19.40	14.53	9.29
Minimum	9	-10	5	-12	8	-24	8	-18	8	-5
Q1	13.0	-1.0	12.0	-1.0	12.5	-1.0	12.0	-1.0	13.0	1.0
Median	15.0	0.0	15.0	1.0	14.0	1.0	15.0	1.0	17.0	2.0
Q3	18.0	2.0	21.0	2.0	17.0	3.0	19.0	3.0	25.0	5.0
Maximum	88	22	136	31	130	57	229	183	86	60
Week 16										
N	75	75	84	84	78	78	89	89	69	69
Mean	18.1	0.9	18.2	0.8	19.4	2.9	20.6	4.9	22.4	4.4
SD	16.33	8.00	14.18	5.31	21.40	14.41	28.35	24.33	13.69	8.28
Minimum	8	-8	6	-12	8	-25	8	-12	8	-5
Q1	12.0	-2.0	12.5	-1.0	13.0	0.0	12.0	-1.0	13.0	1.0
Median	15.0	0.0	14.0	0.0	15.0	1.0	15.0	1.0	19.0	2.0
Q3	19.0	1.0	19.5	2.0	18.0	3.0	19.0	3.0	24.0	6.0
Maximum	138	64	130	25	194	121	255	209	71	45

治験総括報告書 Table 3.2.1.1.1（Section 15.1）（5.3.5.4-2）から引用

表 2.7.4.8-付録-36　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（OCT-101 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: GGT (U/L)

Visit / Statistics	Placebo (N=97)		TAK-385 10mg (N=103)		TAK-385 20mg (N=100)		TAK-385 40mg (N=103)		Leuprorelin (N=80)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 20										
N	75	75	81	81	77	77	87	87	65	65
Mean	18.0	0.7	18.9	1.2	20.3	3.8	20.0	4.4	24.1	6.3
SD	12.52	4.41	14.10	6.04	24.07	15.53	27.36	23.26	19.97	15.06
Minimum	8	-9	9	-22	8	-6	8	-13	9	-3
Q1	12.0	-1.0	13.0	-1.0	13.0	0.0	12.0	-1.0	14.0	1.0
Median	15.0	0.0	15.0	0.0	15.0	1.0	15.0	1.0	18.0	2.0
Q3	19.0	2.0	22.0	2.0	19.0	3.0	20.0	3.0	26.0	5.0
Maximum	98	24	121	28	205	132	259	213	120	87
Week 24										
N	68	68	79	79	76	76	88	88	62	62
Mean	19.1	1.6	18.9	1.2	19.9	3.4	19.9	4.3	24.1	6.1
SD	20.15	11.48	15.06	6.56	19.02	9.75	22.48	18.40	18.13	12.97
Minimum	8	-10	8	-14	8	-4	9	-16	9	-3
Q1	12.0	-2.0	12.0	-1.0	13.0	-1.0	13.0	0.0	14.0	1.0
Median	14.0	0.0	15.0	0.0	16.0	1.0	15.0	1.5	18.5	3.0
Q3	18.0	2.0	21.0	3.0	19.0	3.0	19.0	3.0	27.0	6.0
Maximum	162	88	130	39	146	73	211	165	121	95
Follow-up										
N	77	77	83	83	77	77	89	89	69	69
Mean	17.6	0.4	18.0	0.6	18.1	1.6	18.9	3.2	24.0	6.0
SD	11.58	3.92	12.42	5.56	16.45	7.98	17.79	14.23	20.01	15.14
Minimum	9	-10	5	-25	8	-15	7	-17	9	-5
Q1	12.0	-2.0	12.0	-1.0	13.0	-1.0	11.0	-1.0	13.0	1.0
Median	15.0	0.0	15.0	0.0	15.0	0.0	14.0	0.0	17.0	2.0
Q3	18.0	2.0	20.0	2.0	17.0	2.0	18.0	2.0	25.0	4.0
Maximum	94	20	109	24	138	65	122	96	136	110

治験総括報告書 Table 3.2.1.1.1（Section 15.1）（5.3.5.4-2）から引用

表 2.7.4.8-付録-36　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（OCT-101 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Albumin (g/dL)

Visit / Statistics	Placebo (N=97)		TAK-385 10mg (N=103)		TAK-385 20mg (N=100)		TAK-385 40mg (N=103)		Leuprorelin (N=80)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Baseline										
N	97		103		100		103		80	
Mean	4.23		4.24		4.19		4.24		4.25	
SD	0.224		0.225		0.210		0.239		0.226	
Minimum	3.8		3.7		3.7		3.7		3.7	
Q1	4.10		4.10		4.10		4.10		4.10	
Median	4.20		4.20		4.20		4.20		4.20	
Q3	4.30		4.40		4.30		4.40		4.40	
Maximum	4.9		4.8		4.7		5.0		4.9	
Week 4										
N	97	97	103	103	100	100	103	103	80	80
Mean	4.25	0.01	4.34	0.10	4.37	0.18	4.49	0.24	4.39	0.14
SD	0.239	0.225	0.229	0.219	0.238	0.212	0.224	0.225	0.245	0.220
Minimum	3.6	-0.7	3.8	-0.4	3.9	-0.3	3.9	-0.2	3.8	-0.3
Q1	4.10	-0.10	4.20	0.00	4.20	0.10	4.30	0.10	4.20	0.00
Median	4.20	0.00	4.30	0.10	4.40	0.20	4.50	0.20	4.40	0.20
Q3	4.40	0.20	4.50	0.20	4.50	0.30	4.60	0.40	4.50	0.30
Maximum	4.8	0.6	5.0	0.6	4.9	0.7	4.9	0.8	5.1	0.9
Week 8										
N	95	95	103	103	96	96	101	101	78	78
Mean	4.29	0.06	4.33	0.10	4.38	0.19	4.45	0.21	4.41	0.17
SD	0.209	0.211	0.211	0.223	0.235	0.194	0.248	0.249	0.211	0.211
Minimum	3.8	-0.5	3.7	-0.4	3.7	-0.4	3.3	-0.5	3.9	-0.3
Q1	4.20	0.00	4.20	-0.10	4.20	0.05	4.30	0.10	4.30	0.10
Median	4.30	0.10	4.30	0.10	4.40	0.20	4.50	0.20	4.40	0.20
Q3	4.40	0.20	4.50	0.20	4.60	0.30	4.60	0.40	4.60	0.30
Maximum	4.9	0.5	4.8	0.6	4.9	0.7	5.1	0.9	4.9	0.7
Week 12										
N	93	93	101	101	92	92	101	101	75	75
Mean	4.26	0.02	4.35	0.11	4.35	0.16	4.43	0.18	4.38	0.14
SD	0.223	0.205	0.218	0.241	0.227	0.203	0.244	0.229	0.233	0.221
Minimum	3.7	-0.5	3.9	-0.4	3.8	-0.4	3.6	-0.3	3.7	-0.4
Q1	4.10	-0.10	4.20	0.00	4.20	0.00	4.30	0.00	4.20	0.00
Median	4.30	0.00	4.30	0.10	4.30	0.10	4.40	0.20	4.40	0.10
Q3	4.40	0.10	4.50	0.20	4.50	0.30	4.60	0.30	4.50	0.30
Maximum	4.9	0.6	5.0	1.1	5.0	0.8	5.0	0.8	5.0	0.7
Week 16										
N	74	74	84	84	78	78	89	89	69	69
Mean	4.29	0.05	4.38	0.15	4.39	0.19	4.44	0.19	4.39	0.13
SD	0.244	0.211	0.214	0.226	0.226	0.183	0.223	0.216	0.220	0.225
Minimum	3.8	-0.3	3.8	-0.5	3.9	-0.2	3.9	-0.5	3.9	-0.4
Q1	4.10	-0.10	4.20	0.00	4.20	0.10	4.30	0.00	4.20	0.00
Median	4.30	0.00	4.40	0.15	4.40	0.20	4.50	0.20	4.40	0.10
Q3	4.50	0.10	4.50	0.30	4.50	0.30	4.60	0.30	4.50	0.30
Maximum	4.8	0.7	4.8	0.6	5.0	0.6	4.9	0.7	5.2	1.0

治験総括報告書 Table 3.2.1.1.1（Section 15.1）（5.3.5.4-2）から引用

表 2.7.4.8-付録-36　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（OCT-101 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Albumin (g/dL)

Visit / Statistics	Placebo (N=97)		TAK-385 10mg (N=103)		TAK-385 20mg (N=100)		TAK-385 40mg (N=103)		Leuprorelin (N=80)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 20										
N	75	75	81	81	77	77	87	87	65	65
Mean	4.29	0.05	4.36	0.13	4.35	0.14	4.43	0.17	4.42	0.16
SD	0.205	0.193	0.202	0.233	0.200	0.168	0.243	0.238	0.218	0.213
Minimum	3.8	-0.5	4.0	-0.3	3.8	-0.5	3.5	-0.5	3.9	-0.3
Q1	4.20	-0.10	4.20	0.00	4.20	0.00	4.30	0.00	4.30	0.00
Median	4.30	0.10	4.30	0.10	4.30	0.10	4.40	0.20	4.40	0.20
Q3	4.40	0.20	4.50	0.30	4.50	0.20	4.60	0.30	4.60	0.30
Maximum	5.0	0.5	4.9	0.7	4.8	0.5	5.0	0.7	5.0	0.7
Week 24										
N	68	68	79	79	76	76	88	88	62	62
Mean	4.25	0.01	4.34	0.11	4.36	0.16	4.43	0.18	4.40	0.15
SD	0.213	0.197	0.222	0.237	0.254	0.211	0.254	0.266	0.228	0.206
Minimum	3.8	-0.7	3.9	-0.5	3.8	-0.3	3.6	-0.5	3.8	-0.3
Q1	4.10	-0.10	4.20	0.00	4.20	0.00	4.30	0.00	4.30	0.10
Median	4.20	0.00	4.30	0.10	4.30	0.10	4.45	0.20	4.40	0.20
Q3	4.40	0.10	4.50	0.30	4.60	0.30	4.60	0.30	4.60	0.30
Maximum	4.9	0.5	4.9	0.6	5.0	0.8	5.0	0.9	4.9	0.6
Follow-up										
N	76	76	83	83	77	77	89	89	69	69
Mean	4.28	0.04	4.23	0.00	4.25	0.05	4.31	0.06	4.41	0.15
SD	0.234	0.237	0.217	0.238	0.228	0.218	0.204	0.255	0.236	0.213
Minimum	3.8	-0.5	3.7	-0.6	3.7	-0.6	3.8	-0.8	3.9	-0.2
Q1	4.10	-0.15	4.10	-0.20	4.10	-0.10	4.20	-0.10	4.30	0.00
Median	4.30	0.00	4.20	0.00	4.30	0.10	4.30	0.10	4.40	0.20
Q3	4.45	0.20	4.40	0.10	4.40	0.20	4.40	0.20	4.50	0.30
Maximum	4.8	0.6	4.8	0.6	4.9	0.6	4.9	0.5	4.9	0.7

治験総括報告書 Table 3.2.1.1.1（Section 15.1）（5.3.5.4-2）から引用

表 2.7.4.8-付録-36　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（OCT-101 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Alkaline Phosphatase (U/L)

Visit / Statistics	Placebo (N=97)		TAK-385 10mg (N=103)		TAK-385 20mg (N=100)		TAK-385 40mg (N=103)		Leuprorelin (N=80)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Baseline										
N	97		103		100		103		80	
Mean	172.1		169.1		167.5		168.6		170.2	
SD	46.74		41.91		41.21		39.47		39.58	
Minimum	81		107		66		95		101	
Q1	137.0		138.0		139.0		138.0		140.0	
Median	168.0		162.0		166.0		163.0		162.5	
Q3	200.0		197.0		185.5		201.0		198.5	
Maximum	307		356		329		279		276	
Week 4										
N	97	97	103	103	100	100	103	103	80	80
Mean	172.9	0.8	175.5	6.4	170.7	3.2	174.7	6.1	174.8	4.6
SD	47.86	20.46	44.56	22.00	41.03	22.06	42.58	22.72	38.28	20.08
Minimum	76	-47	100	-49	75	-130	93	-92	111	-33
Q1	141.0	-11.0	140.0	-5.0	140.5	-7.0	136.0	-6.0	145.0	-7.0
Median	165.0	0.0	172.0	5.0	171.0	3.5	176.0	6.0	173.5	2.5
Q3	194.0	11.0	201.0	17.0	189.5	15.0	199.0	21.0	202.5	15.0
Maximum	337	72	339	122	349	65	294	95	271	82
Week 8										
N	95	95	103	103	96	96	101	101	78	78
Mean	170.5	0.6	174.3	5.2	178.7	11.8	180.7	12.6	181.2	10.7
SD	45.09	18.40	43.38	25.50	71.93	51.99	47.62	32.96	45.24	22.83
Minimum	71	-40	108	-51	72	-148	102	-49	109	-43
Q1	137.0	-11.0	139.0	-7.0	142.5	-4.0	142.0	-5.0	147.0	-2.0
Median	165.0	1.0	171.0	1.0	171.5	6.0	174.0	7.0	169.0	3.5
Q3	200.0	12.0	200.0	18.0	192.0	20.0	208.0	21.0	209.0	21.0
Maximum	335	70	356	128	718	421	334	183	297	105
Week 12										
N	93	93	100	100	92	92	101	101	75	75
Mean	169.4	-0.5	178.1	8.5	175.5	10.4	187.1	19.0	187.0	16.2
SD	45.25	19.22	44.30	29.64	41.53	26.25	50.51	34.41	42.29	21.61
Minimum	76	-46	112	-93	70	-107	109	-102	126	-40
Q1	136.0	-10.0	142.5	-7.0	148.5	-4.5	151.0	2.0	155.0	0.0
Median	166.0	-2.0	173.5	7.5	173.0	11.0	179.0	17.0	174.0	14.0
Q3	197.0	10.0	211.0	24.0	201.5	23.0	219.0	32.0	220.0	32.0
Maximum	294	53	343	115	301	143	394	144	303	73
Week 16										
N	75	75	84	84	78	78	89	89	69	69
Mean	167.2	-1.6	180.7	11.1	176.7	11.3	192.9	23.7	195.0	22.3
SD	43.08	16.95	46.05	32.52	38.46	27.89	46.74	30.89	45.50	21.46
Minimum	71	-43	105	-65	68	-124	110	-61	125	-39
Q1	136.0	-10.0	141.5	-5.0	147.0	-5.0	154.0	5.0	163.0	10.0
Median	160.0	0.0	175.0	11.5	182.0	11.0	189.0	26.0	183.0	19.0
Q3	194.0	10.0	203.0	26.5	203.0	31.0	224.0	39.0	225.0	30.0
Maximum	304	39	347	129	266	61	340	137	331	85

治験総括報告書 Table 3.2.1.1.1（Section 15.1）（5.3.5.4-2）から引用

表 2.7.4.8-付録-36　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（OCT-101 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Alkaline Phosphatase (U/L)

Visit / Statistics	Placebo (N=97)		TAK-385 10mg (N=103)		TAK-385 20mg (N=100)		TAK-385 40mg (N=103)		Leuprorelin (N=80)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 20										
N	75	75	81	81	77	77	87	87	65	65
Mean	170.4	1.6	181.4	12.2	179.4	14.2	201.3	31.4	202.6	31.0
SD	47.10	19.49	41.20	30.59	40.98	27.66	53.57	36.43	50.64	26.42
Minimum	64	-39	112	-78	68	-109	109	-59	123	-44
Q1	135.0	-10.0	149.0	-4.0	149.0	-2.0	161.0	8.0	168.0	14.0
Median	159.0	-1.0	185.0	13.0	181.0	10.0	197.0	32.0	196.0	28.0
Q3	205.0	13.0	212.0	25.0	209.0	30.0	227.0	48.0	222.0	44.0
Maximum	283	63	282	103	314	92	350	146	348	113
Week 24										
N	68	68	79	79	76	76	88	88	62	62
Mean	166.9	-1.4	189.3	19.3	185.6	19.4	211.2	41.9	215.8	42.2
SD	49.21	19.05	49.80	29.79	40.20	29.05	54.08	39.05	51.54	30.55
Minimum	71	-51	112	-44	71	-94	114	-49	137	-8
Q1	132.5	-10.5	150.0	-4.0	154.0	4.5	177.0	18.5	180.0	21.0
Median	154.0	-2.0	184.0	19.0	185.5	18.0	204.5	39.0	211.0	38.5
Q3	196.5	9.0	218.0	36.0	214.0	33.0	237.5	63.0	234.0	58.0
Maximum	292	49	341	103	270	82	432	217	372	151
Follow-up										
N	77	77	83	83	77	77	89	89	69	69
Mean	177.5	9.4	181.0	11.3	182.6	17.5	213.3	44.1	219.0	46.3
SD	116.70	113.42	47.65	32.66	43.72	31.54	59.41	47.31	50.26	29.01
Minimum	63	-57	104	-74	72	-94	110	-63	120	-32
Q1	133.0	-14.0	141.0	-6.0	147.0	-1.0	170.0	20.0	187.0	30.0
Median	160.0	-2.0	176.0	9.0	185.0	13.0	206.0	39.0	211.0	42.0
Q3	196.0	7.0	211.0	29.0	209.0	34.0	249.0	67.0	260.0	68.0
Maximum	1124	976	318	88	331	123	420	255	351	118

治験総括報告書 Table 3.2.1.1.1（Section 15.1）（5.3.5.4-2）から引用

表 2.7.4.8-付録-36　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（OCT-101 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Total Bilirubin (mg/dL)

Visit / Statistics	Placebo (N=97)		TAK-385 10mg (N=103)		TAK-385 20mg (N=100)		TAK-385 40mg (N=103)		Leuprorelin (N=80)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Baseline										
N	97		103		100		103		80	
Mean	0.52		0.53		0.51		0.55		0.54	
SD	0.182		0.185		0.223		0.199		0.205	
Minimum	0.2		0.1		0.2		0.2		0.2	
Q1	0.40		0.40		0.40		0.40		0.40	
Median	0.50		0.50		0.40		0.50		0.50	
Q3	0.70		0.70		0.60		0.60		0.70	
Maximum	1.0		1.0		1.2		1.4		1.2	
Week 4										
N	97	97	103	103	100	100	103	103	80	80
Mean	0.53	0.01	0.57	0.04	0.59	0.08	0.60	0.05	0.59	0.05
SD	0.184	0.177	0.212	0.167	0.210	0.174	0.241	0.215	0.211	0.194
Minimum	0.2	-0.4	0.2	-0.4	0.3	-0.4	0.3	-0.6	0.2	-0.5
Q1	0.40	-0.10	0.40	-0.10	0.40	0.00	0.40	-0.10	0.40	-0.10
Median	0.50	0.00	0.50	0.00	0.60	0.10	0.50	0.00	0.60	0.00
Q3	0.60	0.10	0.70	0.10	0.70	0.20	0.70	0.10	0.70	0.20
Maximum	1.0	0.6	1.2	0.5	1.2	0.5	1.9	0.9	1.4	0.5
Week 8										
N	95	95	103	103	96	96	101	101	78	78
Mean	0.53	0.01	0.60	0.06	0.59	0.08	0.59	0.04	0.58	0.05
SD	0.177	0.160	0.223	0.187	0.227	0.224	0.234	0.235	0.226	0.225
Minimum	0.2	-0.5	0.2	-0.7	0.2	-0.4	0.2	-0.7	0.2	-0.6
Q1	0.40	-0.10	0.40	0.00	0.40	-0.10	0.40	-0.10	0.40	-0.10
Median	0.50	0.00	0.60	0.10	0.60	0.10	0.50	0.10	0.55	0.00
Q3	0.60	0.10	0.70	0.20	0.70	0.20	0.70	0.10	0.70	0.20
Maximum	1.0	0.3	1.3	0.7	1.3	0.8	1.8	0.8	1.3	0.8
Week 12										
N	93	93	101	101	92	92	101	101	75	75
Mean	0.55	0.03	0.60	0.07	0.57	0.06	0.58	0.03	0.59	0.06
SD	0.230	0.185	0.293	0.255	0.218	0.198	0.239	0.200	0.203	0.199
Minimum	0.2	-0.5	0.3	-0.5	0.2	-0.7	0.2	-0.4	0.2	-0.4
Q1	0.40	-0.10	0.40	-0.10	0.40	0.00	0.40	-0.10	0.40	-0.10
Median	0.50	0.00	0.60	0.00	0.50	0.10	0.50	0.00	0.50	0.10
Q3	0.70	0.10	0.70	0.20	0.65	0.20	0.70	0.20	0.70	0.20
Maximum	1.3	0.6	2.7	1.9	1.2	0.7	1.8	0.5	1.1	0.6
Week 16										
N	75	75	84	84	78	78	89	89	69	69
Mean	0.56	0.03	0.62	0.08	0.61	0.11	0.61	0.06	0.61	0.07
SD	0.218	0.161	0.240	0.210	0.218	0.207	0.232	0.208	0.213	0.200
Minimum	0.1	-0.5	0.2	-0.3	0.3	-0.4	0.2	-0.4	0.2	-0.4
Q1	0.40	-0.10	0.40	-0.10	0.50	0.00	0.50	-0.10	0.40	-0.10
Median	0.50	0.00	0.60	0.10	0.60	0.10	0.60	0.00	0.60	0.10
Q3	0.70	0.10	0.80	0.20	0.70	0.30	0.70	0.20	0.70	0.20
Maximum	1.1	0.4	1.5	0.7	1.2	0.5	1.5	0.7	1.1	0.6

治験総括報告書 Table 3.2.1.1.1（Section 15.1）（5.3.5.4-2）から引用

表 2.7.4.8-付録-36　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（OCT-101 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Total Bilirubin (mg/dL)

Visit / Statistics	Placebo (N=97)		TAK-385 10mg (N=103)		TAK-385 20mg (N=100)		TAK-385 40mg (N=103)		Leuprorelin (N=80)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 20										
N	75	75	81	81	77	77	87	87	65	65
Mean	0.55	0.02	0.59	0.05	0.59	0.09	0.59	0.04	0.64	0.10
SD	0.216	0.179	0.227	0.192	0.227	0.205	0.245	0.241	0.281	0.261
Minimum	0.2	-0.3	0.3	-0.4	0.2	-0.5	0.2	-0.4	0.2	-0.6
Q1	0.40	-0.10	0.40	-0.10	0.40	0.00	0.40	-0.10	0.40	0.00
Median	0.50	0.00	0.60	0.00	0.50	0.10	0.50	0.00	0.60	0.00
Q3	0.70	0.10	0.70	0.20	0.70	0.20	0.70	0.20	0.70	0.20
Maximum	1.1	0.5	1.3	0.5	1.2	0.6	1.6	1.1	1.7	1.1
Week 24										
N	68	68	79	79	76	76	88	88	62	62
Mean	0.51	0.00	0.56	0.01	0.58	0.08	0.60	0.05	0.57	0.04
SD	0.200	0.184	0.194	0.191	0.219	0.224	0.238	0.195	0.224	0.240
Minimum	0.2	-0.5	0.3	-0.5	0.2	-0.5	0.2	-0.4	0.2	-0.6
Q1	0.40	-0.10	0.40	-0.10	0.40	0.00	0.50	-0.05	0.40	-0.10
Median	0.50	0.00	0.50	0.00	0.55	0.10	0.55	0.00	0.50	0.00
Q3	0.60	0.10	0.70	0.10	0.70	0.20	0.70	0.20	0.70	0.20
Maximum	1.3	0.6	1.0	0.5	1.5	0.6	1.4	0.8	1.6	0.9
Follow-up										
N	77	77	83	83	77	77	89	89	69	69
Mean	0.52	-0.01	0.55	0.01	0.60	0.09	0.63	0.08	0.60	0.06
SD	0.219	0.213	0.199	0.180	0.254	0.181	0.254	0.201	0.231	0.209
Minimum	0.2	-0.6	0.2	-0.4	0.3	-0.3	0.2	-0.5	0.3	-0.4
Q1	0.40	-0.10	0.40	-0.10	0.40	0.00	0.50	-0.10	0.40	-0.10
Median	0.50	0.00	0.50	0.00	0.50	0.10	0.60	0.10	0.60	0.00
Q3	0.60	0.10	0.70	0.10	0.70	0.20	0.70	0.20	0.80	0.10
Maximum	1.3	0.6	1.2	0.4	1.5	0.6	1.6	0.6	1.3	0.7

治験総括報告書 Table 3.2.1.1.1（Section 15.1）（5.3.5.4-2）から引用

表 2.7.4.8-付録-36　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（OCT-101 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Total Protein (g/dL)

Visit / Statistics	Placebo (N=97)		TAK-385 10mg (N=103)		TAK-385 20mg (N=100)		TAK-385 40mg (N=103)		Leuprorelin (N=80)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Baseline										
N	97		103		100		103		80	
Mean	7.01		7.00		6.97		7.00		6.99	
SD	0.380		0.441		0.309		0.412		0.380	
Minimum	6.2		5.9		6.0		6.1		6.1	
Q1	6.80		6.70		6.80		6.70		6.70	
Median	7.00		7.00		7.00		7.00		7.00	
Q3	7.20		7.30		7.10		7.30		7.25	
Maximum	8.0		8.3		7.6		8.0		7.9	
Week 4										
N	97	97	103	103	100	100	103	103	80	80
Mean	7.01	0.00	7.17	0.17	7.22	0.25	7.35	0.35	7.19	0.20
SD	0.412	0.375	0.421	0.364	0.387	0.345	0.384	0.374	0.434	0.391
Minimum	6.0	-1.0	6.4	-0.8	6.4	-0.6	6.6	-0.5	6.0	-0.6
Q1	6.70	-0.20	6.90	-0.10	6.90	0.00	7.00	0.10	6.90	-0.10
Median	7.00	0.00	7.10	0.20	7.20	0.25	7.30	0.30	7.20	0.20
Q3	7.30	0.20	7.40	0.40	7.50	0.50	7.60	0.70	7.45	0.50
Maximum	8.1	1.1	8.2	1.0	8.1	1.0	8.3	1.2	8.6	1.4
Week 8										
N	95	95	103	103	96	96	101	101	78	78
Mean	7.10	0.08	7.14	0.14	7.22	0.25	7.34	0.33	7.20	0.22
SD	0.400	0.359	0.375	0.380	0.364	0.321	0.420	0.412	0.430	0.376
Minimum	6.1	-0.8	6.0	-1.0	6.4	-0.5	6.3	-0.7	6.3	-0.7
Q1	6.90	-0.10	6.90	-0.10	6.95	0.00	7.00	0.10	6.90	0.00
Median	7.10	0.10	7.10	0.10	7.30	0.30	7.30	0.40	7.20	0.20
Q3	7.30	0.30	7.40	0.50	7.40	0.50	7.60	0.60	7.50	0.40
Maximum	8.6	0.9	8.2	0.8	8.1	1.1	8.4	1.4	8.3	1.0
Week 12										
N	93	93	100	100	92	92	101	101	75	75
Mean	7.06	0.05	7.17	0.17	7.21	0.25	7.32	0.31	7.21	0.23
SD	0.404	0.356	0.448	0.425	0.371	0.365	0.409	0.388	0.428	0.408
Minimum	5.9	-0.8	6.3	-0.7	6.2	-0.5	6.5	-0.6	6.2	-0.8
Q1	6.80	-0.10	6.90	-0.10	7.00	0.00	7.00	0.10	6.90	0.00
Median	7.10	0.00	7.10	0.10	7.20	0.30	7.30	0.30	7.20	0.20
Q3	7.40	0.20	7.40	0.45	7.45	0.50	7.60	0.50	7.50	0.50
Maximum	8.2	0.9	8.7	1.5	8.2	1.3	8.2	1.4	8.3	1.5
Week 16										
N	74	74	84	84	78	78	89	89	69	69
Mean	7.12	0.07	7.17	0.21	7.21	0.26	7.29	0.27	7.17	0.19
SD	0.409	0.369	0.396	0.368	0.384	0.323	0.397	0.400	0.422	0.410
Minimum	6.3	-0.6	6.1	-0.7	6.1	-0.5	6.5	-0.7	5.6	-0.9
Q1	6.80	-0.20	6.90	0.00	7.00	0.00	7.00	0.00	6.90	0.00
Median	7.10	0.10	7.20	0.20	7.20	0.25	7.30	0.30	7.10	0.20
Q3	7.40	0.30	7.40	0.50	7.40	0.50	7.60	0.50	7.50	0.50
Maximum	8.1	1.4	8.3	1.0	8.2	1.0	8.4	1.4	8.4	1.2

治験総括報告書 Table 3.2.1.1.1（Section 15.1）（5.3.5.4-2）から引用

表 2.7.4.8-付録-36　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（OCT-101 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Total Protein (g/dL)

Visit / Statistics	Placebo (N=97)		TAK-385 10mg (N=103)		TAK-385 20mg (N=100)		TAK-385 40mg (N=103)		Leuprorelin (N=80)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 20										
N	75	75	81	81	77	77	87	87	65	65
Mean	7.12	0.08	7.15	0.20	7.13	0.18	7.24	0.22	7.18	0.20
SD	0.368	0.338	0.434	0.373	0.326	0.279	0.389	0.391	0.422	0.371
Minimum	6.2	-0.8	6.4	-0.6	6.4	-0.8	6.5	-0.9	5.7	-0.8
Q1	6.90	-0.10	6.80	-0.10	6.90	0.00	6.90	-0.10	6.90	0.00
Median	7.10	0.10	7.10	0.20	7.10	0.20	7.20	0.20	7.20	0.20
Q3	7.30	0.30	7.40	0.50	7.40	0.40	7.50	0.50	7.40	0.50
Maximum	8.2	1.0	8.6	1.0	7.8	0.8	8.3	1.2	8.2	1.1
Week 24										
N	68	68	79	79	76	76	88	88	62	62
Mean	7.01	-0.04	7.10	0.16	7.17	0.23	7.28	0.26	7.18	0.21
SD	0.347	0.353	0.414	0.414	0.365	0.388	0.367	0.434	0.403	0.371
Minimum	6.0	-1.0	6.3	-1.1	6.4	-0.6	6.3	-0.7	6.2	-0.6
Q1	6.80	-0.25	6.80	-0.10	7.00	0.00	7.00	-0.10	6.90	0.00
Median	7.00	0.00	7.10	0.20	7.10	0.20	7.30	0.20	7.15	0.20
Q3	7.25	0.20	7.30	0.50	7.40	0.50	7.55	0.60	7.50	0.50
Maximum	7.9	0.7	8.5	1.0	8.1	1.1	8.1	1.6	8.1	1.0
Follow-up										
N	76	76	83	83	77	77	89	89	69	69
Mean	7.08	0.04	6.94	-0.01	6.95	-0.01	7.03	0.01	7.17	0.18
SD	0.384	0.415	0.364	0.389	0.357	0.388	0.390	0.460	0.364	0.383
Minimum	6.2	-0.8	6.2	-0.9	6.1	-1.1	6.0	-1.3	5.6	-0.9
Q1	6.80	-0.30	6.70	-0.20	6.70	-0.20	6.80	-0.30	6.90	-0.10
Median	7.10	0.05	6.90	0.00	7.00	0.00	7.10	0.00	7.20	0.20
Q3	7.30	0.35	7.20	0.20	7.20	0.30	7.30	0.30	7.40	0.40
Maximum	8.0	0.9	8.4	1.0	8.1	0.9	7.9	1.1	8.1	1.2

治験総括報告書 Table 3.2.1.1.1（Section 15.1）（5.3.5.4-2）から引用

表 2.7.4.8-付録-36　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（OCT-101 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Total Cholesterol (mg/dL)

Visit / Statistics	Placebo (N=97)		TAK-385 10mg (N=103)		TAK-385 20mg (N=100)		TAK-385 40mg (N=103)		Leuprorelin (N=80)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Baseline										
N	97		103		100		103		80	
Mean	183.5		178.4		179.1		179.1		186.1	
SD	28.57		24.91		28.02		29.73		28.74	
Minimum	136		128		121		112		128	
Q1	161.0		160.0		159.0		159.0		164.0	
Median	180.0		178.0		177.0		176.0		184.5	
Q3	203.0		196.0		199.5		200.0		204.0	
Maximum	276		240		260		308		273	
Week 4										
N	97	97	103	103	100	100	103	103	80	80
Mean	183.6	0.1	188.3	10.0	192.1	13.0	195.7	16.6	199.2	13.0
SD	27.86	15.61	27.82	16.60	30.89	16.84	34.12	19.50	29.17	17.08
Minimum	135	-65	118	-25	133	-45	129	-45	141	-25
Q1	163.0	-9.0	166.0	-2.0	168.5	2.5	177.0	6.0	180.0	2.0
Median	185.0	0.0	187.0	9.0	191.5	13.0	190.0	14.0	197.0	12.0
Q3	199.0	9.0	209.0	21.0	207.5	24.5	213.0	29.0	212.0	23.5
Maximum	291	37	258	51	280	61	386	78	293	61
Week 8										
N	95	95	103	103	96	96	101	101	78	78
Mean	188.3	4.8	188.3	9.9	192.4	12.1	197.1	17.8	197.5	11.1
SD	29.01	17.84	27.76	19.25	30.35	17.67	35.00	22.68	30.52	16.86
Minimum	120	-44	138	-37	133	-39	111	-43	135	-33
Q1	169.0	-6.0	166.0	-4.0	171.0	0.5	172.0	2.0	174.0	0.0
Median	183.0	6.0	188.0	11.0	192.5	9.5	193.0	20.0	198.5	10.0
Q3	204.0	16.0	207.0	25.0	213.0	25.5	220.0	30.0	216.0	24.0
Maximum	280	48	256	78	282	49	365	80	293	57
Week 12										
N	93	93	101	101	92	92	101	101	75	75
Mean	187.1	3.5	189.4	10.9	191.8	10.8	196.5	17.3	198.1	11.0
SD	33.13	20.84	29.10	19.46	29.61	20.81	34.51	21.99	31.01	16.86
Minimum	124	-34	140	-34	130	-53	120	-44	128	-50
Q1	164.0	-9.0	169.0	-1.0	173.5	-1.5	176.0	1.0	177.0	1.0
Median	184.0	3.0	187.0	10.0	190.5	12.0	193.0	17.0	195.0	10.0
Q3	201.0	13.0	205.0	19.0	207.0	25.0	211.0	30.0	218.0	21.0
Maximum	293	78	266	72	273	58	373	82	287	55
Week 16										
N	75	75	84	84	78	78	89	89	69	69
Mean	186.7	3.4	193.1	15.1	196.0	12.9	200.1	20.4	202.1	12.6
SD	32.95	18.64	28.94	20.25	27.89	17.87	36.67	21.61	34.19	22.41
Minimum	141	-34	137	-34	146	-50	131	-29	135	-50
Q1	160.0	-10.0	173.0	-1.0	174.0	3.0	180.0	5.0	177.0	1.0
Median	182.0	3.0	192.5	14.5	193.5	13.5	195.0	20.0	204.0	13.0
Q3	203.0	13.0	212.5	31.0	214.0	25.0	219.0	32.0	223.0	23.0
Maximum	287	82	262	84	281	50	389	88	301	87

治験総括報告書 Table 3.2.1.1.1（Section 15.1）（5.3.5.4-2）から引用

表 2.7.4.8-付録-36　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（OCT-101 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Total Cholesterol (mg/dL)

Visit / Statistics	Placebo (N=97)		TAK-385 10mg (N=103)		TAK-385 20mg (N=100)		TAK-385 40mg (N=103)		Leuprorelin (N=80)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 20										
N	75	75	81	81	77	77	87	87	65	65
Mean	188.3	5.0	190.7	12.3	193.6	10.5	198.0	17.9	203.4	13.6
SD	28.80	18.64	30.05	21.24	30.54	19.08	34.39	24.12	32.88	21.19
Minimum	140	-51	118	-28	125	-49	118	-51	134	-46
Q1	169.0	-8.0	168.0	0.0	175.0	0.0	181.0	5.0	179.0	3.0
Median	184.0	6.0	190.0	10.0	189.0	10.0	194.0	16.0	205.0	11.0
Q3	206.0	18.0	205.0	24.0	206.0	24.0	211.0	36.0	219.0	25.0
Maximum	268	47	262	84	289	65	371	78	299	83
Week 24										
N	68	68	79	79	76	76	88	88	62	62
Mean	183.6	-0.8	191.8	13.0	196.2	12.5	199.0	19.0	204.9	15.5
SD	30.36	19.07	29.69	22.41	32.94	21.57	35.33	21.49	33.48	19.98
Minimum	136	-50	135	-40	129	-52	125	-38	128	-26
Q1	162.0	-15.0	167.0	1.0	174.5	0.0	178.0	3.5	180.0	0.0
Median	179.5	0.0	195.0	16.0	197.0	11.5	196.0	19.0	204.5	14.0
Q3	198.5	14.0	218.0	26.0	210.0	26.5	223.0	33.0	224.0	28.0
Maximum	277	31	260	76	278	73	353	75	307	93
Follow-up										
N	77	77	83	83	77	77	89	89	69	69
Mean	186.3	3.2	180.7	2.6	186.9	3.7	190.8	11.0	202.0	12.6
SD	29.97	18.61	26.99	18.68	30.38	22.36	34.44	21.66	30.68	19.28
Minimum	136	-42	132	-45	113	-68	128	-38	126	-39
Q1	165.0	-7.0	161.0	-12.0	168.0	-9.0	168.0	-3.0	178.0	1.0
Median	181.0	3.0	179.0	3.0	184.0	3.0	188.0	10.0	202.0	15.0
Q3	200.0	12.0	201.0	14.0	207.0	17.0	212.0	26.0	225.0	25.0
Maximum	321	49	247	45	288	65	358	67	272	62

治験総括報告書 Table 3.2.1.1.1（Section 15.1）（5.3.5.4-2）から引用

表 2.7.4.8-付録-36　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（OCT-101 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: HDL Cholesterol (mg/dL)

Visit / Statistics	Placebo (N=97) Observed Value at Visit	Placebo (N=97) Change from Baseline	TAK-385 10mg (N=103) Observed Value at Visit	TAK-385 10mg (N=103) Change from Baseline	TAK-385 20mg (N=100) Observed Value at Visit	TAK-385 20mg (N=100) Change from Baseline	TAK-385 40mg (N=103) Observed Value at Visit	TAK-385 40mg (N=103) Change from Baseline	Leuprorelin (N=80) Observed Value at Visit	Leuprorelin (N=80) Change from Baseline
Baseline										
N	97		103		100		103		80	
Mean	64.0		62.9		64.6		63.0		61.7	
SD	12.37		12.77		12.45		10.69		13.17	
Minimum	38		33		30		37		38	
Q1	56.0		54.0		58.0		55.0		53.0	
Median	64.0		62.0		63.0		64.0		61.0	
Q3	72.0		71.0		73.0		71.0		68.0	
Maximum	96		101		97		89		107	
Week 4										
N	97	97	103	103	100	100	103	103	80	80
Mean	64.5	0.5	67.3	4.4	70.3	5.7	70.0	6.9	67.6	5.9
SD	12.32	6.34	14.81	7.07	15.19	7.42	13.46	8.66	14.88	6.99
Minimum	34	-16	34	-17	36	-13	44	-12	31	-12
Q1	56.0	-3.0	56.0	-1.0	60.0	1.0	58.0	1.0	59.0	2.0
Median	64.0	1.0	67.0	4.0	70.0	6.0	72.0	7.0	66.0	6.0
Q3	74.0	5.0	76.0	10.0	78.0	11.0	80.0	13.0	76.0	10.0
Maximum	94	15	113	22	118	28	105	36	112	25
Week 8										
N	95	95	103	103	96	96	101	101	78	78
Mean	65.9	2.0	67.1	4.2	70.1	5.4	69.3	6.2	65.6	4.1
SD	12.84	6.82	14.23	7.61	14.71	7.78	14.52	10.55	13.52	6.87
Minimum	33	-17	37	-17	36	-13	25	-26	36	-11
Q1	58.0	-2.0	58.0	0.0	60.0	0.0	59.0	0.0	57.0	0.0
Median	66.0	2.0	65.0	4.0	68.0	5.0	69.0	6.0	66.0	4.0
Q3	75.0	7.0	75.0	9.0	78.0	11.0	79.0	10.0	74.0	8.0
Maximum	97	16	105	29	113	22	108	39	106	24
Week 12										
N	93	93	101	101	92	92	101	101	75	75
Mean	65.9	2.0	67.4	4.4	69.6	4.8	68.8	5.6	65.9	4.8
SD	13.29	7.23	14.39	8.27	13.37	8.53	14.04	10.03	13.82	7.76
Minimum	37	-17	38	-23	35	-17	36	-18	38	-21
Q1	57.0	-2.0	58.0	0.0	60.5	-3.0	58.0	-1.0	56.0	-1.0
Median	67.0	1.0	66.0	3.0	69.0	6.0	68.0	6.0	67.0	5.0
Q3	75.0	5.0	77.0	10.0	79.0	11.0	78.0	11.0	75.0	9.0
Maximum	101	17	104	31	97	25	107	37	113	27
Week 16										
N	75	75	84	84	78	78	89	89	69	69
Mean	65.9	2.1	69.7	5.7	71.5	6.5	70.3	7.1	66.0	4.3
SD	13.48	7.56	14.41	8.12	14.80	8.23	13.47	8.81	13.63	7.94
Minimum	36	-22	37	-9	36	-10	45	-17	34	-18
Q1	56.0	-2.0	59.5	-1.0	63.0	1.0	59.0	2.0	58.0	0.0
Median	64.0	2.0	67.0	5.0	71.0	6.0	71.0	6.0	68.0	3.0
Q3	78.0	8.0	78.0	12.0	81.0	13.0	80.0	12.0	75.0	10.0
Maximum	94	20	102	26	110	34	102	33	106	28

治験総括報告書 Table 3.2.1.1.1（Section 15.1）（5.3.5.4-2）から引用

表 2.7.4.8-付録-36　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（OCT-101 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: HDL Cholesterol (mg/dL)

Visit / Statistics	Placebo (N=97)		TAK-385 10mg (N=103)		TAK-385 20mg (N=100)		TAK-385 40mg (N=103)		Leuprorelin (N=80)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 20										
N	75	75	81	81	77	77	87	87	65	65
Mean	65.8	2.0	69.2	4.9	70.0	5.1	69.6	6.5	68.1	5.8
SD	12.42	6.87	15.22	9.16	15.18	8.24	14.28	10.20	14.23	8.06
Minimum	32	-16	38	-17	28	-10	36	-20	42	-18
Q1	56.0	-3.0	58.0	-1.0	60.0	0.0	60.0	-1.0	59.0	2.0
Median	65.0	2.0	69.0	4.0	69.0	5.0	70.0	7.0	68.0	6.0
Q3	75.0	7.0	79.0	9.0	80.0	10.0	77.0	14.0	75.0	10.0
Maximum	92	17	110	29	104	27	113	29	109	29
Week 24										
N	68	68	79	79	76	76	88	88	62	62
Mean	65.2	1.4	70.4	5.9	71.9	6.7	69.9	6.7	67.4	5.5
SD	12.40	7.61	15.20	9.13	13.91	8.24	13.41	9.72	13.39	8.37
Minimum	35	-17	38	-15	32	-16	39	-18	41	-15
Q1	56.0	-4.0	60.0	-1.0	65.0	1.0	60.5	0.0	58.0	0.0
Median	65.0	1.5	70.0	6.0	72.5	7.0	71.0	5.0	69.0	7.0
Q3	74.5	5.0	79.0	12.0	80.0	13.0	79.0	13.5	75.0	11.0
Maximum	97	19	112	28	106	27	106	33	99	34
Follow-up										
N	77	77	83	83	77	77	89	89	69	69
Mean	65.2	1.6	66.3	2.3	68.1	3.1	68.1	4.9	67.7	5.9
SD	12.64	7.49	13.84	7.89	14.25	9.32	12.89	8.85	15.63	8.13
Minimum	31	-17	37	-12	31	-20	41	-19	34	-17
Q1	57.0	-3.0	57.0	-4.0	59.0	-2.0	58.0	-2.0	60.0	2.0
Median	64.0	2.0	65.0	1.0	67.0	3.0	69.0	5.0	69.0	6.0
Q3	74.0	7.0	75.0	9.0	76.0	10.0	74.0	10.0	78.0	11.0
Maximum	95	20	113	18	113	34	105	26	113	27

治験総括報告書 Table 3.2.1.1.1（Section 15.1）（5.3.5.4-2）から引用

表 2.7.4.8-付録-36　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（OCT-101 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: LDL Cholesterol (mg/dL)

Visit / Statistics	Placebo (N=97) Observed Value at Visit	Placebo (N=97) Change from Baseline	TAK-385 10mg (N=103) Observed Value at Visit	TAK-385 10mg (N=103) Change from Baseline	TAK-385 20mg (N=100) Observed Value at Visit	TAK-385 20mg (N=100) Change from Baseline	TAK-385 40mg (N=103) Observed Value at Visit	TAK-385 40mg (N=103) Change from Baseline	Leuprorelin (N=80) Observed Value at Visit	Leuprorelin (N=80) Change from Baseline
Baseline										
N	97		103		100		103		80	
Mean	102.9		99.9		98.9		101.2		107.8	
SD	26.31		22.77		22.93		27.22		26.01	
Minimum	49		42		54		41		58	
Q1	85.0		83.0		84.5		83.0		90.0	
Median	101.0		97.0		98.0		97.0		105.0	
Q3	120.0		113.0		109.0		117.0		122.0	
Maximum	197		166		184		215		194	
Week 4										
N	97	97	103	103	100	100	103	103	80	80
Mean	104.0	1.1	105.2	5.3	105.5	6.6	109.1	7.9	113.9	6.1
SD	26.60	12.71	24.87	11.73	25.58	13.04	32.03	15.16	27.78	14.13
Minimum	48	-42	38	-20	54	-39	53	-28	67	-24
Q1	85.0	-6.0	88.0	-3.0	89.0	-2.5	89.0	-3.0	93.0	-3.5
Median	102.0	0.0	101.0	6.0	104.5	7.0	102.0	8.0	112.0	5.0
Q3	121.0	8.0	124.0	14.0	119.5	15.5	123.0	15.0	128.0	15.0
Maximum	202	39	162	33	199	40	273	58	198	46
Week 8										
N	95	95	103	103	96	96	101	101	78	78
Mean	106.9	3.7	105.7	5.8	105.6	5.8	111.4	10.1	114.0	6.0
SD	27.97	14.72	26.10	14.52	25.13	12.23	31.50	15.83	28.98	15.17
Minimum	67	-31	46	-31	51	-24	50	-23	46	-39
Q1	85.0	-6.0	87.0	-4.0	90.0	-1.5	90.0	-2.0	91.0	-3.0
Median	102.0	4.0	104.0	7.0	105.0	5.0	104.0	9.0	110.0	6.5
Q3	120.0	12.0	123.0	15.0	122.0	14.5	129.0	22.0	133.0	16.0
Maximum	192	40	173	71	203	38	269	54	205	49
Week 12										
N	93	93	101	101	92	92	101	101	75	75
Mean	106.6	3.4	106.3	6.4	107.1	6.9	111.8	10.5	116.0	7.0
SD	31.25	16.35	25.74	14.24	26.21	15.24	32.06	16.83	29.17	13.93
Minimum	48	-31	51	-23	51	-28	52	-23	51	-29
Q1	84.0	-8.0	84.0	-2.0	89.0	-3.5	94.0	-3.0	95.0	-1.0
Median	98.0	3.0	109.0	5.0	106.5	7.0	105.0	11.0	117.0	6.0
Q3	124.0	10.0	120.0	14.0	121.5	18.5	126.0	20.0	134.0	16.0
Maximum	213	67	171	67	193	39	259	59	201	35
Week 16										
N	75	75	84	84	78	78	89	89	69	69
Mean	104.0	1.1	106.5	8.3	108.4	6.5	113.1	12.0	117.7	6.9
SD	27.83	13.58	25.67	15.71	25.11	12.77	35.11	18.10	31.63	19.16
Minimum	61	-29	51	-27	54	-39	51	-22	52	-57
Q1	88.0	-6.0	86.0	-0.5	91.0	-1.0	90.0	0.0	91.0	-4.0
Median	98.0	1.0	104.0	9.0	109.5	8.0	106.0	10.0	118.0	5.0
Q3	122.0	8.0	122.5	16.5	124.0	15.0	130.0	23.0	135.0	17.0
Maximum	195	45	186	84	196	29	273	62	215	72

治験総括報告書 Table 3.2.1.1.1（Section 15.1）（5.3.5.4-2）から引用

表 2.7.4.8-付録-36　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（OCT-101 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: LDL Cholesterol (mg/dL)

Visit / Statistics	Placebo (N=97)		TAK-385 10mg (N=103)		TAK-385 20mg (N=100)		TAK-385 40mg (N=103)		Leuprorelin (N=80)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 20										
N	75	75	81	81	77	77	87	87	65	65
Mean	106.8	3.9	104.5	6.3	107.1	5.3	110.8	9.4	118.4	7.7
SD	27.49	13.51	26.97	15.28	26.55	14.82	31.29	16.50	31.84	17.56
Minimum	55	-36	33	-26	59	-34	51	-27	52	-31
Q1	86.0	-5.0	83.0	-1.0	89.0	-4.0	92.0	-3.0	92.0	-5.0
Median	104.0	4.0	103.0	5.0	107.0	7.0	104.0	7.0	117.0	9.0
Q3	124.0	11.0	124.0	14.0	121.0	14.0	123.0	23.0	135.0	18.0
Maximum	205	40	172	70	219	43	259	47	216	73
Week 24										
N	68	68	79	79	76	76	88	88	62	62
Mean	104.5	0.4	106.9	8.5	110.1	7.9	113.4	12.1	121.0	10.2
SD	29.24	14.16	26.20	15.80	29.56	16.65	31.95	14.72	33.51	17.85
Minimum	58	-33	44	-31	57	-32	48	-26	62	-28
Q1	86.5	-9.0	87.0	0.0	86.0	-2.5	92.0	1.0	94.0	-1.0
Median	98.5	1.0	101.0	6.0	108.5	7.0	109.5	12.5	119.0	10.0
Q3	117.5	11.0	126.0	19.0	127.0	17.5	135.0	23.5	137.0	17.0
Maximum	207	36	158	50	206	48	239	52	236	93
Follow-up										
N	77	77	83	83	77	77	89	89	69	69
Mean	105.1	2.2	99.1	0.8	104.5	2.7	108.2	7.1	116.4	5.7
SD	28.22	14.91	25.46	15.59	24.73	16.51	32.47	15.89	28.87	16.14
Minimum	56	-30	41	-30	51	-46	52	-21	52	-43
Q1	87.0	-6.0	80.0	-10.0	88.0	-8.0	86.0	-5.0	94.0	-2.0
Median	101.0	1.0	98.0	1.0	104.0	4.0	103.0	6.0	118.0	5.0
Q3	116.0	10.0	120.0	11.0	119.0	12.0	128.0	17.0	135.0	16.0
Maximum	237	41	167	48	180	49	253	45	187	52

治験総括報告書 Table 3.2.1.1.1（Section 15.1）（5.3.5.4-2）から引用

表 2.7.4.8-付録-36　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（OCT-101 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Triglycerides (mg/dL)

Visit / Statistics	Placebo (N=97)		TAK-385 10mg (N=103)		TAK-385 20mg (N=100)		TAK-385 40mg (N=103)		Leuprorelin (N=80)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Baseline										
N	97		103		100		103		80	
Mean	79.5		73.9		73.6		73.9		86.0	
SD	49.15		47.14		43.62		35.08		79.47	
Minimum	30		27		27		25		33	
Q1	47.0		46.0		46.5		46.0		54.0	
Median	65.0		62.0		59.0		65.0		70.0	
Q3	87.0		87.0		83.5		92.0		98.0	
Maximum	318		345		272		188		720	
Week 4										
N	97	97	103	103	100	100	103	103	80	80
Mean	76.4	-3.2	79.3	5.4	74.0	0.4	85.0	11.0	89.3	3.3
SD	46.12	41.82	54.37	31.86	41.63	37.52	56.89	48.58	55.01	82.04
Minimum	29	-246	24	-81	31	-138	27	-128	26	-625
Q1	50.0	-18.0	50.0	-9.0	48.5	-13.5	50.0	-9.0	58.0	-5.5
Median	63.0	1.0	67.0	3.0	64.0	4.0	69.0	4.0	73.5	7.5
Q3	87.0	13.0	87.0	21.0	92.5	18.0	99.0	26.0	100.0	25.0
Maximum	323	120	404	140	329	151	369	196	358	251
Week 8										
N	95	95	103	103	96	96	101	101	78	78
Mean	79.0	-0.7	76.6	2.8	78.9	4.0	83.0	9.5	94.6	8.1
SD	54.29	34.93	44.18	35.87	57.27	55.60	47.50	37.51	58.56	81.65
Minimum	23	-109	30	-92	27	-135	29	-129	30	-608
Q1	47.0	-19.0	50.0	-14.0	46.0	-13.0	50.0	-10.0	56.0	-10.0
Median	62.0	-3.0	68.0	2.0	66.0	1.0	68.0	4.0	78.0	4.5
Q3	88.0	14.0	84.0	16.0	85.5	15.0	96.0	28.0	106.0	41.0
Maximum	362	159	267	169	408	345	272	120	353	198
Week 12										
N	93	93	101	101	92	92	101	101	75	75
Mean	76.1	-4.2	81.3	7.6	77.1	1.4	87.8	14.3	89.9	2.0
SD	42.92	38.09	56.14	37.95	38.11	43.97	52.51	46.04	48.91	79.60
Minimum	25	-137	30	-100	33	-186	31	-144	30	-606
Q1	47.0	-19.0	51.0	-11.0	47.0	-15.5	52.0	-8.0	53.0	-12.0
Median	66.0	0.0	63.0	4.0	68.0	3.0	75.0	11.0	76.0	7.0
Q3	90.0	13.0	90.0	20.0	92.0	20.0	107.0	36.0	114.0	27.0
Maximum	213	97	408	140	185	112	360	211	264	109
Week 16										
N	75	75	84	84	78	78	89	89	69	69
Mean	92.0	11.6	75.2	4.5	71.5	-7.2	83.9	8.7	95.8	7.6
SD	148.86	146.66	56.64	45.71	30.68	38.32	49.29	43.16	54.92	86.29
Minimum	27	-119	29	-182	28	-143	29	-147	31	-613
Q1	47.0	-16.0	49.0	-14.0	48.0	-18.0	52.0	-12.0	57.0	-7.0
Median	62.0	-2.0	61.0	4.5	63.5	-1.5	68.0	6.0	73.0	8.0
Q3	83.0	9.0	84.5	21.5	88.0	11.0	98.0	23.0	111.0	32.0
Maximum	1300	1229	491	223	176	75	318	169	290	183

治験総括報告書 Table 3.2.1.1.1（Section 15.1）（5.3.5.4-2）から引用

表 2.7.4.8-付録-36　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（OCT-101 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Triglycerides (mg/dL)

Visit / Statistics	Placebo (N=97)		TAK-385 10mg (N=103)		TAK-385 20mg (N=100)		TAK-385 40mg (N=103)		Leuprorelin (N=80)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 20										
N	75	75	81	81	77	77	87	87	65	65
Mean	79.9	-0.6	81.5	10.0	78.1	-0.8	85.4	9.6	85.9	-1.0
SD	42.30	40.67	54.60	38.62	36.54	38.85	57.23	47.93	55.90	90.00
Minimum	29	-267	32	-89	29	-137	33	-123	31	-635
Q1	52.0	-6.0	51.0	-13.0	52.0	-17.0	55.0	-14.0	52.0	-13.0
Median	71.0	4.0	64.0	7.0	71.0	2.0	66.0	8.0	72.0	-5.0
Q3	93.0	14.0	84.0	23.0	94.0	15.0	106.0	24.0	90.0	27.0
Maximum	242	64	305	180	203	122	476	288	363	208
Week 24										
N	68	68	79	79	76	76	88	88	62	62
Mean	78.1	-3.8	76.3	4.7	72.9	-6.6	85.1	9.6	88.2	0.7
SD	45.61	48.27	48.87	31.57	29.69	40.67	57.56	49.22	50.60	91.40
Minimum	27	-279	27	-74	27	-168	33	-139	35	-623
Q1	46.5	-14.5	44.0	-10.0	52.0	-23.5	50.5	-10.5	53.0	-10.0
Median	66.0	-0.5	65.0	3.0	67.0	1.0	66.5	4.0	70.5	3.5
Q3	92.0	14.0	87.0	19.0	90.5	18.0	94.0	26.0	107.0	27.0
Maximum	251	114	271	115	160	83	344	227	299	144
Follow-up										
N	77	77	83	83	77	77	89	89	69	69
Mean	91.3	11.5	77.3	6.4	69.5	-9.5	76.6	1.3	100.3	12.0
SD	76.42	67.35	55.43	47.16	30.13	44.04	42.25	37.28	73.27	97.72
Minimum	33	-156	27	-152	27	-170	31	-134	30	-616
Q1	50.0	-13.0	45.0	-14.0	48.0	-31.0	50.0	-22.0	59.0	-9.0
Median	63.0	2.0	64.0	5.0	63.0	0.0	60.0	2.0	78.0	5.0
Q3	102.0	15.0	83.0	19.0	84.0	15.0	92.0	18.0	106.0	40.0
Maximum	450	370	390	273	197	105	217	110	418	264

治験総括報告書 Table 3.2.1.1.1（Section 15.1）（5.3.5.4-2）から引用

表 2.7.4.8-付録-36　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（OCT-101 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Glucose (mg/dL)

Visit / Statistics	Placebo (N=97)		TAK-385 10mg (N=103)		TAK-385 20mg (N=100)		TAK-385 40mg (N=103)		Leuprorelin (N=80)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Baseline										
N	97		103		100		103		80	
Mean	93.5		93.7		93.0		92.1		91.8	
SD	11.91		21.02		13.90		12.46		10.12	
Minimum	69		75		74		73		63	
Q1	86.0		86.0		86.0		86.0		86.5	
Median	91.0		92.0		91.0		90.0		91.0	
Q3	99.0		96.0		95.0		94.0		97.0	
Maximum	130		282		183		181		125	
Week 4										
N	97	97	103	103	100	100	103	103	80	80
Mean	95.2	1.7	95.2	1.5	89.1	-3.9	92.2	0.1	93.1	1.3
SD	21.91	20.68	22.35	10.76	9.14	14.12	7.68	12.42	12.96	13.36
Minimum	56	-42	71	-22	59	-94	59	-87	57	-43
Q1	87.0	-5.0	87.0	-4.0	84.0	-6.5	88.0	-4.0	87.0	-4.0
Median	91.0	0.0	91.0	1.0	89.0	-1.0	92.0	2.0	92.0	1.0
Q3	98.0	5.0	98.0	4.0	94.0	3.0	97.0	5.0	97.5	6.5
Maximum	276	172	284	51	114	26	111	24	152	58
Week 8										
N	95	95	103	103	96	96	101	101	78	78
Mean	95.8	2.2	94.1	0.4	91.6	-1.8	91.6	-0.7	92.9	0.9
SD	19.67	18.58	18.59	11.90	9.80	15.36	8.45	12.19	8.71	11.07
Minimum	60	-37	63	-44	62	-79	69	-90	66	-42
Q1	87.0	-4.0	86.0	-5.0	86.0	-6.0	87.0	-4.0	87.0	-3.0
Median	94.0	0.0	91.0	0.0	91.0	0.5	91.0	1.0	91.5	2.0
Q3	99.0	7.0	99.0	6.0	96.5	6.0	96.0	5.0	97.0	6.0
Maximum	239	135	238	66	121	32	127	15	118	35
Week 12										
N	93	93	101	101	92	92	101	101	75	75
Mean	93.8	0.5	94.9	1.0	90.6	-2.8	91.7	-0.6	93.5	1.2
SD	16.79	15.66	18.18	13.88	11.71	16.47	7.74	13.43	9.76	11.91
Minimum	66	-38	64	-54	59	-92	72	-97	64	-41
Q1	86.0	-5.0	87.0	-5.0	84.0	-5.0	88.0	-3.0	88.0	-3.0
Median	90.0	0.0	92.0	0.0	90.0	-1.5	91.0	1.0	94.0	1.0
Q3	97.0	7.0	98.0	5.0	95.0	4.0	95.0	6.0	98.0	7.0
Maximum	213	109	228	57	134	36	120	32	137	41
Week 16										
N	75	75	84	84	78	78	89	89	69	69
Mean	96.8	2.8	93.1	-0.9	92.3	-1.6	92.7	0.1	93.5	1.0
SD	25.46	24.63	21.12	10.79	10.55	17.69	7.62	12.94	8.72	10.29
Minimum	80	-41	62	-32	63	-91	76	-89	74	-46
Q1	88.0	-5.0	86.0	-6.5	87.0	-7.0	87.0	-4.0	88.0	-3.0
Median	91.0	1.0	91.0	-1.0	92.0	1.0	92.0	2.0	93.0	1.0
Q3	98.0	6.0	95.5	4.0	97.0	8.0	98.0	7.0	98.0	5.0
Maximum	292	188	260	33	130	38	115	17	127	34

治験総括報告書 Table 3.2.1.1.1（Section 15.1）（5.3.5.4-2）から引用

表 2.7.4.8-付録-36　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（OCT-101 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Glucose (mg/dL)

Visit / Statistics	Placebo (N=97) Observed Value at Visit	Placebo (N=97) Change from Baseline	TAK-385 10mg (N=103) Observed Value at Visit	TAK-385 10mg (N=103) Change from Baseline	TAK-385 20mg (N=100) Observed Value at Visit	TAK-385 20mg (N=100) Change from Baseline	TAK-385 40mg (N=103) Observed Value at Visit	TAK-385 40mg (N=103) Change from Baseline	Leuprorelin (N=80) Observed Value at Visit	Leuprorelin (N=80) Change from Baseline
Week 20										
N	75	75	81	81	77	77	87	87	65	65
Mean	96.6	2.6	95.1	1.0	93.9	0.2	91.6	-1.2	93.4	0.6
SD	15.10	15.11	20.42	10.52	10.77	17.55	8.69	12.69	11.88	12.95
Minimum	75	-40	58	-30	73	-98	67	-77	67	-41
Q1	89.0	-4.0	89.0	-5.0	88.0	-4.0	86.0	-5.0	86.0	-3.0
Median	94.0	1.0	92.0	2.0	91.0	1.0	91.0	-1.0	92.0	0.0
Q3	101.0	8.0	98.0	5.0	99.0	8.0	96.0	5.0	97.0	4.0
Maximum	193	89	254	32	142	48	120	25	154	54
Week 24										
N	68	68	79	79	76	76	88	88	62	62
Mean	95.5	1.3	94.2	0.2	91.2	-2.5	92.4	-0.2	92.7	-0.2
SD	13.40	14.85	19.82	12.10	8.06	15.75	9.04	15.60	8.11	9.69
Minimum	77	-31	70	-38	70	-92	72	-99	74	-31
Q1	88.0	-6.0	86.0	-7.0	85.5	-6.0	86.5	-6.0	88.0	-4.0
Median	93.0	1.5	91.0	1.0	91.0	-0.5	91.5	1.0	92.0	1.0
Q3	100.0	7.5	96.0	6.0	96.0	4.0	98.0	7.0	98.0	4.0
Maximum	163	73	244	47	112	22	120	35	115	36
Follow-up										
N	77	77	83	83	77	77	89	89	69	69
Mean	94.7	0.6	96.1	2.3	90.8	-3.1	92.2	-0.4	94.5	2.0
SD	12.80	12.44	31.35	13.84	10.90	15.60	11.94	13.36	10.92	12.42
Minimum	67	-40	67	-22	66	-82	67	-37	69	-38
Q1	87.0	-4.0	87.0	-6.0	84.0	-7.0	86.0	-5.0	86.0	-4.0
Median	91.0	2.0	92.0	1.0	91.0	-1.0	91.0	1.0	94.0	2.0
Q3	98.0	6.0	100.0	5.0	95.0	4.0	97.0	5.0	99.0	9.0
Maximum	153	63	361	79	125	38	152	52	131	38

治験総括報告書 Table 3.2.1.1.1（Section 15.1）（5.3.5.4-2）から引用

表 2.7.4.8-付録-36　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（OCT-101 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Creatinine (mg/dL)

Visit / Statistics	Placebo (N=97)		TAK-385 10mg (N=103)		TAK-385 20mg (N=100)		TAK-385 40mg (N=103)		Leuprorelin (N=80)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Baseline										
N	97		103		100		103		80	
Mean	0.588		0.598		0.580		0.594		0.605	
SD	0.0769		0.0873		0.0781		0.0738		0.0881	
Minimum	0.41		0.43		0.41		0.43		0.43	
Q1	0.540		0.530		0.525		0.540		0.535	
Median	0.590		0.600		0.575		0.580		0.605	
Q3	0.630		0.660		0.635		0.640		0.670	
Maximum	0.87		0.82		0.75		0.90		0.83	
Week 4										
N	97	97	103	103	100	100	103	103	80	80
Mean	0.586	-0.002	0.614	0.015	0.597	0.018	0.618	0.023	0.619	0.014
SD	0.0823	0.0485	0.0890	0.0519	0.0821	0.0464	0.0769	0.0467	0.0829	0.0514
Minimum	0.39	-0.15	0.43	-0.15	0.42	-0.08	0.41	-0.10	0.46	-0.13
Q1	0.530	-0.020	0.550	-0.010	0.540	-0.015	0.570	-0.010	0.550	-0.020
Median	0.590	0.000	0.600	0.020	0.595	0.020	0.610	0.020	0.610	0.020
Q3	0.640	0.030	0.670	0.050	0.645	0.040	0.660	0.060	0.675	0.050
Maximum	0.86	0.10	0.89	0.15	0.82	0.18	0.82	0.14	0.82	0.15
Week 8										
N	95	95	103	103	96	96	101	101	78	78
Mean	0.590	0.001	0.612	0.013	0.600	0.020	0.612	0.016	0.618	0.015
SD	0.0771	0.0453	0.0843	0.0565	0.0897	0.0513	0.0802	0.0505	0.0832	0.0438
Minimum	0.44	-0.10	0.43	-0.19	0.44	-0.13	0.45	-0.09	0.45	-0.09
Q1	0.540	-0.030	0.560	-0.020	0.525	-0.015	0.560	-0.020	0.550	-0.010
Median	0.590	0.010	0.620	0.010	0.590	0.020	0.610	0.010	0.620	0.020
Q3	0.640	0.030	0.670	0.050	0.665	0.050	0.660	0.050	0.690	0.050
Maximum	0.86	0.11	0.83	0.13	0.85	0.16	0.88	0.15	0.84	0.10
Week 12										
N	93	93	101	101	92	92	101	101	75	75
Mean	0.590	0.000	0.613	0.015	0.600	0.019	0.610	0.014	0.616	0.014
SD	0.0796	0.0472	0.0819	0.0502	0.0862	0.0480	0.0740	0.0513	0.0853	0.0467
Minimum	0.43	-0.12	0.44	-0.10	0.42	-0.09	0.47	-0.09	0.41	-0.10
Q1	0.540	-0.030	0.550	-0.020	0.540	-0.010	0.560	-0.030	0.560	-0.020
Median	0.590	0.000	0.610	0.010	0.600	0.020	0.600	0.020	0.620	0.020
Q3	0.630	0.030	0.670	0.050	0.650	0.050	0.650	0.050	0.670	0.040
Maximum	0.91	0.15	0.85	0.14	0.81	0.15	0.86	0.21	0.85	0.15
Week 16										
N	75	75	84	84	78	78	89	89	69	69
Mean	0.583	-0.006	0.619	0.018	0.596	0.017	0.624	0.029	0.610	0.011
SD	0.0775	0.0527	0.0825	0.0498	0.0823	0.0525	0.0775	0.0589	0.0847	0.0504
Minimum	0.43	-0.23	0.42	-0.09	0.41	-0.13	0.46	-0.12	0.43	-0.11
Q1	0.530	-0.030	0.560	-0.010	0.550	-0.020	0.570	-0.010	0.550	-0.020
Median	0.580	0.000	0.620	0.020	0.610	0.015	0.620	0.030	0.610	0.010
Q3	0.610	0.030	0.680	0.055	0.640	0.060	0.670	0.070	0.660	0.040
Maximum	0.89	0.11	0.83	0.14	0.83	0.14	0.79	0.18	0.88	0.14

治験総括報告書 Table 3.2.1.1.1（Section 15.1）（5.3.5.4-2）から引用

表 2.7.4.8-付録-36　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（OCT-101 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Creatinine (mg/dL)

Visit / Statistics	Placebo (N=97)		TAK-385 10mg (N=103)		TAK-385 20mg (N=100)		TAK-385 40mg (N=103)		Leuprorelin (N=80)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 20										
N	75	75	81	81	77	77	87	87	65	65
Mean	0.590	0.001	0.613	0.011	0.600	0.021	0.609	0.017	0.615	0.017
SD	0.0788	0.0514	0.0867	0.0489	0.0797	0.0505	0.0761	0.0509	0.0842	0.0511
Minimum	0.43	-0.14	0.45	-0.18	0.42	-0.12	0.46	-0.11	0.42	-0.08
Q1	0.530	-0.030	0.560	-0.010	0.560	-0.010	0.540	-0.020	0.580	-0.010
Median	0.590	0.010	0.600	0.020	0.600	0.020	0.610	0.030	0.610	0.020
Q3	0.640	0.040	0.680	0.040	0.640	0.060	0.670	0.060	0.670	0.050
Maximum	0.91	0.11	0.87	0.17	0.85	0.12	0.82	0.14	0.81	0.13
Week 24										
N	68	68	79	79	76	76	88	88	62	62
Mean	0.598	0.005	0.617	0.012	0.601	0.023	0.616	0.022	0.629	0.031
SD	0.0756	0.0505	0.0852	0.0643	0.0805	0.0644	0.0805	0.0542	0.1744	0.1490
Minimum	0.45	-0.09	0.45	-0.11	0.40	-0.14	0.46	-0.13	0.45	-0.13
Q1	0.550	-0.030	0.560	-0.020	0.540	-0.020	0.555	-0.010	0.560	-0.020
Median	0.590	0.000	0.610	0.010	0.610	0.020	0.600	0.020	0.620	0.015
Q3	0.640	0.030	0.670	0.050	0.650	0.060	0.660	0.060	0.660	0.050
Maximum	0.92	0.17	0.90	0.31	0.78	0.23	0.83	0.18	1.80	1.08
Follow-up										
N	77	77	83	83	77	77	89	89	69	69
Mean	0.594	0.003	0.607	0.005	0.595	0.016	0.600	0.006	0.612	0.012
SD	0.0719	0.0533	0.0882	0.0540	0.0787	0.0495	0.0718	0.0479	0.0807	0.0550
Minimum	0.41	-0.14	0.40	-0.17	0.39	-0.15	0.45	-0.11	0.43	-0.11
Q1	0.550	-0.030	0.550	-0.030	0.540	-0.020	0.550	-0.020	0.560	-0.020
Median	0.590	0.000	0.610	0.000	0.590	0.020	0.610	0.000	0.610	0.010
Q3	0.630	0.030	0.670	0.050	0.650	0.050	0.640	0.040	0.660	0.050
Maximum	0.80	0.13	0.88	0.13	0.78	0.14	0.79	0.14	0.82	0.17

治験総括報告書 Table 3.2.1.1.1（Section 15.1）（5.3.5.4-2）から引用

表 2.7.4.8-付録-36　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（OCT-101 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Blood Urea Nitrogen (mg/dL)

Visit / Statistics	Placebo (N=97) Observed Value at Visit	Placebo (N=97) Change from Baseline	TAK-385 10mg (N=103) Observed Value at Visit	TAK-385 10mg (N=103) Change from Baseline	TAK-385 20mg (N=100) Observed Value at Visit	TAK-385 20mg (N=100) Change from Baseline	TAK-385 40mg (N=103) Observed Value at Visit	TAK-385 40mg (N=103) Change from Baseline	Leuprorelin (N=80) Observed Value at Visit	Leuprorelin (N=80) Change from Baseline
Baseline										
N	97		103		100		103		80	
Mean	11.17		10.95		11.32		10.63		10.60	
SD	3.073		2.475		2.733		2.660		2.363	
Minimum	4.8		6.1		5.2		5.5		4.6	
Q1	9.10		9.10		9.45		8.70		8.85	
Median	11.00		10.40		11.05		10.50		10.55	
Q3	13.10		12.90		13.00		12.10		12.05	
Maximum	19.4		17.0		22.6		21.9		18.0	
Week 4										
N	97	97	103	103	100	100	103	103	80	80
Mean	11.06	-0.11	11.66	0.71	12.38	1.06	11.93	1.31	12.00	1.41
SD	2.978	2.525	2.447	2.516	2.909	2.739	2.750	2.504	2.934	2.573
Minimum	4.9	-6.5	6.2	-5.1	6.0	-6.1	4.7	-3.7	6.7	-4.5
Q1	8.80	-1.50	9.80	-0.80	10.10	-0.70	10.20	-0.60	9.95	-0.70
Median	10.50	0.00	11.70	0.90	12.10	1.05	11.60	1.20	11.80	1.40
Q3	12.60	1.50	13.40	2.50	14.05	2.60	13.50	3.00	14.20	3.30
Maximum	20.0	6.0	17.7	5.8	19.5	8.2	21.1	10.0	18.2	8.4
Week 8										
N	95	95	103	103	96	96	101	101	78	78
Mean	11.00	-0.12	11.83	0.89	11.99	0.67	12.09	1.46	12.16	1.53
SD	2.901	2.641	2.674	2.527	2.856	2.668	2.863	2.708	2.990	2.608
Minimum	5.6	-8.5	6.8	-4.1	6.2	-7.2	6.2	-4.9	5.4	-3.6
Q1	8.80	-1.90	9.80	-0.80	10.05	-1.25	10.30	-0.40	10.40	-0.40
Median	10.70	-0.20	11.60	1.00	11.85	0.85	11.80	1.50	11.80	1.80
Q3	13.00	1.30	13.70	2.30	13.30	2.20	14.00	3.30	13.80	3.40
Maximum	19.9	8.5	19.1	9.4	19.9	7.0	19.3	9.3	20.0	7.7
Week 12										
N	93	93	101	101	92	92	101	101	75	75
Mean	10.82	-0.30	11.82	0.91	12.23	0.84	11.88	1.26	12.03	1.34
SD	2.946	2.357	2.706	2.767	2.785	2.458	3.017	2.508	3.148	2.551
Minimum	4.8	-9.1	6.0	-5.7	6.6	-5.5	6.6	-4.0	6.0	-3.5
Q1	8.80	-1.80	10.00	-0.80	10.40	-0.65	9.50	-0.60	9.80	-0.60
Median	10.80	-0.20	11.50	0.90	12.05	0.70	11.50	1.20	11.30	0.90
Q3	12.40	1.30	13.60	2.60	13.80	2.40	13.70	3.00	13.70	2.90
Maximum	20.6	5.1	18.6	8.8	22.0	7.3	20.5	7.7	23.0	10.6
Week 16										
N	75	75	84	84	78	78	89	89	69	69
Mean	10.75	-0.16	11.88	0.93	11.82	0.16	12.47	1.86	11.50	0.85
SD	2.442	2.492	2.491	2.534	2.949	2.903	2.876	2.729	2.729	2.692
Minimum	5.4	-8.3	5.8	-5.6	6.5	-7.2	6.9	-6.2	5.9	-4.2
Q1	9.00	-1.70	10.00	-0.75	9.70	-1.50	10.30	0.40	9.70	-0.90
Median	11.00	0.30	11.80	0.95	11.55	0.20	12.00	2.00	11.10	0.40
Q3	12.80	1.30	13.20	2.45	14.00	1.80	14.50	3.40	13.20	2.10
Maximum	17.5	4.4	18.4	7.7	19.9	9.7	21.2	8.5	19.9	9.9

治験総括報告書 Table 3.2.1.1.1（Section 15.1）（5.3.5.4-2）から引用

表 2.7.4.8-付録-36　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（OCT-101 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Blood Urea Nitrogen (mg/dL)

Visit / Statistics	Placebo (N=97)		TAK-385 10mg (N=103)		TAK-385 20mg (N=100)		TAK-385 40mg (N=103)		Leuprorelin (N=80)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 20										
N	75	75	81	81	77	77	87	87	65	65
Mean	10.90	-0.01	11.82	0.84	12.54	0.88	11.96	1.36	11.81	1.10
SD	3.190	2.650	2.709	2.601	3.417	3.287	2.644	2.796	2.672	2.393
Minimum	5.7	-8.6	5.5	-5.9	6.0	-9.3	6.7	-6.2	8.1	-3.1
Q1	8.50	-1.70	9.80	-1.20	10.10	-0.50	10.00	-0.40	9.70	-0.40
Median	10.10	-0.40	11.60	1.10	11.90	0.90	11.70	1.30	11.10	0.70
Q3	12.40	1.60	13.50	2.80	14.50	2.60	13.80	3.40	13.20	2.40
Maximum	21.7	5.7	17.4	7.7	27.7	9.5	18.3	8.7	20.4	8.0
Week 24										
N	68	68	79	79	76	76	88	88	62	62
Mean	10.74	-0.20	12.28	1.31	12.49	0.89	12.10	1.49	12.28	1.63
SD	2.663	2.599	2.553	2.279	2.925	2.866	2.628	2.808	3.197	2.473
Minimum	5.6	-7.8	6.7	-4.8	7.9	-7.6	7.6	-8.6	5.0	-4.3
Q1	8.95	-1.80	10.40	-0.20	10.35	-0.90	10.45	-0.35	10.40	-0.10
Median	10.55	-0.10	12.30	1.50	12.10	0.95	11.50	1.60	11.85	1.60
Q3	12.45	1.20	14.00	2.80	14.80	2.70	13.65	3.45	14.60	3.00
Maximum	19.7	6.8	21.3	7.8	23.1	6.8	19.8	10.7	20.2	7.3
Follow-up										
N	77	77	83	83	77	77	89	89	69	69
Mean	10.88	-0.01	11.68	0.80	11.80	0.12	11.30	0.69	12.23	1.57
SD	2.649	2.494	2.882	2.625	2.813	2.862	2.693	2.776	3.116	2.702
Minimum	5.6	-4.4	7.0	-4.9	7.3	-9.4	5.9	-8.8	6.3	-4.3
Q1	8.60	-2.30	9.40	-0.90	9.40	-1.50	9.20	-1.20	9.70	-0.60
Median	11.00	-0.20	11.30	0.80	11.50	0.20	11.10	0.80	12.10	1.60
Q3	12.40	2.00	13.40	2.60	13.20	2.40	13.00	2.50	14.40	3.10
Maximum	17.5	6.0	20.0	8.0	19.9	6.3	20.1	7.4	20.1	7.7

治験総括報告書 Table 3.2.1.1.1（Section 15.1）（5.3.5.4-2）から引用

表 2.7.4.8-付録-36　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（OCT-101 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: CK (CPK) (U/L)

Visit / Statistics	Placebo (N=97)		TAK-385 10mg (N=103)		TAK-385 20mg (N=100)		TAK-385 40mg (N=103)		Leuprorelin (N=80)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Baseline										
N	97		103		100		103		80	
Mean	82.8		80.6		75.7		73.0		78.0	
SD	53.59		29.23		26.39		27.80		27.39	
Minimum	33		34		28		26		25	
Q1	56.0		60.0		59.0		57.0		61.0	
Median	70.0		76.0		68.5		70.0		74.5	
Q3	89.0		96.0		90.5		83.0		90.0	
Maximum	500		164		173		258		208	
Week 4										
N	97	97	103	103	100	100	103	103	80	80
Mean	90.8	8.1	86.8	6.3	80.3	4.6	97.5	24.5	87.2	9.2
SD	137.04	135.92	46.18	38.54	35.26	24.26	89.80	88.76	37.00	27.10
Minimum	34	-299	36	-65	30	-109	35	-23	27	-24
Q1	58.0	-11.0	62.0	-9.0	60.0	-7.0	65.0	0.0	65.0	-5.5
Median	73.0	-2.0	78.0	-1.0	73.5	2.0	77.0	10.0	77.0	4.5
Q3	87.0	8.0	105.0	13.0	88.5	13.0	101.0	21.0	100.0	16.0
Maximum	1393	1287	395	279	245	125	844	792	267	191
Week 8										
N	95	95	103	103	96	96	101	101	78	78
Mean	78.7	-4.5	80.4	-0.1	80.1	3.8	85.3	12.1	86.2	8.4
SD	43.04	39.77	32.17	25.11	33.71	26.29	50.87	43.03	41.12	25.16
Minimum	32	-272	29	-79	27	-97	21	-104	26	-25
Q1	55.0	-15.0	60.0	-9.0	58.5	-6.5	63.0	-3.0	62.0	-7.0
Median	70.0	-1.0	74.0	0.0	73.5	2.0	75.0	6.0	74.0	4.0
Q3	85.0	8.0	94.0	10.0	89.0	12.0	94.0	18.0	100.0	13.0
Maximum	333	142	239	113	235	137	500	341	313	136
Week 12										
N	93	93	101	101	92	92	101	101	75	75
Mean	216.1	132.1	83.7	2.6	85.6	10.4	80.1	6.9	84.7	6.8
SD	1320.65	1323.71	33.08	27.89	67.73	55.76	34.36	20.56	38.01	19.82
Minimum	33	-326	26	-64	29	-51	28	-33	23	-27
Q1	57.0	-12.0	62.0	-9.0	62.0	-5.5	58.0	-8.0	61.0	-6.0
Median	67.0	-1.0	80.0	3.0	73.5	3.0	75.0	4.0	80.0	5.0
Q3	86.0	8.0	101.0	15.0	90.5	12.5	91.0	13.0	95.0	17.0
Maximum	12810	12754	250	168	654	496	266	80	293	85
Week 16										
N	75	75	84	84	78	78	89	89	69	69
Mean	75.2	-9.0	87.1	5.7	84.6	9.6	82.3	8.1	82.7	4.8
SD	33.04	44.55	43.68	42.36	33.23	25.12	28.96	19.55	27.39	22.63
Minimum	31	-348	37	-63	27	-41	30	-39	26	-79
Q1	52.0	-13.0	63.5	-10.5	62.0	-5.0	64.0	-3.0	64.0	-4.0
Median	66.0	-3.0	80.5	2.0	77.5	3.0	79.0	8.0	76.0	4.0
Q3	88.0	6.0	102.5	16.0	100.0	17.0	90.0	18.0	96.0	13.0
Maximum	223	52	365	290	194	96	233	66	171	111

治験総括報告書 Table 3.2.1.1.1（Section 15.1）（5.3.5.4-2）から引用

表 2.7.4.8-付録-36　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（OCT-101 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: CK (CPK) (U/L)

Visit / Statistics	Placebo (N=97)		TAK-385 10mg (N=103)		TAK-385 20mg (N=100)		TAK-385 40mg (N=103)		Leuprorelin (N=80)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 20										
N	75	75	81	81	77	77	87	87	65	65
Mean	74.1	-10.1	86.2	5.1	74.5	-0.6	83.7	9.4	90.0	12.2
SD	32.58	43.82	45.74	36.73	24.40	17.45	38.61	24.51	57.41	37.70
Minimum	37	-330	36	-64	21	-44	22	-28	37	-20
Q1	52.0	-17.0	62.0	-8.0	60.0	-10.0	61.0	-7.0	62.0	-1.0
Median	65.0	-5.0	77.0	-1.0	71.0	-1.0	73.0	6.0	81.0	4.0
Q3	84.0	4.0	103.0	12.0	89.0	6.0	100.0	20.0	96.0	17.0
Maximum	229	94	316	193	143	45	305	135	486	278
Week 24										
N	68	68	79	79	76	76	88	88	62	62
Mean	75.9	-6.0	78.1	-3.6	77.4	2.3	87.0	12.9	87.7	10.0
SD	31.35	46.14	24.18	21.94	30.78	23.86	44.26	30.72	45.13	26.59
Minimum	28	-307	37	-77	30	-64	28	-29	24	-28
Q1	58.0	-14.0	60.0	-9.0	57.0	-8.5	63.0	-2.5	59.0	-3.0
Median	67.0	-3.0	77.0	-2.0	69.5	1.0	78.5	8.5	81.5	6.0
Q3	86.0	7.0	92.0	7.0	92.5	10.0	97.0	21.5	102.0	17.0
Maximum	193	120	155	65	202	104	321	222	366	158
Follow-up										
N	77	77	83	83	77	77	89	89	69	69
Mean	73.0	-10.7	75.3	-6.6	77.6	2.6	78.1	3.9	100.3	22.3
SD	32.08	39.97	25.60	23.11	42.99	33.82	38.35	22.99	85.72	66.63
Minimum	32	-309	36	-89	24	-47	34	-31	25	-29
Q1	51.0	-12.0	56.0	-19.0	55.0	-13.0	58.0	-12.0	61.0	-5.0
Median	65.0	-5.0	72.0	-5.0	66.0	-4.0	68.0	0.0	83.0	5.0
Q3	86.0	3.0	87.0	6.0	90.0	7.0	88.0	14.0	108.0	24.0
Maximum	191	50	155	43	323	204	330	74	713	505

治験総括報告書 Table 3.2.1.1.1（Section 15.1）（5.3.5.4-2）から引用

表 2.7.4.8-付録-36　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（OCT-101 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Uric Acid (mg/dL)

Visit / Statistics	Placebo (N=97) Observed Value at Visit	Placebo (N=97) Change from Baseline	TAK-385 10mg (N=103) Observed Value at Visit	TAK-385 10mg (N=103) Change from Baseline	TAK-385 20mg (N=100) Observed Value at Visit	TAK-385 20mg (N=100) Change from Baseline	TAK-385 40mg (N=103) Observed Value at Visit	TAK-385 40mg (N=103) Change from Baseline	Leuprorelin (N=80) Observed Value at Visit	Leuprorelin (N=80) Change from Baseline
Baseline										
N	97		103		100		103		80	
Mean	3.91		3.89		3.91		3.89		4.03	
SD	0.965		0.900		0.839		0.825		0.812	
Minimum	1.8		1.6		1.8		1.5		1.8	
Q1	3.20		3.30		3.45		3.30		3.55	
Median	3.90		3.80		3.80		4.00		4.05	
Q3	4.40		4.30		4.30		4.40		4.60	
Maximum	7.0		6.8		6.4		6.4		6.3	
Week 4										
N	97	97	103	103	100	100	103	103	80	80
Mean	3.94	0.03	4.11	0.22	4.22	0.31	4.28	0.39	4.23	0.20
SD	0.872	0.481	0.917	0.553	0.875	0.599	0.907	0.636	0.768	0.458
Minimum	2.0	-1.3	2.3	-1.2	1.7	-1.2	1.6	-1.0	2.5	-1.0
Q1	3.40	-0.30	3.50	-0.20	3.70	-0.05	3.60	0.00	3.80	-0.05
Median	3.90	0.10	3.90	0.20	4.10	0.20	4.30	0.30	4.20	0.20
Q3	4.50	0.30	4.50	0.50	4.55	0.70	4.80	0.80	4.80	0.50
Maximum	6.8	1.7	7.9	2.3	7.7	2.0	8.1	2.4	6.1	1.3
Week 8										
N	95	95	103	103	96	96	101	101	78	78
Mean	3.93	0.01	4.10	0.21	4.26	0.32	4.37	0.48	4.18	0.15
SD	0.974	0.563	0.972	0.687	0.880	0.567	0.904	0.607	0.697	0.514
Minimum	1.9	-1.5	2.2	-2.6	2.3	-1.0	2.0	-1.1	2.3	-0.9
Q1	3.30	-0.30	3.40	-0.20	3.70	-0.10	3.80	0.10	3.80	-0.20
Median	3.90	0.10	4.10	0.20	4.20	0.30	4.30	0.40	4.30	0.10
Q3	4.70	0.40	4.60	0.70	4.50	0.65	4.90	0.90	4.60	0.50
Maximum	5.8	1.2	6.9	1.7	8.7	2.4	7.0	2.4	5.7	1.6
Week 12										
N	93	93	101	101	92	92	101	101	75	75
Mean	3.89	-0.05	4.11	0.23	4.23	0.30	4.45	0.57	4.31	0.28
SD	0.918	0.486	0.972	0.619	0.809	0.582	0.916	0.650	0.762	0.591
Minimum	1.9	-1.2	1.9	-1.0	2.6	-1.1	1.6	-1.2	2.4	-1.3
Q1	3.40	-0.40	3.50	-0.20	3.75	-0.10	3.70	0.10	3.80	-0.10
Median	3.90	0.00	4.10	0.20	4.10	0.30	4.50	0.50	4.40	0.40
Q3	4.40	0.30	4.60	0.70	4.55	0.70	5.00	0.80	4.80	0.60
Maximum	6.6	1.0	7.3	1.9	7.5	1.8	7.7	2.7	5.9	2.3
Week 16										
N	75	75	84	84	78	78	89	89	69	69
Mean	3.84	-0.10	4.08	0.23	4.26	0.29	4.56	0.69	4.46	0.40
SD	0.936	0.655	0.960	0.627	0.852	0.644	0.895	0.671	0.851	0.576
Minimum	1.9	-2.1	2.3	-1.0	2.1	-1.1	1.9	-1.2	2.3	-1.0
Q1	3.20	-0.50	3.40	-0.20	3.70	-0.10	3.90	0.20	4.00	0.20
Median	3.80	-0.10	4.00	0.10	4.20	0.30	4.70	0.60	4.50	0.50
Q3	4.40	0.30	4.50	0.60	4.90	0.70	5.00	1.10	5.00	0.80
Maximum	7.3	1.6	7.6	2.0	8.0	1.7	7.9	2.6	6.6	1.7

治験総括報告書 Table 3.2.1.1.1（Section 15.1）（5.3.5.4-2）から引用

表 2.7.4.8-付録-36　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（OCT-101 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Uric Acid (mg/dL)

Visit / Statistics	Placebo (N=97)		TAK-385 10mg (N=103)		TAK-385 20mg (N=100)		TAK-385 40mg (N=103)		Leuprorelin (N=80)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 20										
N	75	75	81	81	77	77	87	87	65	65
Mean	3.89	-0.05	4.01	0.14	4.34	0.36	4.51	0.65	4.48	0.43
SD	0.910	0.549	0.920	0.621	0.890	0.644	0.956	0.682	0.932	0.579
Minimum	1.7	-1.7	2.0	-1.2	1.9	-1.2	1.8	-0.5	2.3	-1.3
Q1	3.40	-0.40	3.30	-0.20	3.70	0.00	3.90	0.20	3.80	0.10
Median	3.80	0.00	4.00	0.10	4.20	0.30	4.50	0.60	4.40	0.40
Q3	4.40	0.30	4.50	0.50	4.80	0.70	5.10	1.10	5.10	0.70
Maximum	7.0	1.6	6.6	1.5	8.2	2.1	8.0	2.7	7.2	2.0
Week 24										
N	68	68	79	79	76	76	88	88	62	62
Mean	3.92	-0.06	4.03	0.14	4.28	0.30	4.55	0.69	4.47	0.38
SD	0.837	0.619	0.936	0.566	0.869	0.639	0.905	0.595	0.910	0.583
Minimum	1.9	-1.5	2.3	-1.1	1.7	-1.1	1.9	-0.5	2.3	-0.7
Q1	3.45	-0.60	3.20	-0.20	3.70	-0.10	3.95	0.30	3.90	-0.10
Median	4.00	-0.05	4.00	0.10	4.20	0.30	4.50	0.60	4.50	0.30
Q3	4.50	0.30	4.60	0.60	4.70	0.70	5.10	1.05	5.00	0.70
Maximum	6.5	1.3	6.6	1.7	7.5	2.3	8.4	2.0	7.3	2.1
Follow-up										
N	77	77	83	83	77	77	89	89	69	69
Mean	3.89	-0.04	3.88	0.03	4.07	0.11	4.34	0.47	4.46	0.40
SD	0.970	0.699	0.891	0.629	0.755	0.581	0.872	0.549	0.793	0.633
Minimum	1.5	-1.5	1.7	-1.5	1.6	-1.6	2.2	-1.3	2.6	-1.0
Q1	3.20	-0.50	3.20	-0.30	3.60	-0.30	3.90	0.20	3.90	0.00
Median	3.80	0.00	3.80	0.00	4.00	0.20	4.30	0.40	4.50	0.40
Q3	4.40	0.50	4.30	0.40	4.40	0.50	4.80	0.80	5.00	0.70
Maximum	6.6	1.6	6.7	1.8	6.7	1.2	7.8	2.0	6.2	2.4

治験総括報告書 Table 3.2.1.1.1（Section 15.1）（5.3.5.4-2）から引用

表 2.7.4.8-付録-36　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（OCT-101 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Sodium (mEq/L)

Visit / Statistics	Placebo (N=97)		TAK-385 10mg (N=103)		TAK-385 20mg (N=100)		TAK-385 40mg (N=103)		Leuprorelin (N=80)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Baseline										
N	97		103		100		103		80	
Mean	141.3		141.3		141.2		141.4		141.2	
SD	1.39		1.21		1.25		1.40		1.41	
Minimum	138		138		138		138		137	
Q1	140.0		140.0		140.0		140.0		140.0	
Median	141.0		141.0		141.0		141.0		141.0	
Q3	142.0		142.0		142.0		142.0		142.0	
Maximum	145		144		144		146		145	
Week 4										
N	97	97	103	103	100	100	103	103	80	80
Mean	140.8	-0.5	141.0	-0.3	141.5	0.3	141.8	0.4	142.0	0.9
SD	1.40	1.77	1.49	1.60	1.53	1.56	1.47	1.62	1.51	1.69
Minimum	138	-5	136	-5	139	-4	139	-3	139	-3
Q1	140.0	-1.0	140.0	-2.0	140.0	-1.0	141.0	-1.0	141.0	0.0
Median	141.0	0.0	141.0	0.0	141.0	0.0	142.0	1.0	142.0	1.0
Q3	142.0	1.0	142.0	1.0	142.0	1.0	143.0	1.0	143.0	2.0
Maximum	144	4	144	3	145	4	146	6	147	6
Week 8										
N	95	95	103	103	96	96	101	101	78	78
Mean	140.4	-0.8	141.2	-0.1	141.6	0.4	142.0	0.6	142.1	1.0
SD	1.39	1.83	1.59	1.72	1.58	1.75	1.33	1.67	1.59	1.59
Minimum	137	-5	138	-5	137	-4	138	-4	138	-3
Q1	140.0	-2.0	140.0	-1.0	141.0	-1.0	141.0	0.0	141.0	0.0
Median	140.0	-1.0	141.0	0.0	141.0	0.0	142.0	1.0	142.0	1.0
Q3	141.0	0.0	142.0	1.0	142.0	1.5	143.0	2.0	143.0	2.0
Maximum	145	3	145	4	147	5	146	5	146	5
Week 12										
N	93	93	101	101	92	92	101	101	75	75
Mean	140.6	-0.7	141.1	-0.2	141.6	0.5	142.1	0.7	142.1	1.0
SD	1.48	1.70	1.50	1.53	1.45	1.58	1.49	1.67	1.34	1.56
Minimum	137	-4	137	-4	138	-4	139	-4	139	-2
Q1	140.0	-2.0	140.0	-1.0	141.0	0.0	141.0	0.0	141.0	0.0
Median	140.0	-1.0	141.0	0.0	142.0	1.0	142.0	1.0	142.0	1.0
Q3	141.0	0.0	142.0	1.0	143.0	2.0	143.0	2.0	143.0	2.0
Maximum	148	4	146	3	145	3	146	5	146	4
Week 16										
N	75	75	84	84	78	78	89	89	69	69
Mean	140.1	-1.2	141.3	0.0	141.5	0.3	142.3	1.0	142.4	1.4
SD	1.25	1.72	1.47	1.70	1.51	1.68	1.61	1.82	1.47	1.90
Minimum	137	-5	138	-4	138	-3	139	-3	138	-4
Q1	139.0	-2.0	140.0	-1.0	141.0	-1.0	141.0	-1.0	141.0	0.0
Median	140.0	-1.0	141.0	0.0	141.0	1.0	142.0	1.0	142.0	1.0
Q3	141.0	0.0	142.0	1.0	143.0	1.0	143.0	2.0	143.0	3.0
Maximum	143	3	145	3	145	4	147	6	145	5

治験総括報告書 Table 3.2.1.1.1（Section 15.1）（5.3.5.4-2）から引用

表 2.7.4.8-付録-36　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（OCT-101 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Sodium (mEq/L)

Visit / Statistics	Placebo (N=97)		TAK-385 10mg (N=103)		TAK-385 20mg (N=100)		TAK-385 40mg (N=103)		Leuprorelin (N=80)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 20										
N	75	75	81	81	77	77	87	87	65	65
Mean	140.7	-0.7	141.2	0.0	141.8	0.6	142.3	0.9	142.3	1.3
SD	1.45	1.70	1.72	1.83	1.44	1.74	1.32	1.76	1.49	1.62
Minimum	138	-5	136	-4	139	-4	139	-3	138	-3
Q1	140.0	-2.0	140.0	-1.0	141.0	-1.0	141.0	0.0	141.0	0.0
Median	141.0	-1.0	141.0	0.0	142.0	1.0	142.0	1.0	142.0	2.0
Q3	142.0	0.0	142.0	1.0	143.0	2.0	143.0	2.0	143.0	2.0
Maximum	145	3	145	4	146	5	146	6	146	5
Week 24										
N	68	68	79	79	76	76	88	88	62	62
Mean	140.6	-0.8	140.9	-0.4	141.3	0.1	142.3	0.9	142.3	1.3
SD	1.49	1.72	1.47	1.70	1.44	1.82	1.72	2.08	1.53	1.83
Minimum	138	-4	137	-4	138	-5	139	-4	140	-5
Q1	139.5	-2.0	140.0	-2.0	140.5	-1.0	141.0	0.0	141.0	0.0
Median	140.0	-1.0	141.0	0.0	141.0	0.0	142.5	0.5	142.0	1.0
Q3	142.0	0.0	142.0	1.0	142.0	1.0	143.0	2.0	143.0	2.0
Maximum	144	4	145	4	145	5	147	6	146	5
Follow-up										
N	77	77	83	83	77	77	89	89	69	69
Mean	140.7	-0.6	140.8	-0.5	140.5	-0.6	140.9	-0.5	142.1	1.1
SD	1.46	1.92	1.43	1.48	1.35	1.55	1.53	1.93	1.53	1.98
Minimum	137	-5	136	-3	138	-4	137	-4	139	-4
Q1	140.0	-2.0	140.0	-2.0	140.0	-2.0	140.0	-2.0	141.0	0.0
Median	141.0	-1.0	141.0	0.0	141.0	-1.0	141.0	-1.0	142.0	1.0
Q3	142.0	0.0	142.0	1.0	141.0	0.0	142.0	1.0	143.0	2.0
Maximum	145	5	144	2	144	2	144	4	145	5

治験総括報告書 Table 3.2.1.1.1（Section 15.1）（5.3.5.4-2）から引用

表 2.7.4.8-付録-36　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（OCT-101 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Potassium (mEq/L)

Visit / Statistics	Placebo (N=97)		TAK-385 10mg (N=103)		TAK-385 20mg (N=100)		TAK-385 40mg (N=103)		Leuprorelin (N=80)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Baseline										
N	97		103		100		103		80	
Mean	4.05		4.06		4.07		4.06		4.08	
SD	0.271		0.287		0.277		0.278		0.343	
Minimum	3.5		3.4		3.5		3.5		3.2	
Q1	3.90		3.90		3.90		3.90		3.80	
Median	4.00		4.00		4.00		4.00		4.10	
Q3	4.20		4.20		4.25		4.30		4.30	
Maximum	4.9		5.0		4.9		4.9		4.9	
Week 4										
N	97	97	103	103	100	100	103	103	80	80
Mean	4.03	-0.02	4.14	0.07	4.14	0.07	4.17	0.11	4.15	0.07
SD	0.283	0.344	0.274	0.307	0.278	0.247	0.293	0.308	0.299	0.325
Minimum	3.5	-1.0	3.5	-1.0	3.6	-0.5	3.5	-0.8	3.4	-0.7
Q1	3.80	-0.30	4.00	-0.10	3.90	-0.10	4.00	-0.10	3.95	-0.20
Median	4.00	0.00	4.10	0.10	4.10	0.10	4.10	0.10	4.20	0.10
Q3	4.20	0.20	4.30	0.30	4.30	0.20	4.30	0.30	4.30	0.30
Maximum	5.0	0.8	4.8	0.8	4.8	0.7	5.0	1.3	5.1	0.7
Week 8										
N	95	95	103	103	96	96	101	101	78	78
Mean	4.09	0.04	4.11	0.05	4.11	0.05	4.17	0.11	4.18	0.11
SD	0.317	0.344	0.279	0.274	0.293	0.321	0.307	0.292	0.291	0.371
Minimum	3.4	-1.1	3.6	-0.9	3.5	-0.8	3.6	-0.5	3.6	-1.0
Q1	3.90	-0.10	3.90	-0.10	3.90	-0.20	4.00	-0.10	4.00	-0.10
Median	4.10	0.10	4.10	0.10	4.10	0.00	4.10	0.10	4.10	0.10
Q3	4.30	0.20	4.30	0.20	4.20	0.25	4.30	0.30	4.30	0.30
Maximum	5.2	1.0	4.9	0.8	5.3	0.8	5.1	0.9	5.0	1.5
Week 12										
N	93	93	100	100	92	92	101	101	75	75
Mean	4.06	0.01	4.09	0.03	4.14	0.07	4.16	0.10	4.11	0.04
SD	0.289	0.307	0.275	0.244	0.313	0.273	0.283	0.279	0.252	0.285
Minimum	3.3	-0.7	3.6	-0.5	3.4	-0.7	3.5	-0.6	3.4	-0.7
Q1	3.90	-0.20	3.90	-0.10	4.00	-0.10	3.90	-0.10	3.90	-0.10
Median	4.00	0.00	4.10	0.00	4.10	0.05	4.10	0.10	4.10	0.10
Q3	4.20	0.20	4.30	0.20	4.30	0.20	4.30	0.20	4.30	0.20
Maximum	4.8	0.9	4.8	0.8	5.3	0.9	4.9	1.1	4.6	0.7
Week 16										
N	75	75	84	84	78	78	89	89	69	69
Mean	4.05	0.04	4.09	0.03	4.11	0.04	4.13	0.10	4.09	0.02
SD	0.277	0.288	0.223	0.252	0.276	0.241	0.295	0.276	0.258	0.310
Minimum	3.3	-0.6	3.4	-0.9	3.6	-0.8	3.6	-0.4	3.6	-0.7
Q1	3.90	-0.10	4.00	-0.10	3.90	-0.10	3.90	-0.10	3.90	-0.20
Median	4.10	0.10	4.10	0.00	4.10	0.00	4.10	0.10	4.10	0.00
Q3	4.20	0.20	4.20	0.20	4.30	0.20	4.30	0.30	4.30	0.20
Maximum	4.7	0.9	4.6	0.5	5.0	0.6	5.2	0.9	4.9	0.9

治験総括報告書 Table 3.2.1.1.1（Section 15.1）（5.3.5.4-2）から引用

表 2.7.4.8-付録-36　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（OCT-101 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Potassium (mEq/L)

Visit / Statistics	Placebo (N=97)		TAK-385 10mg (N=103)		TAK-385 20mg (N=100)		TAK-385 40mg (N=103)		Leuprorelin (N=80)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 20										
N	75	75	81	81	77	77	87	87	65	65
Mean	4.04	0.03	4.15	0.08	4.14	0.06	4.15	0.11	4.10	0.01
SD	0.303	0.306	0.243	0.307	0.293	0.277	0.322	0.297	0.338	0.348
Minimum	3.5	-0.7	3.5	-0.9	3.7	-0.5	3.4	-0.6	3.4	-0.9
Q1	3.80	-0.10	4.00	-0.10	3.90	-0.10	4.00	-0.10	3.90	-0.20
Median	4.00	0.00	4.20	0.10	4.10	0.00	4.10	0.10	4.10	0.00
Q3	4.20	0.20	4.30	0.30	4.30	0.20	4.30	0.20	4.30	0.20
Maximum	4.9	0.9	4.9	0.7	5.0	0.7	5.4	1.2	5.1	0.8
Week 24										
N	68	68	79	79	76	76	88	88	62	62
Mean	4.03	0.01	4.12	0.05	4.16	0.08	4.15	0.12	4.09	0.00
SD	0.284	0.271	0.258	0.275	0.243	0.295	0.309	0.294	0.262	0.281
Minimum	3.3	-0.7	3.4	-0.6	3.6	-0.7	3.5	-0.4	3.6	-0.6
Q1	3.90	-0.10	4.00	-0.10	4.00	-0.10	3.90	-0.10	3.90	-0.20
Median	4.00	0.00	4.10	0.10	4.15	0.10	4.10	0.10	4.10	0.00
Q3	4.15	0.15	4.30	0.20	4.35	0.30	4.35	0.30	4.30	0.20
Maximum	4.9	0.7	4.7	0.9	4.8	0.7	5.1	0.9	4.7	0.9
Follow-up										
N	77	77	83	83	77	77	89	89	69	69
Mean	4.03	0.01	4.07	0.01	4.12	0.05	4.15	0.12	4.13	0.06
SD	0.326	0.339	0.272	0.306	0.307	0.287	0.269	0.269	0.298	0.357
Minimum	3.3	-0.8	3.3	-0.6	3.5	-0.6	3.6	-0.4	3.6	-0.7
Q1	3.80	-0.20	3.90	-0.20	3.90	-0.10	3.90	-0.10	3.90	-0.10
Median	4.00	0.00	4.10	0.00	4.20	0.10	4.20	0.10	4.10	0.10
Q3	4.30	0.20	4.20	0.20	4.30	0.30	4.30	0.30	4.30	0.20
Maximum	5.0	1.1	4.7	1.1	4.9	0.6	4.9	0.8	4.9	1.2

治験総括報告書 Table 3.2.1.1.1（Section 15.1）（5.3.5.4-2）から引用

表 2.7.4.8-付録-36　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（OCT-101 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Chloride (mEq/L)

Visit / Statistics	Placebo (N=97)		TAK-385 10mg (N=103)		TAK-385 20mg (N=100)		TAK-385 40mg (N=103)		Leuprorelin (N=80)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Baseline										
N	97		103		100		103		80	
Mean	106.2		106.6		106.5		106.4		106.0	
SD	2.00		1.80		1.99		1.96		1.97	
Minimum	98		103		101		102		97	
Q1	105.0		105.0		105.0		105.0		105.0	
Median	106.0		107.0		106.5		107.0		106.0	
Q3	107.0		107.0		108.0		108.0		107.0	
Maximum	110		112		111		111		110	
Week 4										
N	97	97	103	103	100	100	103	103	80	80
Mean	106.1	-0.1	106.1	-0.5	106.0	-0.5	105.9	-0.5	105.7	-0.3
SD	1.93	2.35	1.97	2.05	1.94	2.20	1.65	2.20	2.02	2.30
Minimum	102	-5	99	-5	102	-6	101	-6	101	-4
Q1	105.0	-2.0	105.0	-2.0	104.0	-2.0	105.0	-2.0	104.5	-2.0
Median	106.0	0.0	106.0	-1.0	106.0	0.0	106.0	0.0	106.0	-1.0
Q3	107.0	1.0	107.0	1.0	107.0	1.0	107.0	1.0	107.0	1.0
Maximum	111	10	110	4	110	5	110	4	112	12
Week 8										
N	95	95	103	103	96	96	101	101	78	78
Mean	105.7	-0.4	106.1	-0.5	106.0	-0.5	105.8	-0.6	105.8	-0.2
SD	1.89	2.52	1.80	2.20	1.92	2.38	2.26	2.48	2.01	2.23
Minimum	101	-6	102	-6	100	-7	98	-9	100	-5
Q1	104.0	-2.0	105.0	-2.0	105.0	-2.0	105.0	-2.0	105.0	-1.0
Median	106.0	-1.0	106.0	0.0	106.0	0.0	106.0	-1.0	106.0	0.0
Q3	107.0	1.0	107.0	0.0	107.5	1.0	107.0	1.0	107.0	1.0
Maximum	110	10	111	6	110	5	111	7	111	9
Week 12										
N	93	93	101	101	92	92	101	101	75	75
Mean	104.0	-2.1	103.8	-2.7	103.8	-2.6	103.7	-2.7	103.8	-2.2
SD	1.84	2.18	1.71	2.01	1.89	2.30	2.02	2.22	1.98	2.31
Minimum	100	-7	101	-8	100	-9	98	-8	100	-7
Q1	103.0	-3.0	103.0	-4.0	102.0	-4.0	102.0	-4.0	102.0	-4.0
Median	104.0	-2.0	104.0	-3.0	104.0	-3.0	104.0	-3.0	104.0	-2.0
Q3	105.0	-1.0	105.0	-1.0	105.0	-1.0	105.0	-1.0	105.0	-1.0
Maximum	109	5	108	2	109	3	109	3	108	6
Week 16										
N	75	75	84	84	78	78	89	89	69	69
Mean	105.5	-0.5	105.7	-0.9	105.9	-0.5	106.2	-0.1	105.9	-0.1
SD	1.73	2.36	2.02	2.38	2.23	2.25	2.40	2.62	1.98	2.47
Minimum	102	-6	99	-8	99	-6	99	-8	100	-6
Q1	104.0	-2.0	104.0	-2.0	105.0	-2.0	105.0	-2.0	104.0	-2.0
Median	105.0	-1.0	106.0	-1.0	106.0	0.0	106.0	0.0	106.0	0.0
Q3	107.0	1.0	107.0	1.0	107.0	1.0	108.0	1.0	107.0	1.0
Maximum	109	7	110	3	111	4	112	7	110	10

治験総括報告書 Table 3.2.1.1.1（Section 15.1）（5.3.5.4-2）から引用

表 2.7.4.8-付録-36　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（OCT-101 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Chloride (mEq/L)

Visit / Statistics	Placebo (N=97)		TAK-385 10mg (N=103)		TAK-385 20mg (N=100)		TAK-385 40mg (N=103)		Leuprorelin (N=80)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 20										
N	75	75	81	81	77	77	87	87	65	65
Mean	105.5	-0.6	105.8	-0.7	106.1	-0.4	106.2	-0.1	105.7	-0.3
SD	2.11	2.65	2.25	2.45	2.11	2.18	2.17	2.57	2.14	2.14
Minimum	98	-11	100	-7	100	-5	101	-6	99	-5
Q1	104.0	-2.0	104.0	-2.0	105.0	-2.0	105.0	-2.0	104.0	-1.0
Median	106.0	0.0	106.0	-1.0	106.0	0.0	106.0	0.0	106.0	0.0
Q3	107.0	1.0	107.0	1.0	107.0	1.0	107.0	2.0	107.0	1.0
Maximum	109	4	110	5	113	5	111	6	110	9
Week 24										
N	68	68	79	79	76	76	88	88	62	62
Mean	104.0	-2.2	103.6	-2.9	103.6	-2.8	103.9	-2.4	103.6	-2.4
SD	1.82	2.39	1.88	2.25	2.07	2.45	1.97	2.54	2.20	2.27
Minimum	101	-9	97	-8	98	-9	99	-9	98	-7
Q1	103.0	-4.0	103.0	-4.0	102.0	-5.0	103.0	-4.0	102.0	-4.0
Median	104.0	-2.0	104.0	-3.0	104.0	-3.0	104.0	-2.0	103.5	-2.5
Q3	105.0	-0.5	105.0	-2.0	105.0	-1.0	105.0	-1.0	105.0	-1.0
Maximum	109	4	110	3	111	3	109	3	108	4
Follow-up										
N	77	77	83	83	77	77	89	89	69	69
Mean	106.2	0.2	106.5	-0.1	106.2	-0.2	106.5	0.2	106.2	0.2
SD	2.02	2.59	1.84	2.31	1.93	2.42	2.11	2.45	2.17	2.48
Minimum	102	-6	102	-6	103	-6	102	-6	102	-6
Q1	105.0	-1.0	105.0	-2.0	105.0	-2.0	105.0	-2.0	105.0	-1.0
Median	106.0	0.0	107.0	0.0	106.0	0.0	107.0	0.0	106.0	0.0
Q3	108.0	1.0	108.0	1.0	107.0	2.0	108.0	2.0	108.0	2.0
Maximum	110	10	110	5	111	6	112	7	112	9

治験総括報告書 Table 3.2.1.1.1（Section 15.1）（5.3.5.4-2）から引用

表 2.7.4.8-付録-36　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（OCT-101 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Calcium (mg/dL)

Visit / Statistics	Placebo (N=97)		TAK-385 10mg (N=103)		TAK-385 20mg (N=100)		TAK-385 40mg (N=103)		Leuprorelin (N=80)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Baseline										
N	97		103		100		103		80	
Mean	8.93		8.94		8.95		8.93		9.00	
SD	0.346		0.263		0.322		0.344		0.331	
Minimum	8.1		8.3		8.0		8.2		8.4	
Q1	8.70		8.80		8.70		8.70		8.75	
Median	8.90		8.90		8.90		8.90		8.90	
Q3	9.10		9.10		9.20		9.10		9.20	
Maximum	9.8		9.6		9.8		10.2		9.9	
Week 4										
N	97	97	103	103	100	100	103	103	80	80
Mean	8.94	0.01	9.12	0.18	9.18	0.23	9.34	0.41	9.25	0.26
SD	0.319	0.332	0.309	0.334	0.364	0.335	0.329	0.337	0.326	0.346
Minimum	8.3	-0.8	8.3	-0.8	8.2	-0.7	8.4	-0.4	8.6	-0.9
Q1	8.70	-0.20	8.90	0.00	8.90	0.00	9.10	0.20	9.00	0.00
Median	8.90	0.00	9.20	0.20	9.20	0.20	9.30	0.40	9.20	0.25
Q3	9.20	0.20	9.30	0.40	9.40	0.50	9.60	0.70	9.40	0.50
Maximum	9.8	1.0	9.7	0.8	10.0	1.0	10.1	1.1	10.4	1.0
Week 8										
N	95	95	103	103	96	96	101	101	78	78
Mean	9.02	0.09	9.08	0.13	9.21	0.26	9.42	0.48	9.36	0.38
SD	0.326	0.339	0.304	0.314	0.350	0.305	0.304	0.359	0.322	0.358
Minimum	8.2	-0.6	8.3	-0.7	8.4	-0.4	8.7	-0.5	8.8	-0.4
Q1	8.80	-0.20	8.80	-0.10	9.00	0.05	9.20	0.30	9.20	0.10
Median	9.00	0.10	9.00	0.20	9.20	0.30	9.40	0.50	9.35	0.40
Q3	9.30	0.30	9.30	0.40	9.40	0.40	9.60	0.70	9.60	0.60
Maximum	9.7	0.9	9.9	0.8	10.1	1.5	10.2	1.3	10.7	1.3
Week 12										
N	93	93	100	100	92	92	101	101	75	75
Mean	8.97	0.03	9.09	0.15	9.22	0.27	9.43	0.50	9.36	0.38
SD	0.346	0.337	0.316	0.310	0.351	0.348	0.335	0.360	0.294	0.316
Minimum	8.2	-0.7	8.3	-0.6	8.4	-0.4	8.4	-0.4	8.6	-0.4
Q1	8.70	-0.20	8.90	-0.10	9.00	0.00	9.20	0.30	9.20	0.20
Median	8.90	0.00	9.10	0.20	9.20	0.30	9.50	0.50	9.30	0.30
Q3	9.20	0.30	9.35	0.40	9.50	0.50	9.60	0.70	9.50	0.70
Maximum	9.8	0.8	9.8	1.1	10.1	1.4	10.2	1.2	10.6	1.0
Week 16										
N	75	75	84	84	78	78	89	89	69	69
Mean	8.98	0.03	9.16	0.22	9.31	0.33	9.44	0.50	9.42	0.42
SD	0.329	0.307	0.270	0.289	0.365	0.327	0.308	0.346	0.328	0.315
Minimum	8.2	-0.6	8.5	-0.5	8.4	-0.5	8.6	-0.2	8.7	-0.5
Q1	8.70	-0.20	9.00	0.00	9.10	0.10	9.20	0.30	9.20	0.30
Median	9.00	0.00	9.20	0.25	9.30	0.30	9.50	0.50	9.40	0.40
Q3	9.20	0.20	9.35	0.40	9.50	0.60	9.70	0.70	9.60	0.60
Maximum	9.6	1.0	9.8	0.9	10.5	1.0	10.3	1.3	10.6	1.3

治験総括報告書 Table 3.2.1.1.1（Section 15.1）（5.3.5.4-2）から引用

表 2.7.4.8-付録-36　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（OCT-101 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Calcium (mg/dL)

Visit / Statistics	Placebo (N=97)		TAK-385 10mg (N=103)		TAK-385 20mg (N=100)		TAK-385 40mg (N=103)		Leuprorelin (N=80)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 20										
N	75	75	81	81	77	77	87	87	65	65
Mean	8.99	0.04	9.13	0.19	9.20	0.23	9.41	0.47	9.46	0.46
SD	0.311	0.332	0.286	0.291	0.353	0.312	0.309	0.384	0.308	0.347
Minimum	8.2	-0.7	8.5	-0.4	8.0	-0.7	8.5	-0.6	8.6	-0.4
Q1	8.80	-0.20	8.90	0.00	9.00	0.00	9.20	0.20	9.30	0.30
Median	9.00	0.10	9.10	0.20	9.20	0.20	9.50	0.50	9.40	0.50
Q3	9.20	0.30	9.30	0.40	9.40	0.40	9.60	0.70	9.60	0.70
Maximum	9.8	0.9	9.9	1.0	10.3	0.8	10.0	1.3	10.7	1.5
Week 24										
N	68	68	79	79	76	76	88	88	62	62
Mean	8.95	0.00	9.09	0.14	9.21	0.23	9.43	0.48	9.38	0.39
SD	0.346	0.326	0.349	0.369	0.396	0.380	0.328	0.401	0.346	0.346
Minimum	8.0	-0.7	8.3	-0.7	8.2	-0.8	8.3	-0.4	8.4	-0.4
Q1	8.70	-0.20	8.90	-0.10	8.95	0.00	9.20	0.30	9.20	0.20
Median	8.90	0.00	9.00	0.10	9.20	0.20	9.40	0.40	9.40	0.40
Q3	9.20	0.20	9.30	0.40	9.45	0.45	9.70	0.80	9.60	0.60
Maximum	9.8	1.0	9.9	1.1	10.2	1.2	10.1	1.4	10.6	1.1
Follow-up										
N	77	77	83	83	77	77	89	89	69	69
Mean	8.97	0.02	8.93	-0.01	8.99	0.01	9.12	0.18	9.37	0.37
SD	0.367	0.372	0.331	0.344	0.321	0.344	0.306	0.379	0.344	0.332
Minimum	8.1	-0.8	8.0	-0.9	8.2	-0.9	8.4	-0.8	8.6	-0.5
Q1	8.70	-0.30	8.70	-0.20	8.80	-0.20	8.90	-0.10	9.20	0.20
Median	9.00	0.00	8.90	0.00	9.00	0.00	9.20	0.20	9.30	0.30
Q3	9.20	0.30	9.20	0.20	9.20	0.30	9.30	0.40	9.60	0.60
Maximum	9.8	0.9	9.7	1.0	9.9	0.9	9.8	1.2	10.8	1.0

治験総括報告書 Table 3.2.1.1.1（Section 15.1）（5.3.5.4-2）から引用

表 2.7.4.8-付録-36　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（OCT-101 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Phosphorus (mg/dL)

Visit / Statistics	Placebo (N=97)		TAK-385 10mg (N=103)		TAK-385 20mg (N=100)		TAK-385 40mg (N=103)		Leuprorelin (N=80)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Baseline										
N	97		103		100		103		80	
Mean	3.62		3.59		3.62		3.60		3.61	
SD	0.494		0.428		0.426		0.461		0.489	
Minimum	2.5		2.4		2.7		2.0		2.7	
Q1	3.30		3.30		3.40		3.30		3.30	
Median	3.60		3.60		3.60		3.70		3.60	
Q3	3.90		3.90		3.80		4.00		3.90	
Maximum	5.0		4.6		5.0		4.7		4.9	
Week 4										
N	97	97	103	103	100	100	103	103	80	80
Mean	3.62	-0.01	3.67	0.08	3.82	0.20	4.03	0.43	3.95	0.34
SD	0.474	0.473	0.413	0.450	0.513	0.538	0.436	0.460	0.434	0.409
Minimum	2.6	-1.4	2.8	-0.9	2.7	-1.2	2.7	-0.5	3.0	-1.0
Q1	3.30	-0.30	3.40	-0.20	3.50	-0.10	3.80	0.10	3.70	0.10
Median	3.60	0.00	3.70	0.10	3.80	0.25	4.00	0.40	3.90	0.30
Q3	3.90	0.30	4.00	0.40	4.10	0.50	4.30	0.80	4.20	0.60
Maximum	4.7	1.0	4.6	1.3	5.0	1.4	5.5	1.8	5.2	1.2
Week 8										
N	95	95	103	103	96	96	101	101	78	78
Mean	3.62	0.00	3.64	0.05	3.87	0.24	4.08	0.47	4.10	0.49
SD	0.504	0.494	0.438	0.471	0.529	0.548	0.436	0.507	0.508	0.501
Minimum	2.4	-1.2	2.5	-1.7	2.8	-1.6	2.8	-0.7	3.1	-0.8
Q1	3.30	-0.40	3.40	-0.30	3.45	-0.15	3.80	0.10	3.70	0.20
Median	3.70	0.00	3.60	0.10	3.80	0.25	4.10	0.50	4.20	0.50
Q3	3.90	0.40	4.00	0.30	4.20	0.60	4.40	0.80	4.40	0.80
Maximum	5.1	1.1	4.8	1.2	5.0	1.6	5.1	1.6	5.4	1.7
Week 12										
N	93	93	100	100	92	92	101	101	75	75
Mean	3.60	-0.03	3.75	0.17	3.97	0.34	4.22	0.62	4.22	0.63
SD	0.533	0.501	0.407	0.441	0.512	0.543	0.471	0.551	0.481	0.464
Minimum	2.4	-1.0	2.5	-0.7	2.8	-1.0	3.0	-0.7	3.3	-0.5
Q1	3.20	-0.30	3.50	-0.20	3.60	-0.10	3.90	0.20	3.90	0.30
Median	3.60	-0.10	3.80	0.20	3.85	0.30	4.30	0.60	4.30	0.60
Q3	3.90	0.20	4.00	0.50	4.30	0.70	4.50	0.90	4.60	0.90
Maximum	5.4	1.8	4.6	1.2	5.2	1.8	5.5	1.9	5.6	1.7
Week 16										
N	75	75	84	84	78	78	89	89	69	69
Mean	3.49	-0.16	3.73	0.14	3.93	0.30	4.19	0.60	4.18	0.61
SD	0.482	0.442	0.408	0.465	0.473	0.539	0.473	0.576	0.472	0.426
Minimum	2.4	-1.2	2.8	-1.5	2.8	-1.6	3.0	-0.6	3.0	-0.9
Q1	3.20	-0.50	3.50	-0.10	3.60	0.00	3.90	0.20	3.90	0.40
Median	3.50	-0.20	3.80	0.10	3.90	0.30	4.20	0.60	4.10	0.60
Q3	3.80	0.10	4.00	0.40	4.40	0.70	4.50	0.90	4.50	0.90
Maximum	4.6	0.9	4.4	1.2	4.8	1.2	5.7	2.2	5.3	1.6

治験総括報告書 Table 3.2.1.1.1（Section 15.1）（5.3.5.4-2）から引用

表 2.7.4.8-付録-36　血液生化学検査値の要約統計量の経時的推移（安全性データの解析対象集団）（OCT-101 試験）（続き）

Laboratory Group: Serum Chemistry
Laboratory Test: Phosphorus (mg/dL)

Visit / Statistics	Placebo (N=97)		TAK-385 10mg (N=103)		TAK-385 20mg (N=100)		TAK-385 40mg (N=103)		Leuprorelin (N=80)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 20										
N	75	75	81	81	77	77	87	87	65	65
Mean	3.57	-0.07	3.73	0.15	3.91	0.27	4.16	0.57	4.16	0.59
SD	0.481	0.486	0.419	0.462	0.576	0.569	0.476	0.609	0.460	0.476
Minimum	2.7	-1.2	2.6	-1.0	2.2	-1.1	2.5	-1.0	3.1	-0.7
Q1	3.20	-0.40	3.50	-0.10	3.60	0.00	3.90	0.10	3.90	0.30
Median	3.60	-0.10	3.70	0.10	4.00	0.30	4.20	0.60	4.20	0.60
Q3	4.00	0.20	4.10	0.50	4.20	0.60	4.50	0.90	4.40	0.90
Maximum	5.0	1.2	4.7	1.3	5.2	1.8	5.2	2.4	5.2	1.6
Week 24										
N	68	68	79	79	76	76	88	88	62	62
Mean	3.59	-0.05	3.76	0.18	3.93	0.30	4.24	0.65	4.33	0.75
SD	0.468	0.474	0.418	0.497	0.499	0.546	0.397	0.515	0.549	0.516
Minimum	2.3	-1.2	2.6	-1.3	2.9	-1.0	3.3	-0.4	2.9	-1.0
Q1	3.30	-0.40	3.50	-0.10	3.60	-0.10	4.00	0.30	4.00	0.50
Median	3.60	0.00	3.70	0.10	3.90	0.30	4.30	0.60	4.40	0.70
Q3	4.00	0.20	4.10	0.60	4.30	0.70	4.50	1.00	4.60	1.10
Maximum	5.0	1.0	4.8	1.2	5.1	1.6	5.3	1.9	5.5	2.1
Follow-up										
N	77	77	83	83	77	77	89	89	69	69
Mean	3.46	-0.17	3.47	-0.12	3.56	-0.08	3.73	0.14	4.07	0.50
SD	0.524	0.447	0.451	0.514	0.459	0.528	0.462	0.615	0.431	0.483
Minimum	2.4	-1.3	2.5	-1.4	2.3	-1.5	2.6	-1.2	3.1	-0.8
Q1	3.10	-0.50	3.10	-0.40	3.20	-0.50	3.40	-0.30	3.70	0.30
Median	3.50	-0.10	3.40	-0.10	3.60	-0.10	3.70	0.10	4.10	0.50
Q3	3.80	0.10	3.80	0.20	3.90	0.30	4.00	0.50	4.40	0.90
Maximum	4.8	1.1	4.6	1.2	4.6	1.2	5.3	1.8	5.1	1.5

治験総括報告書 Table 3.2.1.1.1（Section 15.1）（5.3.5.4-2）から引用

表 2.7.4.8-付録-37　血液生化学検査値のシフトテーブル（安全性データの解析対象集団）（CCT-002 試験）

ALT (U/L)

	Baseline							
	TAK-385 40mg (N=138)				Leuprorelin (N=142)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 4								
Low	-	-	-	-	-	-	-	-
Normal	-	133	3	136	1	134	-	135
High	-	1	1	2	-	3	4	7
Total	-	134	4	138	1	137	4	142
Week 8								
Low	-	-	-	-	-	-	-	-
Normal	-	129	3	132	1	136	-	137
High	-	2	1	3	-	1	4	5
Total	-	131	4	135	1	137	4	142
Week 12								
Low	-	-	-	-	-	-	-	-
Normal	-	122	2	124	1	131	-	132
High	-	5	1	6	-	5	4	9
Total	-	127	3	130	1	136	4	141
Week 16								
Low	-	-	-	-	-	-	-	-
Normal	-	124	2	126	1	128	-	129
High	-	2	1	3	-	5	2	7
Total	-	126	3	129	1	133	2	136
Week 20								
Low	-	-	-	-	-	-	-	-
Normal	-	116	1	117	1	124	-	125
High	-	7	2	9	-	5	2	7
Total	-	123	3	126	1	129	2	132
Week 24								
Low	-	-	-	-	-	-	-	-
Normal	-	112	2	114	1	124	-	125
High	-	7	1	8	-	4	2	6
Total	-	119	3	122	1	128	2	131

治験総括報告書 Table 15.3.2.1.3.1（5.3.5.1-2）から引用

表 2.7.4.8-付録-37　血液生化学検査値のシフトテーブル（安全性データの解析対象集団）（CCT-002 試験）（続き）

ALT (U/L)

	Baseline							
	TAK-385 40mg (N=138)				Leuprorelin (N=142)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Follow-up								
Low	-	-	-	-	-	-	-	-
Normal	-	128	3	131	1	130	-	131
High	-	3	1	4	-	6	4	10
Total	-	131	4	135	1	136	4	141

治験総括報告書 Table 15.3.2.1.3.1（5.3.5.1-2）から引用

表 2.7.4.8-付録-37　血液生化学検査値のシフトテーブル（安全性データの解析対象集団）（CCT-002 試験）（続き）

AST (U/L)

	Baseline							
	TAK-385 40mg (N=138)				Leuprorelin (N=142)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 4								
Low	-	-	-	-	-	1	-	1
Normal	-	135	1	136	-	136	-	136
High	-	1	-	1	-	3	-	3
Total	-	136	1	137	-	140	-	140
Week 8								
Low	-	-	-	-	-	-	-	-
Normal	-	132	1	133	-	138	-	138
High	-	2	-	2	-	3	-	3
Total	-	134	1	135	-	141	-	141
Week 12								
Low	-	-	-	-	-	-	-	-
Normal	-	126	1	127	-	130	-	130
High	-	2	-	2	-	9	-	9
Total	-	128	1	129	-	139	-	139
Week 16								
Low	-	-	-	-	-	-	-	-
Normal	-	126	1	127	-	130	-	130
High	-	2	-	2	-	4	-	4
Total	-	128	1	129	-	134	-	134
Week 20								
Low	-	-	-	-	-	-	-	-
Normal	-	118	-	118	-	124	-	124
High	-	5	1	6	-	6	-	6
Total	-	123	1	124	-	130	-	130
Week 24								
Low	-	-	-	-	-	-	-	-
Normal	-	115	1	116	-	125	-	125
High	-	6	-	6	-	4	-	4
Total	-	121	1	122	-	129	-	129

治験総括報告書 Table 15.3.2.1.3.1（5.3.5.1-2）から引用

表 2.7.4.8-付録-37　血液生化学検査値のシフトテーブル（安全性データの解析対象集団）（CCT-002 試験）（続き）

AST (U/L)

	Baseline							
	TAK-385 40mg (N=138)				Leuprorelin (N=142)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Follow-up								
Low	-	-	-	-	-	-	-	-
Normal	-	132	1	133	-	133	-	133
High	-	-	-	-	-	8	-	8
Total	-	132	1	133	-	141	-	141

治験総括報告書 Table 15.3.2.1.3.1（5.3.5.1-2）から引用

表 2.7.4.8-付録-37　血液生化学検査値のシフトテーブル（安全性データの解析対象集団）（CCT-002 試験）（続き）

Lactate dehydrogenase (LDH) (U/L)

	Baseline							
	TAK-385 40mg (N=138)				Leuprorelin (N=142)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 4								
Low	3	-	-	3	2	1	-	3
Normal	5	126	1	132	2	134	-	136
High	-	1	1	2	-	1	-	1
Total	8	127	2	137	4	136	-	140
Week 8								
Low	2	-	-	2	1	-	-	1
Normal	7	123	1	131	3	135	-	138
High	-	1	1	2	-	2	-	2
Total	9	124	2	135	4	137	-	141
Week 12								
Low	1	1	-	2	1	-	-	1
Normal	7	116	1	124	3	132	-	135
High	-	2	1	3	-	3	-	3
Total	8	119	2	129	4	135	-	139
Week 16								
Low	2	2	-	4	1	-	-	1
Normal	6	115	-	121	3	129	-	132
High	-	2	2	4	-	1	-	1
Total	8	119	2	129	4	130	-	134
Week 20								
Low	2	1	-	3	1	-	-	1
Normal	6	112	1	119	3	126	-	129
High	-	1	1	2	-	-	-	-
Total	8	114	2	124	4	126	-	130
Week 24								
Low	3	1	-	4	1	-	-	1
Normal	5	110	1	116	3	125	-	128
High	-	1	1	2	-	-	-	-
Total	8	112	2	122	4	125	-	129

治験総括報告書 Table 15.3.2.1.3.1（5.3.5.1-2）から引用

表 2.7.4.8-付録-37　血液生化学検査値のシフトテーブル（安全性データの解析対象集団）（CCT-002 試験）（続き）

Lactate dehydrogenase (LDH) (U/L)

	Baseline							
	TAK-385 40mg (N=138)				Leuprorelin (N=142)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Follow-up								
Low	6	1	-	7	1	-	-	1
Normal	3	119	1	123	3	134	-	137
High	-	2	1	3	-	3	-	3
Total	9	122	2	133	4	137	-	141

治験総括報告書 Table 15.3.2.1.3.1（5.3.5.1-2）から引用

表 2.7.4.8-付録-37　血液生化学検査値のシフトテーブル（安全性データの解析対象集団）（CCT-002 試験）（続き）

Gamma glutamyl transferase (GGT) (U/L)

	Baseline							
	TAK-385 40mg (N=138)				Leuprorelin (N=142)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 4								
Low	-	-	-	-	-	-	-	-
Normal	-	113	1	114	-	115	1	116
High	-	11	13	24	-	11	15	26
Total	-	124	14	138	-	126	16	142
Week 8								
Low	-	-	-	-	-	-	-	-
Normal	-	107	-	107	-	115	2	117
High	-	15	13	28	-	11	14	25
Total	-	122	13	135	-	126	16	142
Week 12								
Low	-	-	-	-	-	-	-	-
Normal	-	103	-	103	-	113	1	114
High	-	15	12	27	-	12	15	27
Total	-	118	12	130	-	125	16	141
Week 16								
Low	-	-	-	-	-	-	-	-
Normal	-	100	-	100	-	107	1	108
High	-	17	12	29	-	16	12	28
Total	-	117	12	129	-	123	13	136
Week 20								
Low	-	-	-	-	-	-	-	-
Normal	-	97	-	97	-	101	1	102
High	-	17	12	29	-	18	12	30
Total	-	114	12	126	-	119	13	132
Week 24								
Low	-	-	-	-	-	-	-	-
Normal	-	95	-	95	-	102	1	103
High	-	15	12	27	-	16	12	28
Total	-	110	12	122	-	118	13	131

治験総括報告書 Table 15.3.2.1.3.1（5.3.5.1-2）から引用

表 2.7.4.8-付録-37　血液生化学検査値のシフトテーブル（安全性データの解析対象集団）（CCT-002 試験）（続き）

Gamma glutamyl transferase (GGT) (U/L)

	Baseline							
	TAK-385 40mg (N=138)				Leuprorelin (N=142)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Follow-up								
Low	-	-	-	-	-	-	-	-
Normal	-	103	2	105	-	106	-	106
High	-	18	12	30	-	19	16	35
Total	-	121	14	135	-	125	16	141

治験総括報告書 Table 15.3.2.1.3.1（5.3.5.1-2）から引用

表 2.7.4.8-付録-37　血液生化学検査値のシフトテーブル（安全性データの解析対象集団）（CCT-002 試験）（続き）

Albumin (g/dL)

	Baseline							
	TAK-385 40mg (N=138)				Leuprorelin (N=142)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 4								
Low	-	-	-	-	-	-	-	-
Normal	3	135	-	138	-	142	-	142
High	-	-	-	-	-	-	-	-
Total	3	135	-	138	-	142	-	142
Week 8								
Low	-	-	-	-	-	-	-	-
Normal	2	133	-	135	-	142	-	142
High	-	-	-	-	-	-	-	-
Total	2	133	-	135	-	142	-	142
Week 12								
Low	-	-	-	-	-	-	-	-
Normal	2	128	-	130	-	141	-	141
High	-	-	-	-	-	-	-	-
Total	2	128	-	130	-	141	-	141
Week 16								
Low	-	1	-	1	-	-	-	-
Normal	2	126	-	128	-	136	-	136
High	-	-	-	-	-	-	-	-
Total	2	127	-	129	-	136	-	136
Week 20								
Low	-	-	-	-	-	1	-	1
Normal	2	124	-	126	-	131	-	131
High	-	-	-	-	-	-	-	-
Total	2	124	-	126	-	132	-	132
Week 24								
Low	-	-	-	-	-	-	-	-
Normal	2	120	-	122	-	131	-	131
High	-	-	-	-	-	-	-	-
Total	2	120	-	122	-	131	-	131

治験総括報告書 Table 15.3.2.1.3.1（5.3.5.1-2）から引用

表 2.7.4.8-付録-37　血液生化学検査値のシフトテーブル（安全性データの解析対象集団）（CCT-002 試験）（続き）

Albumin (g/dL)

	Baseline							
	TAK-385 40mg (N=138)				Leuprorelin (N=142)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Follow-up								
Low	-	-	-	-	-	-	-	-
Normal	3	132	-	135	-	141	-	141
High	-	-	-	-	-	-	-	-
Total	3	132	-	135	-	141	-	141

治験総括報告書 Table 15.3.2.1.3.1（5.3.5.1-2）から引用

表 2.7.4.8-付録-37　血液生化学検査値のシフトテーブル（安全性データの解析対象集団）（CCT-002 試験）（続き）

Alkaline phosphatase (ALP) (U/L)

	Baseline							
	TAK-385 40mg (N=138)				Leuprorelin (N=142)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 4								
Low	2	-	-	2	3	-	-	3
Normal	1	132	-	133	2	135	1	138
High	-	2	1	3	-	-	1	1
Total	3	134	1	138	5	135	2	142
Week 8								
Low	1	-	-	1	3	-	-	3
Normal	2	130	-	132	2	135	1	138
High	-	1	1	2	-	-	1	1
Total	3	131	1	135	5	135	2	142
Week 12								
Low	1	-	-	1	1	-	-	1
Normal	2	125	-	127	3	131	1	135
High	-	1	1	2	-	4	1	5
Total	3	126	1	130	4	135	2	141
Week 16								
Low	1	-	-	1	1	-	-	1
Normal	2	123	-	125	3	126	2	131
High	-	2	1	3	-	4	-	4
Total	3	125	1	129	4	130	2	136
Week 20								
Low	1	-	-	1	-	-	-	-
Normal	2	115	-	117	4	124	1	129
High	-	7	1	8	-	2	1	3
Total	3	122	1	126	4	126	2	132
Week 24								
Low	1	-	-	1	-	-	-	-
Normal	2	116	-	118	4	121	1	126
High	-	2	1	3	-	4	1	5
Total	3	118	1	122	4	125	2	131

治験総括報告書 Table 15.3.2.1.3.1（5.3.5.1-2）から引用

表 2.7.4.8-付録-37　血液生化学検査値のシフトテーブル（安全性データの解析対象集団）（CCT-002 試験）（続き）

Alkaline phosphatase (ALP) (U/L)

	Baseline							
	TAK-385 40mg (N=138)				Leuprorelin (N=142)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Follow-up								
Low	2	1	-	3	1	-	-	1
Normal	1	123	-	124	4	129	2	135
High	-	7	1	8	-	5	-	5
Total	3	131	1	135	5	134	2	141

治験総括報告書 Table 15.3.2.1.3.1（5.3.5.1-2）から引用

表 2.7.4.8-付録-37　血液生化学検査値のシフトテーブル（安全性データの解析対象集団）（CCT-002 試験）（続き）

Bilirubin (Total bilirubin) (mg/dL)

	Baseline							
	TAK-385 40mg (N=138)				Leuprorelin (N=142)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 4								
Low	-	-	-	-	-	-	-	-
Normal	-	131	1	132	-	141	-	141
High	-	5	1	6	-	1	-	1
Total	-	136	2	138	-	142	-	142
Week 8								
Low	-	-	-	-	-	-	-	-
Normal	-	128	-	128	-	140	-	140
High	-	5	2	7	-	2	-	2
Total	-	133	2	135	-	142	-	142
Week 12								
Low	-	-	-	-	-	-	-	-
Normal	-	124	1	125	-	137	-	137
High	-	4	1	5	-	4	-	4
Total	-	128	2	130	-	141	-	141
Week 16								
Low	-	-	-	-	-	-	-	-
Normal	-	123	-	123	-	132	-	132
High	-	4	2	6	-	4	-	4
Total	-	127	2	129	-	136	-	136
Week 20								
Low	-	-	-	-	-	-	-	-
Normal	-	119	2	121	-	130	-	130
High	-	5	-	5	-	2	-	2
Total	-	124	2	126	-	132	-	132
Week 24								
Low	-	-	-	-	-	-	-	-
Normal	-	118	2	120	-	128	-	128
High	-	2	-	2	-	3	-	3
Total	-	120	2	122	-	131	-	131

治験総括報告書 Table 15.3.2.1.3.1（5.3.5.1-2）から引用

表 2.7.4.8-付録-37　血液生化学検査値のシフトテーブル（安全性データの解析対象集団）（CCT-002 試験）（続き）

Bilirubin (Total bilirubin) (mg/dL)

	Baseline							
	TAK-385 40mg (N=138)				Leuprorelin (N=142)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Follow-up								
Low	-	-	-	-	-	-	-	-
Normal	-	130	1	131	-	140	-	140
High	-	3	1	4	-	1	-	1
Total	-	133	2	135	-	141	-	141

治験総括報告書 Table 15.3.2.1.3.1（5.3.5.1-2）から引用

表 2.7.4.8-付録-37　血液生化学検査値のシフトテーブル（安全性データの解析対象集団）（CCT-002 試験）（続き）

Protein (Total protein) (g/dL)

	Baseline							
	TAK-385 40mg (N=138)				Leuprorelin (N=142)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 4								
Low	3	-	-	3	8	4	-	12
Normal	32	103	-	135	34	95	-	129
High	-	-	-	-	-	1	-	1
Total	35	103	-	138	42	100	-	142
Week 8								
Low	1	1	-	2	3	1	-	4
Normal	33	100	-	133	39	96	-	135
High	-	-	-	-	-	3	-	3
Total	34	101	-	135	42	100	-	142
Week 12								
Low	3	2	-	5	7	1	-	8
Normal	30	94	-	124	35	98	-	133
High	-	1	-	1	-	-	-	-
Total	33	97	-	130	42	99	-	141
Week 16								
Low	3	1	-	4	2	-	-	2
Normal	30	94	-	124	39	93	-	132
High	-	1	-	1	-	2	-	2
Total	33	96	-	129	41	95	-	136
Week 20								
Low	3	1	-	4	3	1	-	4
Normal	28	93	-	121	37	91	-	128
High	-	1	-	1	-	-	-	-
Total	31	95	-	126	40	92	-	132
Week 24								
Low	5	2	-	7	5	2	-	7
Normal	25	90	-	115	35	87	-	122
High	-	-	-	-	-	2	-	2
Total	30	92	-	122	40	91	-	131

治験総括報告書 Table 15.3.2.1.3.1（5.3.5.1-2）から引用

表 2.7.4.8-付録-37　血液生化学検査値のシフトテーブル（安全性データの解析対象集団）（CCT-002 試験）（続き）

Protein (Total protein) (g/dL)

	Baseline							
	TAK-385 40mg (N=138)				Leuprorelin (N=142)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Follow-up								
Low	13	5	-	18	5	2	-	7
Normal	21	96	-	117	37	96	-	133
High	-	-	-	-	-	1	-	1
Total	34	101	-	135	42	99	-	141

治験総括報告書 Table 15.3.2.1.3.1（5.3.5.1-2）から引用

表 2.7.4.8-付録-37　血液生化学検査値のシフトテーブル（安全性データの解析対象集団）（CCT-002 試験）（続き）

Cholesterol (Total cholesterol) (mg/dL)

	Baseline							
	TAK-385 40mg (N=138)				Leuprorelin (N=142)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 4								
Low	-	-	-	-	-	-	-	-
Normal	-	87	-	87	-	95	2	97
High	-	34	17	51	-	31	14	45
Total	-	121	17	138	-	126	16	142
Week 8								
Low	-	-	-	-	-	-	-	-
Normal	-	77	-	77	-	93	1	94
High	-	42	16	58	-	33	15	48
Total	-	119	16	135	-	126	16	142
Week 12								
Low	-	-	-	-	-	-	-	-
Normal	-	79	-	79	-	86	-	86
High	-	36	15	51	-	39	16	55
Total	-	115	15	130	-	125	16	141
Week 16								
Low	-	1	-	1	-	-	-	-
Normal	-	74	1	75	-	88	1	89
High	-	39	14	53	-	33	14	47
Total	-	114	15	129	-	121	15	136
Week 20								
Low	-	-	-	-	-	-	-	-
Normal	-	78	1	79	-	81	-	81
High	-	33	14	47	-	37	14	51
Total	-	111	15	126	-	118	14	132
Week 24								
Low	-	-	-	-	-	-	-	-
Normal	-	69	-	69	-	80	1	81
High	-	39	14	53	-	37	13	50
Total	-	108	14	122	-	117	14	131

治験総括報告書 Table 15.3.2.1.3.1（5.3.5.1-2）から引用

表 2.7.4.8-付録-37　血液生化学検査値のシフトテーブル（安全性データの解析対象集団）（CCT-002 試験）（続き）

Cholesterol (Total cholesterol) (mg/dL)

	Baseline							
	TAK-385 40mg (N=138)				Leuprorelin (N=142)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Follow-up								
Low	-	-	-	-	-	-	-	-
Normal	-	92	6	98	-	86	-	86
High	-	26	11	37	-	39	16	55
Total	-	118	17	135	-	125	16	141

治験総括報告書 Table 15.3.2.1.3.1（5.3.5.1-2）から引用

表 2.7.4.8-付録-37　血液生化学検査値のシフトテーブル（安全性データの解析対象集団）（CCT-002 試験）（続き）

High density lipoprotein (HDL) cholesterol (mg/dL)

	Baseline							
	TAK-385 40mg (N=138)				Leuprorelin (N=142)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 4								
Low	3	2	-	5	3	1	-	4
Normal	1	121	-	122	3	124	-	127
High	-	8	3	11	-	8	3	11
Total	4	131	3	138	6	133	3	142
Week 8								
Low	2	1	-	3	2	2	-	4
Normal	2	122	-	124	4	127	-	131
High	-	5	3	8	-	4	3	7
Total	4	128	3	135	6	133	3	142
Week 12								
Low	3	1	-	4	1	2	-	3
Normal	1	116	-	117	5	125	1	131
High	-	6	3	9	-	5	2	7
Total	4	123	3	130	6	132	3	141
Week 16								
Low	2	1	-	3	-	-	-	-
Normal	2	115	1	118	4	119	-	123
High	-	6	2	8	-	10	3	13
Total	4	122	3	129	4	129	3	136
Week 20								
Low	2	-	-	2	-	2	-	2
Normal	2	115	1	118	3	115	-	118
High	-	4	2	6	-	9	3	12
Total	4	119	3	126	3	126	3	132
Week 24								
Low	2	1	-	3	1	-	-	1
Normal	2	110	1	113	2	119	-	121
High	-	4	2	6	-	6	3	9
Total	4	115	3	122	3	125	3	131

治験総括報告書 Table 15.3.2.1.3.1（5.3.5.1-2）から引用

表 2.7.4.8-付録-37　血液生化学検査値のシフトテーブル（安全性データの解析対象集団）（CCT-002 試験）（続き）

High density lipoprotein (HDL) cholesterol (mg/dL)

	Baseline							
	TAK-385 40mg (N=138)				Leuprorelin (N=142)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Follow-up								
Low	1	3	-	4	1	-	-	1
Normal	3	123	1	127	5	123	-	128
High	-	3	1	4	-	9	3	12
Total	4	129	2	135	6	132	3	141

治験総括報告書 Table 15.3.2.1.3.1（5.3.5.1-2）から引用

表 2.7.4.8-付録-37　血液生化学検査値のシフトテーブル（安全性データの解析対象集団）（CCT-002 試験）（続き）

Low density lipoprotein (LDL) cholesterol (mg/dL)

	Baseline							
	TAK-385 40mg (N=138)				Leuprorelin (N=142)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 4								
Low	-	-	-	-	3	1	-	4
Normal	3	91	-	94	2	102	3	107
High	-	24	20	44	-	17	14	31
Total	3	115	20	138	5	120	17	142
Week 8								
Low	1	1	-	2	1	1	-	2
Normal	2	88	1	91	4	99	1	104
High	-	24	18	42	-	20	16	36
Total	3	113	19	135	5	120	17	142
Week 12								
Low	1	-	-	1	1	1	-	2
Normal	2	88	1	91	4	93	1	98
High	-	21	17	38	-	25	16	41
Total	3	109	18	130	5	119	17	141
Week 16								
Low	1	1	-	2	-	-	-	-
Normal	2	80	2	84	5	97	-	102
High	-	27	16	43	-	19	15	34
Total	3	108	18	129	5	116	15	136
Week 20								
Low	1	-	-	1	-	-	-	-
Normal	2	82	2	86	5	91	-	96
High	-	23	16	39	-	21	15	36
Total	3	105	18	126	5	112	15	132
Week 24								
Low	1	1	-	2	1	-	-	1
Normal	2	76	-	78	4	89	1	94
High	-	25	17	42	-	22	14	36
Total	3	102	17	122	5	111	15	131

治験総括報告書 Table 15.3.2.1.3.1（5.3.5.1-2）から引用

表 2.7.4.8-付録-37　血液生化学検査値のシフトテーブル（安全性データの解析対象集団）（CCT-002 試験）（続き）

Low density lipoprotein (LDL) cholesterol (mg/dL)

	Baseline							
	TAK-385 40mg (N=138)				Leuprorelin (N=142)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Follow-up								
Low	1	1	-	2	2	-	-	2
Normal	1	98	6	105	3	96	1	100
High	-	14	14	28	-	23	16	39
Total	2	113	20	135	5	119	17	141

治験総括報告書 Table 15.3.2.1.3.1（5.3.5.1-2）から引用

表 2.7.4.8-付録-37　血液生化学検査値のシフトテーブル（安全性データの解析対象集団）（CCT-002 試験）（続き）

Triglycerides (mg/dL)

	Baseline							
	TAK-385 40mg (N=138)				Leuprorelin (N=142)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 4								
Low	1	1	-	2	-	2	-	2
Normal	-	113	1	114	2	107	6	115
High	-	10	12	22	-	11	14	25
Total	1	124	13	138	2	120	20	142
Week 8								
Low	-	-	-	-	-	2	-	2
Normal	1	105	2	108	2	104	8	114
High	-	16	11	27	-	14	12	26
Total	1	121	13	135	2	120	20	142
Week 12								
Low	-	3	-	3	-	2	-	2
Normal	1	97	3	101	2	100	6	108
High	-	16	10	26	-	17	14	31
Total	1	116	13	130	2	119	20	141
Week 16								
Low	-	2	-	2	-	2	-	2
Normal	1	94	3	98	2	100	9	111
High	-	19	10	29	-	14	9	23
Total	1	115	13	129	2	116	18	136
Week 20								
Low	-	-	-	-	1	2	-	3
Normal	1	101	1	103	1	98	8	107
High	-	11	12	23	-	13	9	22
Total	1	112	13	126	2	113	17	132
Week 24								
Low	-	1	-	1	2	1	-	3
Normal	1	95	5	101	-	99	8	107
High	-	13	7	20	-	12	9	21
Total	1	109	12	122	2	112	17	131

治験総括報告書 Table 15.3.2.1.3.1（5.3.5.1-2）から引用

表 2.7.4.8-付録-37　血液生化学検査値のシフトテーブル（安全性データの解析対象集団）（CCT-002 試験）（続き）

Triglycerides (mg/dL)

	Baseline							
	TAK-385 40mg (N=138)				Leuprorelin (N=142)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Follow-up								
Low	-	-	-	-	1	1	-	2
Normal	1	113	5	119	1	102	7	110
High	-	8	8	16	-	16	13	29
Total	1	121	13	135	2	119	20	141

治験総括報告書 Table 15.3.2.1.3.1（5.3.5.1-2）から引用

表 2.7.4.8-付録-37　血液生化学検査値のシフトテーブル（安全性データの解析対象集団）（CCT-002 試験）（続き）

Glucose (mg/dL)

	Baseline							
	TAK-385 40mg (N=138)				Leuprorelin (N=142)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 4								
Low	-	1	-	1	-	-	1	1
Normal	-	125	2	127	-	129	4	133
High	-	8	2	10	-	3	5	8
Total	-	134	4	138	-	132	10	142
Week 8								
Low	-	-	-	-	-	-	-	-
Normal	-	123	3	126	-	122	4	126
High	-	8	1	9	-	10	6	16
Total	-	131	4	135	-	132	10	142
Week 12								
Low	-	-	-	-	-	1	-	1
Normal	-	117	3	120	-	123	7	130
High	-	9	1	10	-	7	3	10
Total	-	126	4	130	-	131	10	141
Week 16								
Low	-	-	-	-	-	1	-	1
Normal	-	119	4	123	-	118	6	124
High	-	6	-	6	-	7	4	11
Total	-	125	4	129	-	126	10	136
Week 20								
Low	-	-	-	-	-	-	-	-
Normal	-	111	4	115	-	113	7	120
High	-	11	-	11	-	9	3	12
Total	-	122	4	126	-	122	10	132
Week 24								
Low	-	-	-	-	-	-	-	-
Normal	-	110	2	112	-	113	7	120
High	-	8	2	10	-	8	3	11
Total	-	118	4	122	-	121	10	131

治験総括報告書 Table 15.3.2.1.3.1（5.3.5.1-2）から引用

表 2.7.4.8-付録-37　血液生化学検査値のシフトテーブル（安全性データの解析対象集団）（CCT-002 試験）（続き）

Glucose (mg/dL)

	Baseline							
	TAK-385 40mg (N=138)				Leuprorelin (N=142)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Follow-up								
Low	-	2	-	2	-	-	-	-
Normal	-	118	4	122	-	121	7	128
High	-	11	-	11	-	10	3	13
Total	-	131	4	135	-	131	10	141

治験総括報告書 Table 15.3.2.1.3.1（5.3.5.1-2）から引用

表 2.7.4.8-付録-37　血液生化学検査値のシフトテーブル（安全性データの解析対象集団）（CCT-002 試験）（続き）

HGB A1C (%)

	Baseline							
	TAK-385 40mg (N=138)				Leuprorelin (N=142)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 4								
Low	3	1	-	4	-	-	-	-
Normal	1	131	-	132	2	137	-	139
High	-	1	1	2	-	2	1	3
Total	4	133	1	138	2	139	1	142
Week 8								
Low	-	-	-	-	1	-	-	1
Normal	4	130	-	134	1	138	-	139
High	-	-	1	1	-	1	1	2
Total	4	130	1	135	2	139	1	142
Week 12								
Low	-	-	-	-	-	-	-	-
Normal	4	125	-	129	2	135	-	137
High	-	-	1	1	-	3	1	4
Total	4	125	1	130	2	138	1	141
Week 16								
Low	-	-	-	-	-	-	-	-
Normal	4	124	-	128	2	131	-	133
High	-	-	1	1	-	2	1	3
Total	4	124	1	129	2	133	1	136
Week 20								
Low	1	-	-	1	-	-	-	-
Normal	3	121	-	124	2	127	-	129
High	-	-	1	1	-	2	1	3
Total	4	121	1	126	2	129	1	132
Week 24								
Low	1	-	-	1	-	-	-	-
Normal	3	116	-	119	2	126	-	128
High	-	1	1	2	-	2	1	3
Total	4	117	1	122	2	128	1	131

治験総括報告書 Table 15.3.2.1.3.1（5.3.5.1-2）から引用

表 2.7.4.8-付録-37　血液生化学検査値のシフトテーブル（安全性データの解析対象集団）（CCT-002 試験）（続き）

HGB A1C (%)

	Baseline							
	TAK-385 40mg (N=138)				Leuprorelin (N=142)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Follow-up								
Low	-	1	-	1	-	-	-	-
Normal	4	129	-	133	2	136	-	138
High	-	-	1	1	-	2	1	3
Total	4	130	1	135	2	138	1	141

治験総括報告書 Table 15.3.2.1.3.1（5.3.5.1-2）から引用

表 2.7.4.8-付録-37　血液生化学検査値のシフトテーブル（安全性データの解析対象集団）（CCT-002 試験）（続き）

Creatinine (mg/dL)

	Baseline							
	TAK-385 40mg (N=138)				Leuprorelin (N=142)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 4								
Low	4	1	-	5	5	2	-	7
Normal	5	118	2	125	4	130	1	135
High	-	4	3	7	-	-	-	-
Total	9	123	5	137	9	132	1	142
Week 8								
Low	4	3	-	7	4	1	-	5
Normal	6	116	3	125	5	129	1	135
High	-	1	2	3	-	2	-	2
Total	10	120	5	135	9	132	1	142
Week 12								
Low	4	4	-	8	7	3	-	10
Normal	6	111	3	120	2	128	1	131
High	-	1	1	2	-	-	-	-
Total	10	116	4	130	9	131	1	141
Week 16								
Low	4	4	-	8	4	3	-	7
Normal	6	110	3	119	5	123	1	129
High	-	1	1	2	-	-	-	-
Total	10	115	4	129	9	126	1	136
Week 20								
Low	3	3	-	6	6	2	-	8
Normal	7	107	2	116	3	119	1	123
High	-	2	2	4	-	1	-	1
Total	10	112	4	126	9	122	1	132
Week 24								
Low	7	2	-	9	6	2	-	8
Normal	3	104	3	110	3	119	1	123
High	-	2	1	3	-	-	-	-
Total	10	108	4	122	9	121	1	131

治験総括報告書 Table 15.3.2.1.3.1（5.3.5.1-2）から引用

表 2.7.4.8-付録-37　血液生化学検査値のシフトテーブル（安全性データの解析対象集団）（CCT-002 試験）（続き）

Creatinine (mg/dL)

	Baseline							
	TAK-385 40mg (N=138)				Leuprorelin (N=142)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Follow-up								
Low	3	1	-	4	5	2	-	7
Normal	7	116	3	126	4	129	1	134
High	-	3	2	5	-	-	-	-
Total	10	120	5	135	9	131	1	141

治験総括報告書 Table 15.3.2.1.3.1（5.3.5.1-2）から引用

表 2.7.4.8-付録-37　血液生化学検査値のシフトテーブル（安全性データの解析対象集団）（CCT-002 試験）（続き）

Blood urea nitrogen (BUN) (mg/dL)

	Baseline							
	TAK-385 40mg (N=138)				Leuprorelin (N=142)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 4								
Low	4	-	-	4	2	-	-	2
Normal	10	123	-	133	9	131	-	140
High	-	1	-	1	-	-	-	-
Total	14	124	-	138	11	131	-	142
Week 8								
Low	4	4	-	8	2	3	-	5
Normal	10	117	-	127	9	128	-	137
High	-	-	-	-	-	-	-	-
Total	14	121	-	135	11	131	-	142
Week 12								
Low	4	5	-	9	2	5	-	7
Normal	10	110	-	120	9	125	-	134
High	-	1	-	1	-	-	-	-
Total	14	116	-	130	11	130	-	141
Week 16								
Low	4	2	-	6	3	2	-	5
Normal	10	112	-	122	8	122	-	130
High	-	1	-	1	-	1	-	1
Total	14	115	-	129	11	125	-	136
Week 20								
Low	2	2	-	4	3	3	-	6
Normal	11	111	-	122	8	118	-	126
High	-	-	-	-	-	-	-	-
Total	13	113	-	126	11	121	-	132
Week 24								
Low	2	1	-	3	1	2	-	3
Normal	10	109	-	119	10	118	-	128
High	-	-	-	-	-	-	-	-
Total	12	110	-	122	11	120	-	131

治験総括報告書 Table 15.3.2.1.3.1（5.3.5.1-2）から引用

表 2.7.4.8-付録-37　血液生化学検査値のシフトテーブル（安全性データの解析対象集団）（CCT-002 試験）（続き）

Blood urea nitrogen (BUN) (mg/dL)

	Baseline							
	TAK-385 40mg (N=138)				Leuprorelin (N=142)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Follow-up								
Low	4	4	-	8	1	3	-	4
Normal	9	118	-	127	10	127	-	137
High	-	-	-	-	-	-	-	-
Total	13	122	-	135	11	130	-	141

治験総括報告書 Table 15.3.2.1.3.1（5.3.5.1-2）から引用

表 2.7.4.8-付録-37　血液生化学検査値のシフトテーブル（安全性データの解析対象集団）（CCT-002 試験）（続き）

Creatine kinase (U/L)

	Baseline							
	TAK-385 40mg (N=138)				Leuprorelin (N=142)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 4								
Low	3	1	-	4	3	1	-	4
Normal	7	112	5	124	1	127	2	130
High	-	7	3	10	1	5	2	8
Total	10	120	8	138	5	133	4	142
Week 8								
Low	2	2	-	4	2	1	-	3
Normal	7	114	6	127	3	130	2	135
High	-	2	2	4	-	2	2	4
Total	9	118	8	135	5	133	4	142
Week 12								
Low	2	3	-	5	2	1	-	3
Normal	7	105	6	118	3	124	2	129
High	-	5	2	7	-	7	2	9
Total	9	113	8	130	5	132	4	141
Week 16								
Low	2	3	-	5	3	1	-	4
Normal	7	107	6	120	2	125	2	129
High	-	2	2	4	-	1	2	3
Total	9	112	8	129	5	127	4	136
Week 20								
Low	1	1	-	2	3	1	-	4
Normal	8	103	6	117	2	118	3	123
High	-	5	2	7	-	4	1	5
Total	9	109	8	126	5	123	4	132
Week 24								
Low	2	2	-	4	3	1	-	4
Normal	7	100	4	111	2	115	2	119
High	-	3	4	7	-	6	2	8
Total	9	105	8	122	5	122	4	131

治験総括報告書 Table 15.3.2.1.3.1（5.3.5.1-2）から引用

表 2.7.4.8-付録-37　血液生化学検査値のシフトテーブル（安全性データの解析対象集団）（CCT-002 試験）（続き）

Creatine kinase (U/L)

	Baseline							
	TAK-385 40mg (N=138)				Leuprorelin (N=142)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Follow-up								
Low	1	3	-	4	4	1	-	5
Normal	9	112	6	127	1	127	2	130
High	-	2	2	4	-	4	2	6
Total	10	117	8	135	5	132	4	141

治験総括報告書 Table 15.3.2.1.3.1（5.3.5.1-2）から引用

表 2.7.4.8-付録-37　血液生化学検査値のシフトテーブル（安全性データの解析対象集団）（CCT-002 試験）（続き）

Urate (mg/dL)

	Baseline							
	TAK-385 40mg (N=138)				Leuprorelin (N=142)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 4								
Low	3	-	-	3	3	2	-	5
Normal	3	132	-	135	1	134	1	136
High	-	-	-	-	-	1	-	1
Total	6	132	-	138	4	137	1	142
Week 8								
Low	2	-	-	2	2	-	-	2
Normal	4	127	-	131	2	137	1	140
High	-	2	-	2	-	-	-	-
Total	6	129	-	135	4	137	1	142
Week 12								
Low	2	-	-	2	4	1	-	5
Normal	4	122	-	126	-	135	1	136
High	-	2	-	2	-	-	-	-
Total	6	124	-	130	4	136	1	141
Week 16								
Low	2	-	-	2	2	-	-	2
Normal	4	121	-	125	2	130	1	133
High	-	2	-	2	-	1	-	1
Total	6	123	-	129	4	131	1	136
Week 20								
Low	2	1	-	3	2	-	-	2
Normal	4	117	-	121	2	125	1	128
High	-	2	-	2	-	2	-	2
Total	6	120	-	126	4	127	1	132
Week 24								
Low	2	1	-	3	2	-	-	2
Normal	4	113	-	117	2	125	1	128
High	-	2	-	2	-	1	-	1
Total	6	116	-	122	4	126	1	131

治験総括報告書 Table 15.3.2.1.3.1（5.3.5.1-2）から引用

表 2.7.4.8-付録-37　血液生化学検査値のシフトテーブル（安全性データの解析対象集団）（CCT-002 試験）（続き）

Urate (mg/dL)

	Baseline							
	TAK-385 40mg (N=138)				Leuprorelin (N=142)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Follow-up								
Low	4	1	-	5	3	-	-	3
Normal	2	127	-	129	1	136	1	138
High	-	1	-	1	-	-	-	-
Total	6	129	-	135	4	136	1	141

治験総括報告書 Table 15.3.2.1.3.1（5.3.5.1-2）から引用

表 2.7.4.8-付録-37　血液生化学検査値のシフトテーブル（安全性データの解析対象集団）（CCT-002 試験）（続き）

Sodium (mEq/L)

	Baseline							
	TAK-385 40mg (N=138)				Leuprorelin (N=142)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 4								
Low	-	-	-	-	-	-	-	-
Normal	1	137	-	138	-	142	-	142
High	-	-	-	-	-	-	-	-
Total	1	137	-	138	-	142	-	142
Week 8								
Low	-	-	-	-	-	-	-	-
Normal	1	134	-	135	-	142	-	142
High	-	-	-	-	-	-	-	-
Total	1	134	-	135	-	142	-	142
Week 12								
Low	-	-	-	-	-	-	-	-
Normal	1	129	-	130	-	140	-	140
High	-	-	-	-	-	1	-	1
Total	1	129	-	130	-	141	-	141
Week 16								
Low	-	-	-	-	-	-	-	-
Normal	1	128	-	129	-	136	-	136
High	-	-	-	-	-	-	-	-
Total	1	128	-	129	-	136	-	136
Week 20								
Low	1	1	-	2	-	-	-	-
Normal	-	124	-	124	-	132	-	132
High	-	-	-	-	-	-	-	-
Total	1	125	-	126	-	132	-	132
Week 24								
Low	-	-	-	-	-	-	-	-
Normal	1	121	-	122	-	131	-	131
High	-	-	-	-	-	-	-	-
Total	1	121	-	122	-	131	-	131

治験総括報告書 Table 15.3.2.1.3.1（5.3.5.1-2）から引用

表 2.7.4.8-付録-37　血液生化学検査値のシフトテーブル（安全性データの解析対象集団）（CCT-002 試験）（続き）

Sodium (mEq/L)

	Baseline							
	TAK-385 40mg (N=138)				Leuprorelin (N=142)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Follow-up								
Low	-	2	-	2	-	-	-	-
Normal	1	132	-	133	-	141	-	141
High	-	-	-	-	-	-	-	-
Total	1	134	-	135	-	141	-	141

治験総括報告書 Table 15.3.2.1.3.1（5.3.5.1-2）から引用

表 2.7.4.8-付録-37　血液生化学検査値のシフトテーブル（安全性データの解析対象集団）（CCT-002 試験）（続き）

Potassium (mEq/L)

	Baseline							
	TAK-385 40mg (N=138)				Leuprorelin (N=142)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 4								
Low	-	-	-	-	-	-	-	-
Normal	1	135	-	136	1	138	-	139
High	-	1	-	1	-	1	-	1
Total	1	136	-	137	1	139	-	140
Week 8								
Low	-	-	-	-	-	1	-	1
Normal	1	134	-	135	1	138	-	139
High	-	-	-	-	-	1	-	1
Total	1	134	-	135	1	140	-	141
Week 12								
Low	-	-	-	-	-	2	-	2
Normal	1	128	-	129	1	136	-	137
High	-	-	-	-	-	-	-	-
Total	1	128	-	129	1	138	-	139
Week 16								
Low	1	-	-	1	-	-	-	-
Normal	-	127	-	127	1	131	-	132
High	-	1	-	1	-	2	-	2
Total	1	128	-	129	1	133	-	134
Week 20								
Low	-	-	-	-	-	-	-	-
Normal	1	120	-	121	1	129	-	130
High	-	3	-	3	-	-	-	-
Total	1	123	-	124	1	129	-	130
Week 24								
Low	-	-	-	-	-	1	-	1
Normal	1	120	-	121	1	127	-	128
High	-	1	-	1	-	-	-	-
Total	1	121	-	122	1	128	-	129

治験総括報告書 Table 15.3.2.1.3.1（5.3.5.1-2）から引用

表 2.7.4.8-付録-37　血液生化学検査値のシフトテーブル（安全性データの解析対象集団）（CCT-002 試験）（続き）

Potassium (mEq/L)

	Baseline							
	TAK-385 40mg (N=138)				Leuprorelin (N=142)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Follow-up								
Low	-	1	-	1	-	-	-	-
Normal	1	131	-	132	1	140	-	141
High	-	-	-	-	-	-	-	-
Total	1	132	-	133	1	140	-	141

治験総括報告書 Table 15.3.2.1.3.1（5.3.5.1-2）から引用

表 2.7.4.8-付録-37　血液生化学検査値のシフトテーブル（安全性データの解析対象集団）（CCT-002 試験）（続き）

Chloride (mEq/L)

	Baseline							
	TAK-385 40mg (N=138)				Leuprorelin (N=142)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 4								
Low	-	-	-	-	-	-	-	-
Normal	-	137	-	137	-	142	-	142
High	-	1	-	1	-	-	-	-
Total	-	138	-	138	-	142	-	142
Week 8								
Low	-	-	-	-	-	-	-	-
Normal	-	135	-	135	-	142	-	142
High	-	-	-	-	-	-	-	-
Total	-	135	-	135	-	142	-	142
Week 12								
Low	-	-	-	-	-	-	-	-
Normal	-	130	-	130	-	140	-	140
High	-	-	-	-	-	1	-	1
Total	-	130	-	130	-	141	-	141
Week 16								
Low	-	-	-	-	-	-	-	-
Normal	-	129	-	129	-	136	-	136
High	-	-	-	-	-	-	-	-
Total	-	129	-	129	-	136	-	136
Week 20								
Low	-	1	-	1	-	-	-	-
Normal	-	125	-	125	-	132	-	132
High	-	-	-	-	-	-	-	-
Total	-	126	-	126	-	132	-	132
Week 24								
Low	-	-	-	-	-	-	-	-
Normal	-	122	-	122	-	130	-	130
High	-	-	-	-	-	1	-	1
Total	-	122	-	122	-	131	-	131

治験総括報告書 Table 15.3.2.1.3.1（5.3.5.1-2）から引用

表 2.7.4.8-付録-37　血液生化学検査値のシフトテーブル（安全性データの解析対象集団）（CCT-002 試験）（続き）

Chloride (mEq/L)

	Baseline							
	TAK-385 40mg (N=138)				Leuprorelin (N=142)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Follow-up								
Low	-	1	-	1	-	1	-	1
Normal	-	134	-	134	-	140	-	140
High	-	-	-	-	-	-	-	-
Total	-	135	-	135	-	141	-	141

治験総括報告書 Table 15.3.2.1.3.1（5.3.5.1-2）から引用

表 2.7.4.8-付録-37　血液生化学検査値のシフトテーブル（安全性データの解析対象集団）（CCT-002 試験）（続き）

Calcium (mg/dL)

	Baseline							
	TAK-385 40mg (N=138)				Leuprorelin (N=142)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 4								
Low	-	-	-	-	-	-	-	-
Normal	9	129	-	138	3	139	-	142
High	-	-	-	-	-	-	-	-
Total	9	129	-	138	3	139	-	142
Week 8								
Low	-	-	-	-	-	-	-	-
Normal	8	127	-	135	3	139	-	142
High	-	-	-	-	-	-	-	-
Total	8	127	-	135	3	139	-	142
Week 12								
Low	-	-	-	-	-	-	-	-
Normal	8	122	-	130	3	138	-	141
High	-	-	-	-	-	-	-	-
Total	8	122	-	130	3	138	-	141
Week 16								
Low	-	-	-	-	-	-	-	-
Normal	8	121	-	129	2	134	-	136
High	-	-	-	-	-	-	-	-
Total	8	121	-	129	2	134	-	136
Week 20								
Low	-	-	-	-	-	-	-	-
Normal	8	118	-	126	2	130	-	132
High	-	-	-	-	-	-	-	-
Total	8	118	-	126	2	130	-	132
Week 24								
Low	-	-	-	-	-	-	-	-
Normal	8	113	-	121	2	129	-	131
High	-	1	-	1	-	-	-	-
Total	8	114	-	122	2	129	-	131

治験総括報告書 Table 15.3.2.1.3.1（5.3.5.1-2）から引用

表 2.7.4.8-付録-37　血液生化学検査値のシフトテーブル（安全性データの解析対象集団）（CCT-002 試験）（続き）

Calcium (mg/dL)

	Baseline							
	TAK-385 40mg (N=138)				Leuprorelin (N=142)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Follow-up								
Low	-	4	-	4	-	-	-	-
Normal	9	122	-	131	3	138	-	141
High	-	-	-	-	-	-	-	-
Total	9	126	-	135	3	138	-	141

治験総括報告書 Table 15.3.2.1.3.1（5.3.5.1-2）から引用

表 2.7.4.8-付録-37　血液生化学検査値のシフトテーブル（安全性データの解析対象集団）（CCT-002 試験）（続き）

Phosphate (mg/dL)

	Baseline							
	TAK-385 40mg (N=138)				Leuprorelin (N=142)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 4								
Low	-	-	-	-	1	1	-	2
Normal	1	132	1	134	5	130	-	135
High	-	4	-	4	-	5	-	5
Total	1	136	1	138	6	136	-	142
Week 8								
Low	-	-	-	-	1	-	-	1
Normal	1	122	1	124	5	133	-	138
High	-	11	-	11	-	3	-	3
Total	1	133	1	135	6	136	-	142
Week 12								
Low	-	-	-	-	-	-	-	-
Normal	1	114	-	115	6	123	-	129
High	-	14	1	15	-	12	-	12
Total	1	128	1	130	6	135	-	141
Week 16								
Low	-	-	-	-	1	-	-	1
Normal	1	116	1	118	5	116	-	121
High	-	11	-	11	-	14	-	14
Total	1	127	1	129	6	130	-	136
Week 20								
Low	-	-	-	-	1	-	-	1
Normal	1	114	1	116	5	112	-	117
High	-	10	-	10	-	14	-	14
Total	1	124	1	126	6	126	-	132
Week 24								
Low	-	-	-	-	-	-	-	-
Normal	1	103	1	105	6	109	-	115
High	-	17	-	17	-	16	-	16
Total	1	120	1	122	6	125	-	131

治験総括報告書 Table 15.3.2.1.3.1（5.3.5.1-2）から引用

表 2.7.4.8-付録-37　血液生化学検査値のシフトテーブル（安全性データの解析対象集団）（CCT-002 試験）（続き）

Phosphate (mg/dL)

	Baseline							
	TAK-385 40mg (N=138)				Leuprorelin (N=142)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Follow-up								
Low	-	-	-	-	-	1	-	1
Normal	1	130	1	132	6	122	-	128
High	-	3	-	3	-	12	-	12
Total	1	133	1	135	6	135	-	141

治験総括報告書 Table 15.3.2.1.3.1（5.3.5.1-2）から引用

表 2.7.4.8-付録-37　血液生化学検査値のシフトテーブル（安全性データの解析対象集団）（CCT-002 試験）（続き）

Magnesium (mg/dL)

	Baseline							
	TAK-385 40mg (N=138)				Leuprorelin (N=142)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 4								
Low	-	2	-	2	2	3	-	5
Normal	1	134	-	135	2	135	-	137
High	-	1	-	1	-	-	-	-
Total	1	137	-	138	4	138	-	142
Week 8								
Low	-	-	-	-	-	-	-	-
Normal	1	134	-	135	4	138	-	142
High	-	-	-	-	-	-	-	-
Total	1	134	-	135	4	138	-	142
Week 12								
Low	-	-	-	-	-	-	-	-
Normal	1	127	-	128	4	137	-	141
High	-	2	-	2	-	-	-	-
Total	1	129	-	130	4	137	-	141
Week 16								
Low	1	1	-	2	-	1	-	1
Normal	-	127	-	127	4	131	-	135
High	-	-	-	-	-	-	-	-
Total	1	128	-	129	4	132	-	136
Week 20								
Low	-	1	-	1	-	1	-	1
Normal	1	124	-	125	4	127	-	131
High	-	-	-	-	-	-	-	-
Total	1	125	-	126	4	128	-	132
Week 24								
Low	-	2	-	2	1	3	-	4
Normal	1	119	-	120	3	124	-	127
High	-	-	-	-	-	-	-	-
Total	1	121	-	122	4	127	-	131

治験総括報告書 Table 15.3.2.1.3.1（5.3.5.1-2）から引用

表 2.7.4.8-付録-37　血液生化学検査値のシフトテーブル（安全性データの解析対象集団）（CCT-002 試験）（続き）

Magnesium (mg/dL)

	Baseline							
	TAK-385 40mg (N=138)				Leuprorelin (N=142)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Follow-up								
Low	-	5	-	5	1	2	-	3
Normal	1	129	-	130	3	135	-	138
High	-	-	-	-	-	-	-	-
Total	1	134	-	135	4	137	-	141

治験総括報告書 Table 15.3.2.1.3.1（5.3.5.1-2）から引用

表 2.7.4.8-付録-37　血液生化学検査値のシフトテーブル（安全性データの解析対象集団）（CCT-002 試験）（続き）

Bile acid (total bile acid [TBA]) (umol/L)

	Baseline							
	TAK-385 40mg (N=138)				Leuprorelin (N=142)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 2								
Low	-	-	-	-	-	-	-	-
Normal	-	128	1	129	-	133	3	136
High	-	5	3	8	-	5	1	6
Total	-	133	4	137	-	138	4	142
Week 4								
Low	-	-	-	-	-	-	-	-
Normal	-	127	3	130	-	133	3	136
High	-	6	1	7	-	5	1	6
Total	-	133	4	137	-	138	4	142
Week 8								
Low	-	-	-	-	-	-	-	-
Normal	-	127	2	129	-	132	2	134
High	-	4	2	6	-	6	2	8
Total	-	131	4	135	-	138	4	142
Week 12								
Low	-	-	-	-	-	-	-	-
Normal	-	127	3	130	-	134	2	136
High	-	-	-	-	-	3	2	5
Total	-	127	3	130	-	137	4	141
Week 16								
Low	-	-	-	-	-	-	-	-
Normal	-	123	2	125	-	131	3	134
High	-	3	1	4	-	1	1	2
Total	-	126	3	129	-	132	4	136
Week 20								
Low	-	-	-	-	-	-	-	-
Normal	-	121	2	123	-	125	3	128
High	-	2	1	3	-	3	1	4
Total	-	123	3	126	-	128	4	132

治験総括報告書 Table 15.3.2.1.3.2（5.3.5.1-2）から引用

表 2.7.4.8-付録-37　血液生化学検査値のシフトテーブル（安全性データの解析対象集団）（CCT-002 試験）（続き）

Bile acid (total bile acid [TBA]) (umol/L)

	Baseline							
	TAK-385 40mg (N=138)				Leuprorelin (N=142)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 24								
Low	-	-	-	-	-	-	-	-
Normal	-	118	-	118	-	122	3	125
High	-	1	3	4	-	5	1	6
Total	-	119	3	122	-	127	4	131
Follow-up								
Low	-	-	-	-	-	-	-	-
Normal	-	128	3	131	-	129	3	132
High	-	3	1	4	-	8	1	9
Total	-	131	4	135	-	137	4	141

治験総括報告書 Table 15.3.2.1.3.2（5.3.5.1-2）から引用

表 2.7.4.8-付録-37　血液生化学検査値のシフトテーブル（安全性データの解析対象集団）（CCT-002 試験）（続き）

Glutamate dehydrogenase (GLDH) (U/L)

	Baseline							
	TAK-385 40mg (N=138)				Leuprorelin (N=142)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 2								
Low	-	-	-	-	-	-	-	-
Normal	-	137	-	137	-	142	-	142
High	-	-	-	-	-	-	-	-
Total	-	137	-	137	-	142	-	142
Week 4								
Low	-	-	-	-	-	-	-	-
Normal	-	137	-	137	-	142	-	142
High	-	-	-	-	-	-	-	-
Total	-	137	-	137	-	142	-	142
Week 8								
Low	-	-	-	-	-	-	-	-
Normal	-	135	-	135	-	142	-	142
High	-	-	-	-	-	-	-	-
Total	-	135	-	135	-	142	-	142
Week 12								
Low	-	-	-	-	-	-	-	-
Normal	-	130	-	130	-	141	-	141
High	-	-	-	-	-	-	-	-
Total	-	130	-	130	-	141	-	141
Week 16								
Low	-	-	-	-	-	-	-	-
Normal	-	129	-	129	-	136	-	136
High	-	-	-	-	-	-	-	-
Total	-	129	-	129	-	136	-	136
Week 20								
Low	-	-	-	-	-	-	-	-
Normal	-	126	-	126	-	132	-	132
High	-	-	-	-	-	-	-	-
Total	-	126	-	126	-	132	-	132

治験総括報告書 Table 15.3.2.1.3.2（5.3.5.1-2）から引用

表 2.7.4.8-付録-37　血液生化学検査値のシフトテーブル（安全性データの解析対象集団）（CCT-002 試験）（続き）

Glutamate dehydrogenase (GLDH) (U/L)

	Baseline							
	TAK-385 40mg (N=138)				Leuprorelin (N=142)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 24								
Low	-	-	-	-	-	-	-	-
Normal	-	122	-	122	-	131	-	131
High	-	-	-	-	-	-	-	-
Total	-	122	-	122	-	131	-	131
Follow-up								
Low	-	-	-	-	-	-	-	-
Normal	-	135	-	135	-	141	-	141
High	-	-	-	-	-	-	-	-
Total	-	135	-	135	-	141	-	141

治験総括報告書 Table 15.3.2.1.3.2（5.3.5.1-2）から引用

表 2.7.4.8-付録-38　血液生化学検査値のシフトテーブル（安全性データの解析対象集団）（3008 試験）

ALT (U/L)

	Baseline							
	TAK-385 40mg (N=33)				Placebo (N=32)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 4								
Low	-	-	-	-	-	-	-	-
Normal	-	32	-	32	-	32	-	32
High	-	1	-	1	-	-	-	-
Total	-	33	-	33	-	32	-	32
Week 8								
Low	-	-	-	-	-	-	-	-
Normal	-	30	-	30	-	31	-	31
High	-	2	-	2	-	-	-	-
Total	-	32	-	32	-	31	-	31
Week 12								
Low	-	-	-	-	-	-	-	-
Normal	-	30	-	30	-	30	-	30
High	-	2	-	2	-	1	-	1
Total	-	32	-	32	-	31	-	31
Follow-up								
Low	-	-	-	-	-	-	-	-
Normal	-	31	-	31	-	32	-	32
High	-	2	-	2	-	-	-	-
Total	-	33	-	33	-	32	-	32

治験総括報告書 Table 15.3.2.1.3（5.3.5.1-3）から引用

表 2.7.4.8-付録-38　血液生化学検査値のシフトテーブル（安全性データの解析対象集団）（3008 試験）（続き）

AST (U/L)

	Baseline							
	TAK-385 40mg (N=33)				Placebo (N=32)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 4								
Low	-	-	-	-	-	-	-	-
Normal	-	32	-	32	-	32	-	32
High	-	1	-	1	-	-	-	-
Total	-	33	-	33	-	32	-	32
Week 8								
Low	-	-	-	-	-	-	-	-
Normal	-	30	-	30	-	31	-	31
High	-	2	-	2	-	-	-	-
Total	-	32	-	32	-	31	-	31
Week 12								
Low	-	-	-	-	-	-	-	-
Normal	-	28	-	28	-	29	-	29
High	-	2	-	2	-	2	-	2
Total	-	30	-	30	-	31	-	31
Follow-up								
Low	-	-	-	-	-	-	-	-
Normal	-	31	-	31	-	31	-	31
High	-	1	-	1	-	-	-	-
Total	-	32	-	32	-	31	-	31

治験総括報告書 Table 15.3.2.1.3（5.3.5.1-3）から引用

表 2.7.4.8-付録-38　血液生化学検査値のシフトテーブル（安全性データの解析対象集団）（3008 試験）（続き）

Lactate dehydrogenase (LDH) (U/L)

	Baseline							
	TAK-385 40mg (N=33)				Placebo (N=32)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 4								
Low	1	-	-	1	-	1	-	1
Normal	-	32	-	32	1	30	-	31
High	-	-	-	-	-	-	-	-
Total	1	32	-	33	1	31	-	32
Week 8								
Low	1	-	-	1	-	-	-	-
Normal	-	31	-	31	1	30	-	31
High	-	-	-	-	-	-	-	-
Total	1	31	-	32	1	30	-	31
Week 12								
Low	1	-	-	1	-	1	-	1
Normal	-	29	-	29	1	29	-	30
High	-	-	-	-	-	-	-	-
Total	1	29	-	30	1	30	-	31
Follow-up								
Low	1	-	-	1	-	-	-	-
Normal	-	31	-	31	1	30	-	31
High	-	-	-	-	-	-	-	-
Total	1	31	-	32	1	30	-	31

治験総括報告書 Table 15.3.2.1.3（5.3.5.1-3）から引用

表 2.7.4.8-付録-38　血液生化学検査値のシフトテーブル（安全性データの解析対象集団）（3008 試験）（続き）

Gamma glutamyl transferase (GGT) (U/L)

	Baseline							
	TAK-385 40mg (N=33)				Placebo (N=32)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 4								
Low	-	-	-	-	-	-	-	-
Normal	-	28	1	29	-	26	-	26
High	-	2	2	4	-	2	4	6
Total	-	30	3	33	-	28	4	32
Week 8								
Low	-	-	-	-	-	-	-	-
Normal	-	26	1	27	-	26	-	26
High	-	3	2	5	-	1	4	5
Total	-	29	3	32	-	27	4	31
Week 12								
Low	-	-	-	-	-	-	-	-
Normal	-	27	-	27	-	25	-	25
High	-	2	3	5	-	2	4	6
Total	-	29	3	32	-	27	4	31
Follow-up								
Low	-	-	-	-	-	-	-	-
Normal	-	29	1	30	-	26	-	26
High	-	1	2	3	-	2	4	6
Total	-	30	3	33	-	28	4	32

治験総括報告書 Table 15.3.2.1.3（5.3.5.1-3）から引用

表 2.7.4.8-付録-38　血液生化学検査値のシフトテーブル（安全性データの解析対象集団）（3008 試験）（続き）

Albumin (g/dL)

	Baseline							
	TAK-385 40mg (N=33)				Placebo (N=32)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 4								
Low	-	-	-	-	-	-	-	-
Normal	-	33	-	33	-	32	-	32
High	-	-	-	-	-	-	-	-
Total	-	33	-	33	-	32	-	32
Week 8								
Low	-	-	-	-	-	-	-	-
Normal	-	32	-	32	-	31	-	31
High	-	-	-	-	-	-	-	-
Total	-	32	-	32	-	31	-	31
Week 12								
Low	-	-	-	-	-	-	-	-
Normal	-	32	-	32	-	31	-	31
High	-	-	-	-	-	-	-	-
Total	-	32	-	32	-	31	-	31
Follow-up								
Low	-	-	-	-	-	-	-	-
Normal	-	33	-	33	-	32	-	32
High	-	-	-	-	-	-	-	-
Total	-	33	-	33	-	32	-	32

治験総括報告書 Table 15.3.2.1.3（5.3.5.1-3）から引用

表 2.7.4.8-付録-38　血液生化学検査値のシフトテーブル（安全性データの解析対象集団）（3008 試験）（続き）

Alkaline phosphatase (ALP) (U/L)

	Baseline							
	TAK-385 40mg (N=33)				Placebo (N=32)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 4								
Low	-	-	-	-	-	1	-	1
Normal	1	32	-	33	-	31	-	31
High	-	-	-	-	-	-	-	-
Total	1	32	-	33	-	32	-	32
Week 8								
Low	-	-	-	-	-	-	-	-
Normal	1	31	-	32	-	31	-	31
High	-	-	-	-	-	-	-	-
Total	1	31	-	32	-	31	-	31
Week 12								
Low	-	-	-	-	-	-	-	-
Normal	1	30	-	31	-	30	-	30
High	-	1	-	1	-	1	-	1
Total	1	31	-	32	-	31	-	31
Follow-up								
Low	-	-	-	-	-	-	-	-
Normal	1	30	-	31	-	32	-	32
High	-	2	-	2	-	-	-	-
Total	1	32	-	33	-	32	-	32

治験総括報告書 Table 15.3.2.1.3（5.3.5.1-3）から引用

表 2.7.4.8-付録-38　血液生化学検査値のシフトテーブル（安全性データの解析対象集団）（3008 試験）（続き）

Bilirubin (Total bilirubin) (mg/dL)

	Baseline							
	TAK-385 40mg (N=33)				Placebo (N=32)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 4								
Low	-	-	-	-	-	-	-	-
Normal	-	32	-	32	-	32	-	32
High	-	-	1	1	-	-	-	-
Total	-	32	1	33	-	32	-	32
Week 8								
Low	-	-	-	-	-	-	-	-
Normal	-	31	-	31	-	31	-	31
High	-	-	1	1	-	-	-	-
Total	-	31	1	32	-	31	-	31
Week 12								
Low	-	-	-	-	-	-	-	-
Normal	-	31	-	31	-	31	-	31
High	-	-	1	1	-	-	-	-
Total	-	31	1	32	-	31	-	31
Follow-up								
Low	-	-	-	-	-	-	-	-
Normal	-	31	-	31	-	32	-	32
High	-	1	1	2	-	-	-	-
Total	-	32	1	33	-	32	-	32

治験総括報告書 Table 15.3.2.1.3（5.3.5.1-3）から引用

表 2.7.4.8-付録-38　血液生化学検査値のシフトテーブル（安全性データの解析対象集団）（3008 試験）（続き）

Protein (Total protein) (g/dL)

	Baseline							
	TAK-385 40mg (N=33)				Placebo (N=32)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 4								
Low	1	1	-	2	3	3	-	6
Normal	6	24	-	30	3	23	-	26
High	-	1	-	1	-	-	-	-
Total	7	26	-	33	6	26	-	32
Week 8								
Low	3	-	-	3	1	3	-	4
Normal	4	24	-	28	5	22	-	27
High	-	1	-	1	-	-	-	-
Total	7	25	-	32	6	25	-	31
Week 12								
Low	3	-	-	3	2	2	-	4
Normal	4	25	-	29	4	23	-	27
High	-	-	-	-	-	-	-	-
Total	7	25	-	32	6	25	-	31
Follow-up								
Low	3	1	-	4	3	2	-	5
Normal	4	25	-	29	3	24	-	27
High	-	-	-	-	-	-	-	-
Total	7	26	-	33	6	26	-	32

治験総括報告書 Table 15.3.2.1.3（5.3.5.1-3）から引用

表 2.7.4.8-付録-38　血液生化学検査値のシフトテーブル（安全性データの解析対象集団）（3008 試験）（続き）

Cholesterol (Total cholesterol) (mg/dL)

	Baseline							
	TAK-385 40mg (N=33)				Placebo (N=32)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 4								
Low	-	-	-	-	-	-	-	-
Normal	-	15	-	15	-	26	3	29
High	-	10	8	18	-	1	2	3
Total	-	25	8	33	-	27	5	32
Week 8								
Low	-	-	-	-	-	-	-	-
Normal	-	14	1	15	-	25	-	25
High	-	10	7	17	-	1	5	6
Total	-	24	8	32	-	26	5	31
Week 12								
Low	-	-	-	-	-	1	-	1
Normal	-	16	1	17	-	21	-	21
High	-	8	7	15	-	4	5	9
Total	-	24	8	32	-	26	5	31
Follow-up								
Low	-	-	-	-	-	-	-	-
Normal	-	21	1	22	-	24	2	26
High	-	4	7	11	-	3	3	6
Total	-	25	8	33	-	27	5	32

治験総括報告書 Table 15.3.2.1.3（5.3.5.1-3）から引用

表 2.7.4.8-付録-38　血液生化学検査値のシフトテーブル（安全性データの解析対象集団）（3008 試験）（続き）

High density lipoprotein (HDL) cholesterol (mg/dL)

	Baseline							
	TAK-385 40mg (N=33)				Placebo (N=32)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 4								
Low	-	1	-	1	1	2	-	3
Normal	-	30	-	30	-	28	-	28
High	-	-	2	2	-	-	1	1
Total	-	31	2	33	1	30	1	32
Week 8								
Low	-	-	-	-	-	-	-	-
Normal	-	29	-	29	1	29	-	30
High	-	1	2	3	-	-	1	1
Total	-	30	2	32	1	29	1	31
Week 12								
Low	-	-	-	-	-	1	-	1
Normal	-	29	-	29	1	27	-	28
High	-	1	2	3	-	1	1	2
Total	-	30	2	32	1	29	1	31
Follow-up								
Low	-	1	-	1	1	1	-	2
Normal	-	30	-	30	-	28	1	29
High	-	-	2	2	-	1	-	1
Total	-	31	2	33	1	30	1	32

治験総括報告書 Table 15.3.2.1.3（5.3.5.1-3）から引用

表 2.7.4.8-付録-38　血液生化学検査値のシフトテーブル（安全性データの解析対象集団）（3008 試験）（続き）

Low density lipoprotein (LDL) cholesterol (mg/dL)

	Baseline							
	TAK-385 40mg (N=33)				Placebo (N=32)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 4								
Low	-	-	-	-	2	-	-	2
Normal	-	16	-	16	-	23	2	25
High	-	10	7	17	-	-	5	5
Total	-	26	7	33	2	23	7	32
Week 8								
Low	-	-	-	-	-	-	-	-
Normal	-	16	2	18	2	22	1	25
High	-	9	5	14	-	-	6	6
Total	-	25	7	32	2	22	7	31
Week 12								
Low	-	-	-	-	-	1	-	1
Normal	-	18	2	20	2	20	1	23
High	-	7	5	12	-	1	6	7
Total	-	25	7	32	2	22	7	31
Follow-up								
Low	-	1	-	1	1	1	-	2
Normal	-	19	1	20	1	21	2	24
High	-	6	6	12	-	1	5	6
Total	-	26	7	33	2	23	7	32

治験総括報告書 Table 15.3.2.1.3（5.3.5.1-3）から引用

表 2.7.4.8-付録-38　血液生化学検査値のシフトテーブル（安全性データの解析対象集団）（3008 試験）（続き）

Triglycerides (mg/dL)

	Baseline							
	TAK-385 40mg (N=33)				Placebo (N=32)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 4								
Low	-	-	-	-	-	-	-	-
Normal	-	23	2	25	2	24	4	30
High	-	3	5	8	-	-	2	2
Total	-	26	7	33	2	24	6	32
Week 8								
Low	-	-	-	-	-	-	-	-
Normal	-	21	2	23	2	23	4	29
High	-	4	5	9	-	-	2	2
Total	-	25	7	32	2	23	6	31
Week 12								
Low	-	-	-	-	-	-	-	-
Normal	-	21	3	24	2	21	5	28
High	-	4	4	8	-	2	1	3
Total	-	25	7	32	2	23	6	31
Follow-up								
Low	-	-	-	-	-	-	-	-
Normal	-	25	4	29	2	21	4	27
High	-	1	3	4	-	3	2	5
Total	-	26	7	33	2	24	6	32

治験総括報告書 Table 15.3.2.1.3（5.3.5.1-3）から引用

表 2.7.4.8-付録-38　血液生化学検査値のシフトテーブル（安全性データの解析対象集団）（3008 試験）（続き）

Glucose (mg/dL)

	Baseline							
	TAK-385 40mg (N=33)				Placebo (N=32)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 4								
Low	-	-	-	-	-	-	-	-
Normal	-	28	1	29	-	27	3	30
High	-	3	1	4	-	1	1	2
Total	-	31	2	33	-	28	4	32
Week 8								
Low	-	-	-	-	-	-	-	-
Normal	-	28	-	28	-	25	3	28
High	-	2	2	4	-	2	1	3
Total	-	30	2	32	-	27	4	31
Week 12								
Low	-	-	-	-	-	1	-	1
Normal	-	26	1	27	-	24	4	28
High	-	4	1	5	-	2	-	2
Total	-	30	2	32	-	27	4	31
Follow-up								
Low	-	1	-	1	-	-	-	-
Normal	-	27	2	29	-	25	3	28
High	-	3	-	3	-	3	1	4
Total	-	31	2	33	-	28	4	32

治験総括報告書 Table 15.3.2.1.3（5.3.5.1-3）から引用

表 2.7.4.8-付録-38　血液生化学検査値のシフトテーブル（安全性データの解析対象集団）（3008 試験）（続き）

HGB A1C (%)

	Baseline							
	TAK-385 40mg (N=33)				Placebo (N=32)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 4								
Low	-	-	-	-	-	-	-	-
Normal	-	33	-	33	1	30	-	31
High	-	-	-	-	-	-	1	1
Total	-	33	-	33	1	30	1	32
Week 8								
Low	-	-	-	-	-	-	-	-
Normal	-	32	-	32	1	29	-	30
High	-	-	-	-	-	-	1	1
Total	-	32	-	32	1	29	1	31
Week 12								
Low	-	-	-	-	-	1	-	1
Normal	-	32	-	32	1	28	-	29
High	-	-	-	-	-	-	1	1
Total	-	32	-	32	1	29	1	31
Follow-up								
Low	-	-	-	-	-	1	-	1
Normal	-	33	-	33	1	29	-	30
High	-	-	-	-	-	-	1	1
Total	-	33	-	33	1	30	1	32

治験総括報告書 Table 15.3.2.1.3（5.3.5.1-3）から引用

表 2.7.4.8-付録-38　血液生化学検査値のシフトテーブル（安全性データの解析対象集団）（3008 試験）（続き）

Creatinine (mg/dL)

	Baseline							
	TAK-385 40mg (N=33)				Placebo (N=32)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 4								
Low	-	-	-	-	-	1	-	1
Normal	-	29	1	30	1	29	1	31
High	-	2	1	3	-	-	-	-
Total	-	31	2	33	1	30	1	32
Week 8								
Low	-	1	-	1	1	1	-	2
Normal	-	29	1	30	-	27	1	28
High	-	-	1	1	-	1	-	1
Total	-	30	2	32	1	29	1	31
Week 12								
Low	-	-	-	-	1	1	-	2
Normal	-	29	1	30	-	28	1	29
High	-	-	1	1	-	-	-	-
Total	-	29	2	31	1	29	1	31
Follow-up								
Low	-	1	-	1	1	3	-	4
Normal	-	29	2	31	-	27	1	28
High	-	1	-	1	-	-	-	-
Total	-	31	2	33	1	30	1	32

治験総括報告書 Table 15.3.2.1.3（5.3.5.1-3）から引用

表 2.7.4.8-付録-38　血液生化学検査値のシフトテーブル（安全性データの解析対象集団）（3008 試験）（続き）

Blood urea nitrogen (BUN) (mg/dL)

	Baseline							
	TAK-385 40mg (N=33)				Placebo (N=32)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 4								
Low	-	-	-	-	2	-	-	2
Normal	-	33	-	33	1	29	-	30
High	-	-	-	-	-	-	-	-
Total	-	33	-	33	3	29	-	32
Week 8								
Low	-	-	-	-	-	3	-	3
Normal	-	32	-	32	3	25	-	28
High	-	-	-	-	-	-	-	-
Total	-	32	-	32	3	28	-	31
Week 12								
Low	-	-	-	-	3	-	-	3
Normal	-	32	-	32	-	28	-	28
High	-	-	-	-	-	-	-	-
Total	-	32	-	32	3	28	-	31
Follow-up								
Low	-	1	-	1	2	-	-	2
Normal	-	32	-	32	1	29	-	30
High	-	-	-	-	-	-	-	-
Total	-	33	-	33	3	29	-	32

治験総括報告書 Table 15.3.2.1.3（5.3.5.1-3）から引用

表 2.7.4.8-付録-38　血液生化学検査値のシフトテーブル（安全性データの解析対象集団）（3008 試験）（続き）

Creatine kinase (U/L)

	Baseline							
	TAK-385 40mg (N=33)				Placebo (N=32)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 4								
Low	1	1	-	2	-	-	-	-
Normal	-	29	-	29	-	29	1	30
High	-	2	-	2	-	1	1	2
Total	1	32	-	33	-	30	2	32
Week 8								
Low	1	1	-	2	-	1	-	1
Normal	-	29	-	29	-	26	1	27
High	-	1	-	1	-	2	1	3
Total	1	31	-	32	-	29	2	31
Week 12								
Low	1	-	-	1	-	-	-	-
Normal	-	31	-	31	-	28	2	30
High	-	-	-	-	-	1	-	1
Total	1	31	-	32	-	29	2	31
Follow-up								
Low	1	-	-	1	-	1	-	1
Normal	-	32	-	32	-	27	2	29
High	-	-	-	-	-	2	-	2
Total	1	32	-	33	-	30	2	32

治験総括報告書 Table 15.3.2.1.3（5.3.5.1-3）から引用

表 2.7.4.8-付録-38　血液生化学検査値のシフトテーブル（安全性データの解析対象集団）（3008 試験）（続き）

Urate (mg/dL)

	Baseline							
	TAK-385 40mg (N=33)				Placebo (N=32)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 4								
Low	-	-	-	-	1	-	-	1
Normal	-	33	-	33	1	30	-	31
High	-	-	-	-	-	-	-	-
Total	-	33	-	33	2	30	-	32
Week 8								
Low	-	-	-	-	-	-	-	-
Normal	-	31	-	31	2	29	-	31
High	-	1	-	1	-	-	-	-
Total	-	32	-	32	2	29	-	31
Week 12								
Low	-	-	-	-	-	-	-	-
Normal	-	32	-	32	2	29	-	31
High	-	-	-	-	-	-	-	-
Total	-	32	-	32	2	29	-	31
Follow-up								
Low	-	-	-	-	1	-	-	1
Normal	-	33	-	33	1	30	-	31
High	-	-	-	-	-	-	-	-
Total	-	33	-	33	2	30	-	32

治験総括報告書 Table 15.3.2.1.3（5.3.5.1-3）から引用

表 2.7.4.8-付録-38　血液生化学検査値のシフトテーブル（安全性データの解析対象集団）（3008 試験）（続き）

Sodium (mEq/L)

	Baseline							
	TAK-385 40mg (N=33)				Placebo (N=32)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 4								
Low	-	-	-	-	-	1	-	1
Normal	-	33	-	33	-	31	-	31
High	-	-	-	-	-	-	-	-
Total	-	33	-	33	-	32	-	32
Week 8								
Low	-	-	-	-	-	-	-	-
Normal	-	32	-	32	-	31	-	31
High	-	-	-	-	-	-	-	-
Total	-	32	-	32	-	31	-	31
Week 12								
Low	-	-	-	-	-	-	-	-
Normal	-	32	-	32	-	31	-	31
High	-	-	-	-	-	-	-	-
Total	-	32	-	32	-	31	-	31
Follow-up								
Low	-	2	-	2	-	-	-	-
Normal	-	31	-	31	-	32	-	32
High	-	-	-	-	-	-	-	-
Total	-	33	-	33	-	32	-	32

治験総括報告書 Table 15.3.2.1.3（5.3.5.1-3）から引用

表 2.7.4.8-付録-38　血液生化学検査値のシフトテーブル（安全性データの解析対象集団）（3008 試験）（続き）

Potassium (mEq/L)

	Baseline							
	TAK-385 40mg (N=33)				Placebo (N=32)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 4								
Low	-	-	-	-	-	-	-	-
Normal	-	33	-	33	-	32	-	32
High	-	-	-	-	-	-	-	-
Total	-	33	-	33	-	32	-	32
Week 8								
Low	-	-	-	-	-	-	-	-
Normal	-	32	-	32	-	31	-	31
High	-	-	-	-	-	-	-	-
Total	-	32	-	32	-	31	-	31
Week 12								
Low	-	-	-	-	-	1	-	1
Normal	-	30	-	30	-	30	-	30
High	-	-	-	-	-	-	-	-
Total	-	30	-	30	-	31	-	31
Follow-up								
Low	-	-	-	-	-	-	-	-
Normal	-	32	-	32	-	31	-	31
High	-	-	-	-	-	-	-	-
Total	-	32	-	32	-	31	-	31

治験総括報告書 Table 15.3.2.1.3（5.3.5.1-3）から引用

表 2.7.4.8-付録-38　血液生化学検査値のシフトテーブル（安全性データの解析対象集団）（3008 試験）（続き）

Chloride (mEq/L)

	Baseline							
	TAK-385 40mg (N=33)				Placebo (N=32)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 4								
Low	-	-	-	-	-	-	-	-
Normal	-	32	1	33	-	32	-	32
High	-	-	-	-	-	-	-	-
Total	-	32	1	33	-	32	-	32
Week 8								
Low	-	-	-	-	-	-	-	-
Normal	-	31	1	32	-	31	-	31
High	-	-	-	-	-	-	-	-
Total	-	31	1	32	-	31	-	31
Week 12								
Low	-	-	-	-	-	-	-	-
Normal	-	31	1	32	-	31	-	31
High	-	-	-	-	-	-	-	-
Total	-	31	1	32	-	31	-	31
Follow-up								
Low	-	-	-	-	-	-	-	-
Normal	-	32	1	33	-	32	-	32
High	-	-	-	-	-	-	-	-
Total	-	32	1	33	-	32	-	32

治験総括報告書 Table 15.3.2.1.3（5.3.5.1-3）から引用

表 2.7.4.8-付録-38　血液生化学検査値のシフトテーブル（安全性データの解析対象集団）（3008 試験）（続き）

Calcium (mg/dL)

	Baseline							
	TAK-385 40mg (N=33)				Placebo (N=32)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 4								
Low	-	1	-	1	-	-	-	-
Normal	1	31	-	32	1	31	-	32
High	-	-	-	-	-	-	-	-
Total	1	32	-	33	1	31	-	32
Week 8								
Low	-	-	-	-	-	-	-	-
Normal	1	31	-	32	1	30	-	31
High	-	-	-	-	-	-	-	-
Total	1	31	-	32	1	30	-	31
Week 12								
Low	-	-	-	-	-	2	-	2
Normal	1	31	-	32	1	28	-	29
High	-	-	-	-	-	-	-	-
Total	1	31	-	32	1	30	-	31
Follow-up								
Low	-	-	-	-	-	1	-	1
Normal	1	32	-	33	1	30	-	31
High	-	-	-	-	-	-	-	-
Total	1	32	-	33	1	31	-	32

治験総括報告書 Table 15.3.2.1.3（5.3.5.1-3）から引用

表 2.7.4.8-付録-38　血液生化学検査値のシフトテーブル（安全性データの解析対象集団）（3008 試験）（続き）

Phosphate (mg/dL)

	Baseline							
	TAK-385 40mg (N=33)				Placebo (N=32)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 4								
Low	-	-	-	-	-	-	-	-
Normal	1	29	2	32	-	32	-	32
High	-	1	-	1	-	-	-	-
Total	1	30	2	33	-	32	-	32
Week 8								
Low	-	-	-	-	-	1	-	1
Normal	1	30	1	32	-	30	-	30
High	-	-	-	-	-	-	-	-
Total	1	30	1	32	-	31	-	31
Week 12								
Low	-	-	-	-	-	-	-	-
Normal	1	27	-	28	-	31	-	31
High	-	3	1	4	-	-	-	-
Total	1	30	1	32	-	31	-	31
Follow-up								
Low	-	1	-	1	-	1	-	1
Normal	1	28	1	30	-	31	-	31
High	-	1	1	2	-	-	-	-
Total	1	30	2	33	-	32	-	32

治験総括報告書 Table 15.3.2.1.3（5.3.5.1-3）から引用

表 2.7.4.8-付録-38　血液生化学検査値のシフトテーブル（安全性データの解析対象集団）（3008 試験）（続き）

Magnesium (mg/dL)

	Baseline							
	TAK-385 40mg (N=33)				Placebo (N=32)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 4								
Low	-	1	-	1	-	-	-	-
Normal	-	31	1	32	1	31	-	32
High	-	-	-	-	-	-	-	-
Total	-	32	1	33	1	31	-	32
Week 8								
Low	-	-	-	-	-	-	-	-
Normal	-	31	-	31	1	30	-	31
High	-	-	1	1	-	-	-	-
Total	-	31	1	32	1	30	-	31
Week 12								
Low	-	-	-	-	1	-	-	1
Normal	-	31	1	32	-	30	-	30
High	-	-	-	-	-	-	-	-
Total	-	31	1	32	1	30	-	31
Follow-up								
Low	-	-	-	-	-	-	-	-
Normal	-	32	1	33	1	31	-	32
High	-	-	-	-	-	-	-	-
Total	-	32	1	33	1	31	-	32

治験総括報告書 Table 15.3.2.1.3（5.3.5.1-3）から引用

表 2.7.4.8-付録-39　血液生化学検査値のシフトテーブル（安全性データの解析対象集団）（CCT-101 試験）

ALT (GPT)

	Baseline																			
	Placebo (N=97)				TAK-385 10mg (N=103)				TAK-385 20mg (N=100)				TAK-385 40mg (N=103)				Leuprorelin (N=80)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 4																				
Low	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	97	-	97	-	101	-	101	-	98	-	98	-	102	-	102	-	78	1	79
High	-	-	-	-	-	2	-	2	-	2	-	2	-	1	-	1	-	1	-	1
Total	-	97	-	97	-	103	-	103	-	100	-	100	-	103	-	103	-	79	1	80
Week 8																				
Low	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	95	-	95	-	103	-	103	-	95	-	95	-	98	-	98	-	75	-	75
High	-	-	-	-	-	-	-	-	-	1	-	1	-	3	-	3	-	2	1	3
Total	-	95	-	95	-	103	-	103	-	96	-	96	-	101	-	101	-	77	1	78
Week 12																				
Low	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	92	-	92	-	100	-	100	-	90	-	90	-	99	-	99	-	71	-	71
High	-	1	-	1	-	1	-	1	-	2	-	2	-	2	-	2	-	3	1	4
Total	-	93	-	93	-	101	-	101	-	92	-	92	-	101	-	101	-	74	1	75
Follow-up																				
Low	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	18	-	18	-	19	-	19	-	22	-	22	-	13	-	13	-	10	-	10
High	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	-	18	-	18	-	19	-	19	-	22	-	22	-	13	-	13	-	10	-	10

治験総括報告書 Table 3.3.1.1.3（Section 15.1）（5.3.5.4-1）から引用

表 2.7.4.8-付録-39　血液生化学検査値のシフトテーブル（安全性データの解析対象集団）（CCT-101 試験）（続き）

AST (GOT)

	Baseline																			
	Placebo (N=97)				TAK-385 10mg (N=103)				TAK-385 20mg (N=100)				TAK-385 40mg (N=103)				Leuprorelin (N=80)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 4																				
Low	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Normal	1	96	-	97	-	103	-	103	-	100	-	100	-	102	-	102	-	80	-	80
High	-	-	-	-	-	-	-	-	-	-	-	-	-	1	-	1	-	-	-	-
Total	1	96	-	97	-	103	-	103	-	100	-	100	-	103	-	103	-	80	-	80
Week 8																				
Low	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Normal	1	94	-	95	-	103	-	103	-	95	-	95	-	100	-	100	-	77	-	77
High	-	-	-	-	-	-	-	-	-	1	-	1	-	1	-	1	-	1	-	1
Total	1	94	-	95	-	103	-	103	-	96	-	96	-	101	-	101	-	78	-	78
Week 12																				
Low	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Normal	1	91	-	92	-	100	-	100	-	91	-	91	-	100	-	100	-	74	-	74
High	-	1	-	1	-	-	-	-	-	1	-	1	-	1	-	1	-	1	-	1
Total	1	92	-	93	-	100	-	100	-	92	-	92	-	101	-	101	-	75	-	75
Follow-up																				
Low	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	18	-	18	-	19	-	19	-	22	-	22	-	13	-	13	-	10	-	10
High	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	-	18	-	18	-	19	-	19	-	22	-	22	-	13	-	13	-	10	-	10

治験総括報告書 Table 3.3.1.1.3（Section 15.1）（5.3.5.4-1）から引用

表 2.7.4.8-付録-39　血液生化学検査値のシフトテーブル（安全性データの解析対象集団）（CCT-101 試験）（続き）

LDH

	Baseline																			
	Placebo (N=97)				TAK-385 10mg (N=103)				TAK-385 20mg (N=100)				TAK-385 40mg (N=103)				Leuprorelin (N=80)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 4																				
Low	2	2	-	4	1	4	-	5	1	2	-	3	1	2	-	3	1	1	-	2
Normal	-	91	2	93	2	95	-	97	3	93	1	97	3	95	-	98	4	73	1	78
High	-	-	-	-	-	1	-	1	-	-	-	-	-	1	1	2	-	-	-	-
Total	2	93	2	97	3	100	-	103	4	95	1	100	4	98	1	103	5	74	1	80
Week 8																				
Low	-	2	-	2	1	3	-	4	1	1	-	2	2	2	-	4	1	-	-	1
Normal	2	89	1	92	2	97	-	99	3	88	-	91	2	93	-	95	4	72	1	77
High	-	-	1	1	-	-	-	-	-	2	1	3	-	1	1	2	-	-	-	-
Total	2	91	2	95	3	100	-	103	4	91	1	96	4	96	1	101	5	72	1	78
Week 12																				
Low	-	-	-	-	-	4	-	4	1	-	-	1	1	-	-	1	1	-	-	1
Normal	2	88	1	91	2	94	-	96	3	87	1	91	3	95	-	98	4	69	1	74
High	-	1	1	2	-	-	-	-	-	-	-	-	-	1	1	2	-	-	-	-
Total	2	89	2	93	2	98	-	100	4	87	1	92	4	96	1	101	5	69	1	75
Follow-up																				
Low	1	2	-	3	-	1	-	1	-	-	-	-	1	-	-	1	-	1	-	1
Normal	-	13	1	14	2	16	-	18	1	21	-	22	-	12	-	12	-	9	-	9
High	-	-	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	1	15	2	18	2	17	-	19	1	21	-	22	1	12	-	13	-	10	-	10

治験総括報告書 Table 3.3.1.1.3（Section 15.1）（5.3.5.4-1）から引用

表 2.7.4.8-付録-39　血液生化学検査値のシフトテーブル（安全性データの解析対象集団）（CCT-101 試験）（続き）

GGT

	Baseline																			
	Placebo (N=97)				TAK-385 10mg (N=103)				TAK-385 20mg (N=100)				TAK-385 40mg (N=103)				Leuprorelin (N=80)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 4																				
Low	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	89	1	90	-	95	1	96	-	92	-	92	-	95	2	97	-	68	1	69
High	-	3	4	7	-	2	5	7	-	3	5	8	-	2	4	6	-	3	8	11
Total	-	92	5	97	-	97	6	103	-	95	5	100	-	97	6	103	-	71	9	80
Week 8																				
Low	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	90	1	91	-	96	1	97	-	89	-	89	-	91	1	92	-	65	-	65
High	-	-	4	4	-	1	5	6	-	2	5	7	-	4	5	9	-	4	9	13
Total	-	90	5	95	-	97	6	103	-	91	5	96	-	95	6	101	-	69	9	78
Week 12																				
Low	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	87	1	88	-	92	1	93	-	84	1	85	-	91	1	92	-	60	-	60
High	-	1	4	5	-	3	5	8	-	4	3	7	-	4	5	9	-	7	8	15
Total	-	88	5	93	-	95	6	101	-	88	4	92	-	95	6	101	-	67	8	75
Follow-up																				
Low	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	17	-	17	-	18	-	18	-	20	-	20	-	12	-	12	-	9	-	9
High	-	1	-	1	-	-	1	1	-	1	1	2	-	-	1	1	-	-	1	1
Total	-	18	-	18	-	18	1	19	-	21	1	22	-	12	1	13	-	9	1	10

治験総括報告書 Table 3.3.1.1.3（Section 15.1）（5.3.5.4-1）から引用

表 2.7.4.8-付録-39　血液生化学検査値のシフトテーブル（安全性データの解析対象集団）（CCT-101 試験）（続き）

Albumin

	Baseline																			
	Placebo (N=97)				TAK-385 10mg (N=103)				TAK-385 20mg (N=100)				TAK-385 40mg (N=103)				Leuprorelin (N=80)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 4																				
Low	4	7	-	11	2	1	-	3	3	2	-	5	-	1	-	1	2	-	-	2
Normal	3	83	-	86	10	90	-	100	10	85	-	95	6	96	-	102	4	73	-	77
High	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	1	-	1
Total	7	90	-	97	12	91	-	103	13	87	-	100	6	97	-	103	6	74	-	80
Week 8																				
Low	2	4	-	6	1	3	-	4	2	1	-	3	1	-	-	1	1	-	-	1
Normal	5	84	-	89	11	88	-	99	10	83	-	93	4	95	-	99	5	72	-	77
High	-	-	-	-	-	-	-	-	-	-	-	-	-	1	-	1	-	-	-	-
Total	7	88	-	95	12	91	-	103	12	84	-	96	5	96	-	101	6	72	-	78
Week 12																				
Low	3	5	-	8	2	-	-	2	2	1	-	3	2	2	-	4	2	-	-	2
Normal	4	81	-	85	10	89	-	99	9	80	-	89	3	94	-	97	4	69	-	73
High	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	7	86	-	93	12	89	-	101	11	81	-	92	5	96	-	101	6	69	-	75
Follow-up																				
Low	-	1	-	1	-	1	-	1	2	1	-	3	1	1	-	2	-	-	-	-
Normal	-	17	-	17	1	17	-	18	3	16	-	19	1	10	-	11	1	9	-	10
High	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	-	18	-	18	1	18	-	19	5	17	-	22	2	11	-	13	1	9	-	10

治験総括報告書 Table 3.3.1.1.3（Section 15.1）（5.3.5.4-1）から引用

表 2.7.4.8-付録-39　血液生化学検査値のシフトテーブル（安全性データの解析対象集団）（CCT-101 試験）（続き）

Alkaline Phosphatase

	Baseline																			
	Placebo (N=97)				TAK-385 10mg (N=103)				TAK-385 20mg (N=100)				TAK-385 40mg (N=103)				Leuprorelin (N=80)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 4																				
Low	5	2	-	7	2	1	-	3	3	2	-	5	2	4	-	6	-	1	-	1
Normal	5	85	-	90	2	98	-	100	1	94	-	95	4	93	-	97	4	75	-	79
High	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	10	87	-	97	4	99	-	103	4	96	-	100	6	97	-	103	4	76	-	80
Week 8																				
Low	8	1	-	9	-	2	-	2	3	2	-	5	3	3	-	6	1	-	-	1
Normal	2	84	-	86	4	97	-	101	1	88	-	89	3	92	-	95	3	74	-	77
High	-	-	-	-	-	-	-	-	-	2	-	2	-	-	-	-	-	-	-	-
Total	10	85	-	95	4	99	-	103	4	92	-	96	6	95	-	101	4	74	-	78
Week 12																				
Low	7	3	-	10	2	1	-	3	2	1	-	3	2	2	-	4	-	-	-	-
Normal	3	80	-	83	2	95	-	97	2	87	-	89	4	92	-	96	3	72	-	75
High	-	-	-	-	-	-	-	-	-	-	-	-	-	1	-	1	-	-	-	-
Total	10	83	-	93	4	96	-	100	4	88	-	92	6	95	-	101	3	72	-	75
Follow-up																				
Low	2	1	-	3	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	15	-	15	1	18	-	19	1	21	-	22	-	13	-	13	1	9	-	10
High	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	2	16	-	18	1	18	-	19	1	21	-	22	-	13	-	13	1	9	-	10

治験総括報告書 Table 3.3.1.1.3（Section 15.1）（5.3.5.4-1）から引用

表 2.7.4.8-付録-39　血液生化学検査値のシフトテーブル（安全性データの解析対象集団）（CCT-101 試験）（続き）

Total Bilirubin

	Baseline																			
	Placebo (N=97)				TAK-385 10mg (N=103)				TAK-385 20mg (N=100)				TAK-385 40mg (N=103)				Leuprorelin (N=80)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 4																				
Low	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	97	-	97	1	99	-	100	-	93	2	95	-	98	1	99	-	76	2	78
High	-	-	-	-	-	3	-	3	-	4	1	5	-	3	1	4	-	2	-	2
Total	-	97	-	97	1	102	-	103	-	97	3	100	-	101	2	103	-	78	2	80
Week 8																				
Low	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	95	-	95	1	100	-	101	-	92	2	94	-	96	2	98	-	73	2	75
High	-	-	-	-	-	2	-	2	-	1	1	2	-	3	-	3	-	3	-	3
Total	-	95	-	95	1	102	-	103	-	93	3	96	-	99	2	101	-	76	2	78
Week 12																				
Low	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	90	-	90	1	95	-	96	-	86	2	88	-	97	-	97	-	71	2	73
High	-	3	-	3	-	5	-	5	-	3	1	4	-	2	2	4	-	2	-	2
Total	-	93	-	93	1	100	-	101	-	89	3	92	-	99	2	101	-	73	2	75
Follow-up																				
Low	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	18	-	18	-	19	-	19	-	21	1	22	-	12	-	12	-	10	-	10
High	-	-	-	-	-	-	-	-	-	-	-	-	-	1	-	1	-	-	-	-
Total	-	18	-	18	-	19	-	19	-	21	1	22	-	13	-	13	-	10	-	10

治験総括報告書 Table 3.3.1.1.3（Section 15.1）（5.3.5.4-1）から引用

表 2.7.4.8-付録-39　血液生化学検査値のシフトテーブル（安全性データの解析対象集団）（CCT-101 試験）（続き）

Total Protein

	Baseline																			
	Placebo (N=97)				TAK-385 10mg (N=103)				TAK-385 20mg (N=100)				TAK-385 40mg (N=103)				Leuprorelin (N=80)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 4																				
Low	5	9	-	14	5	4	-	9	2	3	-	5	1	-	-	1	4	1	-	5
Normal	12	71	-	83	13	81	-	94	12	83	-	95	20	82	-	102	11	63	-	74
High	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	1	-	1
Total	17	80	-	97	18	85	-	103	14	86	-	100	21	82	-	103	15	65	-	80
Week 8																				
Low	2	7	-	9	4	5	-	9	4	2	-	6	1	1	-	2	6	2	-	8
Normal	15	70	-	85	14	80	-	94	9	81	-	90	19	78	-	97	9	61	-	70
High	-	1	-	1	-	-	-	-	-	-	-	-	-	2	-	2	-	-	-	-
Total	17	78	-	95	18	85	-	103	13	83	-	96	20	81	-	101	15	63	-	78
Week 12																				
Low	9	6	-	15	3	3	-	6	3	3	-	6	3	1	-	4	2	1	-	3
Normal	8	70	-	78	15	75	-	90	10	76	-	86	17	80	-	97	13	59	-	72
High	-	-	-	-	-	4	-	4	-	-	-	-	-	-	-	-	-	-	-	-
Total	17	76	-	93	18	82	-	100	13	79	-	92	20	81	-	101	15	60	-	75
Follow-up																				
Low	2	1	-	3	1	-	-	1	-	2	-	2	1	-	-	1	-	1	-	1
Normal	1	14	-	15	2	16	-	18	2	18	-	20	3	9	-	12	-	9	-	9
High	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	3	15	-	18	3	16	-	19	2	20	-	22	4	9	-	13	-	10	-	10

治験総括報告書 Table 3.3.1.1.3（Section 15.1）（5.3.5.4-1）から引用

表 2.7.4.8-付録-39　血液生化学検査値のシフトテーブル（安全性データの解析対象集団）（CCT-101 試験）（続き）

Total Cholesterol

	Baseline																			
	Placebo (N=97)				TAK-385 10mg (N=103)				TAK-385 20mg (N=100)				TAK-385 40mg (N=103)				Leuprorelin (N=80)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 4																				
Low	6	5	-	11	6	2	-	8	2	4	-	6	3	-	-	3	2	1	-	3
Normal	4	68	6	78	9	71	1	81	11	63	1	75	14	66	1	81	4	57	-	61
High	-	2	6	8	-	9	5	14	-	12	7	19	-	12	7	19	-	8	8	16
Total	10	75	12	97	15	82	6	103	13	79	8	100	17	78	8	103	6	66	8	80
Week 8																				
Low	1	3	-	4	3	4	-	7	5	1	-	6	3	-	-	3	3	1	-	4
Normal	8	64	3	75	12	69	1	82	6	66	2	74	13	57	2	72	3	53	2	58
High	-	8	8	16	-	9	5	14	-	10	6	16	-	20	6	26	-	10	6	16
Total	9	75	11	95	15	82	6	103	11	77	8	96	16	77	8	101	6	64	8	78
Week 12																				
Low	5	1	-	6	6	2	-	8	2	4	-	6	4	-	-	4	3	-	-	3
Normal	4	64	4	72	9	69	1	79	8	60	3	71	12	64	2	78	2	52	1	55
High	-	8	7	15	-	9	5	14	-	10	5	15	-	13	6	19	-	10	7	17
Total	9	73	11	93	15	80	6	101	10	74	8	92	16	77	8	101	5	62	8	75
Follow-up																				
Low	2	-	-	2	-	2	-	2	3	2	-	5	-	-	-	-	2	-	-	2
Normal	-	12	-	12	1	14	-	15	3	11	-	14	3	9	1	13	1	7	-	8
High	-	2	2	4	-	-	2	2	-	3	-	3	-	-	-	-	-	-	-	-
Total	2	14	2	18	1	16	2	19	6	16	-	22	3	9	1	13	3	7	-	10

治験総括報告書 Table 3.3.1.1.3（Section 15.1）（5.3.5.4-1）から引用

表 2.7.4.8-付録-39　血液生化学検査値のシフトテーブル（安全性データの解析対象集団）（CCT-101 試験）（続き）

HDL Cholesterol

	Baseline																			
	Placebo (N=97)				TAK-385 10mg (N=103)				TAK-385 20mg (N=100)				TAK-385 40mg (N=103)				Leuprorelin (N=80)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 4																				
Low	-	1	-	1	1	-	-	1	2	-	-	2	-	-	-	-	1	-	-	1
Normal	1	95	-	96	2	98	-	100	1	91	-	92	1	98	-	99	-	75	-	75
High	-	-	-	-	-	1	1	2	-	5	1	6	-	4	-	4	-	3	1	4
Total	1	96	-	97	3	99	1	103	3	96	1	100	1	102	-	103	1	78	1	80
Week 8																				
Low	-	2	-	2	1	1	-	2	2	1	-	3	-	1	-	1	1	2	-	3
Normal	1	91	-	92	2	95	-	97	1	87	-	88	1	95	-	96	-	73	-	73
High	-	1	-	1	-	3	1	4	-	4	1	5	-	4	-	4	-	1	1	2
Total	1	94	-	95	3	99	1	103	3	92	1	96	1	100	-	101	1	76	1	78
Week 12																				
Low	-	1	-	1	-	1	-	1	1	-	-	1	-	1	-	1	-	1	-	1
Normal	1	90	-	91	3	94	-	97	2	87	1	90	1	94	-	95	1	71	1	73
High	-	1	-	1	-	2	1	3	-	1	-	1	-	5	-	5	-	1	-	1
Total	1	92	-	93	3	97	1	101	3	88	1	92	1	100	-	101	1	73	1	75
Follow-up																				
Low	-	-	-	-	1	-	-	1	-	-	-	-	-	-	-	-	-	1	-	1
Normal	-	17	-	17	-	18	-	18	-	22	-	22	-	13	-	13	-	9	-	9
High	-	1	-	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	-	18	-	18	1	18	-	19	-	22	-	22	-	13	-	13	-	10	-	10

治験総括報告書 Table 3.3.1.1.3（Section 15.1）（5.3.5.4-1）から引用

表 2.7.4.8-付録-39　血液生化学検査値のシフトテーブル（安全性データの解析対象集団）（CCT-101 試験）（続き）

LDL Cholesterol

	Baseline																			
	Placebo (N=97)				TAK-385 10mg (N=103)				TAK-385 20mg (N=100)				TAK-385 40mg (N=103)				Leuprorelin (N=80)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 4																				
Low	6	2	-	8	2	1	-	3	5	2	-	7	5	2	-	7	2	-	-	2
Normal	3	74	2	79	4	85	-	89	5	80	1	86	3	74	3	80	3	59	3	65
High	-	4	6	10	-	5	6	11	-	3	4	7	-	10	6	16	-	7	6	13
Total	9	80	8	97	6	91	6	103	10	85	5	100	8	86	9	103	5	66	9	80
Week 8																				
Low	2	-	-	2	3	1	-	4	3	1	-	4	4	-	-	4	3	1	-	4
Normal	6	70	3	79	3	82	2	87	5	77	2	84	4	73	4	81	2	54	2	58
High	-	9	5	14	-	8	4	12	-	5	3	8	-	11	5	16	-	9	7	16
Total	8	79	8	95	6	91	6	103	8	83	5	96	8	84	9	101	5	64	9	78
Week 12																				
Low	3	1	-	4	3	-	-	3	4	2	-	6	4	1	-	5	2	-	-	2
Normal	5	68	3	76	3	84	1	88	4	72	1	77	4	71	3	78	3	55	-	58
High	-	8	5	13	-	5	5	10	-	5	4	9	-	12	6	18	-	6	9	15
Total	8	77	8	93	6	89	6	101	8	79	5	92	8	84	9	101	5	61	9	75
Follow-up																				
Low	1	1	-	2	-	-	-	-	3	-	-	3	1	-	-	1	1	1	-	2
Normal	-	12	-	12	-	17	-	17	-	19	-	19	-	10	2	12	-	7	-	7
High	-	3	1	4	-	-	2	2	-	-	-	-	-	-	-	-	-	1	-	1
Total	1	16	1	18	-	17	2	19	3	19	-	22	1	10	2	13	1	9	-	10

治験総括報告書 Table 3.3.1.1.3（Section 15.1）（5.3.5.4-1）から引用

表 2.7.4.8-付録-39　血液生化学検査値のシフトテーブル（安全性データの解析対象集団）（CCT-101 試験）（続き）

Triglycerides

	Baseline																			
	Placebo (N=97)				TAK-385 10mg (N=103)				TAK-385 20mg (N=100)				TAK-385 40mg (N=103)				Leuprorelin (N=80)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 4																				
Low	15	9	-	24	19	6	-	25	17	9	1	27	14	10	-	24	10	3	-	13
Normal	15	48	3	66	13	56	1	70	14	51	6	71	14	53	2	69	6	51	3	60
High	-	2	5	7	-	5	3	8	-	1	1	2	-	9	1	10	-	5	2	7
Total	30	59	8	97	32	67	4	103	31	61	8	100	28	72	3	103	16	59	5	80
Week 8																				
Low	14	11	-	25	12	12	-	24	20	8	-	28	13	9	1	23	11	4	-	15
Normal	16	42	4	62	20	53	1	74	9	46	5	60	15	52	-	67	5	47	2	54
High	-	4	4	8	-	2	3	5	-	5	3	8	-	9	2	11	-	6	3	9
Total	30	57	8	95	32	67	4	103	29	59	8	96	28	70	3	101	16	57	5	78
Week 12																				
Low	18	10	-	28	17	8	-	25	15	11	-	26	15	7	1	23	7	4	-	11
Normal	11	42	5	58	15	51	2	68	13	40	6	59	13	58	1	72	8	43	2	53
High	-	4	3	7	-	6	2	8	-	5	2	7	-	5	1	6	-	8	3	11
Total	29	56	8	93	32	65	4	101	28	56	8	92	28	70	3	101	15	55	5	75
Follow-up																				
Low	3	-	-	3	3	1	-	4	4	3	-	7	2	-	-	2	1	1	-	2
Normal	1	11	1	13	1	12	1	14	5	9	-	14	1	8	-	9	1	6	-	7
High	-	1	1	2	-	-	1	1	-	1	-	1	-	2	-	2	-	1	-	1
Total	4	12	2	18	4	13	2	19	9	13	-	22	3	10	-	13	2	8	-	10

治験総括報告書 Table 3.3.1.1.3（Section 15.1）（5.3.5.4-1）から引用