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）

Glucose

	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	-	-	-	-	-	3	1	4	-	1	-	1	-	3	-	3
Normal	1	79	6	86	-	92	2	94	-	88	5	93	-	94	5	99	2	69	2	73
High	-	6	4	10	-	6	3	9	-	2	1	3	-	1	2	3	-	3	1	4
Total	1	86	10	97	-	98	5	103	-	93	7	100	-	96	7	103	2	75	3	80
Week 8																				
Low	-	3	-	3	-	2	-	2	-	1	-	1	-	1	-	1	-	1	-	1
Normal	-	76	6	82	-	92	2	94	-	84	6	90	-	92	6	98	2	68	3	73
High	-	6	4	10	-	4	3	7	-	4	1	5	-	1	1	2	-	4	-	4
Total	-	85	10	95	-	98	5	103	-	89	7	96	-	94	7	101	2	73	3	78
Week 12																				
Low	-	2	-	2	-	1	-	1	-	2	-	2	-	-	-	-	-	1	-	1
Normal	-	77	7	84	-	88	2	90	-	79	6	85	-	92	7	99	2	65	3	70
High	-	5	2	7	-	7	3	10	-	4	1	5	-	2	-	2	-	4	-	4
Total	-	84	9	93	-	96	5	101	-	85	7	92	-	94	7	101	2	70	3	75
Follow-up																				
Low	-	-	-	-	-	-	-	-	-	1	-	1	-	-	-	-	-	-	-	-
Normal	1	14	2	17	-	18	-	18	-	19	1	20	-	13	-	13	1	8	-	9
High	-	1	-	1	-	-	1	1	-	1	-	1	-	-	-	-	-	1	-	1
Total	1	15	2	18	-	18	1	19	-	21	1	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）

Creatinine

	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	2	-	6	1	2	-	3	3	1	-	4	2	1	-	3	2	-	-	2
Normal	-	90	-	90	4	93	-	97	6	88	-	94	2	96	-	98	2	73	2	77
High	-	-	1	1	-	1	2	3	-	2	-	2	-	1	1	2	-	1	-	1
Total	4	92	1	97	5	96	2	103	9	91	-	100	4	98	1	103	4	74	2	80
Week 8																				
Low	3	2	-	5	3	4	-	7	3	3	-	6	1	-	-	1	-	1	-	1
Normal	1	87	-	88	2	92	-	94	6	83	-	89	3	95	-	98	4	70	2	76
High	-	1	1	2	-	-	2	2	-	1	-	1	-	1	1	2	-	1	-	1
Total	4	90	1	95	5	96	2	103	9	87	-	96	4	96	1	101	4	72	2	78
Week 12																				
Low	2	2	-	4	1	1	-	2	2	2	-	4	-	-	-	-	2	1	-	3
Normal	1	87	-	88	4	93	1	98	6	79	-	85	4	95	-	99	2	67	2	71
High	-	-	1	1	-	-	1	1	-	3	-	3	-	1	1	2	-	1	-	1
Total	3	89	1	93	5	94	2	101	8	84	-	92	4	96	1	101	4	69	2	75
Follow-up																				
Low	-	-	-	-	1	-	-	1	2	-	-	2	-	-	-	-	-	-	-	-
Normal	-	18	-	18	-	18	-	18	-	19	-	19	-	13	-	13	-	10	-	10
High	-	-	-	-	-	-	-	-	-	1	-	1	-	-	-	-	-	-	-	-
Total	-	18	-	18	1	18	-	19	2	20	-	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）

Blood Urea Nitrogen

	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	-	2	-	-	-	-	-	-	-	-	-	1	-	1	-	-	-	-
Normal	1	94	-	95	-	103	-	103	1	98	1	100	2	99	-	101	1	79	-	80
High	-	-	-	-	-	-	-	-	-	-	-	-	-	-	1	1	-	-	-	-
Total	2	95	-	97	-	103	-	103	1	98	1	100	2	100	1	103	1	79	-	80
Week 8																				
Low	-	1	-	1	-	-	-	-	-	-	-	-	-	-	-	-	-	1	-	1
Normal	2	92	-	94	-	103	-	103	1	94	1	96	2	98	1	101	1	76	-	77
High	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	2	93	-	95	-	103	-	103	1	94	1	96	2	98	1	101	1	77	-	78
Week 12																				
Low	1	5	-	6	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Normal	1	85	-	86	-	101	-	101	1	89	1	91	2	97	1	100	1	72	-	73
High	-	1	-	1	-	-	-	-	-	1	-	1	-	1	-	1	-	2	-	2
Total	2	91	-	93	-	101	-	101	1	90	1	92	2	98	1	101	1	74	-	75
Follow-up																				
Low	-	1	-	1	-	-	-	-	-	1	-	1	-	-	-	-	-	-	-	-
Normal	-	17	-	17	-	19	-	19	-	21	-	21	-	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）

CK (CPK)

	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
Normal	-	92	3	95	-	101	-	101	1	96	-	97	2	95	-	97	-	77	-	77
High	-	1	1	2	-	2	-	2	-	2	-	2	-	5	1	6	-	1	1	2
Total	-	93	4	97	-	103	-	103	1	99	-	100	2	100	1	103	1	78	1	80
Week 8																				
Low	-	-	-	-	-	1	-	1	-	1	-	1	-	1	-	1	1	1	-	2
Normal	-	90	1	91	-	101	-	101	1	92	-	93	2	94	1	97	-	74	-	74
High	-	1	3	4	-	1	-	1	-	2	-	2	-	3	-	3	-	1	1	2
Total	-	91	4	95	-	103	-	103	1	95	-	96	2	98	1	101	1	76	1	78
Week 12																				
Low	-	-	-	-	-	1	-	1	-	1	-	1	-	2	-	2	1	-	-	1
Normal	-	88	2	90	-	99	-	99	1	87	-	88	2	96	-	98	-	73	-	73
High	-	1	2	3	-	1	-	1	-	3	-	3	-	-	1	1	-	-	1	1
Total	-	89	4	93	-	101	-	101	1	91	-	92	2	98	1	101	1	73	1	75
Follow-up																				
Low	-	-	-	-	-	-	-	-	-	-	-	-	-	1	-	1	-	2	-	2
Normal	-	16	1	17	-	19	-	19	-	22	-	22	-	12	-	12	-	7	-	7
High	-	1	-	1	-	-	-	-	-	-	-	-	-	-	-	-	-	1	-	1
Total	-	17	1	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）

Uric Acid

	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	3	2	-	5	1	-	-	1	2	-	-	2	1	-	-	1	-	-	-	-
Normal	3	89	-	92	2	98	-	100	-	96	-	96	3	98	-	101	2	78	-	80
High	-	-	-	-	-	2	-	2	-	2	-	2	-	1	-	1	-	-	-	-
Total	6	91	-	97	3	100	-	103	2	98	-	100	4	99	-	103	2	78	-	80
Week 8																				
Low	4	4	-	8	1	3	-	4	1	-	-	1	1	-	-	1	-	1	-	1
Normal	2	85	-	87	2	97	-	99	-	94	-	94	3	97	-	100	2	75	-	77
High	-	-	-	-	-	-	-	-	-	1	-	1	-	-	-	-	-	-	-	-
Total	6	89	-	95	3	100	-	103	1	95	-	96	4	97	-	101	2	76	-	78
Week 12																				
Low	5	2	-	7	2	-	-	2	-	-	-	-	1	-	-	1	-	1	-	1
Normal	1	85	-	86	1	96	-	97	1	90	-	91	3	96	-	99	2	72	-	74
High	-	-	-	-	-	2	-	2	-	1	-	1	-	1	-	1	-	-	-	-
Total	6	87	-	93	3	98	-	101	1	91	-	92	4	97	-	101	2	73	-	75
Follow-up																				
Low	2	-	-	2	-	1	-	1	1	-	-	1	-	-	-	-	-	-	-	-
Normal	-	16	-	16	-	18	-	18	-	21	-	21	-	13	-	13	1	9	-	10
High	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	2	16	-	18	-	19	-	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）

Sodium

	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	-	103	-	103	-	100	-	100	-	103	-	103	-	80	-	80
High	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	-	97	-	97	-	103	-	103	-	100	-	100	-	103	-	103	-	80	-	80
Week 8																				
Low	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	95	-	95	-	103	-	103	-	96	-	96	-	101	-	101	-	78	-	78
High	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	-	95	-	95	-	103	-	103	-	96	-	96	-	101	-	101	-	78	-	78
Week 12																				
Low	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	92	-	92	-	101	-	101	-	92	-	92	-	101	-	101	-	75	-	75
High	-	1	-	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	-	93	-	93	-	101	-	101	-	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）

Potassium

	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	-	-	-	-	-	1	-	1	1	2	-	3
Normal	1	95	-	96	-	101	-	101	1	99	-	100	1	101	-	102	3	73	-	76
High	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	1	-	1
Total	1	96	-	97	1	102	-	103	1	99	-	100	1	102	-	103	4	76	-	80
Week 8																				
Low	-	3	-	3	-	-	-	-	-	1	-	1	-	-	-	-	-	-	-	-
Normal	1	90	-	91	1	102	-	103	1	93	-	94	1	98	-	99	4	74	-	78
High	-	1	-	1	-	-	-	-	-	1	-	1	-	2	-	2	-	-	-	-
Total	1	94	-	95	1	102	-	103	1	95	-	96	1	100	-	101	4	74	-	78
Week 12																				
Low	-	2	-	2	-	-	-	-	1	1	-	2	-	1	-	1	1	1	-	2
Normal	1	90	-	91	1	99	-	100	-	89	-	89	1	99	-	100	3	70	-	73
High	-	-	-	-	-	-	-	-	-	1	-	1	-	-	-	-	-	-	-	-
Total	1	92	-	93	1	99	-	100	1	91	-	92	1	100	-	101	4	71	-	75
Follow-up																				
Low	-	-	-	-	-	1	-	1	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	18	-	18	-	18	-	18	-	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）

Chloride

	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	-	87	6	93	-	96	4	100	-	93	4	97	-	97	4	101	1	76	1	78
High	-	3	1	4	-	3	-	3	-	1	2	3	-	2	-	2	-	2	-	2
Total	-	90	7	97	-	99	4	103	-	94	6	100	-	99	4	103	1	78	1	80
Week 8																				
Low	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	88	5	93	-	96	4	100	-	89	6	95	-	95	3	98	1	75	1	77
High	-	-	2	2	-	3	-	3	-	1	-	1	-	2	1	3	-	1	-	1
Total	-	88	7	95	-	99	4	103	-	90	6	96	-	97	4	101	1	76	1	78
Week 12																				
Low	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	86	7	93	-	97	4	101	-	87	5	92	-	97	4	101	1	73	1	75
High	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	-	86	7	93	-	97	4	101	-	87	5	92	-	97	4	101	1	73	1	75
Follow-up																				
Low	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	16	1	17	-	18	1	19	-	21	-	21	-	13	-	13	-	10	-	10
High	-	1	-	1	-	-	-	-	-	-	1	1	-	-	-	-	-	-	-	-
Total	-	17	1	18	-	18	1	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）

Calcium

	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	8	6	-	14	2	5	-	7	2	4	-	6	-	1	-	1	-	1	-	1
Normal	8	75	-	83	7	89	-	96	13	81	-	94	18	83	1	102	11	67	-	78
High	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	1	-	1
Total	16	81	-	97	9	94	-	103	15	85	-	100	18	84	1	103	11	69	-	80
Week 8																				
Low	8	4	-	12	1	5	-	6	4	1	-	5	-	-	-	-	-	-	-	-
Normal	8	75	-	83	8	89	-	97	11	80	-	91	17	81	1	99	11	66	-	77
High	-	-	-	-	-	-	-	-	-	-	-	-	-	2	-	2	-	1	-	1
Total	16	79	-	95	9	94	-	103	15	81	-	96	17	83	1	101	11	67	-	78
Week 12																				
Low	10	10	-	20	3	5	-	8	4	1	-	5	2	1	-	3	1	-	-	1
Normal	5	68	-	73	6	86	-	92	10	77	-	87	15	80	1	96	9	64	-	73
High	-	-	-	-	-	-	-	-	-	-	-	-	-	2	-	2	-	1	-	1
Total	15	78	-	93	9	91	-	100	14	78	-	92	17	83	1	101	10	65	-	75
Follow-up																				
Low	-	3	-	3	1	1	-	2	4	1	-	5	-	-	-	-	1	-	-	1
Normal	1	14	-	15	1	16	-	17	3	14	-	17	1	12	-	13	1	8	-	9
High	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	1	17	-	18	2	17	-	19	7	15	-	22	1	12	-	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

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）

Phosphorus

	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	-	87	5	92	-	93	3	96	-	81	3	84	1	77	1	79	-	64	1	65
High	-	2	3	5	-	6	1	7	-	13	3	16	-	21	3	24	-	11	4	15
Total	-	89	8	97	-	99	4	103	-	94	6	100	1	98	4	103	-	75	5	80
Week 8																				
Low	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	83	6	89	-	95	4	99	-	76	2	78	1	71	2	74	-	49	3	52
High	-	4	2	6	-	4	-	4	-	14	4	18	-	25	2	27	-	24	2	26
Total	-	87	8	95	-	99	4	103	-	90	6	96	1	96	4	101	-	73	5	78
Week 12																				
Low	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	79	6	85	-	92	4	96	-	67	3	70	1	50	2	53	-	41	-	41
High	-	6	2	8	-	4	-	4	-	19	3	22	-	46	2	48	-	30	4	34
Total	-	85	8	93	-	96	4	100	-	86	6	92	1	96	4	101	-	71	4	75
Follow-up																				
Low	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	16	2	18	-	19	-	19	-	21	-	21	-	11	-	11	-	6	2	8
High	-	-	-	-	-	-	-	-	-	1	-	1	-	2	-	2	-	2	-	2
Total	-	16	2	18	-	19	-	19	-	22	-	22	-	13	-	13	-	8	2	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-40　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）（OCT-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
Week 16																				
Low	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	75	-	75	-	83	-	83	-	75	-	75	-	83	-	83	-	65	-	65
High	-	-	-	-	-	1	-	1	-	3	-	3	-	6	-	6	-	3	1	4
Total	-	75	-	75	-	84	-	84	-	78	-	78	-	89	-	89	-	68	1	69
Week 20																				
Low	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	74	-	74	-	81	-	81	-	74	-	74	-	84	-	84	-	62	-	62
High	-	1	-	1	-	-	-	-	-	3	-	3	-	3	-	3	-	2	1	3
Total	-	75	-	75	-	81	-	81	-	77	-	77	-	87	-	87	-	64	1	65
Week 24																				
Low	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	68	-	68	-	79	-	79	-	72	-	72	-	84	-	84	-	58	-	58
High	-	-	-	-	-	-	-	-	-	4	-	4	-	4	-	4	-	3	1	4
Total	-	68	-	68	-	79	-	79	-	76	-	76	-	88	-	88	-	61	1	62
Follow-up																				
Low	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	77	-	77	-	82	-	82	-	77	-	77	-	87	-	87	-	66	-	66
High	-	-	-	-	-	1	-	1	-	-	-	-	-	2	-	2	-	2	1	3
Total	-	77	-	77	-	83	-	83	-	77	-	77	-	89	-	89	-	68	1	69

治験総括報告書 Table 3.2.1.1.3（Section 15.1）（5.3.5.4-2）から引用

表 2.7.4.8-付録-40　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）（OCT-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
Week 16																				
Low	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Normal	1	74	-	75	-	84	-	84	-	76	-	76	-	85	-	85	-	68	-	68
High	-	-	-	-	-	-	-	-	-	2	-	2	-	4	-	4	-	1	-	1
Total	1	74	-	75	-	84	-	84	-	78	-	78	-	89	-	89	-	69	-	69
Week 20																				
Low	-	2	-	2	-	-	-	-	-	1	-	1	-	-	-	-	-	-	-	-
Normal	1	72	-	73	-	81	-	81	-	75	-	75	-	86	-	86	-	64	-	64
High	-	-	-	-	-	-	-	-	-	1	-	1	-	1	-	1	-	1	-	1
Total	1	74	-	75	-	81	-	81	-	77	-	77	-	87	-	87	-	65	-	65
Week 24																				
Low	-	1	-	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Normal	1	66	-	67	-	79	-	79	-	74	-	74	-	86	-	86	-	60	-	60
High	-	-	-	-	-	-	-	-	-	2	-	2	-	2	-	2	-	2	-	2
Total	1	67	-	68	-	79	-	79	-	76	-	76	-	88	-	88	-	62	-	62
Follow-up																				
Low	-	1	-	1	-	1	-	1	-	-	-	-	-	-	-	-	-	-	-	-
Normal	1	75	-	76	-	81	-	81	-	77	-	77	-	89	-	89	-	66	-	66
High	-	-	-	-	-	1	-	1	-	-	-	-	-	-	-	-	-	3	-	3
Total	1	76	-	77	-	83	-	83	-	77	-	77	-	89	-	89	-	69	-	69

治験総括報告書 Table 3.2.1.1.3（Section 15.1）（5.3.5.4-2）から引用

表 2.7.4.8-付録-40　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）（OCT-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
Week 16																				
Low	1	4	-	5	-	5	-	5	1	1	-	2	-	1	-	1	1	1	-	2
Normal	-	70	-	70	1	78	-	79	2	73	1	76	3	83	1	87	4	62	1	67
High	-	-	-	-	-	-	-	-	-	-	-	-	-	1	-	1	-	-	-	-
Total	1	74	-	75	1	83	-	84	3	74	1	78	3	85	1	89	5	63	1	69
Week 20																				
Low	-	2	-	2	-	3	-	3	1	1	-	2	2	-	-	2	2	-	-	2
Normal	1	72	-	73	1	77	-	78	2	72	-	74	1	82	-	83	2	59	1	62
High	-	-	-	-	-	-	-	-	-	-	1	1	-	1	1	2	-	1	-	1
Total	1	74	-	75	1	80	-	81	3	73	1	77	3	83	1	87	4	60	1	65
Week 24																				
Low	-	2	-	2	1	2	-	3	1	-	-	1	1	1	-	2	1	-	-	1
Normal	1	65	-	66	-	76	-	76	2	72	-	74	2	82	-	84	3	56	1	60
High	-	-	-	-	-	-	-	-	-	-	1	1	-	1	1	2	-	1	-	1
Total	1	67	-	68	1	78	-	79	3	72	1	76	3	84	1	88	4	57	1	62
Follow-up																				
Low	1	6	-	7	-	2	-	2	1	2	-	3	2	1	-	3	1	-	-	1
Normal	-	70	-	70	1	80	-	81	2	71	1	74	1	83	-	84	4	62	1	67
High	-	-	-	-	-	-	-	-	-	-	-	-	-	1	1	2	-	1	-	1
Total	1	76	-	77	1	82	-	83	3	73	1	77	3	85	1	89	5	63	1	69

治験総括報告書 Table 3.2.1.1.3（Section 15.1）（5.3.5.4-2）から引用

表 2.7.4.8-付録-40　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）（OCT-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
Week 16																				
Low	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	70	1	71	-	77	2	79	-	72	-	72	-	80	1	81	-	57	-	57
High	-	-	4	4	-	2	3	5	-	2	4	6	-	4	4	8	-	4	8	12
Total	-	70	5	75	-	79	5	84	-	74	4	78	-	84	5	89	-	61	8	69
Week 20																				
Low	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	69	1	70	-	75	2	77	-	72	-	72	-	77	2	79	-	53	-	53
High	-	1	4	5	-	1	3	4	-	1	4	5	-	5	3	8	-	5	7	12
Total	-	70	5	75	-	76	5	81	-	73	4	77	-	82	5	87	-	58	7	65
Week 24																				
Low	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	61	1	62	-	72	-	72	-	71	-	71	-	81	1	82	-	51	-	51
High	-	2	4	6	-	2	5	7	-	1	4	5	-	2	4	6	-	4	7	11
Total	-	63	5	68	-	74	5	79	-	72	4	76	-	83	5	88	-	55	7	62
Follow-up																				
Low	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	71	1	72	-	76	2	78	-	71	-	71	-	80	1	81	-	57	-	57
High	-	1	4	5	-	2	3	5	-	2	4	6	-	4	4	8	-	4	8	12
Total	-	72	5	77	-	78	5	83	-	73	4	77	-	84	5	89	-	61	8	69

治験総括報告書 Table 3.2.1.1.3（Section 15.1）（5.3.5.4-2）から引用

表 2.7.4.8-付録-40　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）（OCT-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
Week 16																				
Low	3	4	-	7	2	-	-	2	1	-	-	1	1	-	-	1	-	1	-	1
Normal	4	63	-	67	9	73	-	82	7	70	-	77	3	85	-	88	5	62	-	67
High	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	1	-	1
Total	7	67	-	74	11	73	-	84	8	70	-	78	4	85	-	89	5	64	-	69
Week 20																				
Low	1	1	-	2	-	-	-	-	2	1	-	3	1	1	-	2	1	1	-	2
Normal	6	67	-	73	11	70	-	81	6	68	-	74	3	82	-	85	4	59	-	63
High	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	7	68	-	75	11	70	-	81	8	69	-	77	4	83	-	87	5	60	-	65
Week 24																				
Low	2	1	-	3	1	2	-	3	1	1	-	2	1	1	-	2	3	1	-	4
Normal	3	62	-	65	10	66	-	76	7	67	-	74	3	83	-	86	2	56	-	58
High	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	5	63	-	68	11	68	-	79	8	68	-	76	4	84	-	88	5	57	-	62
Follow-up																				
Low	1	4	-	5	5	4	-	9	1	4	-	5	1	1	-	2	1	1	-	2
Normal	6	65	-	71	6	68	-	74	7	65	-	72	3	84	-	87	4	63	-	67
High	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	7	69	-	76	11	72	-	83	8	69	-	77	4	85	-	89	5	64	-	69

治験総括報告書 Table 3.2.1.1.3（Section 15.1）（5.3.5.4-2）から引用

表 2.7.4.8-付録-40　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）（OCT-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
Week 16																				
Low	5	2	-	7	-	3	-	3	3	1	-	4	2	-	-	2	-	-	-	-
Normal	3	65	-	68	3	78	-	81	-	74	-	74	3	84	-	87	3	66	-	69
High	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	8	67	-	75	3	81	-	84	3	75	-	78	5	84	-	89	3	66	-	69
Week 20																				
Low	5	1	-	6	-	1	-	1	1	2	-	3	2	-	-	2	-	-	-	-
Normal	3	66	-	69	3	77	-	80	2	72	-	74	3	82	-	85	3	62	-	65
High	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	8	67	-	75	3	78	-	81	3	74	-	77	5	82	-	87	3	62	-	65
Week 24																				
Low	5	2	-	7	-	1	-	1	1	-	-	1	1	-	-	1	-	-	-	-
Normal	3	58	-	61	3	75	-	78	1	74	-	75	4	82	-	86	3	57	-	60
High	-	-	-	-	-	-	-	-	-	-	-	-	-	1	-	1	-	2	-	2
Total	8	60	-	68	3	76	-	79	2	74	-	76	5	83	-	88	3	59	-	62
Follow-up																				
Low	5	1	-	6	1	2	-	3	2	1	-	3	-	1	-	1	-	-	-	-
Normal	3	67	-	70	2	78	-	80	1	73	-	74	5	82	-	87	3	66	-	69
High	-	1	-	1	-	-	-	-	-	-	-	-	-	1	-	1	-	-	-	-
Total	8	69	-	77	3	80	-	83	3	74	-	77	5	84	-	89	3	66	-	69

治験総括報告書 Table 3.2.1.1.3（Section 15.1）（5.3.5.4-2）から引用

表 2.7.4.8-付録-40　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）（OCT-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
Week 16																				
Low	-	1	-	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	73	-	73	1	79	-	80	-	73	1	74	-	85	-	85	-	65	2	67
High	-	1	-	1	-	4	-	4	-	3	1	4	-	2	2	4	-	2	-	2
Total	-	75	-	75	1	83	-	84	-	76	2	78	-	87	2	89	-	67	2	69
Week 20																				
Low	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	74	-	74	1	76	-	77	-	69	2	71	-	81	1	82	-	58	1	59
High	-	1	-	1	-	4	-	4	-	6	-	6	-	4	1	5	-	5	1	6
Total	-	75	-	75	1	80	-	81	-	75	2	77	-	85	2	87	-	63	2	65
Week 24																				
Low	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	66	-	66	1	78	-	79	-	71	2	73	-	83	-	83	-	59	2	61
High	-	2	-	2	-	-	-	-	-	3	-	3	-	3	2	5	-	1	-	1
Total	-	68	-	68	1	78	-	79	-	74	2	76	-	86	2	88	-	60	2	62
Follow-up																				
Low	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	74	-	74	1	80	-	81	-	69	2	71	-	84	-	84	-	65	1	66
High	-	3	-	3	-	2	-	2	-	6	-	6	-	3	2	5	-	2	1	3
Total	-	77	-	77	1	82	-	83	-	75	2	77	-	87	2	89	-	67	2	69

治験総括報告書 Table 3.2.1.1.3（Section 15.1）（5.3.5.4-2）から引用

表 2.7.4.8-付録-40　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）（OCT-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
Week 16																				
Low	4	5	-	9	4	4	-	8	2	2	-	4	2	2	-	4	3	1	-	4
Normal	8	57	-	65	11	65	-	76	10	64	-	74	15	69	-	84	12	52	-	64
High	-	-	-	-	-	-	-	-	-	-	-	-	-	1	-	1	-	1	-	1
Total	12	62	-	74	15	69	-	84	12	66	-	78	17	72	-	89	15	54	-	69
Week 20																				
Low	2	3	-	5	-	5	-	5	4	1	-	5	1	4	-	5	4	3	-	7
Normal	11	59	-	70	15	59	-	74	8	64	-	72	15	67	-	82	11	47	-	58
High	-	-	-	-	-	2	-	2	-	-	-	-	-	-	-	-	-	-	-	-
Total	13	62	-	75	15	66	-	81	12	65	-	77	16	71	-	87	15	50	-	65
Week 24																				
Low	3	9	-	12	4	4	-	8	2	3	-	5	2	1	-	3	5	2	-	7
Normal	7	49	-	56	11	59	-	70	10	61	-	71	14	71	-	85	9	46	-	55
High	-	-	-	-	-	1	-	1	-	-	-	-	-	-	-	-	-	-	-	-
Total	10	58	-	68	15	64	-	79	12	64	-	76	16	72	-	88	14	48	-	62
Follow-up																				
Low	2	7	-	9	8	10	-	18	5	9	-	14	4	10	-	14	3	-	-	3
Normal	12	55	-	67	7	57	-	64	7	56	-	63	13	62	-	75	12	54	-	66
High	-	-	-	-	-	1	-	1	-	-	-	-	-	-	-	-	-	-	-	-
Total	14	62	-	76	15	68	-	83	12	65	-	77	17	72	-	89	15	54	-	69

治験総括報告書 Table 3.2.1.1.3（Section 15.1）（5.3.5.4-2）から引用

表 2.7.4.8-付録-40　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）（OCT-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
Week 16																				
Low	3	4	-	7	5	2	-	7	1	-	-	1	5	-	-	5	2	2	-	4
Normal	5	47	5	57	9	51	1	61	6	53	2	61	9	52	1	62	1	44	1	46
High	-	6	5	11	-	13	3	16	-	10	6	16	-	16	6	22	-	12	7	19
Total	8	57	10	75	14	66	4	84	7	63	8	78	14	68	7	89	3	58	8	69
Week 20																				
Low	2	4	-	6	3	3	-	6	3	1	-	4	4	1	-	5	2	-	-	2
Normal	6	47	5	58	9	52	1	62	4	53	3	60	10	53	2	65	1	44	2	47
High	-	6	5	11	-	11	2	13	-	8	5	13	-	12	5	17	-	10	6	16
Total	8	57	10	75	12	66	3	81	7	62	8	77	14	66	7	87	3	54	8	65
Week 24																				
Low	2	5	-	7	2	3	-	5	3	3	-	6	6	-	-	6	1	-	-	1
Normal	5	44	6	55	9	46	2	57	3	51	3	57	8	46	2	56	2	40	1	43
High	-	2	4	6	-	16	1	17	-	8	5	13	-	21	5	26	-	11	7	18
Total	7	51	10	68	11	65	3	79	6	62	8	76	14	67	7	88	3	51	8	62
Follow-up																				
Low	2	1	-	3	7	4	-	11	3	2	-	5	8	2	-	10	2	1	-	3
Normal	6	55	5	66	7	56	3	66	4	54	4	62	6	55	3	64	1	43	1	45
High	-	3	5	8	-	5	1	6	-	6	4	10	-	11	4	15	-	14	7	21
Total	8	59	10	77	14	65	4	83	7	62	8	77	14	68	7	89	3	58	8	69

治験総括報告書 Table 3.2.1.1.3（Section 15.1）（5.3.5.4-2）から引用

表 2.7.4.8-付録-40　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）（OCT-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
Week 16																				
Low	-	3	-	3	1	1	-	2	1	-	-	1	-	-	-	-	-	1	-	1
Normal	1	71	-	72	1	78	-	79	2	71	-	73	1	84	-	85	1	64	1	66
High	-	-	-	-	-	2	1	3	-	3	1	4	-	4	-	4	-	2	-	2
Total	1	74	-	75	2	81	1	84	3	74	1	78	1	88	-	89	1	67	1	69
Week 20																				
Low	-	2	-	2	1	-	-	1	2	-	-	2	1	1	-	2	-	-	-	-
Normal	1	72	-	73	1	76	-	77	1	69	1	71	-	81	-	81	1	60	-	61
High	-	-	-	-	-	2	1	3	-	4	-	4	-	4	-	4	-	3	1	4
Total	1	74	-	75	2	78	1	81	3	73	1	77	1	86	-	87	1	63	1	65
Week 24																				
Low	-	1	-	1	-	1	-	1	1	-	-	1	-	1	-	1	-	-	-	-
Normal	1	65	-	66	2	70	-	72	2	69	1	72	1	83	-	84	1	59	-	60
High	-	1	-	1	-	5	1	6	-	3	-	3	-	3	-	3	-	1	1	2
Total	1	67	-	68	2	76	1	79	3	72	1	76	1	87	-	88	1	60	1	62
Follow-up																				
Low	-	1	-	1	1	1	-	2	1	-	-	1	-	-	-	-	-	2	-	2
Normal	1	75	-	76	1	76	-	77	2	71	1	74	1	85	-	86	1	63	-	64
High	-	-	-	-	-	3	1	4	-	2	-	2	-	3	-	3	-	2	1	3
Total	1	76	-	77	2	80	1	83	3	73	1	77	1	88	-	89	1	67	1	69

治験総括報告書 Table 3.2.1.1.3（Section 15.1）（5.3.5.4-2）から引用

表 2.7.4.8-付録-40　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）（OCT-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
Week 16																				
Low	3	3	-	6	2	1	-	3	5	1	-	6	3	1	-	4	3	1	-	4
Normal	4	55	-	59	4	67	1	72	2	61	2	65	4	63	1	68	1	47	2	50
High	-	3	7	10	-	6	3	9	-	4	3	7	-	11	6	17	-	8	7	15
Total	7	61	7	75	6	74	4	84	7	66	5	78	7	75	7	89	4	56	9	69
Week 20																				
Low	3	1	-	4	3	1	-	4	3	1	-	4	3	-	-	3	3	1	-	4
Normal	4	55	2	61	3	66	-	69	4	62	2	68	4	65	3	72	1	45	2	48
High	-	5	5	10	-	5	3	8	-	2	3	5	-	8	4	12	-	7	6	13
Total	7	61	7	75	6	72	3	81	7	65	5	77	7	73	7	87	4	53	8	65
Week 24																				
Low	3	3	-	6	3	1	-	4	4	1	-	5	3	-	-	3	1	1	-	2
Normal	2	49	2	53	3	62	-	65	3	57	1	61	4	61	-	65	3	42	1	46
High	-	4	5	9	-	7	3	10	-	6	4	10	-	13	7	20	-	7	7	14
Total	5	56	7	68	6	70	3	79	7	64	5	76	7	74	7	88	4	50	8	62
Follow-up																				
Low	2	1	-	3	6	3	-	9	2	3	-	5	4	2	-	6	2	1	-	3
Normal	5	59	3	67	-	65	3	68	5	58	3	66	3	66	3	72	2	49	3	54
High	-	3	4	7	-	5	1	6	-	4	2	6	-	7	4	11	-	6	6	12
Total	7	63	7	77	6	73	4	83	7	65	5	77	7	75	7	89	4	56	9	69

治験総括報告書 Table 3.2.1.1.3（Section 15.1）（5.3.5.4-2）から引用

表 2.7.4.8-付録-40　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）（OCT-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
Week 16																				
Low	13	9	-	22	13	11	-	24	10	9	1	20	13	7	1	21	8	2	-	10
Normal	11	33	2	46	15	40	-	55	12	38	6	56	12	45	1	58	6	41	1	48
High	-	3	4	7	-	3	2	5	-	1	1	2	-	9	1	10	-	7	4	11
Total	24	45	6	75	28	54	2	84	22	48	8	78	25	61	3	89	14	50	5	69
Week 20																				
Low	13	1	-	14	11	5	-	16	15	3	-	18	8	6	-	14	10	3	-	13
Normal	11	43	3	57	15	42	-	57	7	43	5	55	16	48	2	66	4	40	2	46
High	-	1	3	4	1	5	2	8	-	1	3	4	-	6	1	7	-	3	3	6
Total	24	45	6	75	27	52	2	81	22	47	8	77	24	60	3	87	14	46	5	65
Week 24																				
Low	12	7	1	20	17	7	-	24	10	8	-	18	11	9	1	21	9	4	-	13
Normal	9	30	3	42	10	40	-	50	11	39	7	57	14	44	1	59	5	35	3	43
High	-	4	2	6	-	3	2	5	-	-	1	1	-	7	1	8	-	4	2	6
Total	21	41	6	68	27	50	2	79	21	47	8	76	25	60	3	88	14	43	5	62
Follow-up																				
Low	15	4	-	19	16	9	-	25	9	9	2	20	11	10	1	22	4	3	-	7
Normal	10	37	2	49	12	40	-	52	13	37	5	55	14	44	1	59	10	40	2	52
High	-	5	4	9	-	4	2	6	-	1	1	2	-	7	1	8	-	7	3	10
Total	25	46	6	77	28	53	2	83	22	47	8	77	25	61	3	89	14	50	5	69

治験総括報告書 Table 3.2.1.1.3（Section 15.1）（5.3.5.4-2）から引用

表 2.7.4.8-付録-40　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）（OCT-101 試験）（続き）

Glucose

	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	-	-	-	-	-	3	1	4	-	1	-	1	-	3	-	3
Normal	1	79	6	86	-	92	2	94	-	88	5	93	-	94	5	99	2	69	2	73
High	-	6	4	10	-	6	3	9	-	2	1	3	-	1	2	3	-	3	1	4
Total	1	86	10	97	-	98	5	103	-	93	7	100	-	96	7	103	2	75	3	80
Week 8																				
Low	-	3	-	3	-	2	-	2	-	1	-	1	-	1	-	1	-	1	-	1
Normal	-	76	6	82	-	92	2	94	-	84	6	90	-	92	6	98	2	68	3	73
High	-	6	4	10	-	4	3	7	-	4	1	5	-	1	1	2	-	4	-	4
Total	-	85	10	95	-	98	5	103	-	89	7	96	-	94	7	101	2	73	3	78
Week 12																				
Low	-	2	-	2	-	1	-	1	-	2	-	2	-	-	-	-	-	1	-	1
Normal	-	77	7	84	-	88	2	90	-	79	6	85	-	92	7	99	2	65	3	70
High	-	5	2	7	-	7	3	10	-	4	1	5	-	2	-	2	-	4	-	4
Total	-	84	9	93	-	96	5	101	-	85	7	92	-	94	7	101	2	70	3	75
Week 16																				
Low	-	-	-	-	-	3	-	3	-	1	-	1	-	-	-	-	-	-	-	-
Normal	-	62	5	67	-	75	1	76	-	67	6	73	-	82	6	88	1	63	3	67
High	-	5	3	8	-	2	3	5	-	4	-	4	-	-	1	1	-	2	-	2
Total	-	67	8	75	-	80	4	84	-	72	6	78	-	82	7	89	1	65	3	69
Week 20																				
Low	-	-	-	-	-	1	-	1	-	-	-	-	-	1	-	1	-	1	-	1
Normal	-	63	5	68	-	72	2	74	-	69	4	73	-	77	6	83	1	56	3	60
High	-	4	3	7	-	4	2	6	-	3	1	4	-	2	1	3	-	4	-	4
Total	-	67	8	75	-	77	4	81	-	72	5	77	-	80	7	87	1	61	3	65
Week 24																				
Low	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	55	5	60	-	71	2	73	-	68	5	73	-	77	7	84	1	57	3	61
High	-	5	3	8	-	4	2	6	-	3	-	3	-	4	-	4	-	1	-	1
Total	-	60	8	68	-	75	4	79	-	71	5	76	-	81	7	88	1	58	3	62
Follow-up																				
Low	-	1	-	1	-	2	-	2	-	1	-	1	-	1	-	1	-	1	-	1
Normal	-	66	4	70	-	73	2	75	-	65	5	70	-	75	6	81	1	57	3	61
High	-	2	4	6	-	4	2	6	-	5	1	6	-	6	1	7	-	7	-	7
Total	-	69	8	77	-	79	4	83	-	71	6	77	-	82	7	89	1	65	3	69

治験総括報告書 Table 3.2.1.1.3（Section 15.1）（5.3.5.4-2）から引用

表 2.7.4.8-付録-40　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）（OCT-101 試験）（続き）

Creatinine

	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	2	-	6	1	2	-	3	3	1	-	4	2	1	-	3	2	-	-	2
Normal	-	90	-	90	4	93	-	97	6	88	-	94	2	96	-	98	2	73	2	77
High	-	-	1	1	-	1	2	3	-	2	-	2	-	1	1	2	-	1	-	1
Total	4	92	1	97	5	96	2	103	9	91	-	100	4	98	1	103	4	74	2	80
Week 8																				
Low	3	2	-	5	3	4	-	7	3	3	-	6	1	-	-	1	-	1	-	1
Normal	1	87	-	88	2	92	-	94	6	83	-	89	3	95	-	98	4	70	2	76
High	-	1	1	2	-	-	2	2	-	1	-	1	-	1	1	2	-	1	-	1
Total	4	90	1	95	5	96	2	103	9	87	-	96	4	96	1	101	4	72	2	78
Week 12																				
Low	2	2	-	4	1	1	-	2	2	2	-	4	-	-	-	-	2	1	-	3
Normal	1	87	-	88	4	93	1	98	6	79	-	85	4	95	-	99	2	67	2	71
High	-	-	1	1	-	-	1	1	-	3	-	3	-	1	1	2	-	1	-	1
Total	3	89	1	93	5	94	2	101	8	84	-	92	4	96	1	101	4	69	2	75
Week 16																				
Low	2	2	-	4	1	-	-	1	2	1	-	3	1	-	-	1	2	1	-	3
Normal	1	68	-	69	3	78	-	81	5	68	-	73	3	84	1	88	2	61	2	65
High	-	1	1	2	-	-	2	2	-	2	-	2	-	-	-	-	-	1	-	1
Total	3	71	1	75	4	78	2	84	7	71	-	78	4	84	1	89	4	63	2	69
Week 20																				
Low	2	-	-	2	2	-	-	2	2	1	-	3	1	-	-	1	2	-	-	2
Normal	1	71	-	72	2	75	-	77	5	68	-	73	3	80	1	84	2	58	1	61
High	-	-	1	1	-	-	2	2	-	1	-	1	-	2	-	2	-	1	1	2
Total	3	71	1	75	4	75	2	81	7	70	-	77	4	82	1	87	4	59	2	65
Week 24																				
Low	1	-	-	1	1	1	-	2	-	1	-	1	2	-	-	2	-	2	-	2
Normal	1	65	-	66	2	72	-	74	7	68	-	75	2	81	-	83	3	52	2	57
High	-	-	1	1	-	1	2	3	-	-	-	-	-	2	1	3	-	3	-	3
Total	2	65	1	68	3	74	2	79	7	69	-	76	4	83	1	88	3	57	2	62
Follow-up																				
Low	2	1	-	3	3	2	-	5	1	3	-	4	2	-	-	2	-	1	-	1
Normal	1	72	-	73	1	75	-	76	6	67	-	73	2	84	1	87	4	61	2	67
High	-	-	1	1	-	-	2	2	-	-	-	-	-	-	-	-	-	1	-	1
Total	3	73	1	77	4	77	2	83	7	70	-	77	4	84	1	89	4	63	2	69

治験総括報告書 Table 3.2.1.1.3（Section 15.1）（5.3.5.4-2）から引用

表 2.7.4.8-付録-40　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）（OCT-101 試験）（続き）

Blood Urea Nitrogen

	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	-	2	-	-	-	-	-	-	-	-	-	1	-	1	-	-	-	-
Normal	1	94	-	95	-	103	-	103	1	98	1	100	2	99	-	101	1	79	-	80
High	-	-	-	-	-	-	-	-	-	-	-	-	-	-	1	1	-	-	-	-
Total	2	95	-	97	-	103	-	103	1	98	1	100	2	100	1	103	1	79	-	80
Week 8																				
Low	-	1	-	1	-	-	-	-	-	-	-	-	-	-	-	-	-	1	-	1
Normal	2	92	-	94	-	103	-	103	1	94	1	96	2	98	1	101	1	76	-	77
High	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	2	93	-	95	-	103	-	103	1	94	1	96	2	98	1	101	1	77	-	78
Week 12																				
Low	1	5	-	6	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Normal	1	85	-	86	-	101	-	101	1	89	1	91	2	97	1	100	1	72	-	73
High	-	1	-	1	-	-	-	-	-	1	-	1	-	1	-	1	-	2	-	2
Total	2	91	-	93	-	101	-	101	1	90	1	92	2	98	1	101	1	74	-	75
Week 16																				
Low	1	1	-	2	-	1	-	1	-	-	-	-	-	-	-	-	-	1	-	1
Normal	1	72	-	73	-	83	-	83	1	76	1	78	2	84	1	87	1	67	-	68
High	-	-	-	-	-	-	-	-	-	-	-	-	-	2	-	2	-	-	-	-
Total	2	73	-	75	-	84	-	84	1	76	1	78	2	86	1	89	1	68	-	69
Week 20																				
Low	-	2	-	2	-	1	-	1	-	-	-	-	-	-	-	-	-	-	-	-
Normal	2	70	-	72	-	80	-	80	1	72	1	74	2	84	1	87	1	63	-	64
High	-	1	-	1	-	-	-	-	-	3	-	3	-	-	-	-	-	1	-	1
Total	2	73	-	75	-	81	-	81	1	75	1	77	2	84	1	87	1	64	-	65
Week 24																				
Low	-	2	-	2	-	-	-	-	-	-	-	-	-	-	-	-	-	1	-	1
Normal	2	64	-	66	-	78	-	78	1	73	1	75	2	85	1	88	1	59	-	60
High	-	-	-	-	-	1	-	1	-	1	-	1	-	-	-	-	-	1	-	1
Total	2	66	-	68	-	79	-	79	1	74	1	76	2	85	1	88	1	61	-	62
Follow-up																				
Low	-	1	-	1	-	-	-	-	-	-	-	-	-	1	-	1	-	-	-	-
Normal	2	74	-	76	-	83	-	83	1	75	1	77	2	84	1	87	1	67	-	68
High	-	-	-	-	-	-	-	-	-	-	-	-	-	1	-	1	-	1	-	1
Total	2	75	-	77	-	83	-	83	1	75	1	77	2	86	1	89	1	68	-	69

治験総括報告書 Table 3.2.1.1.3（Section 15.1）（5.3.5.4-2）から引用

表 2.7.4.8-付録-40　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）（OCT-101 試験）（続き）

CK (CPK)

	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
Normal	-	92	3	95	-	101	-	101	1	96	-	97	2	95	-	97	-	77	-	77
High	-	1	1	2	-	2	-	2	-	2	-	2	-	5	1	6	-	1	1	2
Total	-	93	4	97	-	103	-	103	1	99	-	100	2	100	1	103	1	78	1	80
Week 8																				
Low	-	-	-	-	-	1	-	1	-	1	-	1	-	1	-	1	1	1	-	2
Normal	-	90	1	91	-	101	-	101	1	92	-	93	2	94	1	97	-	74	-	74
High	-	1	3	4	-	1	-	1	-	2	-	2	-	3	-	3	-	1	1	2
Total	-	91	4	95	-	103	-	103	1	95	-	96	2	98	1	101	1	76	1	78
Week 12																				
Low	-	-	-	-	-	1	-	1	-	1	-	1	-	2	-	2	1	-	-	1
Normal	-	88	2	90	-	99	-	99	1	87	-	88	2	96	-	98	-	73	-	73
High	-	1	2	3	-	1	-	1	-	3	-	3	-	-	1	1	-	-	1	1
Total	-	89	4	93	-	101	-	101	1	91	-	92	2	98	1	101	1	73	1	75
Week 16																				
Low	-	1	-	1	-	-	-	-	-	1	-	1	-	1	-	1	1	-	-	1
Normal	-	71	2	73	-	80	-	80	1	74	-	75	2	85	-	87	-	67	1	68
High	-	-	1	1	-	4	-	4	-	2	-	2	-	-	1	1	-	-	-	-
Total	-	72	3	75	-	84	-	84	1	77	-	78	2	86	1	89	1	67	1	69
Week 20																				
Low	-	-	-	-	-	-	-	-	-	1	-	1	-	1	-	1	-	-	-	-
Normal	-	72	2	74	-	79	-	79	1	75	-	76	2	82	-	84	1	63	-	64
High	-	-	1	1	-	2	-	2	-	-	-	-	-	1	1	2	-	-	1	1
Total	-	72	3	75	-	81	-	81	1	76	-	77	2	84	1	87	1	63	1	65
Week 24																				
Low	-	1	-	1	-	-	-	-	-	1	-	1	-	1	-	1	1	-	-	1
Normal	-	65	1	66	-	79	-	79	1	72	-	73	2	82	-	84	-	60	-	60
High	-	-	1	1	-	-	-	-	-	2	-	2	-	2	1	3	-	-	1	1
Total	-	66	2	68	-	79	-	79	1	75	-	76	2	85	1	88	1	60	1	62
Follow-up																				
Low	-	-	-	-	-	-	-	-	-	1	-	1	-	-	-	-	1	-	-	1
Normal	-	74	2	76	-	83	-	83	1	74	-	75	2	86	-	88	-	63	-	63
High	-	-	1	1	-	-	-	-	-	1	-	1	-	-	1	1	-	4	1	5
Total	-	74	3	77	-	83	-	83	1	76	-	77	2	86	1	89	1	67	1	69

治験総括報告書 Table 3.2.1.1.3（Section 15.1）（5.3.5.4-2）から引用

表 2.7.4.8-付録-40　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）（OCT-101 試験）（続き）

Uric Acid

	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	3	2	-	5	1	-	-	1	2	-	-	2	1	-	-	1	-	-	-	-
Normal	3	89	-	92	2	98	-	100	-	96	-	96	3	98	-	101	2	78	-	80
High	-	-	-	-	-	2	-	2	-	2	-	2	-	1	-	1	-	-	-	-
Total	6	91	-	97	3	100	-	103	2	98	-	100	4	99	-	103	2	78	-	80
Week 8																				
Low	4	4	-	8	1	3	-	4	1	-	-	1	1	-	-	1	-	1	-	1
Normal	2	85	-	87	2	97	-	99	-	94	-	94	3	97	-	100	2	75	-	77
High	-	-	-	-	-	-	-	-	-	1	-	1	-	-	-	-	-	-	-	-
Total	6	89	-	95	3	100	-	103	1	95	-	96	4	97	-	101	2	76	-	78
Week 12																				
Low	5	2	-	7	2	-	-	2	-	-	-	-	1	-	-	1	-	1	-	1
Normal	1	85	-	86	1	96	-	97	1	90	-	91	3	96	-	99	2	72	-	74
High	-	-	-	-	-	2	-	2	-	1	-	1	-	1	-	1	-	-	-	-
Total	6	87	-	93	3	98	-	101	1	91	-	92	4	97	-	101	2	73	-	75
Week 16																				
Low	3	1	-	4	1	-	-	1	1	-	-	1	1	-	-	1	-	2	-	2
Normal	1	69	-	70	2	79	-	81	-	76	-	76	3	84	-	87	1	66	-	67
High	-	1	-	1	-	2	-	2	-	1	-	1	-	1	-	1	-	-	-	-
Total	4	71	-	75	3	81	-	84	1	77	-	78	4	85	-	89	1	68	-	69
Week 20																				
Low	3	2	-	5	1	-	-	1	1	-	-	1	1	-	-	1	-	1	-	1
Normal	1	69	-	70	1	79	-	80	-	75	-	75	3	82	-	85	1	62	-	63
High	-	-	-	-	-	-	-	-	-	1	-	1	-	1	-	1	-	1	-	1
Total	4	71	-	75	2	79	-	81	1	76	-	77	4	83	-	87	1	64	-	65
Week 24																				
Low	2	1	-	3	2	2	-	4	1	-	-	1	1	-	-	1	-	1	-	1
Normal	2	63	-	65	-	75	-	75	-	74	-	74	3	83	-	86	-	60	-	60
High	-	-	-	-	-	-	-	-	-	1	-	1	-	1	-	1	-	1	-	1
Total	4	64	-	68	2	77	-	79	1	75	-	76	4	84	-	88	-	62	-	62
Follow-up																				
Low	3	1	-	4	1	1	-	2	1	-	-	1	1	-	-	1	-	-	-	-
Normal	1	72	-	73	2	79	-	81	-	76	-	76	3	84	-	87	1	68	-	69
High	-	-	-	-	-	-	-	-	-	-	-	-	-	1	-	1	-	-	-	-
Total	4	73	-	77	3	80	-	83	1	76	-	77	4	85	-	89	1	68	-	69

治験総括報告書 Table 3.2.1.1.3（Section 15.1）（5.3.5.4-2）から引用

表 2.7.4.8-付録-40　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）（OCT-101 試験）（続き）

Sodium

	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	-	103	-	103	-	100	-	100	-	103	-	103	-	80	-	80
High	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	-	97	-	97	-	103	-	103	-	100	-	100	-	103	-	103	-	80	-	80
Week 8																				
Low	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	95	-	95	-	103	-	103	-	96	-	96	-	101	-	101	-	78	-	78
High	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	-	95	-	95	-	103	-	103	-	96	-	96	-	101	-	101	-	78	-	78
Week 12																				
Low	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	92	-	92	-	101	-	101	-	92	-	92	-	101	-	101	-	75	-	75
High	-	1	-	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	-	93	-	93	-	101	-	101	-	92	-	92	-	101	-	101	-	75	-	75
Week 16																				
Low	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	75	-	75	-	84	-	84	-	78	-	78	-	89	-	89	-	69	-	69
High	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	-	75	-	75	-	84	-	84	-	78	-	78	-	89	-	89	-	69	-	69
Week 20																				
Low	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	75	-	75	-	81	-	81	-	77	-	77	-	87	-	87	-	65	-	65
High	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	-	75	-	75	-	81	-	81	-	77	-	77	-	87	-	87	-	65	-	65
Week 24																				
Low	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	68	-	68	-	79	-	79	-	76	-	76	-	88	-	88	-	62	-	62
High	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	-	68	-	68	-	79	-	79	-	76	-	76	-	88	-	88	-	62	-	62
Follow-up																				
Low	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	77	-	77	-	83	-	83	-	77	-	77	-	89	-	89	-	69	-	69
High	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	-	77	-	77	-	83	-	83	-	77	-	77	-	89	-	89	-	69	-	69

治験総括報告書 Table 3.2.1.1.3（Section 15.1）（5.3.5.4-2）から引用

表 2.7.4.8-付録-40　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）（OCT-101 試験）（続き）

Potassium

	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	-	-	-	-	-	1	-	1	1	2	-	3
Normal	1	95	-	96	-	101	-	101	1	99	-	100	1	101	-	102	3	73	-	76
High	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	1	-	1
Total	1	96	-	97	1	102	-	103	1	99	-	100	1	102	-	103	4	76	-	80
Week 8																				
Low	-	3	-	3	-	-	-	-	-	1	-	1	-	-	-	-	-	-	-	-
Normal	1	90	-	91	1	102	-	103	1	93	-	94	1	98	-	99	4	74	-	78
High	-	1	-	1	-	-	-	-	-	1	-	1	-	2	-	2	-	-	-	-
Total	1	94	-	95	1	102	-	103	1	95	-	96	1	100	-	101	4	74	-	78
Week 12																				
Low	-	2	-	2	-	-	-	-	1	1	-	2	-	1	-	1	1	1	-	2
Normal	1	90	-	91	1	99	-	100	-	89	-	89	1	99	-	100	3	70	-	73
High	-	-	-	-	-	-	-	-	-	1	-	1	-	-	-	-	-	-	-	-
Total	1	92	-	93	1	99	-	100	1	91	-	92	1	100	-	101	4	71	-	75
Week 16																				
Low	-	3	-	3	1	-	-	1	-	-	-	-	-	-	-	-	-	-	-	-
Normal	1	71	-	72	-	83	-	83	1	77	-	78	1	87	-	88	4	65	-	69
High	-	-	-	-	-	-	-	-	-	-	-	-	-	1	-	1	-	-	-	-
Total	1	74	-	75	1	83	-	84	1	77	-	78	1	88	-	89	4	65	-	69
Week 20																				
Low	-	2	-	2	-	1	-	1	-	-	-	-	-	2	-	2	2	-	-	2
Normal	1	72	-	73	1	79	-	80	1	76	-	77	1	82	-	83	2	60	-	62
High	-	-	-	-	-	-	-	-	-	-	-	-	-	2	-	2	-	1	-	1
Total	1	74	-	75	1	80	-	81	1	76	-	77	1	86	-	87	4	61	-	65
Week 24																				
Low	-	1	-	1	-	1	-	1	-	-	-	-	1	1	-	2	-	-	-	-
Normal	-	67	-	67	1	77	-	78	1	75	-	76	-	85	-	85	4	58	-	62
High	-	-	-	-	-	-	-	-	-	-	-	-	-	1	-	1	-	-	-	-
Total	-	68	-	68	1	78	-	79	1	75	-	76	1	87	-	88	4	58	-	62
Follow-up																				
Low	-	6	-	6	-	2	-	2	-	2	-	2	-	-	-	-	-	-	-	-
Normal	1	70	-	71	1	80	-	81	1	74	-	75	1	88	-	89	4	65	-	69
High	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	1	76	-	77	1	82	-	83	1	76	-	77	1	88	-	89	4	65	-	69

治験総括報告書 Table 3.2.1.1.3（Section 15.1）（5.3.5.4-2）から引用

表 2.7.4.8-付録-40　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）（OCT-101 試験）（続き）

Chloride

	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	-	87	6	93	-	96	4	100	-	93	4	97	-	97	4	101	1	76	1	78
High	-	3	1	4	-	3	-	3	-	1	2	3	-	2	-	2	-	2	-	2
Total	-	90	7	97	-	99	4	103	-	94	6	100	-	99	4	103	1	78	1	80
Week 8																				
Low	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	88	5	93	-	96	4	100	-	89	6	95	-	95	3	98	1	75	1	77
High	-	-	2	2	-	3	-	3	-	1	-	1	-	2	1	3	-	1	-	1
Total	-	88	7	95	-	99	4	103	-	90	6	96	-	97	4	101	1	76	1	78
Week 12																				
Low	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	86	7	93	-	97	4	101	-	87	5	92	-	97	4	101	1	73	1	75
High	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	-	86	7	93	-	97	4	101	-	87	5	92	-	97	4	101	1	73	1	75
Week 16																				
Low	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	69	6	75	-	80	3	83	-	69	5	74	-	79	2	81	1	66	1	68
High	-	-	-	-	-	1	-	1	-	4	-	4	-	6	2	8	-	1	-	1
Total	-	69	6	75	-	81	3	84	-	73	5	78	-	85	4	89	1	67	1	69
Week 20																				
Low	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	69	6	75	-	75	3	78	-	69	5	74	-	79	3	82	1	61	-	62
High	-	-	-	-	-	3	-	3	-	3	-	3	-	4	1	5	-	2	1	3
Total	-	69	6	75	-	78	3	81	-	72	5	77	-	83	4	87	1	63	1	65
Week 24																				
Low	-	-	-	-	-	1	-	1	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	62	6	68	-	74	3	77	-	70	5	75	-	84	4	88	1	60	1	62
High	-	-	-	-	-	1	-	1	-	1	-	1	-	-	-	-	-	-	-	-
Total	-	62	6	68	-	76	3	79	-	71	5	76	-	84	4	88	1	60	1	62
Follow-up																				
Low	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	67	5	72	-	77	3	80	-	68	4	72	-	78	3	81	1	61	1	63
High	-	4	1	5	-	3	-	3	-	5	-	5	-	7	1	8	-	6	-	6
Total	-	71	6	77	-	80	3	83	-	73	4	77	-	85	4	89	1	67	1	69

治験総括報告書 Table 3.2.1.1.3（Section 15.1）（5.3.5.4-2）から引用

表 2.7.4.8-付録-40　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）（OCT-101 試験）（続き）

Calcium

	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	8	6	-	14	2	5	-	7	2	4	-	6	-	1	-	1	-	1	-	1
Normal	8	75	-	83	7	89	-	96	13	81	-	94	18	83	1	102	11	67	-	78
High	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	1	-	1
Total	16	81	-	97	9	94	-	103	15	85	-	100	18	84	1	103	11	69	-	80
Week 8																				
Low	8	4	-	12	1	5	-	6	4	1	-	5	-	-	-	-	-	-	-	-
Normal	8	75	-	83	8	89	-	97	11	80	-	91	17	81	1	99	11	66	-	77
High	-	-	-	-	-	-	-	-	-	-	-	-	-	2	-	2	-	1	-	1
Total	16	79	-	95	9	94	-	103	15	81	-	96	17	83	1	101	11	67	-	78
Week 12																				
Low	10	10	-	20	3	5	-	8	4	1	-	5	2	1	-	3	1	-	-	1
Normal	5	68	-	73	6	86	-	92	10	77	-	87	15	80	1	96	9	64	-	73
High	-	-	-	-	-	-	-	-	-	-	-	-	-	2	-	2	-	1	-	1
Total	15	78	-	93	9	91	-	100	14	78	-	92	17	83	1	101	10	65	-	75
Week 16																				
Low	9	2	-	11	1	1	-	2	2	-	-	2	1	-	-	1	-	-	-	-
Normal	5	59	-	64	6	76	-	82	6	69	-	75	16	70	1	87	9	59	-	68
High	-	-	-	-	-	-	-	-	-	1	-	1	-	1	-	1	-	1	-	1
Total	14	61	-	75	7	77	-	84	8	70	-	78	17	71	1	89	9	60	-	69
Week 20																				
Low	5	2	-	7	1	2	-	3	2	4	-	6	1	-	-	1	-	1	-	1
Normal	9	59	-	68	6	72	-	78	6	64	-	70	16	69	1	86	8	54	-	62
High	-	-	-	-	-	-	-	-	-	1	-	1	-	-	-	-	-	2	-	2
Total	14	61	-	75	7	74	-	81	8	69	-	77	17	69	1	87	8	57	-	65
Week 24																				
Low	6	6	-	12	2	5	-	7	3	4	-	7	1	-	-	1	-	2	-	2
Normal	5	51	-	56	5	67	-	72	5	63	-	68	16	70	1	87	7	52	-	59
High	-	-	-	-	-	-	-	-	-	1	-	1	-	-	-	-	-	1	-	1
Total	11	57	-	68	7	72	-	79	8	68	-	76	17	70	1	88	7	55	-	62
Follow-up																				
Low	7	8	-	15	4	13	-	17	2	9	-	11	3	4	-	7	-	1	-	1
Normal	7	55	-	62	3	63	-	66	6	60	-	66	14	67	1	82	9	58	-	67
High	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	1	-	1
Total	14	63	-	77	7	76	-	83	8	69	-	77	17	71	1	89	9	60	-	69

治験総括報告書 Table 3.2.1.1.3（Section 15.1）（5.3.5.4-2）から引用

表 2.7.4.8-付録-40　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）（OCT-101 試験）（続き）

Phosphorus

	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	-	87	5	92	-	93	3	96	-	81	3	84	1	77	1	79	-	64	1	65
High	-	2	3	5	-	6	1	7	-	13	3	16	-	21	3	24	-	11	4	15
Total	-	89	8	97	-	99	4	103	-	94	6	100	1	98	4	103	-	75	5	80
Week 8																				
Low	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	83	6	89	-	95	4	99	-	76	2	78	1	71	2	74	-	49	3	52
High	-	4	2	6	-	4	-	4	-	14	4	18	-	25	2	27	-	24	2	26
Total	-	87	8	95	-	99	4	103	-	90	6	96	1	96	4	101	-	73	5	78
Week 12																				
Low	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	79	6	85	-	92	4	96	-	67	3	70	1	50	2	53	-	41	-	41
High	-	6	2	8	-	4	-	4	-	19	3	22	-	46	2	48	-	30	4	34
Total	-	85	8	93	-	96	4	100	-	86	6	92	1	96	4	101	-	71	4	75
Week 16																				
Low	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	67	4	71	-	79	4	83	-	55	3	58	1	52	1	54	-	45	-	45
High	-	2	2	4	-	1	-	1	-	17	3	20	-	32	3	35	-	21	3	24
Total	-	69	6	75	-	80	4	84	-	72	6	78	1	84	4	89	-	66	3	69
Week 20																				
Low	-	-	-	-	-	-	-	-	-	1	-	1	-	-	-	-	-	-	-	-
Normal	-	67	6	73	-	74	3	77	-	60	3	63	1	48	2	51	-	43	1	44
High	-	2	-	2	-	4	-	4	-	10	3	13	-	34	2	36	-	19	2	21
Total	-	69	6	75	-	78	3	81	-	71	6	77	1	82	4	87	-	62	3	65
Week 24																				
Low	-	1	-	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	61	4	65	-	70	3	73	-	54	4	58	1	53	2	56	-	30	-	30
High	-	2	-	2	-	6	-	6	-	16	2	18	-	30	2	32	-	29	3	32
Total	-	64	4	68	-	76	3	79	-	70	6	76	1	83	4	88	-	59	3	62
Follow-up																				
Low	-	-	-	-	-	-	-	-	-	1	-	1	-	-	-	-	-	-	-	-
Normal	-	69	4	73	-	75	4	79	-	68	6	74	1	78	4	83	-	49	2	51
High	-	2	2	4	-	4	-	4	-	2	-	2	-	6	-	6	-	17	1	18
Total	-	71	6	77	-	79	4	83	-	71	6	77	1	84	4	89	-	66	3	69

治験総括報告書 Table 3.2.1.1.3（Section 15.1）（5.3.5.4-2）から引用

表 2.7.4.8-付録-41　血液生化学検査値の MAV の発現頻度（安全性データの解析対象集団）（CCT-002 試験）

	Number of Subjects (%)	
	TAK-385 40mg (N=138)	Leuprorelin (N=142)
Total protein		
Total protein Lower	0/138(0.0)	0/142(0.0)
Total protein Upper	0/138(0.0)	0/142(0.0)
Albumin		
Albumin Lower	0/138(0.0)	0/142(0.0)
Blood urea nitrogen		
Blood urea nitrogen Upper	0/138(0.0)	0/142(0.0)
Urate		
Urate Upper	0/138(0.0)	0/142(0.0)
Creatinine		
Creatinine Upper	0/138(0.0)	0/142(0.0)
Total cholesterol		
Total cholesterol Upper	6/138(4.3)	4/142(2.8)
Triglycerides		
Triglycerides Upper	4/138(2.9)	12/142(8.5)
Total bilirubin		
Total bilirubin Upper	0/138(0.0)	0/142(0.0)
Sodium		
Sodium Lower	0/138(0.0)	0/142(0.0)
Sodium Upper	0/138(0.0)	0/142(0.0)
Potassium		
Potassium Lower	0/138(0.0)	0/142(0.0)
Potassium Upper	0/138(0.0)	0/142(0.0)

治験総括報告書 Table 15.3.2.1.4.2（5.3.5.1-2）から引用

表 2.7.4.8-付録-41　血液生化学検査値の MAV の発現頻度（安全性データの解析対象集団）（CCT-002 試験）（続き）

	Number of Subjects (%)	
	TAK-385 40mg (N=138)	Leuprorelin (N=142)
Chloride		
Chloride Lower	0/138(0.0)	0/142(0.0)
Chloride Upper	0/138(0.0)	0/142(0.0)
Calcium		
Calcium Lower	0/138(0.0)	0/142(0.0)
Calcium Upper	0/138(0.0)	0/142(0.0)
Phosphate		
Phosphate Lower	0/138(0.0)	0/142(0.0)
Phosphate Upper	0/138(0.0)	0/142(0.0)
Alkaline phosphatase		
Alkaline phosphatase Upper	0/138(0.0)	0/142(0.0)
Creatine kinase		
Creatine kinase Upper	1/138(0.7)	0/142(0.0)
AST		
AST Upper	2/138(1.4)	0/142(0.0)
ALT		
ALT Upper	3/138(2.2)	2/142(1.4)
GGT		
GGT Upper	10/138(7.2)	6/142(4.2)
Glucose		
Glucose Lower	0/138(0.0)	0/142(0.0)
Glucose Upper	0/138(0.0)	0/142(0.0)
Magnesium		
Magnesium Lower	0/138(0.0)	0/142(0.0)
Magnesium Upper	0/138(0.0)	0/142(0.0)

治験総括報告書 Table 15.3.2.1.4.3（5.3.5.1-2）から引用

表 2.7.4.8-付録-41　血液生化学検査値の MAV の発現頻度（安全性データの解析対象集団）（CCT-002 試験）（続き）

	Number of Subjects (%)	
	TAK-385 40mg (N=138)	Leuprorelin (N=142)
HGB A1C		
HGB A1C Upper	0/138(0.0)	2/142(1.4)

治験総括報告書 Table 15.3.2.1.4.4（5.3.5.1-2）から引用

表 2.7.4.8-付録-42　血液生化学検査値の MAV の発現頻度（安全性データの解析対象集団）（3008 試験）

	Number of Subjects (%)	
	TAK-385 40mg (N=33)	Placebo (N=32)
Total protein		
Total protein Lower	0/33(0.0)	0/32(0.0)
Total protein Upper	0/33(0.0)	0/32(0.0)
Albumin		
Albumin Lower	0/33(0.0)	0/32(0.0)
Blood urea nitrogen		
Blood urea nitrogen Upper	0/33(0.0)	0/32(0.0)
Urate		
Urate Upper	0/33(0.0)	0/32(0.0)
Creatinine		
Creatinine Upper	0/33(0.0)	0/32(0.0)
Total cholesterol		
Total cholesterol Upper	2/33(6.1)	0/32(0.0)
Triglycerides		
Triglycerides Upper	0/33(0.0)	3/32(9.4)
Total bilirubin		
Total bilirubin Upper	1/33(3.0)	0/32(0.0)
Sodium		
Sodium Lower	0/33(0.0)	0/32(0.0)
Sodium Upper	0/33(0.0)	0/32(0.0)
Potassium		
Potassium Lower	0/33(0.0)	0/32(0.0)
Potassium Upper	0/33(0.0)	0/32(0.0)

治験総括報告書 Table 15.3.2.1.4.2（5.3.5.1-3）から引用

表 2.7.4.8-付録-42　血液生化学検査値の MAV の発現頻度（安全性データの解析対象集団）（3008 試験）（続き）

	Number of Subjects (%)	
	TAK-385 40mg (N=33)	Placebo (N=32)
Chloride		
Chloride Lower	0/33(0.0)	0/32(0.0)
Chloride Upper	0/33(0.0)	0/32(0.0)
Calcium		
Calcium Lower	0/33(0.0)	0/32(0.0)
Calcium Upper	0/33(0.0)	0/32(0.0)
Phosphate		
Phosphate Lower	0/33(0.0)	0/32(0.0)
Phosphate Upper	0/33(0.0)	0/32(0.0)
Alkaline phosphatase		
Alkaline phosphatase Upper	0/33(0.0)	0/32(0.0)
Creatine kinase		
Creatine kinase Upper	0/33(0.0)	0/32(0.0)
AST		
AST Upper	0/33(0.0)	0/32(0.0)
ALT		
ALT Upper	0/33(0.0)	0/32(0.0)
GGT		
GGT Upper	1/33(3.0)	0/32(0.0)
Glucose		
Glucose Lower	0/33(0.0)	0/32(0.0)
Glucose Upper	0/33(0.0)	0/32(0.0)
Magnesium		
Magnesium Lower	0/33(0.0)	0/32(0.0)
Magnesium Upper	0/33(0.0)	0/32(0.0)

治験総括報告書 Table 15.3.2.1.4.3（5.3.5.1-3）から引用

表 2.7.4.8-付録-42　血液生化学検査値の MAV の発現頻度（安全性データの解析対象集団）（3008 試験）（続き）

	Number of Subjects (%)	
	TAK-385 40mg (N=33)	Placebo (N=32)
HGB A1C		
HGB A1C Upper	0/33(0.0)	0/32(0.0)

治験総括報告書 Table 15.3.2.1.4.4（5.3.5.1-3）から引用

表 2.7.4.8-付録-43　尿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）

Protein

	Baseline					
	TAK-385 40mg (N=138)			Leuprorelin (N=142)		
Visit	Normal	Abnormal	Total	Normal	Abnormal	Total
Week 4						
Normal	95	31	126	104	33	137
Abnormal	7	5	12	3	2	5
Total	102	36	138	107	35	142
Week 8						
Normal	95	30	125	104	34	138
Abnormal	4	6	10	3	1	4
Total	99	36	135	107	35	142
Week 12						
Normal	93	31	124	102	33	135
Abnormal	2	4	6	4	2	6
Total	95	35	130	106	35	141
Week 16						
Normal	92	32	124	102	32	134
Abnormal	2	3	5	2	-	2
Total	94	35	129	104	32	136
Week 20						
Normal	89	34	123	100	30	130
Abnormal	2	1	3	1	1	2
Total	91	35	126	101	31	132
Week 24						
Normal	87	28	115	98	31	129
Abnormal	3	4	7	2	-	2
Total	90	32	122	100	31	131
Follow-up						
Normal	97	32	129	104	35	139
Abnormal	2	4	6	2	-	2
Total	99	36	135	106	35	141

治験総括報告書 Table 15.3.2.2.2（5.3.5.1-2）から引用

表 2.7.4.8-付録-43　尿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

	Baseline					
	TAK-385 40mg (N=138)			Leuprorelin (N=142)		
Visit	Normal	Abnormal	Total	Normal	Abnormal	Total
Week 4						
Normal	138	-	138	142	-	142
Abnormal	-	-	-	-	-	-
Total	138	-	138	142	-	142
Week 8						
Normal	135	-	135	142	-	142
Abnormal	-	-	-	-	-	-
Total	135	-	135	142	-	142
Week 12						
Normal	130	-	130	139	-	139
Abnormal	-	-	-	2	-	2
Total	130	-	130	141	-	141
Week 16						
Normal	129	-	129	136	-	136
Abnormal	-	-	-	-	-	-
Total	129	-	129	136	-	136
Week 20						
Normal	126	-	126	131	-	131
Abnormal	-	-	-	1	-	1
Total	126	-	126	132	-	132
Week 24						
Normal	122	-	122	130	-	130
Abnormal	-	-	-	1	-	1
Total	122	-	122	131	-	131
Follow-up						
Normal	135	-	135	139	-	139
Abnormal	-	-	-	2	-	2
Total	135	-	135	141	-	141

治験総括報告書 Table 15.3.2.2.2（5.3.5.1-2）から引用

表 2.7.4.8-付録-43　尿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）

Occult Blood

	Baseline					
	TAK-385 40mg (N=138)			Leuprorelin (N=142)		
Visit	Normal	Abnormal	Total	Normal	Abnormal	Total
Week 4						
Normal	15	79	94	18	64	82
Abnormal	5	39	44	7	53	60
Total	20	118	138	25	117	142
Week 8						
Normal	16	87	103	23	88	111
Abnormal	3	29	32	2	29	31
Total	19	116	135	25	117	142
Week 12						
Normal	16	89	105	22	98	120
Abnormal	2	23	25	2	19	21
Total	18	112	130	24	117	141
Week 16						
Normal	16	92	108	23	90	113
Abnormal	2	19	21	1	22	23
Total	18	111	129	24	112	136
Week 20						
Normal	17	84	101	21	90	111
Abnormal	1	24	25	2	19	21
Total	18	108	126	23	109	132
Week 24						
Normal	15	81	96	22	90	112
Abnormal	3	23	26	1	18	19
Total	18	104	122	23	108	131
Follow-up						
Normal	16	82	98	24	93	117
Abnormal	4	33	37	-	24	24
Total	20	115	135	24	117	141

治験総括報告書 Table 15.3.2.2.2（5.3.5.1-2）から引用

表 2.7.4.8-付録-43　尿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

	Baseline					
	TAK-385 40mg (N=138)			Leuprorelin (N=142)		
Visit	Normal	Abnormal	Total	Normal	Abnormal	Total
Week 4						
Normal	138	-	138	142	-	142
Abnormal	-	-	-	-	-	-
Total	138	-	138	142	-	142
Week 8						
Normal	135	-	135	142	-	142
Abnormal	-	-	-	-	-	-
Total	135	-	135	142	-	142
Week 12						
Normal	130	-	130	141	-	141
Abnormal	-	-	-	-	-	-
Total	130	-	130	141	-	141
Week 16						
Normal	129	-	129	136	-	136
Abnormal	-	-	-	-	-	-
Total	129	-	129	136	-	136
Week 20						
Normal	126	-	126	132	-	132
Abnormal	-	-	-	-	-	-
Total	126	-	126	132	-	132
Week 24						
Normal	122	-	122	131	-	131
Abnormal	-	-	-	-	-	-
Total	122	-	122	131	-	131
Follow-up						
Normal	135	-	135	141	-	141
Abnormal	-	-	-	-	-	-
Total	135	-	135	141	-	141

治験総括報告書 Table 15.3.2.2.2（5.3.5.1-2）から引用

表 2.7.4.8-付録-43　尿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）

Urobilinogen

	Baseline					
	TAK-385 40mg (N=138)			Leuprorelin (N=142)		
Visit	Normal	Abnormal	Total	Normal	Abnormal	Total
Week 4						
Normal	138	-	138	142	-	142
Abnormal	-	-	-	-	-	-
Total	138	-	138	142	-	142
Week 8						
Normal	135	-	135	142	-	142
Abnormal	-	-	-	-	-	-
Total	135	-	135	142	-	142
Week 12						
Normal	130	-	130	141	-	141
Abnormal	-	-	-	-	-	-
Total	130	-	130	141	-	141
Week 16						
Normal	129	-	129	136	-	136
Abnormal	-	-	-	-	-	-
Total	129	-	129	136	-	136
Week 20						
Normal	126	-	126	132	-	132
Abnormal	-	-	-	-	-	-
Total	126	-	126	132	-	132
Week 24						
Normal	122	-	122	131	-	131
Abnormal	-	-	-	-	-	-
Total	122	-	122	131	-	131
Follow-up						
Normal	135	-	135	141	-	141
Abnormal	-	-	-	-	-	-
Total	135	-	135	141	-	141

治験総括報告書 Table 15.3.2.2.2（5.3.5.1-2）から引用

表 2.7.4.8-付録-44　尿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）

Protein

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

治験総括報告書 Table 15.3.2.2.2（5.3.5.1-3）から引用

表 2.7.4.8-付録-44　尿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

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

治験総括報告書 Table 15.3.2.2.2（5.3.5.1-3）から引用

表 2.7.4.8-付録-44　尿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）

Occult Blood

	Baseline					
	TAK-385 40mg (N=33)			Placebo (N=32)		
Visit	Normal	Abnormal	Total	Normal	Abnormal	Total
Week 4						
Normal	6	24	30	3	11	14
Abnormal	-	3	3	3	15	18
Total	6	27	33	6	26	32
Week 8						
Normal	5	22	27	5	16	21
Abnormal	1	4	5	1	9	10
Total	6	26	32	6	25	31
Week 12						
Normal	6	19	25	6	17	23
Abnormal	-	7	7	-	8	8
Total	6	26	32	6	25	31
Follow-up						
Normal	6	20	26	6	14	20
Abnormal	-	7	7	-	12	12
Total	6	27	33	6	26	32

治験総括報告書 Table 15.3.2.2.2（5.3.5.1-3）から引用

表 2.7.4.8-付録-44　尿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

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

治験総括報告書 Table 15.3.2.2.2（5.3.5.1-3）から引用

表 2.7.4.8-付録-44　尿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）

Urobilinogen

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

治験総括報告書 Table 15.3.2.2.2（5.3.5.1-3）から引用

表 2.7.4.8-付録-45　バイタルサイン及び体重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-001 試験）

Systolic Blood Pressure (mmHg)

Visit / Statistics	Placebo (N=57) Observed Value at Visit	Placebo (N=57) Change from Baseline	TAK-385 10mg (N=48) Observed Value at Visit	TAK-385 10mg (N=48) Change from Baseline	TAK-385 20mg (N=55) Observed Value at Visit	TAK-385 20mg (N=55) Change from Baseline	TAK-385 40mg (N=54) Observed Value at Visit	TAK-385 40mg (N=54) Change from Baseline
Week 0								
N	57		48		55		54	
Mean	116.2		116.8		116.7		116.8	
SD	13.33		13.70		14.17		16.10	
Minimum	90		90		91		86	
Q1	105.0		106.5		108.0		105.0	
Median	118.0		116.5		116.0		116.0	
Q3	124.0		127.5		122.0		126.0	
Maximum	148		142		172		172	
Week 4								
N	57	57	48	48	55	55	54	54
Mean	117.5	1.4	117.1	0.3	117.4	0.7	116.5	-0.3
SD	13.30	9.88	14.01	10.99	15.07	12.10	16.13	10.33
Minimum	89	-20	90	-27	70	-40	86	-27
Q1	107.0	-5.0	108.5	-7.5	110.0	-7.0	104.0	-5.0
Median	119.0	2.0	114.0	1.0	116.0	2.0	114.0	0.0
Q3	127.0	9.0	126.5	7.5	125.0	7.0	125.0	8.0
Maximum	148	20	150	21	152	24	176	17
Week 8								
N	56	56	48	48	54	54	54	54
Mean	114.6	-1.9	114.1	-2.7	114.3	-2.5	115.1	-1.7
SD	14.14	11.05	14.03	13.13	12.97	10.06	16.77	11.02
Minimum	85	-27	93	-43	85	-29	86	-29
Q1	105.0	-9.0	104.0	-8.5	106.0	-10.0	103.0	-9.0
Median	112.0	-3.0	113.0	-3.0	113.0	-3.0	110.5	-1.0
Q3	122.0	5.0	121.0	5.0	122.0	3.0	124.0	5.0
Maximum	156	25	150	33	146	22	176	24
Week 12								
N	55	55	47	47	53	53	54	54
Mean	116.3	-0.1	115.4	-1.5	113.8	-3.5	114.1	-2.7
SD	13.54	12.20	12.08	10.23	13.14	10.50	15.53	10.70
Minimum	84	-36	93	-26	90	-27	88	-21
Q1	108.0	-7.0	105.0	-7.0	104.0	-9.0	104.0	-12.0
Median	113.0	1.0	115.0	-2.0	111.0	-3.0	111.5	-3.0
Q3	127.0	9.0	123.0	4.0	123.0	3.0	120.0	5.0
Maximum	146	19	148	24	152	18	160	29

治験総括報告書 Table 3.3.2.1.1（Section 16.1.9.5）（5.3.5.1-1）から引用

表 2.7.4.8-付録-45　バイタルサイン及び体重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-001 試験）（続き）

Systolic Blood Pressure (mmHg)

Visit / Statistics	Placebo (N=57) Observed Value at Visit	Placebo (N=57) Change from Baseline	TAK-385 10mg (N=48) Observed Value at Visit	TAK-385 10mg (N=48) Change from Baseline	TAK-385 20mg (N=55) Observed Value at Visit	TAK-385 20mg (N=55) Change from Baseline	TAK-385 40mg (N=54) Observed Value at Visit	TAK-385 40mg (N=54) Change from Baseline
Follow-up								
N	57	57	48	48	55	55	54	54
Mean	114.2	-2.0	116.1	-0.7	112.5	-4.2	114.7	-2.1
SD	14.92	10.63	14.77	13.08	12.43	10.30	16.60	12.54
Minimum	86	-32	91	-29	92	-26	81	-27
Q1	104.0	-8.0	105.0	-9.5	106.0	-13.0	103.0	-11.0
Median	112.0	-2.0	114.5	-2.0	113.0	-6.0	114.0	-1.0
Q3	125.0	6.0	124.5	7.5	119.0	3.0	126.0	6.0
Maximum	154	29	148	28	146	17	173	21

治験総括報告書 Table 3.3.2.1.1（Section 16.1.9.5）（5.3.5.1-1）から引用

表 2.7.4.8-付録-45　バイタルサイン及び体重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-001 試験）（続き）

Diastolic Blood Pressure (mmHg)

Visit / Statistics	Placebo (N=57) Observed Value at Visit	Placebo (N=57) Change from Baseline	TAK-385 10mg (N=48) Observed Value at Visit	TAK-385 10mg (N=48) Change from Baseline	TAK-385 20mg (N=55) Observed Value at Visit	TAK-385 20mg (N=55) Change from Baseline	TAK-385 40mg (N=54) Observed Value at Visit	TAK-385 40mg (N=54) Change from Baseline
Week 0								
N	57		48		55		54	
Mean	70.9		69.6		72.5		71.5	
SD	10.86		10.33		9.77		10.32	
Minimum	48		50		50		53	
Q1	64.0		62.5		66.0		65.0	
Median	72.0		69.5		72.0		70.0	
Q3	78.0		76.5		78.0		77.0	
Maximum	99		92		94		102	
Week 4								
N	57	57	48	48	55	55	54	54
Mean	73.3	2.4	72.1	2.4	72.1	-0.4	72.6	1.1
SD	10.77	8.66	9.90	7.34	11.02	9.89	11.43	8.04
Minimum	47	-17	56	-14	46	-29	51	-18
Q1	66.0	-3.0	65.0	-1.0	64.0	-5.0	65.0	-2.0
Median	72.0	2.0	71.0	4.0	71.0	1.0	72.0	1.0
Q3	82.0	10.0	78.0	9.0	78.0	5.0	77.0	6.0
Maximum	93	21	97	14	99	24	109	18
Week 8								
N	56	56	48	48	54	54	54	54
Mean	72.0	0.9	69.4	-0.2	70.0	-2.5	72.1	0.6
SD	10.08	8.38	10.30	6.33	9.46	8.55	11.90	9.78
Minimum	49	-20	50	-19	42	-32	55	-21
Q1	66.0	-4.5	61.5	-4.0	65.0	-7.0	64.0	-6.0
Median	70.5	-0.5	68.0	0.0	70.0	-2.0	70.0	0.0
Q3	79.0	5.5	77.5	3.5	76.0	2.0	78.0	8.0
Maximum	94	20	96	18	94	26	108	22
Week 12								
N	55	55	47	47	53	53	54	54
Mean	70.7	-0.4	70.3	0.4	70.6	-1.9	72.4	0.9
SD	10.95	8.61	9.78	7.32	10.47	10.34	11.00	7.22
Minimum	40	-29	54	-14	49	-22	55	-17
Q1	63.0	-4.0	63.0	-3.0	63.0	-7.0	64.0	-4.0
Median	72.0	0.0	69.0	0.0	70.0	-2.0	71.5	1.0
Q3	79.0	4.0	78.0	5.0	77.0	2.0	78.0	6.0
Maximum	95	20	93	26	100	50	105	17

治験総括報告書 Table 3.3.2.1.1（Section 16.1.9.5）（5.3.5.1-1）から引用

表 2.7.4.8-付録-45　バイタルサイン及び体重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-001 試験）（続き）

Diastolic Blood Pressure (mmHg)

Visit / Statistics	Placebo (N=57) Observed Value at Visit	Placebo (N=57) Change from Baseline	TAK-385 10mg (N=48) Observed Value at Visit	TAK-385 10mg (N=48) Change from Baseline	TAK-385 20mg (N=55) Observed Value at Visit	TAK-385 20mg (N=55) Change from Baseline	TAK-385 40mg (N=54) Observed Value at Visit	TAK-385 40mg (N=54) Change from Baseline
Follow-up								
N	57	57	48	48	55	55	54	54
Mean	69.6	-1.3	69.9	0.3	68.3	-4.2	69.6	-2.0
SD	9.42	8.42	9.99	8.00	10.87	9.14	11.62	6.80
Minimum	50	-18	51	-18	44	-26	51	-17
Q1	63.0	-7.0	62.5	-5.5	59.0	-10.0	62.0	-7.0
Median	70.0	-3.0	68.0	-1.0	69.0	-3.0	68.0	-2.0
Q3	77.0	5.0	75.0	3.5	76.0	3.0	76.0	2.0
Maximum	90	20	96	21	99	18	106	15

治験総括報告書 Table 3.3.2.1.1（Section 16.1.9.5）（5.3.5.1-1）から引用

表 2.7.4.8-付録-45　バイタルサイン及び体重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-001 試験）（続き）

Pulse (bpm)

Visit / Statistics	Placebo (N=57) Observed Value at Visit	Placebo (N=57) Change from Baseline	TAK-385 10mg (N=48) Observed Value at Visit	TAK-385 10mg (N=48) Change from Baseline	TAK-385 20mg (N=55) Observed Value at Visit	TAK-385 20mg (N=55) Change from Baseline	TAK-385 40mg (N=54) Observed Value at Visit	TAK-385 40mg (N=54) Change from Baseline
Week 0								
N	57		48		55		54	
Mean	74.9		71.1		74.9		73.5	
SD	10.63		8.54		10.95		11.34	
Minimum	49		49		46		48	
Q1	68.0		64.0		69.0		65.0	
Median	75.0		72.0		72.0		71.5	
Q3	84.0		76.0		83.0		81.0	
Maximum	98		91		96		103	
Week 4								
N	57	57	48	48	55	55	54	54
Mean	75.8	0.8	72.8	1.6	72.9	-1.9	73.0	-0.5
SD	11.20	8.42	10.69	9.91	9.54	7.57	11.92	8.13
Minimum	46	-15	54	-16	54	-22	48	-24
Q1	68.0	-4.0	65.0	-5.0	66.0	-8.0	66.0	-5.0
Median	74.0	0.0	72.0	0.5	71.0	0.0	72.0	0.0
Q3	85.0	6.0	78.5	4.5	80.0	4.0	81.0	4.0
Maximum	99	24	94	31	97	11	99	23
Week 8								
N	56	56	48	48	54	54	54	54
Mean	74.5	-0.5	73.1	2.0	72.8	-2.0	72.1	-1.4
SD	12.30	8.37	8.67	9.09	9.66	9.70	9.71	7.31
Minimum	50	-18	55	-20	55	-18	48	-18
Q1	64.5	-6.5	66.0	-3.0	66.0	-10.0	66.0	-6.0
Median	76.0	-0.5	73.5	1.0	72.5	-1.0	71.0	-1.0
Q3	80.5	3.0	78.5	7.5	79.0	3.0	77.0	3.0
Maximum	117	20	94	26	92	24	100	16
Week 12								
N	55	55	47	47	53	53	54	54
Mean	75.5	0.5	73.0	1.4	73.2	-1.9	73.3	-0.2
SD	11.70	8.83	8.63	8.57	9.56	10.04	9.47	8.82
Minimum	56	-14	54	-24	55	-26	40	-20
Q1	67.0	-7.0	68.0	-3.0	66.0	-8.0	68.0	-5.0
Median	73.0	0.0	72.0	-1.0	72.0	-3.0	72.0	-0.5
Q3	84.0	7.0	79.0	6.0	79.0	4.0	80.0	5.0
Maximum	102	21	91	22	99	24	91	24

治験総括報告書 Table 3.3.2.1.1（Section 16.1.9.5）（5.3.5.1-1）から引用

表 2.7.4.8-付録-45　バイタルサイン及び体重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-001 試験）（続き）

Pulse (bpm)

Visit / Statistics	Placebo (N=57) Observed Value at Visit	Placebo (N=57) Change from Baseline	TAK-385 10mg (N=48) Observed Value at Visit	TAK-385 10mg (N=48) Change from Baseline	TAK-385 20mg (N=55) Observed Value at Visit	TAK-385 20mg (N=55) Change from Baseline	TAK-385 40mg (N=54) Observed Value at Visit	TAK-385 40mg (N=54) Change from Baseline
Follow-up								
N	57	57	48	48	55	55	54	54
Mean	75.9	1.0	75.2	4.1	75.6	0.8	74.5	1.0
SD	10.28	8.56	9.61	8.90	10.75	11.48	10.41	8.52
Minimum	55	-16	58	-18	53	-18	43	-17
Q1	69.0	-4.0	68.5	-2.5	67.0	-10.0	67.0	-5.0
Median	77.0	-1.0	74.5	5.5	75.0	-1.0	74.5	1.0
Q3	81.0	6.0	82.5	10.0	85.0	10.0	82.0	8.0
Maximum	103	20	96	25	98	23	101	19

治験総括報告書 Table 3.3.2.1.1（Section 16.1.9.5）（5.3.5.1-1）から引用

表 2.7.4.8-付録-45　バイタルサイン及び体重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-001 試験）（続き）

Temperature (℃)

Visit / Statistics	Placebo (N=57) Observed Value at Visit	Placebo (N=57) Change from Baseline	TAK-385 10mg (N=48) Observed Value at Visit	TAK-385 10mg (N=48) Change from Baseline	TAK-385 20mg (N=55) Observed Value at Visit	TAK-385 20mg (N=55) Change from Baseline	TAK-385 40mg (N=54) Observed Value at Visit	TAK-385 40mg (N=54) Change from Baseline
Week 0								
N	57		48		55		54	
Mean	36.39		36.31		36.25		36.37	
SD	0.410		0.411		0.440		0.442	
Minimum	35.4		34.8		35.0		35.5	
Q1	36.20		36.10		35.90		36.00	
Median	36.40		36.30		36.30		36.40	
Q3	36.70		36.60		36.70		36.70	
Maximum	37.3		37.1		37.0		37.7	
Week 4								
N	57	57	48	48	55	55	54	54
Mean	36.46	0.07	36.35	0.04	36.30	0.05	36.23	-0.14
SD	0.415	0.402	0.463	0.419	0.404	0.477	0.479	0.442
Minimum	35.3	-1.1	35.4	-1.0	35.3	-1.3	34.8	-1.1
Q1	36.20	-0.10	36.00	-0.20	36.00	-0.20	35.80	-0.40
Median	36.50	0.10	36.35	0.10	36.40	0.00	36.30	-0.10
Q3	36.80	0.30	36.75	0.35	36.60	0.30	36.50	0.20
Maximum	37.4	1.1	37.2	0.7	37.1	1.5	37.7	0.6
Week 8								
N	56	56	48	48	54	54	54	54
Mean	36.35	-0.04	36.28	-0.03	36.27	0.01	36.15	-0.22
SD	0.423	0.483	0.462	0.433	0.404	0.389	0.548	0.523
Minimum	35.2	-1.3	35.0	-0.8	35.4	-1.1	34.0	-1.8
Q1	36.05	-0.20	36.00	-0.40	36.00	-0.20	35.80	-0.60
Median	36.40	0.00	36.30	-0.10	36.30	0.00	36.20	-0.20
Q3	36.70	0.30	36.60	0.25	36.60	0.30	36.50	0.10
Maximum	37.2	1.1	37.1	0.9	37.1	0.8	37.2	0.8
Week 12								
N	55	55	47	47	53	53	54	54
Mean	36.37	-0.01	36.30	-0.01	36.24	-0.03	36.20	-0.16
SD	0.423	0.465	0.376	0.364	0.418	0.390	0.505	0.483
Minimum	35.4	-1.0	35.4	-0.8	35.1	-0.7	34.4	-1.4
Q1	36.00	-0.30	36.00	-0.20	36.00	-0.30	35.80	-0.50
Median	36.50	0.00	36.30	-0.10	36.30	0.00	36.25	-0.10
Q3	36.70	0.30	36.60	0.30	36.50	0.20	36.60	0.10
Maximum	37.3	1.1	37.0	0.7	37.0	0.9	37.7	1.1

治験総括報告書 Table 3.3.2.1.1（Section 16.1.9.5）（5.3.5.1-1）から引用

表 2.7.4.8-付録-45　バイタルサイン及び体重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-001 試験）（続き）

Temperature (℃ C)

Visit / Statistics	Placebo (N=57) Observed Value at Visit	Placebo (N=57) Change from Baseline	TAK-385 10mg (N=48) Observed Value at Visit	TAK-385 10mg (N=48) Change from Baseline	TAK-385 20mg (N=55) Observed Value at Visit	TAK-385 20mg (N=55) Change from Baseline	TAK-385 40mg (N=54) Observed Value at Visit	TAK-385 40mg (N=54) Change from Baseline
Follow-up								
N	57	57	48	48	55	55	54	54
Mean	36.44	0.05	36.36	0.05	36.44	0.19	36.44	0.07
SD	0.444	0.503	0.336	0.362	0.388	0.474	0.480	0.481
Minimum	35.2	-1.6	35.6	-0.8	35.6	-0.8	35.0	-1.4
Q1	36.20	-0.20	36.15	-0.15	36.10	-0.10	36.30	-0.20
Median	36.50	0.00	36.35	0.10	36.50	0.20	36.45	0.10
Q3	36.80	0.40	36.60	0.30	36.80	0.40	36.70	0.40
Maximum	37.3	1.4	36.9	1.0	37.0	1.7	37.6	1.1

治験総括報告書 Table 3.3.2.1.1（Section 16.1.9.5）（5.3.5.1-1）から引用

表 2.7.4.8-付録-45　バイタルサイン及び体重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-001 試験）（続き）

Weight (kg)

Visit / Statistics	Placebo (N=57) Observed Value at Visit	Placebo (N=57) Change from Baseline	TAK-385 10mg (N=48) Observed Value at Visit	TAK-385 10mg (N=48) Change from Baseline	TAK-385 20mg (N=55) Observed Value at Visit	TAK-385 20mg (N=55) Change from Baseline	TAK-385 40mg (N=54) Observed Value at Visit	TAK-385 40mg (N=54) Change from Baseline
Week 0								
N	57		48		55		54	
Mean	60.73		57.85		54.73		57.18	
SD	11.759		7.781		7.724		7.153	
Minimum	44.3		41.4		41.3		43.0	
Q1	50.40		52.90		49.60		52.80	
Median	59.20		57.15		54.00		56.00	
Q3	69.60		62.25		59.00		61.00	
Maximum	85.6		77.8		83.0		78.2	
Week 4								
N	57	57	48	48	55	55	54	54
Mean	60.80	0.07	57.56	-0.29	54.26	-0.47	56.54	-0.64
SD	11.815	0.853	7.993	0.990	7.714	0.797	7.351	0.820
Minimum	44.8	-1.7	40.4	-2.1	41.0	-2.6	42.5	-2.4
Q1	50.40	-0.50	51.60	-1.00	49.40	-1.00	52.00	-1.20
Median	59.00	0.00	56.70	-0.30	53.00	-0.40	55.60	-0.50
Q3	70.10	0.50	62.50	0.50	59.20	0.00	60.50	0.00
Maximum	85.0	2.7	77.9	1.8	82.0	1.0	78.5	1.0
Week 8								
N	56	56	48	48	54	54	54	54
Mean	60.94	-0.06	57.45	-0.39	54.03	-0.64	56.51	-0.67
SD	11.735	1.256	8.096	1.134	7.960	0.869	7.466	1.131
Minimum	44.4	-4.1	39.7	-2.9	40.2	-3.0	42.8	-3.6
Q1	51.35	-0.60	52.15	-1.40	49.20	-1.10	51.50	-1.40
Median	59.70	0.00	56.45	-0.45	52.65	-0.65	55.85	-0.70
Q3	69.20	0.55	62.10	0.50	59.00	0.00	60.20	0.00
Maximum	85.6	3.7	78.6	1.7	82.2	1.1	76.8	3.1
Week 12								
N	55	55	47	47	53	53	54	54
Mean	60.83	-0.17	57.59	-0.26	54.17	-0.52	56.49	-0.69
SD	11.820	1.580	8.089	1.306	7.966	1.060	7.598	1.322
Minimum	45.0	-6.4	40.5	-4.4	40.0	-3.5	43.0	-4.1
Q1	51.20	-0.80	52.20	-1.20	49.40	-1.10	51.30	-1.50
Median	58.70	0.00	56.80	-0.10	53.30	-0.50	55.65	-0.85
Q3	69.30	0.70	61.60	0.80	58.70	0.00	60.00	0.20
Maximum	86.3	3.0	78.0	2.3	82.5	1.8	78.7	2.8

治験総括報告書 Table 3.3.2.1.1（Section 16.1.9.5）（5.3.5.1-1）から引用

表 2.7.4.8-付録-45　バイタルサイン及び体重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-001 試験）（続き）

Weight (kg)

Visit / Statistics	Placebo (N=57) Observed Value at Visit	Placebo (N=57) Change from Baseline	TAK-385 10mg (N=48) Observed Value at Visit	TAK-385 10mg (N=48) Change from Baseline	TAK-385 20mg (N=55) Observed Value at Visit	TAK-385 20mg (N=55) Change from Baseline	TAK-385 40mg (N=54) Observed Value at Visit	TAK-385 40mg (N=54) Change from Baseline
Follow-up								
N	57	57	48	48	55	55	54	54
Mean	60.34	-0.39	57.61	-0.23	54.70	-0.02	57.08	-0.11
SD	11.928	1.948	8.260	1.677	7.950	1.252	7.746	1.620
Minimum	42.5	-7.2	39.2	-6.4	40.7	-2.7	43.8	-3.0
Q1	51.00	-1.20	52.25	-1.10	50.00	-0.80	51.70	-1.30
Median	58.00	-0.20	56.65	0.00	54.10	-0.10	55.95	-0.20
Q3	69.20	0.60	61.15	0.70	59.50	0.70	61.30	0.90
Maximum	85.6	4.5	78.5	3.1	83.4	3.7	75.6	4.9

治験総括報告書 Table 3.3.2.1.1（Section 16.1.9.5）（5.3.5.1-1）から引用

表 2.7.4.8-付録-46　バイタルサイン及び体重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-002 試験）

Systolic Blood Pressure (mmHg)

Visit / Statistics	TAK-385 40mg (N=138) Observed Value at Visit	TAK-385 40mg (N=138) Change from Baseline	Leuprorelin (N=142) Observed Value at Visit	Leuprorelin (N=142) Change from Baseline
Baseline				
N	138		142	
Mean	115.8		116.8	
SD	13.82		13.73	
Minimum	83		87	
Q1	106.0		106.0	
Median	114.0		116.0	
Q3	125.0		125.0	
Maximum	164		154	
Week 4				
N	138	138	142	142
Mean	116.3	0.5	117.1	0.2
SD	14.11	11.90	14.46	10.36
Minimum	88	-35	91	-30
Q1	105.0	-7.0	105.0	-6.0
Median	115.0	1.0	116.0	0.5
Q3	126.0	6.0	126.0	7.0
Maximum	172	40	157	29
Week 8				
N	135	135	142	142
Mean	116.1	0.3	118.9	2.1
SD	14.21	11.05	13.94	10.22
Minimum	84	-32	92	-28
Q1	106.0	-7.0	110.0	-4.0
Median	115.0	0.0	118.0	2.0
Q3	125.0	7.0	128.0	10.0
Maximum	164	30	163	27

治験総括報告書 Table 15.3.3.1（5.3.5.1-2）から引用

表 2.7.4.8-付録-46　バイタルサイン及び体重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-002 試験）（続き）

Systolic Blood Pressure (mmHg)

Visit / Statistics	TAK-385 40mg (N=138) Observed Value at Visit	TAK-385 40mg (N=138) Change from Baseline	Leuprorelin (N=142) Observed Value at Visit	Leuprorelin (N=142) Change from Baseline
Week 12				
N	130	130	141	141
Mean	116.3	0.7	119.0	2.1
SD	13.79	10.80	14.81	11.24
Minimum	84	-21	92	-26
Q1	105.0	-6.0	107.0	-6.0
Median	115.0	0.0	118.0	2.0
Q3	127.0	6.0	129.0	9.0
Maximum	149	46	165	33
Week 16				
N	129	129	136	136
Mean	117.0	1.5	118.0	1.3
SD	12.92	11.11	13.96	10.71
Minimum	91	-22	83	-32
Q1	107.0	-6.0	108.5	-5.0
Median	116.0	0.0	116.0	1.0
Q3	126.0	8.0	127.5	9.0
Maximum	154	34	166	27
Week 20				
N	126	126	132	132
Mean	116.7	1.0	118.8	2.2
SD	15.07	11.69	14.64	12.02
Minimum	86	-28	82	-41
Q1	106.0	-6.0	110.0	-6.0
Median	114.0	0.0	119.0	1.5
Q3	128.0	8.0	128.0	10.5
Maximum	152	43	187	33
Week 24				
N	122	122	131	131
Mean	117.5	1.3	117.9	1.2
SD	14.32	11.49	13.89	11.34
Minimum	84	-29	88	-30
Q1	108.0	-6.0	108.0	-6.0
Median	116.5	1.0	117.0	1.0
Q3	126.0	9.0	128.0	10.0
Maximum	167	41	158	33

治験総括報告書 Table 15.3.3.1（5.3.5.1-2）から引用

表 2.7.4.8-付録-46　バイタルサイン及び体重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-002 試験）（続き）

Systolic Blood Pressure (mmHg)

Visit / Statistics	TAK-385 40mg (N=138) Observed Value at Visit	TAK-385 40mg (N=138) Change from Baseline	Leuprorelin (N=142) Observed Value at Visit	Leuprorelin (N=142) Change from Baseline
Follow-up				
N	135	135	141	141
Mean	116.3	0.6	117.5	0.8
SD	12.73	11.35	13.56	10.68
Minimum	89	-28	85	-32
Q1	106.0	-7.0	108.0	-6.0
Median	116.0	1.0	117.0	1.0
Q3	126.0	8.0	127.0	8.0
Maximum	143	34	155	22

治験総括報告書 Table 15.3.3.1（5.3.5.1-2）から引用

表 2.7.4.8-付録-46　バイタルサイン及び体重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-002 試験）（続き）

Diastolic Blood Pressure (mmHg)

Visit / Statistics	TAK-385 40mg (N=138) Observed Value at Visit	TAK-385 40mg (N=138) Change from Baseline	Leuprorelin (N=142) Observed Value at Visit	Leuprorelin (N=142) Change from Baseline
Baseline				
N	138		142	
Mean	69.0		70.8	
SD	10.96		11.35	
Minimum	42		50	
Q1	61.0		63.0	
Median	68.0		70.0	
Q3	78.0		78.0	
Maximum	101		105	
Week 4				
N	138	138	142	142
Mean	71.8	2.8	72.4	1.6
SD	10.14	7.93	11.70	8.02
Minimum	52	-16	45	-19
Q1	64.0	-2.0	64.0	-4.0
Median	70.5	1.5	71.0	2.0
Q3	78.0	8.0	81.0	5.0
Maximum	97	36	102	25
Week 8				
N	135	135	142	142
Mean	72.1	3.1	73.7	2.9
SD	10.33	8.65	11.70	7.95
Minimum	40	-19	50	-19
Q1	65.0	-2.0	65.0	-3.0
Median	71.0	3.0	73.0	3.0
Q3	79.0	8.0	80.0	9.0
Maximum	99	26	116	25

治験総括報告書 Table 15.3.3.1（5.3.5.1-2）から引用

表 2.7.4.8-付録-46　バイタルサイン及び体重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-002 試験）（続き）

Diastolic Blood Pressure (mmHg)

Visit / Statistics	TAK-385 40mg (N=138) Observed Value at Visit	TAK-385 40mg (N=138) Change from Baseline	Leuprorelin (N=142) Observed Value at Visit	Leuprorelin (N=142) Change from Baseline
Week 12				
N	130	130	141	141
Mean	72.6	3.6	74.8	4.0
SD	11.28	8.52	12.54	7.72
Minimum	48	-20	48	-18
Q1	65.0	-3.0	66.0	-1.0
Median	71.5	4.0	73.0	4.0
Q3	82.0	8.0	82.0	9.0
Maximum	99	36	124	32
Week 16				
N	129	129	136	136
Mean	72.8	3.9	74.1	3.5
SD	10.84	9.20	11.51	7.62
Minimum	52	-18	52	-16
Q1	65.0	-2.0	67.0	-1.0
Median	71.0	5.0	72.0	4.0
Q3	81.0	9.0	80.0	8.0
Maximum	106	29	111	28
Week 20				
N	126	126	132	132
Mean	73.5	4.4	74.6	4.1
SD	12.36	10.19	11.79	8.56
Minimum	48	-22	49	-15
Q1	64.0	-2.0	67.0	-2.0
Median	72.0	4.0	74.0	4.0
Q3	83.0	10.0	82.0	9.5
Maximum	111	36	113	31
Week 24				
N	122	122	131	131
Mean	72.2	2.8	74.4	3.8
SD	11.06	8.52	11.22	8.76
Minimum	45	-21	50	-18
Q1	64.0	-2.0	66.0	-2.0
Median	73.0	2.0	73.0	3.0
Q3	80.0	8.0	82.0	10.0
Maximum	111	27	107	25

治験総括報告書 Table 15.3.3.1（5.3.5.1-2）から引用

表 2.7.4.8-付録-46　バイタルサイン及び体重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-002 試験）（続き）

Diastolic Blood Pressure (mmHg)

Visit / Statistics	TAK-385 40mg (N=138) Observed Value at Visit	TAK-385 40mg (N=138) Change from Baseline	Leuprorelin (N=142) Observed Value at Visit	Leuprorelin (N=142) Change from Baseline
Follow-up				
N	135	135	141	141
Mean	71.2	2.1	73.4	2.6
SD	10.13	8.51	11.58	8.26
Minimum	44	-19	46	-24
Q1	64.0	-4.0	66.0	-3.0
Median	70.0	3.0	71.0	1.0
Q3	80.0	8.0	82.0	8.0
Maximum	99	28	107	24

治験総括報告書 Table 15.3.3.1（5.3.5.1-2）から引用

表 2.7.4.8-付録-46　バイタルサイン及び体重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-002 試験）（続き）

Pulse Rate (bpm)

Visit / Statistics	TAK-385 40mg (N=138) Observed Value at Visit	TAK-385 40mg (N=138) Change from Baseline	Leuprorelin (N=142) Observed Value at Visit	Leuprorelin (N=142) Change from Baseline
Baseline				
N	138		142	
Mean	72.9		75.5	
SD	9.41		10.56	
Minimum	55		52	
Q1	66.0		69.0	
Median	71.5		74.0	
Q3	79.0		83.0	
Maximum	107		109	
Week 4				
N	138	138	142	142
Mean	72.6	-0.3	74.3	-1.2
SD	10.44	9.08	11.33	8.95
Minimum	51	-33	49	-25
Q1	65.0	-5.0	66.0	-7.0
Median	72.5	0.0	72.0	-1.0
Q3	79.0	5.0	80.0	4.0
Maximum	108	32	109	22
Week 8				
N	135	135	142	142
Mean	71.8	-0.9	75.1	-0.4
SD	9.71	8.65	10.50	8.27
Minimum	51	-25	55	-24
Q1	65.0	-7.0	67.0	-5.0
Median	71.0	-1.0	74.0	-1.0
Q3	77.0	5.0	82.0	4.0
Maximum	103	22	112	28

治験総括報告書 Table 15.3.3.1（5.3.5.1-2）から引用

表 2.7.4.8-付録-46　バイタルサイン及び体重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-002 試験）（続き）

Pulse Rate (bpm)

Visit / Statistics	TAK-385 40mg (N=138) Observed Value at Visit	TAK-385 40mg (N=138) Change from Baseline	Leuprorelin (N=142) Observed Value at Visit	Leuprorelin (N=142) Change from Baseline
Week 12				
N	130	130	141	141
Mean	72.3	-0.2	75.3	-0.2
SD	8.93	9.23	10.81	8.68
Minimum	50	-24	54	-19
Q1	66.0	-6.0	68.0	-5.0
Median	72.0	0.0	74.0	-1.0
Q3	78.0	5.0	82.0	5.0
Maximum	92	25	117	27
Week 16				
N	129	129	136	136
Mean	73.3	0.8	75.4	0.0
SD	9.70	9.64	11.36	9.64
Minimum	53	-27	51	-20
Q1	66.0	-6.0	68.5	-6.0
Median	74.0	1.0	73.0	0.0
Q3	80.0	7.0	81.5	5.0
Maximum	102	22	110	35
Week 20				
N	126	126	132	132
Mean	74.2	1.8	75.6	0.3
SD	10.48	9.19	11.05	9.13
Minimum	51	-21	51	-25
Q1	67.0	-4.0	67.5	-5.5
Median	73.5	2.0	74.0	-1.0
Q3	81.0	8.0	82.5	7.0
Maximum	108	28	112	29
Week 24				
N	122	122	131	131
Mean	73.4	0.8	74.8	-0.7
SD	9.47	9.36	10.27	9.72
Minimum	50	-26	52	-36
Q1	68.0	-5.0	69.0	-7.0
Median	73.0	0.5	74.0	0.0
Q3	81.0	6.0	81.0	5.0
Maximum	96	27	109	28

治験総括報告書 Table 15.3.3.1（5.3.5.1-2）から引用

表 2.7.4.8-付録-46　バイタルサイン及び体重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-002 試験）（続き）

Pulse Rate (bpm)

Visit / Statistics	TAK-385 40mg (N=138) Observed Value at Visit	TAK-385 40mg (N=138) Change from Baseline	Leuprorelin (N=142) Observed Value at Visit	Leuprorelin (N=142) Change from Baseline
Follow-up				
N	135	135	141	141
Mean	74.1	1.3	75.8	0.3
SD	9.42	8.27	10.49	8.57
Minimum	52	-24	54	-28
Q1	68.0	-4.0	68.0	-5.0
Median	73.0	1.0	75.0	1.0
Q3	82.0	7.0	81.0	5.0
Maximum	100	21	117	25

治験総括報告書 Table 15.3.3.1（5.3.5.1-2）から引用

表 2.7.4.8-付録-46　バイタルサイン及び体重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-002 試験）（続き）

Body temperature (C)

Visit / Statistics	TAK-385 40mg (N=138) Observed Value at Visit	TAK-385 40mg (N=138) Change from Baseline	Leuprorelin (N=142) Observed Value at Visit	Leuprorelin (N=142) Change from Baseline
Baseline				
N	138		142	
Mean	36.40		36.43	
SD	0.397		0.439	
Minimum	35.2		35.1	
Q1	36.10		36.20	
Median	36.40		36.50	
Q3	36.70		36.70	
Maximum	37.4		38.5	
Week 4				
N	138	138	142	142
Mean	36.35	-0.04	36.40	-0.03
SD	0.405	0.367	0.392	0.444
Minimum	35.1	-1.0	35.3	-2.0
Q1	36.10	-0.20	36.10	-0.30
Median	36.40	0.00	36.50	0.00
Q3	36.70	0.10	36.70	0.30
Maximum	37.1	1.3	37.4	1.0
Week 8				
N	135	135	142	142
Mean	36.35	-0.05	36.33	-0.10
SD	0.429	0.385	0.404	0.440
Minimum	35.0	-1.2	35.1	-2.5
Q1	36.10	-0.30	36.10	-0.30
Median	36.40	-0.10	36.40	-0.10
Q3	36.60	0.20	36.60	0.10
Maximum	37.8	1.2	37.1	1.1

治験総括報告書 Table 15.3.3.1（5.3.5.1-2）から引用

表 2.7.4.8-付録-46　バイタルサイン及び体重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-002 試験）（続き）

Body temperature (C)

Visit / Statistics	TAK-385 40mg (N=138) Observed Value at Visit	TAK-385 40mg (N=138) Change from Baseline	Leuprorelin (N=142) Observed Value at Visit	Leuprorelin (N=142) Change from Baseline
Week 12				
N	130	130	141	141
Mean	36.34	-0.06	36.32	-0.11
SD	0.398	0.403	0.404	0.479
Minimum	35.3	-1.4	35.2	-2.3
Q1	36.10	-0.30	36.10	-0.40
Median	36.40	0.00	36.40	-0.10
Q3	36.60	0.20	36.60	0.20
Maximum	37.1	1.0	37.1	1.1
Week 16				
N	129	129	136	136
Mean	36.34	-0.06	36.30	-0.13
SD	0.396	0.417	0.403	0.407
Minimum	35.3	-1.3	35.2	-1.7
Q1	36.10	-0.30	36.00	-0.40
Median	36.40	-0.10	36.30	-0.10
Q3	36.60	0.20	36.60	0.10
Maximum	37.4	1.1	37.1	1.0
Week 20				
N	126	126	132	132
Mean	36.34	-0.05	36.33	-0.09
SD	0.440	0.425	0.389	0.441
Minimum	35.1	-1.3	35.1	-2.4
Q1	36.10	-0.30	36.10	-0.30
Median	36.40	-0.05	36.40	-0.10
Q3	36.70	0.20	36.60	0.10
Maximum	37.2	1.3	37.3	0.9
Week 24				
N	122	122	131	131
Mean	36.34	-0.05	36.37	-0.05
SD	0.414	0.399	0.395	0.463
Minimum	34.8	-1.4	35.1	-2.3
Q1	36.10	-0.30	36.20	-0.30
Median	36.40	0.00	36.40	-0.10
Q3	36.70	0.20	36.60	0.20
Maximum	37.1	1.0	37.1	1.3

治験総括報告書 Table 15.3.3.1（5.3.5.1-2）から引用

表 2.7.4.8-付録-46　バイタルサイン及び体重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-002 試験）（続き）

Body temperature (C)

Visit / Statistics	TAK-385 40mg (N=138) Observed Value at Visit	TAK-385 40mg (N=138) Change from Baseline	Leuprorelin (N=142) Observed Value at Visit	Leuprorelin (N=142) Change from Baseline
Follow-up				
N	135	135	141	141
Mean	36.44	0.05	36.30	-0.13
SD	0.370	0.409	0.413	0.447
Minimum	35.1	-1.1	35.1	-2.6
Q1	36.20	-0.20	36.10	-0.30
Median	36.50	0.00	36.30	-0.20
Q3	36.70	0.30	36.60	0.10
Maximum	37.1	1.4	37.1	1.1

治験総括報告書 Table 15.3.3.1（5.3.5.1-2）から引用

表 2.7.4.8-付録-46　バイタルサイン及び体重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-002 試験）（続き）

Weight (kg)

Visit / Statistics	TAK-385 40mg (N=138) Observed Value at Visit	TAK-385 40mg (N=138) Change from Baseline	Leuprorelin (N=142) Observed Value at Visit	Leuprorelin (N=142) Change from Baseline
Baseline				
N	138		142	
Mean	58.16		59.53	
SD	9.167		9.907	
Minimum	42.0		40.1	
Q1	51.70		52.90	
Median	56.55		58.80	
Q3	64.50		64.80	
Maximum	87.6		93.7	
Week 4				
N	138	138	142	142
Mean	57.43	-0.73	59.05	-0.48
SD	9.229	0.958	9.902	1.034
Minimum	40.8	-3.9	40.1	-2.9
Q1	50.50	-1.40	51.50	-1.10
Median	55.95	-0.75	57.95	-0.45
Q3	63.50	-0.10	64.10	0.10
Maximum	87.3	2.6	92.0	4.8
Week 8				
N	135	135	142	142
Mean	57.52	-0.75	58.67	-0.87
SD	9.257	1.173	9.838	1.198
Minimum	39.9	-4.4	39.3	-5.5
Q1	50.80	-1.40	51.50	-1.40
Median	56.40	-0.60	58.15	-0.80
Q3	63.30	0.00	63.90	-0.20
Maximum	86.2	2.3	92.2	4.1

治験総括報告書 Table 15.3.3.1（5.3.5.1-2）から引用

表 2.7.4.8-付録-46　バイタルサイン及び体重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-002 試験）（続き）

Weight (kg)

Visit / Statistics	TAK-385 40mg (N=138) Observed Value at Visit	TAK-385 40mg (N=138) Change from Baseline	Leuprorelin (N=142) Observed Value at Visit	Leuprorelin (N=142) Change from Baseline
Week 12				
N	130	130	141	141
Mean	57.69	-0.68	58.74	-0.80
SD	9.327	1.329	9.965	1.328
Minimum	39.6	-4.3	37.9	-6.9
Q1	51.00	-1.40	51.80	-1.60
Median	56.50	-0.80	58.10	-0.70
Q3	62.90	0.30	63.70	-0.20
Maximum	87.0	2.3	93.0	3.7
Week 16				
N	129	129	136	136
Mean	57.73	-0.58	58.25	-0.72
SD	9.407	1.602	9.259	1.748
Minimum	39.7	-5.0	37.7	-10.3
Q1	50.60	-1.60	51.35	-1.65
Median	56.30	-0.50	57.50	-0.60
Q3	63.20	0.50	63.70	0.30
Maximum	87.0	3.6	92.7	4.1
Week 20				
N	126	126	132	132
Mean	57.88	-0.40	58.40	-0.68
SD	9.539	1.811	9.303	2.026
Minimum	40.4	-5.7	38.5	-12.2
Q1	51.10	-1.30	51.55	-1.60
Median	56.75	-0.40	57.80	-0.50
Q3	63.30	0.70	63.60	0.40
Maximum	87.0	5.4	93.2	4.3
Week 24				
N	122	122	131	131
Mean	58.07	-0.33	58.58	-0.54
SD	9.733	1.905	9.558	2.246
Minimum	39.6	-6.1	38.2	-13.3
Q1	51.20	-1.50	51.40	-1.60
Median	57.15	-0.15	57.70	-0.40
Q3	64.00	0.90	63.70	0.60
Maximum	87.2	5.9	96.5	5.7

治験総括報告書 Table 15.3.3.3.1（5.3.5.1-2）から引用

表 2.7.4.8-付録-46　バイタルサイン及び体重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-002 試験）（続き）

Weight (kg)

Visit / Statistics	TAK-385 40mg (N=138) Observed Value at Visit	TAK-385 40mg (N=138) Change from Baseline	Leuprorelin (N=142) Observed Value at Visit	Leuprorelin (N=142) Change from Baseline
Follow-up				
N	135	135	141	141
Mean	58.48	0.28	59.17	-0.41
SD	9.686	1.993	10.222	2.241
Minimum	40.1	-5.8	38.1	-14.4
Q1	51.40	-0.80	51.50	-1.20
Median	57.40	0.30	57.70	-0.40
Q3	64.50	1.60	63.80	0.80
Maximum	88.0	6.8	95.0	6.2

治験総括報告書 Table 15.3.3.1（5.3.5.1-2）から引用

表 2.7.4.8-付録-47　バイタルサイン及び体重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）

Systolic Blood Pressure (mmHg)

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	112.5		114.2	
SD	12.30		11.76	
Minimum	84		93	
Q1	106.0		104.5	
Median	112.0		114.0	
Q3	121.0		125.0	
Maximum	136		131	
Week 4				
N	33	33	32	32
Mean	114.2	1.6	112.7	-1.5
SD	13.31	10.25	11.28	10.49
Minimum	90	-17	91	-28
Q1	104.0	-5.0	105.5	-5.5
Median	114.0	1.0	112.0	-1.0
Q3	121.0	8.0	122.5	4.0
Maximum	147	27	135	26
Week 8				
N	32	32	31	31
Mean	112.2	0.2	114.0	-0.6
SD	12.51	10.44	12.36	9.92
Minimum	91	-20	86	-18
Q1	102.0	-6.5	105.0	-7.0
Median	111.0	-0.5	112.0	0.0
Q3	120.5	7.0	125.0	6.0
Maximum	146	25	139	24

治験総括報告書 Table 15.3.3.3.1（5.3.5.1-3）から引用

表 2.7.4.8-付録-47　バイタルサイン及び体重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）

Systolic Blood Pressure (mmHg)

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	115.2	3.3	111.2	-3.4
SD	14.99	12.86	12.35	10.50
Minimum	90	-21	91	-34
Q1	101.0	-6.0	102.0	-11.0
Median	116.0	5.0	110.0	-4.0
Q3	124.5	12.0	120.0	4.0
Maximum	157	32	135	16
Follow-up				
N	33	33	32	32
Mean	110.2	-2.4	112.8	-1.4
SD	12.14	10.47	12.84	11.62
Minimum	86	-22	85	-35
Q1	104.0	-8.0	104.5	-7.0
Median	111.0	-3.0	114.0	-2.0
Q3	117.0	5.0	121.5	5.0
Maximum	142	22	138	25

治験総括報告書 Table 15.3.3.1（5.3.5.1-3）から引用

表 2.7.4.8-付録-47　バイタルサイン及び体重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）

Diastolic Blood Pressure (mmHg)

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	70.5		69.9	
SD	9.38		9.58	
Minimum	54		42	
Q1	64.0		63.5	
Median	71.0		70.0	
Q3	76.0		77.0	
Maximum	94		88	
Week 4				
N	33	33	32	32
Mean	72.6	2.2	67.8	-2.1
SD	9.98	11.57	8.28	8.62
Minimum	55	-36	50	-23
Q1	66.0	-6.0	63.5	-8.0
Median	72.0	2.0	68.0	-3.0
Q3	80.0	9.0	72.5	2.0
Maximum	94	24	83	23
Week 8				
N	32	32	31	31
Mean	69.6	-0.7	69.5	-0.4
SD	9.38	11.30	9.79	9.26
Minimum	49	-30	48	-22
Q1	65.0	-8.5	62.0	-6.0
Median	69.5	0.0	69.0	1.0
Q3	76.0	4.5	75.0	5.0
Maximum	95	21	90	18

治験総括報告書 Table 15.3.3.3.1（5.3.5.1-3）から引用

表 2.7.4.8-付録-47　バイタルサイン及び体重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）

Diastolic Blood Pressure (mmHg)

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	72.7	2.4	68.5	-1.4
SD	11.74	10.05	8.37	7.91
Minimum	53	-23	51	-18
Q1	64.0	-3.5	63.0	-7.0
Median	72.5	2.0	68.0	-2.0
Q3	80.0	8.5	75.0	4.0
Maximum	99	25	85	18
Follow-up				
N	33	33	32	32
Mean	66.8	-3.6	67.6	-2.3
SD	9.47	8.94	9.06	9.42
Minimum	49	-22	50	-16
Q1	61.0	-8.0	61.0	-9.0
Median	67.0	-2.0	67.5	-2.0
Q3	75.0	3.0	74.0	3.0
Maximum	85	11	86	23

治験総括報告書 Table 15.3.3.1（5.3.5.1-3）から引用

表 2.7.4.8-付録-47　バイタルサイン及び体重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）

Pulse Rate (bpm)

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	72.2		72.7	
SD	10.19		10.22	
Minimum	56		56	
Q1	66.0		66.0	
Median	71.0		71.5	
Q3	78.0		76.5	
Maximum	105		99	
Week 4				
N	33	33	32	32
Mean	74.1	1.8	73.1	0.4
SD	13.66	8.84	9.20	8.92
Minimum	55	-15	60	-19
Q1	63.0	-3.0	66.0	-3.5
Median	70.0	0.0	71.0	0.0
Q3	84.0	5.0	78.5	6.0
Maximum	110	21	99	25
Week 8				
N	32	32	31	31
Mean	75.3	3.1	73.7	1.0
SD	13.61	10.28	11.13	9.26
Minimum	53	-12	57	-25
Q1	64.0	-4.0	66.0	-3.0
Median	75.0	0.0	70.0	1.0
Q3	87.0	9.5	79.0	7.0
Maximum	101	27	106	20

治験総括報告書 Table 15.3.3.1（5.3.5.1-3）から引用

表 2.7.4.8-付録-47　バイタルサイン及び体重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）

Pulse Rate (bpm)

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	77.0	4.8	73.0	0.3
SD	14.63	10.76	10.01	9.25
Minimum	52	-14	54	-24
Q1	67.5	-2.5	68.0	-4.0
Median	73.0	4.0	72.0	1.0
Q3	87.5	11.0	75.0	7.0
Maximum	114	34	103	15
Follow-up				
N	33	33	32	32
Mean	76.5	4.2	75.1	2.4
SD	11.19	8.63	12.33	11.25
Minimum	57	-9	56	-29
Q1	70.0	-3.0	66.0	-3.0
Median	77.0	5.0	73.5	3.0
Q3	84.0	11.0	81.0	12.0
Maximum	110	22	112	22

治験総括報告書 Table 15.3.3.1（5.3.5.1-3）から引用

表 2.7.4.8-付録-47　バイタルサイン及び体重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）

Body temperature (C)

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	36.36		36.34	
SD	0.467		0.452	
Minimum	35.1		35.1	
Q1	36.10		36.10	
Median	36.40		36.40	
Q3	36.70		36.60	
Maximum	37.1		37.0	
Week 4				
N	33	33	32	32
Mean	36.40	0.04	36.45	0.11
SD	0.457	0.439	0.374	0.346
Minimum	35.1	-0.9	35.6	-0.6
Q1	36.20	-0.20	36.15	-0.10
Median	36.50	0.00	36.50	0.10
Q3	36.70	0.30	36.70	0.30
Maximum	37.1	1.1	37.2	1.1
Week 8				
N	32	32	31	31
Mean	36.34	-0.03	36.55	0.17
SD	0.443	0.326	0.443	0.356
Minimum	35.0	-1.1	35.5	-0.5
Q1	36.15	-0.10	36.30	-0.10
Median	36.40	0.00	36.60	0.10
Q3	36.65	0.10	36.80	0.40
Maximum	36.9	0.6	37.1	1.0

治験総括報告書 Table 15.3.3.1（5.3.5.1-3）から引用

表 2.7.4.8-付録-47　バイタルサイン及び体重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）

Body temperature (C)

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	36.33	-0.04	36.45	0.08
SD	0.414	0.330	0.378	0.334
Minimum	35.4	-1.0	35.8	-0.8
Q1	36.15	-0.20	36.10	-0.10
Median	36.50	0.00	36.60	0.10
Q3	36.60	0.25	36.70	0.30
Maximum	37.0	0.4	37.1	0.6
Follow-up				
N	33	33	32	32
Mean	36.54	0.18	36.40	0.07
SD	0.402	0.424	0.440	0.453
Minimum	35.7	-0.8	35.2	-0.8
Q1	36.40	-0.10	36.15	-0.25
Median	36.70	0.20	36.45	0.00
Q3	36.80	0.40	36.70	0.35
Maximum	37.3	1.1	37.2	0.9

治験総括報告書 Table 15.3.3.1（5.3.5.1-3）から引用

表 2.7.4.8-付録-47　バイタルサイン及び体重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）

Weight (kg)

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	57.55		57.47	
SD	11.775		11.511	
Minimum	42.9		42.6	
Q1	48.80		49.05	
Median	52.40		53.80	
Q3	64.50		64.90	
Maximum	88.0		87.3	
Week 4				
N	33	33	32	32
Mean	57.04	-0.50	57.63	0.17
SD	11.799	1.424	11.482	0.927
Minimum	41.9	-3.2	42.8	-2.4
Q1	47.30	-1.40	48.55	-0.25
Median	52.50	-0.80	53.95	0.15
Q3	64.40	-0.30	64.40	0.60
Maximum	86.2	5.3	87.3	2.3
Week 8				
N	32	32	31	31
Mean	57.06	-0.57	58.04	0.32
SD	12.056	1.690	11.250	1.250
Minimum	42.2	-4.5	43.5	-2.2
Q1	47.10	-1.30	47.60	-0.70
Median	52.15	-0.95	54.80	0.30
Q3	64.55	-0.05	65.00	1.10
Maximum	85.9	5.2	86.6	3.4

治験総括報告書 Table 15.3.3.1（5.3.5.1-3）から引用

表 2.7.4.8-付録-47　バイタルサイン及び体重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）

Weight (kg)

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	57.10	-0.53	58.20	0.48
SD	12.298	1.906	11.116	1.566
Minimum	42.4	-5.3	43.9	-3.1
Q1	47.15	-1.55	48.80	-0.40
Median	52.85	-0.65	55.20	0.30
Q3	62.95	0.25	65.60	1.00
Maximum	87.6	5.0	86.3	3.5
Follow-up				
N	33	33	32	32
Mean	57.79	0.25	58.03	0.56
SD	12.260	1.976	10.820	1.835
Minimum	43.5	-5.2	44.5	-3.7
Q1	48.20	-0.60	49.05	-0.25
Median	53.30	0.00	55.35	0.35
Q3	62.30	1.00	64.75	1.30
Maximum	88.1	5.1	86.8	5.0

治験総括報告書 Table 15.3.3.1（5.3.5.1-3）から引用

表 2.7.4.8-付録-48　バイタルサイン及び体重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）

Systolic Blood Pressure (mmHg)

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	111.2		112.3		108.2		113.8		112.0	
SD	12.58		12.58		13.40		13.32		13.19	
Minimum	84		80		79		89		85	
Q1	103.0		103.0		99.0		104.0		103.0	
Median	110.0		111.0		107.0		112.0		110.0	
Q3	117.0		122.0		115.0		121.0		120.5	
Maximum	156		144		150		151		152	
Week 4										
N	97	97	103	103	100	100	103	103	80	80
Mean	110.0	-1.2	111.6	-0.7	108.3	0.1	112.1	-1.7	110.8	-1.2
SD	13.12	10.55	13.90	10.95	12.55	9.84	13.24	10.06	12.54	9.74
Minimum	83	-26	75	-21	83	-35	82	-31	90	-25
Q1	103.0	-8.0	100.0	-9.0	99.5	-5.5	102.0	-7.0	102.0	-7.0
Median	110.0	-1.0	112.0	0.0	108.5	1.5	110.0	-1.0	109.0	-1.0
Q3	118.0	6.0	123.0	6.0	116.5	7.0	121.0	6.0	118.0	6.0
Maximum	145	22	148	34	140	20	152	21	147	21
Week 8										
N	95	95	103	103	96	96	101	101	78	78
Mean	110.5	-0.5	112.0	-0.3	108.4	0.1	112.9	-0.9	112.4	0.5
SD	12.43	9.94	13.17	9.41	11.77	11.67	15.65	10.30	11.91	8.84
Minimum	79	-31	86	-27	80	-33	84	-31	84	-22
Q1	103.0	-4.0	101.0	-6.0	100.0	-8.0	103.0	-8.0	106.0	-5.0
Median	111.0	1.0	112.0	-1.0	108.0	1.0	109.0	0.0	112.0	0.0
Q3	118.0	5.0	122.0	6.0	115.5	8.0	122.0	6.0	118.0	6.0
Maximum	146	24	143	20	141	26	184	34	142	22
Week 12										
N	93	93	101	101	92	92	101	101	75	75
Mean	109.6	-1.5	111.4	-1.0	107.4	-0.6	111.2	-2.6	111.0	-1.3
SD	10.76	9.98	12.41	9.84	11.47	11.24	14.68	11.61	15.23	11.78
Minimum	87	-27	78	-29	79	-31	80	-33	78	-26
Q1	101.0	-7.0	103.0	-6.0	99.5	-6.0	101.0	-9.0	100.0	-10.0
Median	110.0	-1.0	111.0	-1.0	107.5	0.5	110.0	-3.0	109.0	-4.0
Q3	116.0	5.0	118.0	5.0	115.0	5.5	119.0	4.0	121.0	9.0
Maximum	147	20	153	19	136	30	155	30	157	24
Follow-up										
N	18	18	19	19	22	22	13	13	10	10
Mean	108.7	-2.6	110.0	-2.5	107.5	-0.5	110.1	-6.4	105.5	-0.6
SD	14.94	14.29	11.25	8.44	9.45	12.55	9.68	8.49	11.63	7.28
Minimum	72	-38	89	-21	90	-26	93	-26	86	-16
Q1	103.0	-8.0	103.0	-8.0	100.0	-10.0	104.0	-11.0	100.0	-5.0
Median	109.0	-1.0	108.0	-1.0	109.5	-1.0	109.0	-6.0	104.5	1.0
Q3	117.0	7.0	120.0	4.0	114.0	4.0	117.0	0.0	106.0	3.0
Maximum	134	21	129	10	125	27	125	7	132	11

治験総括報告書 Table 3.3.2.1.1（Section 15.1）（5.3.5.4-1）から引用

表 2.7.4.8-付録-48　バイタルサイン及び体重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）

Diastolic Blood Pressure (mmHg)

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	66.7		68.6		65.6		69.3		67.7	
SD	9.46		9.69		9.72		10.51		10.43	
Minimum	46		49		50		41		44	
Q1	60.0		61.0		59.0		62.0		60.5	
Median	66.0		69.0		64.0		69.0		66.0	
Q3	73.0		74.0		72.0		76.0		74.0	
Maximum	91		101		93		99		95	
Week 4										
N	97	97	103	103	100	100	103	103	80	80
Mean	67.3	0.6	67.4	-1.2	65.4	-0.2	69.6	0.3	68.0	0.3
SD	9.56	7.15	10.94	8.32	9.44	7.95	11.27	8.21	10.34	6.82
Minimum	42	-16	48	-19	44	-29	40	-24	40	-18
Q1	61.0	-5.0	59.0	-6.0	60.0	-4.0	61.0	-4.0	62.0	-5.0
Median	66.0	0.0	66.0	-1.0	65.0	1.0	69.0	0.0	67.5	1.0
Q3	74.0	5.0	74.0	2.0	71.0	5.0	78.0	6.0	72.5	5.0
Maximum	90	20	94	31	95	20	100	21	96	16
Week 8										
N	95	95	103	103	96	96	101	101	78	78
Mean	67.1	0.6	67.8	-0.8	66.0	0.3	69.2	-0.1	69.6	2.1
SD	9.20	7.92	10.61	7.40	9.67	7.79	11.02	8.26	10.26	7.35
Minimum	48	-21	46	-24	47	-28	48	-19	45	-15
Q1	61.0	-4.0	60.0	-6.0	58.0	-4.0	62.0	-6.0	63.0	-3.0
Median	67.0	0.0	67.0	-1.0	65.0	1.0	67.0	0.0	68.0	2.0
Q3	72.0	6.0	74.0	4.0	71.0	5.0	77.0	5.0	76.0	7.0
Maximum	90	26	91	16	92	24	100	21	97	21
Week 12										
N	93	93	101	101	92	92	101	101	75	75
Mean	65.5	-1.0	67.2	-1.2	65.5	0.0	67.8	-1.5	69.3	1.7
SD	9.06	8.49	10.18	7.90	8.63	7.68	10.37	9.20	12.01	9.51
Minimum	41	-26	40	-21	50	-22	46	-21	41	-29
Q1	60.0	-6.0	59.0	-6.0	60.0	-4.0	61.0	-8.0	63.0	-4.0
Median	64.0	-2.0	68.0	0.0	64.5	0.0	67.0	-1.0	69.0	1.0
Q3	70.0	4.0	73.0	4.0	70.5	4.5	74.0	4.0	75.0	7.0
Maximum	90	29	94	19	90	19	111	20	97	24
Follow-up										
N	18	18	19	19	22	22	13	13	10	10
Mean	64.2	2.0	68.5	-0.9	64.5	-1.8	68.2	-0.5	61.8	-3.2
SD	10.36	10.35	9.08	10.16	9.68	9.70	11.36	7.64	8.01	8.52
Minimum	44	-16	51	-22	51	-24	47	-11	50	-12
Q1	59.0	-3.0	62.0	-6.0	56.0	-8.0	60.0	-4.0	55.0	-12.0
Median	62.5	0.0	70.0	-1.0	63.0	-1.0	68.0	-1.0	61.0	-3.0
Q3	71.0	9.0	76.0	4.0	72.0	4.0	74.0	2.0	69.0	0.0
Maximum	91	31	84	29	88	18	93	19	75	11

治験総括報告書 Table 3.3.2.1.1（Section 15.1）（5.3.5.4-1）から引用

表 2.7.4.8-付録-48　バイタルサイン及び体重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）

Pulse (bpm)

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	73.2		72.1		74.3		73.0		71.7	
SD	10.44		9.86		10.14		10.13		9.88	
Minimum	46		54		48		50		54	
Q1	66.0		65.0		67.0		64.0		65.0	
Median	73.0		71.0		73.0		73.0		70.0	
Q3	80.0		78.0		81.0		80.0		78.0	
Maximum	104		96		96		99		106	
Week 4										
N	97	97	103	103	100	100	103	103	80	80
Mean	73.3	0.1	72.9	0.8	73.4	-0.9	72.3	-0.6	70.9	-0.8
SD	9.90	8.83	11.29	9.91	9.73	8.97	9.45	8.95	10.52	10.87
Minimum	51	-29	52	-29	48	-25	50	-25	46	-33
Q1	66.0	-5.0	64.0	-5.0	66.0	-7.0	66.0	-6.0	63.0	-7.0
Median	73.0	1.0	72.0	0.0	74.0	0.0	72.0	0.0	70.0	-0.5
Q3	79.0	6.0	80.0	6.0	79.5	4.0	78.0	4.0	77.5	4.5
Maximum	106	23	118	38	102	20	111	36	96	35
Week 8										
N	95	95	103	103	96	96	101	101	78	78
Mean	73.5	0.4	73.3	1.2	73.4	-0.9	73.4	0.4	71.5	-0.1
SD	10.15	8.80	11.36	8.64	9.69	8.33	9.93	9.23	10.02	9.04
Minimum	47	-24	54	-20	54	-20	47	-17	48	-19
Q1	66.0	-6.0	64.0	-4.0	66.5	-6.0	67.0	-6.0	66.0	-7.0
Median	72.0	1.0	73.0	1.0	72.5	-1.0	73.0	-1.0	72.0	0.0
Q3	80.0	7.0	81.0	6.0	78.0	4.0	80.0	5.0	76.0	6.0
Maximum	108	22	107	28	101	29	96	26	107	36
Week 12										
N	93	93	101	101	92	92	101	101	75	75
Mean	73.0	0.0	73.2	1.0	73.5	-0.5	72.3	-0.7	71.1	-0.9
SD	9.14	8.03	10.32	9.02	10.85	10.44	10.15	10.74	10.56	9.63
Minimum	46	-26	50	-21	55	-27	51	-29	44	-20
Q1	66.0	-5.0	66.0	-5.0	65.0	-7.0	65.0	-7.0	62.0	-7.0
Median	73.0	0.0	73.0	0.0	73.0	0.0	72.0	-1.0	72.0	-1.0
Q3	78.0	6.0	80.0	5.0	79.0	5.0	77.0	5.0	79.0	5.0
Maximum	95	20	106	26	106	25	101	32	93	26
Follow-up										
N	18	18	19	19	22	22	13	13	10	10
Mean	74.1	4.3	73.7	1.7	74.8	-1.0	74.8	5.2	74.6	5.7
SD	10.59	9.57	10.73	7.96	11.35	9.45	10.88	12.24	9.00	10.57
Minimum	58	-20	55	-13	47	-23	57	-15	61	-10
Q1	65.0	0.0	65.0	-5.0	70.0	-9.0	69.0	-6.0	71.0	-1.0
Median	74.0	4.0	75.0	3.0	75.0	0.5	73.0	10.0	74.0	4.5
Q3	79.0	13.0	78.0	7.0	80.0	5.0	80.0	13.0	81.0	12.0
Maximum	96	17	95	14	99	15	95	23	88	27

治験総括報告書 Table 3.3.2.1.1（Section 15.1）（5.3.5.4-1）から引用

表 2.7.4.8-付録-48　バイタルサイン及び体重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）

Temperature (℃)

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	36.40		36.43		36.36		36.44		36.40	
SD	0.392		0.398		0.457		0.372		0.401	
Minimum	34.8		34.8		35.0		35.3		35.5	
Q1	36.20		36.20		36.10		36.20		36.15	
Median	36.50		36.50		36.40		36.50		36.45	
Q3	36.70		36.70		36.70		36.70		36.70	
Maximum	37.1		37.4		37.3		37.2		37.2	
Week 4										
N	97	97	103	103	100	100	103	103	80	80
Mean	36.41	0.01	36.38	-0.04	36.34	-0.02	36.36	-0.08	36.38	-0.02
SD	0.397	0.399	0.443	0.420	0.422	0.398	0.390	0.378	0.383	0.391
Minimum	35.2	-1.4	35.0	-1.5	35.0	-1.5	35.3	-0.9	35.1	-1.3
Q1	36.20	-0.20	36.10	-0.30	36.10	-0.30	36.10	-0.30	36.20	-0.20
Median	36.50	0.10	36.50	0.00	36.40	-0.05	36.40	-0.10	36.50	0.00
Q3	36.70	0.30	36.70	0.30	36.65	0.20	36.60	0.20	36.60	0.20
Maximum	37.2	1.0	37.3	0.7	37.1	1.3	37.0	0.8	37.1	1.0
Week 8										
N	95	95	103	103	96	96	101	101	78	78
Mean	36.44	0.04	36.34	-0.08	36.32	-0.04	36.36	-0.07	36.31	-0.08
SD	0.439	0.387	0.453	0.444	0.455	0.484	0.422	0.400	0.450	0.422
Minimum	35.4	-0.8	35.0	-2.0	34.9	-1.1	35.2	-0.9	35.1	-1.7
Q1	36.30	-0.20	36.10	-0.30	36.10	-0.40	36.10	-0.30	36.00	-0.30
Median	36.50	0.00	36.40	0.00	36.40	-0.10	36.40	-0.10	36.40	-0.10
Q3	36.70	0.30	36.70	0.20	36.60	0.20	36.70	0.10	36.70	0.10
Maximum	37.5	1.2	37.3	0.7	37.2	1.5	37.2	1.3	37.0	1.2
Week 12										
N	93	93	101	101	92	92	101	101	75	75
Mean	36.44	0.04	36.39	-0.05	36.33	-0.03	36.35	-0.08	36.21	-0.18
SD	0.389	0.446	0.468	0.450	0.404	0.458	0.398	0.413	0.412	0.383
Minimum	35.1	-1.2	35.0	-1.4	35.1	-1.6	35.1	-1.5	35.1	-1.0
Q1	36.20	-0.30	36.10	-0.30	36.10	-0.30	36.10	-0.30	35.90	-0.40
Median	36.50	0.00	36.40	-0.10	36.40	-0.10	36.40	-0.10	36.20	-0.20
Q3	36.70	0.30	36.60	0.20	36.60	0.20	36.60	0.20	36.50	0.00
Maximum	37.3	1.7	38.2	1.8	37.3	1.3	37.4	1.2	37.1	0.6
Follow-up										
N	18	18	19	19	22	22	13	13	10	10
Mean	36.47	0.07	36.47	-0.07	36.45	0.01	36.44	0.10	36.41	-0.15
SD	0.345	0.358	0.325	0.364	0.438	0.462	0.275	0.507	0.338	0.292
Minimum	35.8	-0.7	35.9	-1.0	35.6	-1.2	36.0	-1.1	35.6	-0.5
Q1	36.30	-0.20	36.20	-0.20	36.20	-0.10	36.20	0.00	36.30	-0.40
Median	36.50	0.15	36.50	0.00	36.40	0.05	36.40	0.10	36.50	-0.15
Q3	36.70	0.30	36.80	0.20	36.70	0.10	36.60	0.40	36.70	-0.10
Maximum	37.2	0.7	37.0	0.5	37.6	1.2	36.9	0.8	36.7	0.5

治験総括報告書 Table 3.3.2.1.1（Section 15.1）（5.3.5.4-1）から引用

表 2.7.4.8-付録-48　バイタルサイン及び体重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）

Weight (kg)

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	53.78		54.76		51.33		54.86		56.24	
SD	8.063		8.892		6.427		8.453		8.768	
Minimum	38.7		37.7		37.7		42.5		40.8	
Q1	48.30		49.00		47.15		48.80		48.65	
Median	52.70		53.30		50.65		53.30		54.90	
Q3	57.60		58.50		54.45		58.00		62.45	
Maximum	81.5		88.9		76.2		83.8		78.2	
Week 4										
N	97	97	103	103	100	100	103	103	80	80
Mean	53.92	0.14	54.53	-0.22	50.87	-0.46	54.03	-0.84	55.56	-0.68
SD	8.077	0.864	8.856	0.935	6.509	0.865	8.571	0.918	8.521	1.142
Minimum	37.2	-2.1	37.7	-4.8	37.7	-2.7	41.0	-4.5	41.5	-3.4
Q1	48.10	-0.40	49.00	-0.80	46.40	-1.10	47.70	-1.40	48.50	-1.50
Median	53.50	0.00	53.40	-0.10	49.95	-0.25	52.20	-0.90	53.50	-0.50
Q3	57.40	0.60	58.20	0.30	54.50	0.10	57.40	-0.20	61.30	-0.15
Maximum	81.2	2.7	88.8	1.7	75.4	1.6	83.9	1.1	77.0	5.6
Week 8										
N	95	95	103	103	96	96	101	101	78	78
Mean	53.93	0.01	54.38	-0.37	50.70	-0.72	54.03	-0.92	55.29	-0.91
SD	8.037	0.958	8.880	1.164	6.518	1.109	8.696	1.164	8.838	1.037
Minimum	36.7	-2.6	37.8	-4.3	37.4	-3.2	40.4	-5.8	40.8	-3.8
Q1	47.50	-0.50	49.30	-1.20	46.05	-1.50	47.70	-1.50	48.20	-1.80
Median	53.50	0.00	53.30	-0.30	50.30	-0.70	52.40	-0.90	53.20	-0.60
Q3	57.50	0.60	58.00	0.40	54.30	0.05	57.20	-0.30	62.10	-0.20
Maximum	80.3	2.7	89.5	2.5	73.0	1.6	84.7	2.5	77.1	1.0
Week 12										
N	93	93	101	101	92	92	101	101	75	75
Mean	53.95	0.11	54.37	-0.46	50.49	-0.70	54.17	-0.78	55.31	-1.07
SD	8.201	1.174	9.151	1.185	6.085	1.425	8.751	1.470	8.783	1.126
Minimum	36.6	-3.7	38.0	-4.3	38.2	-6.3	40.4	-7.5	40.2	-3.9
Q1	47.90	-0.70	49.00	-1.20	46.00	-1.65	47.80	-1.70	47.90	-1.90
Median	53.00	0.20	52.70	-0.50	50.65	-0.55	52.70	-0.60	53.00	-0.90
Q3	57.30	1.00	57.40	0.40	54.55	0.30	58.40	0.10	61.70	-0.20
Maximum	80.8	2.8	90.5	2.3	69.9	2.4	85.1	3.8	77.2	1.7
Follow-up										
N	18	18	19	19	22	22	13	13	10	10
Mean	53.54	0.77	58.16	0.20	50.68	-0.16	56.13	0.38	56.49	-0.94
SD	9.641	0.932	11.948	1.660	6.573	1.123	7.902	1.482	9.626	1.339
Minimum	42.5	-1.0	43.8	-2.5	41.0	-2.5	44.0	-1.4	43.0	-3.0
Q1	46.50	0.00	50.20	-1.00	46.50	-0.70	51.50	-0.30	47.40	-2.00
Median	52.15	0.50	55.60	-0.60	49.60	-0.05	54.70	0.00	57.95	-0.75
Q3	56.00	1.50	63.00	1.60	54.00	0.60	59.40	0.80	63.60	0.00
Maximum	76.8	2.8	91.6	3.4	71.8	1.9	73.1	4.6	70.1	1.3

治験総括報告書 Table 3.3.2.1.1（Section 15.1）（5.3.5.4-1）から引用

表 2.7.4.8-付録-49　バイタルサイン及び体重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）

Systolic Blood Pressure (mmHg)

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	111.2		112.3		108.2		113.8		112.0	
SD	12.58		12.58		13.40		13.32		13.19	
Minimum	84		80		79		89		85	
Q1	103.0		103.0		99.0		104.0		103.0	
Median	110.0		111.0		107.0		112.0		110.0	
Q3	117.0		122.0		115.0		121.0		120.5	
Maximum	156		144		150		151		152	
Week 4										
N	97	97	103	103	100	100	103	103	80	80
Mean	110.0	-1.2	111.6	-0.7	108.3	0.1	112.1	-1.7	110.8	-1.2
SD	13.12	10.55	13.90	10.95	12.55	9.84	13.24	10.06	12.54	9.74
Minimum	83	-26	75	-21	83	-35	82	-31	90	-25
Q1	103.0	-8.0	100.0	-9.0	99.5	-5.5	102.0	-7.0	102.0	-7.0
Median	110.0	-1.0	112.0	0.0	108.5	1.5	110.0	-1.0	109.0	-1.0
Q3	118.0	6.0	123.0	6.0	116.5	7.0	121.0	6.0	118.0	6.0
Maximum	145	22	148	34	140	20	152	21	147	21
Week 8										
N	95	95	103	103	96	96	101	101	78	78
Mean	110.5	-0.5	112.0	-0.3	108.4	0.1	112.9	-0.9	112.4	0.5
SD	12.43	9.94	13.17	9.41	11.77	11.67	15.65	10.30	11.91	8.84
Minimum	79	-31	86	-27	80	-33	84	-31	84	-22
Q1	103.0	-4.0	101.0	-6.0	100.0	-8.0	103.0	-8.0	106.0	-5.0
Median	111.0	1.0	112.0	-1.0	108.0	1.0	109.0	0.0	112.0	0.0
Q3	118.0	5.0	122.0	6.0	115.5	8.0	122.0	6.0	118.0	6.0
Maximum	146	24	143	20	141	26	184	34	142	22
Week 12										
N	93	93	101	101	92	92	101	101	75	75
Mean	109.6	-1.5	111.4	-1.0	107.4	-0.6	111.2	-2.6	111.0	-1.3
SD	10.76	9.98	12.41	9.84	11.47	11.24	14.68	11.61	15.23	11.78
Minimum	87	-27	78	-29	79	-31	80	-33	78	-26
Q1	101.0	-7.0	103.0	-6.0	99.5	-6.0	101.0	-9.0	100.0	-10.0
Median	110.0	-1.0	111.0	-1.0	107.5	0.5	110.0	-3.0	109.0	-4.0
Q3	116.0	5.0	118.0	5.0	115.0	5.5	119.0	4.0	121.0	9.0
Maximum	147	20	153	19	136	30	155	30	157	24
Week 16										
N	75	75	84	84	78	78	89	89	69	69
Mean	109.9	-1.4	110.6	-1.7	107.5	-0.7	109.1	-4.3	113.5	0.4
SD	12.65	10.14	11.99	8.69	11.96	12.68	14.49	8.97	13.97	11.08
Minimum	86	-26	85	-28	80	-38	80	-28	85	-22
Q1	101.0	-8.0	102.0	-7.0	97.0	-8.0	100.0	-10.0	102.0	-7.0
Median	107.0	-2.0	109.5	-2.0	108.0	1.5	107.0	-3.0	114.0	0.0
Q3	117.0	5.0	117.5	4.0	115.0	7.0	115.0	2.0	122.0	8.0
Maximum	143	24	154	20	140	31	158	12	152	30

治験総括報告書 Table 3.2.2.1.1（Section 15.1）（5.3.5.4-2）から引用

表 2.7.4.8-付録-49　バイタルサイン及び体重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）

Systolic Blood Pressure (mmHg)

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	110.5	-0.7	110.9	-1.6	107.6	-0.7	112.0	-1.6	112.0	-1.2
SD	13.15	12.02	13.66	10.17	12.93	13.15	13.86	10.36	14.71	9.82
Minimum	80	-33	79	-23	82	-25	87	-27	86	-20
Q1	103.0	-6.0	101.0	-8.0	98.0	-8.0	102.0	-9.0	104.0	-9.0
Median	109.0	0.0	108.0	-3.0	104.0	-1.0	110.0	-2.0	110.0	0.0
Q3	117.0	7.0	122.0	5.0	118.0	6.0	122.0	6.0	120.0	5.0
Maximum	154	31	144	33	146	49	148	31	146	18
Week 24										
N	68	68	79	79	76	76	88	88	62	62
Mean	111.0	-0.6	110.1	-2.3	107.9	-0.8	111.1	-2.3	112.4	-1.4
SD	11.38	10.43	11.81	9.56	11.37	12.64	13.30	10.94	14.58	10.66
Minimum	82	-23	88	-20	85	-43	88	-25	81	-22
Q1	104.0	-7.5	101.0	-9.0	100.0	-8.5	102.0	-10.0	102.0	-10.0
Median	110.0	-2.0	110.0	-3.0	107.5	0.5	111.0	-3.0	112.0	0.0
Q3	117.0	6.0	119.0	5.0	114.5	8.0	119.5	5.0	121.0	6.0
Maximum	141	34	140	23	142	40	152	23	146	19
Follow-up										
N	77	77	83	83	77	77	89	89	69	69
Mean	112.7	1.3	110.4	-2.0	108.9	0.6	111.4	-2.1	110.7	-2.4
SD	13.68	12.07	12.07	9.49	12.02	13.60	13.45	10.71	13.66	10.49
Minimum	79	-29	85	-33	89	-36	89	-25	81	-26
Q1	102.0	-7.0	101.0	-9.0	100.0	-8.0	102.0	-10.0	102.0	-8.0
Median	112.0	2.0	110.0	-2.0	108.0	2.0	108.0	-2.0	110.0	-2.0
Q3	121.0	9.0	118.0	3.0	116.0	10.0	119.0	6.0	119.0	3.0
Maximum	143	33	139	27	143	33	157	23	146	27

治験総括報告書 Table 3.2.2.1.1（Section 15.1）（5.3.5.4-2）から引用

表 2.7.4.8-付録-49　バイタルサイン及び体重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）

Diastolic Blood Pressure (mmHg)

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	66.7		68.6		65.6		69.3		67.7	
SD	9.46		9.69		9.72		10.51		10.43	
Minimum	46		49		50		41		44	
Q1	60.0		61.0		59.0		62.0		60.5	
Median	66.0		69.0		64.0		69.0		66.0	
Q3	73.0		74.0		72.0		76.0		74.0	
Maximum	91		101		93		99		95	
Week 4										
N	97	97	103	103	100	100	103	103	80	80
Mean	67.3	0.6	67.4	-1.2	65.4	-0.2	69.6	0.3	68.0	0.3
SD	9.56	7.15	10.94	8.32	9.44	7.95	11.27	8.21	10.34	6.82
Minimum	42	-16	48	-19	44	-29	40	-24	40	-18
Q1	61.0	-5.0	59.0	-6.0	60.0	-4.0	61.0	-4.0	62.0	-5.0
Median	66.0	0.0	66.0	-1.0	65.0	1.0	69.0	0.0	67.5	1.0
Q3	74.0	5.0	74.0	2.0	71.0	5.0	78.0	6.0	72.5	5.0
Maximum	90	20	94	31	95	20	100	21	96	16
Week 8										
N	95	95	103	103	96	96	101	101	78	78
Mean	67.1	0.6	67.8	-0.8	66.0	0.3	69.2	-0.1	69.6	2.1
SD	9.20	7.92	10.61	7.40	9.67	7.79	11.02	8.26	10.26	7.35
Minimum	48	-21	46	-24	47	-28	48	-19	45	-15
Q1	61.0	-4.0	60.0	-6.0	58.0	-4.0	62.0	-6.0	63.0	-3.0
Median	67.0	0.0	67.0	-1.0	65.0	1.0	67.0	0.0	68.0	2.0
Q3	72.0	6.0	74.0	4.0	71.0	5.0	77.0	5.0	76.0	7.0
Maximum	90	26	91	16	92	24	100	21	97	21
Week 12										
N	93	93	101	101	92	92	101	101	75	75
Mean	65.5	-1.0	67.2	-1.2	65.5	0.0	67.8	-1.5	69.3	1.7
SD	9.06	8.49	10.18	7.90	8.63	7.68	10.37	9.20	12.01	9.51
Minimum	41	-26	40	-21	50	-22	46	-21	41	-29
Q1	60.0	-6.0	59.0	-6.0	60.0	-4.0	61.0	-8.0	63.0	-4.0
Median	64.0	-2.0	68.0	0.0	64.5	0.0	67.0	-1.0	69.0	1.0
Q3	70.0	4.0	73.0	4.0	70.5	4.5	74.0	4.0	75.0	7.0
Maximum	90	29	94	19	90	19	111	20	97	24
Week 16										
N	75	75	84	84	78	78	89	89	69	69
Mean	65.7	-1.8	66.4	-2.0	65.3	-0.1	67.6	-1.8	69.3	1.2
SD	10.62	7.90	9.06	6.27	9.70	8.93	11.00	8.10	10.53	8.48
Minimum	46	-26	49	-21	40	-22	38	-24	45	-17
Q1	58.0	-7.0	60.0	-6.0	59.0	-4.0	60.0	-7.0	62.0	-4.0
Median	64.0	-2.0	65.0	-2.5	65.5	0.0	66.0	-2.0	68.0	1.0
Q3	72.0	3.0	73.0	1.0	71.0	6.0	74.0	4.0	76.0	8.0
Maximum	91	16	91	13	89	19	103	20	96	17

治験総括報告書 Table 3.2.2.1.1（Section 15.1）（5.3.5.4-2）から引用

表 2.7.4.8-付録-49　バイタルサイン及び体重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）

Diastolic Blood Pressure (mmHg)

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	66.9	-0.6	67.2	-1.2	65.2	-0.3	68.5	-1.1	68.2	0.1
SD	11.04	10.14	10.51	7.92	9.28	9.23	10.83	8.59	11.08	8.48
Minimum	46	-30	40	-26	50	-20	50	-25	44	-18
Q1	59.0	-6.0	59.0	-4.0	58.0	-7.0	61.0	-6.0	60.0	-6.0
Median	65.0	0.0	67.0	-1.0	64.0	0.0	67.0	-1.0	69.0	1.0
Q3	73.0	5.0	73.0	3.0	70.0	6.0	75.0	4.0	75.0	5.0
Maximum	104	35	93	24	99	25	99	25	94	22
Week 24										
N	68	68	79	79	76	76	88	88	62	62
Mean	67.4	-0.1	66.4	-1.8	65.1	-0.5	67.6	-1.9	70.2	1.7
SD	10.15	9.00	8.55	7.36	9.96	8.56	10.46	8.95	10.92	8.83
Minimum	50	-32	46	-22	44	-22	38	-30	45	-16
Q1	61.0	-7.0	60.0	-7.0	59.0	-5.5	59.0	-7.0	62.0	-5.0
Median	66.0	1.0	67.0	-1.0	65.0	0.0	68.5	-2.0	70.0	2.5
Q3	73.5	6.0	72.0	4.0	69.0	5.0	74.0	4.5	75.0	8.0
Maximum	95	22	87	17	99	19	93	21	98	26
Follow-up										
N	77	77	83	83	77	77	89	89	69	69
Mean	67.1	-0.6	66.0	-2.4	64.9	-0.5	67.6	-1.8	68.3	0.2
SD	9.64	9.29	9.41	8.10	9.91	10.59	9.95	8.04	11.12	8.77
Minimum	48	-21	45	-22	40	-24	44	-18	42	-26
Q1	61.0	-8.0	58.0	-8.0	58.0	-7.0	61.0	-7.0	60.0	-5.0
Median	65.0	-1.0	66.0	-3.0	64.0	-1.0	67.0	-3.0	67.0	1.0
Q3	73.0	7.0	71.0	3.0	71.0	6.0	74.0	3.0	75.0	7.0
Maximum	98	23	90	24	95	28	103	26	98	17

治験総括報告書 Table 3.2.2.1.1（Section 15.1）（5.3.5.4-2）から引用

表 2.7.4.8-付録-49　バイタルサイン及び体重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）

Pulse (bpm)

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	73.2		72.1		74.3		73.0		71.7	
SD	10.44		9.86		10.14		10.13		9.88	
Minimum	46		54		48		50		54	
Q1	66.0		65.0		67.0		64.0		65.0	
Median	73.0		71.0		73.0		73.0		70.0	
Q3	80.0		78.0		81.0		80.0		78.0	
Maximum	104		96		96		99		106	
Week 4										
N	97	97	103	103	100	100	103	103	80	80
Mean	73.3	0.1	72.9	0.8	73.4	-0.9	72.3	-0.6	70.9	-0.8
SD	9.90	8.83	11.29	9.91	9.73	8.97	9.45	8.95	10.52	10.87
Minimum	51	-29	52	-29	48	-25	50	-25	46	-33
Q1	66.0	-5.0	64.0	-5.0	66.0	-7.0	66.0	-6.0	63.0	-7.0
Median	73.0	1.0	72.0	0.0	74.0	0.0	72.0	0.0	70.0	-0.5
Q3	79.0	6.0	80.0	6.0	79.5	4.0	78.0	4.0	77.5	4.5
Maximum	106	23	118	38	102	20	111	36	96	35
Week 8										
N	95	95	103	103	96	96	101	101	78	78
Mean	73.5	0.4	73.3	1.2	73.4	-0.9	73.4	0.4	71.5	-0.1
SD	10.15	8.80	11.36	8.64	9.69	8.33	9.93	9.23	10.02	9.04
Minimum	47	-24	54	-20	54	-20	47	-17	48	-19
Q1	66.0	-6.0	64.0	-4.0	66.5	-6.0	67.0	-6.0	66.0	-7.0
Median	72.0	1.0	73.0	1.0	72.5	-1.0	73.0	-1.0	72.0	0.0
Q3	80.0	7.0	81.0	6.0	78.0	4.0	80.0	5.0	76.0	6.0
Maximum	108	22	107	28	101	29	96	26	107	36
Week 12										
N	93	93	101	101	92	92	101	101	75	75
Mean	73.0	0.0	73.2	1.0	73.5	-0.5	72.3	-0.7	71.1	-0.9
SD	9.14	8.03	10.32	9.02	10.85	10.44	10.15	10.74	10.56	9.63
Minimum	46	-26	50	-21	55	-27	51	-29	44	-20
Q1	66.0	-5.0	66.0	-5.0	65.0	-7.0	65.0	-7.0	62.0	-7.0
Median	73.0	0.0	73.0	0.0	73.0	0.0	72.0	-1.0	72.0	-1.0
Q3	78.0	6.0	80.0	5.0	79.0	5.0	77.0	5.0	79.0	5.0
Maximum	95	20	106	26	106	25	101	32	93	26
Week 16										
N	75	75	84	84	78	78	89	89	69	69
Mean	73.0	-1.0	71.8	-0.3	73.4	-0.5	73.0	-0.4	72.3	0.2
SD	9.68	10.01	10.18	8.48	10.80	8.74	9.70	9.07	9.80	9.91
Minimum	50	-25	49	-18	51	-22	54	-22	52	-19
Q1	66.0	-7.0	66.0	-6.0	67.0	-6.0	66.0	-8.0	65.0	-6.0
Median	71.0	-1.0	71.0	-1.0	72.0	-0.5	72.0	0.0	73.0	0.0
Q3	80.0	7.0	77.5	4.0	80.0	5.0	81.0	6.0	78.0	6.0
Maximum	102	24	107	27	105	18	94	26	102	38

治験総括報告書 Table 3.2.2.1.1（Section 15.1）（5.3.5.4-2）から引用

表 2.7.4.8-付録-49　バイタルサイン及び体重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）

Pulse (bpm)

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	74.7	0.7	74.1	1.7	74.1	0.3	74.4	0.9	71.6	-0.4
SD	9.99	11.67	9.68	7.99	10.49	8.85	10.21	10.79	11.42	10.27
Minimum	53	-41	53	-18	56	-19	53	-26	50	-25
Q1	68.0	-5.0	66.0	-3.0	66.0	-5.0	68.0	-5.0	65.0	-6.0
Median	73.0	1.0	75.0	2.0	72.0	0.0	74.0	0.0	70.0	-3.0
Q3	81.0	7.0	81.0	7.0	81.0	6.0	82.0	7.0	77.0	6.0
Maximum	98	32	98	18	105	22	98	36	104	40
Week 24										
N	68	68	79	79	76	76	88	88	62	62
Mean	74.8	0.5	71.5	-1.0	73.1	-1.0	73.9	0.3	71.1	-0.6
SD	10.85	9.80	8.74	9.04	9.81	9.51	9.25	9.46	9.76	9.18
Minimum	48	-36	54	-22	55	-28	52	-25	48	-20
Q1	67.5	-4.5	66.0	-7.0	65.5	-7.0	67.5	-4.5	64.0	-7.0
Median	75.5	1.0	72.0	0.0	73.0	-0.5	74.5	1.0	72.0	0.0
Q3	81.0	6.0	78.0	4.0	81.5	5.0	80.0	5.0	78.0	6.0
Maximum	102	22	96	20	93	18	97	25	92	27
Follow-up										
N	77	77	83	83	77	77	89	89	69	69
Mean	76.1	1.9	73.4	1.2	74.4	0.6	75.8	2.4	71.9	-0.3
SD	10.37	10.21	9.68	8.04	9.41	9.22	9.94	10.13	9.15	7.97
Minimum	46	-31	52	-20	58	-21	52	-29	46	-17
Q1	68.0	-3.0	67.0	-3.0	67.0	-6.0	70.0	-2.0	65.0	-6.0
Median	75.0	2.0	74.0	2.0	73.0	1.0	75.0	3.0	71.0	0.0
Q3	84.0	8.0	79.0	7.0	80.0	8.0	84.0	8.0	78.0	6.0
Maximum	102	22	96	18	95	21	104	30	90	23

治験総括報告書 Table 3.2.2.1.1（Section 15.1）（5.3.5.4-2）から引用

表 2.7.4.8-付録-49　バイタルサイン及び体重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）

Temperature (° C)

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	36.40		36.43		36.36		36.44		36.40	
SD	0.392		0.398		0.457		0.372		0.401	
Minimum	34.8		34.8		35.0		35.3		35.5	
Q1	36.20		36.20		36.10		36.20		36.15	
Median	36.50		36.50		36.40		36.50		36.45	
Q3	36.70		36.70		36.70		36.70		36.70	
Maximum	37.1		37.4		37.3		37.2		37.2	
Week 4										
N	97	97	103	103	100	100	103	103	80	80
Mean	36.41	0.01	36.38	-0.04	36.34	-0.02	36.36	-0.08	36.38	-0.02
SD	0.397	0.399	0.443	0.420	0.422	0.398	0.390	0.378	0.383	0.391
Minimum	35.2	-1.4	35.0	-1.5	35.0	-1.5	35.3	-0.9	35.1	-1.3
Q1	36.20	-0.20	36.10	-0.30	36.10	-0.30	36.10	-0.30	36.20	-0.20
Median	36.50	0.10	36.50	0.00	36.40	-0.05	36.40	-0.10	36.50	0.00
Q3	36.70	0.30	36.70	0.30	36.65	0.20	36.60	0.20	36.60	0.20
Maximum	37.2	1.0	37.3	0.7	37.1	1.3	37.0	0.8	37.1	1.0
Week 8										
N	95	95	103	103	96	96	101	101	78	78
Mean	36.44	0.04	36.34	-0.08	36.32	-0.04	36.36	-0.07	36.31	-0.08
SD	0.439	0.387	0.453	0.444	0.455	0.484	0.422	0.400	0.450	0.422
Minimum	35.4	-0.8	35.0	-2.0	34.9	-1.1	35.2	-0.9	35.1	-1.7
Q1	36.30	-0.20	36.10	-0.30	36.10	-0.40	36.10	-0.30	36.00	-0.30
Median	36.50	0.00	36.40	0.00	36.40	-0.10	36.40	-0.10	36.40	-0.10
Q3	36.70	0.30	36.70	0.20	36.60	0.20	36.70	0.10	36.70	0.10
Maximum	37.5	1.2	37.3	0.7	37.2	1.5	37.2	1.3	37.0	1.2
Week 12										
N	93	93	101	101	92	92	101	101	75	75
Mean	36.44	0.04	36.39	-0.05	36.33	-0.03	36.35	-0.08	36.21	-0.18
SD	0.389	0.446	0.468	0.450	0.404	0.458	0.398	0.413	0.412	0.383
Minimum	35.1	-1.2	35.0	-1.4	35.1	-1.6	35.1	-1.5	35.1	-1.0
Q1	36.20	-0.30	36.10	-0.30	36.10	-0.30	36.10	-0.30	35.90	-0.40
Median	36.50	0.00	36.40	-0.10	36.40	-0.10	36.40	-0.10	36.20	-0.20
Q3	36.70	0.30	36.60	0.20	36.60	0.20	36.60	0.20	36.50	0.00
Maximum	37.3	1.7	38.2	1.8	37.3	1.3	37.4	1.2	37.1	0.6
Week 16										
N	75	75	84	84	78	78	89	89	69	69
Mean	36.46	0.05	36.32	-0.08	36.37	0.03	36.35	-0.10	36.31	-0.06
SD	0.435	0.494	0.429	0.436	0.393	0.386	0.443	0.424	0.386	0.380
Minimum	35.1	-1.1	35.1	-1.2	35.2	-0.9	34.9	-1.7	35.1	-1.1
Q1	36.20	-0.30	36.10	-0.35	36.10	-0.20	36.20	-0.30	36.10	-0.30
Median	36.50	0.10	36.40	-0.10	36.40	0.00	36.40	-0.10	36.30	-0.10
Q3	36.80	0.40	36.60	0.20	36.70	0.20	36.70	0.20	36.60	0.10
Maximum	37.3	1.5	37.1	1.0	37.0	1.2	37.5	0.8	37.2	1.1

治験総括報告書 Table 3.2.2.1.1（Section 15.1）（5.3.5.4-2）から引用

表 2.7.4.8-付録-49　バイタルサイン及び体重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）

Temperature (°C)

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	36.41	0.00	36.28	-0.12	36.30	-0.04	36.38	-0.06	36.25	-0.12
SD	0.417	0.480	0.471	0.472	0.378	0.439	0.429	0.431	0.341	0.415
Minimum	35.4	-1.3	34.6	-1.4	35.3	-1.3	34.8	-1.6	35.5	-1.7
Q1	36.10	-0.20	36.00	-0.50	36.00	-0.30	36.10	-0.30	36.00	-0.30
Median	36.50	0.00	36.30	-0.10	36.40	0.00	36.50	-0.10	36.30	-0.10
Q3	36.70	0.30	36.60	0.20	36.50	0.20	36.70	0.20	36.50	0.10
Maximum	37.2	1.5	37.0	1.1	37.0	1.6	37.1	1.0	36.9	0.6
Week 24										
N	68	68	79	79	76	76	88	88	62	62
Mean	36.51	0.11	36.32	-0.09	36.36	0.02	36.31	-0.14	36.21	-0.16
SD	0.451	0.384	0.420	0.507	0.366	0.374	0.462	0.431	0.443	0.411
Minimum	35.0	-1.0	35.2	-1.4	35.2	-0.8	35.0	-1.2	35.0	-1.2
Q1	36.40	-0.10	36.10	-0.40	36.15	-0.20	36.10	-0.40	36.00	-0.40
Median	36.60	0.10	36.40	-0.10	36.40	0.00	36.40	-0.10	36.30	-0.10
Q3	36.80	0.30	36.60	0.20	36.60	0.20	36.60	0.10	36.50	0.10
Maximum	37.2	1.1	37.0	1.6	37.3	1.0	37.4	1.1	36.9	0.7
Follow-up										
N	77	77	83	83	77	77	89	89	69	69
Mean	36.52	0.12	36.41	0.01	36.46	0.12	36.56	0.11	36.32	-0.06
SD	0.423	0.456	0.462	0.471	0.442	0.427	0.377	0.366	0.465	0.403
Minimum	35.1	-1.0	35.1	-1.4	34.6	-1.0	35.4	-1.0	35.0	-0.9
Q1	36.30	-0.20	36.20	-0.20	36.20	-0.10	36.40	-0.10	36.00	-0.40
Median	36.50	0.10	36.50	0.10	36.50	0.10	36.60	0.10	36.40	-0.10
Q3	36.80	0.30	36.70	0.30	36.80	0.40	36.80	0.30	36.60	0.20
Maximum	37.5	1.7	37.2	1.4	37.3	1.5	37.3	1.1	37.3	0.9

治験総括報告書 Table 3.2.2.1.1（Section 15.1）（5.3.5.4-2）から引用

表 2.7.4.8-付録-49　バイタルサイン及び体重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）

Weight (kg)

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	53.78		54.76		51.33		54.86		56.24	
SD	8.063		8.892		6.427		8.453		8.768	
Minimum	38.7		37.7		37.7		42.5		40.8	
Q1	48.30		49.00		47.15		48.80		48.65	
Median	52.70		53.30		50.65		53.30		54.90	
Q3	57.60		58.50		54.45		58.00		62.45	
Maximum	81.5		88.9		76.2		83.8		78.2	
Week 4										
N	97	97	103	103	100	100	103	103	80	80
Mean	53.92	0.14	54.53	-0.22	50.87	-0.46	54.03	-0.84	55.56	-0.68
SD	8.077	0.864	8.856	0.935	6.509	0.865	8.571	0.918	8.521	1.142
Minimum	37.2	-2.1	37.7	-4.8	37.7	-2.7	41.0	-4.5	41.5	-3.4
Q1	48.10	-0.40	49.00	-0.80	46.40	-1.10	47.70	-1.40	48.50	-1.50
Median	53.50	0.00	53.40	-0.10	49.95	-0.25	52.20	-0.90	53.50	-0.50
Q3	57.40	0.60	58.20	0.30	54.50	0.10	57.40	-0.20	61.30	-0.15
Maximum	81.2	2.7	88.8	1.7	75.4	1.6	83.9	1.1	77.0	5.6
Week 8										
N	95	95	103	103	96	96	101	101	78	78
Mean	53.93	0.01	54.38	-0.37	50.70	-0.72	54.03	-0.92	55.29	-0.91
SD	8.037	0.958	8.880	1.164	6.518	1.109	8.696	1.164	8.838	1.037
Minimum	36.7	-2.6	37.8	-4.3	37.4	-3.2	40.4	-5.8	40.8	-3.8
Q1	47.50	-0.50	49.30	-1.20	46.05	-1.50	47.70	-1.50	48.20	-1.80
Median	53.50	0.00	53.30	-0.30	50.30	-0.70	52.40	-0.90	53.20	-0.60
Q3	57.50	0.60	58.00	0.40	54.30	0.05	57.20	-0.30	62.10	-0.20
Maximum	80.3	2.7	89.5	2.5	73.0	1.6	84.7	2.5	77.1	1.0
Week 12										
N	93	93	101	101	92	92	101	101	75	75
Mean	53.95	0.11	54.37	-0.46	50.49	-0.70	54.17	-0.78	55.31	-1.07
SD	8.201	1.174	9.151	1.185	6.085	1.425	8.751	1.470	8.783	1.126
Minimum	36.6	-3.7	38.0	-4.3	38.2	-6.3	40.4	-7.5	40.2	-3.9
Q1	47.90	-0.70	49.00	-1.20	46.00	-1.65	47.80	-1.70	47.90	-1.90
Median	53.00	0.20	52.70	-0.50	50.65	-0.55	52.70	-0.60	53.00	-0.90
Q3	57.30	1.00	57.40	0.40	54.55	0.30	58.40	0.10	61.70	-0.20
Maximum	80.8	2.8	90.5	2.3	69.9	2.4	85.1	3.8	77.2	1.7
Week 16										
N	75	75	84	84	78	78	89	89	69	69
Mean	53.81	-0.11	53.67	-0.36	50.43	-1.03	54.06	-0.78	55.22	-0.88
SD	7.860	1.267	8.147	1.236	6.188	1.736	9.016	1.751	8.762	1.491
Minimum	37.1	-4.2	38.4	-3.0	38.0	-9.0	40.9	-8.0	40.7	-5.2
Q1	47.40	-1.00	48.90	-1.30	46.20	-1.60	48.10	-1.80	47.70	-1.70
Median	53.10	0.10	52.25	-0.25	50.50	-0.80	52.30	-0.50	53.50	-0.80
Q3	56.80	0.60	57.40	0.50	54.40	0.00	58.10	0.30	62.00	0.00
Maximum	79.8	2.9	76.6	3.6	67.2	2.7	85.5	4.5	76.0	2.3

治験総括報告書 Table 3.2.2.1.1（Section 15.1）（5.3.5.4-2）から引用

表 2.7.4.8-付録-49　バイタルサイン及び体重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）

Weight (kg)

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	53.89	-0.03	53.72	-0.42	50.48	-0.95	54.20	-0.66	55.70	-0.78
SD	8.030	1.460	8.057	1.419	6.221	2.060	9.162	1.979	8.863	1.571
Minimum	37.3	-5.8	38.4	-3.1	37.8	-10.7	40.8	-9.8	38.4	-4.9
Q1	47.30	-1.10	49.40	-1.60	46.10	-1.60	47.70	-2.00	49.60	-1.70
Median	53.00	0.00	51.70	-0.50	50.90	-0.50	52.20	-0.50	54.00	-0.60
Q3	57.80	1.00	58.40	0.50	54.50	0.20	58.30	0.60	62.20	0.40
Maximum	81.6	3.0	76.4	3.7	65.5	2.5	85.3	4.2	78.0	2.0
Week 24										
N	68	68	79	79	76	76	88	88	62	62
Mean	54.53	0.07	54.03	-0.21	50.64	-0.82	54.10	-0.70	55.54	-0.92
SD	8.109	1.542	8.324	1.585	6.326	2.151	9.084	2.146	9.147	1.576
Minimum	37.9	-5.3	38.3	-4.6	37.7	-10.4	39.7	-8.8	38.1	-5.4
Q1	48.40	-1.10	48.30	-1.20	45.85	-1.60	48.10	-2.00	49.00	-1.80
Median	53.80	0.15	52.20	-0.10	50.95	-0.50	52.10	-0.60	54.00	-1.00
Q3	57.25	1.05	59.90	0.90	54.90	0.45	58.25	0.75	62.00	0.30
Maximum	83.5	3.3	77.6	5.6	65.8	3.7	84.9	4.4	78.2	2.2
Follow-up										
N	77	77	83	83	77	77	89	89	69	69
Mean	54.21	0.21	54.25	0.15	51.09	-0.36	54.76	-0.07	55.40	-0.71
SD	8.062	1.636	8.272	1.739	6.277	2.204	9.144	2.127	8.877	1.808
Minimum	37.7	-5.3	38.7	-4.9	38.0	-9.9	40.5	-6.5	38.2	-5.6
Q1	47.70	-0.70	48.80	-0.80	46.30	-0.90	48.50	-1.20	49.10	-1.60
Median	53.70	0.20	52.60	0.20	51.80	-0.20	52.50	-0.10	54.00	-0.50
Q3	57.40	1.30	59.50	1.20	55.10	1.10	59.10	1.40	60.80	0.60
Maximum	83.1	3.6	77.4	5.9	66.3	3.7	86.2	5.4	78.2	2.7

治験総括報告書 Table 3.2.2.1.1（Section 15.1）（5.3.5.4-2）から引用

表 2.7.4.8-付録-50　バイタルサインの MAV の発現頻度（安全性データの解析対象集団）（CCT-002 試験）

	Number of Subjects (%)	
	TAK-385 40mg (N=138)	Leuprorelin (N=142)
Systolic Blood Pressure		
Systolic Blood Pressure Lower	3/138(2.2)	2/142(1.4)
Systolic Blood Pressure Upper	0/138(0.0)	1/142(0.7)
Diastolic Blood Pressure		
Diastolic Blood Pressure Lower	5/138(3.6)	5/142(3.5)
Diastolic Blood Pressure Upper	2/138(1.4)	3/142(2.1)
Pulse Rate		
Pulse Rate Lower	0/138(0.0)	1/142(0.7)
Pulse Rate Upper	0/138(0.0)	0/142(0.0)
Body temperature		
Body temperature Lower	23/138(16.7)	23/142(16.2)
Body temperature Upper	1/138(0.7)	0/142(0.0)

治験総括報告書 Table 15.3.3.3（5.3.5.1-2）から引用

表 2.7.4.8-付録-51　バイタルサインの MAV の発現頻度（安全性データの解析対象集団）（3008 試験）

	Number of Subjects (%)	
	TAK-385 40mg (N=33)	Placebo (N=32)
Systolic Blood Pressure		
Systolic Blood Pressure Lower	0/33(0.0)	0/32(0.0)
Systolic Blood Pressure Upper	0/33(0.0)	0/32(0.0)
Diastolic Blood Pressure		
Diastolic Blood Pressure Lower	2/33(6.1)	1/32(3.1)
Diastolic Blood Pressure Upper	0/33(0.0)	0/32(0.0)
Pulse Rate		
Pulse Rate Lower	0/33(0.0)	0/32(0.0)
Pulse Rate Upper	0/33(0.0)	0/32(0.0)
Body temperature		
Body temperature Lower	4/33(12.1)	2/32(6.3)
Body temperature Upper	0/33(0.0)	0/32(0.0)

治験総括報告書 Table 15.3.3.3（5.3.5.1-3）から引用

表 2.7.4.8-付録-52　12 誘導心電図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-001 試験）

Heart Rate (bpm)

Visit / Statistics	Placebo (N=57) Observed Value at Visit	Placebo (N=57) Change from Baseline	TAK-385 10mg (N=48) Observed Value at Visit	TAK-385 10mg (N=48) Change from Baseline	TAK-385 20mg (N=55) Observed Value at Visit	TAK-385 20mg (N=55) Change from Baseline	TAK-385 40mg (N=54) Observed Value at Visit	TAK-385 40mg (N=54) Change from Baseline
Week 0								
N	57		48		55		54	
Mean	65.6		63.2		66.1		64.3	
SD	9.98		6.81		9.82		9.57	
Minimum	46		50		47		45	
Q1	59.0		59.0		58.0		58.0	
Median	63.0		63.0		65.0		62.0	
Q3	72.0		67.0		74.0		70.0	
Maximum	94		81		90		89	
Week 4								
N	57	57	48	48	55	55	54	54
Mean	66.2	0.5	63.9	0.6	62.9	-3.1	63.7	-0.6
SD	9.98	8.97	8.69	7.02	7.79	6.88	9.47	6.23
Minimum	47	-23	46	-18	49	-22	45	-23
Q1	59.0	-5.0	58.5	-4.0	57.0	-8.0	58.0	-4.0
Median	66.0	1.0	63.5	0.0	62.0	-2.0	62.5	0.0
Q3	72.0	5.0	69.0	5.0	68.0	1.0	69.0	3.0
Maximum	91	25	85	21	86	11	90	13
Week 8								
N	56	56	48	48	54	54	54	54
Mean	66.1	0.4	63.4	0.2	63.3	-2.8	62.6	-1.6
SD	11.37	7.94	6.87	6.71	8.76	6.99	9.20	7.60
Minimum	48	-18	47	-16	43	-21	44	-26
Q1	59.0	-4.0	58.5	-4.0	57.0	-6.0	56.0	-5.0
Median	65.5	0.5	63.5	0.0	62.0	-3.0	61.5	-2.0
Q3	73.0	6.5	69.5	4.5	68.0	1.0	69.0	3.0
Maximum	105	13	76	17	85	15	83	14
Week 12								
N	55	55	47	47	53	53	54	54
Mean	65.7	0.0	64.7	1.2	64.3	-1.9	64.7	0.4
SD	9.11	8.13	7.70	5.66	10.35	9.16	9.51	8.61
Minimum	50	-24	48	-13	48	-32	37	-18
Q1	61.0	-6.0	59.0	-2.0	58.0	-6.0	59.0	-6.0
Median	65.0	1.0	65.0	2.0	63.0	-2.0	64.0	0.0
Q3	70.0	4.0	70.0	5.0	70.0	3.0	70.0	6.0
Maximum	88	25	82	14	94	20	96	22

治験総括報告書 Table 3.3.2.2.1（Section 16.1.9.5）（5.3.5.1-1）から引用

表 2.7.4.8-付録-52　12 誘導心電図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-001 試験）（続き）

Heart Rate (bpm)

Visit / Statistics	Placebo (N=57) Observed Value at Visit	Placebo (N=57) Change from Baseline	TAK-385 10mg (N=48) Observed Value at Visit	TAK-385 10mg (N=48) Change from Baseline	TAK-385 20mg (N=55) Observed Value at Visit	TAK-385 20mg (N=55) Change from Baseline	TAK-385 40mg (N=54) Observed Value at Visit	TAK-385 40mg (N=54) Change from Baseline
Follow-up								
N	57	57	48	48	55	55	54	54
Mean	68.1	2.4	65.7	2.5	67.6	1.5	65.5	1.3
SD	10.02	8.96	8.66	7.06	11.70	10.18	9.46	7.05
Minimum	51	-17	49	-12	46	-26	43	-11
Q1	60.0	-2.0	58.5	-3.5	58.0	-5.0	60.0	-2.0
Median	67.0	0.0	65.5	2.0	66.0	1.0	64.0	0.0
Q3	74.0	7.0	71.5	6.0	75.0	8.0	71.0	4.0
Maximum	94	32	90	21	98	28	93	23

治験総括報告書 Table 3.3.2.2.1（Section 16.1.9.5）（5.3.5.1-1）から引用

表 2.7.4.8-付録-52　12 誘導心電図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-001 試験）（続き）

RR Interval (msec)

Visit / Statistics	Placebo (N=57) Observed Value at Visit	Placebo (N=57) Change from Baseline	TAK-385 10mg (N=48) Observed Value at Visit	TAK-385 10mg (N=48) Change from Baseline	TAK-385 20mg (N=55) Observed Value at Visit	TAK-385 20mg (N=55) Change from Baseline	TAK-385 40mg (N=54) Observed Value at Visit	TAK-385 40mg (N=54) Change from Baseline
Week 0								
N	57		48		55		54	
Mean	929.0		953.6		923.4		948.6	
SD	131.40		102.59		136.90		142.25	
Minimum	638		721		664		668	
Q1	833.0		886.5		811.0		845.0	
Median	938.0		945.0		909.0		958.5	
Q3	1013.0		1017.0		1017.0		1022.0	
Maximum	1200		1200		1277		1360	
Week 4								
N	57	57	48	48	55	55	54	54
Mean	924.1	-4.9	950.3	-3.4	963.3	39.9	960.1	11.5
SD	140.08	116.80	131.36	99.39	116.71	95.36	144.23	83.87
Minimum	652	-275	706	-232	698	-200	666	-170
Q1	833.0	-70.0	862.5	-82.5	882.0	-16.0	864.0	-27.0
Median	909.0	0.0	938.0	-2.5	959.0	42.0	954.5	5.0
Q3	1016.0	70.0	1023.0	73.0	1053.0	101.0	1034.0	55.0
Maximum	1300	250	1304	287	1224	221	1333	241
Week 8								
N	56	56	48	48	54	54	54	54
Mean	925.9	-2.2	955.3	1.6	961.4	37.7	972.6	23.9
SD	147.37	113.30	114.25	101.37	137.57	103.91	145.17	107.35
Minimum	571	-260	789	-228	703	-226	660	-180
Q1	816.5	-88.5	857.0	-66.0	880.0	-18.0	864.0	-46.0
Median	915.5	-5.5	937.5	0.0	952.5	39.5	971.0	23.0
Q3	1017.0	76.0	1035.0	65.0	1042.0	97.0	1071.0	70.0
Maximum	1250	287	1277	246	1395	310	1360	379
Week 12								
N	55	55	47	47	53	53	54	54
Mean	925.3	-2.4	935.6	-12.8	951.3	29.8	942.0	-6.6
SD	122.13	105.96	115.13	84.06	146.18	130.42	139.43	119.33
Minimum	682	-273	723	-195	635	-272	623	-234
Q1	857.0	-64.0	854.0	-56.0	857.0	-43.0	855.0	-106.0
Median	923.0	-21.0	915.0	-20.0	952.0	31.0	938.0	8.5
Q3	984.0	82.0	1016.0	33.0	1029.0	90.0	1017.0	86.0
Maximum	1200	262	1250	233	1247	480	1480	194

治験総括報告書 Table 3.3.2.2.1（Section 16.1.9.5）（5.3.5.1-1）から引用

表 2.7.4.8-付録-52　12 誘導心電図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-001 試験）（続き）

RR Interval (msec)

Visit / Statistics	Placebo (N=57) Observed Value at Visit	Placebo (N=57) Change from Baseline	TAK-385 10mg (N=48) Observed Value at Visit	TAK-385 10mg (N=48) Change from Baseline	TAK-385 20mg (N=55) Observed Value at Visit	TAK-385 20mg (N=55) Change from Baseline	TAK-385 40mg (N=54) Observed Value at Visit	TAK-385 40mg (N=54) Change from Baseline
Follow-up								
N	57	57	48	48	55	55	54	54
Mean	896.5	-32.5	924.8	-28.8	910.2	-13.1	929.9	-18.8
SD	125.38	109.48	121.27	99.47	152.56	138.94	135.07	105.50
Minimum	634	-326	665	-267	610	-347	645	-325
Q1	811.0	-102.0	836.5	-91.0	793.0	-101.0	822.0	-64.0
Median	881.0	-6.0	916.0	-21.5	908.0	-14.0	931.0	0.0
Q3	1000.0	23.0	1017.0	47.0	1040.0	80.0	1000.0	42.0
Maximum	1176	183	1224	174	1304	362	1360	173

治験総括報告書 Table 3.3.2.2.1（Section 16.1.9.5）（5.3.5.1-1）から引用

表 2.7.4.8-付録-52　12 誘導心電図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-001 試験）（続き）

PR Interval (msec)

Visit / Statistics	Placebo (N=57) Observed Value at Visit	Placebo (N=57) Change from Baseline	TAK-385 10mg (N=48) Observed Value at Visit	TAK-385 10mg (N=48) Change from Baseline	TAK-385 20mg (N=55) Observed Value at Visit	TAK-385 20mg (N=55) Change from Baseline	TAK-385 40mg (N=54) Observed Value at Visit	TAK-385 40mg (N=54) Change from Baseline
Week 0								
N	57		48		55		54	
Mean	149.9		151.5		149.4		151.3	
SD	21.23		19.56		19.92		20.19	
Minimum	105		104		102		124	
Q1	140.0		138.5		136.0		135.0	
Median	146.0		151.5		147.0		147.0	
Q3	162.0		162.5		164.0		160.0	
Maximum	216		192		202		222	
Week 4								
N	57	57	48	48	55	55	54	54
Mean	151.3	1.4	151.3	-0.2	149.3	-0.1	152.6	1.3
SD	24.43	10.48	20.04	11.70	22.13	8.88	20.54	9.35
Minimum	94	-20	114	-28	108	-22	116	-22
Q1	140.0	-5.0	136.0	-6.5	135.0	-6.0	136.0	-3.0
Median	149.0	1.0	150.0	-0.5	147.0	0.0	149.0	0.5
Q3	163.0	5.0	163.5	6.0	164.0	5.0	166.0	7.0
Maximum	250	34	196	36	208	28	208	26
Week 8								
N	56	56	48	48	54	54	54	54
Mean	151.3	0.8	151.8	0.3	149.9	0.1	151.9	0.6
SD	23.12	9.12	20.23	9.39	21.29	9.49	23.28	11.45
Minimum	104	-20	98	-20	100	-20	108	-26
Q1	138.0	-5.0	139.0	-5.0	133.0	-5.0	134.0	-6.0
Median	150.0	0.0	150.0	-0.5	149.0	-1.0	149.0	1.0
Q3	164.0	6.0	162.0	6.0	165.0	6.0	167.0	8.0
Maximum	230	24	194	32	206	30	230	30
Week 12								
N	55	55	47	47	53	53	54	54
Mean	150.1	-0.3	153.7	2.7	151.3	0.8	152.5	1.2
SD	22.63	10.44	18.34	8.48	18.75	10.01	23.55	13.15
Minimum	105	-22	116	-10	106	-25	108	-28
Q1	138.0	-6.0	139.0	-2.0	138.0	-4.0	135.0	-6.0
Median	148.0	-2.0	154.0	2.0	152.0	0.0	149.0	0.0
Q3	166.0	5.0	163.0	7.0	160.0	7.0	166.0	8.0
Maximum	230	27	192	32	202	23	234	36

治験総括報告書 Table 3.3.2.2.1（Section 16.1.9.5）（5.3.5.1-1）から引用

表 2.7.4.8-付録-52　12 誘導心電図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-001 試験）（続き）

PR Interval (msec)

Visit / Statistics	Placebo (N=57) Observed Value at Visit	Placebo (N=57) Change from Baseline	TAK-385 10mg (N=48) Observed Value at Visit	TAK-385 10mg (N=48) Change from Baseline	TAK-385 20mg (N=55) Observed Value at Visit	TAK-385 20mg (N=55) Change from Baseline	TAK-385 40mg (N=54) Observed Value at Visit	TAK-385 40mg (N=54) Change from Baseline
Follow-up								
N	57	57	48	48	55	55	54	54
Mean	149.7	-0.2	152.4	1.0	149.8	0.4	150.0	-1.3
SD	22.76	10.87	20.09	11.65	24.00	11.95	18.21	10.34
Minimum	110	-30	116	-28	95	-38	112	-27
Q1	136.0	-6.0	136.5	-5.0	132.0	-6.0	140.0	-8.0
Median	146.0	-2.0	151.0	2.0	153.0	-1.0	145.5	0.0
Q3	162.0	7.0	163.0	6.5	164.0	10.0	160.0	4.0
Maximum	214	27	196	36	210	38	206	18

治験総括報告書 Table 3.3.2.2.1（Section 16.1.9.5）（5.3.5.1-1）から引用

表 2.7.4.8-付録-52　12 誘導心電図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-001 試験）（続き）

QRS Interval (msec)

Visit / Statistics	Placebo (N=57) Observed Value at Visit	Placebo (N=57) Change from Baseline	TAK-385 10mg (N=48) Observed Value at Visit	TAK-385 10mg (N=48) Change from Baseline	TAK-385 20mg (N=55) Observed Value at Visit	TAK-385 20mg (N=55) Change from Baseline	TAK-385 40mg (N=54) Observed Value at Visit	TAK-385 40mg (N=54) Change from Baseline
Week 0								
N	57		48		55		54	
Mean	87.1		87.6		85.5		89.0	
SD	10.57		9.55		8.32		9.68	
Minimum	63		67		70		56	
Q1	80.0		82.0		80.0		83.0	
Median	86.0		86.0		84.0		90.0	
Q3	96.0		94.0		93.0		96.0	
Maximum	107		107		100		106	
Week 4								
N	57	57	48	48	55	55	54	54
Mean	87.4	0.3	88.2	0.6	86.7	1.2	89.5	0.5
SD	11.18	4.96	9.49	4.74	9.54	4.91	9.55	4.83
Minimum	62	-14	69	-12	63	-13	63	-16
Q1	80.0	-2.0	80.0	-2.0	82.0	-2.0	84.0	-2.0
Median	86.0	1.0	87.5	1.0	86.0	0.0	90.0	0.0
Q3	95.0	4.0	96.5	3.5	95.0	3.0	96.0	4.0
Maximum	110	10	107	14	105	14	108	14
Week 8								
N	56	56	48	48	54	54	54	54
Mean	86.1	-1.1	88.3	0.7	86.4	0.9	89.9	1.0
SD	11.57	6.39	9.75	4.96	9.12	4.40	9.93	4.53
Minimum	58	-22	69	-21	63	-7	63	-12
Q1	79.0	-3.5	82.0	-2.0	80.0	-2.0	83.0	0.0
Median	86.0	0.0	86.0	0.0	86.0	0.0	90.0	0.5
Q3	94.0	2.0	97.0	4.0	93.0	2.0	97.0	4.0
Maximum	112	14	110	10	106	14	108	10
Week 12								
N	55	55	47	47	53	53	54	54
Mean	86.9	-0.4	87.4	-0.1	87.3	1.7	89.3	0.4
SD	11.39	5.34	8.73	4.29	12.92	9.23	9.25	5.01
Minimum	63	-15	68	-12	60	-24	66	-10
Q1	76.0	-4.0	82.0	-2.0	80.0	0.0	83.0	-3.0
Median	86.0	0.0	86.0	0.0	86.0	0.0	90.0	0.5
Q3	96.0	4.0	96.0	2.0	94.0	4.0	96.0	4.0
Maximum	110	12	103	20	144	55	107	13

治験総括報告書 Table 3.3.2.2.1（Section 16.1.9.5）（5.3.5.1-1）から引用

表 2.7.4.8-付録-52　12 誘導心電図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-001 試験）（続き）

QRS Interval (msec)

Visit / Statistics	Placebo (N=57) Observed Value at Visit	Placebo (N=57) Change from Baseline	TAK-385 10mg (N=48) Observed Value at Visit	TAK-385 10mg (N=48) Change from Baseline	TAK-385 20mg (N=55) Observed Value at Visit	TAK-385 20mg (N=55) Change from Baseline	TAK-385 40mg (N=54) Observed Value at Visit	TAK-385 40mg (N=54) Change from Baseline
Follow-up								
N	57	57	48	48	55	55	54	54
Mean	86.3	-0.8	87.9	0.4	85.9	0.4	89.5	0.6
SD	10.72	4.68	9.28	4.72	9.61	4.30	9.57	4.76
Minimum	58	-12	66	-8	66	-6	63	-16
Q1	80.0	-4.0	82.0	-2.0	78.0	-3.0	84.0	-2.0
Median	86.0	0.0	88.0	0.0	86.0	0.0	90.0	0.0
Q3	94.0	2.0	94.0	2.0	94.0	2.0	96.0	4.0
Maximum	108	10	108	20	104	12	108	13

治験総括報告書 Table 3.3.2.2.1（Section 16.1.9.5）（5.3.5.1-1）から引用

表 2.7.4.8-付録-52　12 誘導心電図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-001 試験）（続き）

QT Interval (msec)

Visit / Statistics	Placebo (N=57) Observed Value at Visit	Placebo (N=57) Change from Baseline	TAK-385 10mg (N=48) Observed Value at Visit	TAK-385 10mg (N=48) Change from Baseline	TAK-385 20mg (N=55) Observed Value at Visit	TAK-385 20mg (N=55) Change from Baseline	TAK-385 40mg (N=54) Observed Value at Visit	TAK-385 40mg (N=54) Change from Baseline
Week 0								
N	57		48		55		54	
Mean	400.9		405.0		402.0		412.2	
SD	27.92		28.04		31.53		40.61	
Minimum	324		359		345		350	
Q1	383.0		388.5		379.0		390.0	
Median	400.0		403.0		398.0		407.5	
Q3	420.0		419.0		420.0		431.0	
Maximum	462		513		470		580	
Week 4								
N	57	57	48	48	55	55	54	54
Mean	400.5	-0.4	403.1	-1.9	407.3	5.3	407.5	-4.7
SD	26.56	23.18	26.49	17.19	26.79	19.78	32.61	32.12
Minimum	340	-46	353	-38	360	-42	352	-192
Q1	378.0	-20.0	382.5	-11.0	386.0	-7.0	383.0	-10.0
Median	400.0	-1.0	400.0	-2.5	407.0	6.0	406.0	-1.0
Q3	425.0	14.0	421.0	7.5	428.0	17.0	424.0	10.0
Maximum	456	58	475	60	466	47	488	50
Week 8								
N	56	56	48	48	54	54	54	54
Mean	402.0	2.1	400.8	-4.3	407.5	5.7	409.3	-2.9
SD	29.05	20.45	21.05	23.05	29.17	22.22	30.07	30.25
Minimum	352	-44	338	-80	343	-40	366	-176
Q1	378.0	-12.0	387.5	-15.5	382.0	-12.0	384.0	-12.0
Median	404.5	0.0	400.5	-4.0	409.0	4.0	407.0	-1.0
Q3	419.0	10.0	415.0	10.5	428.0	23.0	425.0	12.0
Maximum	466	59	448	53	476	56	494	50
Week 12								
N	55	55	47	47	53	53	54	54
Mean	399.4	-0.8	400.3	-3.7	406.0	4.7	404.6	-7.6
SD	24.44	22.19	22.37	22.20	28.98	23.71	33.93	37.06
Minimum	346	-35	355	-99	331	-55	346	-224
Q1	386.0	-20.0	383.0	-14.0	388.0	-8.0	379.0	-16.0
Median	400.0	-4.0	398.0	-2.0	408.0	4.0	402.0	-1.0
Q3	418.0	19.0	414.0	10.0	418.0	20.0	428.0	10.0
Maximum	451	51	468	43	460	76	522	56

治験総括報告書 Table 3.3.2.2.1（Section 16.1.9.5）（5.3.5.1-1）から引用

表 2.7.4.8-付録-52　12 誘導心電図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-001 試験）（続き）

QT Interval (msec)

Visit / Statistics	Placebo (N=57) Observed Value at Visit	Placebo (N=57) Change from Baseline	TAK-385 10mg (N=48) Observed Value at Visit	TAK-385 10mg (N=48) Change from Baseline	TAK-385 20mg (N=55) Observed Value at Visit	TAK-385 20mg (N=55) Change from Baseline	TAK-385 40mg (N=54) Observed Value at Visit	TAK-385 40mg (N=54) Change from Baseline
Follow-up								
N	57	57	48	48	55	55	54	54
Mean	395.3	-5.6	398.9	-6.2	395.8	-6.2	399.6	-12.6
SD	26.60	23.02	23.70	23.33	30.17	24.45	31.16	32.35
Minimum	322	-64	354	-108	340	-62	346	-210
Q1	383.0	-22.0	384.0	-18.0	376.0	-23.0	373.0	-22.0
Median	396.0	-8.0	394.0	-3.5	393.0	-6.0	398.0	-10.0
Q3	416.0	9.0	413.0	6.0	417.0	10.0	422.0	4.0
Maximum	444	51	464	37	473	46	480	26

治験総括報告書 Table 3.3.2.2.1（Section 16.1.9.5）（5.3.5.1-1）から引用

表 2.7.4.8-付録-52　12 誘導心電図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-001 試験）（続き）

QTcF Interval (msec)

Visit / Statistics	Placebo (N=57) Observed Value at Visit	Placebo (N=57) Change from Baseline	TAK-385 10mg (N=48) Observed Value at Visit	TAK-385 10mg (N=48) Change from Baseline	TAK-385 20mg (N=55) Observed Value at Visit	TAK-385 20mg (N=55) Change from Baseline	TAK-385 40mg (N=54) Observed Value at Visit	TAK-385 40mg (N=54) Change from Baseline
Week 0								
N	57		48		55		54	
Mean	411.6		412.0		413.3		420.4	
SD	19.69		24.46		19.25		37.44	
Minimum	373		369		381		371	
Q1	395.0		394.5		400.0		399.0	
Median	409.0		410.0		412.0		414.0	
Q3	425.0		422.5		426.0		432.0	
Maximum	459		509		465		638	
Week 4								
N	57	57	48	48	55	55	54	54
Mean	412.2	0.6	410.8	-1.3	412.8	-0.5	413.6	-6.8
SD	20.53	13.11	19.53	15.95	16.77	12.24	18.19	33.43
Minimum	378	-28	375	-63	382	-27	376	-225
Q1	398.0	-8.0	398.0	-9.0	396.0	-12.0	401.0	-9.0
Median	409.0	-1.0	406.0	0.0	414.0	-1.0	411.0	-3.5
Q3	426.0	12.0	423.5	8.5	424.0	7.0	426.0	5.0
Maximum	463	30	448	37	452	28	451	29
Week 8								
N	56	56	48	48	54	54	54	54
Mean	413.4	2.6	407.6	-4.4	413.4	0.2	413.9	-6.6
SD	18.97	13.66	19.03	20.73	17.46	14.00	18.20	33.77
Minimum	381	-23	353	-79	384	-29	380	-221
Q1	397.5	-6.0	395.0	-9.5	397.0	-8.0	402.0	-10.0
Median	412.0	2.0	408.5	-1.0	416.0	-0.5	413.0	-4.0
Q3	429.0	8.5	420.5	8.5	425.0	9.0	424.0	6.0
Maximum	453	40	442	28	460	36	451	36
Week 12								
N	55	55	47	47	53	53	54	54
Mean	410.5	-0.5	409.9	-1.8	413.6	0.7	413.2	-7.2
SD	17.90	16.49	17.29	20.04	18.91	14.49	21.82	38.03
Minimum	376	-33	379	-96	377	-33	374	-256
Q1	400.0	-9.0	400.0	-13.0	398.0	-10.0	396.0	-13.0
Median	409.0	-1.0	407.0	-2.0	414.0	0.0	416.0	-4.0
Q3	425.0	12.0	419.0	11.0	427.0	10.0	429.0	7.0
Maximum	453	38	457	26	448	38	459	38

治験総括報告書 Table 3.3.2.2.1（Section 16.1.9.5）（5.3.5.1-1）から引用

表 2.7.4.8-付録-52　12 誘導心電図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-001 試験）（続き）

QTcF Interval (msec)

Visit / Statistics	Placebo (N=57) Observed Value at Visit	Placebo (N=57) Change from Baseline	TAK-385 10mg (N=48) Observed Value at Visit	TAK-385 10mg (N=48) Change from Baseline	TAK-385 20mg (N=55) Observed Value at Visit	TAK-385 20mg (N=55) Change from Baseline	TAK-385 40mg (N=54) Observed Value at Visit	TAK-385 40mg (N=54) Change from Baseline
Follow-up								
N	57	57	48	48	55	55	54	54
Mean	410.7	-0.9	410.2	-1.8	409.3	-4.0	409.9	-10.5
SD	20.02	14.63	20.49	20.82	17.41	12.46	18.62	34.28
Minimum	364	-37	366	-101	373	-32	374	-237
Q1	396.0	-12.0	399.5	-8.0	395.0	-11.0	398.0	-17.0
Median	412.0	2.0	407.5	-0.5	409.0	-3.0	410.5	-8.0
Q3	421.0	8.0	419.5	5.5	421.0	3.0	420.0	8.0
Maximum	451	27	471	46	450	30	451	21

治験総括報告書 Table 3.3.2.2.1（Section 16.1.9.5）（5.3.5.1-1）から引用

表 2.7.4.8-付録-53　12 誘導心電図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）

Heart Rate (bpm)

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	64.5		63.0		65.6		63.3		63.1	
SD	10.66		9.42		9.72		8.79		7.67	
Minimum	39		43		45		43		47	
Q1	58.0		56.0		59.5		58.0		58.5	
Median	63.0		62.0		64.0		63.0		63.0	
Q3	71.0		70.0		70.5		68.0		67.5	
Maximum	96		84		115		92		92	
Week 4										
N	97	97	102	102	100	100	103	103	80	80
Mean	64.6	0.1	64.5	1.3	63.8	-1.9	62.2	-1.0	61.1	-2.0
SD	9.65	8.45	9.40	7.71	9.08	6.12	9.06	7.35	8.30	7.34
Minimum	45	-25	48	-15	45	-17	39	-19	46	-18
Q1	58.0	-5.0	57.0	-4.0	57.0	-5.0	57.0	-5.0	55.0	-6.0
Median	64.0	0.0	64.0	1.0	63.0	-2.0	62.0	-2.0	60.0	-3.0
Q3	70.0	5.0	69.0	5.0	69.0	2.0	68.0	3.0	65.5	2.0
Maximum	109	22	103	36	102	12	91	22	84	21
Week 8										
N	95	95	103	103	96	96	101	101	78	78
Mean	64.5	0.0	64.0	1.0	64.5	-1.4	62.5	-0.8	60.9	-2.2
SD	9.04	8.39	9.42	7.21	8.16	7.36	8.60	7.46	8.91	6.42
Minimum	41	-16	46	-17	44	-29	45	-21	45	-18
Q1	59.0	-7.0	57.0	-3.0	59.5	-5.0	57.0	-5.0	55.0	-7.0
Median	63.0	0.0	63.0	1.0	64.0	-1.0	63.0	0.0	60.0	-2.0
Q3	70.0	5.0	70.0	6.0	69.5	4.0	69.0	3.0	65.0	2.0
Maximum	90	31	92	22	100	14	83	21	105	14
Week 12										
N	93	93	101	101	91	91	101	101	75	75
Mean	64.1	-0.3	63.1	0.1	64.5	-1.3	62.9	-0.4	61.3	-2.1
SD	9.41	8.34	9.18	6.64	9.59	9.14	8.61	8.75	8.53	7.27
Minimum	42	-23	44	-14	45	-37	48	-22	42	-20
Q1	57.0	-5.0	57.0	-5.0	57.0	-6.0	57.0	-5.0	55.0	-8.0
Median	62.0	0.0	61.0	-1.0	63.0	-1.0	62.0	1.0	61.0	-2.0
Q3	69.0	4.0	69.0	5.0	72.0	3.0	69.0	4.0	66.0	3.0
Maximum	93	29	87	27	93	24	85	26	86	16
Follow-up										
N	18	18	19	19	22	22	13	13	10	10
Mean	65.1	0.7	64.7	1.0	69.7	4.7	66.0	6.0	62.0	1.4
SD	10.33	10.05	11.20	6.15	10.67	9.88	8.39	8.88	7.10	6.40
Minimum	53	-19	49	-15	47	-10	51	-5	49	-4
Q1	58.0	-8.0	54.0	-3.0	62.0	-4.0	63.0	-3.0	58.0	-4.0
Median	63.0	2.0	64.0	1.0	70.0	5.0	66.0	5.0	64.0	0.5
Q3	71.0	8.0	74.0	6.0	76.0	13.0	70.0	14.0	68.0	4.0
Maximum	94	16	87	10	95	26	83	20	71	17

治験総括報告書 Table 3.3.2.2.1（Section 15.1）（5.3.5.4-1）から引用

表 2.7.4.8-付録-53　12 誘導心電図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）

RR Interval (msec)

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	949.9		969.3		926.5		958.5		959.4	
SD	154.97		145.96		127.36		129.53		114.18	
Minimum	622		712		520		652		652	
Q1	842.0		857.0		847.0		870.0		881.0	
Median	951.0		953.0		925.0		940.0		949.0	
Q3	1034.0		1071.0		1001.0		1034.0		1023.0	
Maximum	1502		1388		1315		1304		1277	
Week 4										
N	97	97	102	102	100	100	103	103	80	80
Mean	941.4	-8.5	942.0	-24.6	952.9	26.4	978.0	19.4	992.9	33.5
SD	131.17	119.28	127.90	104.24	131.88	89.39	141.86	103.37	126.24	111.73
Minimum	550	-327	577	-345	584	-194	659	-288	708	-311
Q1	855.0	-75.0	870.0	-77.0	860.5	-31.5	881.0	-38.0	910.0	-28.0
Median	938.0	0.0	929.0	-11.5	945.5	18.0	958.0	30.0	997.0	47.5
Q3	1027.0	75.0	1035.0	56.0	1043.5	77.5	1048.0	81.0	1087.0	89.5
Maximum	1308	282	1242	175	1320	258	1426	276	1286	290
Week 8										
N	95	95	103	103	96	96	101	101	78	78
Mean	944.1	-6.9	950.9	-18.4	939.9	16.0	969.3	11.4	996.7	37.6
SD	133.44	118.98	133.18	109.71	118.61	113.12	132.06	105.42	128.43	98.49
Minimum	663	-347	649	-349	598	-232	720	-294	571	-204
Q1	857.0	-81.0	857.0	-83.0	858.5	-51.0	864.0	-57.0	923.0	-26.0
Median	938.0	1.0	952.0	-13.0	929.5	18.0	952.0	0.0	1000.0	27.0
Q3	1017.0	90.0	1050.0	47.0	1001.0	70.0	1050.0	95.0	1072.0	105.0
Maximum	1456	199	1284	219	1361	477	1318	285	1333	294
Week 12										
N	93	93	101	101	91	91	101	101	75	75
Mean	947.4	-4.7	966.3	-4.2	943.2	17.8	966.5	8.7	994.1	38.2
SD	132.77	114.32	133.83	100.44	142.34	126.33	129.48	122.86	145.50	121.49
Minimum	642	-327	669	-253	575	-367	706	-344	698	-254
Q1	860.0	-69.0	870.0	-74.0	833.0	-44.0	870.0	-58.0	904.0	-45.0
Median	944.0	0.0	968.0	6.0	944.0	14.0	953.0	-6.0	970.0	35.0
Q3	1034.0	74.0	1053.0	61.0	1048.0	80.0	1056.0	99.0	1072.0	117.0
Maximum	1401	234	1350	236	1311	405	1301	310	1409	448
Follow-up										
N	18	18	19	19	22	22	13	13	10	10
Mean	935.8	-19.2	948.7	-15.9	875.8	-49.9	917.8	-87.7	973.2	-20.5
SD	129.23	147.12	162.92	104.98	141.43	131.13	120.92	136.53	116.20	101.79
Minimum	634	-241	690	-192	632	-238	723	-272	845	-266
Q1	836.0	-168.0	811.0	-89.0	789.0	-178.0	857.0	-229.0	876.0	-61.0
Median	948.0	-38.5	929.0	-16.0	855.0	-68.0	888.0	-39.0	932.5	-9.0
Q3	1034.0	90.0	1094.0	52.0	968.0	45.0	952.0	37.0	1026.0	65.0
Maximum	1120	288	1220	268	1277	224	1169	77	1203	72

治験総括報告書 Table 3.3.2.2.1（Section 15.1）（5.3.5.4-1）から引用

表 2.7.4.8-付録-53　12 誘導心電図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）

PR Interval (msec)

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	153.2		150.7		152.0		151.0		150.3	
SD	28.09		17.52		24.16		22.19		19.87	
Minimum	105		100		101		115		112	
Q1	137.0		140.0		136.0		136.0		136.5	
Median	150.0		152.0		148.5		148.0		150.0	
Q3	165.0		162.0		165.5		164.0		164.5	
Maximum	332		198		241		262		216	
Week 4										
N	97	97	102	102	100	100	103	103	80	80
Mean	150.9	-2.2	149.3	-1.2	149.5	-2.5	148.2	-2.8	150.4	0.1
SD	18.45	22.92	17.64	9.96	21.67	13.35	18.49	17.91	21.60	10.67
Minimum	107	-174	100	-34	109	-91	115	-124	116	-30
Q1	137.0	-5.0	140.0	-5.0	134.0	-8.0	136.0	-8.0	135.5	-5.5
Median	150.0	0.0	148.0	-1.5	148.0	-2.0	144.0	-1.0	146.5	0.5
Q3	164.0	6.0	158.0	4.0	161.5	4.0	160.0	4.0	164.0	6.0
Maximum	197	38	212	26	223	25	204	28	238	24
Week 8										
N	95	95	103	103	96	96	101	101	78	78
Mean	149.8	-3.6	150.4	-0.3	151.5	-1.0	149.3	-2.3	149.6	-1.4
SD	17.66	22.19	18.94	10.15	21.68	13.24	19.73	17.55	19.92	11.62
Minimum	111	-168	90	-48	110	-92	100	-126	114	-34
Q1	137.0	-7.0	140.0	-6.0	138.0	-6.0	136.0	-7.0	134.0	-8.0
Median	150.0	-2.0	150.0	0.0	149.0	0.0	148.0	0.0	150.0	0.0
Q3	160.0	5.0	160.0	6.0	164.0	6.0	164.0	5.0	163.0	5.0
Maximum	188	46	200	21	230	28	202	30	208	21
Week 12										
N	93	93	101	101	91	91	101	101	74	74
Mean	150.3	-3.4	150.7	-0.1	151.9	-0.9	148.1	-3.5	148.0	-2.3
SD	19.39	21.62	18.14	10.08	24.44	14.74	18.16	17.31	20.93	12.46
Minimum	104	-176	103	-40	105	-90	104	-121	102	-32
Q1	139.0	-6.0	140.0	-5.0	135.0	-6.0	136.0	-9.0	133.0	-10.0
Median	150.0	-1.0	150.0	2.0	147.0	0.0	144.0	-3.0	142.5	-3.0
Q3	160.0	4.0	161.0	6.0	166.0	6.0	160.0	4.0	162.0	4.0
Maximum	231	35	206	20	244	37	194	40	201	30
Follow-up										
N	18	18	19	19	22	22	13	13	10	10
Mean	149.3	-1.6	147.8	-0.9	149.2	-2.4	144.1	-1.8	148.6	-5.0
SD	17.36	11.55	21.10	8.58	19.10	12.52	22.53	16.11	18.89	15.41
Minimum	122	-21	103	-18	112	-28	120	-24	125	-26
Q1	138.0	-9.0	128.0	-4.0	140.0	-12.0	126.0	-14.0	132.0	-18.0
Median	145.5	-1.5	151.0	-2.0	144.5	2.0	142.0	-4.0	143.0	-7.0
Q3	160.0	3.0	160.0	2.0	170.0	4.0	148.0	10.0	164.0	10.0
Maximum	185	30	186	20	179	24	200	28	179	20

治験総括報告書 Table 3.3.2.2.1（Section 15.1）（5.3.5.4-1）から引用

表 2.7.4.8-付録-53　12 誘導心電図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）

QRS Interval (msec)

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	88.7		88.9		88.9		87.4		90.2	
SD	11.04		9.91		11.14		9.19		8.36	
Minimum	63		63		53		64		60	
Q1	84.0		82.0		83.5		82.0		86.0	
Median	88.0		89.0		89.5		88.0		90.0	
Q3	96.0		94.0		94.5		92.0		94.0	
Maximum	121		116		131		114		109	
Week 4										
N	97	97	102	102	100	100	103	103	80	80
Mean	88.4	-0.3	89.2	0.3	89.0	0.2	88.5	1.0	91.6	1.5
SD	10.63	4.55	9.46	3.63	11.02	5.60	10.06	4.65	8.54	4.29
Minimum	63	-19	63	-10	53	-20	60	-10	63	-10
Q1	82.0	-2.0	82.0	-2.0	82.5	-2.0	83.0	-2.0	88.0	-1.0
Median	88.0	0.0	89.0	0.0	90.5	0.0	88.0	0.0	92.0	1.0
Q3	96.0	2.0	95.0	2.0	96.0	2.0	93.0	3.0	96.0	3.0
Maximum	119	12	116	12	121	21	115	17	113	12
Week 8										
N	95	95	103	103	96	96	101	101	78	78
Mean	88.7	0.0	89.9	1.0	89.7	0.6	88.3	0.8	91.3	0.9
SD	9.31	4.78	10.03	4.39	11.28	4.91	9.70	4.75	8.81	3.87
Minimum	70	-18	60	-16	56	-12	56	-14	60	-12
Q1	82.0	-2.0	83.0	-2.0	83.0	-2.0	82.0	-2.0	86.0	-2.0
Median	87.0	0.0	90.0	1.0	90.0	0.0	90.0	0.0	90.5	0.5
Q3	96.0	2.0	97.0	3.0	96.0	2.0	93.0	4.0	96.0	3.0
Maximum	110	19	116	12	137	20	113	20	110	13
Week 12										
N	93	93	101	101	91	91	101	101	75	75
Mean	88.3	-0.3	89.8	0.8	90.0	1.0	87.5	0.0	90.9	0.5
SD	10.47	4.14	10.31	4.71	11.79	5.51	9.62	5.00	9.29	5.05
Minimum	64	-12	63	-17	60	-10	60	-18	60	-16
Q1	82.0	-2.0	84.0	-2.0	84.0	-2.0	82.0	-2.0	86.0	-1.0
Median	86.0	0.0	90.0	0.0	91.0	0.0	88.0	0.0	91.0	0.0
Q3	94.0	2.0	98.0	4.0	95.0	4.0	92.0	2.0	96.0	3.0
Maximum	123	14	110	14	132	22	114	17	115	14
Follow-up										
N	18	18	19	19	22	22	13	13	10	10
Mean	89.4	0.1	90.6	-0.2	88.9	-0.4	88.5	-0.4	88.4	0.2
SD	9.89	3.64	8.78	5.73	8.65	4.24	14.52	6.45	7.00	3.91
Minimum	72	-5	80	-10	66	-16	63	-14	78	-4
Q1	82.0	-2.0	84.0	-4.0	86.0	-2.0	84.0	-2.0	82.0	-2.0
Median	91.0	-1.0	88.0	0.0	90.0	0.0	88.0	0.0	88.0	-0.5
Q3	98.0	2.0	96.0	2.0	95.0	2.0	96.0	2.0	94.0	0.0
Maximum	106	7	109	16	104	4	113	12	99	10

治験総括報告書 Table 3.3.2.2.1（Section 15.1）（5.3.5.4-1）から引用

表 2.7.4.8-付録-53　12 誘導心電図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）

QT Interval (msec)

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	404.6		406.3		404.0		406.8		409.6	
SD	29.96		31.16		29.75		26.94		23.64	
Minimum	340		333		308		344		352	
Q1	384.0		386.0		384.5		388.0		392.5	
Median	403.0		405.0		402.5		405.0		406.0	
Q3	423.0		430.0		423.0		428.0		425.5	
Maximum	484		506		496		477		472	
Week 4										
N	97	97	102	102	100	100	103	103	80	80
Mean	404.8	0.2	402.8	-3.0	408.3	4.3	409.9	3.1	415.1	5.5
SD	30.44	21.31	28.45	18.15	26.98	18.54	25.65	19.47	26.04	22.13
Minimum	338	-61	324	-81	333	-45	352	-48	348	-71
Q1	386.0	-12.0	382.0	-14.0	389.5	-4.0	391.0	-12.0	396.0	-9.0
Median	404.0	0.0	404.0	-1.0	406.5	3.0	408.0	0.0	416.0	6.0
Q3	418.0	12.0	423.0	10.0	428.0	13.5	431.0	19.0	434.0	16.5
Maximum	528	66	496	28	493	96	480	52	471	58
Week 8										
N	95	95	103	103	96	96	101	101	78	78
Mean	404.3	-1.2	403.1	-3.2	406.1	1.5	407.6	1.1	413.6	4.8
SD	25.95	21.38	28.85	19.75	25.16	22.89	27.32	19.16	25.45	19.23
Minimum	345	-70	320	-57	331	-64	348	-49	332	-42
Q1	388.0	-14.0	383.0	-14.0	389.5	-11.5	388.0	-10.0	396.0	-8.0
Median	404.0	0.0	402.0	-2.0	403.5	2.0	405.0	0.0	414.5	2.5
Q3	422.0	10.0	422.0	10.0	422.0	12.5	424.0	15.0	432.0	18.0
Maximum	471	40	496	39	488	98	482	45	472	60
Week 12										
N	93	93	101	101	91	91	101	101	75	75
Mean	405.5	-0.4	406.0	-0.4	407.6	2.6	405.8	-0.8	415.3	6.7
SD	28.62	21.99	31.60	19.42	28.12	24.69	24.50	21.39	27.83	21.81
Minimum	335	-66	320	-54	340	-46	348	-61	354	-42
Q1	384.0	-13.0	386.0	-14.0	390.0	-12.0	393.0	-14.0	397.0	-11.0
Median	407.0	0.0	408.0	-2.0	406.0	3.0	404.0	-2.0	412.0	5.0
Q3	424.0	16.0	424.0	13.0	424.0	16.0	423.0	14.0	431.0	20.0
Maximum	471	46	486	60	500	98	470	51	496	59
Follow-up										
N	18	18	19	19	22	22	13	13	10	10
Mean	402.9	-3.2	405.2	-1.1	391.9	-11.8	400.0	-15.3	412.3	2.6
SD	29.00	23.76	36.11	23.53	21.81	25.82	24.90	25.20	20.98	14.84
Minimum	354	-44	358	-54	356	-52	350	-50	386	-24
Q1	372.0	-20.0	376.0	-12.0	378.0	-34.0	388.0	-38.0	390.0	-5.0
Median	407.0	-8.0	396.0	-4.0	386.0	-10.0	402.0	-18.0	413.0	4.0
Q3	432.0	16.0	425.0	14.0	406.0	2.0	412.0	4.0	427.0	10.0
Maximum	444	32	493	48	442	44	438	24	446	28

治験総括報告書 Table 3.3.2.2.1（Section 15.1）（5.3.5.4-1）から引用

表 2.7.4.8-付録-53　12 誘導心電図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）

QTcF Interval (msec)

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	412.6		411.2		415.1		413.4		415.8	
SD	18.84		19.78		20.34		19.52		15.62	
Minimum	351		350		338		366		384	
Q1	400.0		400.0		403.0		400.0		405.0	
Median	414.0		411.0		415.0		412.0		414.0	
Q3	425.0		423.0		428.5		427.0		427.0	
Maximum	460		480		476		465		447	
Week 4										
N	97	97	102	102	100	100	103	103	80	80
Mean	413.8	1.2	411.5	0.4	415.7	0.7	413.9	0.5	416.7	0.9
SD	21.30	18.03	18.39	11.93	18.53	15.44	18.06	15.89	17.42	14.03
Minimum	363	-41	371	-33	359	-43	370	-35	374	-35
Q1	404.0	-9.0	401.0	-10.0	402.0	-7.5	402.0	-9.0	406.0	-8.0
Median	414.0	0.0	411.0	1.0	416.0	1.0	413.0	0.0	415.5	3.0
Q3	423.0	10.0	421.0	8.0	429.5	9.0	426.0	10.0	428.0	10.0
Maximum	542	113	467	34	463	103	478	67	459	37
Week 8										
N	95	95	103	103	96	96	101	101	78	78
Mean	412.8	-0.5	410.5	-0.7	415.1	-0.9	412.5	-0.7	414.7	-0.3
SD	16.68	13.88	18.08	12.23	17.81	16.93	17.84	14.20	16.63	13.13
Minimum	369	-44	364	-32	380	-55	365	-33	379	-32
Q1	403.0	-10.0	399.0	-8.0	402.0	-9.0	400.0	-10.0	403.0	-9.0
Median	414.0	0.0	407.0	-2.0	414.0	-1.0	411.0	-1.0	413.5	-2.0
Q3	425.0	9.0	422.0	8.0	425.0	6.0	427.0	8.0	425.0	9.0
Maximum	447	53	488	32	486	102	446	33	465	34
Week 12										
N	93	93	101	101	91	91	101	101	75	75
Mean	413.5	-0.2	411.1	-0.1	416.5	0.3	411.1	-2.1	416.9	1.7
SD	17.15	13.69	19.64	12.76	19.21	18.48	16.05	13.62	17.74	15.63
Minimum	373	-40	355	-26	376	-43	368	-41	377	-57
Q1	403.0	-10.0	400.0	-9.0	404.0	-10.0	401.0	-11.0	408.0	-7.0
Median	416.0	0.0	411.0	-1.0	415.0	-2.0	412.0	-2.0	417.0	1.0
Q3	425.0	8.0	423.0	7.0	428.0	10.0	422.0	6.0	426.0	10.0
Maximum	449	41	472	36	487	90	442	35	476	49
Follow-up										
N	18	18	19	19	22	22	13	13	10	10
Mean	412.6	-1.0	413.3	1.2	410.8	-4.0	411.9	-3.4	416.7	5.5
SD	21.13	13.94	23.61	15.84	17.26	13.92	15.35	12.06	17.19	12.84
Minimum	363	-40	372	-32	375	-40	378	-25	397	-13
Q1	404.0	-9.0	398.0	-9.0	398.0	-12.0	406.0	-15.0	402.0	-6.0
Median	413.5	1.5	406.0	1.0	410.5	-7.5	408.0	-1.0	415.0	8.0
Q3	427.0	6.0	430.0	13.0	425.0	8.0	423.0	5.0	429.0	12.0
Maximum	449	26	471	36	442	17	439	14	444	31

治験総括報告書 Table 3.3.2.2.1（Section 15.1）（5.3.5.4-1）から引用

表 2.7.4.8-付録-54　12 誘導心電図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）

Heart Rate (bpm)

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	64.5		63.0		65.6		63.3		63.1	
SD	10.66		9.42		9.72		8.79		7.67	
Minimum	39		43		45		43		47	
Q1	58.0		56.0		59.5		58.0		58.5	
Median	63.0		62.0		64.0		63.0		63.0	
Q3	71.0		70.0		70.5		68.0		67.5	
Maximum	96		84		115		92		92	
Week 4										
N	97	97	102	102	100	100	103	103	80	80
Mean	64.6	0.1	64.5	1.3	63.8	-1.9	62.2	-1.0	61.1	-2.0
SD	9.65	8.45	9.40	7.71	9.08	6.12	9.06	7.35	8.30	7.34
Minimum	45	-25	48	-15	45	-17	39	-19	46	-18
Q1	58.0	-5.0	57.0	-4.0	57.0	-5.0	57.0	-5.0	55.0	-6.0
Median	64.0	0.0	64.0	1.0	63.0	-2.0	62.0	-2.0	60.0	-3.0
Q3	70.0	5.0	69.0	5.0	69.0	2.0	68.0	3.0	65.5	2.0
Maximum	109	22	103	36	102	12	91	22	84	21
Week 8										
N	95	95	103	103	96	96	101	101	78	78
Mean	64.5	0.0	64.0	1.0	64.5	-1.4	62.5	-0.8	60.9	-2.2
SD	9.04	8.39	9.42	7.21	8.16	7.36	8.60	7.46	8.91	6.42
Minimum	41	-16	46	-17	44	-29	45	-21	45	-18
Q1	59.0	-7.0	57.0	-3.0	59.5	-5.0	57.0	-5.0	55.0	-7.0
Median	63.0	0.0	63.0	1.0	64.0	-1.0	63.0	0.0	60.0	-2.0
Q3	70.0	5.0	70.0	6.0	69.5	4.0	69.0	3.0	65.0	2.0
Maximum	90	31	92	22	100	14	83	21	105	14
Week 12										
N	93	93	101	101	91	91	101	101	75	75
Mean	64.1	-0.3	63.1	0.1	64.5	-1.3	62.9	-0.4	61.3	-2.1
SD	9.41	8.34	9.18	6.64	9.59	9.14	8.61	8.75	8.53	7.27
Minimum	42	-23	44	-14	45	-37	48	-22	42	-20
Q1	57.0	-5.0	57.0	-5.0	57.0	-6.0	57.0	-5.0	55.0	-8.0
Median	62.0	0.0	61.0	-1.0	63.0	-1.0	62.0	1.0	61.0	-2.0
Q3	69.0	4.0	69.0	5.0	72.0	3.0	69.0	4.0	66.0	3.0
Maximum	93	29	87	27	93	24	85	26	86	16
Week 16										
N	75	75	84	84	78	78	89	89	69	69
Mean	64.9	0.3	63.1	0.3	64.0	-1.9	63.3	-0.3	61.3	-2.2
SD	8.01	8.71	9.53	7.18	10.19	7.40	8.83	7.59	8.38	7.32
Minimum	44	-19	44	-15	43	-22	46	-24	42	-17
Q1	59.0	-5.0	57.0	-4.0	57.0	-7.0	58.0	-4.0	56.0	-8.0
Median	64.0	0.0	62.0	0.0	62.5	-1.0	63.0	0.0	60.0	-3.0
Q3	69.0	6.0	70.5	4.0	69.0	2.0	69.0	4.0	67.0	2.0
Maximum	86	24	91	24	103	20	91	21	83	22

治験総括報告書 Table 3.2.2.2.1（Section 15.1）（5.3.5.4-2）から引用

表 2.7.4.8-付録-54　12 誘導心電図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）

Heart Rate (bpm)

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	65.5	1.0	63.8	0.8	64.4	-1.3	63.7	0.0	62.2	-1.4
SD	7.41	8.94	9.20	7.81	9.26	7.53	9.06	9.04	9.69	9.08
Minimum	47	-22	42	-15	47	-22	47	-26	46	-17
Q1	60.0	-5.0	57.0	-5.0	59.0	-6.0	57.0	-5.0	55.0	-7.0
Median	65.0	1.0	65.0	0.0	62.0	-1.0	63.0	-1.0	62.0	-3.0
Q3	69.0	7.0	70.0	6.0	69.0	3.0	69.0	4.0	66.0	4.0
Maximum	87	30	86	22	96	24	96	30	97	39
Week 24										
N	68	68	79	79	76	76	88	88	62	62
Mean	65.9	1.1	62.4	-0.5	64.3	-1.5	64.0	0.1	61.6	-1.7
SD	9.95	8.58	8.32	6.64	9.69	8.96	8.08	8.28	7.90	7.31
Minimum	40	-21	47	-17	46	-26	46	-32	45	-15
Q1	58.0	-3.5	56.0	-5.0	58.0	-6.5	57.5	-4.0	57.0	-7.0
Median	67.0	1.0	62.0	0.0	64.0	-1.0	64.5	0.5	61.0	-2.0
Q3	72.0	6.5	68.0	4.0	70.0	4.0	70.0	5.5	67.0	4.0
Maximum	92	18	84	22	91	24	82	17	80	14
Follow-up										
N	77	77	83	83	77	77	89	89	69	69
Mean	66.9	2.4	64.3	1.6	65.6	-0.2	66.2	2.5	62.8	-0.8
SD	9.95	8.97	9.10	6.51	9.37	8.63	9.42	9.77	8.72	7.06
Minimum	46	-27	39	-15	44	-25	47	-26	45	-15
Q1	60.0	-3.0	58.0	-3.0	60.0	-7.0	59.0	-2.0	56.0	-5.0
Median	65.0	3.0	63.0	1.0	65.0	0.0	65.0	3.0	61.0	-1.0
Q3	72.0	8.0	71.0	6.0	72.0	6.0	73.0	7.0	69.0	3.0
Maximum	96	29	88	16	90	21	95	28	85	16

治験総括報告書 Table 3.2.2.2.1（Section 15.1）（5.3.5.4-2）から引用

表 2.7.4.8-付録-54　12 誘導心電図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）

RR Interval (msec)

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	949.9		969.3		926.5		958.5		959.4	
SD	154.97		145.96		127.36		129.53		114.18	
Minimum	622		712		520		652		652	
Q1	842.0		857.0		847.0		870.0		881.0	
Median	951.0		953.0		925.0		940.0		949.0	
Q3	1034.0		1071.0		1001.0		1034.0		1023.0	
Maximum	1502		1388		1315		1304		1277	
Week 4										
N	97	97	102	102	100	100	103	103	80	80
Mean	941.4	-8.5	942.0	-24.6	952.9	26.4	978.0	19.4	992.9	33.5
SD	131.17	119.28	127.90	104.24	131.88	89.39	141.86	103.37	126.24	111.73
Minimum	550	-327	577	-345	584	-194	659	-288	708	-311
Q1	855.0	-75.0	870.0	-77.0	860.5	-31.5	881.0	-38.0	910.0	-28.0
Median	938.0	0.0	929.0	-11.5	945.5	18.0	958.0	30.0	997.0	47.5
Q3	1027.0	75.0	1035.0	56.0	1043.5	77.5	1048.0	81.0	1087.0	89.5
Maximum	1308	282	1242	175	1320	258	1426	276	1286	290
Week 8										
N	95	95	103	103	96	96	101	101	78	78
Mean	944.1	-6.9	950.9	-18.4	939.9	16.0	969.3	11.4	996.7	37.6
SD	133.44	118.98	133.18	109.71	118.61	113.12	132.06	105.42	128.43	98.49
Minimum	663	-347	649	-349	598	-232	720	-294	571	-204
Q1	857.0	-81.0	857.0	-83.0	858.5	-51.0	864.0	-57.0	923.0	-26.0
Median	938.0	1.0	952.0	-13.0	929.5	18.0	952.0	0.0	1000.0	27.0
Q3	1017.0	90.0	1050.0	47.0	1001.0	70.0	1050.0	95.0	1072.0	105.0
Maximum	1456	199	1284	219	1361	477	1318	285	1333	294
Week 12										
N	93	93	101	101	91	91	101	101	75	75
Mean	947.4	-4.7	966.3	-4.2	943.2	17.8	966.5	8.7	994.1	38.2
SD	132.77	114.32	133.83	100.44	142.34	126.33	129.48	122.86	145.50	121.49
Minimum	642	-327	669	-253	575	-367	706	-344	698	-254
Q1	860.0	-69.0	870.0	-74.0	833.0	-44.0	870.0	-58.0	904.0	-45.0
Median	944.0	0.0	968.0	6.0	944.0	14.0	953.0	-6.0	970.0	35.0
Q3	1034.0	74.0	1053.0	61.0	1048.0	80.0	1056.0	99.0	1072.0	117.0
Maximum	1401	234	1350	236	1311	405	1301	310	1409	448
Week 16										
N	75	75	84	84	78	78	89	89	69	69
Mean	936.3	-13.0	965.7	-4.7	955.9	29.2	960.4	7.7	987.9	33.9
SD	114.93	128.51	145.20	102.17	140.16	111.03	135.74	111.07	130.01	106.42
Minimum	698	-353	656	-278	580	-248	659	-268	722	-283
Q1	858.0	-106.0	845.0	-66.5	867.0	-27.0	866.0	-56.0	896.0	-38.0
Median	936.0	-6.0	962.5	-7.5	954.0	15.0	946.0	12.0	991.0	39.0
Q3	1012.0	74.0	1037.5	51.0	1049.0	90.0	1034.0	65.0	1071.0	107.0
Maximum	1336	444	1356	277	1364	421	1359	346	1429	242

治験総括報告書 Table 3.2.2.2.1（Section 15.1）（5.3.5.4-2）から引用

表 2.7.4.8-付録-54　12 誘導心電図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）

RR Interval (msec)

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	924.1	-25.2	956.4	-11.6	944.0	15.2	952.7	1.1	980.5	26.6
SD	105.09	126.01	142.92	115.27	126.00	107.15	124.56	120.83	143.30	126.70
Minimum	690	-383	690	-391	625	-389	619	-339	614	-415
Q1	861.0	-101.0	856.0	-89.0	862.0	-58.0	867.0	-70.0	909.0	-59.0
Median	922.0	0.0	926.0	5.0	957.0	16.0	942.0	7.0	961.0	34.0
Q3	992.0	71.0	1042.0	74.0	1017.0	85.0	1053.0	78.0	1091.0	110.0
Maximum	1272	234	1400	215	1276	286	1268	310	1292	266
Week 24										
N	68	68	79	79	76	76	88	88	62	62
Mean	930.8	-16.8	971.6	2.9	947.5	22.0	947.0	-2.6	984.6	27.2
SD	144.65	113.59	128.25	102.48	141.16	125.03	120.96	114.85	128.63	111.28
Minimum	647	-309	714	-387	653	-277	732	-234	749	-193
Q1	828.5	-99.0	871.0	-56.0	854.5	-51.0	855.0	-74.0	890.0	-64.0
Median	909.0	-14.0	962.0	4.0	926.5	14.5	924.0	-11.5	979.0	36.5
Q3	1034.0	45.0	1071.0	69.0	1030.5	100.0	1034.0	63.5	1048.0	103.0
Maximum	1465	220	1270	275	1304	315	1277	390	1310	293
Follow-up										
N	77	77	83	83	77	77	89	89	69	69
Mean	911.9	-37.1	946.0	-25.9	929.7	2.2	917.6	-35.1	967.8	13.8
SD	131.81	129.07	139.63	99.10	136.81	125.45	124.47	130.34	128.68	105.32
Minimum	623	-340	678	-289	662	-355	630	-341	699	-260
Q1	833.0	-107.0	845.0	-106.0	832.0	-80.0	822.0	-107.0	865.0	-61.0
Median	923.0	-28.0	945.0	-20.0	921.0	8.0	910.0	-34.0	983.0	17.0
Q3	1000.0	42.0	1028.0	35.0	1000.0	91.0	1002.0	29.0	1061.0	80.0
Maximum	1297	311	1537	185	1344	339	1266	294	1307	221

治験総括報告書 Table 3.2.2.2.1（Section 15.1）（5.3.5.4-2）から引用

表 2.7.4.8-付録-54　12 誘導心電図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）

PR Interval (msec)

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	153.2		150.7		152.0		151.0		150.3	
SD	28.09		17.52		24.16		22.19		19.87	
Minimum	105		100		101		115		112	
Q1	137.0		140.0		136.0		136.0		136.5	
Median	150.0		152.0		148.5		148.0		150.0	
Q3	165.0		162.0		165.5		164.0		164.5	
Maximum	332		198		241		262		216	
Week 4										
N	97	97	102	102	100	100	103	103	80	80
Mean	150.9	-2.2	149.3	-1.2	149.5	-2.5	148.2	-2.8	150.4	0.1
SD	18.45	22.92	17.64	9.96	21.67	13.35	18.49	17.91	21.60	10.67
Minimum	107	-174	100	-34	109	-91	115	-124	116	-30
Q1	137.0	-5.0	140.0	-5.0	134.0	-8.0	136.0	-8.0	135.5	-5.5
Median	150.0	0.0	148.0	-1.5	148.0	-2.0	144.0	-1.0	146.5	0.5
Q3	164.0	6.0	158.0	4.0	161.5	4.0	160.0	4.0	164.0	6.0
Maximum	197	38	212	26	223	25	204	28	238	24
Week 8										
N	95	95	103	103	96	96	101	101	78	78
Mean	149.8	-3.6	150.4	-0.3	151.5	-1.0	149.3	-2.3	149.6	-1.4
SD	17.66	22.19	18.94	10.15	21.68	13.24	19.73	17.55	19.92	11.62
Minimum	111	-168	90	-48	110	-92	100	-126	114	-34
Q1	137.0	-7.0	140.0	-6.0	138.0	-6.0	136.0	-7.0	134.0	-8.0
Median	150.0	-2.0	150.0	0.0	149.0	0.0	148.0	0.0	150.0	0.0
Q3	160.0	5.0	160.0	6.0	164.0	6.0	164.0	5.0	163.0	5.0
Maximum	188	46	200	21	230	28	202	30	208	21
Week 12										
N	93	93	101	101	91	91	101	101	74	74
Mean	150.3	-3.4	150.7	-0.1	151.9	-0.9	148.1	-3.5	148.0	-2.3
SD	19.39	21.62	18.14	10.08	24.44	14.74	18.16	17.31	20.93	12.46
Minimum	104	-176	103	-40	105	-90	104	-121	102	-32
Q1	139.0	-6.0	140.0	-5.0	135.0	-6.0	136.0	-9.0	133.0	-10.0
Median	150.0	-1.0	150.0	2.0	147.0	0.0	144.0	-3.0	142.5	-3.0
Q3	160.0	4.0	161.0	6.0	166.0	6.0	160.0	4.0	162.0	4.0
Maximum	231	35	206	20	244	37	194	40	201	30
Week 16										
N	75	75	84	84	78	78	89	89	69	69
Mean	151.9	-2.3	151.2	-0.1	150.6	-1.5	147.7	-4.2	149.9	-0.2
SD	18.42	23.99	15.39	11.90	25.97	19.07	20.27	18.99	20.04	12.61
Minimum	102	-170	122	-46	101	-95	98	-141	120	-24
Q1	141.0	-7.0	140.0	-5.5	134.0	-8.0	135.0	-10.0	134.0	-6.0
Median	152.0	0.0	150.0	0.0	145.0	-1.5	144.0	-1.0	148.0	0.0
Q3	164.0	8.0	160.0	6.0	164.0	6.0	162.0	4.0	160.0	6.0
Maximum	226	38	204	29	237	109	210	28	206	50

治験総括報告書 Table 3.2.2.2.1（Section 15.1）（5.3.5.4-2）から引用

表 2.7.4.8-付録-54　12 誘導心電図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）

PR Interval (msec)

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	153.4	-0.7	151.7	0.3	149.2	-2.8	149.0	-3.0	152.0	1.6
SD	22.01	23.82	16.49	11.40	23.20	19.08	21.24	20.48	21.55	15.28
Minimum	103	-168	114	-34	80	-95	89	-146	114	-30
Q1	140.0	-4.0	141.0	-4.0	136.0	-8.0	136.0	-4.0	135.0	-4.0
Median	153.0	1.0	150.0	1.0	147.0	0.0	146.0	0.0	149.0	1.0
Q3	169.0	8.0	158.0	7.0	160.0	7.0	166.0	6.0	163.0	8.0
Maximum	246	36	208	26	237	43	198	29	226	86
Week 24										
N	68	68	79	79	76	76	88	88	62	62
Mean	152.2	-2.4	152.4	0.8	152.1	0.1	149.1	-2.7	151.0	1.0
SD	18.46	25.40	16.99	10.91	22.70	16.96	18.71	18.08	17.75	10.20
Minimum	110	-184	115	-26	112	-86	110	-115	118	-27
Q1	144.0	-5.0	144.0	-6.0	136.5	-6.0	135.5	-8.0	139.0	-5.0
Median	150.0	0.0	152.0	2.0	146.5	0.0	147.0	0.0	152.0	0.0
Q3	161.0	6.5	163.0	7.0	166.0	7.0	162.0	6.0	163.0	7.0
Maximum	235	34	214	28	245	69	192	33	210	25
Follow-up										
N	77	77	83	83	77	77	89	89	68	68
Mean	150.2	-3.4	151.8	0.7	150.3	-2.0	147.3	-4.7	149.8	0.0
SD	19.55	23.23	17.18	10.65	23.74	14.62	19.07	18.49	19.13	10.26
Minimum	116	-162	115	-24	108	-96	107	-142	114	-27
Q1	136.0	-5.0	139.0	-6.0	133.0	-9.0	134.0	-8.0	136.0	-8.0
Median	150.0	0.0	152.0	0.0	148.0	0.0	144.0	-4.0	148.0	0.5
Q3	162.0	8.0	162.0	8.0	162.0	4.0	160.0	4.0	161.5	6.0
Maximum	236	27	206	38	249	29	198	28	206	27

治験総括報告書 Table 3.2.2.2.1（Section 15.1）（5.3.5.4-2）から引用

表 2.7.4.8-付録-54　12 誘導心電図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）

QRS Interval (msec)

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	88.7		88.9		88.9		87.4		90.2	
SD	11.04		9.91		11.14		9.19		8.36	
Minimum	63		63		53		64		60	
Q1	84.0		82.0		83.5		82.0		86.0	
Median	88.0		89.0		89.5		88.0		90.0	
Q3	96.0		94.0		94.5		92.0		94.0	
Maximum	121		116		131		114		109	
Week 4										
N	97	97	102	102	100	100	103	103	80	80
Mean	88.4	-0.3	89.2	0.3	89.0	0.2	88.5	1.0	91.6	1.5
SD	10.63	4.55	9.46	3.63	11.02	5.60	10.06	4.65	8.54	4.29
Minimum	63	-19	63	-10	53	-20	60	-10	63	-10
Q1	82.0	-2.0	82.0	-2.0	82.5	-2.0	83.0	-2.0	88.0	-1.0
Median	88.0	0.0	89.0	0.0	90.5	0.0	88.0	0.0	92.0	1.0
Q3	96.0	2.0	95.0	2.0	96.0	2.0	93.0	3.0	96.0	3.0
Maximum	119	12	116	12	121	21	115	17	113	12
Week 8										
N	95	95	103	103	96	96	101	101	78	78
Mean	88.7	0.0	89.9	1.0	89.7	0.6	88.3	0.8	91.3	0.9
SD	9.31	4.78	10.03	4.39	11.28	4.91	9.70	4.75	8.81	3.87
Minimum	70	-18	60	-16	56	-12	56	-14	60	-12
Q1	82.0	-2.0	83.0	-2.0	83.0	-2.0	82.0	-2.0	86.0	-2.0
Median	87.0	0.0	90.0	1.0	90.0	0.0	90.0	0.0	90.5	0.5
Q3	96.0	2.0	97.0	3.0	96.0	2.0	93.0	4.0	96.0	3.0
Maximum	110	19	116	12	137	20	113	20	110	13
Week 12										
N	93	93	101	101	91	91	101	101	75	75
Mean	88.3	-0.3	89.8	0.8	90.0	1.0	87.5	0.0	90.9	0.5
SD	10.47	4.14	10.31	4.71	11.79	5.51	9.62	5.00	9.29	5.05
Minimum	64	-12	63	-17	60	-10	60	-18	60	-16
Q1	82.0	-2.0	84.0	-2.0	84.0	-2.0	82.0	-2.0	86.0	-1.0
Median	86.0	0.0	90.0	0.0	91.0	0.0	88.0	0.0	91.0	0.0
Q3	94.0	2.0	98.0	4.0	95.0	4.0	92.0	2.0	96.0	3.0
Maximum	123	14	110	14	132	22	114	17	115	14
Week 16										
N	75	75	84	84	78	78	89	89	69	69
Mean	88.2	-0.5	89.3	0.9	89.8	1.1	87.8	0.7	91.5	1.0
SD	10.01	4.26	10.20	4.17	12.09	5.00	8.89	4.90	9.09	4.09
Minimum	67	-14	63	-8	56	-10	56	-14	56	-10
Q1	82.0	-2.0	84.0	-2.0	84.0	-2.0	84.0	-2.0	88.0	-2.0
Median	86.0	0.0	88.5	0.0	90.0	1.5	88.0	0.0	92.0	1.0
Q3	94.0	2.0	94.0	3.5	96.0	4.0	93.0	3.0	96.0	3.0
Maximum	110	10	113	16	125	20	113	17	114	10

治験総括報告書 Table 3.2.2.2.1（Section 15.1）（5.3.5.4-2）から引用

表 2.7.4.8-付録-54　12 誘導心電図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）

QRS Interval (msec)

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	88.9	0.2	89.1	0.5	89.6	0.8	86.9	-0.2	92.2	1.5
SD	10.68	4.25	9.98	4.34	12.70	3.91	9.89	4.51	9.08	3.94
Minimum	65	-13	63	-8	53	-9	56	-14	56	-8
Q1	83.0	-3.0	84.0	-2.0	84.0	-2.0	80.0	-3.0	88.0	0.0
Median	88.0	0.0	88.0	0.0	90.0	1.0	88.0	0.0	92.0	2.0
Q3	95.0	3.0	94.0	3.0	94.0	3.0	93.0	2.0	96.0	3.0
Maximum	116	12	112	17	130	13	112	12	115	13
Week 24										
N	68	68	79	79	76	76	88	88	62	62
Mean	88.3	-0.4	88.7	0.3	89.6	1.0	88.5	1.3	91.7	1.5
SD	9.98	4.63	9.94	5.08	12.73	5.15	9.57	5.34	8.98	4.81
Minimum	63	-19	62	-14	56	-17	56	-14	56	-10
Q1	82.0	-2.0	81.0	-3.0	84.0	-2.0	82.0	-1.5	88.0	-2.0
Median	87.0	0.0	90.0	0.0	89.5	0.0	90.0	0.0	91.5	1.0
Q3	94.0	2.0	94.0	4.0	94.0	4.0	94.0	4.0	96.0	4.0
Maximum	114	17	108	14	128	18	112	16	113	17
Follow-up										
N	77	77	83	83	77	77	89	89	69	69
Mean	88.7	0.1	88.6	0.1	88.9	0.1	88.3	1.2	91.4	0.9
SD	9.76	4.13	9.55	4.86	12.75	6.40	9.79	6.04	8.85	4.12
Minimum	67	-10	64	-12	60	-24	60	-23	56	-10
Q1	83.0	-2.0	81.0	-3.0	82.0	-2.0	82.0	-2.0	87.0	-2.0
Median	88.0	0.0	89.0	0.0	90.0	0.0	89.0	0.0	92.0	0.0
Q3	92.0	2.0	96.0	4.0	95.0	2.0	95.0	4.0	96.0	4.0
Maximum	114	13	106	14	132	20	113	20	111	13

治験総括報告書 Table 3.2.2.2.1（Section 15.1）（5.3.5.4-2）から引用

表 2.7.4.8-付録-54　12 誘導心電図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）

QT Interval (msec)

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	404.6		406.3		404.0		406.8		409.6	
SD	29.96		31.16		29.75		26.94		23.64	
Minimum	340		333		308		344		352	
Q1	384.0		386.0		384.5		388.0		392.5	
Median	403.0		405.0		402.5		405.0		406.0	
Q3	423.0		430.0		423.0		428.0		425.5	
Maximum	484		506		496		477		472	
Week 4										
N	97	97	102	102	100	100	103	103	80	80
Mean	404.8	0.2	402.8	-3.0	408.3	4.3	409.9	3.1	415.1	5.5
SD	30.44	21.31	28.45	18.15	26.98	18.54	25.65	19.47	26.04	22.13
Minimum	338	-61	324	-81	333	-45	352	-48	348	-71
Q1	386.0	-12.0	382.0	-14.0	389.5	-4.0	391.0	-12.0	396.0	-9.0
Median	404.0	0.0	404.0	-1.0	406.5	3.0	408.0	0.0	416.0	6.0
Q3	418.0	12.0	423.0	10.0	428.0	13.5	431.0	19.0	434.0	16.5
Maximum	528	66	496	28	493	96	480	52	471	58
Week 8										
N	95	95	103	103	96	96	101	101	78	78
Mean	404.3	-1.2	403.1	-3.2	406.1	1.5	407.6	1.1	413.6	4.8
SD	25.95	21.38	28.85	19.75	25.16	22.89	27.32	19.16	25.45	19.23
Minimum	345	-70	320	-57	331	-64	348	-49	332	-42
Q1	388.0	-14.0	383.0	-14.0	389.5	-11.5	388.0	-10.0	396.0	-8.0
Median	404.0	0.0	402.0	-2.0	403.5	2.0	405.0	0.0	414.5	2.5
Q3	422.0	10.0	422.0	10.0	422.0	12.5	424.0	15.0	432.0	18.0
Maximum	471	40	496	39	488	98	482	45	472	60
Week 12										
N	93	93	101	101	91	91	101	101	75	75
Mean	405.5	-0.4	406.0	-0.4	407.6	2.6	405.8	-0.8	415.3	6.7
SD	28.62	21.99	31.60	19.42	28.12	24.69	24.50	21.39	27.83	21.81
Minimum	335	-66	320	-54	340	-46	348	-61	354	-42
Q1	384.0	-13.0	386.0	-14.0	390.0	-12.0	393.0	-14.0	397.0	-11.0
Median	407.0	0.0	408.0	-2.0	406.0	3.0	404.0	-2.0	412.0	5.0
Q3	424.0	16.0	424.0	13.0	424.0	16.0	423.0	14.0	431.0	20.0
Maximum	471	46	486	60	500	98	470	51	496	59
Week 16										
N	75	75	84	84	78	78	89	89	69	69
Mean	400.5	-3.8	406.6	0.4	407.8	3.8	406.0	0.3	413.5	4.4
SD	26.25	24.09	28.42	19.76	29.07	22.12	29.27	18.93	26.10	22.71
Minimum	334	-72	346	-42	306	-50	350	-56	360	-79
Q1	384.0	-20.0	388.0	-11.5	390.0	-12.0	385.0	-12.0	394.0	-10.0
Median	403.0	-2.0	402.5	-0.5	406.5	4.0	406.0	1.0	413.0	4.0
Q3	414.0	13.0	425.0	13.0	428.0	20.0	423.0	11.0	432.0	18.0
Maximum	474	50	480	51	478	78	473	44	461	56

治験総括報告書 Table 3.2.2.2.1（Section 15.1）（5.3.5.4-2）から引用

表 2.7.4.8-付録-54　12 誘導心電図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）

QT Interval (msec)

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	399.8	-4.5	402.8	-3.5	406.9	2.5	403.5	-1.9	413.5	3.7
SD	23.33	22.14	27.96	17.92	27.59	22.18	25.86	21.43	26.04	24.00
Minimum	342	-68	332	-46	336	-47	325	-76	351	-94
Q1	388.0	-16.0	386.0	-18.0	392.0	-12.0	387.0	-14.0	399.0	-10.0
Median	399.0	-4.0	401.0	-2.0	407.0	3.0	404.0	1.0	412.0	7.0
Q3	415.0	12.0	420.0	8.0	426.0	14.0	421.0	12.0	430.0	21.0
Maximum	480	46	466	44	475	106	474	37	485	43
Week 24										
N	68	68	79	79	76	76	88	88	62	62
Mean	401.1	-3.0	405.9	-0.2	406.6	3.0	404.4	-1.0	416.5	5.6
SD	28.45	20.74	29.53	19.14	28.64	25.56	25.45	21.04	27.84	22.15
Minimum	333	-48	336	-57	331	-55	352	-63	364	-60
Q1	386.0	-18.0	388.0	-14.0	389.0	-15.0	384.0	-13.5	396.0	-4.0
Median	400.5	-5.5	406.0	-2.0	401.5	6.0	399.5	-2.0	416.0	6.0
Q3	418.5	9.0	428.0	14.0	422.5	18.0	423.5	9.0	436.0	20.0
Maximum	469	50	476	56	474	88	456	70	476	63
Follow-up										
N	77	77	83	83	77	77	89	89	69	69
Mean	396.9	-7.4	400.0	-6.4	400.5	-3.7	397.3	-8.4	409.7	0.5
SD	26.68	21.89	28.63	17.94	29.30	23.68	26.82	21.45	29.86	23.99
Minimum	326	-81	320	-50	341	-56	326	-63	328	-52
Q1	380.0	-20.0	379.0	-20.0	380.0	-15.0	380.0	-22.0	392.0	-12.0
Median	396.0	-4.0	396.0	-6.0	398.0	-6.0	394.0	-10.0	410.0	0.0
Q3	413.0	4.0	426.0	6.0	418.0	10.0	412.0	2.0	426.0	17.0
Maximum	488	36	448	35	485	90	480	62	492	68

治験総括報告書 Table 3.2.2.2.1（Section 15.1）（5.3.5.4-2）から引用

表 2.7.4.8-付録-54　12 誘導心電図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）

QTcF Interval (msec)

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	412.6		411.2		415.1		413.4		415.8	
SD	18.84		19.78		20.34		19.52		15.62	
Minimum	351		350		338		366		384	
Q1	400.0		400.0		403.0		400.0		405.0	
Median	414.0		411.0		415.0		412.0		414.0	
Q3	425.0		423.0		428.5		427.0		427.0	
Maximum	460		480		476		465		447	
Week 4										
N	97	97	102	102	100	100	103	103	80	80
Mean	413.8	1.2	411.5	0.4	415.7	0.7	413.9	0.5	416.7	0.9
SD	21.30	18.03	18.39	11.93	18.53	15.44	18.06	15.89	17.42	14.03
Minimum	363	-41	371	-33	359	-43	370	-35	374	-35
Q1	404.0	-9.0	401.0	-10.0	402.0	-7.5	402.0	-9.0	406.0	-8.0
Median	414.0	0.0	411.0	1.0	416.0	1.0	413.0	0.0	415.5	3.0
Q3	423.0	10.0	421.0	8.0	429.5	9.0	426.0	10.0	428.0	10.0
Maximum	542	113	467	34	463	103	478	67	459	37
Week 8										
N	95	95	103	103	96	96	101	101	78	78
Mean	412.8	-0.5	410.5	-0.7	415.1	-0.9	412.5	-0.7	414.7	-0.3
SD	16.68	13.88	18.08	12.23	17.81	16.93	17.84	14.20	16.63	13.13
Minimum	369	-44	364	-32	380	-55	365	-33	379	-32
Q1	403.0	-10.0	399.0	-8.0	402.0	-9.0	400.0	-10.0	403.0	-9.0
Median	414.0	0.0	407.0	-2.0	414.0	-1.0	411.0	-1.0	413.5	-2.0
Q3	425.0	9.0	422.0	8.0	425.0	6.0	427.0	8.0	425.0	9.0
Maximum	447	53	488	32	486	102	446	33	465	34
Week 12										
N	93	93	101	101	91	91	101	101	75	75
Mean	413.5	-0.2	411.1	-0.1	416.5	0.3	411.1	-2.1	416.9	1.7
SD	17.15	13.69	19.64	12.76	19.21	18.48	16.05	13.62	17.74	15.63
Minimum	373	-40	355	-26	376	-43	368	-41	377	-57
Q1	403.0	-10.0	400.0	-9.0	404.0	-10.0	401.0	-11.0	408.0	-7.0
Median	416.0	0.0	411.0	-1.0	415.0	-2.0	412.0	-2.0	417.0	1.0
Q3	425.0	8.0	423.0	7.0	428.0	10.0	422.0	6.0	426.0	10.0
Maximum	449	41	472	36	487	90	442	35	476	49
Week 16										
N	75	75	84	84	78	78	89	89	69	69
Mean	409.9	-2.4	412.3	1.3	414.8	-0.3	412.2	-0.9	415.8	-0.2
SD	18.72	16.58	16.79	13.32	19.28	16.35	19.71	14.42	17.21	14.12
Minimum	364	-51	371	-32	366	-34	369	-53	386	-38
Q1	395.0	-13.0	400.5	-8.0	404.0	-11.0	400.0	-9.0	403.0	-8.0
Median	413.0	-2.0	412.0	0.5	416.0	-1.0	412.0	-1.0	414.0	0.0
Q3	422.0	7.0	424.5	10.0	428.0	8.0	431.0	8.0	428.0	8.0
Maximum	452	53	452	37	473	75	449	29	461	34

治験総括報告書 Table 3.2.2.2.1（Section 15.1）（5.3.5.4-2）から引用

表 2.7.4.8-付録-54　12 誘導心電図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）

QTcF Interval (msec)

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	410.8	-1.5	409.6	-1.8	415.4	0.3	410.6	-2.3	417.3	0.5
SD	15.68	14.32	17.56	12.66	18.47	17.42	16.93	13.55	17.79	15.90
Minimum	380	-38	359	-32	371	-46	372	-50	382	-41
Q1	397.0	-12.0	397.0	-10.0	403.0	-8.0	398.0	-9.0	405.0	-11.0
Median	411.0	-1.0	409.0	-3.0	415.0	-1.0	410.0	-1.0	412.0	2.0
Q3	423.0	9.0	422.0	7.0	429.0	9.0	423.0	5.0	430.0	12.0
Maximum	448	29	446	48	466	103	445	25	455	27
Week 24										
N	68	68	79	79	76	76	88	88	62	62
Mean	411.7	-0.8	410.3	-0.8	414.9	0.0	412.3	-0.9	419.3	1.9
SD	18.75	16.17	20.03	14.29	19.54	20.97	17.94	14.74	19.01	14.38
Minimum	376	-37	358	-48	371	-54	364	-37	377	-38
Q1	398.0	-10.5	401.0	-9.0	402.0	-10.5	400.5	-10.0	406.0	-7.0
Median	412.0	-0.5	410.0	0.0	411.0	-1.5	413.0	0.0	421.5	3.0
Q3	427.0	10.0	422.0	8.0	426.0	9.0	427.0	10.0	431.0	12.0
Maximum	449	54	466	32	470	99	447	30	470	39
Follow-up										
N	77	77	83	83	77	77	89	89	69	69
Mean	410.0	-2.4	408.1	-2.8	411.0	-4.2	409.5	-3.6	414.8	-1.3
SD	16.21	14.35	16.99	12.45	19.10	18.00	19.51	13.04	22.61	17.27
Minimum	371	-39	363	-34	370	-41	364	-30	340	-55
Q1	400.0	-12.0	395.0	-11.0	400.0	-15.0	396.0	-12.0	402.0	-13.0
Median	410.0	-4.0	408.0	-2.0	409.0	-3.0	410.0	-3.0	415.0	-2.0
Q3	421.0	4.0	422.0	6.0	424.0	3.0	421.0	3.0	426.0	9.0
Maximum	448	40	440	24	475	104	470	41	472	38

治験総括報告書 Table 3.2.2.2.1（Section 15.1）（5.3.5.4-2）から引用

表 2.7.4.8-付録-55　12 誘導心電図のシフトテーブル（安全性データの解析対象集団）（CCT-001 試験）

ECG Interpretation

	Week 0			
	Placebo (N=57)			
Visit	Within Normal Limits	Abnormal, Not Clinically Significant	Abnormal, Clinically Significant	Total
Week 4				
Within Normal Limits	46	3	-	49
Abnormal, Not Clinically Significant	4	4	-	8
Abnormal, Clinically Significant	-	-	-	-
Total	50	7	-	57
Week 8				
Within Normal Limits	43	4	-	47
Abnormal, Not Clinically Significant	6	2	-	8
Abnormal, Clinically Significant	1	-	-	1
Total	50	6	-	56
Week 12				
Within Normal Limits	45	3	-	48
Abnormal, Not Clinically Significant	4	3	-	7
Abnormal, Clinically Significant	-	-	-	-
Total	49	6	-	55
Follow-up				
Within Normal Limits	45	5	-	50
Abnormal, Not Clinically Significant	4	2	-	6
Abnormal, Clinically Significant	1	-	-	1
Total	50	7	-	57

治験総括報告書 Table 3.3.2.2.3（Section 16.1.9.5）（5.3.5.1-1）から引用

表 2.7.4.8-付録-55　12 誘導心電図のシフトテーブル（安全性データの解析対象集団）（CCT-001 試験）（続き）

ECG Interpretation

	Week 0			
	TAK-385 10mg (N=48)			
Visit	Within Normal Limits	Abnormal, Not Clinically Significant	Abnormal, Clinically Significant	Total
Week 4				
Within Normal Limits	39	-	-	39
Abnormal, Not Clinically Significant	3	6	-	9
Abnormal, Clinically Significant	-	-	-	-
Total	42	6	-	48
Week 8				
Within Normal Limits	37	2	-	39
Abnormal, Not Clinically Significant	5	4	-	9
Abnormal, Clinically Significant	-	-	-	-
Total	42	6	-	48
Week 12				
Within Normal Limits	40	2	-	42
Abnormal, Not Clinically Significant	1	4	-	5
Abnormal, Clinically Significant	-	-	-	-
Total	41	6	-	47
Follow-up				
Within Normal Limits	38	2	-	40
Abnormal, Not Clinically Significant	4	4	-	8
Abnormal, Clinically Significant	-	-	-	-
Total	42	6	-	48

治験総括報告書 Table 3.3.2.2.3（Section 16.1.9.5）（5.3.5.1-1）から引用

表 2.7.4.8-付録-55　12 誘導心電図のシフトテーブル（安全性データの解析対象集団）（CCT-001 試験）（続き）

ECG Interpretation

	Week 0			
	TAK-385 20mg (N=55)			
Visit	Within Normal Limits	Abnormal, Not Clinically Significant	Abnormal, Clinically Significant	Total
Week 4				
Within Normal Limits	40	3	-	43
Abnormal, Not Clinically Significant	5	7	-	12
Abnormal, Clinically Significant	-	-	-	-
Total	45	10	-	55
Week 8				
Within Normal Limits	44	3	-	47
Abnormal, Not Clinically Significant	-	7	-	7
Abnormal, Clinically Significant	-	-	-	-
Total	44	10	-	54
Week 12				
Within Normal Limits	42	4	-	46
Abnormal, Not Clinically Significant	2	4	-	6
Abnormal, Clinically Significant	-	1	-	1
Total	44	9	-	53
Follow-up				
Within Normal Limits	43	4	-	47
Abnormal, Not Clinically Significant	2	6	-	8
Abnormal, Clinically Significant	-	-	-	-
Total	45	10	-	55

治験総括報告書 Table 3.3.2.2.3（Section 16.1.9.5）（5.3.5.1-1）から引用

表 2.7.4.8-付録-55　12 誘導心電図のシフトテーブル（安全性データの解析対象集団）（CCT-001 試験）（続き）

ECG Interpretation

	Week 0			
	TAK-385 40mg (N=54)			
Visit	Within Normal Limits	Abnormal, Not Clinically Significant	Abnormal, Clinically Significant	Total
Week 4				
Within Normal Limits	34	8	-	42
Abnormal, Not Clinically Significant	6	5	1	12
Abnormal, Clinically Significant	-	-	-	-
Total	40	13	1	54
Week 8				
Within Normal Limits	35	6	-	41
Abnormal, Not Clinically Significant	5	7	1	13
Abnormal, Clinically Significant	-	-	-	-
Total	40	13	1	54
Week 12				
Within Normal Limits	34	5	1	40
Abnormal, Not Clinically Significant	6	8	-	14
Abnormal, Clinically Significant	-	-	-	-
Total	40	13	1	54
Follow-up				
Within Normal Limits	37	8	1	46
Abnormal, Not Clinically Significant	3	5	-	8
Abnormal, Clinically Significant	-	-	-	-
Total	40	13	1	54

治験総括報告書 Table 3.3.2.2.3（Section 16.1.9.5）（5.3.5.1-1）から引用

表 2.7.4.8-付録-56　12 誘導心電図のシフトテーブル（安全性データの解析対象集団）（CCT-002 試験）

Interpretation

Visit	Baseline TAK-385 40mg (N=138) Within Normal Limits	Abnormal but not Clinically Significant	Abnormal and Clinically Significant	Total
Week 24				
Within Normal Limits	125	6	-	131
Abnormal but not Clinically Significant	3	4	-	7
Abnormal and Clinically Significant	-	-	-	-
Total	128	10	-	138
Follow-up				
Within Normal Limits	123	7	-	130
Abnormal but not Clinically Significant	2	2	-	4
Abnormal and Clinically Significant	1	-	-	1
Total	126	9	-	135

治験総括報告書 Table 15.3.4.1（5.3.5.1-2）から引用

表 2.7.4.8-付録-56　12 誘導心電図のシフトテーブル（安全性データの解析対象集団）（CCT-002 試験）（続き）

Interpretation

	Baseline			
	Leuprorelin (N=142)			
Visit	Within Normal Limits	Abnormal but not Clinically Significant	Abnormal and Clinically Significant	Total
Week 24				
Within Normal Limits	133	3	-	136
Abnormal but not Clinically Significant	1	3	-	4
Abnormal and Clinically Significant	1	-	-	1
Total	135	6	-	141
Follow-up				
Within Normal Limits	131	3	-	134
Abnormal but not Clinically Significant	4	3	-	7
Abnormal and Clinically Significant	-	-	-	-
Total	135	6	-	141

治験総括報告書 Table 15.3.4.1（5.3.5.1-2）から引用

表 2.7.4.8-付録-57　12 誘導心電図のシフトテーブル（安全性データの解析対象集団）（3008 試験）

Interpretation

Visit	Baseline TAK-385 40mg (N=33) Within Normal Limits	Abnormal but not Clinically Significant	Abnormal and Clinically Significant	Total
Week 12				
Within Normal Limits	28	1	-	29
Abnormal but not Clinically Significant	2	1	-	3
Abnormal and Clinically Significant	1	-	-	1
Total	31	2	-	33
Follow-up				
Within Normal Limits	31	1	-	32
Abnormal but not Clinically Significant	-	1	-	1
Abnormal and Clinically Significant	-	-	-	-
Total	31	2	-	33

治験総括報告書 Table 15.3.4.1（5.3.5.1-3）から引用

表 2.7.4.8-付録-57　12 誘導心電図のシフトテーブル（安全性データの解析対象集団）（3008 試験）（続き）

Interpretation

	Baseline			
	Placebo (N=32)			
Visit	Within Normal Limits	Abnormal but not Clinically Significant	Abnormal and Clinically Significant	Total
Week 12				
Within Normal Limits	30	-	-	30
Abnormal but not Clinically Significant	-	2	-	2
Abnormal and Clinically Significant	-	-	-	-
Total	30	2	-	32
Follow-up				
Within Normal Limits	29	1	-	30
Abnormal but not Clinically Significant	1	1	-	2
Abnormal and Clinically Significant	-	-	-	-
Total	30	2	-	32

治験総括報告書 Table 15.3.4.1（5.3.5.1-3）から引用

表 2.7.4.8-付録-58　12 誘導心電図のシフトテーブル（安全性データの解析対象集団）（CCT-101 試験）

ECG Interpretation

	Baseline							
	Placebo (N=97)				TAK-385 10mg (N=103)			
Visit	Within Normal Limits	Abnormal, Not Clinically Significant	Abnormal, Clinically Significant	Total	Within Normal Limits	Abnormal, Not Clinically Significant	Abnormal, Clinically Significant	Total
Week 4								
Within Normal Limits	71	10	-	81	77	9	-	86
Abnormal, Not Clinically Significant	5	11	-	16	6	10	-	16
Abnormal, Clinically Significant	-	-	-	-	-	-	-	-
Total	76	21	-	97	83	19	-	102
Week 8								
Within Normal Limits	72	13	-	85	80	13	-	93
Abnormal, Not Clinically Significant	3	7	-	10	3	6	-	9
Abnormal, Clinically Significant	-	-	-	-	1	-	-	1
Total	75	20	-	95	84	19	-	103
Week 12								
Within Normal Limits	70	11	-	81	76	9	-	85
Abnormal, Not Clinically Significant	2	9	-	11	5	10	-	15
Abnormal, Clinically Significant	1	-	-	1	1	-	-	1
Total	73	20	-	93	82	19	-	101
Follow-up								
Within Normal Limits	15	1	-	16	13	1	-	14
Abnormal, Not Clinically Significant	-	2	-	2	1	3	-	4
Abnormal, Clinically Significant	-	-	-	-	1	-	-	1
Total	15	3	-	18	15	4	-	19

治験総括報告書 Table 3.3.2.2.3（Section 15.1）（5.3.5.4-1）から引用

表 2.7.4.8-付録-58　12 誘導心電図のシフトテーブル（安全性データの解析対象集団）（CCT-101 試験）（続き）

ECG Interpretation

	Baseline							
	TAK-385 20mg (N=100)				TAK-385 40mg (N=103)			
Visit	Within Normal Limits	Abnormal, Not Clinically Significant	Abnormal, Clinically Significant	Total	Within Normal Limits	Abnormal, Not Clinically Significant	Abnormal, Clinically Significant	Total
Week 4								
Within Normal Limits	80	4	-	84	84	7	-	91
Abnormal, Not Clinically Significant	7	9	-	16	2	10	-	12
Abnormal, Clinically Significant	-	-	-	-	-	-	-	-
Total	87	13	-	100	86	17	-	103
Week 8								
Within Normal Limits	75	4	-	79	78	8	-	86
Abnormal, Not Clinically Significant	9	8	-	17	7	8	-	15
Abnormal, Clinically Significant	-	-	-	-	-	-	-	-
Total	84	12	-	96	85	16	-	101
Week 12								
Within Normal Limits	75	2	-	77	80	9	-	89
Abnormal, Not Clinically Significant	4	10	-	14	5	7	-	12
Abnormal, Clinically Significant	-	-	-	-	-	-	-	-
Total	79	12	-	91	85	16	-	101
Follow-up								
Within Normal Limits	18	-	-	18	11	2	-	13
Abnormal, Not Clinically Significant	1	3	-	4	-	-	-	-
Abnormal, Clinically Significant	-	-	-	-	-	-	-	-
Total	19	3	-	22	11	2	-	13

治験総括報告書 Table 3.3.2.2.3（Section 15.1）（5.3.5.4-1）から引用

表 2.7.4.8-付録-58　12 誘導心電図のシフトテーブル（安全性データの解析対象集団）（CCT-101 試験）（続き）

ECG Interpretation

	Baseline			
	Leuprorelin (N=80)			
Visit	Within Normal Limits	Abnormal, Not Clinically Significant	Abnormal, Clinically Significant	Total
Week 4				
Within Normal Limits	64	5	-	69
Abnormal, Not Clinically Significant	5	6	-	11
Abnormal, Clinically Significant	-	-	-	-
Total	69	11	-	80
Week 8				
Within Normal Limits	62	3	-	65
Abnormal, Not Clinically Significant	5	8	-	13
Abnormal, Clinically Significant	-	-	-	-
Total	67	11	-	78
Week 12				
Within Normal Limits	59	4	-	63
Abnormal, Not Clinically Significant	5	7	-	12
Abnormal, Clinically Significant	-	-	-	-
Total	64	11	-	75
Follow-up				
Within Normal Limits	10	-	-	10
Abnormal, Not Clinically Significant	-	-	-	-
Abnormal, Clinically Significant	-	-	-	-
Total	10	-	-	10

治験総括報告書 Table 3.3.2.2.3（Section 15.1）（5.3.5.4-1）から引用

表 2.7.4.8-付録-59　12 誘導心電図のシフトテーブル（安全性データの解析対象集団）（OCT-101 試験）

ECG Interpretation

	Baseline							
	Placebo (N=97)				TAK-385 10mg (N=103)			
Visit	Within Normal Limits	Abnormal, Not Clinically Significant	Abnormal, Clinically Significant	Total	Within Normal Limits	Abnormal, Not Clinically Significant	Abnormal, Clinically Significant	Total
Week 4								
Within Normal Limits	71	10	-	81	77	9	-	86
Abnormal, Not Clinically Significant	5	11	-	16	6	10	-	16
Abnormal, Clinically Significant	-	-	-	-	-	-	-	-
Total	76	21	-	97	83	19	-	102
Week 8								
Within Normal Limits	72	13	-	85	80	13	-	93
Abnormal, Not Clinically Significant	3	7	-	10	3	6	-	9
Abnormal, Clinically Significant	-	-	-	-	1	-	-	1
Total	75	20	-	95	84	19	-	103
Week 12								
Within Normal Limits	70	11	-	81	76	9	-	85
Abnormal, Not Clinically Significant	2	9	-	11	5	10	-	15
Abnormal, Clinically Significant	1	-	-	1	1	-	-	1
Total	73	20	-	93	82	19	-	101
Week 16								
Within Normal Limits	54	11	-	65	65	8	-	73
Abnormal, Not Clinically Significant	5	5	-	10	4	7	-	11
Abnormal, Clinically Significant	-	-	-	-	-	-	-	-
Total	59	16	-	75	69	15	-	84
Week 20								
Within Normal Limits	54	11	-	65	65	6	-	71
Abnormal, Not Clinically Significant	5	5	-	10	1	9	-	10
Abnormal, Clinically Significant	-	-	-	-	-	-	-	-
Total	59	16	-	75	66	15	-	81
Week 24								
Within Normal Limits	52	8	-	60	62	7	-	69
Abnormal, Not Clinically Significant	1	7	-	8	3	7	-	10
Abnormal, Clinically Significant	-	-	-	-	-	-	-	-
Total	53	15	-	68	65	14	-	79
Follow-up								
Within Normal Limits	55	10	-	65	66	5	-	71
Abnormal, Not Clinically Significant	4	8	-	12	2	10	-	12
Abnormal, Clinically Significant	-	-	-	-	-	-	-	-
Total	59	18	-	77	68	15	-	83

治験総括報告書 Table 3.2.2.2.3（Section 15.1）（5.3.5.4-2）から引用

表 2.7.4.8-付録-59　12 誘導心電図のシフトテーブル（安全性データの解析対象集団）（OCT-101 試験）（続き）

ECG Interpretation

	Baseline							
	TAK-385 20mg (N=100)				TAK-385 40mg (N=103)			
Visit	Within Normal Limits	Abnormal, Not Clinically Significant	Abnormal, Clinically Significant	Total	Within Normal Limits	Abnormal, Not Clinically Significant	Abnormal, Clinically Significant	Total
Week 4								
Within Normal Limits	80	4	-	84	84	7	-	91
Abnormal, Not Clinically Significant	7	9	-	16	2	10	-	12
Abnormal, Clinically Significant	-	-	-	-	-	-	-	-
Total	87	13	-	100	86	17	-	103
Week 8								
Within Normal Limits	75	4	-	79	78	8	-	86
Abnormal, Not Clinically Significant	9	8	-	17	7	8	-	15
Abnormal, Clinically Significant	-	-	-	-	-	-	-	-
Total	84	12	-	96	85	16	-	101
Week 12								
Within Normal Limits	75	2	-	77	80	9	-	89
Abnormal, Not Clinically Significant	4	10	-	14	5	7	-	12
Abnormal, Clinically Significant	-	-	-	-	-	-	-	-
Total	79	12	-	91	85	16	-	101
Week 16								
Within Normal Limits	60	3	-	63	67	8	-	75
Abnormal, Not Clinically Significant	8	7	-	15	7	7	-	14
Abnormal, Clinically Significant	-	-	-	-	-	-	-	-
Total	68	10	-	78	74	15	-	89
Week 20								
Within Normal Limits	64	2	-	66	67	7	-	74
Abnormal, Not Clinically Significant	3	8	-	11	6	7	-	13
Abnormal, Clinically Significant	-	-	-	-	-	-	-	-
Total	67	10	-	77	73	14	-	87
Week 24								
Within Normal Limits	61	2	-	63	71	8	-	79
Abnormal, Not Clinically Significant	4	8	-	12	3	6	-	9
Abnormal, Clinically Significant	1	-	-	1	-	-	-	-
Total	66	10	-	76	74	14	-	88
Follow-up								
Within Normal Limits	62	3	-	65	67	10	-	77
Abnormal, Not Clinically Significant	5	7	-	12	7	4	-	11
Abnormal, Clinically Significant	-	-	-	-	-	1	-	1
Total	67	10	-	77	74	15	-	89

治験総括報告書 Table 3.2.2.2.3（Section 15.1）（5.3.5.4-2）から引用

表 2.7.4.8-付録-59　12 誘導心電図のシフトテーブル（安全性データの解析対象集団）（OCT-101 試験）（続き）

ECG Interpretation

	Baseline			
	Leuprorelin (N=80)			
Visit	Within Normal Limits	Abnormal, Not Clinically Significant	Abnormal, Clinically Significant	Total
Week 4				
Within Normal Limits	64	5	-	69
Abnormal, Not Clinically Significant	5	6	-	11
Abnormal, Clinically Significant	-	-	-	-
Total	69	11	-	80
Week 8				
Within Normal Limits	62	3	-	65
Abnormal, Not Clinically Significant	5	8	-	13
Abnormal, Clinically Significant	-	-	-	-
Total	67	11	-	78
Week 12				
Within Normal Limits	59	4	-	63
Abnormal, Not Clinically Significant	5	7	-	12
Abnormal, Clinically Significant	-	-	-	-
Total	64	11	-	75
Week 16				
Within Normal Limits	56	6	-	62
Abnormal, Not Clinically Significant	2	5	-	7
Abnormal, Clinically Significant	-	-	-	-
Total	58	11	-	69
Week 20				
Within Normal Limits	51	3	-	54
Abnormal, Not Clinically Significant	5	6	-	11
Abnormal, Clinically Significant	-	-	-	-
Total	56	9	-	65
Week 24				
Within Normal Limits	51	3	-	54
Abnormal, Not Clinically Significant	2	6	-	8
Abnormal, Clinically Significant	-	-	-	-
Total	53	9	-	62
Follow-up				
Within Normal Limits	55	6	-	61
Abnormal, Not Clinically Significant	3	5	-	8
Abnormal, Clinically Significant	-	-	-	-
Total	58	11	-	69

治験総括報告書 Table 3.2.2.2.3（Section 15.1）（5.3.5.4-2）から引用

表 2.7.4.8-付録-60　年齢別の有害事象の発現頻度（安全性データの解析対象集団）（併合解析）

Age (years): 20<= - <30

System Organ Class Preferred Term	Number of Subjects (%) TAK-385 10mg (N=18)	 TAK-385 20mg (N=24)	 TAK-385 40mg (N=22)	 Leuprorelin (N=16)	 Placebo (N=19)
Subjects with Any TEAEs	16(88.9)	24(100.0)	22(100.0)	16(100.0)	14(73.7)
血液およびリンパ系障害	-	1(4.2)	-	-	-
貧血	-	1(4.2)	-	-	-
好酸球増加症	-	-	-	-	-
鉄欠乏性貧血	-	-	-	-	-
心臓障害	-	-	-	-	1(5.3)
動悸	-	-	-	-	-
心室性期外収縮	-	-	-	-	1(5.3)
右脚ブロック	-	-	-	-	-
不整脈	-	-	-	-	-
徐脈	-	-	-	-	-
洞性徐脈	-	-	-	-	-
先天性、家族性および遺伝性障害	-	-	-	-	-
皮様嚢腫	-	-	-	-	-
脊髄空洞症	-	-	-	-	-
耳および迷路障害	2(11.1)	-	1(4.5)	1(6.3)	1(5.3)
回転性めまい	1(5.6)	-	-	-	1(5.3)
メニエール病	-	-	1(4.5)	-	-
感音性難聴	-	-	-	1(6.3)	-
耳鳴	-	-	-	-	-
難聴	1(5.6)	-	-	-	-
耳不快感	-	-	-	-	-
乗物酔い	-	-	-	-	-
突発性難聴	-	-	-	-	-
頭位性回転性めまい	-	-	-	-	-
内分泌障害	-	-	-	-	-
自己免疫性甲状腺炎	-	-	-	-	-
エストロゲン欠乏症	-	-	-	-	-
眼障害	-	-	-	-	-
眼乾燥	-	-	-	-	-
眼瞼炎	-	-	-	-	-
アレルギー性結膜炎	-	-	-	-	-
眼瞼そう痒症	-	-	-	-	-
角膜炎	-	-	-	-	-
眼充血	-	-	-	-	-
眼精疲労	-	-	-	-	-
霰粒腫	-	-	-	-	-

併合解析報告書 Table 4.8.5.3.1.1（5.3.5.3-1）から引用
数字は例数、（ ）内は%
事象名：MedDRA/J ver.[redacted]

表 2.7.4.8-付録-60　年齢別の有害事象の発現頻度（安全性データの解析対象集団）（併合解析）（続き）

Age (years): 20<= - <30

System Organ Class Preferred Term	Number of Subjects (%) TAK-385 10mg (N=18)	 TAK-385 20mg (N=24)	 TAK-385 40mg (N=22)	 Leuprorelin (N=16)	 Placebo (N=19)
眼障害 (Continued)					
結膜出血	-	-	-	-	-
眼脂	-	-	-	-	-
眼瞼浮腫	-	-	-	-	-
開放隅角緑内障	-	-	-	-	-
閃輝暗点	-	-	-	-	-
強膜炎	-	-	-	-	-
霧視	-	-	-	-	-
胃腸障害	4(22.2)	2(8.3)	4(18.2)	4(25.0)	7(36.8)
下痢	1(5.6)	1(4.2)	1(4.5)	1(6.3)	2(10.5)
上腹部痛	-	1(4.2)	1(4.5)	1(6.3)	1(5.3)
悪心	2(11.1)	-	-	2(12.5)	-
齲歯	-	-	1(4.5)	-	-
便秘	1(5.6)	-	-	1(6.3)	1(5.3)
腹部不快感	-	-	-	-	-
口内炎	-	-	-	-	-
嘔吐	1(5.6)	-	1(4.5)	-	1(5.3)
歯痛	-	-	-	-	2(10.5)
腹部膨満	-	-	-	-	-
胃炎	-	1(4.2)	-	1(6.3)	-
腹痛	1(5.6)	-	-	-	-
下腹部痛	-	-	-	-	-
胃食道逆流性疾患	-	-	-	-	-
腸炎	-	-	-	-	1(5.3)
胃ポリープ	-	-	-	-	-
歯周病	-	-	-	-	-
直腸炎	-	-	1(4.5)	-	-
歯の脱落	-	-	-	-	-
裂肛	-	-	-	-	-
慢性胃炎	-	-	-	-	-
虚血性大腸炎	-	-	-	-	-
消化不良	-	-	-	-	-
軟便	-	-	-	-	-
出血性胃炎	-	-	-	-	-
舌炎	-	-	-	-	-
痔核	-	-	-	-	1(5.3)
大腸ポリープ	-	-	-	-	-
腰ヘルニア	-	-	-	-	-
口腔粘膜血腫	-	-	-	-	-

併合解析報告書 Table 4.8.5.3.1.1（5.3.5.3-1）から引用
数字は例数、（ ）内は%
事象名：MedDRA/J ver.[redacted]

表 2.7.4.8-付録-60　年齢別の有害事象の発現頻度（安全性データの解析対象集団）（併合解析）（続き）

Age (years): 20<= - <30

System Organ Class Preferred Term	Number of Subjects (%) TAK-385 10mg (N=18)	 TAK-385 20mg (N=24)	 TAK-385 40mg (N=22)	 Leuprorelin (N=16)	 Placebo (N=19)
一般・全身障害および投与部位の状態	1(5.6)	1(4.2)	1(4.5)	3(18.8)	4(21.1)
倦怠感	-	-	1(4.5)	1(6.3)	2(10.5)
疲労	-	-	-	-	-
発熱	-	-	-	-	1(5.3)
浮腫	1(5.6)	-	-	-	-
末梢性浮腫	-	-	-	1(6.3)	-
注射部位反応	-	-	-	1(6.3)	-
注射部位紅斑	-	-	-	-	-
注射部位腫脹	-	1(4.2)	-	-	-
注射部位疼痛	-	-	-	-	-
胸痛	-	-	-	-	-
悪寒	-	-	-	-	-
熱感	-	-	-	-	-
注射部位内出血	-	-	-	-	-
注射部位硬結	-	-	-	1(6.3)	-
口渇	-	-	-	-	-
嚢胞	-	-	-	-	-
不快感	-	-	-	-	-
冷感	-	-	-	-	-
びくびく感	-	-	-	-	-
硬結	-	-	-	-	-
炎症	-	-	-	-	-
注射部位皮膚炎	-	-	-	-	-
注射部位知覚低下	-	-	-	-	-
注射部位腫瘤	-	-	-	-	-
注射部位そう痒感	-	-	-	-	-
注射部位発疹	-	-	-	-	1(5.3)
局所腫脹	-	-	-	-	-
末梢腫脹	-	-	-	-	-
仮性嚢胞	-	-	-	-	-
血管穿刺部位内出血	-	-	-	-	-
肝胆道系障害	-	-	-	-	-
肝機能異常	-	-	-	-	-
脂肪肝	-	-	-	-	-
免疫系障害	1(5.6)	-	2(9.1)	-	2(10.5)
季節性アレルギー	1(5.6)	-	2(9.1)	-	2(10.5)
感染症および寄生虫症	5(27.8)	14(58.3)	12(54.5)	7(43.8)	6(31.6)
ウイルス性上気道感染	3(16.7)	10(41.7)	8(36.4)	3(18.8)	5(26.3)
胃腸炎	-	4(16.7)	1(4.5)	2(12.5)	-
膀胱炎	-	-	-	-	-

併合解析報告書 Table 4.8.5.3.1.1（5.3.5.3-1）から引用
数字は例数、( ) 内は%
事象名：MedDRA/J ver.[redacted]

表 2.7.4.8-付録-60　年齢別の有害事象の発現頻度（安全性データの解析対象集団）（併合解析）（続き）

Age (years): 20<= - <30

System Organ Class Preferred Term	Number of Subjects (%) TAK-385 10mg (N=18)	 TAK-385 20mg (N=24)	 TAK-385 40mg (N=22)	 Leuprorelin (N=16)	 Placebo (N=19)
感染症および寄生虫症 (Continued)					
咽頭炎	2(11.1)	-	1(4.5)	-	-
インフルエンザ	-	-	3(13.6)	1(6.3)	-
扁桃炎	-	1(4.2)	-	-	-
外陰部腟カンジダ症	-	-	-	-	-
細菌性外陰腟炎	-	-	-	-	-
歯肉炎	-	-	-	1(6.3)	-
麦粒腫	1(5.6)	1(4.2)	1(4.5)	-	-
口腔ヘルペス	-	-	-	-	-
歯冠周囲炎	1(5.6)	1(4.2)	-	1(6.3)	-
副鼻腔炎	-	-	-	-	-
外陰部炎	-	-	-	-	-
気管支炎	-	-	-	-	-
ウイルス性胃腸炎	-	-	-	-	-
細菌性腟症	-	-	-	-	-
結膜炎	-	-	-	-	-
急性副鼻腔炎	-	-	-	-	-
口角口唇炎	1(5.6)	-	-	1(6.3)	-
毛包炎	-	-	-	-	-
陰部ヘルペス	-	-	-	-	-
帯状疱疹	-	-	-	-	-
喉頭炎	-	-	-	-	-
外耳炎	-	-	-	-	-
腹膜炎	-	-	-	-	-
肺炎	-	-	-	-	-
鼻炎	-	-	-	-	-
足部白癬	-	-	-	-	-
バルトリン腺炎	-	-	-	-	-
細菌性気管支炎	-	-	-	-	-
蜂巣炎	-	-	1(4.5)	-	-
クラミジア感染	-	-	-	-	-
慢性扁桃炎	-	-	-	-	-
涙嚢炎	-	1(4.2)	-	-	-
爪の皮膚糸状菌症	-	-	-	-	-
真菌感染	-	-	-	-	-
せつ	-	-	-	-	-
ノロウイルス性胃腸炎	-	-	1(4.5)	-	-
真菌性性器感染	-	-	-	-	-
ヘルペスウイルス感染	-	-	-	-	-
膿痂疹	-	-	-	-	-
感染性皮膚嚢腫	-	-	-	-	-
食道カンジダ症	-	-	-	-	-

併合解析報告書 Table 4.8.5.3.1.1（5.3.5.3-1）から引用
数字は例数、( ) 内は%
事象名：MedDRA/J ver.[redacted]

表 2.7.4.8-付録-60　年齢別の有害事象の発現頻度（安全性データの解析対象集団）（併合解析）（続き）

Age (years): 20<= - <30

System Organ Class Preferred Term	Number of Subjects (%) TAK-385 10mg (N=18)	 TAK-385 20mg (N=24)	 TAK-385 40mg (N=22)	 Leuprorelin (N=16)	 Placebo (N=19)
感染症および寄生虫症 (Continued)					
中耳炎	-	-	-	-	-
爪囲炎	-	-	-	-	-
軟骨膜炎	-	-	-	-	-
歯周炎	-	-	-	-	-
マイコプラズマ性肺炎	-	-	-	-	-
腎盂腎炎	-	-	-	-	-
卵管炎	-	-	-	-	-
唾液腺炎	-	-	-	-	1(5.3)
レンサ球菌感染	-	1(4.2)	-	-	-
歯膿瘍	-	-	-	-	-
腟感染	-	-	-	-	-
ウイルス性下痢	-	-	-	-	-
傷害、中毒および処置合併症	-	-	-	1(6.3)	2(10.5)
挫傷	-	-	-	-	-
転倒	-	-	-	-	1(5.3)
処置による疼痛	-	-	-	-	-
交通事故	-	-	-	-	-
熱中症	-	-	-	1(6.3)	-
節足動物刺傷	-	-	-	-	1(5.3)
靱帯損傷	-	-	-	-	-
靱帯捻挫	-	-	-	-	-
骨挫傷	-	-	-	-	-
毒性物質曝露	-	-	-	-	-
腓骨骨折	-	-	-	-	1(5.3)
切開部位そう痒感	-	-	-	-	-
筋断裂	-	-	-	-	-
外傷後頚部症候群	-	-	-	-	-
皮下血腫	-	-	-	-	-
熱傷	-	-	-	-	-
歯牙破折	-	-	-	-	-
尺骨骨折	-	-	-	-	-
創傷	-	-	-	-	-
臨床検査	-	2(8.3)	4(18.2)	2(12.5)	2(10.5)
骨密度減少	-	1(4.2)	-	-	-
γ-グルタミルトランスフェラーゼ増加	-	-	1(4.5)	-	-
アラニンアミノトランスフェラーゼ増加	-	-	1(4.5)	-	-
血中クレアチンホスホキナーゼ増加	-	-	1(4.5)	1(6.3)	2(10.5)
骨吸収試験異常	-	-	-	-	-
血中コレステロール増加	-	-	-	-	-

併合解析報告書 Table 4.8.5.3.1.1（5.3.5.3-1）から引用
数字は例数、( ) 内は%
事象名：MedDRA/J ver.[redacted]

表 2.7.4.8-付録-60　年齢別の有害事象の発現頻度（安全性データの解析対象集団）（併合解析）（続き）

Age (years): 20<= - <30

System Organ Class Preferred Term	Number of Subjects (%) TAK-385 10mg (N=18)	 TAK-385 20mg (N=24)	 TAK-385 40mg (N=22)	 Leuprorelin (N=16)	 Placebo (N=19)
臨床検査 (Continued)					
肝機能検査値上昇	-	-	-	-	-
アスパラギン酸アミノトランスフェラーゼ増加	-	-	1(4.5)	-	1(5.3)
血中アルカリホスファターゼ増加	-	-	1(4.5)	-	-
低比重リポ蛋白増加	-	-	-	-	-
血中トリグリセリド増加	-	-	-	-	-
体重増加	-	-	-	-	-
体重減少	-	-	-	-	-
血中ビリルビン増加	-	-	2(9.1)	-	-
血中リン増加	-	-	-	1(6.3)	-
好酸球数増加	-	1(4.2)	-	-	-
血圧上昇	-	-	-	-	-
尿中血陽性	-	-	-	-	-
白血球数増加	-	-	-	-	-
血中クレアチニン増加	-	-	-	-	-
血中ブドウ糖増加	-	-	-	-	-
血中尿酸増加	-	-	-	-	-
肝機能検査異常	-	-	-	-	-
尿中蛋白陽性	-	-	-	-	-
白血球数減少	-	-	-	-	-
血中カルシウム減少	-	-	-	-	-
血中鉄減少	-	-	-	-	-
血中鉄増加	-	-	-	-	-
血中乳酸脱水素酵素増加	-	-	-	-	1(5.3)
尿中血	-	-	-	-	-
心電図ＰＲ短縮	-	-	-	-	-
心電図ＱＴ延長	-	-	-	-	-
心電図ＱＴ短縮	-	-	-	-	-
心電図Ｔ波振幅減少	-	-	-	-	-
心電図異常	-	-	-	-	-
尿中ブドウ糖陽性	-	1(4.2)	-	-	-
グリコヘモグロビン増加	-	-	-	-	-
ヘモグロビン減少	-	-	-	-	-
ヘリコバクター検査陽性	-	-	-	-	-
肝酵素上昇	-	-	-	-	-
脂質増加	-	-	-	-	-
血小板数減少	-	-	-	-	-
総胆汁酸増加	-	-	-	-	-
代謝および栄養障害	-	-	1(4.5)	1(6.3)	-
高脂血症	-	-	-	-	-
脂質異常症	-	-	-	-	-

併合解析報告書 Table 4.8.5.3.1.1（5.3.5.3-1）から引用
数字は例数、( ) 内は%
事象名：MedDRA/J ver.[redacted]