表 2.7.4-51 臨床検査値の基準値範囲内からの逸脱状況の変化（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

	Total N=185																	
	Week 28			Week 32			Week 36			Week 40			Week 44			Week 48		
	Low[#2]	Normal[#2]	High[#2]	Low[#2]	Normal[#2]	High[#2]	Low[#2]	Normal[#2]	High[#2]	Low[#2]	Normal[#2]	High[#2]	Low[#2]	Normal[#2]	High[#2]	Low[#2]	Normal[#2]	High[#2]
Chloride (mEq/L)																		
Baseline[#1]																		
Low[#2]	0	3	0	0	3	0	0	3	0	0	3	0	0	3	0	0	3	0
Normal[#2]	2	169	1	0	168	1	0	164	0	0	158	2	1	157	1	0	156	3
High[#2]	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Potassium (mEq/L)																		
Baseline[#1]																		
Low[#2]	0	4	0	1	3	0	1	3	0	2	2	0	1	3	0	1	3	0
Normal[#2]	7	160	3	2	164	1	1	161	0	3	155	0	2	153	2	4	152	1
High[#2]	0	0	1	0	0	1	0	0	1	0	0	1	0	1	0	0	1	0
Cholesterol (mg/dL)																		
Baseline[#1]																		
Low[#2]	7	4	0	6	4	0	7	3	0	8	2	0	8	2	0	7	3	0
Normal[#2]	6	116	13	7	112	14	6	115	7	6	106	12	5	106	12	6	110	7
High[#2]	0	12	17	0	11	18	0	10	19	0	10	19	0	12	17	0	10	19

#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.
#2 : Low (High) : Under (Over) the Lower (Upper) Limit of Reference Range. Normal : Within the Reference Range.

PAGE: 53 of 63
PROGRAM: t077 (OUTPUT: t14_03_04_11_lb_shift)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Table 14.3.4-11 より改変

表 2.7.4-51　臨床検査値の基準値範囲内からの逸脱状況の変化（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

	Total N=185		
	Week 52		
	Low[#2]	Normal[#2]	High[#2]
Chloride (mEq/L)			
Baseline[#1]			
Low[#2]	0	3	0
Normal[#2]	0	154	3
High[#2]	0	0	0
Potassium (mEq/L)			
Baseline[#1]			
Low[#2]	1	3	0
Normal[#2]	3	150	2
High[#2]	0	1	0
Cholesterol (mg/dL)			
Baseline[#1]			
Low[#2]	7	3	0
Normal[#2]	5	110	6
High[#2]	0	12	17

#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.
#2 : Low (High) : Under (Over) the Lower (Upper) Limit of Reference Range. Normal : Within the Reference Range.

PAGE: 54 of 63
PROGRAM: t077 (OUTPUT: t14_03_04_11_lb_shift)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Table 14.3.4-11 より改変

表 2.7.4-51　臨床検査値の基準値範囲内からの逸脱状況の変化（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

	Cohort 1 (0%/5%) N=94																	
	Week 4			Week 8			Week 12			Week 16			Week 20			Week 24		
	Low[#2]	Normal[#2]	High[#2]	Low[#2]	Normal[#2]	High[#2]	Low[#2]	Normal[#2]	High[#2]	Low[#2]	Normal[#2]	High[#2]	Low[#2]	Normal[#2]	High[#2]	Low[#2]	Normal[#2]	High[#2]
Triglycerides (mg/dL)																		
Baseline[#1]																		
Low[#2]	7	9	0	7	8	1	6	9	1	5	9	1	6	8	0	9	3	2
Normal[#2]	6	50	4	7	48	4	9	45	6	8	48	3	12	45	3	7	46	7
High[#2]	0	10	8	0	9	9	0	10	8	0	11	6	0	7	10	0	6	10

#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.
#2 : Low (High) : Under (Over) the Lower (Upper) Limit of Reference Range. Normal : Within the Reference Range.

PAGE: 55 of 63
PROGRAM: t077 (OUTPUT: t14_03_04_11_lb_shift)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Table 14.3.4-11 より改変

表 2.7.4-51 臨床検査値の基準値範囲内からの逸脱状況の変化（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

	Cohort 1 (0%/5%) N=94																	
	Week 28			Week 32			Week 36			Week 40			Week 44			Week 48		
	Low[#2]	Normal[#2]	High[#2]	Low[#2]	Normal[#2]	High[#2]	Low[#2]	Normal[#2]	High[#2]	Low[#2]	Normal[#2]	High[#2]	Low[#2]	Normal[#2]	High[#2]	Low[#2]	Normal[#2]	High[#2]
Triglycerides (mg/dL)																		
Baseline[#1]																		
Low[#2]	5	9	0	7	6	1	7	7	0	4	9	1	5	9	0	6	6	1
Normal[#2]	12	41	7	7	47	5	6	42	9	9	42	4	7	44	6	5	47	5
High[#2]	0	7	9	2	4	10	0	8	8	0	9	7	1	6	8	0	7	9

#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.
#2 : Low (High) : Under (Over) the Lower (Upper) Limit of Reference Range. Normal : Within the Reference Range.

PAGE: 56 of 63
PROGRAM: t077 (OUTPUT: t14_03_04_11_lb_shift)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Table 14.3.4-11 より改変

表 2.7.4-51　臨床検査値の基準値範囲内からの逸脱状況の変化（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

	Cohort 1 (0%/5%) N=94		
	Week 52		
	Low[#2]	Normal[#2]	High[#2]
Triglycerides (mg/dL)			
Baseline[#1]			
Low[#2]	5	8	1
Normal[#2]	10	43	2
High[#2]	0	5	11

#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.
#2 : Low (High) : Under (Over) the Lower (Upper) Limit of Reference Range. Normal : Within the Reference Range.

PAGE: 57 of 63
PROGRAM: t077 (OUTPUT: t14_03_04_11_lb_shift)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Table 14.3.4-11 より改変

表 2.7.4-51 臨床検査値の基準値範囲内からの逸脱状況の変化（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

	Cohort 1 (5%/5%) N=91																	
	Week 4			Week 8			Week 12			Week 16			Week 20			Week 24		
	Low[#2]	Normal[#2]	High[#2]	Low[#2]	Normal[#2]	High[#2]	Low[#2]	Normal[#2]	High[#2]	Low[#2]	Normal[#2]	High[#2]	Low[#2]	Normal[#2]	High[#2]	Low[#2]	Normal[#2]	High[#2]
Triglycerides (mg/dL)																		
Baseline[#1]																		
Low[#2]	10	16	0	9	15	0	12	11	0	12	12	0	14	10	0	11	13	0
Normal[#2]	9	37	4	7	34	8	10	34	5	7	39	3	10	34	4	6	38	5
High[#2]	0	7	6	1	7	5	1	7	5	0	6	6	0	7	6	0	7	6

#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.
#2 : Low (High) : Under (Over) the Lower (Upper) Limit of Reference Range. Normal : Within the Reference Range.

PAGE: 58 of 63
PROGRAM: t077 (OUTPUT: t14_03_04_11_lb_shift)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Table 14.3.4-11 より改変

表 2.7.4-51　臨床検査値の基準値範囲内からの逸脱状況の変化（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

	Cohort 1 (5%/5%) N=91																	
	Week 28			Week 32			Week 36			Week 40			Week 44			Week 48		
	Low[#2]	Normal[#2]	High[#2]	Low[#2]	Normal[#2]	High[#2]	Low[#2]	Normal[#2]	High[#2]	Low[#2]	Normal[#2]	High[#2]	Low[#2]	Normal[#2]	High[#2]	Low[#2]	Normal[#2]	High[#2]
Triglycerides (mg/dL)																		
Baseline[#1]																		
Low[#2]	7	14	2	9	11	2	10	10	0	10	10	0	8	12	0	9	11	0
Normal[#2]	8	33	8	9	34	5	8	32	7	6	32	7	7	30	6	9	25	9
High[#2]	1	6	6	1	8	4	0	9	4	0	9	4	0	7	6	0	7	6

#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.
#2 : Low (High) : Under (Over) the Lower (Upper) Limit of Reference Range. Normal : Within the Reference Range.

PAGE: 59 of 63
PROGRAM: t077 (OUTPUT: t14_03_04_11_lb_shift)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Table 14.3.4-11 より改変

表 2.7.4-51　臨床検査値の基準値範囲内からの逸脱状況の変化（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

	Cohort 1 (5%/5%) N=91		
	Week 52		
	Low[#2]	Normal[#2]	High[#2]
Triglycerides (mg/dL)			
Baseline[#1]			
Low[#2]	5	14	0
Normal[#2]	8	28	7
High[#2]	0	5	8

#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.
#2 : Low (High) : Under (Over) the Lower (Upper) Limit of Reference Range. Normal : Within the Reference Range.

PAGE: 60 of 63
PROGRAM: t077 (OUTPUT: t14_03_04_11_lb_shift)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Table 14.3.4-11 より改変

表 2.7.4-51 臨床検査値の基準値範囲内からの逸脱状況の変化（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

	Total N=185																	
	Week 4			Week 8			Week 12			Week 16			Week 20			Week 24		
	Low[#2]	Normal[#2]	High[#2]	Low[#2]	Normal[#2]	High[#2]	Low[#2]	Normal[#2]	High[#2]	Low[#2]	Normal[#2]	High[#2]	Low[#2]	Normal[#2]	High[#2]	Low[#2]	Normal[#2]	High[#2]
Triglycerides (mg/dL)																		
Baseline[#1]																		
Low[#2]	17	25	0	16	23	1	18	20	1	17	21	1	20	18	0	20	16	2
Normal[#2]	15	87	8	14	82	12	19	79	11	15	87	6	22	79	7	13	84	12
High[#2]	0	17	14	1	16	14	1	17	13	0	17	12	0	14	16	0	13	16

#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.
#2 : Low (High) : Under (Over) the Lower (Upper) Limit of Reference Range. Normal : Within the Reference Range.

PAGE: 61 of 63
PROGRAM: t077 (OUTPUT: t14_03_04_11_lb_shift)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Table 14.3.4-11 より改変

表 2.7.4-51　臨床検査値の基準値範囲内からの逸脱状況の変化（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

	Total N=185																	
	Week 28			Week 32			Week 36			Week 40			Week 44			Week 48		
	Low[#2]	Normal[#2]	High[#2]	Low[#2]	Normal[#2]	High[#2]	Low[#2]	Normal[#2]	High[#2]	Low[#2]	Normal[#2]	High[#2]	Low[#2]	Normal[#2]	High[#2]	Low[#2]	Normal[#2]	High[#2]
Triglycerides (mg/dL)																		
Baseline[#1]																		
Low[#2]	12	23	2	16	17	3	17	17	0	14	19	1	13	21	0	15	17	1
Normal[#2]	20	74	15	16	81	10	14	74	16	15	74	11	14	74	12	14	72	14
High[#2]	1	13	15	3	12	14	0	17	12	0	18	11	1	13	14	0	14	15

#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.
#2 : Low (High) : Under (Over) the Lower (Upper) Limit of Reference Range. Normal : Within the Reference Range.

PAGE: 62 of 63
PROGRAM: t077 (OUTPUT: t14_03_04_11_lb_shift)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Table 14.3.4-11 より改変

表 2.7.4-51　臨床検査値の基準値範囲内からの逸脱状況の変化（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

	Total N=185		
	Week 52		
	Low[#2]	Normal[#2]	High[#2]
Triglycerides (mg/dL)			
Baseline[#1]			
Low[#2]	10	22	1
Normal[#2]	18	71	9
High[#2]	0	10	19

#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.
#2 : Low (High) : Under (Over) the Lower (Upper) Limit of Reference Range. Normal : Within the Reference Range.

PAGE: 63 of 63
PROGRAM: t077 (OUTPUT: t14_03_04_11_lb_shift)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Table 14.3.4-11 より改変

表 2.7.4-52 バイタルサインの基本統計量（BBI-4000-04 試験）
[Safety]

Parameter	Unit	Treatment	Visit	N	n	Mean	Std	Minimum	Median	Maximum
Systolic Blood Pressure	mmHg	BBI-4000 gel 0%	Screening	52	51	122.9	16.99	84	124.0	163
			Baseline 3	52	52	119.6	16.31	95	117.5	174
			Week 2	52	52	118.3	17.00	87	117.5	169
			Week 4	52	52	117.8	15.82	85	118.0	153
			Week 6-3	52	51	116.6	16.37	88	113.0	150
			Follow-up	52	51	118.6	14.49	89	116.0	156
		BBI-4000 gel 5%	Screening	52	52	120.7	13.01	92	119.5	145
			Baseline 3	52	52	118.3	14.32	88	119.0	149
			Week 2	52	52	115.9	12.70	84	118.0	143
			Week 4	52	52	116.9	14.34	91	118.0	143
			Week 6-3	51	51	116.4	12.49	96	114.0	141
			Follow-up	51	49	114.6	13.15	85	113.0	142
		BBI-4000 gel 10%	Screening	51	51	118.2	15.50	91	116.0	176
			Baseline 3	51	51	117.1	15.74	84	116.0	152
			Week 2	51	50	113.1	11.66	97	111.5	147
			Week 4	51	51	117.8	14.36	91	117.0	163
			Week 6-3	51	50	115.0	13.28	92	113.0	158
			Follow-up	51	50	117.1	15.12	93	116.0	168
		BBI-4000 gel 15%	Screening	52	52	120.2	15.18	92	119.5	182
			Baseline 3	52	52	118.8	14.97	90	116.5	170
			Week 2	52	52	116.0	13.25	85	115.5	150
			Week 4	52	52	115.5	12.37	86	116.0	142
			Week 6-3	52	50	114.0	14.34	88	113.0	152
			Follow-up	51	51	116.1	12.75	86	114.0	143

Source：5.3.5.1-1 Table 14.3.4-8 より改変

表 2.7.4-52　バイタルサインの基本統計量（BBI-4000-04 試験）（続き）
[Safety]

Parameter	Unit	Treatment	Visit	N	n	Mean	Std	Minimum	Median	Maximum
Diastolic Blood Pressure	mmHg	BBI-4000 gel 0%	Screening	52	51	79.9	13.45	54	80.0	123
			Baseline 3	52	52	77.4	12.39	55	76.0	117
			Week 2	52	52	76.9	12.47	50	75.0	118
			Week 4	52	52	75.3	12.84	54	73.0	117
			Week 6-3	52	51	74.4	13.63	52	75.0	101
			Follow-up	52	51	76.0	12.15	50	75.0	108
		BBI-4000 gel 5%	Screening	52	52	75.5	9.62	55	76.5	100
			Baseline 3	52	52	74.6	10.69	52	75.5	107
			Week 2	52	52	72.7	9.33	54	71.0	98
			Week 4	52	52	72.9	8.51	59	72.0	95
			Week 6-3	51	51	71.8	9.04	53	71.0	88
			Follow-up	51	49	74.2	8.83	56	74.0	93
		BBI-4000 gel 10%	Screening	51	51	75.7	12.01	48	74.0	115
			Baseline 3	51	51	74.7	11.24	49	73.0	103
			Week 2	51	50	72.0	10.52	53	71.0	98
			Week 4	51	51	73.2	11.87	50	73.0	102
			Week 6-3	51	50	71.5	10.96	48	70.5	104
			Follow-up	51	50	74.6	11.21	52	74.0	106
		BBI-4000 gel 15%	Screening	52	52	77.1	10.15	53	77.0	108
			Baseline 3	52	52	76.2	11.14	56	74.0	116
			Week 2	52	52	74.0	11.85	53	73.5	116
			Week 4	52	52	73.2	10.93	53	73.0	110
			Week 6-3	52	50	72.2	10.19	55	72.0	95
			Follow-up	51	51	72.7	9.65	45	71.0	104

Source：5.3.5.1-1 Table 14.3.4-8 より改変

表 2.7.4-52　バイタルサインの基本統計量（BBI-4000-04 試験）（続き）
[Safety]

Parameter	Unit	Treatment	Visit	N	n	Mean	Std	Minimum	Median	Maximum
Pulse Rate	bpm	BBI-4000 gel 0%	Screening	52	51	74.6	9.58	60	75.0	97
			Baseline 3	52	52	75.9	10.13	57	75.5	107
			Week 2	52	52	72.8	9.64	54	72.0	98
			Week 4	52	52	72.7	8.80	54	72.5	95
			Week 6-3	52	51	72.2	10.15	51	72.0	98
			Follow-up	52	51	76.0	9.77	57	75.0	99
		BBI-4000 gel 5%	Screening	52	52	71.7	9.96	50	70.0	95
			Baseline 3	52	52	71.8	8.38	56	71.5	90
			Week 2	52	52	72.3	10.11	50	71.5	98
			Week 4	52	52	72.0	9.17	51	72.0	98
			Week 6-3	51	51	73.5	9.55	48	73.0	97
			Follow-up	51	49	73.6	10.18	49	73.0	92
		BBI-4000 gel 10%	Screening	51	51	73.3	9.73	58	72.0	98
			Baseline 3	51	51	75.9	12.71	54	73.0	127
			Week 2	51	50	71.1	10.77	51	71.5	100
			Week 4	51	51	73.7	10.75	49	72.0	98
			Week 6-3	51	50	72.3	11.38	52	70.5	105
			Follow-up	51	50	74.9	12.69	49	71.0	125
		BBI-4000 gel 15%	Screening	52	52	76.5	11.57	53	75.0	107
			Baseline 3	52	52	78.6	11.14	56	79.0	99
			Week 2	52	52	76.2	11.99	47	74.0	99
			Week 4	52	52	72.4	11.05	53	71.0	98
			Week 6-3	52	50	72.6	9.78	55	71.0	98
			Follow-up	51	51	77.5	11.61	55	77.0	98

Source：5.3.5.1-1 Table 14.3.4-8 より改変

表 2.7.4-52　バイタルサインの基本統計量（BBI-4000-04 試験）（続き）
[Safety]

Parameter	Unit	Treatment	Visit	N	n	Mean	Std	Minimum	Median	Maximum
Temperature	C	BBI-4000 gel 0%	Screening	52	51	36.58	0.473	35.6	36.60	37.5
			Baseline 3	52	52	36.58	0.393	35.5	36.60	37.3
			Week 2	52	52	36.49	0.436	35.4	36.55	37.4
			Week 4	52	52	36.50	0.352	35.7	36.55	37.3
			Week 6-3	52	51	36.45	0.343	35.6	36.40	37.3
			Follow-up	52	51	36.51	0.398	35.5	36.50	37.2
		BBI-4000 gel 5%	Screening	52	52	36.59	0.423	35.6	36.60	37.4
			Baseline 3	52	52	36.58	0.362	35.8	36.60	37.3
			Week 2	52	52	36.58	0.319	35.9	36.60	37.2
			Week 4	52	52	36.52	0.368	35.6	36.50	37.6
			Week 6-3	51	51	36.51	0.325	35.6	36.50	37.2
			Follow-up	51	49	36.53	0.356	35.8	36.50	37.4
		BBI-4000 gel 10%	Screening	51	51	36.53	0.388	35.7	36.60	37.2
			Baseline 3	51	51	36.54	0.405	35.6	36.60	37.4
			Week 2	51	50	36.53	0.393	35.7	36.60	37.1
			Week 4	51	51	36.51	0.414	35.6	36.60	37.1
			Week 6-3	51	50	36.42	0.429	35.5	36.50	37.4
			Follow-up	51	50	36.50	0.364	35.7	36.50	37.3
		BBI-4000 gel 15%	Screening	52	52	36.63	0.398	35.1	36.70	37.2
			Baseline 3	52	52	36.58	0.422	35.6	36.65	37.4
			Week 2	52	52	36.59	0.432	35.5	36.60	37.6
			Week 4	52	52	36.53	0.358	35.8	36.60	37.2
			Week 6-3	52	50	36.46	0.375	35.7	36.50	37.4
			Follow-up	51	51	36.55	0.380	35.5	36.60	37.5

Source：5.3.5.1-1 Table 14.3.4-8 より改変

表 2.7.4-53　バイタルサインの基本統計量（BBI-4000-06 試験）
（Safety Analysis Set）

	BBI-4000 0% N=140	BBI-4000 5% N=141
Systolic Blood Pressure (mmHg)		
Screening		
n	140	141
Mean (SD)	117.1 (12.19)	119.1 (16.14)
Median	117.0	119.0
Min , Max	86 , 151	92 , 196
Baseline 3		
n	140	141
Mean (SD)	116.0 (13.80)	117.6 (14.45)
Median	113.5	117.0
Min , Max	93 , 154	88 , 162
Week 2		
n	138	139
Mean (SD)	115.2 (13.19)	114.8 (13.80)
Median	115.0	114.0
Min , Max	83 , 161	89 , 154
Week 4		
n	136	138
Mean (SD)	114.8 (13.17)	115.9 (15.27)
Median	113.0	114.0
Min , Max	82 , 152	87 , 172

PAGE: 1 of 8
PROGRAM: t078 (OUTPUT: t14_03_04_15_vs_stat)
DATE: 2019/05/21
PROTOCOL NO: BBI-4000-06
Source：5.3.5.1-2 Table 14.3.4-15 より改変

表 2.7.4-53　バイタルサインの基本統計量（BBI-4000-06 試験）（続き）
（Safety Analysis Set）

	BBI-4000 0% N=140	BBI-4000 5% N=141
Week 6-3		
n	139	139
Mean (SD)	114.7 (13.09)	115.1 (14.75)
Median	114.0	115.0
Min , Max	77 , 156	87 , 160
Follow-up		
n	45	47
Mean (SD)	116.0 (12.26)	115.4 (12.22)
Median	114.0	113.0
Min , Max	95 , 150	86 , 136

PAGE: 2 of 8
PROGRAM: t078 (OUTPUT: t14_03_04_15_vs_stat)
DATE: 2019/05/21
PROTOCOL NO: BBI-4000-06
Source：5.3.5.1-2 Table 14.3.4-15 より改変

表 2.7.4-53 バイタルサインの基本統計量（BBI-4000-06 試験）（続き）
（Safety Analysis Set）

	BBI-4000 0% N=140	BBI-4000 5% N=141
Diastolic Blood Pressure (mmHg)		
Screening		
n	140	141
Mean (SD)	75.0 (10.37)	75.3 (11.34)
Median	75.5	75.0
Min , Max	49 , 109	46 , 111
Baseline 3		
n	140	141
Mean (SD)	73.8 (11.32)	73.7 (10.69)
Median	72.5	73.0
Min , Max	40 , 105	37 , 108
Week 2		
n	138	139
Mean (SD)	72.8 (10.97)	72.8 (10.95)
Median	72.0	72.0
Min , Max	37 , 110	49 , 124
Week 4		
n	136	138
Mean (SD)	72.5 (10.47)	72.2 (11.52)
Median	72.5	72.0
Min , Max	46 , 105	42 , 111

PAGE: 3 of 8
PROGRAM: t078 (OUTPUT: t14_03_04_15_vs_stat)
DATE: 2019/05/21
PROTOCOL NO: BBI-4000-06
Source：5.3.5.1-2 Table 14.3.4-15 より改変

表 2.7.4-53　バイタルサインの基本統計量（BBI-4000-06 試験）（続き）
（Safety Analysis Set）

	BBI-4000 0% N=140	BBI-4000 5% N=141
Week 6-3		
n	139	139
Mean (SD)	72.6 (10.45)	72.0 (11.20)
Median	71.0	71.0
Min , Max	45 , 100	41 , 114
Follow-up		
n	45	47
Mean (SD)	74.5 (11.46)	73.5 (8.94)
Median	72.0	72.0
Min , Max	47 , 100	52 , 98

PAGE: 4 of 8
PROGRAM: t078 (OUTPUT: t14_03_04_15_vs_stat)
DATE: 2019/05/21
PROTOCOL NO: BBI-4000-06
Source：5.3.5.1-2 Table 14.3.4-15 より改変

表 2.7.4-53 バイタルサインの基本統計量（BBI-4000-06 試験）（続き）
（Safety Analysis Set）

	BBI-4000 0% N=140	BBI-4000 5% N=141
Pulse Rate (beats/min)		
Screening		
n	140	141
Mean (SD)	74.3 (11.40)	73.9 (11.50)
Median	74.0	71.0
Min , Max	52 , 117	47 , 121
Baseline 3		
n	140	141
Mean (SD)	75.6 (11.23)	75.8 (11.13)
Median	75.0	75.0
Min , Max	52 , 125	45 , 109
Week 2		
n	138	139
Mean (SD)	75.9 (9.87)	74.6 (10.92)
Median	75.0	72.0
Min , Max	54 , 103	53 , 126
Week 4		
n	136	138
Mean (SD)	75.2 (10.53)	74.2 (10.36)
Median	76.0	74.0
Min , Max	50 , 107	47 , 103

PAGE: 5 of 8
PROGRAM: t078 (OUTPUT: t14_03_04_15_vs_stat)
DATE: 2019/05/21
PROTOCOL NO: BBI-4000-06
Source：5.3.5.1-2 Table 14.3.4-15 より改変

表 2.7.4-53　バイタルサインの基本統計量（BBI-4000-06 試験）（続き）
（Safety Analysis Set）

	BBI-4000 0% N=140	BBI-4000 5% N=141
Week 6-3		
n	139	139
Mean (SD)	74.8 (10.31)	75.7 (10.64)
Median	73.0	74.0
Min , Max	49 , 115	55 , 116
Follow-up		
n	45	47
Mean (SD)	76.6 (10.41)	75.4 (10.55)
Median	76.0	74.0
Min , Max	55 , 107	50 , 99

PAGE: 6 of 8
PROGRAM: t078 (OUTPUT: t14_03_04_15_vs_stat)
DATE: 2019/05/21
PROTOCOL NO: BBI-4000-06
Source：5.3.5.1-2 Table 14.3.4-15 より改変

表 2.7.4-53 バイタルサインの基本統計量（BBI-4000-06 試験）（続き）
（Safety Analysis Set）

	BBI-4000 0% N=140	BBI-4000 5% N=141
Temperature (C)		
Screening		
n	140	141
Mean (SD)	36.62 (0.419)	36.60 (0.338)
Median	36.60	36.60
Min , Max	35.1 , 37.4	35.5 , 37.4
Baseline 3		
n	140	141
Mean (SD)	36.60 (0.345)	36.62 (0.357)
Median	36.60	36.70
Min , Max	35.5 , 37.3	35.5 , 37.4
Week 2		
n	138	139
Mean (SD)	36.59 (0.368)	36.58 (0.335)
Median	36.60	36.60
Min , Max	35.1 , 37.6	35.6 , 37.4
Week 4		
n	136	138
Mean (SD)	36.51 (0.381)	36.55 (0.330)
Median	36.60	36.50
Min , Max	35.5 , 37.3	35.7 , 37.4

PAGE: 7 of 8
PROGRAM: t078 (OUTPUT: t14_03_04_15_vs_stat)
DATE: 2019/05/21
PROTOCOL NO: BBI-4000-06
Source：5.3.5.1-2 Table 14.3.4-15 より改変

表 2.7.4-53　バイタルサインの基本統計量（BBI-4000-06 試験）（続き）
（Safety Analysis Set）

	BBI-4000 0% N=140	BBI-4000 5% N=141
Week 6-3		
n	139	139
Mean (SD)	36.53 (0.382)	36.55 (0.338)
Median	36.50	36.60
Min , Max	35.1 , 37.4	35.6 , 37.2
Follow-up		
n	45	47
Mean (SD)	36.59 (0.422)	36.54 (0.420)
Median	36.60	36.60
Min , Max	35.5 , 37.8	35.3 , 37.4

PAGE: 8 of 8
PROGRAM: t078 (OUTPUT: t14_03_04_15_vs_stat)
DATE: 2019/05/21
PROTOCOL NO: BBI-4000-06
Source：5.3.5.1-2 Table 14.3.4-15 より改変

表 2.7.4-54　バイタルサインの基本統計量（BBI-4000-07 試験）
（Safety Analysis Set）

	Cohort 1 (0%/5%) N=94	Cohort 1 (5%/5%) N=91	Total N=185
Systolic Blood Pressure (mmHg)			
Baseline[#1]			
n	94	91	185
Mean (SD)	115.9 (14.13)	118.4 (15.81)	117.2 (14.99)
Median	113.0	117.0	115.0
Min , Max	93 , 154	88 , 162	88 , 162
Week 2			
n	91	90	181
Mean (SD)	116.7 (14.34)	117.7 (15.55)	117.2 (14.92)
Median	114.0	117.5	116.0
Min , Max	92 , 177	82 , 163	82 , 177
Week 4			
n	94	89	183
Mean (SD)	115.2 (12.95)	117.3 (14.03)	116.2 (13.49)
Median	113.5	116.0	115.0
Min , Max	89 , 163	87 , 161	87 , 163
Week 6			
n	93	90	183
Mean (SD)	117.7 (13.03)	117.8 (14.80)	117.7 (13.89)
Median	118.0	114.0	116.0
Min , Max	85 , 161	92 , 193	85 , 193

#1 : Baseline is defined as the value at Baseline 3 in BBI-4000-06 trial.

PAGE: 1 of 20
PROGRAM: t078 (OUTPUT: t14_03_04_15_vs_stat)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Table 14.3.4-15 より改変

表 2.7.4-54　バイタルサインの基本統計量（BBI-4000-07 試験）（続き）
（Safety Analysis Set）

	Cohort 1 (0%/5%) N=94	Cohort 1 (5%/5%) N=91	Total N=185
Week 8			
n	93	86	179
Mean (SD)	116.7 (14.73)	115.7 (14.38)	116.2 (14.53)
Median	116.0	113.5	115.0
Min , Max	91 , 174	90 , 155	90 , 174
Week 12			
n	94	85	179
Mean (SD)	117.8 (13.71)	117.5 (15.84)	117.6 (14.72)
Median	117.0	116.0	116.0
Min , Max	87 , 165	82 , 177	82 , 177
Week 16			
n	91	85	176
Mean (SD)	119.1 (14.57)	118.3 (14.09)	118.7 (14.30)
Median	118.0	119.0	119.0
Min , Max	84 , 176	91 , 158	84 , 176
Week 20			
n	91	85	176
Mean (SD)	117.2 (14.82)	117.1 (14.40)	117.1 (14.58)
Median	115.0	114.0	115.0
Min , Max	87 , 164	87 , 168	87 , 168

#1 : Baseline is defined as the value at Baseline 3 in BBI-4000-06 trial.

PAGE: 2 of 20
PROGRAM: t078 (OUTPUT: t14_03_04_15_vs_stat)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Table 14.3.4-15 より改変

表 2.7.4-54　バイタルサインの基本統計量（BBI-4000-07 試験）（続き）
（Safety Analysis Set）

	Cohort 1 (0%/5%) N=94	Cohort 1 (5%/5%) N=91	Total N=185
Week 24			
n	90	86	176
Mean (SD)	118.2 (13.64)	118.2 (14.04)	118.2 (13.80)
Median	117.0	116.5	117.0
Min , Max	88 , 158	91 , 161	88 , 161
Week 28			
n	90	85	175
Mean (SD)	117.9 (12.92)	118.0 (13.57)	117.9 (13.20)
Median	116.0	117.0	117.0
Min , Max	93 , 166	94 , 157	93 , 166
Week 32			
n	89	83	172
Mean (SD)	117.3 (14.44)	117.1 (13.40)	117.2 (13.91)
Median	117.0	118.0	117.5
Min , Max	89 , 174	90 , 149	89 , 174
Week 36			
n	87	80	167
Mean (SD)	116.1 (14.30)	116.3 (13.22)	116.2 (13.75)
Median	115.0	116.0	116.0
Min , Max	86 , 156	75 , 146	75 , 156

#1 : Baseline is defined as the value at Baseline 3 in BBI-4000-06 trial.

PAGE: 3 of 20
PROGRAM: t078 (OUTPUT: t14_03_04_15_vs_stat)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Table 14.3.4-15 より改変

表 2.7.4-54　バイタルサインの基本統計量（BBI-4000-07 試験）（続き）
（Safety Analysis Set）

	Cohort 1 (0%/5%) N=94	Cohort 1 (5%/5%) N=91	Total N=185
Week 40			
n	85	78	163
Mean (SD)	117.4 (13.34)	115.8 (13.79)	116.7 (13.54)
Median	117.0	115.5	117.0
Min , Max	90 , 157	85 , 155	85 , 157
Week 44			
n	87	76	163
Mean (SD)	115.8 (14.13)	117.6 (15.97)	116.6 (15.00)
Median	114.0	116.5	115.0
Min , Max	89 , 152	93 , 164	89 , 164
Week 48			
n	86	76	162
Mean (SD)	115.8 (14.79)	118.2 (16.60)	116.9 (15.67)
Median	112.5	116.5	114.0
Min , Max	86 , 169	90 , 170	86 , 170
Week 52			
n	85	75	160
Mean (SD)	115.5 (12.72)	116.3 (16.80)	115.9 (14.73)
Median	114.0	113.0	114.0
Min , Max	91 , 146	91 , 183	91 , 183

#1 : Baseline is defined as the value at Baseline 3 in BBI-4000-06 trial.

PAGE: 4 of 20
PROGRAM: t078 (OUTPUT: t14_03_04_15_vs_stat)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Table 14.3.4-15 より改変

表 2.7.4-54　バイタルサインの基本統計量（BBI-4000-07 試験）（続き）
（Safety Analysis Set）

	Cohort 1 (0%/5%) N=94	Cohort 1 (5%/5%) N=91	Total N=185
Follow-up			
n	85	74	159
Mean (SD)	116.2 (13.01)	119.6 (17.13)	117.8 (15.11)
Median	116.0	116.0	116.0
Min , Max	82 , 155	95 , 173	82 , 173

#1 : Baseline is defined as the value at Baseline 3 in BBI-4000-06 trial.

PAGE: 5 of 20
PROGRAM: t078 (OUTPUT: t14_03_04_15_vs_stat)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Table 14.3.4-15 より改変

表 2.7.4-54 バイタルサインの基本統計量（BBI-4000-07 試験）（続き）
（Safety Analysis Set）

	Cohort 1 (0%/5%) N=94	Cohort 1 (5%/5%) N=91	Total N=185
Diastolic Blood Pressure (mmHg)			
Baseline[#1]			
n	94	91	185
Mean (SD)	73.7 (11.61)	73.9 (11.23)	73.8 (11.39)
Median	72.5	73.0	73.0
Min , Max	40 , 105	37 , 107	37 , 107
Week 2			
n	91	90	181
Mean (SD)	73.8 (10.96)	73.9 (11.54)	73.9 (11.22)
Median	73.0	75.0	74.0
Min , Max	44 , 107	42 , 114	42 , 114
Week 4			
n	94	89	183
Mean (SD)	73.5 (11.09)	73.8 (11.47)	73.7 (11.25)
Median	73.0	73.0	73.0
Min , Max	49 , 107	47 , 105	47 , 107
Week 6			
n	93	90	183
Mean (SD)	74.4 (9.62)	73.6 (10.97)	74.0 (10.29)
Median	73.0	74.0	73.0
Min , Max	56 , 114	47 , 102	47 , 114

#1 : Baseline is defined as the value at Baseline 3 in BBI-4000-06 trial.

PAGE: 6 of 20
PROGRAM: t078 (OUTPUT: t14_03_04_15_vs_stat)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Table 14.3.4-15 より改変

表 2.7.4-54　バイタルサインの基本統計量（BBI-4000-07 試験）（続き）
（Safety Analysis Set）

	Cohort 1 (0%/5%) N=94	Cohort 1 (5%/5%) N=91	Total N=185
Week 8			
n	93	86	179
Mean (SD)	72.7 (11.07)	72.9 (10.68)	72.8 (10.85)
Median	72.0	73.0	73.0
Min , Max	50 , 106	48 , 99	48 , 106
Week 12			
n	94	85	179
Mean (SD)	73.6 (10.81)	73.6 (11.24)	73.6 (10.99)
Median	73.0	75.0	74.0
Min , Max	45 , 104	48 , 99	45 , 104
Week 16			
n	91	85	176
Mean (SD)	75.0 (10.22)	74.0 (10.64)	74.6 (10.41)
Median	75.0	75.0	75.0
Min , Max	52 , 110	47 , 96	47 , 110
Week 20			
n	91	85	176
Mean (SD)	74.3 (11.86)	72.6 (10.45)	73.5 (11.20)
Median	74.0	72.0	73.5
Min , Max	44 , 106	52 , 101	44 , 106

#1 : Baseline is defined as the value at Baseline 3 in BBI-4000-06 trial.

PAGE: 7 of 20
PROGRAM: t078 (OUTPUT: t14_03_04_15_vs_stat)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Table 14.3.4-15 より改変

表 2.7.4-54　バイタルサインの基本統計量（BBI-4000-07 試験）（続き）
（Safety Analysis Set）

	Cohort 1 (0%/5%) N=94	Cohort 1 (5%/5%) N=91	Total N=185
Week 24			
n	90	86	176
Mean (SD)	74.1 (10.32)	73.0 (10.60)	73.6 (10.44)
Median	73.0	74.0	73.0
Min , Max	53 , 108	45 , 96	45 , 108
Week 28			
n	90	85	175
Mean (SD)	73.2 (10.76)	73.3 (9.49)	73.2 (10.13)
Median	70.0	72.0	72.0
Min , Max	48 , 109	53 , 96	48 , 109
Week 32			
n	89	83	172
Mean (SD)	73.7 (10.96)	72.6 (10.62)	73.2 (10.78)
Median	72.0	74.0	73.0
Min , Max	50 , 103	45 , 102	45 , 103
Week 36			
n	87	80	167
Mean (SD)	73.6 (10.28)	72.6 (10.24)	73.1 (10.24)
Median	72.0	74.0	72.0
Min , Max	51 , 105	46 , 90	46 , 105

#1 : Baseline is defined as the value at Baseline 3 in BBI-4000-06 trial.

PAGE: 8 of 20
PROGRAM: t078 (OUTPUT: t14_03_04_15_vs_stat)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Table 14.3.4-15 より改変

表 2.7.4-54　バイタルサインの基本統計量（BBI-4000-07 試験）（続き）
（Safety Analysis Set）

	Cohort 1 (0%/5%) N=94	Cohort 1 (5%/5%) N=91	Total N=185
Week 40			
n	85	78	163
Mean (SD)	73.6 (10.96)	72.2 (10.91)	72.9 (10.93)
Median	73.0	71.5	72.0
Min , Max	56 , 105	36 , 98	36 , 105
Week 44			
n	87	76	163
Mean (SD)	73.7 (11.40)	72.3 (10.65)	73.0 (11.05)
Median	72.0	71.0	71.0
Min , Max	52 , 110	42 , 99	42 , 110
Week 48			
n	86	76	162
Mean (SD)	73.0 (11.81)	72.9 (12.89)	73.0 (12.29)
Median	72.0	72.0	72.0
Min , Max	40 , 120	35 , 107	35 , 120
Week 52			
n	85	75	160
Mean (SD)	72.2 (9.75)	73.3 (11.11)	72.7 (10.39)
Median	71.0	74.0	72.0
Min , Max	53 , 104	41 , 96	41 , 104

#1 : Baseline is defined as the value at Baseline 3 in BBI-4000-06 trial.

PAGE: 9 of 20
PROGRAM: t078 (OUTPUT: t14_03_04_15_vs_stat)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Table 14.3.4-15 より改変

表 2.7.4-54　バイタルサインの基本統計量（BBI-4000-07 試験）（続き）
（Safety Analysis Set）

	Cohort 1 (0%/5%) N=94	Cohort 1 (5%/5%) N=91	Total N=185
Follow-up			
n	85	74	159
Mean (SD)	74.7 (11.15)	73.6 (12.97)	74.2 (12.00)
Median	74.0	74.0	74.0
Min , Max	55 , 113	41 , 111	41 , 113

#1 : Baseline is defined as the value at Baseline 3 in BBI-4000-06 trial.

PAGE: 10 of 20
PROGRAM: t078 (OUTPUT: t14_03_04_15_vs_stat)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Table 14.3.4-15 より改変

表 2.7.4-54 バイタルサインの基本統計量（BBI-4000-07 試験）（続き）
（Safety Analysis Set）

	Cohort 1 (0%/5%) N=94	Cohort 1 (5%/5%) N=91	Total N=185
Pulse Rate (beats/min)			
Baseline[#1]			
n	94	91	185
Mean (SD)	75.2 (10.40)	75.9 (11.34)	75.6 (10.85)
Median	75.0	76.0	76.0
Min , Max	52 , 101	45 , 109	45 , 109
Week 2			
n	91	90	181
Mean (SD)	73.9 (9.38)	76.1 (11.01)	75.0 (10.25)
Median	74.0	75.0	74.0
Min , Max	57 , 98	54 , 119	54 , 119
Week 4			
n	94	89	183
Mean (SD)	74.6 (9.69)	75.7 (11.17)	75.1 (10.42)
Median	74.5	74.0	74.0
Min , Max	51 , 99	48 , 113	48 , 113
Week 6			
n	93	90	183
Mean (SD)	75.0 (9.79)	75.7 (10.09)	75.3 (9.92)
Median	74.0	76.0	75.0
Min , Max	50 , 99	49 , 120	49 , 120

#1 : Baseline is defined as the value at Baseline 3 in BBI-4000-06 trial.

PAGE: 11 of 20
PROGRAM: t078 (OUTPUT: t14_03_04_15_vs_stat)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Table 14.3.4-15 より改変

表 2.7.4-54　バイタルサインの基本統計量（BBI-4000-07 試験）（続き）
（Safety Analysis Set）

	Cohort 1 (0%/5%) N=94	Cohort 1 (5%/5%) N=91	Total N=185
Week 8			
n	93	86	179
Mean (SD)	75.0 (10.97)	76.9 (10.63)	75.9 (10.82)
Median	72.0	76.0	75.0
Min , Max	49 , 110	54 , 117	49 , 117
Week 12			
n	94	85	179
Mean (SD)	75.6 (10.96)	75.7 (11.21)	75.7 (11.05)
Median	75.0	74.0	74.0
Min , Max	52 , 116	51 , 125	51 , 125
Week 16			
n	91	85	176
Mean (SD)	76.9 (11.26)	75.5 (11.74)	76.2 (11.49)
Median	75.0	74.0	75.0
Min , Max	55 , 111	46 , 126	46 , 126
Week 20			
n	91	85	176
Mean (SD)	76.4 (12.04)	76.8 (12.18)	76.6 (12.07)
Median	75.0	76.0	75.0
Min , Max	53 , 102	53 , 126	53 , 126

#1 : Baseline is defined as the value at Baseline 3 in BBI-4000-06 trial.

PAGE: 12 of 20
PROGRAM: t078 (OUTPUT: t14_03_04_15_vs_stat)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Table 14.3.4-15 より改変

表 2.7.4-54　バイタルサインの基本統計量（BBI-4000-07 試験）（続き）
（Safety Analysis Set）

	Cohort 1 (0%/5%) N=94	Cohort 1 (5%/5%) N=91	Total N=185
Week 24			
n	90	86	176
Mean (SD)	75.3 (11.13)	76.9 (11.59)	76.1 (11.35)
Median	75.0	77.0	76.5
Min , Max	51 , 111	51 , 120	51 , 120
Week 28			
n	90	85	175
Mean (SD)	76.1 (11.78)	77.5 (11.06)	76.7 (11.42)
Median	76.0	76.0	76.0
Min , Max	47 , 109	56 , 113	47 , 113
Week 32			
n	89	83	172
Mean (SD)	76.1 (11.27)	75.8 (12.18)	75.9 (11.69)
Median	74.0	73.0	74.0
Min , Max	49 , 103	57 , 131	49 , 131
Week 36			
n	87	80	167
Mean (SD)	74.8 (10.74)	74.8 (10.31)	74.8 (10.50)
Median	74.0	73.5	74.0
Min , Max	50 , 98	52 , 106	50 , 106

#1 : Baseline is defined as the value at Baseline 3 in BBI-4000-06 trial.

PAGE: 13 of 20
PROGRAM: t078 (OUTPUT: t14_03_04_15_vs_stat)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Table 14.3.4-15 より改変

表 2.7.4-54　バイタルサインの基本統計量（BBI-4000-07 試験）（続き）
（Safety Analysis Set）

	Cohort 1 (0%/5%) N=94	Cohort 1 (5%/5%) N=91	Total N=185
Week 40			
n	85	78	163
Mean (SD)	74.4 (10.66)	75.7 (12.72)	75.0 (11.67)
Median	74.0	73.0	74.0
Min , Max	50 , 98	49 , 110	49 , 110
Week 44			
n	87	76	163
Mean (SD)	73.6 (11.21)	75.4 (11.88)	74.4 (11.52)
Median	74.0	74.5	74.0
Min , Max	46 , 98	49 , 118	46 , 118
Week 48			
n	86	76	162
Mean (SD)	73.3 (9.75)	75.3 (12.96)	74.3 (11.38)
Median	73.0	71.0	72.5
Min , Max	52 , 97	52 , 126	52 , 126
Week 52			
n	85	75	160
Mean (SD)	73.8 (12.06)	75.2 (12.46)	74.5 (12.23)
Median	74.0	73.0	73.5
Min , Max	44 , 104	53 , 118	44 , 118

#1 : Baseline is defined as the value at Baseline 3 in BBI-4000-06 trial.

PAGE: 14 of 20
PROGRAM: t078 (OUTPUT: t14_03_04_15_vs_stat)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Table 14.3.4-15 より改変

表 2.7.4-54　バイタルサインの基本統計量（BBI-4000-07 試験）（続き）
（Safety Analysis Set）

	Cohort 1 (0%/5%) N=94	Cohort 1 (5%/5%) N=91	Total N=185
Follow-up			
n	85	74	159
Mean (SD)	74.2 (11.11)	75.7 (12.75)	74.9 (11.89)
Median	74.0	73.0	74.0
Min , Max	53 , 102	49 , 117	49 , 117

#1 : Baseline is defined as the value at Baseline 3 in BBI-4000-06 trial.

PAGE: 15 of 20
PROGRAM: t078 (OUTPUT: t14_03_04_15_vs_stat)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Table 14.3.4-15 より改変

表 2.7.4-54　バイタルサインの基本統計量（BBI-4000-07 試験）（続き）
（Safety Analysis Set）

	Cohort 1 (0%/5%) N=94	Cohort 1 (5%/5%) N=91	Total N=185
Temperature (C)			
Baseline[#1]			
n	94	91	185
Mean (SD)	36.59 (0.363)	36.62 (0.374)	36.60 (0.368)
Median	36.60	36.60	36.60
Min , Max	35.5 , 37.3	35.5 , 37.4	35.5 , 37.4
Week 2			
n	91	90	181
Mean (SD)	36.57 (0.432)	36.57 (0.353)	36.57 (0.394)
Median	36.60	36.60	36.60
Min , Max	35.4 , 37.7	35.4 , 37.5	35.4 , 37.7
Week 4			
n	94	89	183
Mean (SD)	36.56 (0.410)	36.61 (0.346)	36.59 (0.380)
Median	36.60	36.60	36.60
Min , Max	35.3 , 37.8	36.0 , 37.8	35.3 , 37.8
Week 6			
n	93	90	183
Mean (SD)	36.56 (0.358)	36.58 (0.325)	36.57 (0.341)
Median	36.60	36.60	36.60
Min , Max	35.2 , 37.8	35.6 , 37.4	35.2 , 37.8

#1 : Baseline is defined as the value at Baseline 3 in BBI-4000-06 trial.

PAGE: 16 of 20
PROGRAM: t078 (OUTPUT: t14_03_04_15_vs_stat)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Table 14.3.4-15 より改変

表 2.7.4-54　バイタルサインの基本統計量（BBI-4000-07 試験）（続き）
（Safety Analysis Set）

	Cohort 1 (0%/5%) N=94	Cohort 1 (5%/5%) N=91	Total N=185
Week 8			
n	93	86	179
Mean (SD)	36.58 (0.329)	36.64 (0.369)	36.61 (0.349)
Median	36.60	36.70	36.60
Min , Max	35.7 , 37.4	35.9 , 38.1	35.7 , 38.1
Week 12			
n	94	85	179
Mean (SD)	36.55 (0.396)	36.60 (0.324)	36.57 (0.363)
Median	36.50	36.60	36.60
Min , Max	35.3 , 37.4	35.5 , 37.3	35.3 , 37.4
Week 16			
n	91	85	176
Mean (SD)	36.54 (0.398)	36.57 (0.359)	36.55 (0.379)
Median	36.60	36.60	36.60
Min , Max	35.0 , 37.5	35.5 , 37.4	35.0 , 37.5
Week 20			
n	91	85	176
Mean (SD)	36.51 (0.395)	36.56 (0.380)	36.53 (0.387)
Median	36.50	36.60	36.55
Min , Max	35.2 , 37.5	35.0 , 37.5	35.0 , 37.5

#1 : Baseline is defined as the value at Baseline 3 in BBI-4000-06 trial.

PAGE: 17 of 20
PROGRAM: t078 (OUTPUT: t14_03_04_15_vs_stat)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Table 14.3.4-15 より改変

表 2.7.4-54　バイタルサインの基本統計量（BBI-4000-07 試験）（続き）
（Safety Analysis Set）

	Cohort 1 (0%/5%) N=94	Cohort 1 (5%/5%) N=91	Total N=185
Week 24			
n	90	86	176
Mean (SD)	36.49 (0.355)	36.58 (0.350)	36.53 (0.354)
Median	36.50	36.60	36.60
Min , Max	35.1 , 37.3	35.7 , 37.6	35.1 , 37.6
Week 28			
n	90	85	175
Mean (SD)	36.54 (0.406)	36.56 (0.389)	36.55 (0.397)
Median	36.60	36.60	36.60
Min , Max	35.1 , 37.6	35.0 , 37.3	35.0 , 37.6
Week 32			
n	89	83	172
Mean (SD)	36.57 (0.380)	36.56 (0.355)	36.56 (0.367)
Median	36.60	36.60	36.60
Min , Max	35.4 , 37.5	35.6 , 37.4	35.4 , 37.5
Week 36			
n	87	80	167
Mean (SD)	36.48 (0.395)	36.55 (0.416)	36.51 (0.405)
Median	36.50	36.60	36.50
Min , Max	35.3 , 37.5	35.2 , 37.4	35.2 , 37.5

#1 : Baseline is defined as the value at Baseline 3 in BBI-4000-06 trial.

PAGE: 18 of 20
PROGRAM: t078 (OUTPUT: t14_03_04_15_vs_stat)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Table 14.3.4-15 より改変

表 2.7.4-54　バイタルサインの基本統計量（BBI-4000-07 試験）（続き）
（Safety Analysis Set）

	Cohort 1 (0%/5%) N=94	Cohort 1 (5%/5%) N=91	Total N=185
Week 40			
n	85	78	163
Mean (SD)	36.54 (0.400)	36.63 (0.311)	36.58 (0.362)
Median	36.50	36.60	36.60
Min , Max	35.5 , 37.3	35.6 , 37.4	35.5 , 37.4
Week 44			
n	87	76	163
Mean (SD)	36.44 (0.450)	36.62 (0.298)	36.52 (0.396)
Median	36.50	36.65	36.60
Min , Max	35.0 , 37.4	35.8 , 37.3	35.0 , 37.4
Week 48			
n	86	76	162
Mean (SD)	36.52 (0.399)	36.60 (0.345)	36.55 (0.376)
Median	36.55	36.70	36.60
Min , Max	35.6 , 37.7	35.6 , 37.2	35.6 , 37.7
Week 52			
n	85	75	160
Mean (SD)	36.57 (0.361)	36.56 (0.376)	36.57 (0.367)
Median	36.60	36.60	36.60
Min , Max	35.3 , 37.4	35.6 , 37.4	35.3 , 37.4

#1 : Baseline is defined as the value at Baseline 3 in BBI-4000-06 trial.

PAGE: 19 of 20
PROGRAM: t078 (OUTPUT: t14_03_04_15_vs_stat)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Table 14.3.4-15 より改変

表 2.7.4-54　バイタルサインの基本統計量（BBI-4000-07 試験）（続き）
（Safety Analysis Set）

	Cohort 1 (0%/5%) N=94	Cohort 1 (5%/5%) N=91	Total N=185
Follow-up			
n	85	74	159
Mean (SD)	36.50 (0.381)	36.57 (0.368)	36.53 (0.376)
Median	36.50	36.60	36.50
Min , Max	35.6 , 37.6	35.6 , 37.4	35.6 , 37.6

#1 : Baseline is defined as the value at Baseline 3 in BBI-4000-06 trial.

PAGE: 20 of 20
PROGRAM: t078 (OUTPUT: t14_03_04_15_vs_stat)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Table 14.3.4-15 より改変

表 2.7.4-55　局所忍容性の各スコアの被験者数及びその割合（BBI-4000-04 試験）
[Safety]

Local Tolerability	Location	Visit	Score	BBI-4000 gel 0% N=52	BBI-4000 gel 5% N=52	BBI-4000 gel 10% N=51	BBI-4000 gel 15% N=52
Dryness	Right Axilla	Baseline 3	Total	52	52	51	52
(By Investigator)			0-Absent	52 (100.0)	52 (100.0)	51 (100.0)	52 (100.0)
			1-Minimal	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			2-Mild	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			3-Moderate	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			4-Severe	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		Week 2	Total	52	52	50	52
			0-Absent	52 (100.0)	52 (100.0)	49 (98.0)	52 (100.0)
			1-Minimal	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			2-Mild	0 (0.0)	0 (0.0)	1 (2.0)	0 (0.0)
			3-Moderate	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			4-Severe	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		Week 4	Total	52	52	51	52
			0-Absent	52 (100.0)	52 (100.0)	50 (98.0)	52 (100.0)
			1-Minimal	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			2-Mild	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			3-Moderate	0 (0.0)	0 (0.0)	1 (2.0)	0 (0.0)
			4-Severe	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		Week 6-3	Total	51	51	50	50
			0-Absent	51 (100.0)	51 (100.0)	50 (100.0)	49 (98.0)
			1-Minimal	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.0)
			2-Mild	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			3-Moderate	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			4-Severe	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		Follow-up	Total	51	49	50	51
			0-Absent	51 (100.0)	49 (100.0)	50 (100.0)	51 (100.0)
			1-Minimal	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			2-Mild	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			3-Moderate	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			4-Severe	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

Source：5.3.5.1-1 Table 14.3.4-10 より改変

表 2.7.4-55　局所忍容性の各スコアの被験者数及びその割合（BBI-4000-04 試験）（続き）
[Safety]

Local Tolerability	Location	Visit	Score	BBI-4000 gel 0% N=52	BBI-4000 gel 5% N=52	BBI-4000 gel 10% N=51	BBI-4000 gel 15% N=52
Dryness	Left Axilla	Baseline 3	Total	52	52	51	52
(By Investigator)			0-Absent	52 (100.0)	52 (100.0)	51 (100.0)	52 (100.0)
			1-Minimal	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			2-Mild	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			3-Moderate	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			4-Severe	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		Week 2	Total	52	52	50	52
			0-Absent	52 (100.0)	52 (100.0)	50 (100.0)	52 (100.0)
			1-Minimal	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			2-Mild	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			3-Moderate	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			4-Severe	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		Week 4	Total	52	52	51	52
			0-Absent	52 (100.0)	51 (98.1)	50 (98.0)	52 (100.0)
			1-Minimal	0 (0.0)	1 (1.9)	0 (0.0)	0 (0.0)
			2-Mild	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			3-Moderate	0 (0.0)	0 (0.0)	1 (2.0)	0 (0.0)
			4-Severe	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		Week 6-3	Total	51	51	50	50
			0-Absent	51 (100.0)	51 (100.0)	50 (100.0)	49 (98.0)
			1-Minimal	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.0)
			2-Mild	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			3-Moderate	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			4-Severe	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		Follow-up	Total	51	49	50	51
			0-Absent	51 (100.0)	49 (100.0)	50 (100.0)	51 (100.0)
			1-Minimal	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			2-Mild	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			3-Moderate	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			4-Severe	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

Source：5.3.5.1-1 Table 14.3.4-10 より改変

表 2.7.4-55　局所忍容性の各スコアの被験者数及びその割合（BBI-4000-04 試験）（続き）
[Safety]

Local Tolerability	Location	Visit	Score	BBI-4000 gel 0% N=52	BBI-4000 gel 5% N=52	BBI-4000 gel 10% N=51	BBI-4000 gel 15% N=52
Erythema	Right Axilla	Baseline 3	Total	52	52	51	52
(By Investigator)			0-Absent	52 (100.0)	51 (98.1)	51 (100.0)	50 (96.2)
			1-Minimal	0 (0.0)	1 (1.9)	0 (0.0)	1 (1.9)
			2-Mild	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.9)
			3-Moderate	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			4-Severe	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		Week 2	Total	52	52	50	52
			0-Absent	52 (100.0)	48 (92.3)	46 (92.0)	48 (92.3)
			1-Minimal	0 (0.0)	2 (3.8)	1 (2.0)	1 (1.9)
			2-Mild	0 (0.0)	2 (3.8)	3 (6.0)	2 (3.8)
			3-Moderate	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.9)
			4-Severe	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		Week 4	Total	52	52	51	52
			0-Absent	52 (100.0)	49 (94.2)	47 (92.2)	48 (92.3)
			1-Minimal	0 (0.0)	3 (5.8)	2 (3.9)	3 (5.8)
			2-Mild	0 (0.0)	0 (0.0)	1 (2.0)	1 (1.9)
			3-Moderate	0 (0.0)	0 (0.0)	1 (2.0)	0 (0.0)
			4-Severe	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		Week 6-3	Total	51	51	50	50
			0-Absent	51 (100.0)	49 (96.1)	45 (90.0)	43 (86.0)
			1-Minimal	0 (0.0)	2 (3.9)	2 (4.0)	4 (8.0)
			2-Mild	0 (0.0)	0 (0.0)	3 (6.0)	2 (4.0)
			3-Moderate	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.0)
			4-Severe	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		Follow-up	Total	51	49	50	51
			0-Absent	51 (100.0)	48 (98.0)	48 (96.0)	50 (98.0)
			1-Minimal	0 (0.0)	0 (0.0)	1 (2.0)	0 (0.0)
			2-Mild	0 (0.0)	1 (2.0)	1 (2.0)	1 (2.0)
			3-Moderate	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			4-Severe	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

Source：5.3.5.1-1 Table 14.3.4-10 より改変

表 2.7.4-55　局所忍容性の各スコアの被験者数及びその割合（BBI-4000-04 試験）（続き）
[Safety]

Local Tolerability	Location	Visit	Score	BBI-4000 gel 0% N=52	BBI-4000 gel 5% N=52	BBI-4000 gel 10% N=51	BBI-4000 gel 15% N=52
Erythema	Left Axilla	Baseline 3	Total	52	52	51	52
(By Investigator)			0-Absent	52 (100.0)	52 (100.0)	51 (100.0)	50 (96.2)
			1-Minimal	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			2-Mild	0 (0.0)	0 (0.0)	0 (0.0)	2 (3.8)
			3-Moderate	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			4-Severe	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		Week 2	Total	52	52	50	52
			0-Absent	52 (100.0)	48 (92.3)	48 (96.0)	48 (92.3)
			1-Minimal	0 (0.0)	1 (1.9)	1 (2.0)	0 (0.0)
			2-Mild	0 (0.0)	2 (3.8)	1 (2.0)	4 (7.7)
			3-Moderate	0 (0.0)	1 (1.9)	0 (0.0)	0 (0.0)
			4-Severe	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		Week 4	Total	52	52	51	52
			0-Absent	52 (100.0)	49 (94.2)	46 (90.2)	50 (96.2)
			1-Minimal	0 (0.0)	3 (5.8)	3 (5.9)	2 (3.8)
			2-Mild	0 (0.0)	0 (0.0)	1 (2.0)	0 (0.0)
			3-Moderate	0 (0.0)	0 (0.0)	1 (2.0)	0 (0.0)
			4-Severe	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		Week 6-3	Total	51	51	50	50
			0-Absent	50 (98.0)	49 (96.1)	46 (92.0)	42 (84.0)
			1-Minimal	1 (2.0)	2 (3.9)	2 (4.0)	2 (4.0)
			2-Mild	0 (0.0)	0 (0.0)	2 (4.0)	3 (6.0)
			3-Moderate	0 (0.0)	0 (0.0)	0 (0.0)	3 (6.0)
			4-Severe	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		Follow-up	Total	51	49	50	51
			0-Absent	51 (100.0)	48 (98.0)	50 (100.0)	49 (96.1)
			1-Minimal	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.0)
			2-Mild	0 (0.0)	1 (2.0)	0 (0.0)	1 (2.0)
			3-Moderate	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			4-Severe	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

Source：5.3.5.1-1 Table 14.3.4-10 より改変

表 2.7.4-55　局所忍容性の各スコアの被験者数及びその割合（BBI-4000-04 試験）（続き）
[Safety]

Local Tolerability	Location	Visit	Score	BBI-4000 gel 0% N=52	BBI-4000 gel 5% N=52	BBI-4000 gel 10% N=51	BBI-4000 gel 15% N=52
Scaling	Right Axilla	Baseline 3	Total	52	52	51	52
(By Investigator)			0-Absent	52 (100.0)	52 (100.0)	51 (100.0)	52 (100.0)
			1-Minimal	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			2-Mild	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			3-Moderate	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			4-Severe	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		Week 2	Total	52	52	50	52
			0-Absent	52 (100.0)	52 (100.0)	50 (100.0)	49 (94.2)
			1-Minimal	0 (0.0)	0 (0.0)	0 (0.0)	3 (5.8)
			2-Mild	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			3-Moderate	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			4-Severe	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		Week 4	Total	52	52	51	52
			0-Absent	52 (100.0)	52 (100.0)	50 (98.0)	52 (100.0)
			1-Minimal	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			2-Mild	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			3-Moderate	0 (0.0)	0 (0.0)	1 (2.0)	0 (0.0)
			4-Severe	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		Week 6-3	Total	51	51	50	50
			0-Absent	51 (100.0)	50 (98.0)	49 (98.0)	49 (98.0)
			1-Minimal	0 (0.0)	1 (2.0)	1 (2.0)	1 (2.0)
			2-Mild	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			3-Moderate	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			4-Severe	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		Follow-up	Total	51	49	50	51
			0-Absent	51 (100.0)	49 (100.0)	50 (100.0)	51 (100.0)
			1-Minimal	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			2-Mild	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			3-Moderate	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			4-Severe	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

Source：5.3.5.1-1 Table 14.3.4-10 より改変

表 2.7.4-55　局所忍容性の各スコアの被験者数及びその割合（BBI-4000-04 試験）（続き）
[Safety]

Local Tolerability	Location	Visit	Score	BBI-4000 gel 0% N=52	BBI-4000 gel 5% N=52	BBI-4000 gel 10% N=51	BBI-4000 gel 15% N=52
Scaling	Left Axilla	Baseline 3	Total	52	52	51	52
(By Investigator)			0-Absent	52 (100.0)	52 (100.0)	51 (100.0)	52 (100.0)
			1-Minimal	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			2-Mild	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			3-Moderate	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			4-Severe	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		Week 2	Total	52	52	50	52
			0-Absent	52 (100.0)	52 (100.0)	50 (100.0)	50 (96.2)
			1-Minimal	0 (0.0)	0 (0.0)	0 (0.0)	2 (3.8)
			2-Mild	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			3-Moderate	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			4-Severe	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		Week 4	Total	52	52	51	52
			0-Absent	52 (100.0)	51 (98.1)	50 (98.0)	52 (100.0)
			1-Minimal	0 (0.0)	1 (1.9)	0 (0.0)	0 (0.0)
			2-Mild	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			3-Moderate	0 (0.0)	0 (0.0)	1 (2.0)	0 (0.0)
			4-Severe	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		Week 6-3	Total	51	51	50	50
			0-Absent	51 (100.0)	50 (98.0)	49 (98.0)	48 (96.0)
			1-Minimal	0 (0.0)	1 (2.0)	1 (2.0)	0 (0.0)
			2-Mild	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.0)
			3-Moderate	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			4-Severe	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		Follow-up	Total	51	49	50	51
			0-Absent	51 (100.0)	49 (100.0)	50 (100.0)	50 (98.0)
			1-Minimal	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.0)
			2-Mild	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			3-Moderate	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			4-Severe	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

Source：5.3.5.1-1 Table 14.3.4-10 より改変

表 2.7.4-55　局所忍容性の各スコアの被験者数及びその割合（BBI-4000-04 試験）（続き）
[Safety]

Local Tolerability	Location	Visit	Score	BBI-4000 gel 0% N=52	BBI-4000 gel 5% N=52	BBI-4000 gel 10% N=51	BBI-4000 gel 15% N=52
Burning	Right Axilla	Baseline 3	Total	52	52	51	52
(By Subject)			0-Absent	45 (86.5)	50 (96.2)	45 (88.2)	48 (92.3)
			1-Minimal	4 (7.7)	0 (0.0)	0 (0.0)	1 (1.9)
			2-Mild	0 (0.0)	1 (1.9)	1 (2.0)	2 (3.8)
			3-Moderate	1 (1.9)	1 (1.9)	4 (7.8)	1 (1.9)
			4-Severe	2 (3.8)	0 (0.0)	1 (2.0)	0 (0.0)
		Week 2	Total	52	52	50	52
			0-Absent	48 (92.3)	47 (90.4)	47 (94.0)	41 (78.8)
			1-Minimal	4 (7.7)	4 (7.7)	2 (4.0)	8 (15.4)
			2-Mild	0 (0.0)	1 (1.9)	1 (2.0)	2 (3.8)
			3-Moderate	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.9)
			4-Severe	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		Week 4	Total	52	52	51	52
			0-Absent	50 (96.2)	47 (90.4)	45 (88.2)	47 (90.4)
			1-Minimal	0 (0.0)	2 (3.8)	4 (7.8)	2 (3.8)
			2-Mild	2 (3.8)	2 (3.8)	2 (3.9)	2 (3.8)
			3-Moderate	0 (0.0)	1 (1.9)	0 (0.0)	1 (1.9)
			4-Severe	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		Week 6-3	Total	51	51	50	50
			0-Absent	49 (96.1)	45 (88.2)	48 (96.0)	45 (90.0)
			1-Minimal	2 (3.9)	5 (9.8)	1 (2.0)	3 (6.0)
			2-Mild	0 (0.0)	1 (2.0)	1 (2.0)	1 (2.0)
			3-Moderate	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.0)
			4-Severe	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		Follow-up	Total	51	49	50	51
			0-Absent	50 (98.0)	45 (91.8)	50 (100.0)	49 (96.1)
			1-Minimal	0 (0.0)	3 (6.1)	0 (0.0)	0 (0.0)
			2-Mild	1 (2.0)	1 (2.0)	0 (0.0)	2 (3.9)
			3-Moderate	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			4-Severe	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

Source：5.3.5.1-1 Table 14.3.4-10 より改変

表 2.7.4-55　局所忍容性の各スコアの被験者数及びその割合（BBI-4000-04 試験）（続き）
[Safety]

Local Tolerability	Location	Visit	Score	BBI-4000 gel 0% N=52	BBI-4000 gel 5% N=52	BBI-4000 gel 10% N=51	BBI-4000 gel 15% N=52
Burning	Left Axilla	Baseline 3	Total	52	52	51	52
(By Subject)			0-Absent	45 (86.5)	50 (96.2)	46 (90.2)	48 (92.3)
			1-Minimal	4 (7.7)	0 (0.0)	0 (0.0)	1 (1.9)
			2-Mild	0 (0.0)	2 (3.8)	0 (0.0)	2 (3.8)
			3-Moderate	1 (1.9)	0 (0.0)	4 (7.8)	1 (1.9)
			4-Severe	2 (3.8)	0 (0.0)	1 (2.0)	0 (0.0)
		Week 2	Total	52	52	50	52
			0-Absent	48 (92.3)	45 (86.5)	47 (94.0)	41 (78.8)
			1-Minimal	4 (7.7)	5 (9.6)	2 (4.0)	8 (15.4)
			2-Mild	0 (0.0)	2 (3.8)	1 (2.0)	2 (3.8)
			3-Moderate	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.9)
			4-Severe	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		Week 4	Total	52	52	51	52
			0-Absent	50 (96.2)	46 (88.5)	44 (86.3)	47 (90.4)
			1-Minimal	0 (0.0)	2 (3.8)	5 (9.8)	2 (3.8)
			2-Mild	2 (3.8)	3 (5.8)	2 (3.9)	2 (3.8)
			3-Moderate	0 (0.0)	1 (1.9)	0 (0.0)	1 (1.9)
			4-Severe	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		Week 6-3	Total	51	51	50	50
			0-Absent	49 (96.1)	44 (86.3)	49 (98.0)	45 (90.0)
			1-Minimal	2 (3.9)	6 (11.8)	1 (2.0)	2 (4.0)
			2-Mild	0 (0.0)	1 (2.0)	0 (0.0)	1 (2.0)
			3-Moderate	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.0)
			4-Severe	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		Follow-up	Total	51	49	50	51
			0-Absent	50 (98.0)	45 (91.8)	50 (100.0)	49 (96.1)
			1-Minimal	0 (0.0)	3 (6.1)	0 (0.0)	0 (0.0)
			2-Mild	1 (2.0)	1 (2.0)	0 (0.0)	2 (3.9)
			3-Moderate	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			4-Severe	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

Source：5.3.5.1-1 Table 14.3.4-10 より改変

表 2.7.4-55　局所忍容性の各スコアの被験者数及びその割合（BBI-4000-04 試験）（続き）
[Safety]

Local Tolerability	Location	Visit	Score	BBI-4000 gel 0% N=52	BBI-4000 gel 5% N=52	BBI-4000 gel 10% N=51	BBI-4000 gel 15% N=52
Itching	Right Axilla	Baseline 3	Total	52	52	51	52
(By Subject)			0-Absent	47 (90.4)	49 (94.2)	46 (90.2)	50 (96.2)
			1-Minimal	5 (9.6)	1 (1.9)	1 (2.0)	1 (1.9)
			2-Mild	0 (0.0)	1 (1.9)	2 (3.9)	0 (0.0)
			3-Moderate	0 (0.0)	1 (1.9)	2 (3.9)	1 (1.9)
			4-Severe	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		Week 2	Total	52	52	50	52
			0-Absent	50 (96.2)	49 (94.2)	43 (86.0)	42 (80.8)
			1-Minimal	2 (3.8)	3 (5.8)	5 (10.0)	8 (15.4)
			2-Mild	0 (0.0)	0 (0.0)	2 (4.0)	1 (1.9)
			3-Moderate	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.9)
			4-Severe	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		Week 4	Total	52	52	51	52
			0-Absent	48 (92.3)	50 (96.2)	40 (78.4)	48 (92.3)
			1-Minimal	3 (5.8)	1 (1.9)	8 (15.7)	2 (3.8)
			2-Mild	1 (1.9)	1 (1.9)	1 (2.0)	2 (3.8)
			3-Moderate	0 (0.0)	0 (0.0)	2 (3.9)	0 (0.0)
			4-Severe	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		Week 6-3	Total	51	51	50	50
			0-Absent	51 (100.0)	46 (90.2)	44 (88.0)	43 (86.0)
			1-Minimal	0 (0.0)	3 (5.9)	5 (10.0)	4 (8.0)
			2-Mild	0 (0.0)	2 (3.9)	1 (2.0)	3 (6.0)
			3-Moderate	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			4-Severe	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		Follow-up	Total	51	49	50	51
			0-Absent	51 (100.0)	47 (95.9)	48 (96.0)	49 (96.1)
			1-Minimal	0 (0.0)	2 (4.1)	1 (2.0)	1 (2.0)
			2-Mild	0 (0.0)	0 (0.0)	1 (2.0)	0 (0.0)
			3-Moderate	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.0)
			4-Severe	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

Source：5.3.5.1-1 Table 14.3.4-10 より改変

表 2.7.4-55　局所忍容性の各スコアの被験者数及びその割合（BBI-4000-04 試験）（続き）
[Safety]

Local Tolerability	Location	Visit	Score	BBI-4000 gel 0% N=52	BBI-4000 gel 5% N=52	BBI-4000 gel 10% N=51	BBI-4000 gel 15% N=52
Itching	Left Axilla	Baseline 3	Total	52	52	51	52
(By Subject)			0-Absent	48 (92.3)	50 (96.2)	46 (90.2)	50 (96.2)
			1-Minimal	4 (7.7)	1 (1.9)	2 (3.9)	1 (1.9)
			2-Mild	0 (0.0)	0 (0.0)	2 (3.9)	1 (1.9)
			3-Moderate	0 (0.0)	1 (1.9)	1 (2.0)	0 (0.0)
			4-Severe	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		Week 2	Total	52	52	50	52
			0-Absent	50 (96.2)	47 (90.4)	45 (90.0)	42 (80.8)
			1-Minimal	1 (1.9)	3 (5.8)	3 (6.0)	6 (11.5)
			2-Mild	1 (1.9)	2 (3.8)	2 (4.0)	4 (7.7)
			3-Moderate	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			4-Severe	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		Week 4	Total	52	52	51	52
			0-Absent	48 (92.3)	48 (92.3)	42 (82.4)	47 (90.4)
			1-Minimal	3 (5.8)	3 (5.8)	5 (9.8)	3 (5.8)
			2-Mild	1 (1.9)	1 (1.9)	2 (3.9)	2 (3.8)
			3-Moderate	0 (0.0)	0 (0.0)	2 (3.9)	0 (0.0)
			4-Severe	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		Week 6-3	Total	51	51	50	50
			0-Absent	51 (100.0)	47 (92.2)	44 (88.0)	44 (88.0)
			1-Minimal	0 (0.0)	2 (3.9)	3 (6.0)	3 (6.0)
			2-Mild	0 (0.0)	2 (3.9)	2 (4.0)	2 (4.0)
			3-Moderate	0 (0.0)	0 (0.0)	1 (2.0)	0 (0.0)
			4-Severe	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.0)
		Follow-up	Total	51	49	50	51
			0-Absent	51 (100.0)	46 (93.9)	48 (96.0)	48 (94.1)
			1-Minimal	0 (0.0)	2 (4.1)	0 (0.0)	2 (3.9)
			2-Mild	0 (0.0)	1 (2.0)	2 (4.0)	0 (0.0)
			3-Moderate	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.0)
			4-Severe	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

Source：5.3.5.1-1 Table 14.3.4-10 より改変

表 2.7.4-56　局所忍容性のクロステーブル（BBI-4000-04 試験）
[Safety]

				Week 6-3				
Local Tolerability	Location	Treatment	Baseline 3	0-Absent	1-Minimal	2-Mild	3-Moderate	4-Severe
Dryness	Right Axilla	BBI-4000 gel 0%	0-Absent	51	0	0	0	0
(By Investigator)			1-Minimal	0	0	0	0	0
			2-Mild	0	0	0	0	0
			3-Moderate	0	0	0	0	0
			4-Severe	0	0	0	0	0
		BBI-4000 gel 5%	0-Absent	51	0	0	0	0
			1-Minimal	0	0	0	0	0
			2-Mild	0	0	0	0	0
			3-Moderate	0	0	0	0	0
			4-Severe	0	0	0	0	0
		BBI-4000 gel 10%	0-Absent	50	0	0	0	0
			1-Minimal	0	0	0	0	0
			2-Mild	0	0	0	0	0
			3-Moderate	0	0	0	0	0
			4-Severe	0	0	0	0	0
		BBI-4000 gel 15%	0-Absent	49	1	0	0	0
			1-Minimal	0	0	0	0	0
			2-Mild	0	0	0	0	0
			3-Moderate	0	0	0	0	0
			4-Severe	0	0	0	0	0
	Left Axilla	BBI-4000 gel 0%	0-Absent	51	0	0	0	0
			1-Minimal	0	0	0	0	0
			2-Mild	0	0	0	0	0
			3-Moderate	0	0	0	0	0
			4-Severe	0	0	0	0	0
		BBI-4000 gel 5%	0-Absent	51	0	0	0	0
			1-Minimal	0	0	0	0	0
			2-Mild	0	0	0	0	0
			3-Moderate	0	0	0	0	0
			4-Severe	0	0	0	0	0
		BBI-4000 gel 10%	0-Absent	50	0	0	0	0
			1-Minimal	0	0	0	0	0
			2-Mild	0	0	0	0	0
			3-Moderate	0	0	0	0	0
			4-Severe	0	0	0	0	0
		BBI-4000 gel 15%	0-Absent	49	1	0	0	0
			1-Minimal	0	0	0	0	0
			2-Mild	0	0	0	0	0
			3-Moderate	0	0	0	0	0
			4-Severe	0	0	0	0	0

Source：5.3.5.1-1 Table 14.3.4-11 より改変

表 2.7.4-56 局所忍容性のクロステーブル（BBI-4000-04 試験）（続き）
[Safety]

				Week 6-3				
Local Tolerability	Location	Treatment	Baseline 3	0-Absent	1-Minimal	2-Mild	3-Moderate	4-Severe
Erythema	Right Axilla	BBI-4000 gel 0%	0-Absent	51	0	0	0	0
(By Investigator)			1-Minimal	0	0	0	0	0
			2-Mild	0	0	0	0	0
			3-Moderate	0	0	0	0	0
			4-Severe	0	0	0	0	0
		BBI-4000 gel 5%	0-Absent	48	2	0	0	0
			1-Minimal	1	0	0	0	0
			2-Mild	0	0	0	0	0
			3-Moderate	0	0	0	0	0
			4-Severe	0	0	0	0	0
		BBI-4000 gel 10%	0-Absent	45	2	3	0	0
			1-Minimal	0	0	0	0	0
			2-Mild	0	0	0	0	0
			3-Moderate	0	0	0	0	0
			4-Severe	0	0	0	0	0
		BBI-4000 gel 15%	0-Absent	42	3	2	1	0
			1-Minimal	0	1	0	0	0
			2-Mild	1	0	0	0	0
			3-Moderate	0	0	0	0	0
			4-Severe	0	0	0	0	0
	Left Axilla	BBI-4000 gel 0%	0-Absent	50	1	0	0	0
			1-Minimal	0	0	0	0	0
			2-Mild	0	0	0	0	0
			3-Moderate	0	0	0	0	0
			4-Severe	0	0	0	0	0
		BBI-4000 gel 5%	0-Absent	49	2	0	0	0
			1-Minimal	0	0	0	0	0
			2-Mild	0	0	0	0	0
			3-Moderate	0	0	0	0	0
			4-Severe	0	0	0	0	0
		BBI-4000 gel 10%	0-Absent	46	2	2	0	0
			1-Minimal	0	0	0	0	0
			2-Mild	0	0	0	0	0
			3-Moderate	0	0	0	0	0
			4-Severe	0	0	0	0	0
		BBI-4000 gel 15%	0-Absent	41	2	2	3	0
			1-Minimal	0	0	0	0	0
			2-Mild	1	0	1	0	0
			3-Moderate	0	0	0	0	0
			4-Severe	0	0	0	0	0

Source：5.3.5.1-1 Table 14.3.4-11 より改変

表 2.7.4-56 局所忍容性のクロステーブル（BBI-4000-04 試験）（続き）
[Safety]

				Week 6-3				
Local Tolerability	Location	Treatment	Baseline 3	0-Absent	1-Minimal	2-Mild	3-Moderate	4-Severe
Scaling	Right Axilla	BBI-4000 gel 0%	0-Absent	51	0	0	0	0
(By Investigator)			1-Minimal	0	0	0	0	0
			2-Mild	0	0	0	0	0
			3-Moderate	0	0	0	0	0
			4-Severe	0	0	0	0	0
		BBI-4000 gel 5%	0-Absent	50	1	0	0	0
			1-Minimal	0	0	0	0	0
			2-Mild	0	0	0	0	0
			3-Moderate	0	0	0	0	0
			4-Severe	0	0	0	0	0
		BBI-4000 gel 10%	0-Absent	49	1	0	0	0
			1-Minimal	0	0	0	0	0
			2-Mild	0	0	0	0	0
			3-Moderate	0	0	0	0	0
			4-Severe	0	0	0	0	0
		BBI-4000 gel 15%	0-Absent	49	1	0	0	0
			1-Minimal	0	0	0	0	0
			2-Mild	0	0	0	0	0
			3-Moderate	0	0	0	0	0
			4-Severe	0	0	0	0	0
	Left Axilla	BBI-4000 gel 0%	0-Absent	51	0	0	0	0
			1-Minimal	0	0	0	0	0
			2-Mild	0	0	0	0	0
			3-Moderate	0	0	0	0	0
			4-Severe	0	0	0	0	0
		BBI-4000 gel 5%	0-Absent	50	1	0	0	0
			1-Minimal	0	0	0	0	0
			2-Mild	0	0	0	0	0
			3-Moderate	0	0	0	0	0
			4-Severe	0	0	0	0	0
		BBI-4000 gel 10%	0-Absent	49	1	0	0	0
			1-Minimal	0	0	0	0	0
			2-Mild	0	0	0	0	0
			3-Moderate	0	0	0	0	0
			4-Severe	0	0	0	0	0
		BBI-4000 gel 15%	0-Absent	48	0	2	0	0
			1-Minimal	0	0	0	0	0
			2-Mild	0	0	0	0	0
			3-Moderate	0	0	0	0	0
			4-Severe	0	0	0	0	0

Source：5.3.5.1-1 Table 14.3.4-11 より改変

表 2.7.4-56 局所忍容性のクロステーブル（BBI-4000-04 試験）（続き）
[Safety]

				Week 6-3				
Local Tolerability	Location	Treatment	Baseline 3	0-Absent	1-Minimal	2-Mild	3-Moderate	4-Severe
Burning	Right Axilla	BBI-4000 gel 0%	0-Absent	43	1	0	0	0
(By Subject)			1-Minimal	3	1	0	0	0
			2-Mild	0	0	0	0	0
			3-Moderate	1	0	0	0	0
			4-Severe	2	0	0	0	0
		BBI-4000 gel 5%	0-Absent	45	3	1	0	0
			1-Minimal	0	0	0	0	0
			2-Mild	0	1	0	0	0
			3-Moderate	0	1	0	0	0
			4-Severe	0	0	0	0	0
		BBI-4000 gel 10%	0-Absent	44	1	0	0	0
			1-Minimal	0	0	0	0	0
			2-Mild	1	0	0	0	0
			3-Moderate	3	0	1	0	0
			4-Severe	0	0	0	0	0
		BBI-4000 gel 15%	0-Absent	44	3	0	1	0
			1-Minimal	0	0	0	0	0
			2-Mild	1	0	0	0	0
			3-Moderate	0	0	1	0	0
			4-Severe	0	0	0	0	0
	Left Axilla	BBI-4000 gel 0%	0-Absent	43	1	0	0	0
			1-Minimal	3	1	0	0	0
			2-Mild	0	0	0	0	0
			3-Moderate	1	0	0	0	0
			4-Severe	2	0	0	0	0
		BBI-4000 gel 5%	0-Absent	44	4	1	0	0
			1-Minimal	0	0	0	0	0
			2-Mild	0	2	0	0	0
			3-Moderate	0	0	0	0	0
			4-Severe	0	0	0	0	0
		BBI-4000 gel 10%	0-Absent	45	1	0	0	0
			1-Minimal	0	0	0	0	0
			2-Mild	0	0	0	0	0
			3-Moderate	4	0	0	0	0
			4-Severe	0	0	0	0	0
		BBI-4000 gel 15%	0-Absent	44	2	0	2	0
			1-Minimal	0	0	0	0	0
			2-Mild	1	0	0	0	0
			3-Moderate	0	0	1	0	0
			4-Severe	0	0	0	0	0

Source：5.3.5.1-1 Table 14.3.4-11 より改変

表 2.7.4-56 局所忍容性のクロステーブル（BBI-4000-04 試験）（続き）
[Safety]

				Week 6-3				
Local Tolerability	Location	Treatment	Baseline 3	0-Absent	1-Minimal	2-Mild	3-Moderate	4-Severe
Itching	Right Axilla	BBI-4000 gel 0%	0-Absent	46	0	0	0	0
(By Subject)			1-Minimal	5	0	0	0	0
			2-Mild	0	0	0	0	0
			3-Moderate	0	0	0	0	0
			4-Severe	0	0	0	0	0
		BBI-4000 gel 5%	0-Absent	43	3	2	0	0
			1-Minimal	1	0	0	0	0
			2-Mild	1	0	0	0	0
			3-Moderate	1	0	0	0	0
			4-Severe	0	0	0	0	0
		BBI-4000 gel 10%	0-Absent	41	4	1	0	0
			1-Minimal	1	0	0	0	0
			2-Mild	2	0	0	0	0
			3-Moderate	0	1	0	0	0
			4-Severe	0	0	0	0	0
		BBI-4000 gel 15%	0-Absent	42	4	3	0	0
			1-Minimal	0	0	0	0	0
			2-Mild	0	0	0	0	0
			3-Moderate	1	0	0	0	0
			4-Severe	0	0	0	0	0
	Left Axilla	BBI-4000 gel 0%	0-Absent	47	0	0	0	0
			1-Minimal	4	0	0	0	0
			2-Mild	0	0	0	0	0
			3-Moderate	0	0	0	0	0
			4-Severe	0	0	0	0	0
		BBI-4000 gel 5%	0-Absent	45	2	2	0	0
			1-Minimal	1	0	0	0	0
			2-Mild	0	0	0	0	0
			3-Moderate	1	0	0	0	0
			4-Severe	0	0	0	0	0
		BBI-4000 gel 10%	0-Absent	41	2	2	1	0
			1-Minimal	2	0	0	0	0
			2-Mild	1	1	0	0	0
			3-Moderate	0	0	0	0	0
			4-Severe	0	0	0	0	0
		BBI-4000 gel 15%	0-Absent	43	3	2	0	1
			1-Minimal	0	0	0	0	0
			2-Mild	1	0	0	0	0
			3-Moderate	0	0	0	0	0
			4-Severe	0	0	0	0	0

Source：5.3.5.1-1 Table 14.3.4-11 より改変

表 2.7.4-57　局所忍容性の基本統計量（BBI-4000-06 試験）（Safety Analysis Set）

	BBI-4000 0% N=140	BBI-4000 5% N=141
Investigator, Dryness Severity		
Baseline 3		
n	140	141
Mean (SD)	0.0 (0.00)	0.0 (0.08)
Median	0.0	0.0
Min , Max	0 , 0	0 , 1
Week 2		
n	138	139
Mean (SD)	0.0 (0.00)	0.0 (0.15)
Median	0.0	0.0
Min , Max	0 , 0	0 , 1
Week 4		
n	136	138
Mean (SD)	0.0 (0.00)	0.0 (0.28)
Median	0.0	0.0
Min , Max	0 , 0	0 , 3

Local tolerability score is defined as below.
0 : Absent, 1 : Minimal, 2 : Mild, 3 : Moderate, 4 : Severe
The greater result of left axilla or right axilla is used for Local Tolerability analysis.

PAGE: 1 of 6
PROGRAM: t079 (OUTPUT: t14_03_04_17_lt_mean)
DATE: 2019/05/21
PROTOCOL NO: BBI-4000-06
Source：5.3.5.1-2 Table 14.3.4-17 より改変

表 2.7.4-57　局所忍容性の基本統計量（BBI-4000-06 試験）（続き）
（Safety Analysis Set）

	BBI-4000 0% N=140	BBI-4000 5% N=141
Week 6-3		
n	139	139
Mean (SD)	0.0 (0.00)	0.1 (0.38)
Median	0.0	0.0
Min , Max	0 , 0	0 , 3
Follow-up		
n	45	47
Mean (SD)	0.0 (0.00)	0.0 (0.00)
Median	0.0	0.0
Min , Max	0 , 0	0 , 0

Local tolerability score is defined as below.
0 : Absent, 1 : Minimal, 2 : Mild, 3 : Moderate, 4 : Severe
The greater result of left axilla or right axilla is used for Local Tolerability analysis.

PAGE: 2 of 6
PROGRAM: t079 (OUTPUT: t14_03_04_17_lt_mean)
DATE: 2019/05/21
PROTOCOL NO: BBI-4000-06
Source：5.3.5.1-2 Table 14.3.4-17 より改変

表 2.7.4-57　局所忍容性の基本統計量（BBI-4000-06 試験）（続き）
（Safety Analysis Set）

	BBI-4000 0% N=140	BBI-4000 5% N=141
Investigator, Erythema Severity		
Baseline 3		
n	140	141
Mean (SD)	0.0 (0.21)	0.0 (0.21)
Median	0.0	0.0
Min , Max	0 , 2	0 , 2
Week 2		
n	138	139
Mean (SD)	0.0 (0.21)	0.1 (0.41)
Median	0.0	0.0
Min , Max	0 , 2	0 , 2
Week 4		
n	136	138
Mean (SD)	0.0 (0.15)	0.2 (0.62)
Median	0.0	0.0
Min , Max	0 , 1	0 , 3

Local tolerability score is defined as below.
0 : Absent, 1 : Minimal, 2 : Mild, 3 : Moderate, 4 : Severe
The greater result of left axilla or right axilla is used for Local Tolerability analysis.

PAGE: 3 of 6
PROGRAM: t079 (OUTPUT: t14_03_04_17_lt_mean)
DATE: 2019/05/21
PROTOCOL NO: BBI-4000-06
Source：5.3.5.1-2 Table 14.3.4-17 より改変

表 2.7.4-57　局所忍容性の基本統計量（BBI-4000-06 試験）（続き）
（Safety Analysis Set）

	BBI-4000 0% N=140	BBI-4000 5% N=141
Week 6-3		
n	139	139
Mean (SD)	0.0 (0.17)	0.2 (0.59)
Median	0.0	0.0
Min , Max	0 , 2	0 , 3
Follow-up		
n	45	47
Mean (SD)	0.0 (0.00)	0.0 (0.00)
Median	0.0	0.0
Min , Max	0 , 0	0 , 0

Local tolerability score is defined as below.
0 : Absent, 1 : Minimal, 2 : Mild, 3 : Moderate, 4 : Severe
The greater result of left axilla or right axilla is used for Local Tolerability analysis.

PAGE: 4 of 6
PROGRAM: t079 (OUTPUT: t14_03_04_17_lt_mean)
DATE: 2019/05/21
PROTOCOL NO: BBI-4000-06
Source：5.3.5.1-2 Table 14.3.4-17 より改変

表 2.7.4-57　局所忍容性の基本統計量（BBI-4000-06 試験）（続き）
（Safety Analysis Set）

	BBI-4000 0% N=140	BBI-4000 5% N=141
Investigator, Scaling Severity		
Baseline 3		
n	140	141
Mean (SD)	0.0 (0.00)	0.0 (0.00)
Median	0.0	0.0
Min , Max	0 , 0	0 , 0
Week 2		
n	138	139
Mean (SD)	0.0 (0.00)	0.0 (0.17)
Median	0.0	0.0
Min , Max	0 , 0	0 , 1
Week 4		
n	136	138
Mean (SD)	0.0 (0.00)	0.1 (0.41)
Median	0.0	0.0
Min , Max	0 , 0	0 , 3

Local tolerability score is defined as below.
0 : Absent, 1 : Minimal, 2 : Mild, 3 : Moderate, 4 : Severe
The greater result of left axilla or right axilla is used for Local Tolerability analysis.

PAGE: 5 of 6
PROGRAM: t079 (OUTPUT: t14_03_04_17_lt_mean)
DATE: 2019/05/21
PROTOCOL NO: BBI-4000-06
Source：5.3.5.1-2 Table 14.3.4-17 より改変

表 2.7.4-57　局所忍容性の基本統計量（BBI-4000-06 試験）（続き）
（Safety Analysis Set）

	BBI-4000 0% N=140	BBI-4000 5% N=141
Week 6-3		
n	139	139
Mean (SD)	0.0 (0.00)	0.1 (0.31)
Median	0.0	0.0
Min , Max	0 , 0	0 , 3
Follow-up		
n	45	47
Mean (SD)	0.0 (0.00)	0.0 (0.15)
Median	0.0	0.0
Min , Max	0 , 0	0 , 1

Local tolerability score is defined as below.
0 : Absent, 1 : Minimal, 2 : Mild, 3 : Moderate, 4 : Severe
The greater result of left axilla or right axilla is used for Local Tolerability analysis.

PAGE: 6 of 6
PROGRAM: t079 (OUTPUT: t14_03_04_17_lt_mean)
DATE: 2019/05/21
PROTOCOL NO: BBI-4000-06
Source：5.3.5.1-2 Table 14.3.4-17 より改変

表 2.7.4-57　局所忍容性の基本統計量（BBI-4000-06 試験）（続き）
（Safety Analysis Set）

	BBI-4000 0% N=140	BBI-4000 5% N=141
Subject, Burning Tolerability		
Baseline 3		
n	140	141
Mean (SD)	0.0 (0.19)	0.0 (0.08)
Median	0.0	0.0
Min , Max	0 , 2	0 , 1
Week 2		
n	138	139
Mean (SD)	0.1 (0.35)	0.0 (0.22)
Median	0.0	0.0
Min , Max	0 , 3	0 , 2
Week 4		
n	136	138
Mean (SD)	0.0 (0.28)	0.1 (0.42)
Median	0.0	0.0
Min , Max	0 , 3	0 , 3

Local tolerability score is defined as below.
0 : Absent, 1 : Minimal, 2 : Mild, 3 : Moderate, 4 : Severe
The greater result of left axilla or right axilla is used for Local Tolerability analysis.

PAGE: 1 of 4
PROGRAM: t080 (OUTPUT: t14_03_04_18_lt_mean)
DATE: 2019/05/21
PROTOCOL NO: BBI-4000-06
Source：5.3.5.1-2 Table 14.3.4-18 より改変

表 2.7.4-57　局所忍容性の基本統計量（BBI-4000-06 試験）（続き）
（Safety Analysis Set）

	BBI-4000 0% N=140	BBI-4000 5% N=141
Week 6-3		
n	139	139
Mean (SD)	0.0 (0.12)	0.1 (0.35)
Median	0.0	0.0
Min , Max	0 , 1	0 , 2
Follow-up		
n	45	47
Mean (SD)	0.0 (0.00)	0.0 (0.00)
Median	0.0	0.0
Min , Max	0 , 0	0 , 0

Local tolerability score is defined as below.
0 : Absent, 1 : Minimal, 2 : Mild, 3 : Moderate, 4 : Severe
The greater result of left axilla or right axilla is used for Local Tolerability analysis.

PAGE: 2 of 4
PROGRAM: t080 (OUTPUT: t14_03_04_18_lt_mean)
DATE: 2019/05/21
PROTOCOL NO: BBI-4000-06
Source：5.3.5.1-2 Table 14.3.4-18 より改変

表 2.7.4-57　局所忍容性の基本統計量（BBI-4000-06 試験）（続き）
（Safety Analysis Set）

	BBI-4000 0% N=140	BBI-4000 5% N=141
Subject, Itching Tolerability		
Baseline 3		
n	140	141
Mean (SD)	0.0 (0.19)	0.1 (0.42)
Median	0.0	0.0
Min , Max	0 , 1	0 , 3
Week 2		
n	138	139
Mean (SD)	0.1 (0.31)	0.2 (0.47)
Median	0.0	0.0
Min , Max	0 , 2	0 , 2
Week 4		
n	136	138
Mean (SD)	0.1 (0.29)	0.2 (0.60)
Median	0.0	0.0
Min , Max	0 , 2	0 , 3

Local tolerability score is defined as below.
0 : Absent, 1 : Minimal, 2 : Mild, 3 : Moderate, 4 : Severe
The greater result of left axilla or right axilla is used for Local Tolerability analysis.

PAGE: 3 of 4
PROGRAM: t080 (OUTPUT: t14_03_04_18_lt_mean)
DATE: 2019/05/21
PROTOCOL NO: BBI-4000-06
Source：5.3.5.1-2 Table 14.3.4-18 より改変

表 2.7.4-57　局所忍容性の基本統計量（BBI-4000-06 試験）（続き）
（Safety Analysis Set）

	BBI-4000 0% N=140	BBI-4000 5% N=141
Week 6-3		
n	139	139
Mean (SD)	0.0 (0.22)	0.2 (0.48)
Median	0.0	0.0
Min , Max	0 , 2	0 , 3
Follow-up		
n	45	47
Mean (SD)	0.0 (0.00)	0.1 (0.32)
Median	0.0	0.0
Min , Max	0 , 0	0 , 2

Local tolerability score is defined as below.
0 : Absent, 1 : Minimal, 2 : Mild, 3 : Moderate, 4 : Severe
The greater result of left axilla or right axilla is used for Local Tolerability analysis.

PAGE: 4 of 4
PROGRAM: t080 (OUTPUT: t14_03_04_18_lt_mean)
DATE: 2019/05/21
PROTOCOL NO: BBI-4000-06
Source：5.3.5.1-2 Table 14.3.4-18 より改変

表 2.7.4-58　局所忍容性の基本統計量（BBI-4000-07 試験）
（Safety Analysis Set）

	Cohort 1 (0%/5%) N=94	Cohort 1 (5%/5%) N=91	Total N=185
Investigator, Dryness Severity			
Week 2			
n	91	90	181
Mean (SD)	0.0 (0.23)	0.1 (0.33)	0.0 (0.28)
Median	0.0	0.0	0.0
Min , Max	0 , 2	0 , 2	0 , 2
Week 4			
n	94	89	183
Mean (SD)	0.1 (0.34)	0.1 (0.33)	0.1 (0.33)
Median	0.0	0.0	0.0
Min , Max	0 , 3	0 , 2	0 , 3
Week 6			
n	93	90	183
Mean (SD)	0.0 (0.00)	0.0 (0.15)	0.0 (0.10)
Median	0.0	0.0	0.0
Min , Max	0 , 0	0 , 1	0 , 1

Local tolerability score is defined as below.
0 : Absent, 1 : Minimal, 2 : Mild, 3 : Moderate, 4 : Severe
The greater result of left axilla or right axilla is used for Local Tolerability analysis.

PAGE: 1 of 18
PROGRAM: t079 (OUTPUT: t14_03_04_17_lt_mean)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Table 14.3.4-17 より改変

表 2.7.4-58 局所忍容性の基本統計量（BBI-4000-07 試験）（続き）
（Safety Analysis Set）

	Cohort 1 (0%/5%) N=94	Cohort 1 (5%/5%) N=91	Total N=185
Week 8			
n	93	86	179
Mean (SD)	0.0 (0.10)	0.1 (0.40)	0.0 (0.29)
Median	0.0	0.0	0.0
Min , Max	0 , 1	0 , 3	0 , 3
Week 12			
n	94	85	179
Mean (SD)	0.0 (0.25)	0.0 (0.15)	0.0 (0.21)
Median	0.0	0.0	0.0
Min , Max	0 , 2	0 , 1	0 , 2
Week 16			
n	91	85	176
Mean (SD)	0.0 (0.25)	0.1 (0.28)	0.1 (0.27)
Median	0.0	0.0	0.0
Min , Max	0 , 2	0 , 2	0 , 2

Local tolerability score is defined as below.
0 : Absent, 1 : Minimal, 2 : Mild, 3 : Moderate, 4 : Severe
The greater result of left axilla or right axilla is used for Local Tolerability analysis.

PAGE: 2 of 18
PROGRAM: t079 (OUTPUT: t14_03_04_17_lt_mean)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Table 14.3.4-17 より改変

表 2.7.4-58　局所忍容性の基本統計量（BBI-4000-07 試験）（続き）
（Safety Analysis Set）

	Cohort 1 (0%/5%) N=94	Cohort 1 (5%/5%) N=91	Total N=185
Week 20			
n	91	85	176
Mean (SD)	0.0 (0.15)	0.1 (0.39)	0.1 (0.29)
Median	0.0	0.0	0.0
Min , Max	0 , 1	0 , 2	0 , 2
Week 24			
n	90	86	176
Mean (SD)	0.1 (0.27)	0.1 (0.33)	0.1 (0.30)
Median	0.0	0.0	0.0
Min , Max	0 , 2	0 , 2	0 , 2
Week 28			
n	90	85	175
Mean (SD)	0.1 (0.27)	0.1 (0.26)	0.1 (0.27)
Median	0.0	0.0	0.0
Min , Max	0 , 2	0 , 1	0 , 2

Local tolerability score is defined as below.
0 : Absent, 1 : Minimal, 2 : Mild, 3 : Moderate, 4 : Severe
The greater result of left axilla or right axilla is used for Local Tolerability analysis.

PAGE: 3 of 18
PROGRAM: t079 (OUTPUT: t14_03_04_17_lt_mean)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Table 14.3.4-17 より改変

表 2.7.4-58　局所忍容性の基本統計量（BBI-4000-07 試験）（続き）
（Safety Analysis Set）

	Cohort 1 (0%/5%) N=94	Cohort 1 (5%/5%) N=91	Total N=185
Week 32			
n	89	83	172
Mean (SD)	0.0 (0.18)	0.0 (0.22)	0.0 (0.20)
Median	0.0	0.0	0.0
Min , Max	0 , 1	0 , 1	0 , 1
Week 36			
n	87	80	167
Mean (SD)	0.1 (0.30)	0.1 (0.38)	0.1 (0.34)
Median	0.0	0.0	0.0
Min , Max	0 , 2	0 , 3	0 , 3
Week 40			
n	85	78	163
Mean (SD)	0.1 (0.47)	0.1 (0.22)	0.1 (0.38)
Median	0.0	0.0	0.0
Min , Max	0 , 3	0 , 1	0 , 3

Local tolerability score is defined as below.
0 : Absent, 1 : Minimal, 2 : Mild, 3 : Moderate, 4 : Severe
The greater result of left axilla or right axilla is used for Local Tolerability analysis.

PAGE: 4 of 18
PROGRAM: t079 (OUTPUT: t14_03_04_17_lt_mean)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Table 14.3.4-17 より改変

表 2.7.4-58　局所忍容性の基本統計量（BBI-4000-07 試験）（続き）
（Safety Analysis Set）

	Cohort 1 (0%/5%) N=94	Cohort 1 (5%/5%) N=91	Total N=185
Week 44			
n	87	76	163
Mean (SD)	0.1 (0.41)	0.1 (0.25)	0.1 (0.34)
Median	0.0	0.0	0.0
Min , Max	0 , 3	0 , 1	0 , 3
Week 48			
n	86	76	162
Mean (SD)	0.1 (0.35)	0.1 (0.28)	0.1 (0.32)
Median	0.0	0.0	0.0
Min , Max	0 , 2	0 , 2	0 , 2
Week 52			
n	85	75	160
Mean (SD)	0.0 (0.19)	0.1 (0.38)	0.1 (0.30)
Median	0.0	0.0	0.0
Min , Max	0 , 1	0 , 2	0 , 2

Local tolerability score is defined as below.
0 : Absent, 1 : Minimal, 2 : Mild, 3 : Moderate, 4 : Severe
The greater result of left axilla or right axilla is used for Local Tolerability analysis.

PAGE: 5 of 18
PROGRAM: t079 (OUTPUT: t14_03_04_17_lt_mean)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Table 14.3.4-17 より改変

表 2.7.4-58　局所忍容性の基本統計量（BBI-4000-07 試験）（続き）
（Safety Analysis Set）

	Cohort 1 (0%/5%) N=94	Cohort 1 (5%/5%) N=91	Total N=185
Follow-up			
n	85	74	159
Mean (SD)	0.0 (0.11)	0.0 (0.00)	0.0 (0.08)
Median	0.0	0.0	0.0
Min , Max	0 , 1	0 , 0	0 , 1

Local tolerability score is defined as below.
0 : Absent, 1 : Minimal, 2 : Mild, 3 : Moderate, 4 : Severe
The greater result of left axilla or right axilla is used for Local Tolerability analysis.

PAGE: 6 of 18
PROGRAM: t079 (OUTPUT: t14_03_04_17_lt_mean)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Table 14.3.4-17 より改変

表 2.7.4-58　局所忍容性の基本統計量（BBI-4000-07 試験）（続き）
（Safety Analysis Set）

	Cohort 1 (0%/5%) N=94	Cohort 1 (5%/5%) N=91	Total N=185
Investigator, Erythema Severity			
Week 2			
n	91	90	181
Mean (SD)	0.1 (0.51)	0.2 (0.64)	0.2 (0.58)
Median	0.0	0.0	0.0
Min , Max	0 , 3	0 , 3	0 , 3
Week 4			
n	94	89	183
Mean (SD)	0.1 (0.47)	0.3 (0.81)	0.2 (0.67)
Median	0.0	0.0	0.0
Min , Max	0 , 2	0 , 3	0 , 3
Week 6			
n	93	90	183
Mean (SD)	0.1 (0.45)	0.3 (0.64)	0.2 (0.56)
Median	0.0	0.0	0.0
Min , Max	0 , 2	0 , 3	0 , 3

Local tolerability score is defined as below.
0 : Absent, 1 : Minimal, 2 : Mild, 3 : Moderate, 4 : Severe
The greater result of left axilla or right axilla is used for Local Tolerability analysis.

PAGE: 7 of 18
PROGRAM: t079 (OUTPUT: t14_03_04_17_lt_mean)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Table 14.3.4-17 より改変

表 2.7.4-58 局所忍容性の基本統計量（BBI-4000-07 試験）（続き）
（Safety Analysis Set）

	Cohort 1 (0%/5%) N=94	Cohort 1 (5%/5%) N=91	Total N=185
Week 8			
n	93	86	179
Mean (SD)	0.2 (0.43)	0.3 (0.74)	0.2 (0.60)
Median	0.0	0.0	0.0
Min , Max	0 , 2	0 , 3	0 , 3
Week 12			
n	94	85	179
Mean (SD)	0.3 (0.70)	0.2 (0.61)	0.3 (0.66)
Median	0.0	0.0	0.0
Min , Max	0 , 3	0 , 3	0 , 3
Week 16			
n	91	85	176
Mean (SD)	0.2 (0.49)	0.3 (0.63)	0.2 (0.56)
Median	0.0	0.0	0.0
Min , Max	0 , 2	0 , 3	0 , 3

Local tolerability score is defined as below.
0 : Absent, 1 : Minimal, 2 : Mild, 3 : Moderate, 4 : Severe
The greater result of left axilla or right axilla is used for Local Tolerability analysis.

PAGE: 8 of 18
PROGRAM: t079 (OUTPUT: t14_03_04_17_lt_mean)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Table 14.3.4-17 より改変

表 2.7.4-58 局所忍容性の基本統計量（BBI-4000-07 試験）（続き）
（Safety Analysis Set）

	Cohort 1 (0%/5%) N=94	Cohort 1 (5%/5%) N=91	Total N=185
Week 20			
n	91	85	176
Mean (SD)	0.2 (0.49)	0.2 (0.60)	0.2 (0.54)
Median	0.0	0.0	0.0
Min , Max	0 , 2	0 , 3	0 , 3
Week 24			
n	90	86	176
Mean (SD)	0.2 (0.55)	0.2 (0.55)	0.2 (0.55)
Median	0.0	0.0	0.0
Min , Max	0 , 3	0 , 3	0 , 3
Week 28			
n	90	85	175
Mean (SD)	0.2 (0.50)	0.2 (0.65)	0.2 (0.58)
Median	0.0	0.0	0.0
Min , Max	0 , 2	0 , 3	0 , 3

Local tolerability score is defined as below.
0 : Absent, 1 : Minimal, 2 : Mild, 3 : Moderate, 4 : Severe
The greater result of left axilla or right axilla is used for Local Tolerability analysis.

PAGE: 9 of 18
PROGRAM: t079 (OUTPUT: t14_03_04_17_lt_mean)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Table 14.3.4-17 より改変

表 2.7.4-58　局所忍容性の基本統計量（BBI-4000-07 試験）（続き）
（Safety Analysis Set）

	Cohort 1 (0%/5%) N=94	Cohort 1 (5%/5%) N=91	Total N=185
Week 32			
n	89	83	172
Mean (SD)	0.2 (0.52)	0.2 (0.49)	0.2 (0.50)
Median	0.0	0.0	0.0
Min , Max	0 , 3	0 , 2	0 , 3
Week 36			
n	87	80	167
Mean (SD)	0.2 (0.57)	0.3 (0.72)	0.3 (0.65)
Median	0.0	0.0	0.0
Min , Max	0 , 3	0 , 3	0 , 3
Week 40			
n	85	78	163
Mean (SD)	0.1 (0.43)	0.3 (0.61)	0.2 (0.53)
Median	0.0	0.0	0.0
Min , Max	0 , 2	0 , 3	0 , 3

Local tolerability score is defined as below.
0 : Absent, 1 : Minimal, 2 : Mild, 3 : Moderate, 4 : Severe
The greater result of left axilla or right axilla is used for Local Tolerability analysis.

PAGE: 10 of 18
PROGRAM: t079 (OUTPUT: t14_03_04_17_lt_mean)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Table 14.3.4-17 より改変

表 2.7.4-58　局所忍容性の基本統計量（BBI-4000-07 試験）（続き）
（Safety Analysis Set）

	Cohort 1 (0%/5%) N=94	Cohort 1 (5%/5%) N=91	Total N=185
Week 44			
n	87	76	163
Mean (SD)	0.2 (0.70)	0.4 (0.69)	0.3 (0.69)
Median	0.0	0.0	0.0
Min , Max	0 , 3	0 , 2	0 , 3
Week 48			
n	86	76	162
Mean (SD)	0.1 (0.51)	0.2 (0.52)	0.2 (0.51)
Median	0.0	0.0	0.0
Min , Max	0 , 3	0 , 2	0 , 3
Week 52			
n	85	75	160
Mean (SD)	0.1 (0.39)	0.3 (0.68)	0.2 (0.55)
Median	0.0	0.0	0.0
Min , Max	0 , 2	0 , 3	0 , 3

Local tolerability score is defined as below.
0 : Absent, 1 : Minimal, 2 : Mild, 3 : Moderate, 4 : Severe
The greater result of left axilla or right axilla is used for Local Tolerability analysis.

PAGE: 11 of 18
PROGRAM: t079 (OUTPUT: t14_03_04_17_lt_mean)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Table 14.3.4-17 より改変

表 2.7.4-58　局所忍容性の基本統計量（BBI-4000-07 試験）（続き）
（Safety Analysis Set）

	Cohort 1 (0%/5%) N=94	Cohort 1 (5%/5%) N=91	Total N=185
Follow-up			
n	85	74	159
Mean (SD)	0.0 (0.26)	0.0 (0.20)	0.0 (0.23)
Median	0.0	0.0	0.0
Min , Max	0 , 2	0 , 1	0 , 2

Local tolerability score is defined as below.
0 : Absent, 1 : Minimal, 2 : Mild, 3 : Moderate, 4 : Severe
The greater result of left axilla or right axilla is used for Local Tolerability analysis.

PAGE: 12 of 18
PROGRAM: t079 (OUTPUT: t14_03_04_17_lt_mean)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Table 14.3.4-17 より改変

表 2.7.4-58 局所忍容性の基本統計量（BBI-4000-07 試験）（続き）
（Safety Analysis Set）

	Cohort 1 (0%/5%) N=94	Cohort 1 (5%/5%) N=91	Total N=185
Investigator, Scaling Severity			
Week 2			
n	91	90	181
Mean (SD)	0.0 (0.18)	0.1 (0.48)	0.1 (0.36)
Median	0.0	0.0	0.0
Min , Max	0 , 1	0 , 3	0 , 3
Week 4			
n	94	89	183
Mean (SD)	0.0 (0.15)	0.1 (0.39)	0.1 (0.29)
Median	0.0	0.0	0.0
Min , Max	0 , 1	0 , 3	0 , 3
Week 6			
n	93	90	183
Mean (SD)	0.0 (0.15)	0.0 (0.18)	0.0 (0.16)
Median	0.0	0.0	0.0
Min , Max	0 , 1	0 , 1	0 , 1

Local tolerability score is defined as below.
0 : Absent, 1 : Minimal, 2 : Mild, 3 : Moderate, 4 : Severe
The greater result of left axilla or right axilla is used for Local Tolerability analysis.

PAGE: 13 of 18
PROGRAM: t079 (OUTPUT: t14_03_04_17_lt_mean)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Table 14.3.4-17 より改変

表 2.7.4-58　局所忍容性の基本統計量（BBI-4000-07 試験）（続き）
（Safety Analysis Set）

	Cohort 1 (0%/5%) N=94	Cohort 1 (5%/5%) N=91	Total N=185
Week 8			
n	93	86	179
Mean (SD)	0.0 (0.15)	0.1 (0.50)	0.1 (0.36)
Median	0.0	0.0	0.0
Min , Max	0 , 1	0 , 3	0 , 3
Week 12			
n	94	85	179
Mean (SD)	0.1 (0.27)	0.0 (0.26)	0.1 (0.27)
Median	0.0	0.0	0.0
Min , Max	0 , 2	0 , 2	0 , 2
Week 16			
n	91	85	176
Mean (SD)	0.0 (0.10)	0.1 (0.28)	0.0 (0.21)
Median	0.0	0.0	0.0
Min , Max	0 , 1	0 , 1	0 , 1

Local tolerability score is defined as below.
0 : Absent, 1 : Minimal, 2 : Mild, 3 : Moderate, 4 : Severe
The greater result of left axilla or right axilla is used for Local Tolerability analysis.

PAGE: 14 of 18
PROGRAM: t079 (OUTPUT: t14_03_04_17_lt_mean)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Table 14.3.4-17 より改変

表 2.7.4-58　局所忍容性の基本統計量（BBI-4000-07 試験）（続き）
（Safety Analysis Set）

	Cohort 1 (0%/5%) N=94	Cohort 1 (5%/5%) N=91	Total N=185
Week 20			
n	91	85	176
Mean (SD)	0.0 (0.10)	0.1 (0.26)	0.0 (0.20)
Median	0.0	0.0	0.0
Min , Max	0 , 1	0 , 1	0 , 1
Week 24			
n	90	86	176
Mean (SD)	0.1 (0.36)	0.1 (0.39)	0.1 (0.38)
Median	0.0	0.0	0.0
Min , Max	0 , 3	0 , 3	0 , 3
Week 28			
n	90	85	175
Mean (SD)	0.1 (0.45)	0.1 (0.43)	0.1 (0.44)
Median	0.0	0.0	0.0
Min , Max	0 , 3	0 , 3	0 , 3

Local tolerability score is defined as below.
0 : Absent, 1 : Minimal, 2 : Mild, 3 : Moderate, 4 : Severe
The greater result of left axilla or right axilla is used for Local Tolerability analysis.

PAGE: 15 of 18
PROGRAM: t079 (OUTPUT: t14_03_04_17_lt_mean)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Table 14.3.4-17 より改変

表 2.7.4-58　局所忍容性の基本統計量（BBI-4000-07 試験）（続き）
（Safety Analysis Set）

	Cohort 1 (0%/5%) N=94	Cohort 1 (5%/5%) N=91	Total N=185
Week 32			
n	89	83	172
Mean (SD)	0.0 (0.18)	0.0 (0.22)	0.0 (0.20)
Median	0.0	0.0	0.0
Min , Max	0 , 1	0 , 1	0 , 1
Week 36			
n	87	80	167
Mean (SD)	0.0 (0.26)	0.1 (0.43)	0.1 (0.35)
Median	0.0	0.0	0.0
Min , Max	0 , 2	0 , 3	0 , 3
Week 40			
n	85	78	163
Mean (SD)	0.1 (0.50)	0.0 (0.19)	0.1 (0.38)
Median	0.0	0.0	0.0
Min , Max	0 , 3	0 , 1	0 , 3

Local tolerability score is defined as below.
0 : Absent, 1 : Minimal, 2 : Mild, 3 : Moderate, 4 : Severe
The greater result of left axilla or right axilla is used for Local Tolerability analysis.

PAGE: 16 of 18
PROGRAM: t079 (OUTPUT: t14_03_04_17_lt_mean)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Table 14.3.4-17 より改変

表 2.7.4-58　局所忍容性の基本統計量（BBI-4000-07 試験）（続き）
（Safety Analysis Set）

	Cohort 1 (0%/5%) N=94	Cohort 1 (5%/5%) N=91	Total N=185
Week 44			
n	87	76	163
Mean (SD)	0.1 (0.30)	0.1 (0.35)	0.1 (0.32)
Median	0.0	0.0	0.0
Min , Max	0 , 2	0 , 2	0 , 2
Week 48			
n	86	76	162
Mean (SD)	0.1 (0.32)	0.1 (0.22)	0.1 (0.28)
Median	0.0	0.0	0.0
Min , Max	0 , 2	0 , 1	0 , 2
Week 52			
n	85	75	160
Mean (SD)	0.0 (0.15)	0.1 (0.43)	0.1 (0.32)
Median	0.0	0.0	0.0
Min , Max	0 , 1	0 , 3	0 , 3

Local tolerability score is defined as below.
0 : Absent, 1 : Minimal, 2 : Mild, 3 : Moderate, 4 : Severe
The greater result of left axilla or right axilla is used for Local Tolerability analysis.

PAGE: 17 of 18
PROGRAM: t079 (OUTPUT: t14_03_04_17_lt_mean)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Table 14.3.4-17 より改変

表 2.7.4-58　局所忍容性の基本統計量（BBI-4000-07 試験）（続き）
（Safety Analysis Set）

	Cohort 1 (0%/5%) N=94	Cohort 1 (5%/5%) N=91	Total N=185
Follow-up			
n	85	74	159
Mean (SD)	0.0 (0.15)	0.0 (0.00)	0.0 (0.11)
Median	0.0	0.0	0.0
Min , Max	0 , 1	0 , 0	0 , 1

Local tolerability score is defined as below.
0 : Absent, 1 : Minimal, 2 : Mild, 3 : Moderate, 4 : Severe
The greater result of left axilla or right axilla is used for Local Tolerability analysis.

PAGE: 18 of 18
PROGRAM: t079 (OUTPUT: t14_03_04_17_lt_mean)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Table 14.3.4-17 より改変

表 2.7.4-58　局所忍容性の基本統計量（BBI-4000-07 試験）（続き）
（Safety Analysis Set）

	Cohort 1 (0%/5%) N=94	Cohort 1 (5%/5%) N=91	Total N=185
Subject, Burning Tolerability			
Week 2			
n	91	90	181
Mean (SD)	0.1 (0.53)	0.1 (0.32)	0.1 (0.44)
Median	0.0	0.0	0.0
Min , Max	0 , 4	0 , 2	0 , 4
Week 4			
n	94	89	183
Mean (SD)	0.1 (0.35)	0.0 (0.26)	0.1 (0.31)
Median	0.0	0.0	0.0
Min , Max	0 , 2	0 , 2	0 , 2
Week 6			
n	93	90	183
Mean (SD)	0.1 (0.48)	0.1 (0.27)	0.1 (0.39)
Median	0.0	0.0	0.0
Min , Max	0 , 4	0 , 2	0 , 4

Local tolerability score is defined as below.
0 : Absent, 1 : Minimal, 2 : Mild, 3 : Moderate, 4 : Severe
The greater result of left axilla or right axilla is used for Local Tolerability analysis.

PAGE: 1 of 12
PROGRAM: t080 (OUTPUT: t14_03_04_18_lt_mean)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Table 14.3.4-18 より改変

表 2.7.4-58　局所忍容性の基本統計量（BBI-4000-07 試験）（続き）
（Safety Analysis Set）

	Cohort 1 (0%/5%) N=94	Cohort 1 (5%/5%) N=91	Total N=185
Week 8			
n	93	86	179
Mean (SD)	0.1 (0.43)	0.1 (0.41)	0.1 (0.42)
Median	0.0	0.0	0.0
Min , Max	0 , 3	0 , 2	0 , 3
Week 12			
n	94	85	179
Mean (SD)	0.1 (0.55)	0.1 (0.51)	0.1 (0.53)
Median	0.0	0.0	0.0
Min , Max	0 , 4	0 , 3	0 , 4
Week 16			
n	91	85	176
Mean (SD)	0.1 (0.23)	0.1 (0.28)	0.1 (0.26)
Median	0.0	0.0	0.0
Min , Max	0 , 1	0 , 2	0 , 2

Local tolerability score is defined as below.
0 : Absent, 1 : Minimal, 2 : Mild, 3 : Moderate, 4 : Severe
The greater result of left axilla or right axilla is used for Local Tolerability analysis.

PAGE: 2 of 12
PROGRAM: t080 (OUTPUT: t14_03_04_18_lt_mean)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Table 14.3.4-18 より改変

表 2.7.4-58　局所忍容性の基本統計量（BBI-4000-07 試験）（続き）
（Safety Analysis Set）

	Cohort 1 (0%/5%) N=94	Cohort 1 (5%/5%) N=91	Total N=185
Week 20			
n	91	85	176
Mean (SD)	0.0 (0.31)	0.1 (0.41)	0.1 (0.36)
Median	0.0	0.0	0.0
Min , Max	0 , 3	0 , 2	0 , 3
Week 24			
n	90	86	176
Mean (SD)	0.1 (0.37)	0.1 (0.32)	0.1 (0.35)
Median	0.0	0.0	0.0
Min , Max	0 , 3	0 , 2	0 , 3
Week 28			
n	90	85	175
Mean (SD)	0.1 (0.44)	0.1 (0.46)	0.1 (0.45)
Median	0.0	0.0	0.0
Min , Max	0 , 4	0 , 3	0 , 4

Local tolerability score is defined as below.
0 : Absent, 1 : Minimal, 2 : Mild, 3 : Moderate, 4 : Severe
The greater result of left axilla or right axilla is used for Local Tolerability analysis.

PAGE: 3 of 12
PROGRAM: t080 (OUTPUT: t14_03_04_18_lt_mean)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Table 14.3.4-18 より改変

表 2.7.4-58　局所忍容性の基本統計量（BBI-4000-07 試験）（続き）
（Safety Analysis Set）

	Cohort 1 (0%/5%) N=94	Cohort 1 (5%/5%) N=91	Total N=185
Week 32			
n	89	83	172
Mean (SD)	0.1 (0.36)	0.1 (0.52)	0.1 (0.45)
Median	0.0	0.0	0.0
Min , Max	0 , 3	0 , 3	0 , 3
Week 36			
n	87	80	167
Mean (SD)	0.0 (0.34)	0.2 (0.58)	0.1 (0.47)
Median	0.0	0.0	0.0
Min , Max	0 , 3	0 , 4	0 , 4
Week 40			
n	85	78	163
Mean (SD)	0.1 (0.37)	0.1 (0.38)	0.1 (0.38)
Median	0.0	0.0	0.0
Min , Max	0 , 3	0 , 2	0 , 3

Local tolerability score is defined as below.
0 : Absent, 1 : Minimal, 2 : Mild, 3 : Moderate, 4 : Severe
The greater result of left axilla or right axilla is used for Local Tolerability analysis.

PAGE: 4 of 12
PROGRAM: t080 (OUTPUT: t14_03_04_18_lt_mean)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Table 14.3.4-18 より改変

表 2.7.4-58　局所忍容性の基本統計量（BBI-4000-07 試験）（続き）
（Safety Analysis Set）

	Cohort 1 (0%/5%) N=94	Cohort 1 (5%/5%) N=91	Total N=185
Week 44			
n	87	76	163
Mean (SD)	0.1 (0.48)	0.1 (0.37)	0.1 (0.43)
Median	0.0	0.0	0.0
Min , Max	0 , 3	0 , 2	0 , 3
Week 48			
n	86	76	162
Mean (SD)	0.1 (0.49)	0.1 (0.41)	0.1 (0.45)
Median	0.0	0.0	0.0
Min , Max	0 , 4	0 , 2	0 , 4
Week 52			
n	85	75	160
Mean (SD)	0.1 (0.59)	0.1 (0.45)	0.1 (0.53)
Median	0.0	0.0	0.0
Min , Max	0 , 4	0 , 3	0 , 4

Local tolerability score is defined as below.
0 : Absent, 1 : Minimal, 2 : Mild, 3 : Moderate, 4 : Severe
The greater result of left axilla or right axilla is used for Local Tolerability analysis.

PAGE: 5 of 12
PROGRAM: t080 (OUTPUT: t14_03_04_18_lt_mean)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Table 14.3.4-18 より改変

表 2.7.4-58　局所忍容性の基本統計量（BBI-4000-07 試験）（続き）
（Safety Analysis Set）

	Cohort 1 (0%/5%) N=94	Cohort 1 (5%/5%) N=91	Total N=185
Follow-up			
n	85	74	159
Mean (SD)	0.0 (0.33)	0.0 (0.12)	0.0 (0.25)
Median	0.0	0.0	0.0
Min , Max	0 , 3	0 , 1	0 , 3

Local tolerability score is defined as below.
0 : Absent, 1 : Minimal, 2 : Mild, 3 : Moderate, 4 : Severe
The greater result of left axilla or right axilla is used for Local Tolerability analysis.

PAGE: 6 of 12
PROGRAM: t080 (OUTPUT: t14_03_04_18_lt_mean)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Table 14.3.4-18 より改変

表 2.7.4-58　局所忍容性の基本統計量（BBI-4000-07 試験）（続き）
（Safety Analysis Set）

	Cohort 1 (0%/5%) N=94	Cohort 1 (5%/5%) N=91	Total N=185
Subject, Itching Tolerability			
Week 2			
n	91	90	181
Mean (SD)	0.1 (0.51)	0.2 (0.60)	0.2 (0.56)
Median	0.0	0.0	0.0
Min , Max	0 , 4	0 , 3	0 , 4
Week 4			
n	94	89	183
Mean (SD)	0.1 (0.51)	0.3 (0.66)	0.2 (0.59)
Median	0.0	0.0	0.0
Min , Max	0 , 2	0 , 3	0 , 3
Week 6			
n	93	90	183
Mean (SD)	0.2 (0.58)	0.3 (0.72)	0.3 (0.66)
Median	0.0	0.0	0.0
Min , Max	0 , 4	0 , 3	0 , 4

Local tolerability score is defined as below.
0 : Absent, 1 : Minimal, 2 : Mild, 3 : Moderate, 4 : Severe
The greater result of left axilla or right axilla is used for Local Tolerability analysis.

PAGE: 7 of 12
PROGRAM: t080 (OUTPUT: t14_03_04_18_lt_mean)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Table 14.3.4-18 より改変

表 2.7.4-58　局所忍容性の基本統計量（BBI-4000-07 試験）（続き）
（Safety Analysis Set）

	Cohort 1 (0%/5%) N=94	Cohort 1 (5%/5%) N=91	Total N=185
Week 8			
n	93	86	179
Mean (SD)	0.2 (0.66)	0.3 (0.66)	0.2 (0.66)
Median	0.0	0.0	0.0
Min , Max	0 , 3	0 , 4	0 , 4
Week 12			
n	94	85	179
Mean (SD)	0.4 (0.88)	0.4 (0.84)	0.4 (0.86)
Median	0.0	0.0	0.0
Min , Max	0 , 4	0 , 4	0 , 4
Week 16			
n	91	85	176
Mean (SD)	0.3 (0.71)	0.3 (0.67)	0.3 (0.69)
Median	0.0	0.0	0.0
Min , Max	0 , 3	0 , 3	0 , 3

Local tolerability score is defined as below.
0 : Absent, 1 : Minimal, 2 : Mild, 3 : Moderate, 4 : Severe
The greater result of left axilla or right axilla is used for Local Tolerability analysis.

PAGE: 8 of 12
PROGRAM: t080 (OUTPUT: t14_03_04_18_lt_mean)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Table 14.3.4-18 より改変

表 2.7.4-58　局所忍容性の基本統計量（BBI-4000-07 試験）（続き）
（Safety Analysis Set）

	Cohort 1 (0%/5%) N=94	Cohort 1 (5%/5%) N=91	Total N=185
Week 20			
n	91	85	176
Mean (SD)	0.4 (0.80)	0.2 (0.55)	0.3 (0.69)
Median	0.0	0.0	0.0
Min , Max	0 , 4	0 , 2	0 , 4
Week 24			
n	90	86	176
Mean (SD)	0.3 (0.81)	0.3 (0.56)	0.3 (0.70)
Median	0.0	0.0	0.0
Min , Max	0 , 4	0 , 2	0 , 4
Week 28			
n	90	85	175
Mean (SD)	0.3 (0.77)	0.4 (0.68)	0.3 (0.73)
Median	0.0	0.0	0.0
Min , Max	0 , 4	0 , 3	0 , 4

Local tolerability score is defined as below.
0 : Absent, 1 : Minimal, 2 : Mild, 3 : Moderate, 4 : Severe
The greater result of left axilla or right axilla is used for Local Tolerability analysis.

PAGE: 9 of 12
PROGRAM: t080 (OUTPUT: t14_03_04_18_lt_mean)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Table 14.3.4-18 より改変

表 2.7.4-58 局所忍容性の基本統計量（BBI-4000-07 試験）（続き）
（Safety Analysis Set）

	Cohort 1 (0%/5%) N=94	Cohort 1 (5%/5%) N=91	Total N=185
Week 32			
n	89	83	172
Mean (SD)	0.3 (0.71)	0.4 (0.74)	0.3 (0.72)
Median	0.0	0.0	0.0
Min , Max	0 , 3	0 , 3	0 , 3
Week 36			
n	87	80	167
Mean (SD)	0.3 (0.78)	0.3 (0.78)	0.3 (0.78)
Median	0.0	0.0	0.0
Min , Max	0 , 4	0 , 4	0 , 4
Week 40			
n	85	78	163
Mean (SD)	0.3 (0.82)	0.3 (0.60)	0.3 (0.72)
Median	0.0	0.0	0.0
Min , Max	0 , 4	0 , 2	0 , 4

Local tolerability score is defined as below.
0 : Absent, 1 : Minimal, 2 : Mild, 3 : Moderate, 4 : Severe
The greater result of left axilla or right axilla is used for Local Tolerability analysis.

PAGE: 10 of 12
PROGRAM: t080 (OUTPUT: t14_03_04_18_lt_mean)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Table 14.3.4-18 より改変

表 2.7.4-58　局所忍容性の基本統計量（BBI-4000-07 試験）（続き）
（Safety Analysis Set）

	Cohort 1 (0%/5%) N=94	Cohort 1 (5%/5%) N=91	Total N=185
Week 44			
n	87	76	163
Mean (SD)	0.3 (0.83)	0.3 (0.68)	0.3 (0.76)
Median	0.0	0.0	0.0
Min , Max	0 , 3	0 , 3	0 , 3
Week 48			
n	86	76	162
Mean (SD)	0.3 (0.90)	0.3 (0.60)	0.3 (0.77)
Median	0.0	0.0	0.0
Min , Max	0 , 4	0 , 2	0 , 4
Week 52			
n	85	75	160
Mean (SD)	0.3 (0.88)	0.3 (0.56)	0.3 (0.75)
Median	0.0	0.0	0.0
Min , Max	0 , 4	0 , 2	0 , 4

Local tolerability score is defined as below.
0 : Absent, 1 : Minimal, 2 : Mild, 3 : Moderate, 4 : Severe
The greater result of left axilla or right axilla is used for Local Tolerability analysis.

PAGE: 11 of 12
PROGRAM: t080 (OUTPUT: t14_03_04_18_lt_mean)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Table 14.3.4-18 より改変

表 2.7.4-58　局所忍容性の基本統計量（BBI-4000-07 試験）（続き）
（Safety Analysis Set）

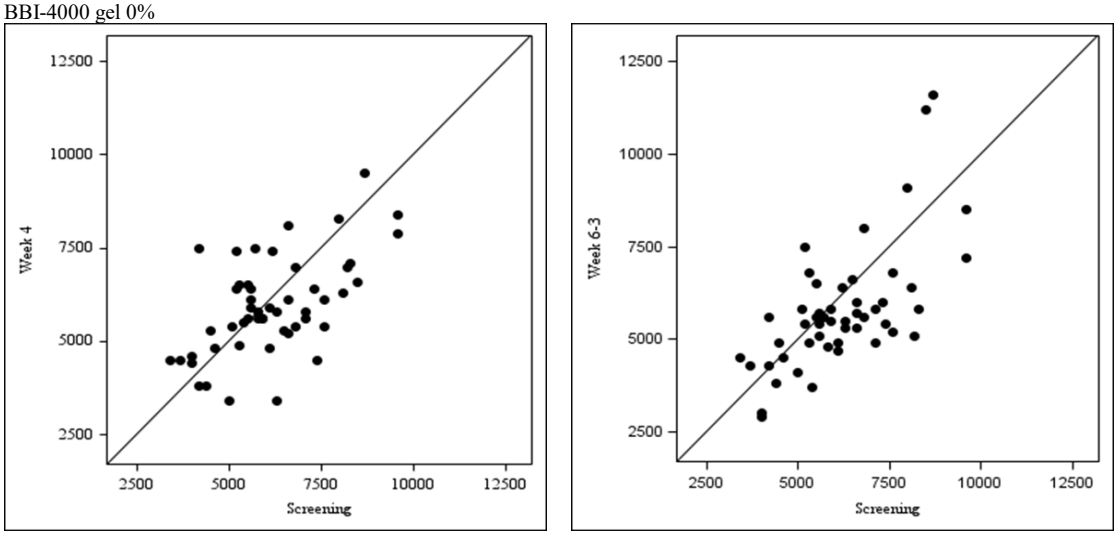
	Cohort 1 (0%/5%) N=94	Cohort 1 (5%/5%) N=91	Total N=185
Follow-up			
n	85	74	159
Mean (SD)	0.1 (0.40)	0.1 (0.25)	0.1 (0.34)
Median	0.0	0.0	0.0
Min , Max	0 , 3	0 , 1	0 , 3

Local tolerability score is defined as below.
0 : Absent, 1 : Minimal, 2 : Mild, 3 : Moderate, 4 : Severe
The greater result of left axilla or right axilla is used for Local Tolerability analysis.

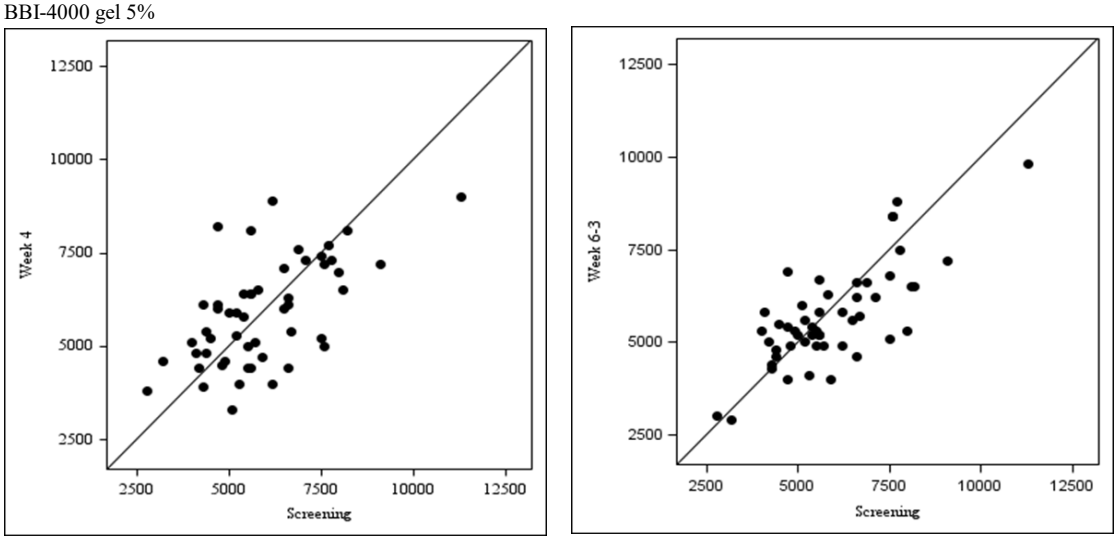
PAGE: 12 of 12
PROGRAM: t080 (OUTPUT: t14_03_04_18_lt_mean)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Table 14.3.4-18 より改変

図 2.7.4-1　臨床検査値の散布図（BBI-4000-04 試験）
Leukocytes (/uL)
[Safety]

BBI-4000 gel 0%



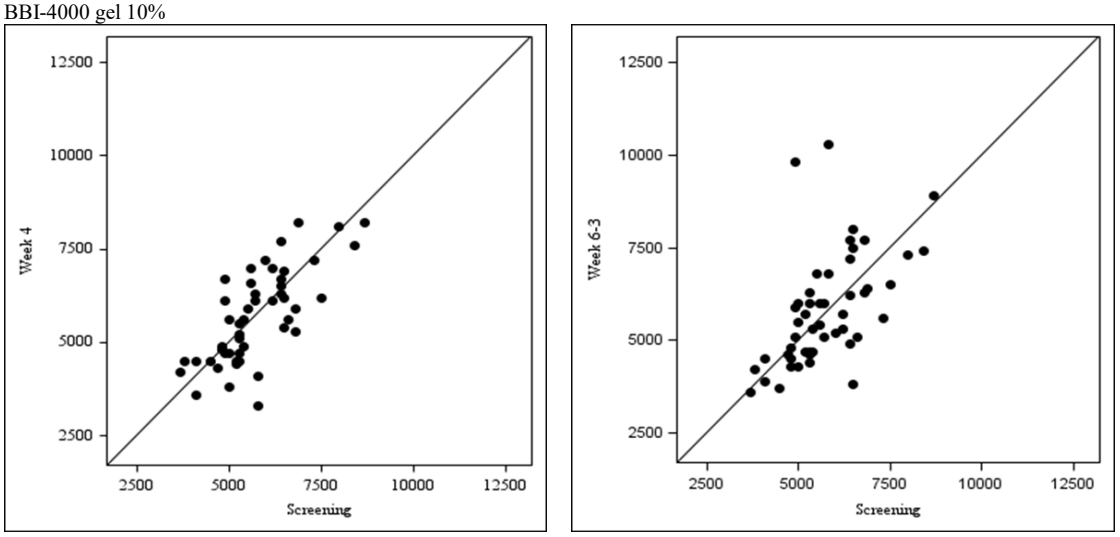
BBI-4000 gel 5%



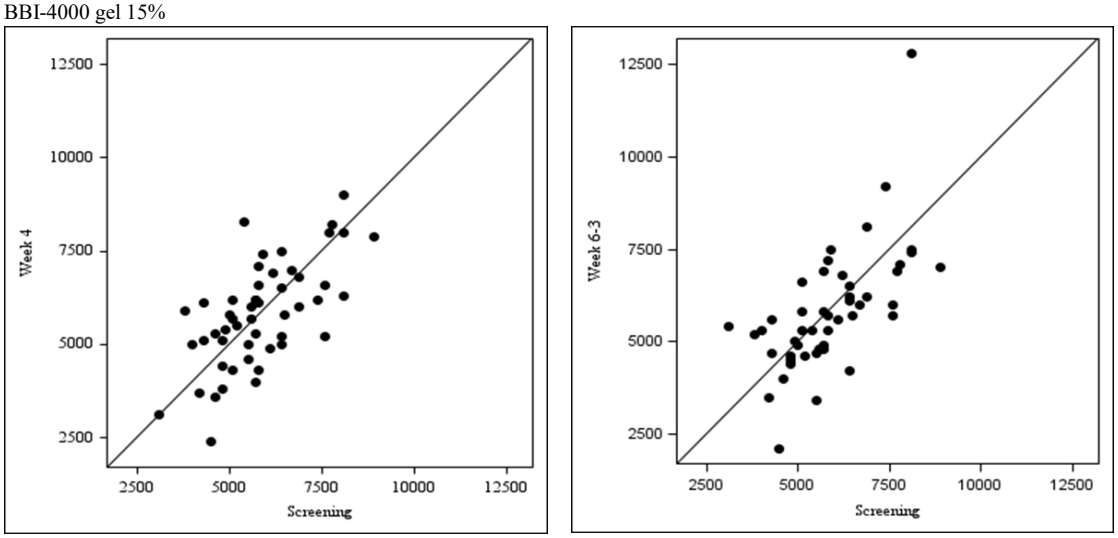
Source：5.3.5.1-1 Figure 14.3.4-1 より改変

図 2.7.4-1　臨床検査値の散布図（BBI-4000-04 試験）（続き）
Leukocytes (/uL)
[Safety]

BBI-4000 gel 10%



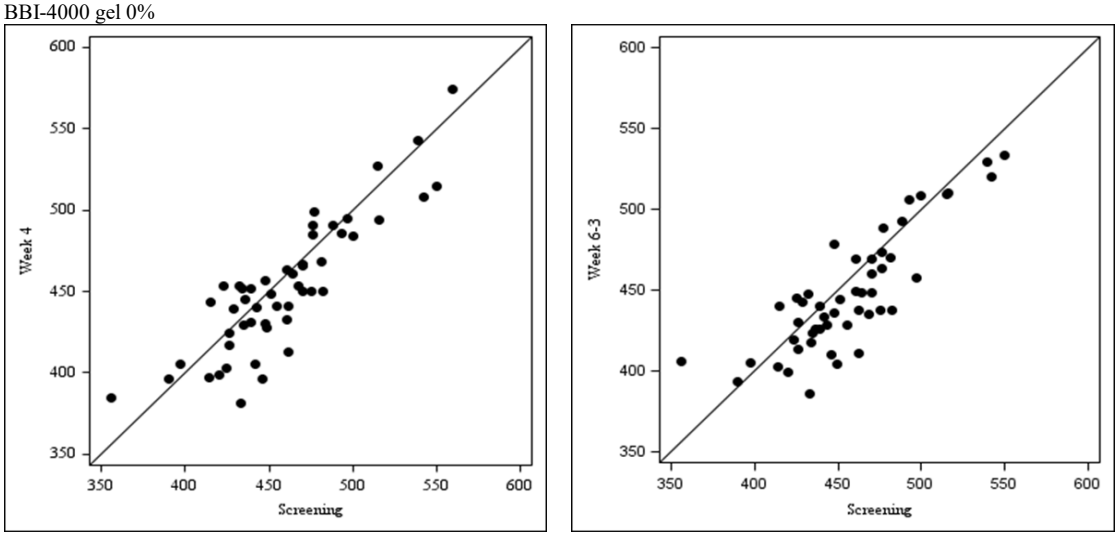
BBI-4000 gel 15%



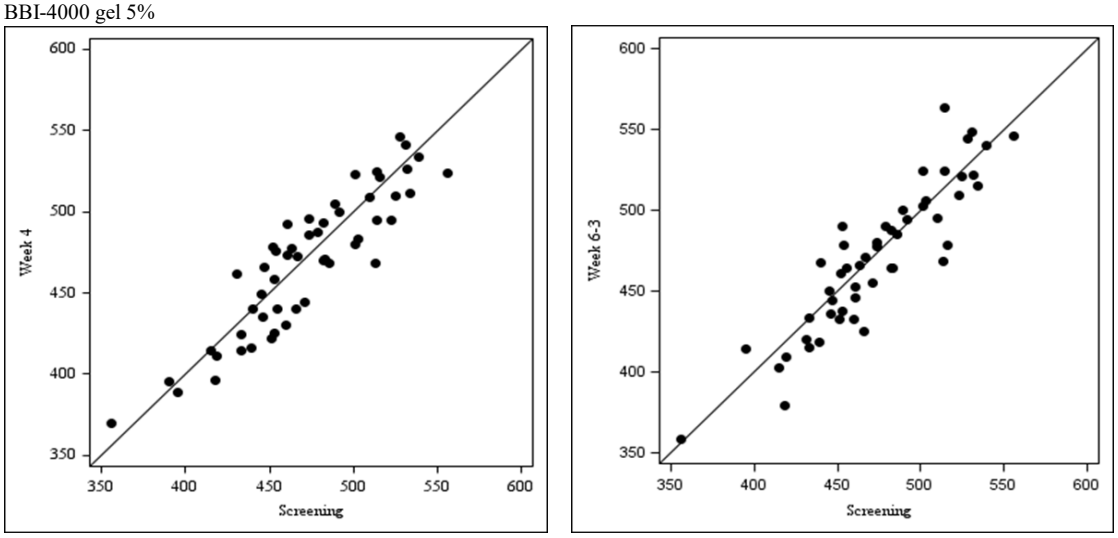
Source：5.3.5.1-1 Figure 14.3.4-1 より改変

図 2.7.4-1　臨床検査値の散布図（BBI-4000-04 試験）（続き）
Erythrocytes (x10^4/uL)
[Safety]

BBI-4000 gel 0%



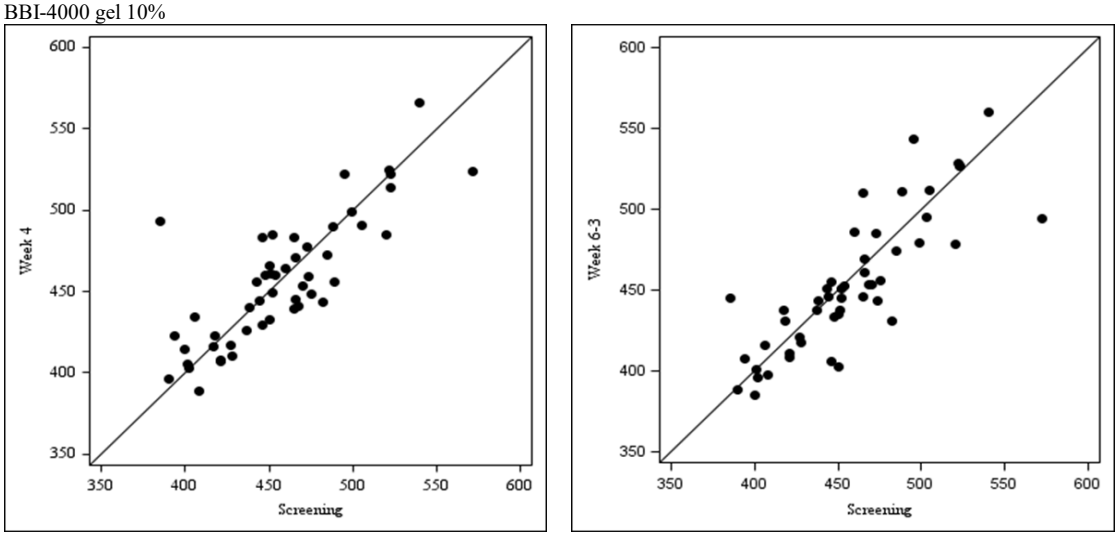
BBI-4000 gel 5%



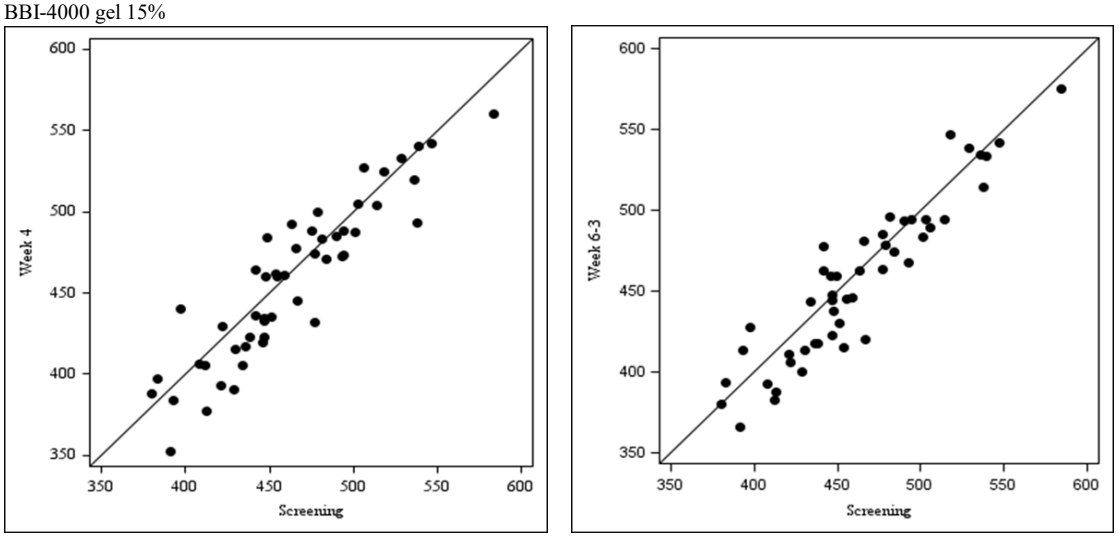
Source：5.3.5.1-1 Figure 14.3.4-1 より改変

図 2.7.4-1　臨床検査値の散布図（BBI-4000-04 試験）（続き）
Erythrocytes (x10^4/uL)
[Safety]

BBI-4000 gel 10%



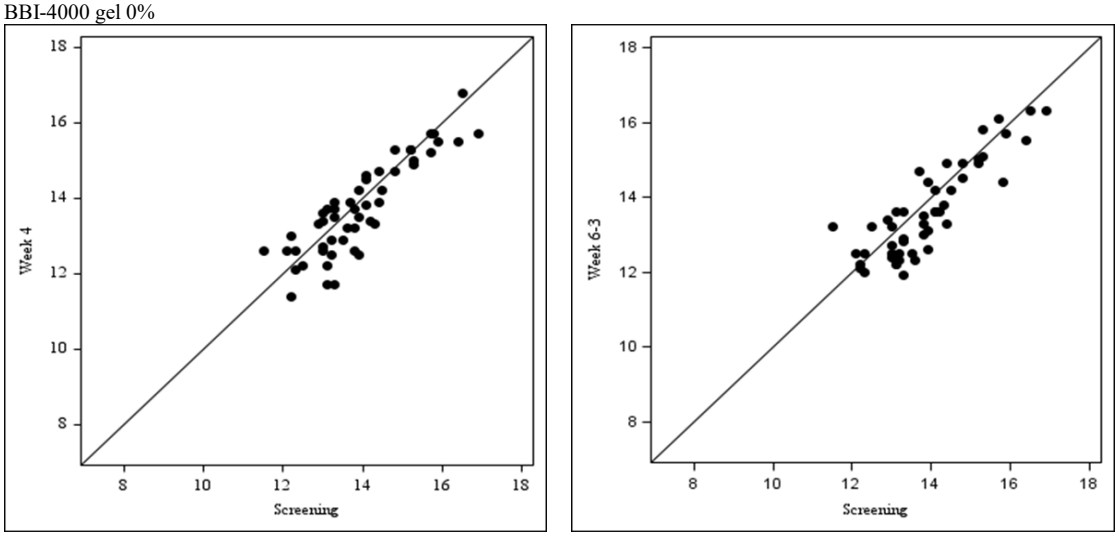
BBI-4000 gel 15%



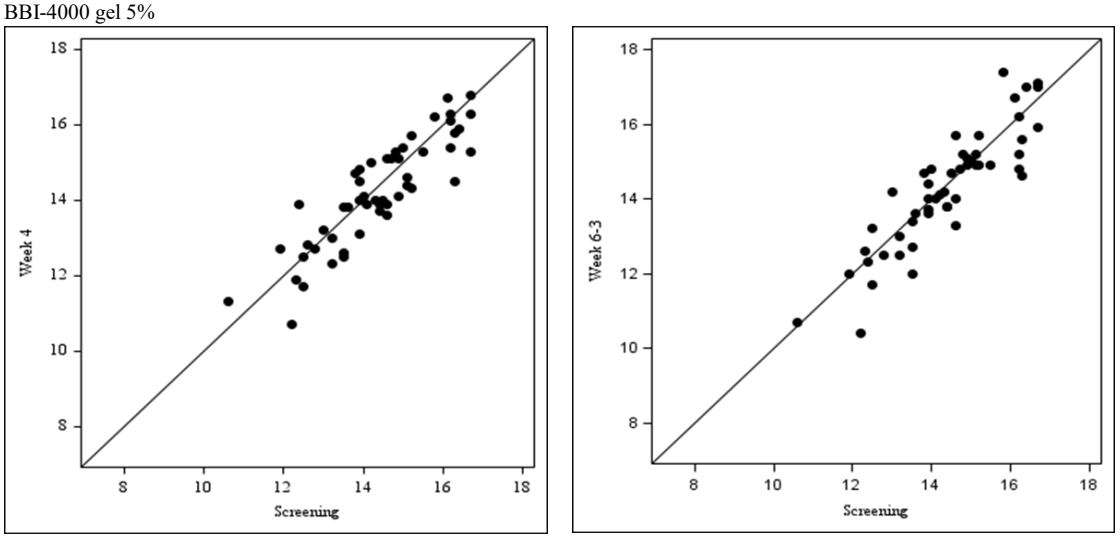
Source：5.3.5.1-1 Figure 14.3.4-1 より改変

図 2.7.4-1　臨床検査値の散布図（BBI-4000-04 試験）（続き）
Hemoglobin (g/dL)
[Safety]

BBI-4000 gel 0%



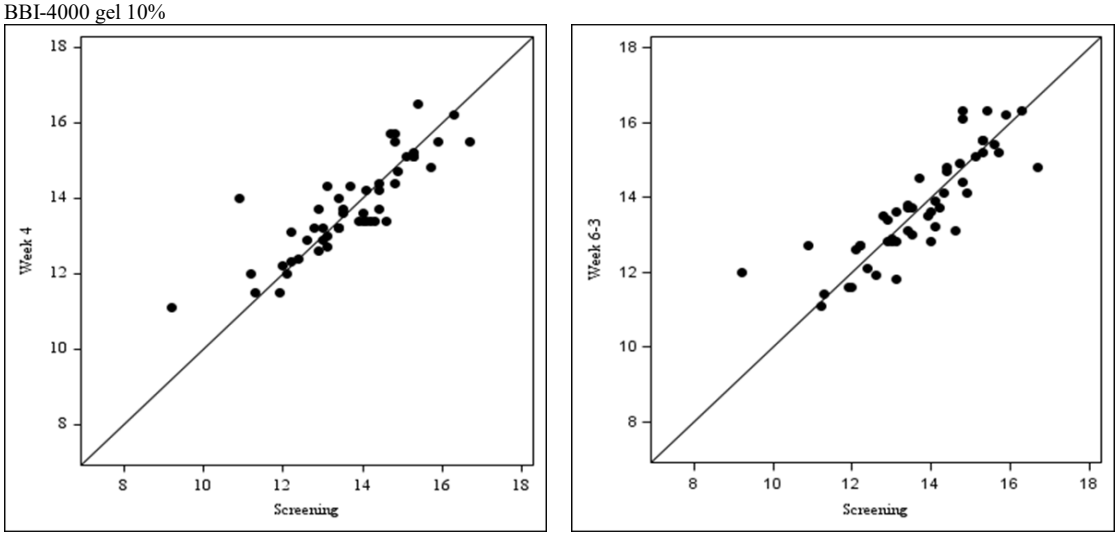
BBI-4000 gel 5%



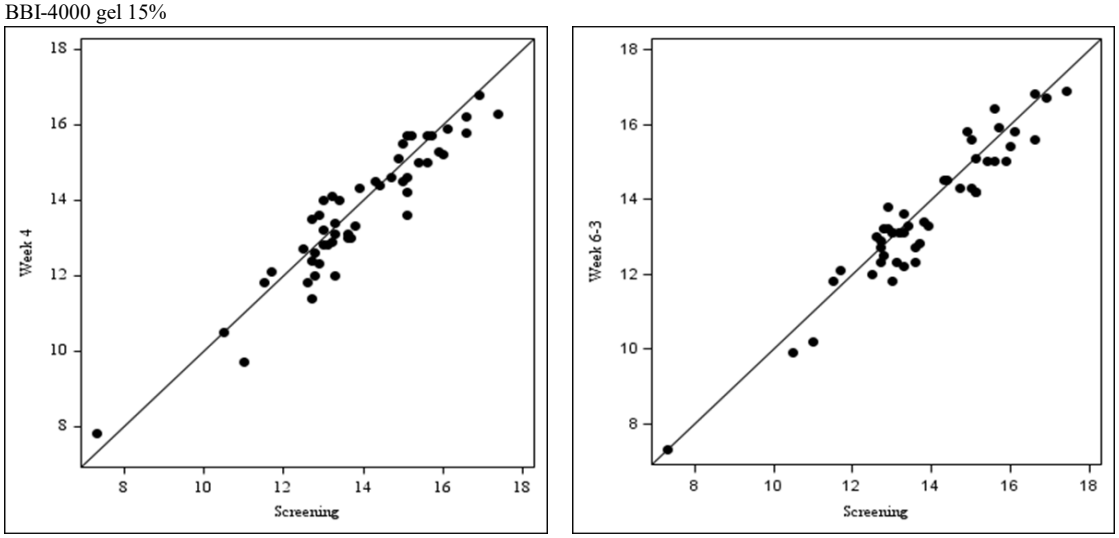
Source：5.3.5.1-1 Figure 14.3.4-1 より改変

図 2.7.4-1　臨床検査値の散布図（BBI-4000-04 試験）（続き）
Hemoglobin (g/dL)
[Safety]

BBI-4000 gel 10%



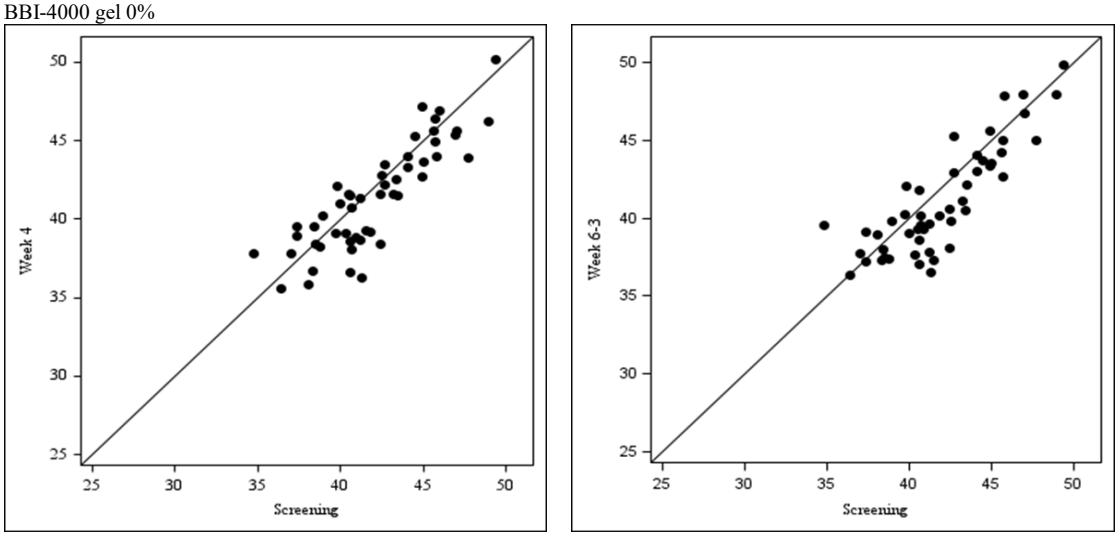
BBI-4000 gel 15%



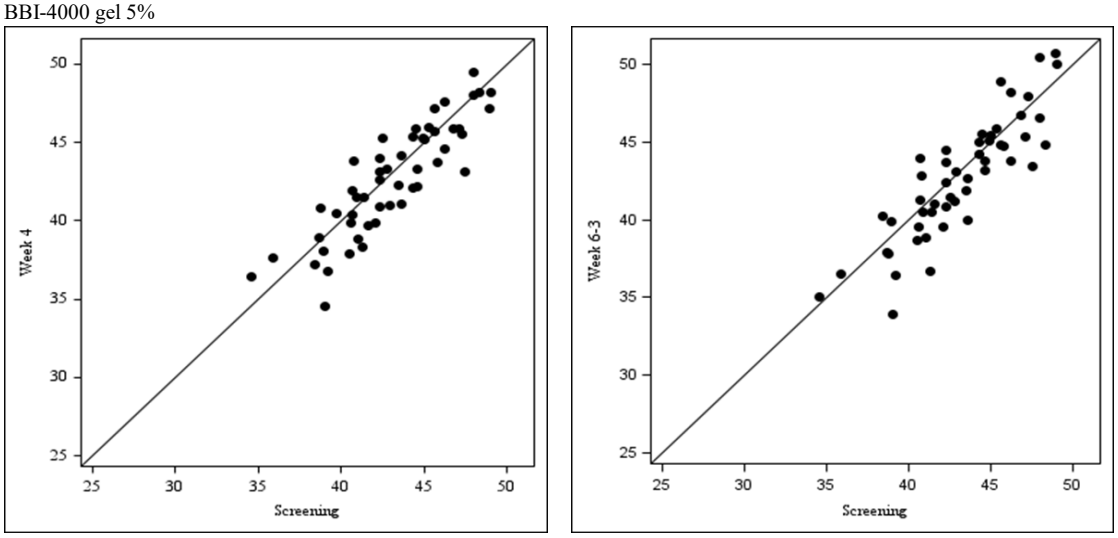
Source：5.3.5.1-1 Figure 14.3.4-1 より改変

図 2.7.4-1　臨床検査値の散布図（BBI-4000-04 試験）（続き）
Hematocrit (%)
[Safety]

BBI-4000 gel 0%



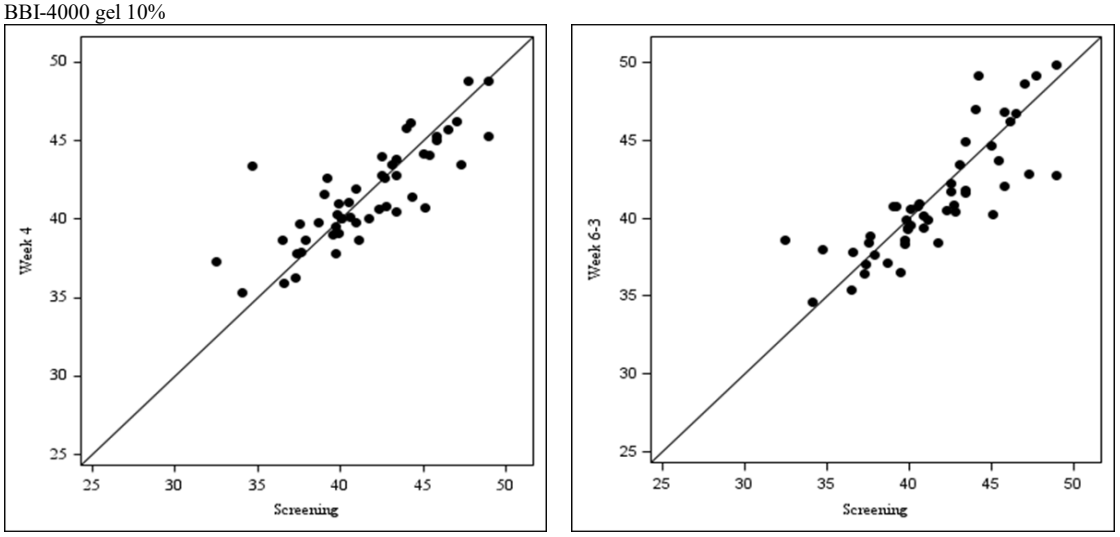
BBI-4000 gel 5%



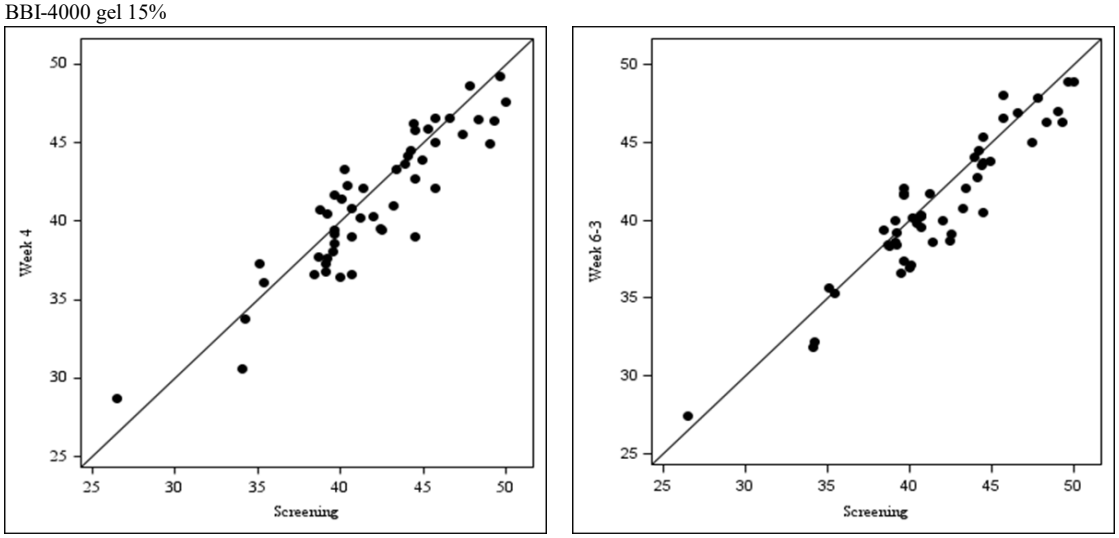
Source：5.3.5.1-1 Figure 14.3.4-1 より改変

図 2.7.4-1　臨床検査値の散布図（BBI-4000-04 試験）（続き）
Hematocrit (%)
[Safety]

BBI-4000 gel 10%



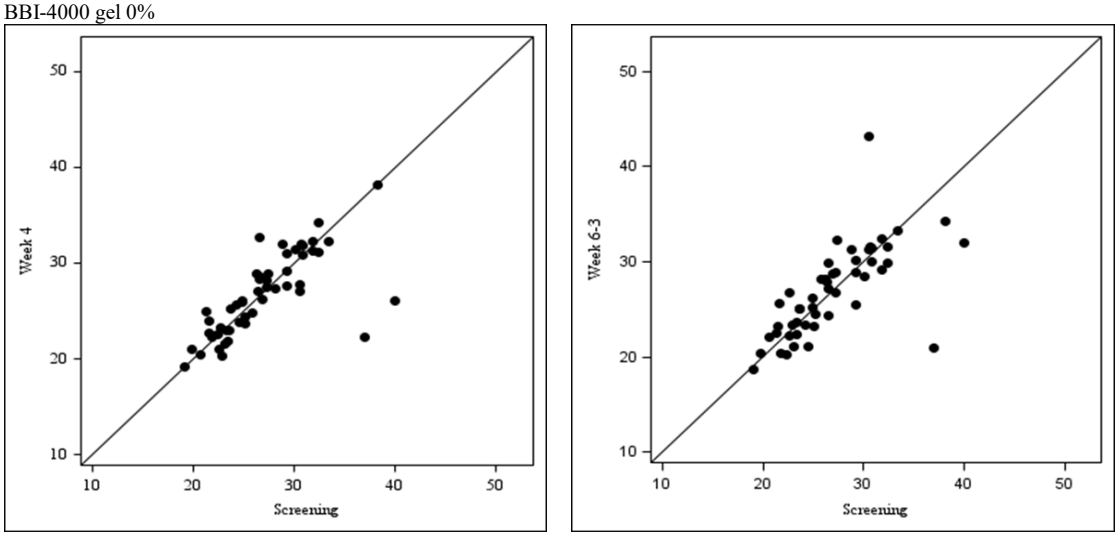
BBI-4000 gel 15%



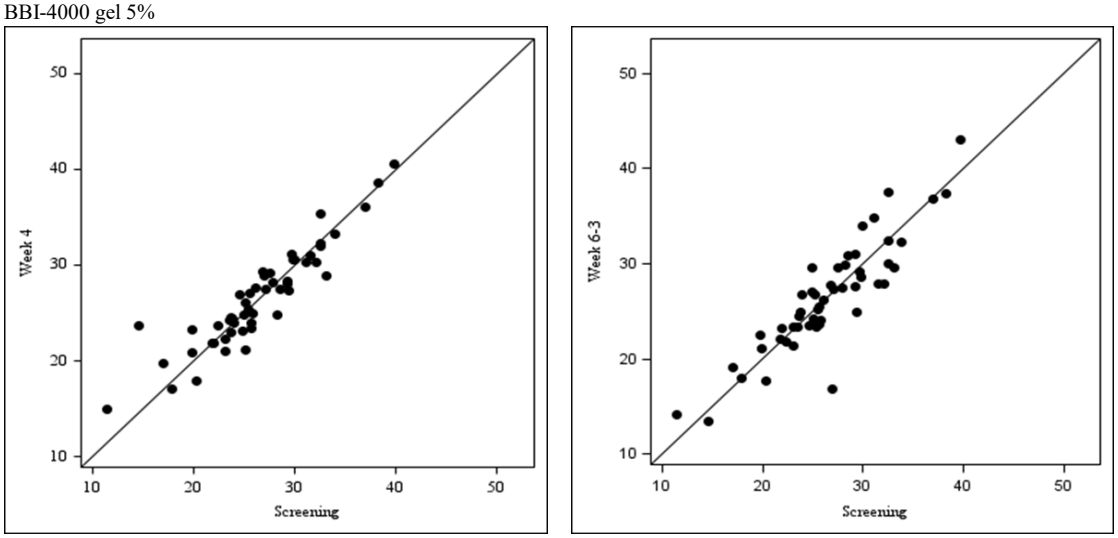
Source：5.3.5.1-1 Figure 14.3.4-1 より改変

図 2.7.4-1　臨床検査値の散布図（BBI-4000-04 試験）（続き）
Platelets (x10^4/uL)
[Safety]

BBI-4000 gel 0%



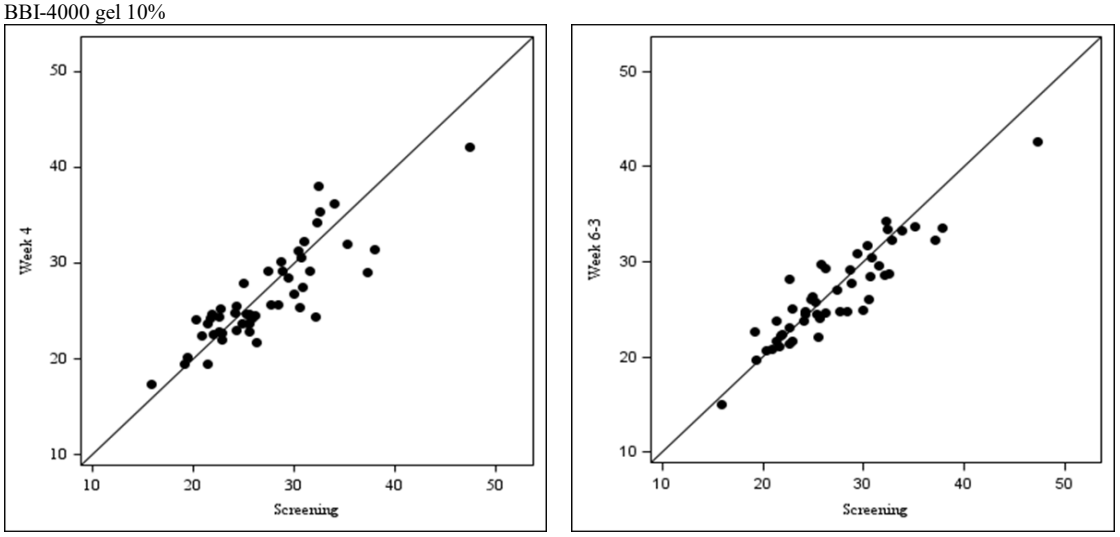
BBI-4000 gel 5%



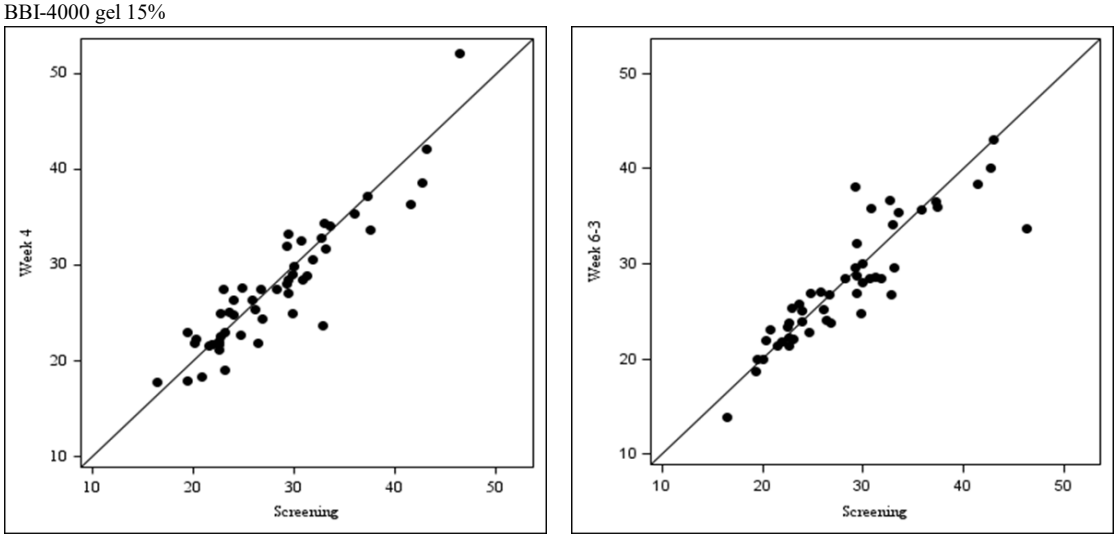
Source：5.3.5.1-1 Figure 14.3.4-1 より改変

図 2.7.4-1　臨床検査値の散布図（BBI-4000-04 試験）（続き）
Platelets (x10^4/uL)
[Safety]

BBI-4000 gel 10%



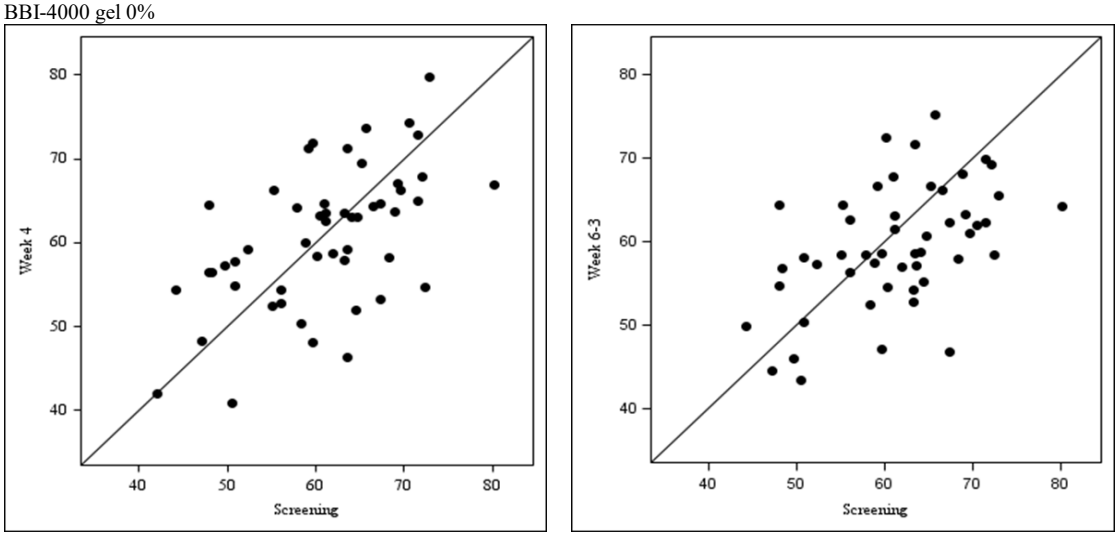
BBI-4000 gel 15%



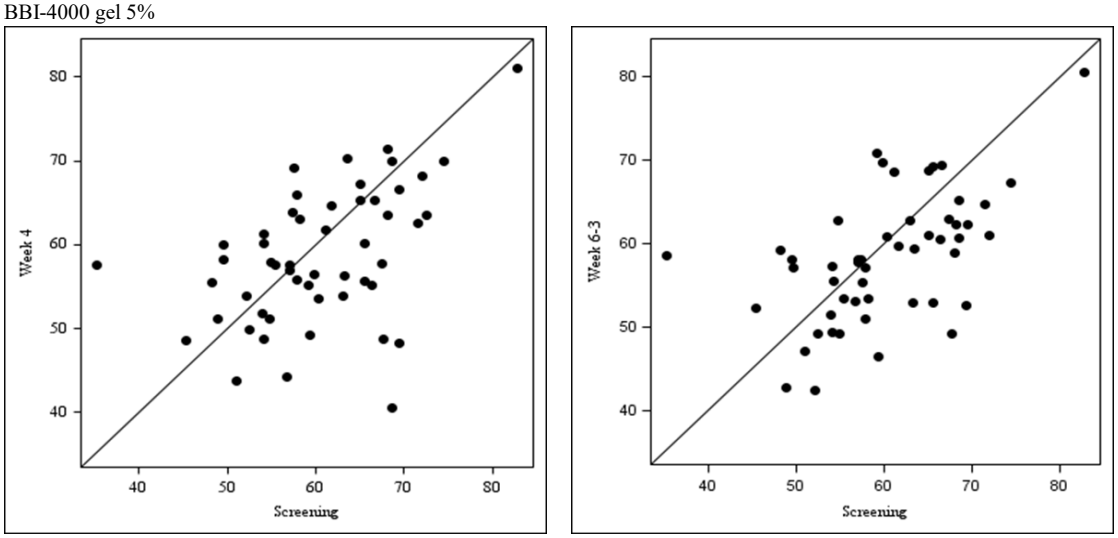
Source：5.3.5.1-1 Figure 14.3.4-1 より改変

図 2.7.4-1　臨床検査値の散布図（BBI-4000-04 試験）（続き）
Neutrophils/Leukocytes (%)
[Safety]

BBI-4000 gel 0%



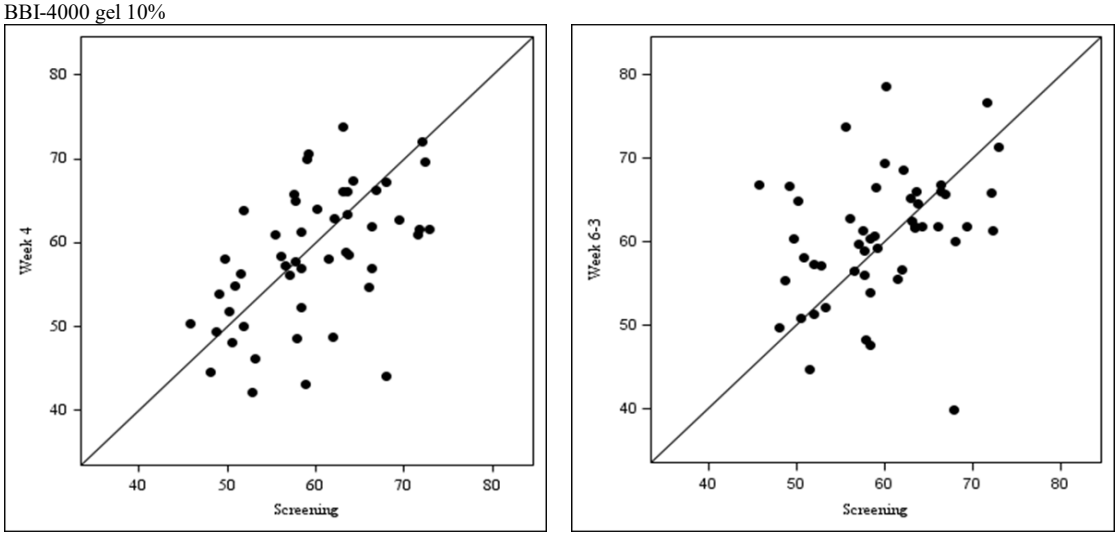
BBI-4000 gel 5%



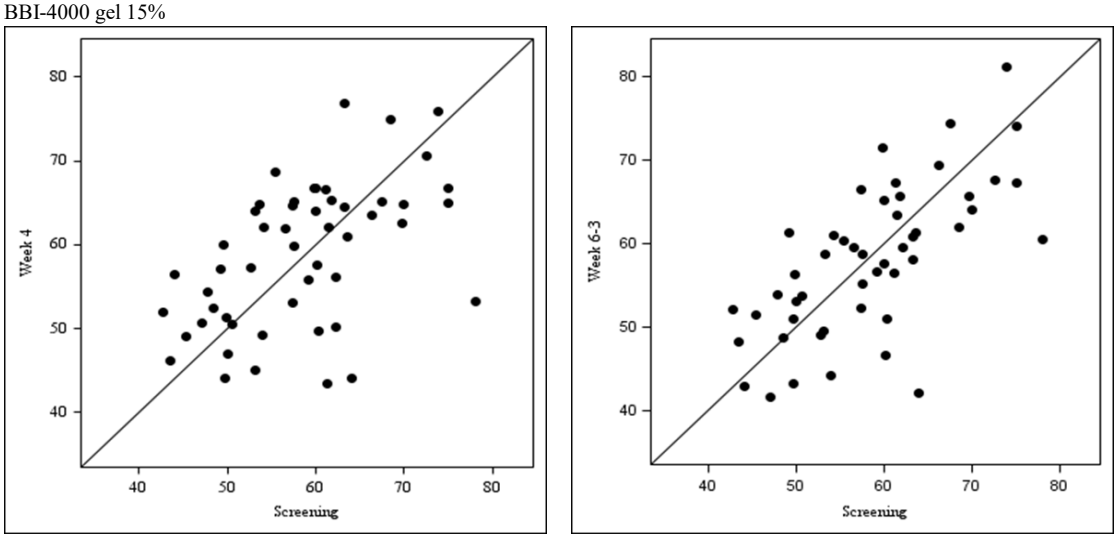
Source：5.3.5.1-1 Figure 14.3.4-1 より改変

図 2.7.4-1　臨床検査値の散布図（BBI-4000-04 試験）（続き）
Neutrophils/Leukocytes (%)
[Safety]

BBI-4000 gel 10%



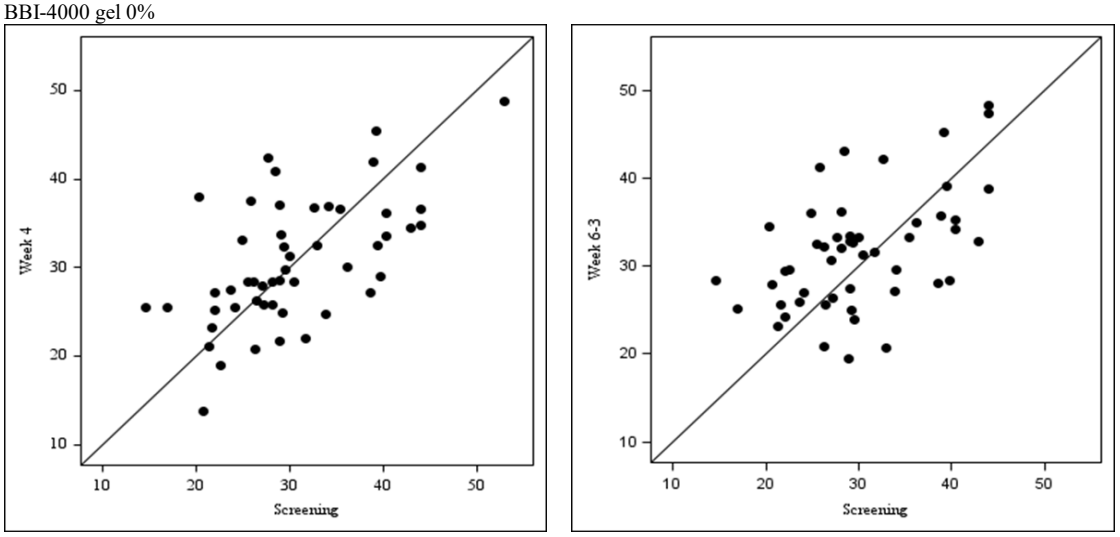
BBI-4000 gel 15%



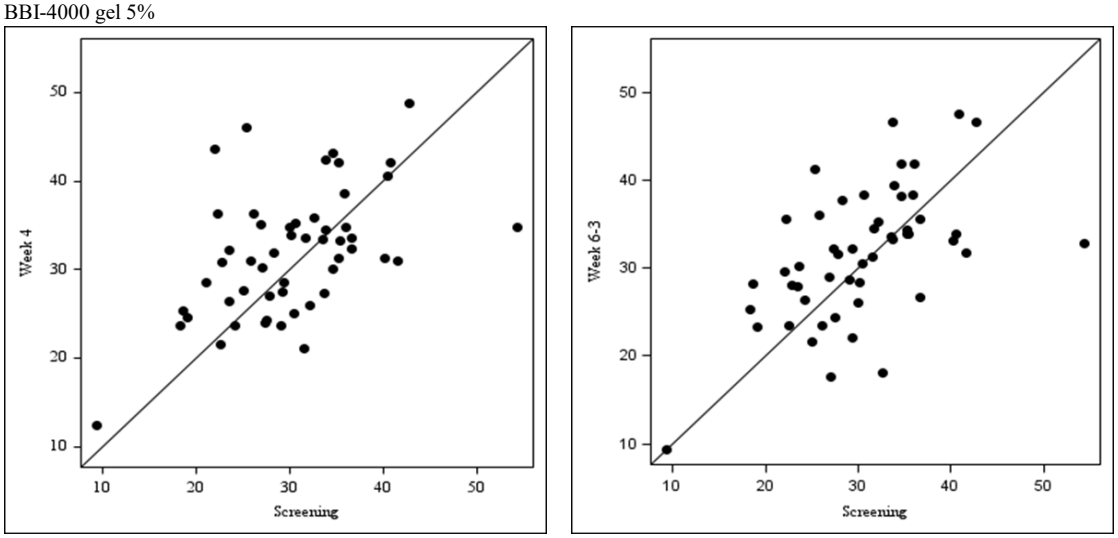
Source：5.3.5.1-1 Figure 14.3.4-1 より改変

図 2.7.4-1　臨床検査値の散布図（BBI-4000-04 試験）（続き）
Lymphocytes/Leukocytes (%)
[Safety]

BBI-4000 gel 0%



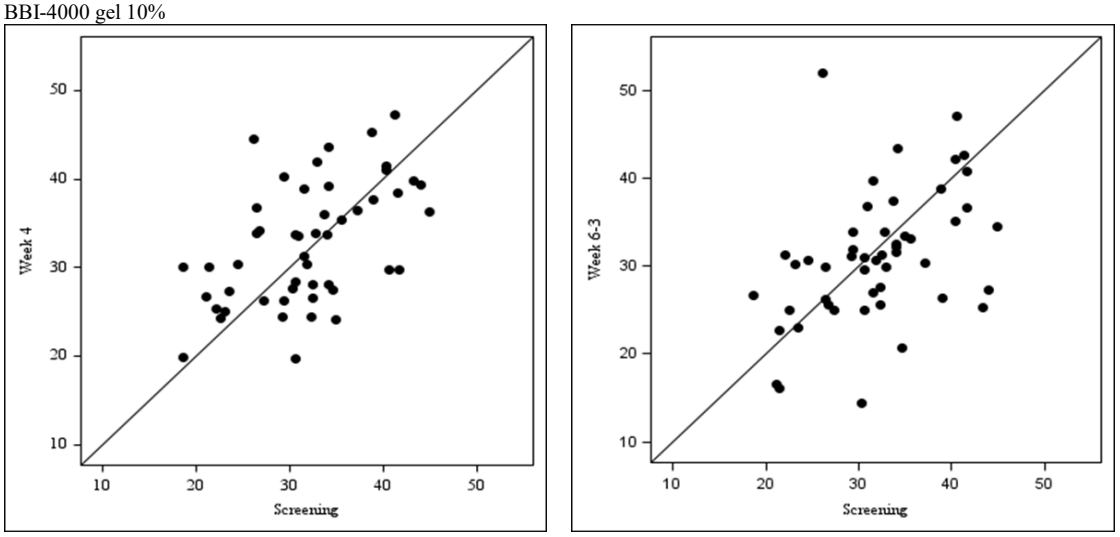
BBI-4000 gel 5%



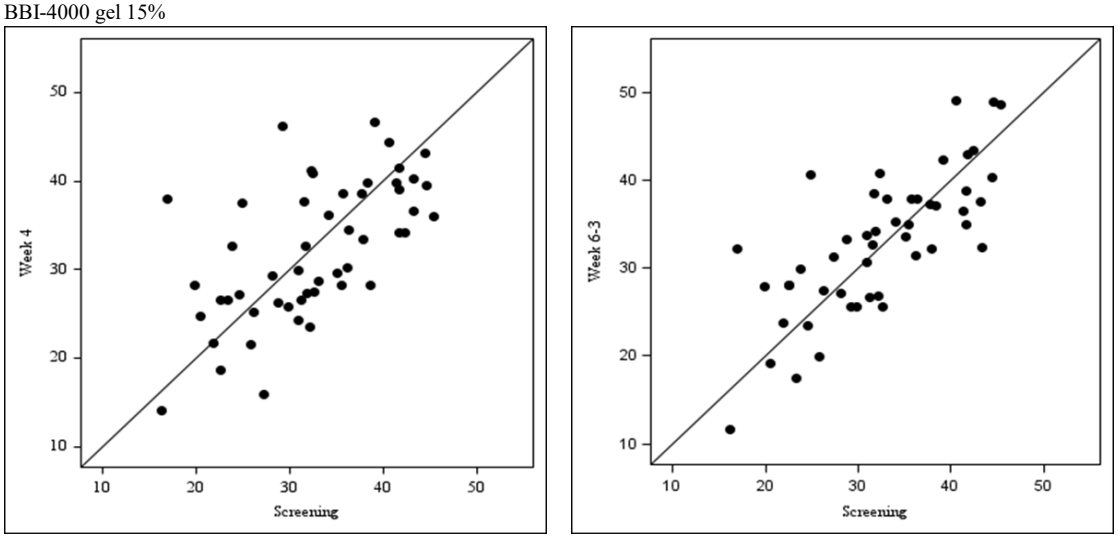
Source：5.3.5.1-1 Figure 14.3.4-1 より改変

図 2.7.4-1　臨床検査値の散布図（BBI-4000-04 試験）（続き）
Lymphocytes/Leukocytes (%)
[Safety]

BBI-4000 gel 10%



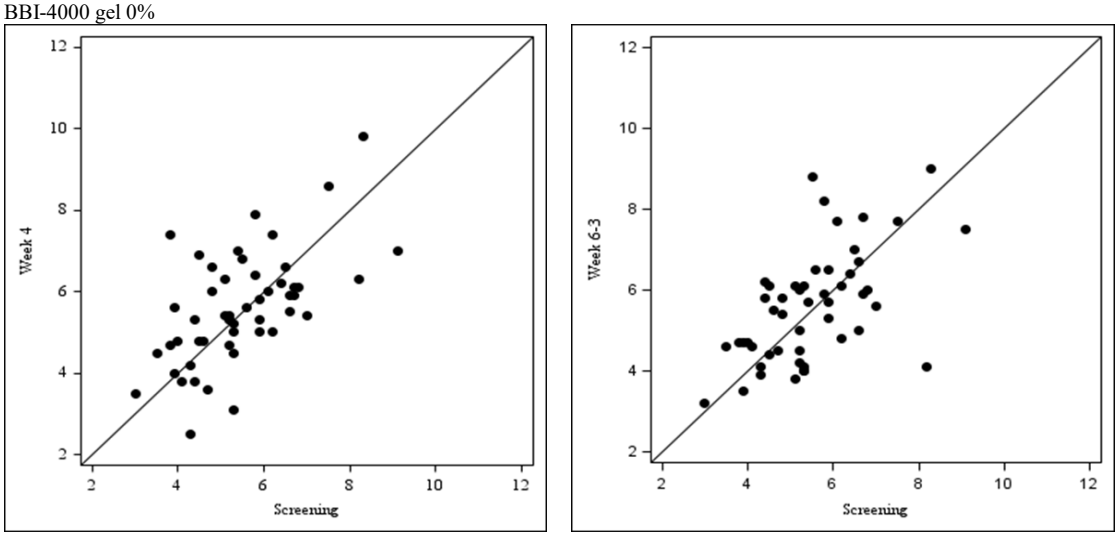
BBI-4000 gel 15%



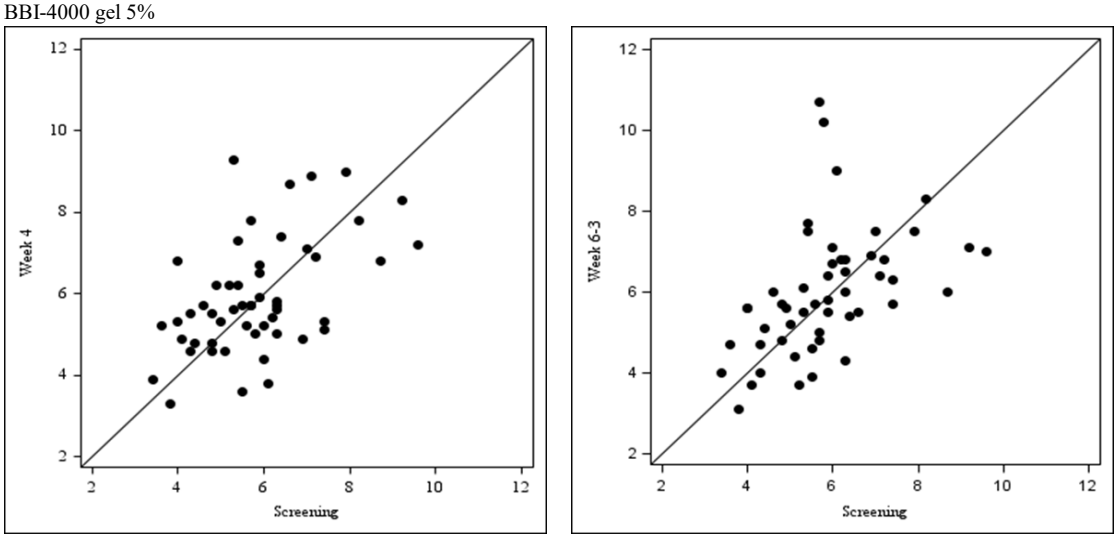
Source：5.3.5.1-1 Figure 14.3.4-1 より改変

図 2.7.4-1　臨床検査値の散布図（BBI-4000-04 試験）（続き）
Monocytes/Leukocytes (%)
[Safety]

BBI-4000 gel 0%



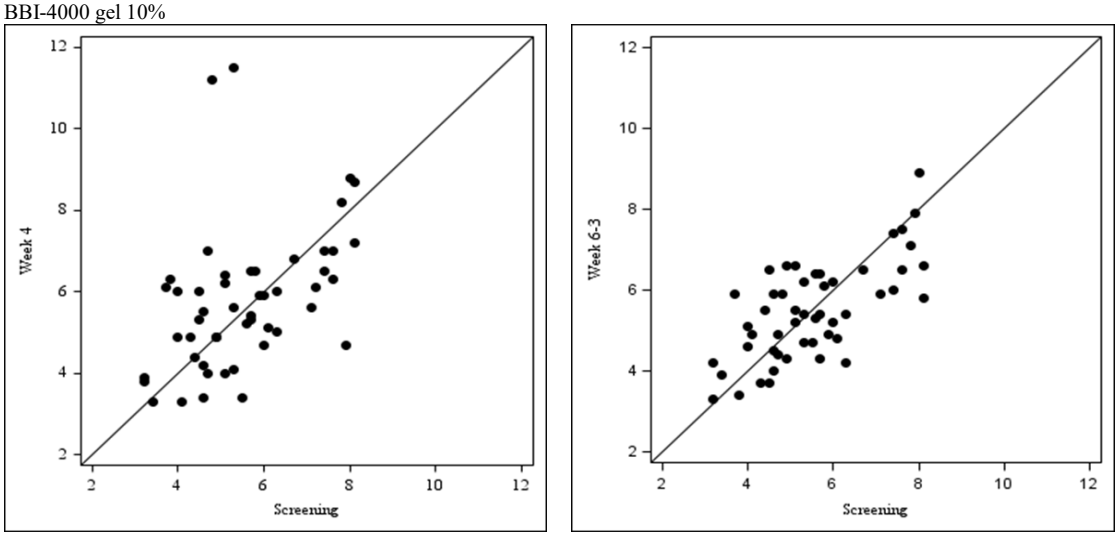
BBI-4000 gel 5%



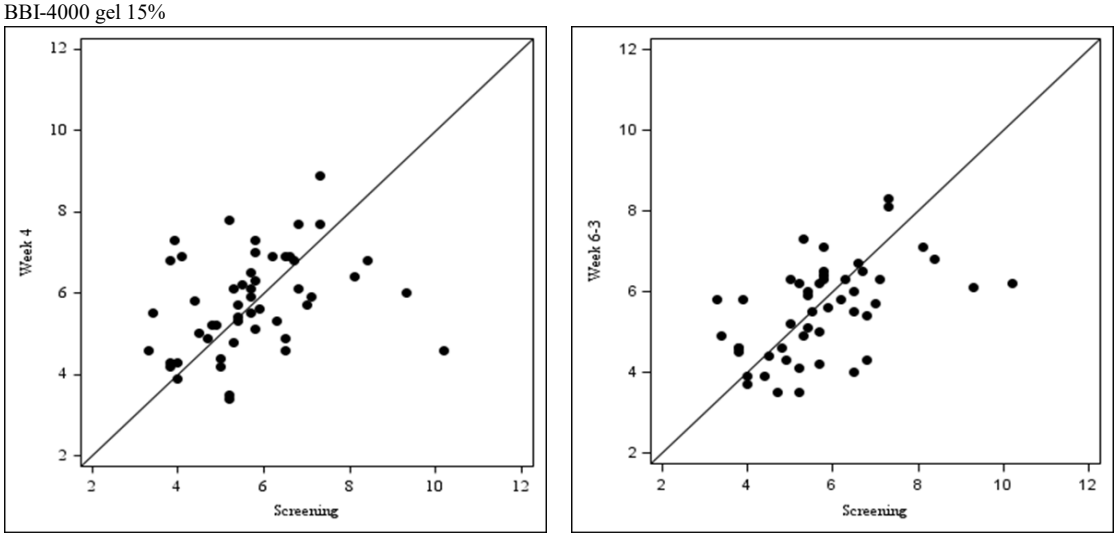
Source：5.3.5.1-1 Figure 14.3.4-1 より改変

図 2.7.4-1　臨床検査値の散布図（BBI-4000-04 試験）（続き）
Monocytes/Leukocytes (%)
[Safety]

BBI-4000 gel 10%



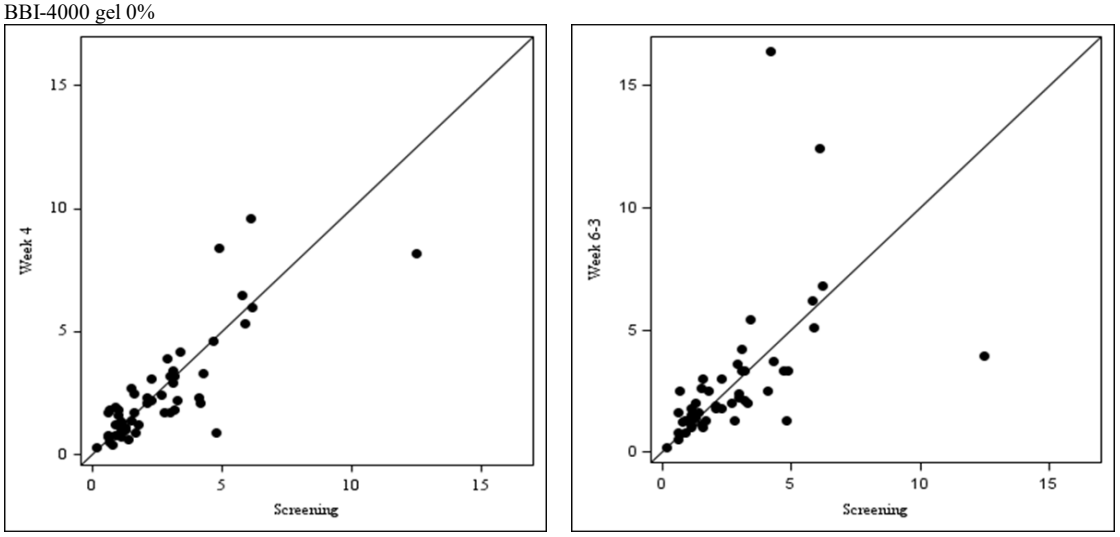
BBI-4000 gel 15%



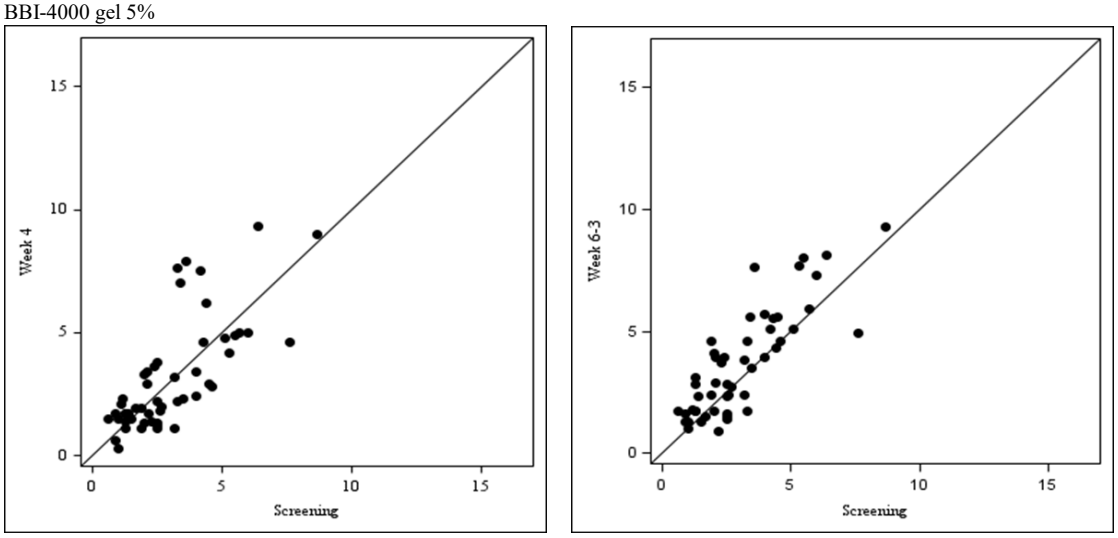
Source：5.3.5.1-1 Figure 14.3.4-1 より改変

図 2.7.4-1　臨床検査値の散布図（BBI-4000-04 試験）（続き）
Eosinophils/Leukocytes (%)
[Safety]

BBI-4000 gel 0%



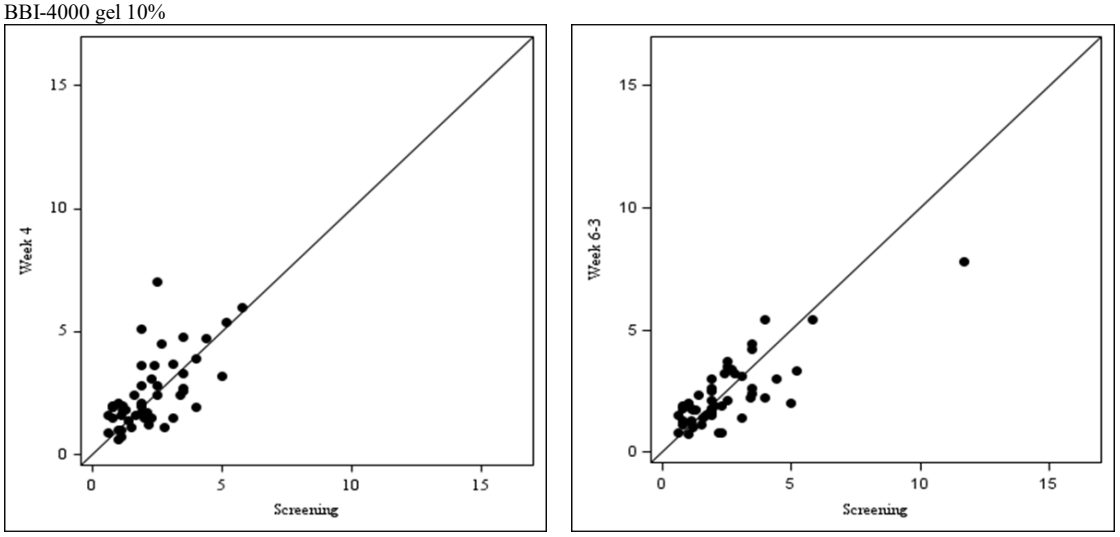
BBI-4000 gel 5%



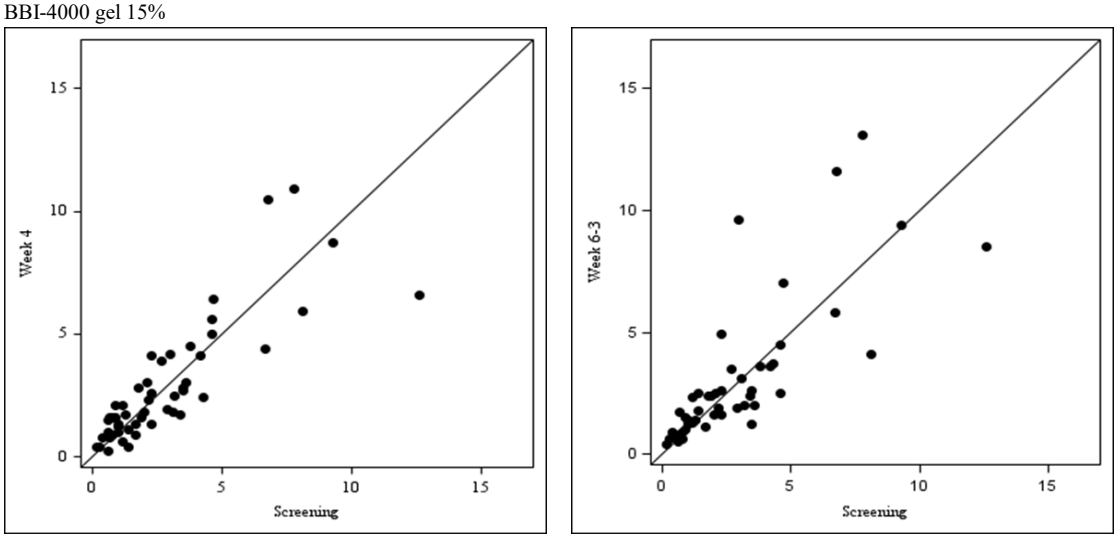
Source：5.3.5.1-1 Figure 14.3.4-1 より改変

図 2.7.4-1　臨床検査値の散布図（BBI-4000-04 試験）（続き）
Eosinophils/Leukocytes (%)
[Safety]

BBI-4000 gel 10%



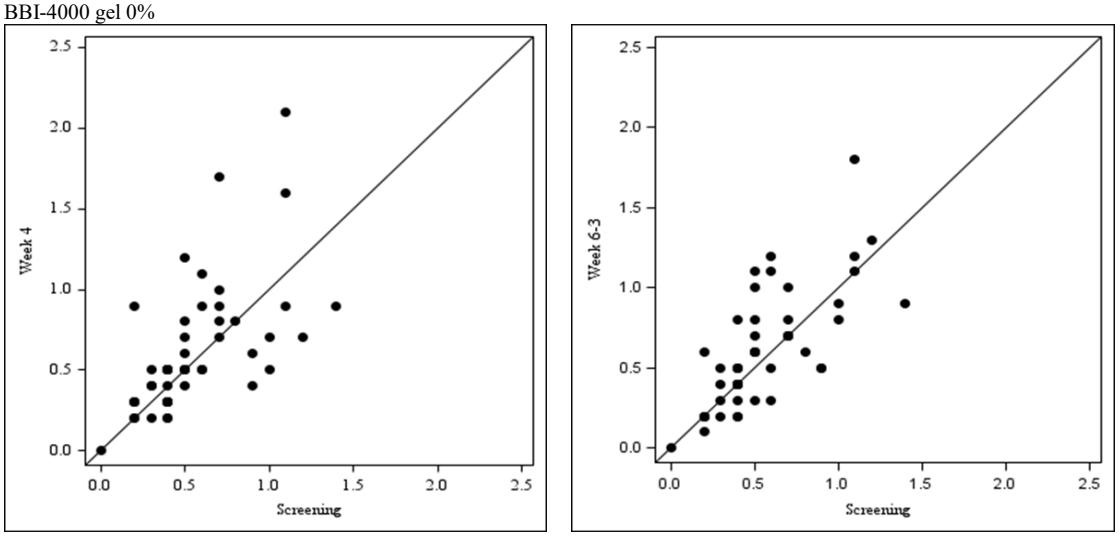
BBI-4000 gel 15%



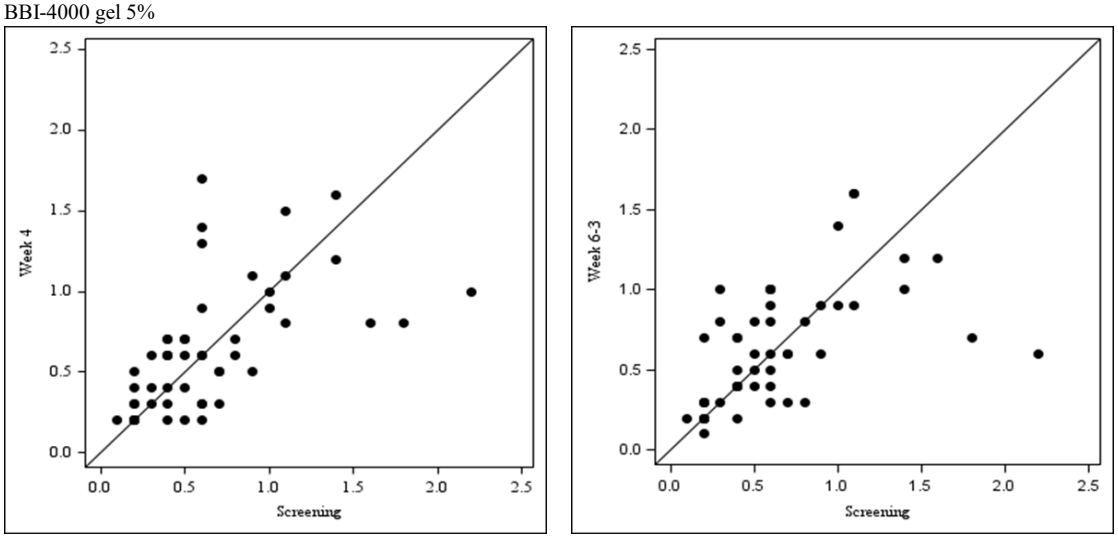
Source：5.3.5.1-1 Figure 14.3.4-1 より改変

図 2.7.4-1 臨床検査値の散布図（BBI-4000-04 試験）（続き）
Basophils/Leukocytes (%)
[Safety]

BBI-4000 gel 0%



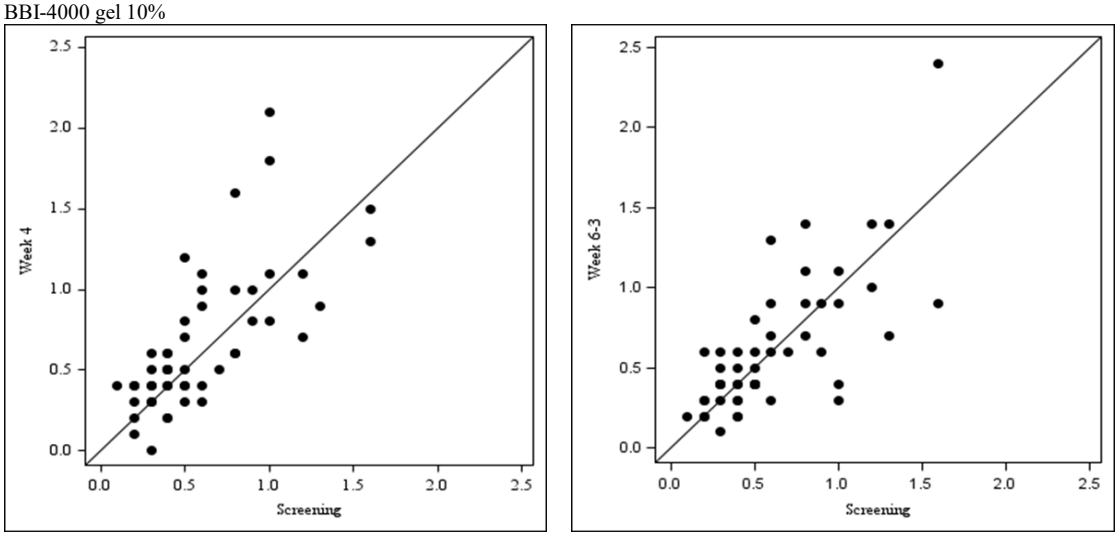
BBI-4000 gel 5%



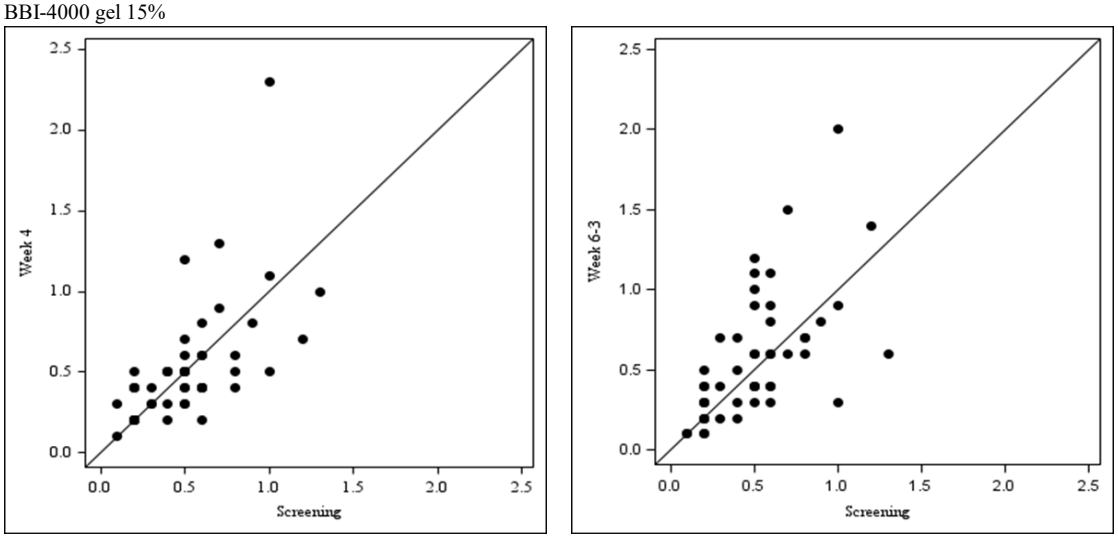
Source：5.3.5.1-1 Figure 14.3.4-1 より改変

図 2.7.4-1 臨床検査値の散布図（BBI-4000-04 試験）（続き）
Basophils/Leukocytes (%)
[Safety]

BBI-4000 gel 10%



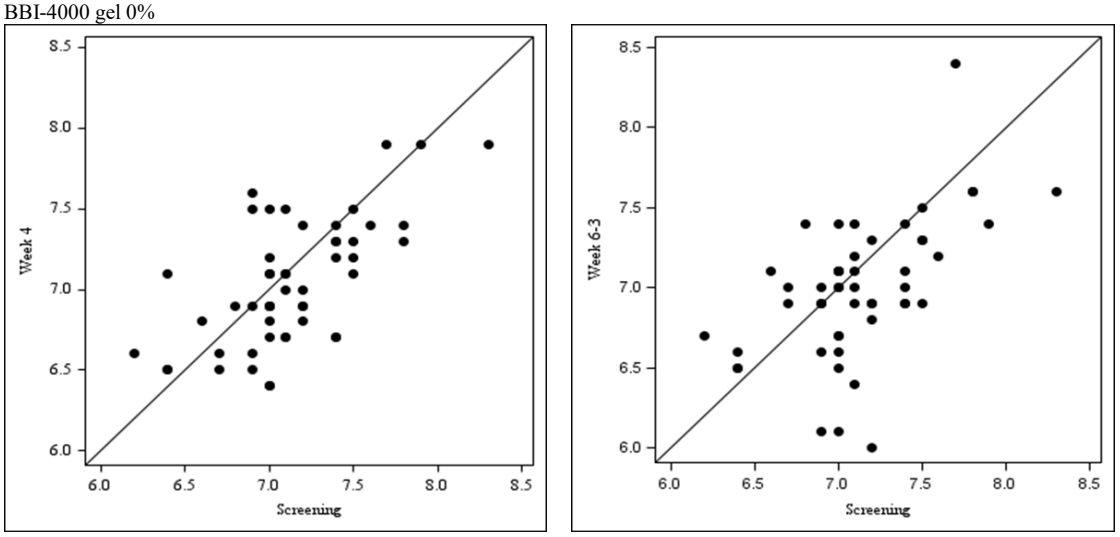
BBI-4000 gel 15%



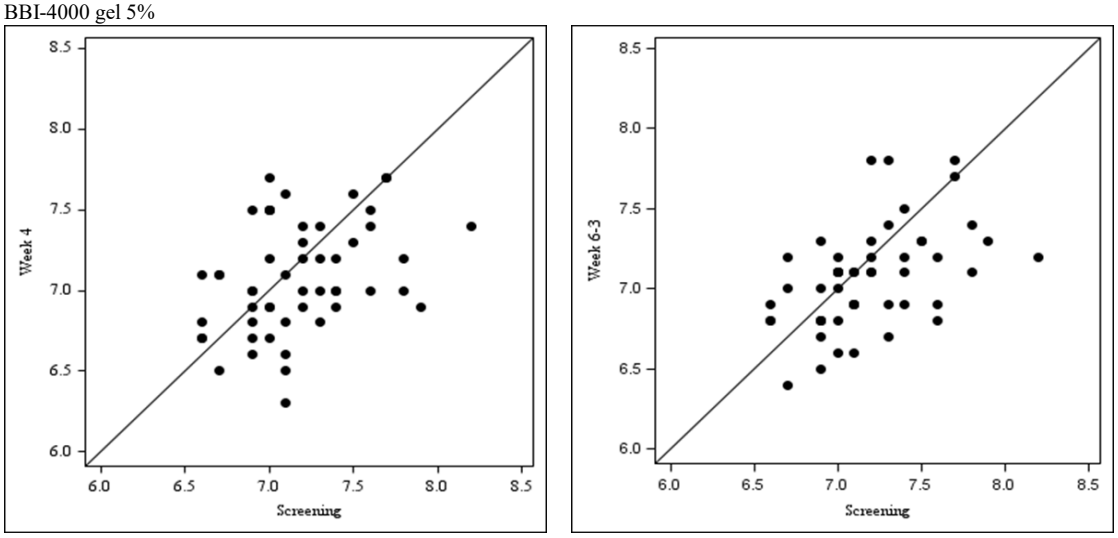
Source：5.3.5.1-1 Figure 14.3.4-1 より改変

図 2.7.4-1　臨床検査値の散布図（BBI-4000-04 試験）（続き）
Protein (g/dL)
[Safety]

BBI-4000 gel 0%



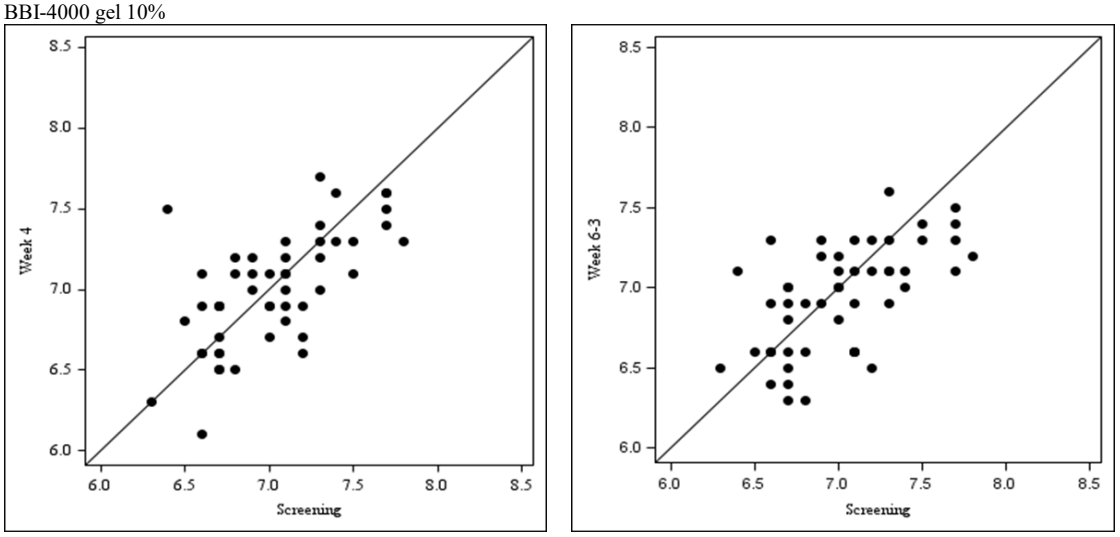
BBI-4000 gel 5%



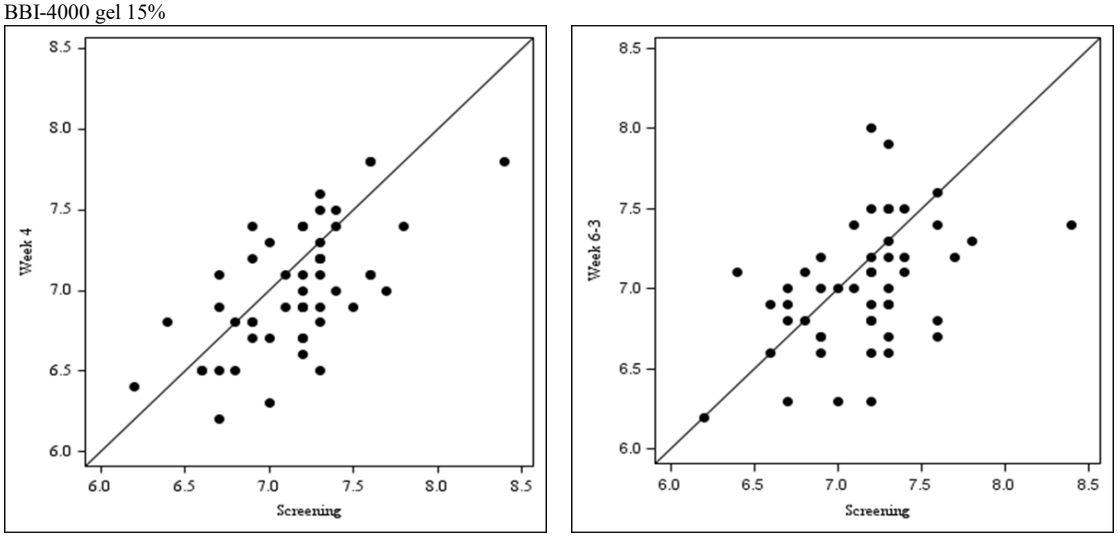
Source：5.3.5.1-1 Figure 14.3.4-1 より改変

図 2.7.4-1　臨床検査値の散布図（BBI-4000-04 試験）（続き）
Protein (g/dL)
[Safety]

BBI-4000 gel 10%



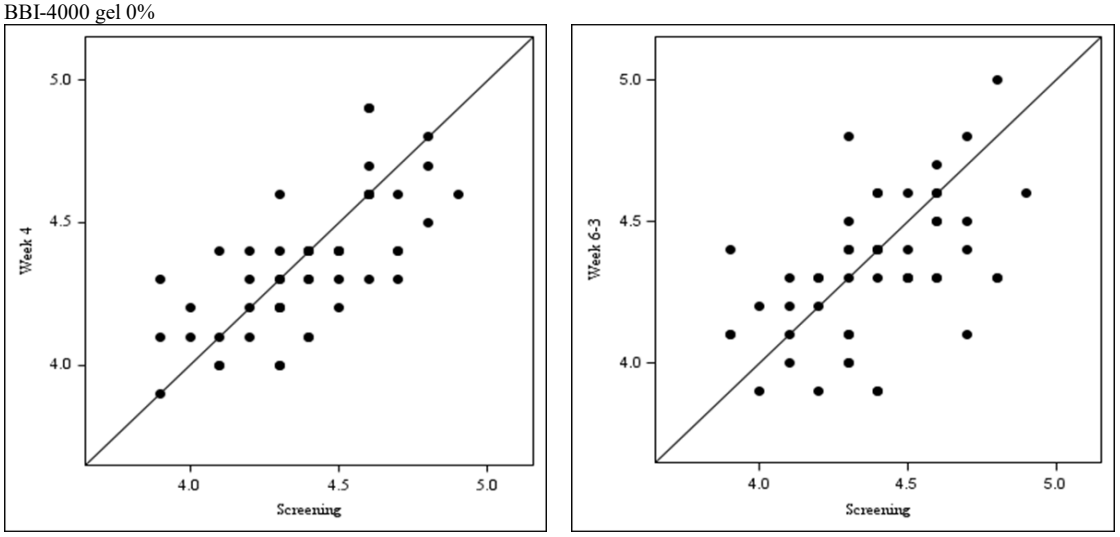
BBI-4000 gel 15%



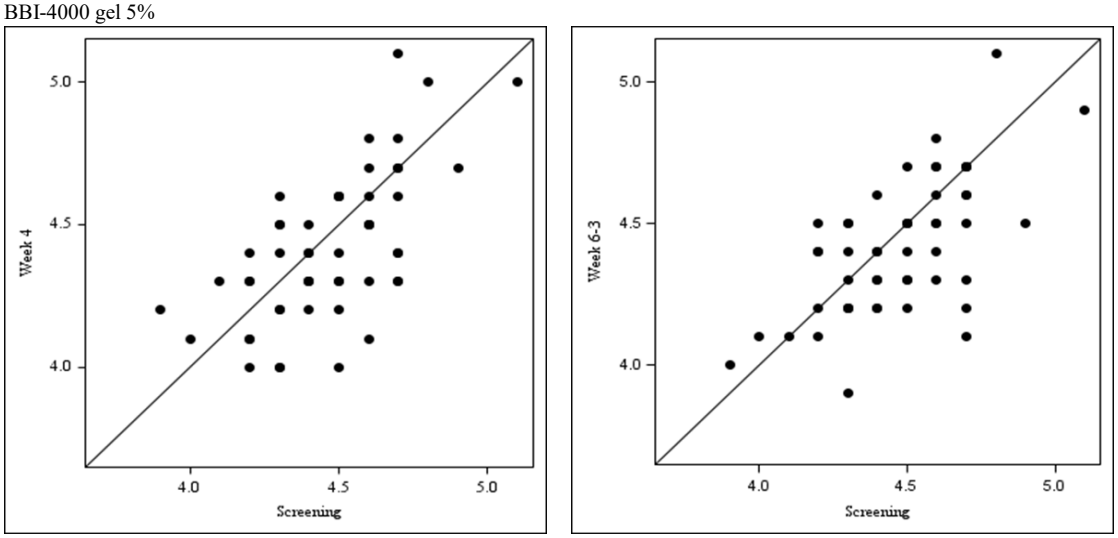
Source：5.3.5.1-1 Figure 14.3.4-1 より改変

図 2.7.4-1　臨床検査値の散布図（BBI-4000-04 試験）（続き）
Albumin (g/dL)
[Safety]

BBI-4000 gel 0%



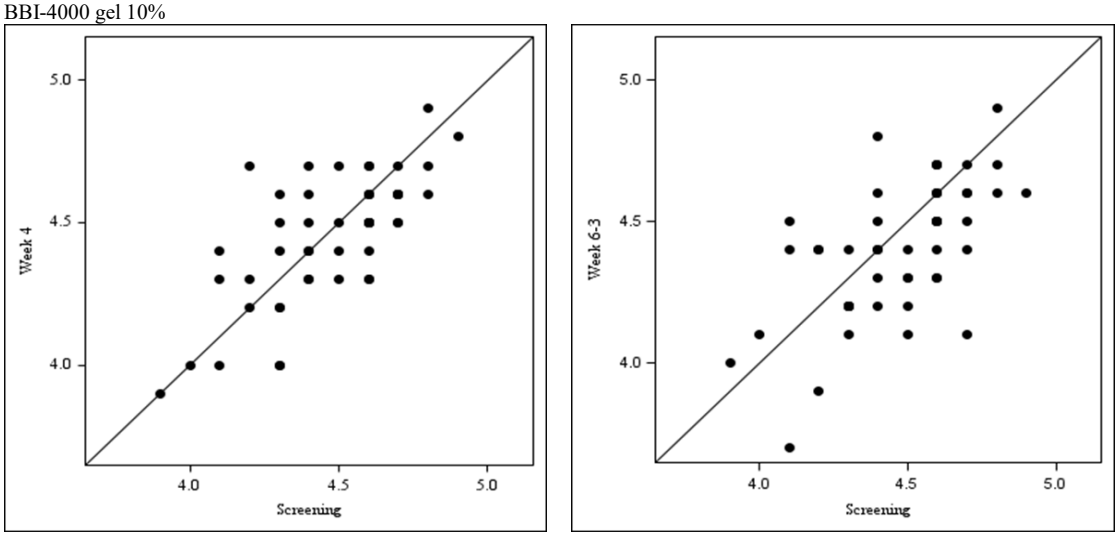
BBI-4000 gel 5%



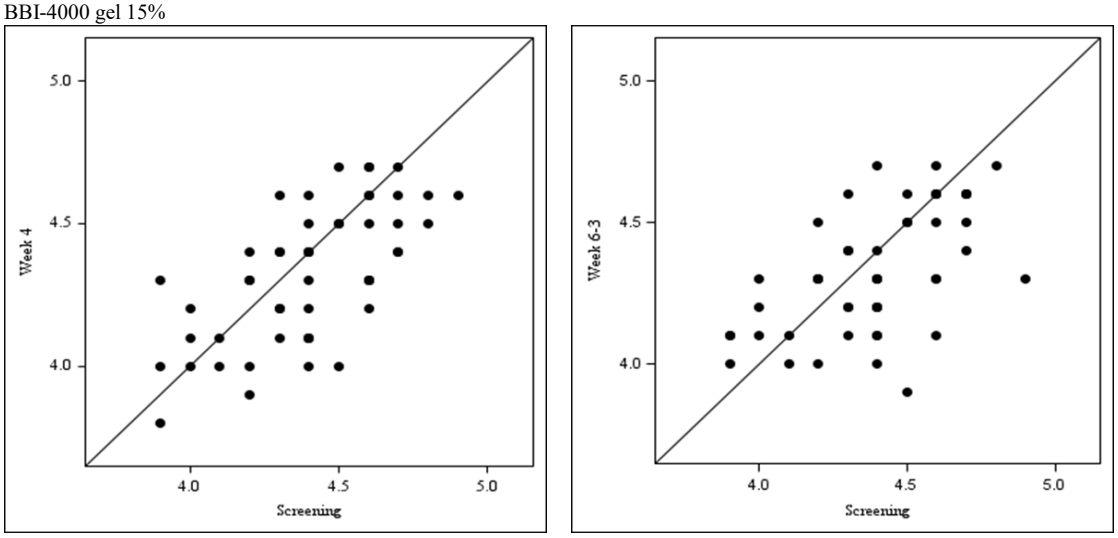
Source：5.3.5.1-1 Figure 14.3.4-1 より改変

図 2.7.4-1　臨床検査値の散布図（BBI-4000-04 試験）（続き）
Albumin (g/dL)
[Safety]

BBI-4000 gel 10%



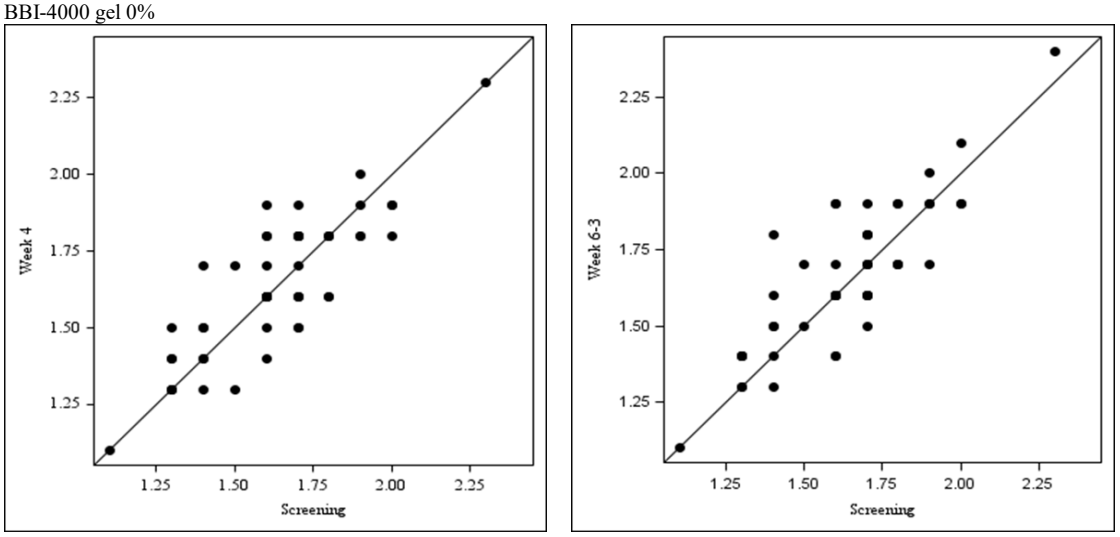
BBI-4000 gel 15%



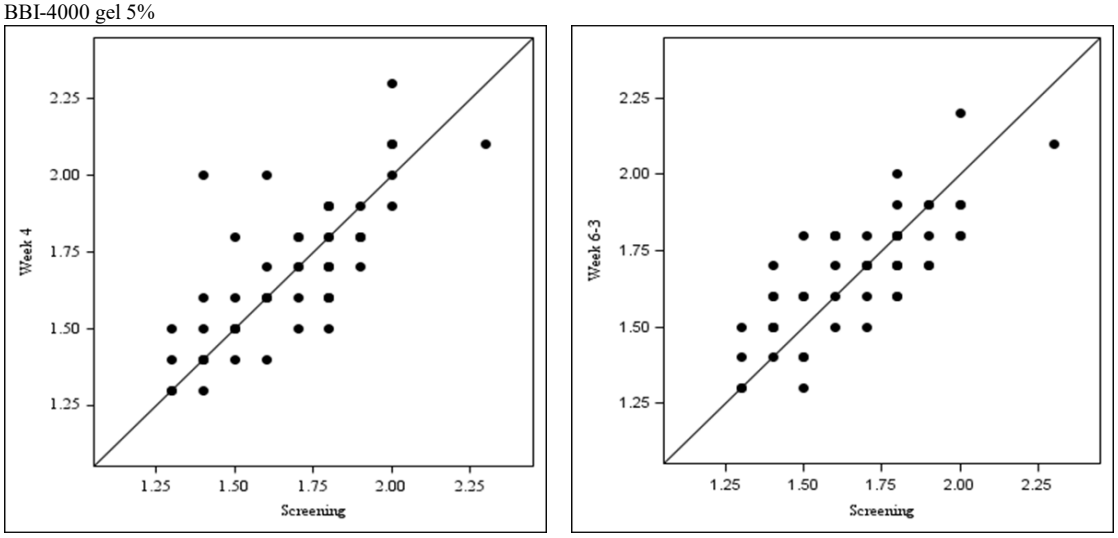
Source：5.3.5.1-1 Figure 14.3.4-1 より改変

図 2.7.4-1　臨床検査値の散布図（BBI-4000-04 試験）（続き）
Albumin/Globulin
[Safety]

BBI-4000 gel 0%



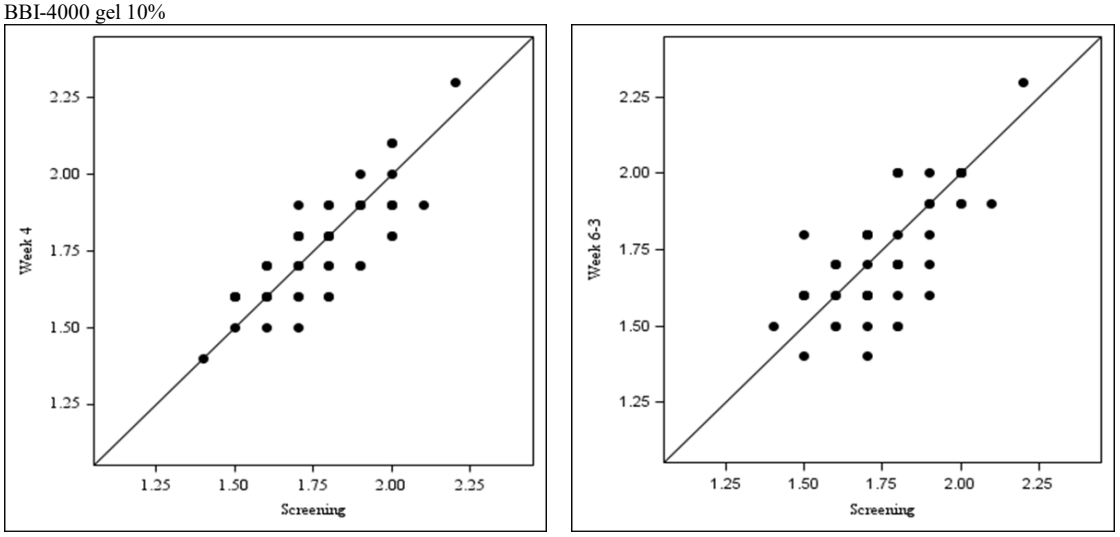
BBI-4000 gel 5%



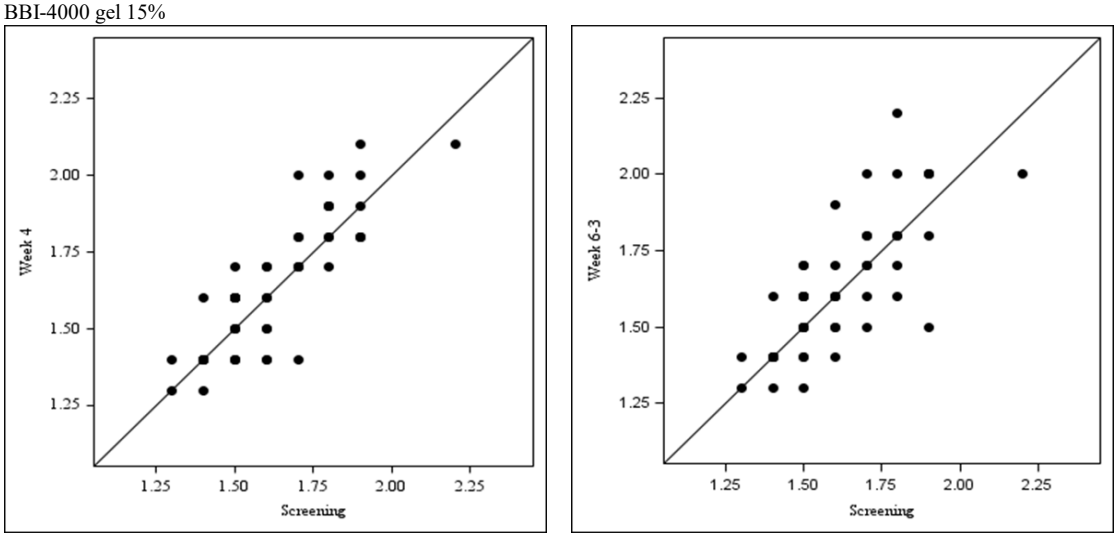
Source：5.3.5.1-1 Figure 14.3.4-1 より改変

図 2.7.4-1　臨床検査値の散布図（BBI-4000-04 試験）（続き）
Albumin/Globulin
[Safety]

BBI-4000 gel 10%



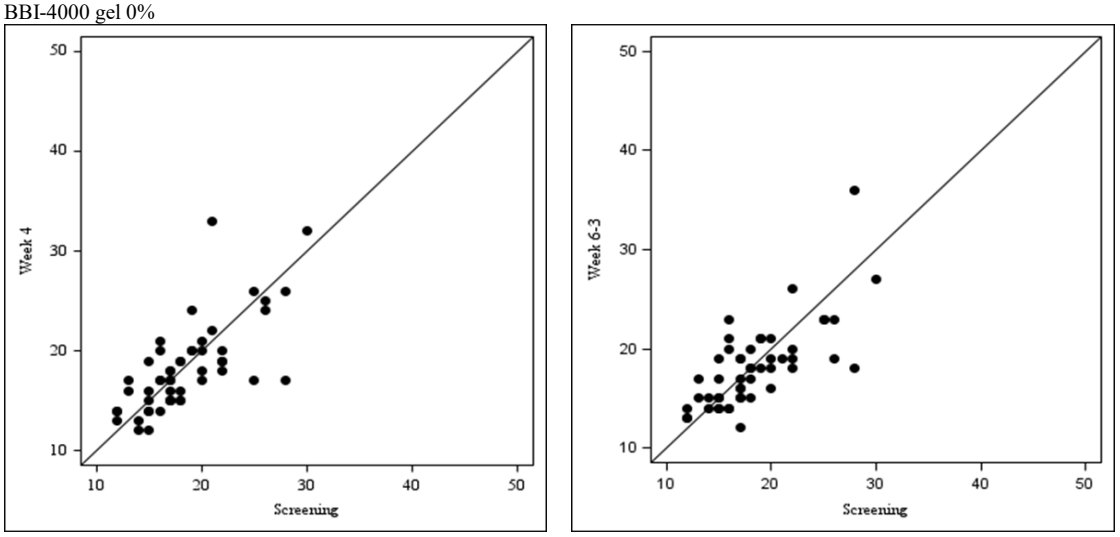
BBI-4000 gel 15%



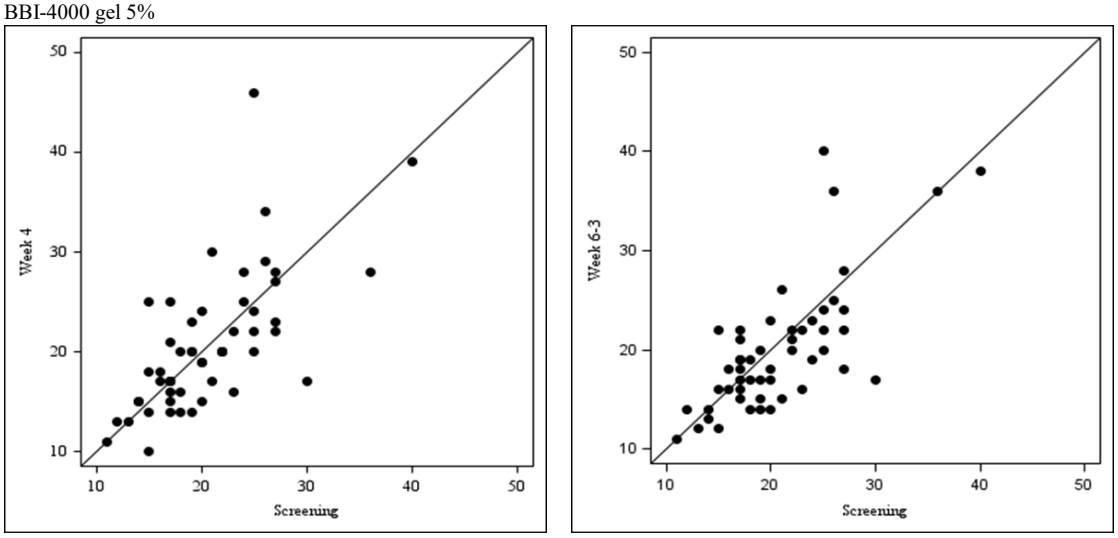
Source：5.3.5.1-1 Figure 14.3.4-1 より改変

図 2.7.4-1　臨床検査値の散布図（BBI-4000-04 試験）（続き）
Aspartate Aminotransferase (U/L)
[Safety]

BBI-4000 gel 0%



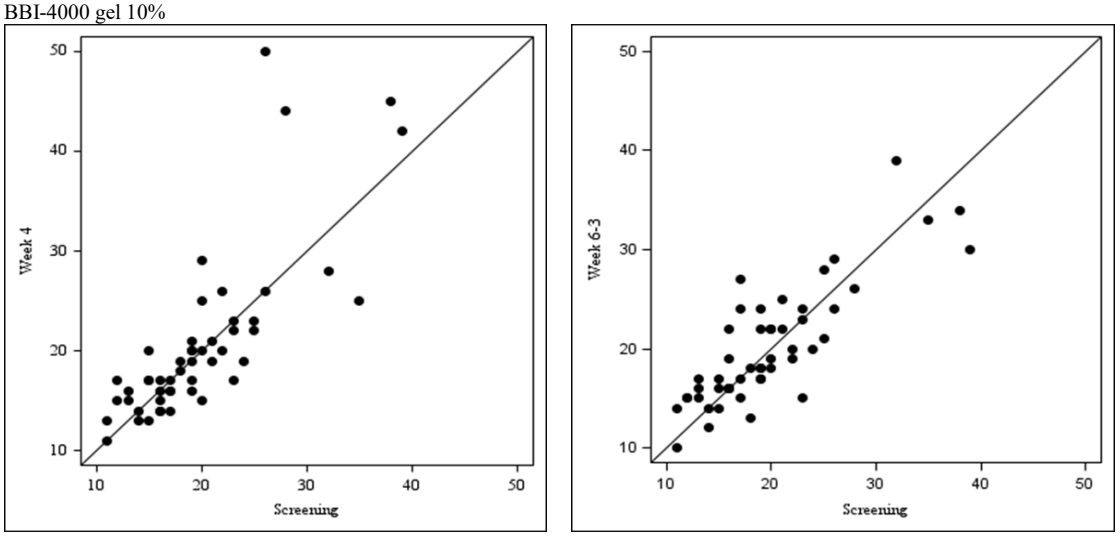
BBI-4000 gel 5%



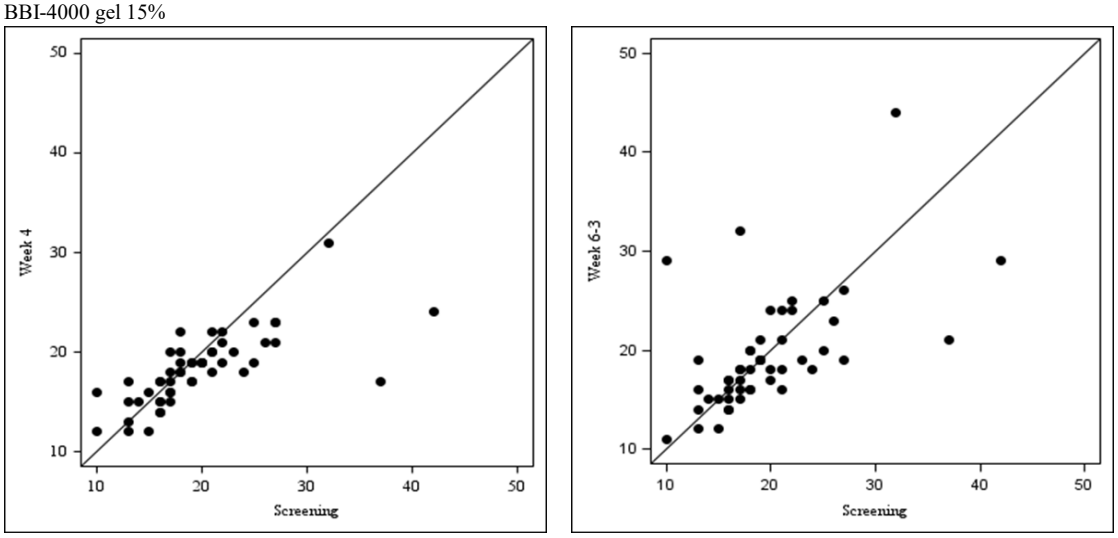
Source：5.3.5.1-1 Figure 14.3.4-1 より改変

図 2.7.4-1　臨床検査値の散布図（BBI-4000-04 試験）（続き）
Aspartate Aminotransferase (U/L)
[Safety]

BBI-4000 gel 10%



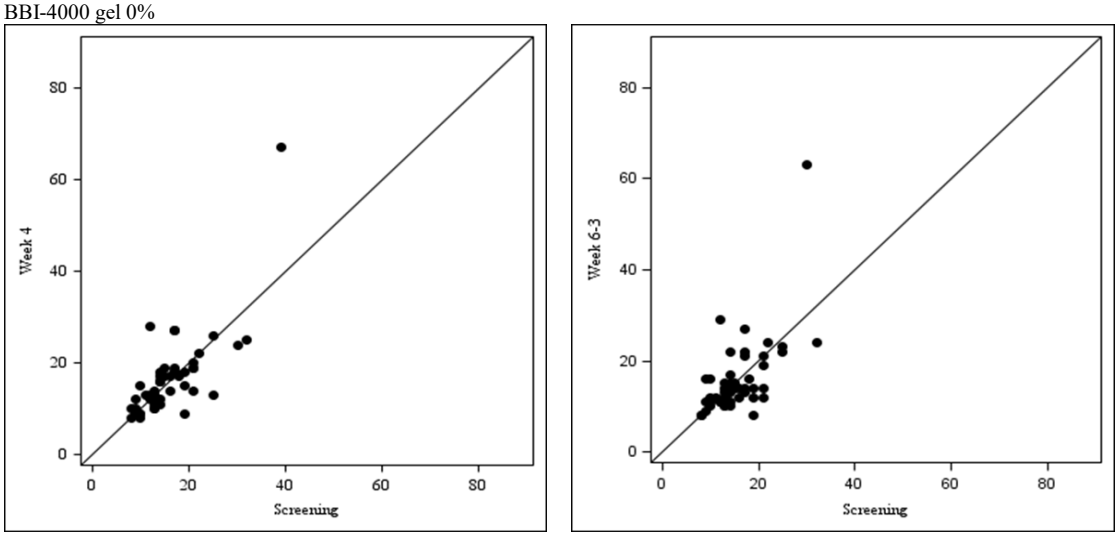
BBI-4000 gel 15%



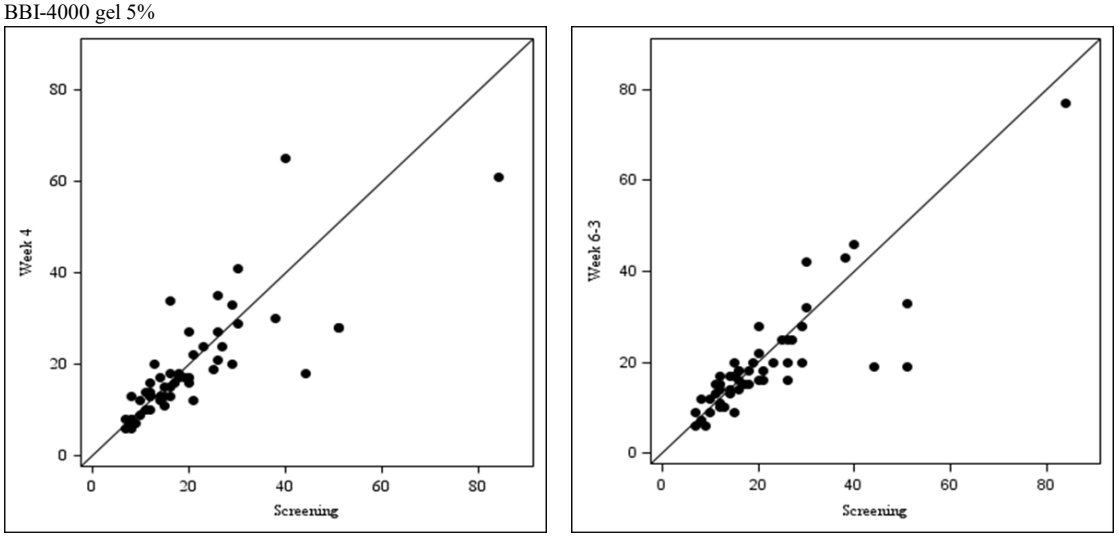
Source：5.3.5.1-1 Figure 14.3.4-1 より改変

図 2.7.4-1　臨床検査値の散布図（BBI-4000-04 試験）（続き）
Alanine Aminotransferase (U/L)
[Safety]

BBI-4000 gel 0%



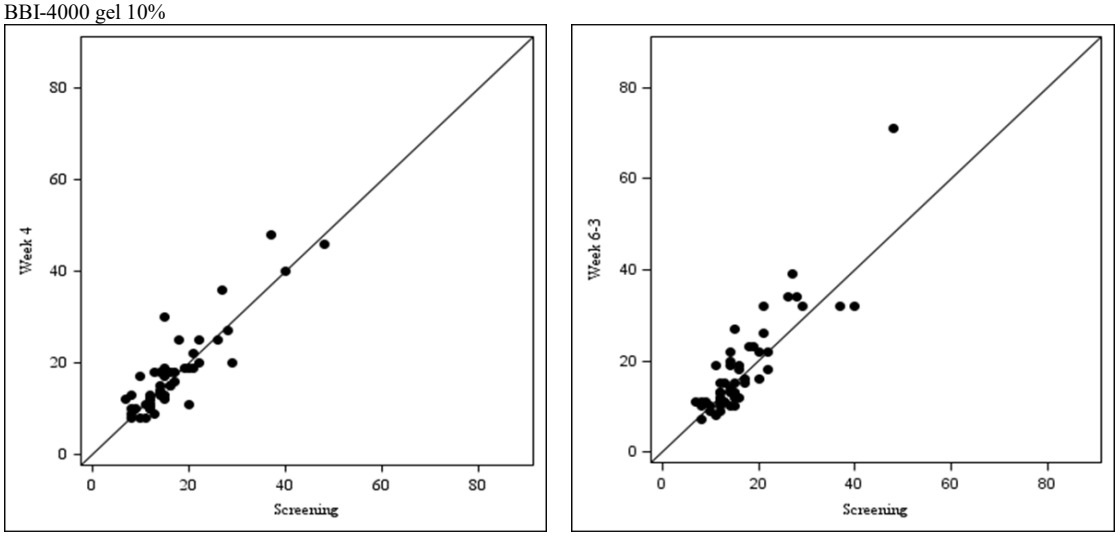
BBI-4000 gel 5%



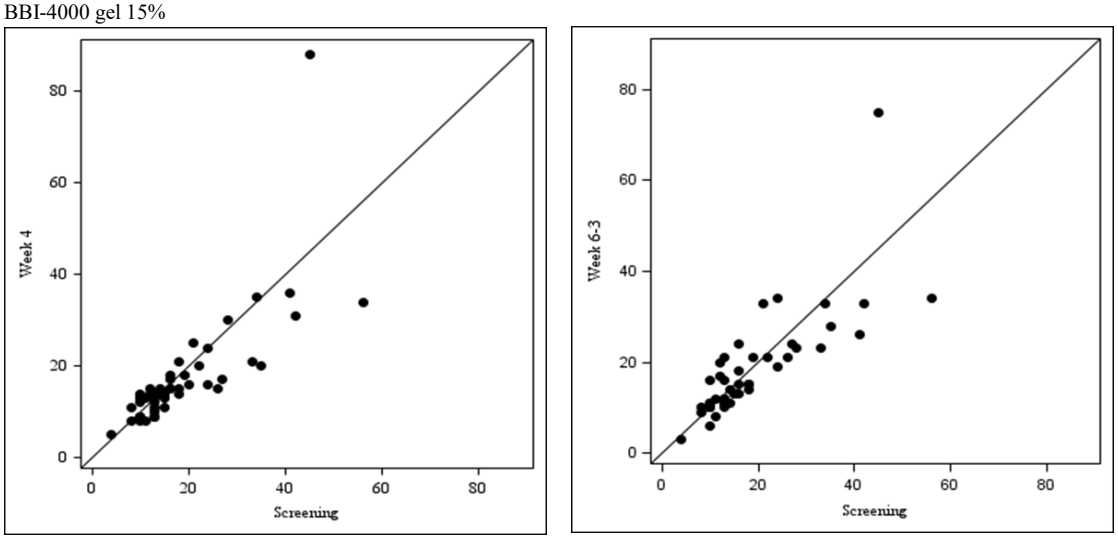
Source：5.3.5.1-1 Figure 14.3.4-1 より改変

図 2.7.4-1　臨床検査値の散布図（BBI-4000-04 試験）（続き）
Alanine Aminotransferase (U/L)
[Safety]

BBI-4000 gel 10%



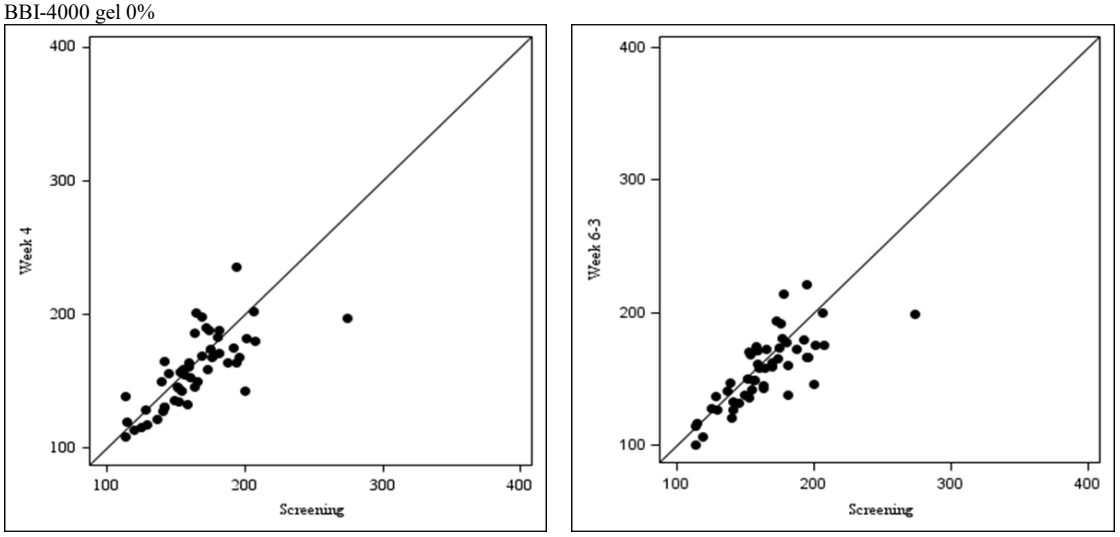
BBI-4000 gel 15%



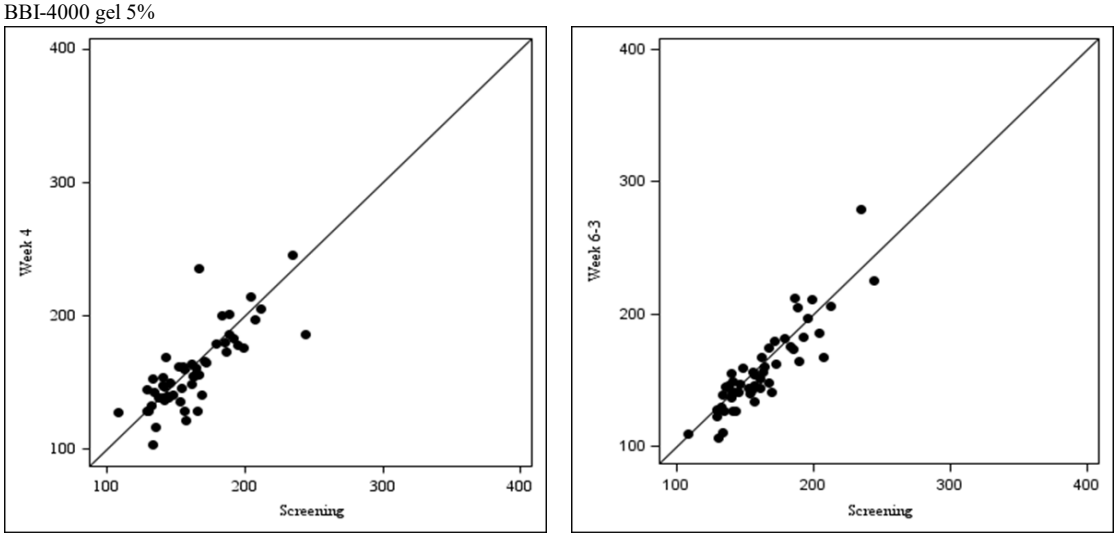
Source：5.3.5.1-1 Figure 14.3.4-1 より改変

図 2.7.4-1　臨床検査値の散布図（BBI-4000-04 試験）（続き）
Lactate Dehydrogenase (U/L)
[Safety]

BBI-4000 gel 0%



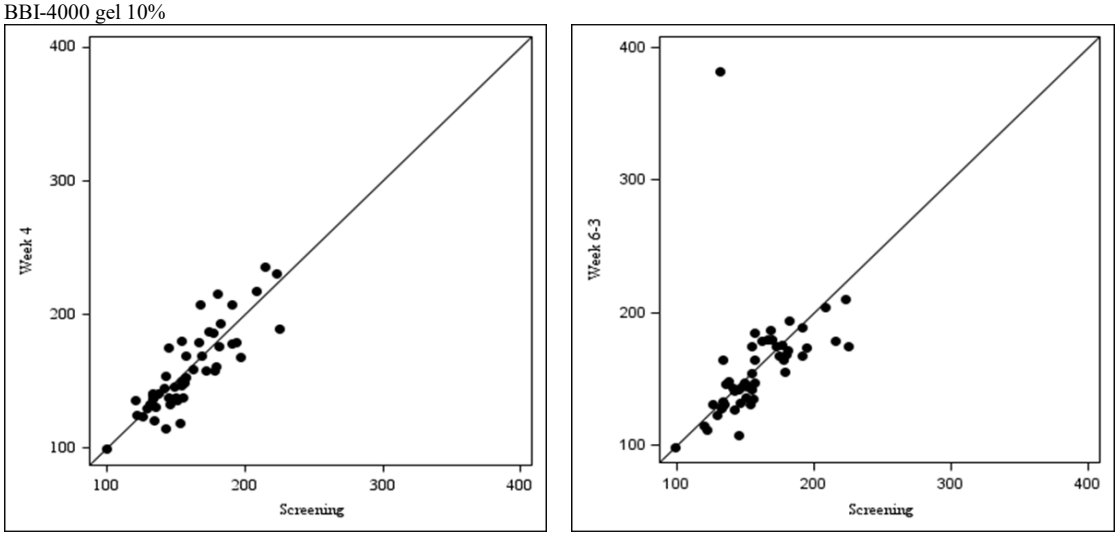
BBI-4000 gel 5%



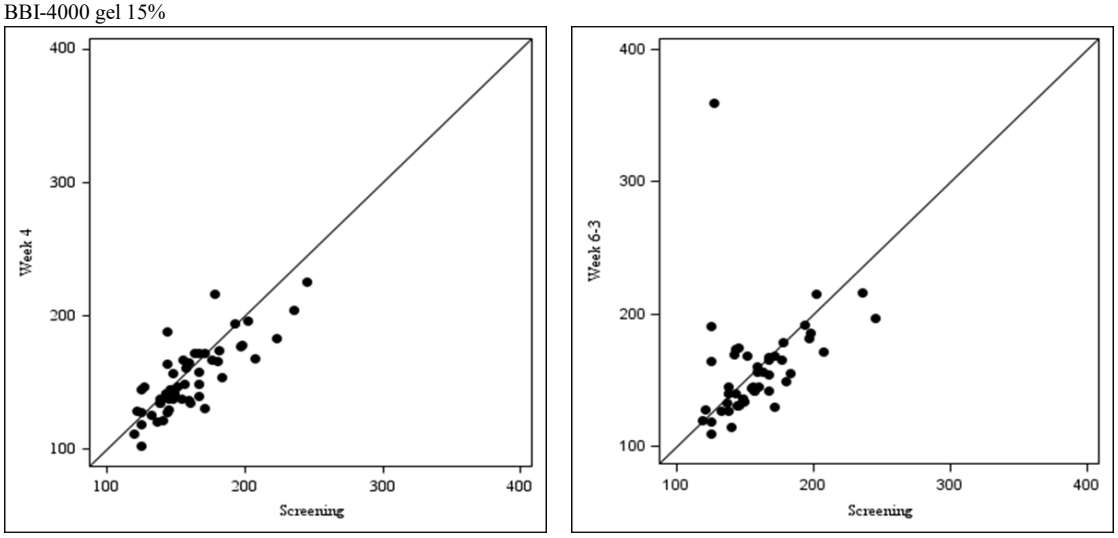
Source：5.3.5.1-1 Figure 14.3.4-1 より改変

図 2.7.4-1　臨床検査値の散布図（BBI-4000-04 試験）（続き）
Lactate Dehydrogenase (U/L)
[Safety]

BBI-4000 gel 10%



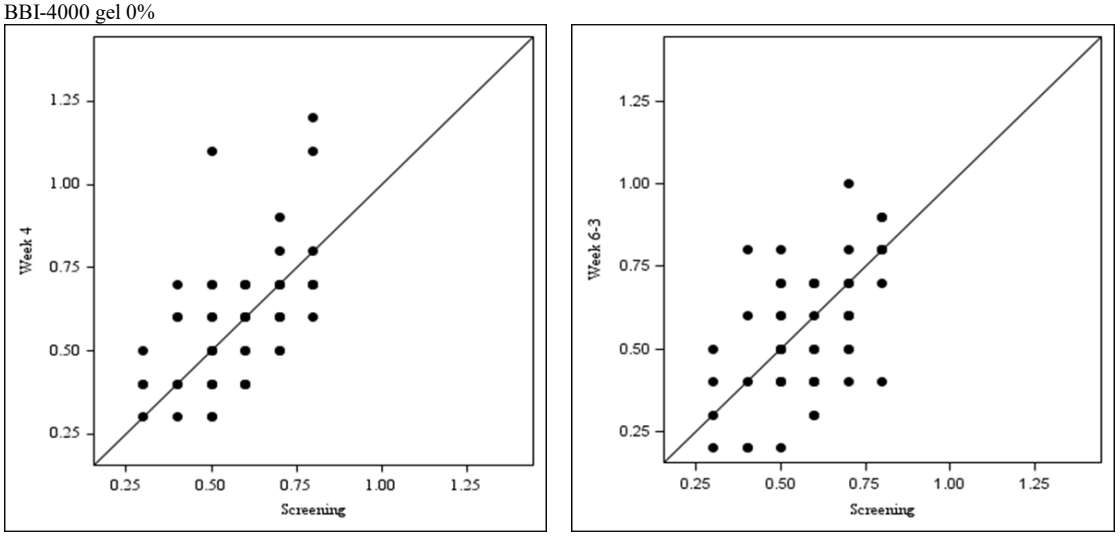
BBI-4000 gel 15%



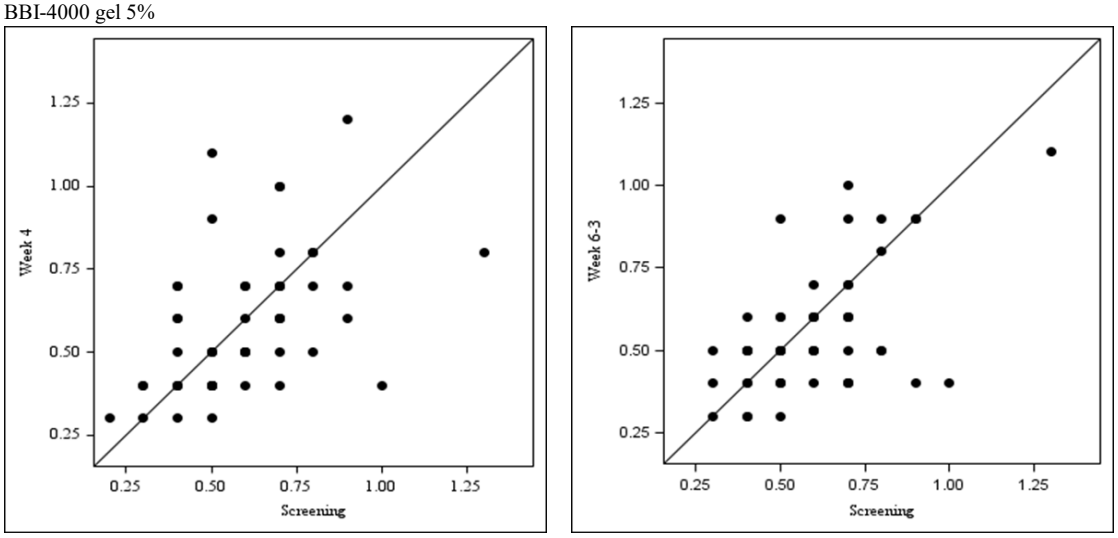
Source：5.3.5.1-1 Figure 14.3.4-1 より改変

図 2.7.4-1　臨床検査値の散布図（BBI-4000-04 試験）（続き）
Bilirubin (mg/dL)
[Safety]

BBI-4000 gel 0%



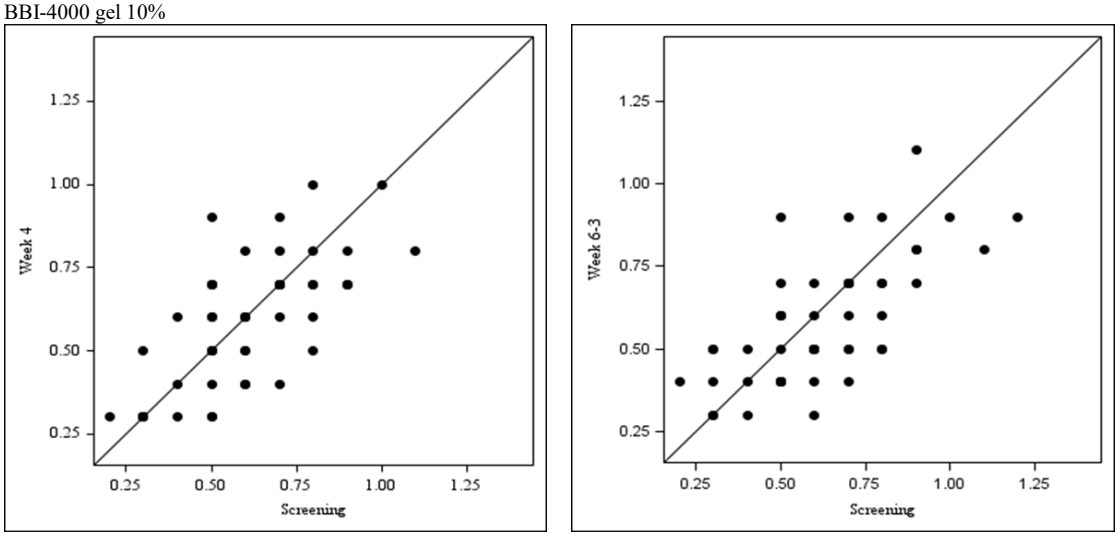
BBI-4000 gel 5%



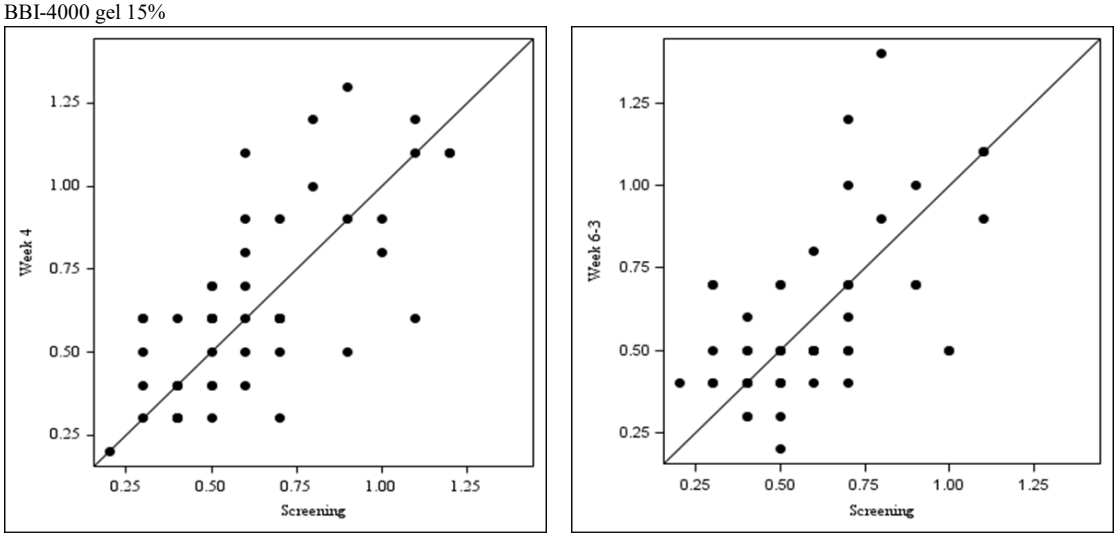
Source：5.3.5.1-1 Figure 14.3.4-1 より改変

図 2.7.4-1 臨床検査値の散布図（BBI-4000-04 試験）（続き）
Bilirubin (mg/dL)
[Safety]

BBI-4000 gel 10%



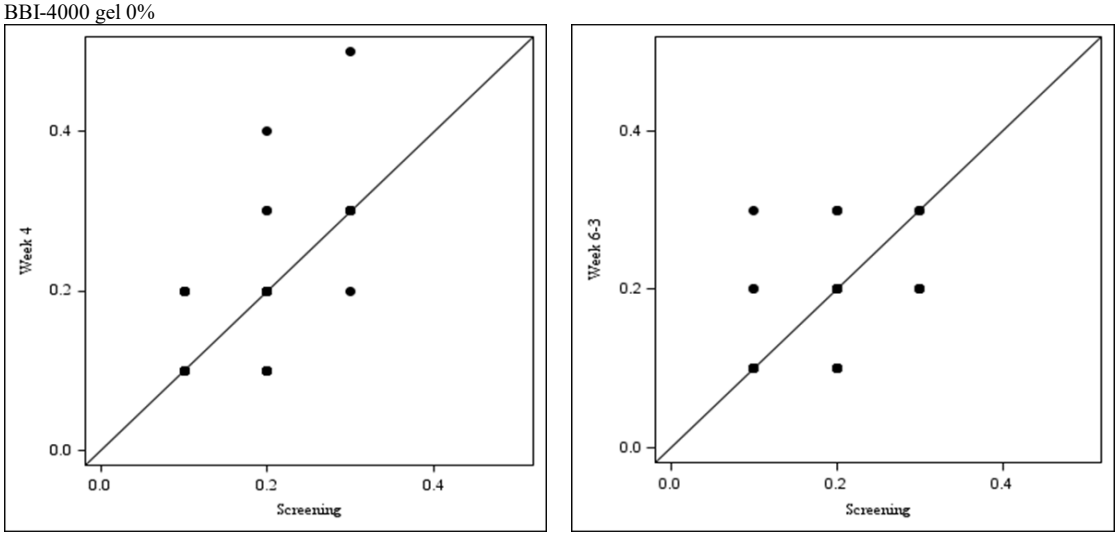
BBI-4000 gel 15%



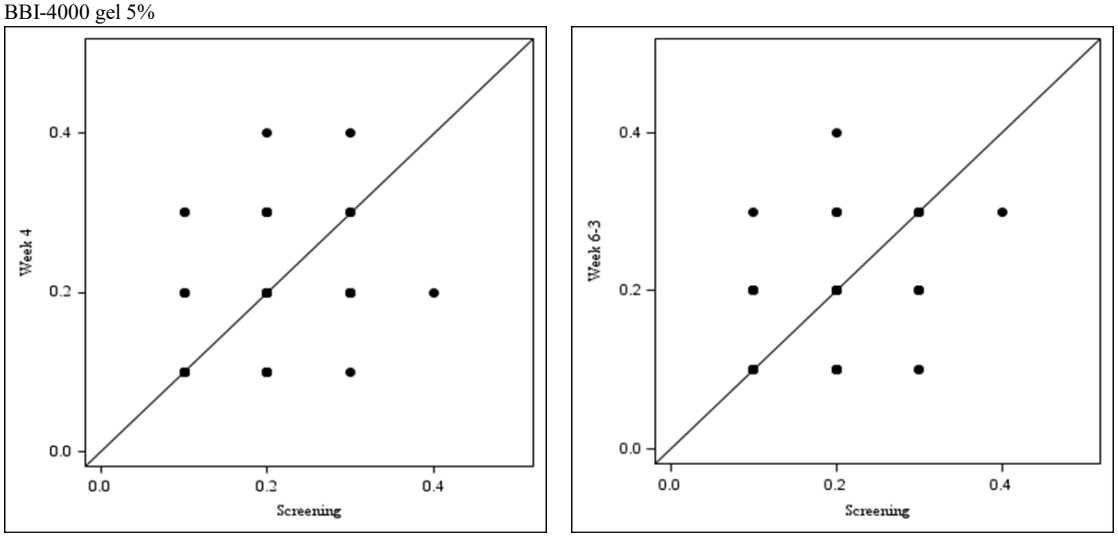
Source：5.3.5.1-1 Figure 14.3.4-1 より改変

図 2.7.4-1　臨床検査値の散布図（BBI-4000-04 試験）（続き）
Direct Bilirubin (mg/dL)
[Safety]

BBI-4000 gel 0%



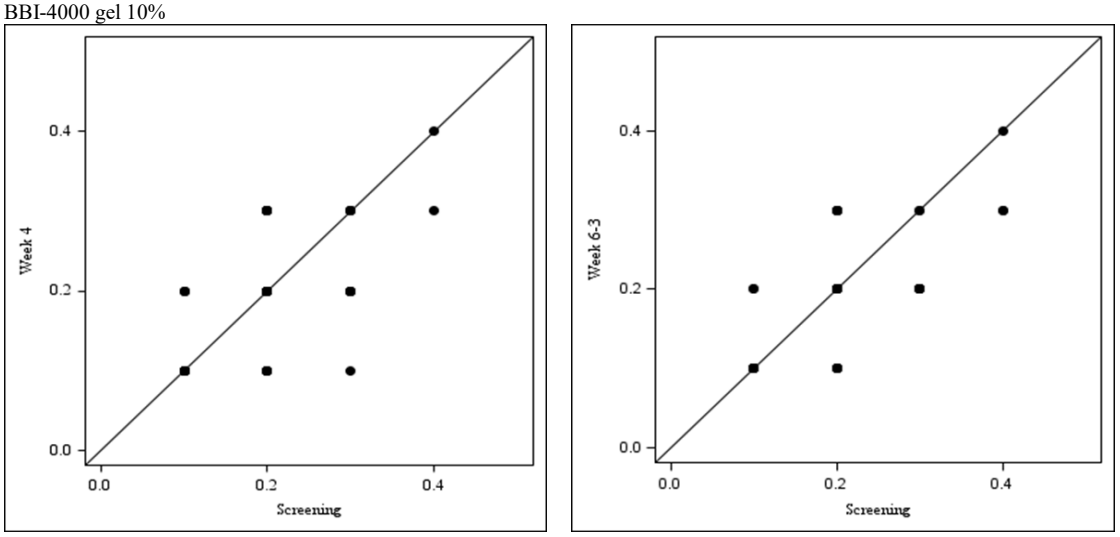
BBI-4000 gel 5%



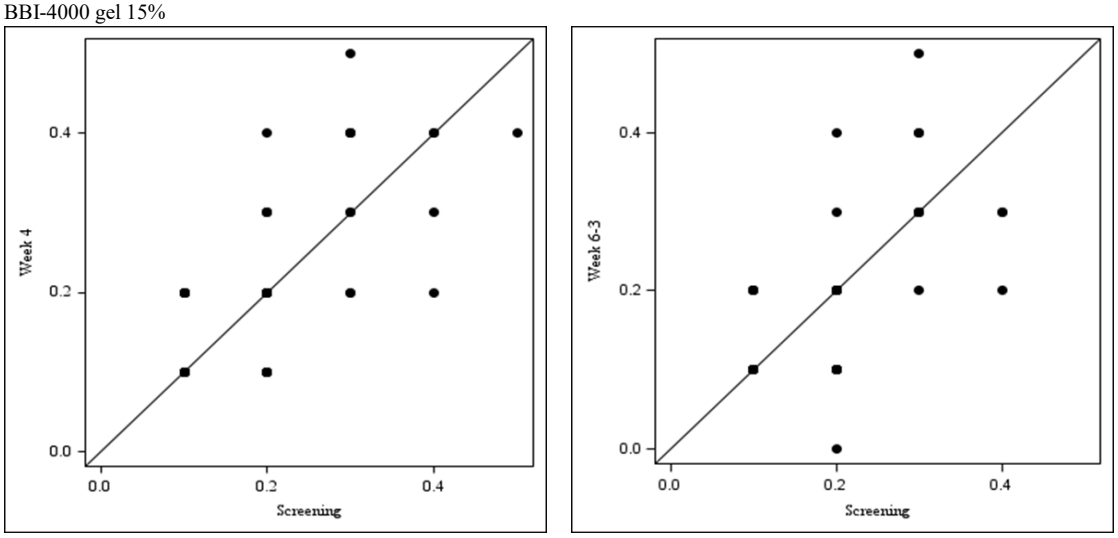
Source：5.3.5.1-1 Figure 14.3.4-1 より改変

図 2.7.4-1　臨床検査値の散布図（BBI-4000-04 試験）（続き）
Direct Bilirubin (mg/dL)
[Safety]

BBI-4000 gel 10%



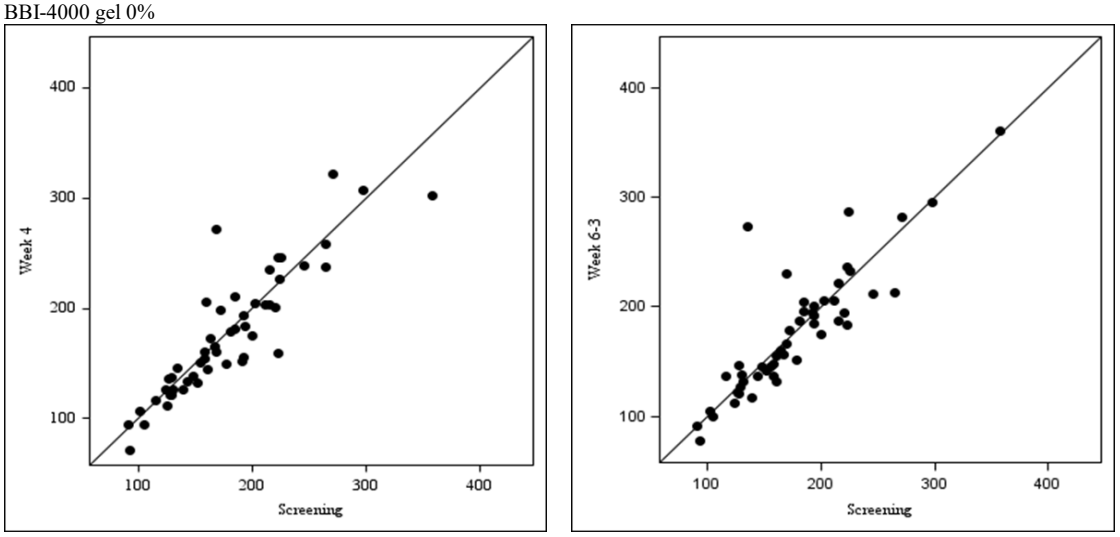
BBI-4000 gel 15%



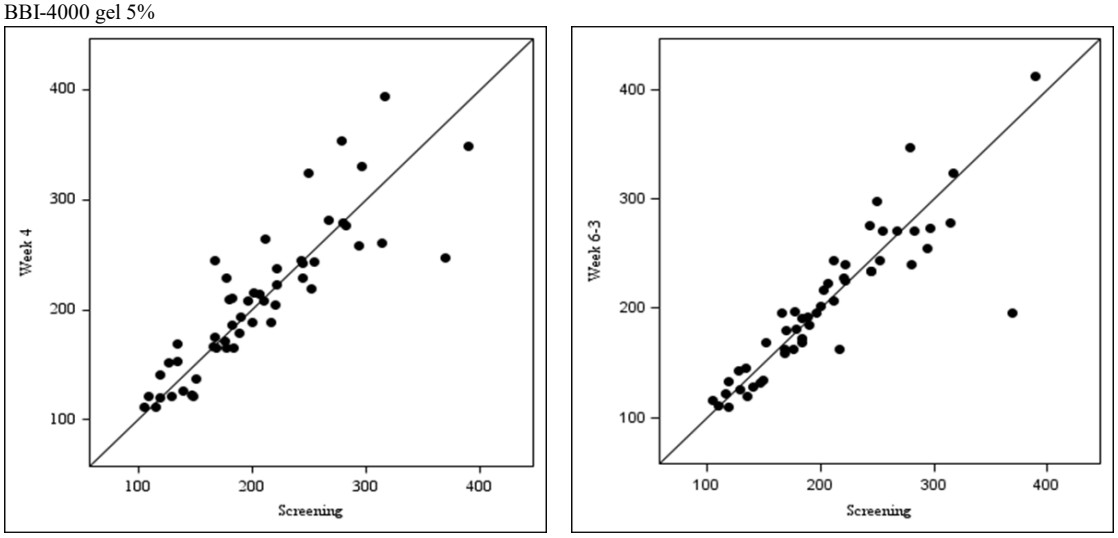
Source：5.3.5.1-1 Figure 14.3.4-1 より改変

図 2.7.4-1　臨床検査値の散布図（BBI-4000-04 試験）（続き）
Alkaline Phosphatase (U/L)
[Safety]

BBI-4000 gel 0%



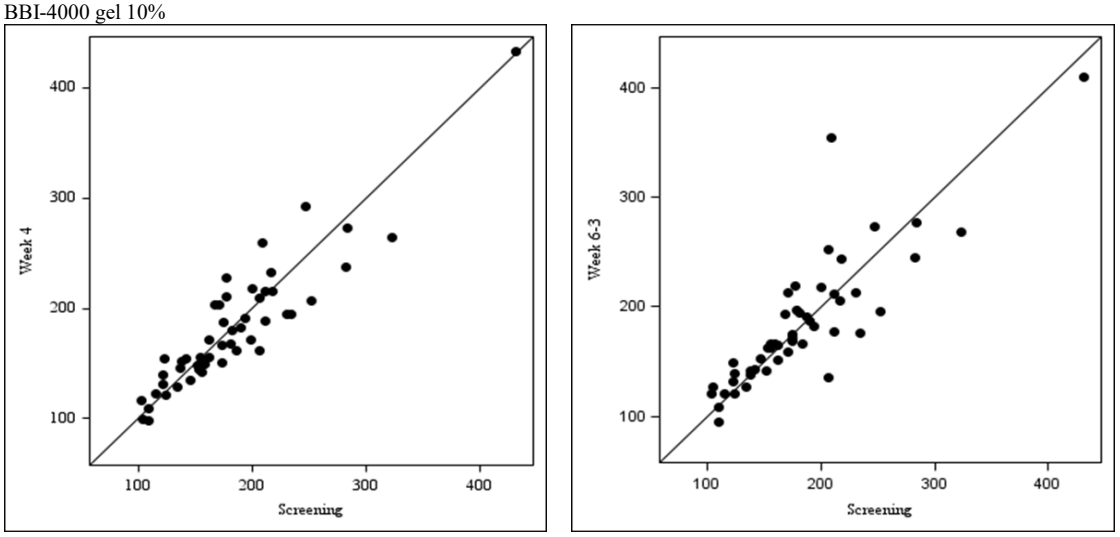
BBI-4000 gel 5%



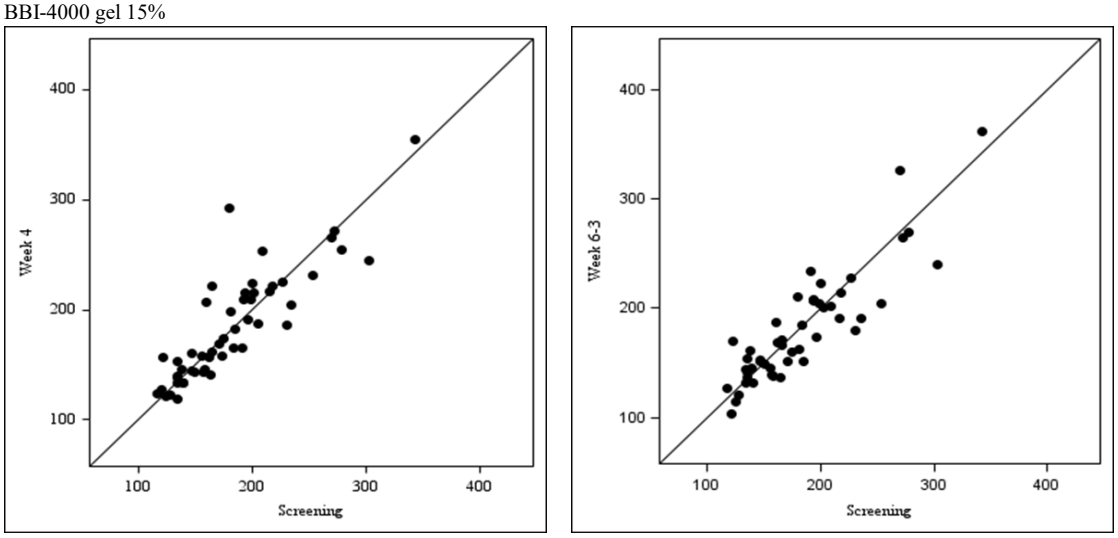
Source：5.3.5.1-1 Figure 14.3.4-1 より改変

図 2.7.4-1　臨床検査値の散布図（BBI-4000-04 試験）（続き）
Alkaline Phosphatase (U/L)
[Safety]

BBI-4000 gel 10%



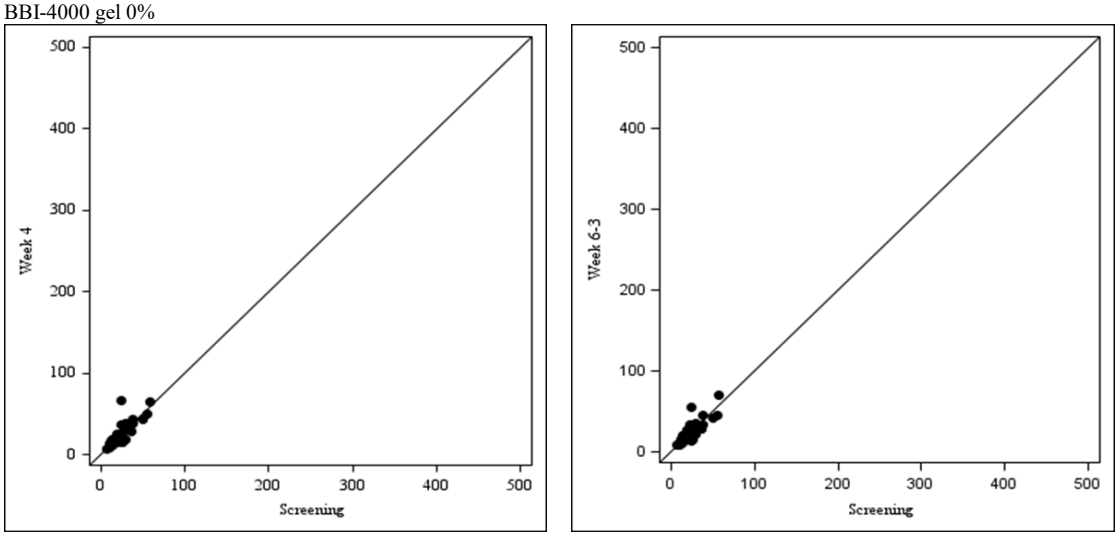
BBI-4000 gel 15%



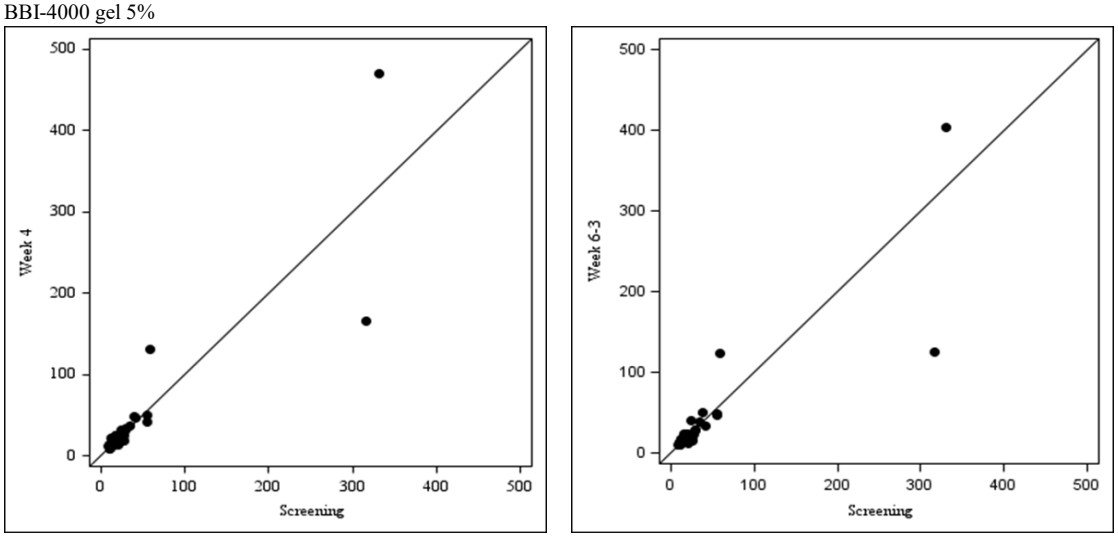
Source：5.3.5.1-1 Figure 14.3.4-1 より改変

図 2.7.4-1 臨床検査値の散布図（BBI-4000-04 試験）（続き）
Gamma Glutamyl Transferase (U/L)
[Safety]

BBI-4000 gel 0%



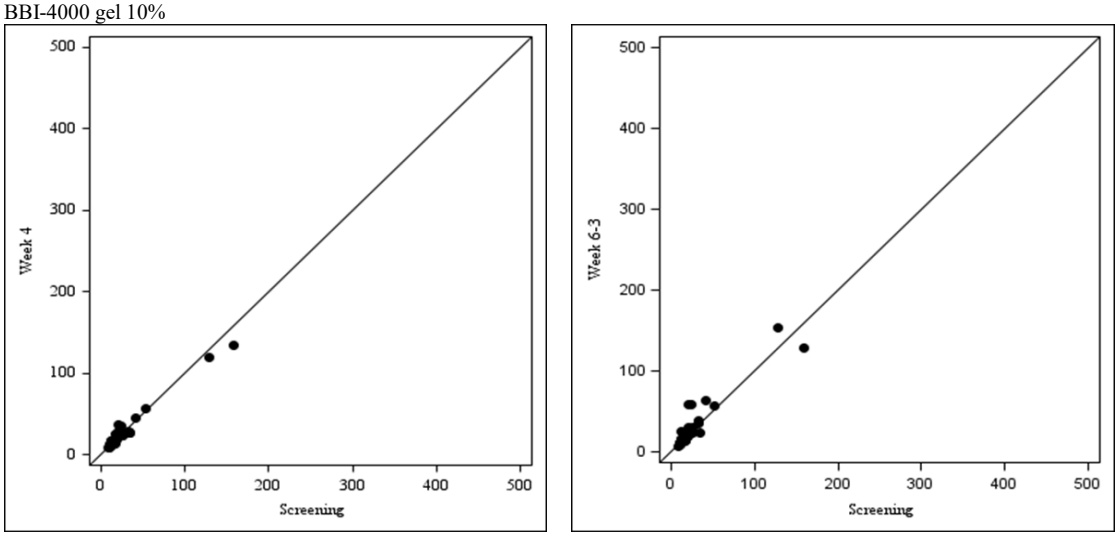
BBI-4000 gel 5%



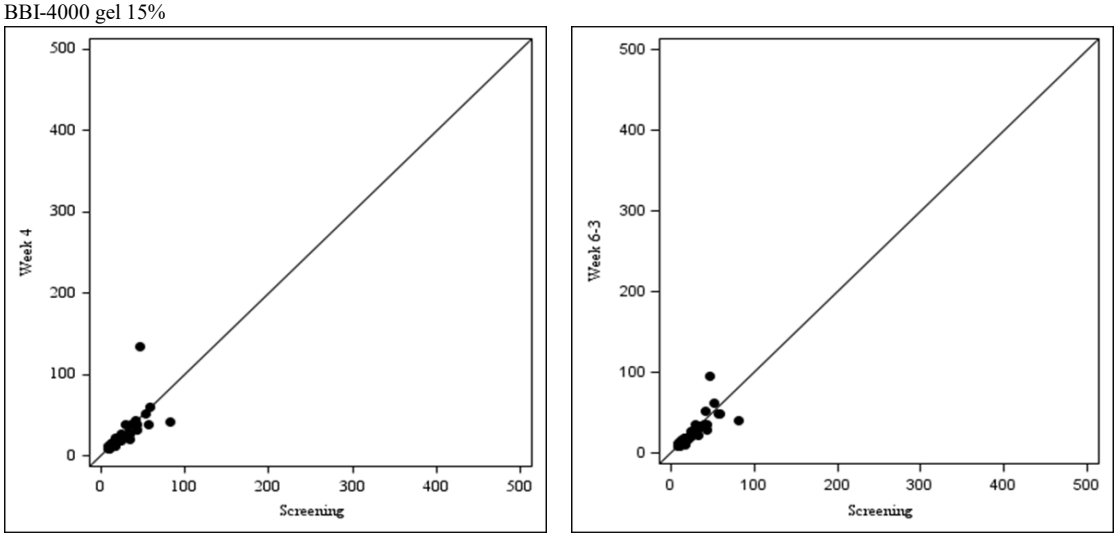
Source：5.3.5.1-1 Figure 14.3.4-1 より改変

図 2.7.4-1　臨床検査値の散布図（BBI-4000-04 試験）（続き）
Gamma Glutamyl Transferase (U/L)
[Safety]

BBI-4000 gel 10%



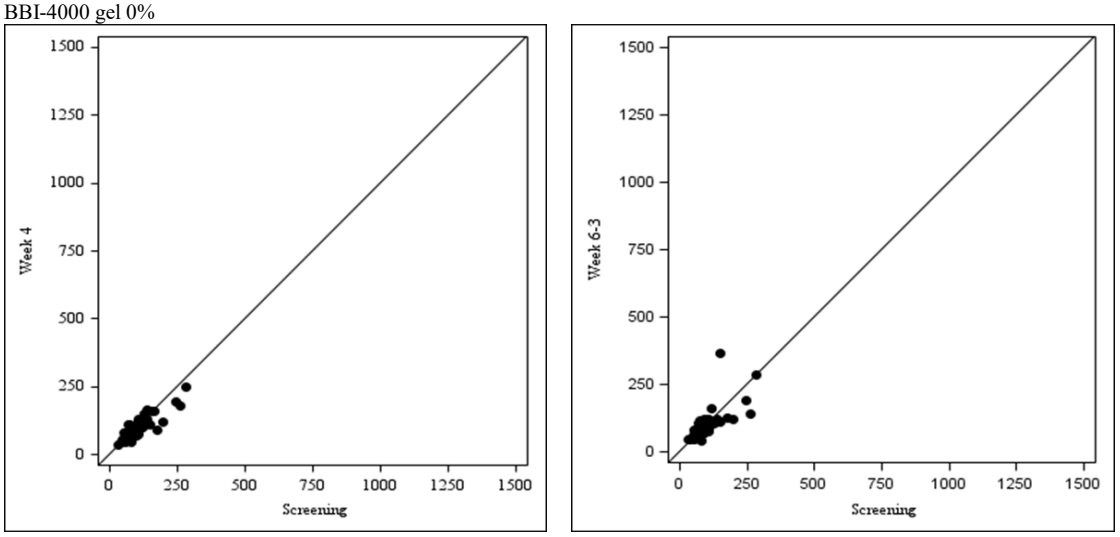
BBI-4000 gel 15%



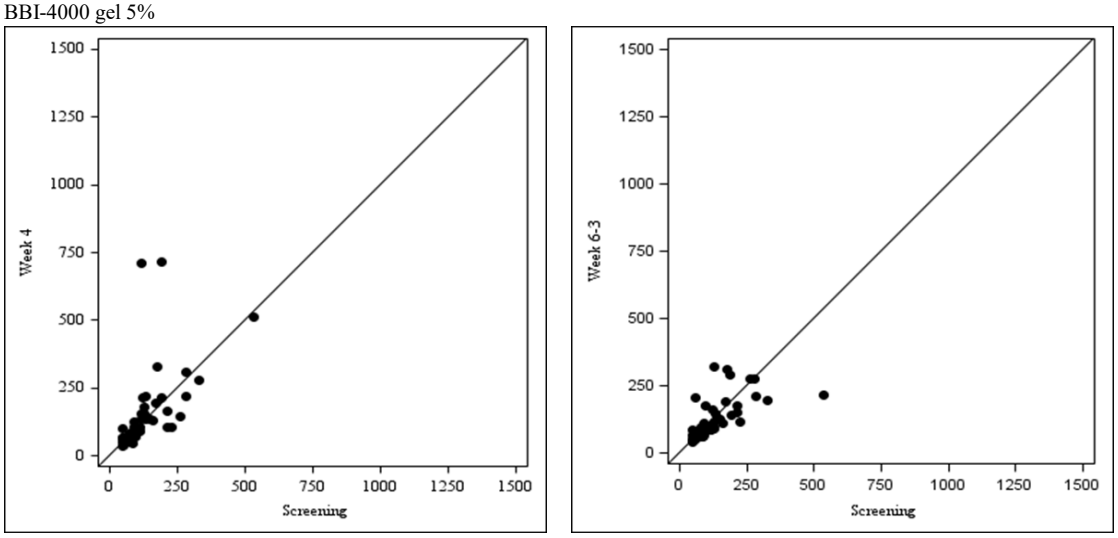
Source：5.3.5.1-1 Figure 14.3.4-1 より改変

図 2.7.4-1　臨床検査値の散布図（BBI-4000-04 試験）（続き）
Creatine Kinase (U/L)
[Safety]

BBI-4000 gel 0%



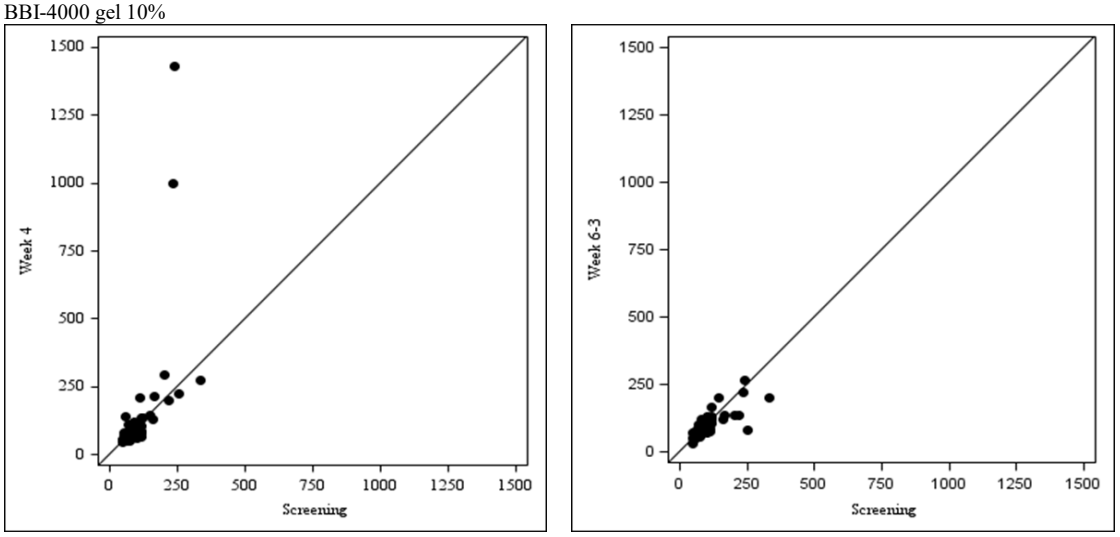
BBI-4000 gel 5%



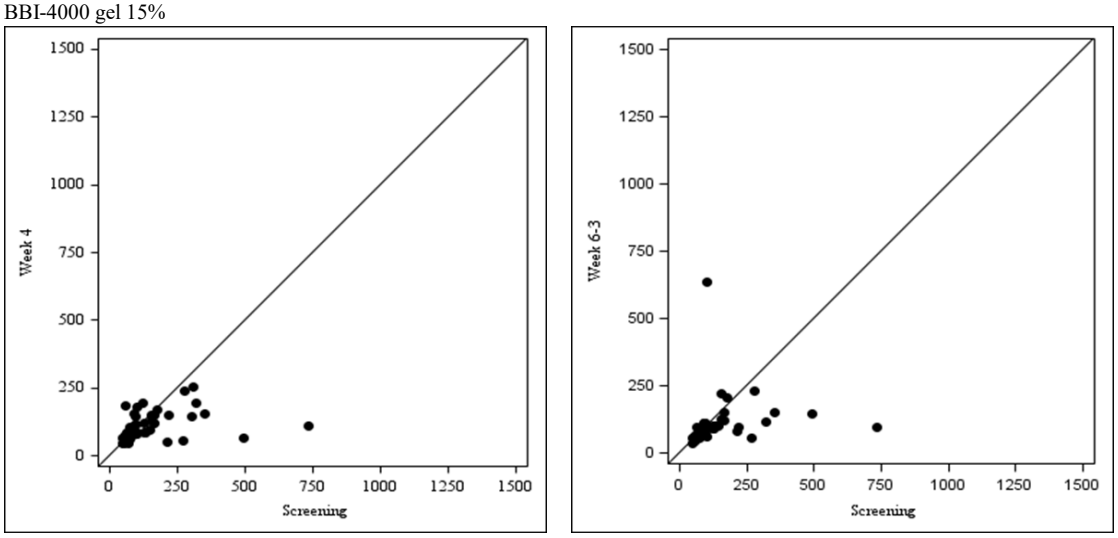
Source：5.3.5.1-1 Figure 14.3.4-1 より改変

図 2.7.4-1　臨床検査値の散布図（BBI-4000-04 試験）（続き）
Creatine Kinase (U/L)
[Safety]

BBI-4000 gel 10%



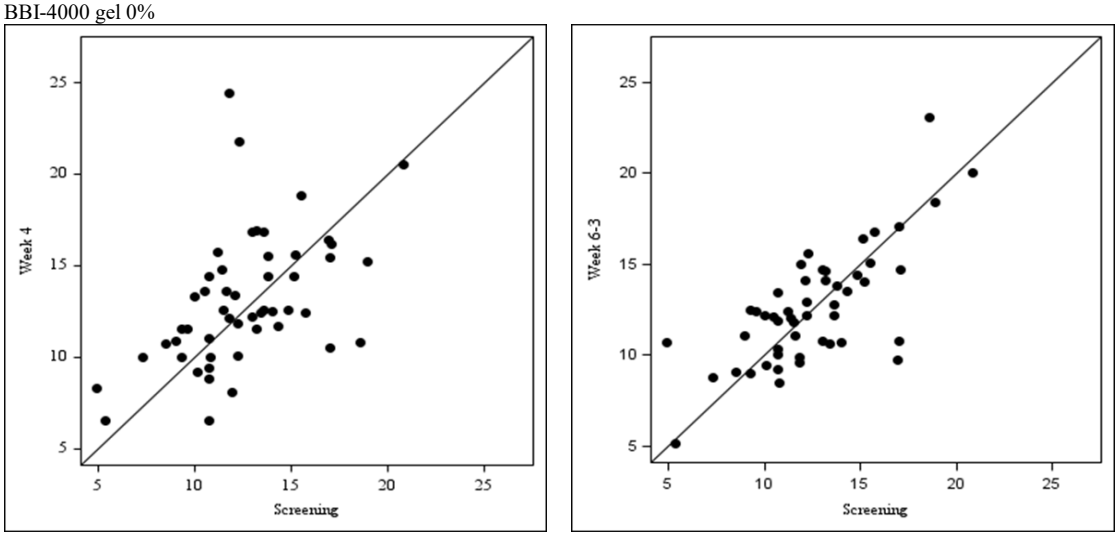
BBI-4000 gel 15%



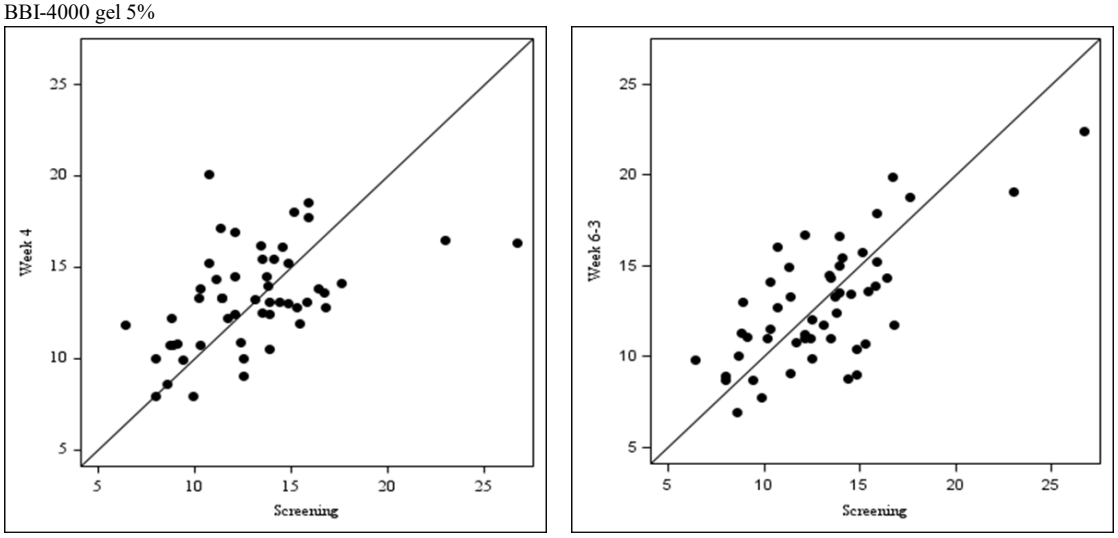
Source：5.3.5.1-1 Figure 14.3.4-1 より改変

図 2.7.4-1　臨床検査値の散布図（BBI-4000-04 試験）（続き）
Urea Nitrogen (mg/dL)
[Safety]

BBI-4000 gel 0%



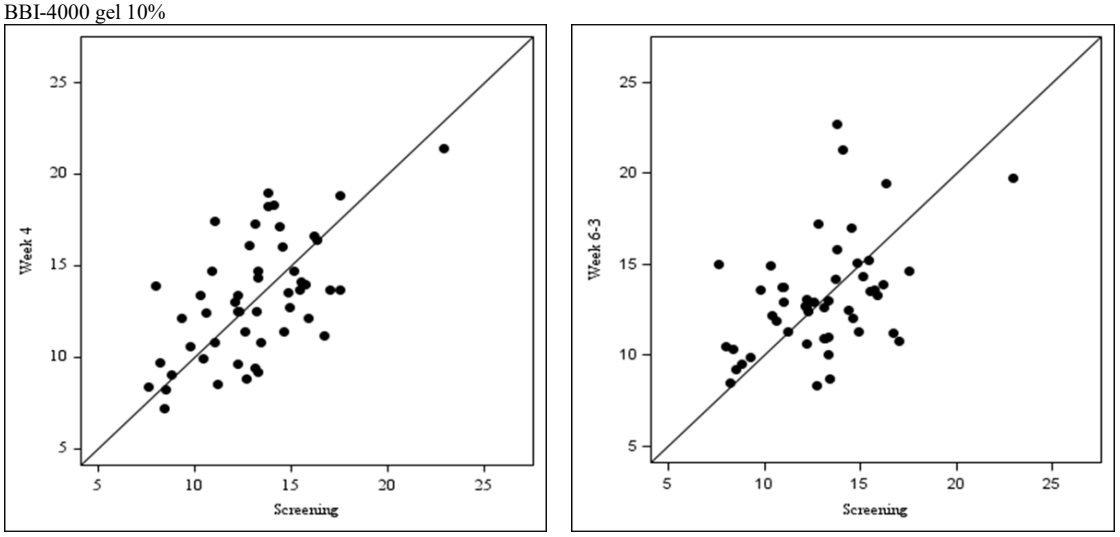
BBI-4000 gel 5%



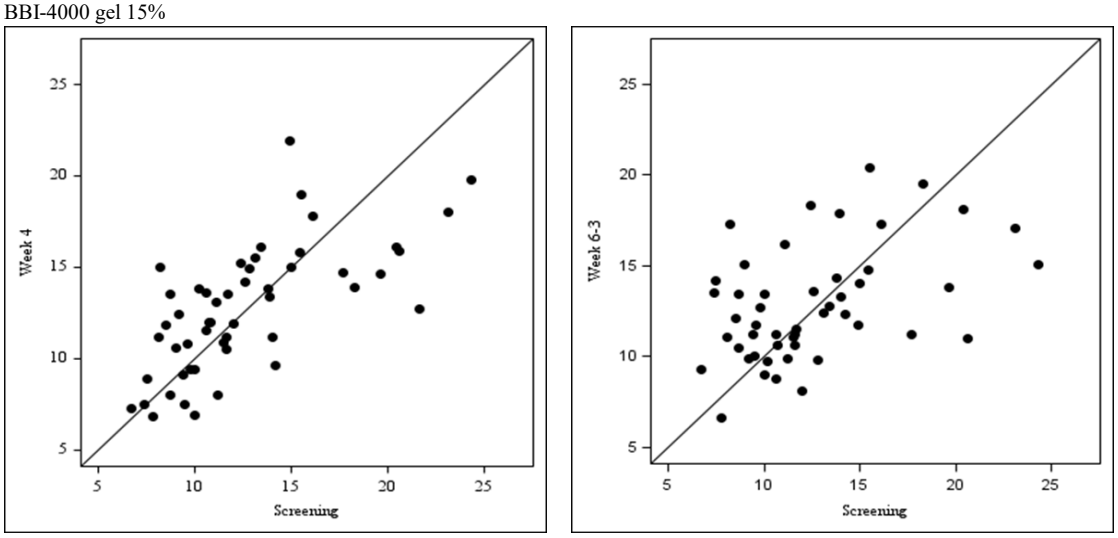
Source：5.3.5.1-1 Figure 14.3.4-1 より改変

図 2.7.4-1　臨床検査値の散布図（BBI-4000-04 試験）（続き）
Urea Nitrogen (mg/dL)
[Safety]

BBI-4000 gel 10%



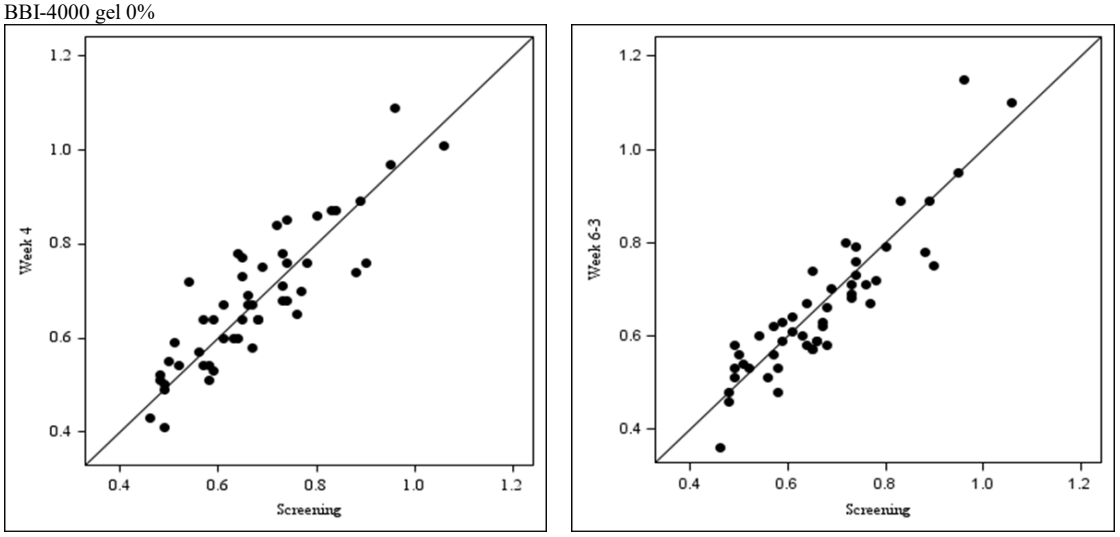
BBI-4000 gel 15%



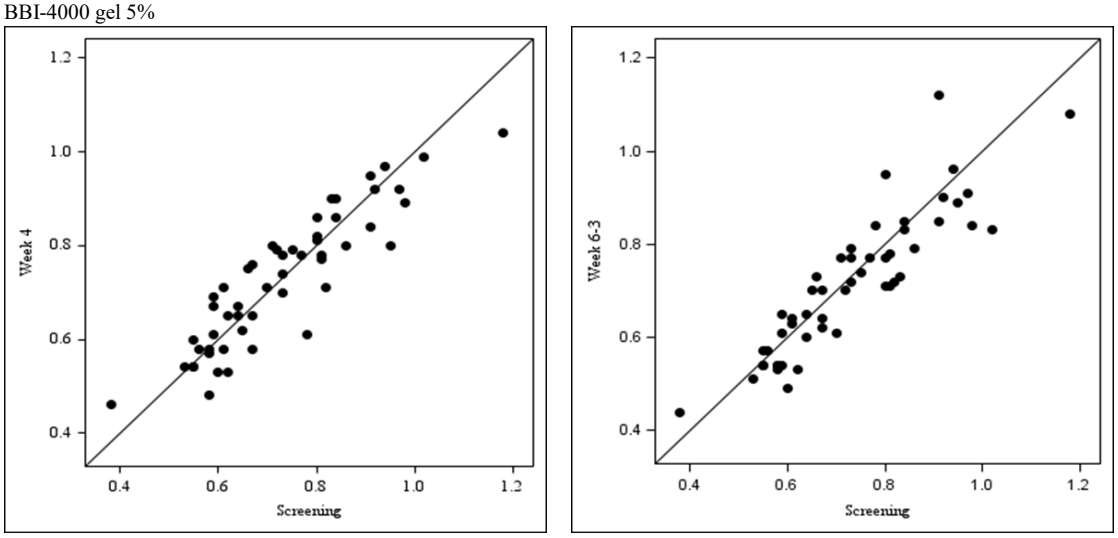
Source：5.3.5.1-1 Figure 14.3.4-1 より改変

図 2.7.4-1　臨床検査値の散布図（BBI-4000-04 試験）（続き）
Creatinine (mg/dL)
[Safety]

BBI-4000 gel 0%



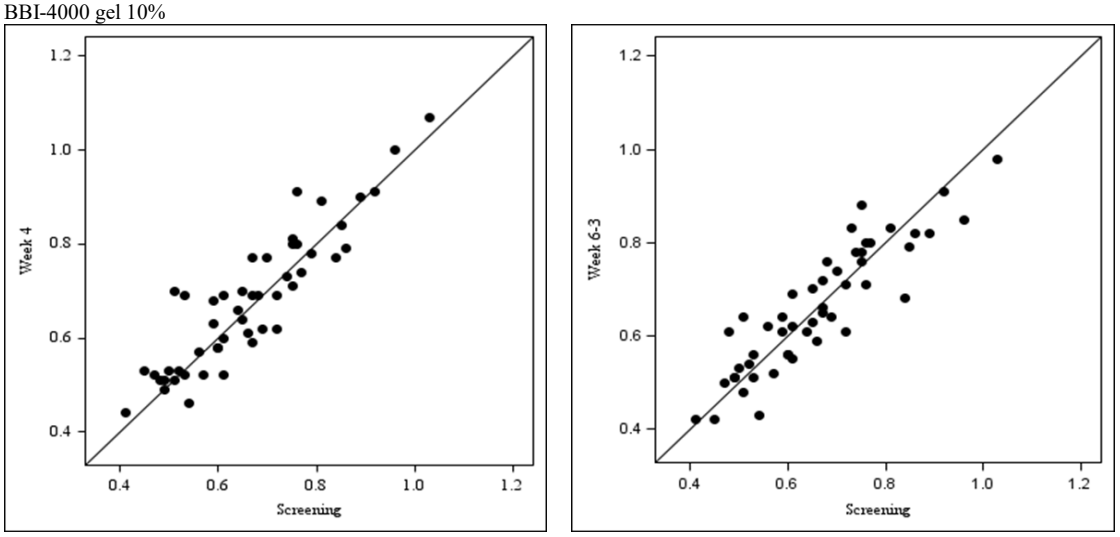
BBI-4000 gel 5%



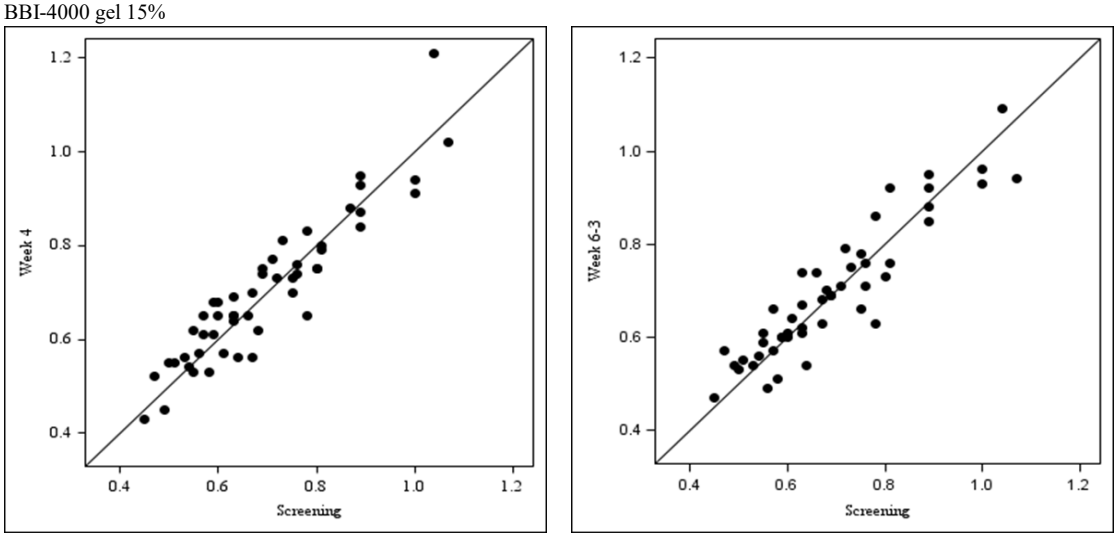
Source：5.3.5.1-1 Figure 14.3.4-1 より改変

図 2.7.4-1 臨床検査値の散布図（BBI-4000-04 試験）（続き）
Creatinine (mg/dL)
[Safety]

BBI-4000 gel 10%



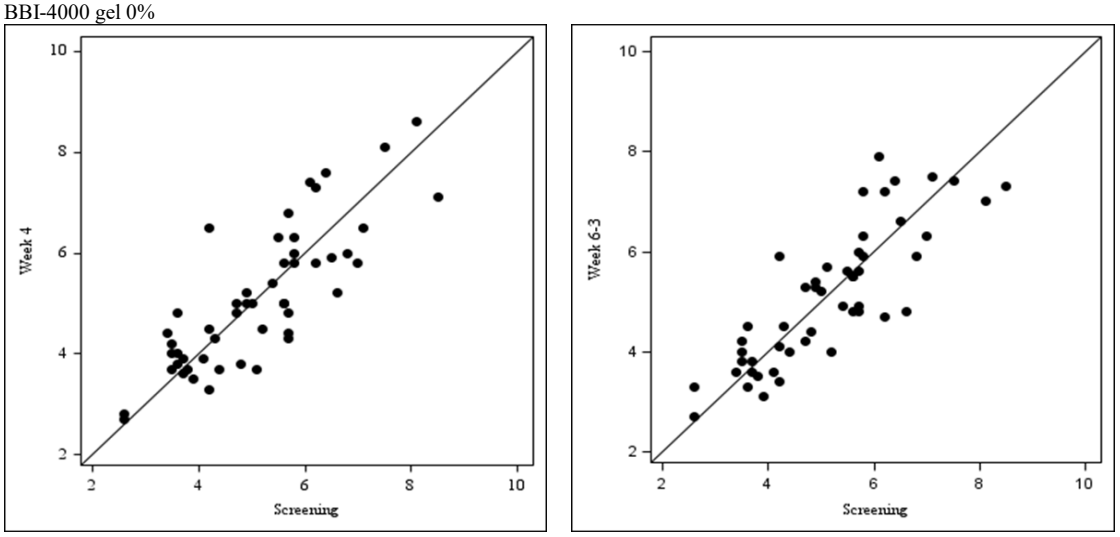
BBI-4000 gel 15%



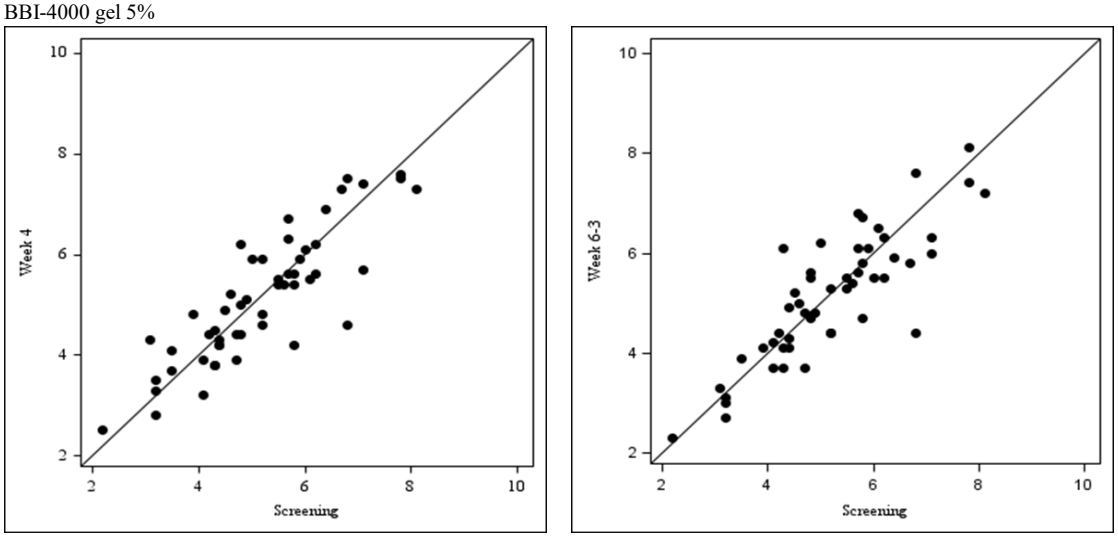
Source：5.3.5.1-1 Figure 14.3.4-1 より改変

図 2.7.4-1　臨床検査値の散布図（BBI-4000-04 試験）（続き）
Urate (mg/dL)
[Safety]

BBI-4000 gel 0%



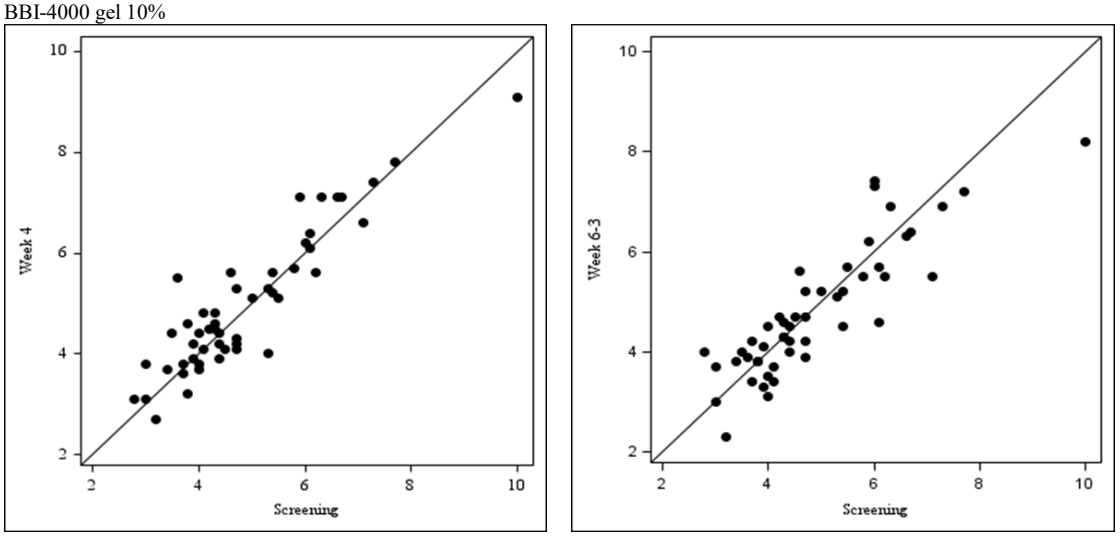
BBI-4000 gel 5%



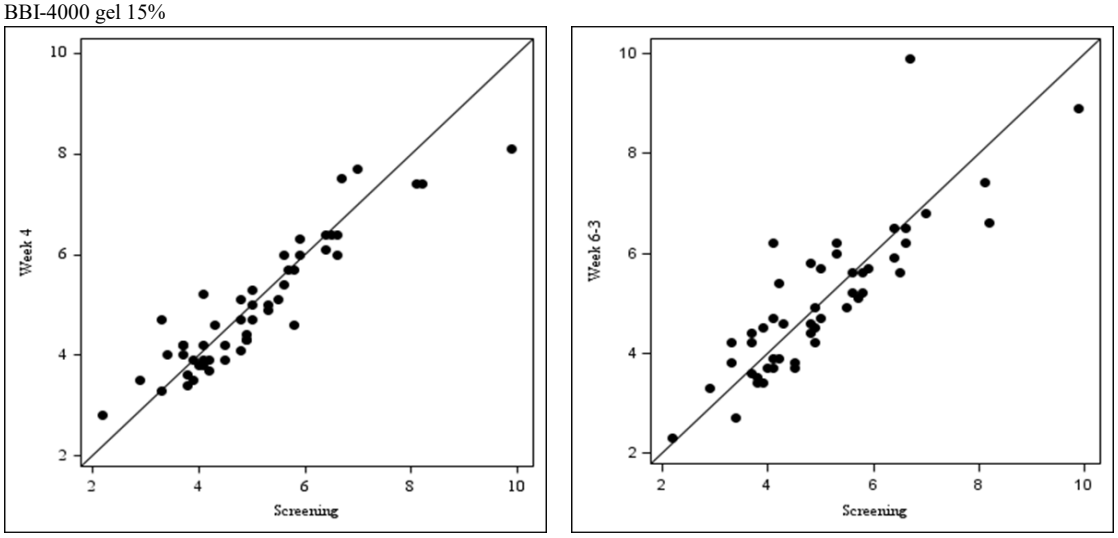
Source：5.3.5.1-1 Figure 14.3.4-1 より改変

図 2.7.4-1　臨床検査値の散布図（BBI-4000-04 試験）（続き）
Urate (mg/dL)
[Safety]

BBI-4000 gel 10%



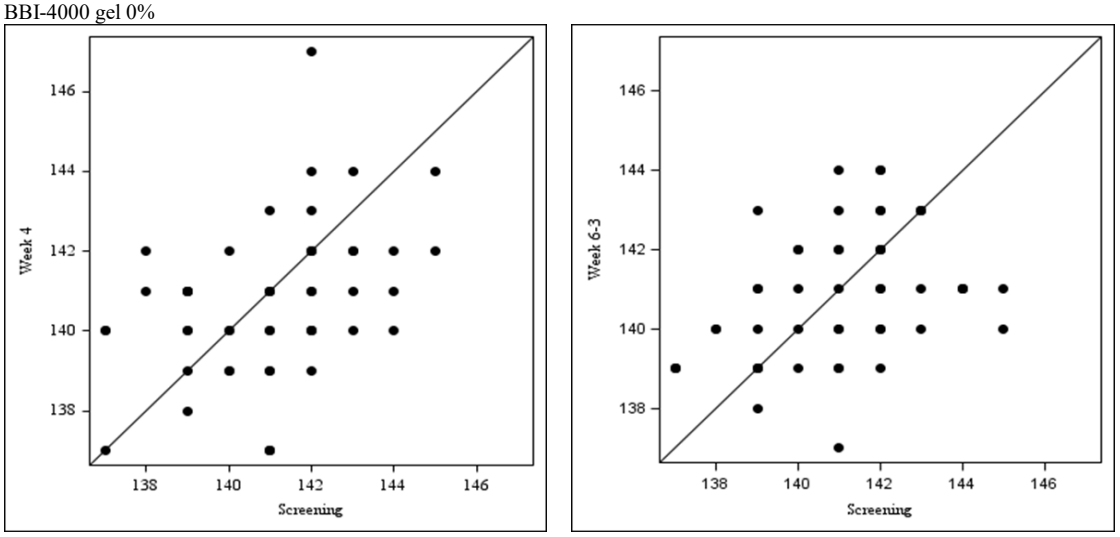
BBI-4000 gel 15%



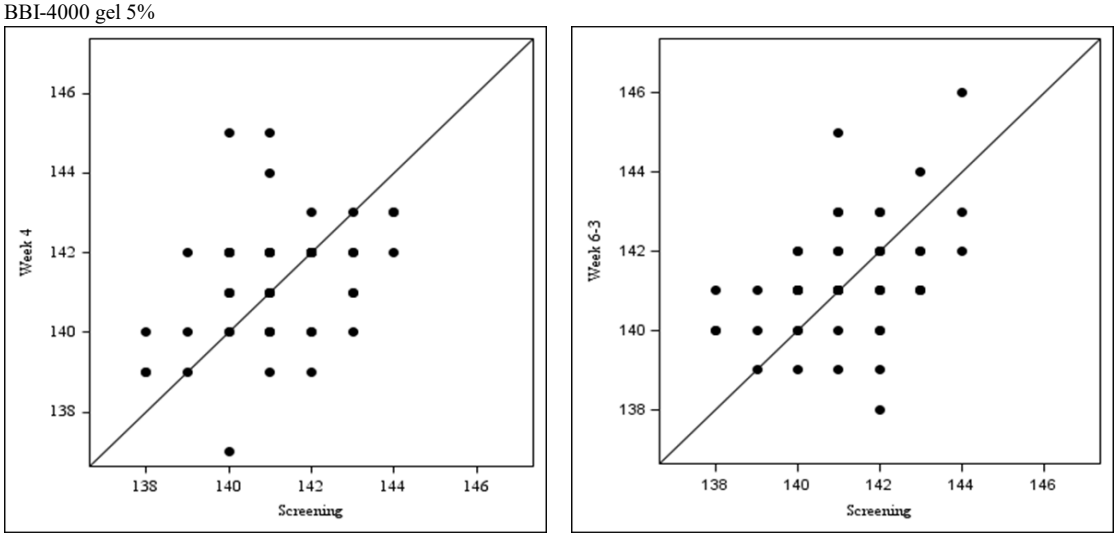
Source：5.3.5.1-1 Figure 14.3.4-1 より改変

図 2.7.4-1　臨床検査値の散布図（BBI-4000-04 試験）（続き）
Sodium (mEq/L)
[Safety]

BBI-4000 gel 0%



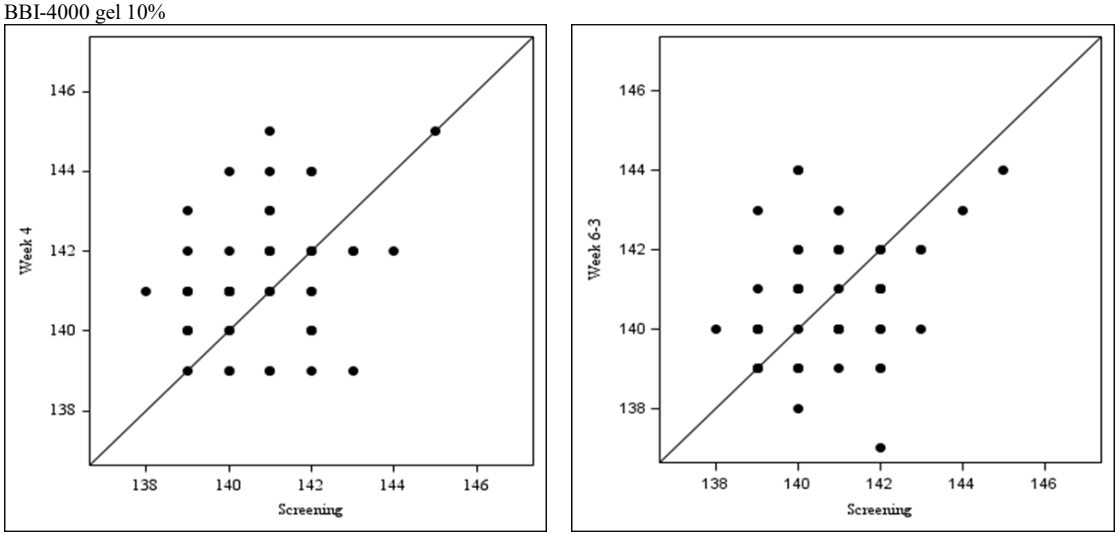
BBI-4000 gel 5%



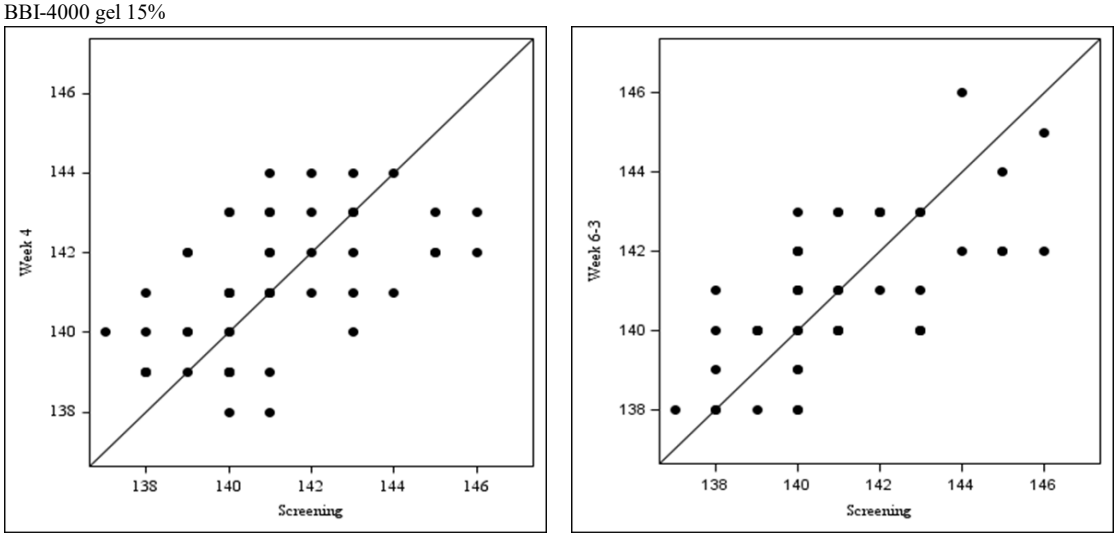
Source：5.3.5.1-1 Figure 14.3.4-1 より改変

図 2.7.4-1　臨床検査値の散布図（BBI-4000-04 試験）（続き）
Sodium (mEq/L)
[Safety]

BBI-4000 gel 10%



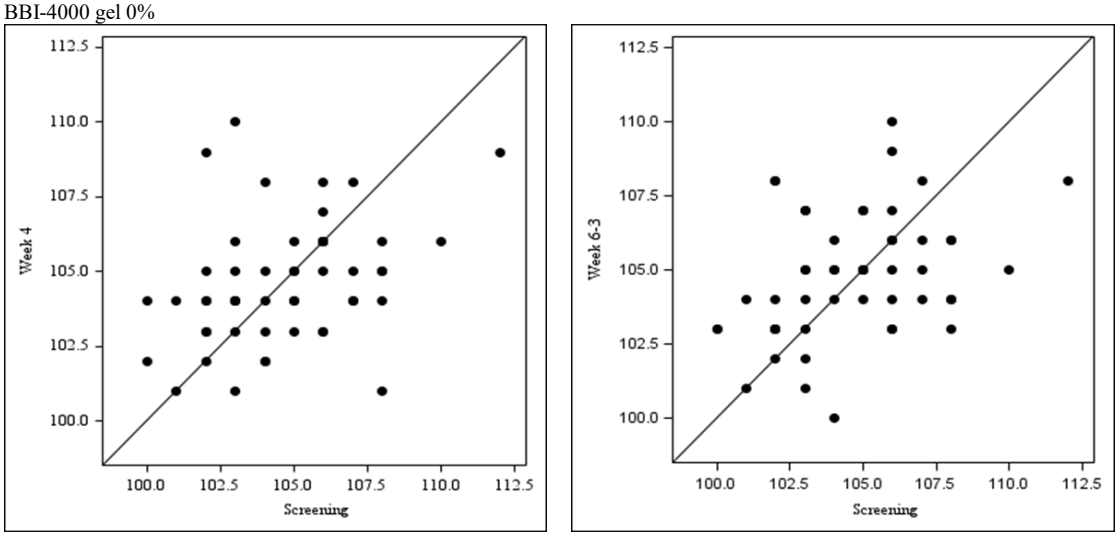
BBI-4000 gel 15%



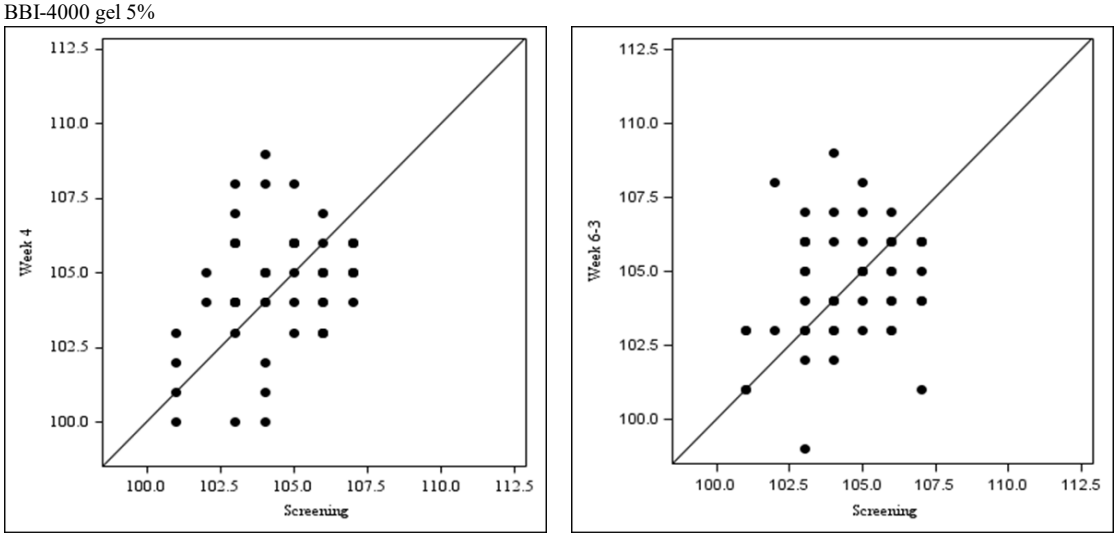
Source：5.3.5.1-1 Figure 14.3.4-1 より改変

図 2.7.4-1 臨床検査値の散布図（BBI-4000-04 試験）（続き）
Chloride (mEq/L)
[Safety]

BBI-4000 gel 0%



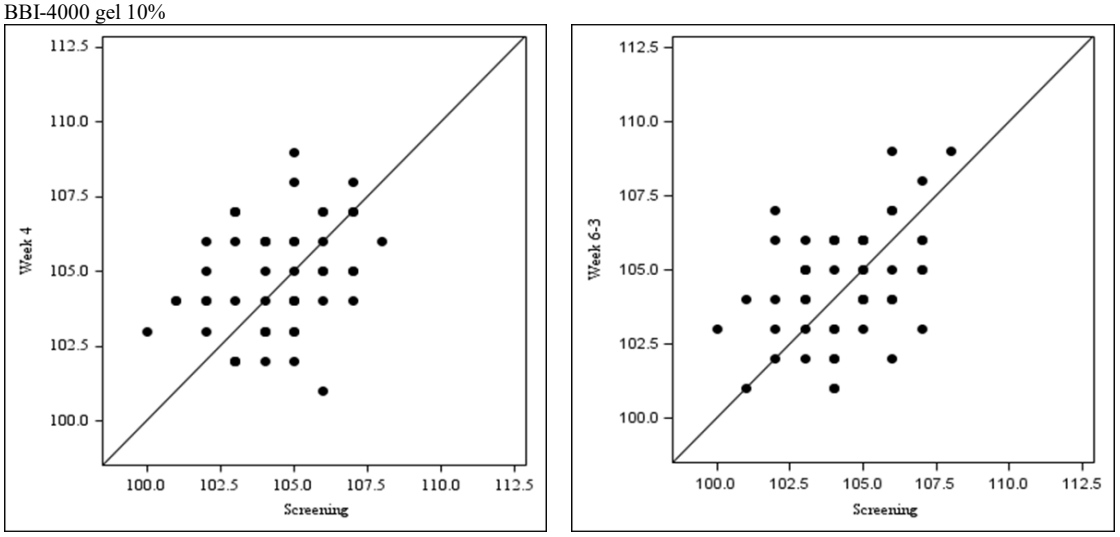
BBI-4000 gel 5%



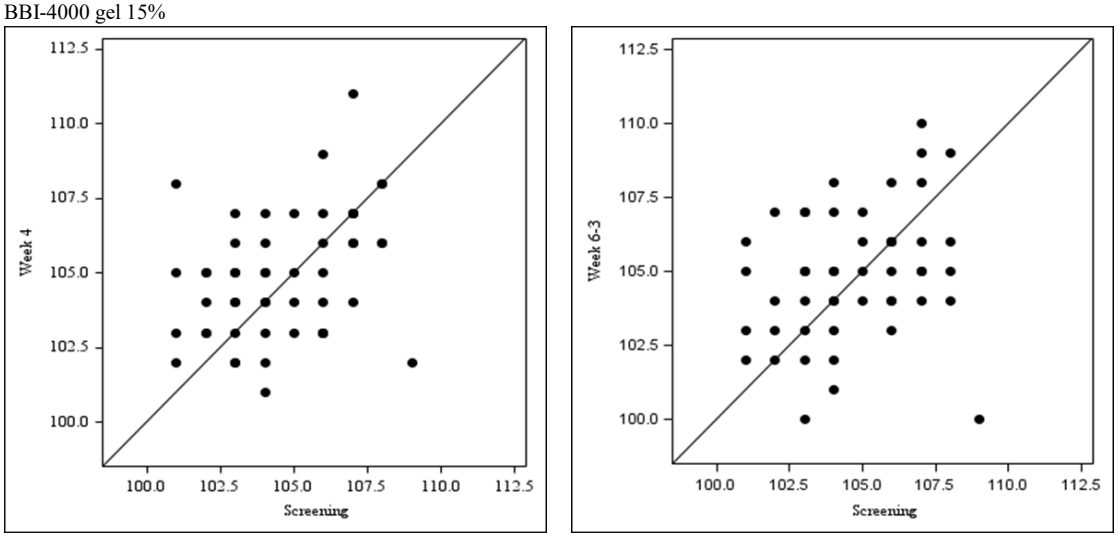
Source：5.3.5.1-1 Figure 14.3.4-1 より改変

図 2.7.4-1 臨床検査値の散布図（BBI-4000-04 試験）（続き）
Chloride (mEq/L)
[Safety]

BBI-4000 gel 10%



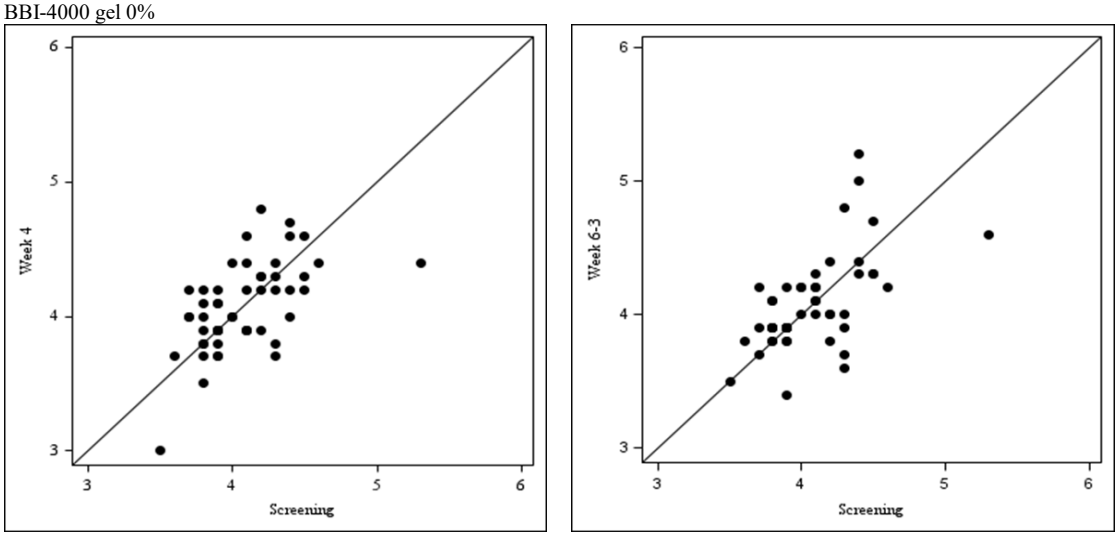
BBI-4000 gel 15%



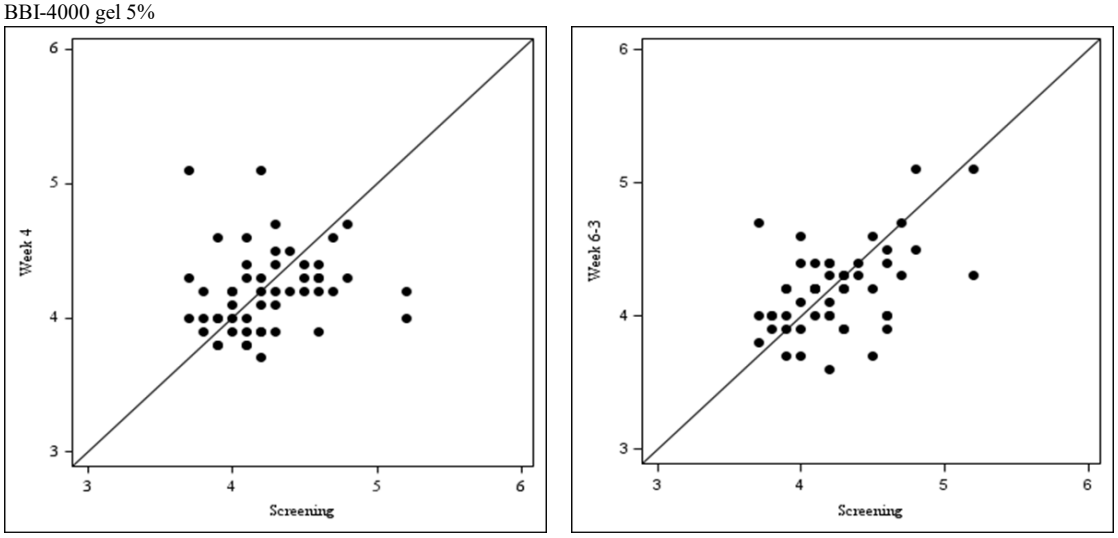
Source：5.3.5.1-1 Figure 14.3.4-1 より改変

図 2.7.4-1　臨床検査値の散布図（BBI-4000-04 試験）（続き）
Potassium (mEq/L)
[Safety]

BBI-4000 gel 0%



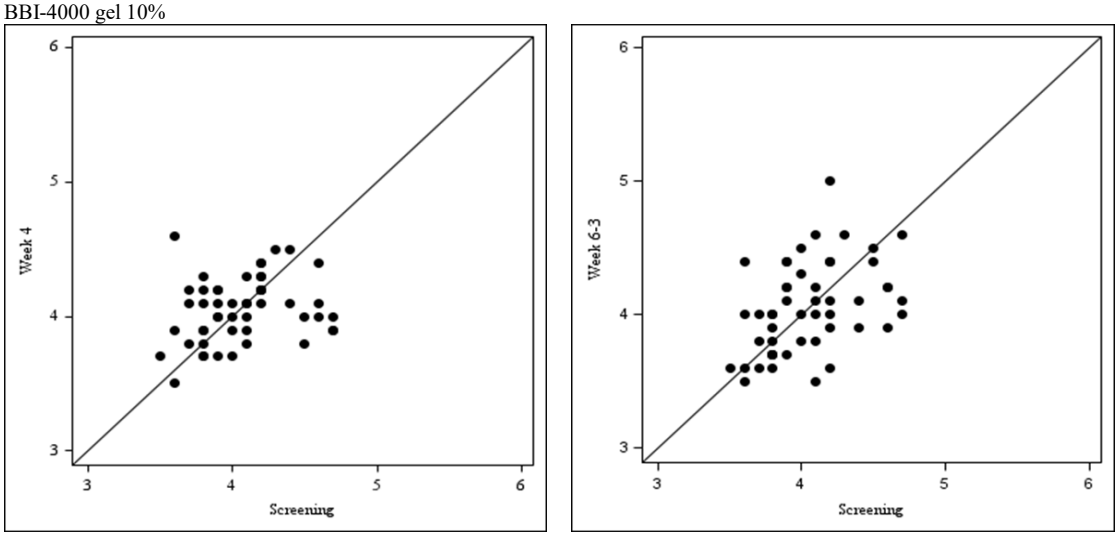
BBI-4000 gel 5%



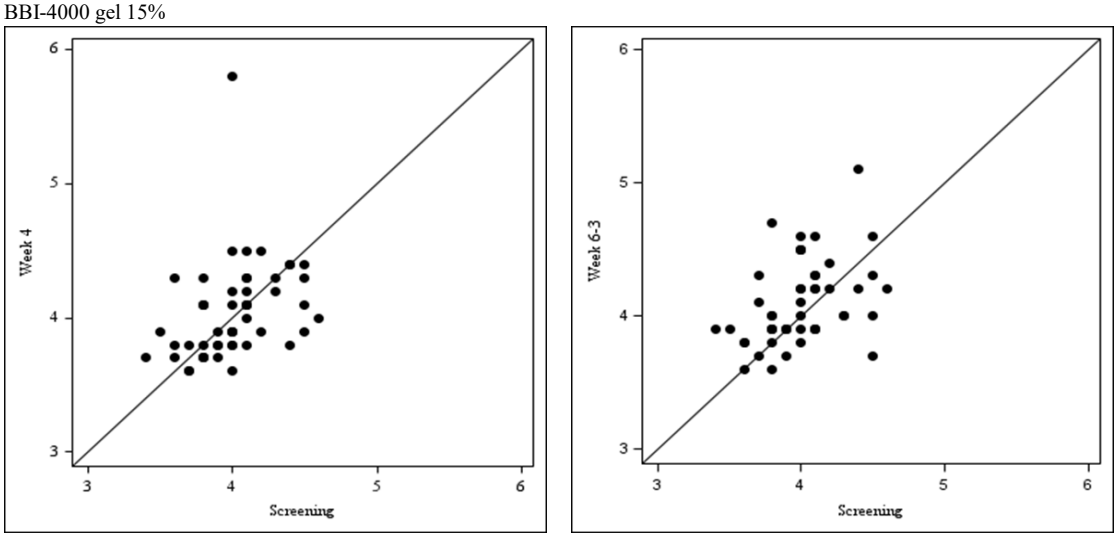
Source：5.3.5.1-1 Figure 14.3.4-1 より改変

図 2.7.4-1　臨床検査値の散布図（BBI-4000-04 試験）（続き）
Potassium (mEq/L)
[Safety]

BBI-4000 gel 10%



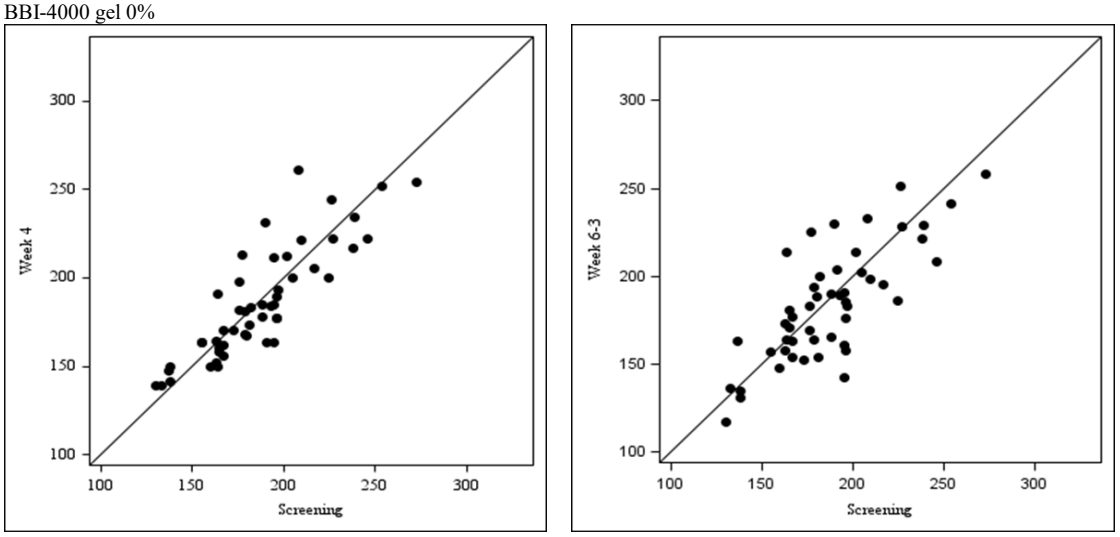
BBI-4000 gel 15%



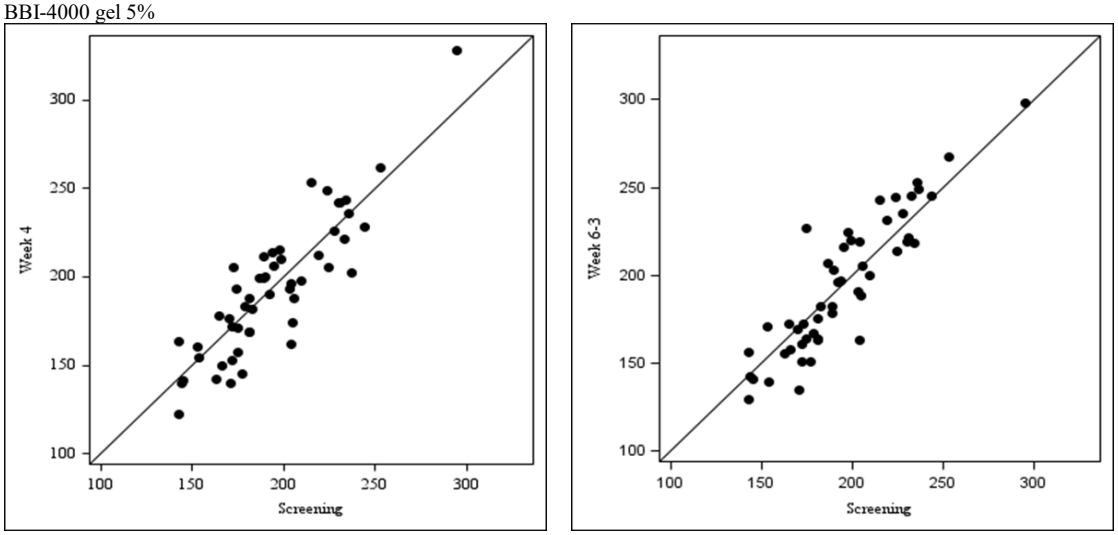
Source：5.3.5.1-1 Figure 14.3.4-1 より改変

図 2.7.4-1　臨床検査値の散布図（BBI-4000-04 試験）（続き）
Cholesterol (mg/dL)
[Safety]

BBI-4000 gel 0%



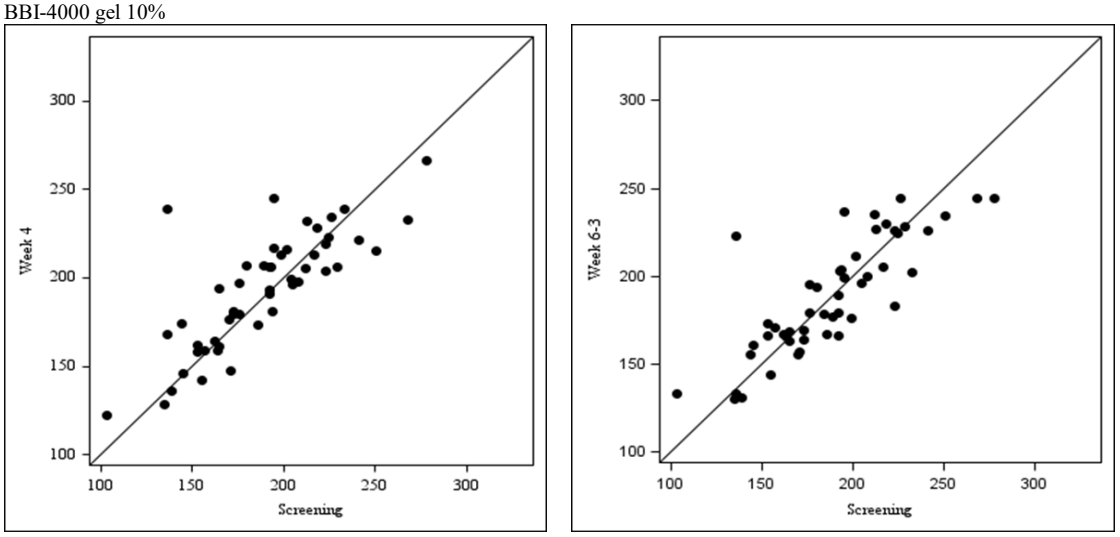
BBI-4000 gel 5%



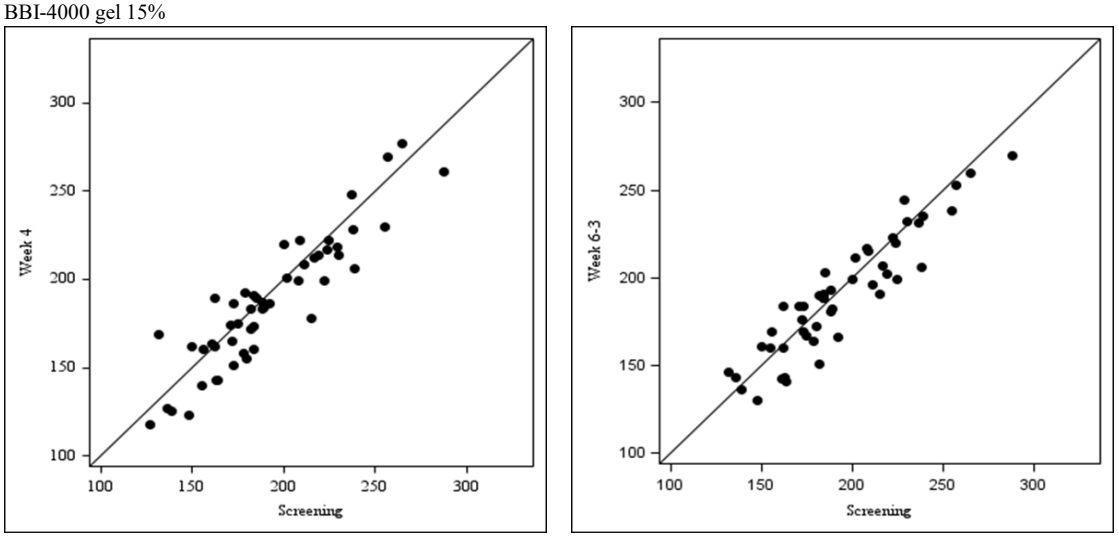
Source：5.3.5.1-1 Figure 14.3.4-1 より改変

図 2.7.4-1　臨床検査値の散布図（BBI-4000-04 試験）（続き）
Cholesterol (mg/dL)
[Safety]

BBI-4000 gel 10%



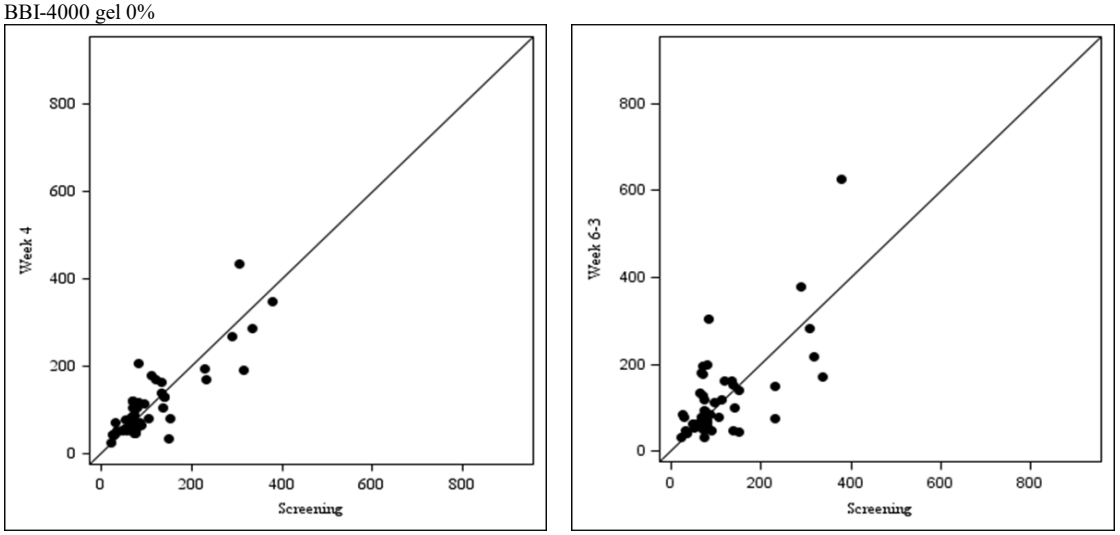
BBI-4000 gel 15%



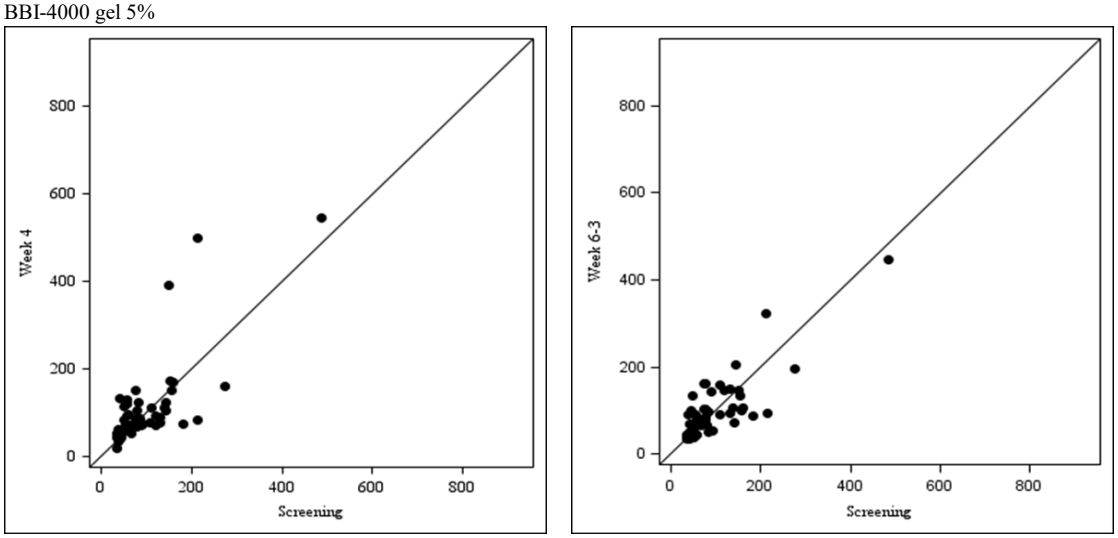
Source：5.3.5.1-1 Figure 14.3.4-1 より改変

図 2.7.4-1　臨床検査値の散布図（BBI-4000-04 試験）（続き）
Triglycerides (mg/dL)
[Safety]

BBI-4000 gel 0%



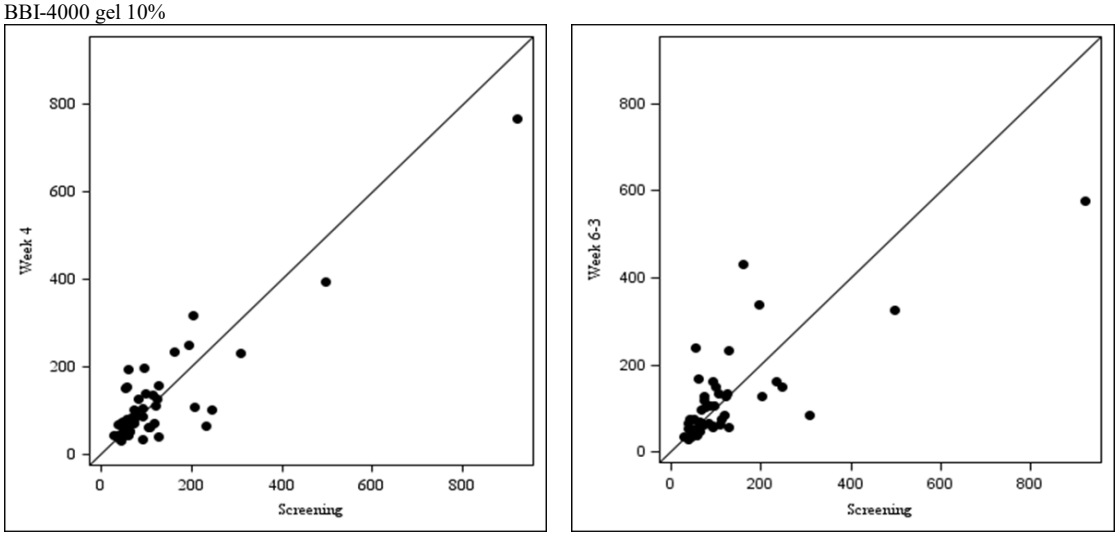
BBI-4000 gel 5%



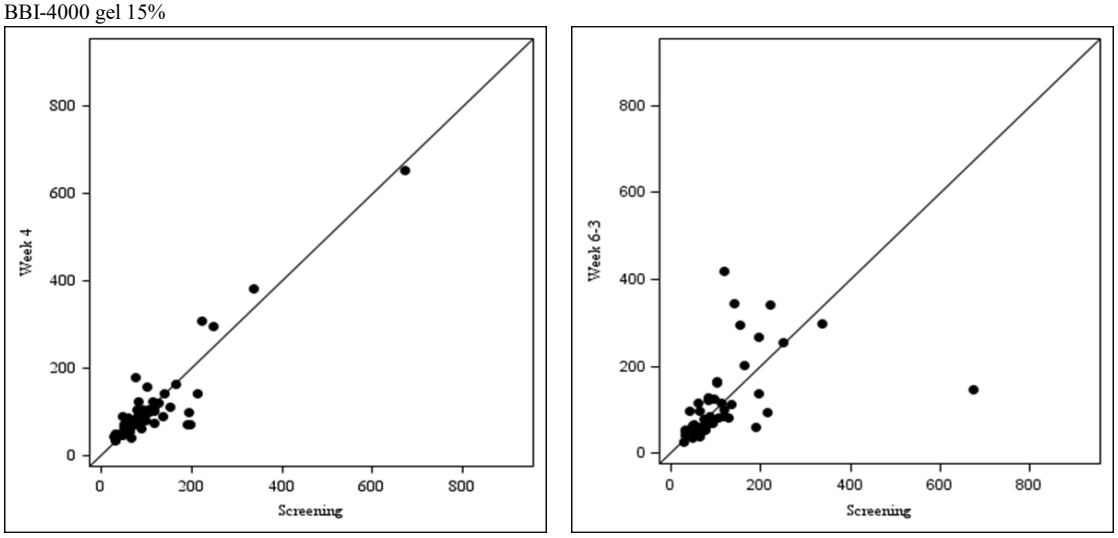
Source：5.3.5.1-1 Figure 14.3.4-1 より改変

図 2.7.4-1　臨床検査値の散布図（BBI-4000-04 試験）（続き）
Triglycerides (mg/dL)
[Safety]

BBI-4000 gel 10%



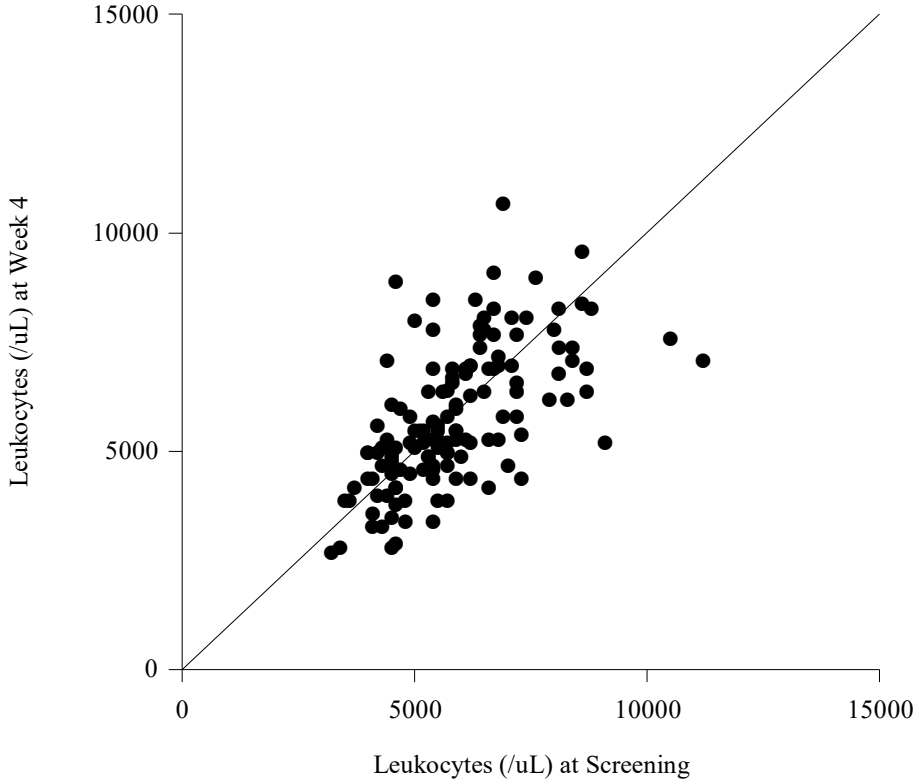
BBI-4000 gel 15%



Source：5.3.5.1-1 Figure 14.3.4-1 より改変

図 2.7.4-2　臨床検査値の散布図（BBI-4000-06 試験）
Hematology（Safety Analysis Set）

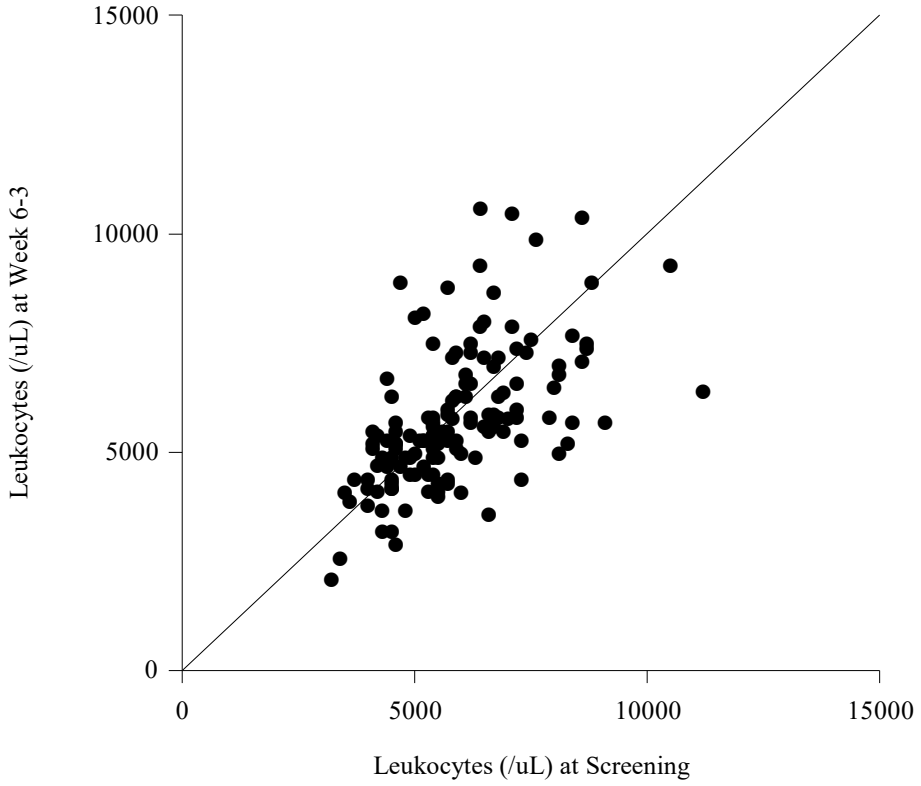
BBI-4000 0%



PAGE: 1 of 40
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/04/09
PROTOCOL NO: BBI-4000-06
Source：5.3.5.1-2 Figure 14.3.4-3 より改変

図 2.7.4-2　臨床検査値の散布図（BBI-4000-06 試験）（続き）
Hematology（Safety Analysis Set）

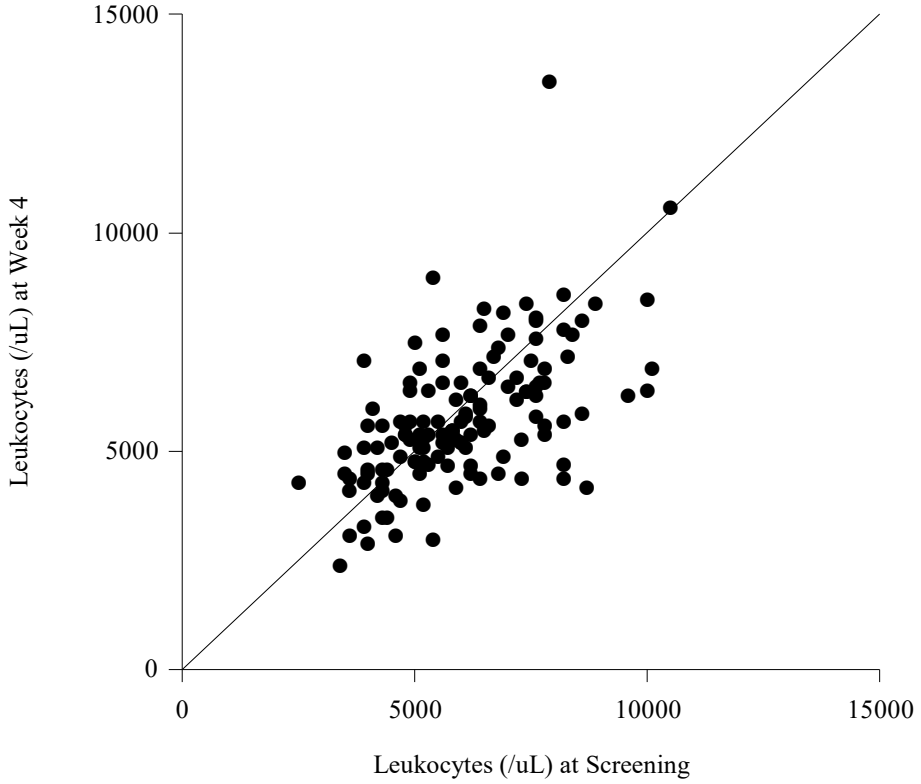
BBI-4000 0%



PAGE: 2 of 40
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/04/09
PROTOCOL NO: BBI-4000-06
Source：5.3.5.1-2 Figure 14.3.4-3 より改変

図 2.7.4-2　臨床検査値の散布図（BBI-4000-06 試験）（続き）
Hematology（Safety Analysis Set）

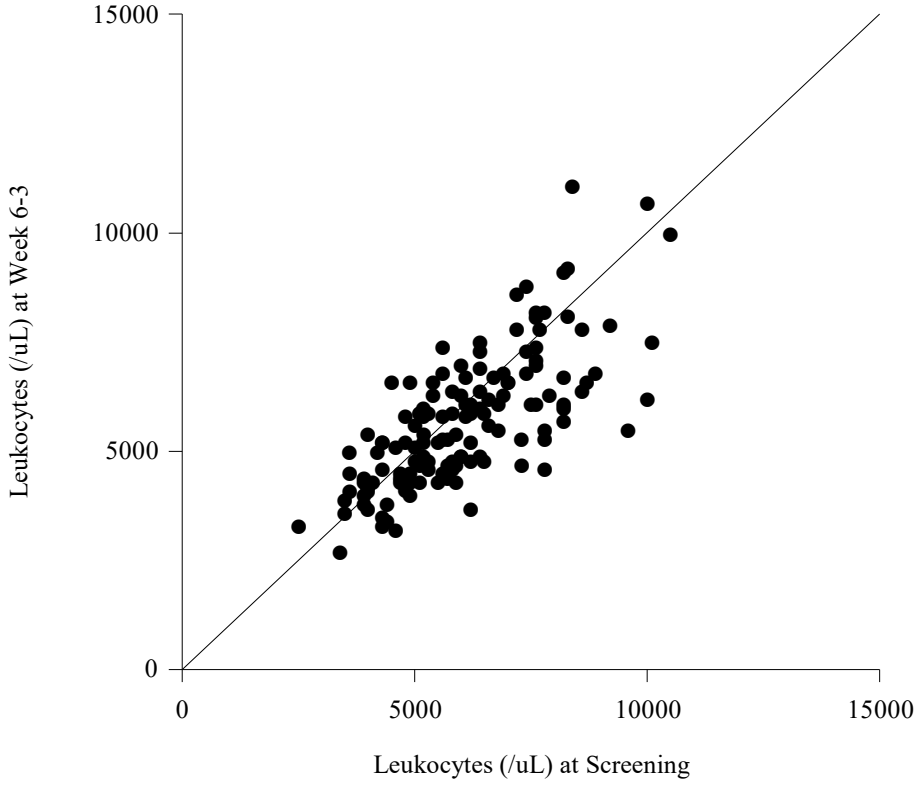
BBI-4000 5%



PAGE: 3 of 40
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/04/09
PROTOCOL NO: BBI-4000-06
Source：5.3.5.1-2 Figure 14.3.4-3 より改変

図 2.7.4-2　臨床検査値の散布図（BBI-4000-06 試験）（続き）
Hematology（Safety Analysis Set）

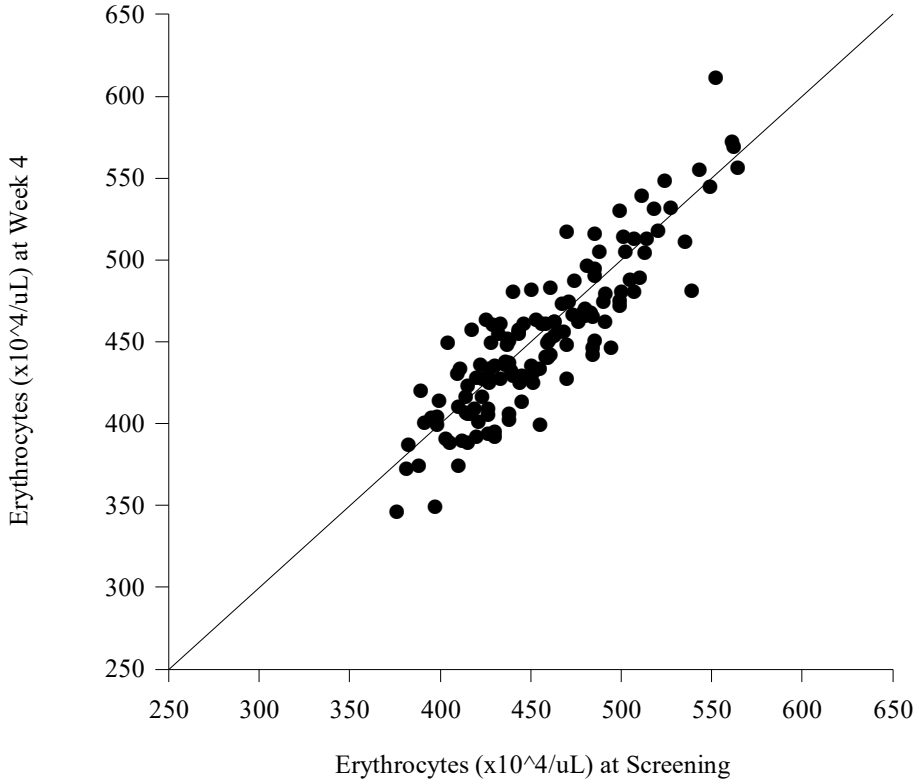
BBI-4000 5%



PAGE: 4 of 40
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/04/09
PROTOCOL NO: BBI-4000-06
Source：5.3.5.1-2 Figure 14.3.4-3 より改変

図 2.7.4-2　臨床検査値の散布図（BBI-4000-06 試験）（続き）
Hematology（Safety Analysis Set）

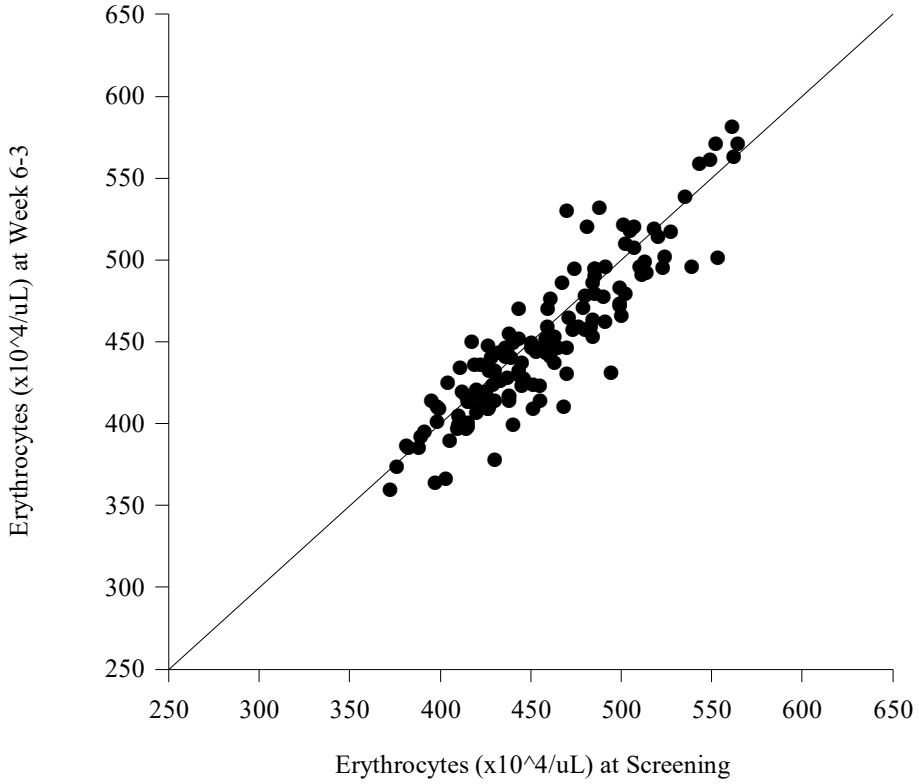
BBI-4000 0%



PAGE: 5 of 40
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/04/09
PROTOCOL NO: BBI-4000-06
Source：5.3.5.1-2 Figure 14.3.4-3 より改変

図 2.7.4-2　臨床検査値の散布図（BBI-4000-06 試験）（続き）
Hematology（Safety Analysis Set）

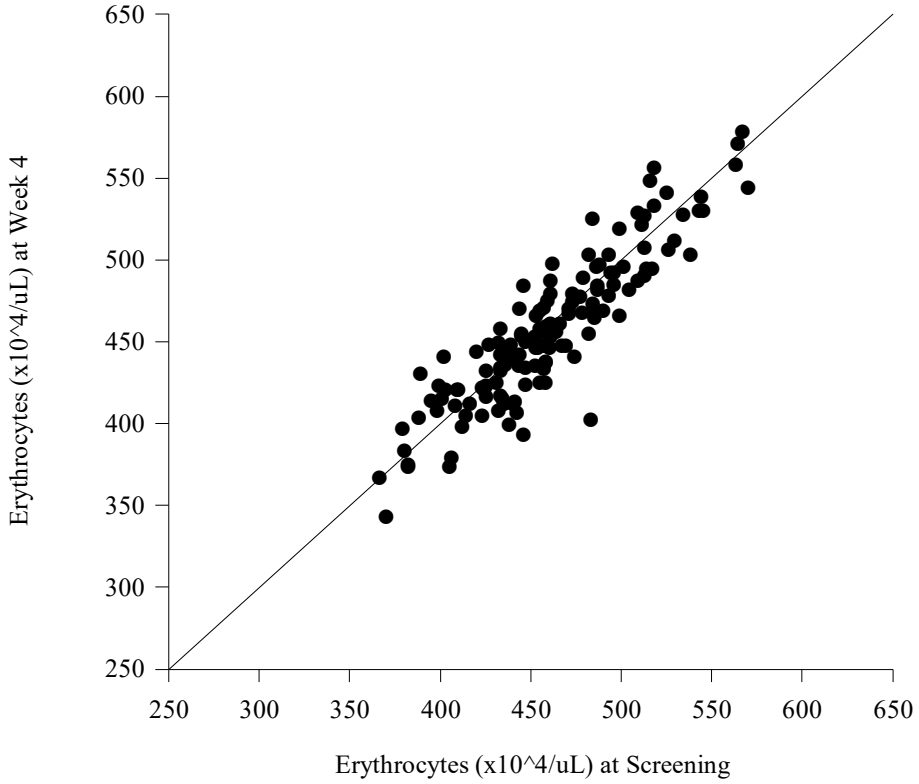
BBI-4000 0%



PAGE: 6 of 40
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/04/09
PROTOCOL NO: BBI-4000-06
Source：5.3.5.1-2 Figure 14.3.4-3 より改変

図 2.7.4-2　臨床検査値の散布図（BBI-4000-06 試験）（続き）
Hematology（Safety Analysis Set）

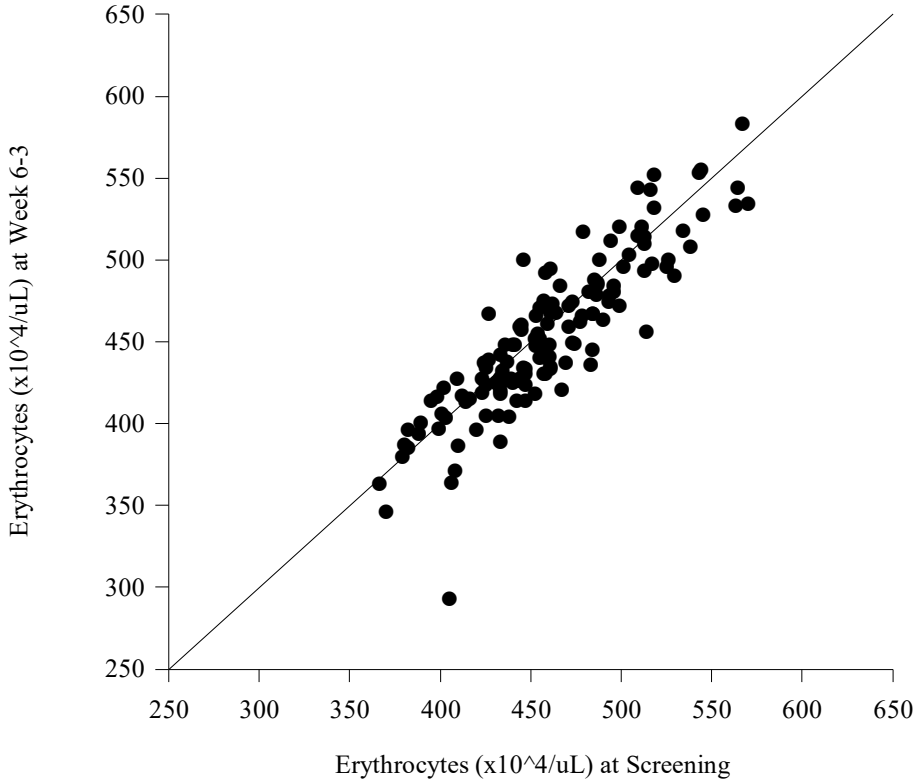
BBI-4000 5%



PAGE: 7 of 40
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/04/09
PROTOCOL NO: BBI-4000-06
Source：5.3.5.1-2 Figure 14.3.4-3 より改変

図 2.7.4-2　臨床検査値の散布図（BBI-4000-06 試験）（続き）
Hematology（Safety Analysis Set）

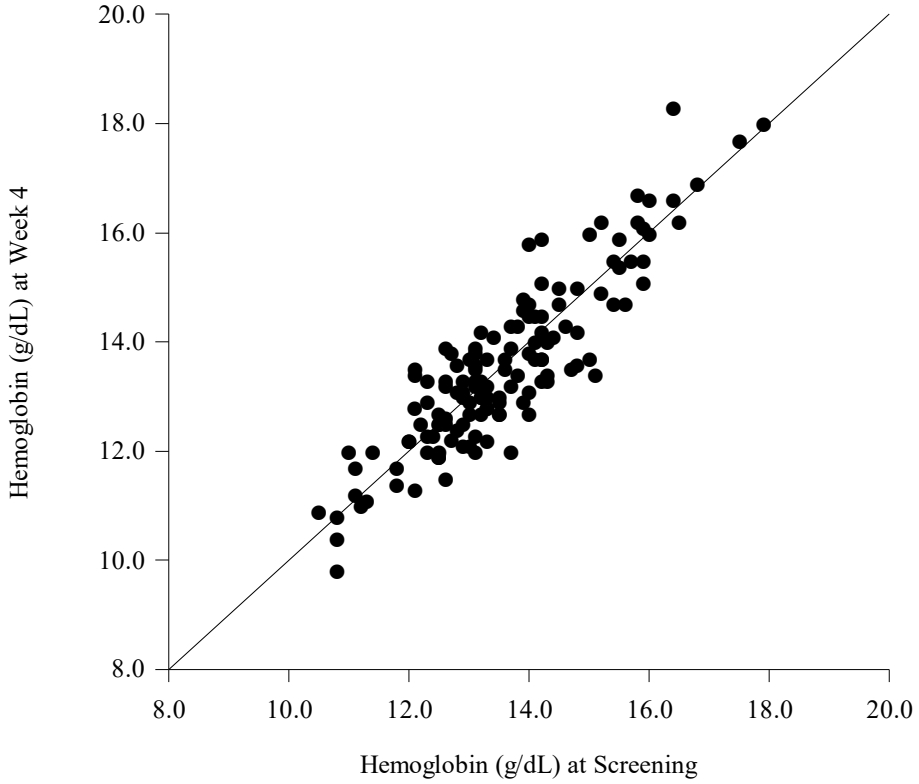
BBI-4000 5%



PAGE: 8 of 40
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/04/09
PROTOCOL NO: BBI-4000-06
Source：5.3.5.1-2 Figure 14.3.4-3 より改変

図 2.7.4-2　臨床検査値の散布図（BBI-4000-06 試験）（続き）
Hematology（Safety Analysis Set）

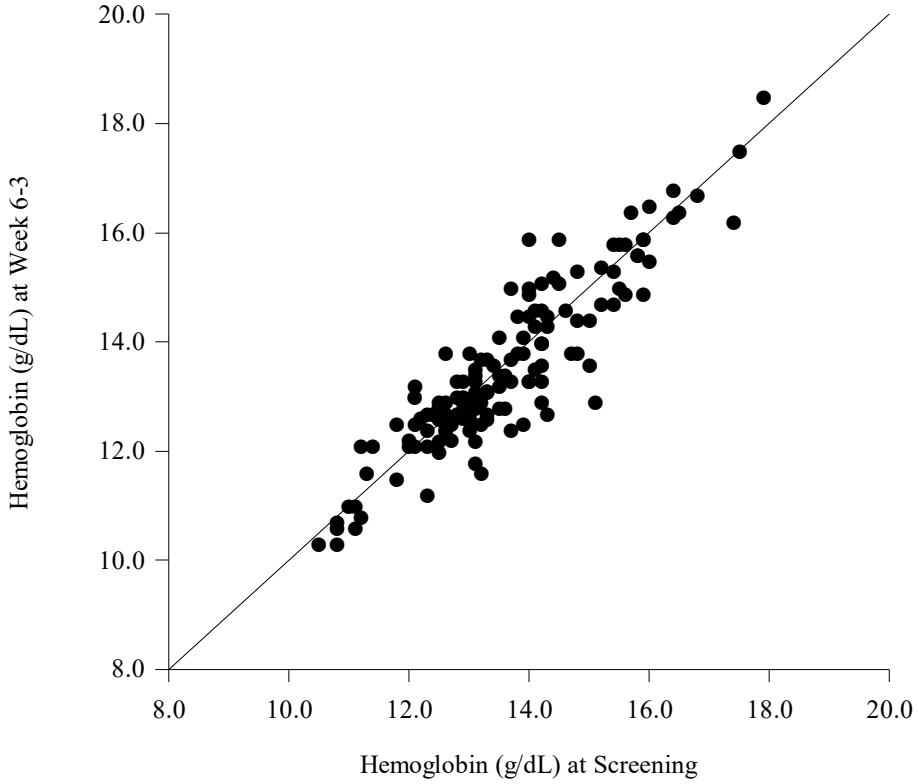
BBI-4000 0%



PAGE: 9 of 40
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/04/09
PROTOCOL NO: BBI-4000-06
Source：5.3.5.1-2 Figure 14.3.4-3 より改変

図 2.7.4-2　臨床検査値の散布図（BBI-4000-06 試験）（続き）
Hematology（Safety Analysis Set）

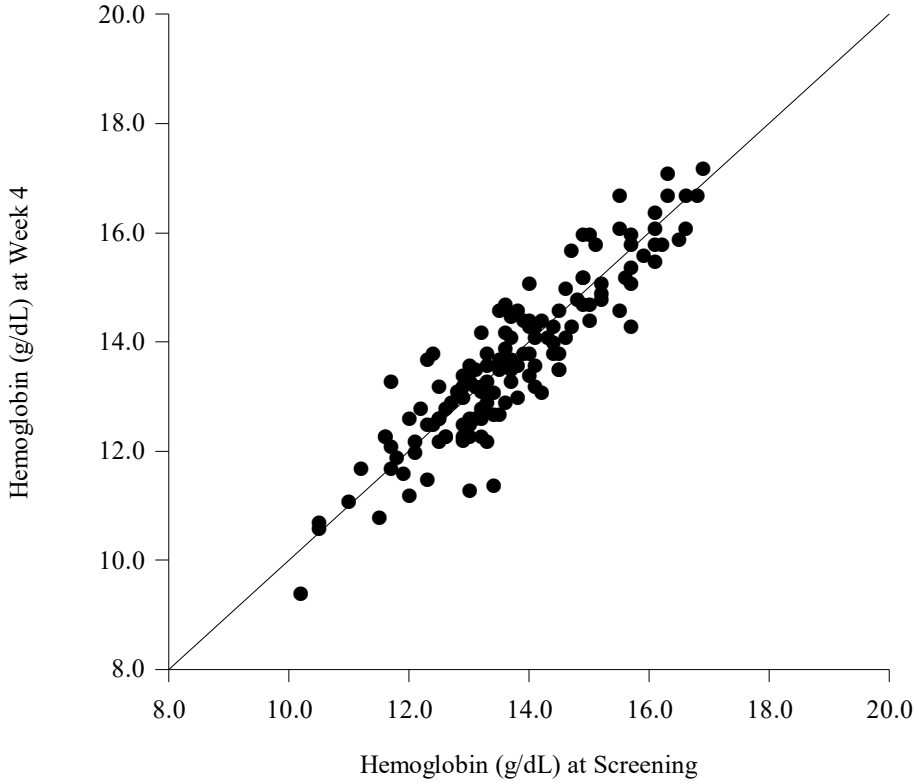
BBI-4000 0%



PAGE: 10 of 40
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/04/09
PROTOCOL NO: BBI-4000-06
Source：5.3.5.1-2 Figure 14.3.4-3 より改変

図 2.7.4-2　臨床検査値の散布図（BBI-4000-06 試験）（続き）
Hematology（Safety Analysis Set）

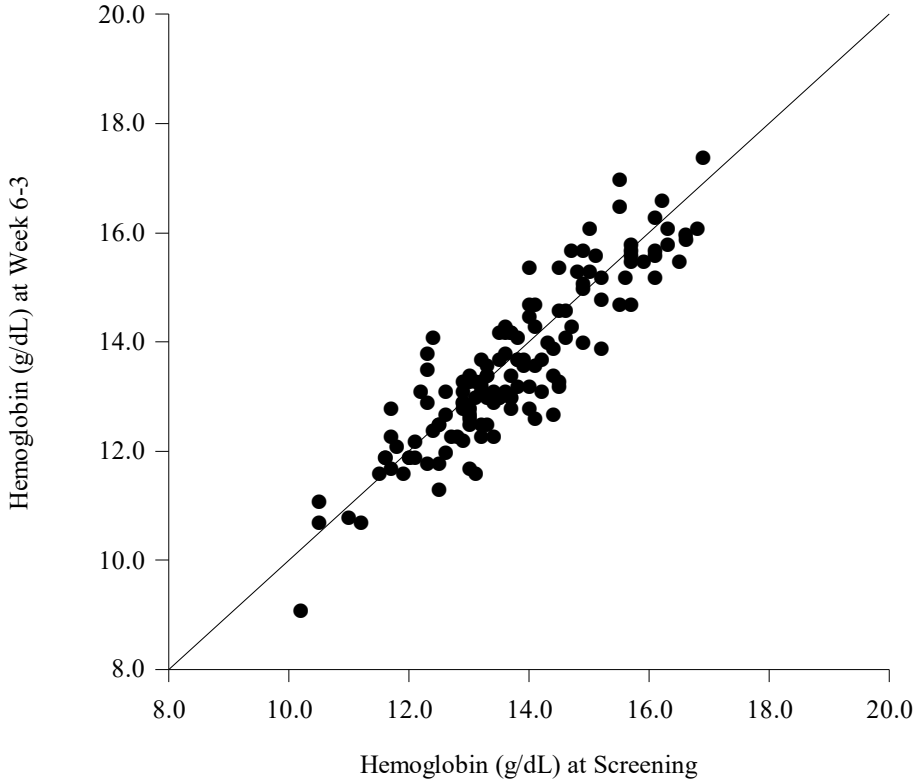
BBI-4000 5%



PAGE: 11 of 40
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/04/09
PROTOCOL NO: BBI-4000-06
Source：5.3.5.1-2 Figure 14.3.4-3 より改変

図 2.7.4-2　臨床検査値の散布図（BBI-4000-06 試験）（続き）
Hematology（Safety Analysis Set）

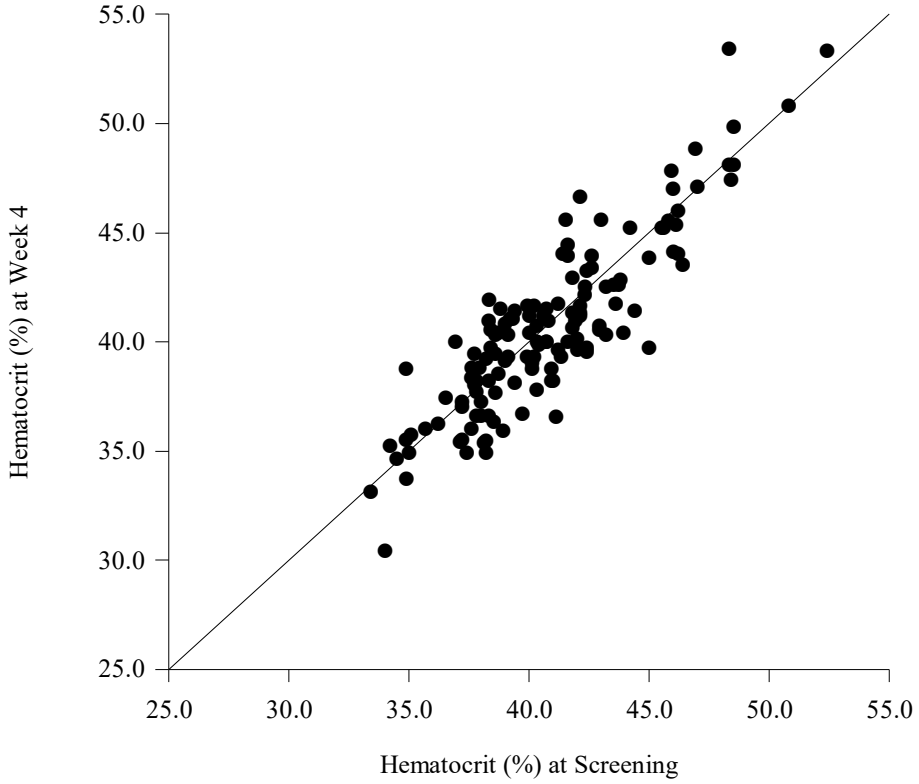
BBI-4000 5%



PAGE: 12 of 40
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/04/09
PROTOCOL NO: BBI-4000-06
Source：5.3.5.1-2 Figure 14.3.4-3 より改変

図 2.7.4-2　臨床検査値の散布図（BBI-4000-06 試験）（続き）
Hematology（Safety Analysis Set）

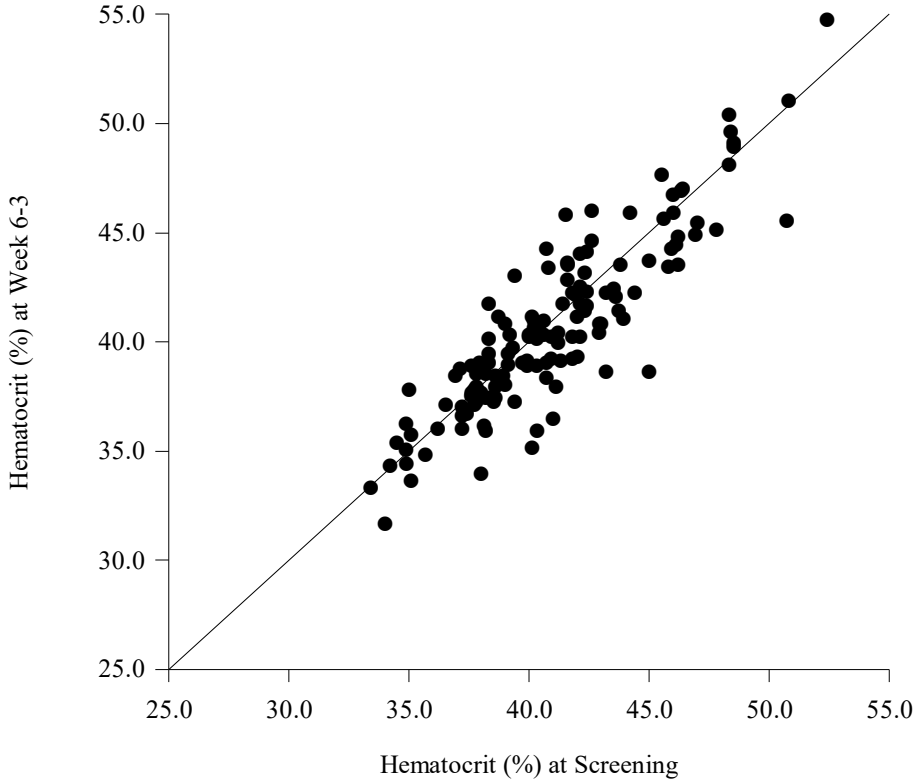
BBI-4000 0%



PAGE: 13 of 40
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/04/09
PROTOCOL NO: BBI-4000-06
Source：5.3.5.1-2 Figure 14.3.4-3 より改変

図 2.7.4-2　臨床検査値の散布図（BBI-4000-06 試験）（続き）
Hematology（Safety Analysis Set）

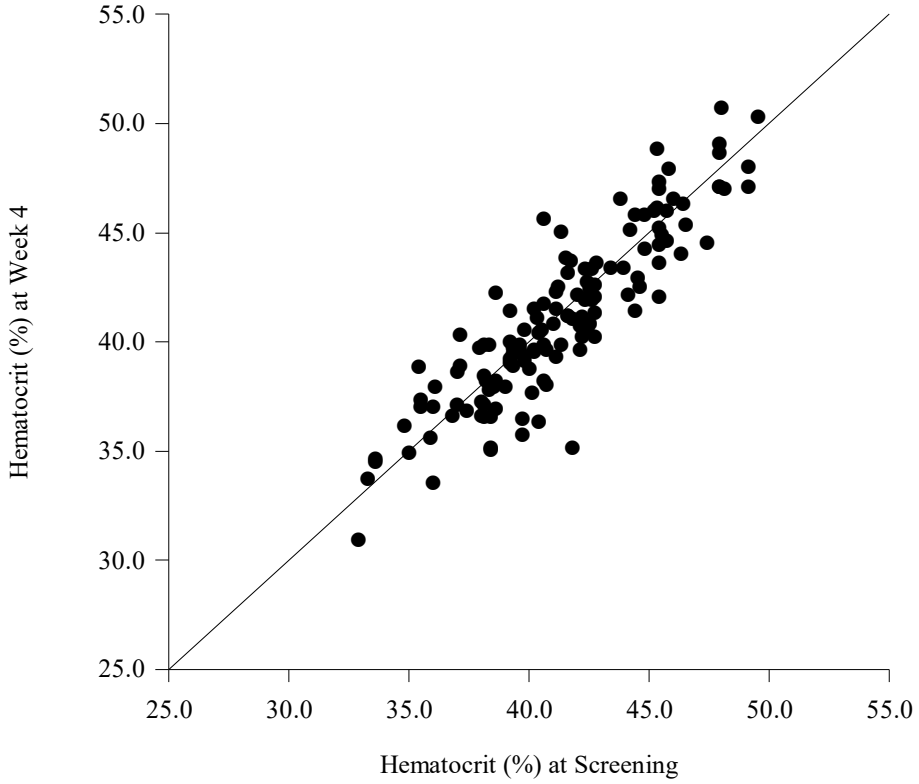
BBI-4000 0%



PAGE: 14 of 40
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/04/09
PROTOCOL NO: BBI-4000-06
Source：5.3.5.1-2 Figure 14.3.4-3 より改変

図 2.7.4-2　臨床検査値の散布図（BBI-4000-06 試験）（続き）
Hematology（Safety Analysis Set）

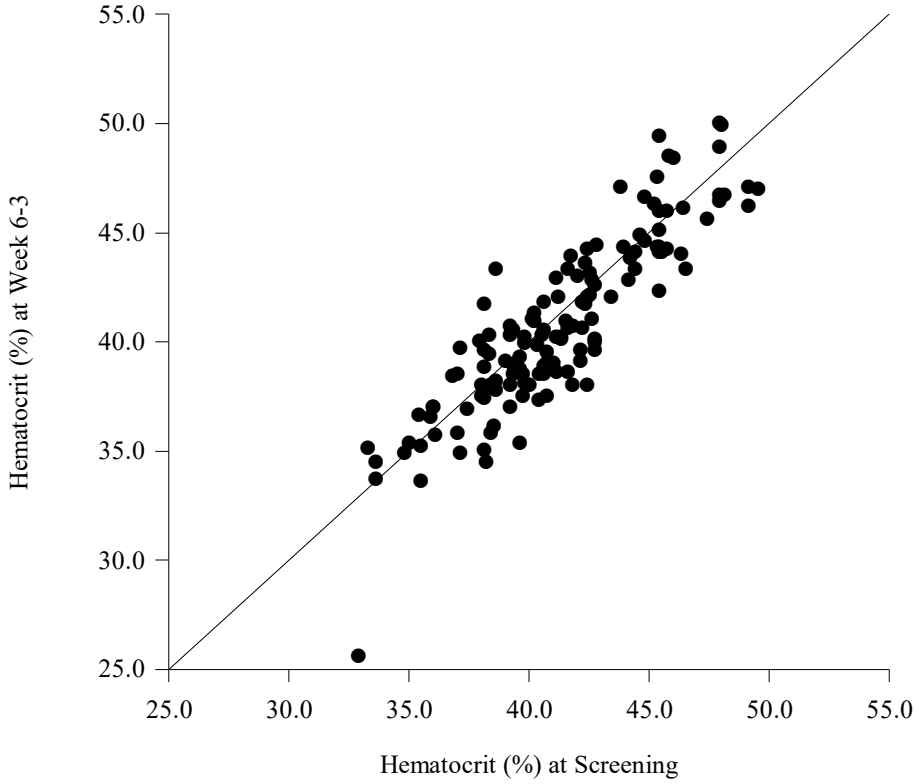
BBI-4000 5%



PAGE: 15 of 40
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/04/09
PROTOCOL NO: BBI-4000-06
Source：5.3.5.1-2 Figure 14.3.4-3 より改変

図 2.7.4-2　臨床検査値の散布図（BBI-4000-06 試験）（続き）
Hematology（Safety Analysis Set）

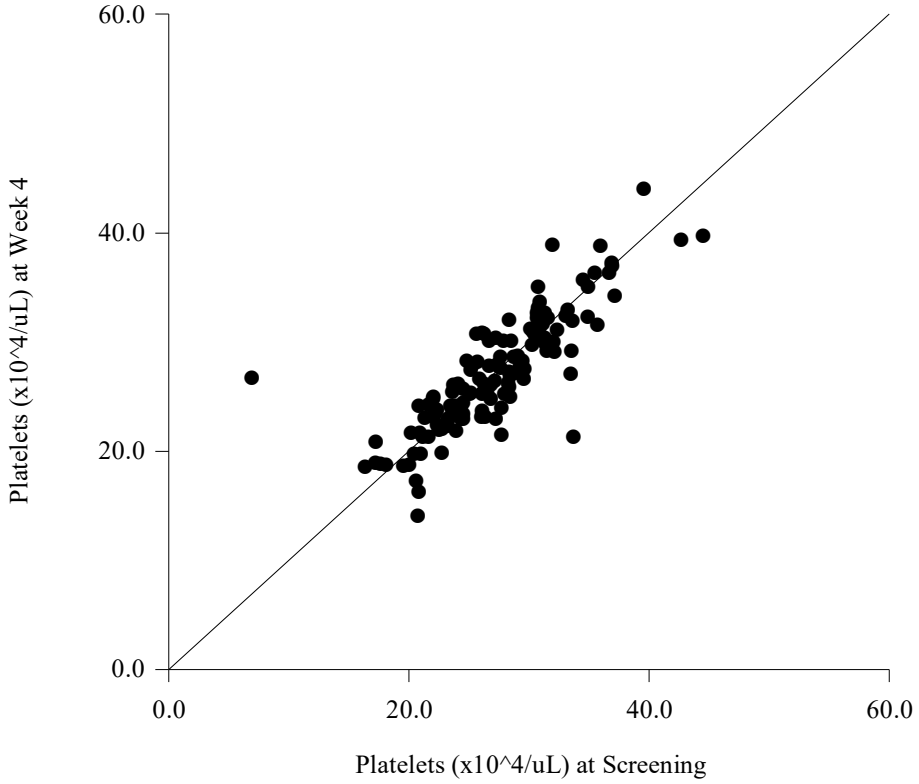
BBI-4000 5%



PAGE: 16 of 40
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/04/09
PROTOCOL NO: BBI-4000-06
Source：5.3.5.1-2 Figure 14.3.4-3 より改変

図 2.7.4-2　臨床検査値の散布図（BBI-4000-06 試験）（続き）
Hematology（Safety Analysis Set）

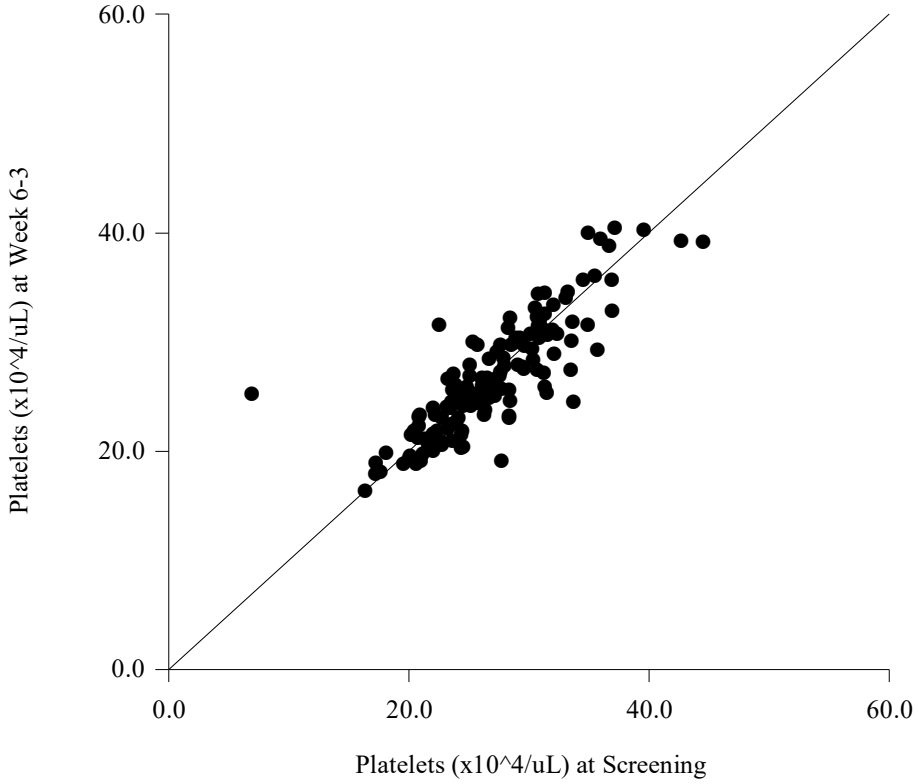
BBI-4000 0%



PAGE: 17 of 40
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/04/09
PROTOCOL NO: BBI-4000-06
Source：5.3.5.1-2 Figure 14.3.4-3 より改変

図 2.7.4-2　臨床検査値の散布図（BBI-4000-06 試験）（続き）
Hematology（Safety Analysis Set）

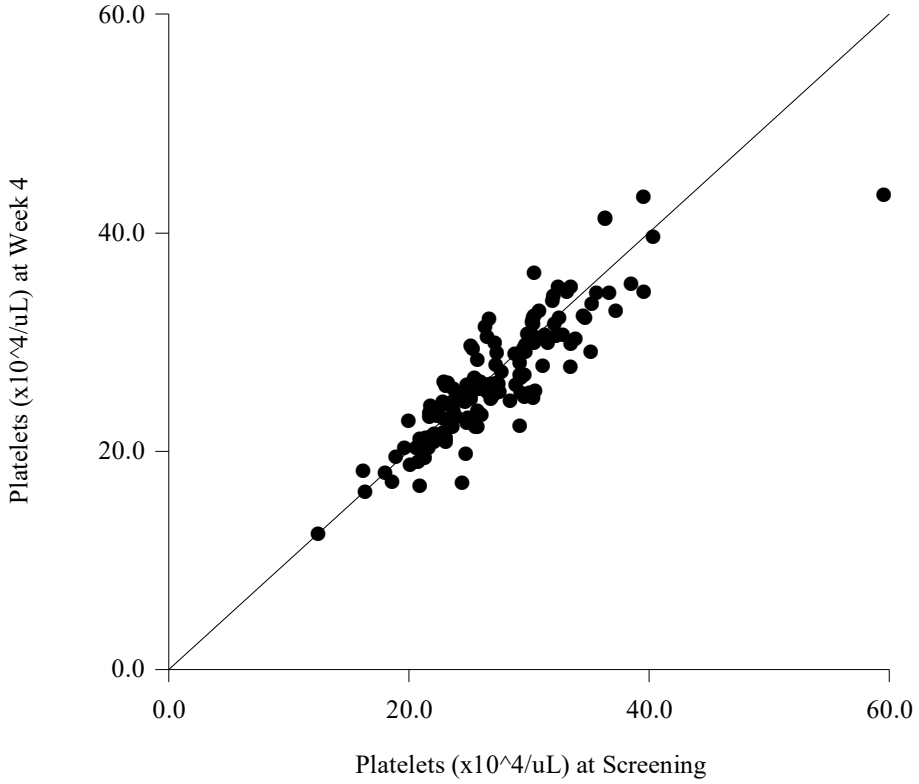
BBI-4000 0%



PAGE: 18 of 40
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/04/09
PROTOCOL NO: BBI-4000-06
Source：5.3.5.1-2 Figure 14.3.4-3 より改変

図 2.7.4-2　臨床検査値の散布図（BBI-4000-06 試験）（続き）
Hematology（Safety Analysis Set）

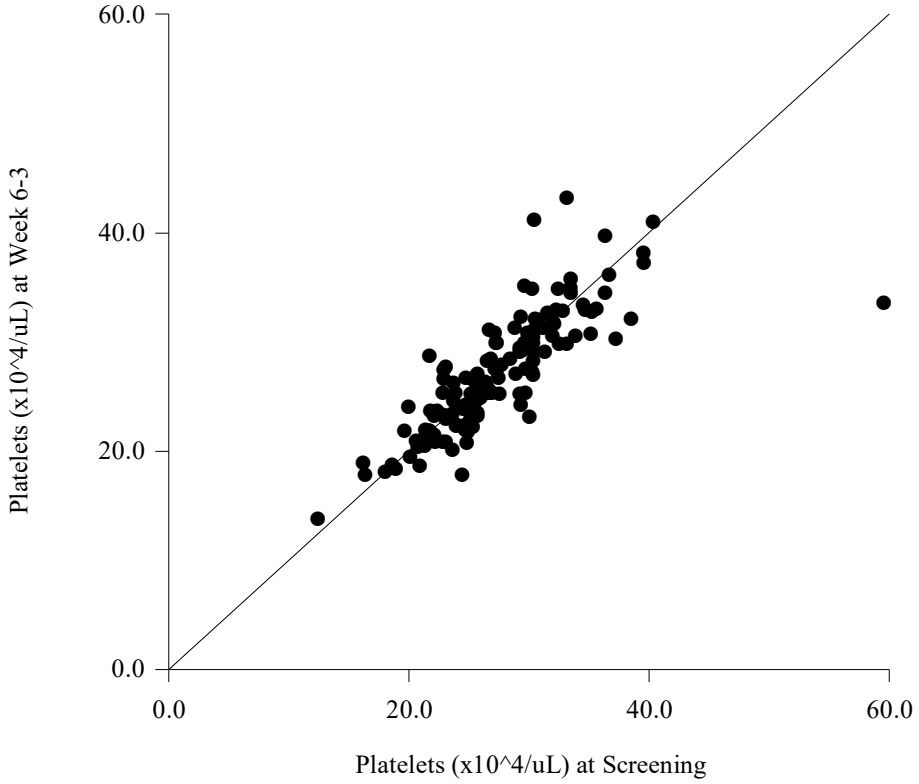
BBI-4000 5%



PAGE: 19 of 40
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/04/09
PROTOCOL NO: BBI-4000-06
Source：5.3.5.1-2 Figure 14.3.4-3 より改変

図 2.7.4-2　臨床検査値の散布図（BBI-4000-06 試験）（続き）
Hematology（Safety Analysis Set）

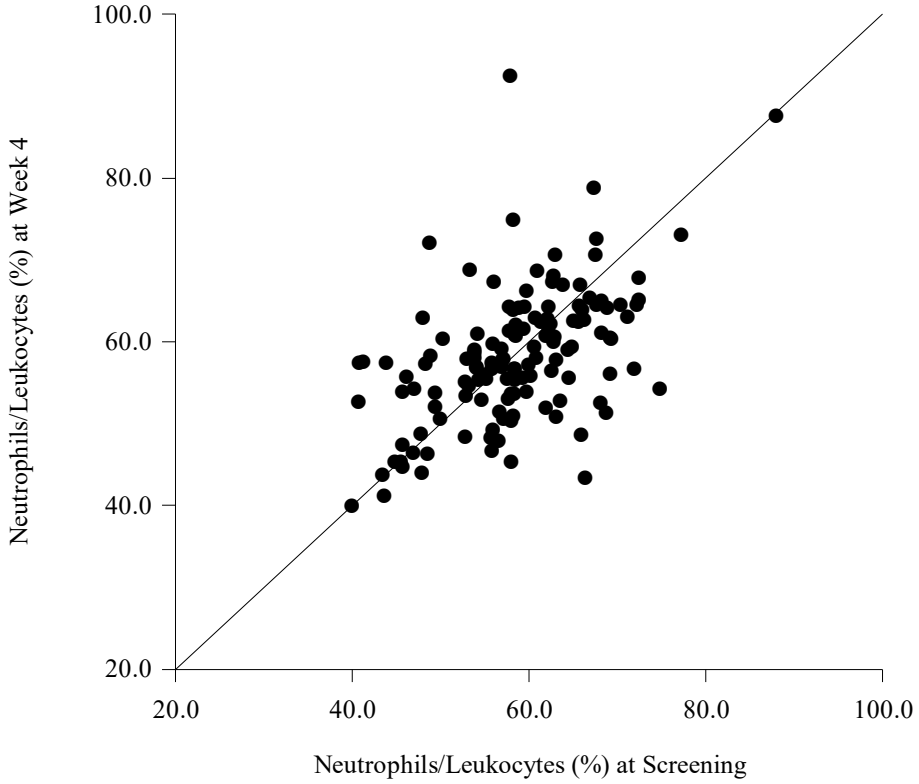
BBI-4000 5%



PAGE: 20 of 40
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/04/09
PROTOCOL NO: BBI-4000-06
Source：5.3.5.1-2 Figure 14.3.4-3 より改変

図 2.7.4-2　臨床検査値の散布図（BBI-4000-06 試験）（続き）
Hematology（Safety Analysis Set）

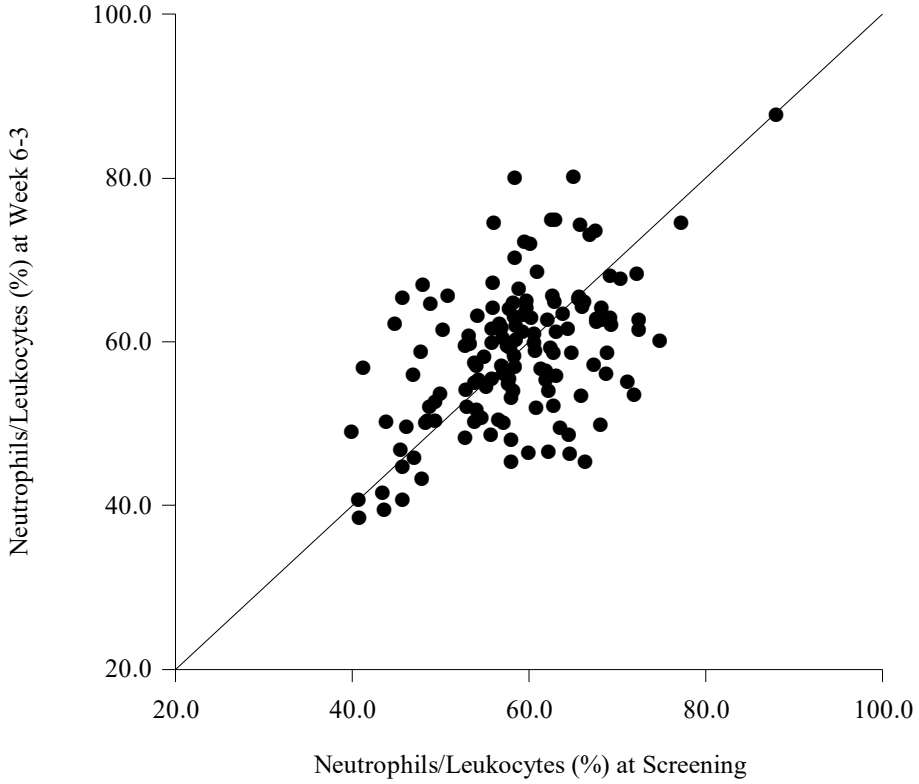
BBI-4000 0%



PAGE: 21 of 40
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/04/09
PROTOCOL NO: BBI-4000-06
Source：5.3.5.1-2 Figure 14.3.4-3 より改変

図 2.7.4-2　臨床検査値の散布図（BBI-4000-06 試験）（続き）
Hematology（Safety Analysis Set）

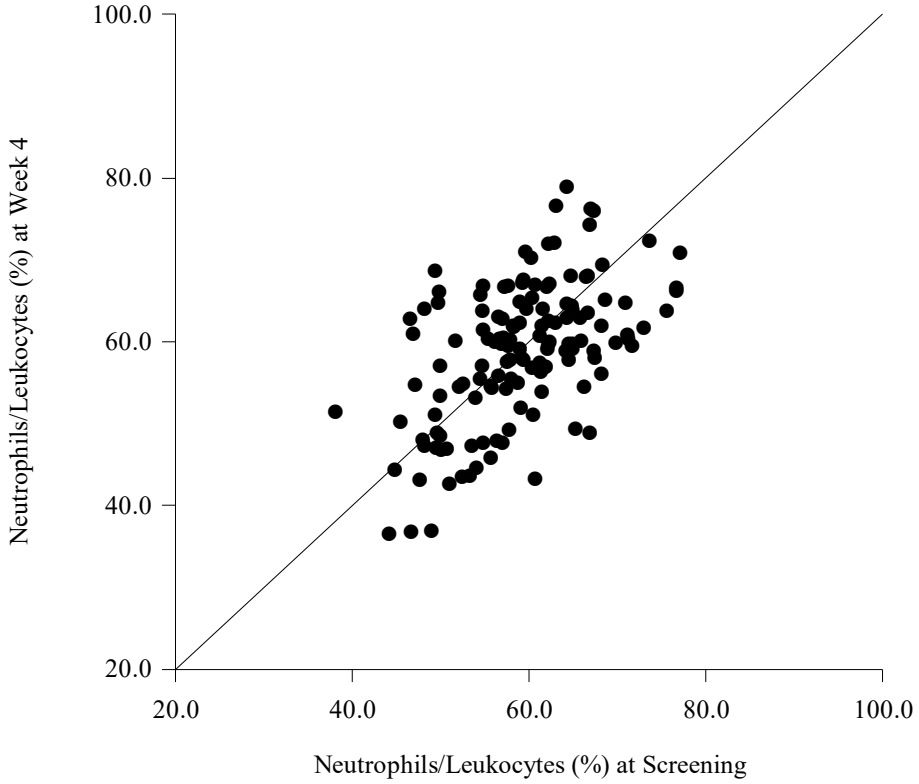
BBI-4000 0%



PAGE: 22 of 40
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/04/09
PROTOCOL NO: BBI-4000-06
Source：5.3.5.1-2 Figure 14.3.4-3 より改変

図 2.7.4-2　臨床検査値の散布図（BBI-4000-06 試験）（続き）
Hematology（Safety Analysis Set）

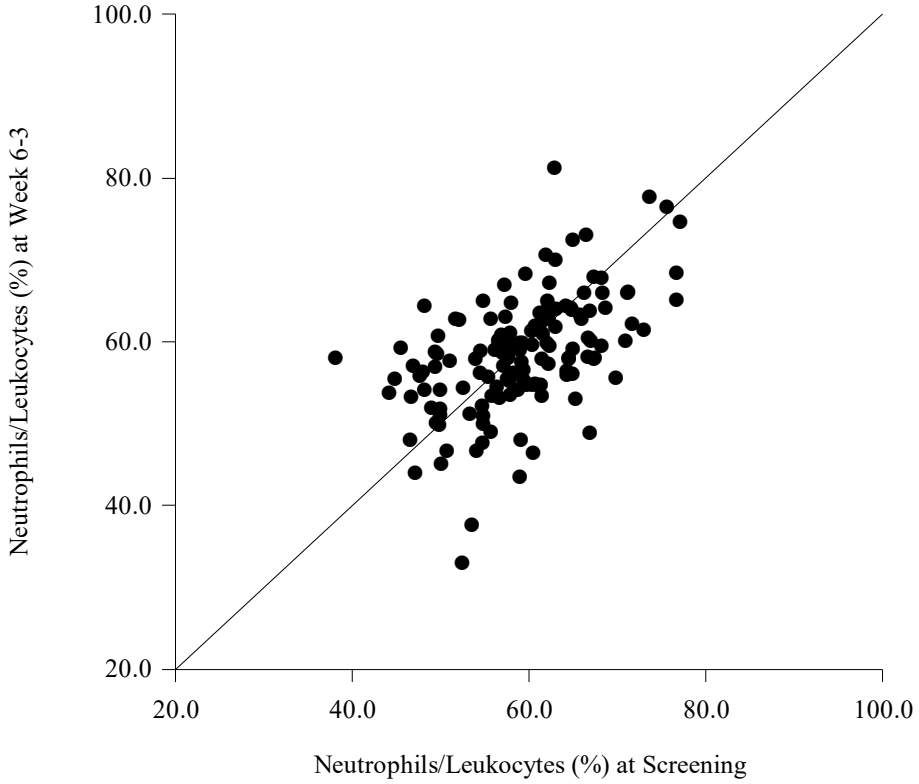
BBI-4000 5%



PAGE: 23 of 40
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/04/09
PROTOCOL NO: BBI-4000-06
Source：5.3.5.1-2 Figure 14.3.4-3 より改変

図 2.7.4-2　臨床検査値の散布図（BBI-4000-06 試験）（続き）
Hematology（Safety Analysis Set）

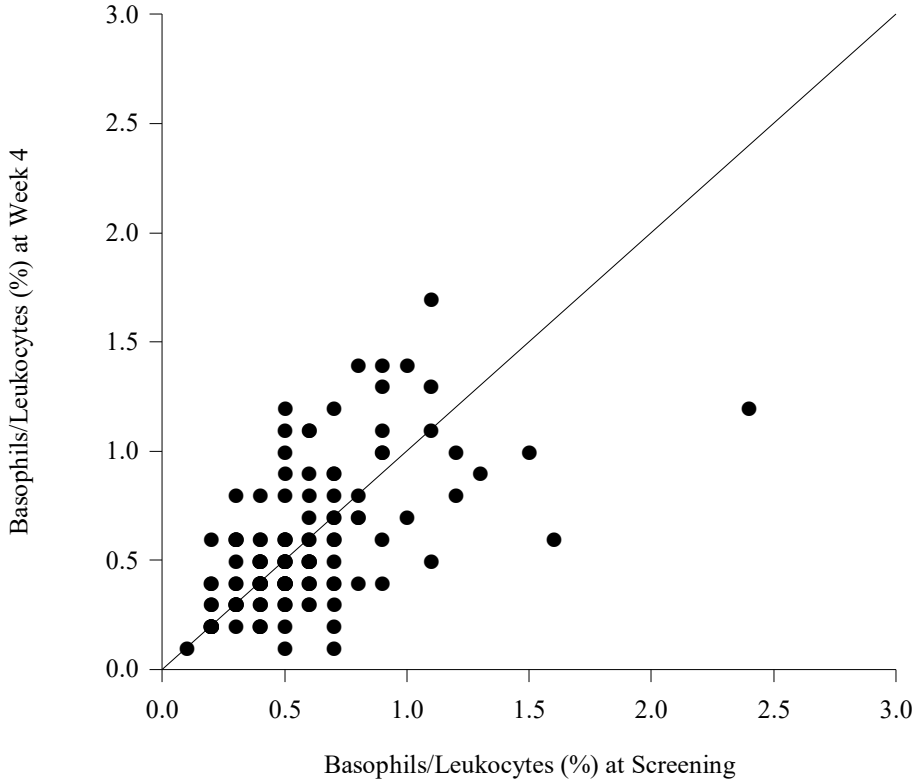
BBI-4000 5%



PAGE: 24 of 40
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/04/09
PROTOCOL NO: BBI-4000-06
Source：5.3.5.1-2 Figure 14.3.4-3 より改変

図 2.7.4-2　臨床検査値の散布図（BBI-4000-06 試験）（続き）
Hematology（Safety Analysis Set）

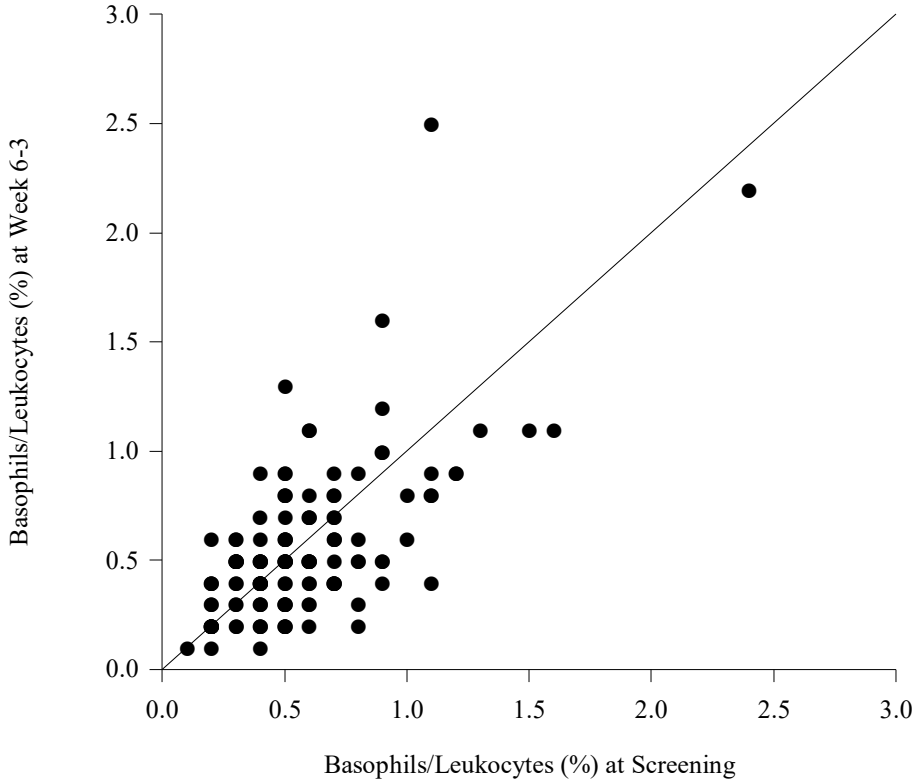
BBI-4000 0%



PAGE: 25 of 40
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/04/09
PROTOCOL NO: BBI-4000-06
Source：5.3.5.1-2 Figure 14.3.4-3 より改変

図 2.7.4-2　臨床検査値の散布図（BBI-4000-06 試験）（続き）
Hematology（Safety Analysis Set）

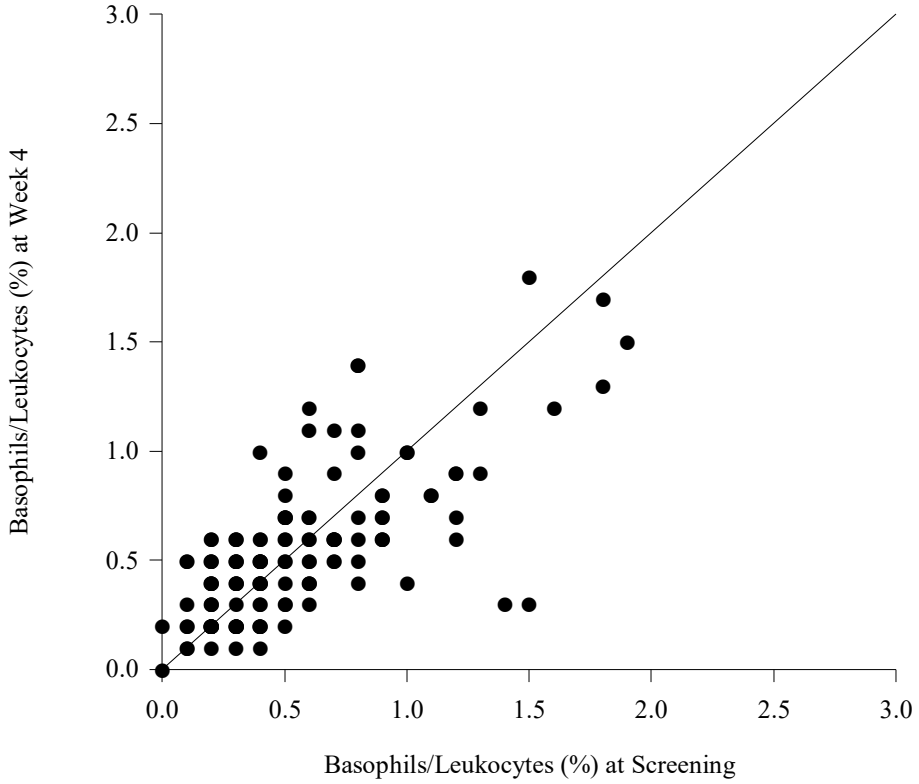
BBI-4000 0%



PAGE: 26 of 40
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/04/09
PROTOCOL NO: BBI-4000-06
Source：5.3.5.1-2 Figure 14.3.4-3 より改変

図 2.7.4-2　臨床検査値の散布図（BBI-4000-06 試験）（続き）
Hematology（Safety Analysis Set）

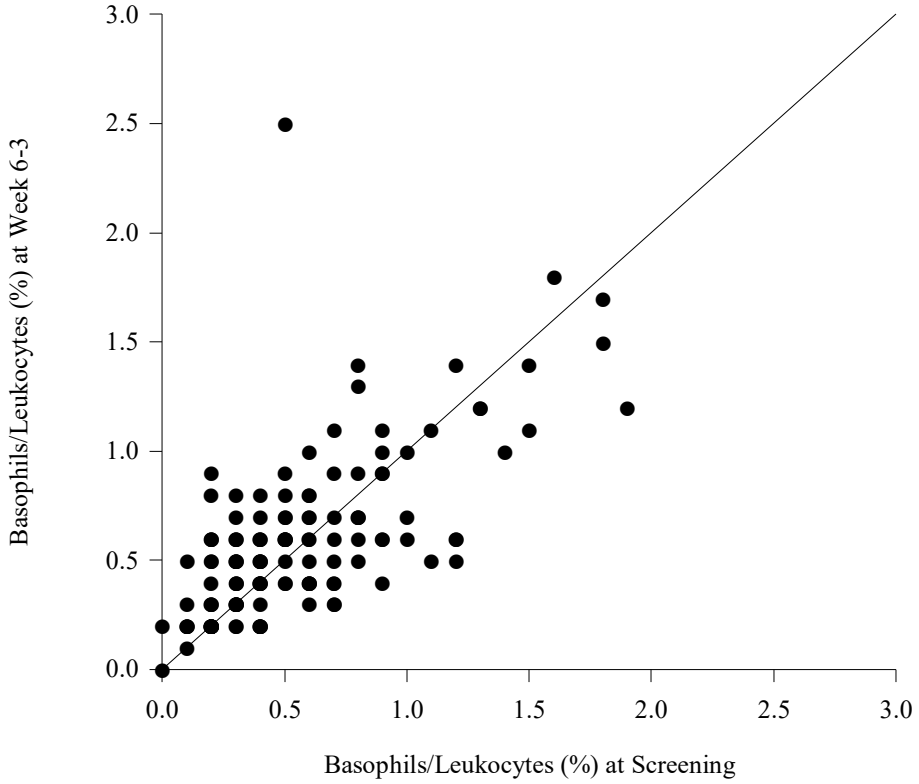
BBI-4000 5%



PAGE: 27 of 40
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/04/09
PROTOCOL NO: BBI-4000-06
Source：5.3.5.1-2 Figure 14.3.4-3 より改変

図 2.7.4-2　臨床検査値の散布図（BBI-4000-06 試験）（続き）
Hematology（Safety Analysis Set）

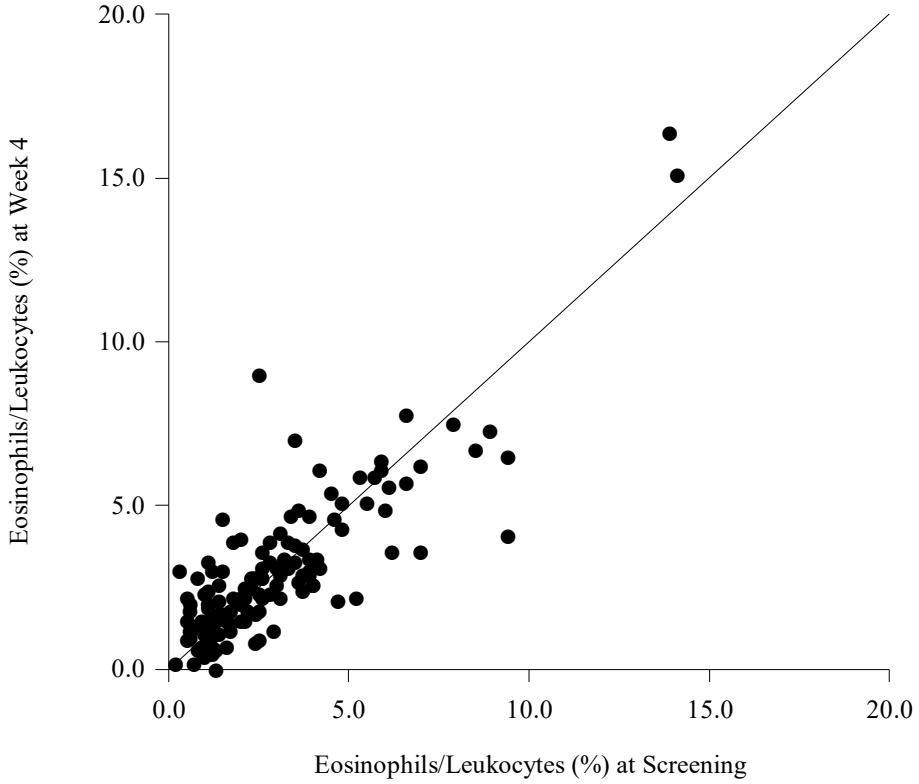
BBI-4000 5%



PAGE: 28 of 40
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/04/09
PROTOCOL NO: BBI-4000-06
Source：5.3.5.1-2 Figure 14.3.4-3 より改変

図 2.7.4-2　臨床検査値の散布図（BBI-4000-06 試験）（続き）
Hematology（Safety Analysis Set）

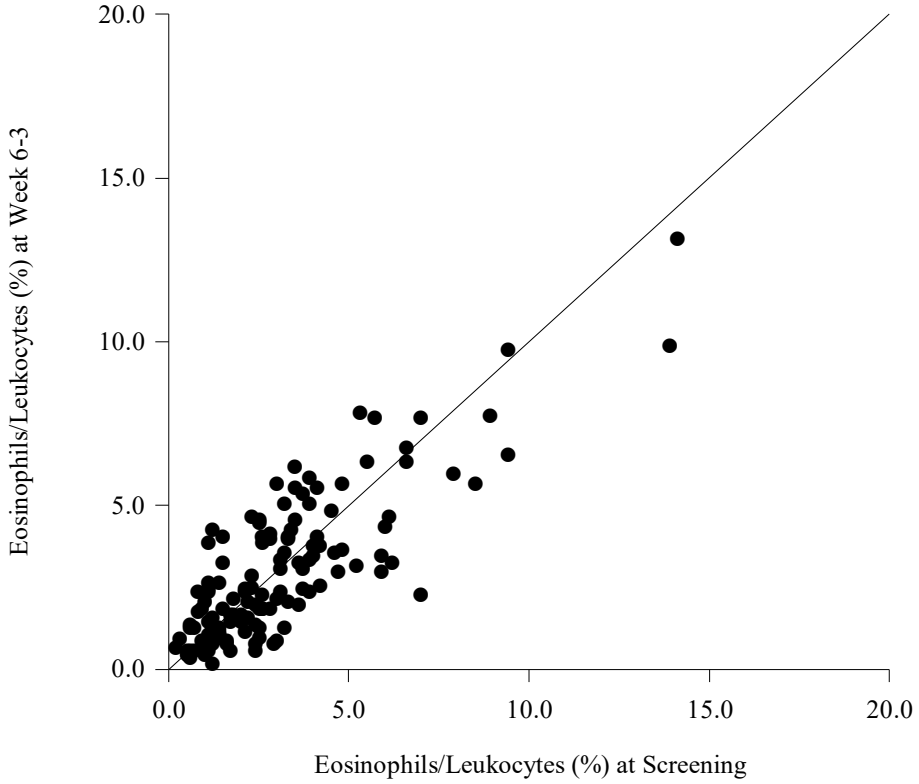
BBI-4000 0%



PAGE: 29 of 40
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/04/09
PROTOCOL NO: BBI-4000-06
Source：5.3.5.1-2 Figure 14.3.4-3 より改変

図 2.7.4-2　臨床検査値の散布図（BBI-4000-06 試験）（続き）
Hematology（Safety Analysis Set）

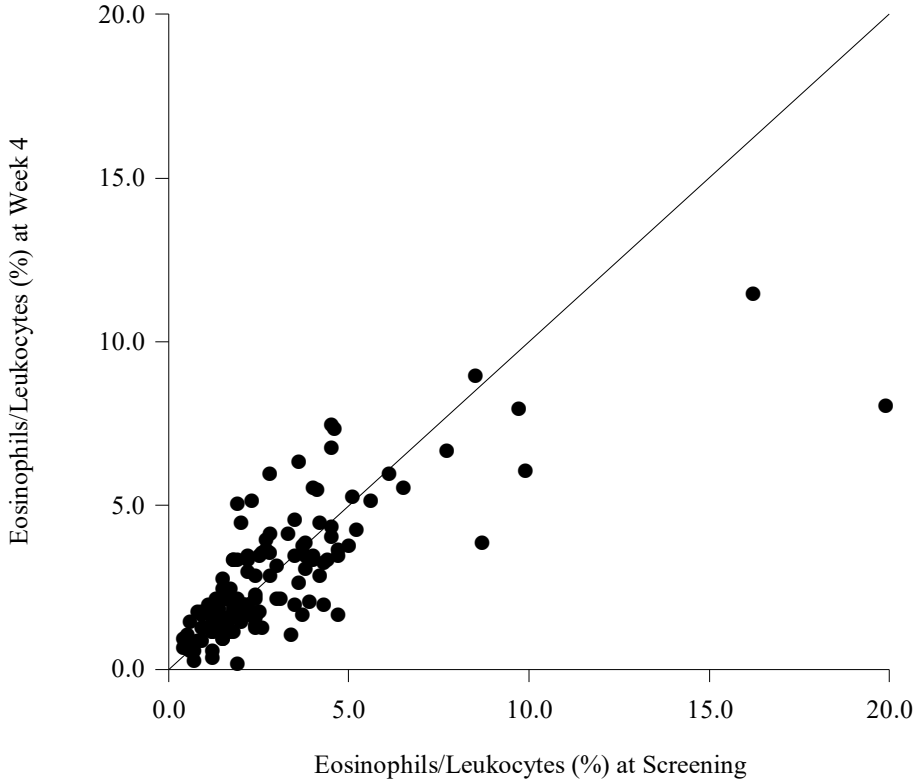
BBI-4000 0%



PAGE: 30 of 40
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/04/09
PROTOCOL NO: BBI-4000-06
Source：5.3.5.1-2 Figure 14.3.4-3 より改変

図 2.7.4-2　臨床検査値の散布図（BBI-4000-06 試験）（続き）
Hematology（Safety Analysis Set）

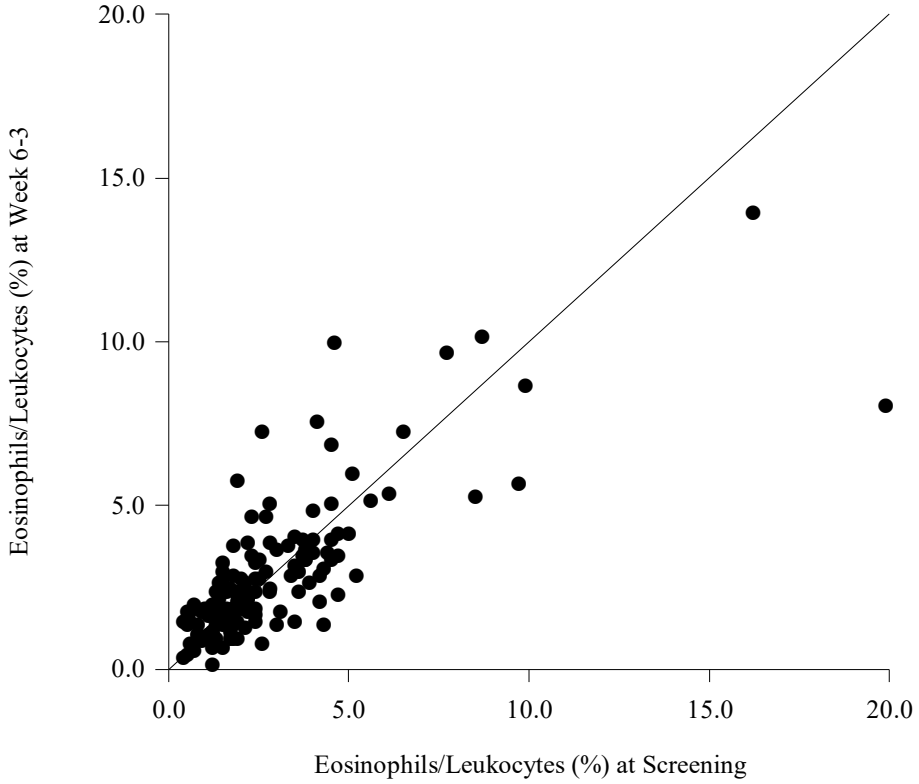
BBI-4000 5%



PAGE: 31 of 40
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/04/09
PROTOCOL NO: BBI-4000-06
Source：5.3.5.1-2 Figure 14.3.4-3 より改変

図 2.7.4-2　臨床検査値の散布図（BBI-4000-06 試験）（続き）
Hematology（Safety Analysis Set）

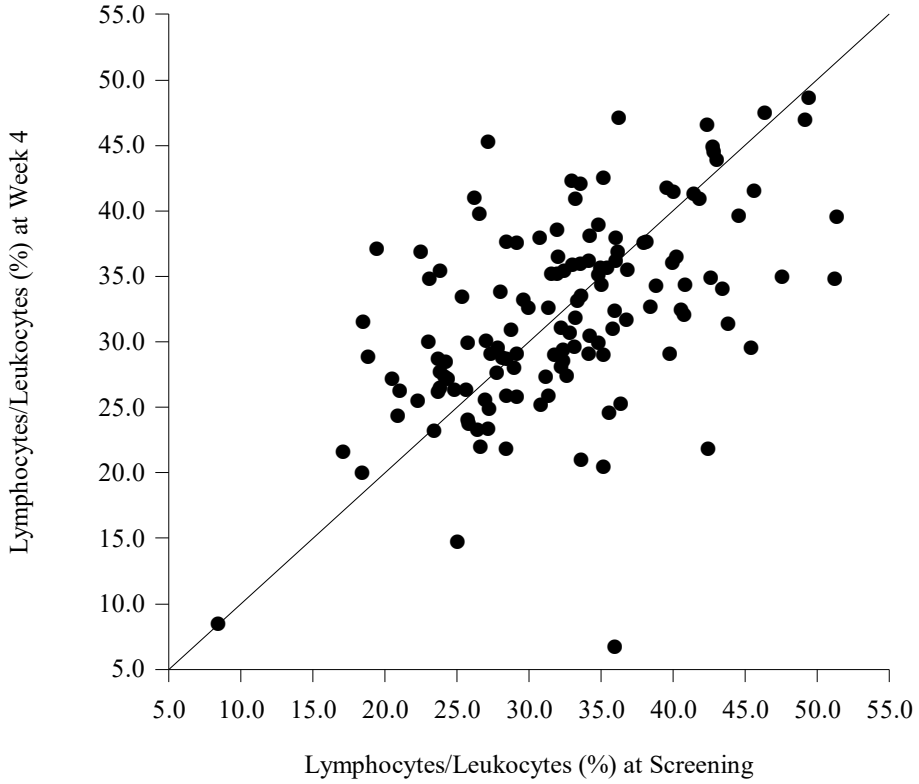
BBI-4000 5%



PAGE: 32 of 40
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/04/09
PROTOCOL NO: BBI-4000-06
Source：5.3.5.1-2 Figure 14.3.4-3 より改変

図 2.7.4-2　臨床検査値の散布図（BBI-4000-06 試験）（続き）
Hematology（Safety Analysis Set）

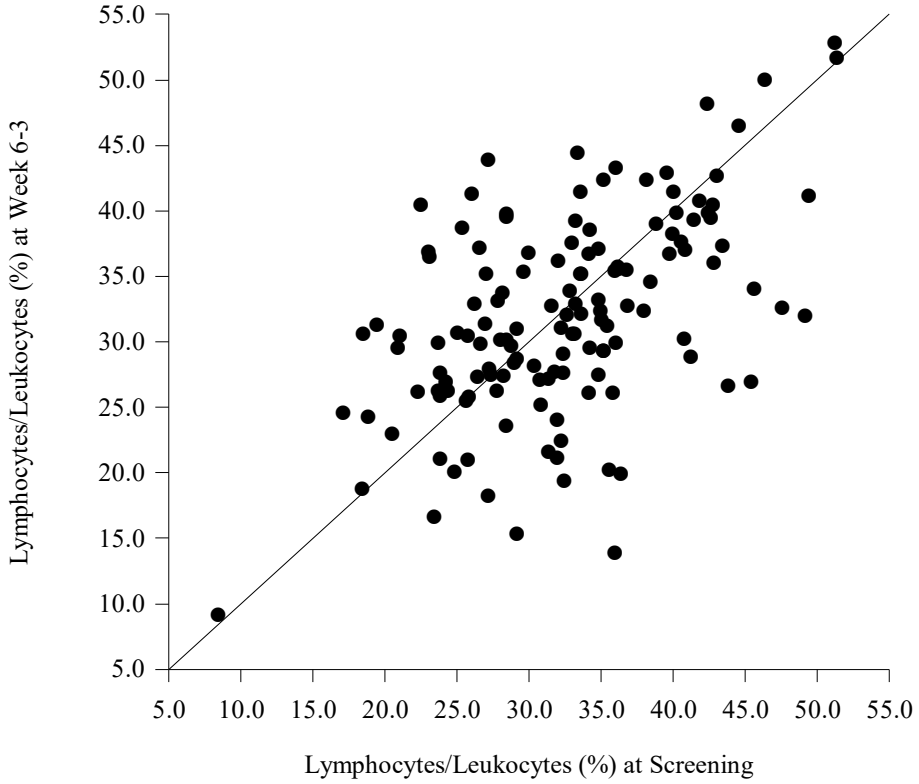
BBI-4000 0%



PAGE: 33 of 40
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/04/09
PROTOCOL NO: BBI-4000-06
Source：5.3.5.1-2 Figure 14.3.4-3 より改変

図 2.7.4-2　臨床検査値の散布図（BBI-4000-06 試験）（続き）
Hematology（Safety Analysis Set）

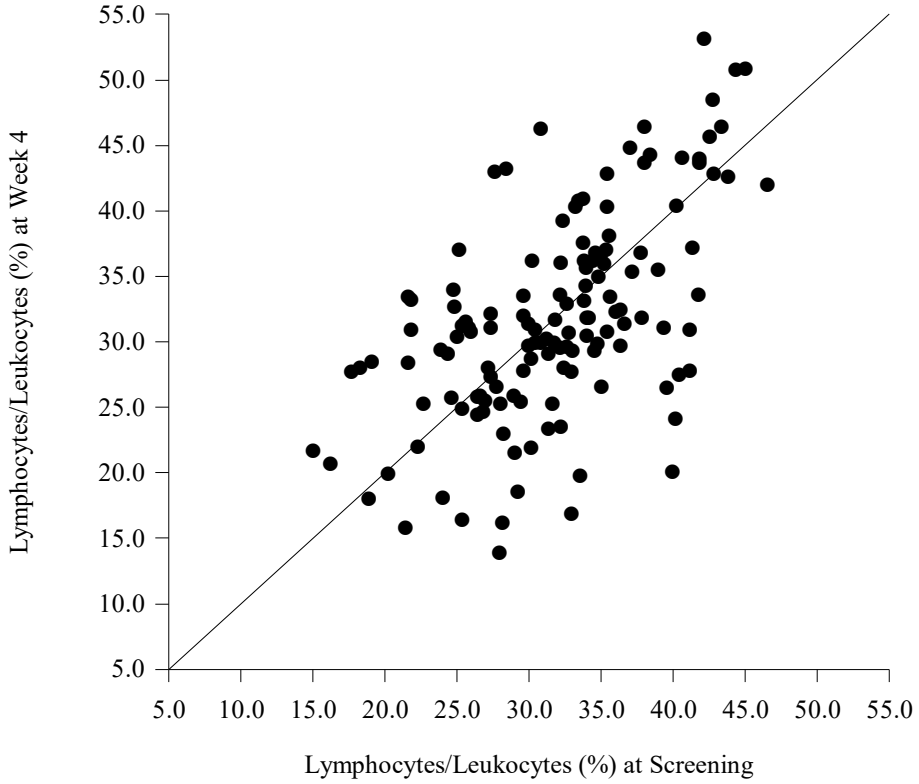
BBI-4000 0%



PAGE: 34 of 40
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/04/09
PROTOCOL NO: BBI-4000-06
Source：5.3.5.1-2 Figure 14.3.4-3 より改変

図 2.7.4-2　臨床検査値の散布図（BBI-4000-06 試験）（続き）
Hematology（Safety Analysis Set）

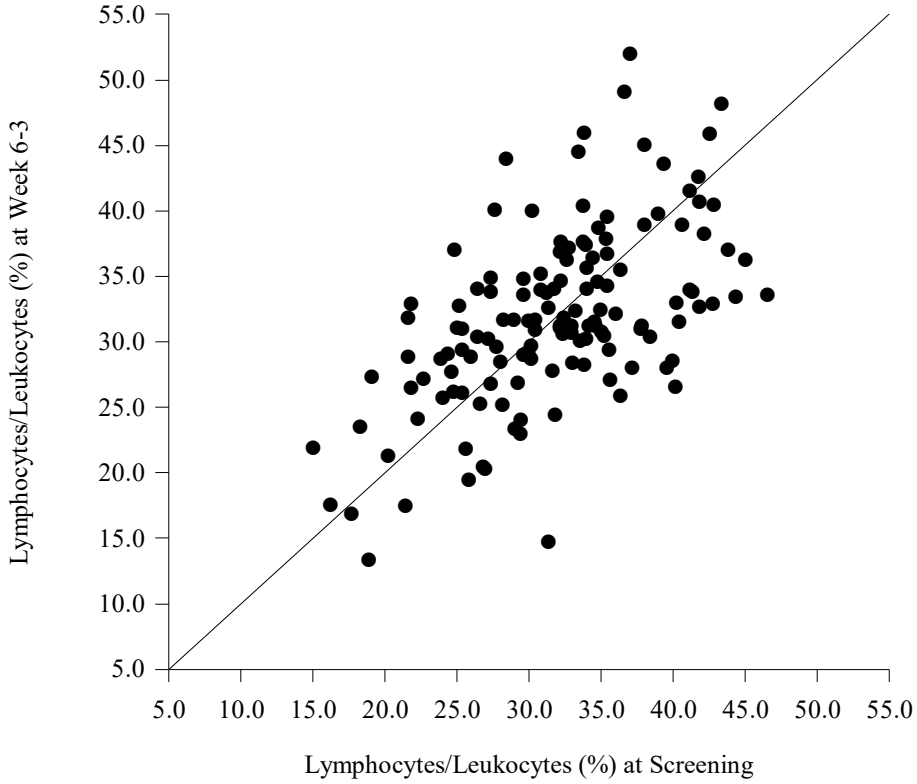
BBI-4000 5%



PAGE: 35 of 40
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/04/09
PROTOCOL NO: BBI-4000-06
Source：5.3.5.1-2 Figure 14.3.4-3 より改変

図 2.7.4-2　臨床検査値の散布図（BBI-4000-06 試験）（続き）
Hematology（Safety Analysis Set）

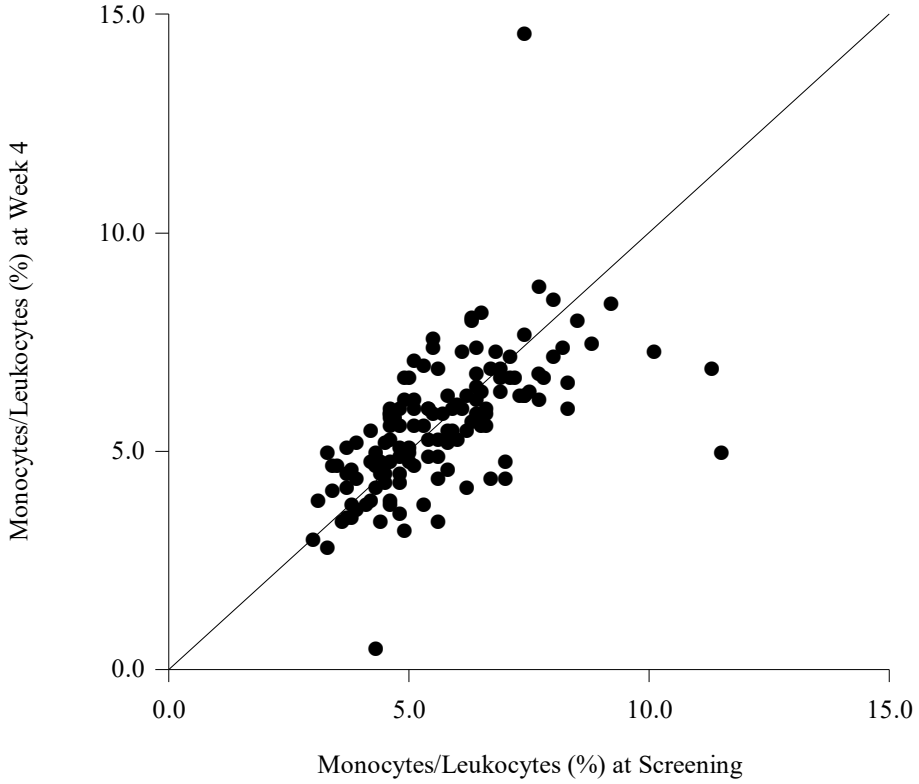
BBI-4000 5%



PAGE: 36 of 40
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/04/09
PROTOCOL NO: BBI-4000-06
Source：5.3.5.1-2 Figure 14.3.4-3 より改変

図 2.7.4-2　臨床検査値の散布図（BBI-4000-06 試験）（続き）
Hematology（Safety Analysis Set）

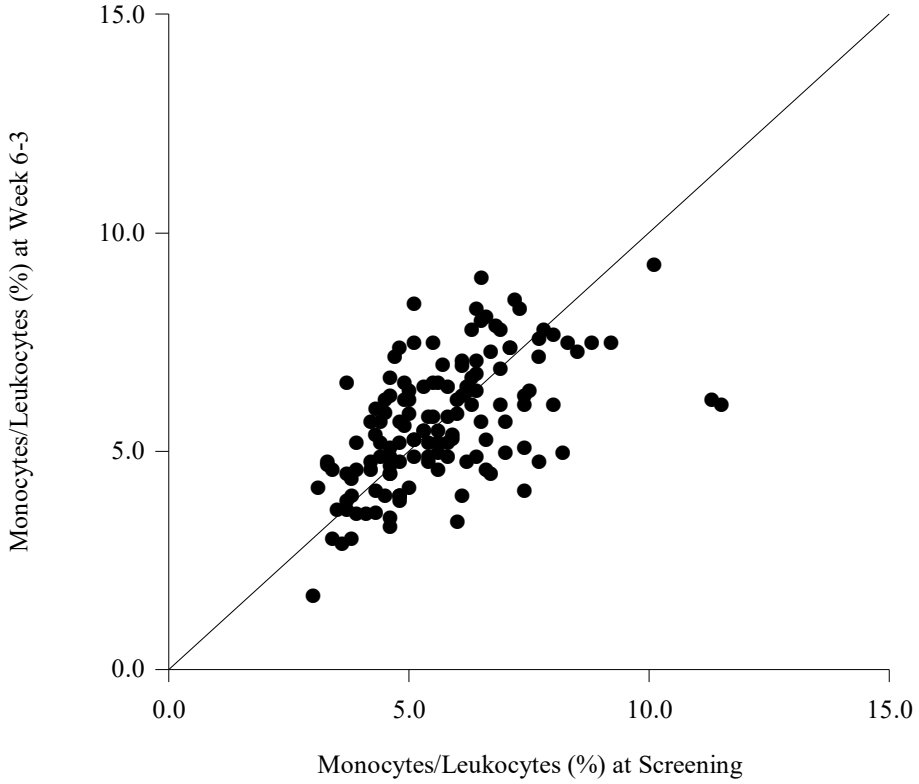
BBI-4000 0%



PAGE: 37 of 40
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/04/09
PROTOCOL NO: BBI-4000-06
Source：5.3.5.1-2 Figure 14.3.4-3 より改変

図 2.7.4-2　臨床検査値の散布図（BBI-4000-06 試験）（続き）
Hematology（Safety Analysis Set）

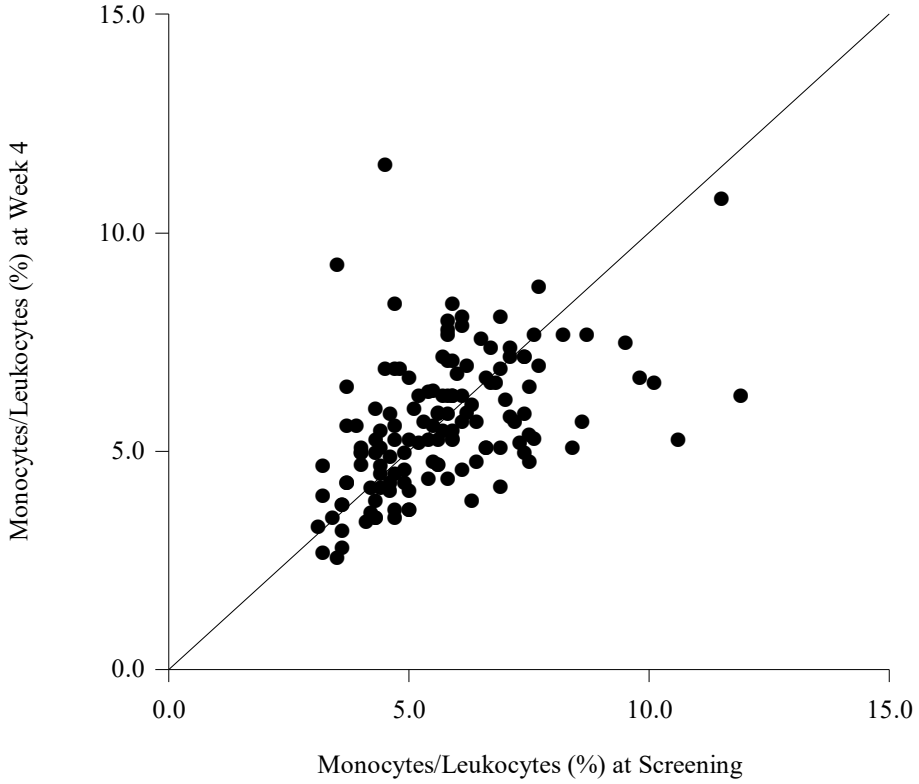
BBI-4000 0%



PAGE: 38 of 40
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/04/09
PROTOCOL NO: BBI-4000-06
Source：5.3.5.1-2 Figure 14.3.4-3 より改変

図 2.7.4-2　臨床検査値の散布図（BBI-4000-06 試験）（続き）
Hematology（Safety Analysis Set）

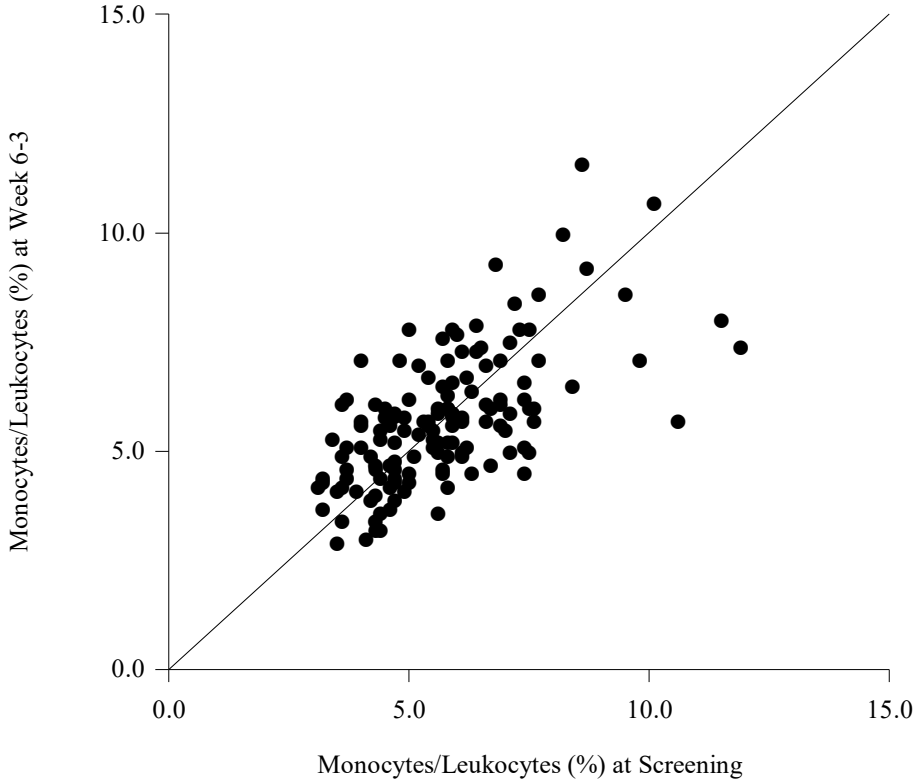
BBI-4000 5%



PAGE: 39 of 40
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/04/09
PROTOCOL NO: BBI-4000-06
Source：5.3.5.1-2 Figure 14.3.4-3 より改変

図 2.7.4-2　臨床検査値の散布図（BBI-4000-06 試験）（続き）
Hematology（Safety Analysis Set）

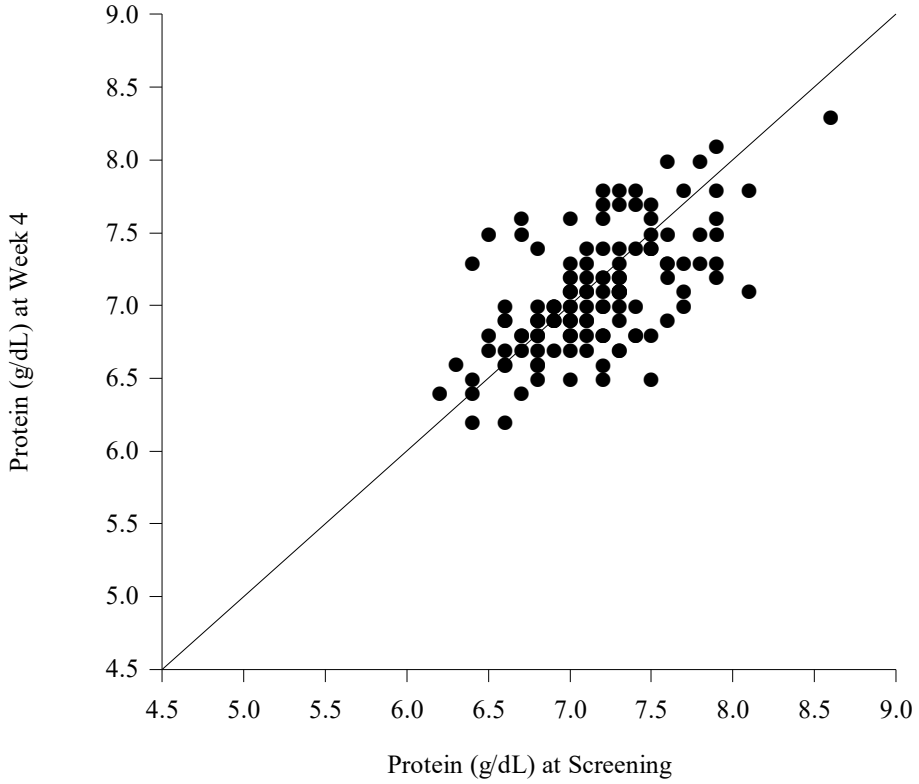
BBI-4000 5%



PAGE: 40 of 40
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/04/09
PROTOCOL NO: BBI-4000-06
Source：5.3.5.1-2 Figure 14.3.4-3 より改変

図 2.7.4-2　臨床検査値の散布図（BBI-4000-06 試験）（続き）
Biochemical（Safety Analysis Set）

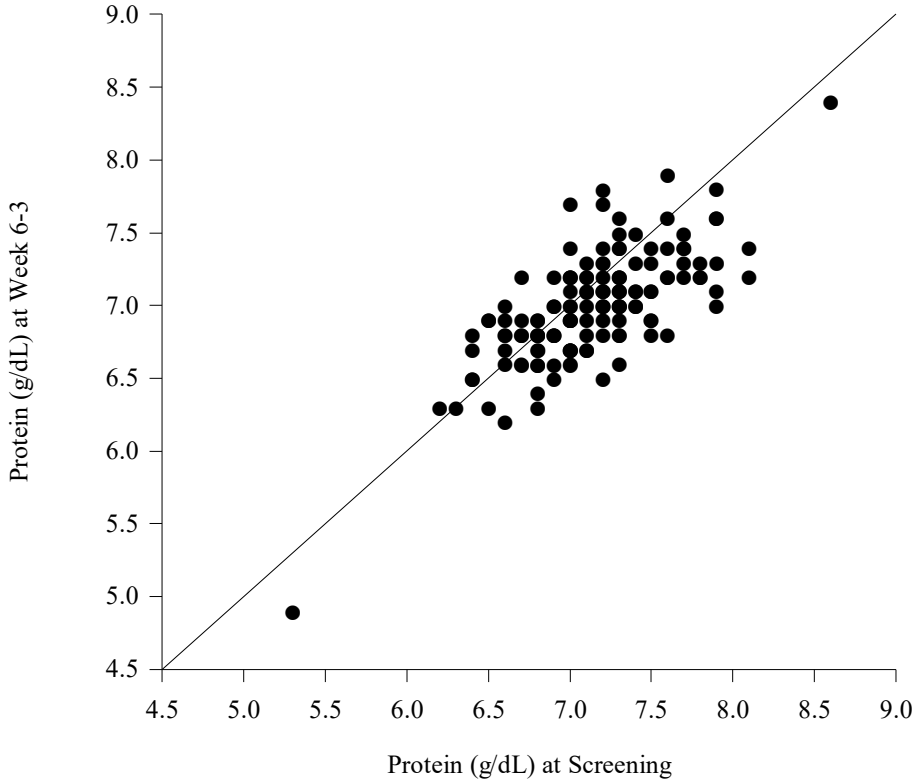
BBI-4000 0%



PAGE: 1 of 76
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/03/19
PROTOCOL NO: BBI-4000-06
Source：5.3.5.1-2 Figure 14.3.4-4 より改変

図 2.7.4-2　臨床検査値の散布図（BBI-4000-06 試験）（続き）
Biochemical（Safety Analysis Set）

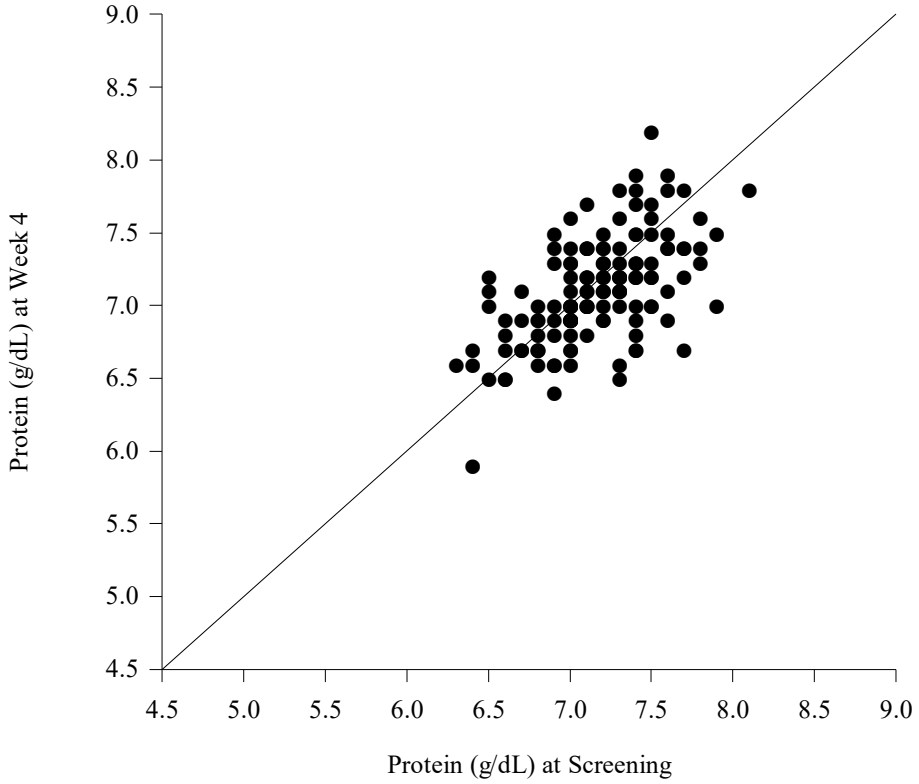
BBI-4000 0%



PAGE: 2 of 76
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/03/19
PROTOCOL NO: BBI-4000-06
Source：5.3.5.1-2 Figure 14.3.4-4 より改変

図 2.7.4-2　臨床検査値の散布図（BBI-4000-06 試験）（続き）
Biochemical（Safety Analysis Set）

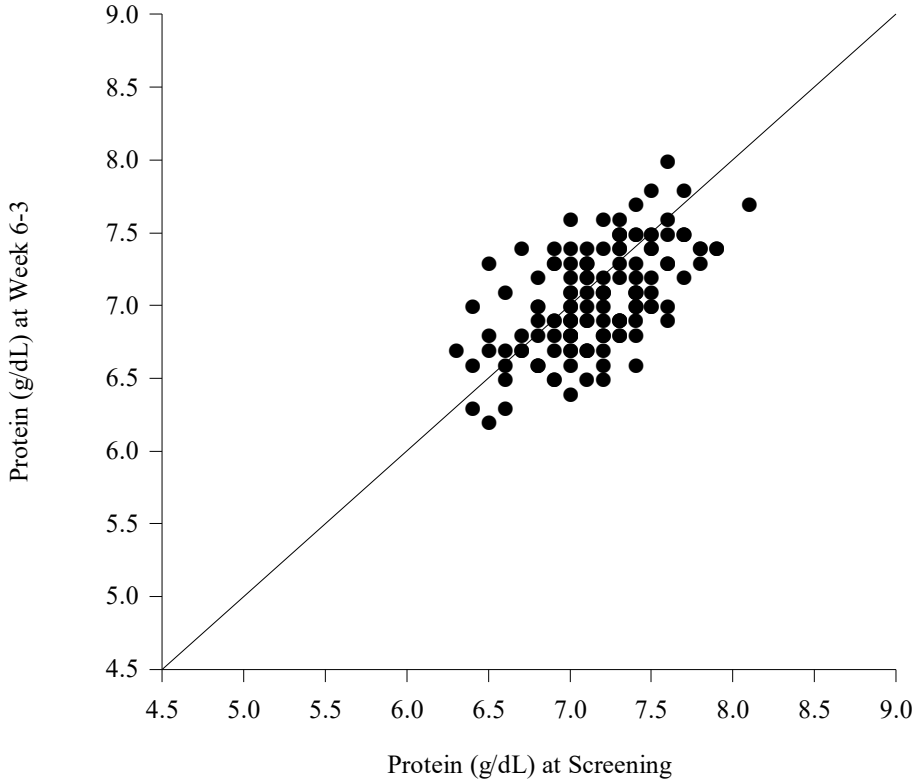
BBI-4000 5%



PAGE: 3 of 76
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/03/19
PROTOCOL NO: BBI-4000-06
Source：5.3.5.1-2 Figure 14.3.4-4 より改変

図 2.7.4-2　臨床検査値の散布図（BBI-4000-06 試験）（続き）
Biochemical（Safety Analysis Set）

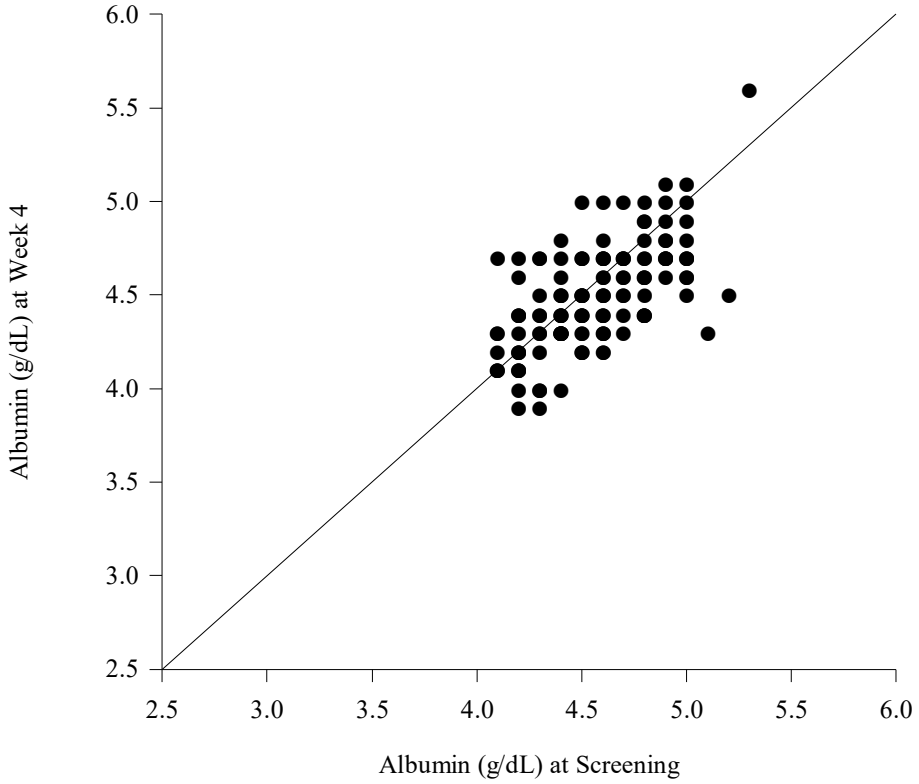
BBI-4000 5%



PAGE: 4 of 76
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/03/19
PROTOCOL NO: BBI-4000-06
Source：5.3.5.1-2 Figure 14.3.4-4 より改変

図 2.7.4-2　臨床検査値の散布図（BBI-4000-06 試験）（続き）
Biochemical（Safety Analysis Set）

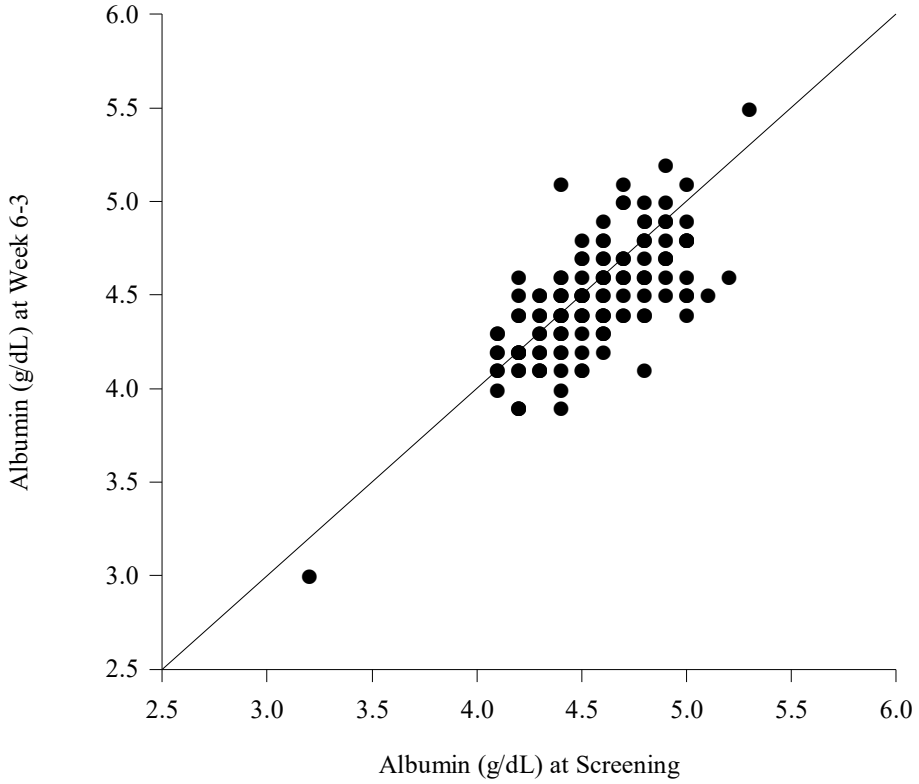
BBI-4000 0%



PAGE: 5 of 76
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/03/19
PROTOCOL NO: BBI-4000-06
Source：5.3.5.1-2 Figure 14.3.4-4 より改変

図 2.7.4-2　臨床検査値の散布図（BBI-4000-06 試験）（続き）
Biochemical（Safety Analysis Set）

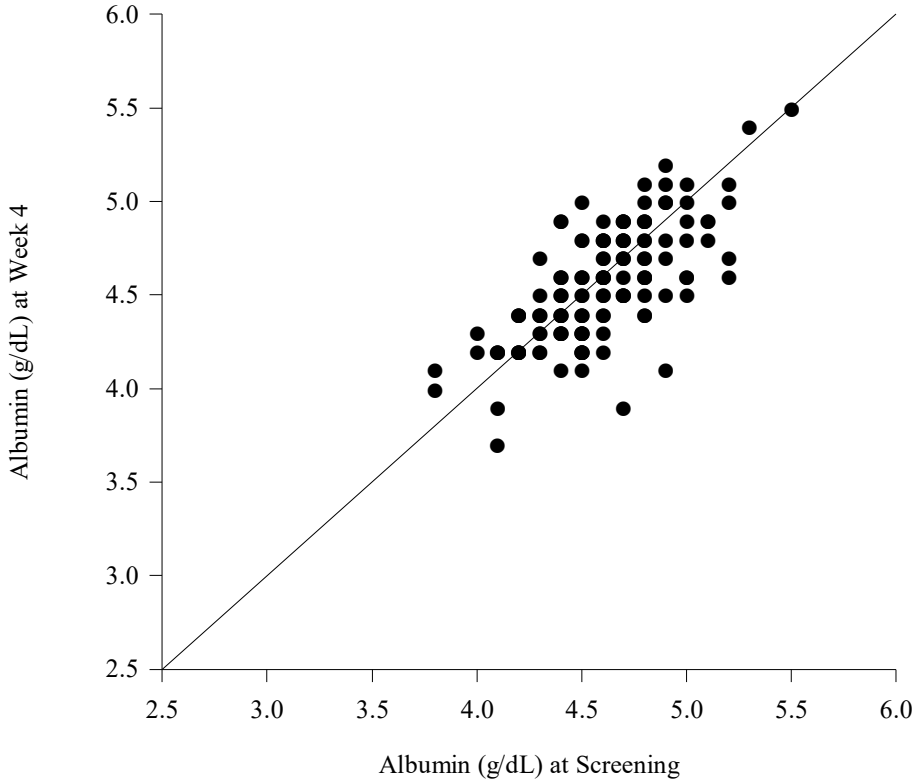
BBI-4000 0%



PAGE: 6 of 76
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/03/19
PROTOCOL NO: BBI-4000-06
Source：5.3.5.1-2 Figure 14.3.4-4 より改変

図 2.7.4-2　臨床検査値の散布図（BBI-4000-06 試験）（続き）
Biochemical（Safety Analysis Set）

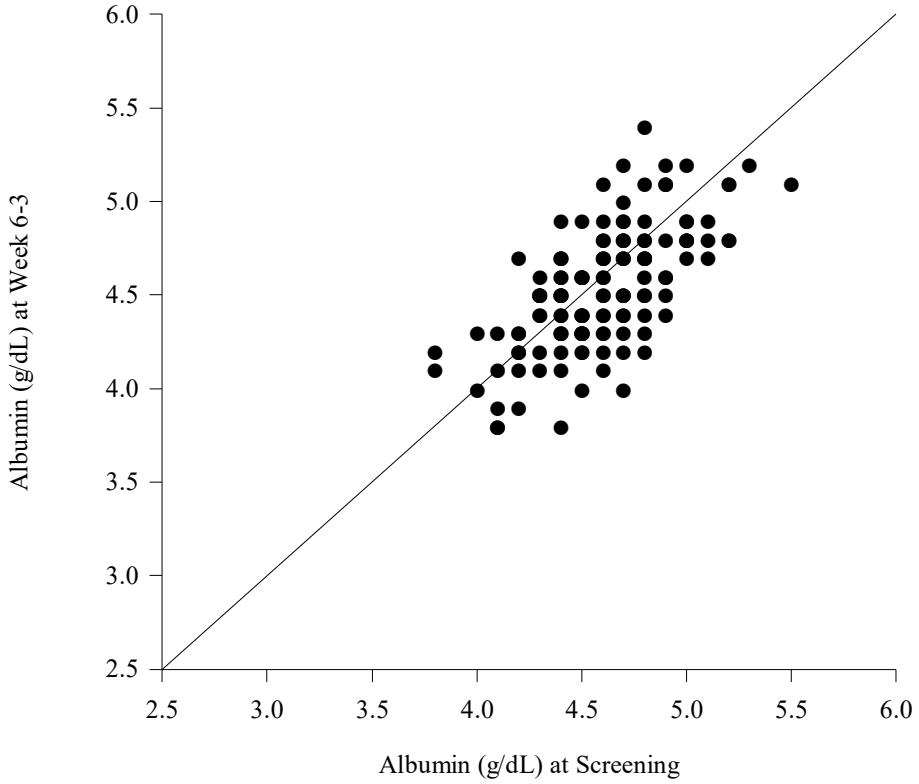
BBI-4000 5%



PAGE: 7 of 76
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/03/19
PROTOCOL NO: BBI-4000-06
Source：5.3.5.1-2 Figure 14.3.4-4 より改変

図 2.7.4-2　臨床検査値の散布図（BBI-4000-06 試験）（続き）
Biochemical（Safety Analysis Set）

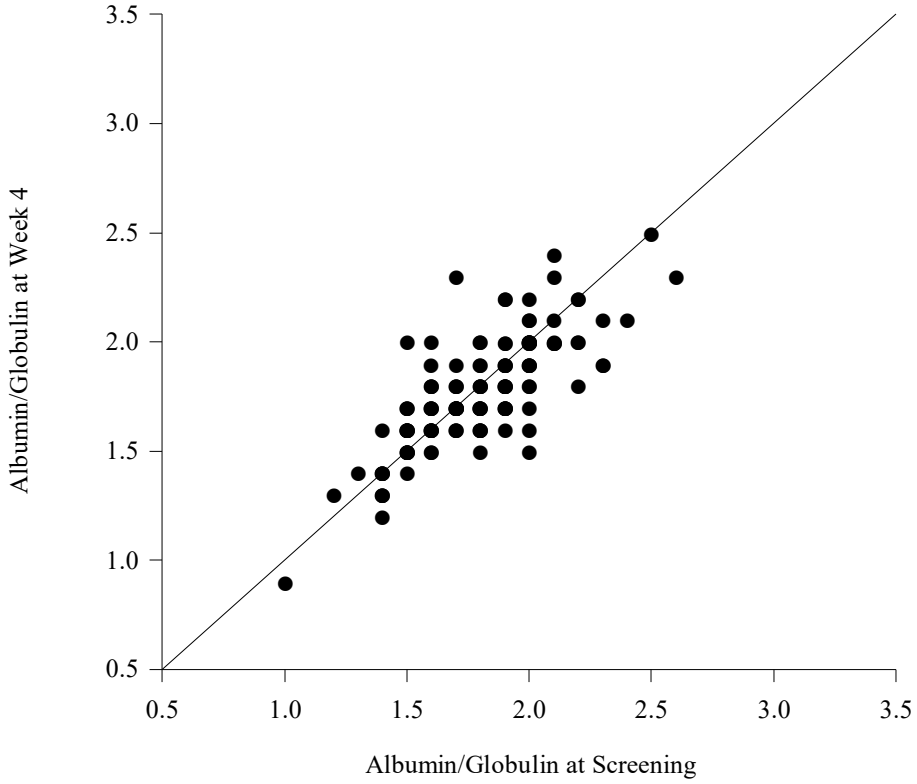
BBI-4000 5%



PAGE: 8 of 76
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/03/19
PROTOCOL NO: BBI-4000-06
Source：5.3.5.1-2 Figure 14.3.4-4 より改変

図 2.7.4-2　臨床検査値の散布図（BBI-4000-06 試験）（続き）
Biochemical（Safety Analysis Set）

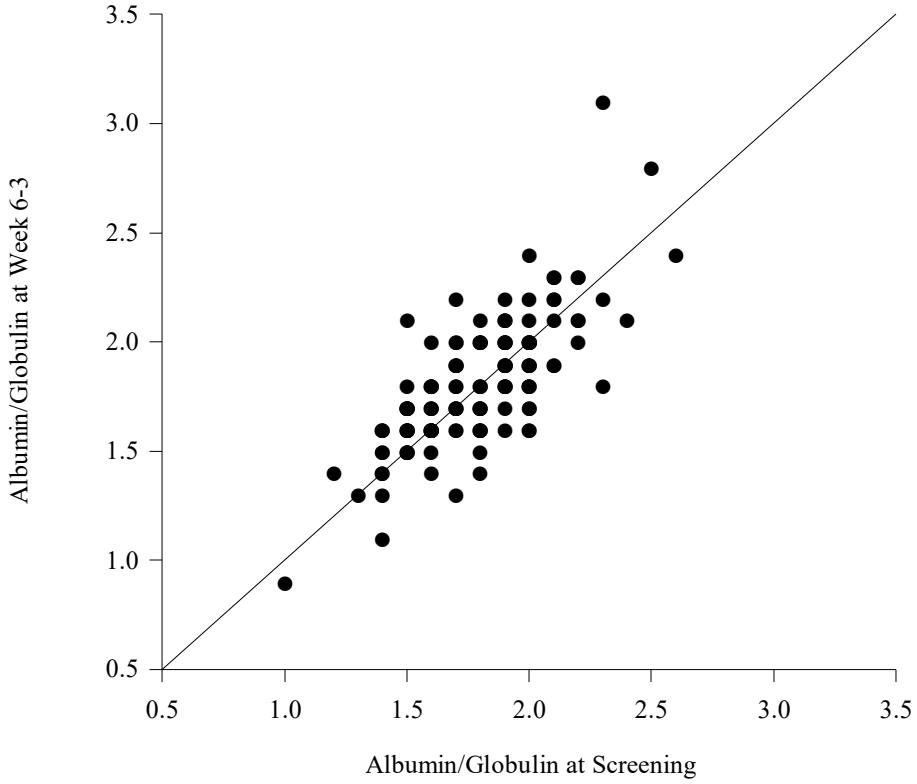
BBI-4000 0%



PAGE: 9 of 76
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/03/19
PROTOCOL NO: BBI-4000-06
Source：5.3.5.1-2 Figure 14.3.4-4 より改変

図 2.7.4-2　臨床検査値の散布図（BBI-4000-06 試験）（続き）
Biochemical（Safety Analysis Set）

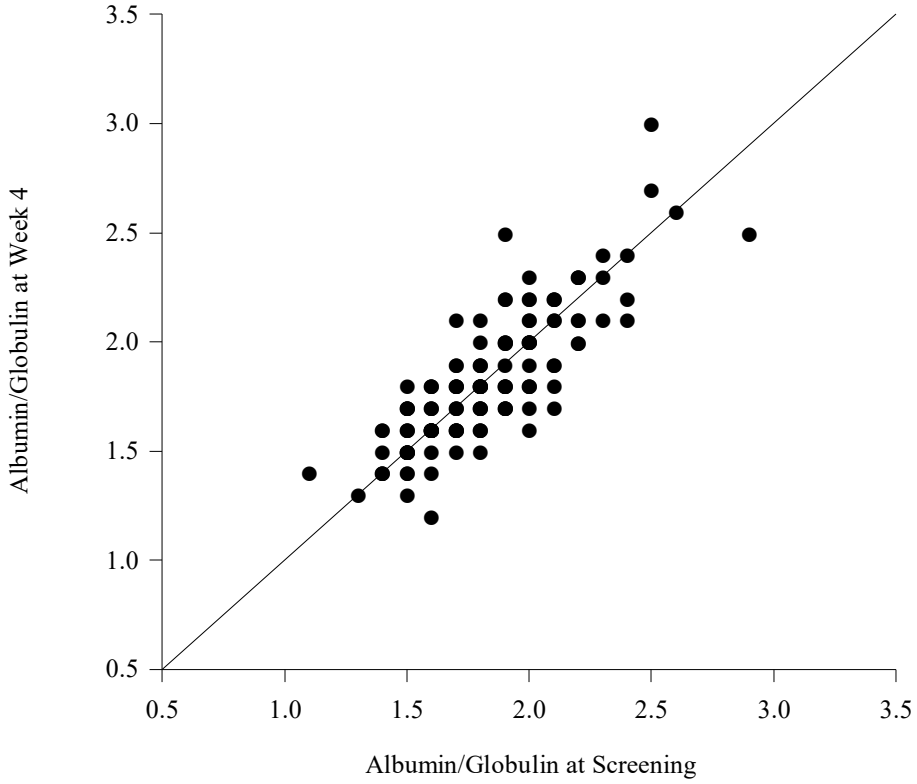
BBI-4000 0%



PAGE: 10 of 76
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/03/19
PROTOCOL NO: BBI-4000-06
Source：5.3.5.1-2 Figure 14.3.4-4 より改変

図 2.7.4-2　臨床検査値の散布図（BBI-4000-06 試験）（続き）
Biochemical（Safety Analysis Set）

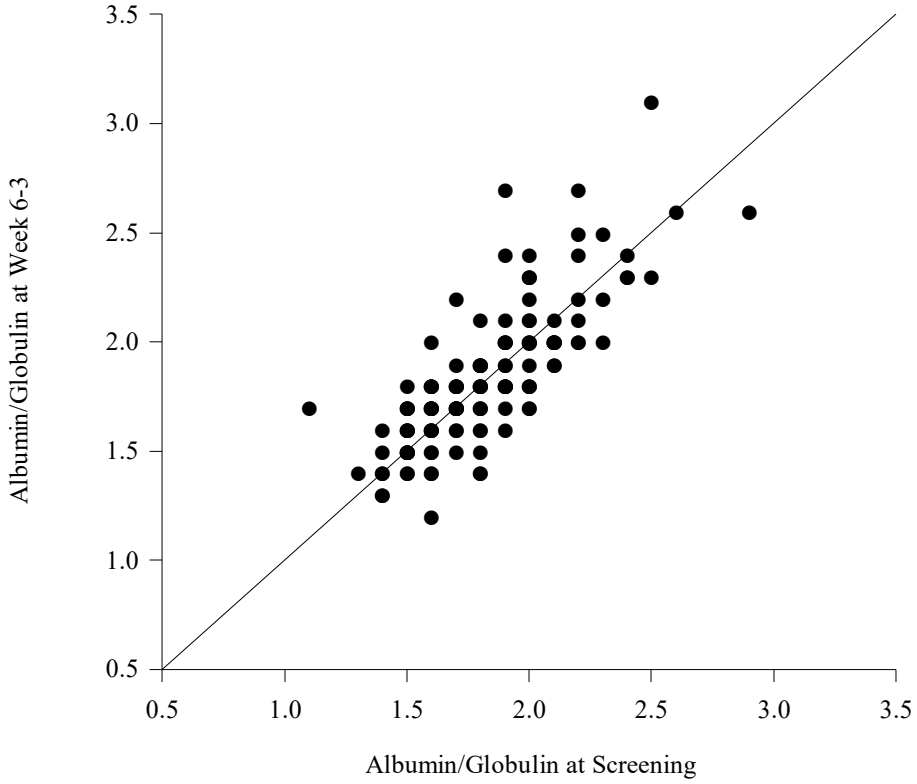
BBI-4000 5%



PAGE: 11 of 76
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/03/19
PROTOCOL NO: BBI-4000-06
Source：5.3.5.1-2 Figure 14.3.4-4 より改変

図 2.7.4-2　臨床検査値の散布図（BBI-4000-06 試験）（続き）
Biochemical（Safety Analysis Set）

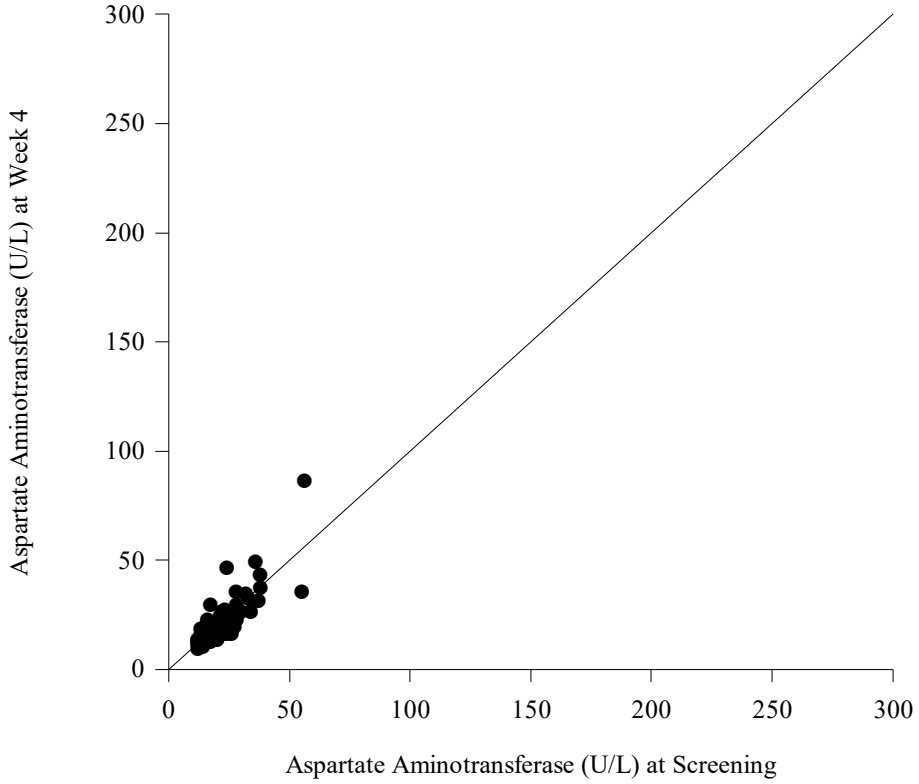
BBI-4000 5%



PAGE: 12 of 76
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/03/19
PROTOCOL NO: BBI-4000-06
Source：5.3.5.1-2 Figure 14.3.4-4 より改変

図 2.7.4-2　臨床検査値の散布図（BBI-4000-06 試験）（続き）
Biochemical（Safety Analysis Set）

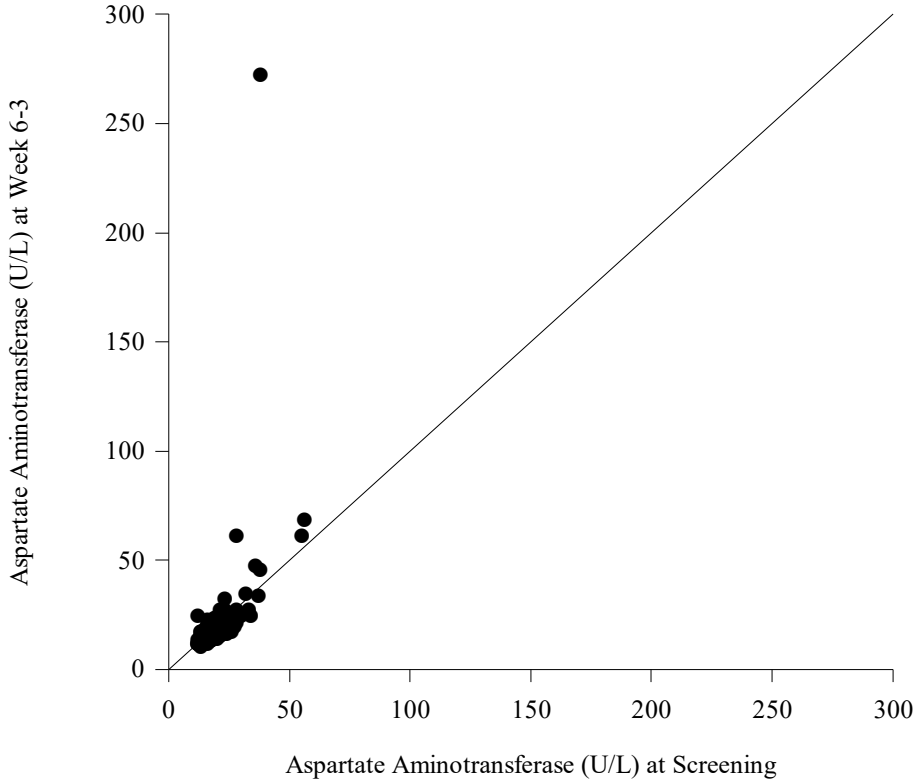
BBI-4000 0%



PAGE: 13 of 76
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/03/19
PROTOCOL NO: BBI-4000-06
Source：5.3.5.1-2 Figure 14.3.4-4 より改変

図 2.7.4-2　臨床検査値の散布図（BBI-4000-06 試験）（続き）
Biochemical（Safety Analysis Set）

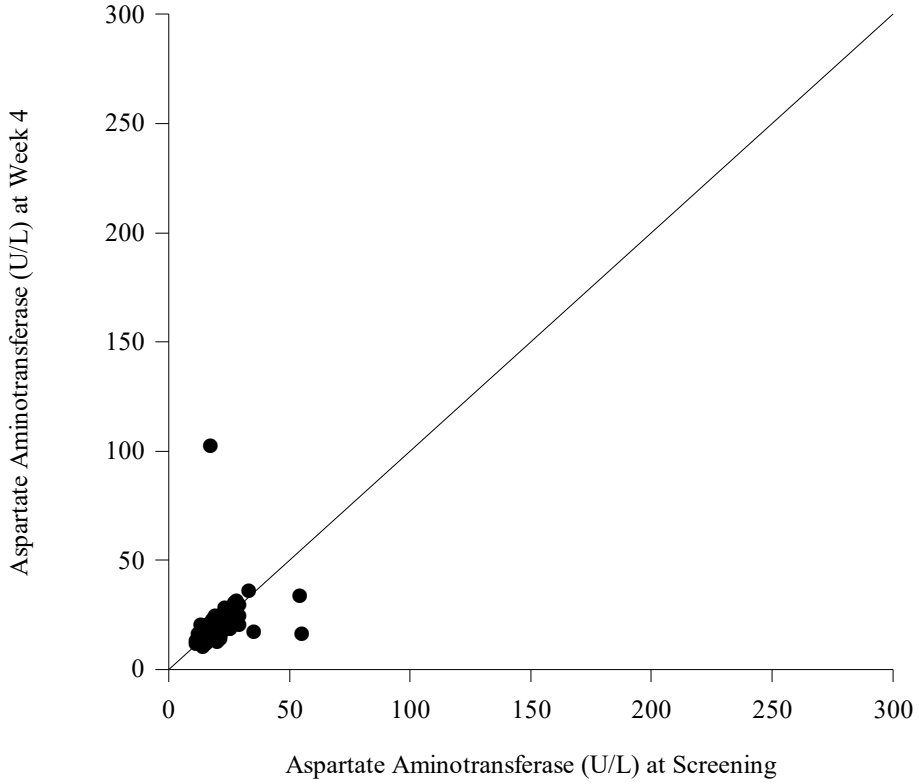
BBI-4000 0%



PAGE: 14 of 76
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/03/19
PROTOCOL NO: BBI-4000-06
Source：5.3.5.1-2 Figure 14.3.4-4 より改変

図 2.7.4-2　臨床検査値の散布図（BBI-4000-06 試験）（続き）
Biochemical（Safety Analysis Set）

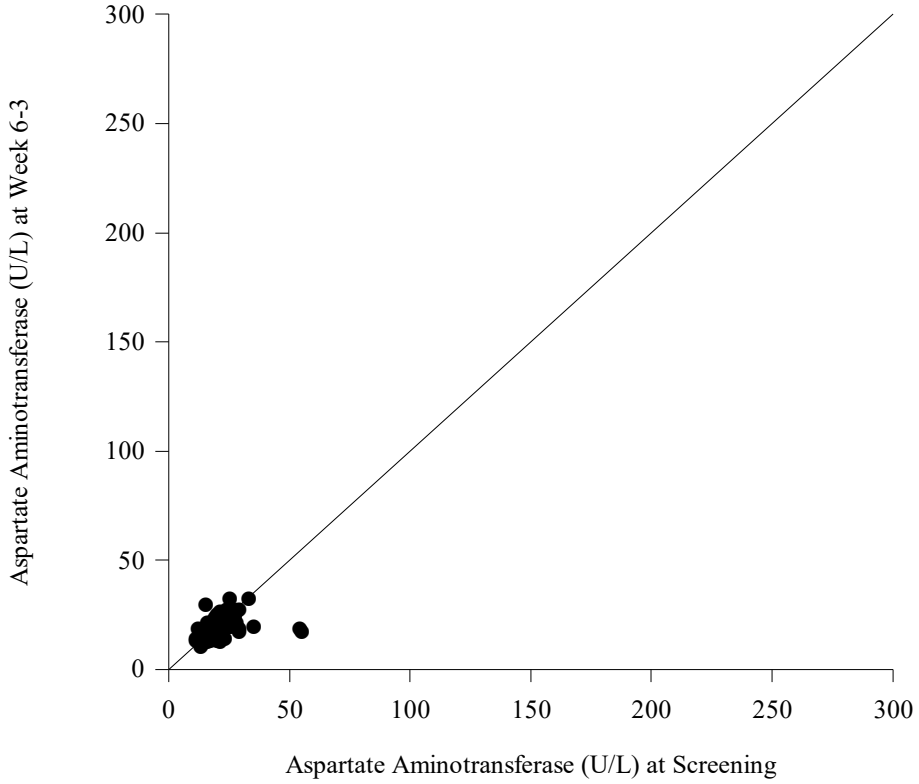
BBI-4000 5%



PAGE: 15 of 76
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/03/19
PROTOCOL NO: BBI-4000-06
Source：5.3.5.1-2 Figure 14.3.4-4 より改変

図 2.7.4-2　臨床検査値の散布図（BBI-4000-06 試験）（続き）
Biochemical（Safety Analysis Set）

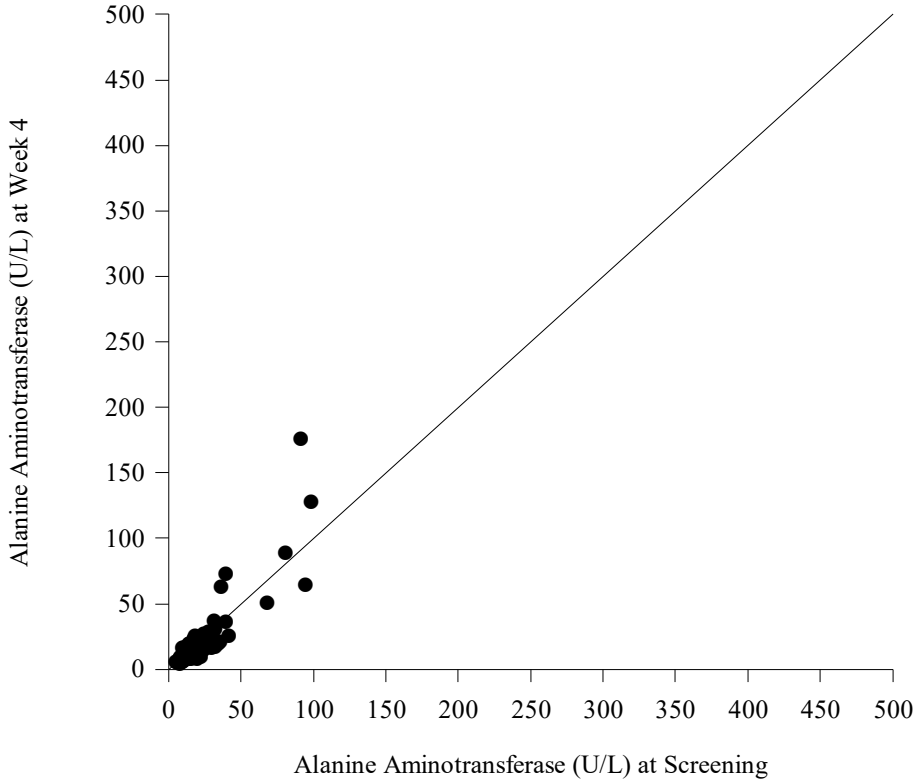
BBI-4000 5%



PAGE: 16 of 76
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/03/19
PROTOCOL NO: BBI-4000-06
Source：5.3.5.1-2 Figure 14.3.4-4 より改変

図 2.7.4-2　臨床検査値の散布図（BBI-4000-06 試験）（続き）
Biochemical（Safety Analysis Set）

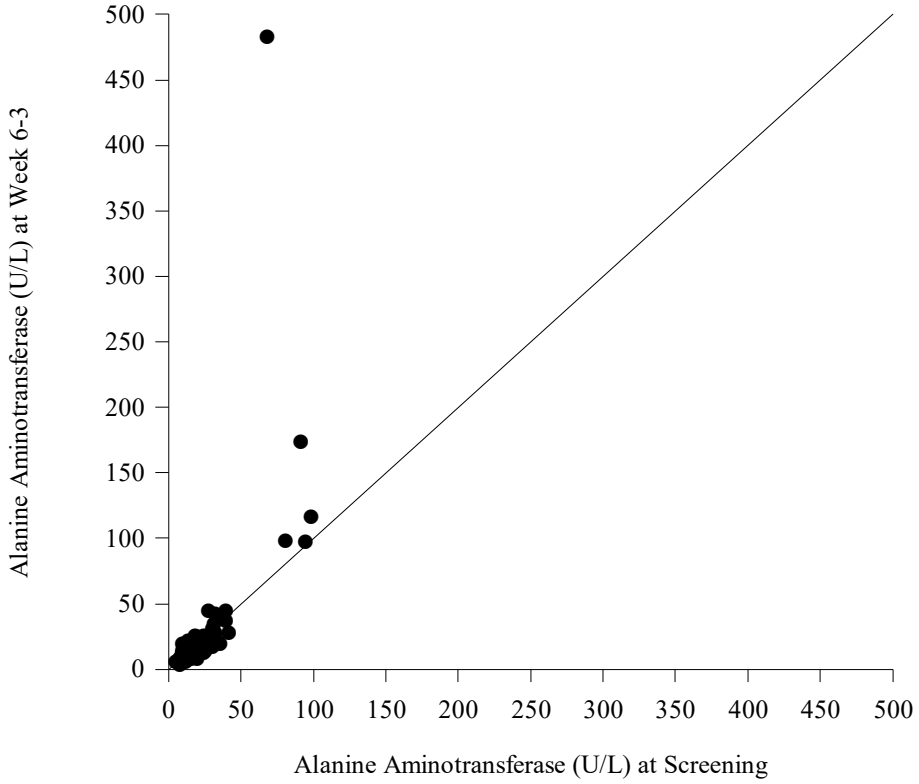
BBI-4000 0%



PAGE: 17 of 76
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/03/19
PROTOCOL NO: BBI-4000-06
Source：5.3.5.1-2 Figure 14.3.4-4 より改変

図 2.7.4-2　臨床検査値の散布図（BBI-4000-06 試験）（続き）
Biochemical（Safety Analysis Set）

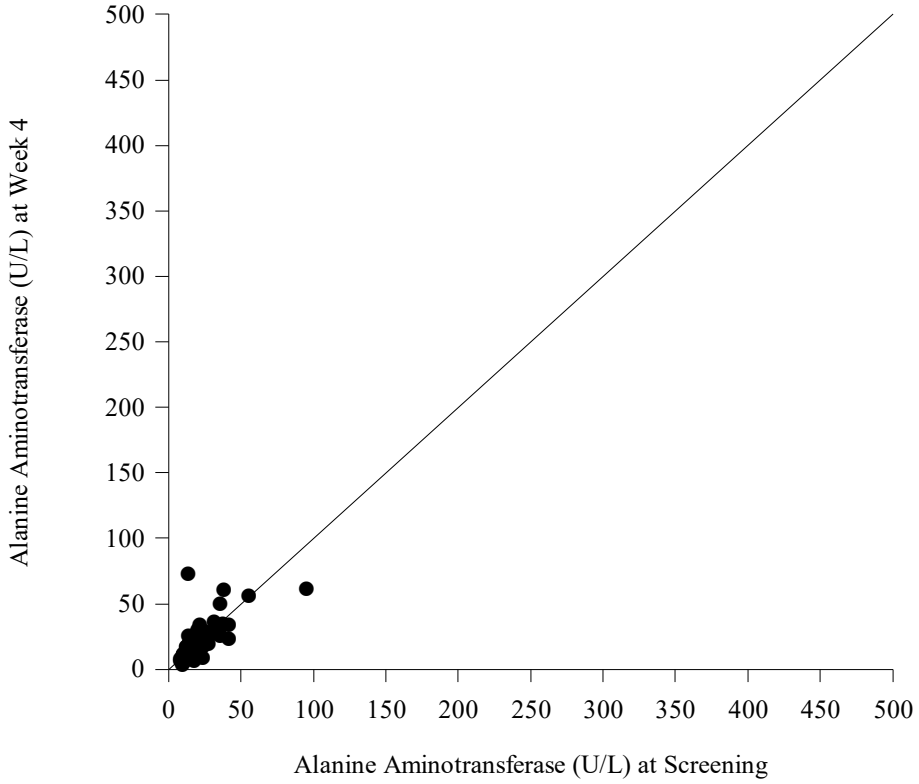
BBI-4000 0%



PAGE: 18 of 76
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/03/19
PROTOCOL NO: BBI-4000-06
Source：5.3.5.1-2 Figure 14.3.4-4 より改変

図 2.7.4-2　臨床検査値の散布図（BBI-4000-06 試験）（続き）
Biochemical（Safety Analysis Set）

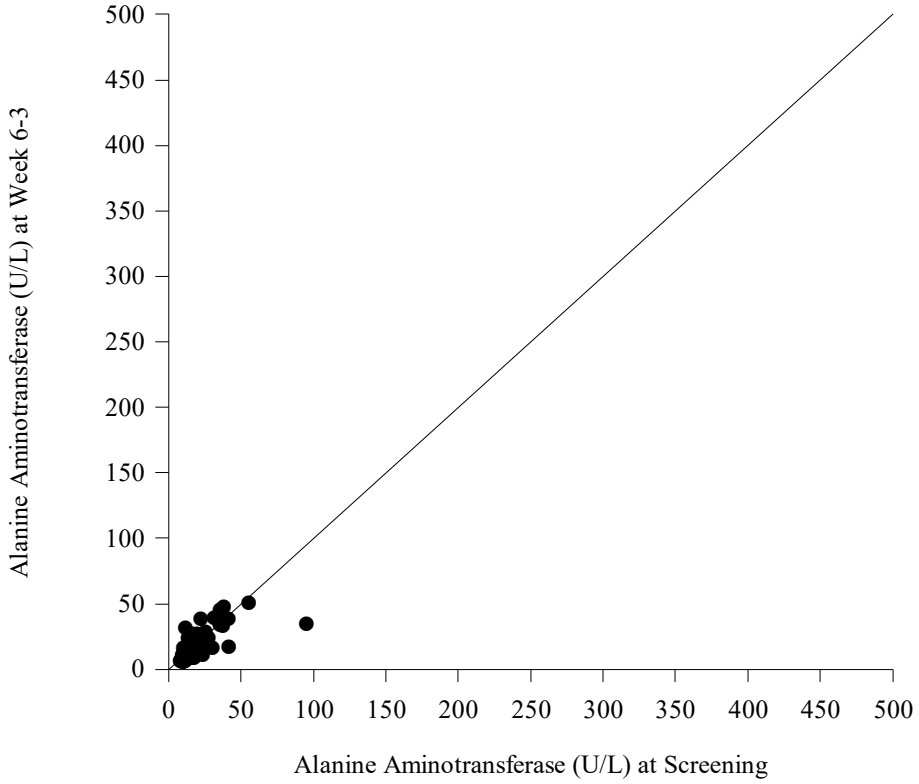
BBI-4000 5%



PAGE: 19 of 76
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/03/19
PROTOCOL NO: BBI-4000-06
Source：5.3.5.1-2 Figure 14.3.4-4 より改変

図 2.7.4-2　臨床検査値の散布図（BBI-4000-06 試験）（続き）
Biochemical（Safety Analysis Set）

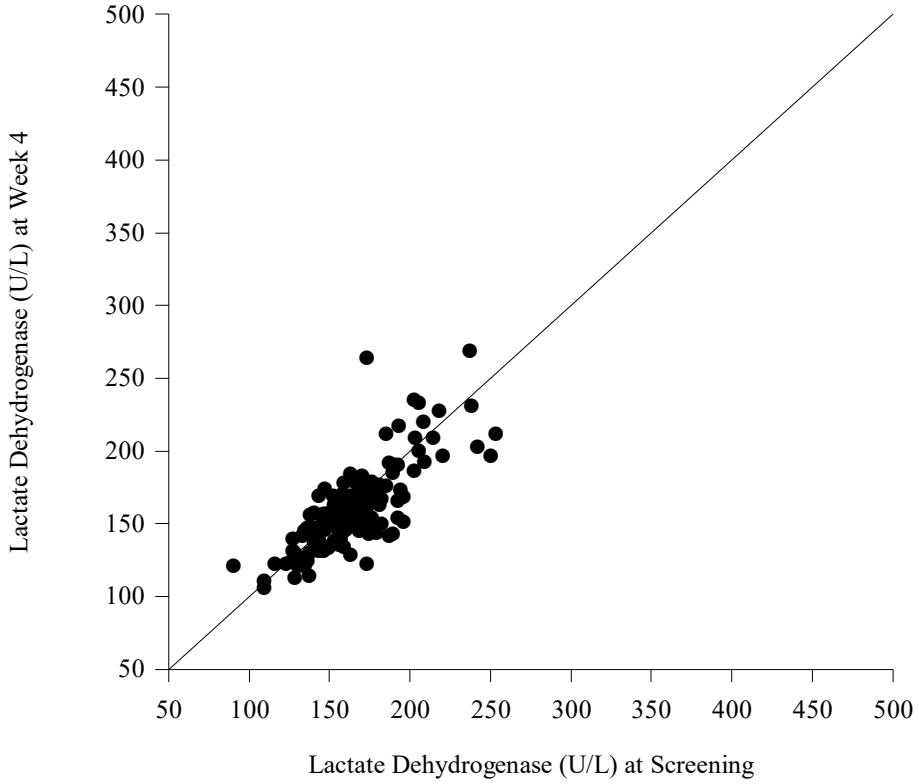
BBI-4000 5%



PAGE: 20 of 76
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/03/19
PROTOCOL NO: BBI-4000-06
Source：5.3.5.1-2 Figure 14.3.4-4 より改変

図 2.7.4-2　臨床検査値の散布図（BBI-4000-06 試験）（続き）
Biochemical（Safety Analysis Set）

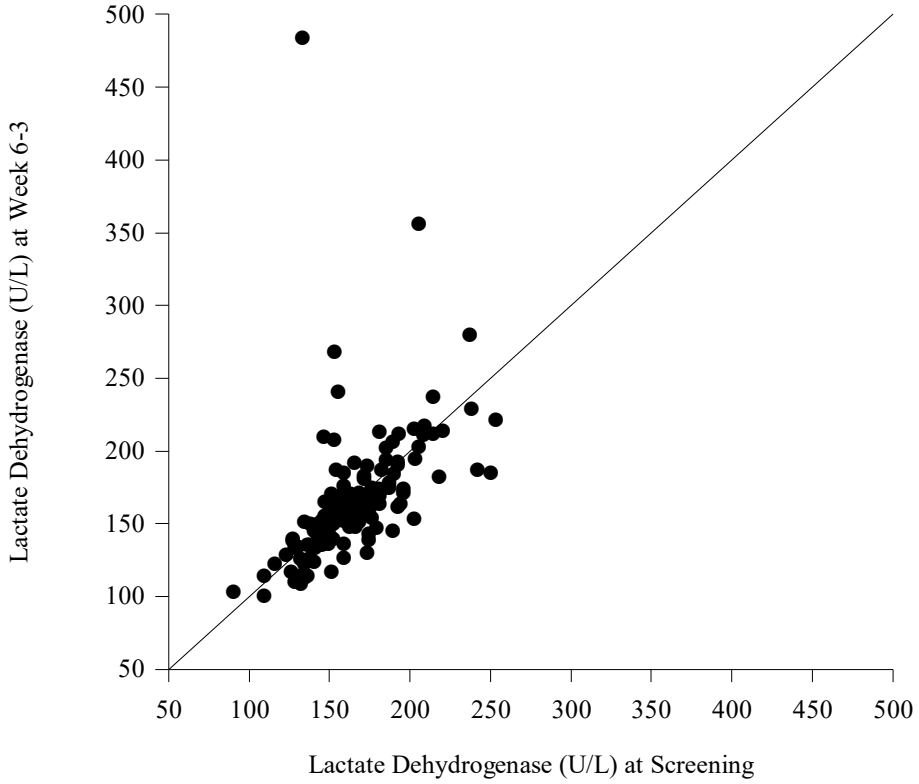
BBI-4000 0%



PAGE: 21 of 76
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/03/19
PROTOCOL NO: BBI-4000-06
Source：5.3.5.1-2 Figure 14.3.4-4 より改変

図 2.7.4-2　臨床検査値の散布図（BBI-4000-06 試験）（続き）
Biochemical（Safety Analysis Set）

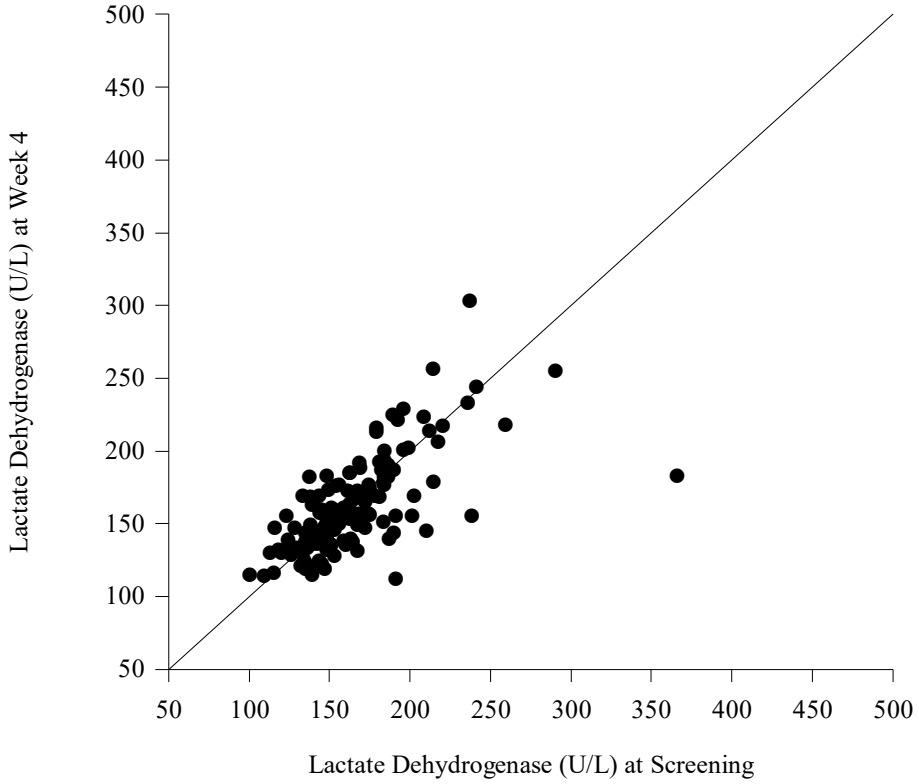
BBI-4000 0%



PAGE: 22 of 76
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/03/19
PROTOCOL NO: BBI-4000-06
Source：5.3.5.1-2 Figure 14.3.4-4 より改変

図 2.7.4-2　臨床検査値の散布図（BBI-4000-06 試験）（続き）
Biochemical（Safety Analysis Set）

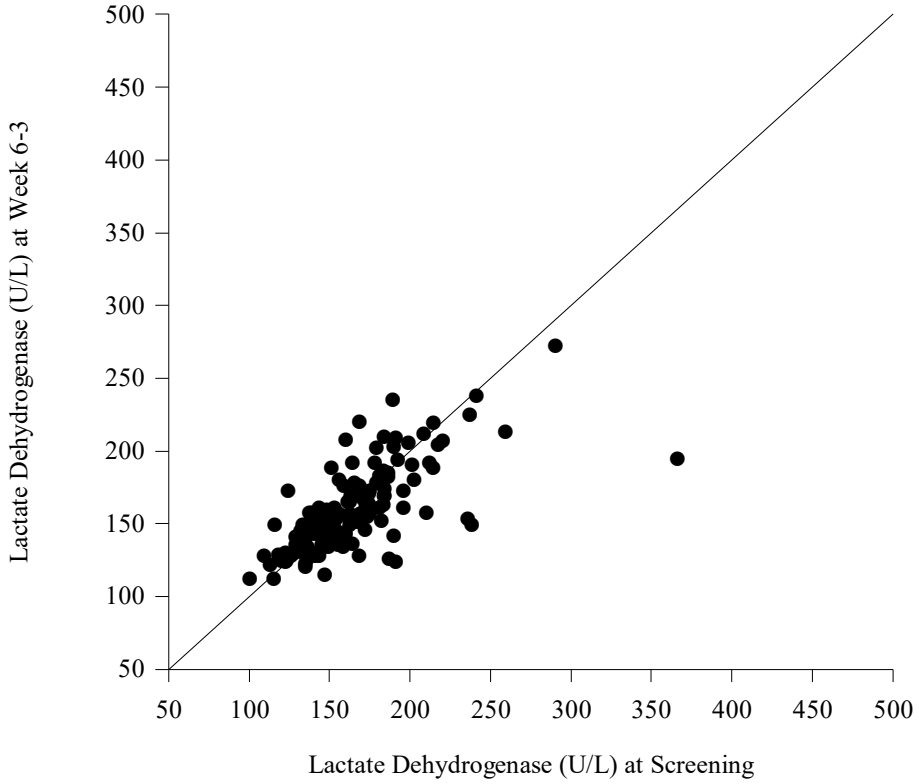
BBI-4000 5%



PAGE: 23 of 76
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/03/19
PROTOCOL NO: BBI-4000-06
Source：5.3.5.1-2 Figure 14.3.4-4 より改変

図 2.7.4-2　臨床検査値の散布図（BBI-4000-06 試験）（続き）
Biochemical（Safety Analysis Set）

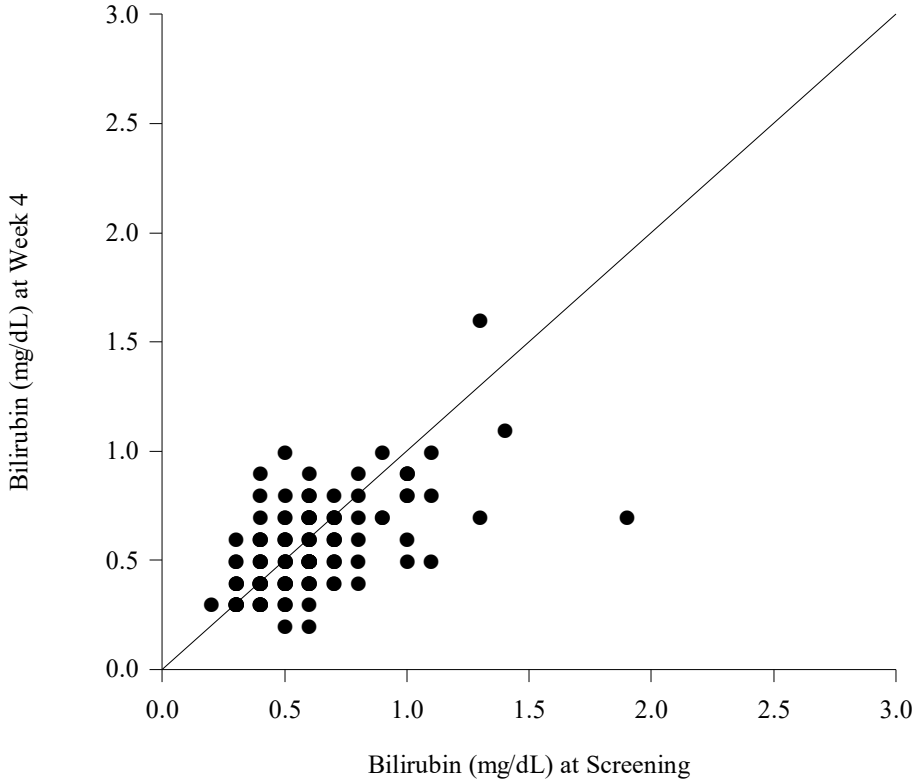
BBI-4000 5%



PAGE: 24 of 76
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/03/19
PROTOCOL NO: BBI-4000-06
Source：5.3.5.1-2 Figure 14.3.4-4 より改変

図 2.7.4-2　臨床検査値の散布図（BBI-4000-06 試験）（続き）
Biochemical（Safety Analysis Set）

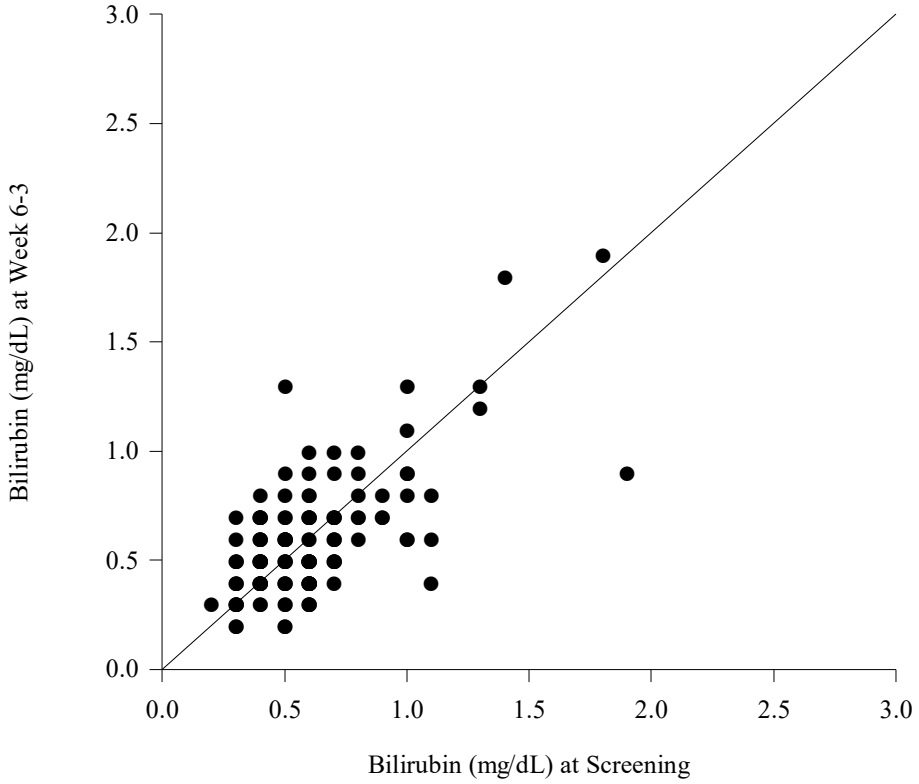
BBI-4000 0%



PAGE: 25 of 76
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/03/19
PROTOCOL NO: BBI-4000-06
Source：5.3.5.1-2 Figure 14.3.4-4 より改変

図 2.7.4-2　臨床検査値の散布図（BBI-4000-06 試験）（続き）
Biochemical（Safety Analysis Set）

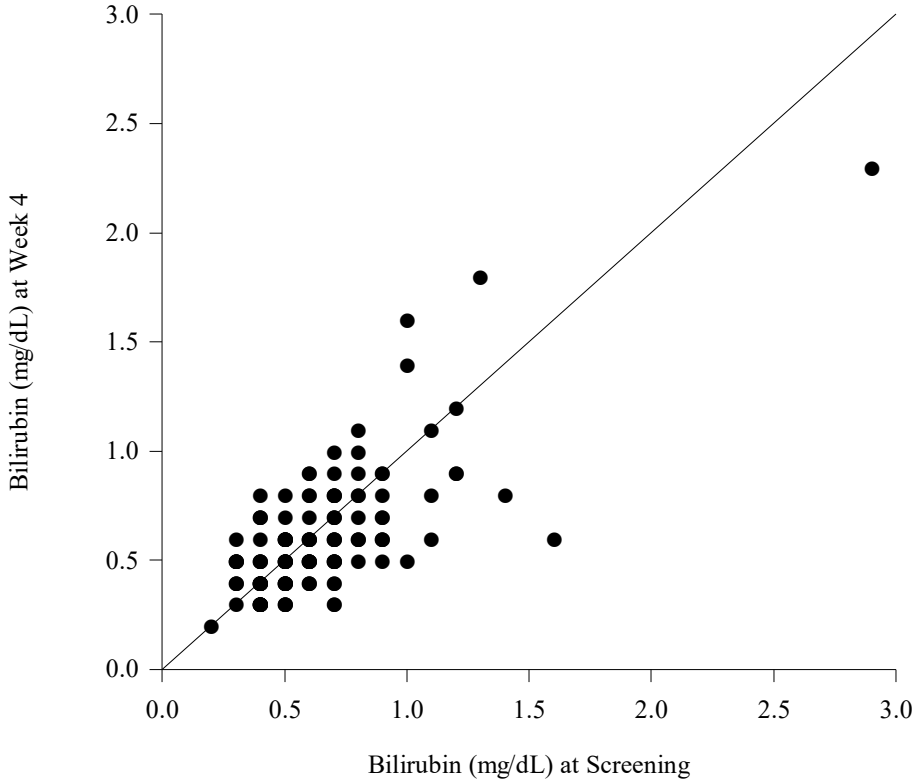
BBI-4000 0%



PAGE: 26 of 76
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/03/19
PROTOCOL NO: BBI-4000-06
Source：5.3.5.1-2 Figure 14.3.4-4 より改変

図 2.7.4-2　臨床検査値の散布図（BBI-4000-06 試験）（続き）
Biochemical（Safety Analysis Set）

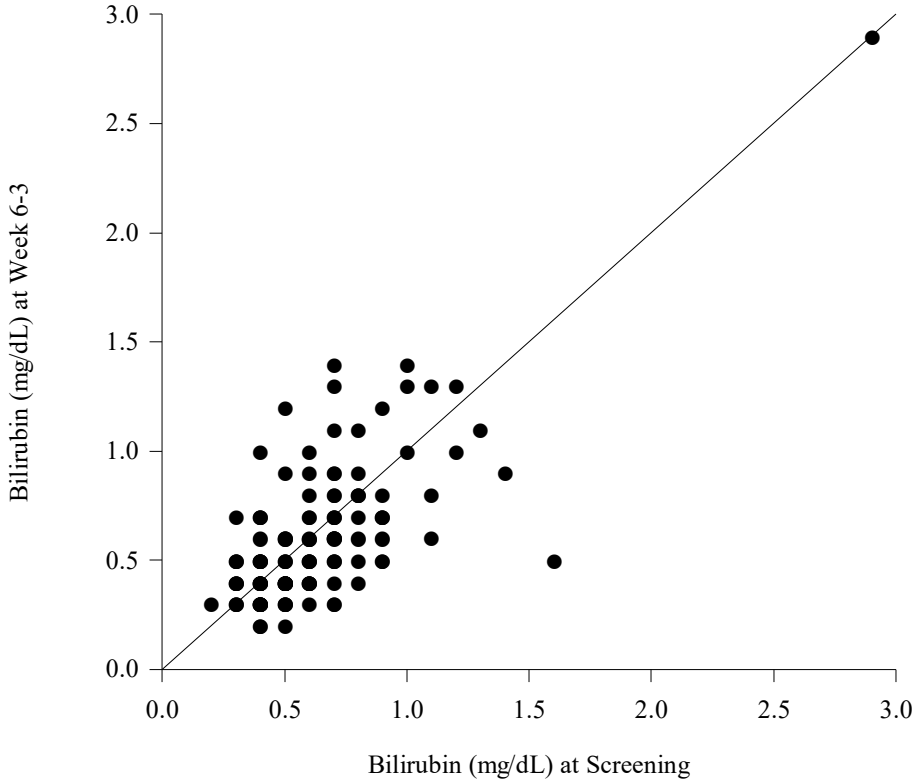
BBI-4000 5%



PAGE: 27 of 76
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/03/19
PROTOCOL NO: BBI-4000-06
Source：5.3.5.1-2 Figure 14.3.4-4 より改変

図 2.7.4-2　臨床検査値の散布図（BBI-4000-06 試験）（続き）
Biochemical（Safety Analysis Set）

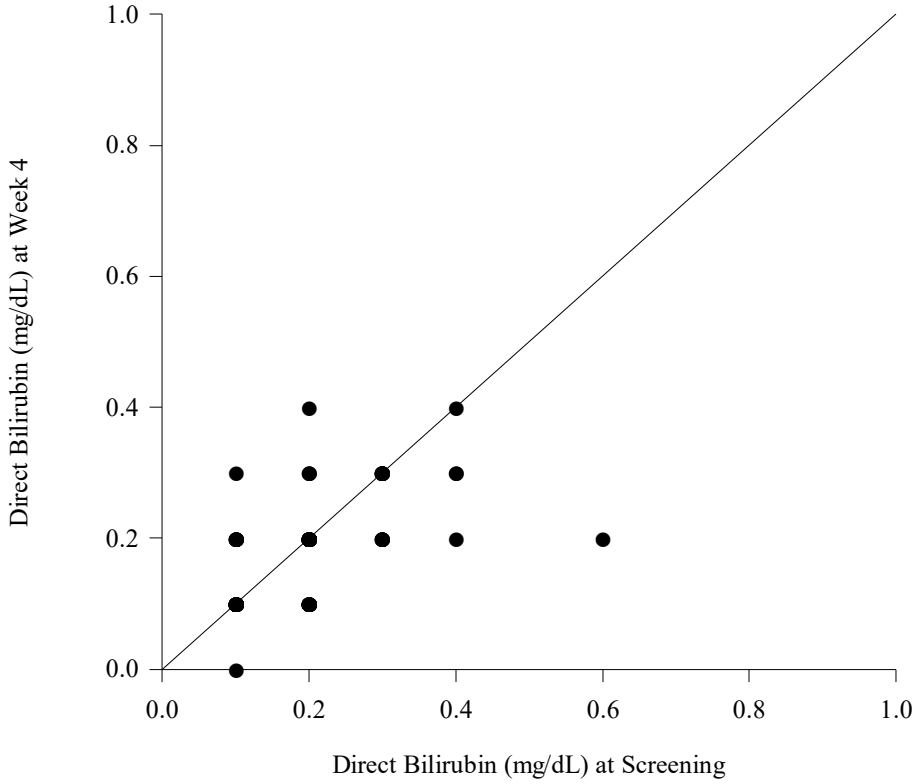
BBI-4000 5%



PAGE: 28 of 76
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/03/19
PROTOCOL NO: BBI-4000-06
Source：5.3.5.1-2 Figure 14.3.4-4 より改変

図 2.7.4-2　臨床検査値の散布図（BBI-4000-06 試験）（続き）
Biochemical（Safety Analysis Set）

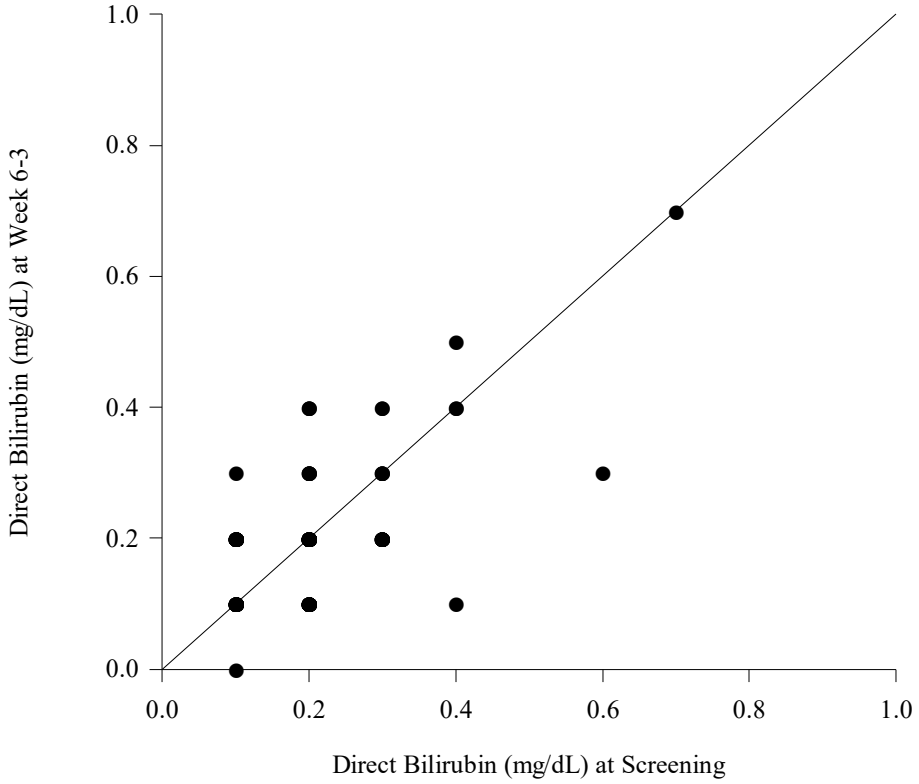
BBI-4000 0%



PAGE: 29 of 76
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/03/19
PROTOCOL NO: BBI-4000-06
Source：5.3.5.1-2 Figure 14.3.4-4 より改変

図 2.7.4-2　臨床検査値の散布図（BBI-4000-06 試験）（続き）
Biochemical（Safety Analysis Set）

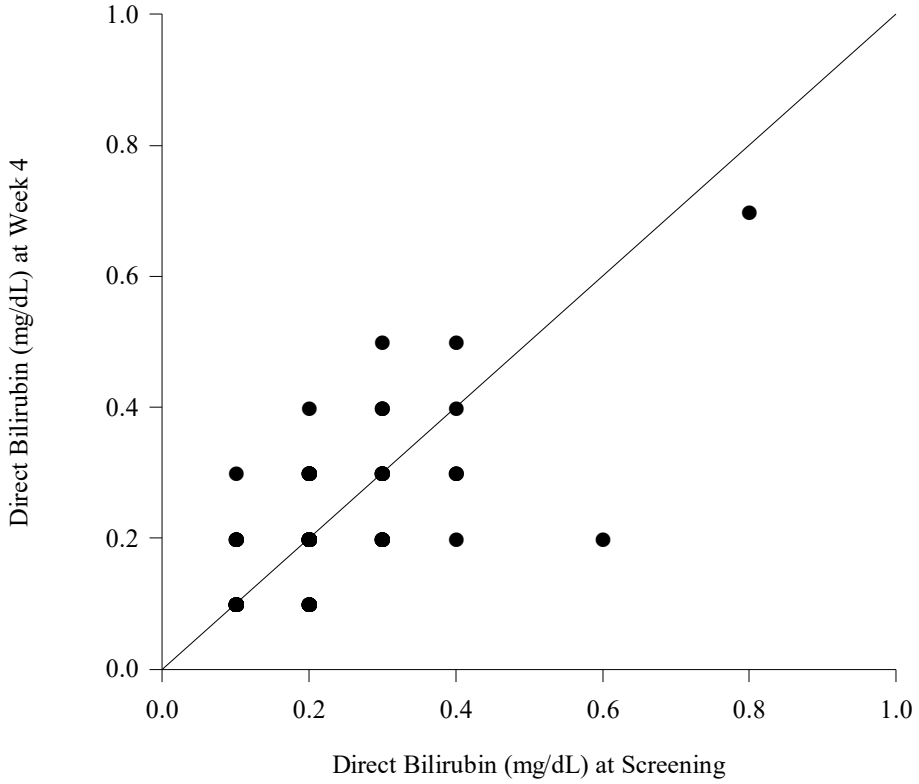
BBI-4000 0%



PAGE: 30 of 76
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/03/19
PROTOCOL NO: BBI-4000-06
Source：5.3.5.1-2 Figure 14.3.4-4 より改変

図 2.7.4-2　臨床検査値の散布図（BBI-4000-06 試験）（続き）
Biochemical（Safety Analysis Set）

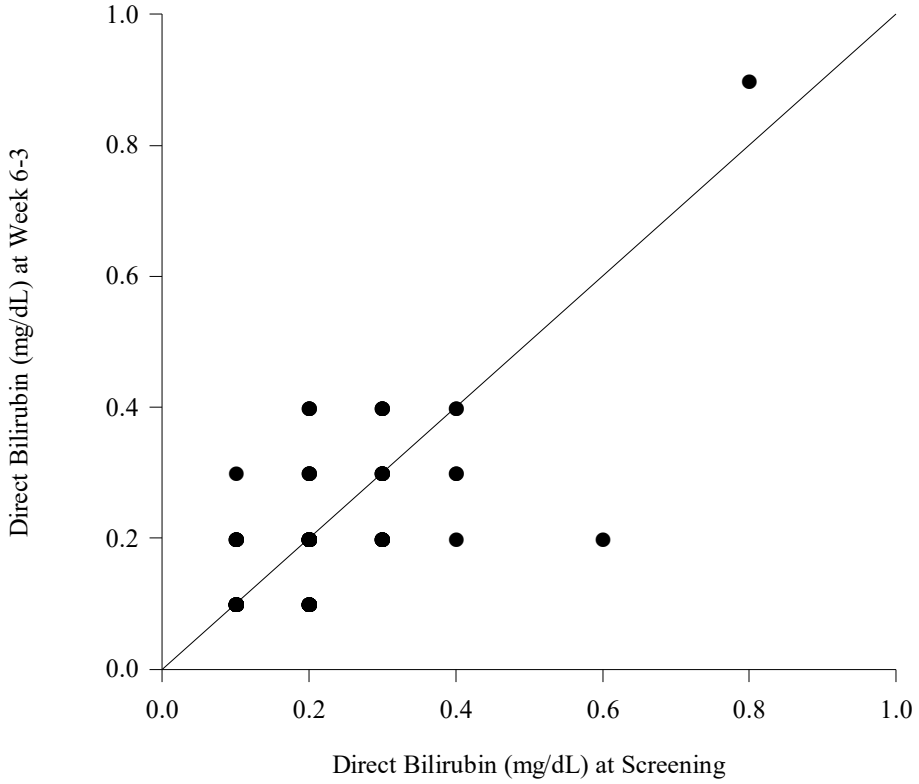
BBI-4000 5%



PAGE: 31 of 76
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/03/19
PROTOCOL NO: BBI-4000-06
Source：5.3.5.1-2 Figure 14.3.4-4 より改変

図 2.7.4-2　臨床検査値の散布図（BBI-4000-06 試験）（続き）
Biochemical（Safety Analysis Set）

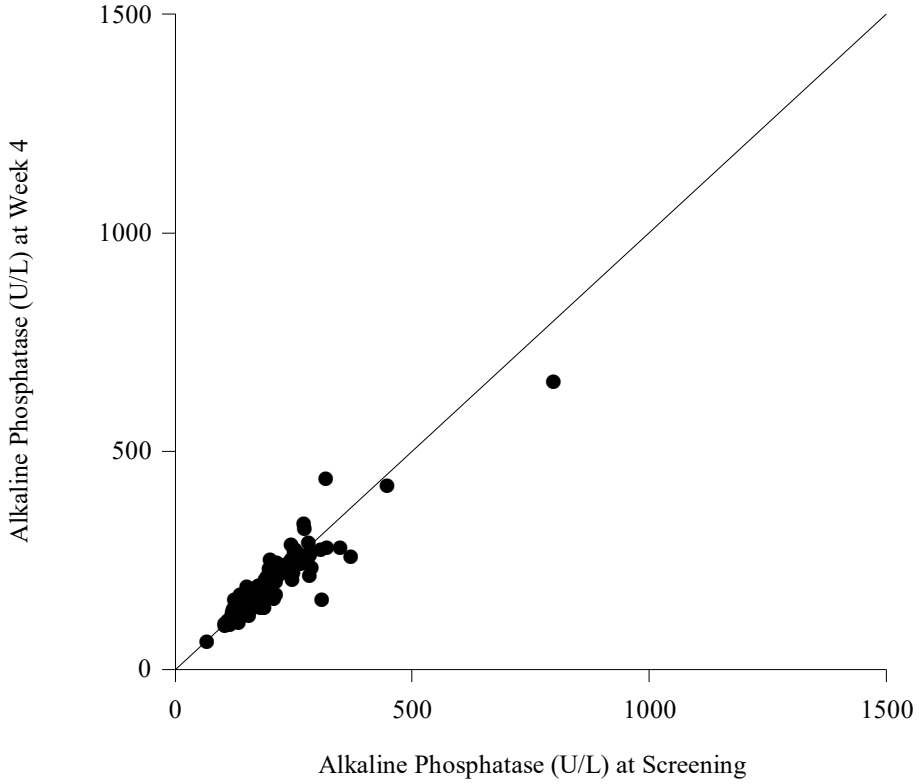
BBI-4000 5%



PAGE: 32 of 76
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/03/19
PROTOCOL NO: BBI-4000-06
Source：5.3.5.1-2 Figure 14.3.4-4 より改変

図 2.7.4-2　臨床検査値の散布図（BBI-4000-06 試験）（続き）
Biochemical（Safety Analysis Set）

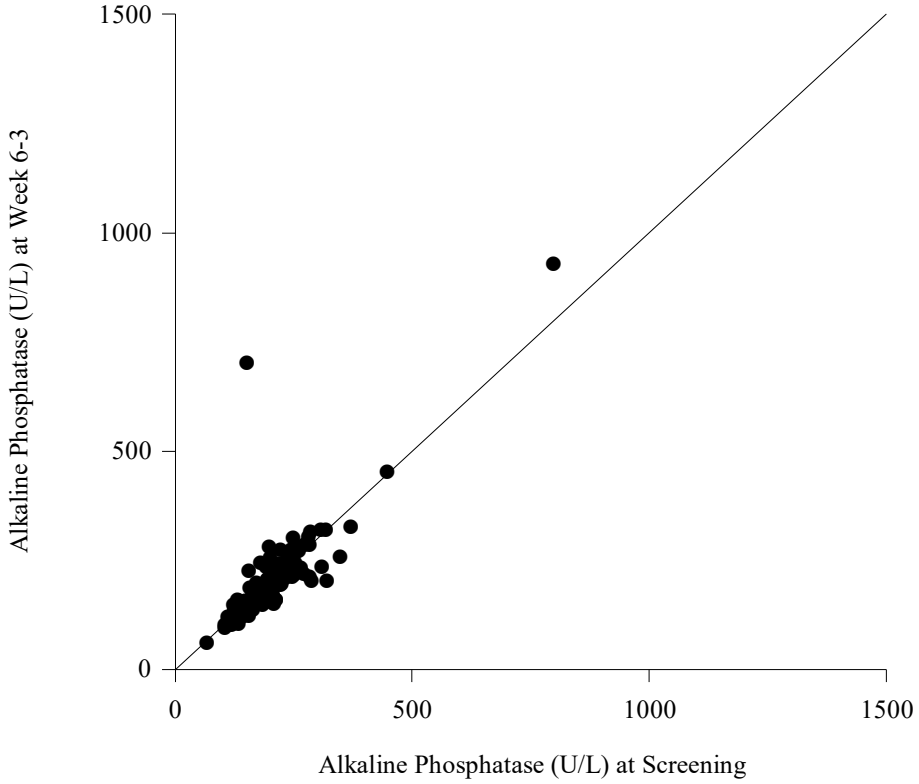
BBI-4000 0%



PAGE: 33 of 76
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/03/19
PROTOCOL NO: BBI-4000-06
Source：5.3.5.1-2 Figure 14.3.4-4 より改変

図 2.7.4-2　臨床検査値の散布図（BBI-4000-06 試験）（続き）
Biochemical（Safety Analysis Set）

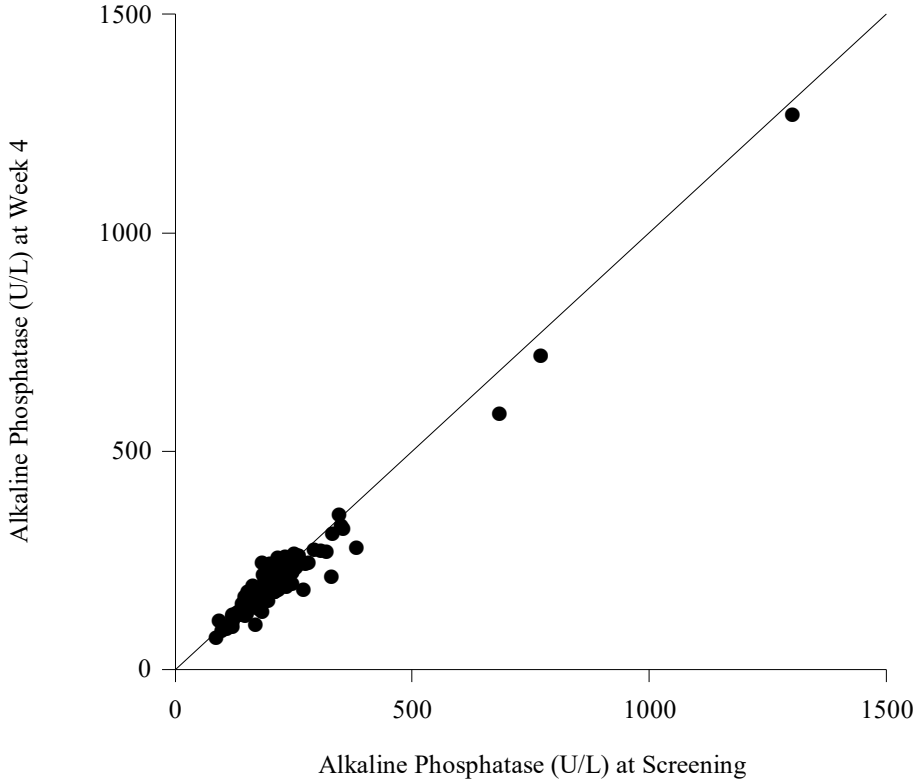
BBI-4000 0%



PAGE: 34 of 76
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/03/19
PROTOCOL NO: BBI-4000-06
Source：5.3.5.1-2 Figure 14.3.4-4 より改変

図 2.7.4-2　臨床検査値の散布図（BBI-4000-06 試験）（続き）
Biochemical（Safety Analysis Set）

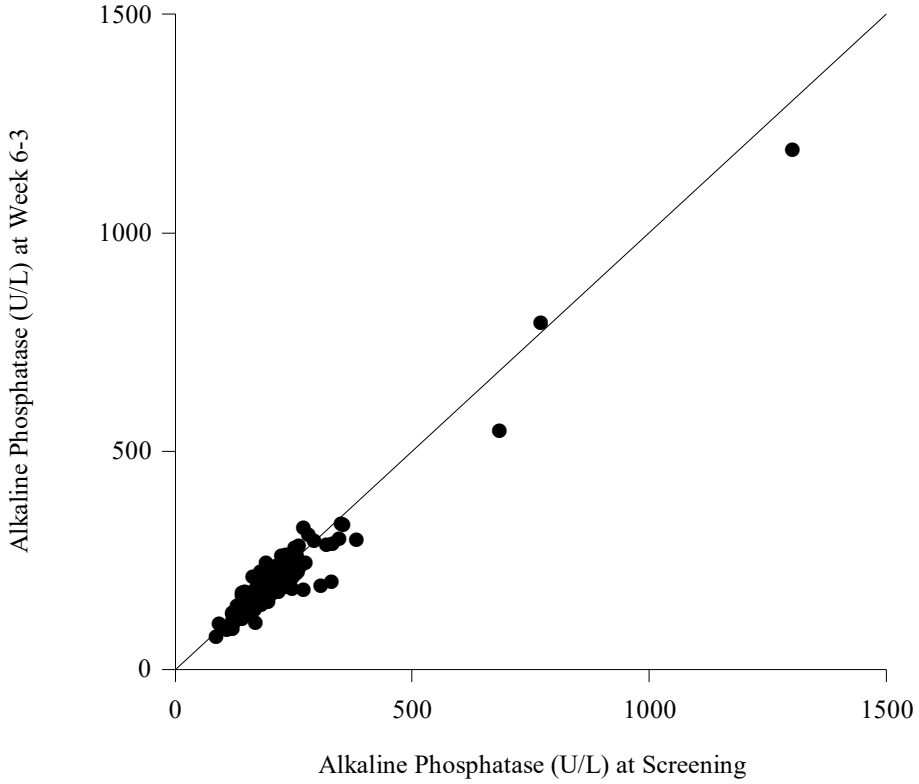
BBI-4000 5%



PAGE: 35 of 76
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/03/19
PROTOCOL NO: BBI-4000-06
Source：5.3.5.1-2 Figure 14.3.4-4 より改変

図 2.7.4-2　臨床検査値の散布図（BBI-4000-06 試験）（続き）
Biochemical（Safety Analysis Set）

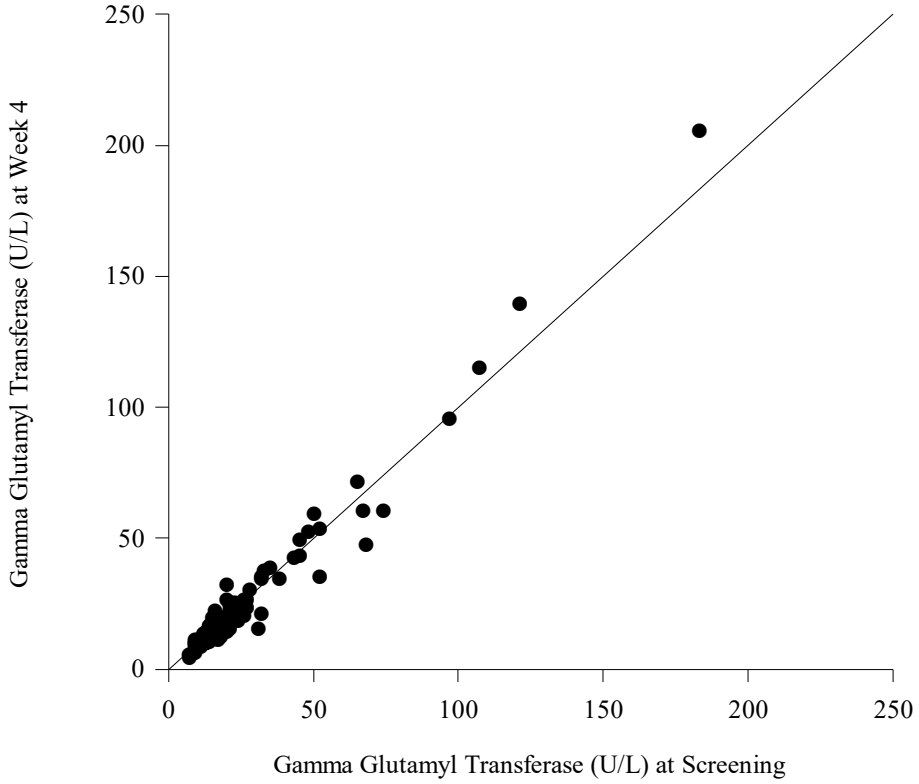
BBI-4000 5%



PAGE: 36 of 76
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/03/19
PROTOCOL NO: BBI-4000-06
Source：5.3.5.1-2 Figure 14.3.4-4 より改変

図 2.7.4-2　臨床検査値の散布図（BBI-4000-06 試験）（続き）
Biochemical（Safety Analysis Set）

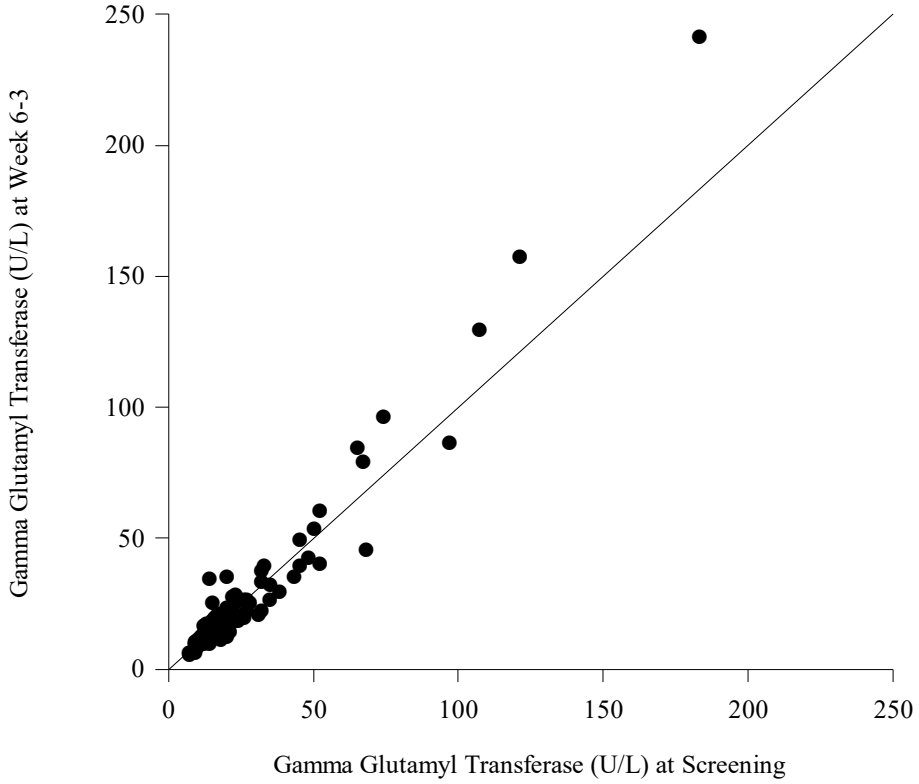
BBI-4000 0%



PAGE: 37 of 76
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/03/19
PROTOCOL NO: BBI-4000-06
Source：5.3.5.1-2 Figure 14.3.4-4 より改変

図 2.7.4-2　臨床検査値の散布図（BBI-4000-06 試験）（続き）
Biochemical（Safety Analysis Set）

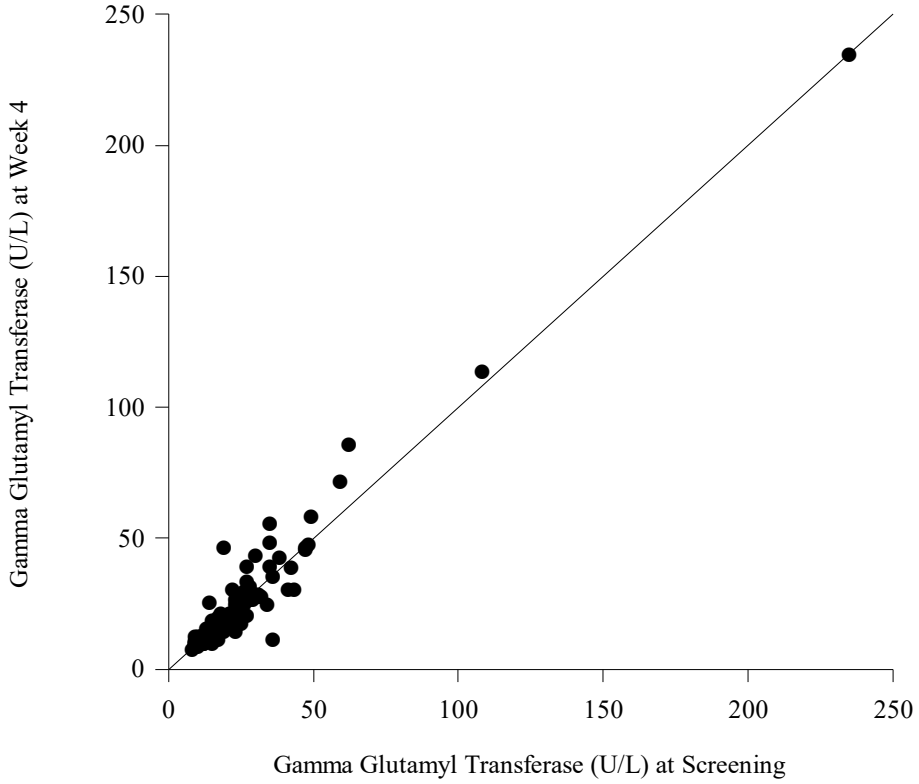
BBI-4000 0%



PAGE: 38 of 76
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/03/19
PROTOCOL NO: BBI-4000-06
Source：5.3.5.1-2 Figure 14.3.4-4 より改変

図 2.7.4-2　臨床検査値の散布図（BBI-4000-06 試験）（続き）
Biochemical（Safety Analysis Set）

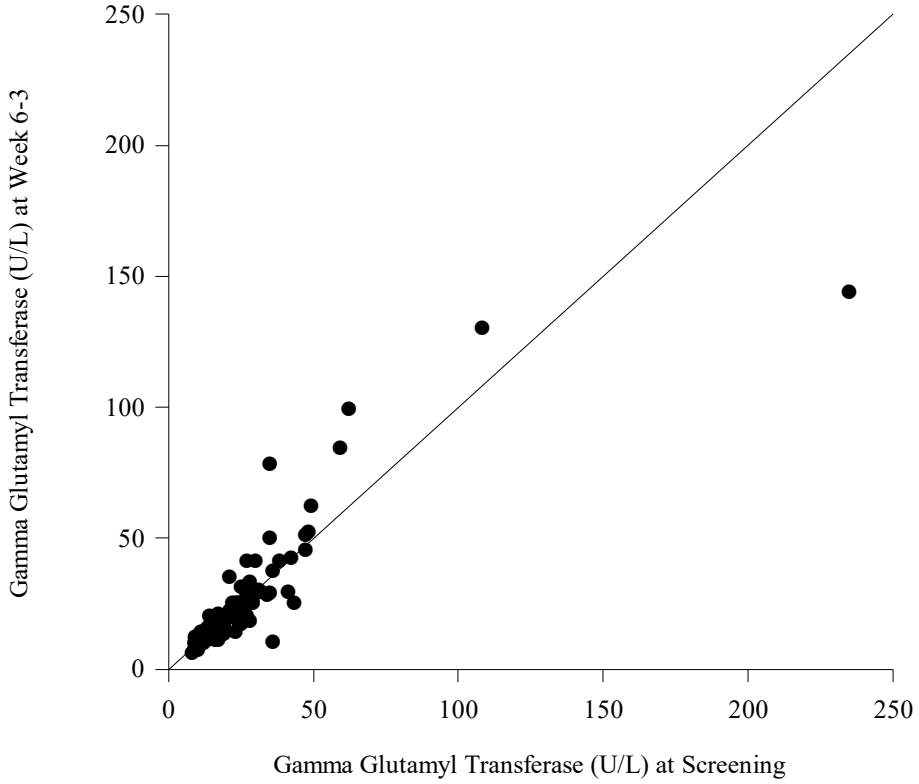
BBI-4000 5%



PAGE: 39 of 76
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/03/19
PROTOCOL NO: BBI-4000-06
Source：5.3.5.1-2 Figure 14.3.4-4 より改変

図 2.7.4-2　臨床検査値の散布図（BBI-4000-06 試験）（続き）
Biochemical（Safety Analysis Set）

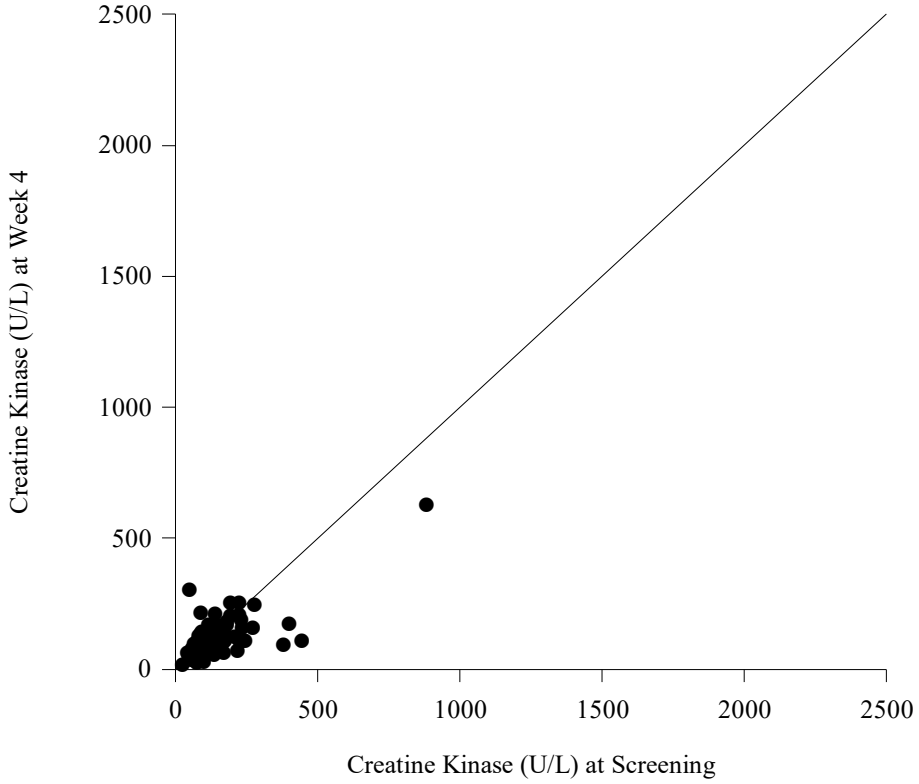
BBI-4000 5%



PAGE: 40 of 76
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/03/19
PROTOCOL NO: BBI-4000-06
Source：5.3.5.1-2 Figure 14.3.4-4 より改変

図 2.7.4-2　臨床検査値の散布図（BBI-4000-06 試験）（続き）
Biochemical（Safety Analysis Set）

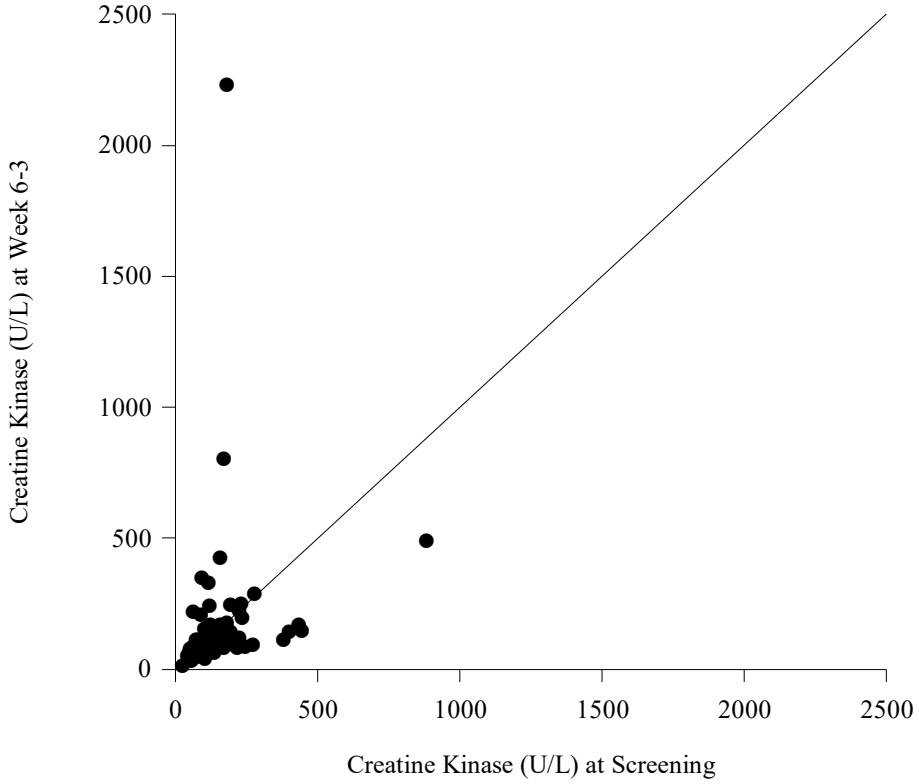
BBI-4000 0%



PAGE: 41 of 76
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/03/19
PROTOCOL NO: BBI-4000-06
Source：5.3.5.1-2 Figure 14.3.4-4 より改変

図 2.7.4-2　臨床検査値の散布図（BBI-4000-06 試験）（続き）
Biochemical（Safety Analysis Set）

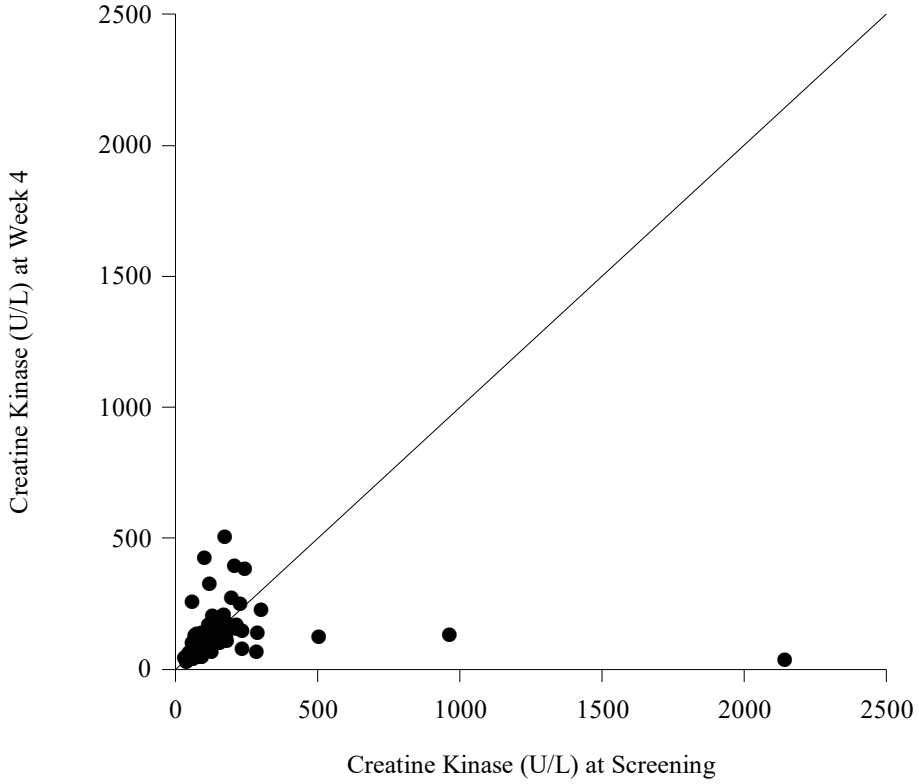
BBI-4000 0%



PAGE: 42 of 76
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/03/19
PROTOCOL NO: BBI-4000-06
Source：5.3.5.1-2 Figure 14.3.4-4 より改変

図 2.7.4-2　臨床検査値の散布図（BBI-4000-06 試験）（続き）
Biochemical（Safety Analysis Set）

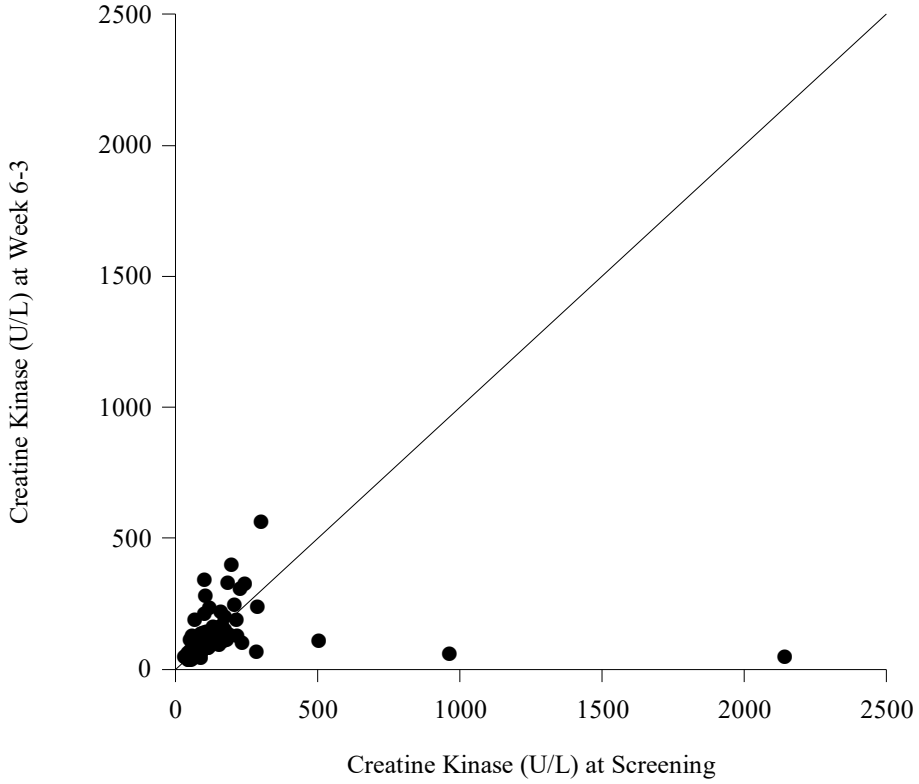
BBI-4000 5%



PAGE: 43 of 76
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/03/19
PROTOCOL NO: BBI-4000-06
Source：5.3.5.1-2 Figure 14.3.4-4 より改変

図 2.7.4-2　臨床検査値の散布図（BBI-4000-06 試験）（続き）
Biochemical（Safety Analysis Set）

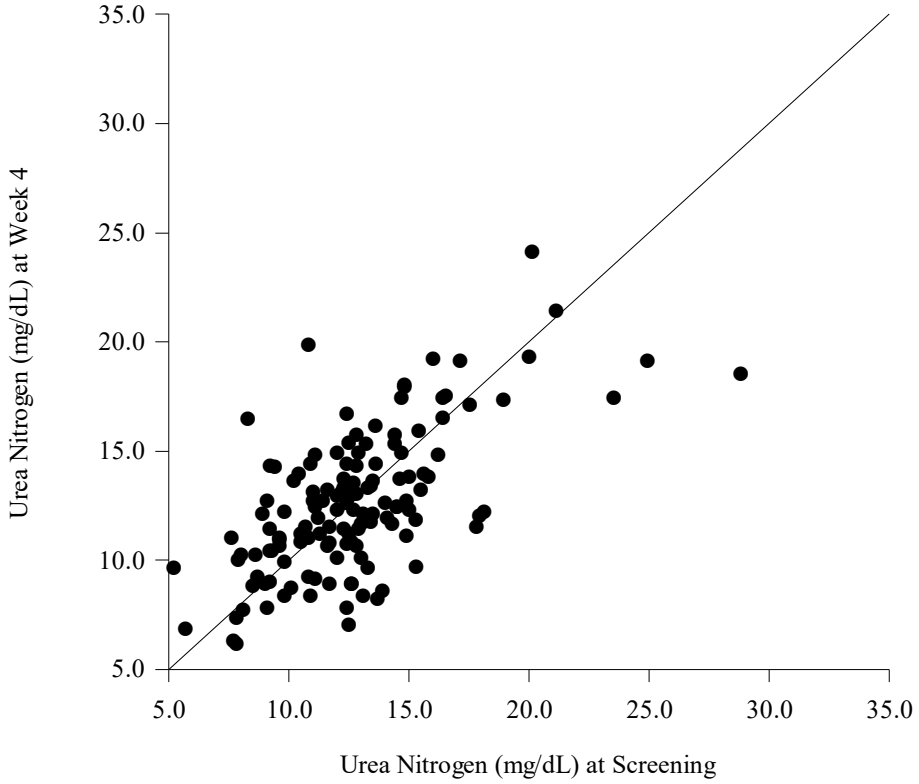
BBI-4000 5%



PAGE: 44 of 76
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/03/19
PROTOCOL NO: BBI-4000-06
Source：5.3.5.1-2 Figure 14.3.4-4 より改変

図 2.7.4-2　臨床検査値の散布図（BBI-4000-06 試験）（続き）
Biochemical（Safety Analysis Set）

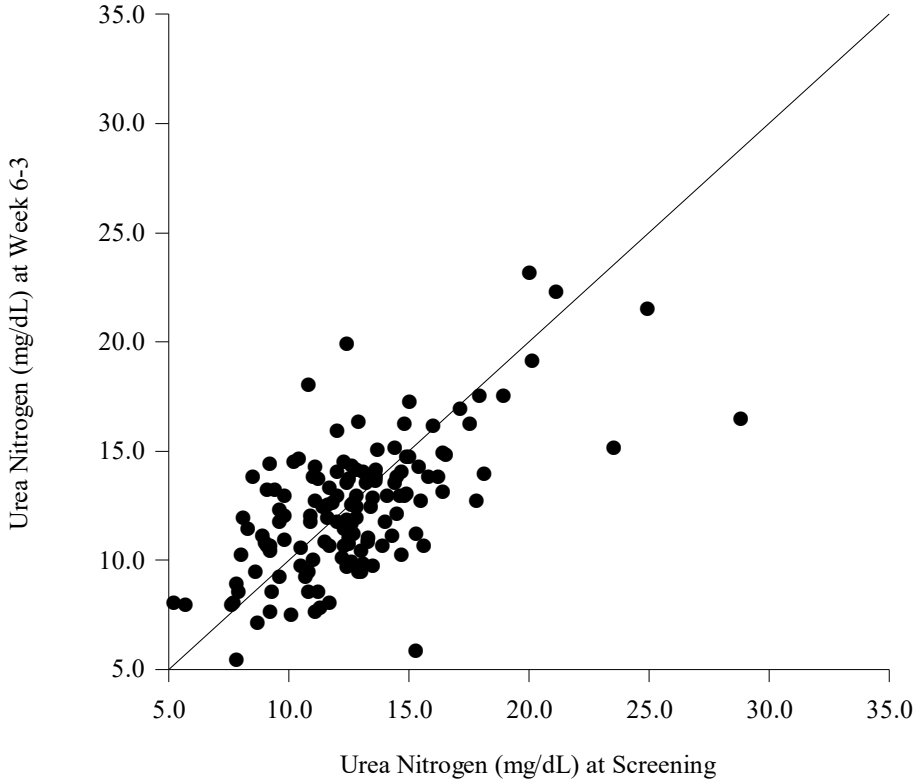
BBI-4000 0%



PAGE: 45 of 76
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/03/19
PROTOCOL NO: BBI-4000-06
Source：5.3.5.1-2 Figure 14.3.4-4 より改変

図 2.7.4-2　臨床検査値の散布図（BBI-4000-06 試験）（続き）
Biochemical（Safety Analysis Set）

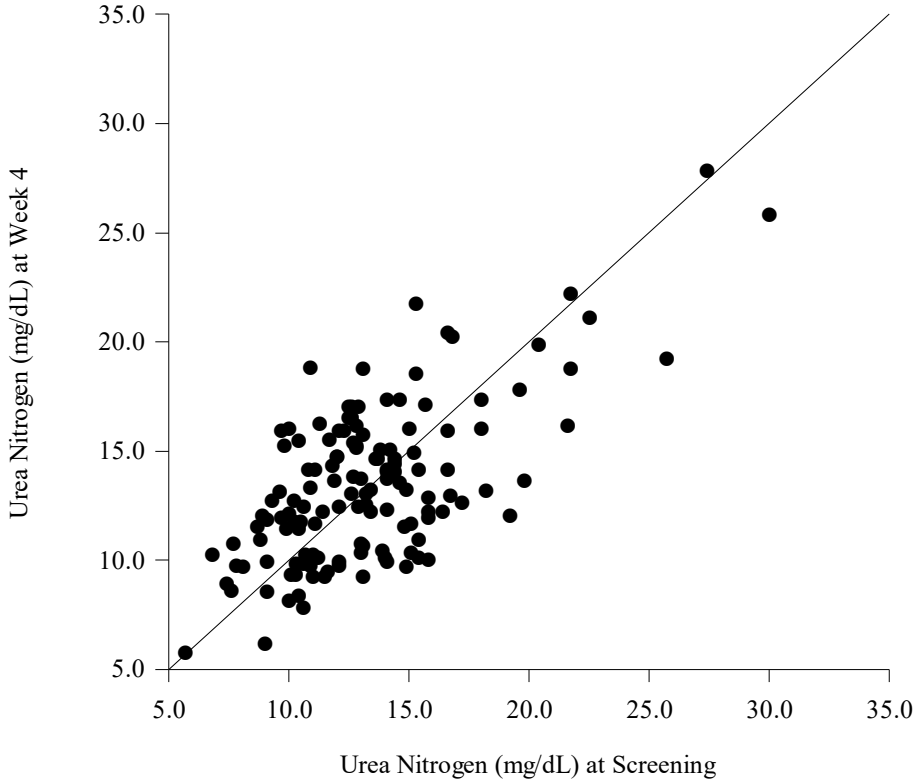
BBI-4000 0%



PAGE: 46 of 76
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/03/19
PROTOCOL NO: BBI-4000-06
Source：5.3.5.1-2 Figure 14.3.4-4 より改変

図 2.7.4-2　臨床検査値の散布図（BBI-4000-06 試験）（続き）
Biochemical（Safety Analysis Set）

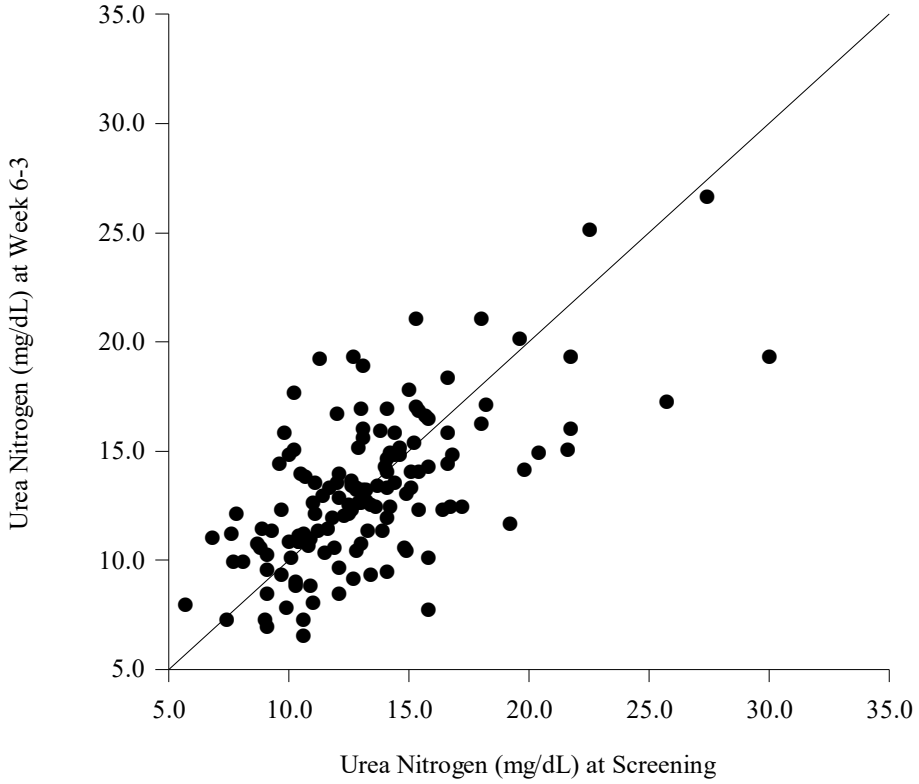
BBI-4000 5%



PAGE: 47 of 76
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/03/19
PROTOCOL NO: BBI-4000-06
Source：5.3.5.1-2 Figure 14.3.4-4 より改変

図 2.7.4-2　臨床検査値の散布図（BBI-4000-06 試験）（続き）
Biochemical（Safety Analysis Set）

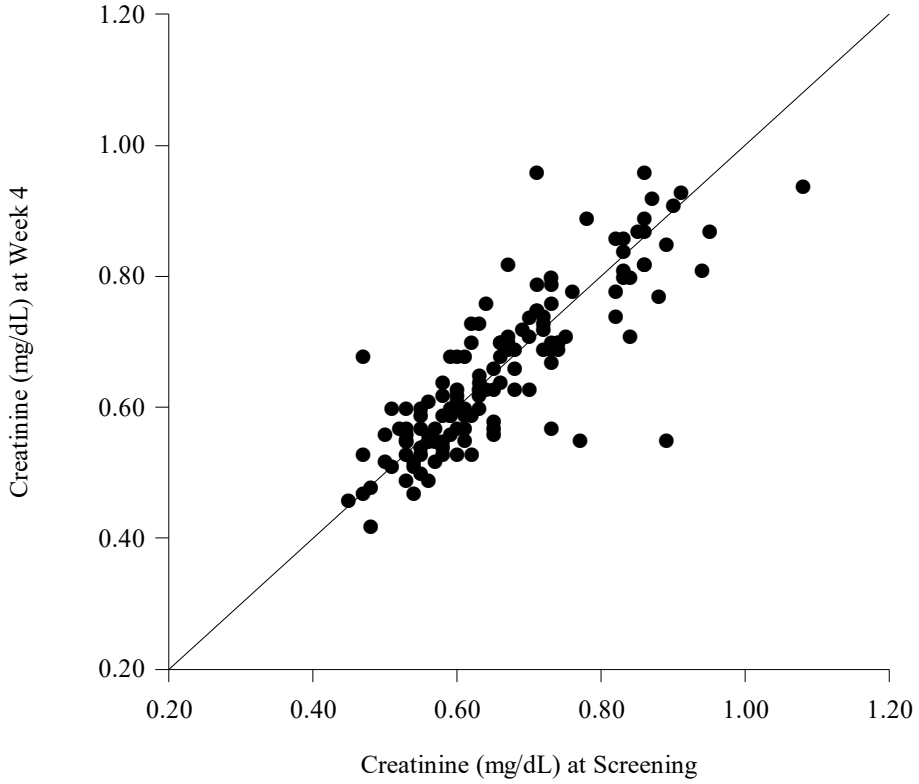
BBI-4000 5%



PAGE: 48 of 76
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/03/19
PROTOCOL NO: BBI-4000-06
Source：5.3.5.1-2 Figure 14.3.4-4 より改変

図 2.7.4-2　臨床検査値の散布図（BBI-4000-06 試験）（続き）
Biochemical（Safety Analysis Set）

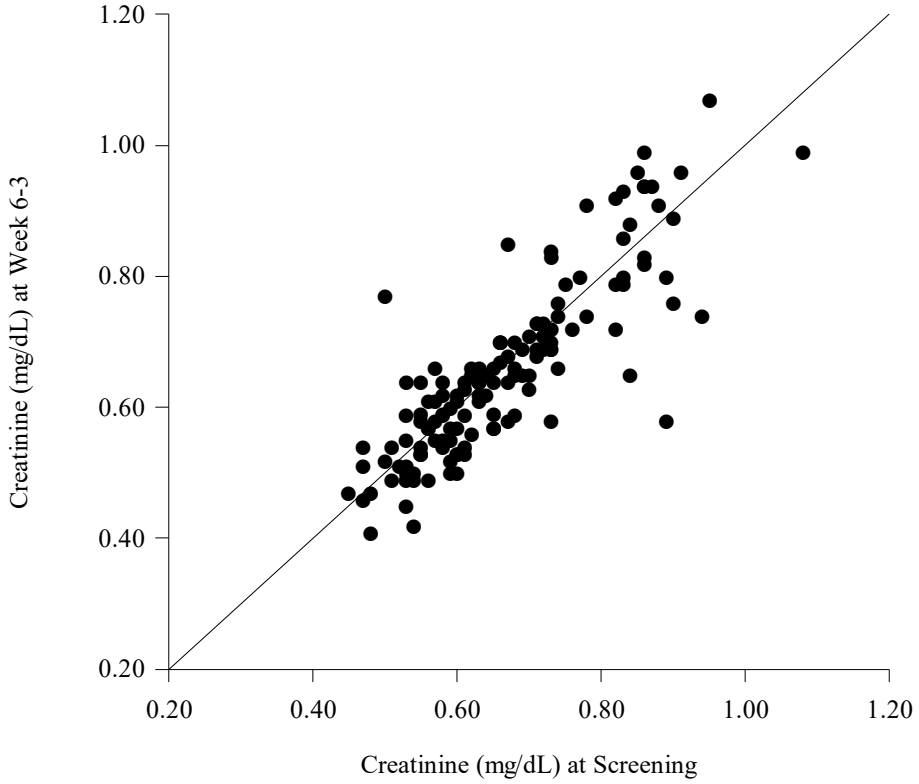
BBI-4000 0%



PAGE: 49 of 76
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/03/19
PROTOCOL NO: BBI-4000-06
Source：5.3.5.1-2 Figure 14.3.4-4 より改変

図 2.7.4-2　臨床検査値の散布図（BBI-4000-06 試験）（続き）
Biochemical（Safety Analysis Set）

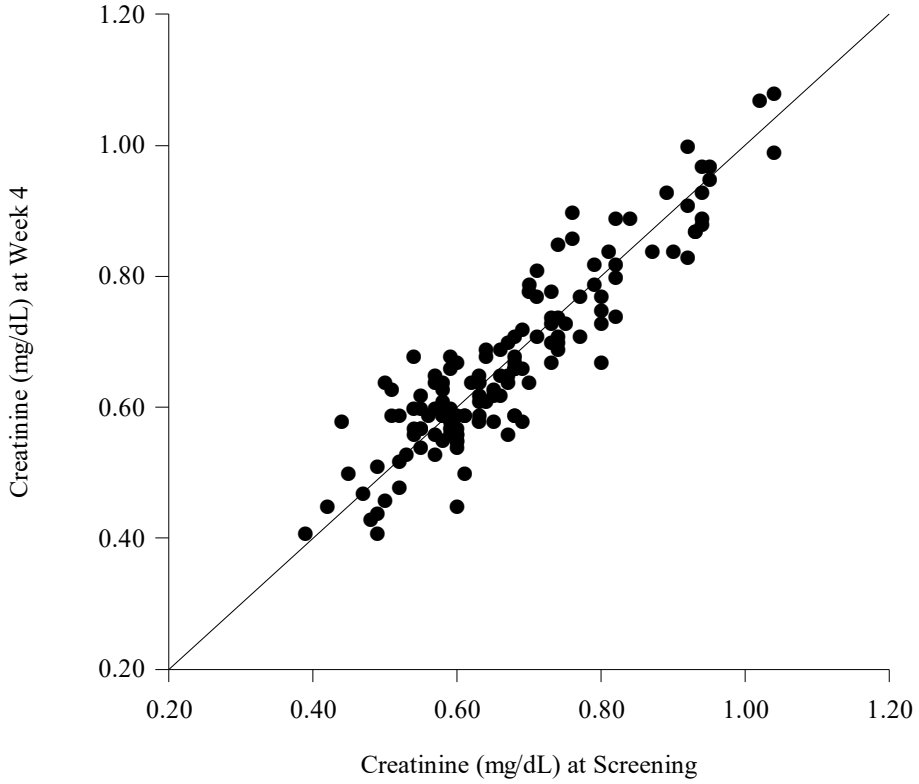
BBI-4000 0%



PAGE: 50 of 76
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/03/19
PROTOCOL NO: BBI-4000-06
Source：5.3.5.1-2 Figure 14.3.4-4 より改変

図 2.7.4-2　臨床検査値の散布図（BBI-4000-06 試験）（続き）
Biochemical（Safety Analysis Set）

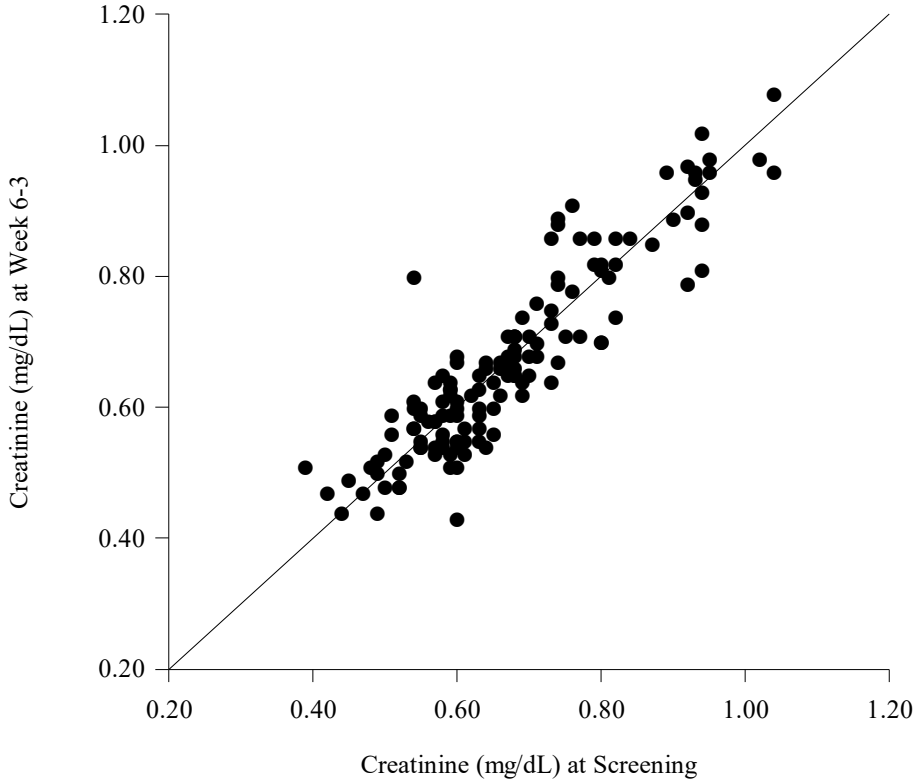
BBI-4000 5%



PAGE: 51 of 76
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/03/19
PROTOCOL NO: BBI-4000-06
Source：5.3.5.1-2 Figure 14.3.4-4 より改変

図 2.7.4-2　臨床検査値の散布図（BBI-4000-06 試験）（続き）
Biochemical（Safety Analysis Set）

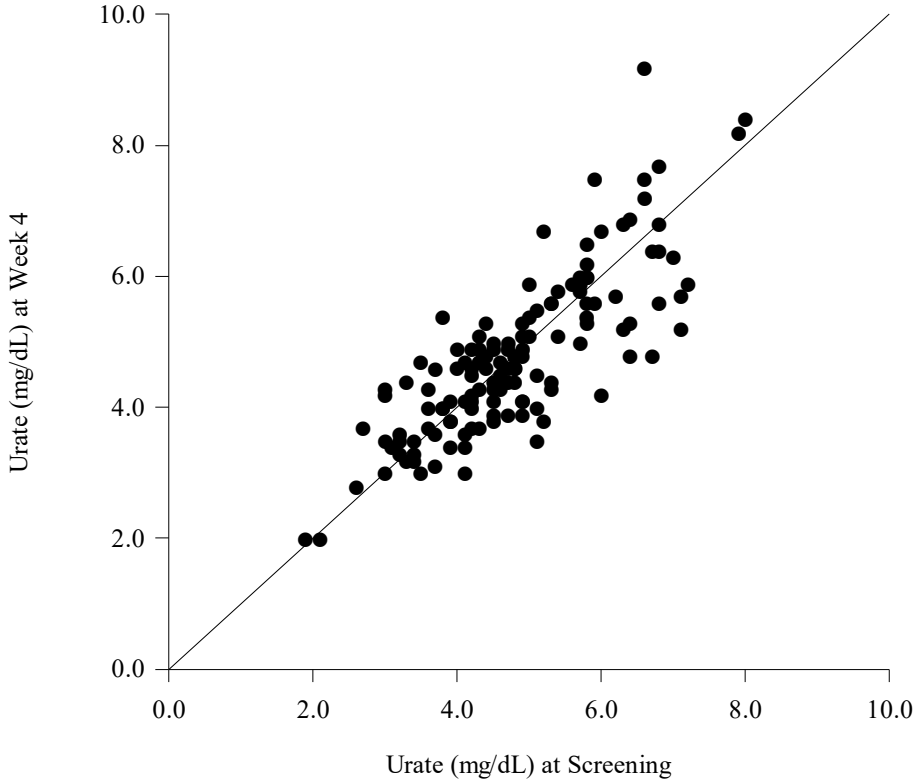
BBI-4000 5%



PAGE: 52 of 76
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/03/19
PROTOCOL NO: BBI-4000-06
Source：5.3.5.1-2 Figure 14.3.4-4 より改変

図 2.7.4-2　臨床検査値の散布図（BBI-4000-06 試験）（続き）
Biochemical（Safety Analysis Set）

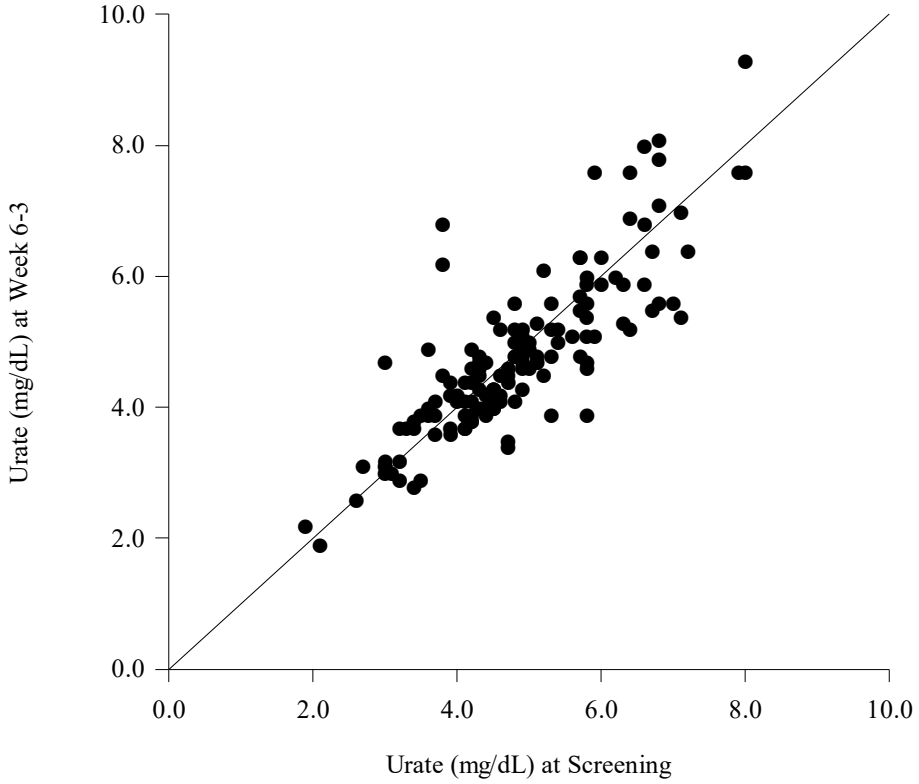
BBI-4000 0%



PAGE: 53 of 76
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/03/19
PROTOCOL NO: BBI-4000-06
Source：5.3.5.1-2 Figure 14.3.4-4 より改変

図 2.7.4-2　臨床検査値の散布図（BBI-4000-06 試験）（続き）
Biochemical（Safety Analysis Set）

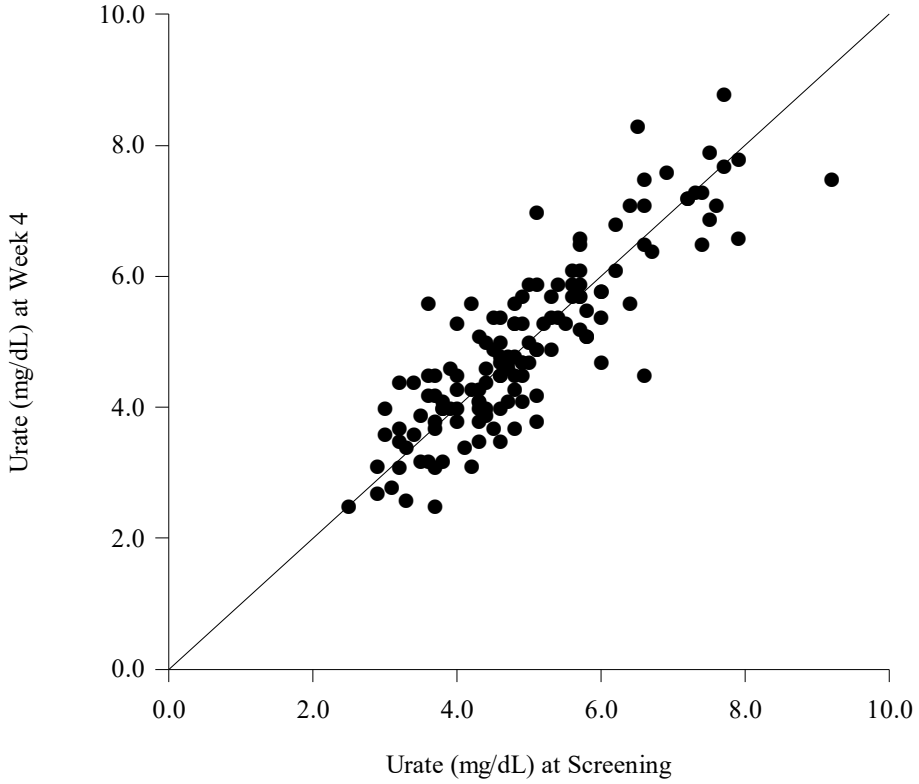
BBI-4000 0%



PAGE: 54 of 76
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/03/19
PROTOCOL NO: BBI-4000-06
Source：5.3.5.1-2 Figure 14.3.4-4 より改変

図 2.7.4-2　臨床検査値の散布図（BBI-4000-06 試験）（続き）
Biochemical（Safety Analysis Set）

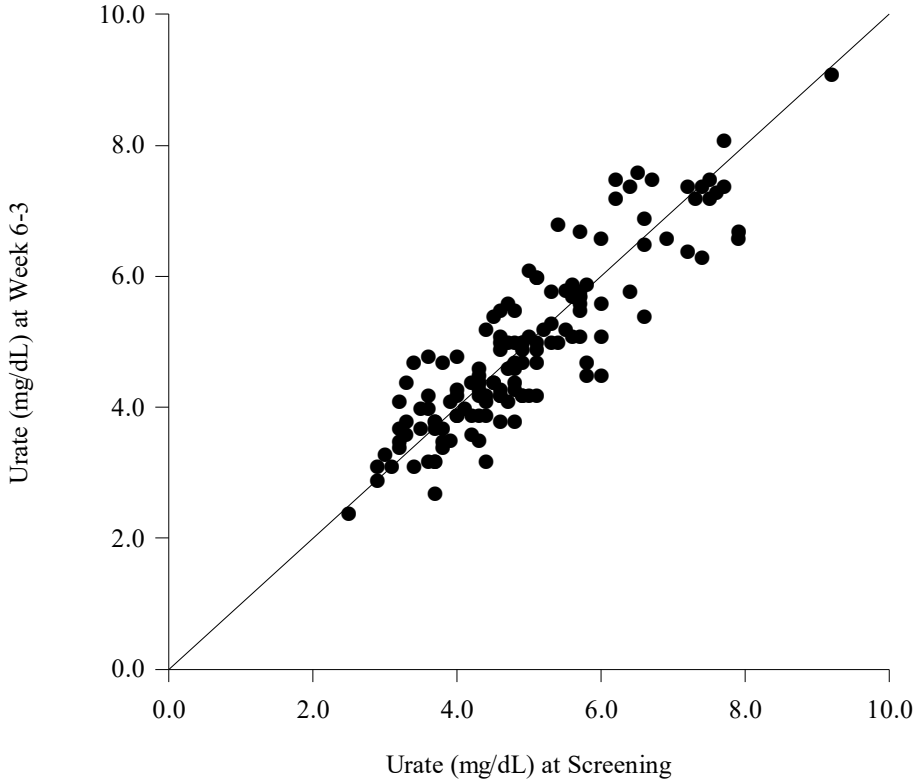
BBI-4000 5%



PAGE: 55 of 76
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/03/19
PROTOCOL NO: BBI-4000-06
Source：5.3.5.1-2 Figure 14.3.4-4 より改変

図 2.7.4-2　臨床検査値の散布図（BBI-4000-06 試験）（続き）
Biochemical（Safety Analysis Set）

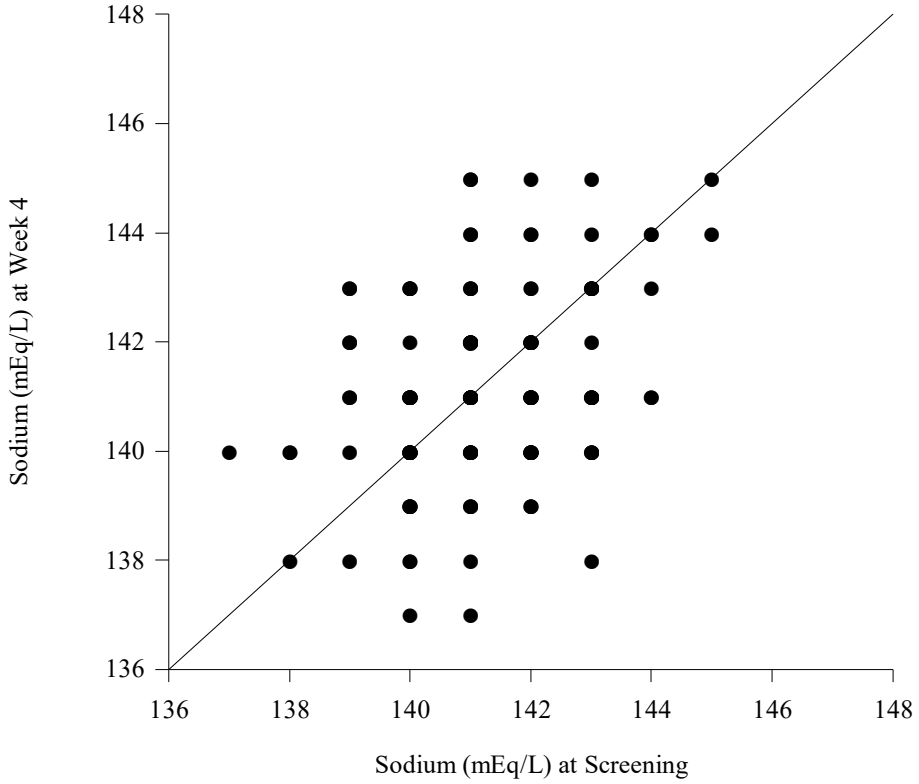
BBI-4000 5%



PAGE: 56 of 76
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/03/19
PROTOCOL NO: BBI-4000-06
Source：5.3.5.1-2 Figure 14.3.4-4 より改変

図 2.7.4-2　臨床検査値の散布図（BBI-4000-06 試験）（続き）
Biochemical（Safety Analysis Set）

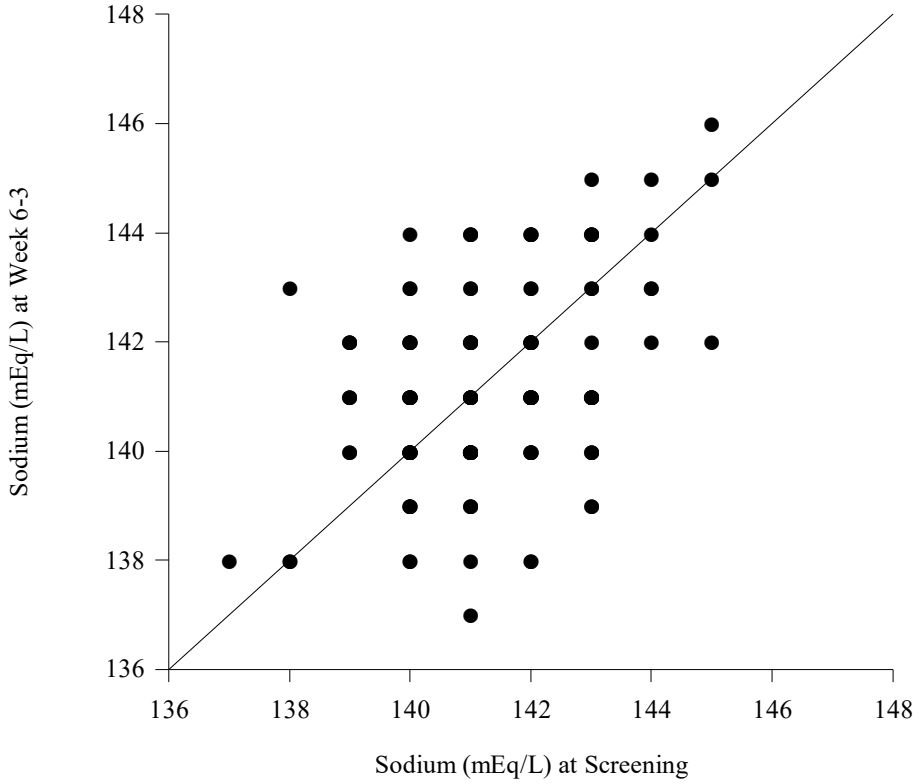
BBI-4000 0%



PAGE: 57 of 76
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/03/19
PROTOCOL NO: BBI-4000-06
Source：5.3.5.1-2 Figure 14.3.4-4 より改変

図 2.7.4-2　臨床検査値の散布図（BBI-4000-06 試験）（続き）
Biochemical（Safety Analysis Set）

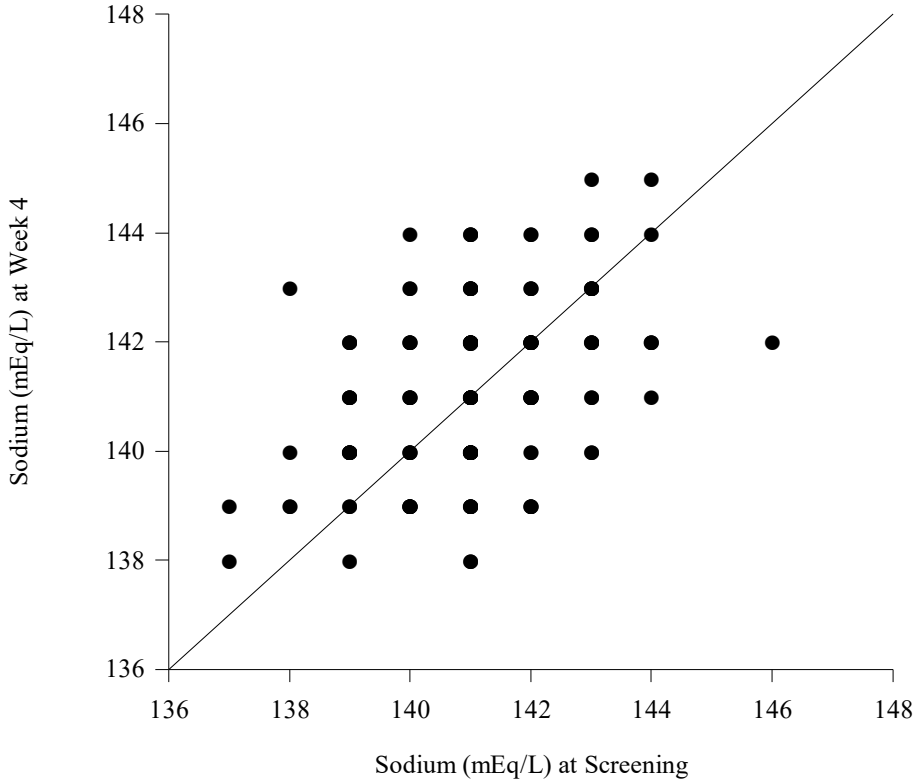
BBI-4000 0%



PAGE: 58 of 76
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/03/19
PROTOCOL NO: BBI-4000-06
Source：5.3.5.1-2 Figure 14.3.4-4 より改変

図 2.7.4-2　臨床検査値の散布図（BBI-4000-06 試験）（続き）
Biochemical（Safety Analysis Set）

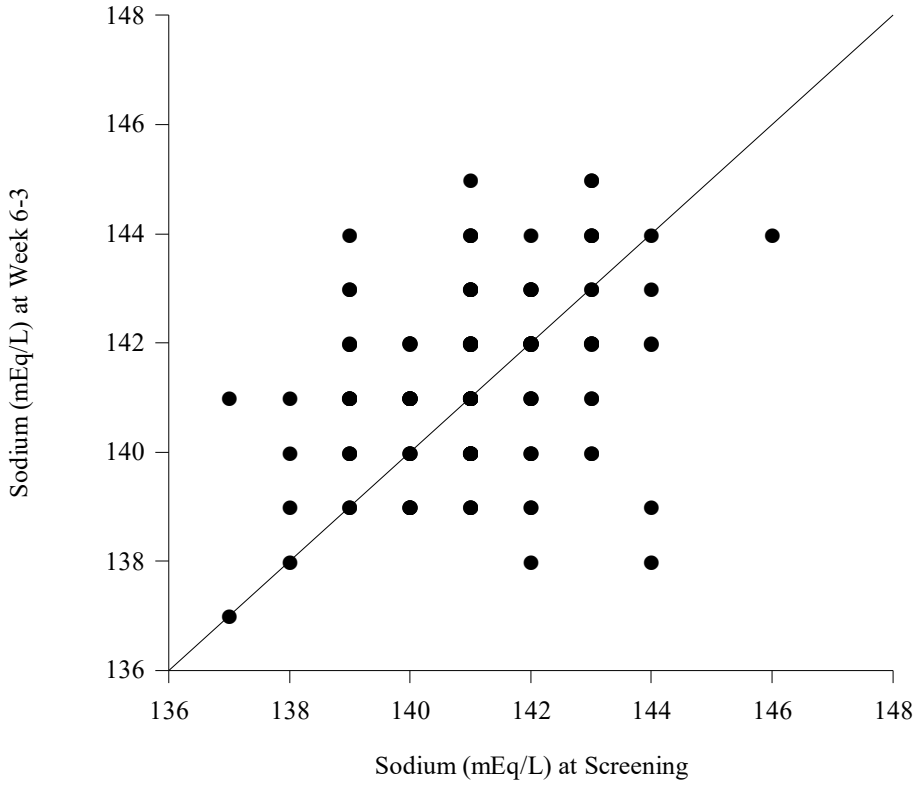
BBI-4000 5%



PAGE: 59 of 76
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/03/19
PROTOCOL NO: BBI-4000-06
Source：5.3.5.1-2 Figure 14.3.4-4 より改変

図 2.7.4-2　臨床検査値の散布図（BBI-4000-06 試験）（続き）
Biochemical（Safety Analysis Set）

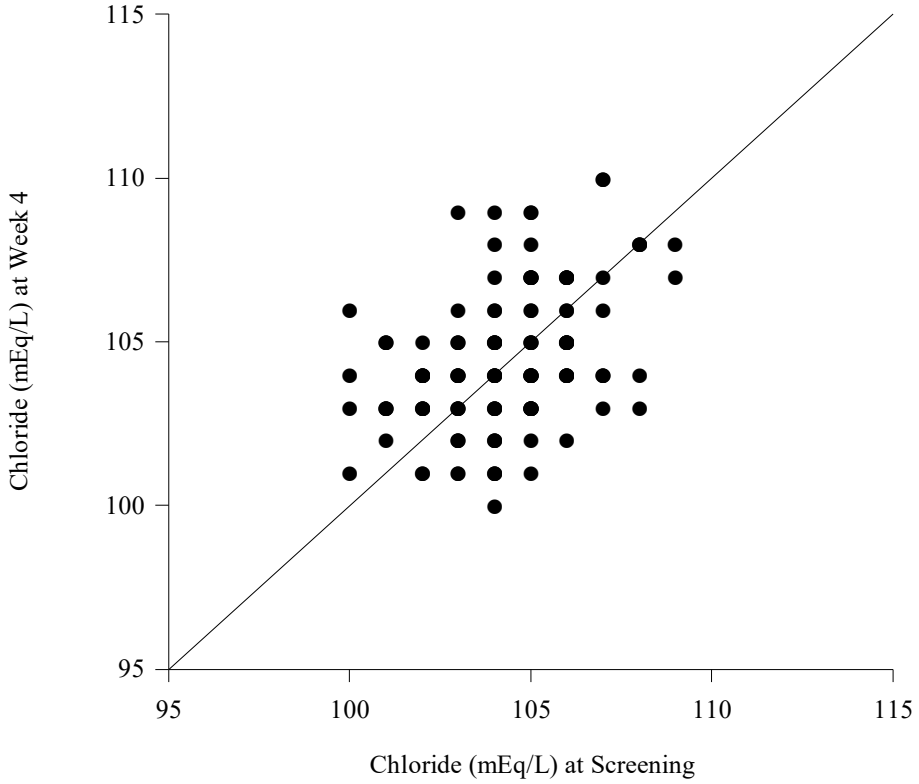
BBI-4000 5%



PAGE: 60 of 76
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/03/19
PROTOCOL NO: BBI-4000-06
Source：5.3.5.1-2 Figure 14.3.4-4 より改変

図 2.7.4-2　臨床検査値の散布図（BBI-4000-06 試験）（続き）
Biochemical（Safety Analysis Set）

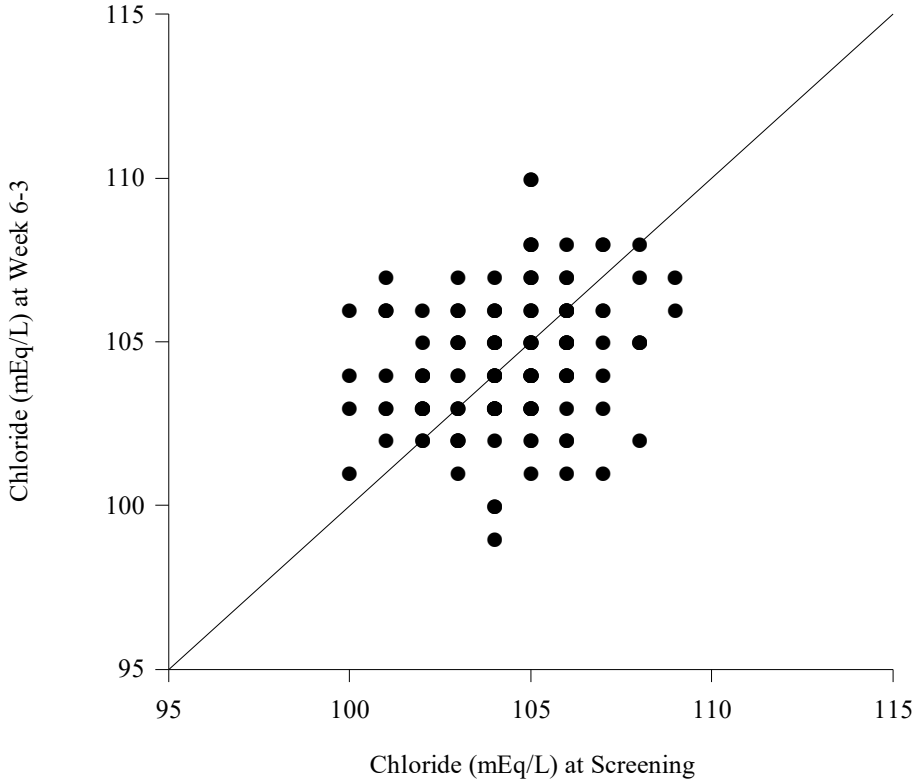
BBI-4000 0%



PAGE: 61 of 76
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/03/19
PROTOCOL NO: BBI-4000-06
Source：5.3.5.1-2 Figure 14.3.4-4 より改変

図 2.7.4-2　臨床検査値の散布図（BBI-4000-06 試験）（続き）
Biochemical（Safety Analysis Set）

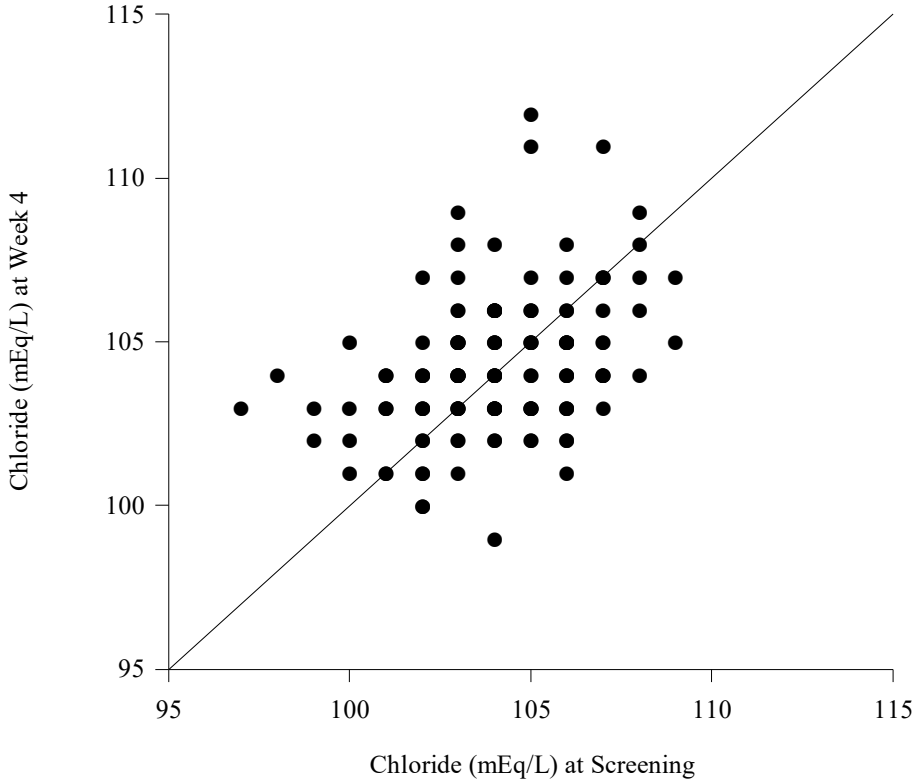
BBI-4000 0%



PAGE: 62 of 76
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/03/19
PROTOCOL NO: BBI-4000-06
Source：5.3.5.1-2 Figure 14.3.4-4 より改変

図 2.7.4-2　臨床検査値の散布図（BBI-4000-06 試験）（続き）
Biochemical（Safety Analysis Set）

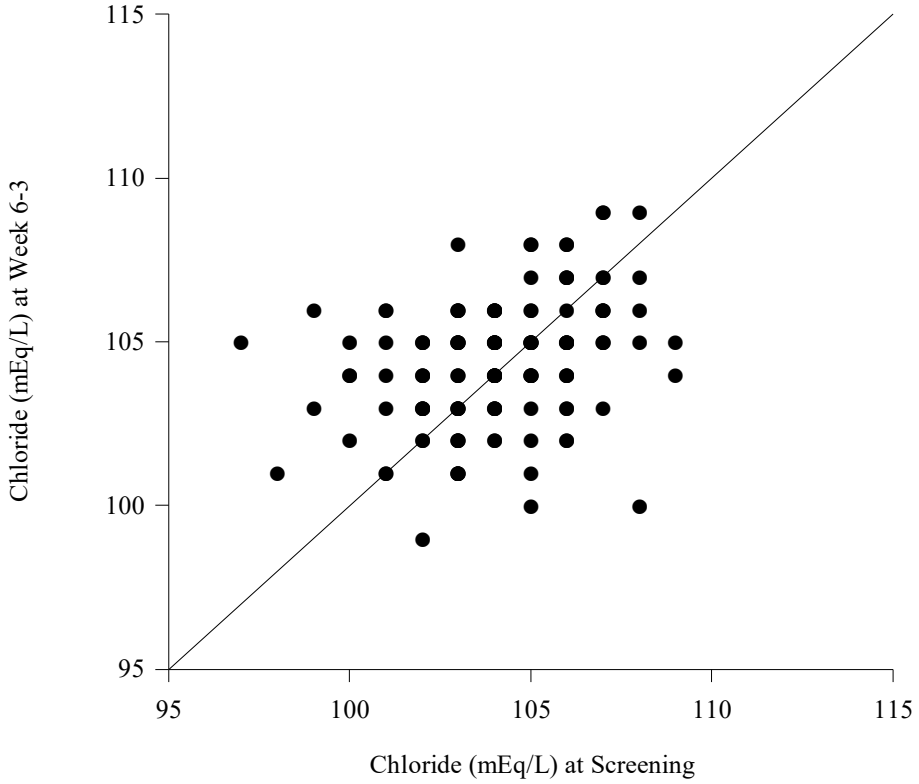
BBI-4000 5%



PAGE: 63 of 76
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/03/19
PROTOCOL NO: BBI-4000-06
Source：5.3.5.1-2 Figure 14.3.4-4 より改変

図 2.7.4-2　臨床検査値の散布図（BBI-4000-06 試験）（続き）
Biochemical（Safety Analysis Set）

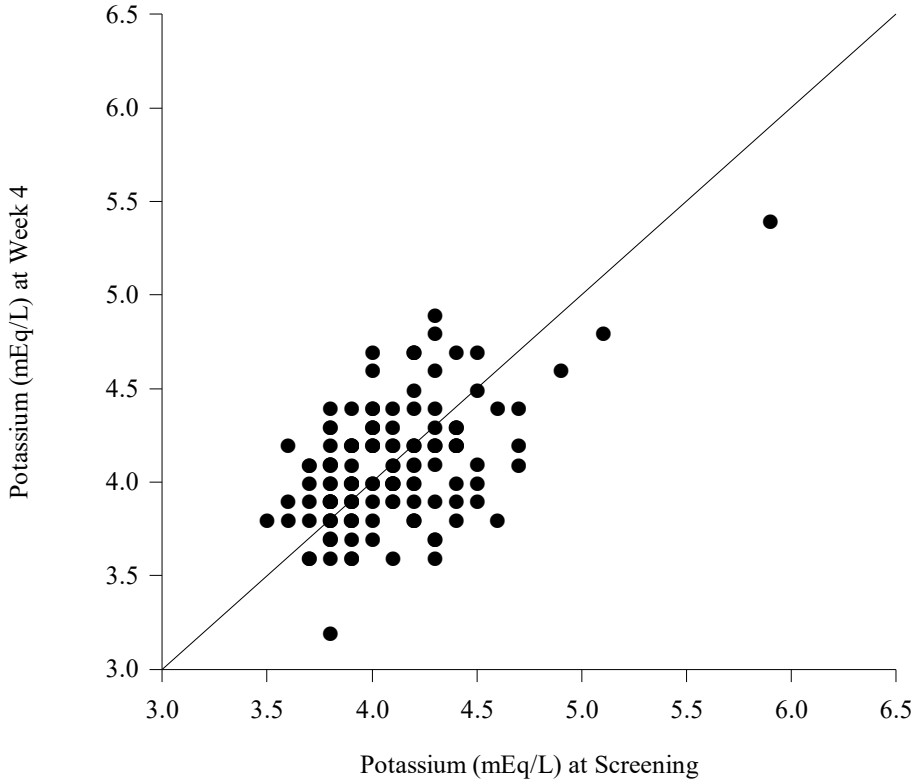
BBI-4000 5%



PAGE: 64 of 76
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/03/19
PROTOCOL NO: BBI-4000-06
Source：5.3.5.1-2 Figure 14.3.4-4 より改変

図 2.7.4-2　臨床検査値の散布図（BBI-4000-06 試験）（続き）
Biochemical（Safety Analysis Set）

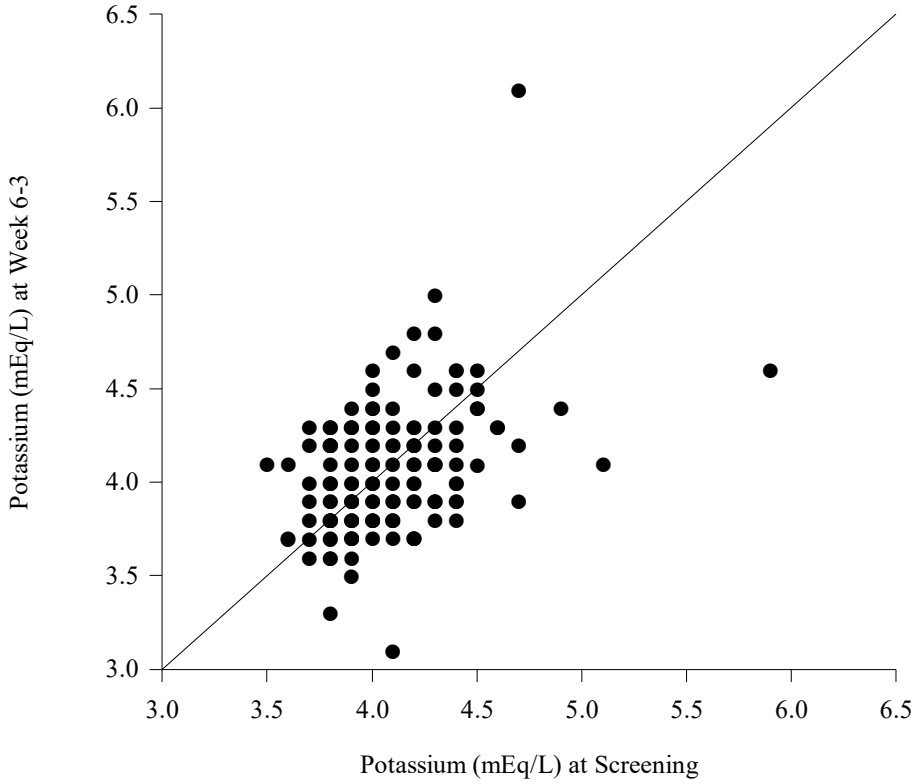
BBI-4000 0%



PAGE: 65 of 76
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/03/19
PROTOCOL NO: BBI-4000-06
Source：5.3.5.1-2 Figure 14.3.4-4 より改変

図 2.7.4-2　臨床検査値の散布図（BBI-4000-06 試験）（続き）
Biochemical（Safety Analysis Set）

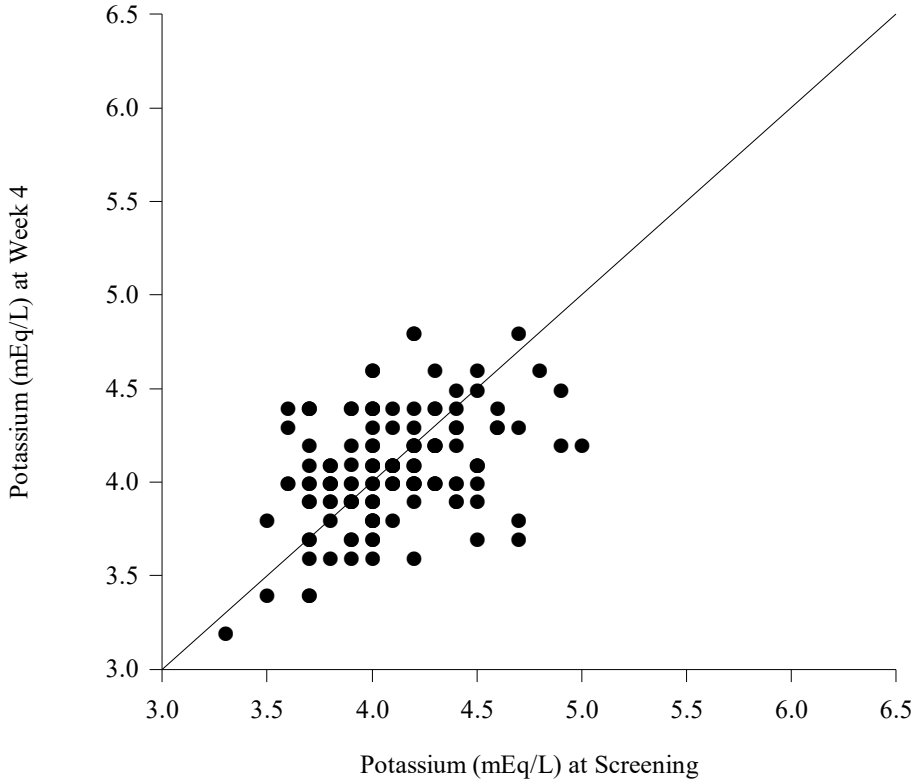
BBI-4000 0%



PAGE: 66 of 76
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/03/19
PROTOCOL NO: BBI-4000-06
Source：5.3.5.1-2 Figure 14.3.4-4 より改変

図 2.7.4-2　臨床検査値の散布図（BBI-4000-06 試験）（続き）
Biochemical（Safety Analysis Set）

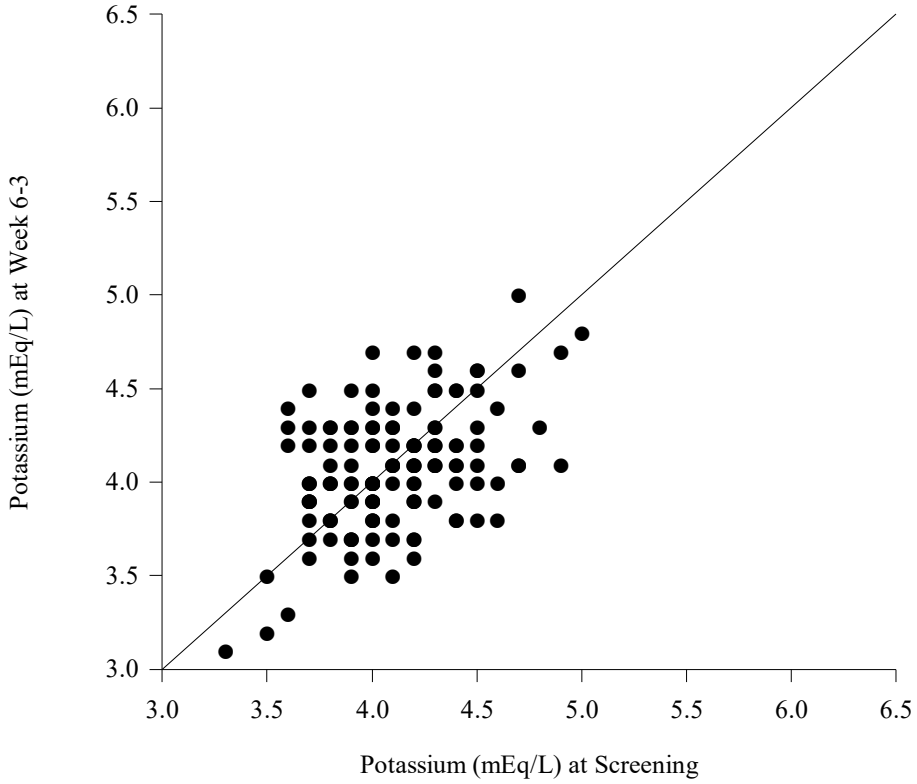
BBI-4000 5%



PAGE: 67 of 76
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/03/19
PROTOCOL NO: BBI-4000-06
Source：5.3.5.1-2 Figure 14.3.4-4 より改変

図 2.7.4-2　臨床検査値の散布図（BBI-4000-06 試験）（続き）
Biochemical（Safety Analysis Set）

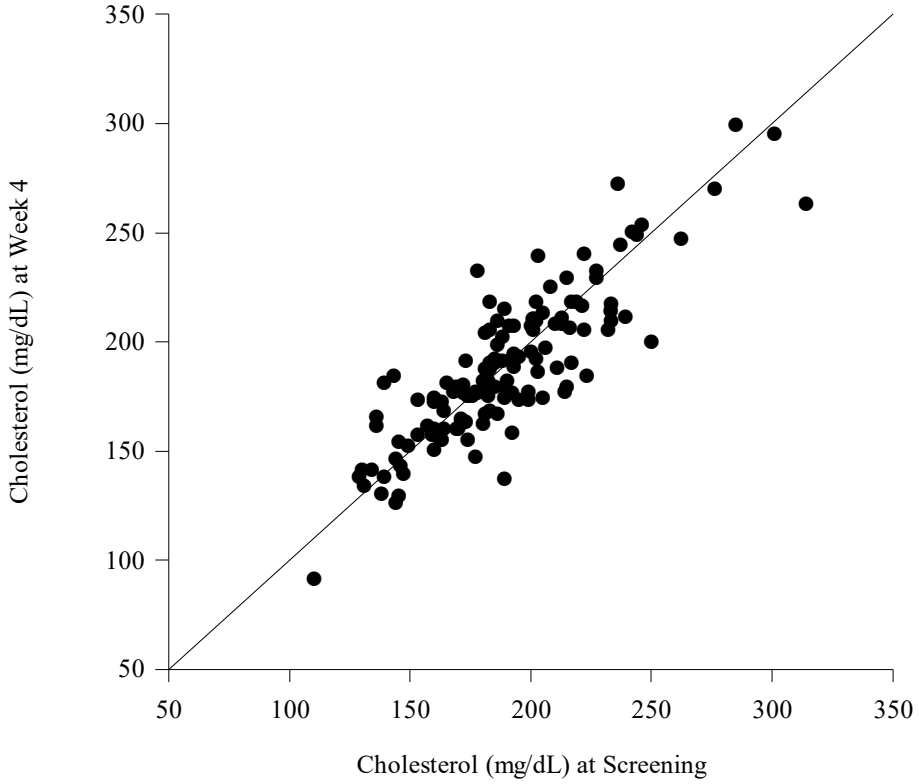
BBI-4000 5%



PAGE: 68 of 76
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/03/19
PROTOCOL NO: BBI-4000-06
Source：5.3.5.1-2 Figure 14.3.4-4 より改変

図 2.7.4-2　臨床検査値の散布図（BBI-4000-06 試験）（続き）
Biochemical（Safety Analysis Set）

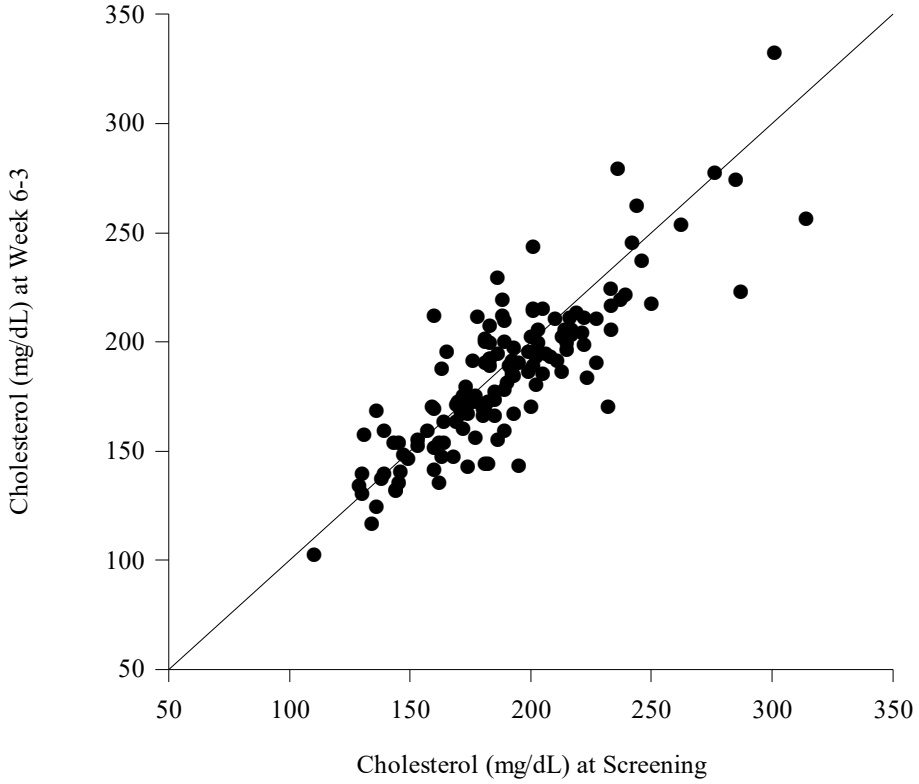
BBI-4000 0%



PAGE: 69 of 76
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/03/19
PROTOCOL NO: BBI-4000-06
Source：5.3.5.1-2 Figure 14.3.4-4 より改変

図 2.7.4-2　臨床検査値の散布図（BBI-4000-06 試験）（続き）
Biochemical（Safety Analysis Set）

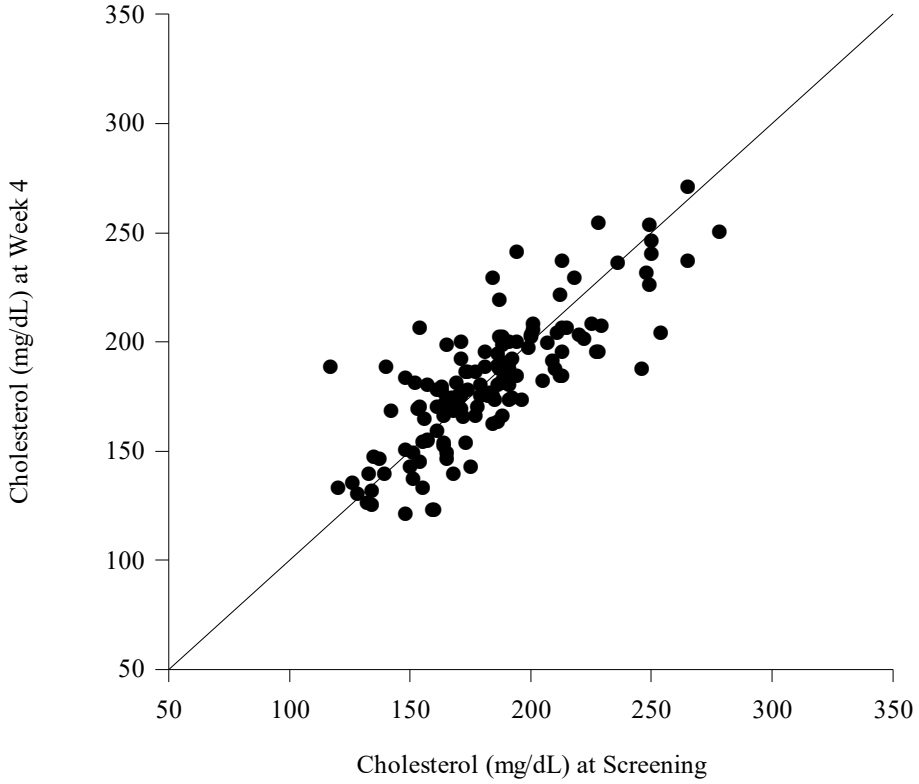
BBI-4000 0%



PAGE: 70 of 76
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/03/19
PROTOCOL NO: BBI-4000-06
Source：5.3.5.1-2 Figure 14.3.4-4 より改変

図 2.7.4-2　臨床検査値の散布図（BBI-4000-06 試験）（続き）
Biochemical（Safety Analysis Set）

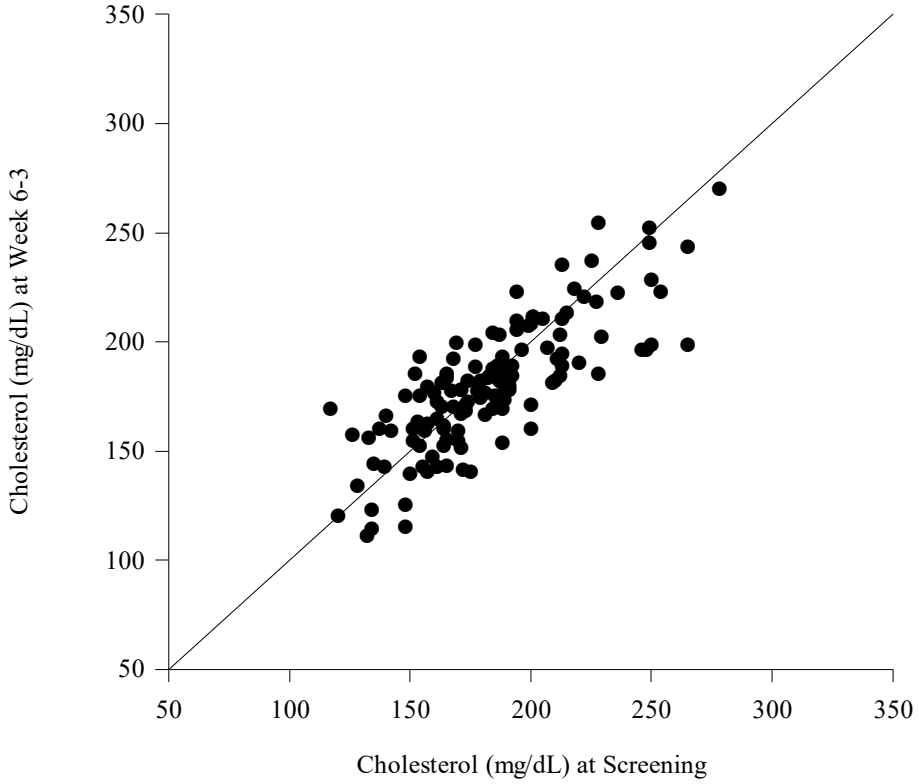
BBI-4000 5%



PAGE: 71 of 76
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/03/19
PROTOCOL NO: BBI-4000-06
Source：5.3.5.1-2 Figure 14.3.4-4 より改変

図 2.7.4-2　臨床検査値の散布図（BBI-4000-06 試験）（続き）
Biochemical（Safety Analysis Set）

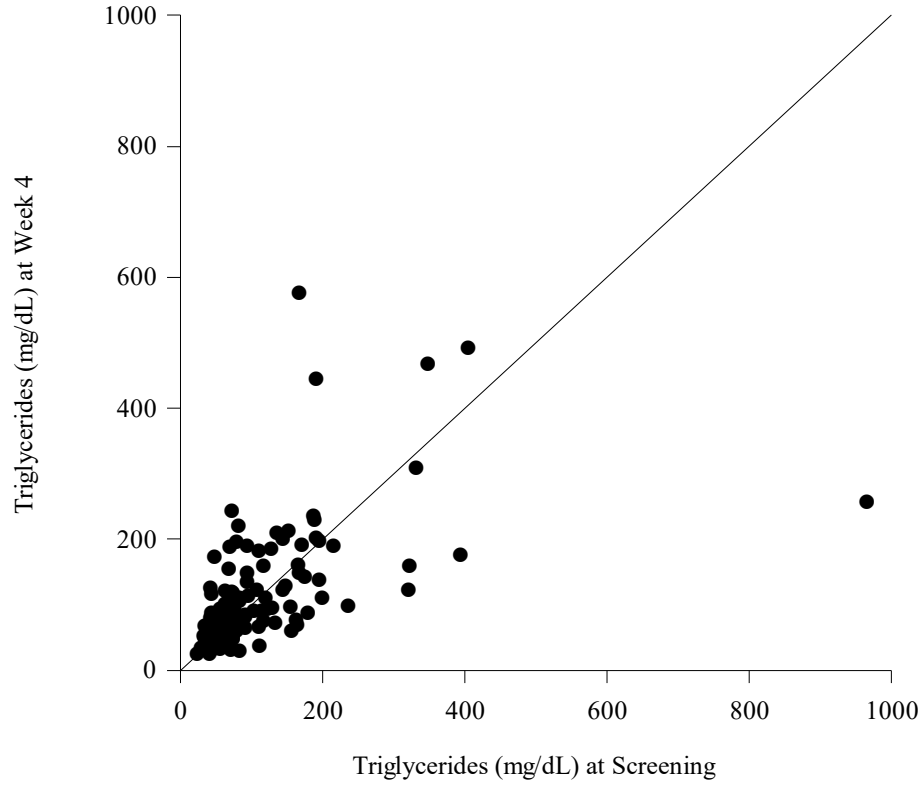
BBI-4000 5%



PAGE: 72 of 76
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/03/19
PROTOCOL NO: BBI-4000-06
Source：5.3.5.1-2 Figure 14.3.4-4 より改変

図 2.7.4-2　臨床検査値の散布図（BBI-4000-06 試験）（続き）
Biochemical（Safety Analysis Set）

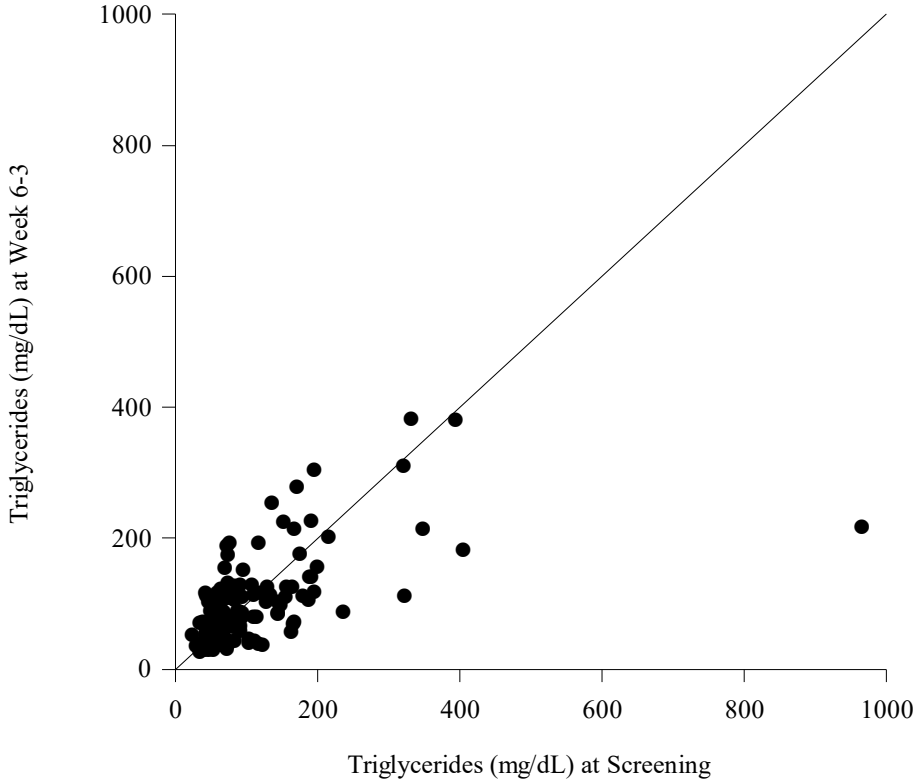
BBI-4000 0%



PAGE: 73 of 76
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/03/19
PROTOCOL NO: BBI-4000-06
Source：5.3.5.1-2 Figure 14.3.4-4 より改変

図 2.7.4-2　臨床検査値の散布図（BBI-4000-06 試験）（続き）
Biochemical（Safety Analysis Set）

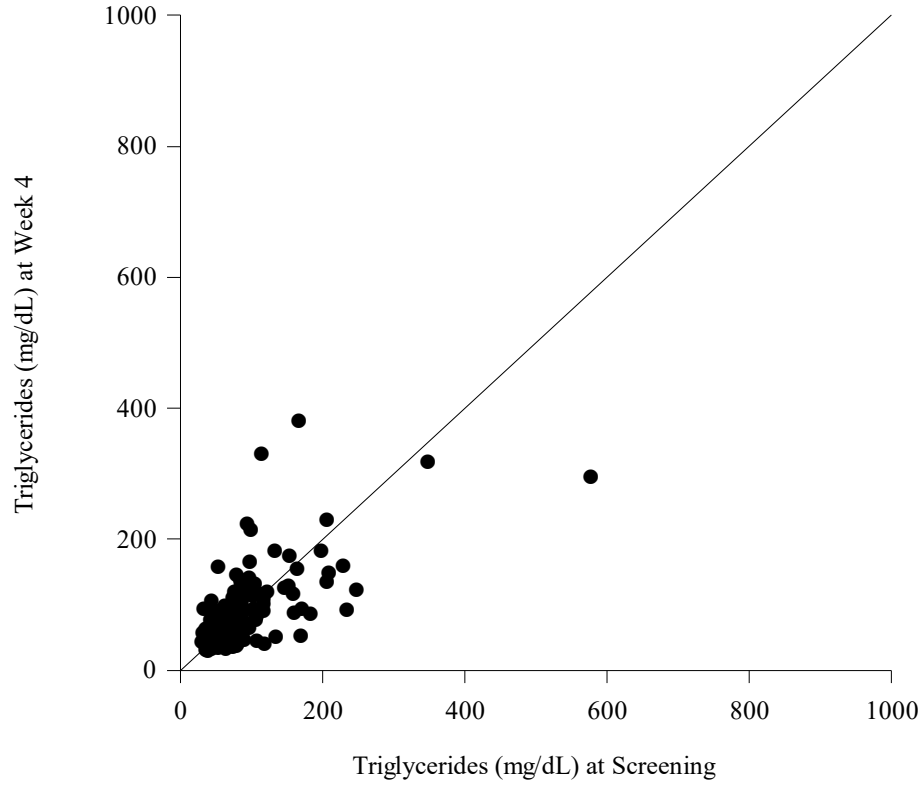
BBI-4000 0%



PAGE: 74 of 76
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/03/19
PROTOCOL NO: BBI-4000-06
Source：5.3.5.1-2 Figure 14.3.4-4 より改変

図 2.7.4-2　臨床検査値の散布図（BBI-4000-06 試験）（続き）
Biochemical（Safety Analysis Set）

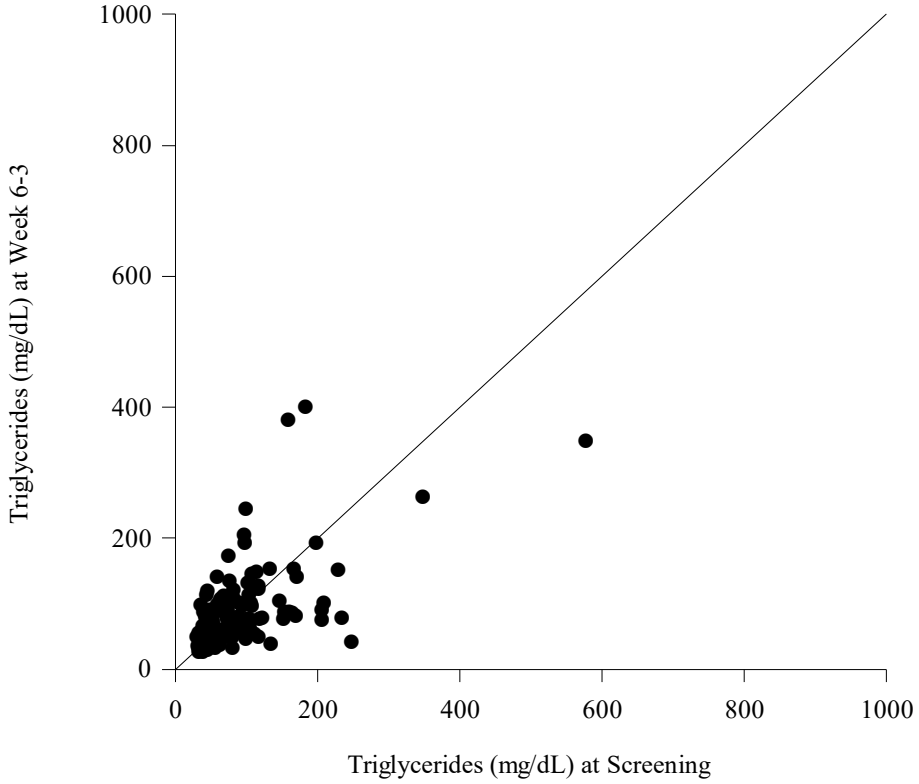
BBI-4000 5%



PAGE: 75 of 76
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/03/19
PROTOCOL NO: BBI-4000-06
Source：5.3.5.1-2 Figure 14.3.4-4 より改変

図 2.7.4-2　臨床検査値の散布図（BBI-4000-06 試験）（続き）
Biochemical（Safety Analysis Set）

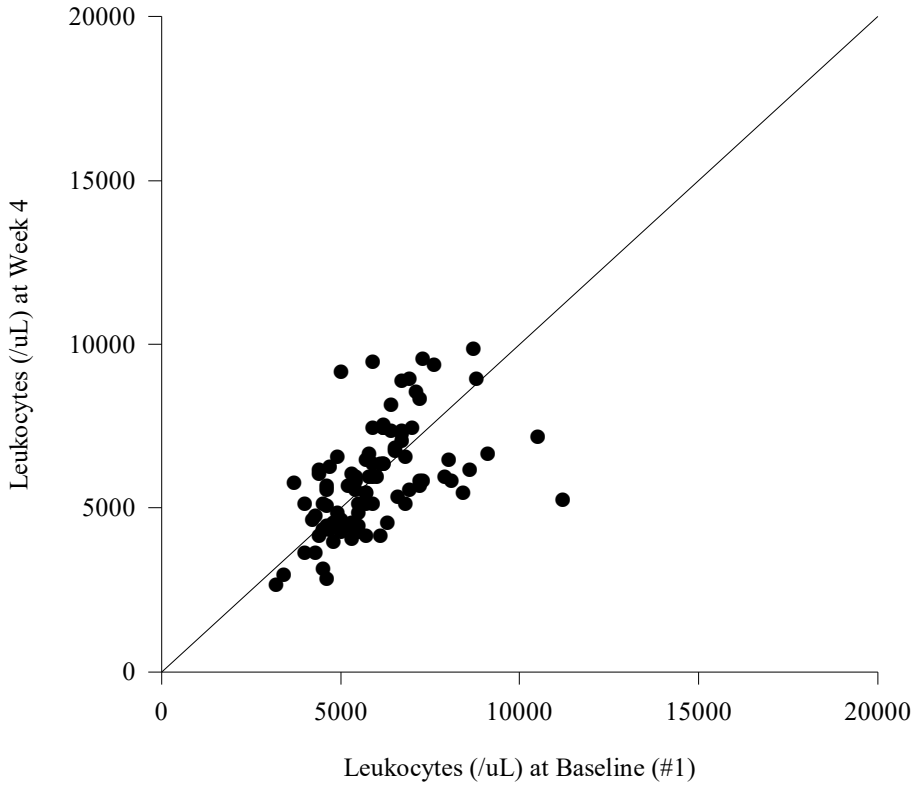
BBI-4000 5%



PAGE: 76 of 76
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/03/19
PROTOCOL NO: BBI-4000-06
Source：5.3.5.1-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）
Hematology（Safety Analysis Set）

Cohort 1 (0%/5%)

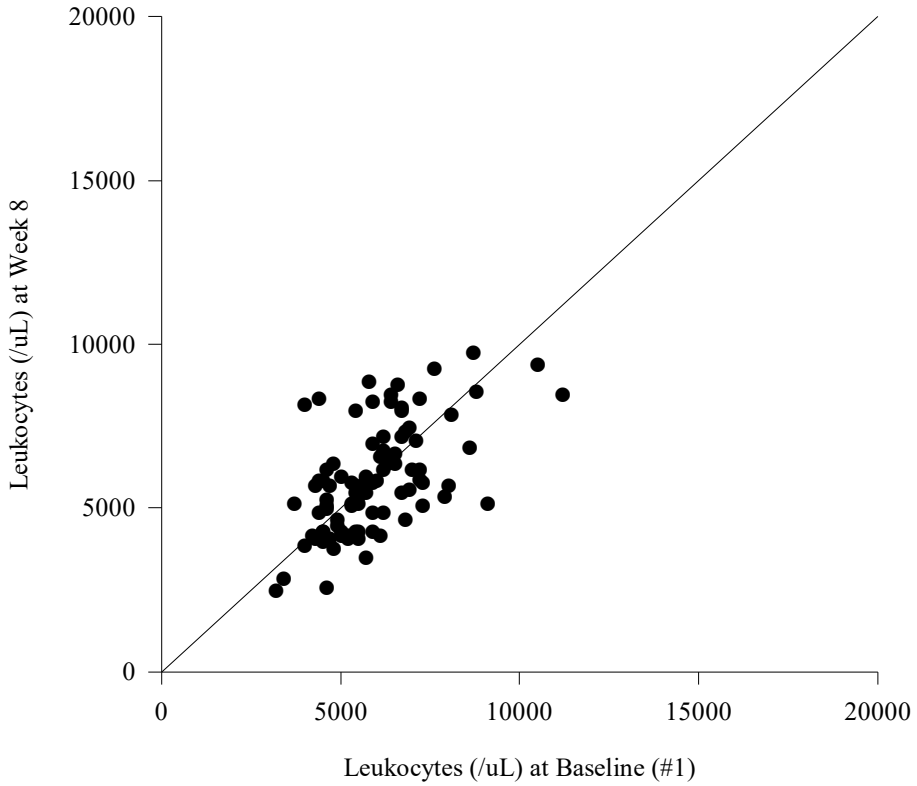


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 1 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (0%/5%)

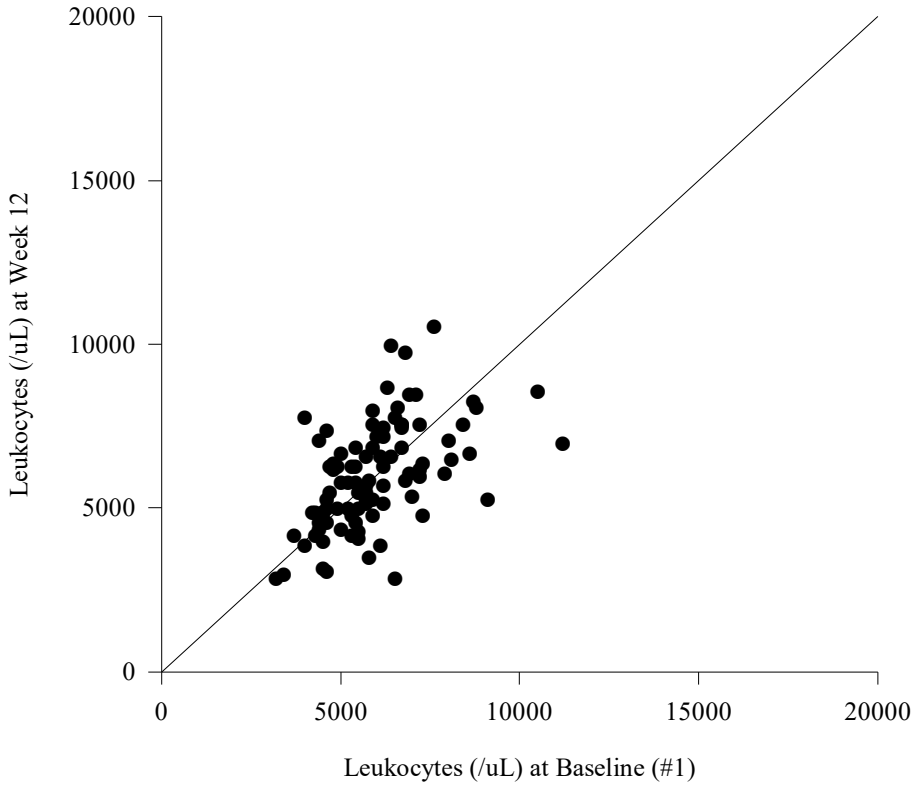


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 2 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (0%/5%)

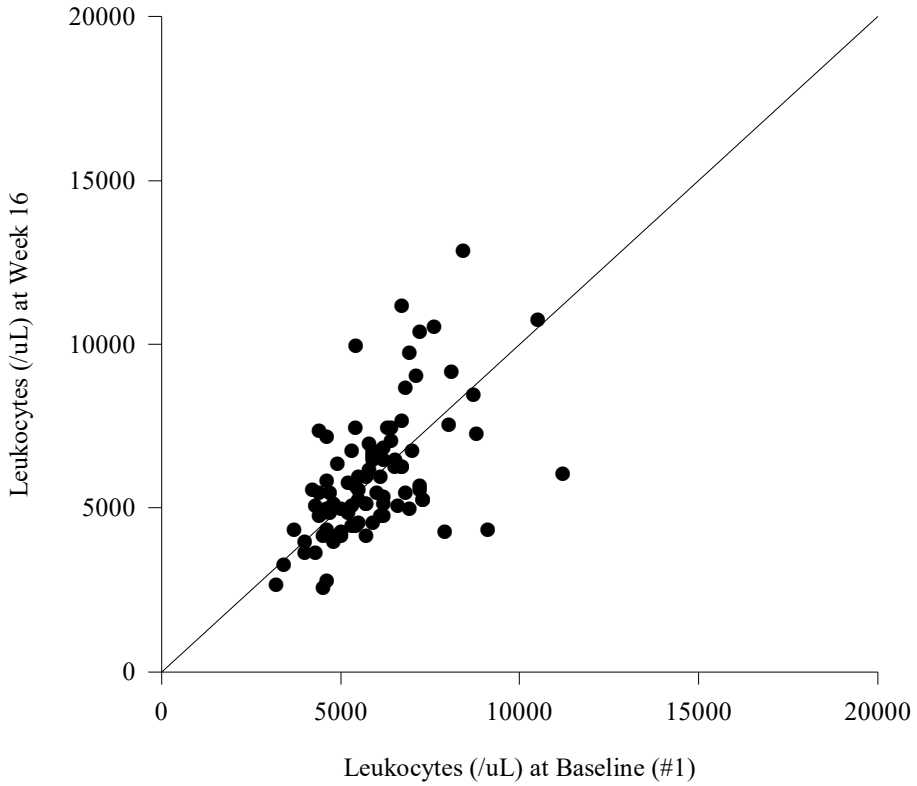


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 3 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (0%/5%)

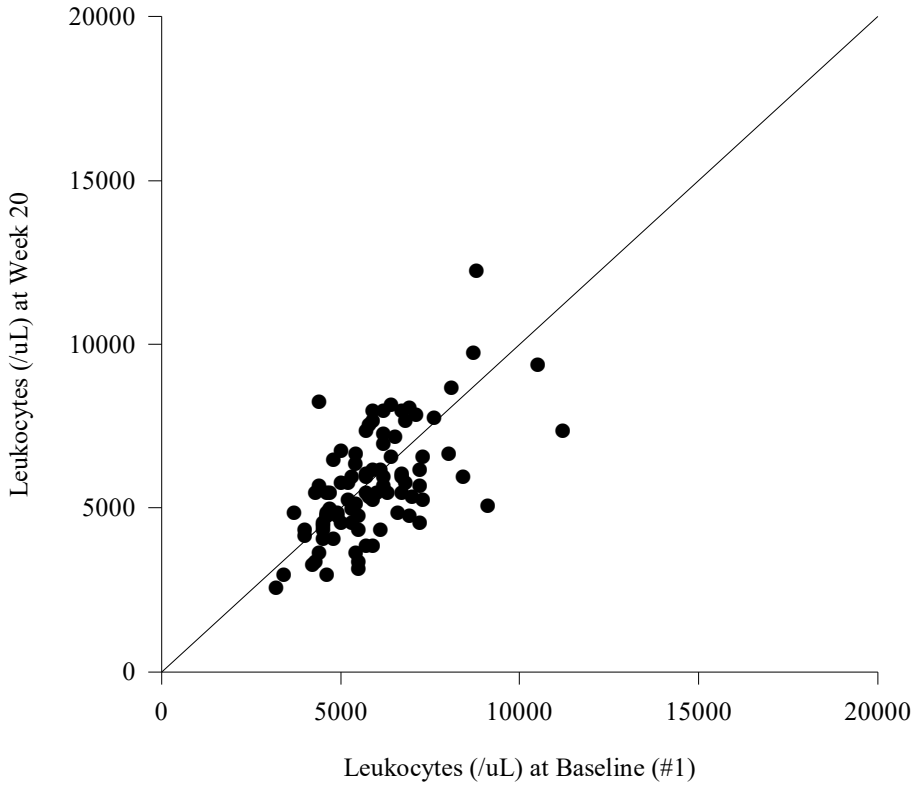


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 4 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (0%/5%)

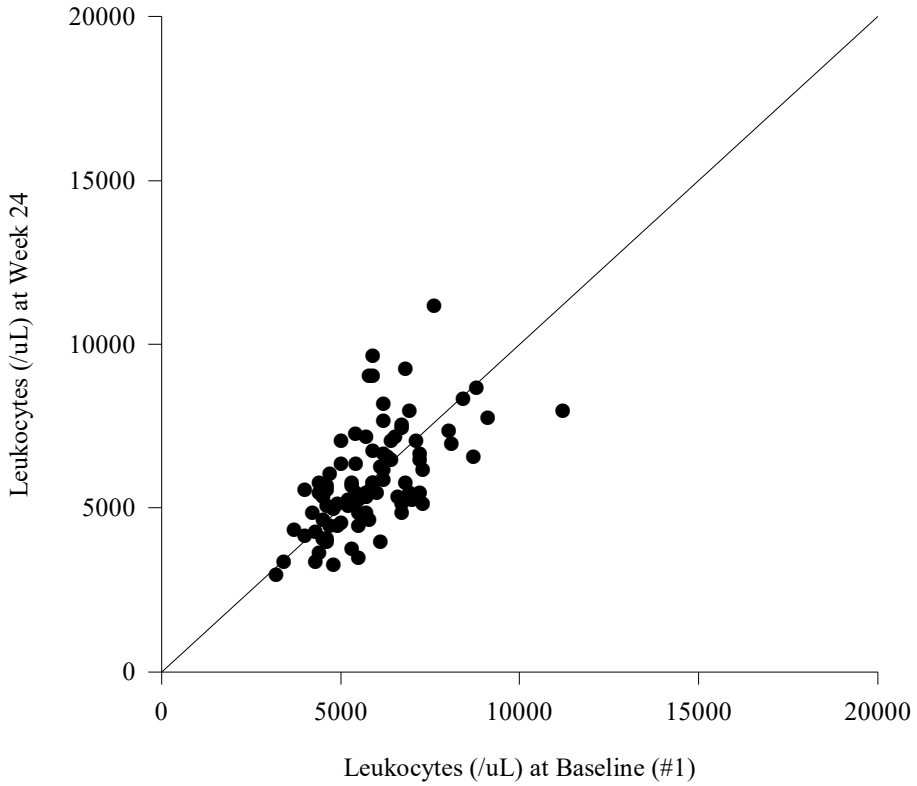


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 5 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (0%/5%)

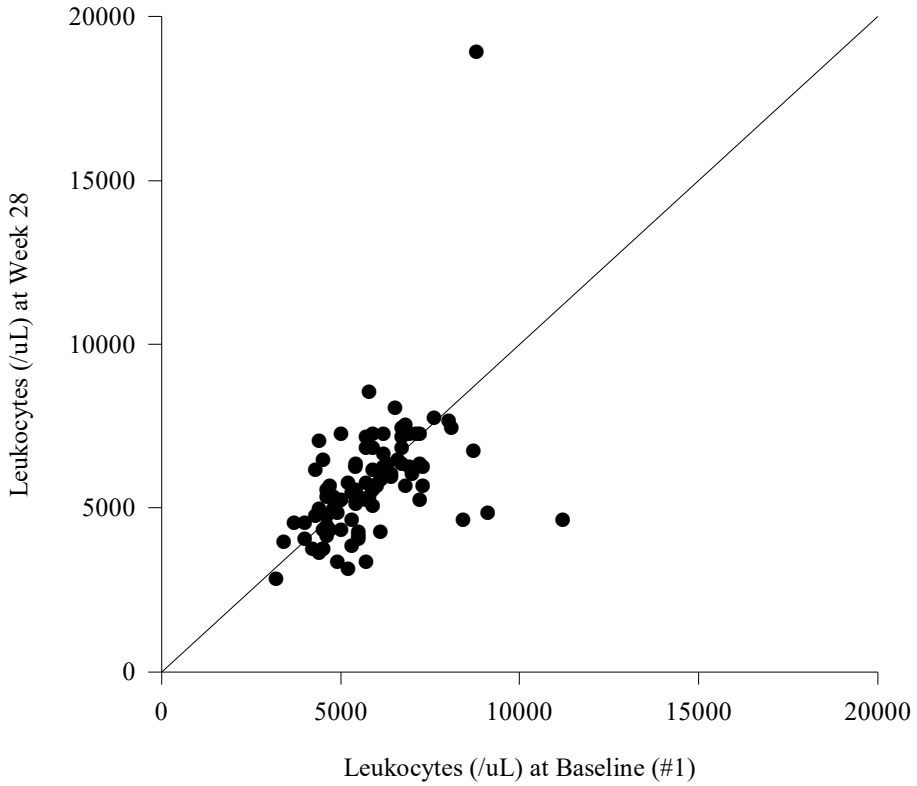


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 6 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (0%/5%)

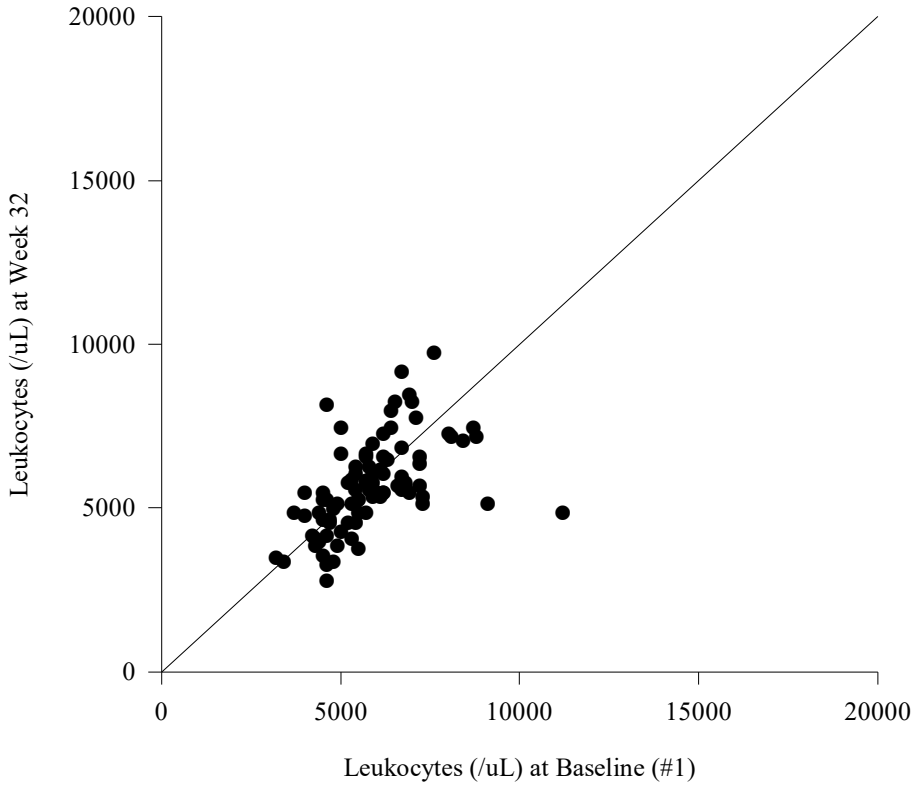


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 7 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (0%/5%)

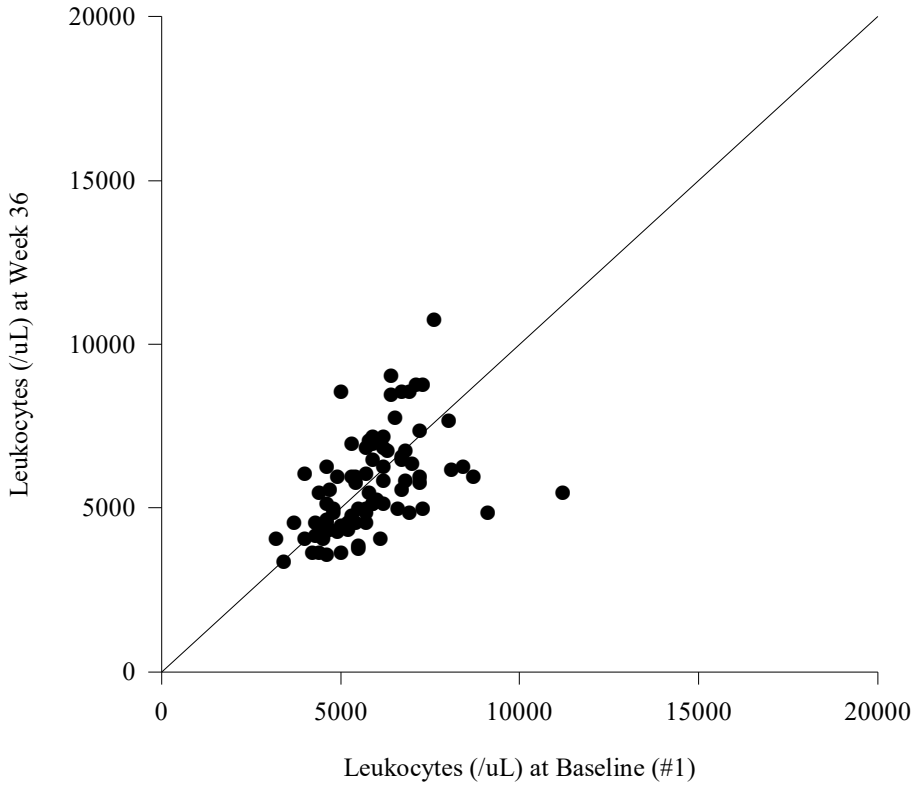


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 8 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (0%/5%)

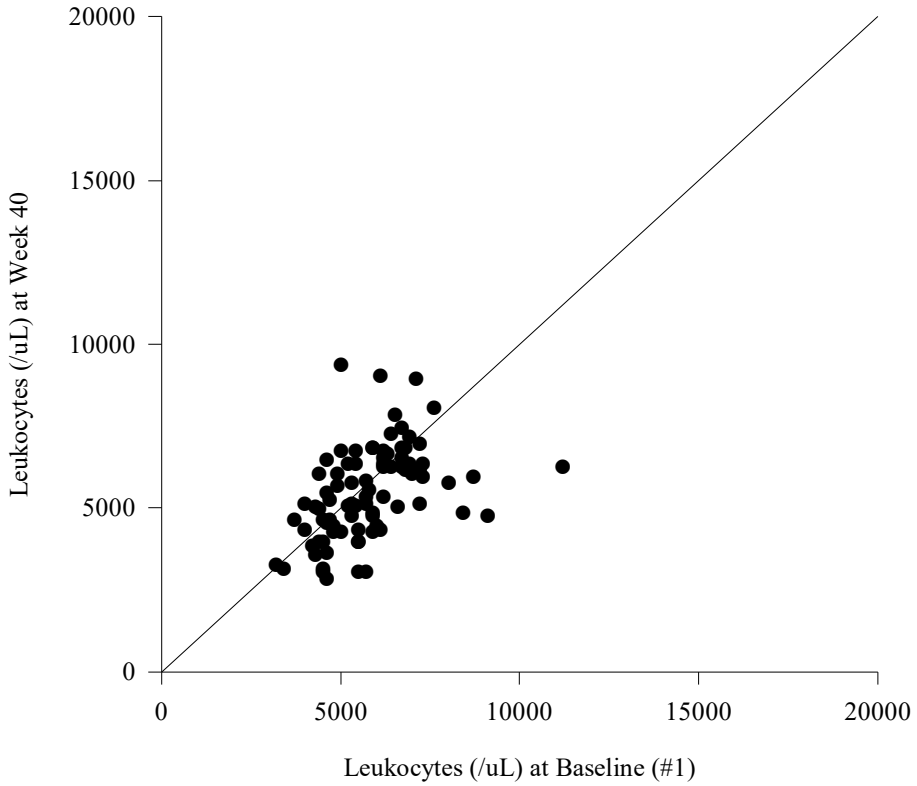


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 9 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (0%/5%)

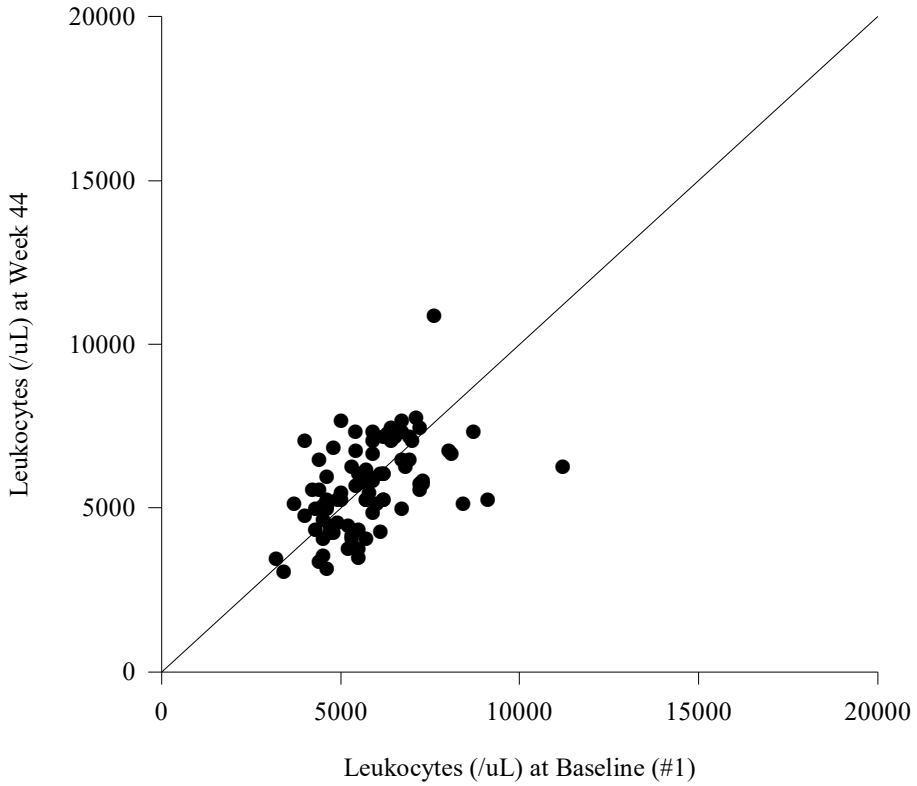


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 10 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (0%/5%)

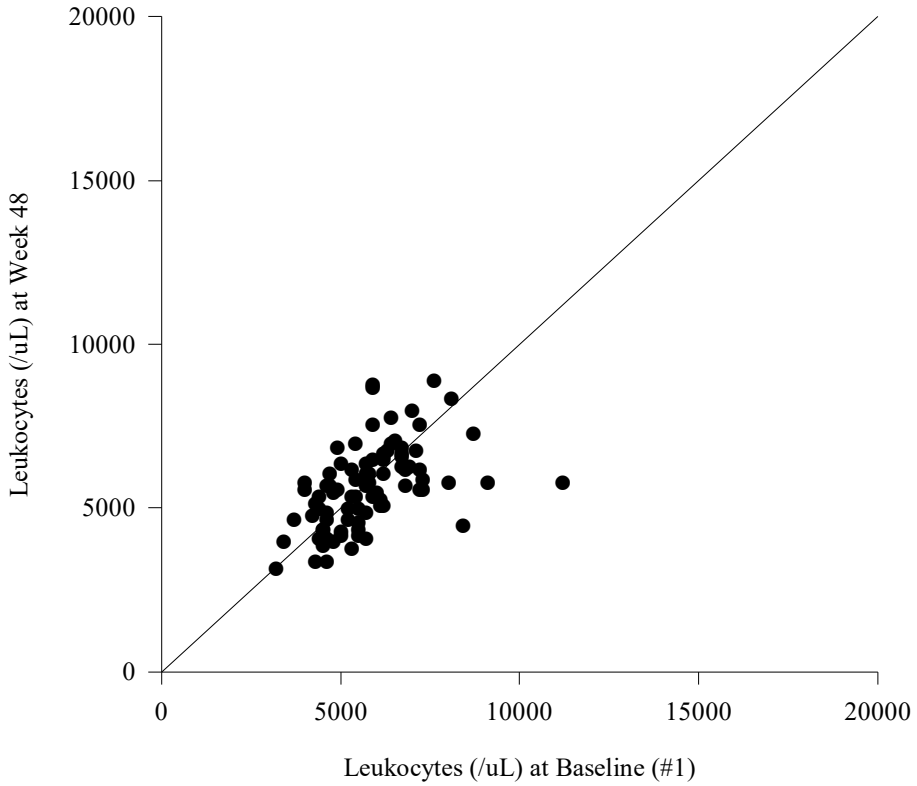


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 11 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (0%/5%)

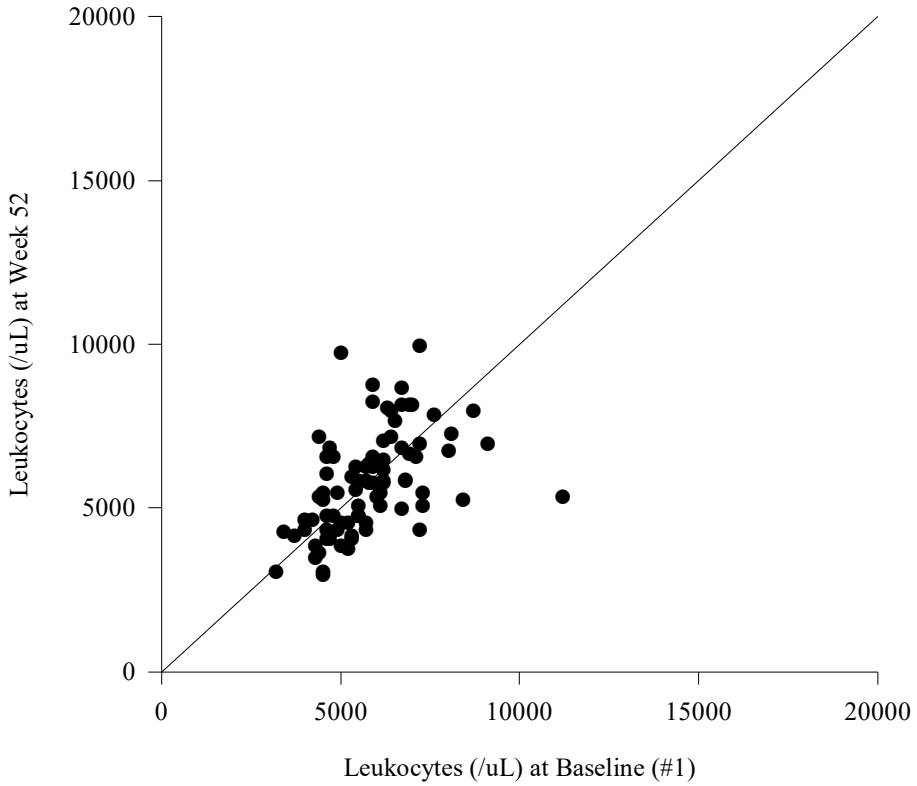


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 12 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (0%/5%)

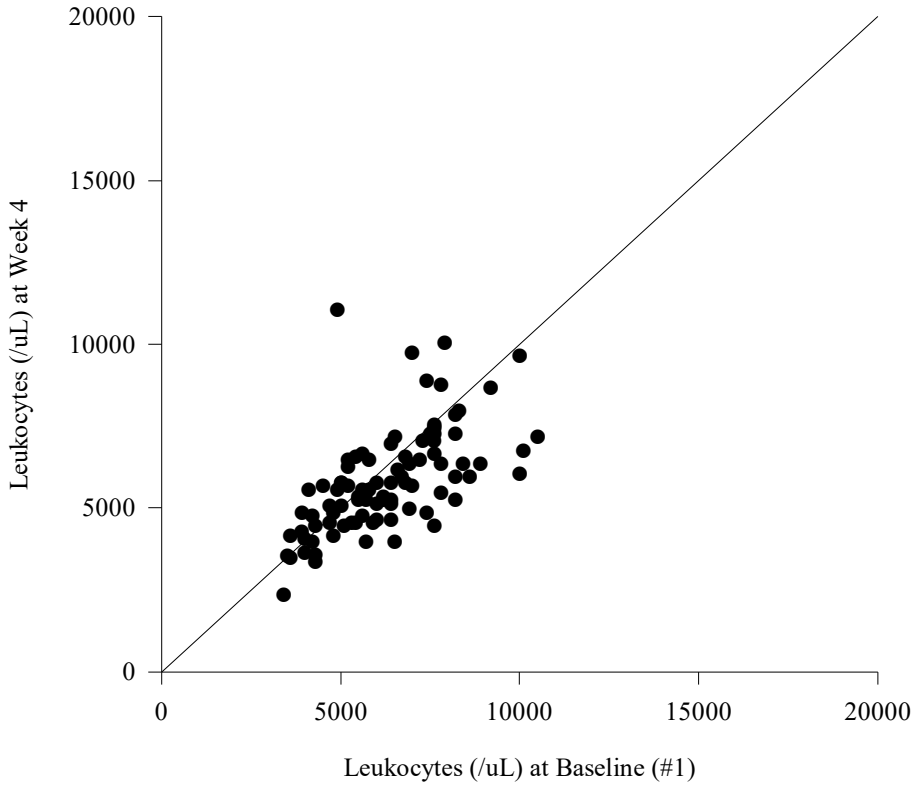


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 13 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (5%/5%)

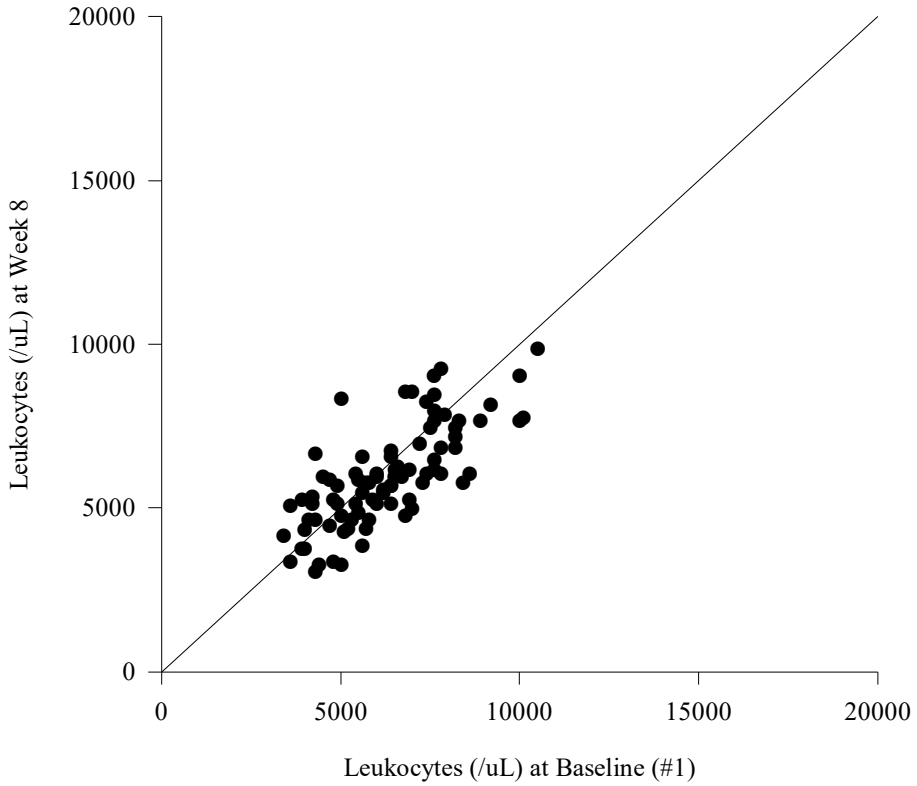


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 14 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (5%/5%)

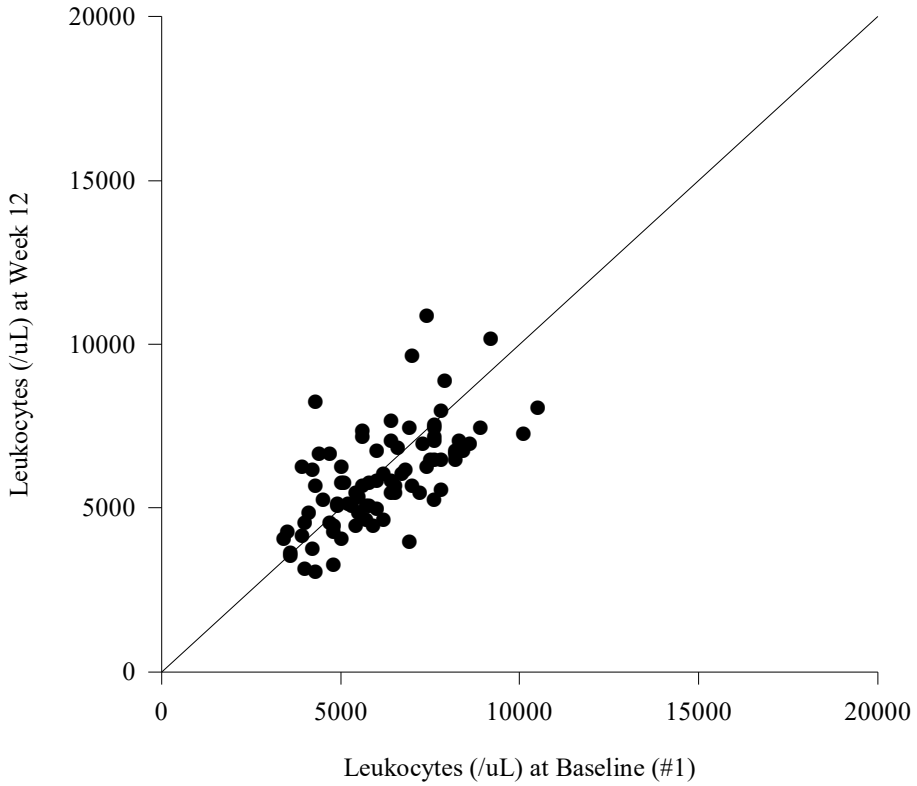


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 15 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (5%/5%)

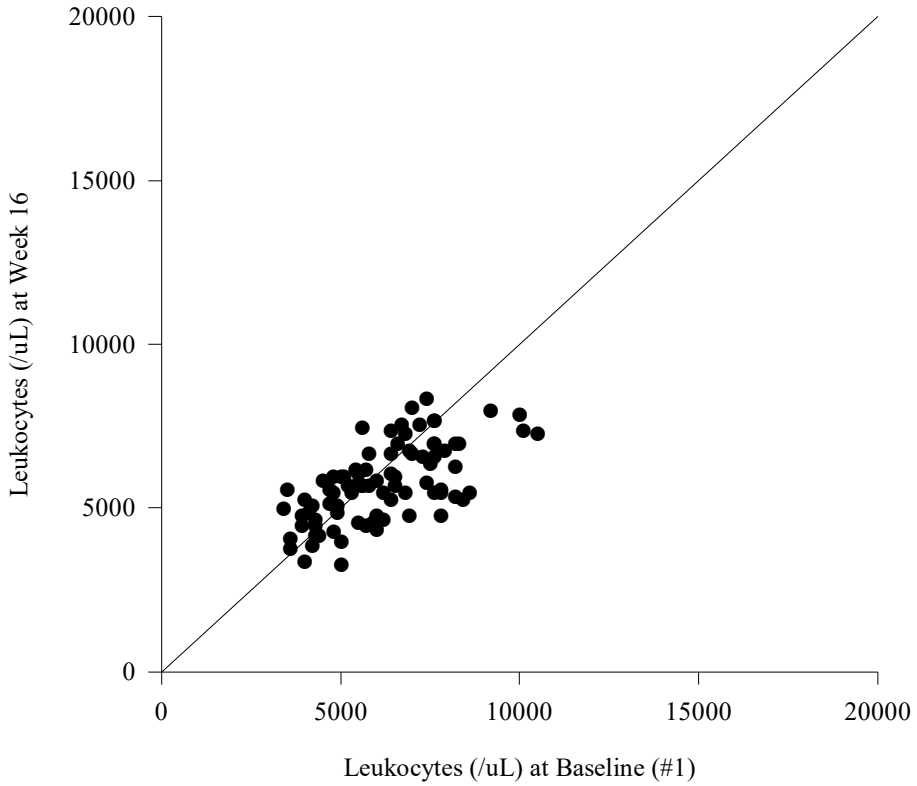


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 16 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (5%/5%)

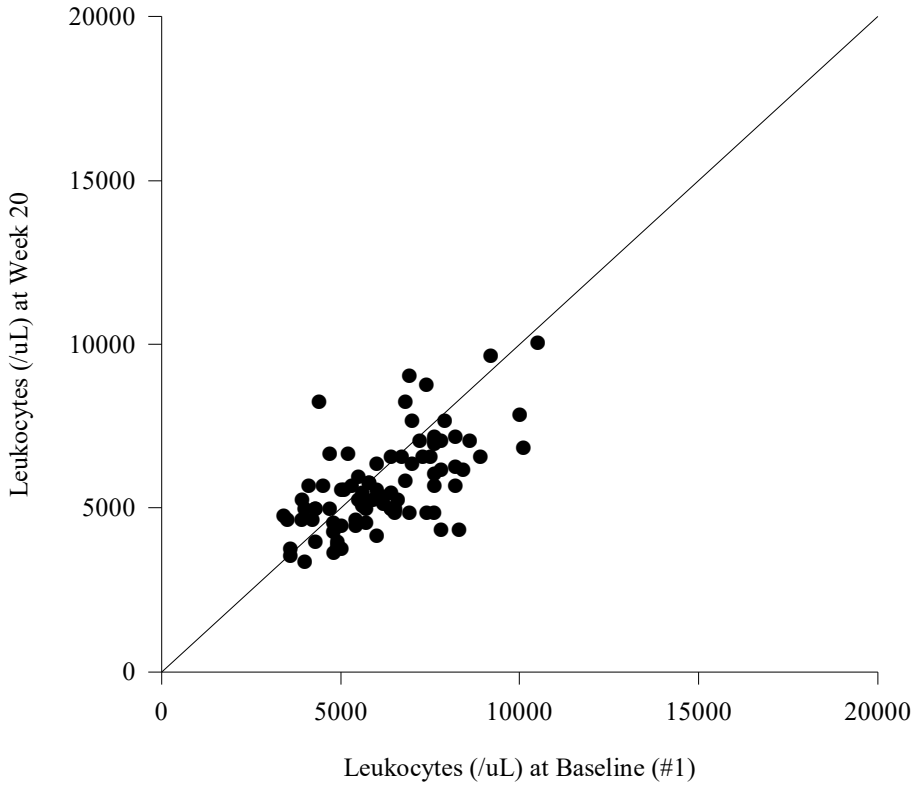


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 17 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (5%/5%)

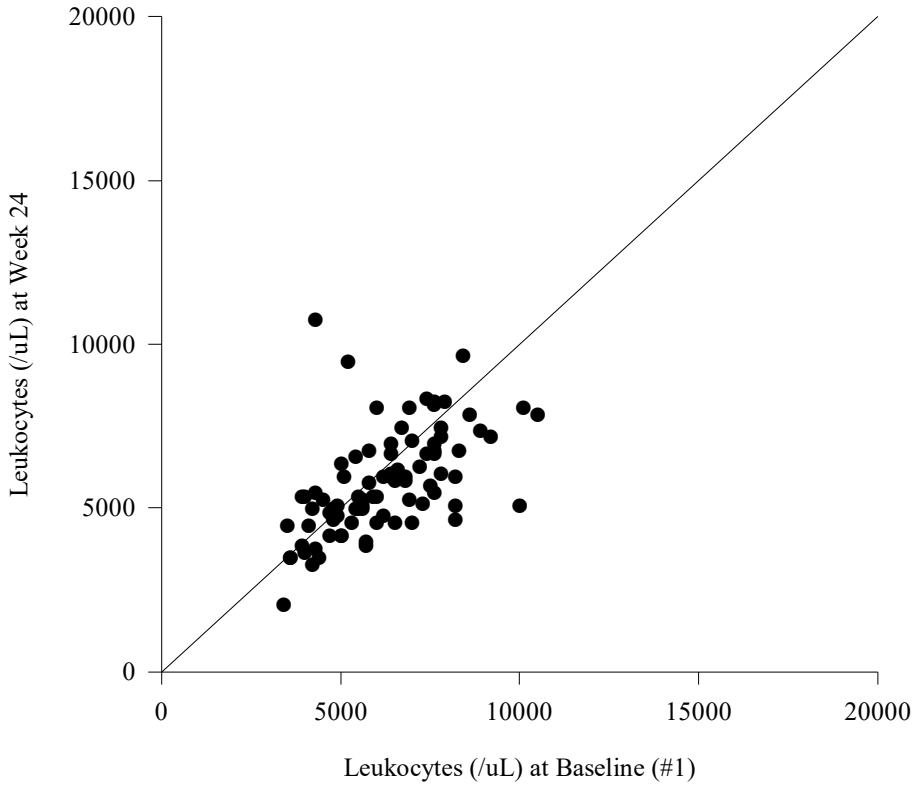


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 18 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (5%/5%)

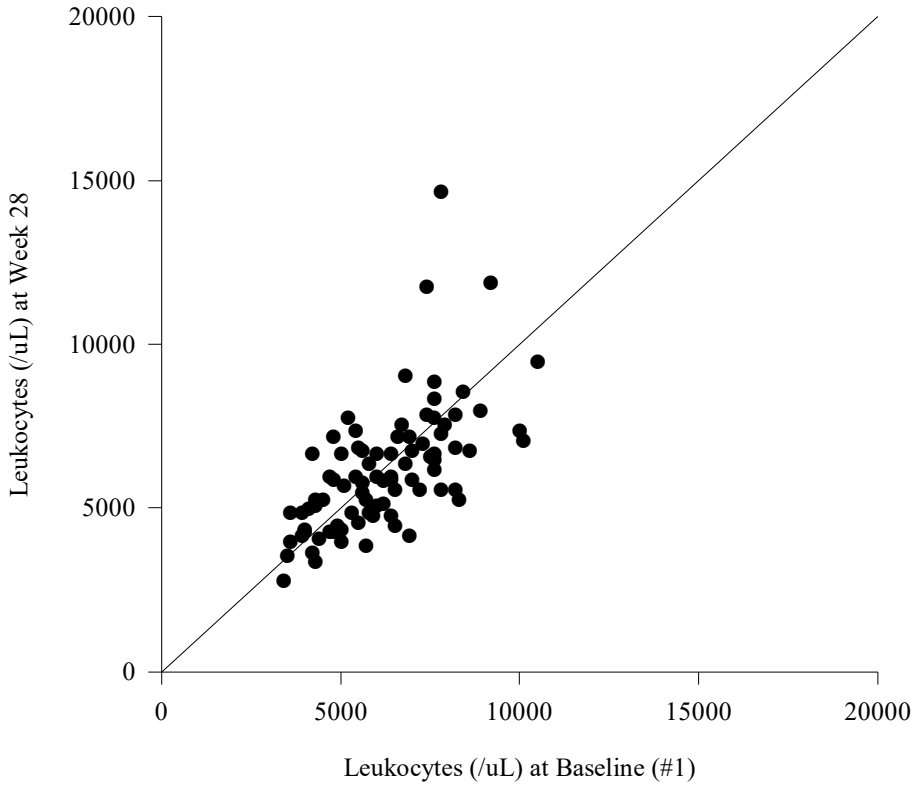


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 19 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (5%/5%)

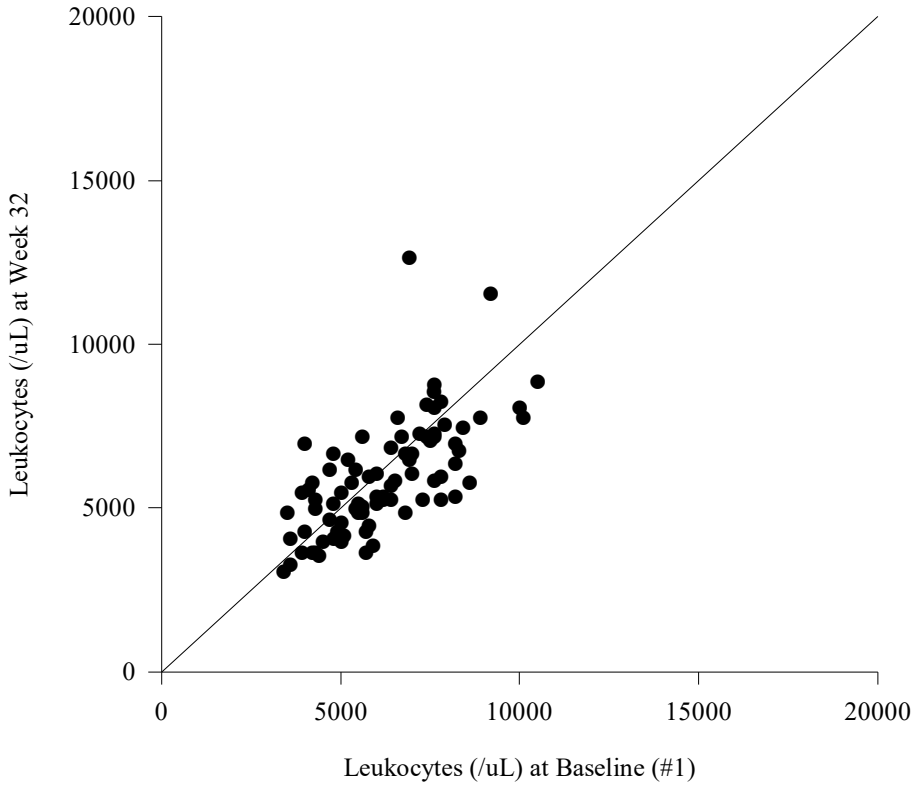


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 20 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (5%/5%)

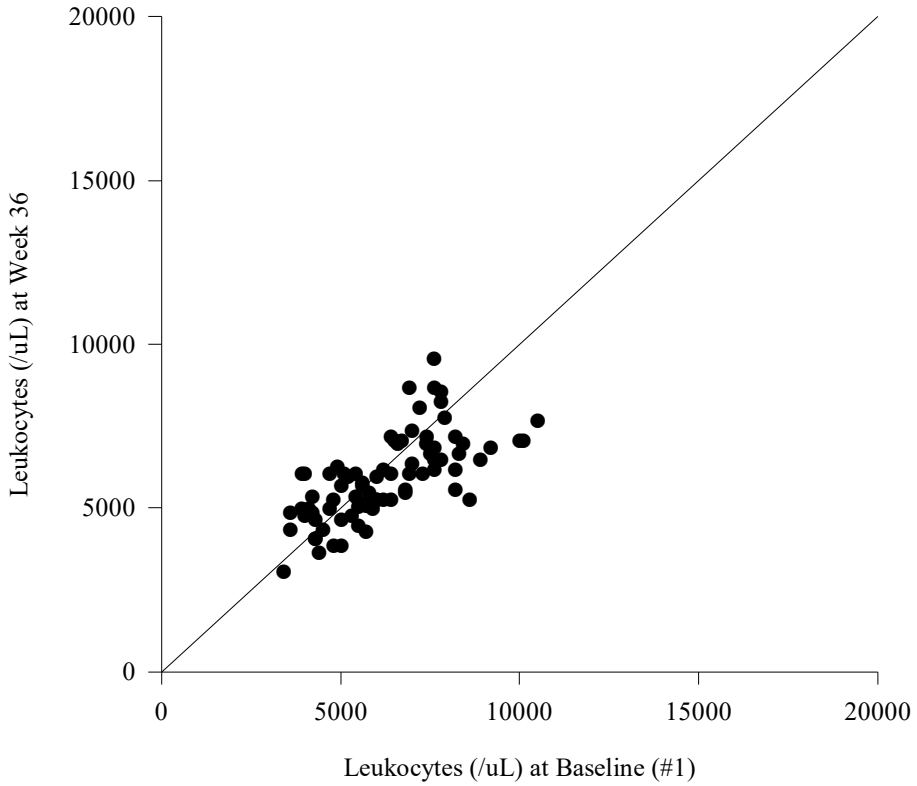


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 21 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (5%/5%)

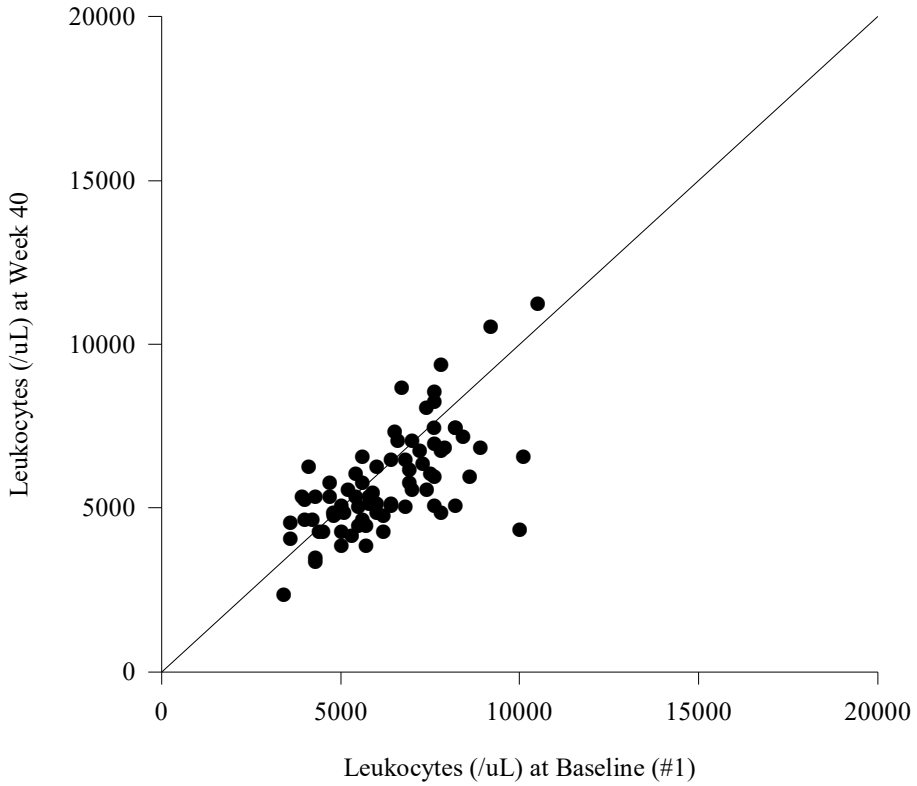


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 22 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (5%/5%)

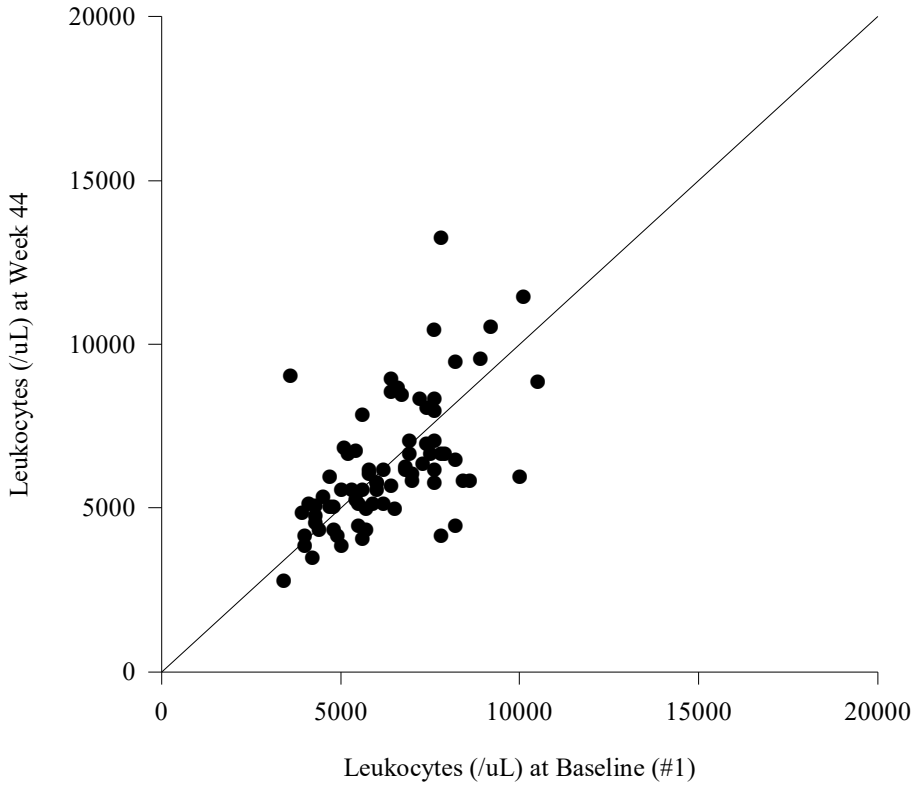


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 23 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (5%/5%)

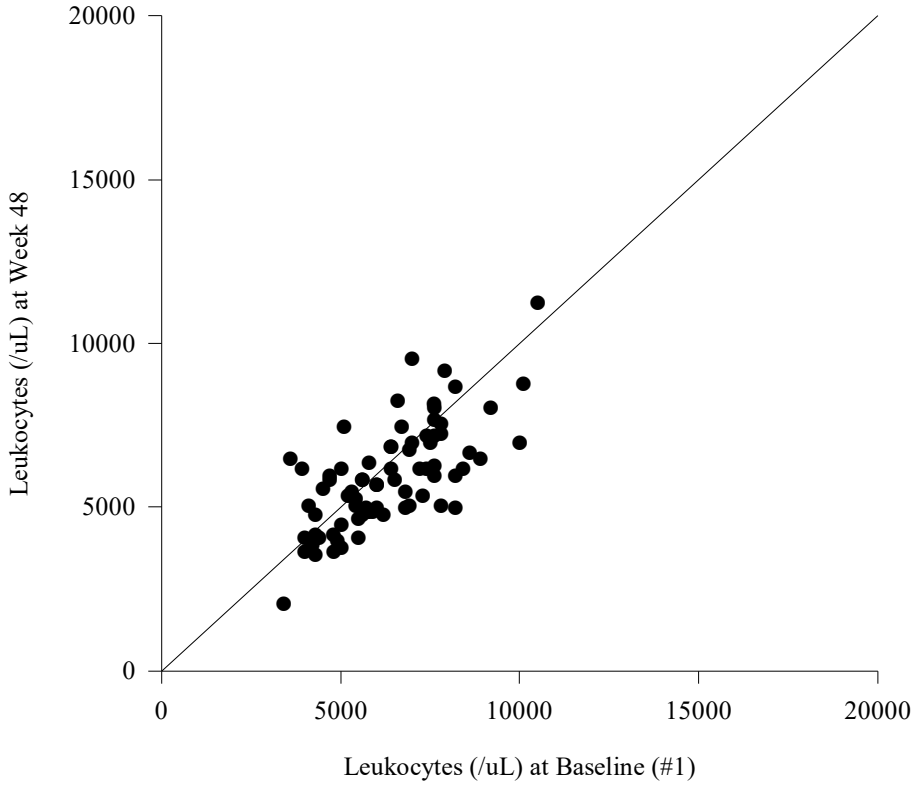


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 24 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (5%/5%)

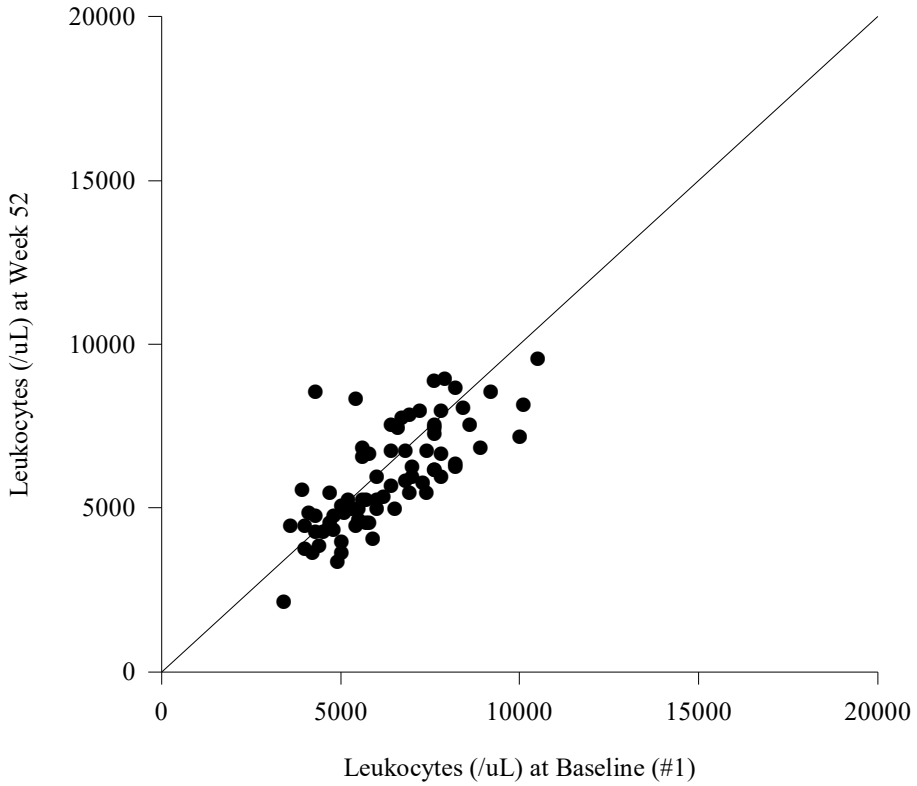


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 25 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (5%/5%)

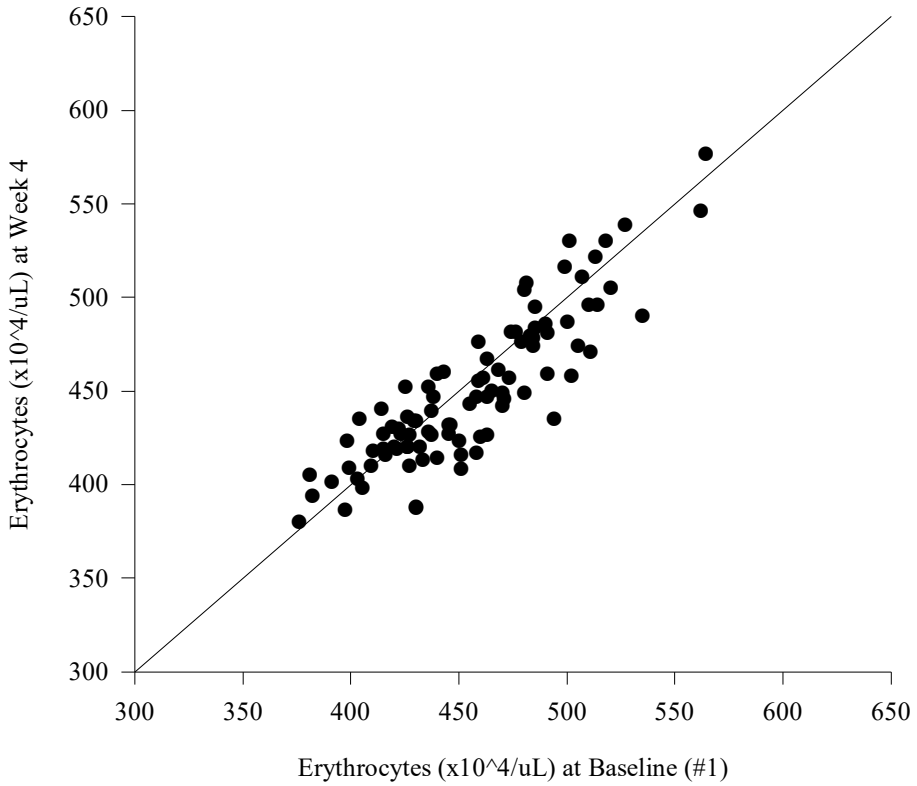


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 26 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (0%/5%)

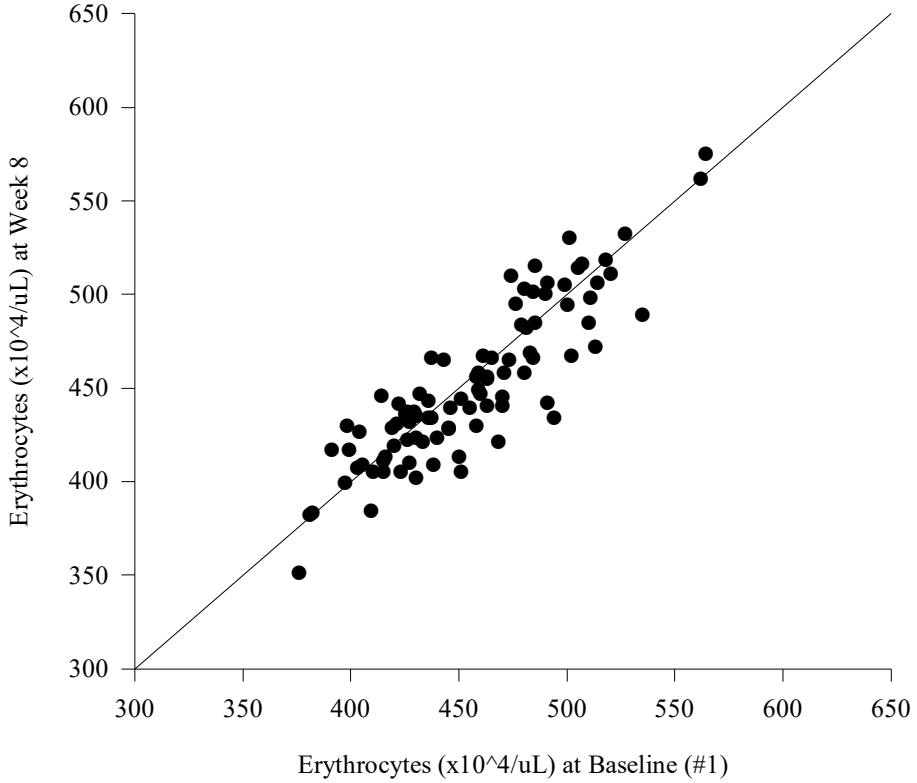


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 27 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (0%/5%)

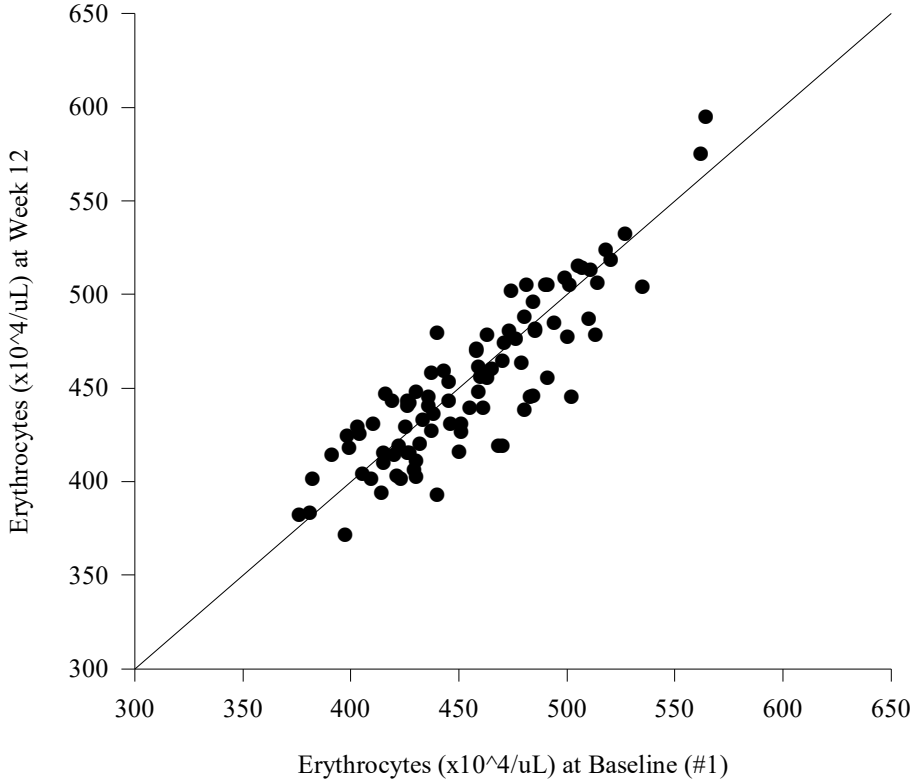


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 28 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (0%/5%)

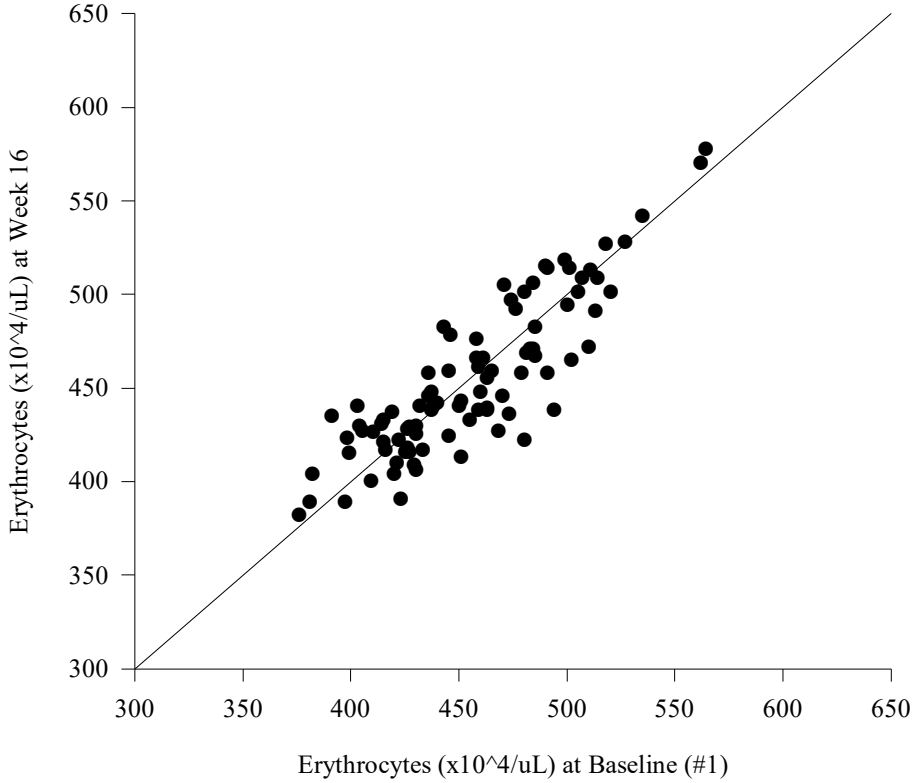


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 29 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (0%/5%)

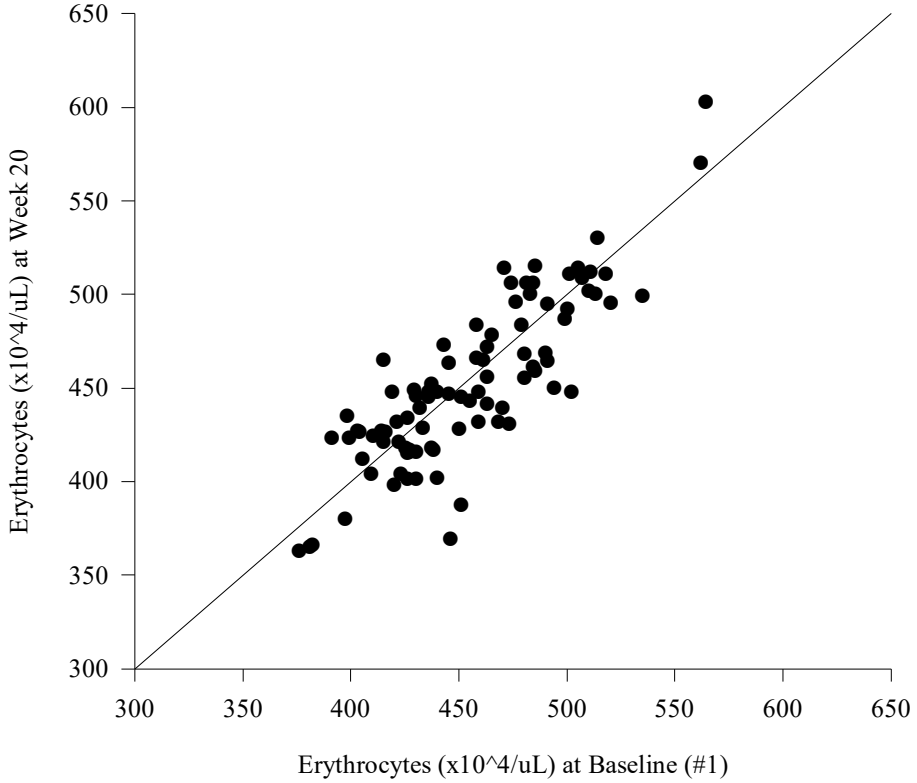


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 30 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (0%/5%)

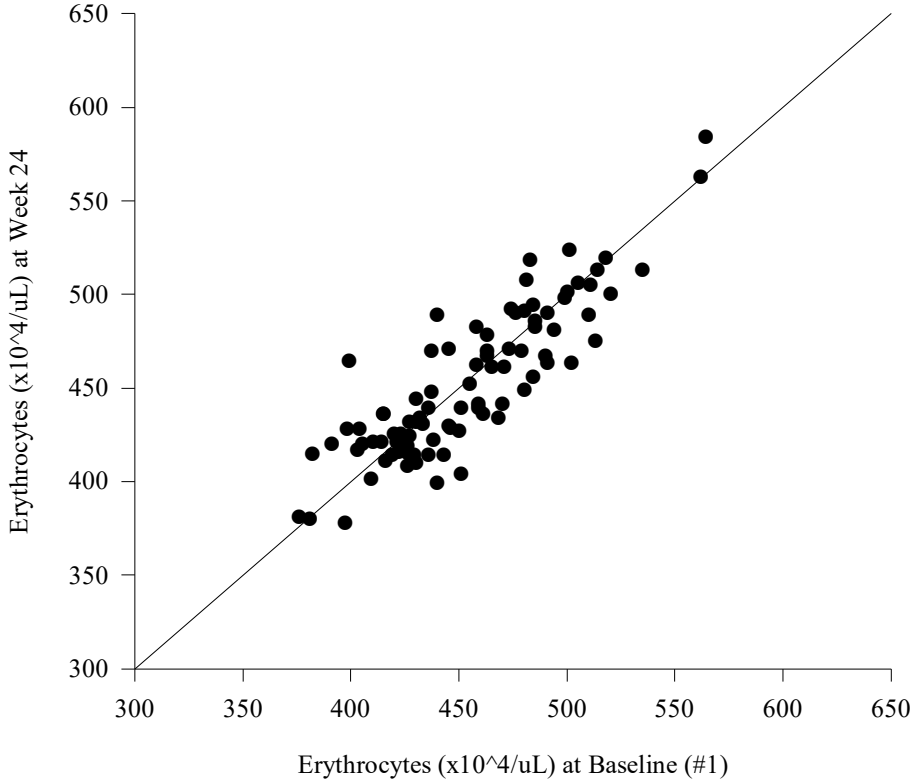


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 31 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (0%/5%)

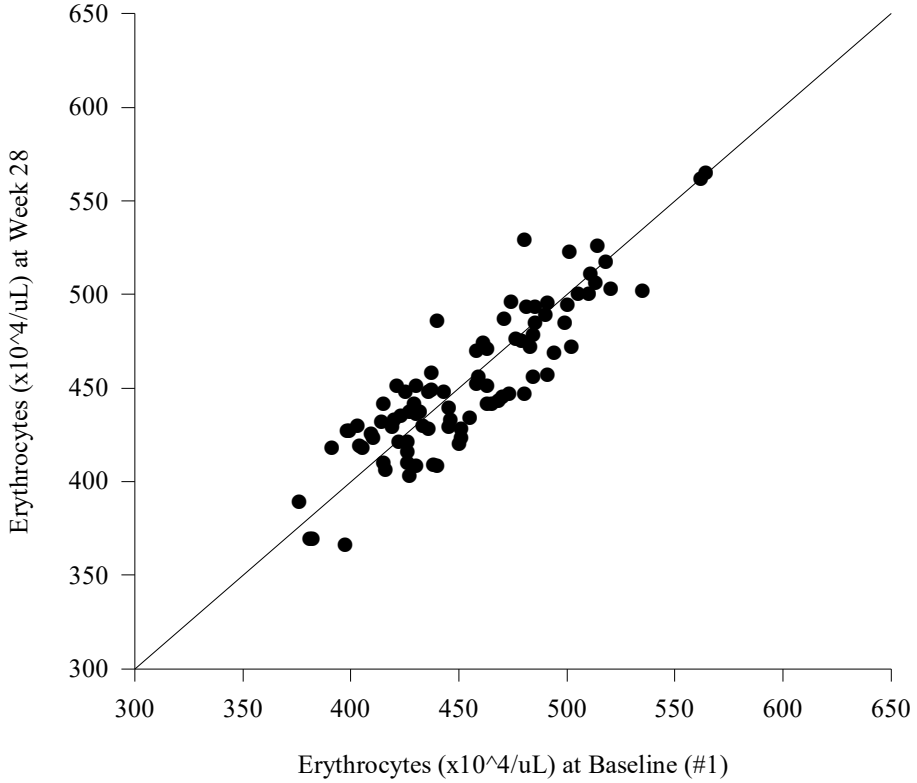


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 32 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (0%/5%)

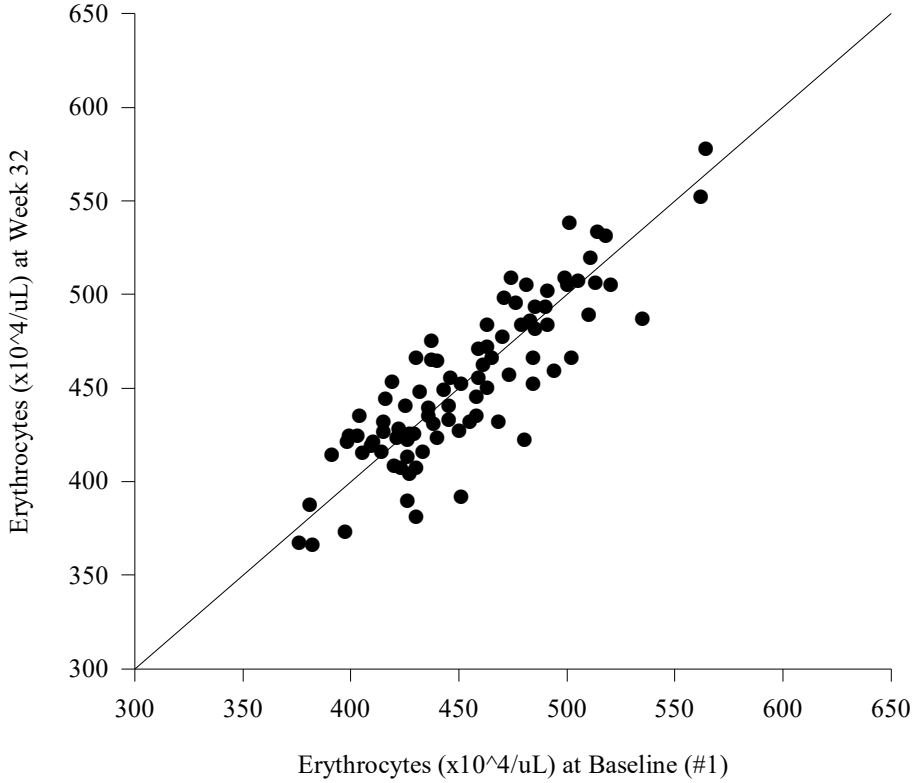


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 33 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (0%/5%)

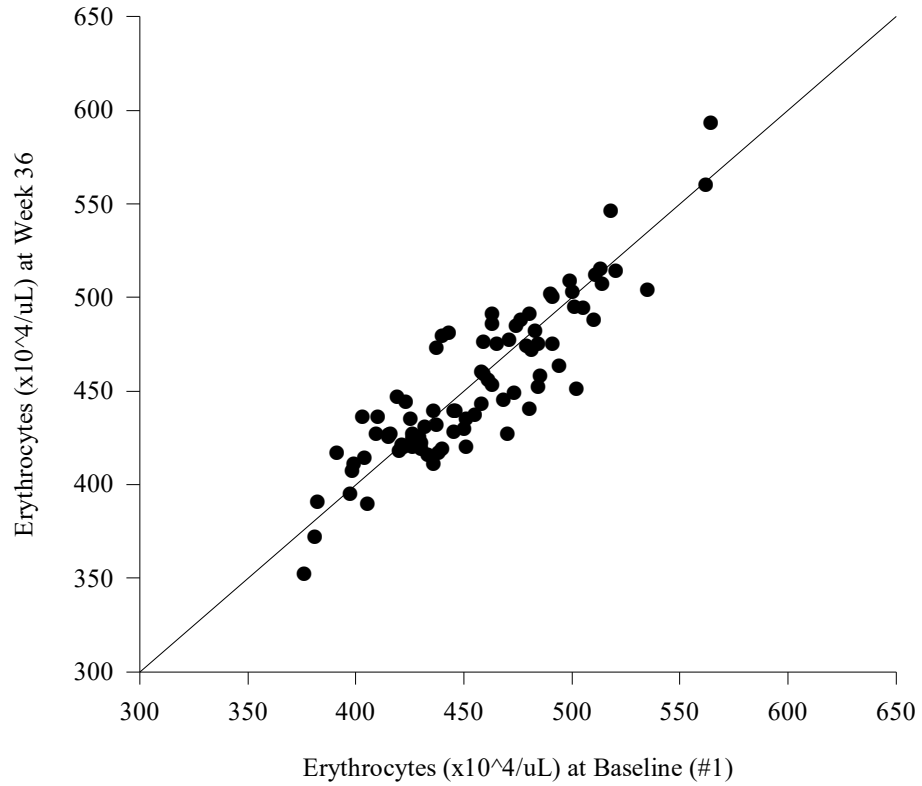


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 34 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (0%/5%)

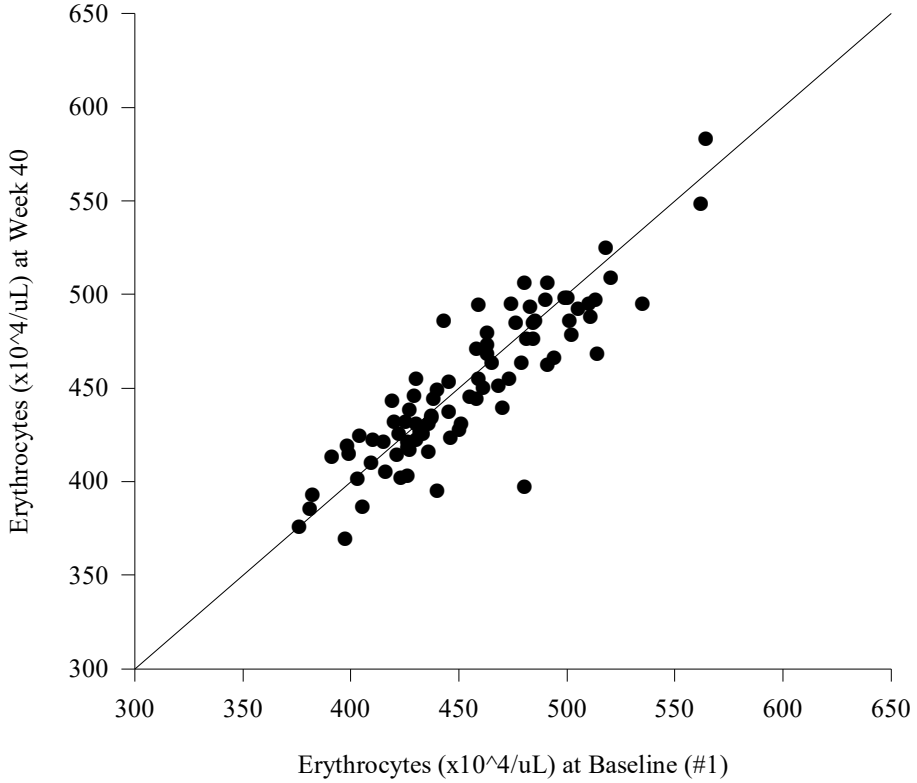


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 35 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (0%/5%)

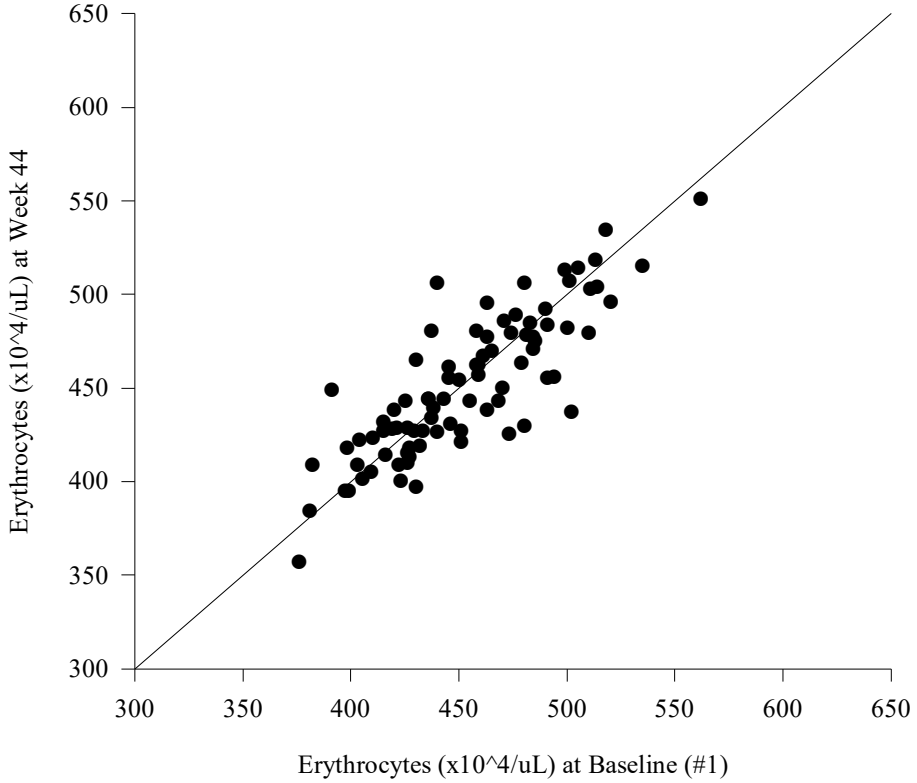


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 36 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (0%/5%)

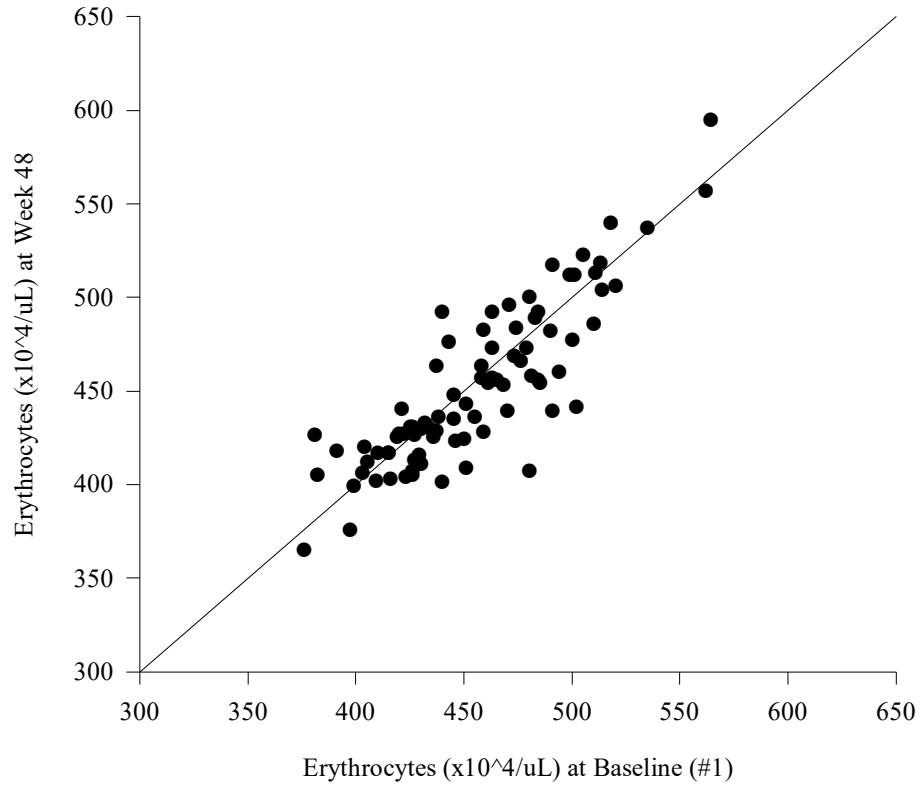


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 37 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (0%/5%)

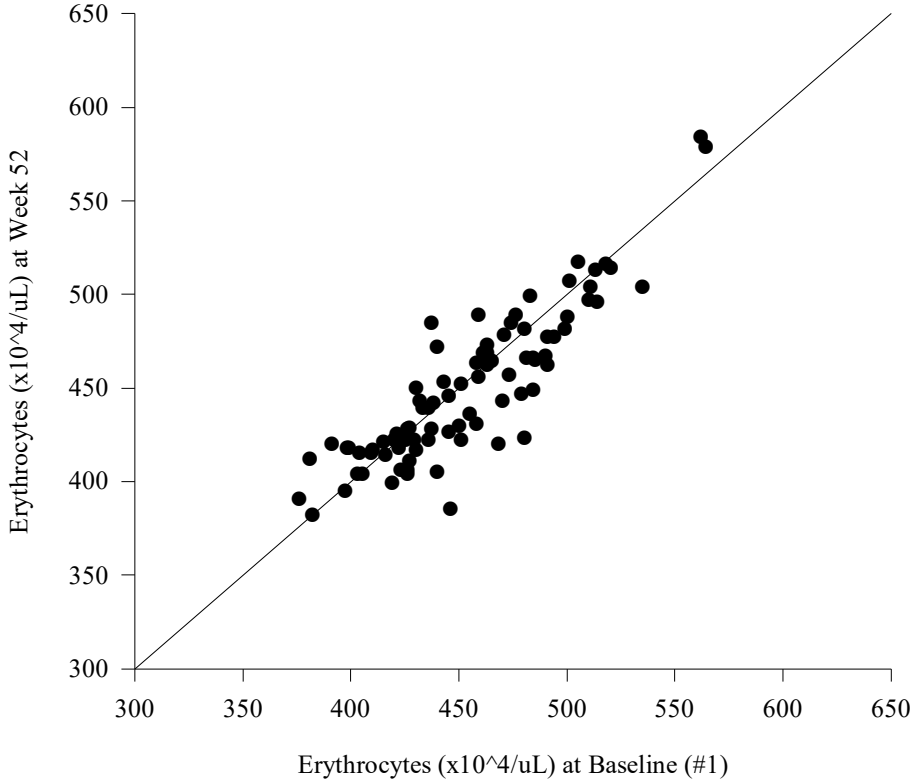


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 38 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (0%/5%)

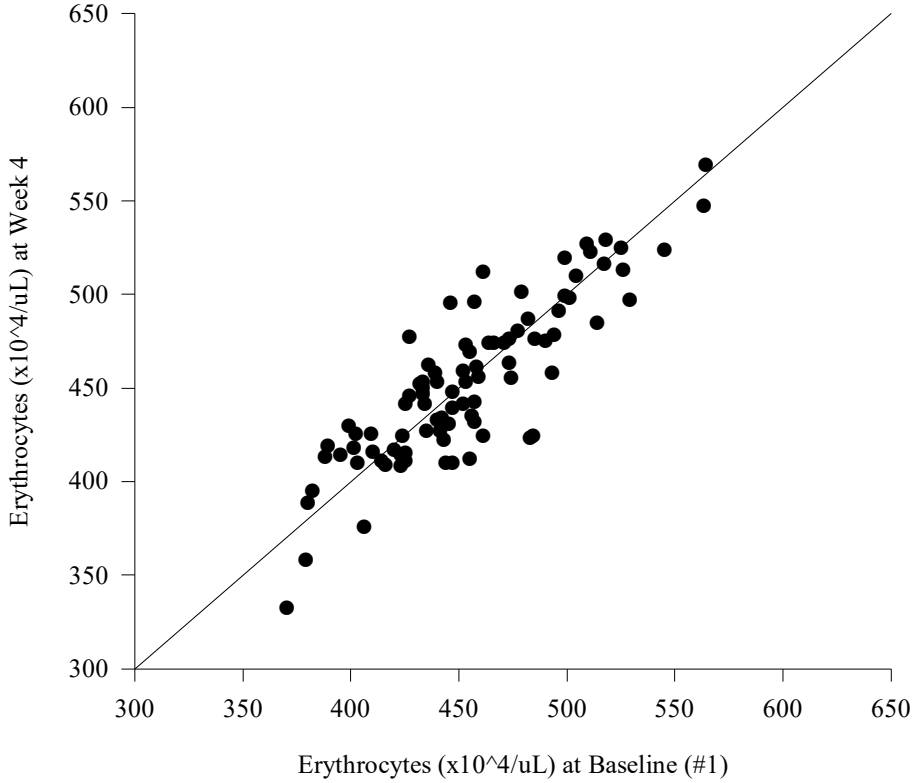


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 39 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (5%/5%)

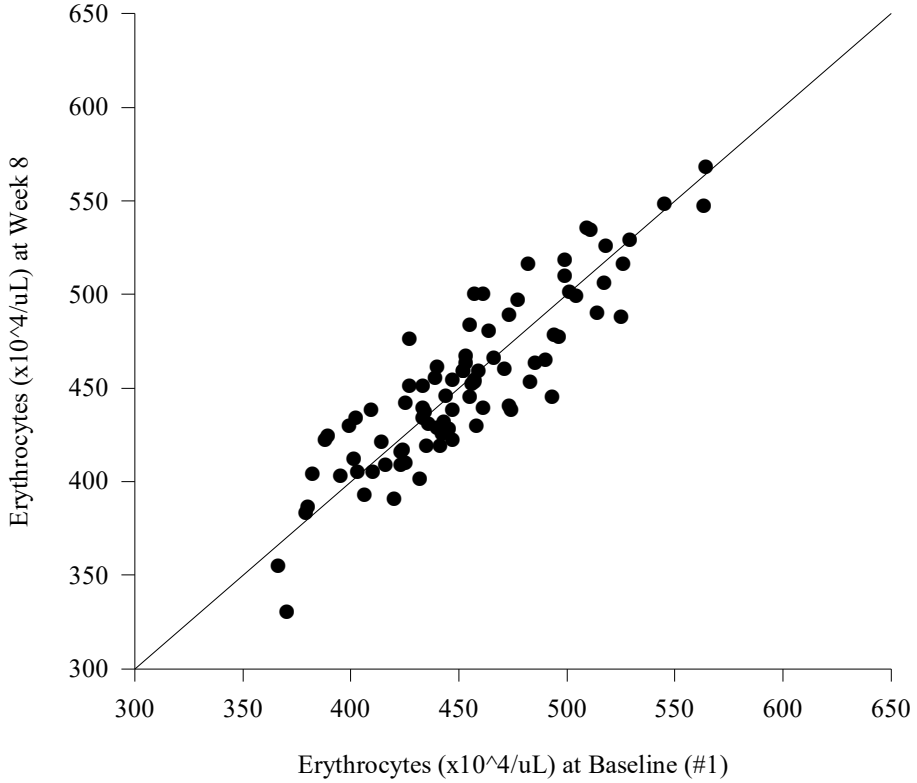


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 40 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (5%/5%)

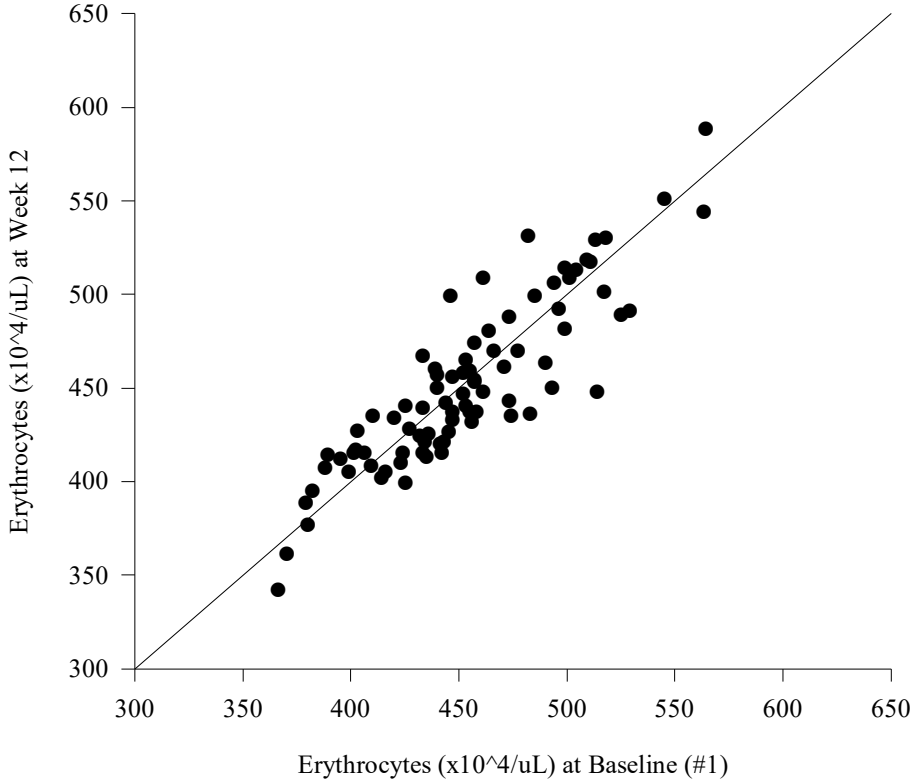


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 41 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (5%/5%)

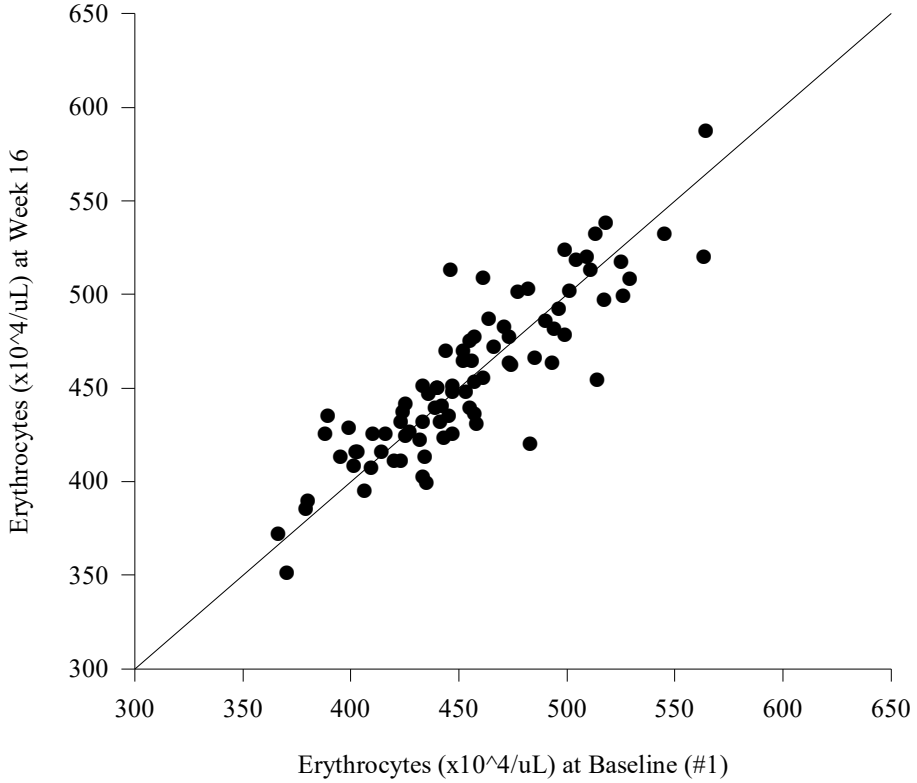


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 42 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (5%/5%)

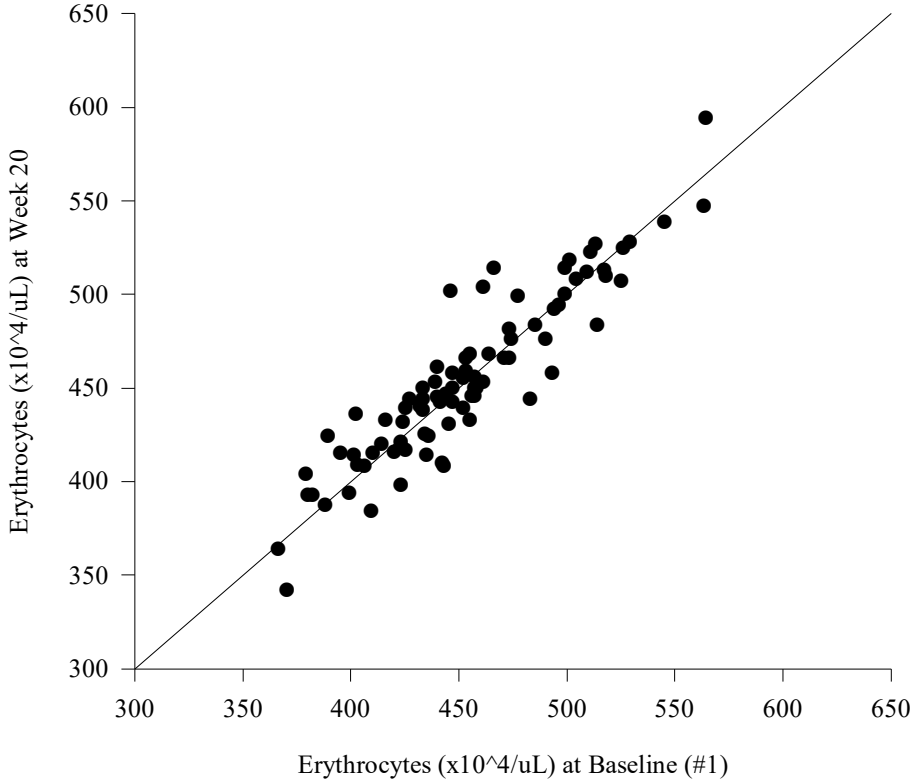


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 43 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (5%/5%)

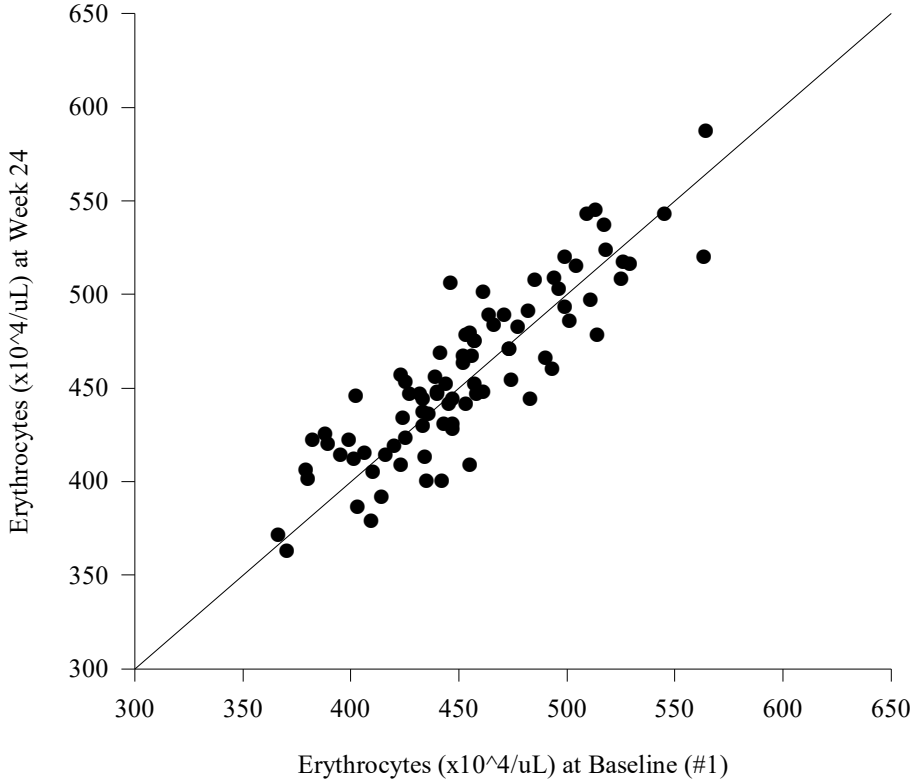


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 44 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (5%/5%)

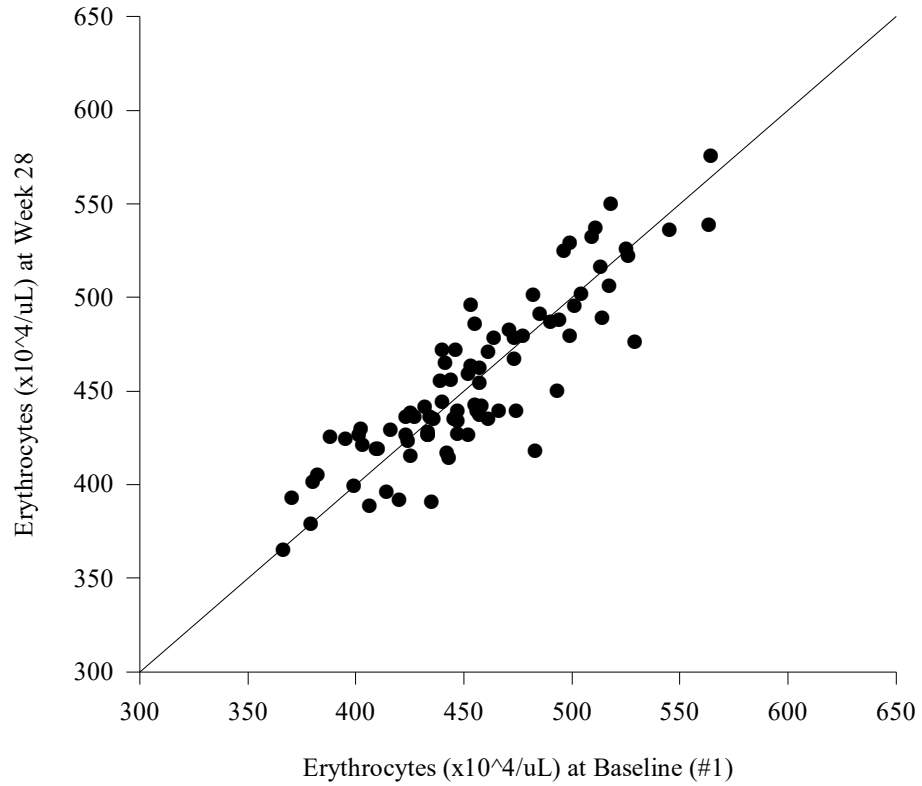


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 45 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (5%/5%)

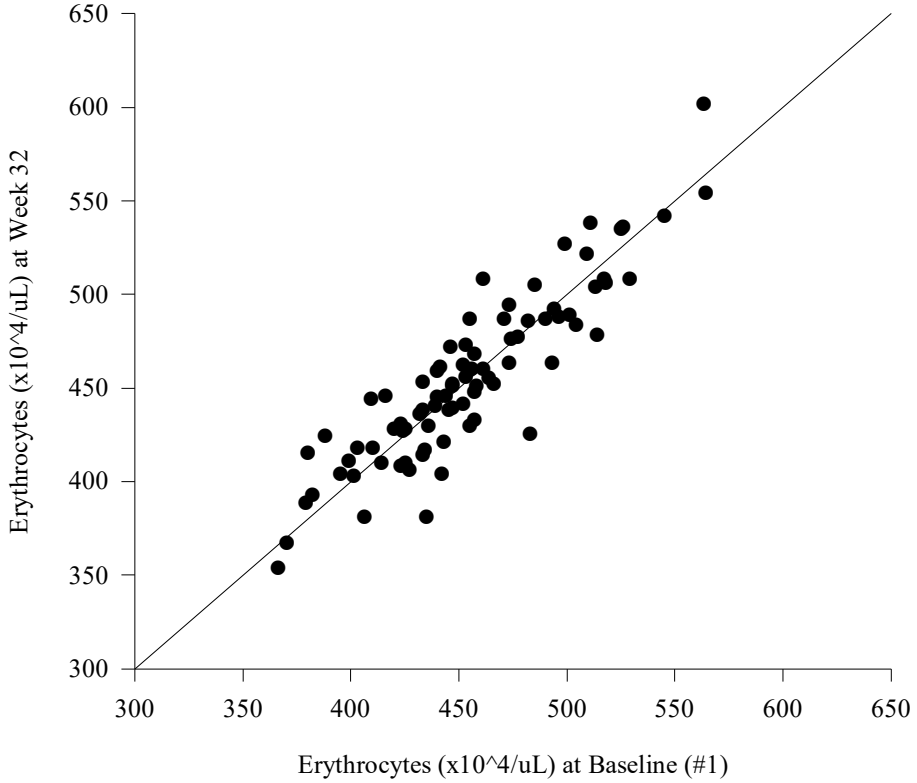


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 46 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (5%/5%)

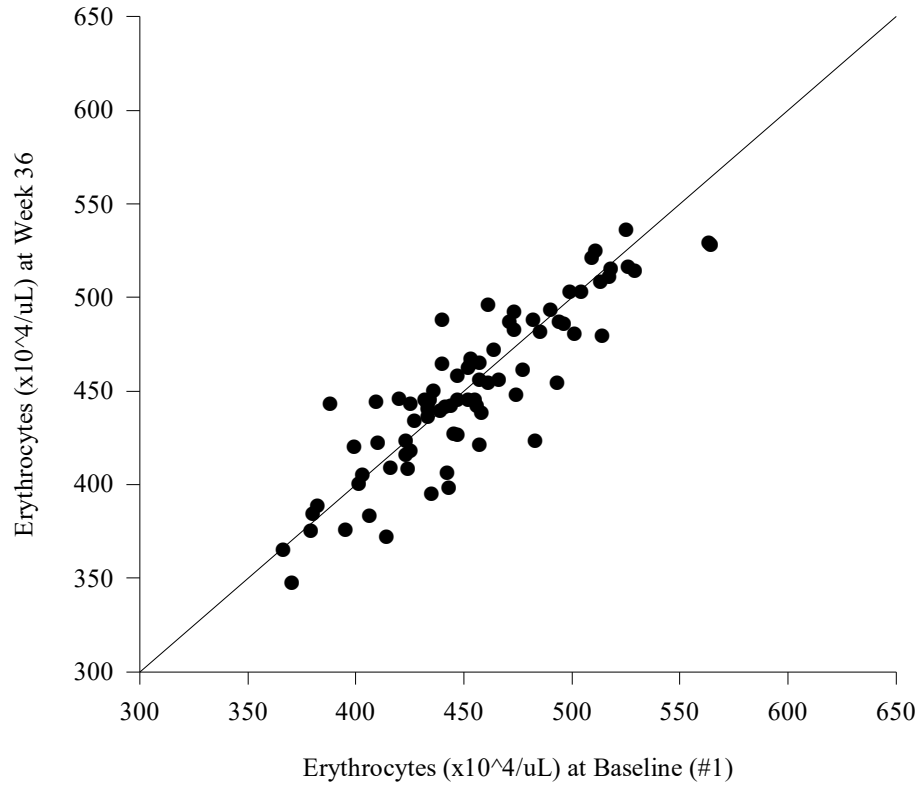


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 47 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (5%/5%)

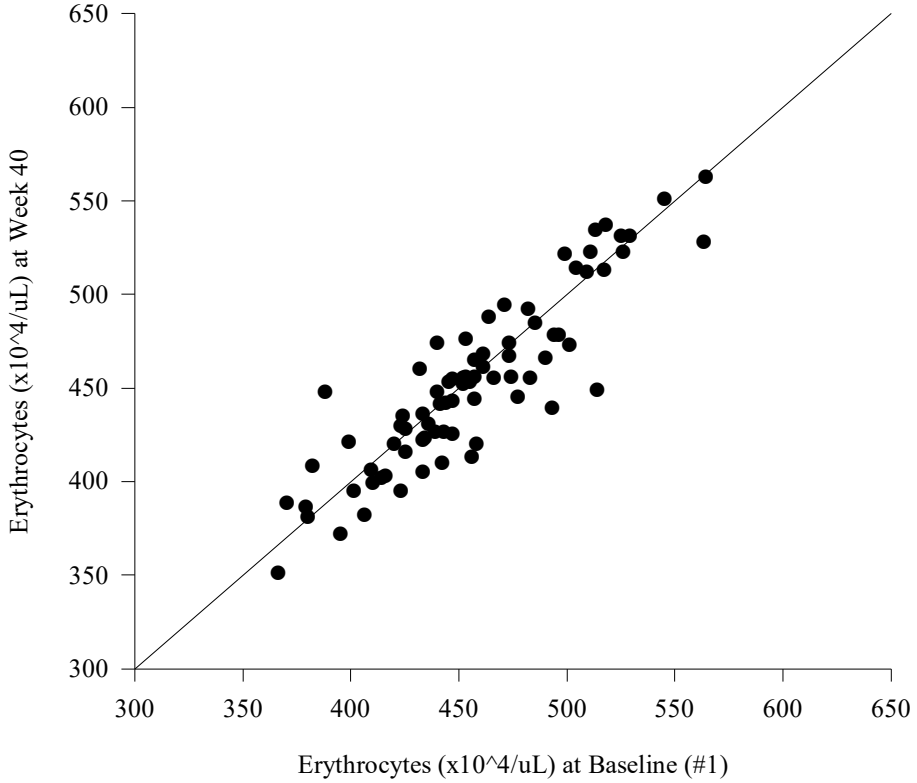


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 48 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (5%/5%)

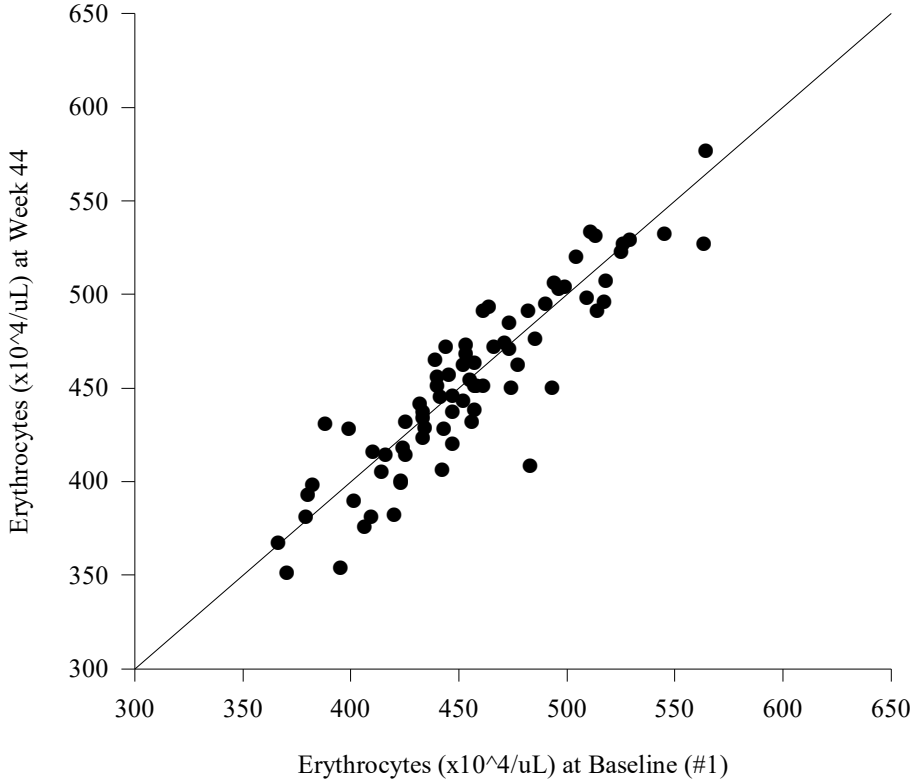


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 49 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (5%/5%)

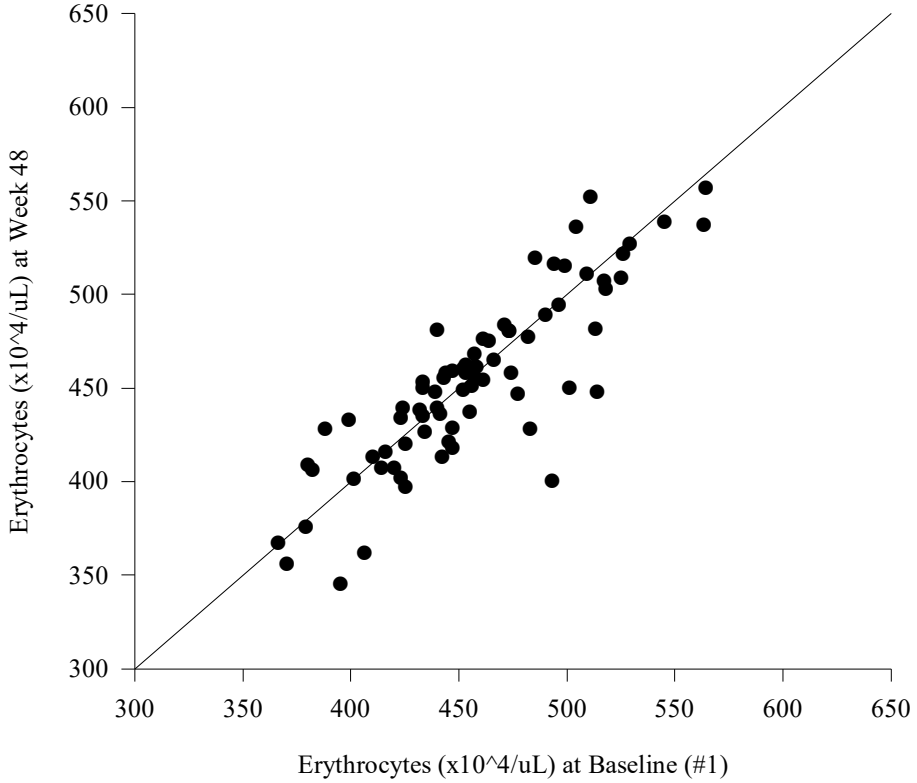


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 50 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (5%/5%)

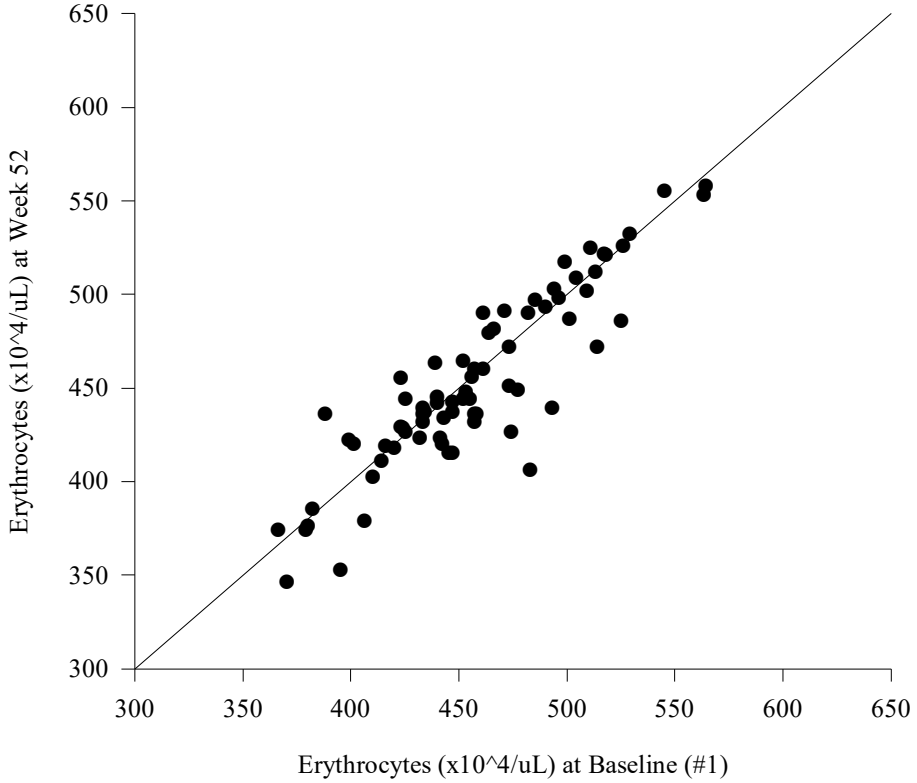


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 51 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (5%/5%)

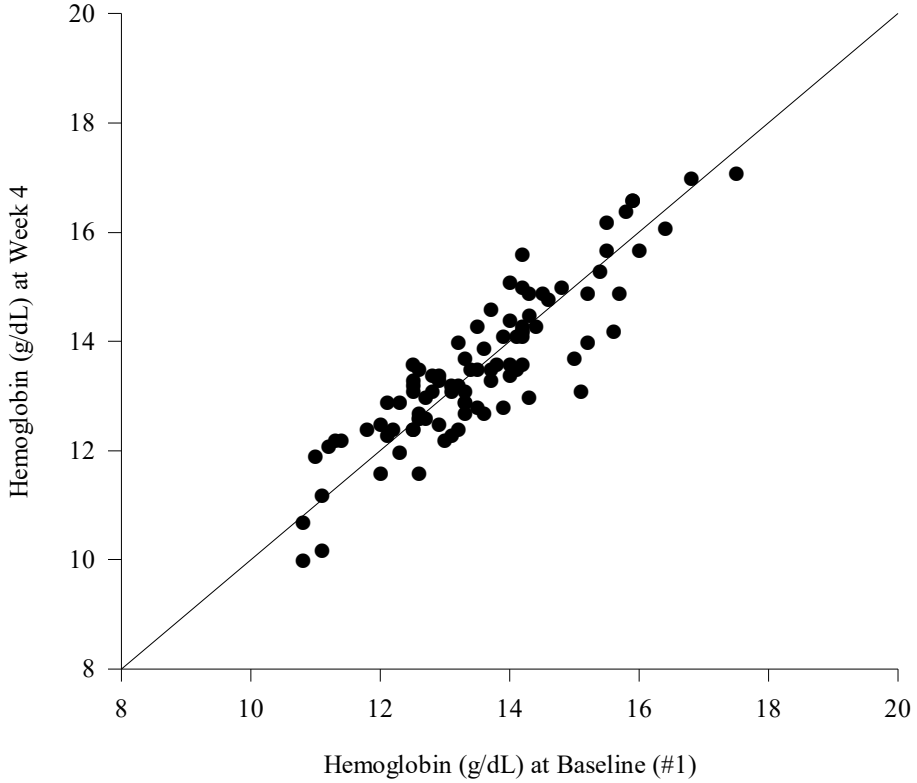


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 52 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (0%/5%)

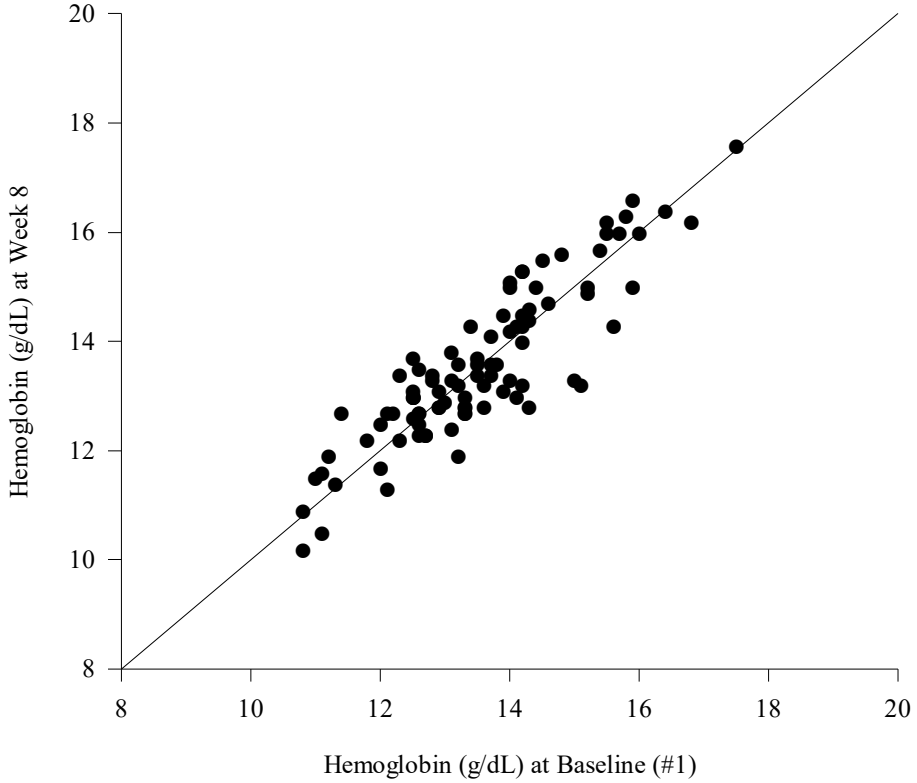


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 53 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (0%/5%)

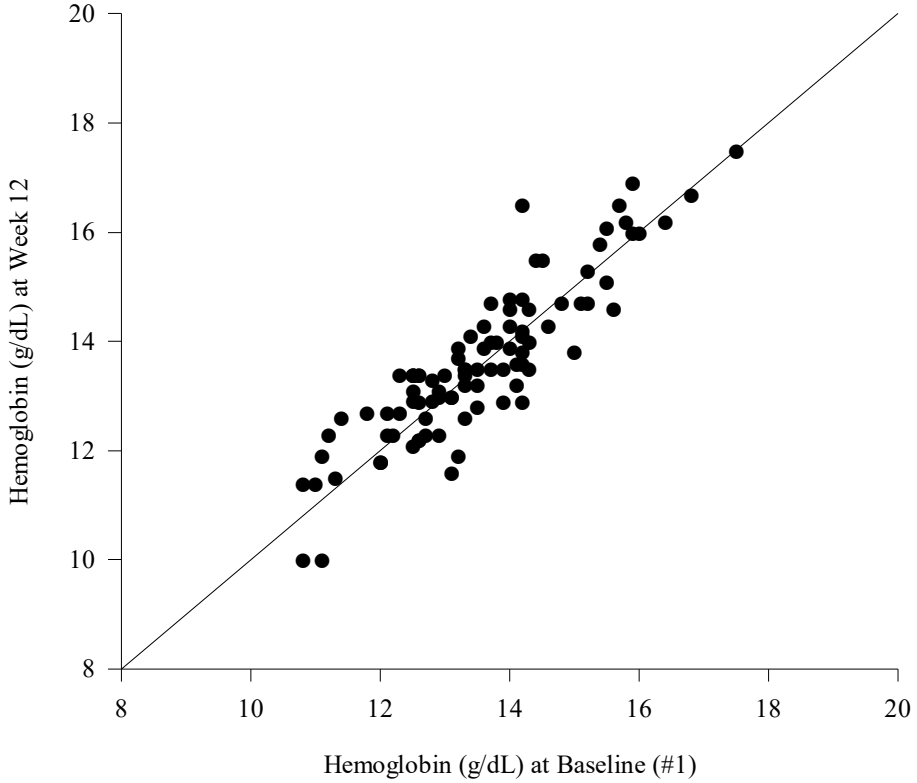


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 54 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (0%/5%)

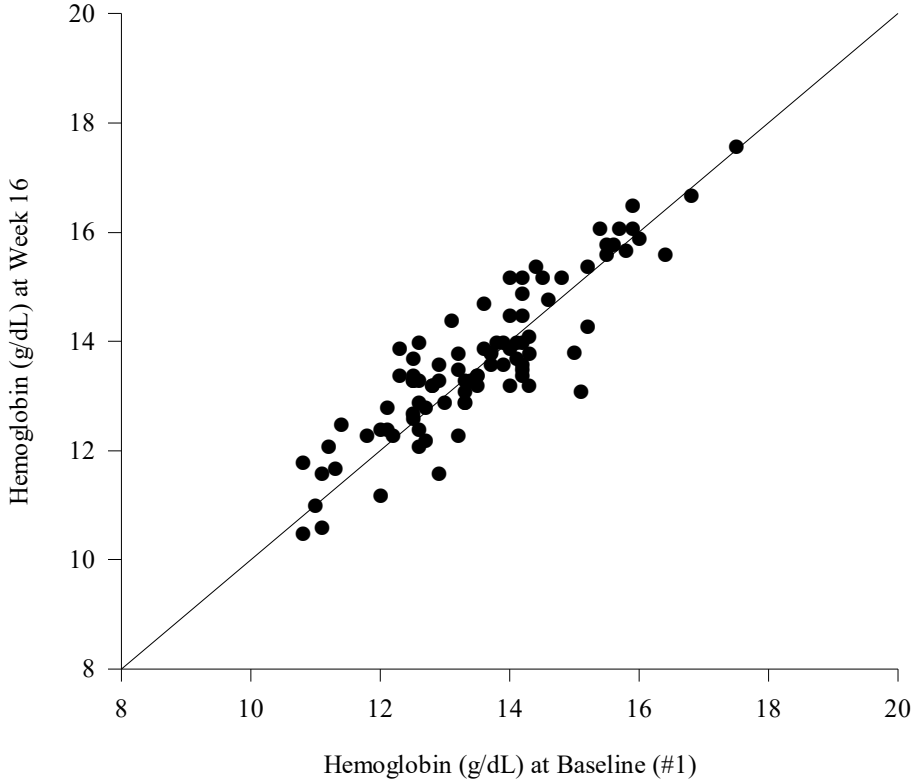


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 55 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (0%/5%)

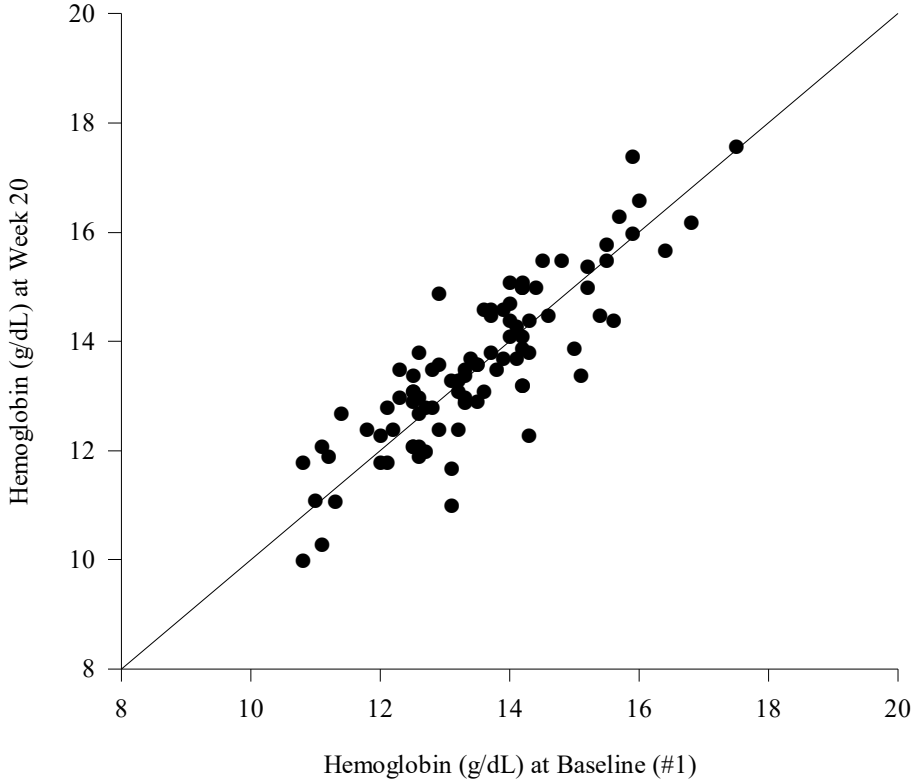


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 56 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (0%/5%)

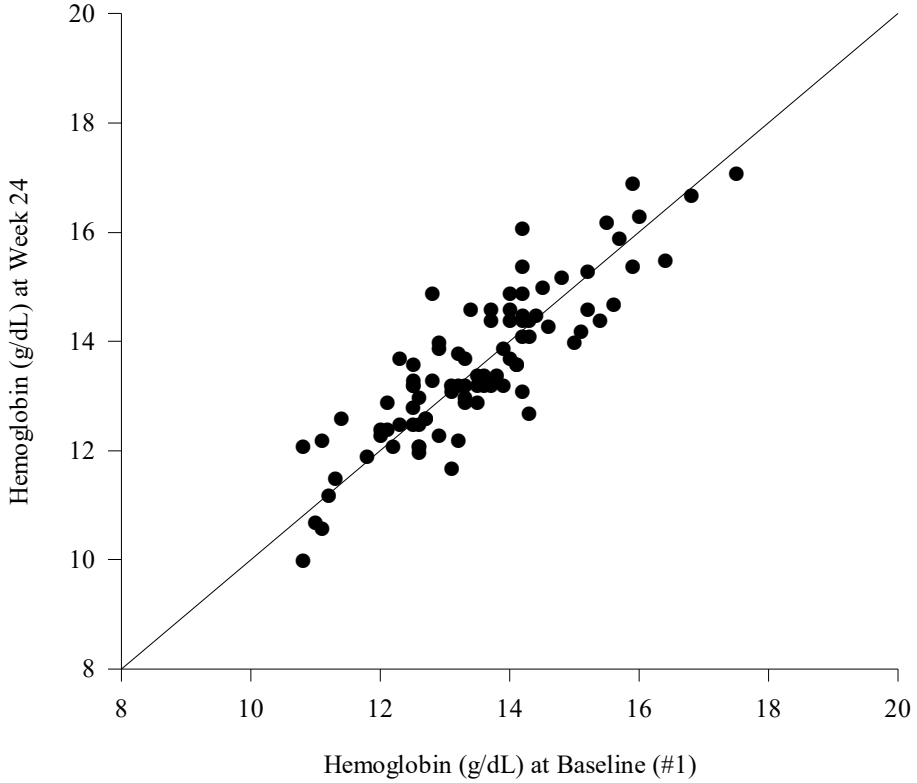


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 57 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (0%/5%)

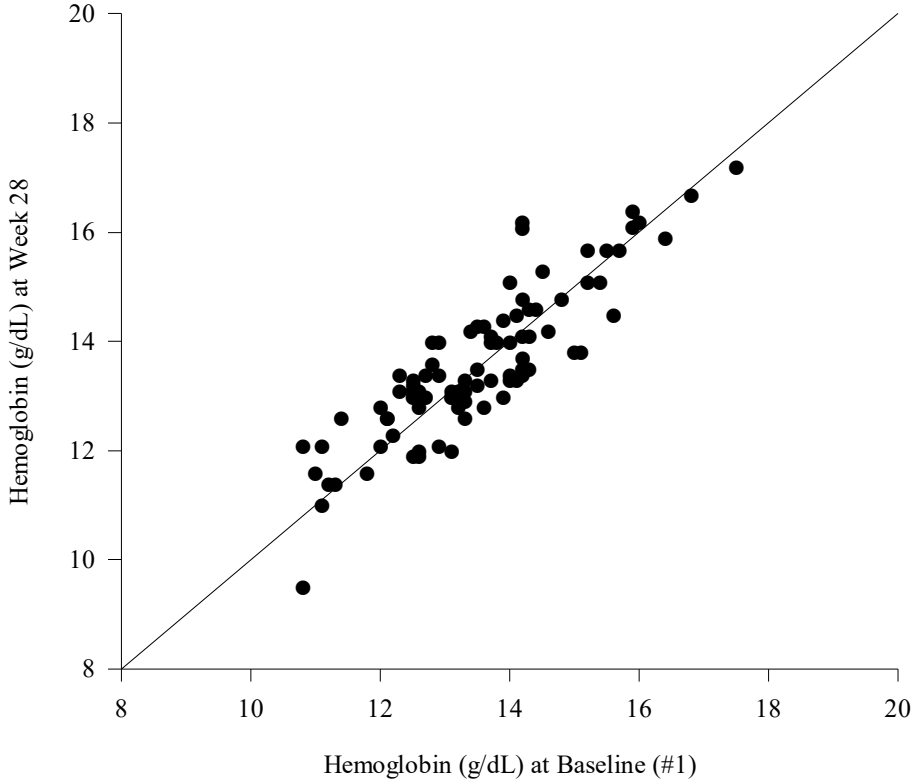


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 58 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (0%/5%)

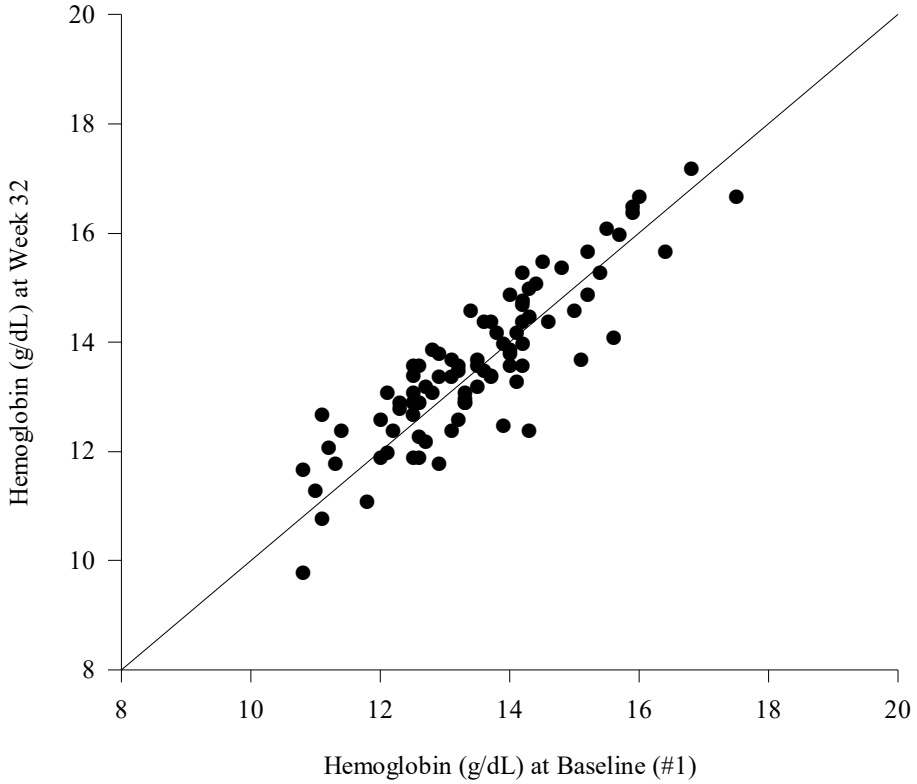


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 59 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (0%/5%)

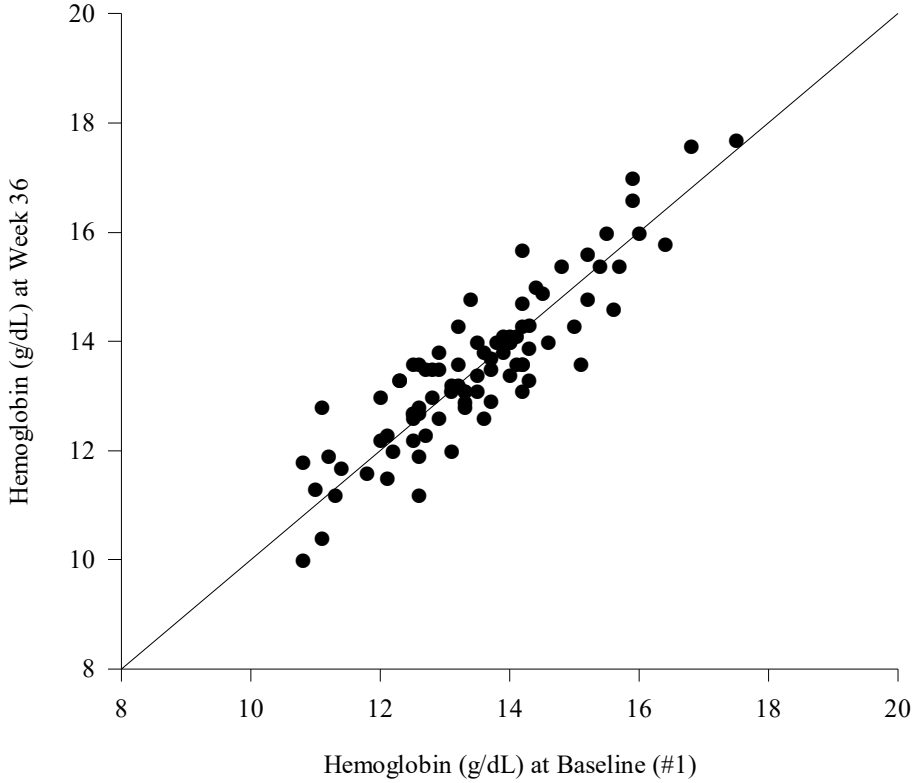


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 60 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (0%/5%)

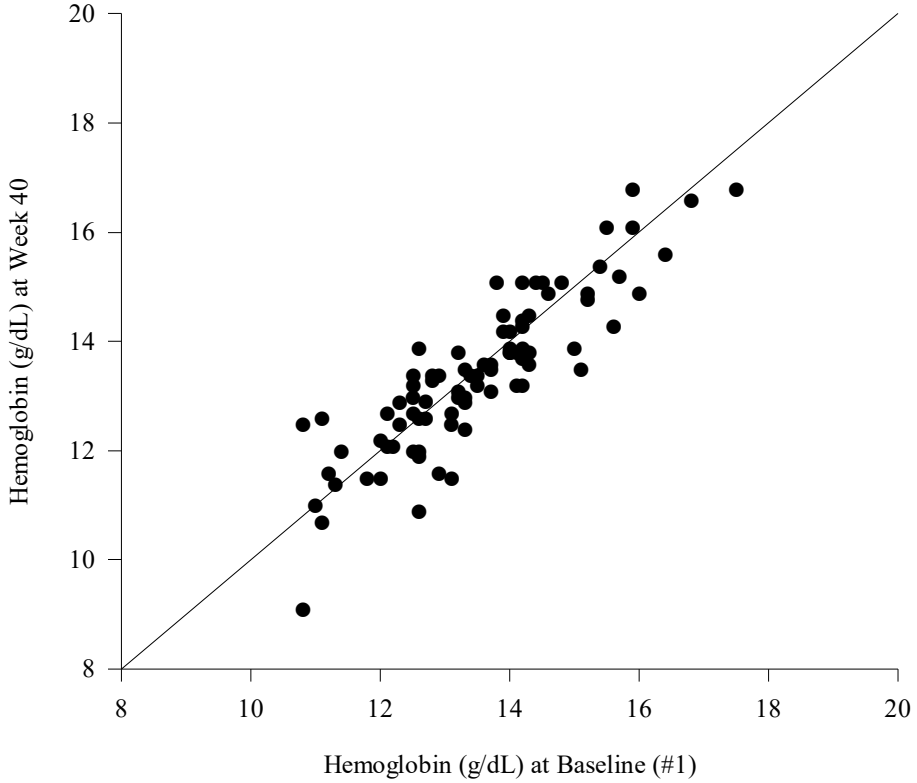


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 61 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (0%/5%)

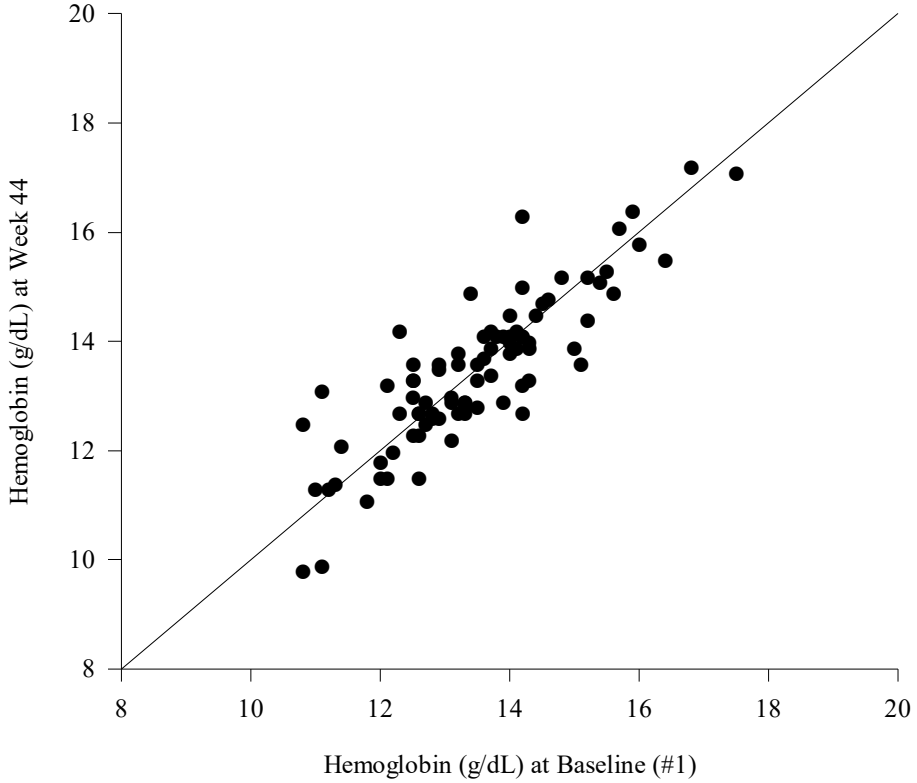


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 62 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (0%/5%)

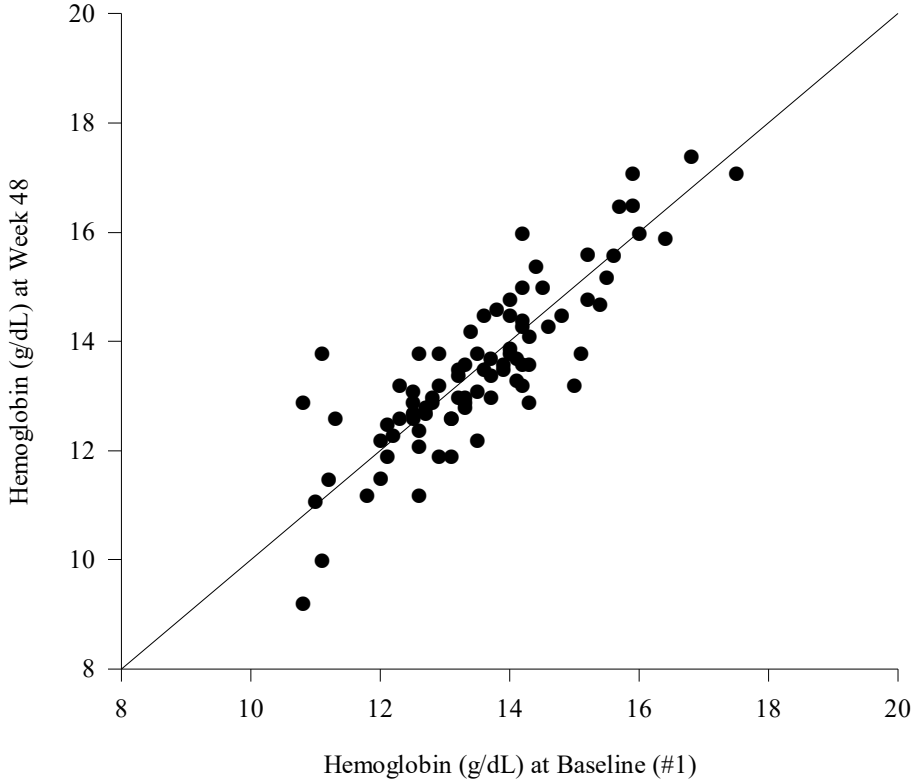


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 63 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (0%/5%)

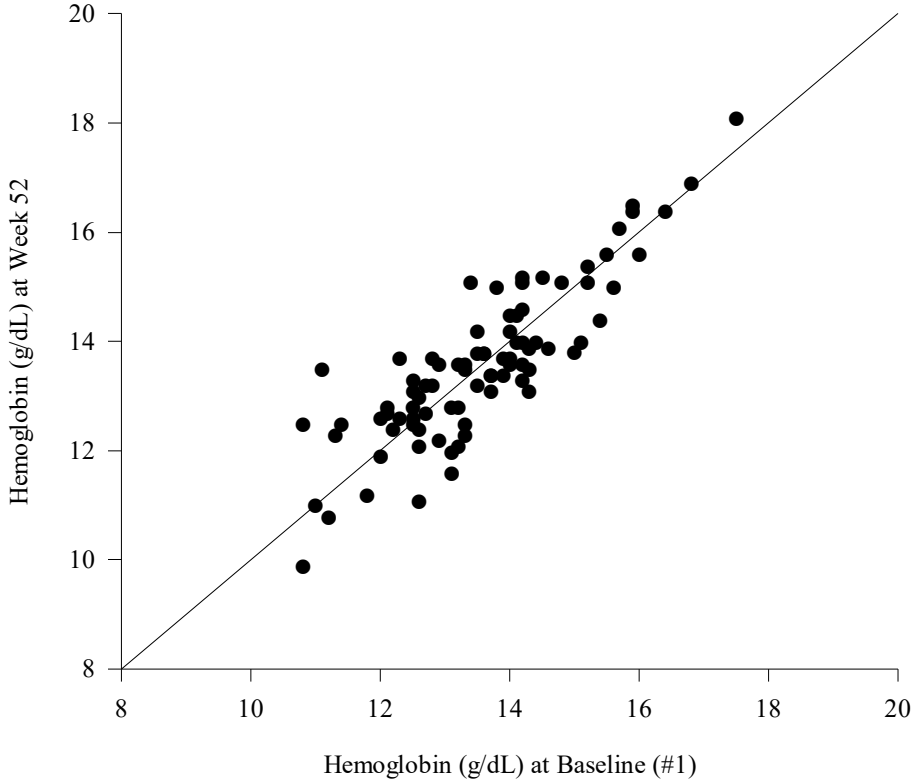


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 64 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (0%/5%)

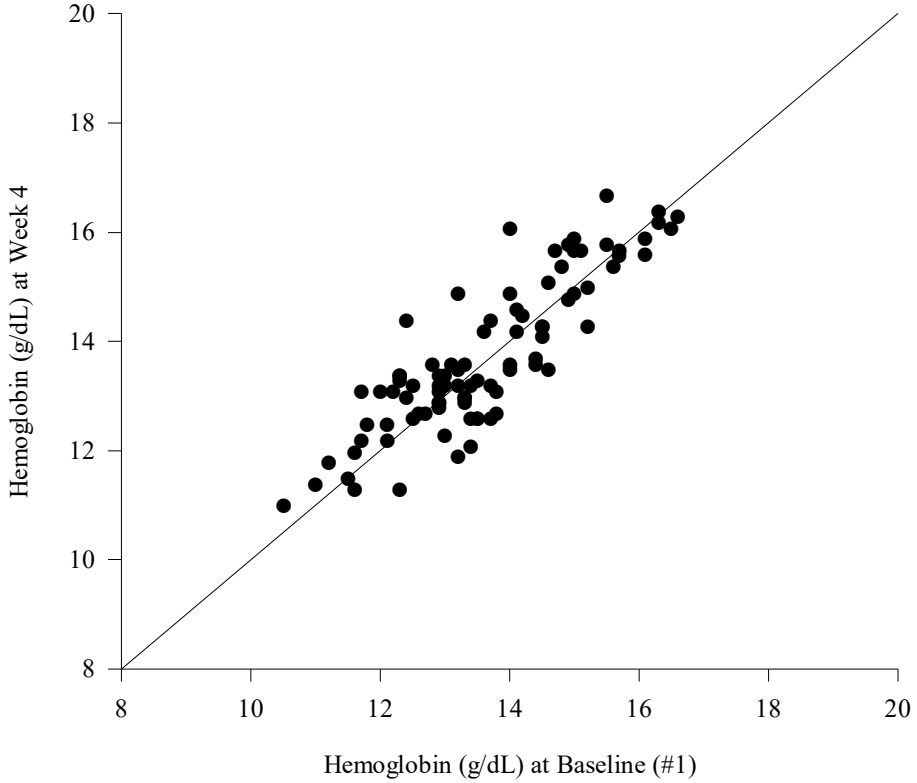


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 65 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (5%/5%)

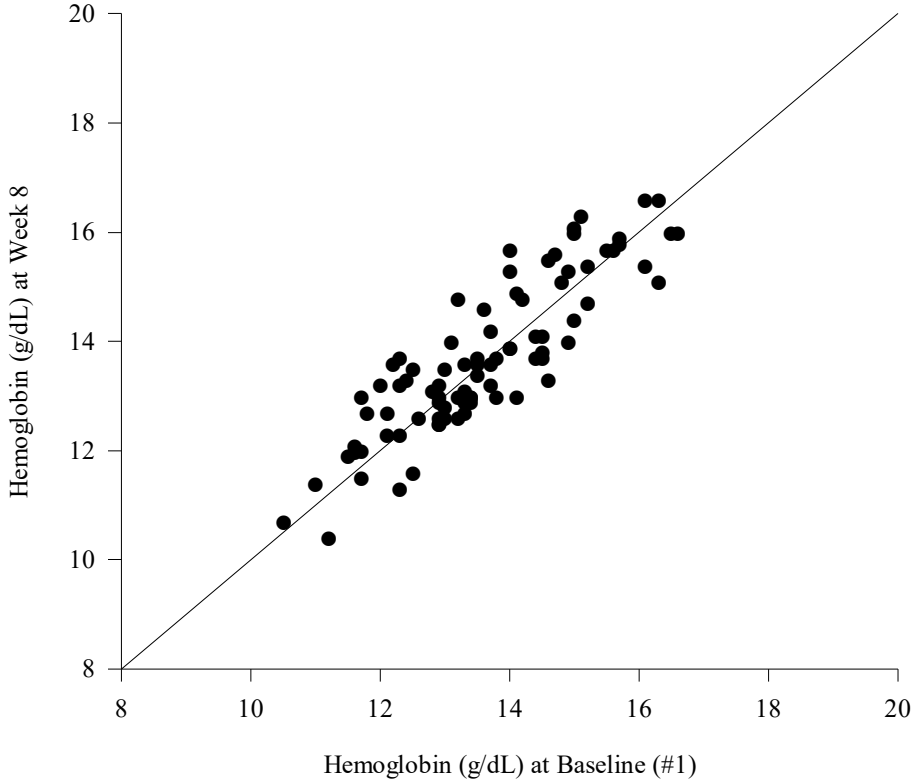


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 66 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (5%/5%)

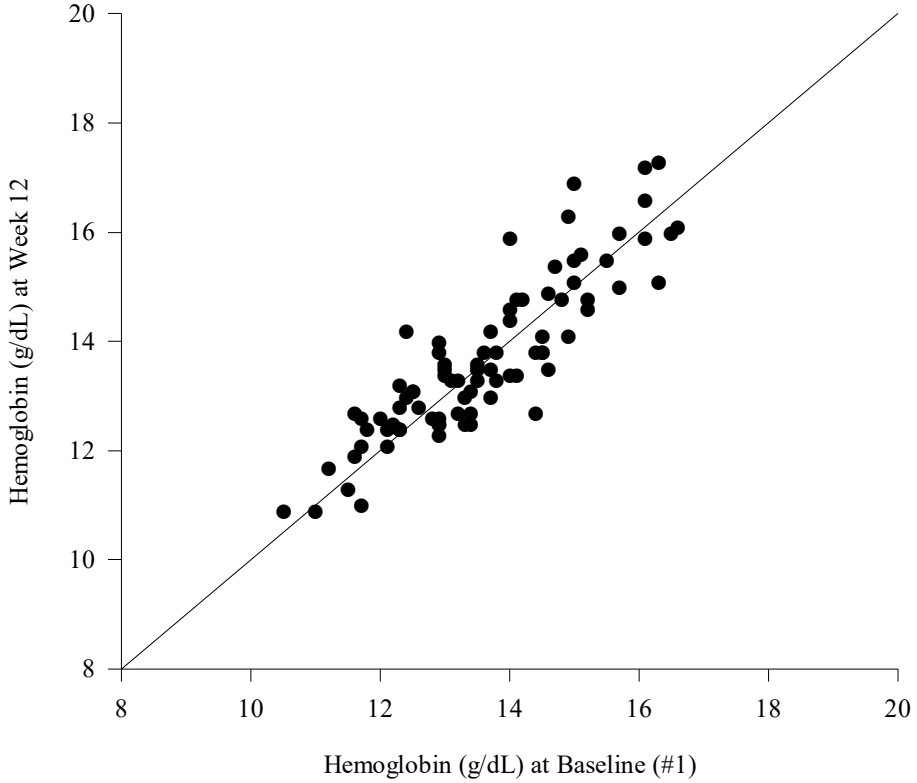


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 67 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (5%/5%)

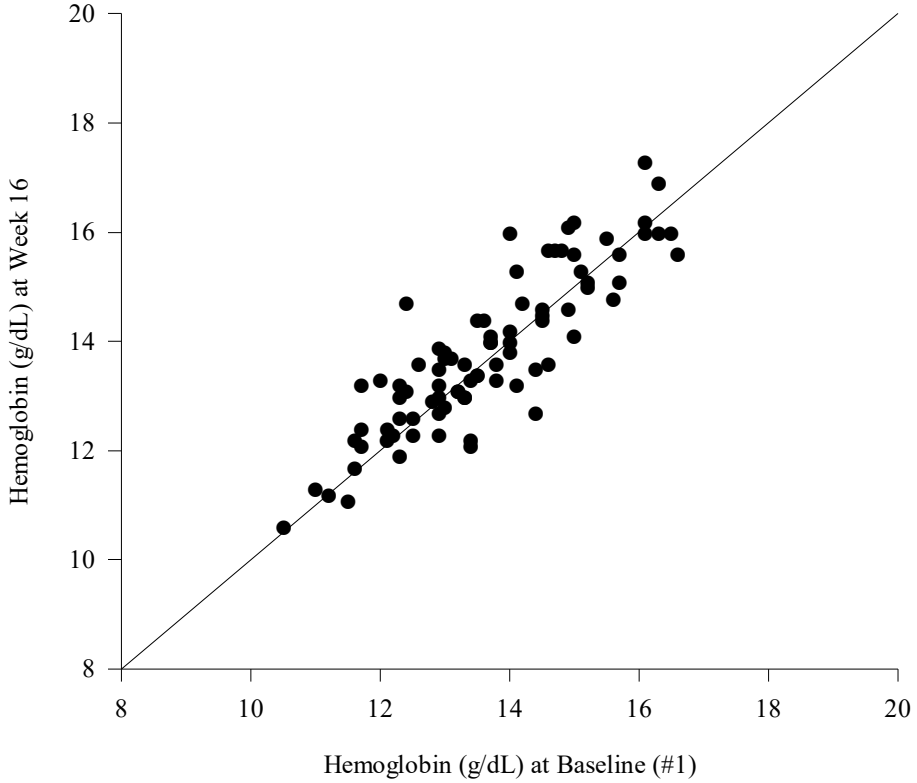


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 68 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (5%/5%)

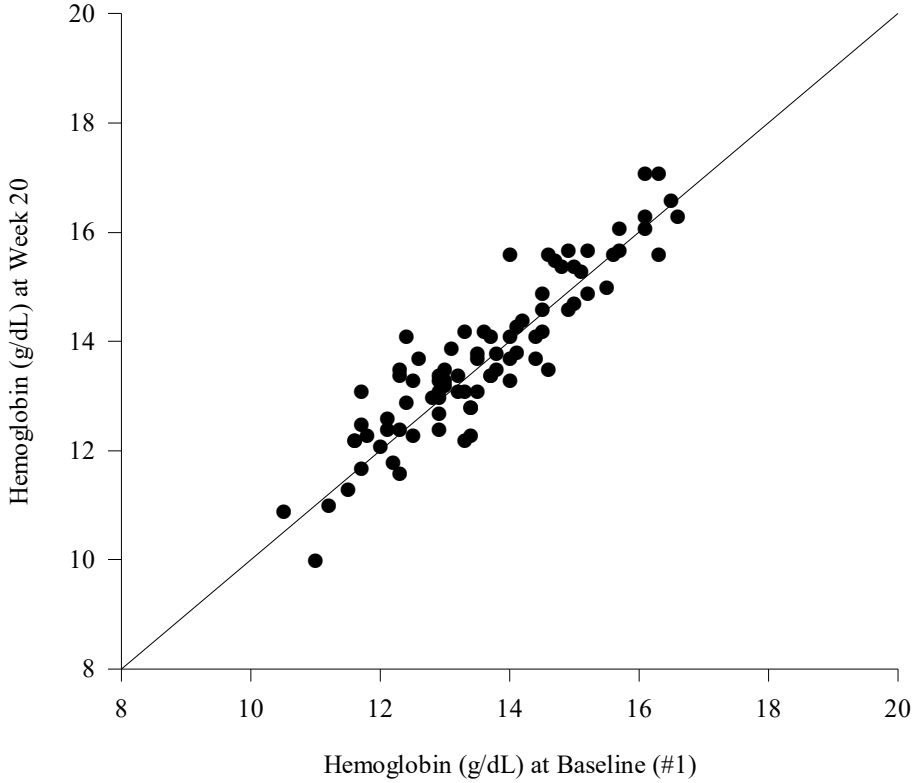


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 69 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (5%/5%)

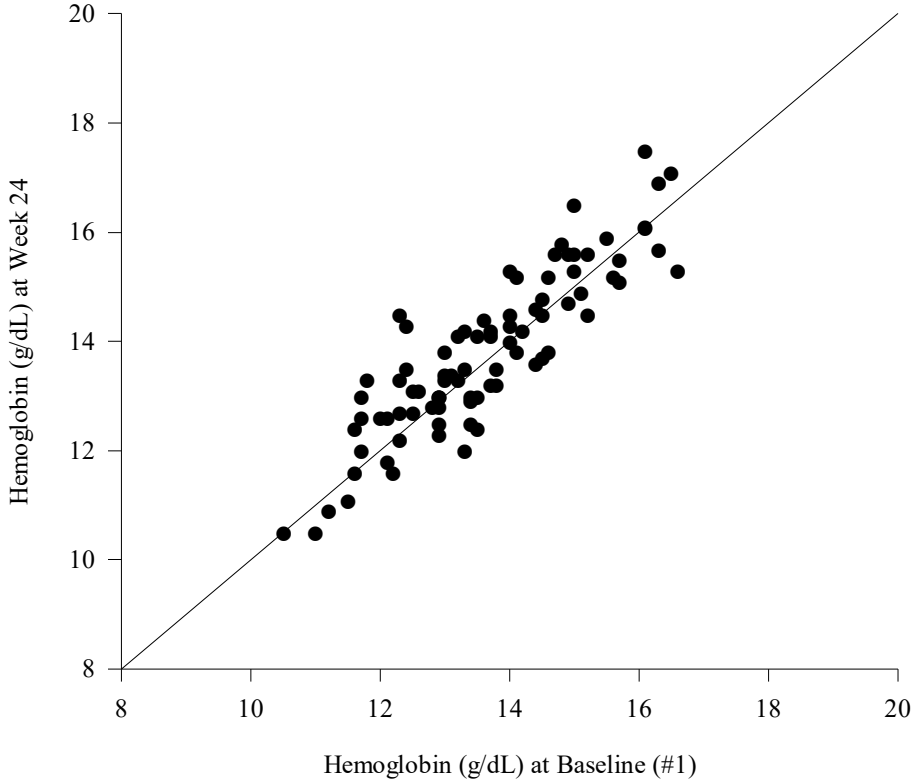


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 70 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (5%/5%)

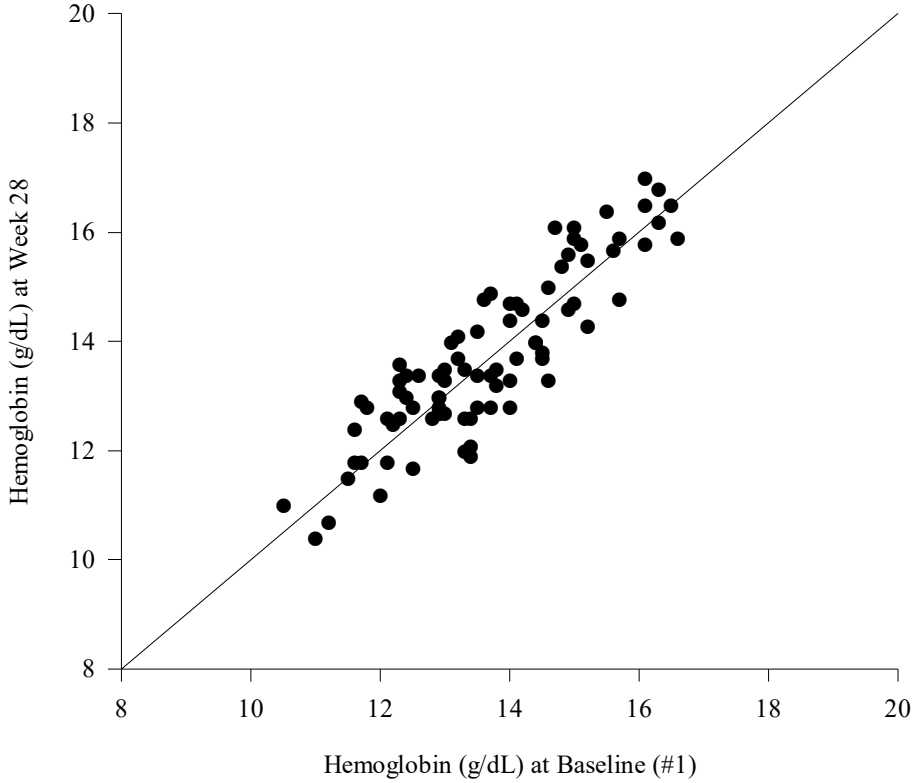


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 71 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (5%/5%)

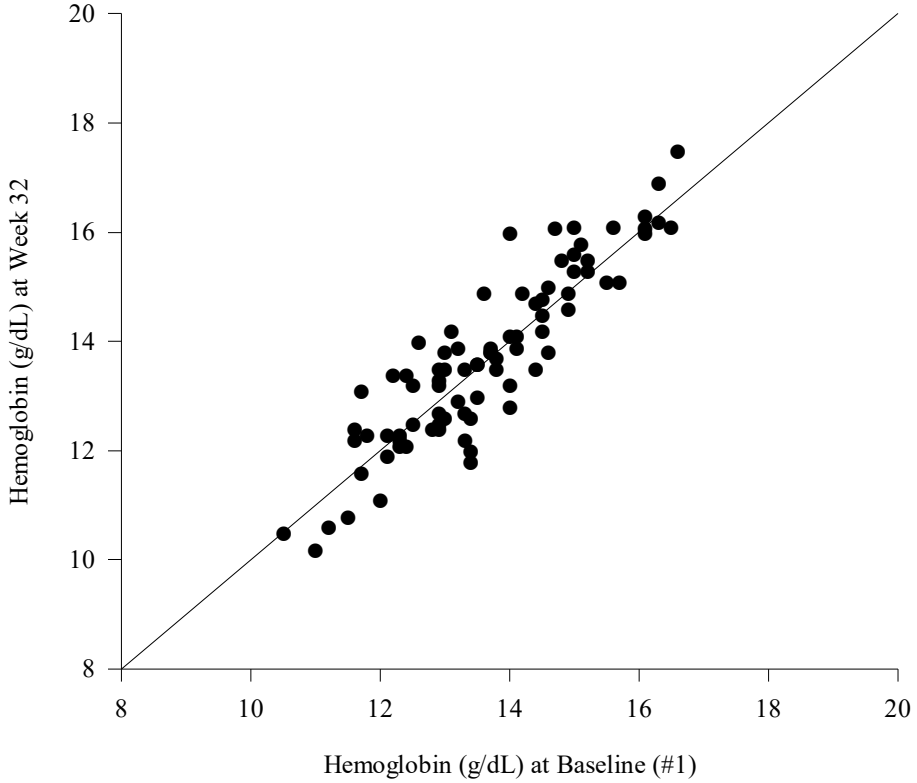


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 72 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (5%/5%)

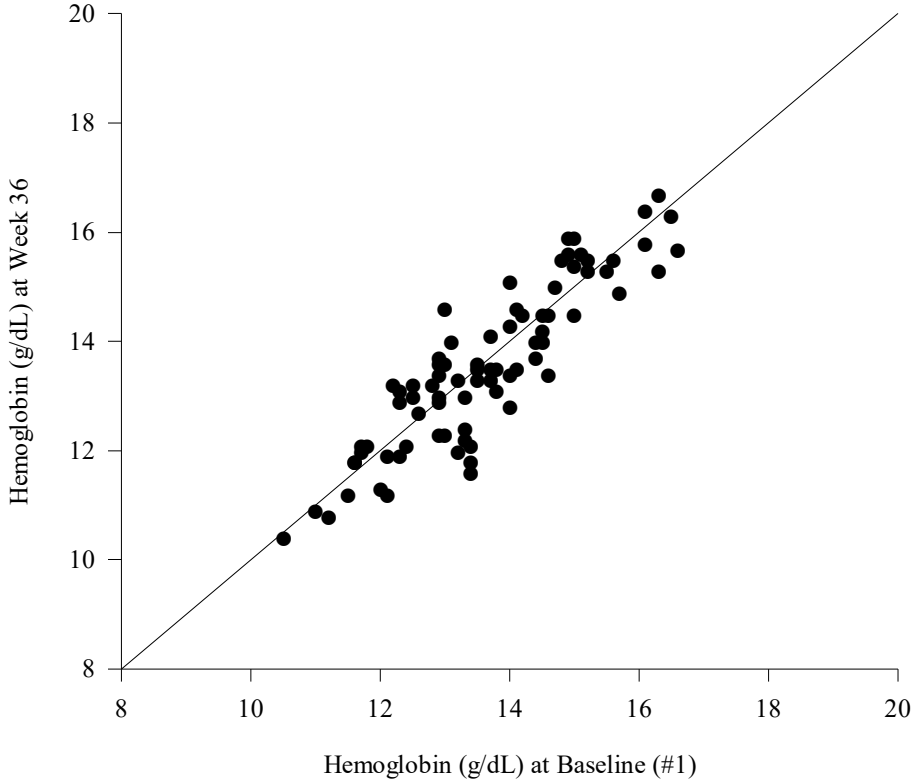


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 73 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (5%/5%)

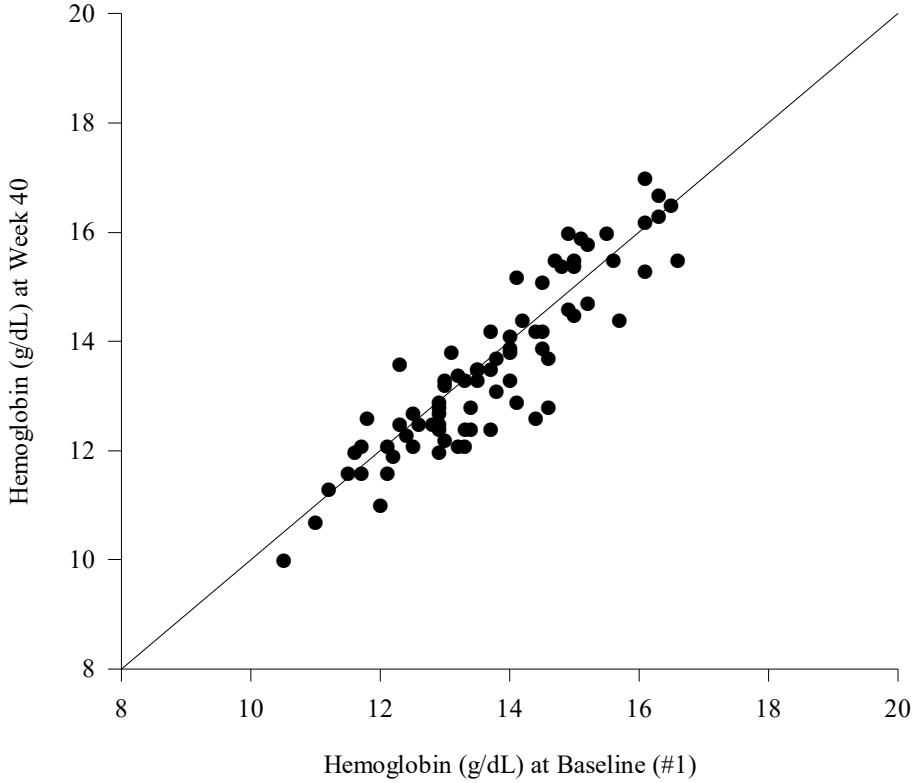


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 74 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (5%/5%)

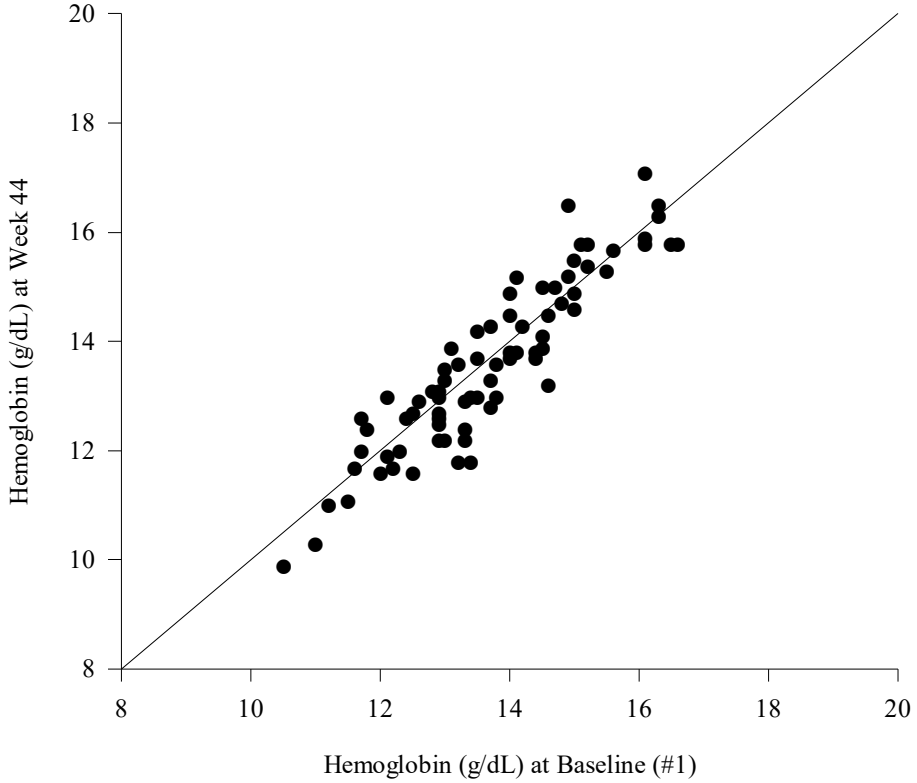


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 75 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (5%/5%)

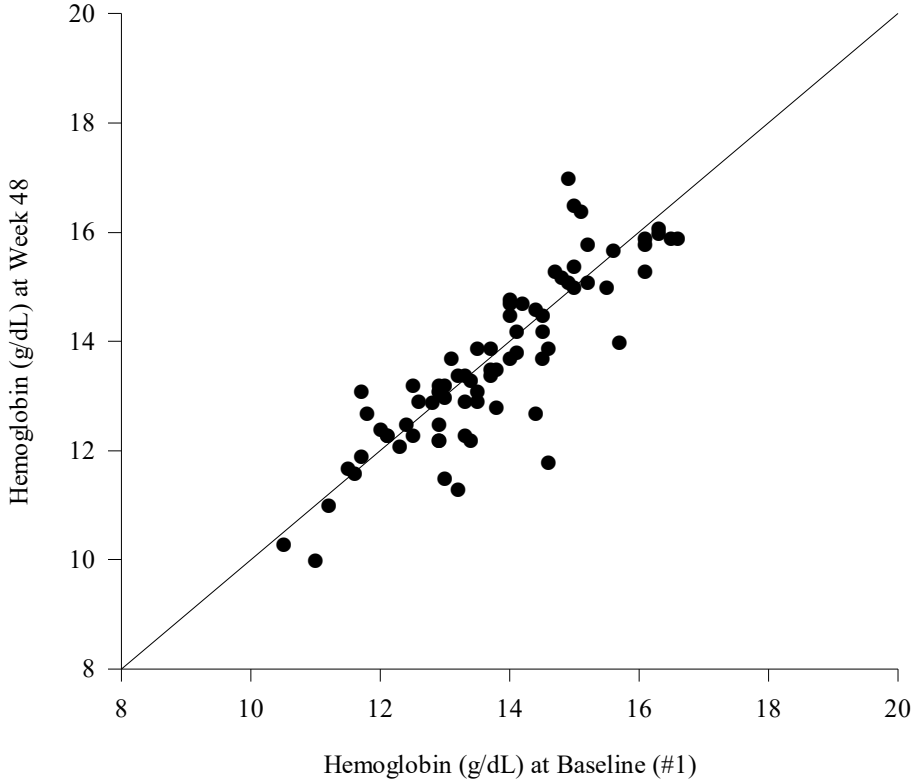


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 76 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (5%/5%)

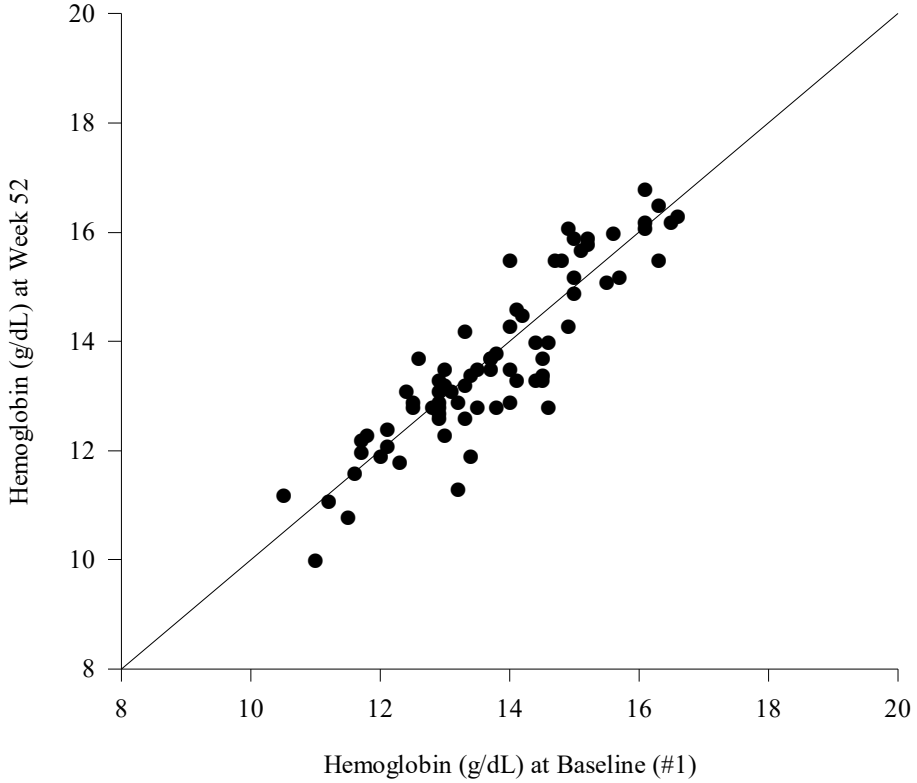


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 77 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (5%/5%)

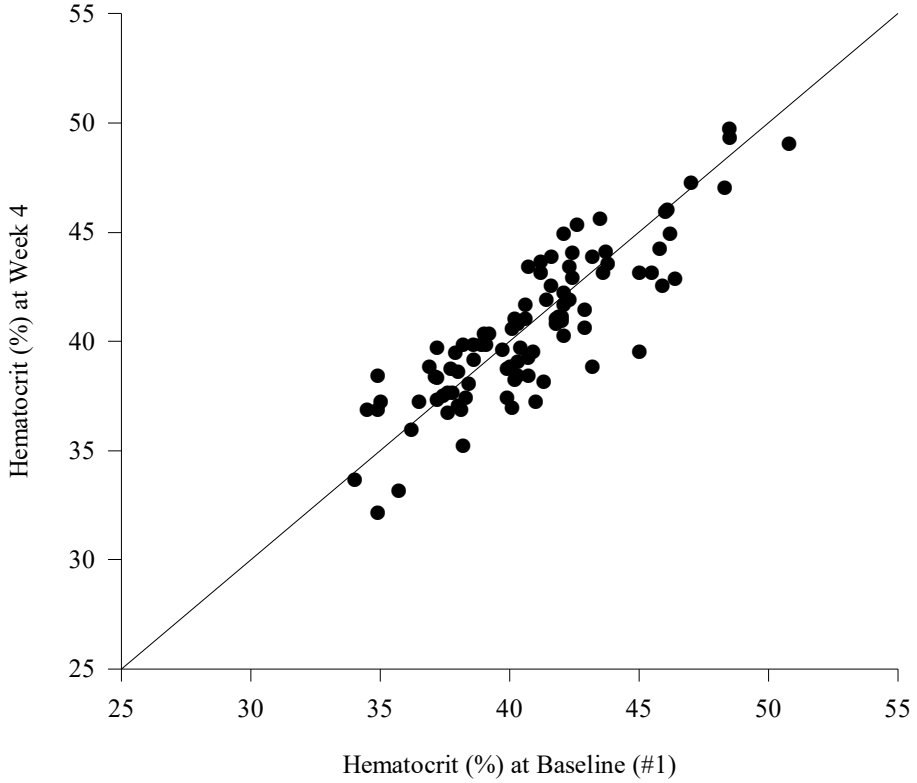


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 78 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set

Cohort 1 (0%/5%)

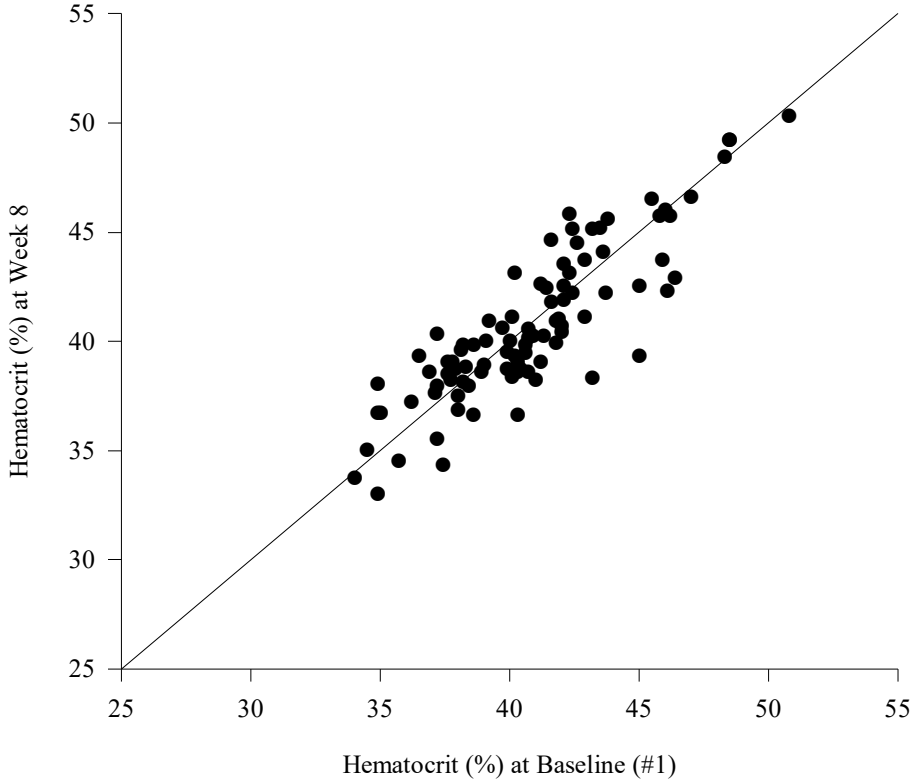


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 79 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (0%/5%)

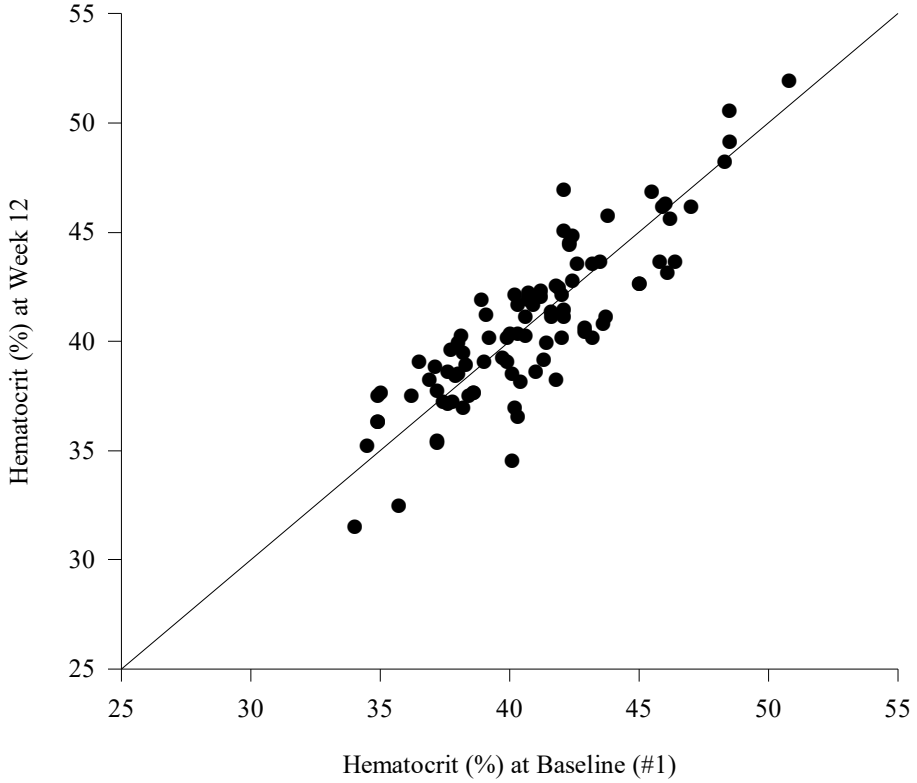


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 80 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (0%/5%)

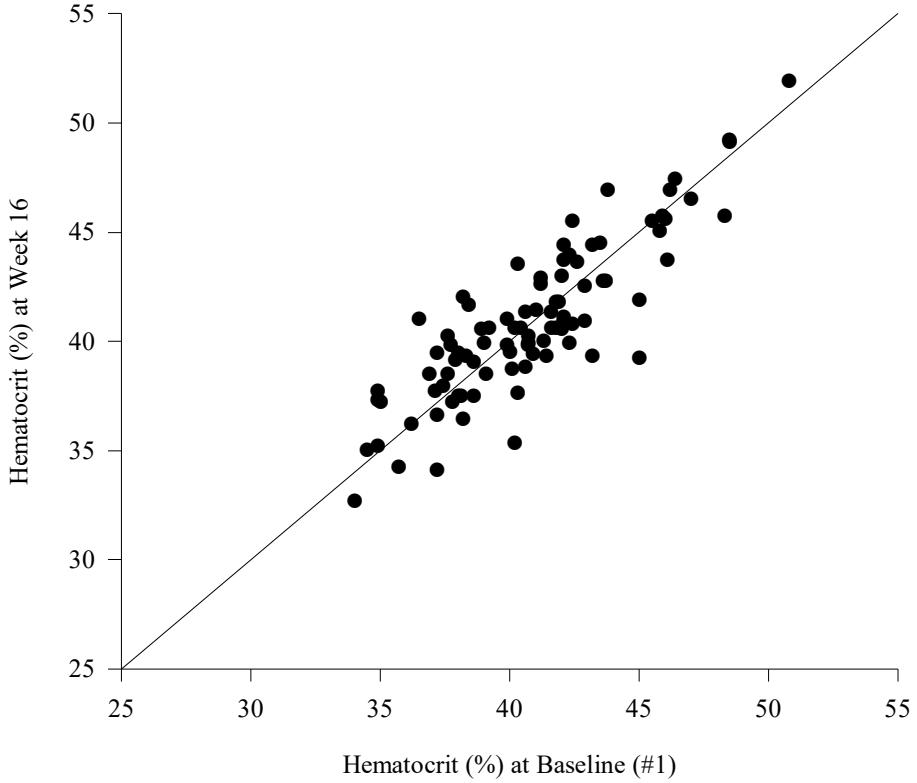


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 81 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (0%/5%)

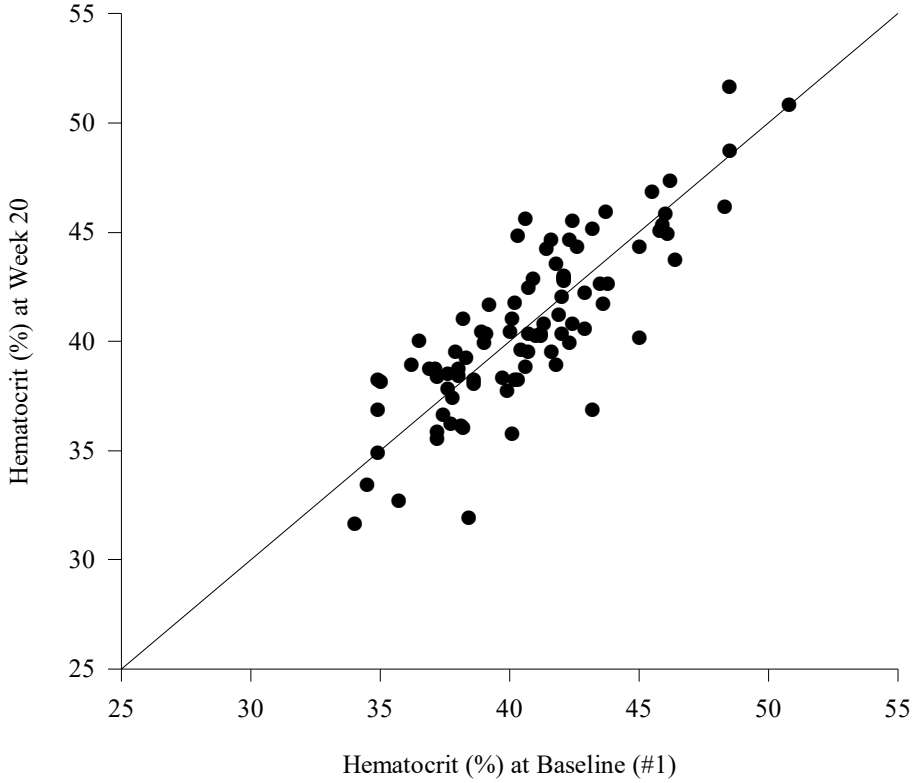


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 82 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (0%/5%)

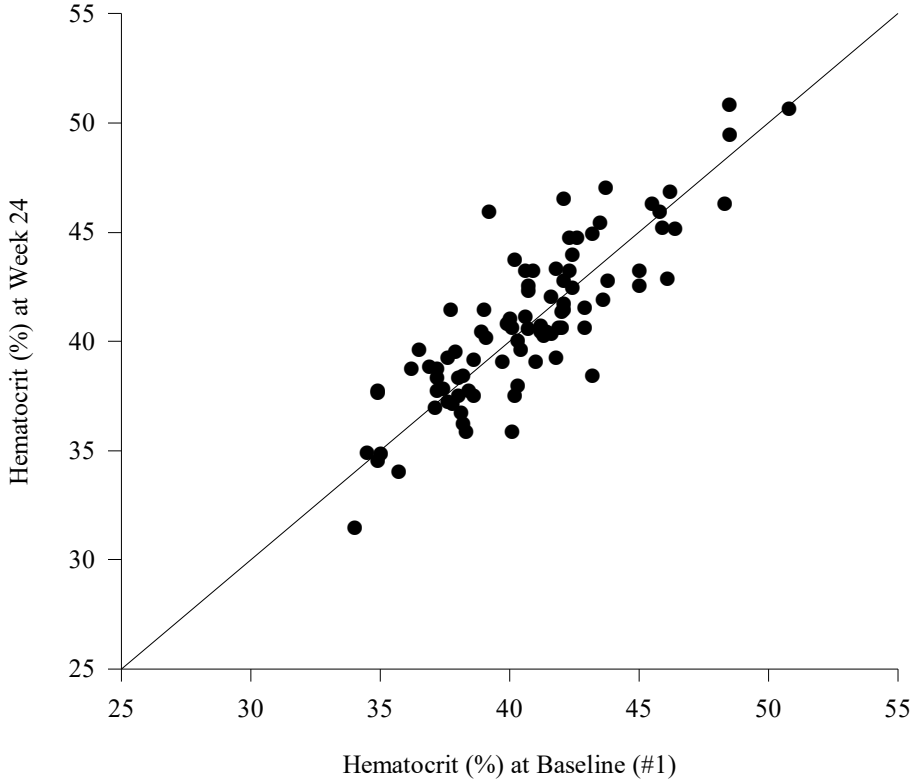


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 83 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (0%/5%)

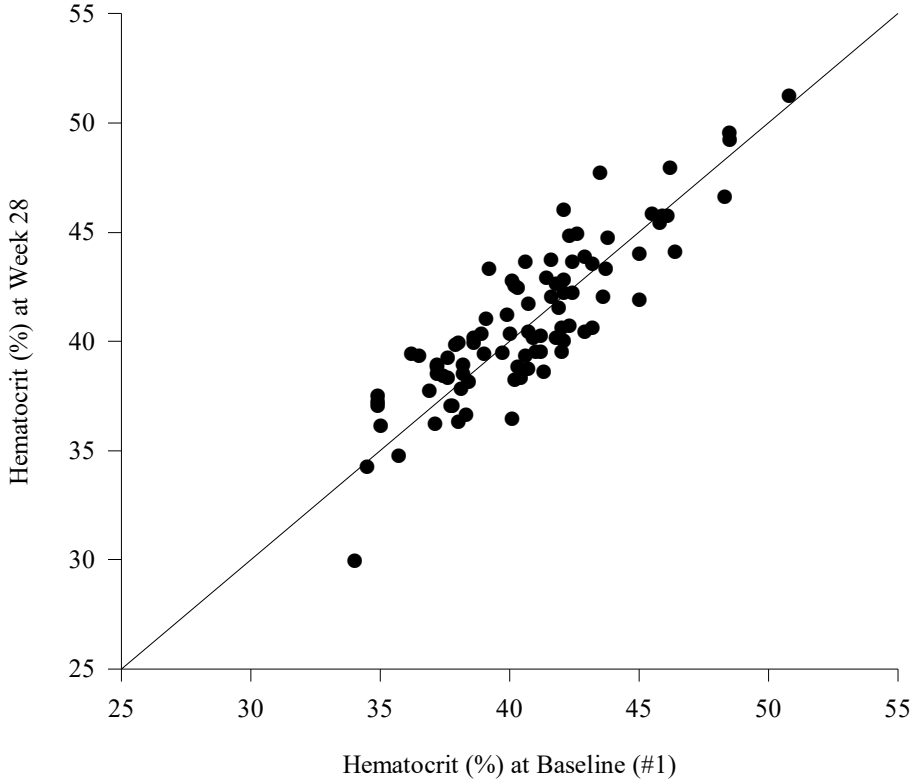


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 84 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (0%/5%)

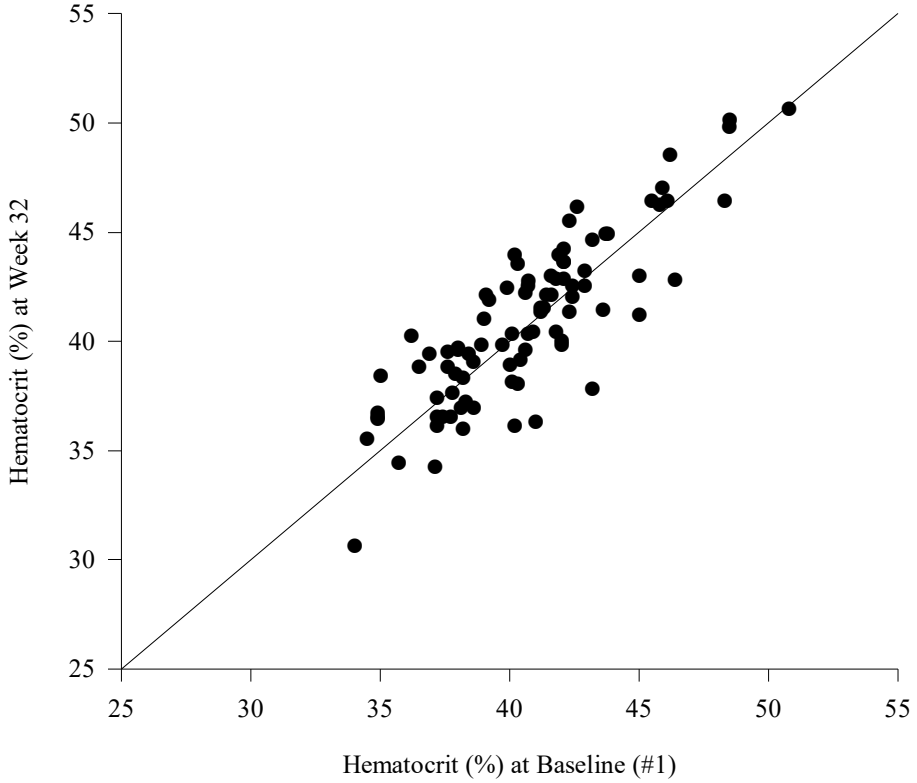


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 85 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (0%/5%)

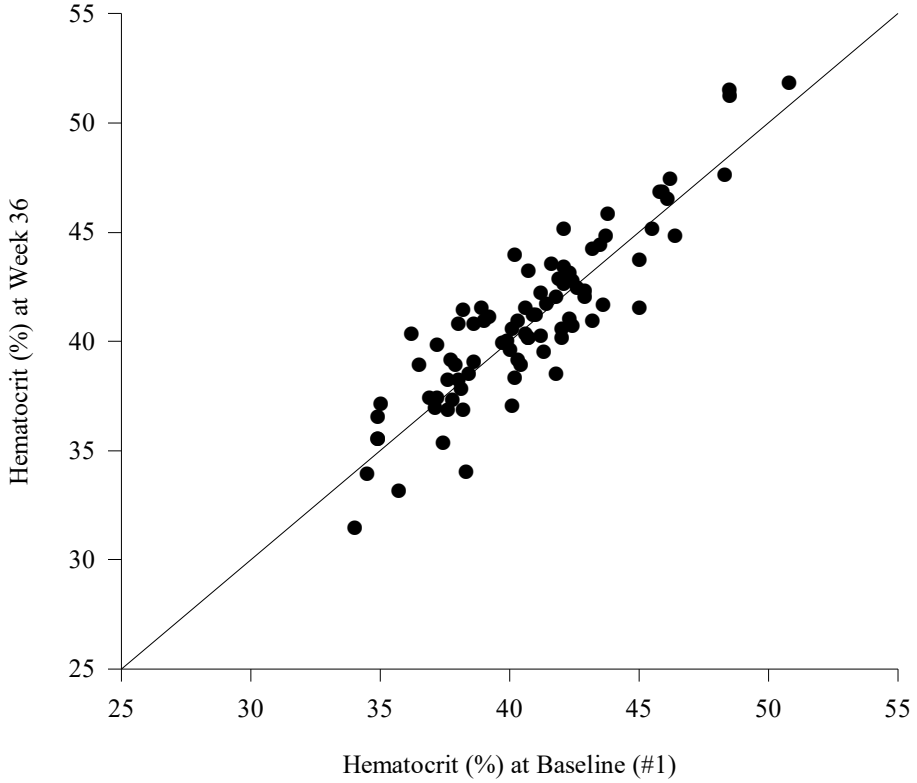


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 86 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (0%/5%)

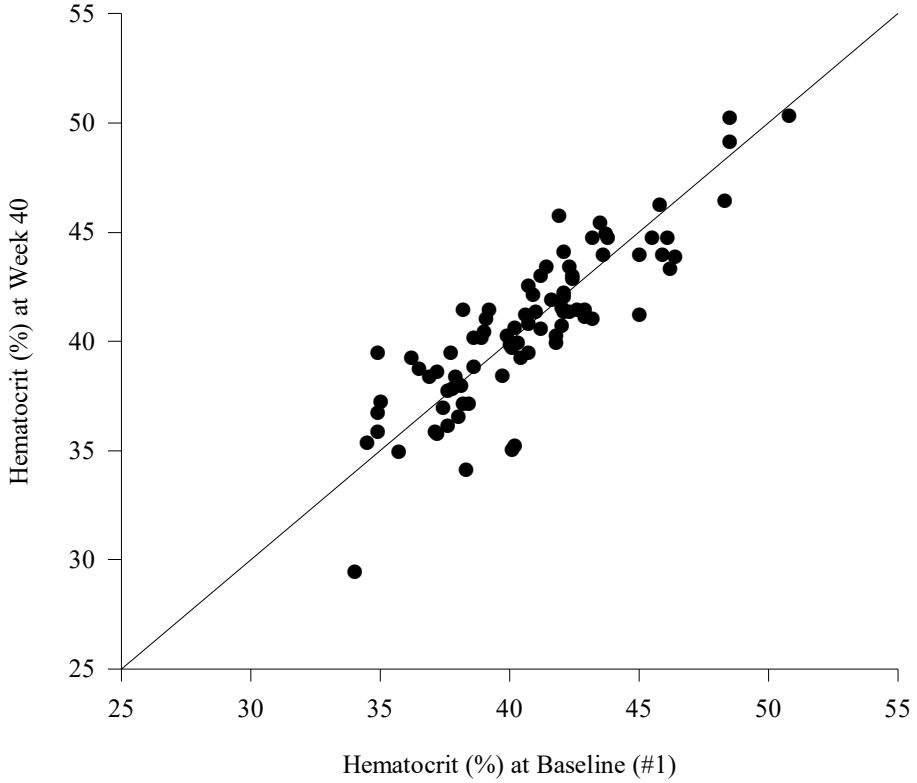


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 87 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (0%/5%)

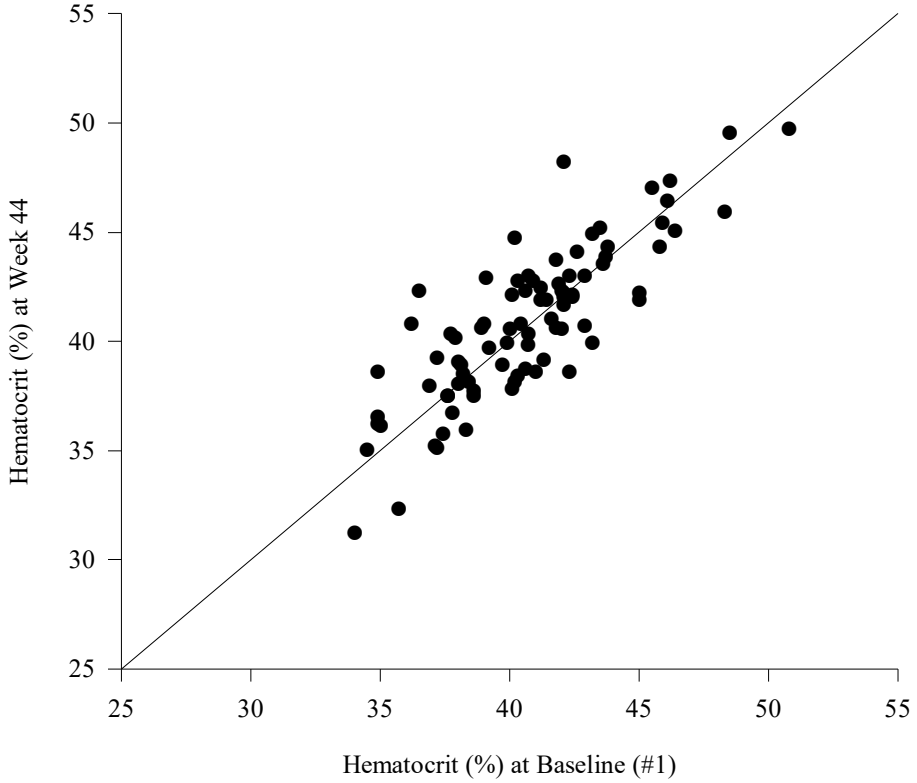


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 88 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (0%/5%)

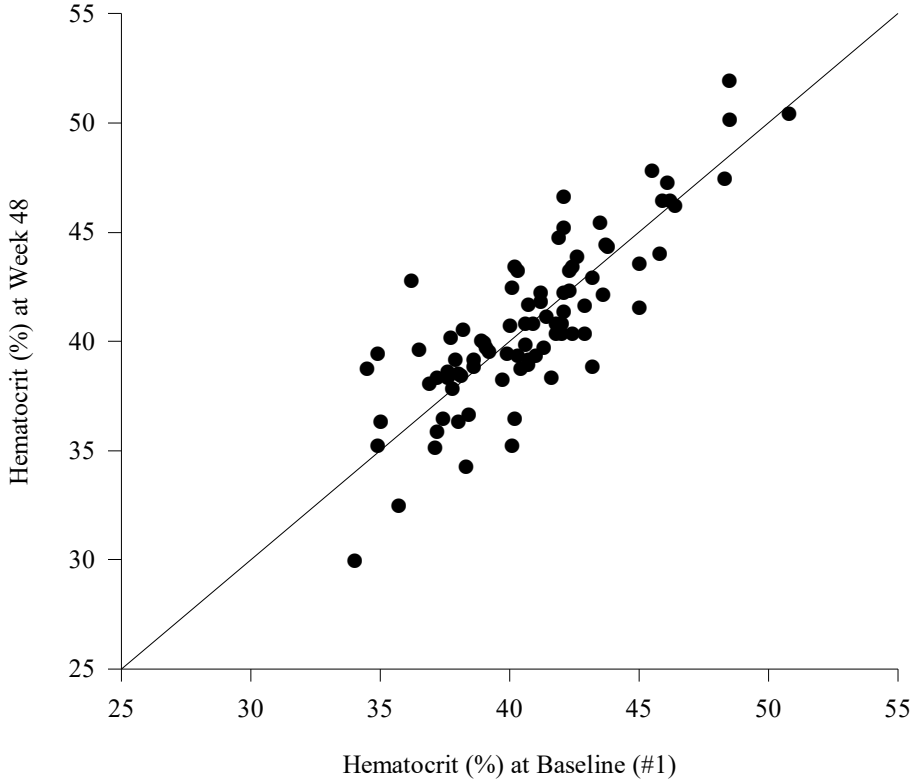


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 89 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (0%/5%)

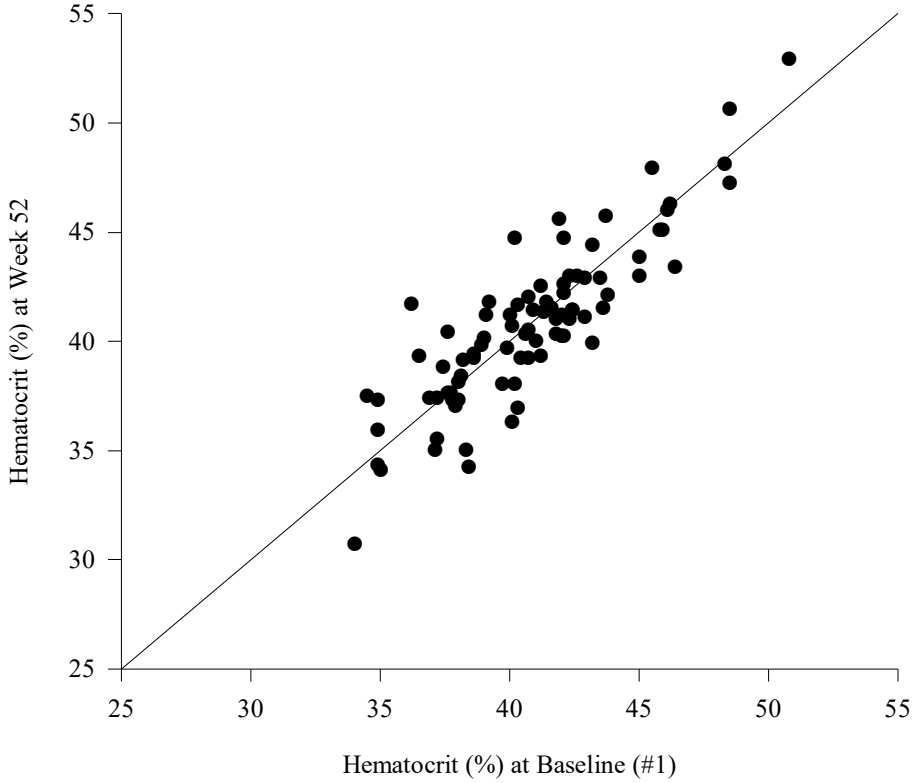


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 90 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (0%/5%)

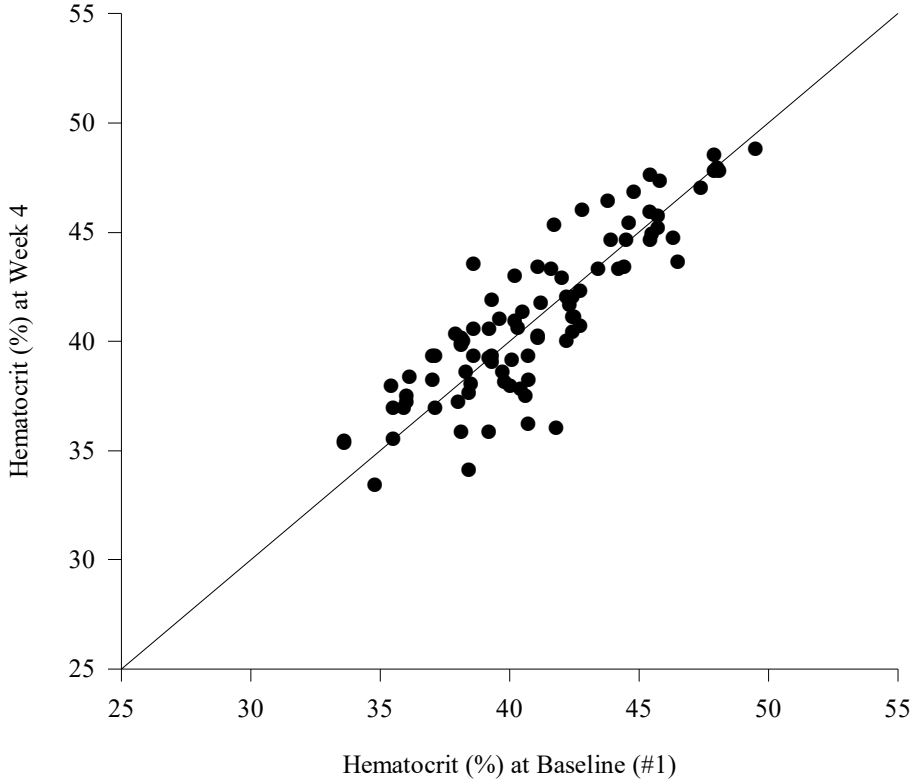


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 91 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (5%/5%)

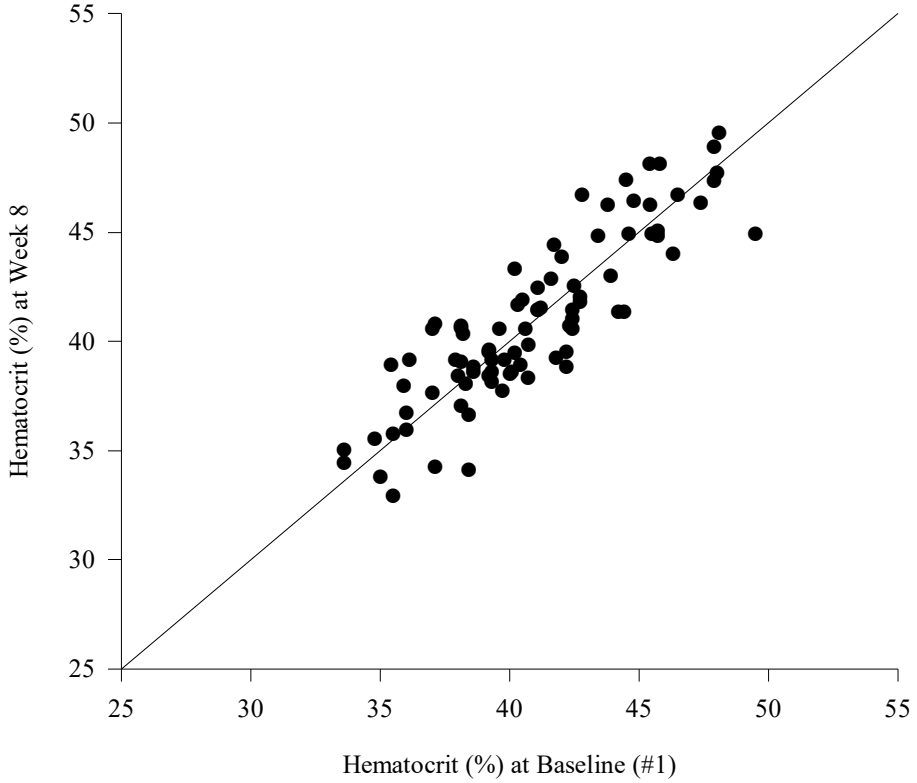


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 92 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (5%/5%)

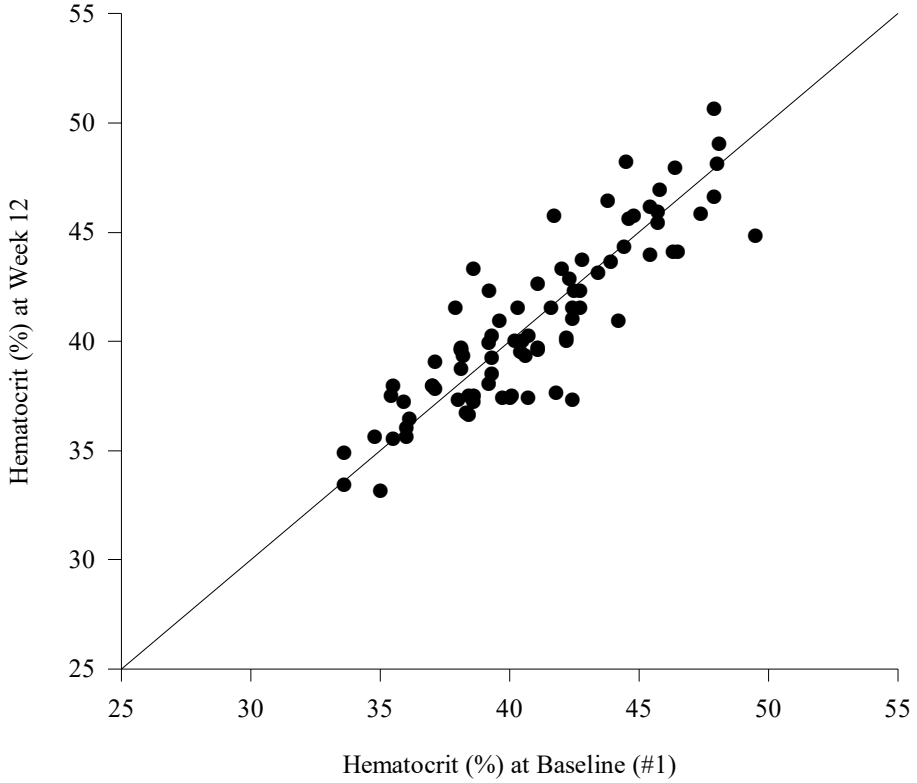


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 93 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (5%/5%)

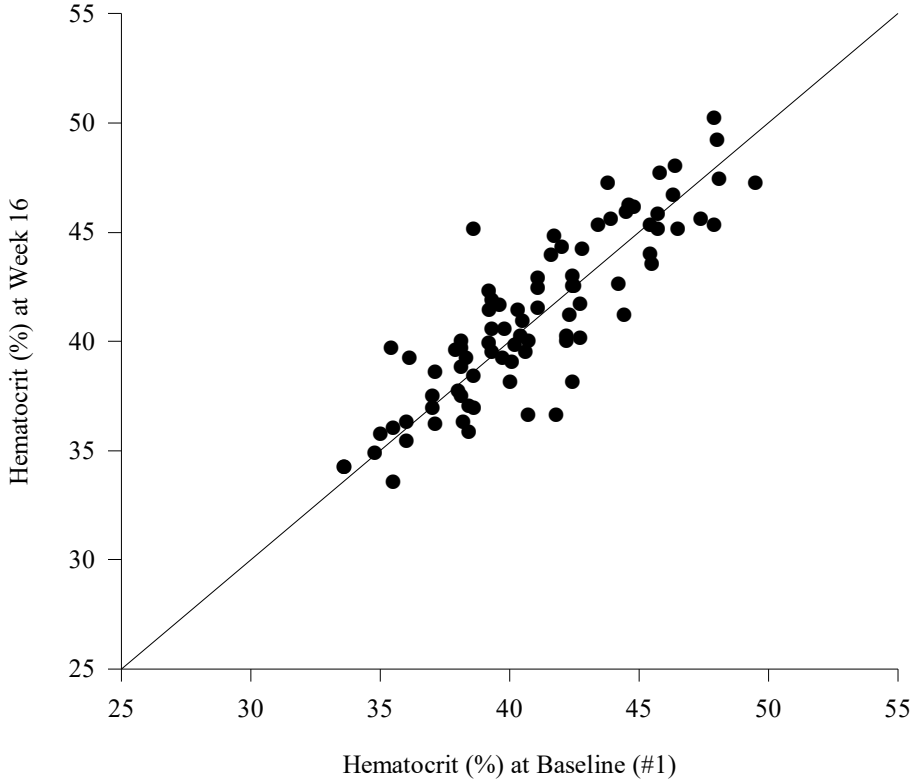


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 94 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (5%/5%)

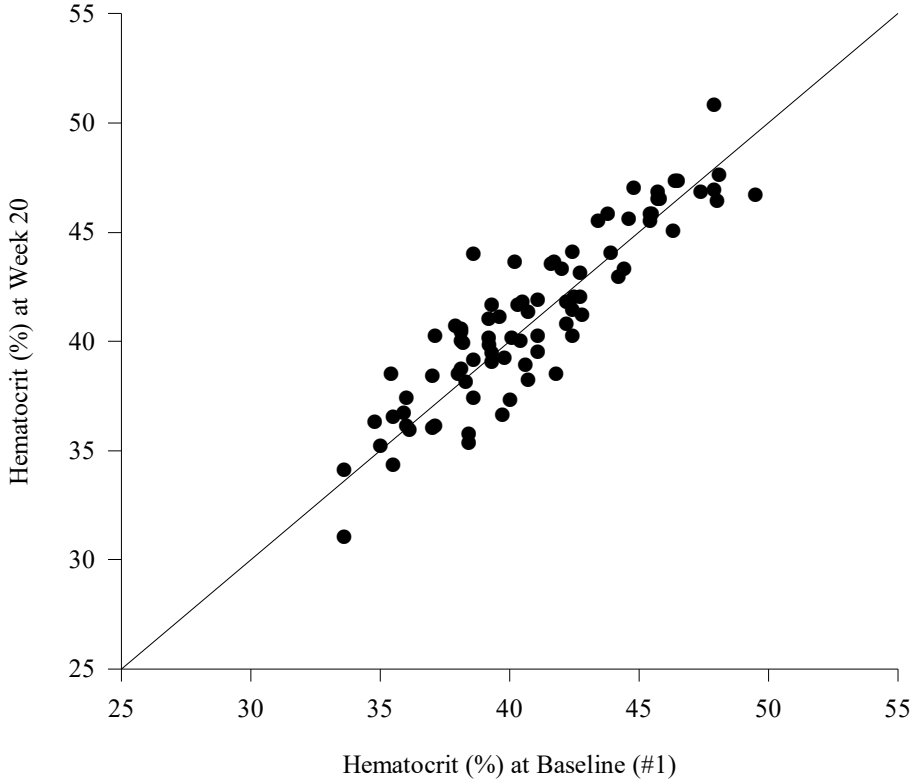


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 95 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (5%/5%)

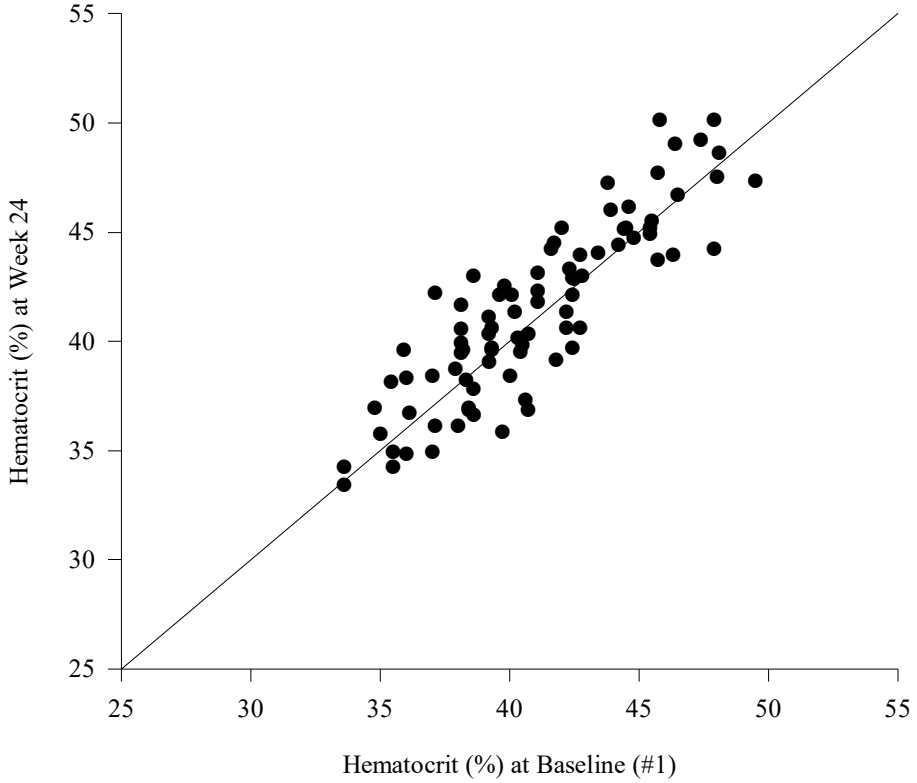


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 96 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (5%/5%)

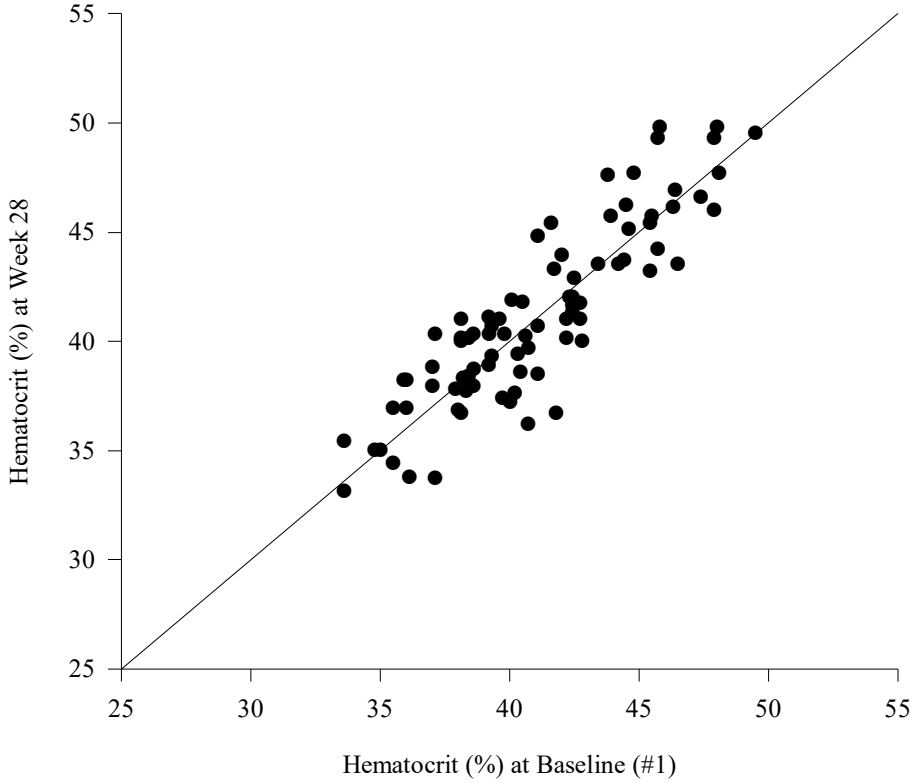


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 97 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (5%/5%)

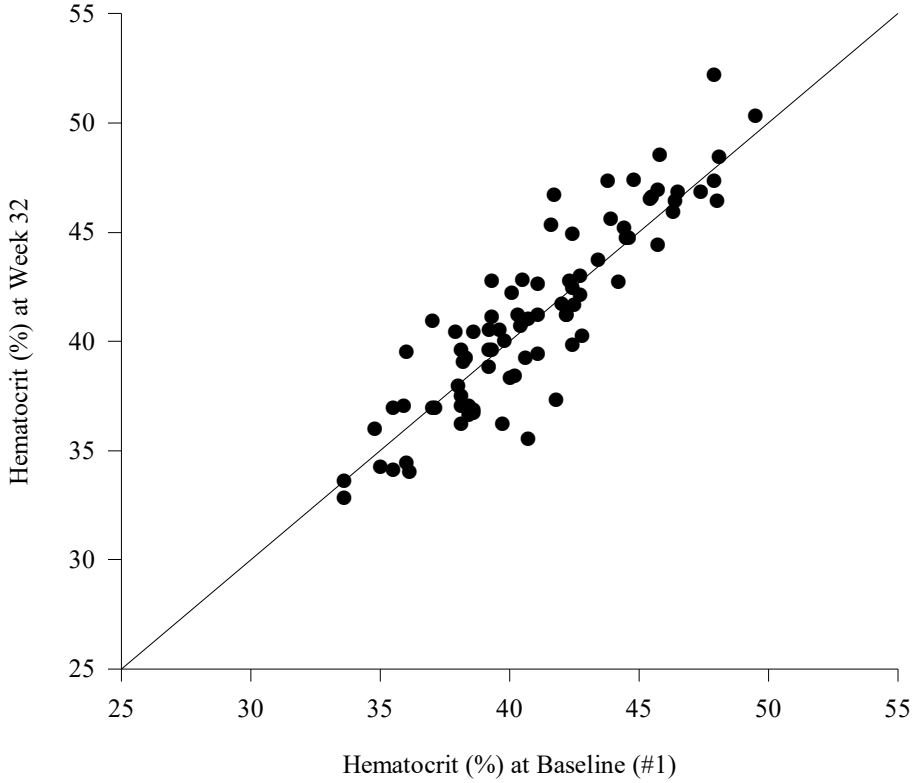


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 98 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (5%/5%)

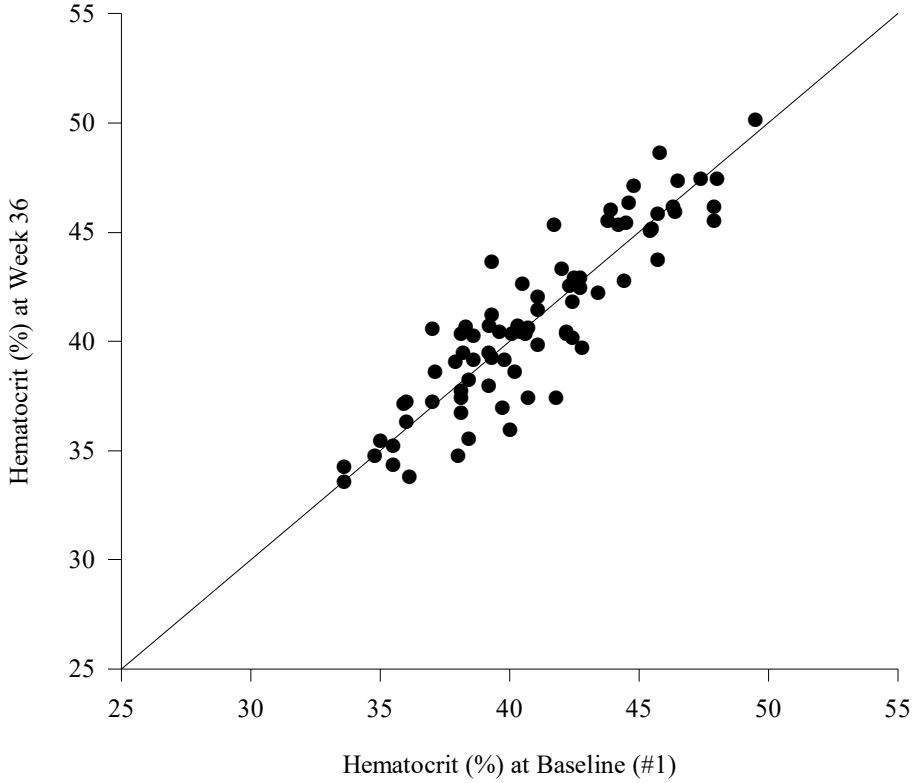


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 99 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (5%/5%)

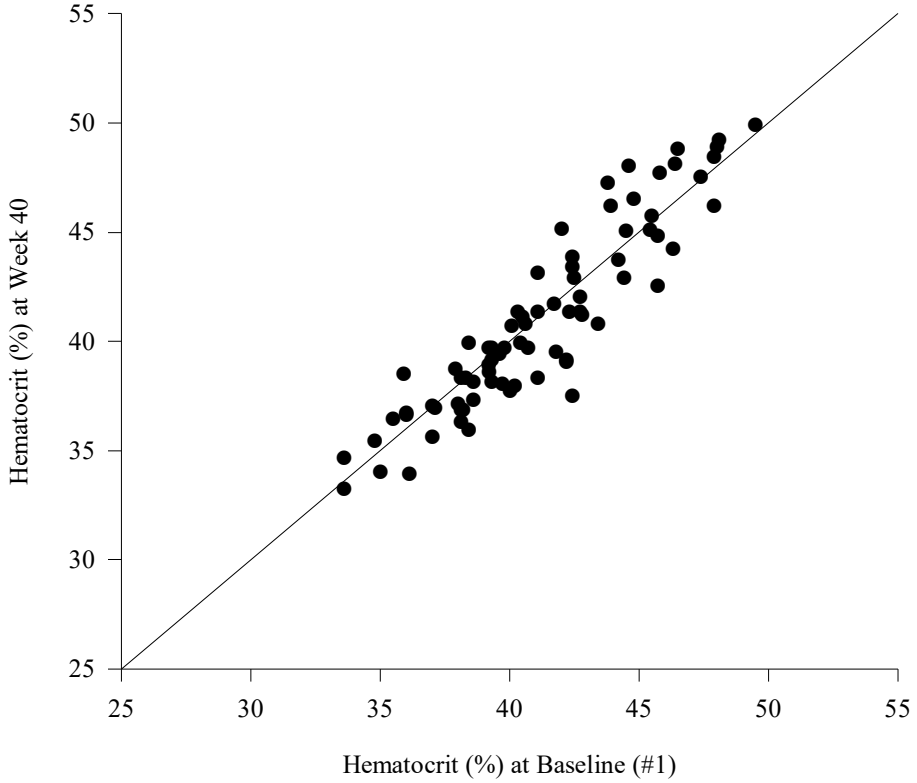


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 100 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (5%/5%)

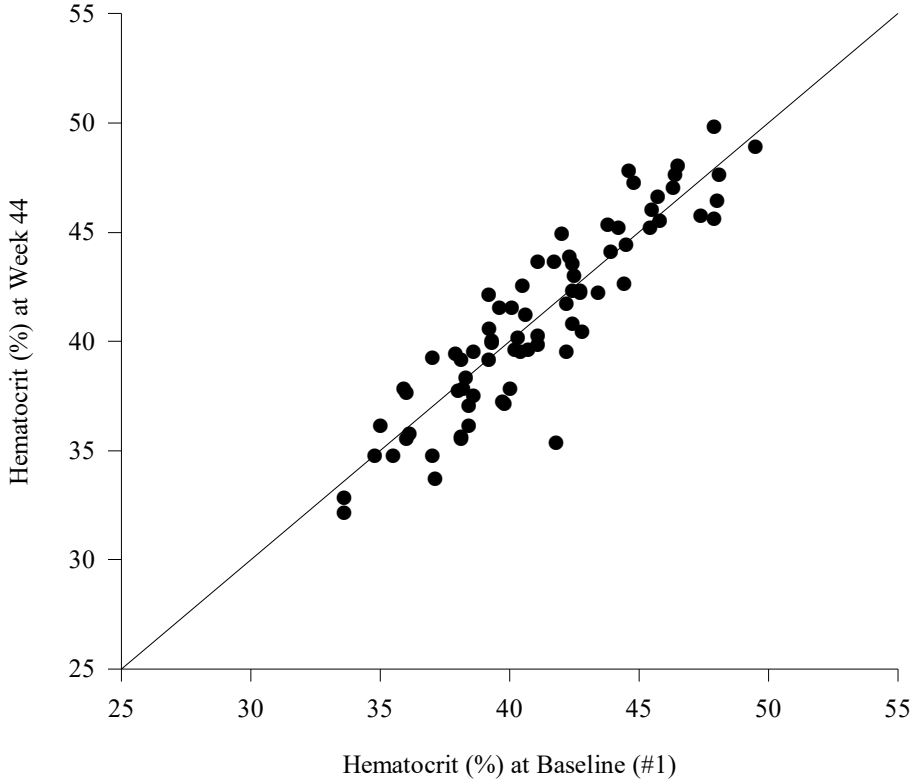


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 101 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (5%/5%)

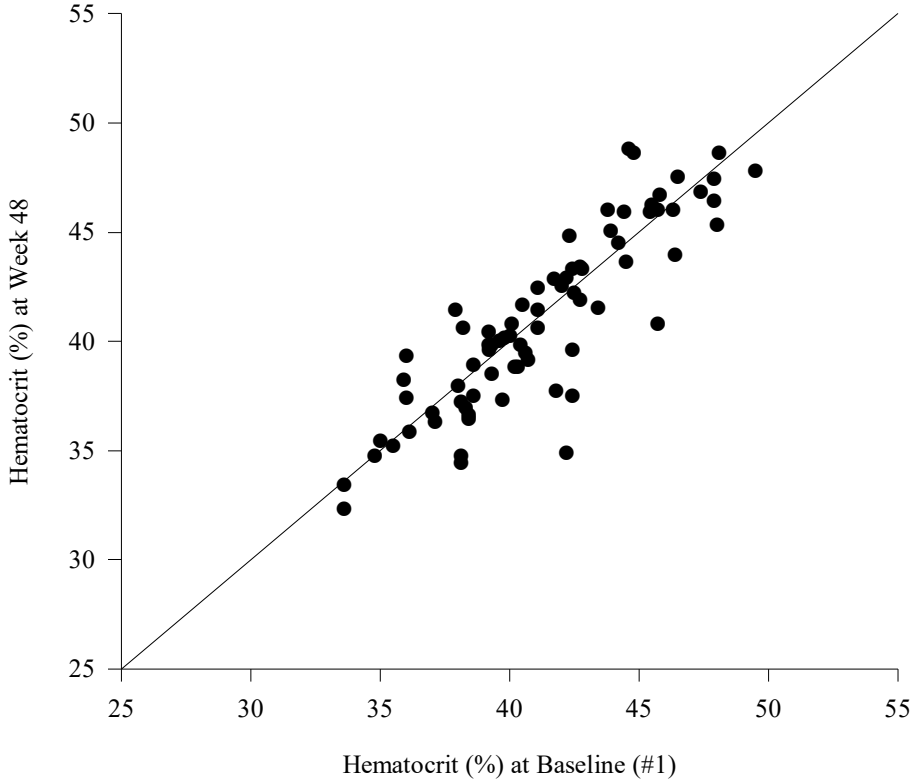


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 102 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (5%/5%)

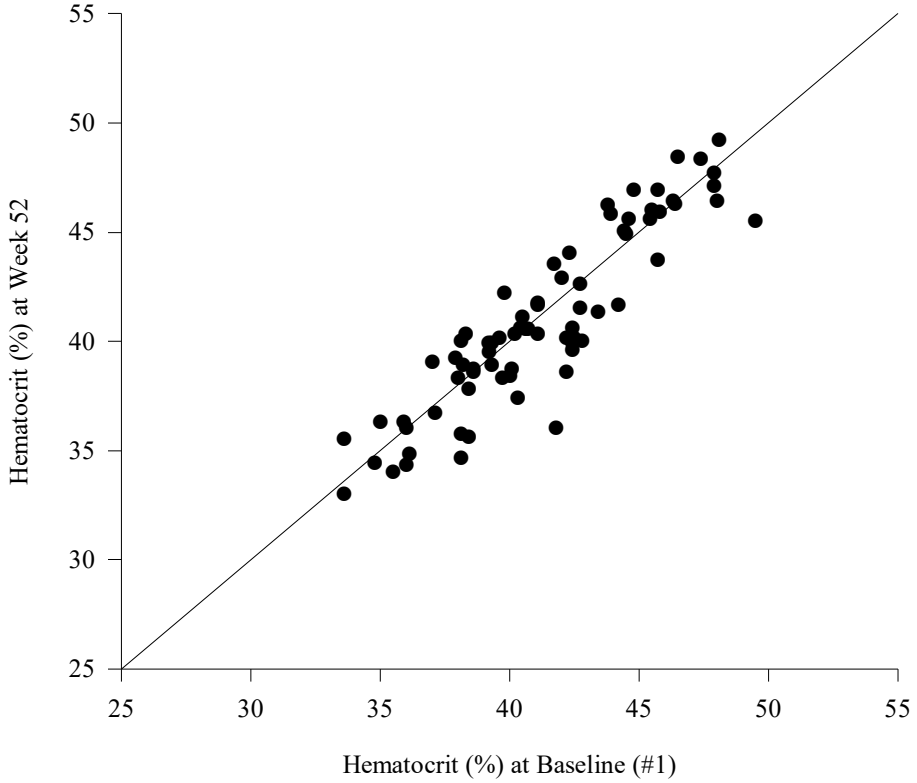


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 103 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (5%/5%)

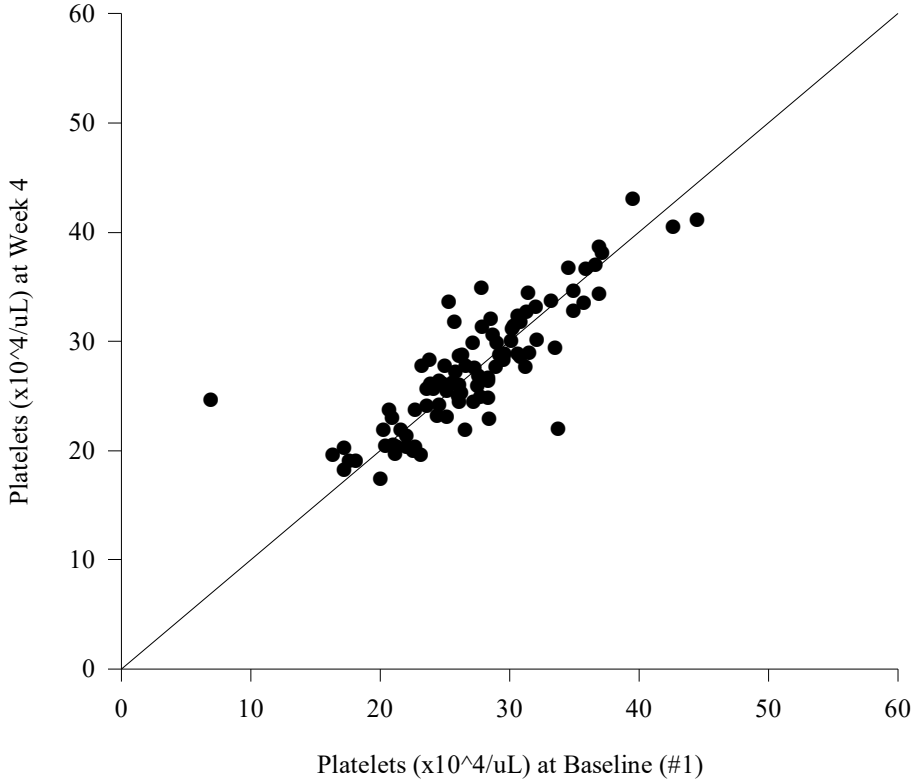


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 104 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (0%/5%)

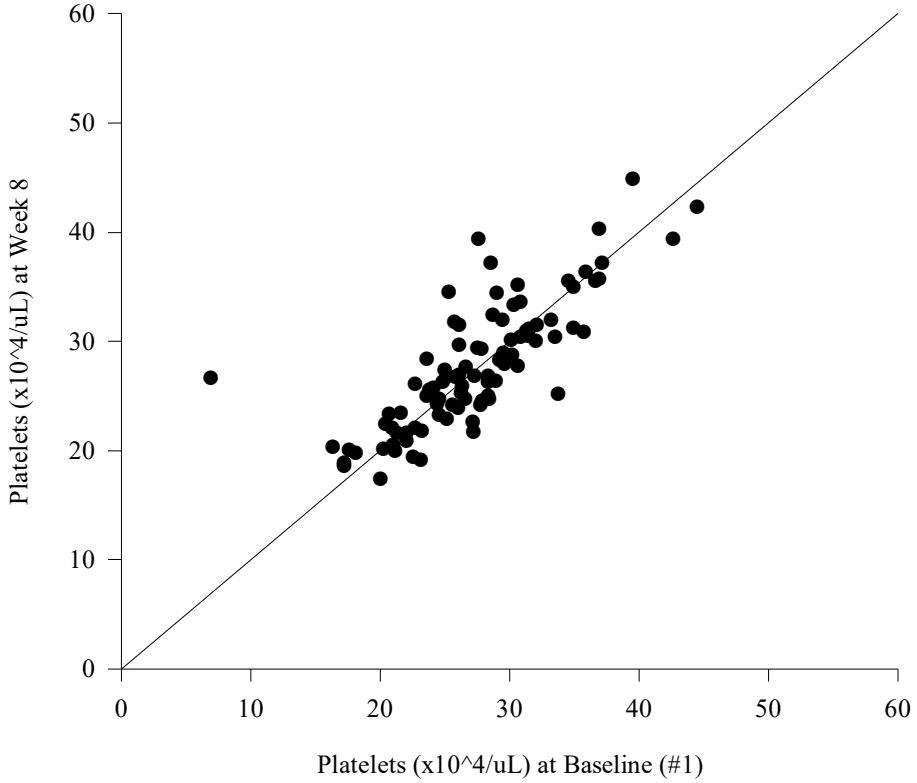


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 105 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (0%/5%)

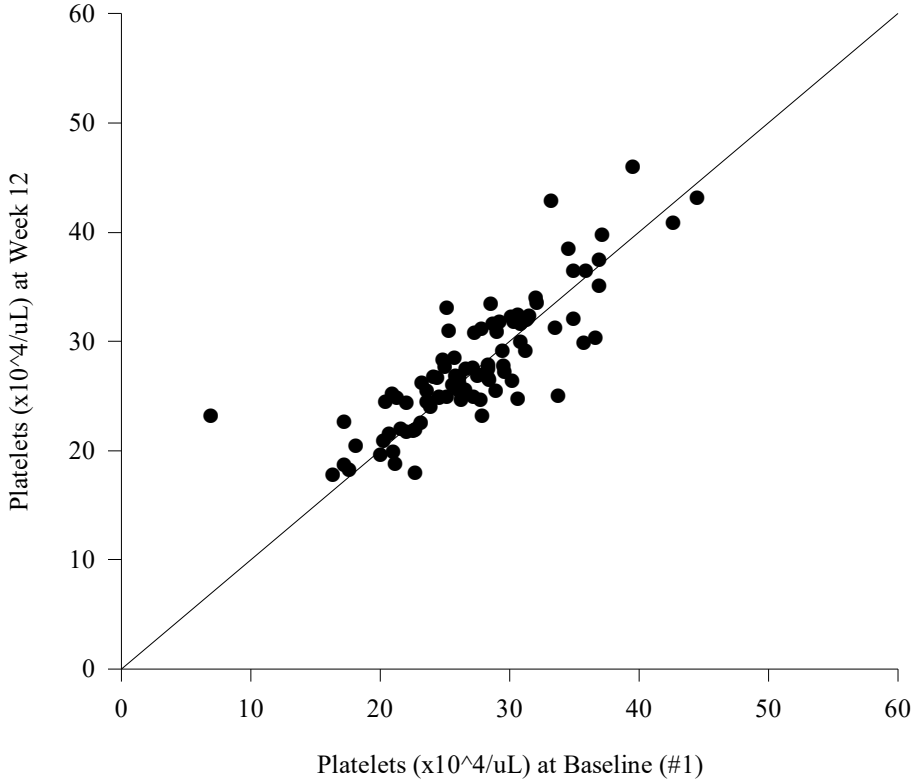


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 106 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (0%/5%)

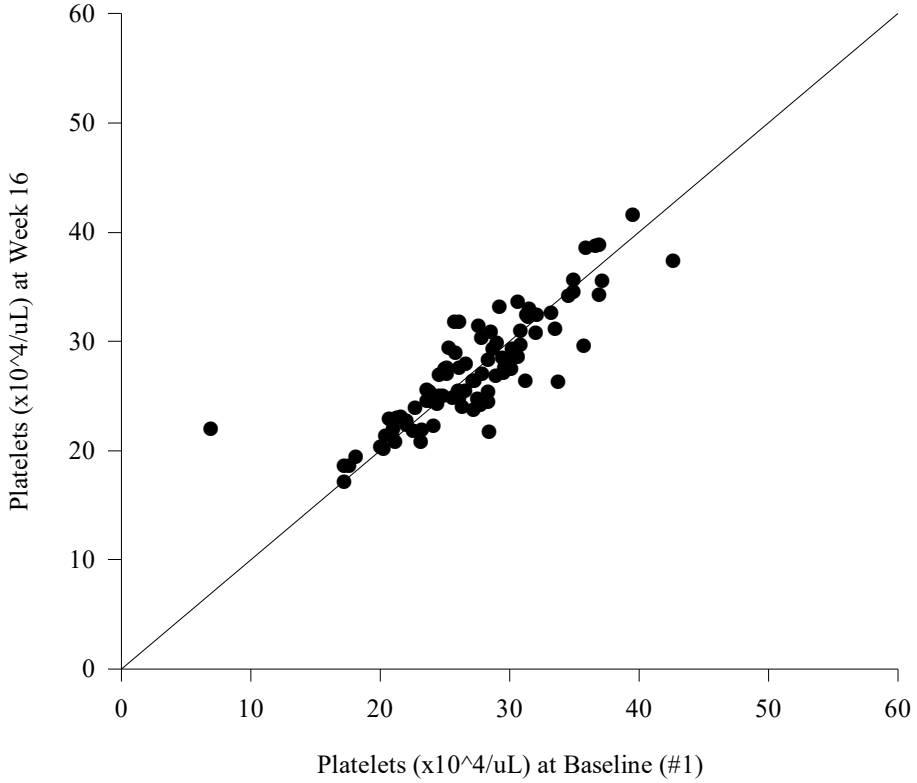


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 107 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (0%/5%)

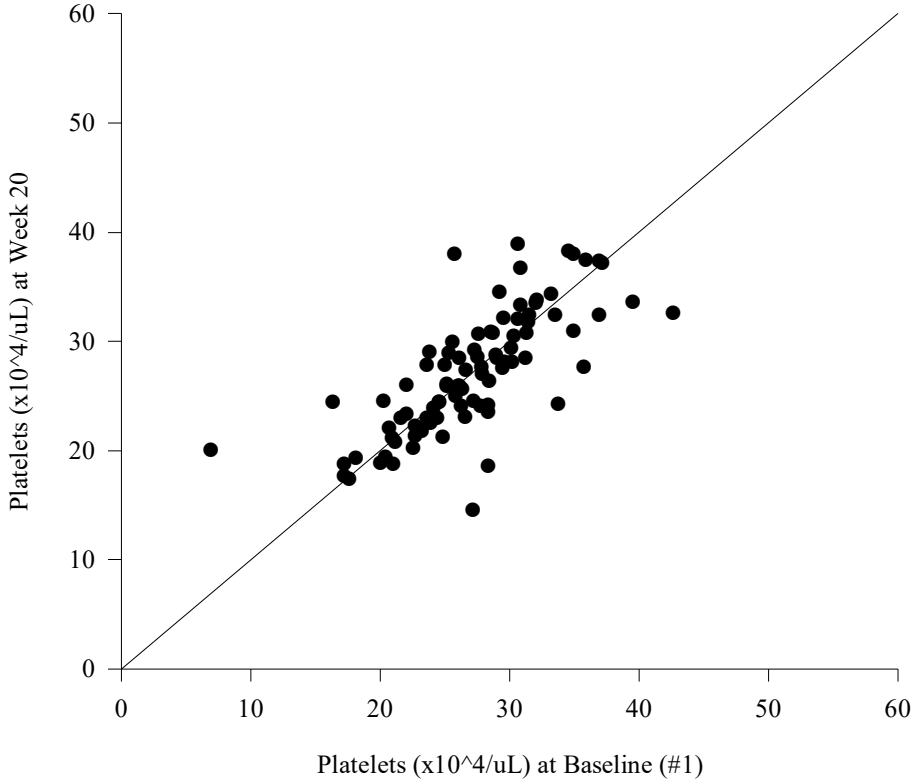


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 108 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (0%/5%)

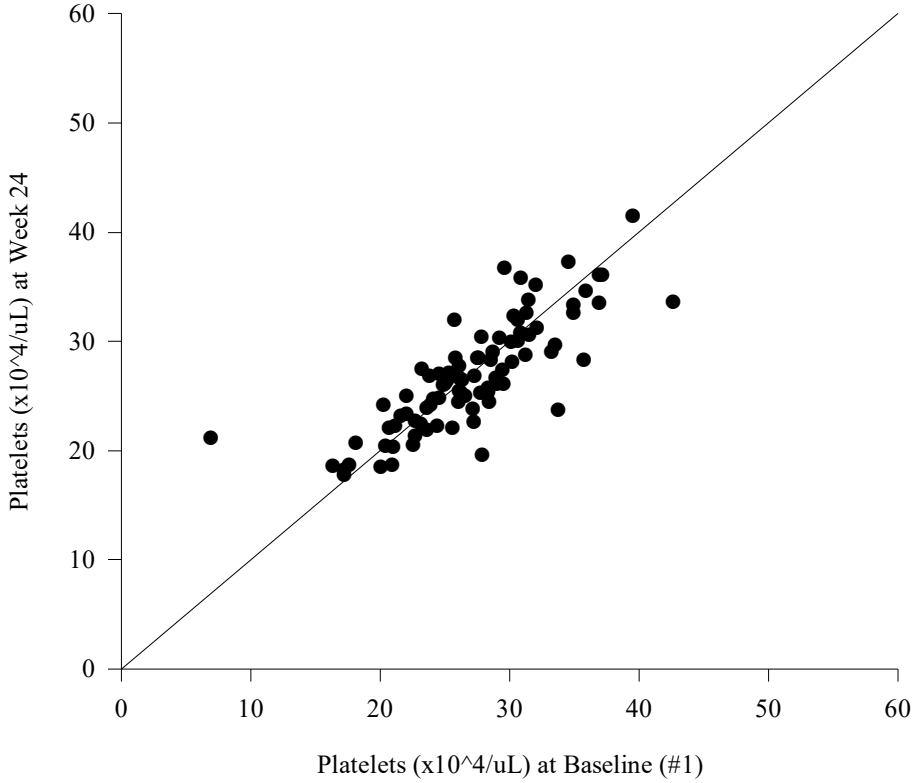


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 109 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (0%/5%)

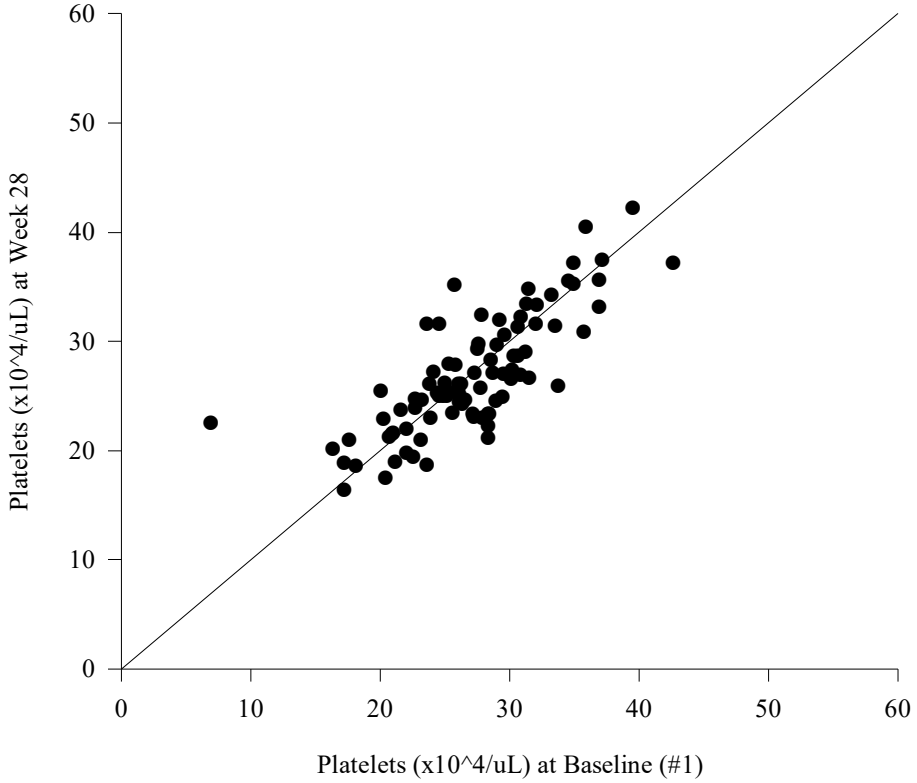


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 110 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (0%/5%)

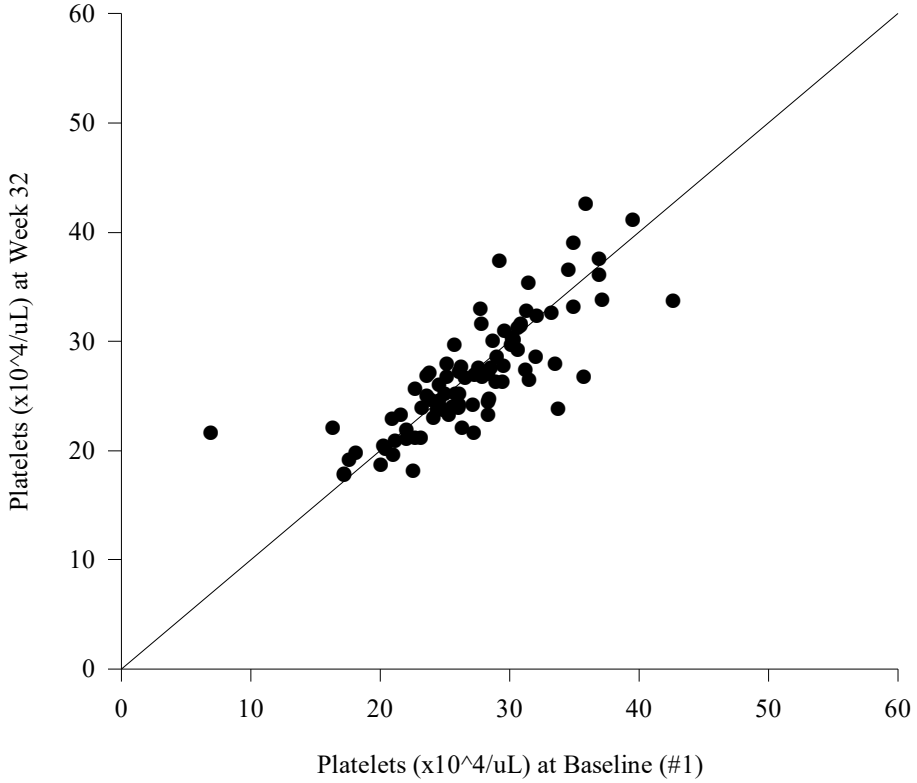


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 111 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (0%/5%)

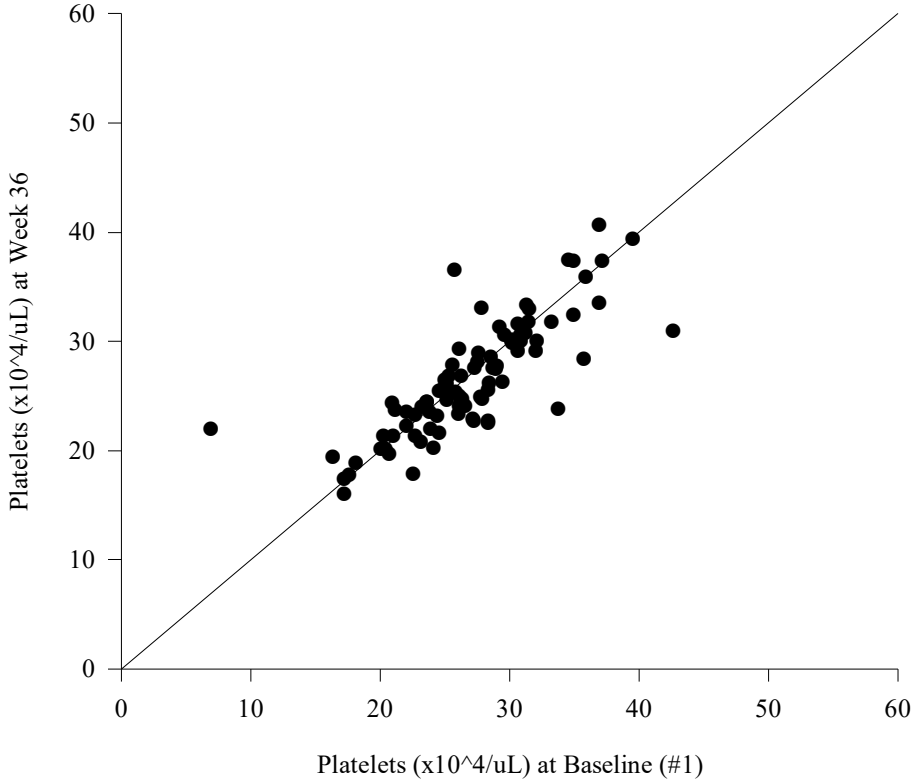


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 112 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (0%/5%)

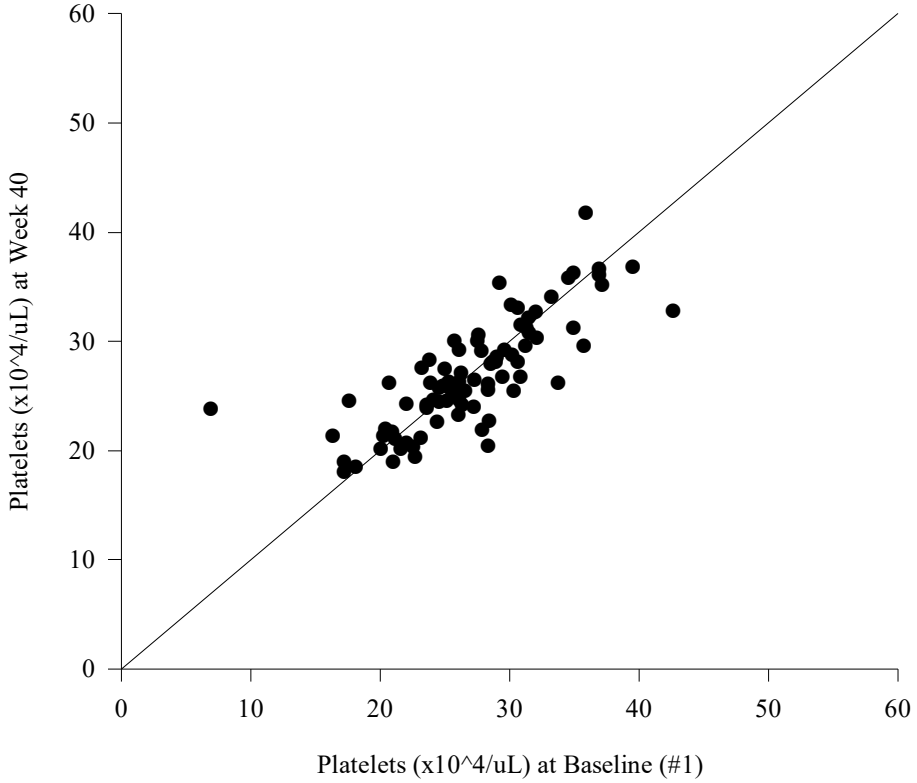


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 113 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (0%/5%)

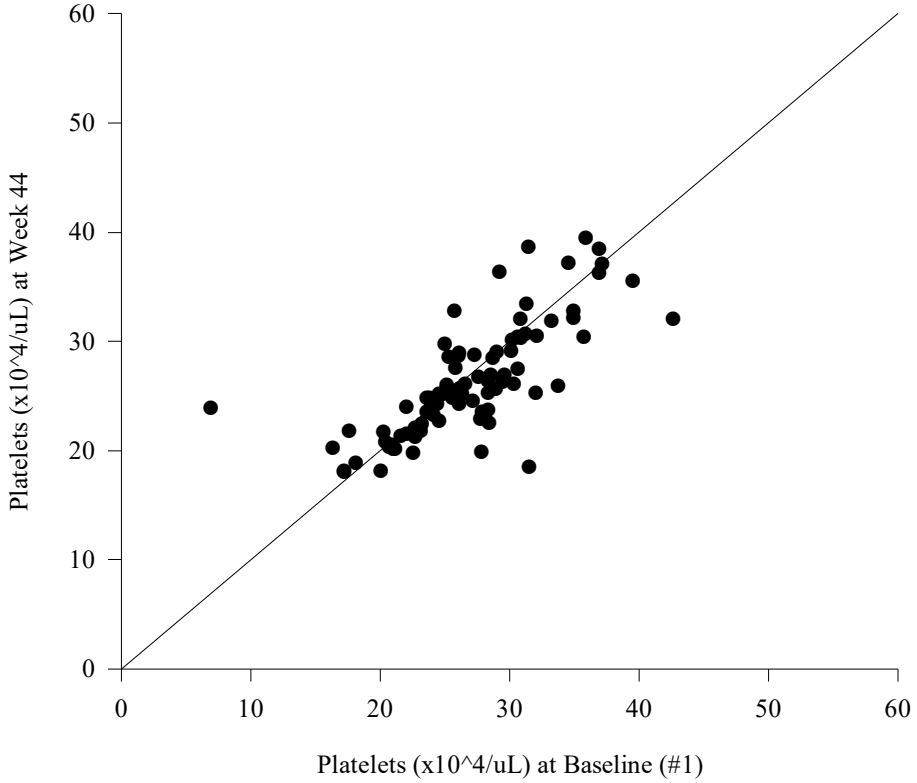


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 114 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (0%/5%)

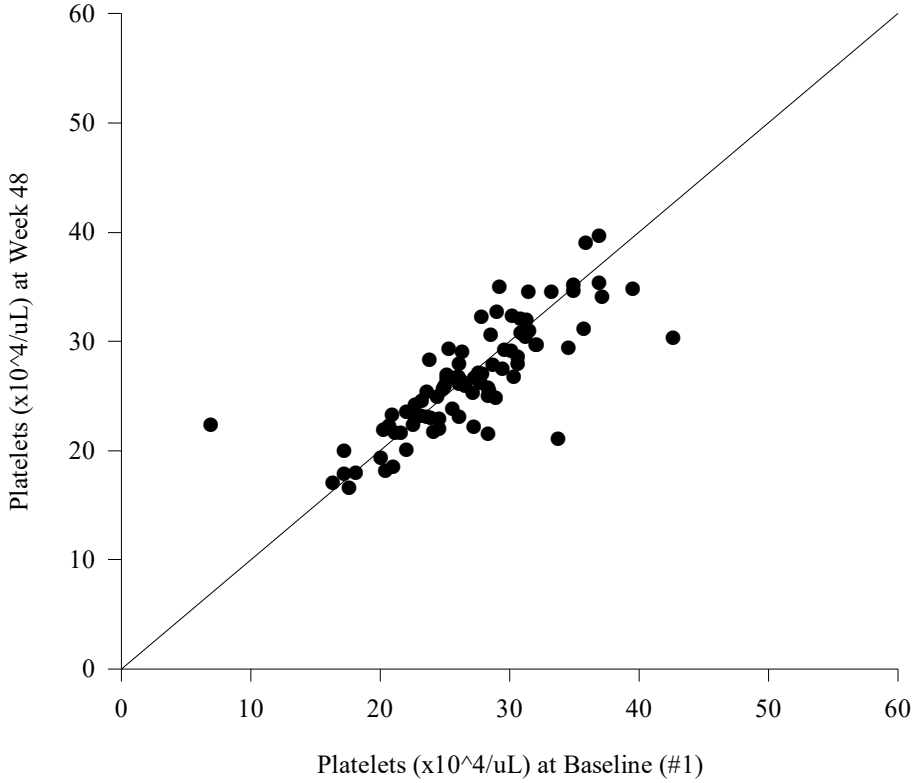


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 115 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (0%/5%)

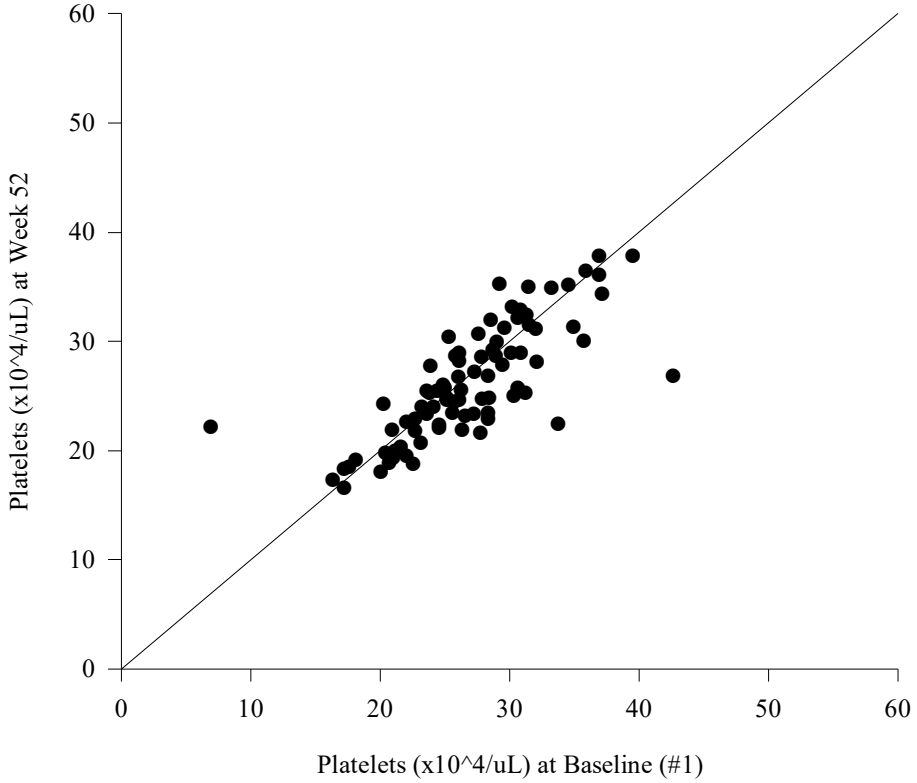


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 116 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (0%/5%)

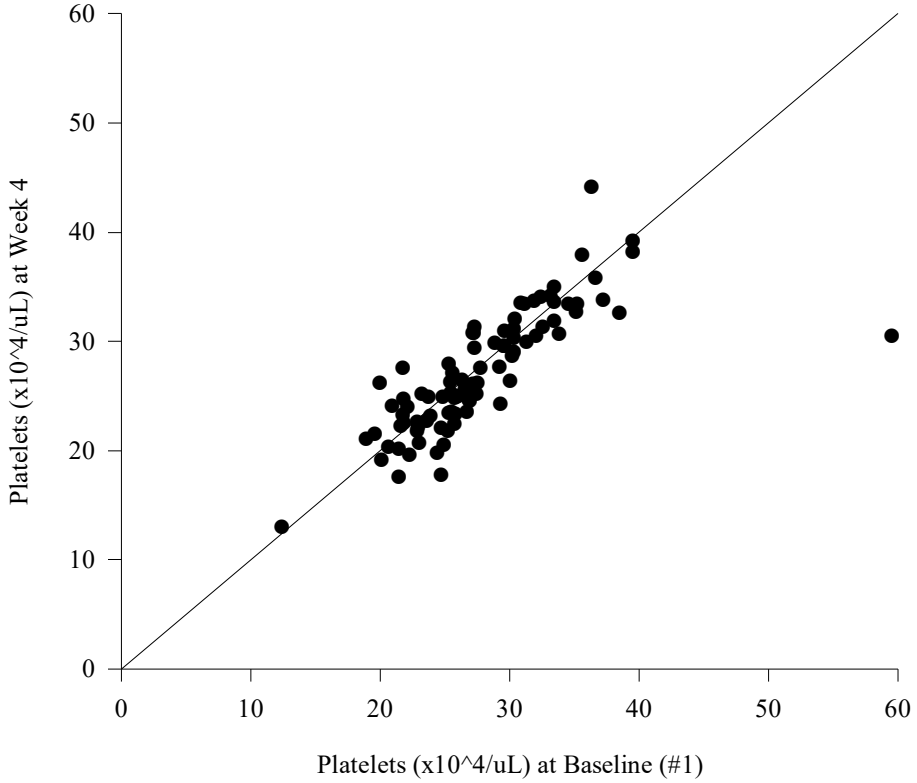


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 117 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (5%/5%)

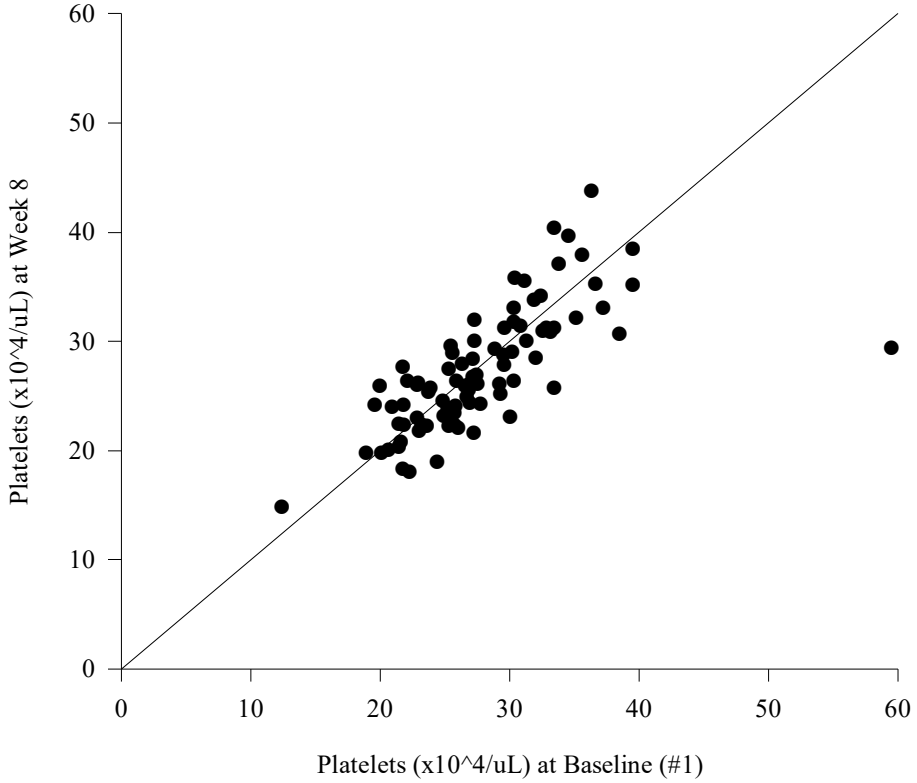


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 118 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (5%/5%)

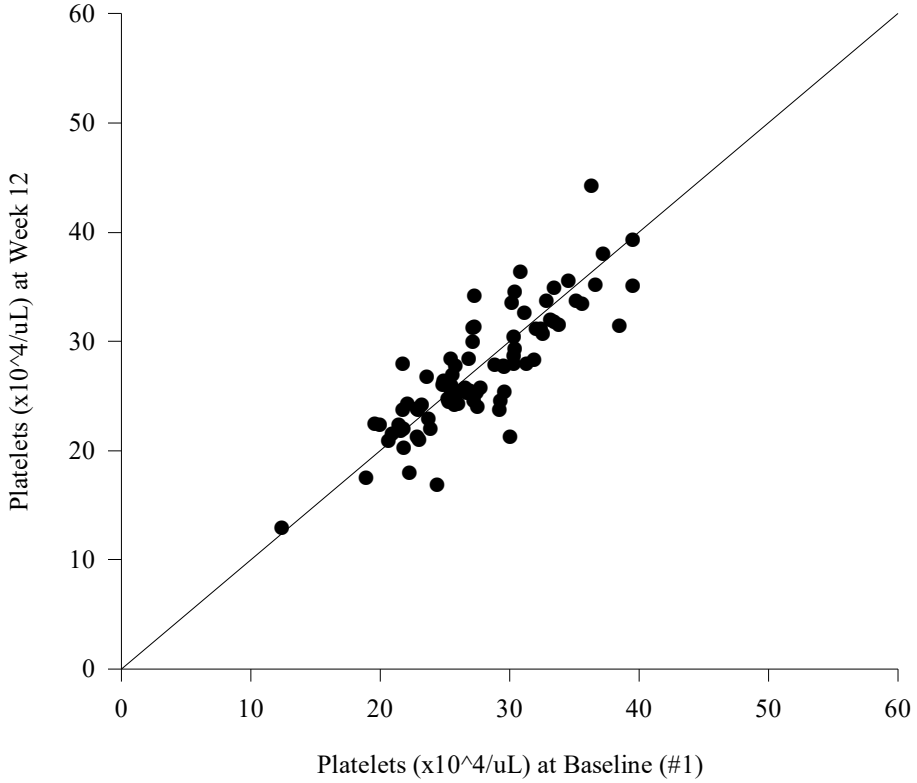


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 119 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (5%/5%)

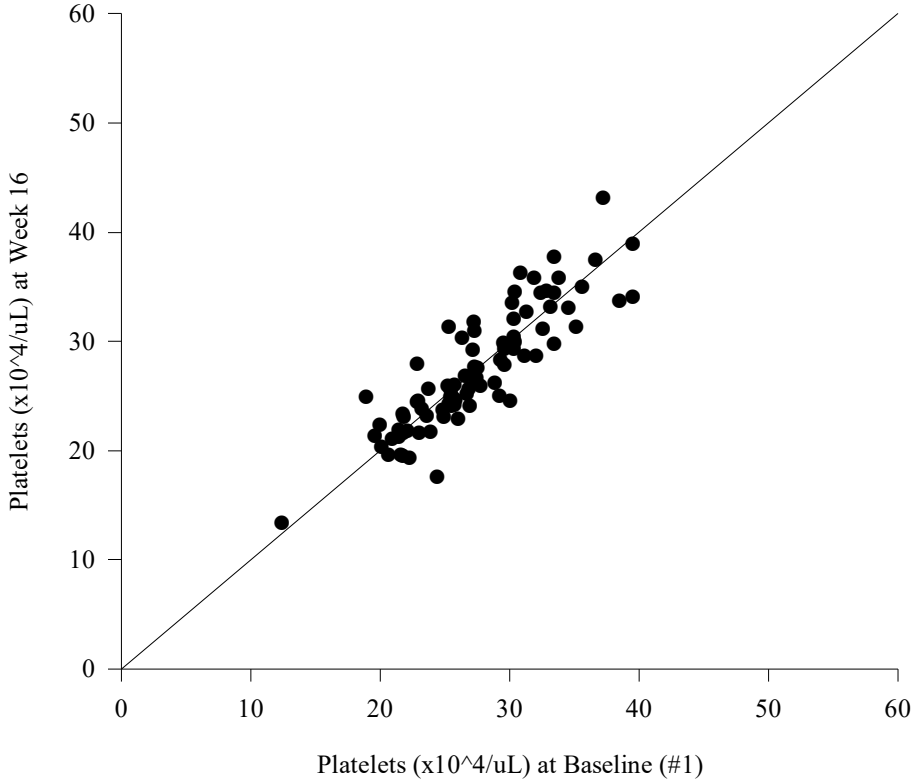


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 120 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (5%/5%)

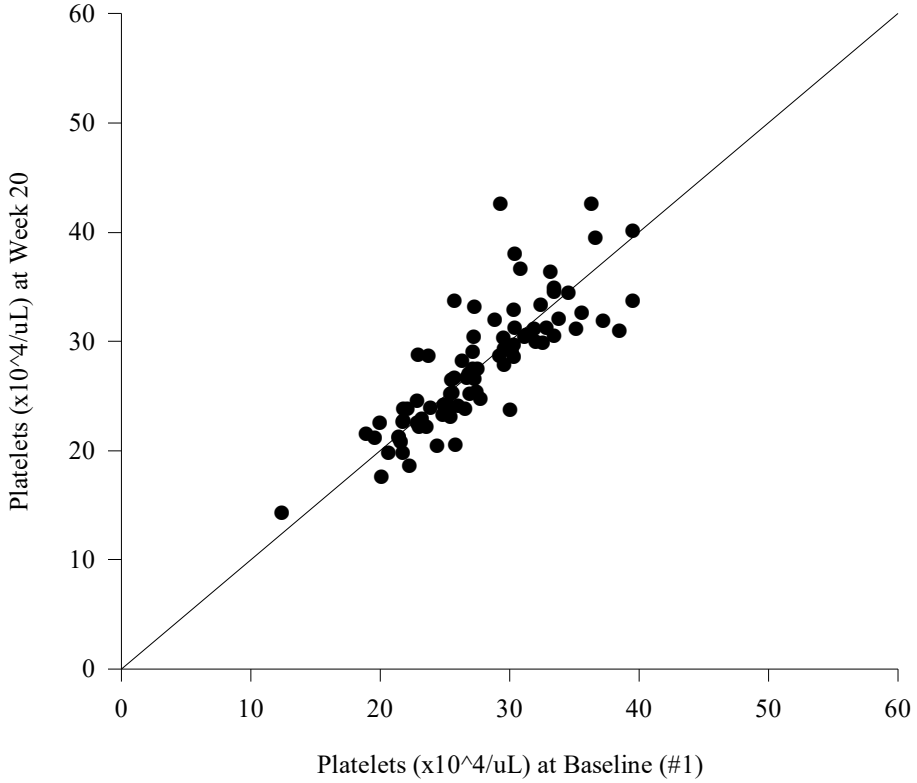


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 121 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (5%/5%)

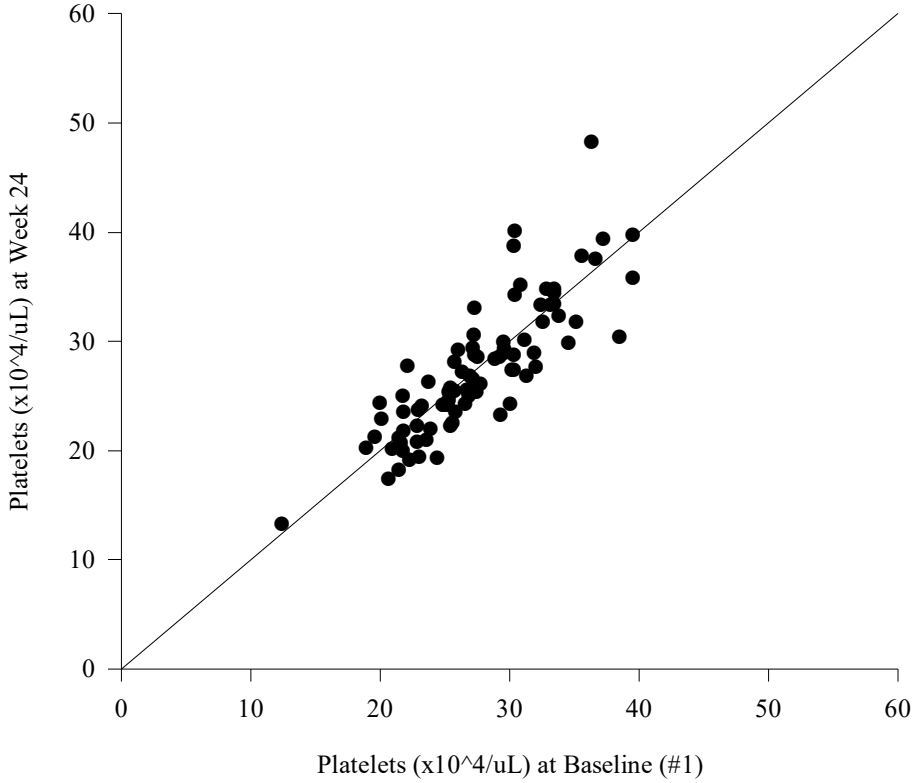


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 122 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (5%/5%)

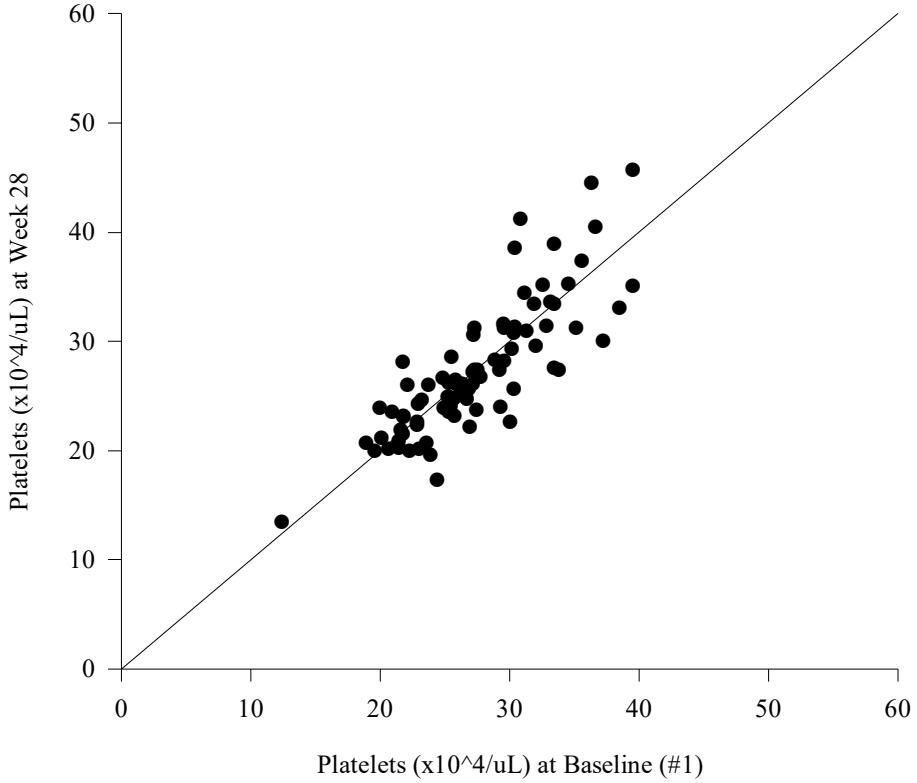


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 123 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (5%/5%)

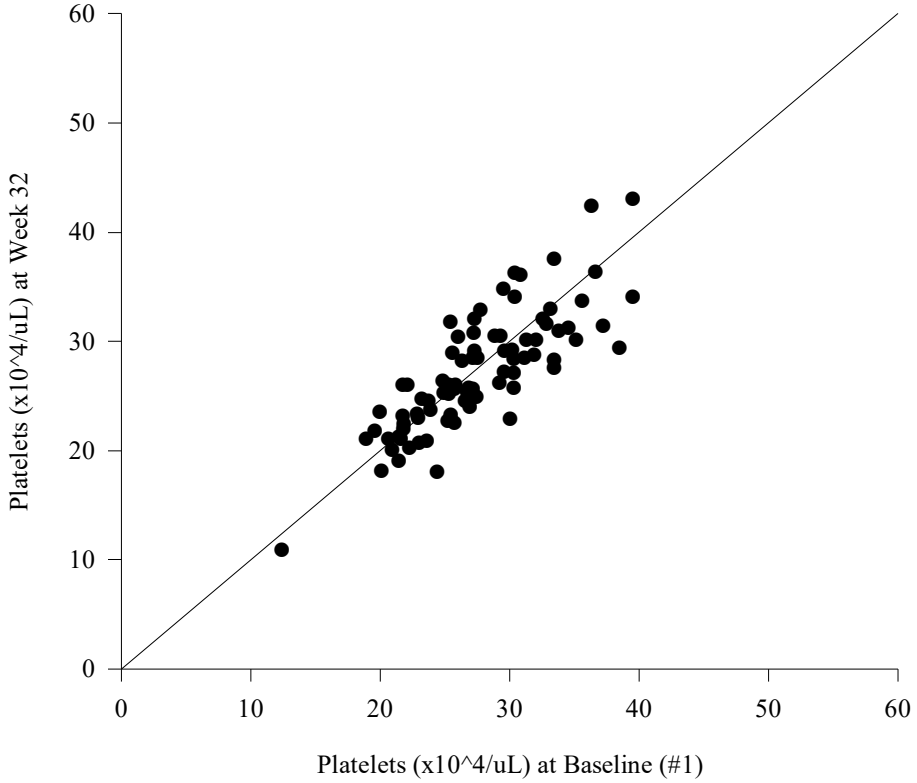


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 124 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (5%/5%)

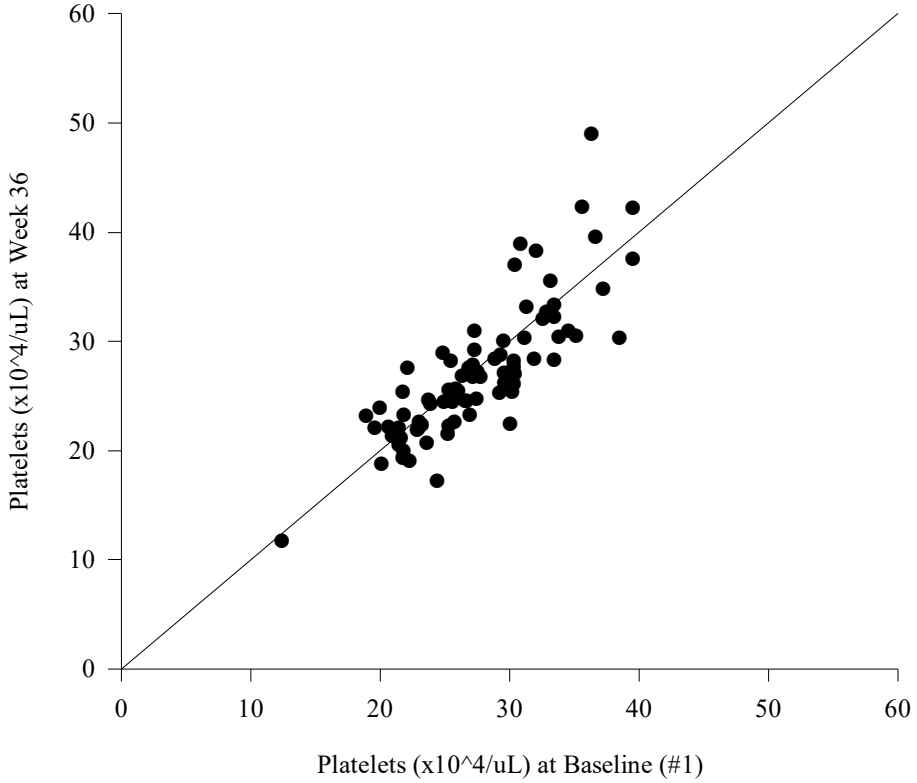


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 125 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (5%/5%)

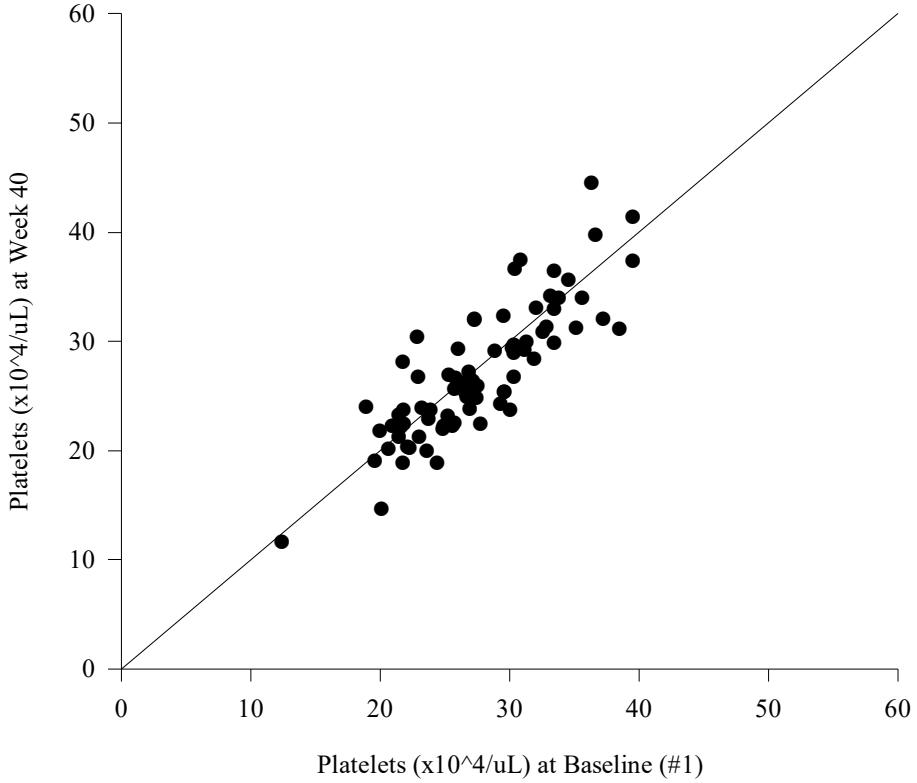


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 126 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (5%/5%)

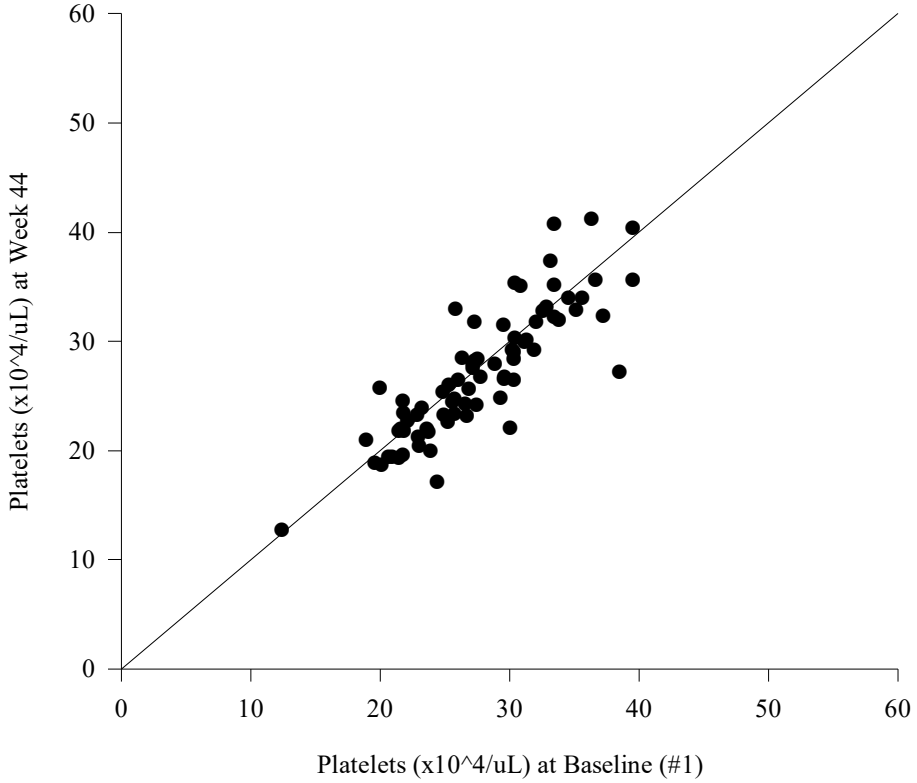


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 127 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (5%/5%)

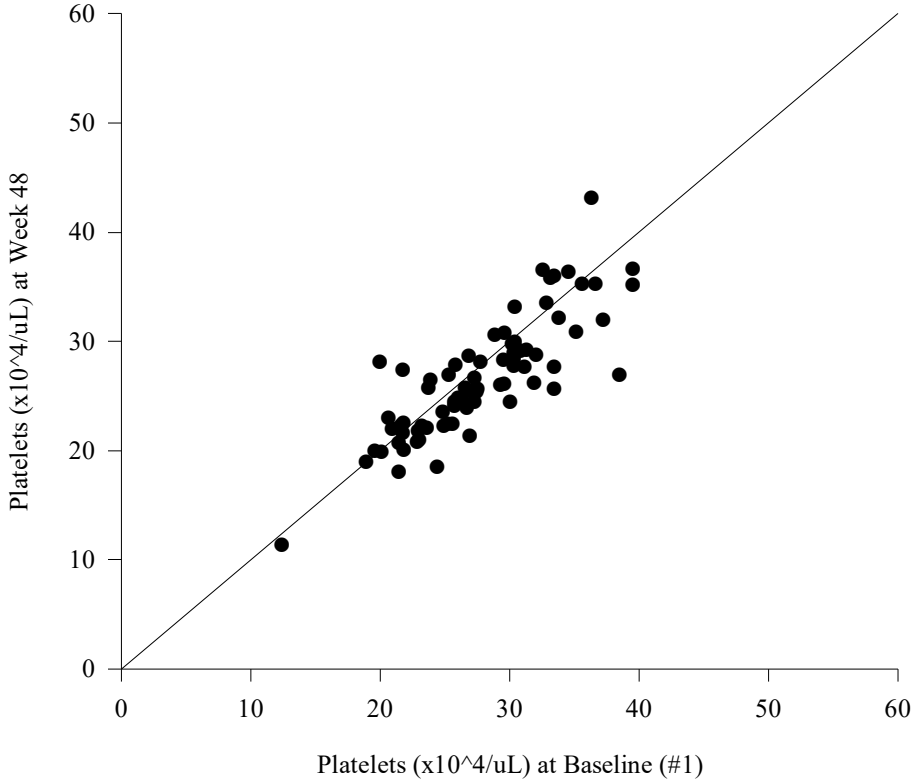


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 128 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (5%/5%)

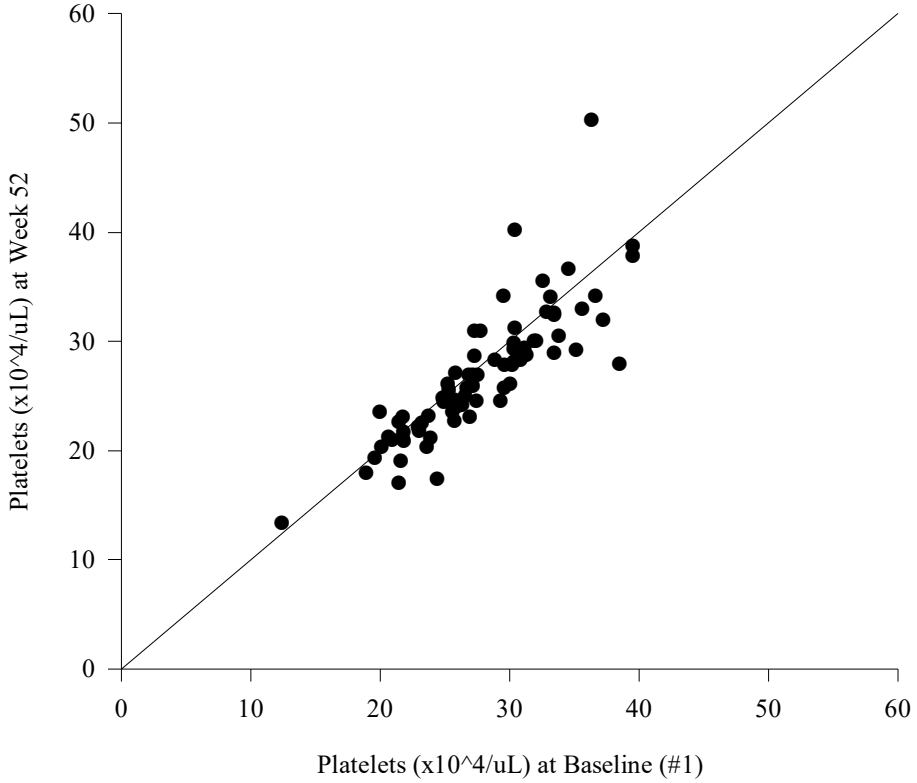


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 129 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (5%/5%)

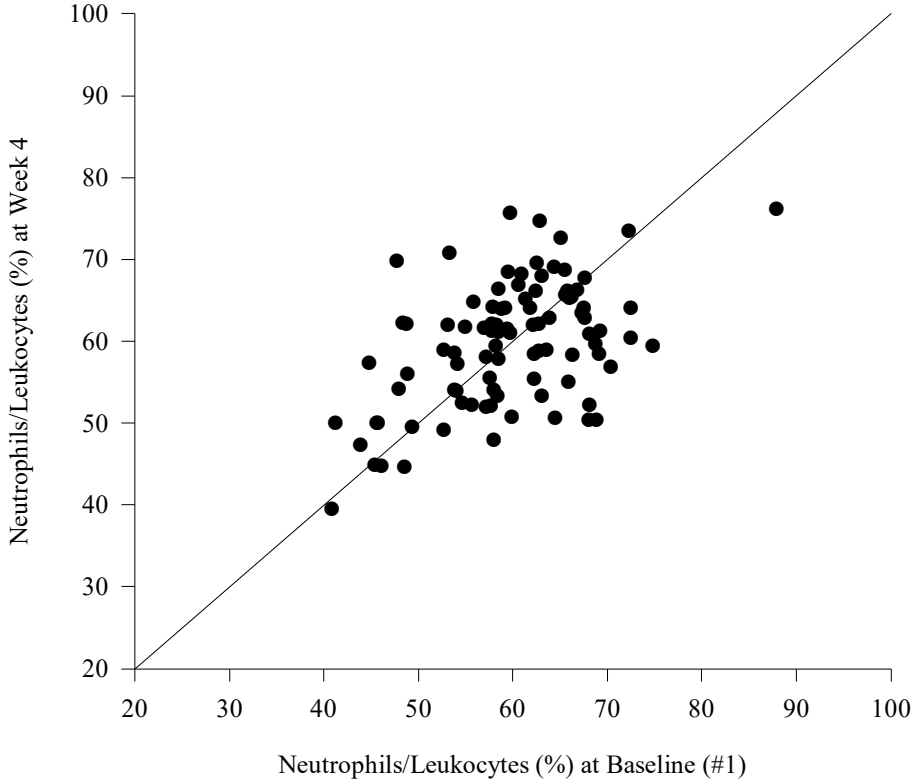


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 130 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (0%/5%)

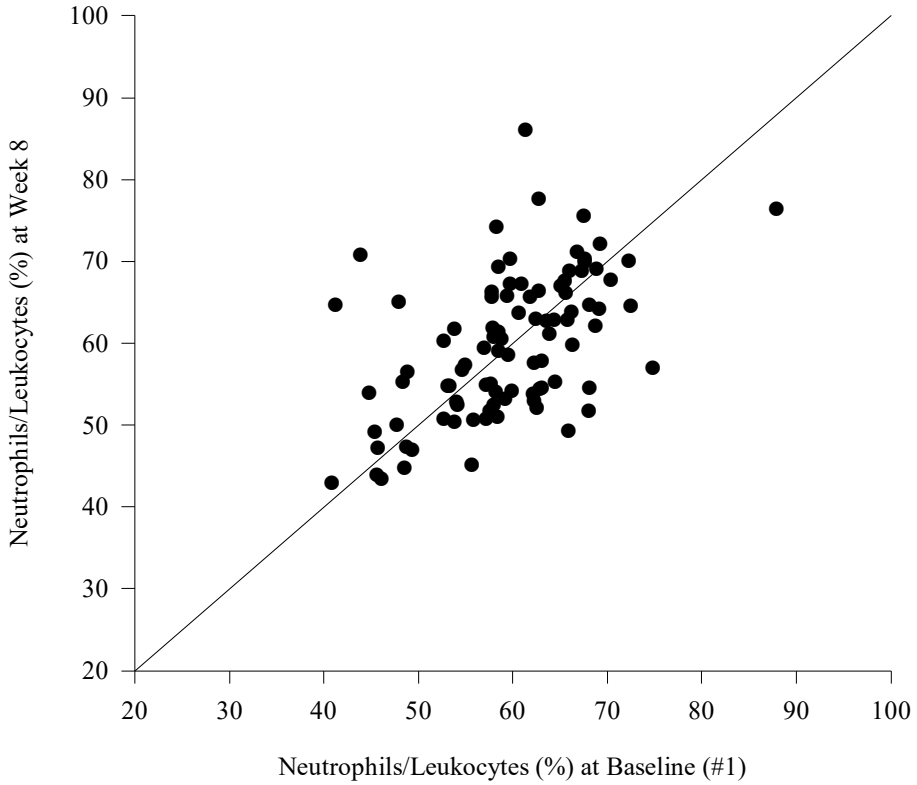


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 131 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）
Hematology（Safety Analysis Set）

Cohort 1 (0%/5%)

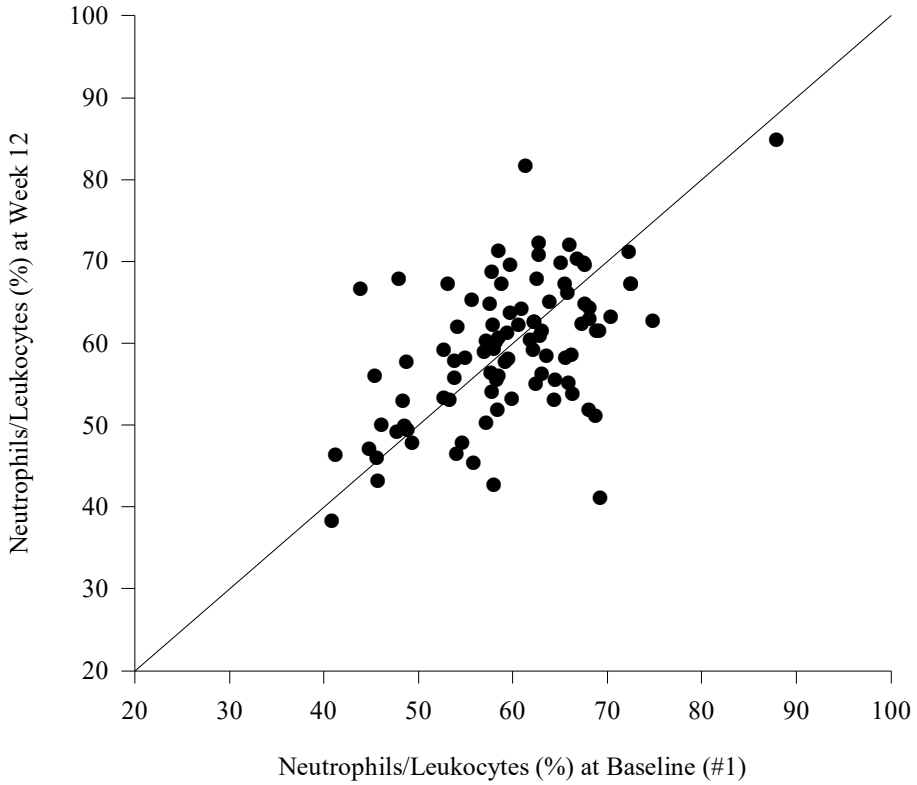


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 132 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）
Hematology（Safety Analysis Set）

Cohort 1 (0%/5%)

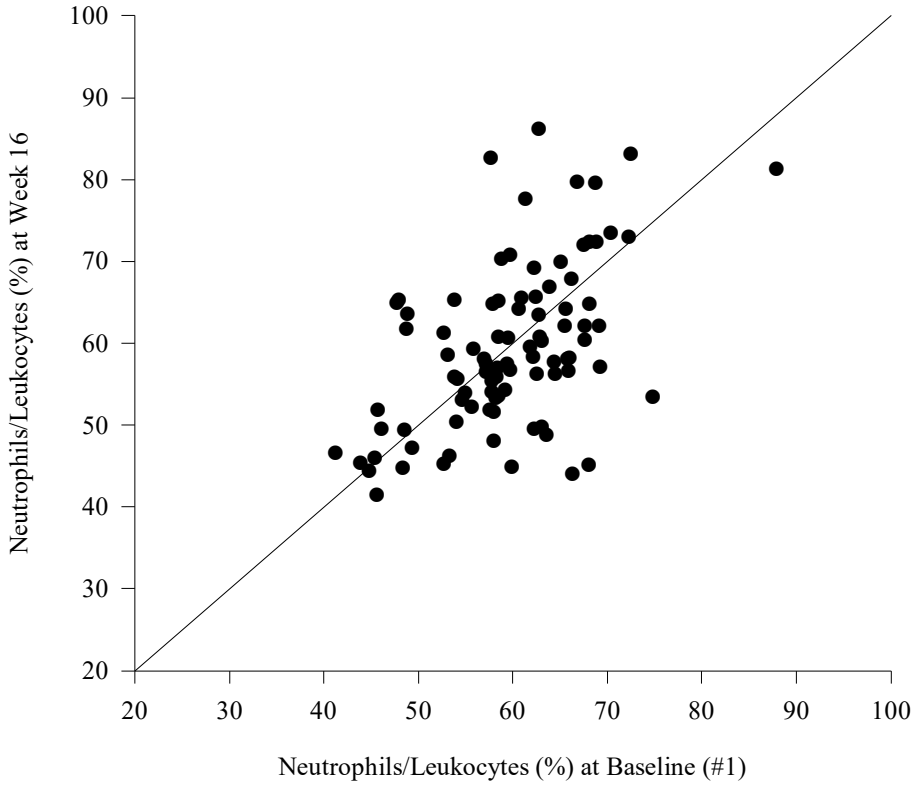


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 133 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (0%/5%)

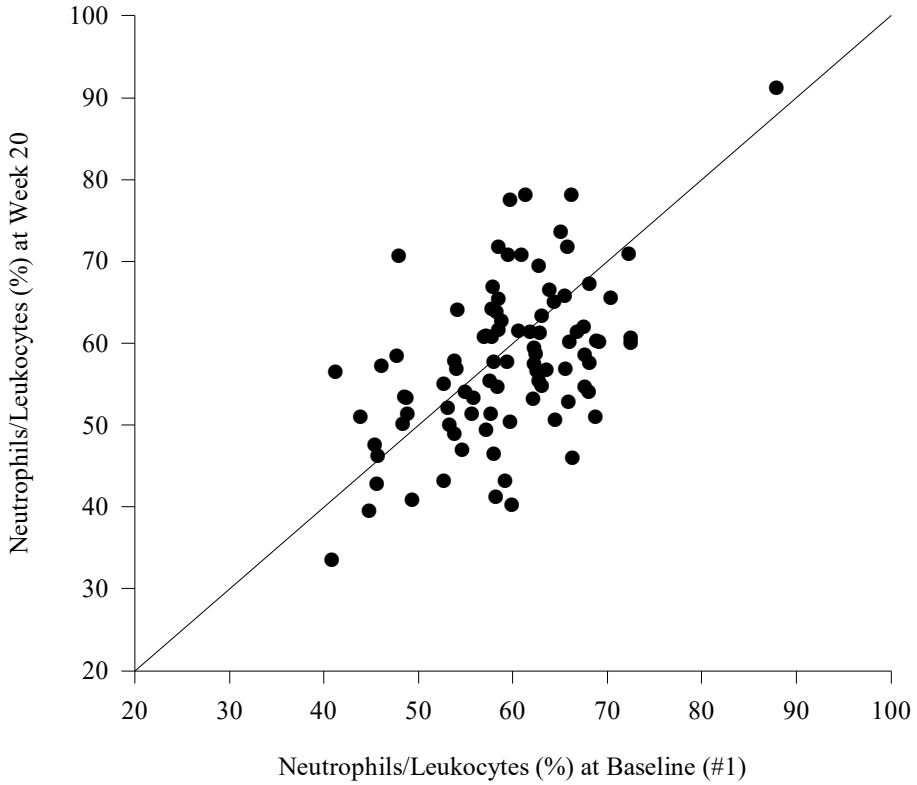


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 134 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (0%/5%)

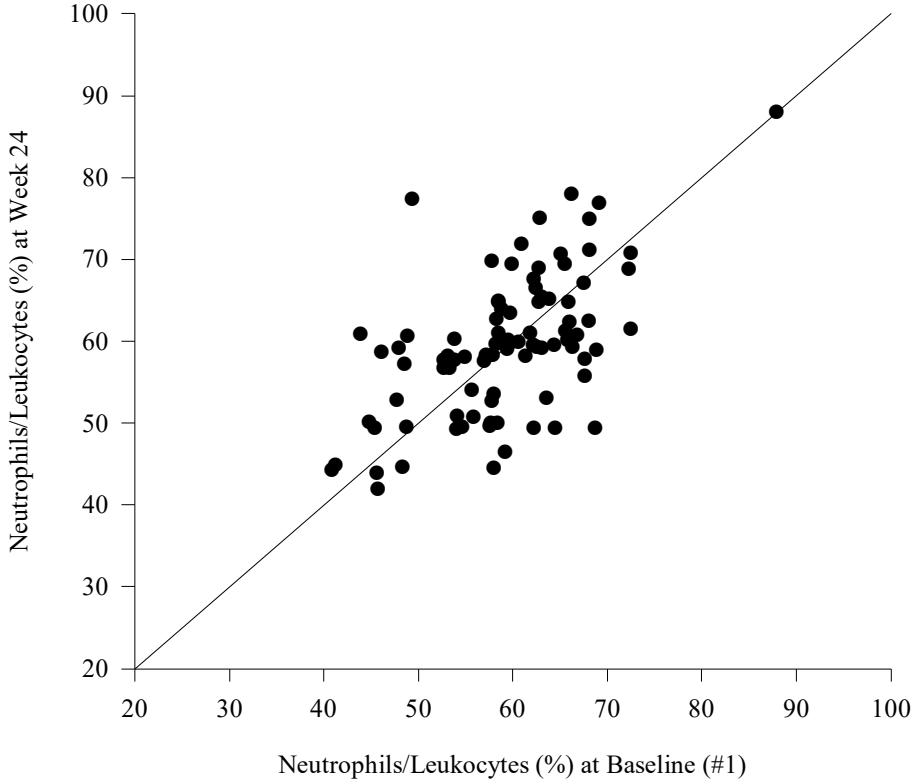


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 135 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (0%/5%)

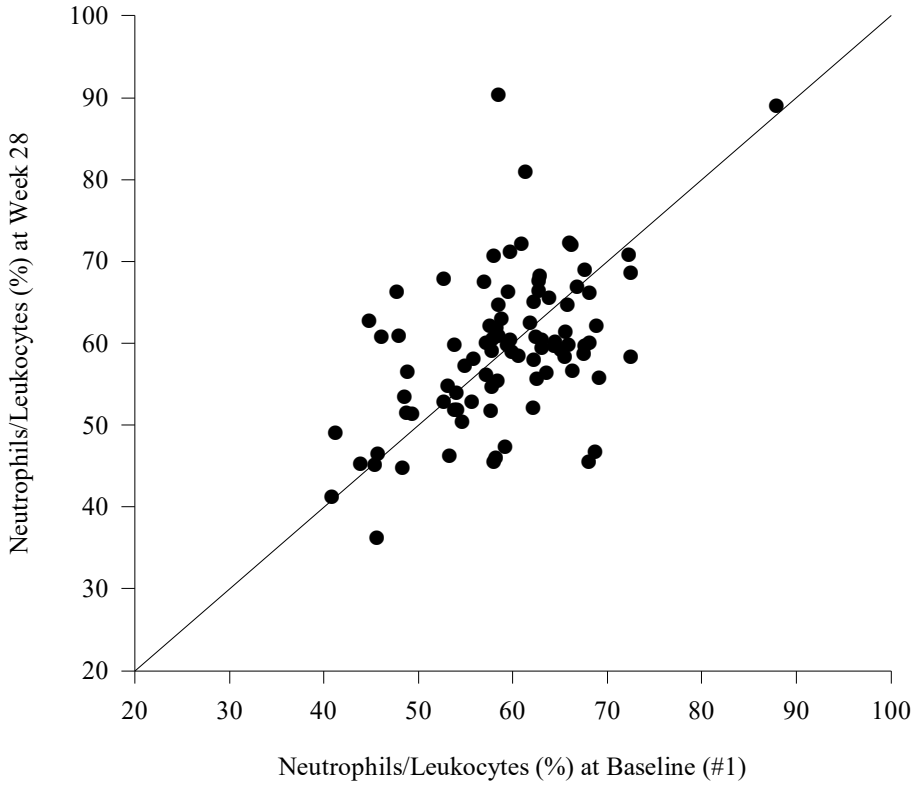


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 136 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (0%/5%)

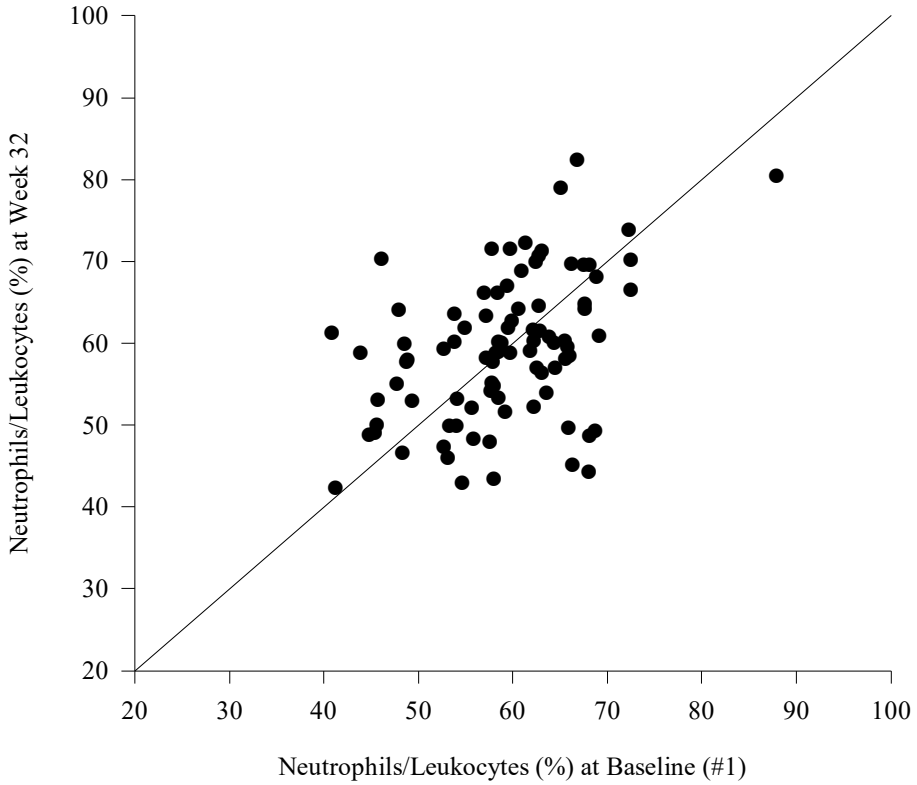


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 137 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (0%/5%)

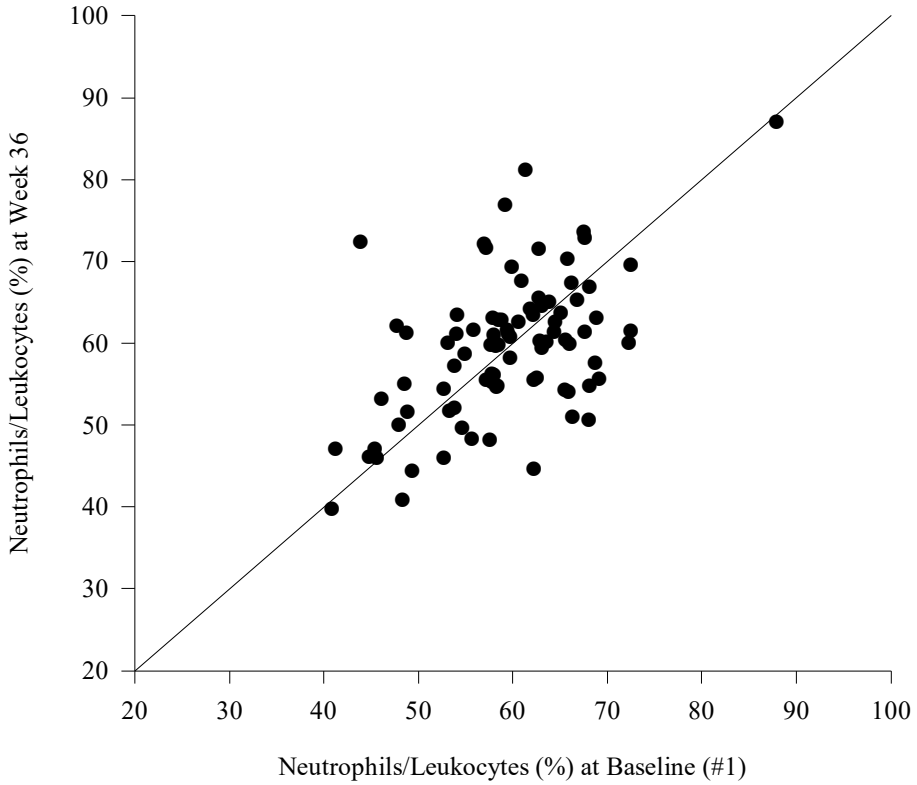


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 138 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (0%/5%)

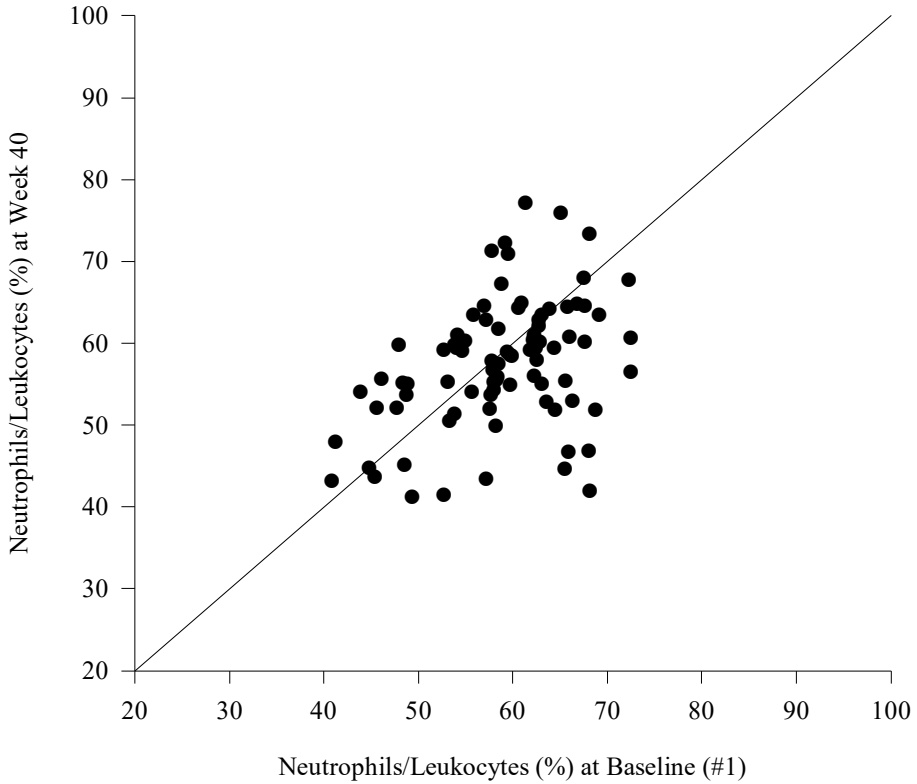


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 139 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (0%/5%)

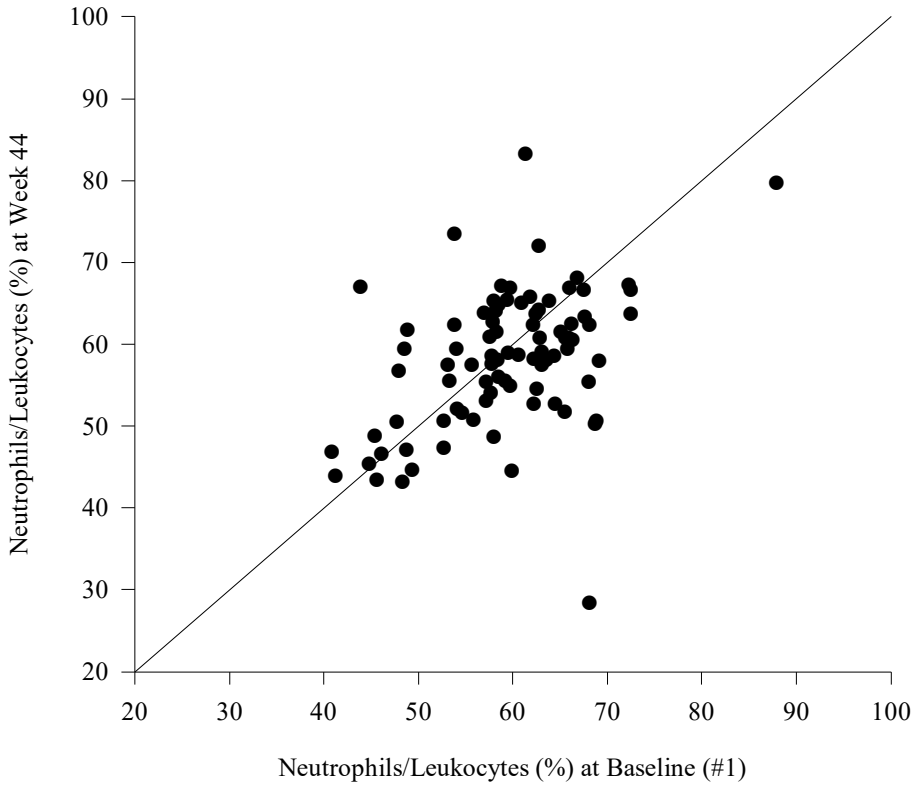


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 140 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (0%/5%)

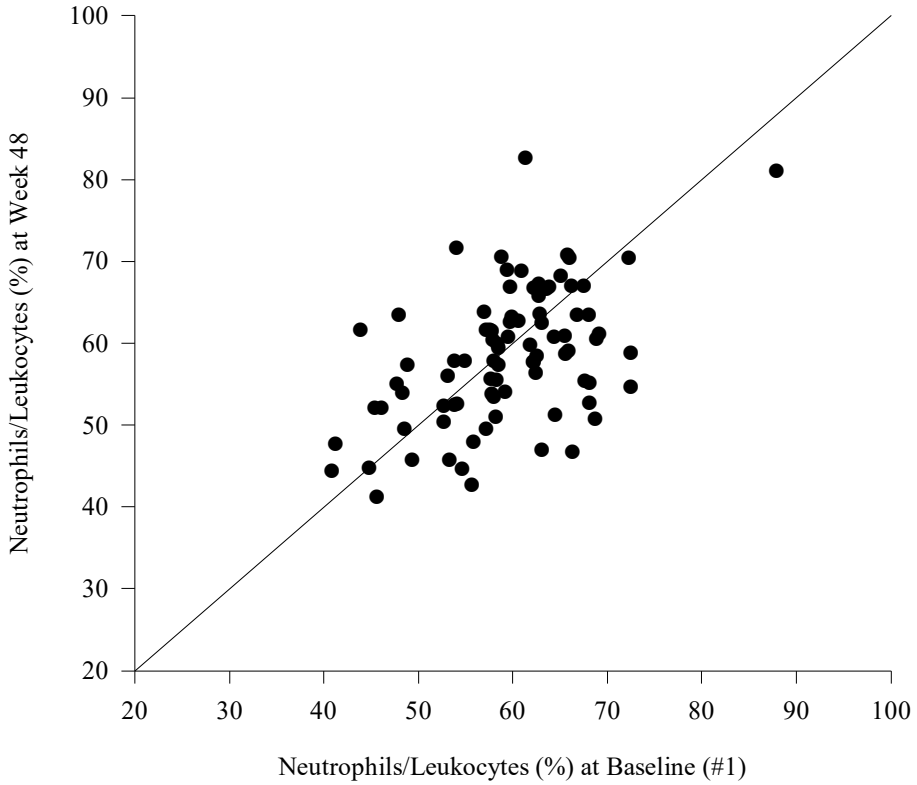


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 141 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (0%/5%)

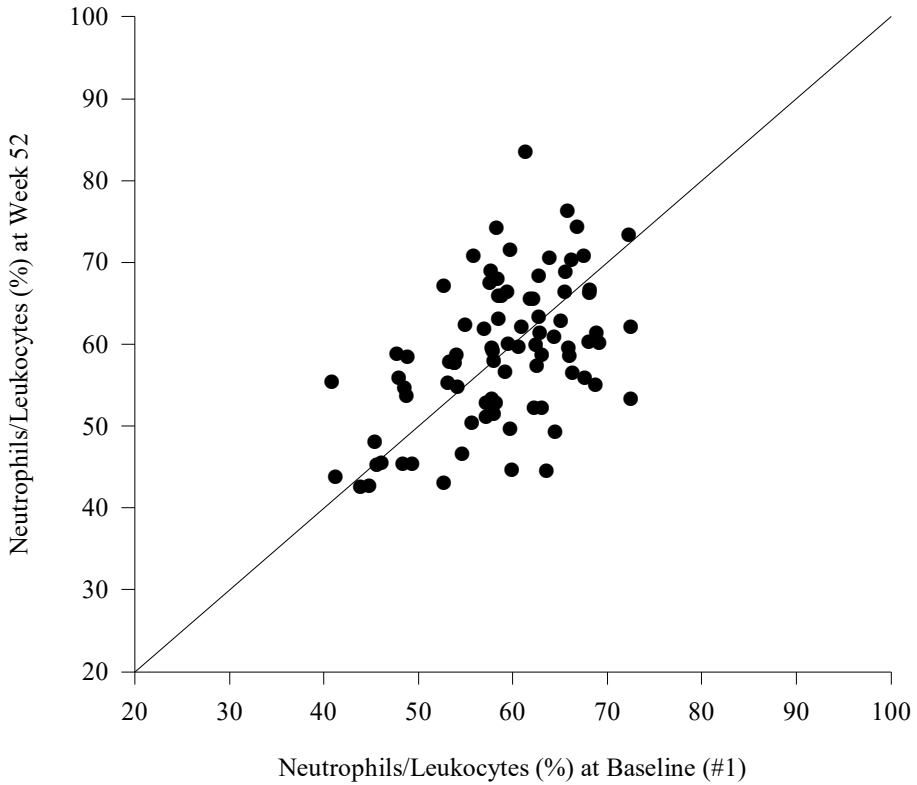


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 142 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (0%/5%)

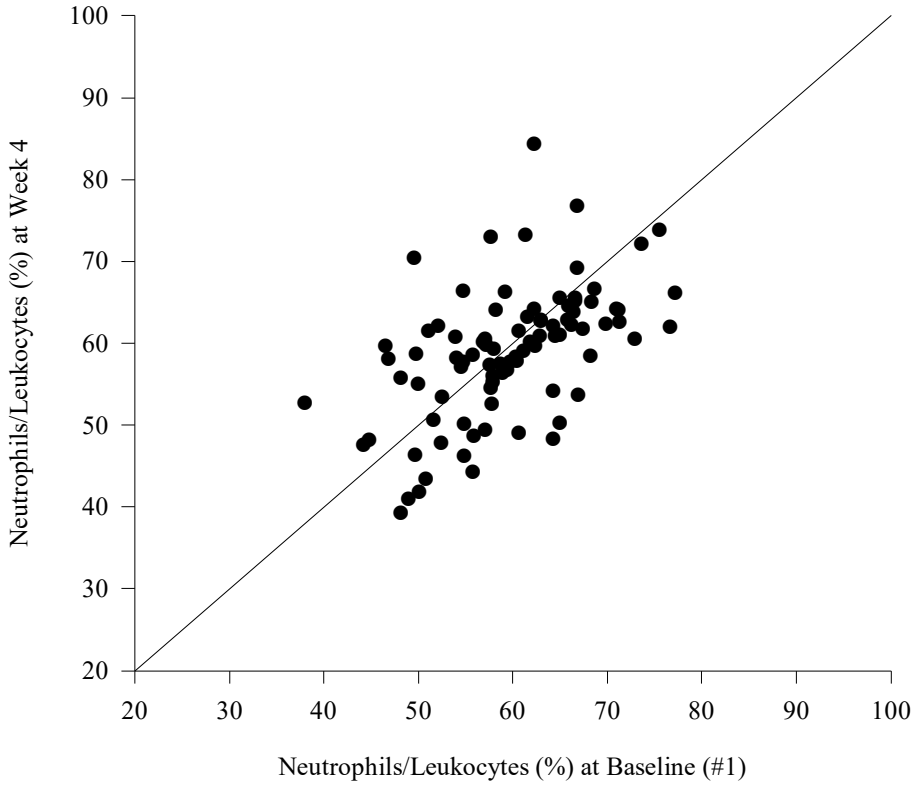


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 143 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (5%/5%)

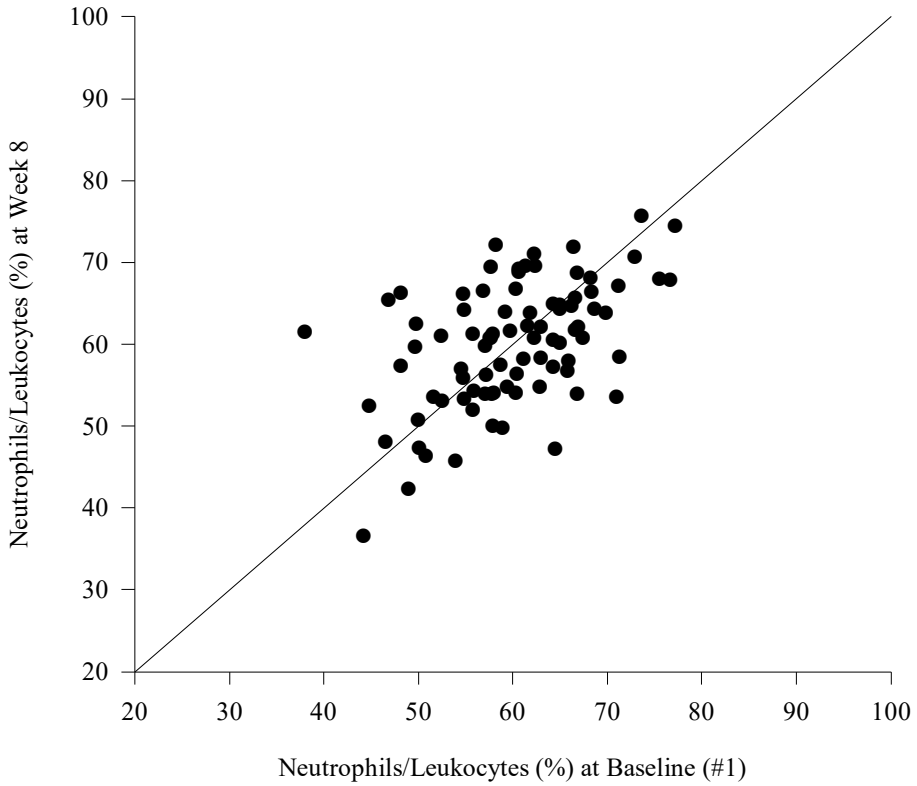


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 144 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (5%/5%)

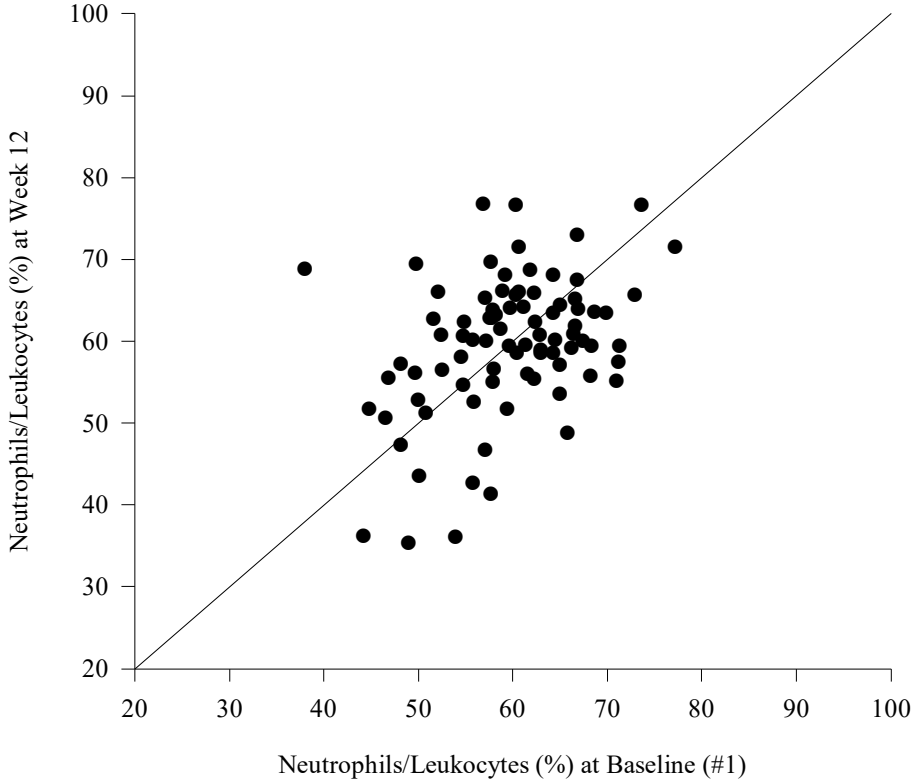


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 145 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (5%/5%)

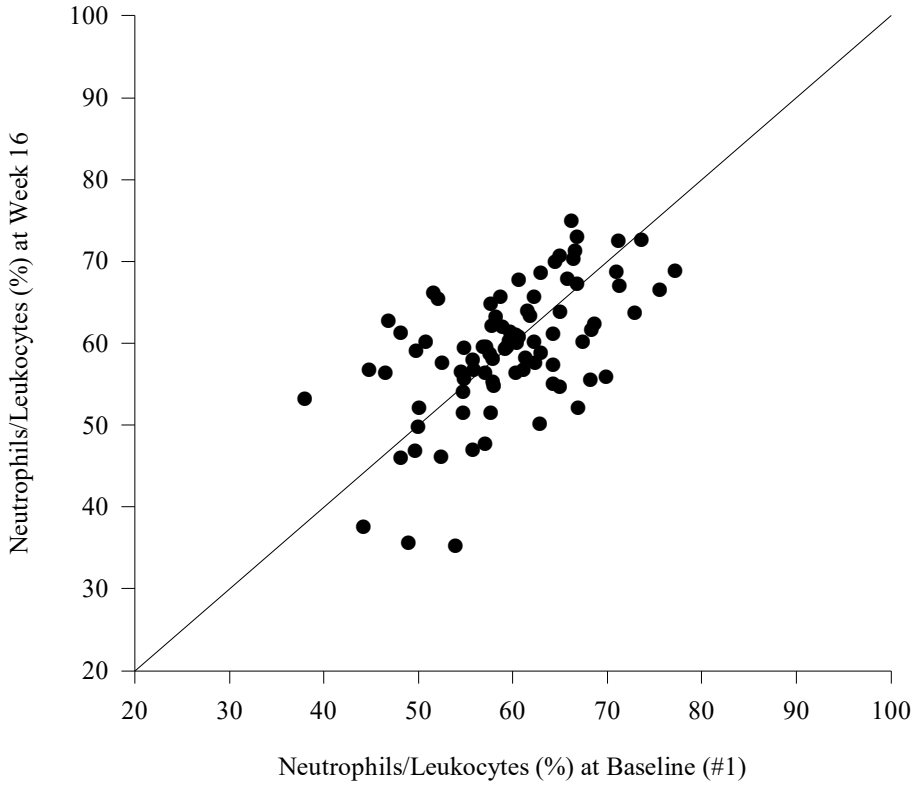


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 146 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (5%/5%)

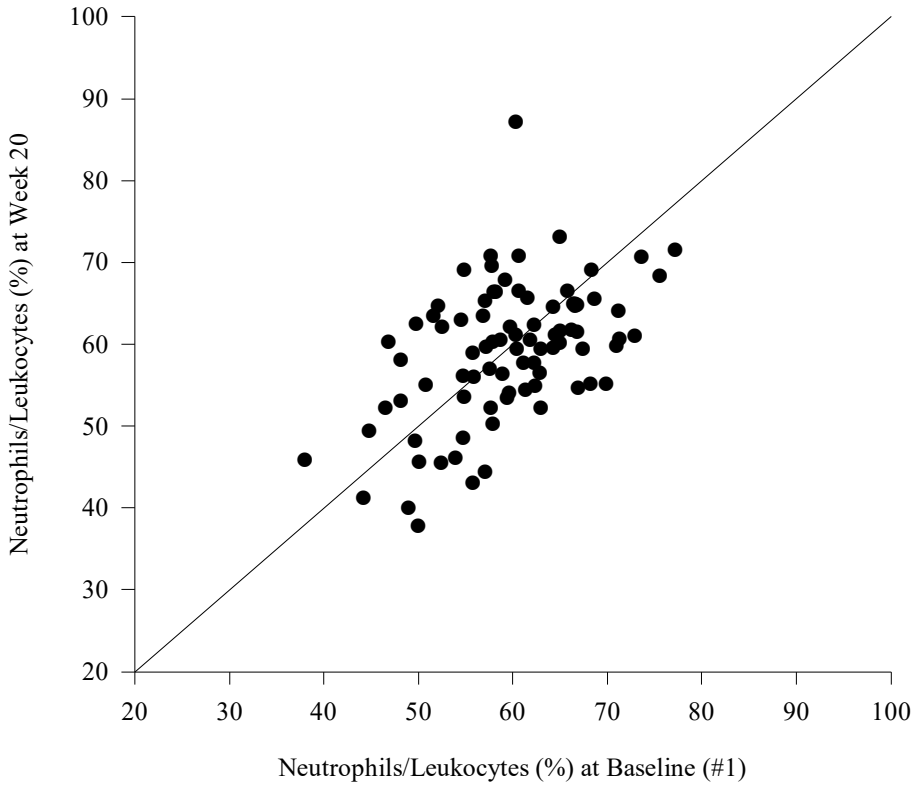


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 147 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (5%/5%)

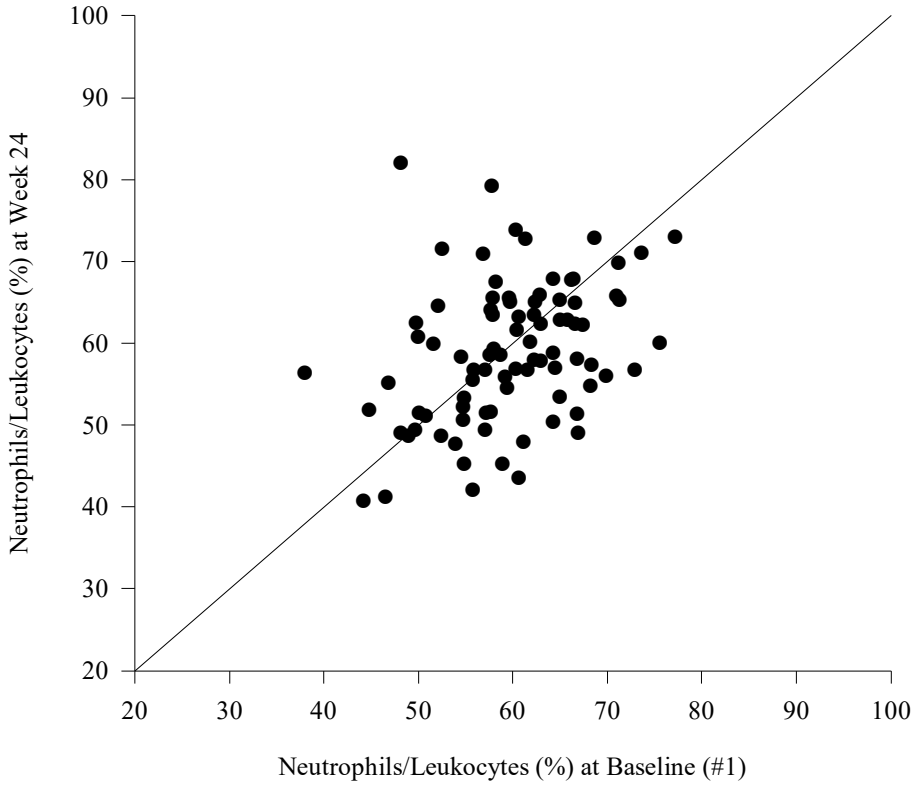


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 148 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (5%/5%)

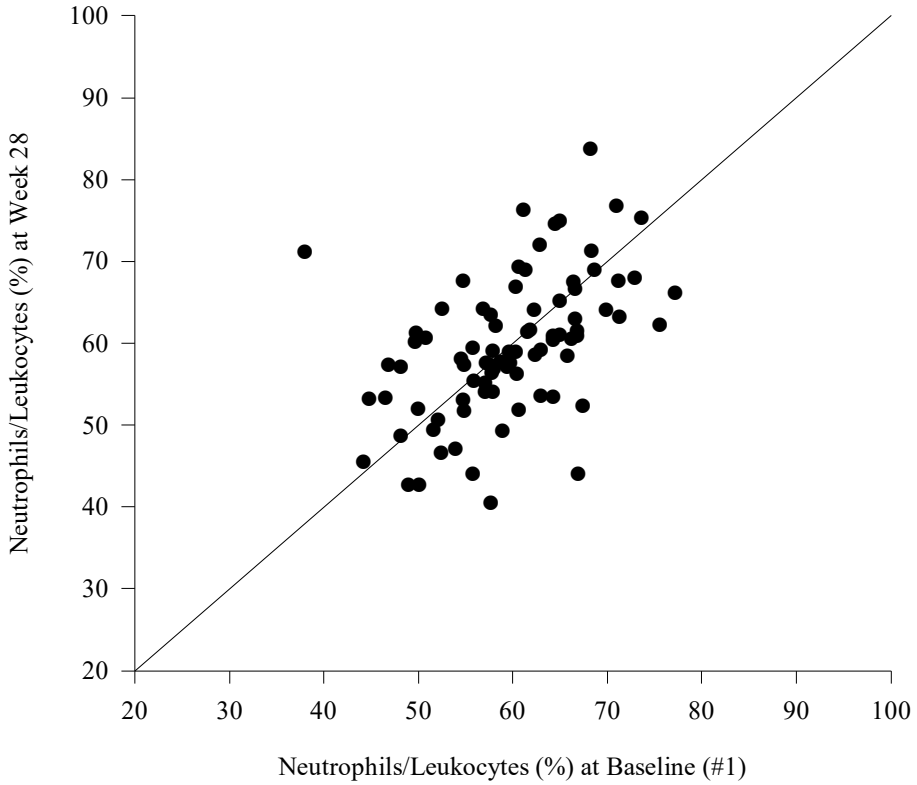


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 149 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (5%/5%)

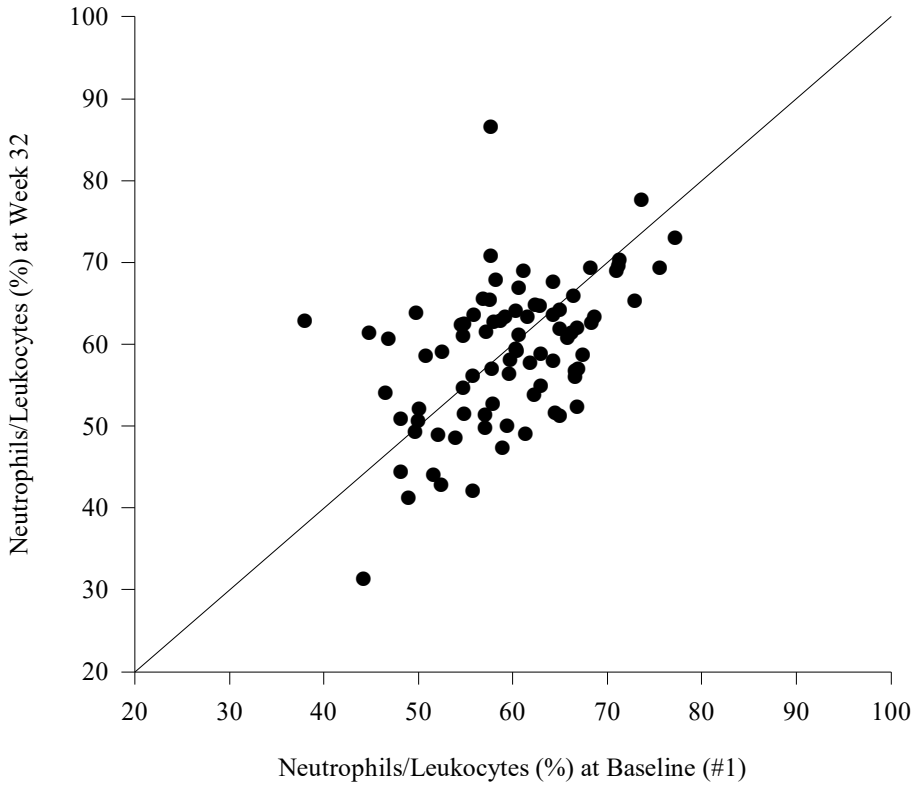


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 150 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (5%/5%)

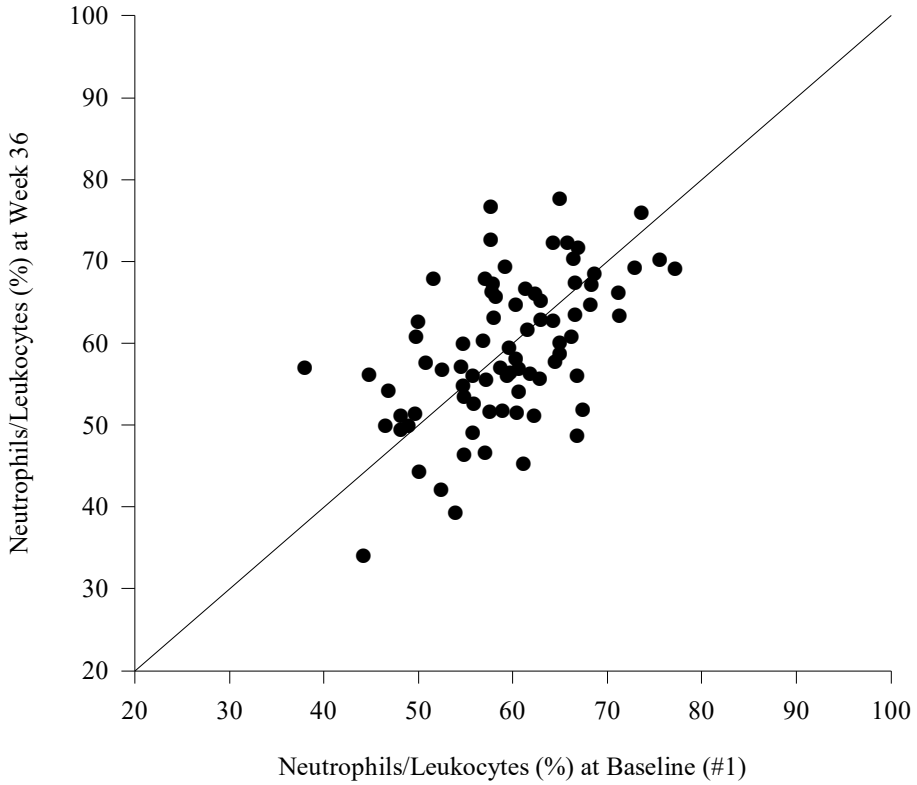


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 151 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (5%/5%)

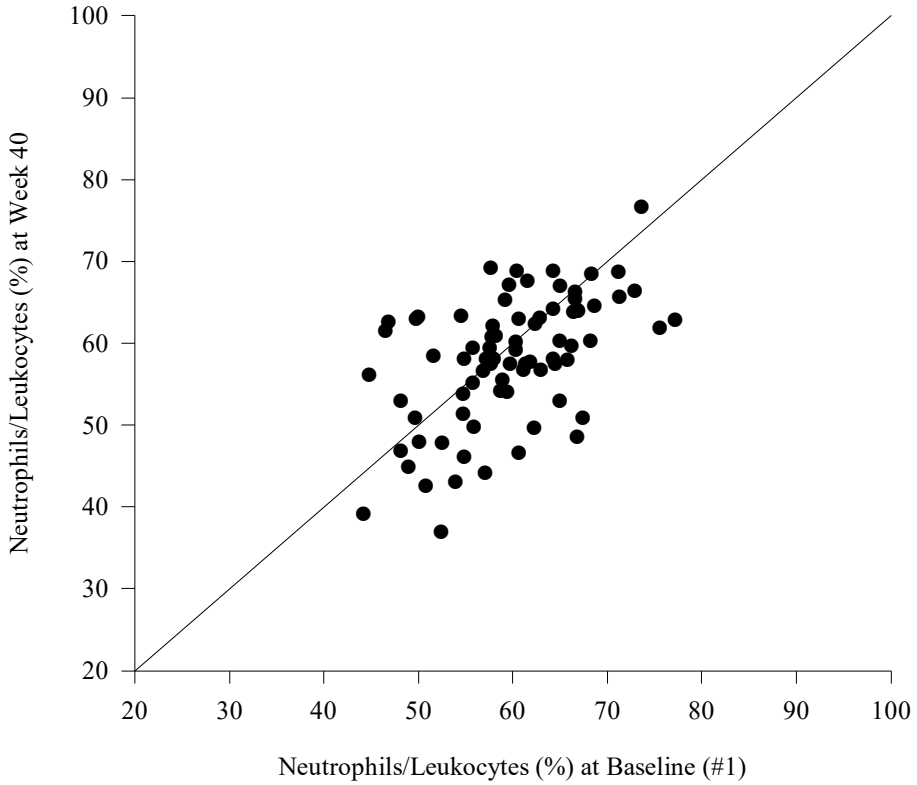


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 152 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (5%/5%)

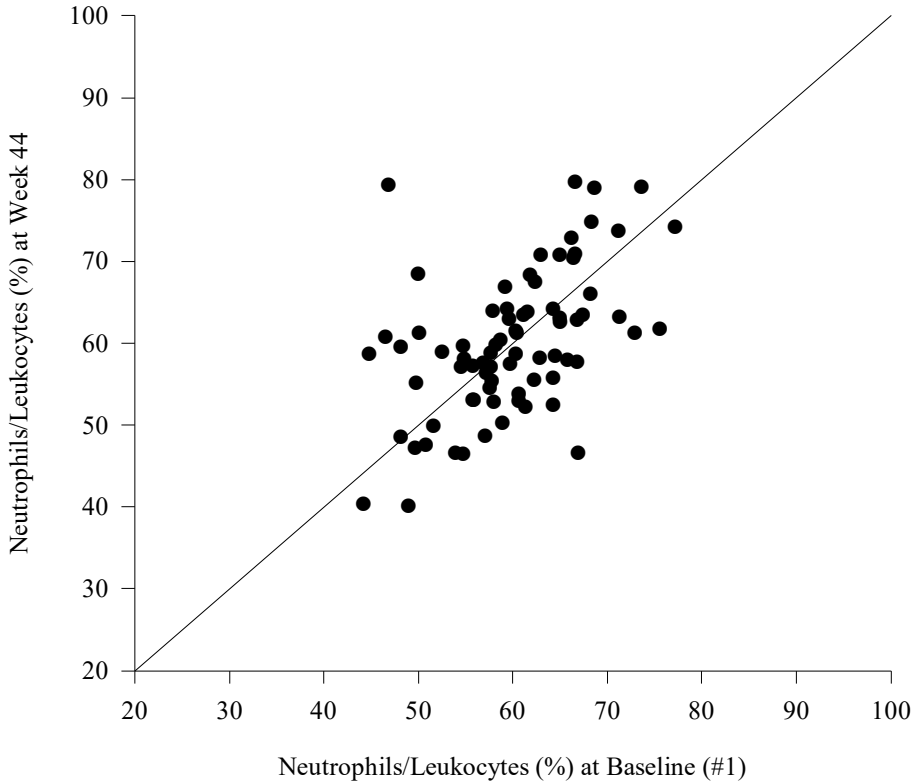


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 153 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (5%/5%)

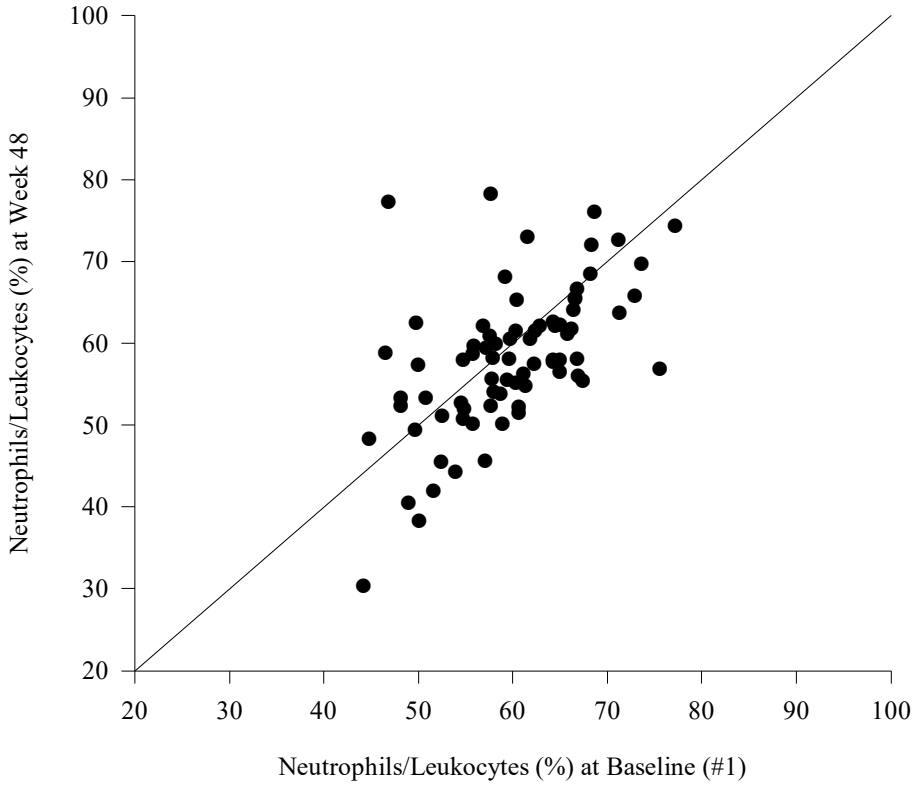


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 154 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (5%/5%)

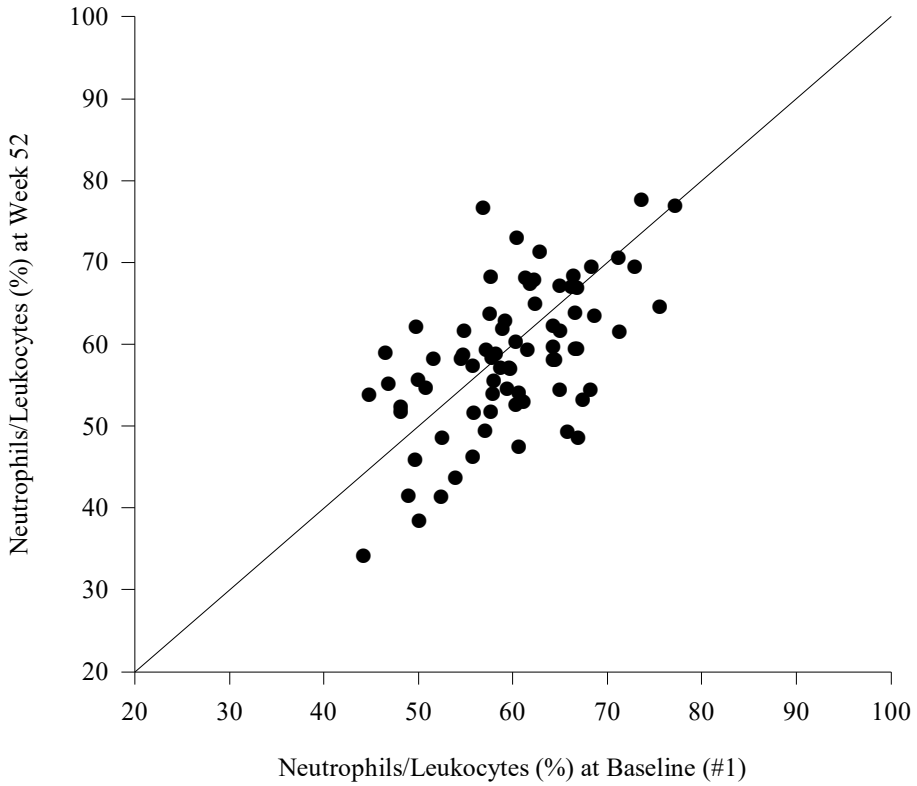


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 155 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (5%/5%)

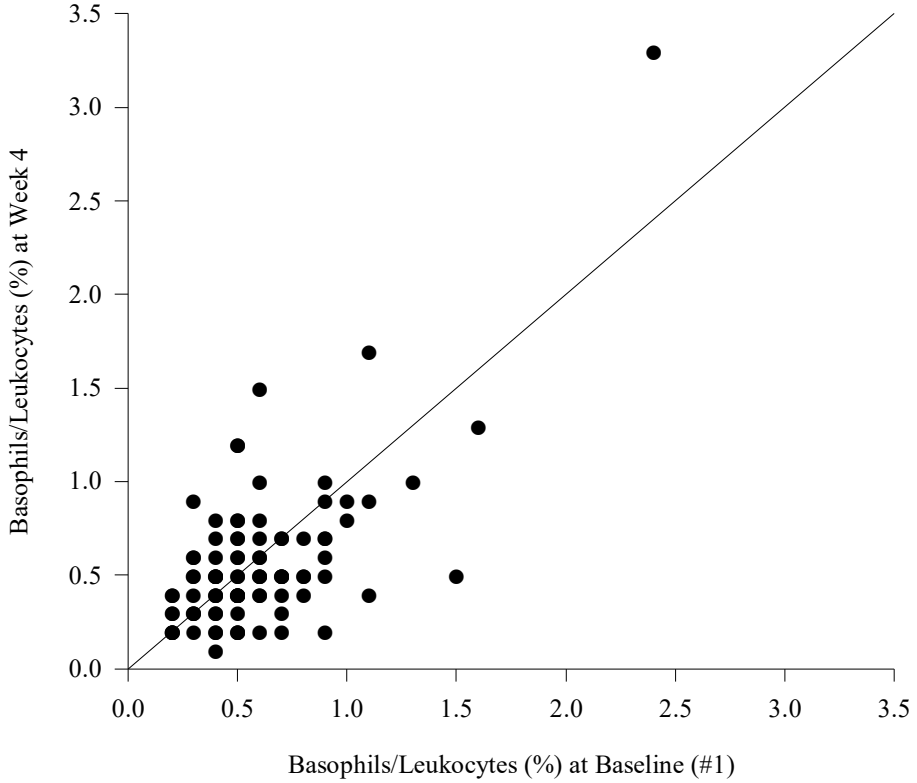


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 156 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (0%/5%)

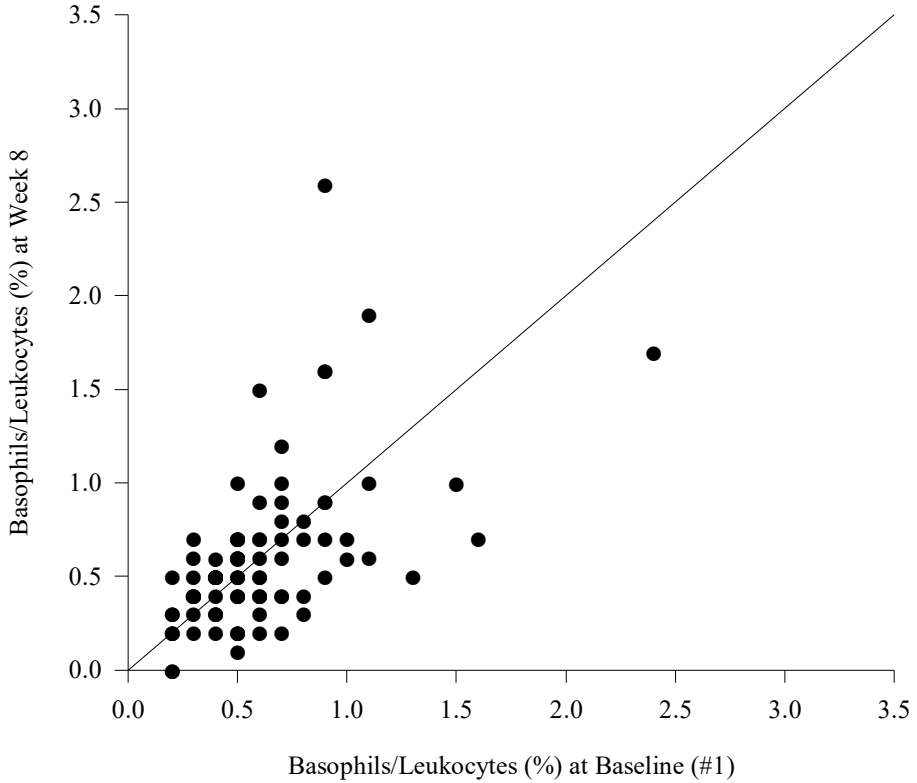


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 157 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）
Hematology（Safety Analysis Set）

Cohort 1 (0%/5%)

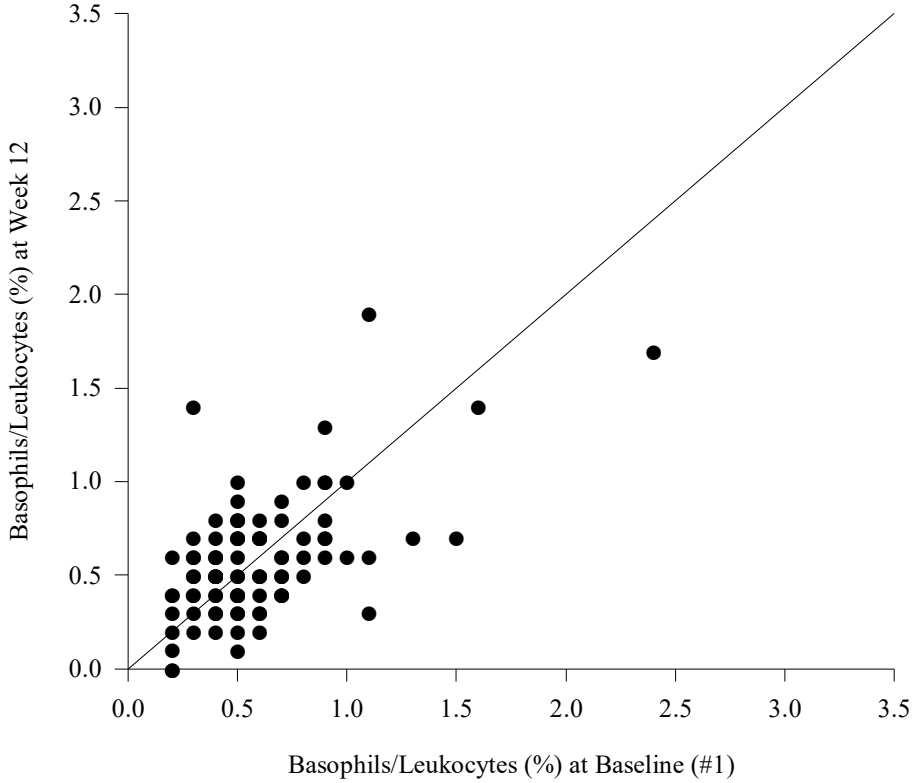


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 158 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）
Hematology（Safety Analysis Set）

Cohort 1 (0%/5%)

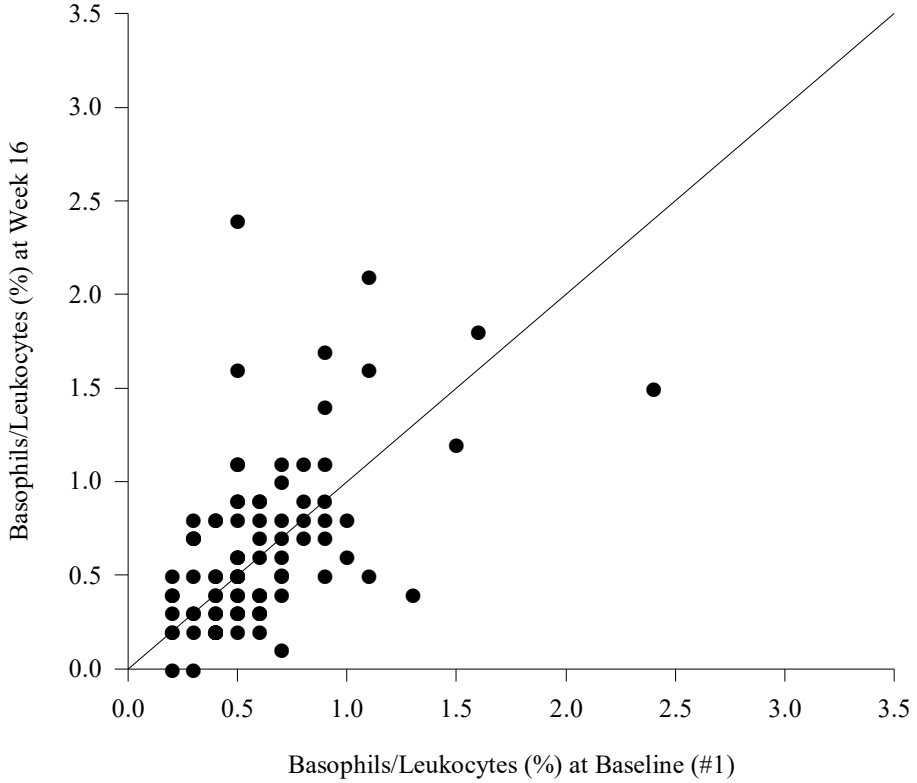


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 159 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (0%/5%)

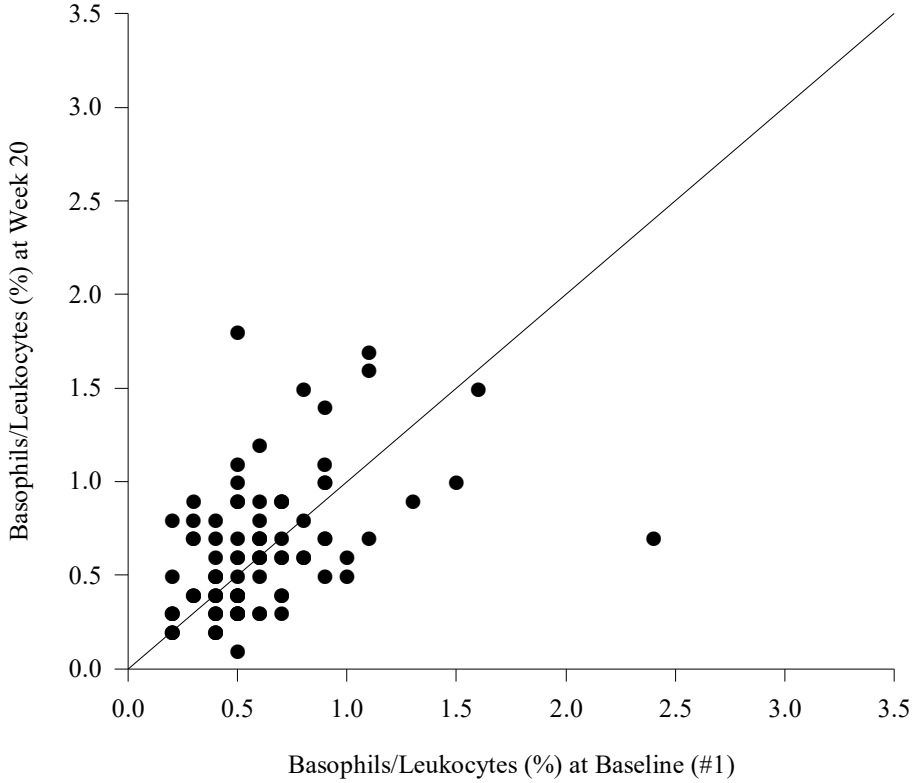


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 160 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (0%/5%)

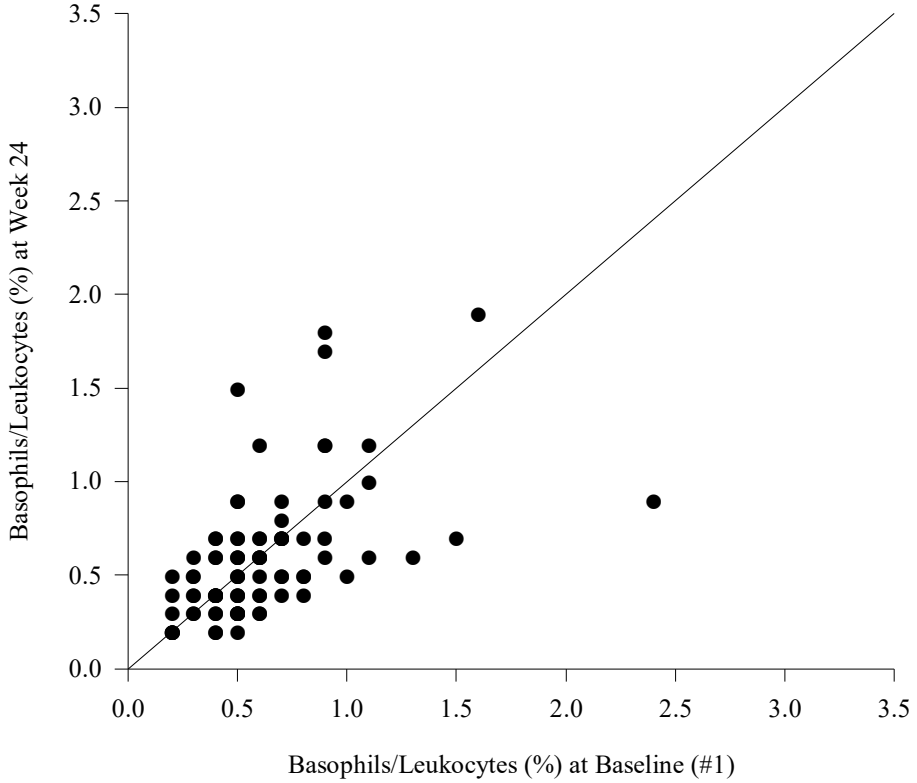


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 161 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (0%/5%)

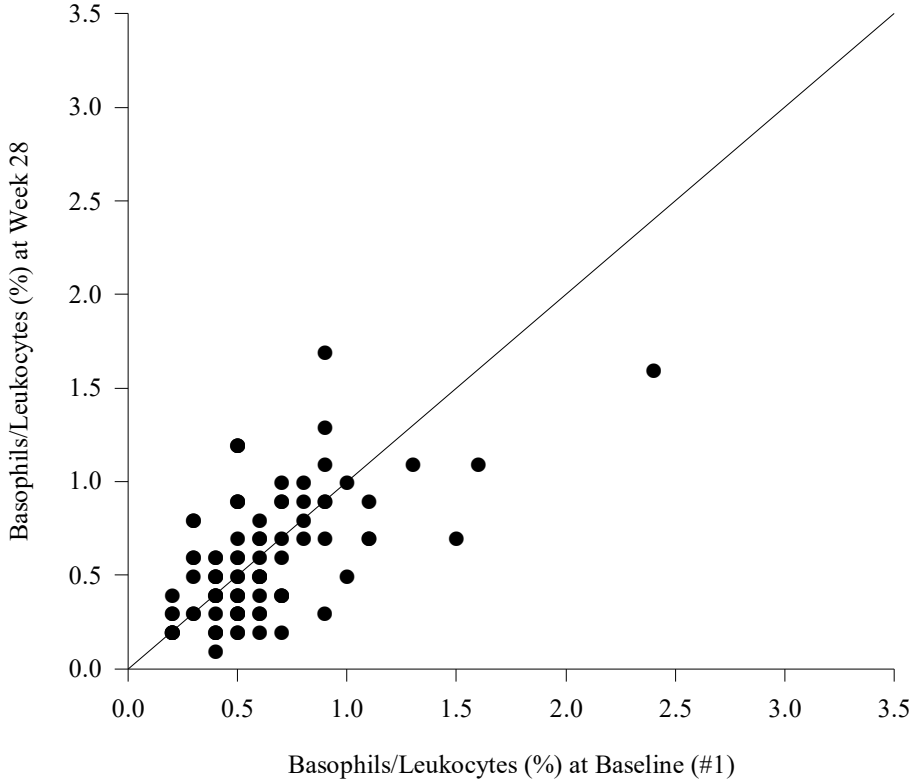


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 162 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (0%/5%)

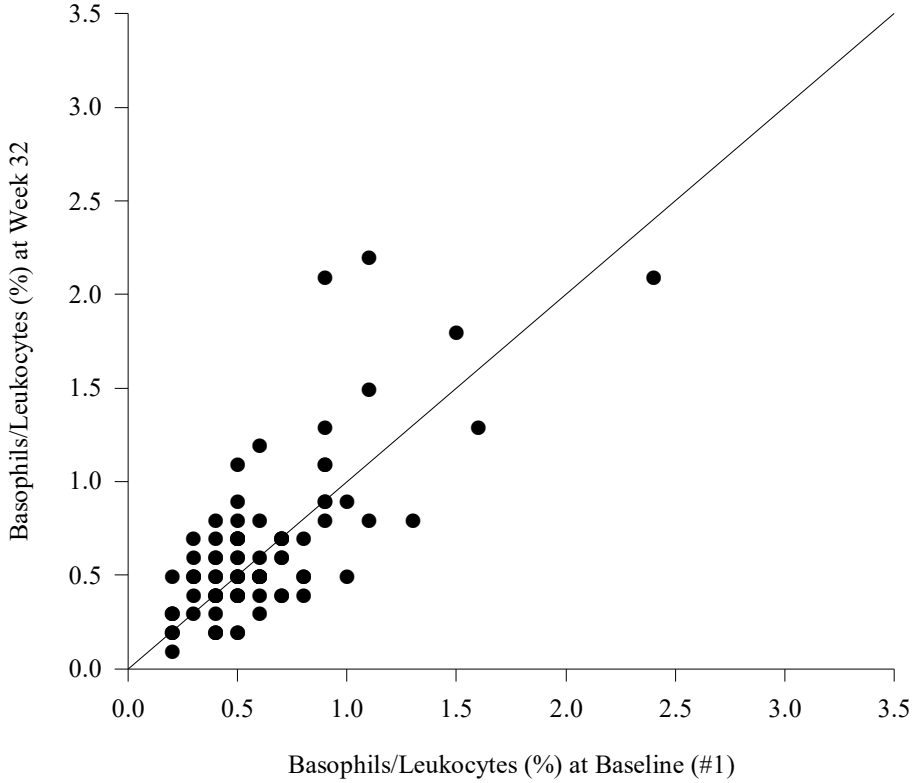


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 163 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (0%/5%)

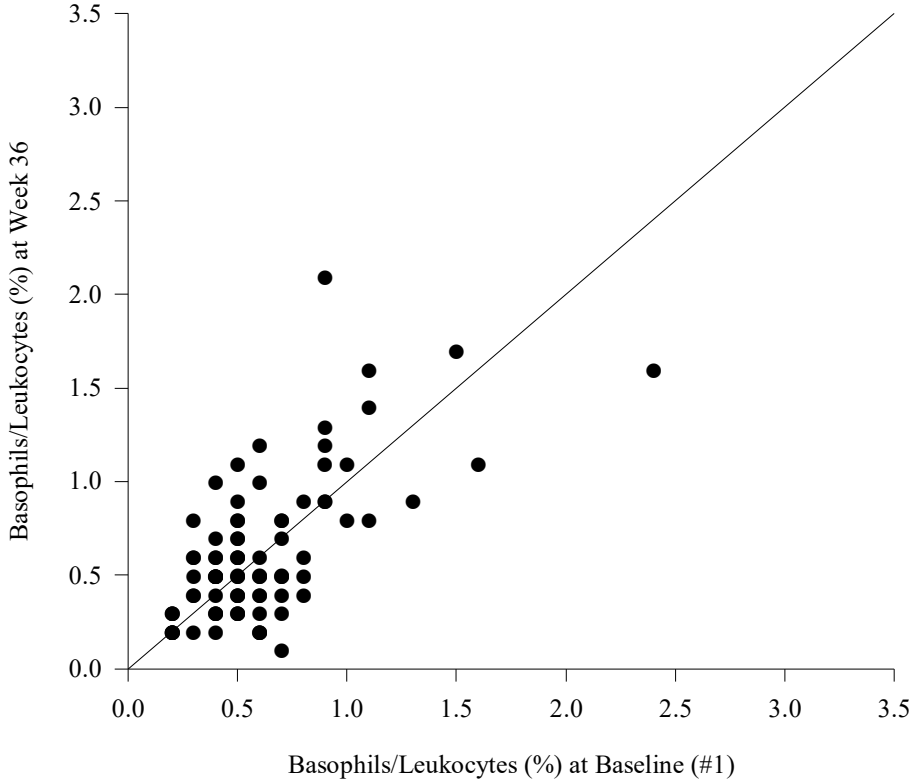


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 164 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (0%/5%)

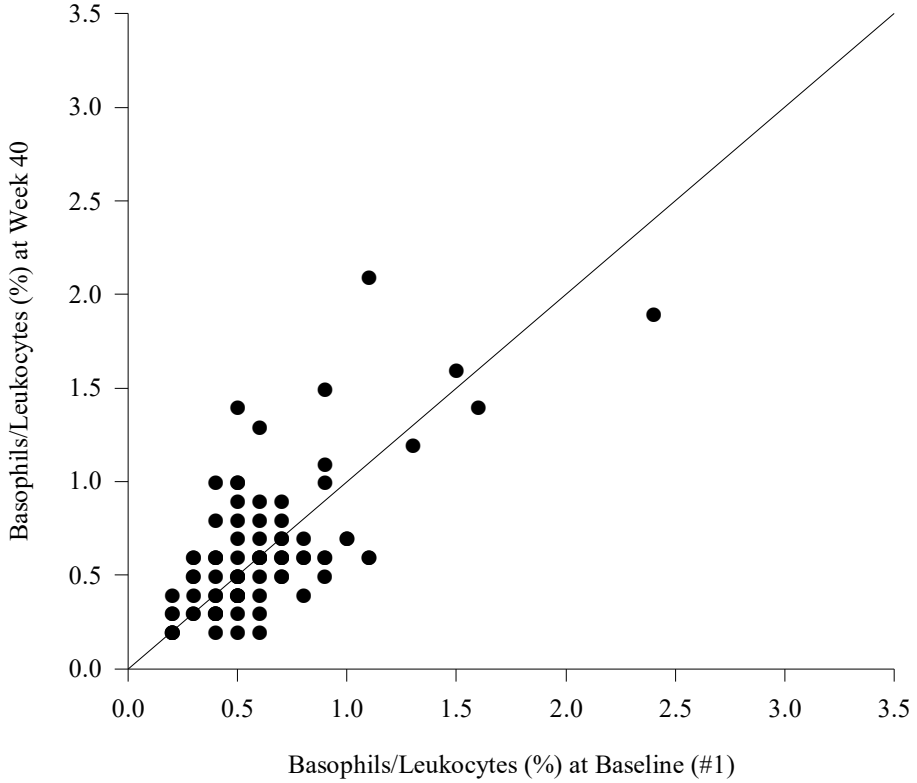


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 165 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (0%/5%)

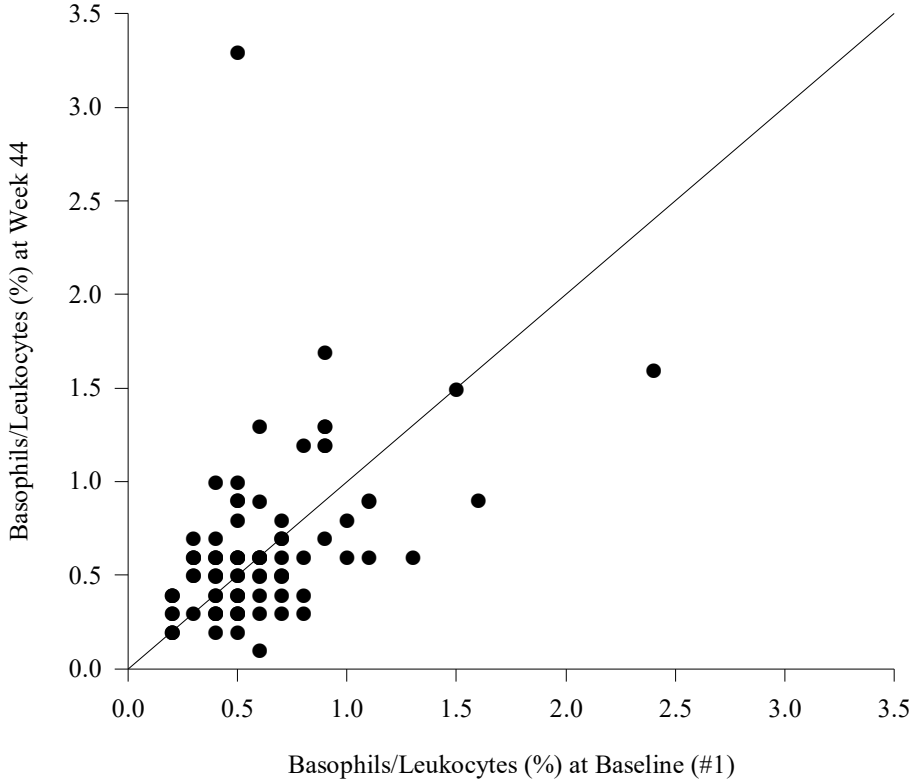


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 166 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (0%/5%)

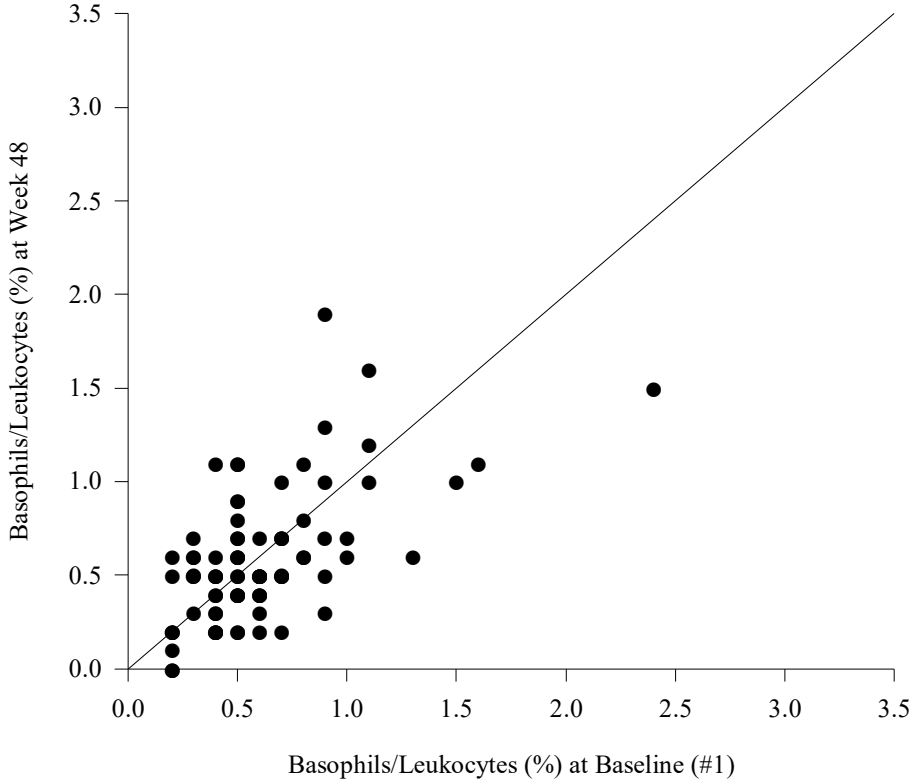


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 167 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (0%/5%)

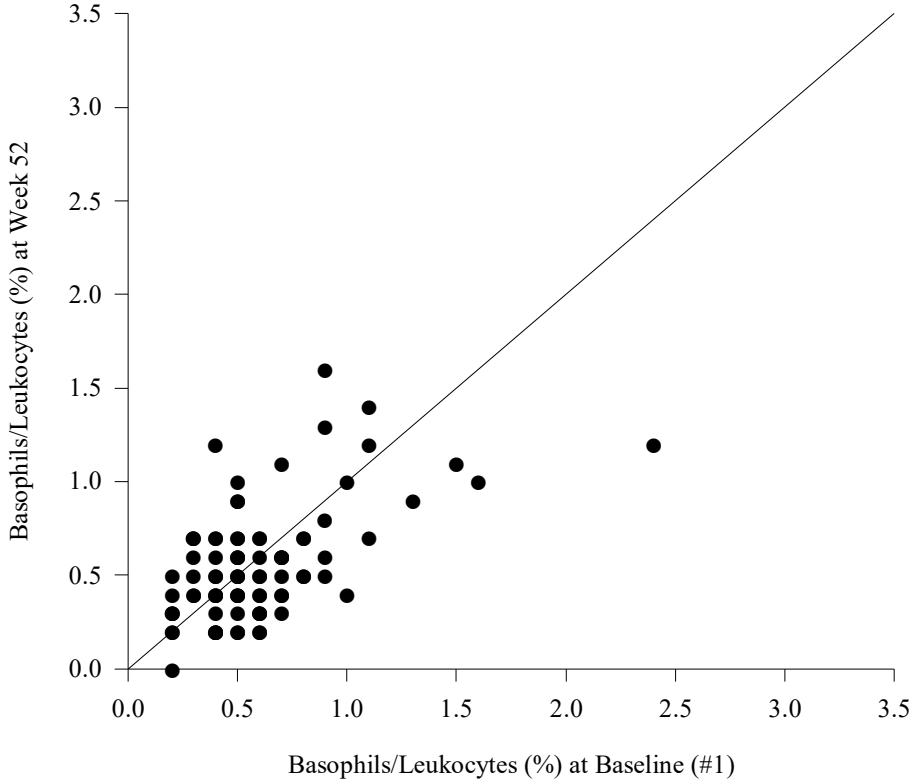


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 168 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (0%/5%)

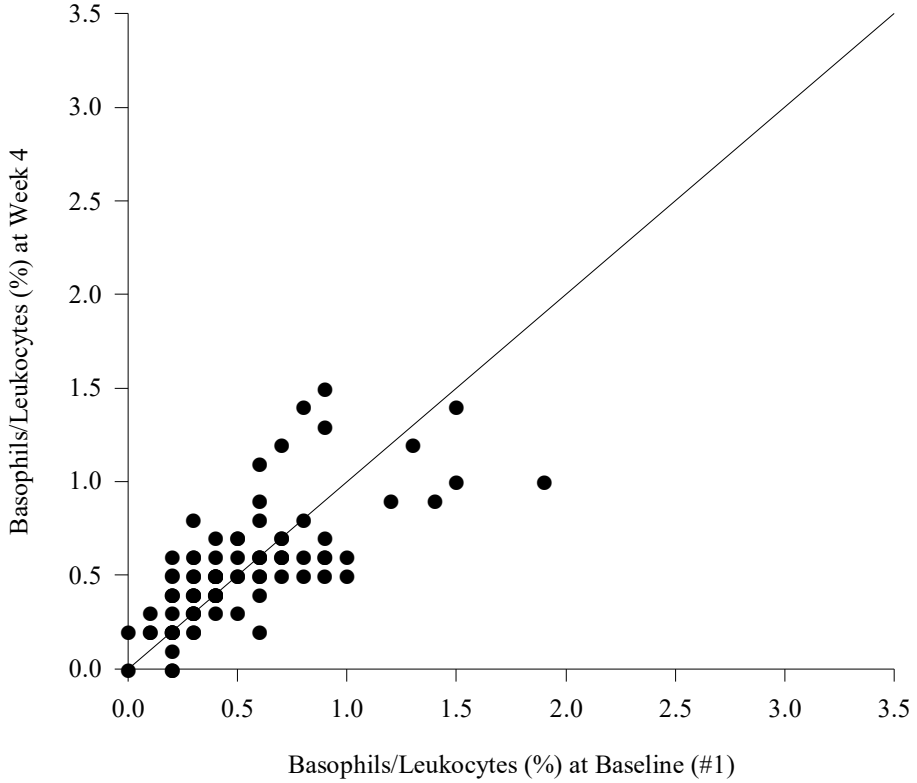


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 169 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (5%/5%)

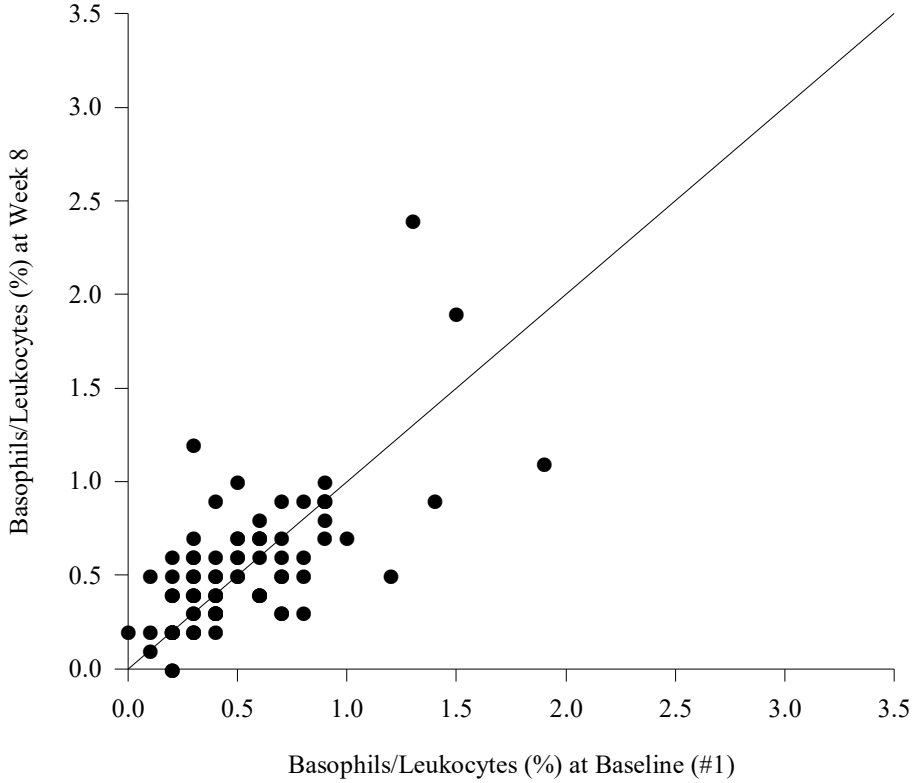


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 170 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (5%/5%)

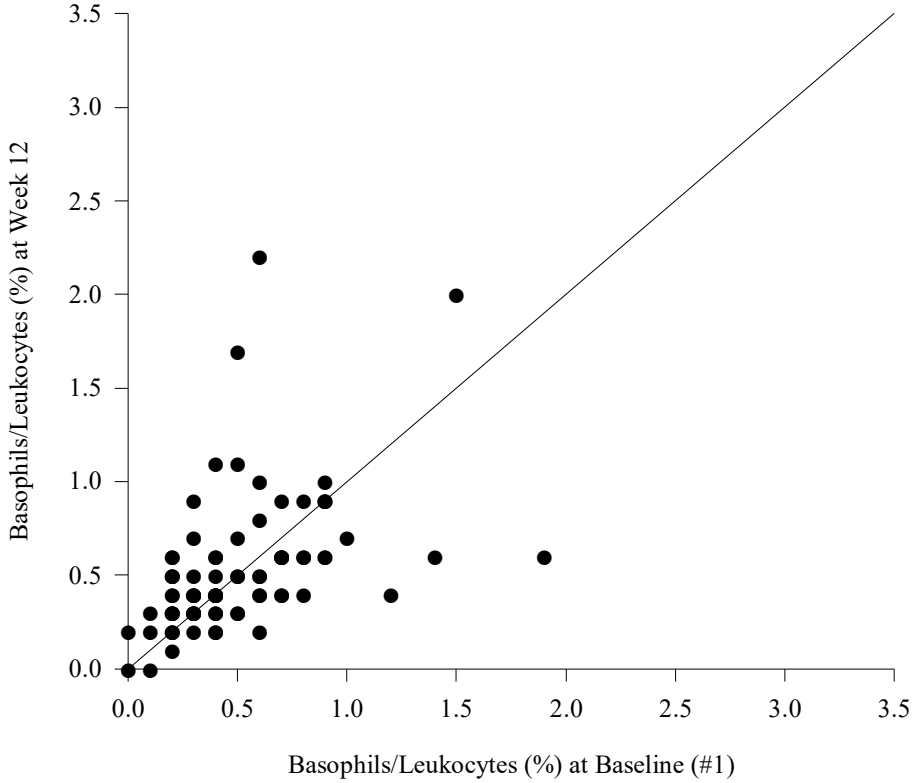


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 171 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (5%/5%)

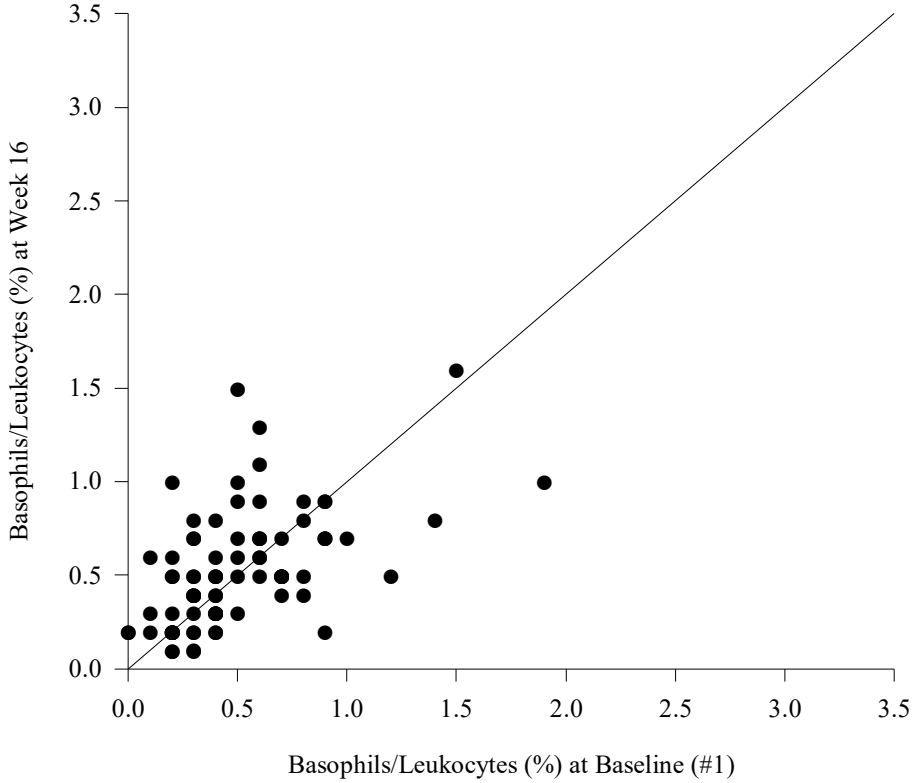


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 172 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (5%/5%)

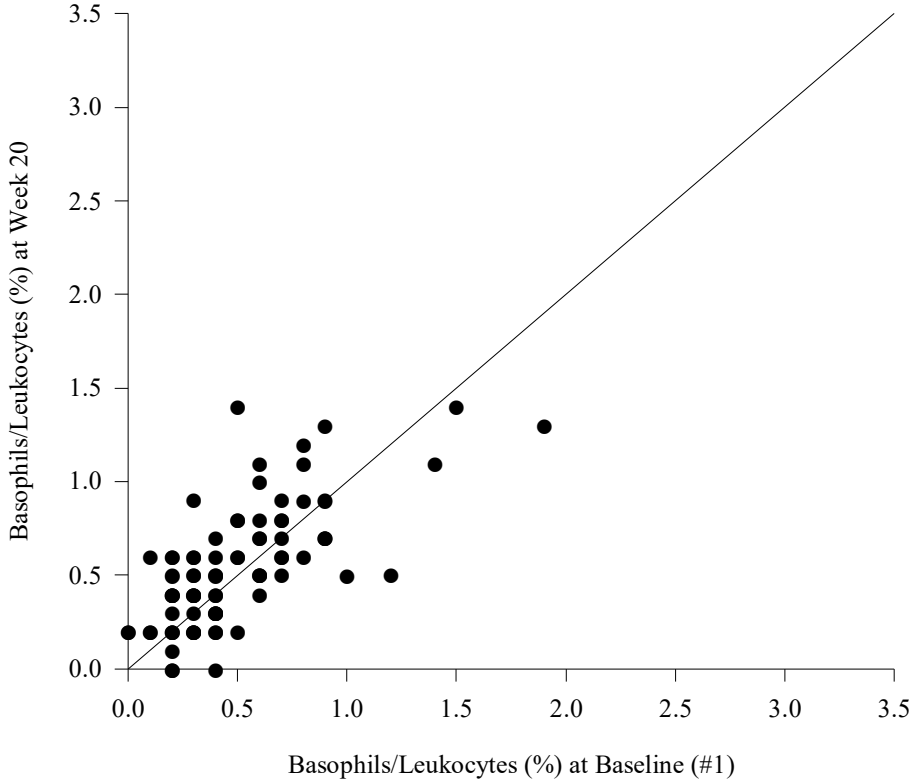


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 173 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (5%/5%)

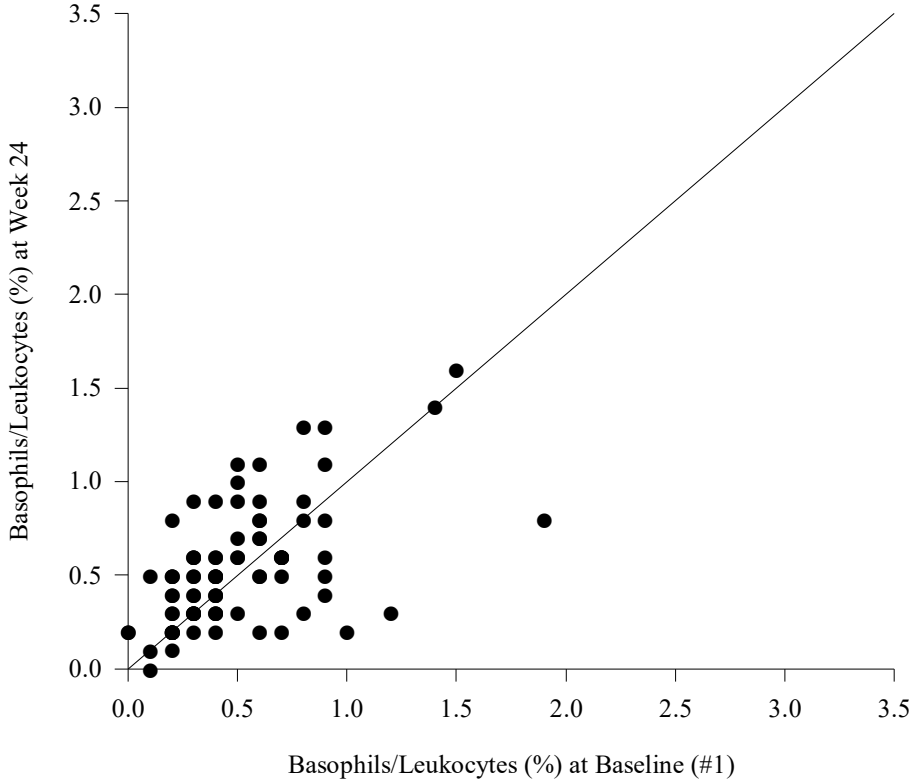


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 174 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (5%/5%)

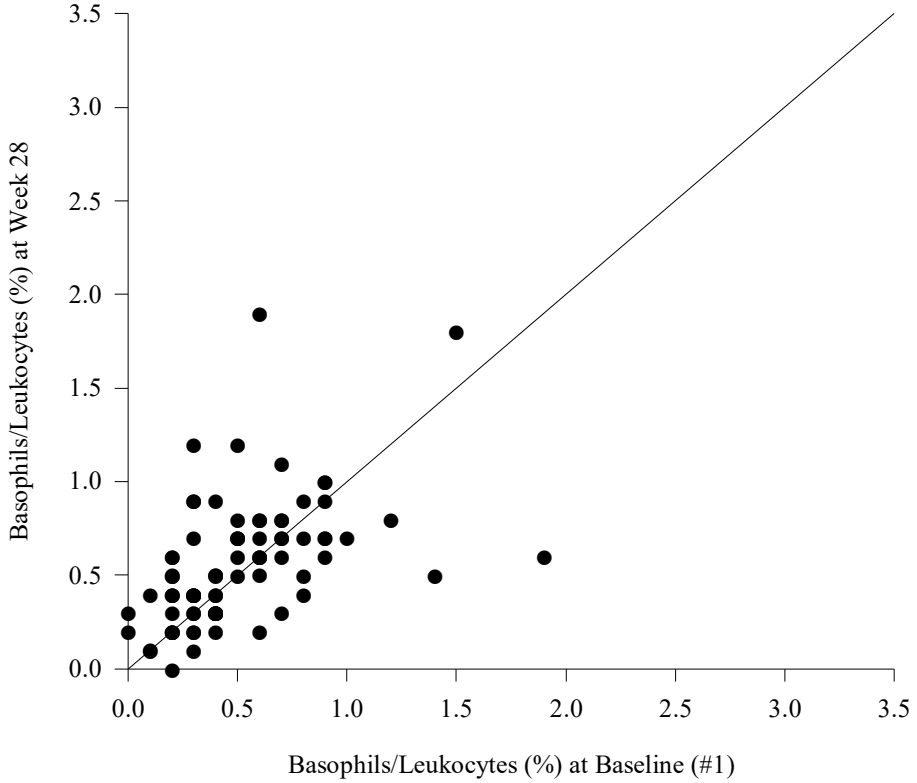


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 175 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (5%/5%)

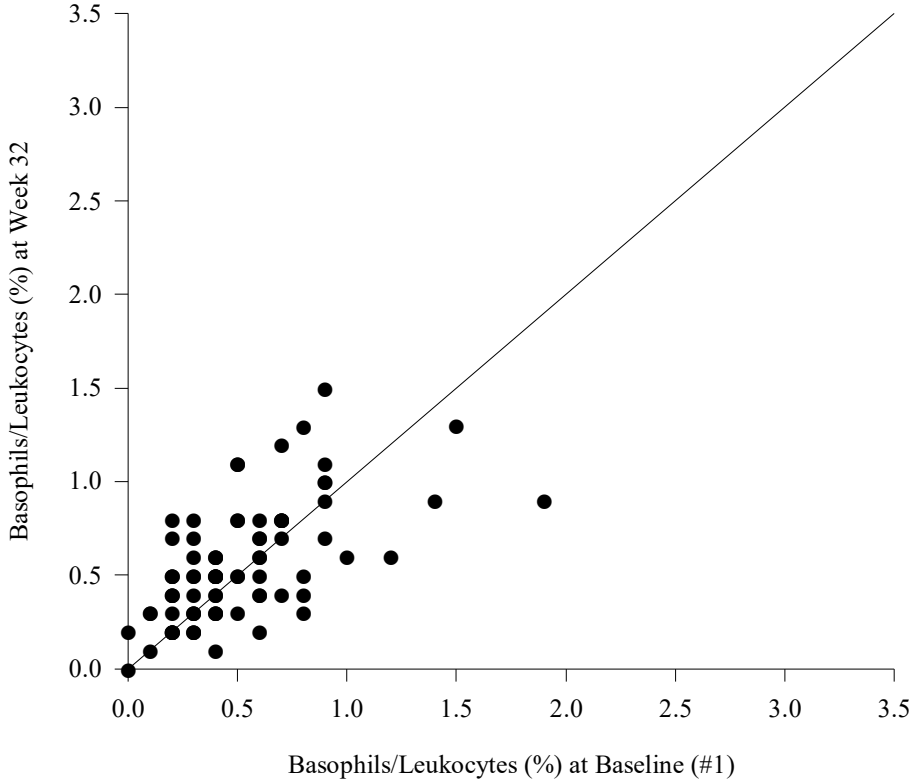


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 176 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (5%/5%)

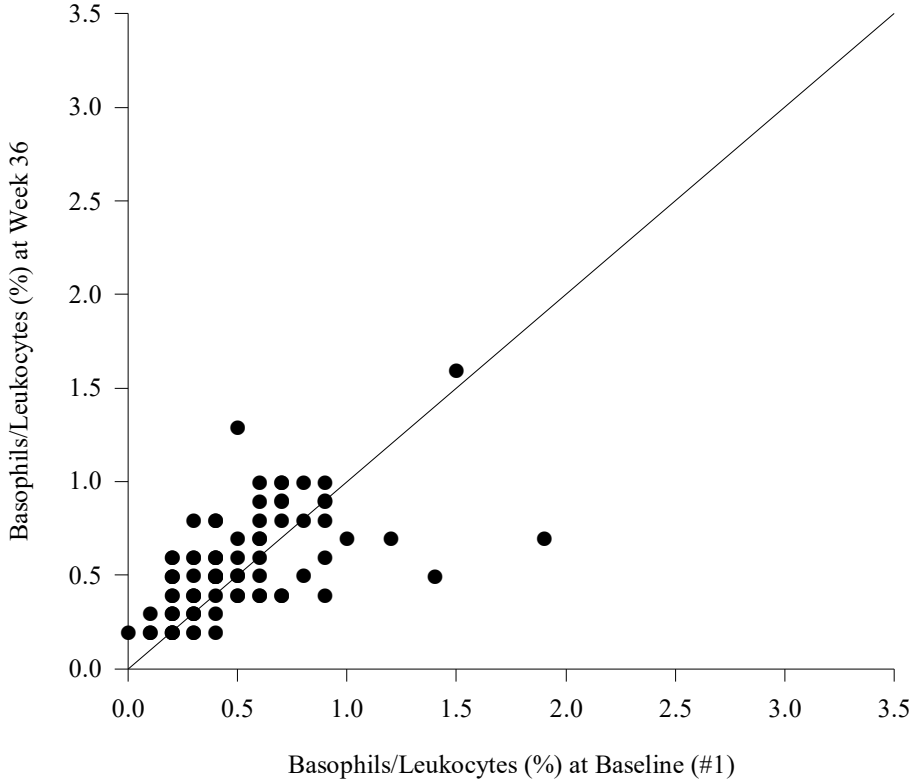


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 177 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (5%/5%)

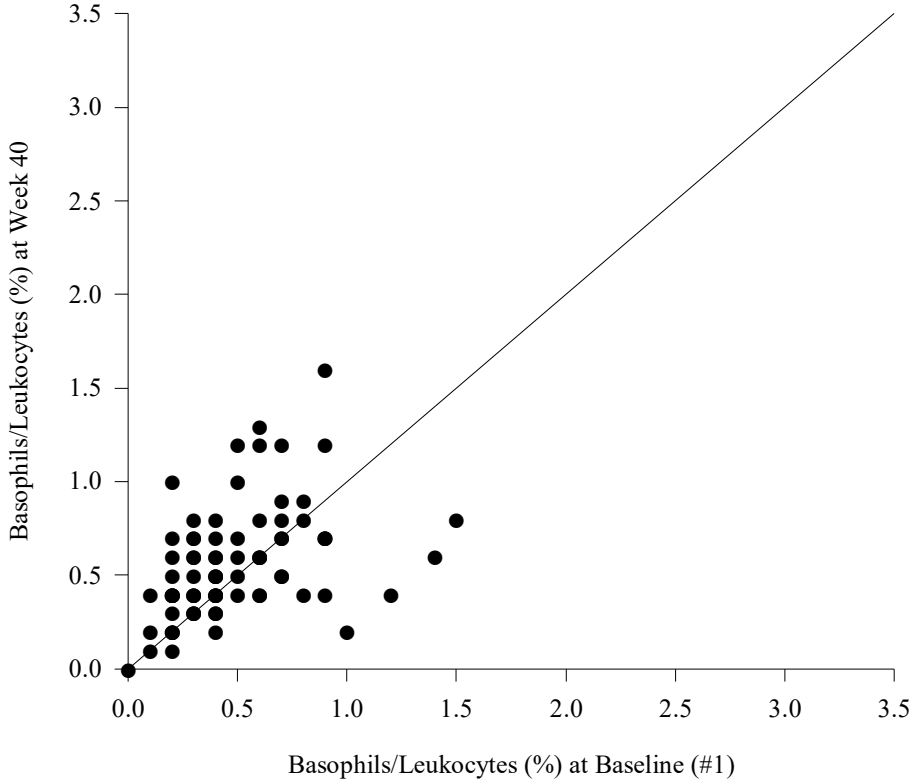


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 178 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (5%/5%)

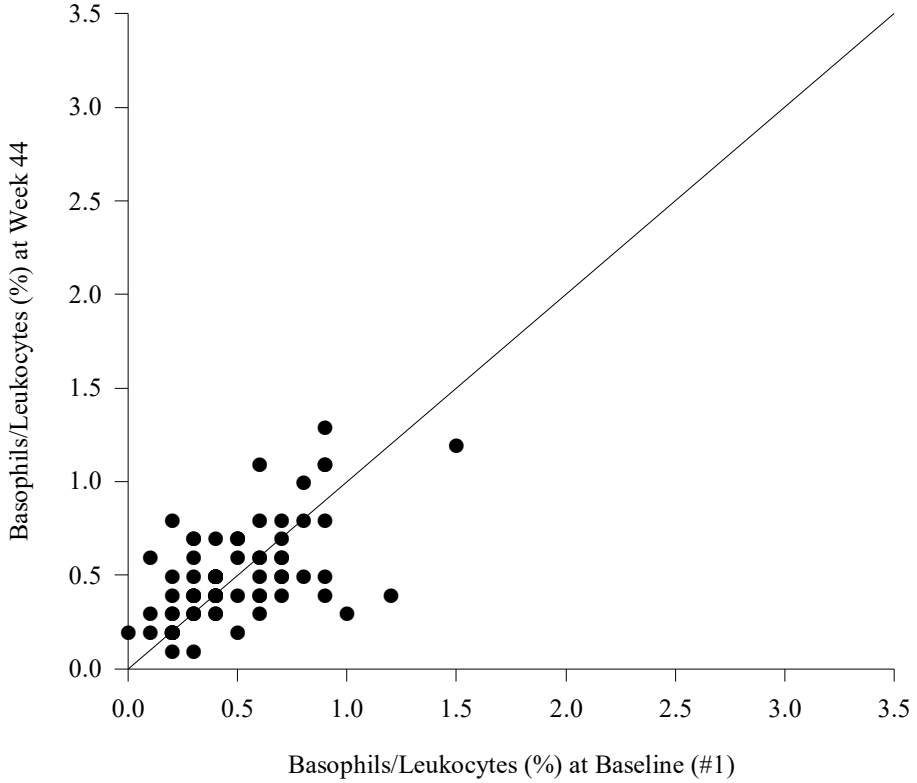


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 179 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (5%/5%)

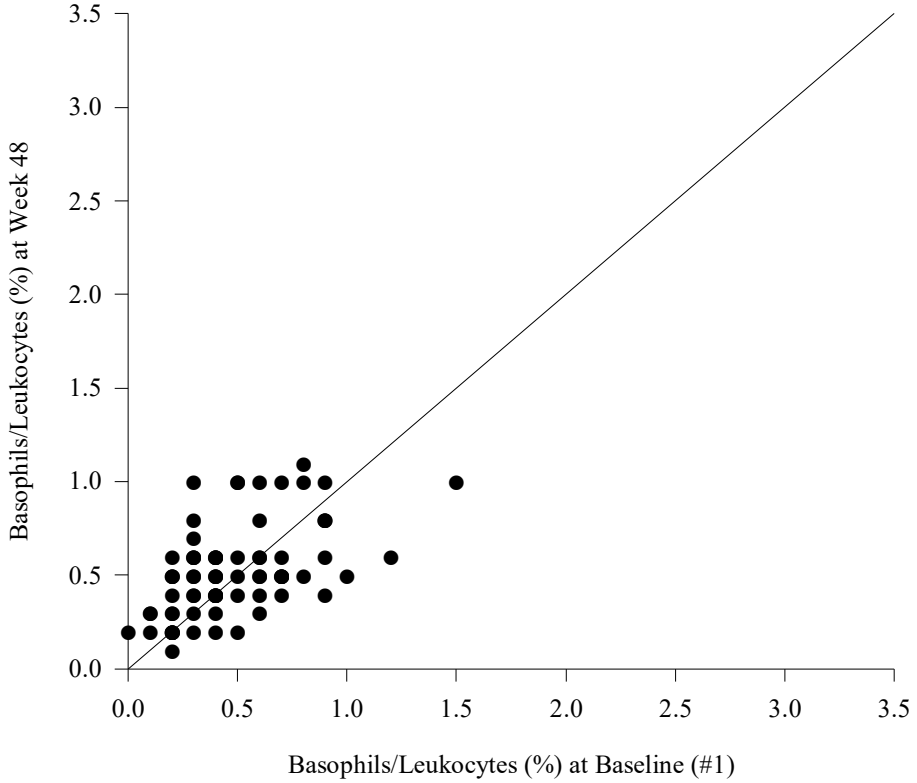


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 180 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (5%/5%)

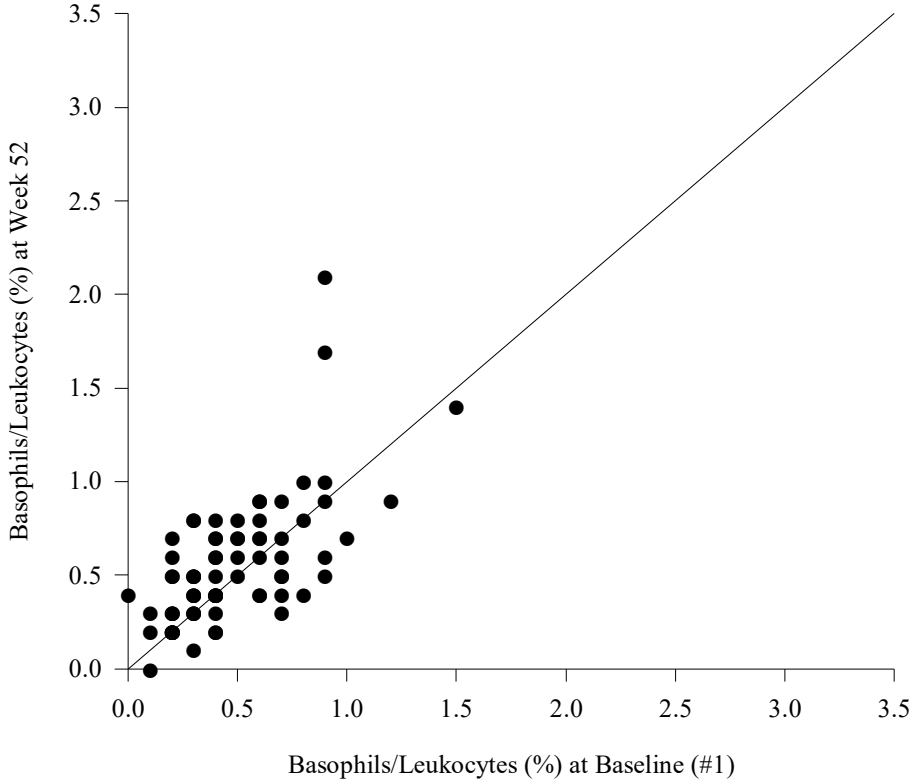


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 181 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (5%/5%)

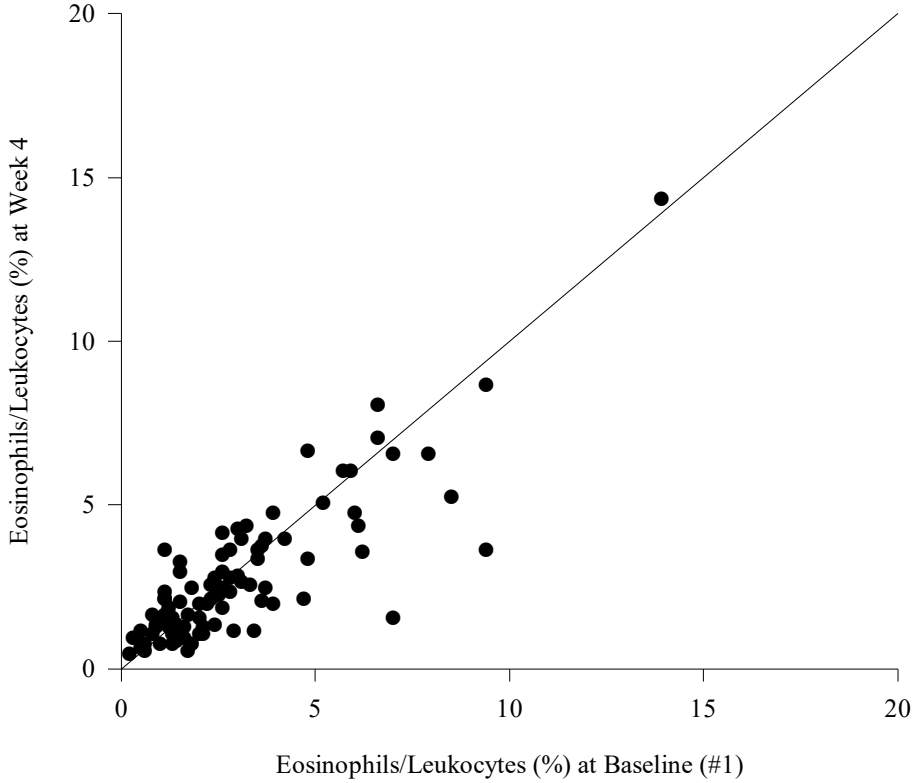


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 182 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (0%/5%)

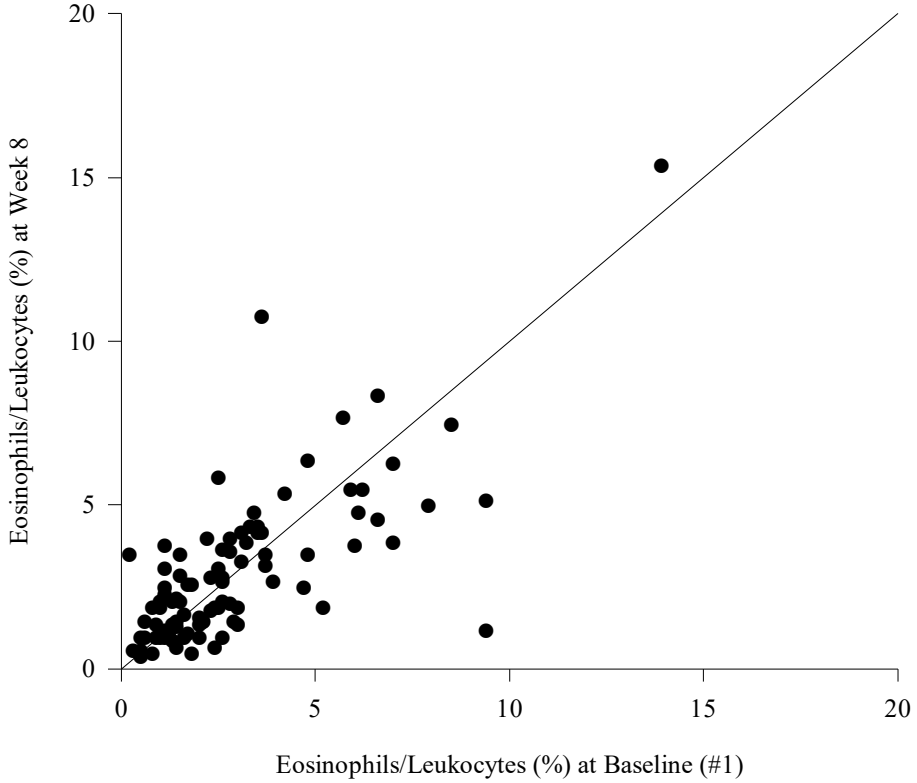


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 183 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (0%/5%)

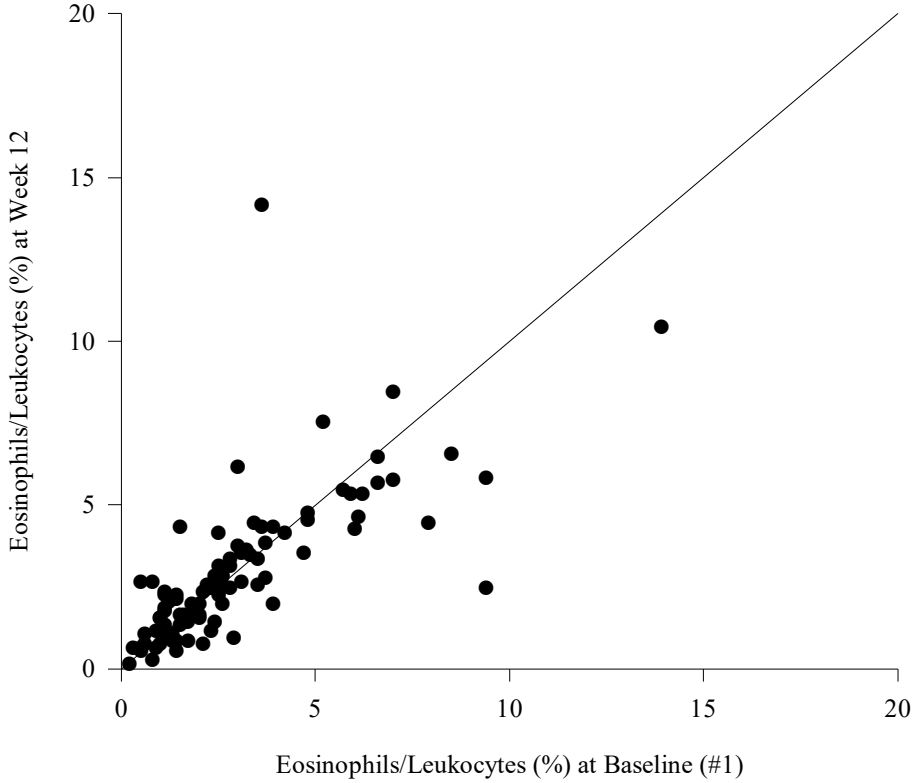


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 184 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (0%/5%)

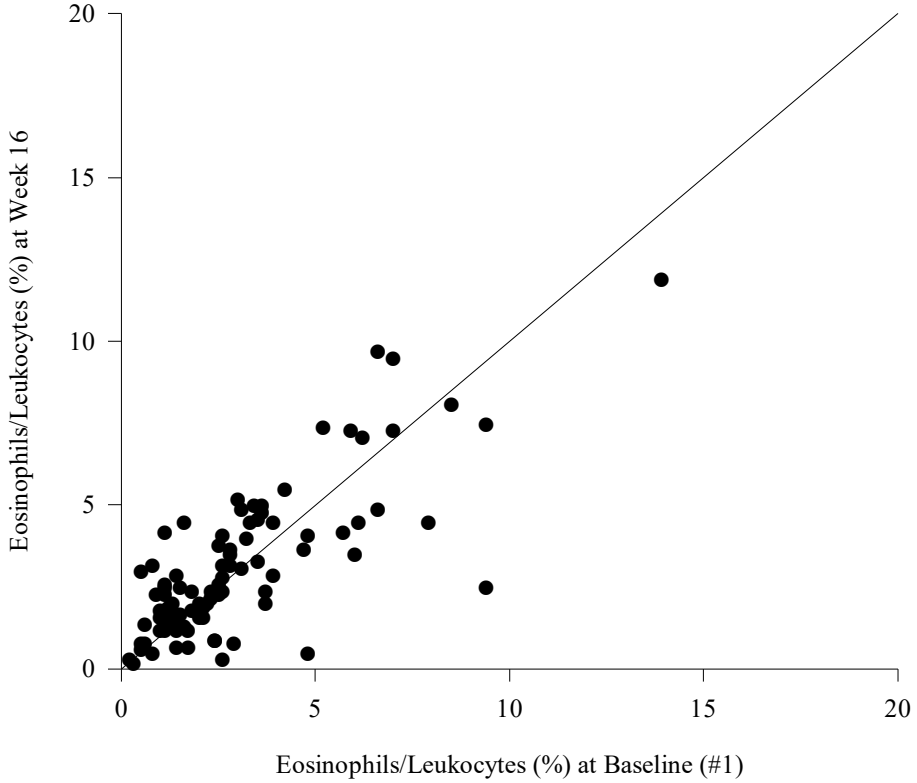


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 185 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (0%/5%)

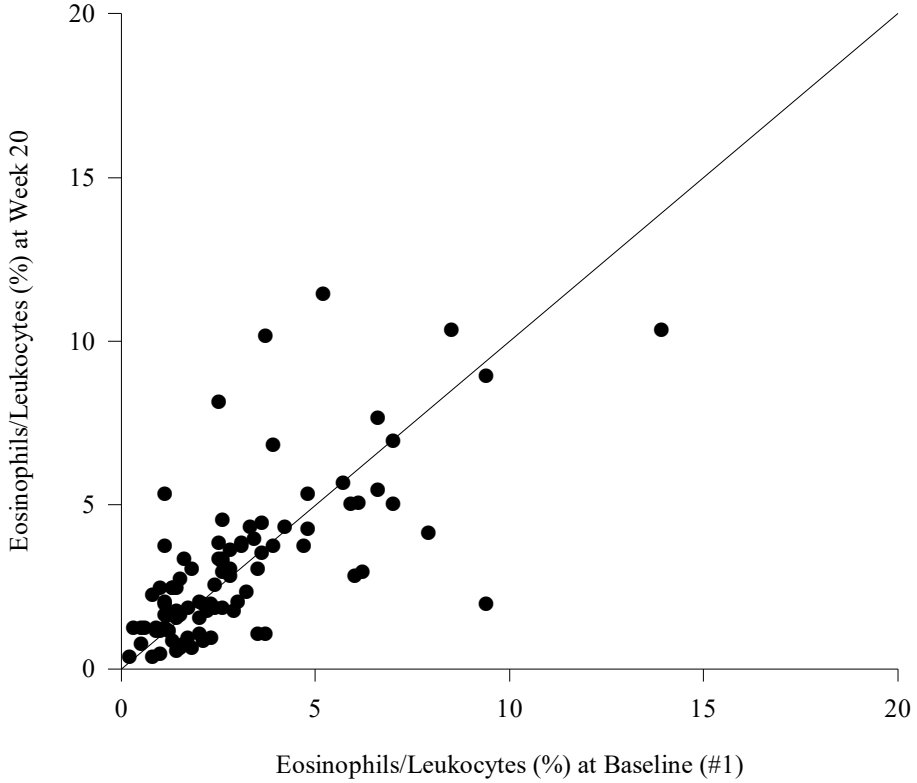


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 186 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (0%/5%)

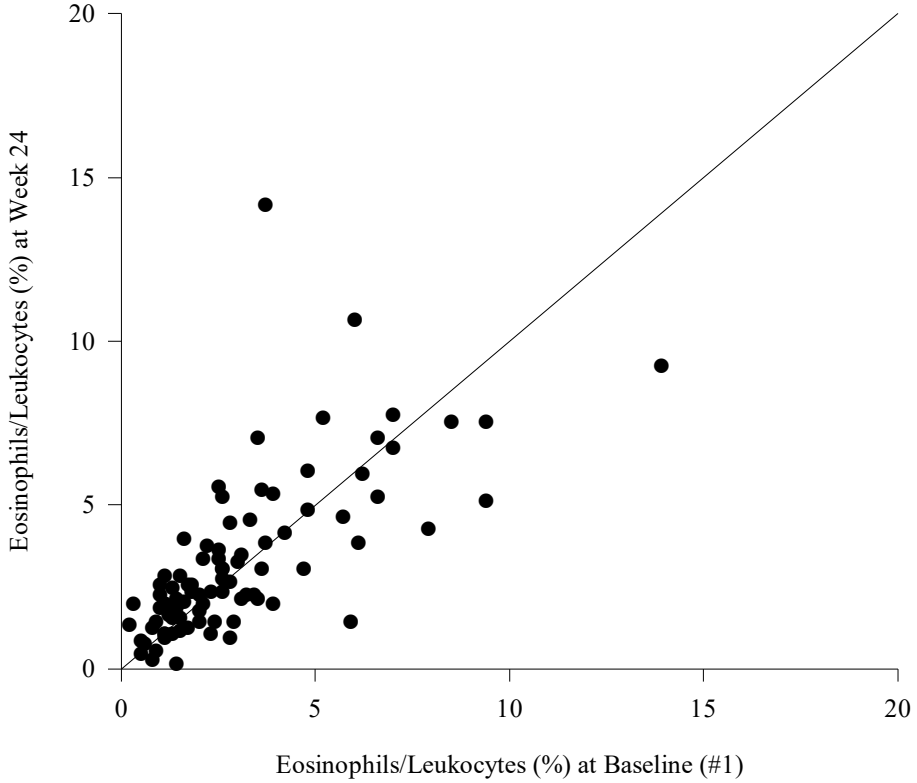


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 187 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (0%/5%)

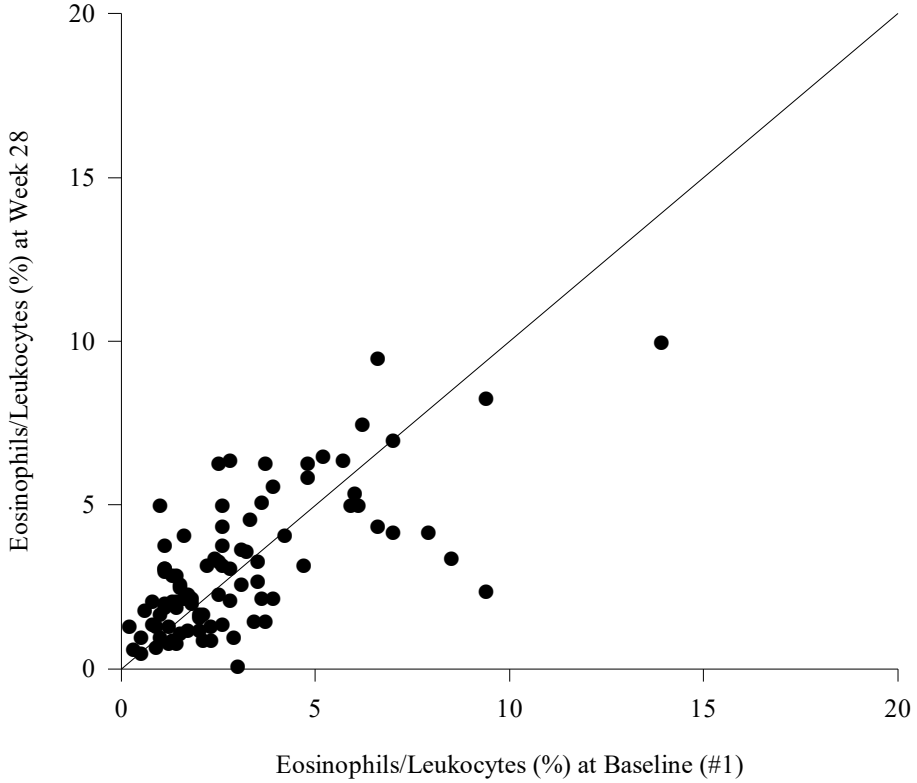


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 188 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (0%/5%)

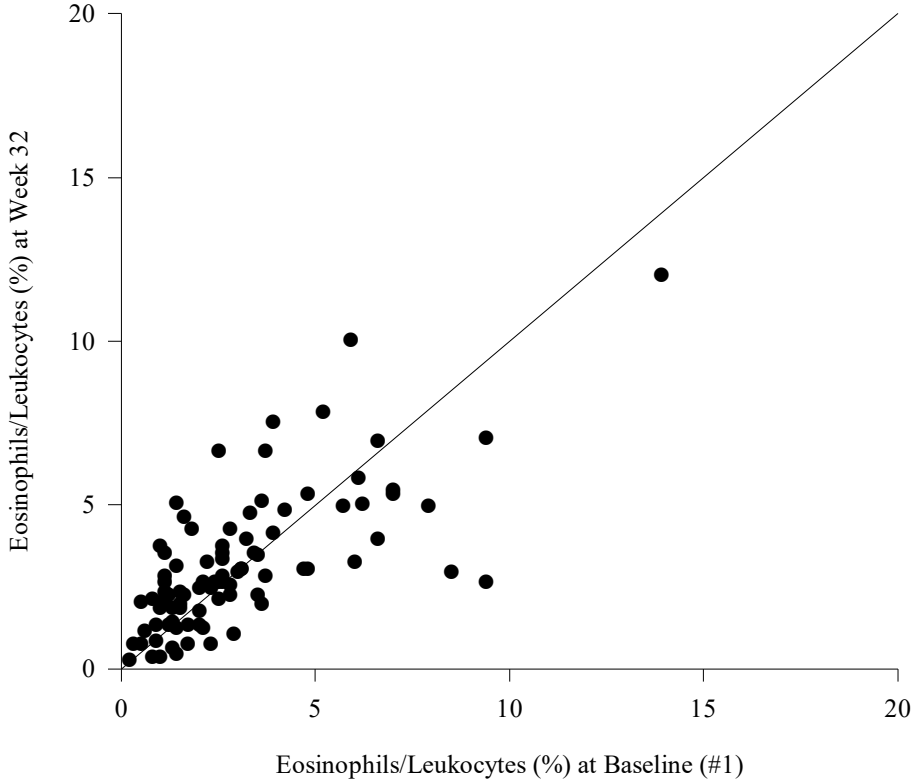


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 189 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (0%/5%)

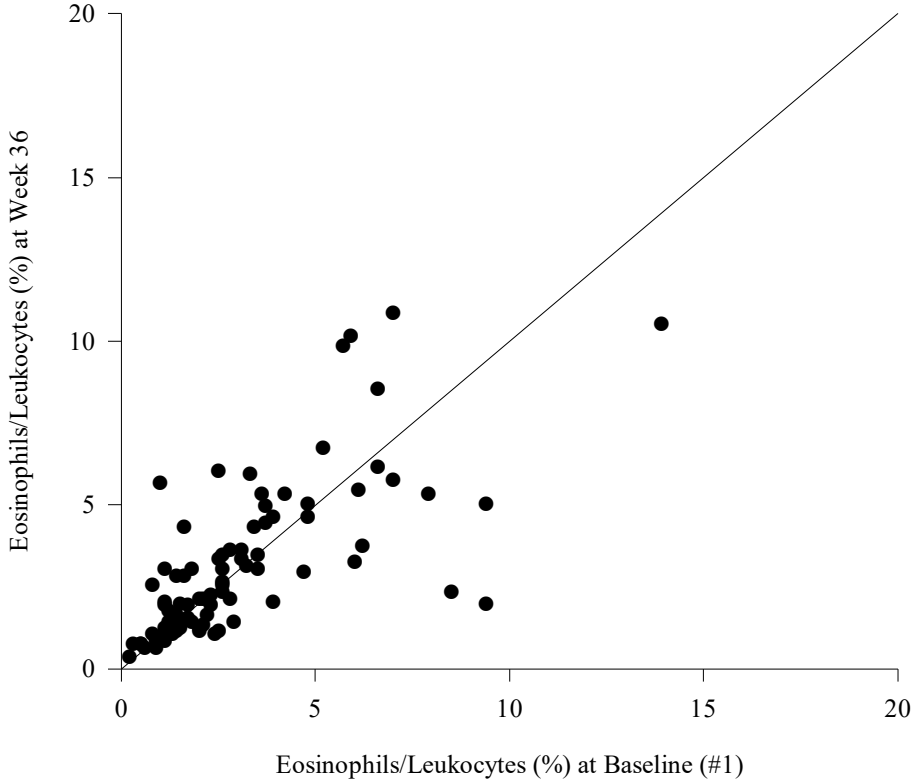


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 190 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (0%/5%)

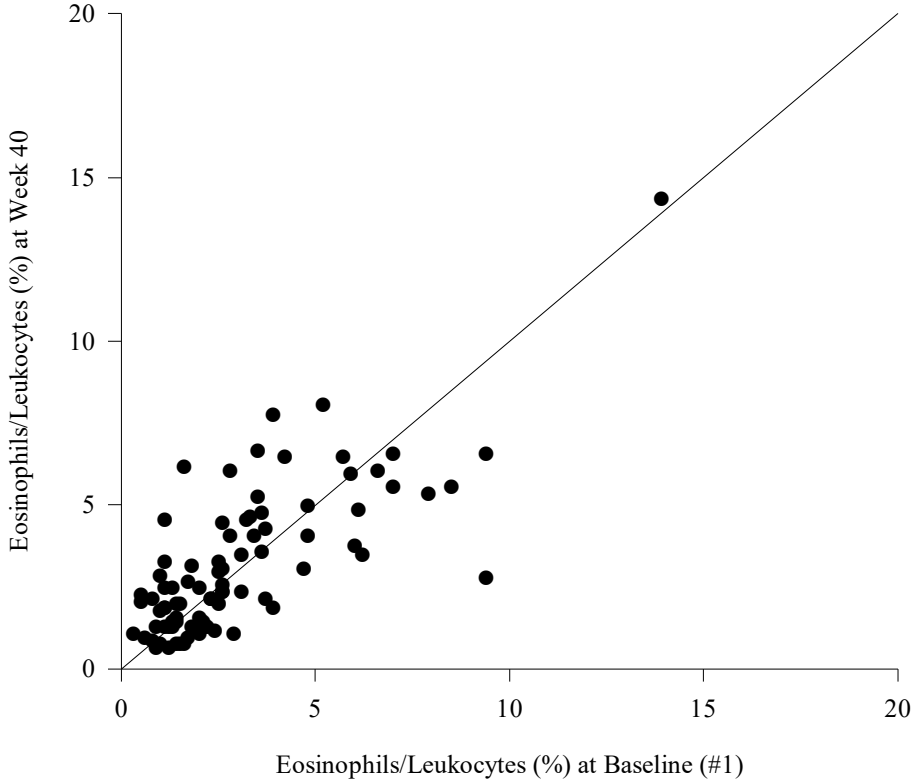


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 191 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (0%/5%)

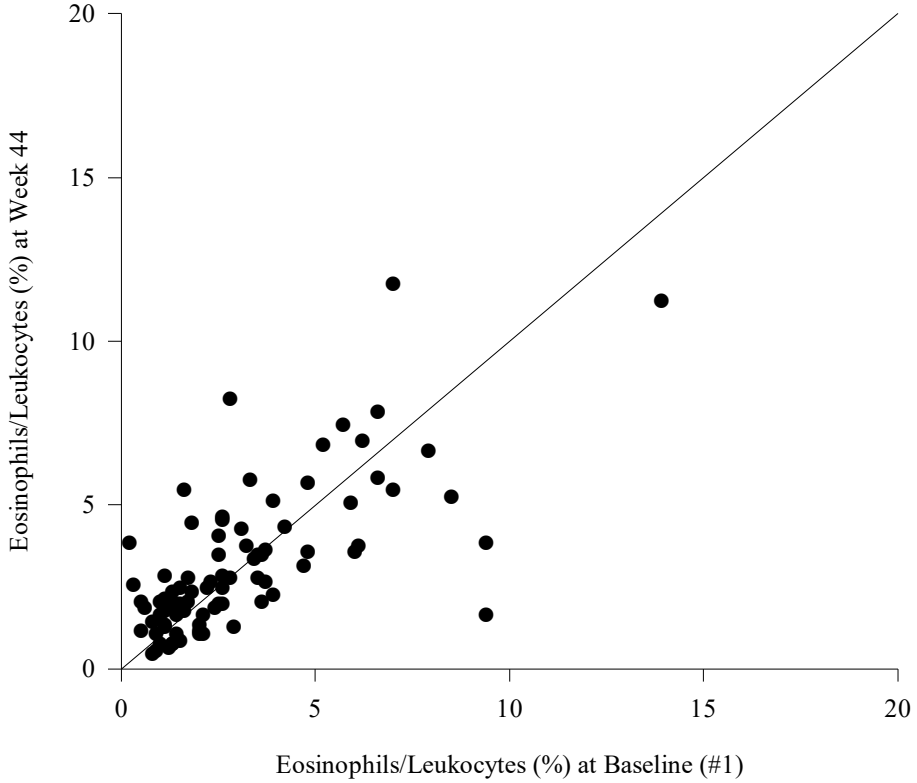


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 192 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (0%/5%)

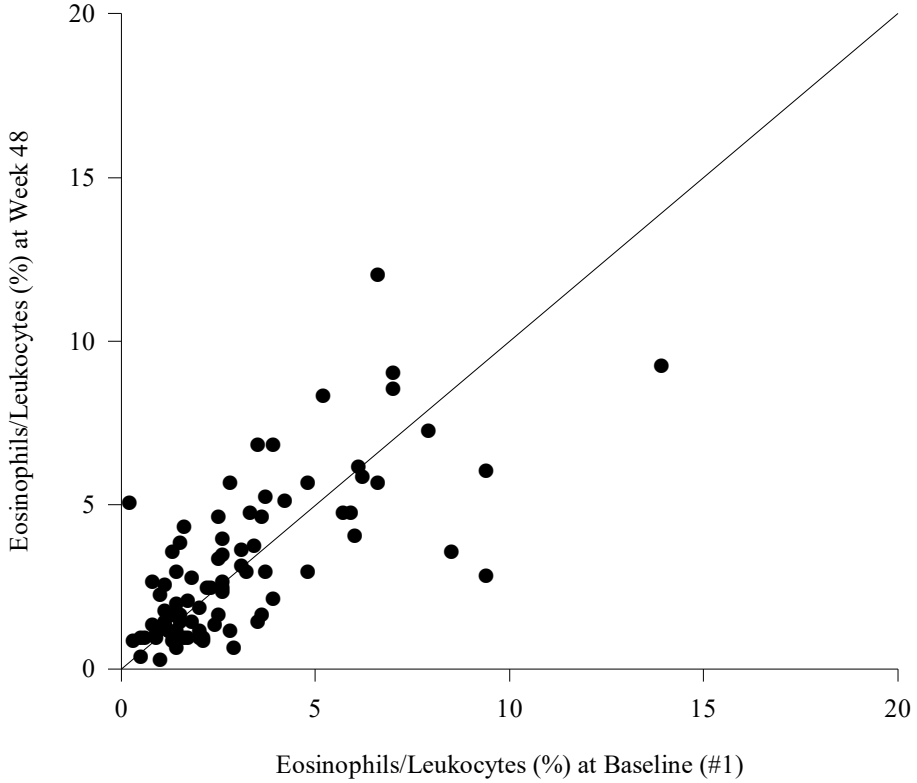


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 193 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (0%/5%)

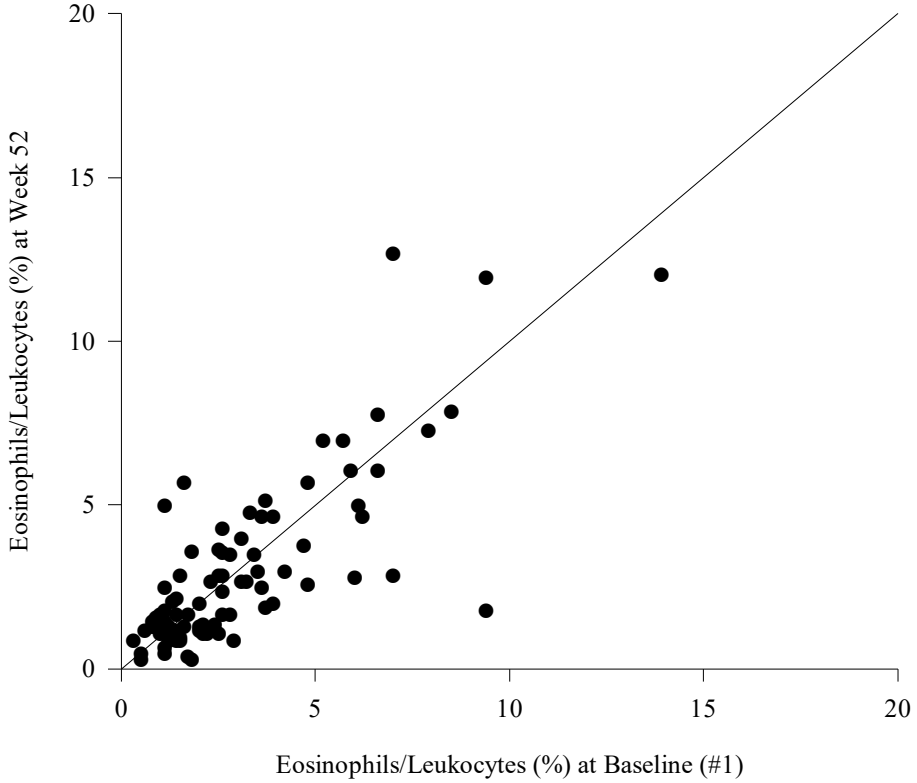


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 194 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (0%/5%)

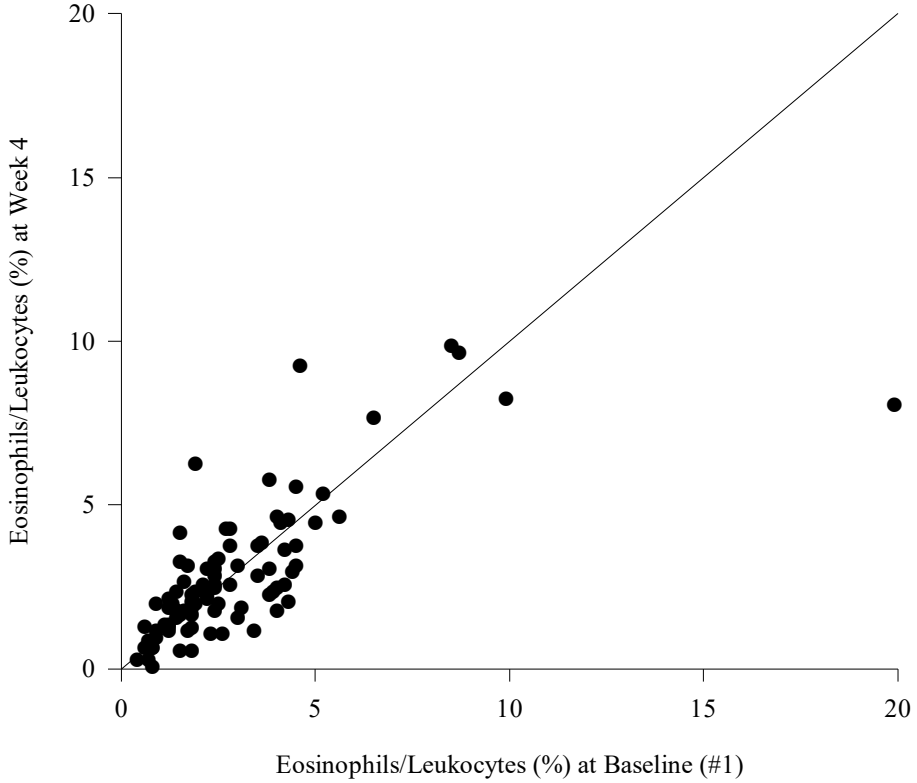


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 195 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (5%/5%)

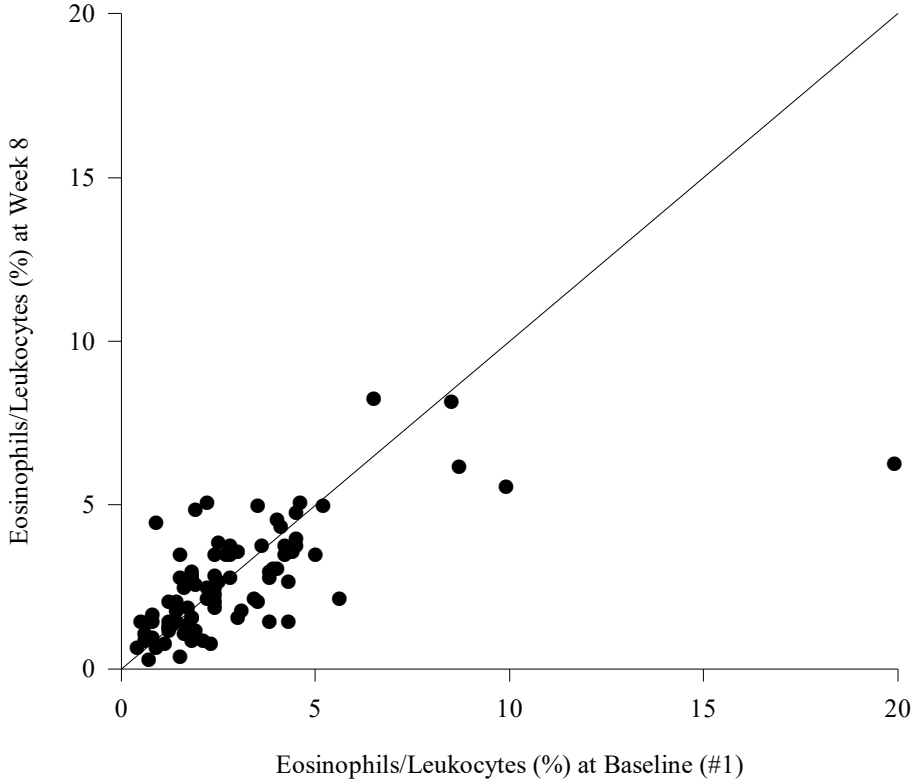


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 196 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (5%/5%)

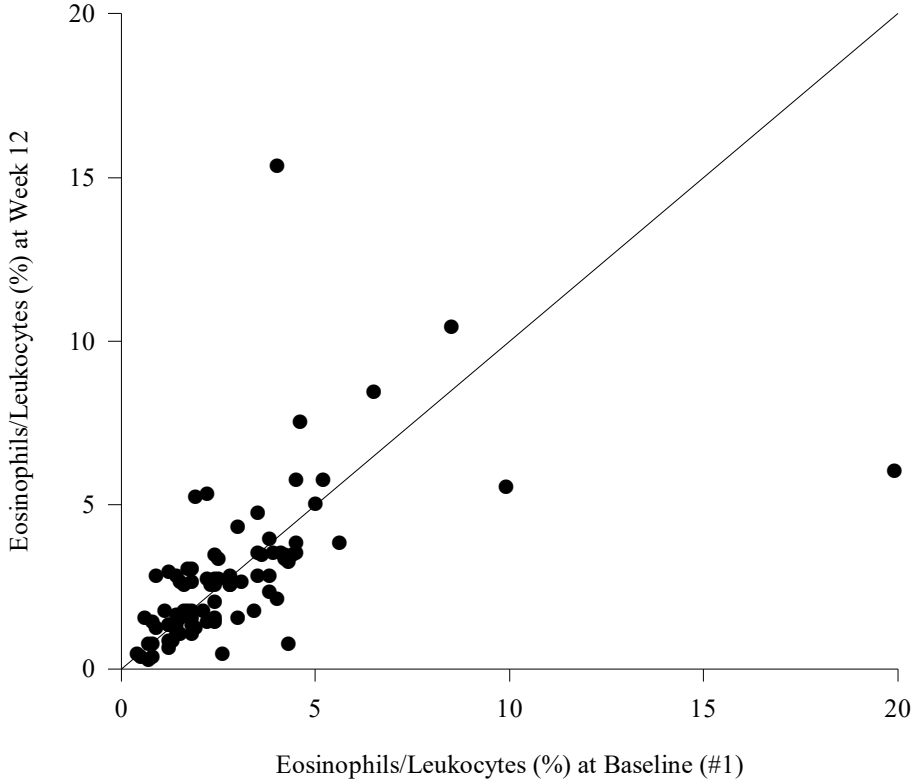


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 197 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (5%/5%)

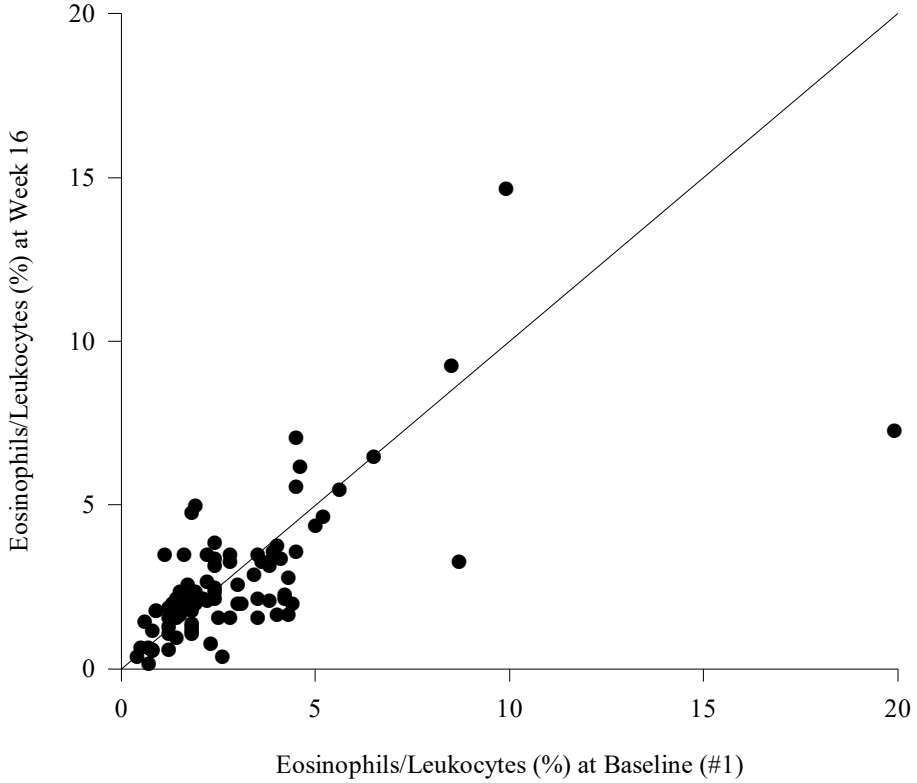


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 198 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (5%/5%)

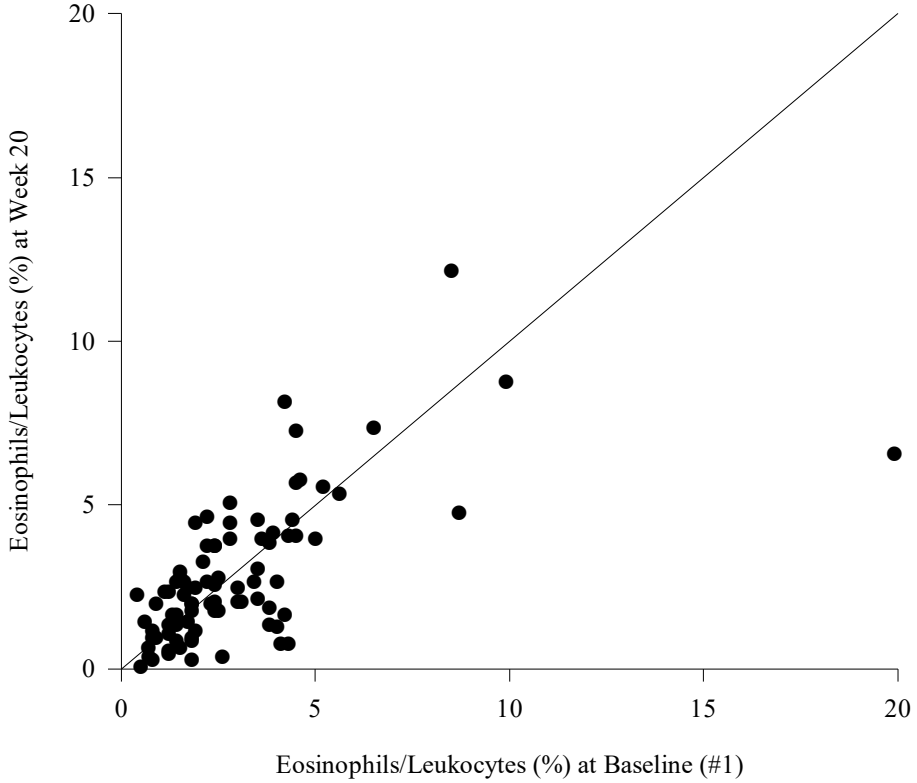


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 199 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (5%/5%)

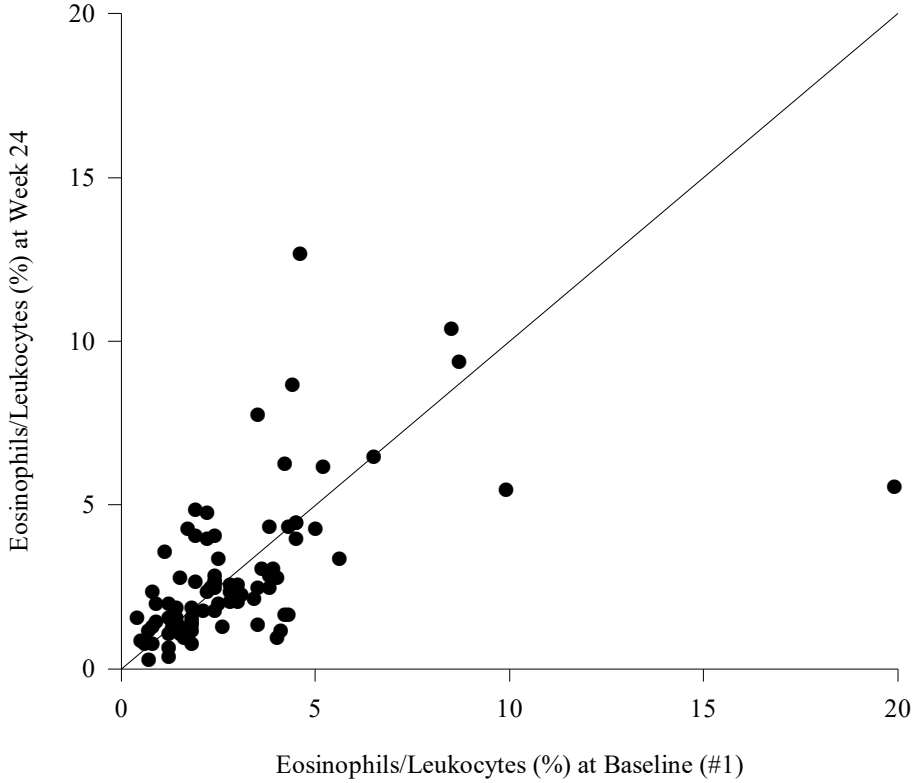


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 200 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (5%/5%)

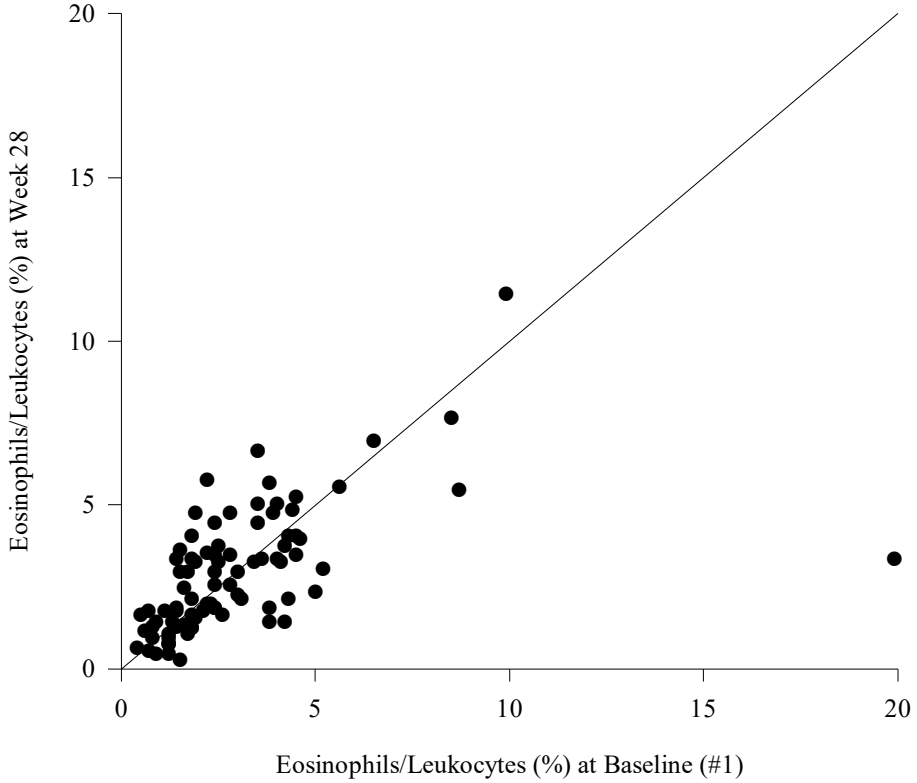


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 201 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (5%/5%)

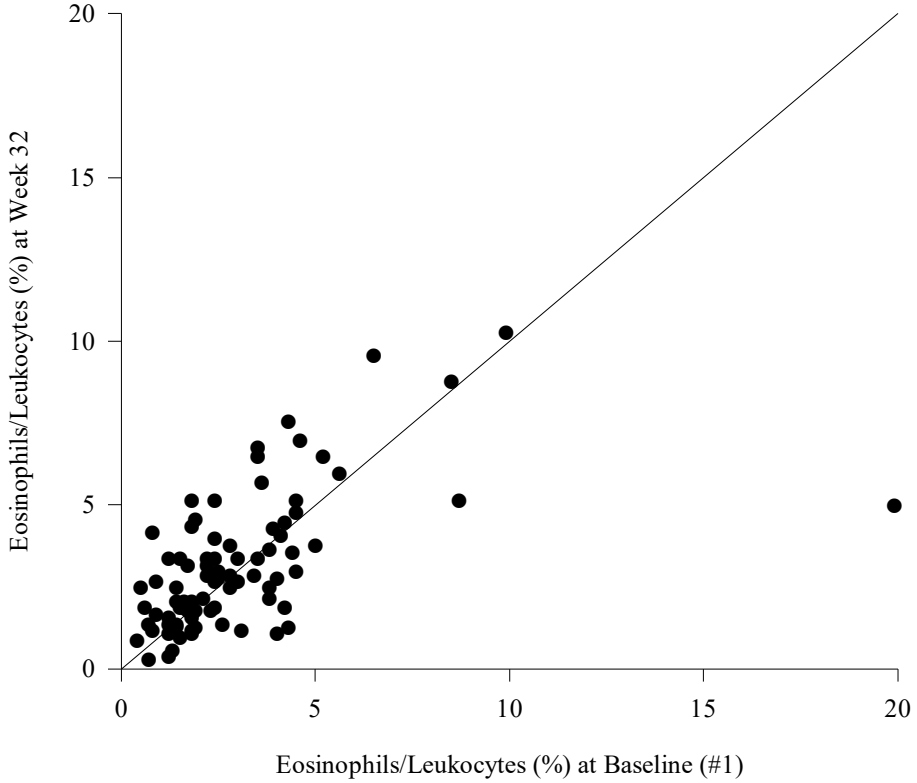


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 202 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (5%/5%)

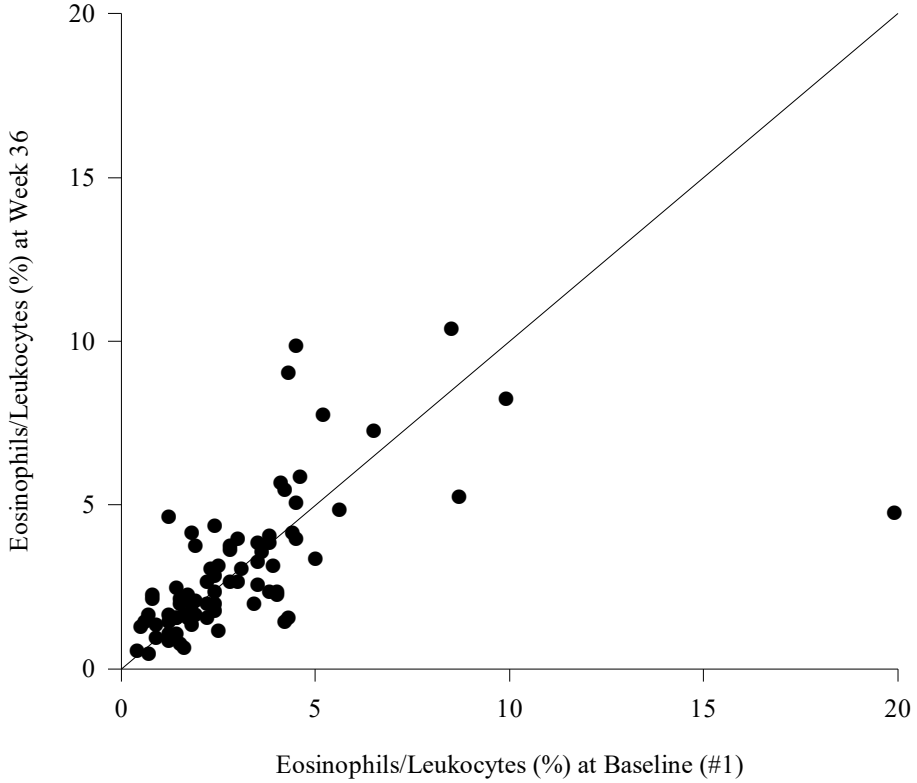


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 203 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (5%/5%)

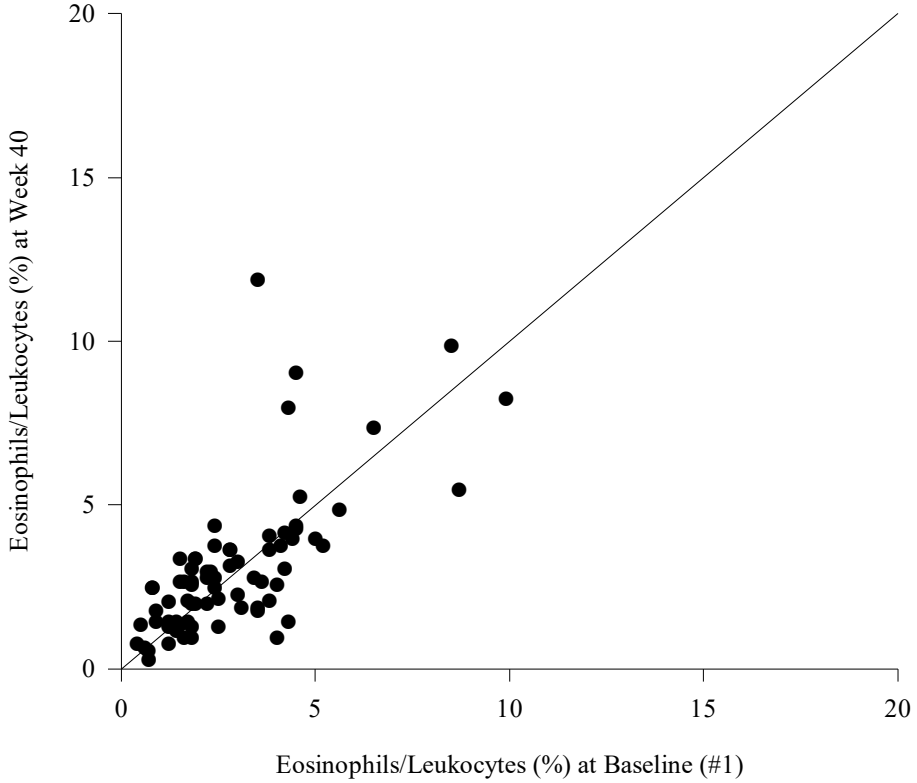


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 204 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (5%/5%)

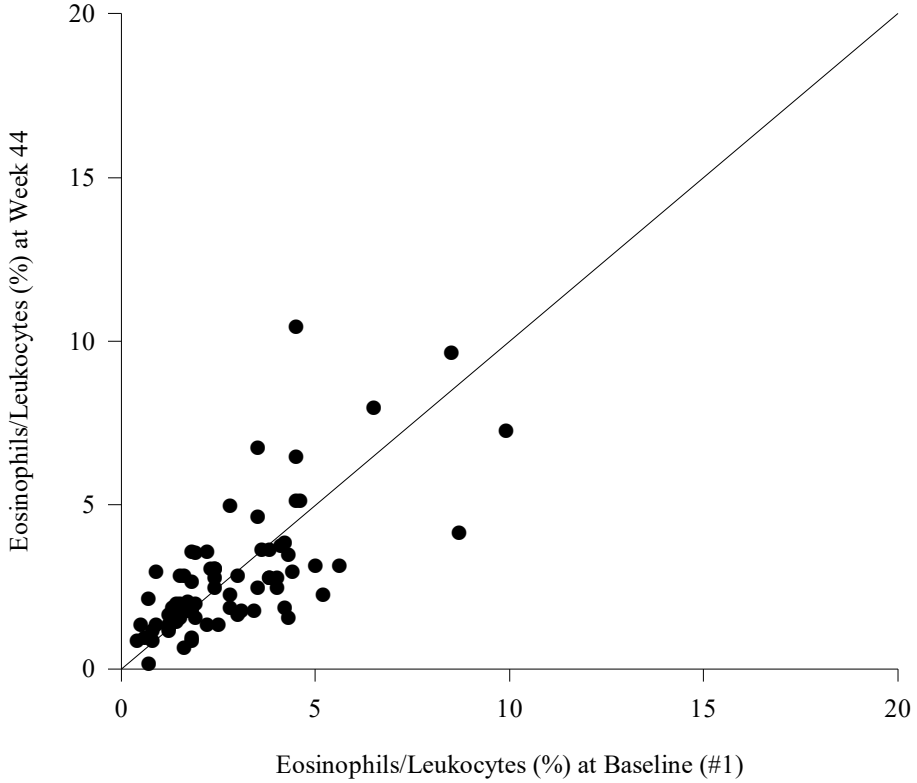


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 205 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (5%/5%)

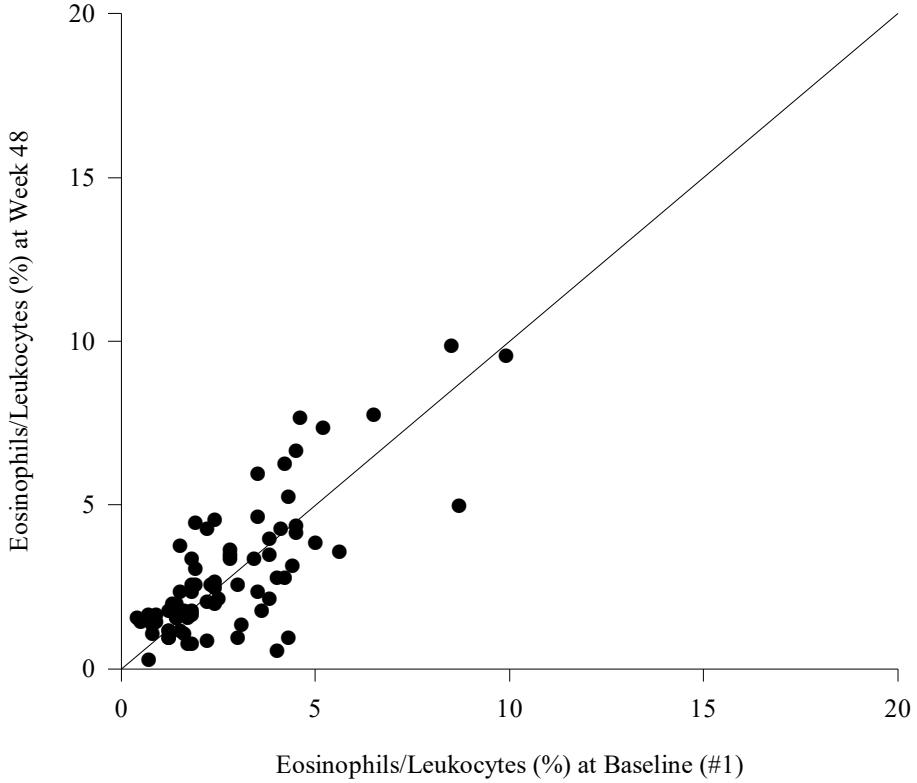


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 206 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (5%/5%)

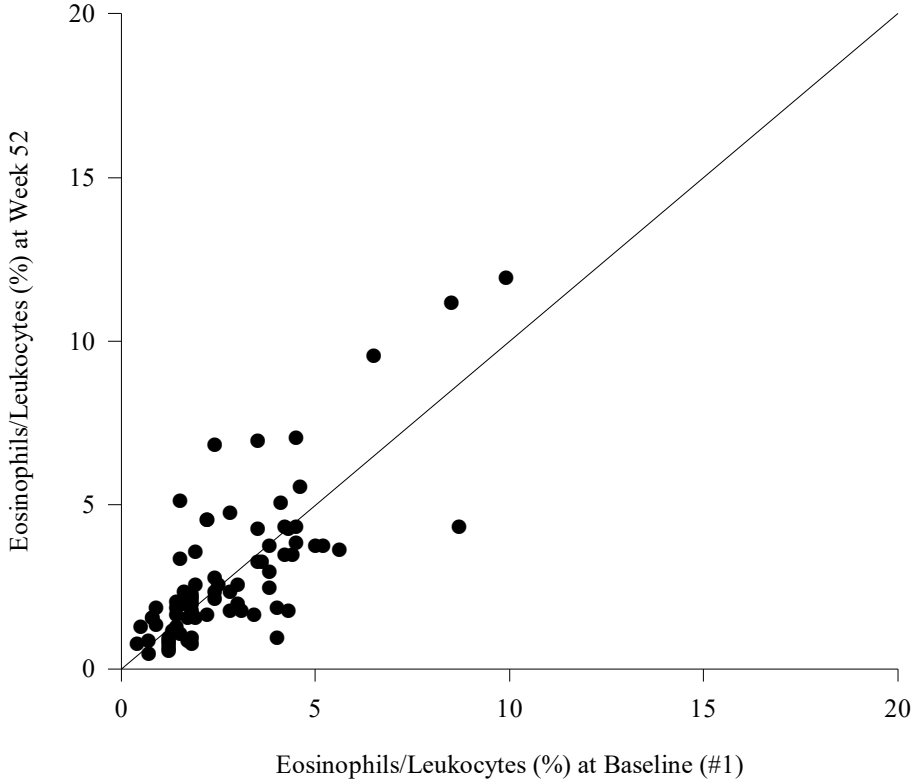


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 207 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (5%/5%)

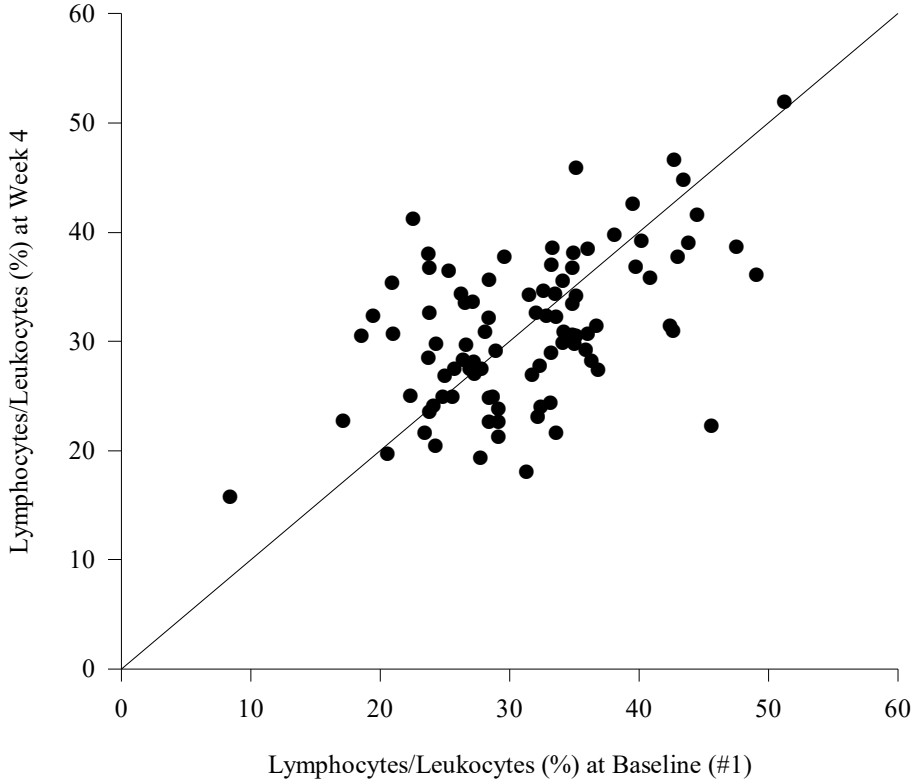


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 208 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (0%/5%)

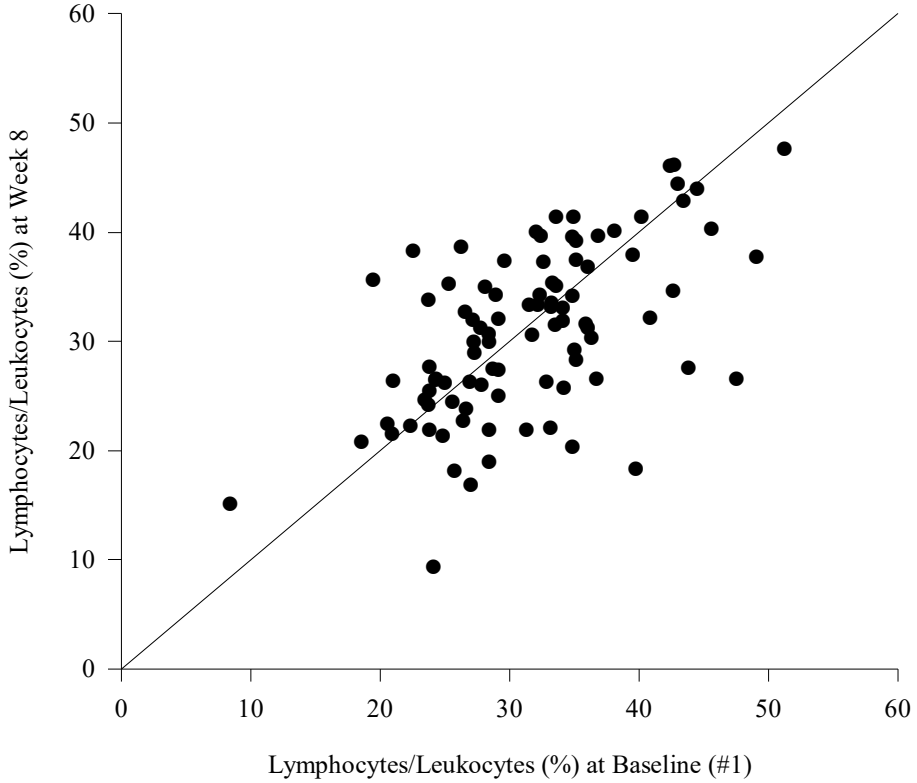


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 209 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (0%/5%)

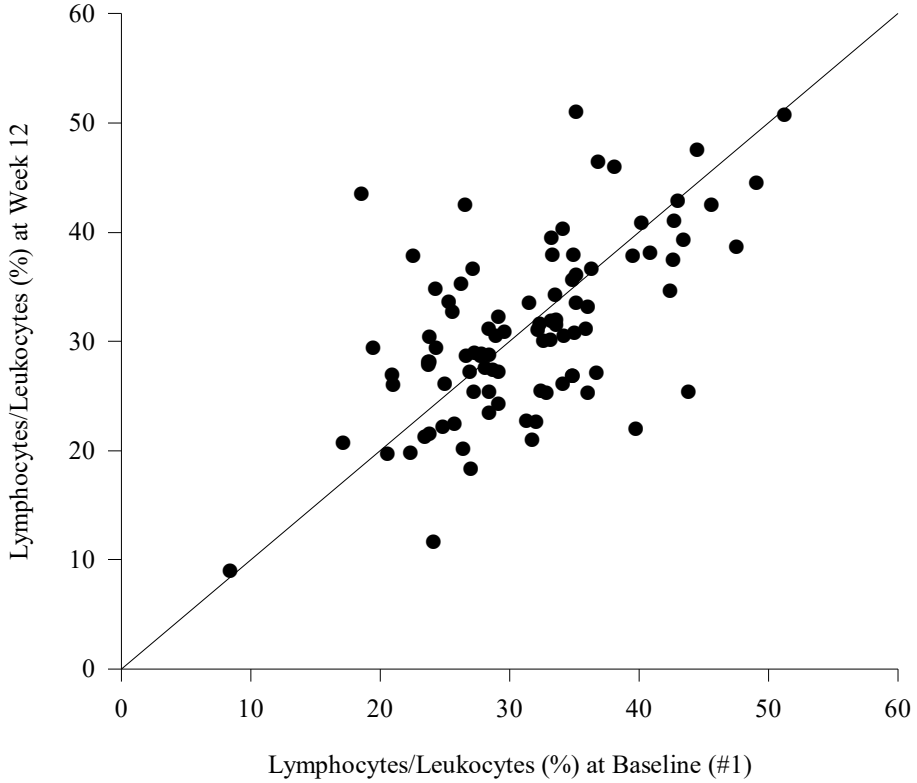


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 210 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (0%/5%)

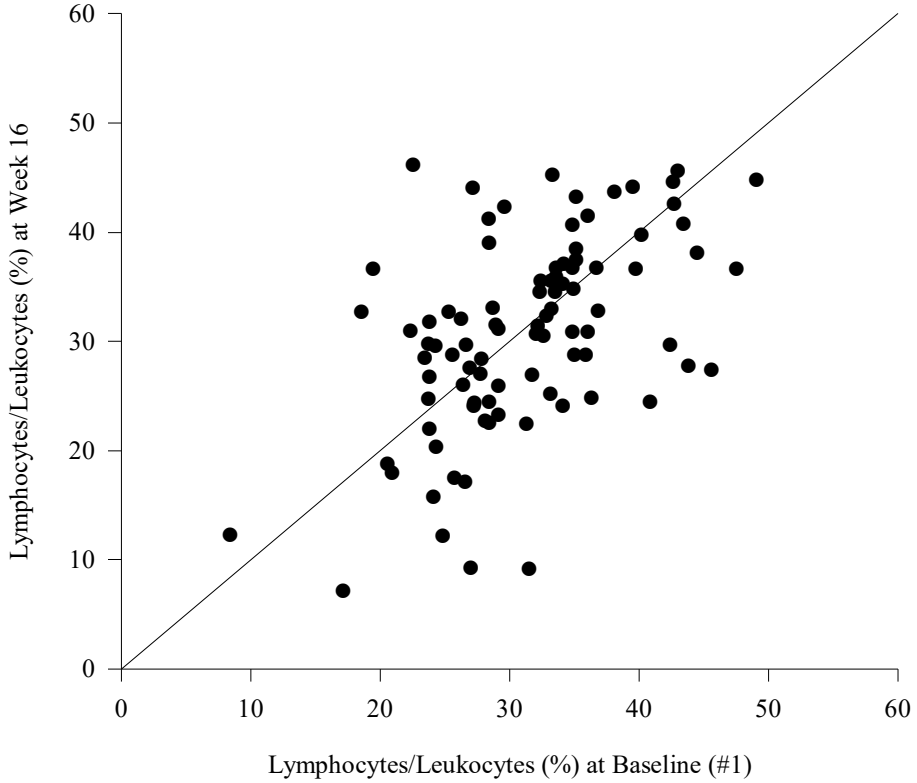


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 211 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (0%/5%)

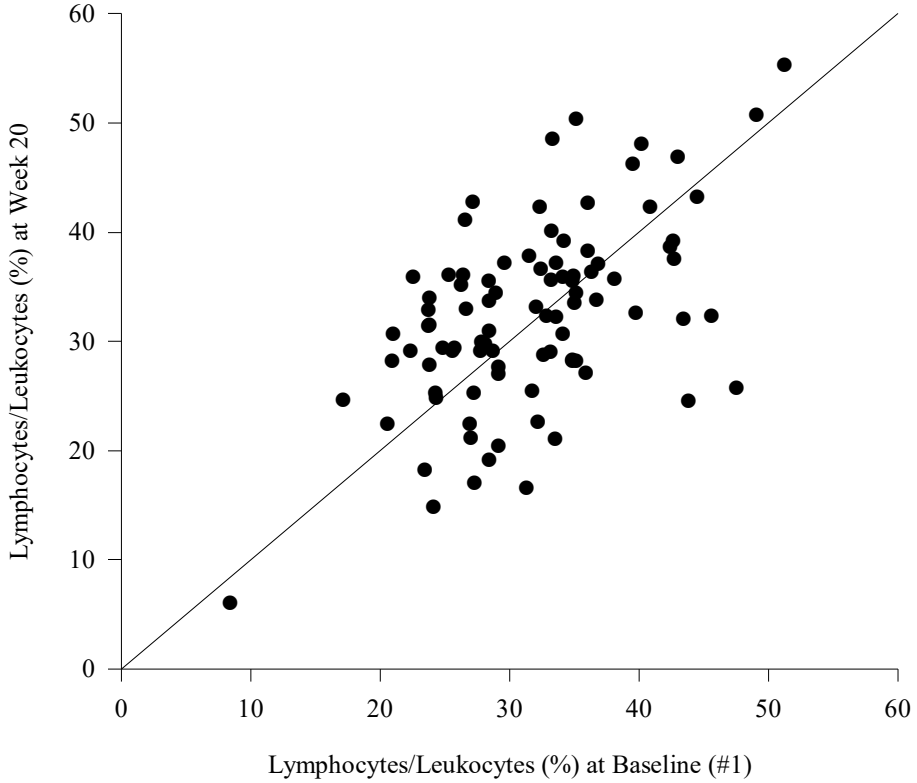


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 212 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (0%/5%)

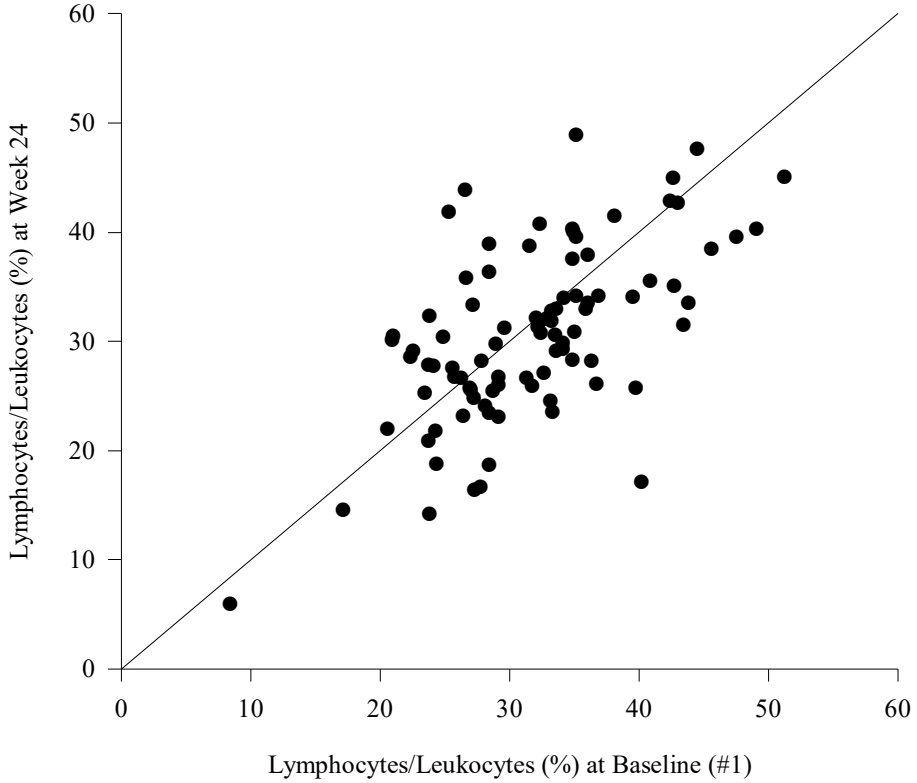


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 213 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (0%/5%)

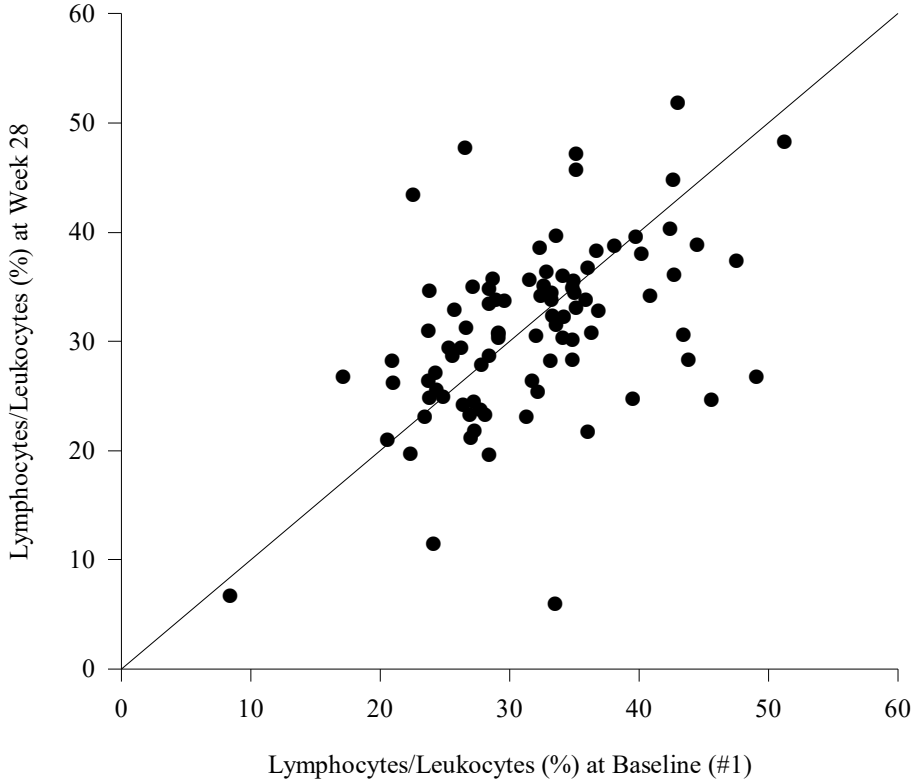


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 214 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (0%/5%)

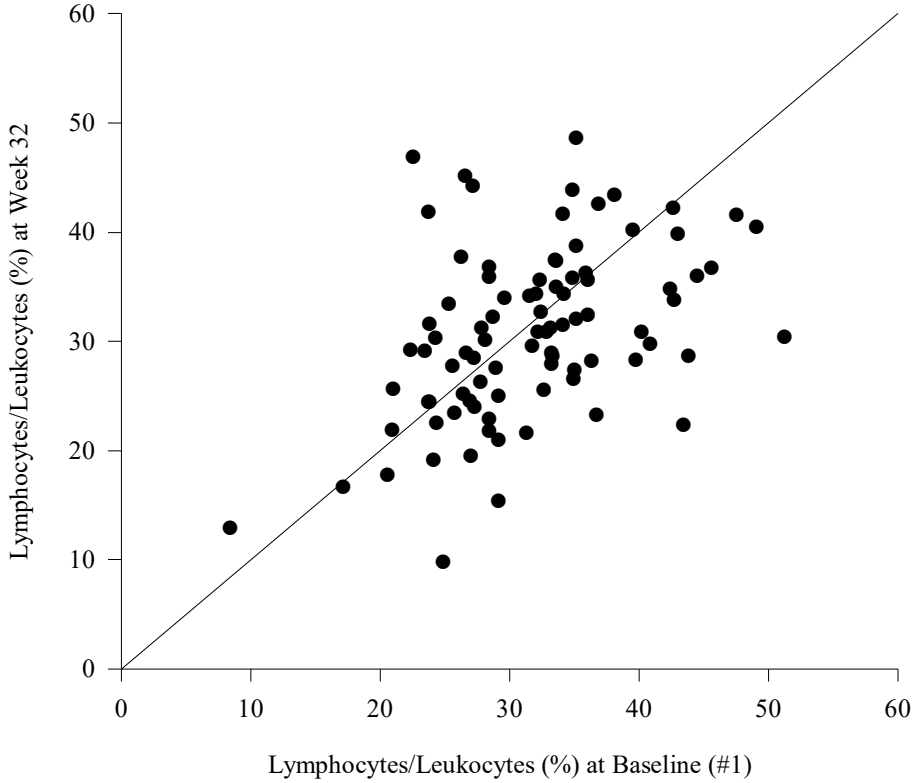


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 215 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (0%/5%)

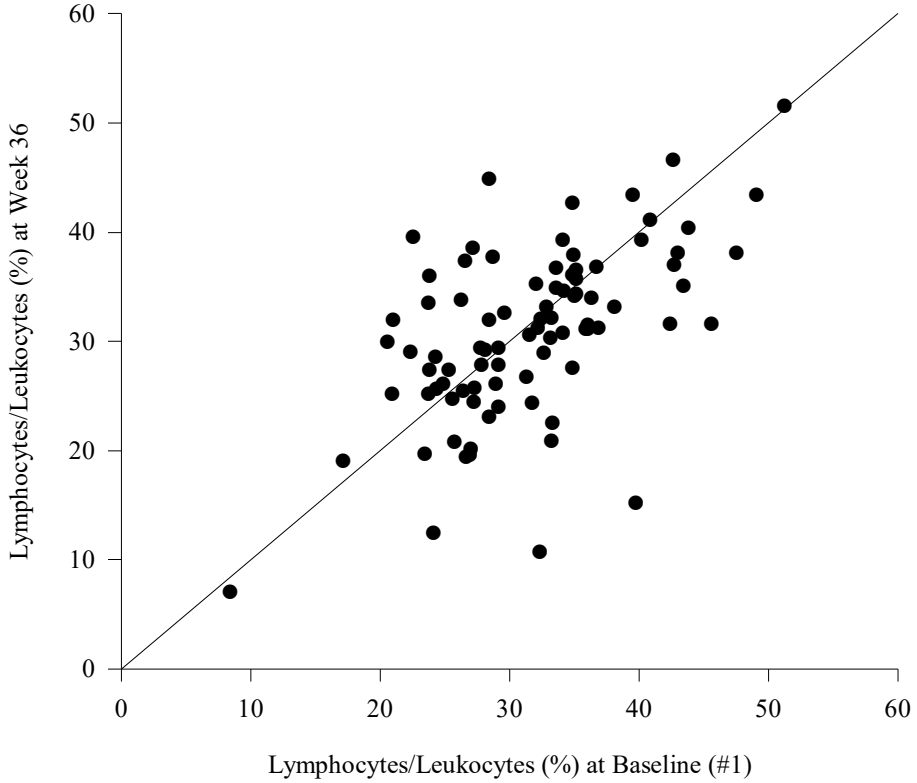


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 216 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (0%/5%)

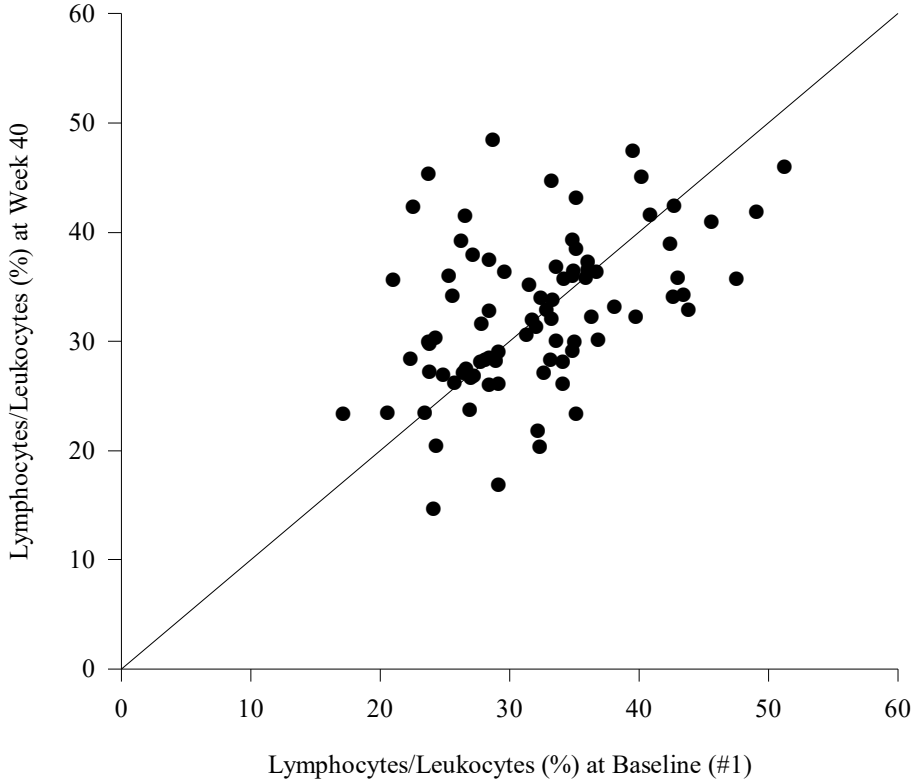


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 217 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (0%/5%)

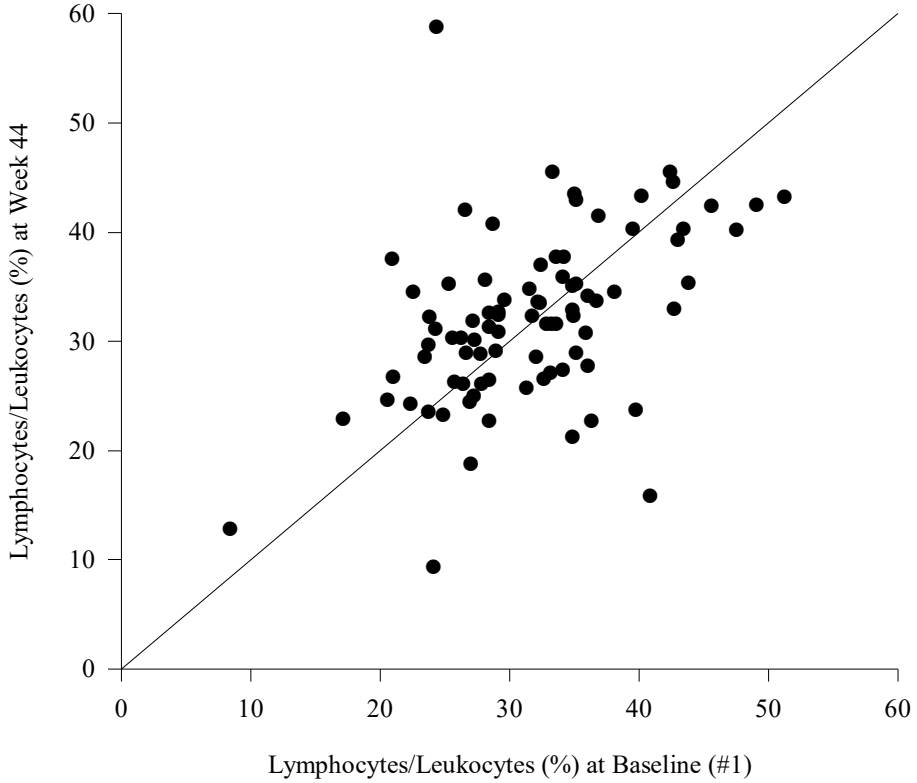


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 218 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (0%/5%)

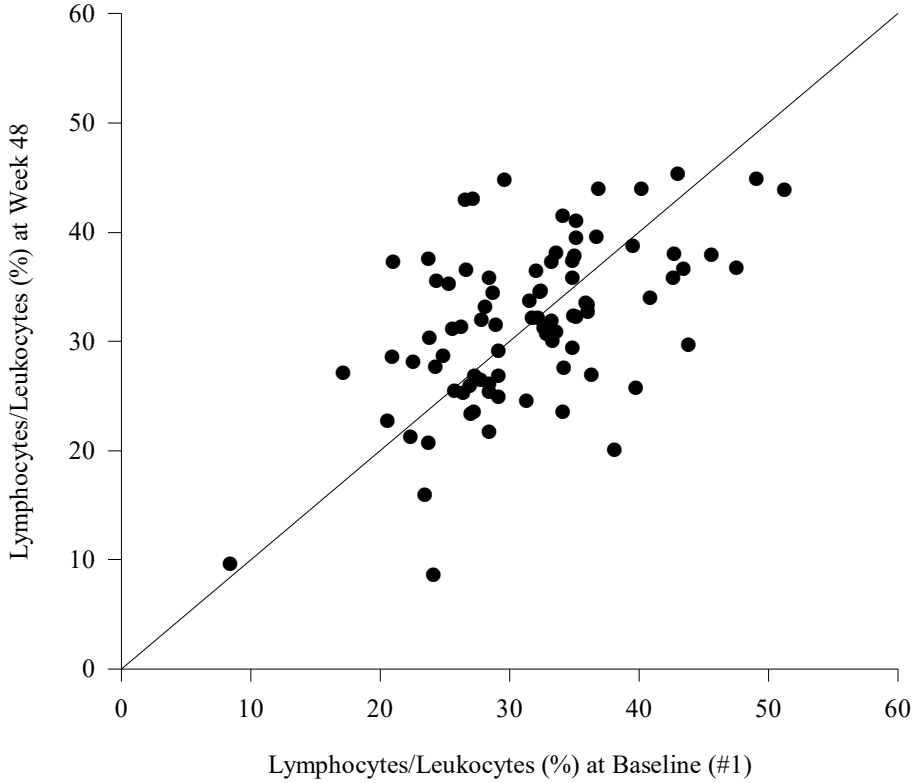


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 219 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (0%/5%)

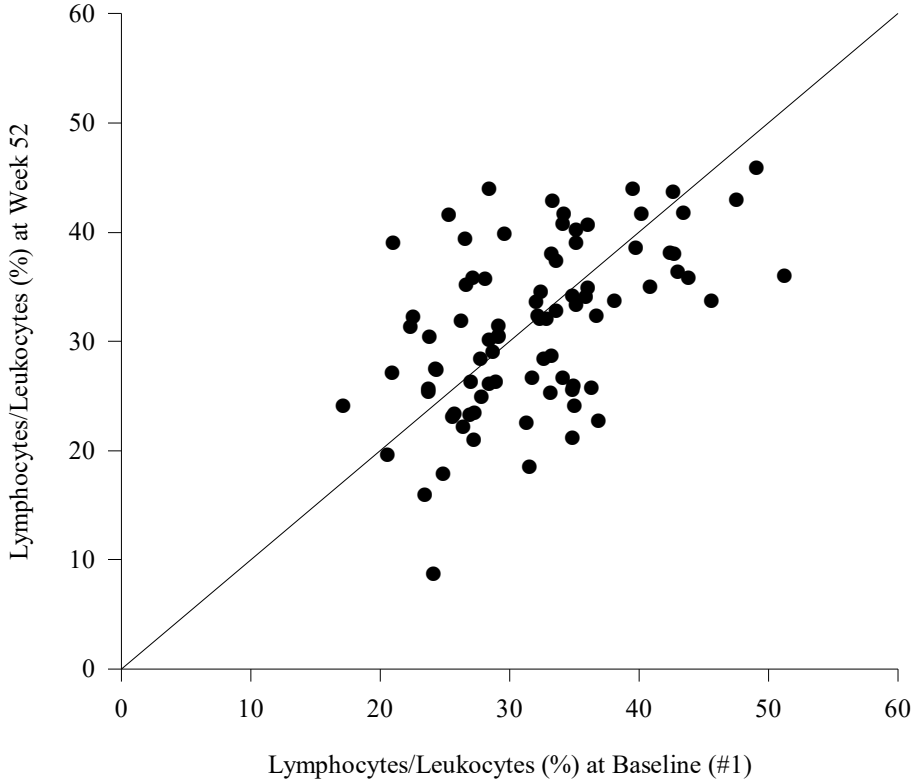


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 220 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (0%/5%)

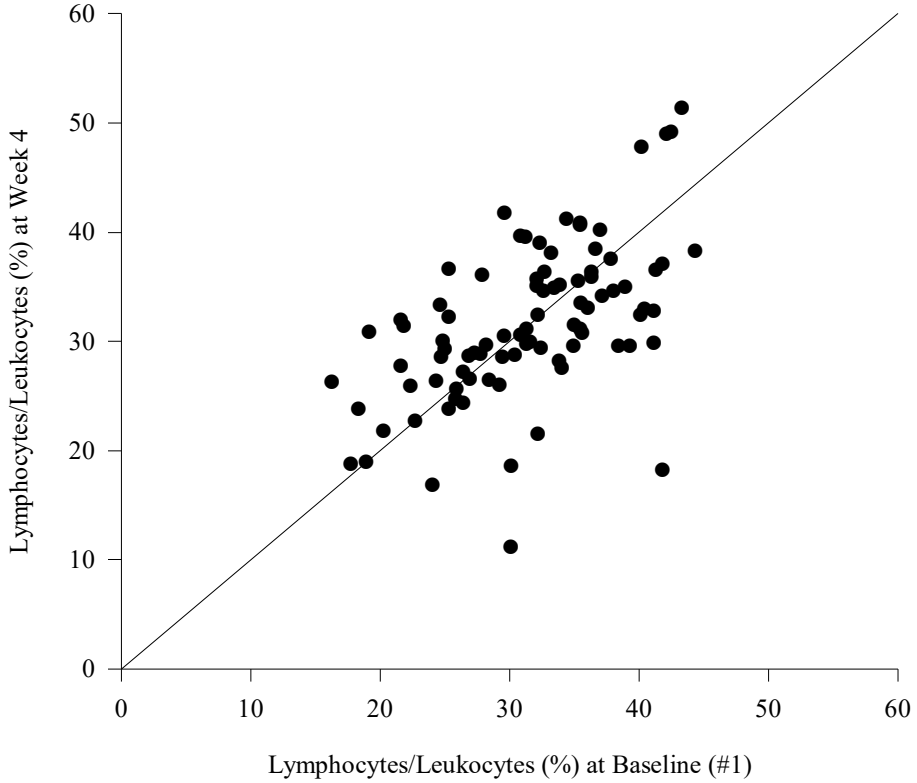


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 221 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (5%/5%)

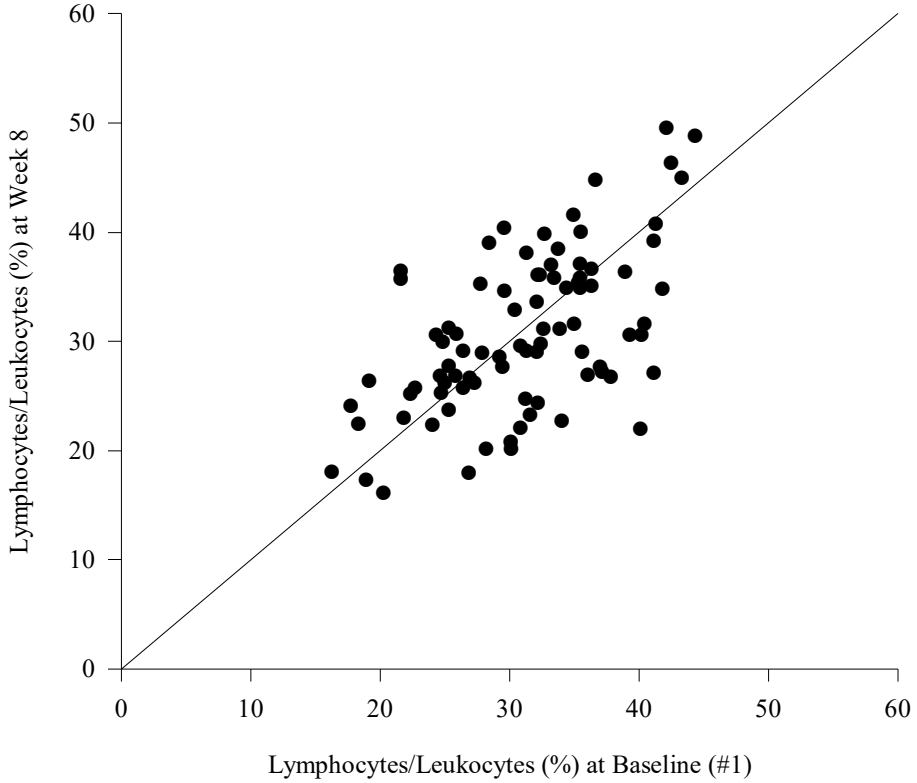


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 222 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (5%/5%)

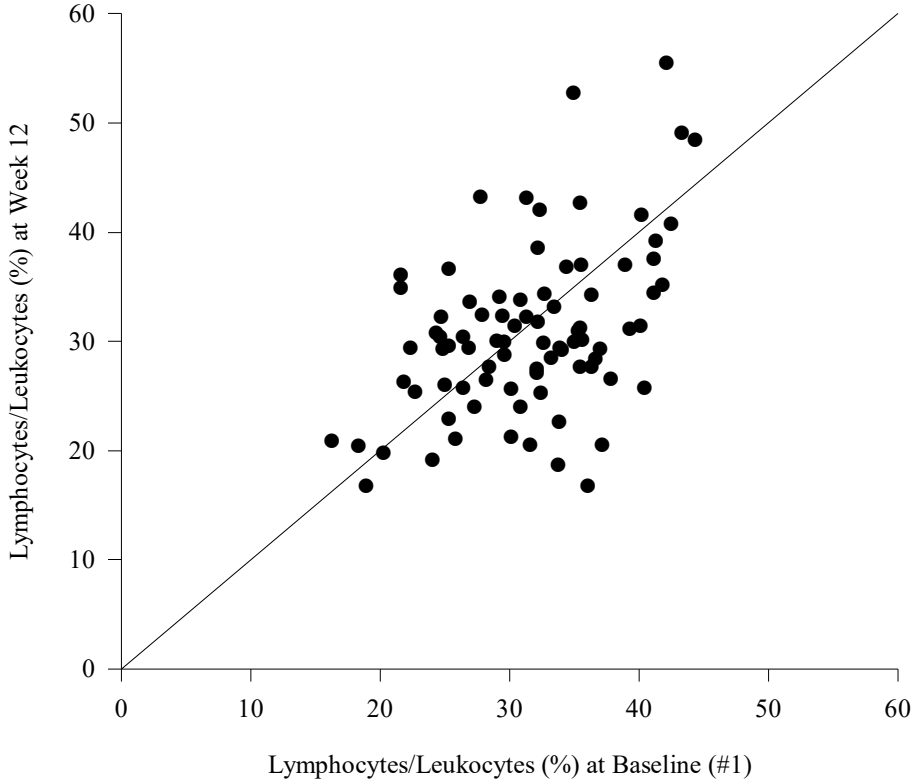


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 223 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (5%/5%)

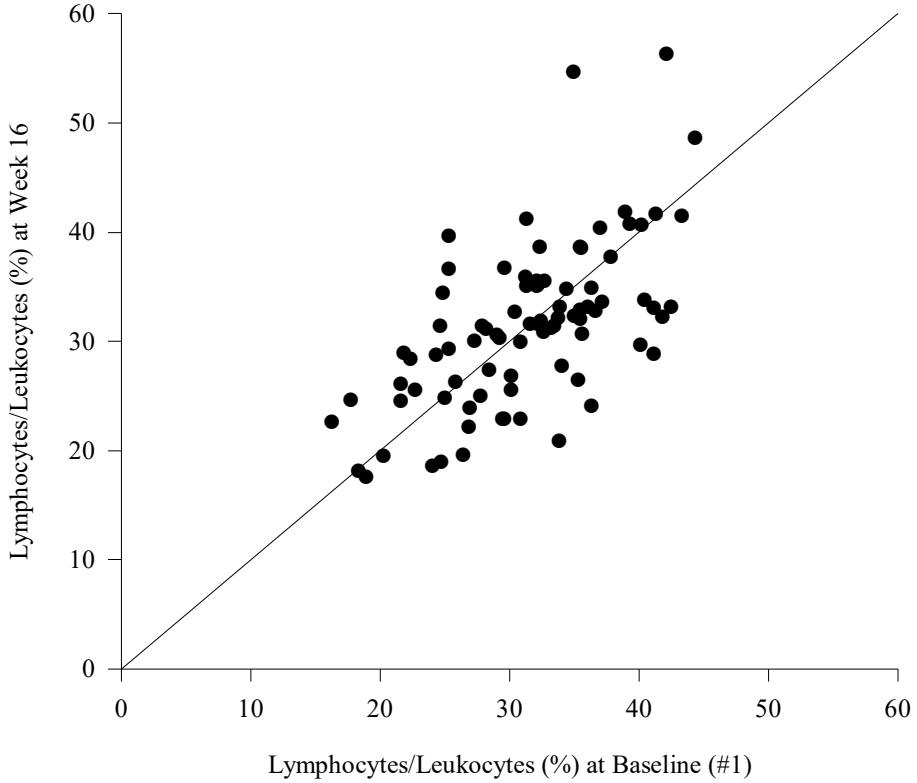


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 224 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (5%/5%)

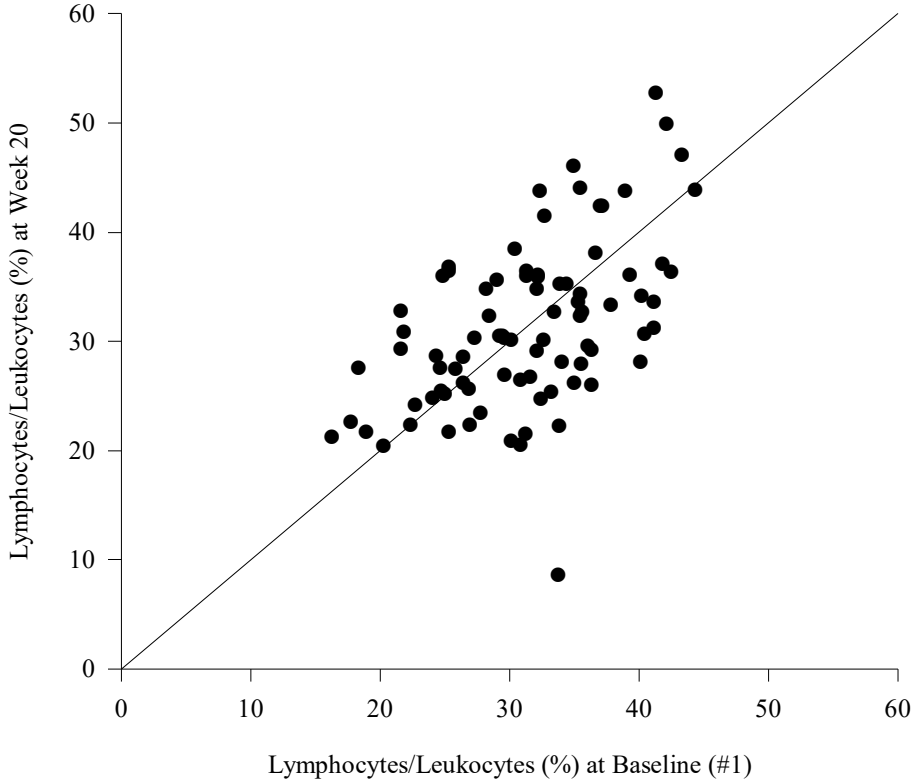


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 225 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (5%/5%)

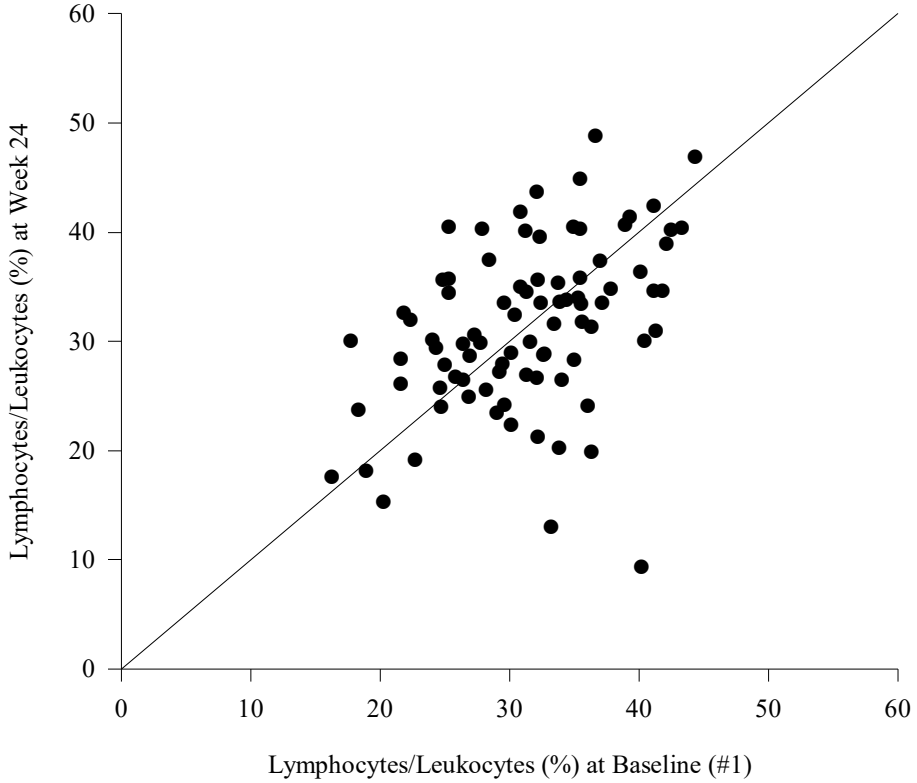


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 226 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (5%/5%)

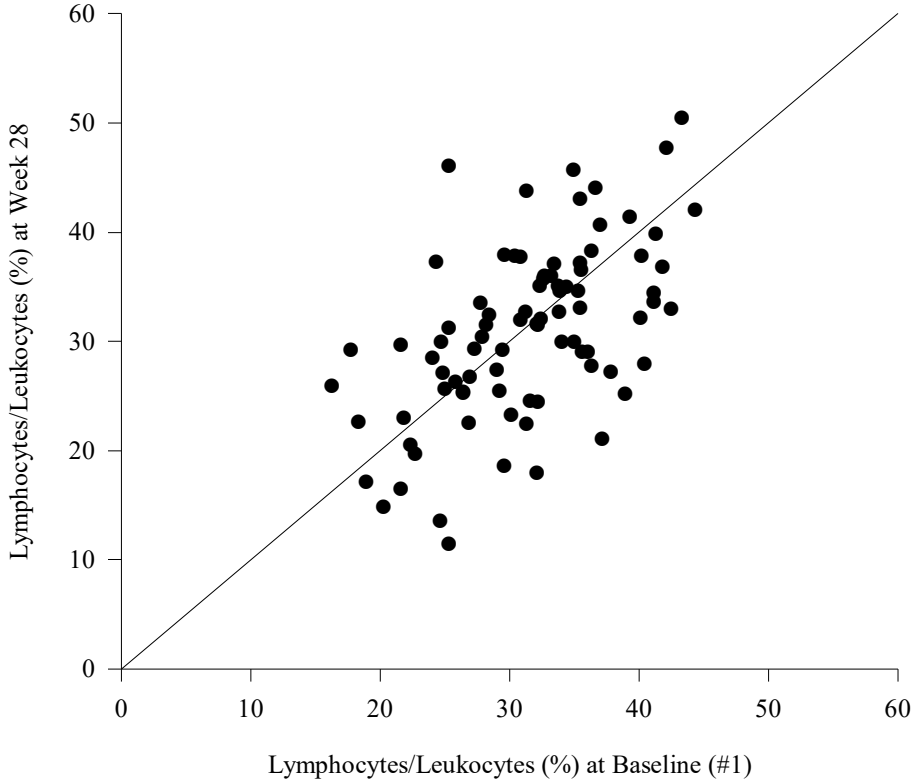


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 227 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (5%/5%)

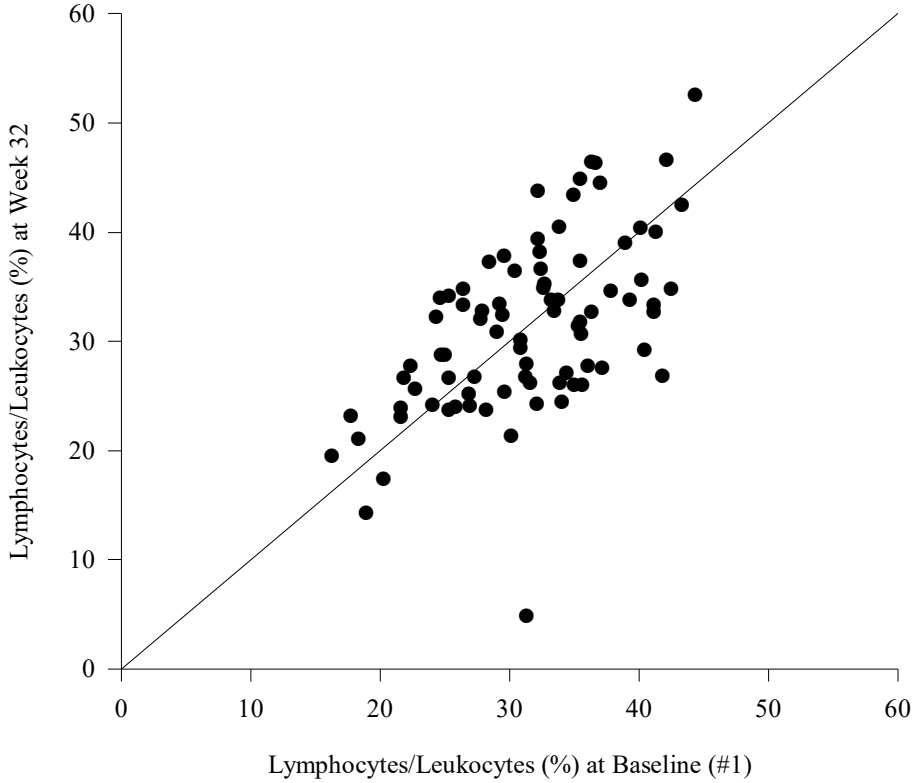


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 228 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (5%/5%)

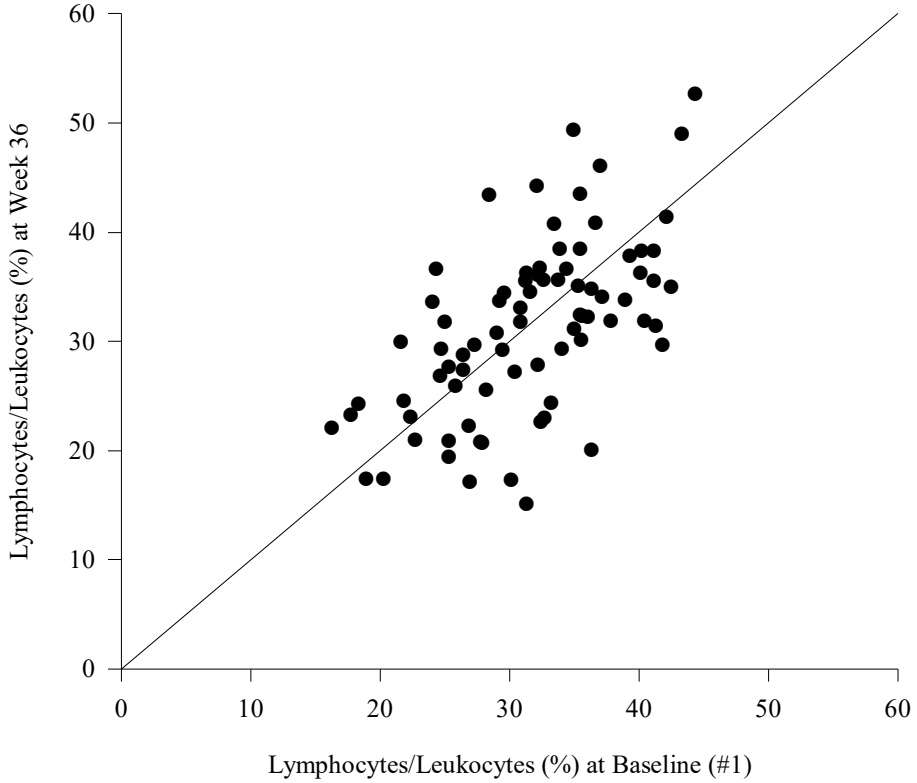


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 229 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (5%/5%)

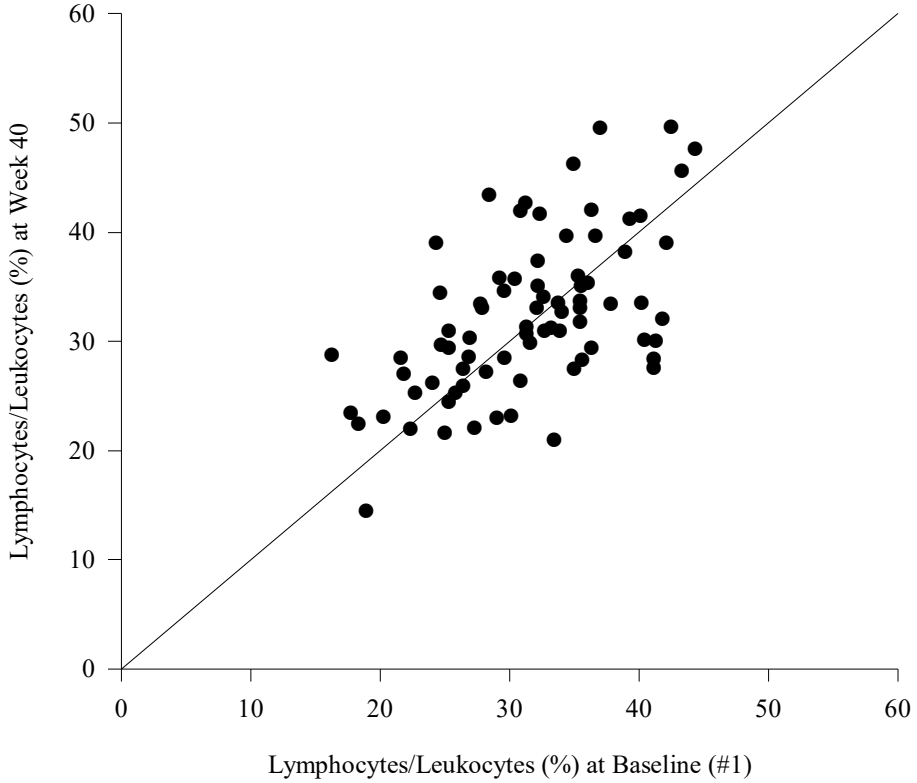


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 230 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (5%/5%)

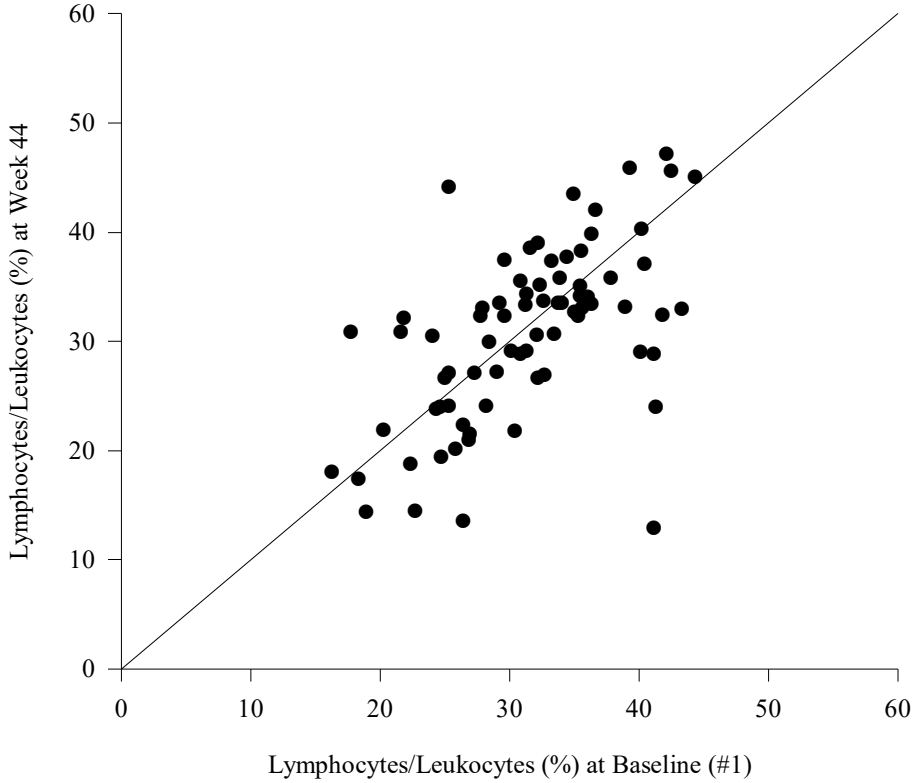


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 231 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (5%/5%)

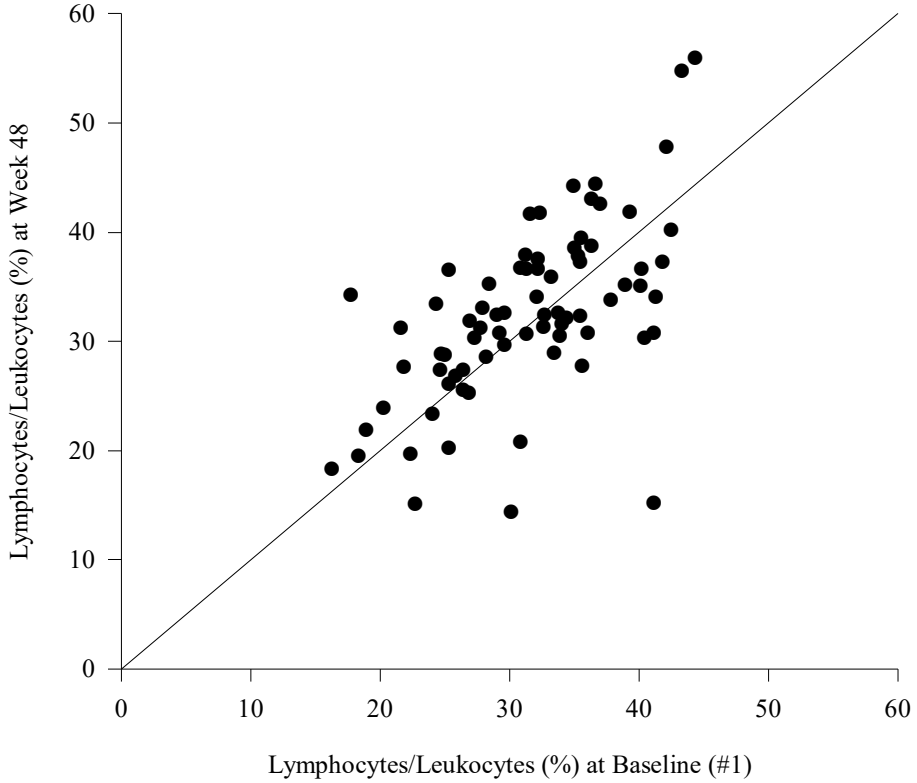


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 232 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (5%/5%)

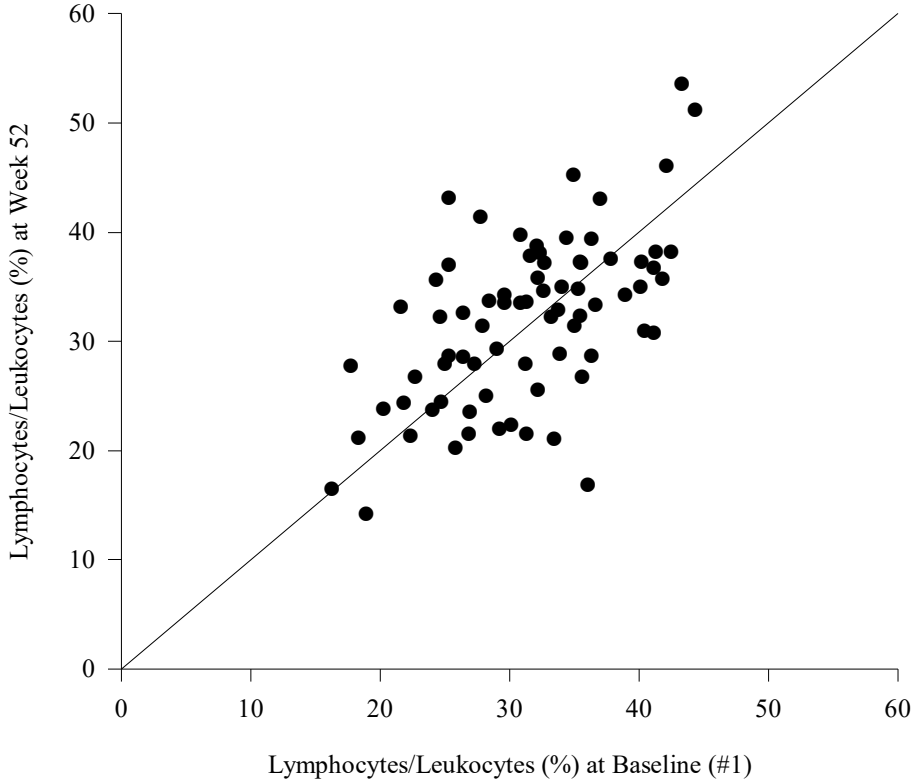


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 233 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (5%/5%)

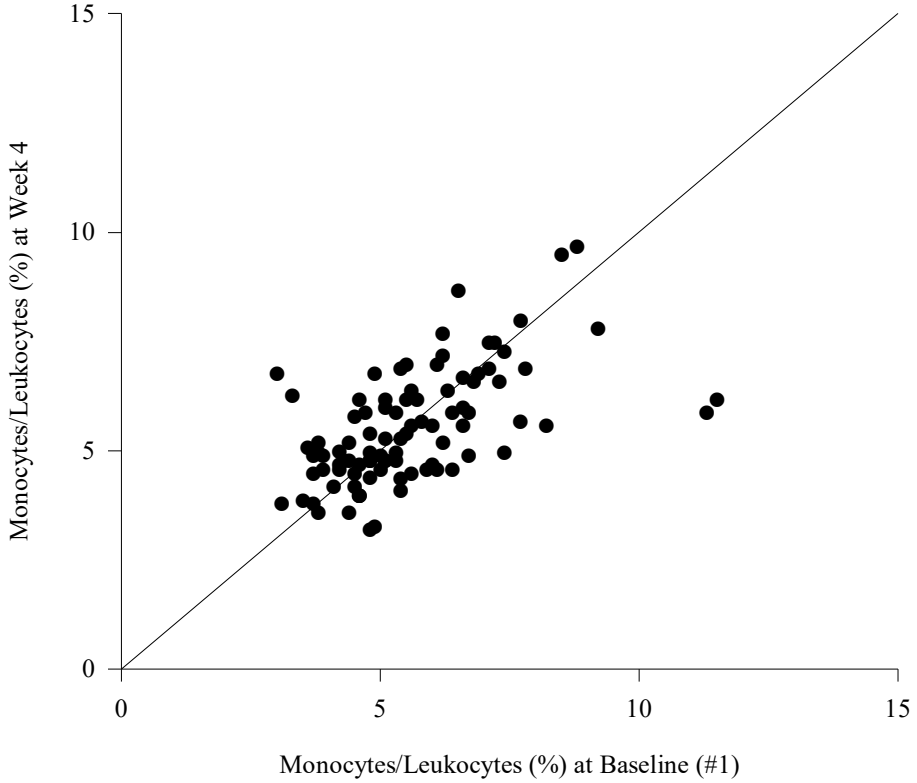


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 234 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (0%/5%)

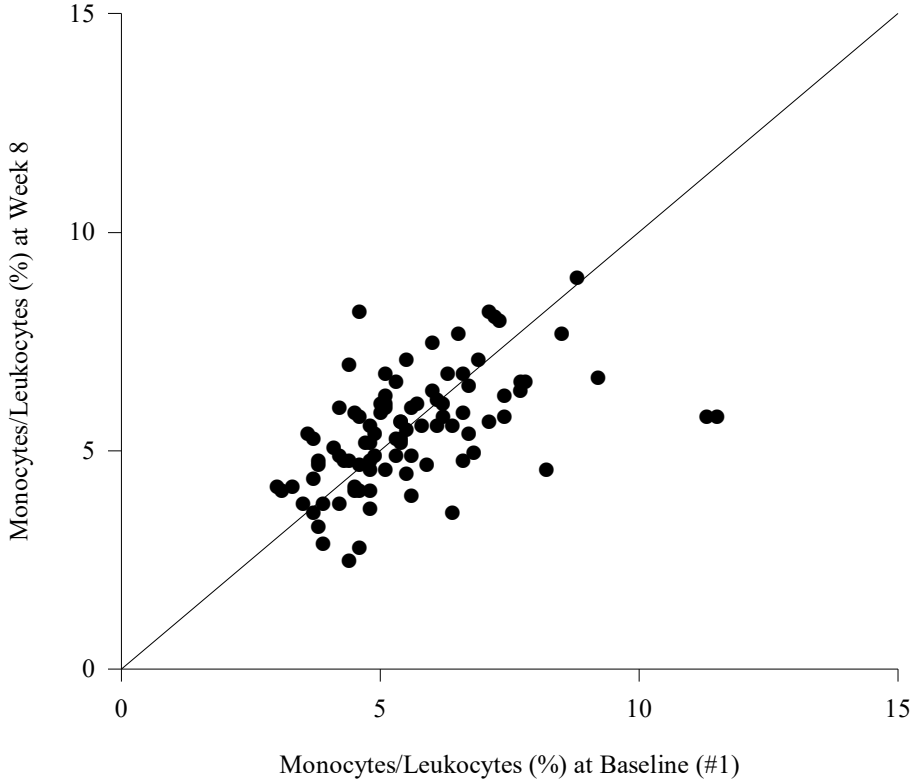


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 235 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (0%/5%)

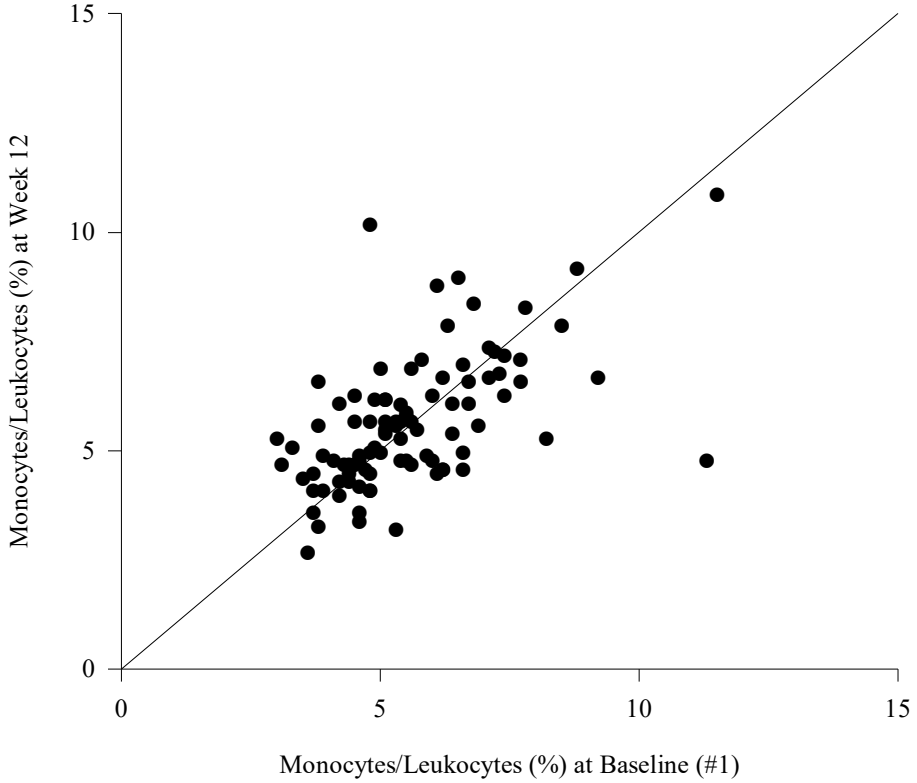


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 236 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (0%/5%)

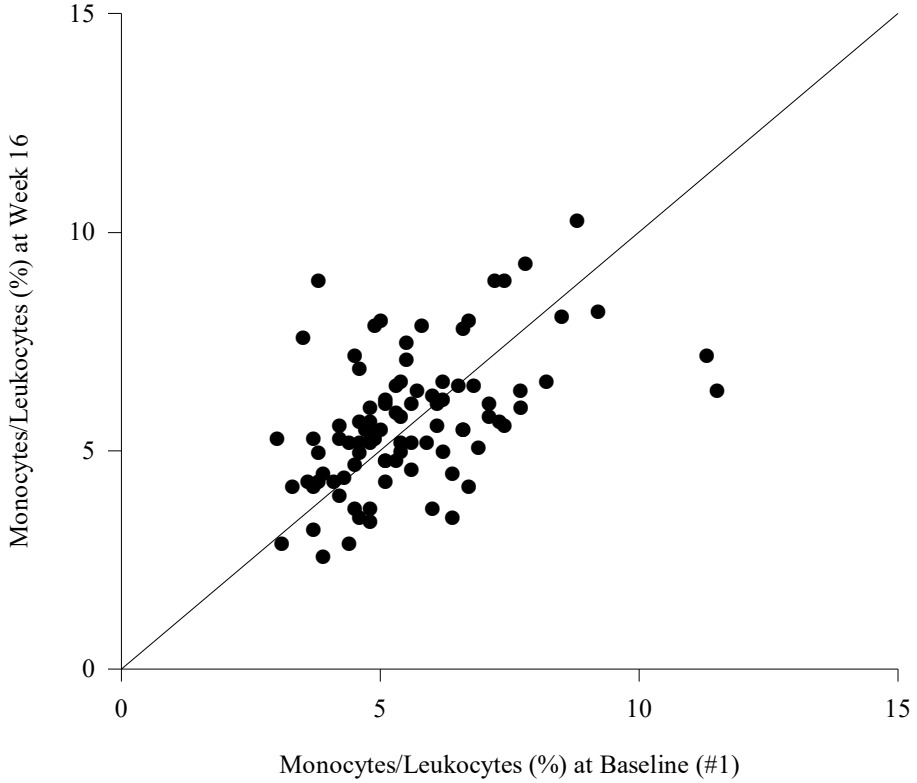


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 237 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (0%/5%)

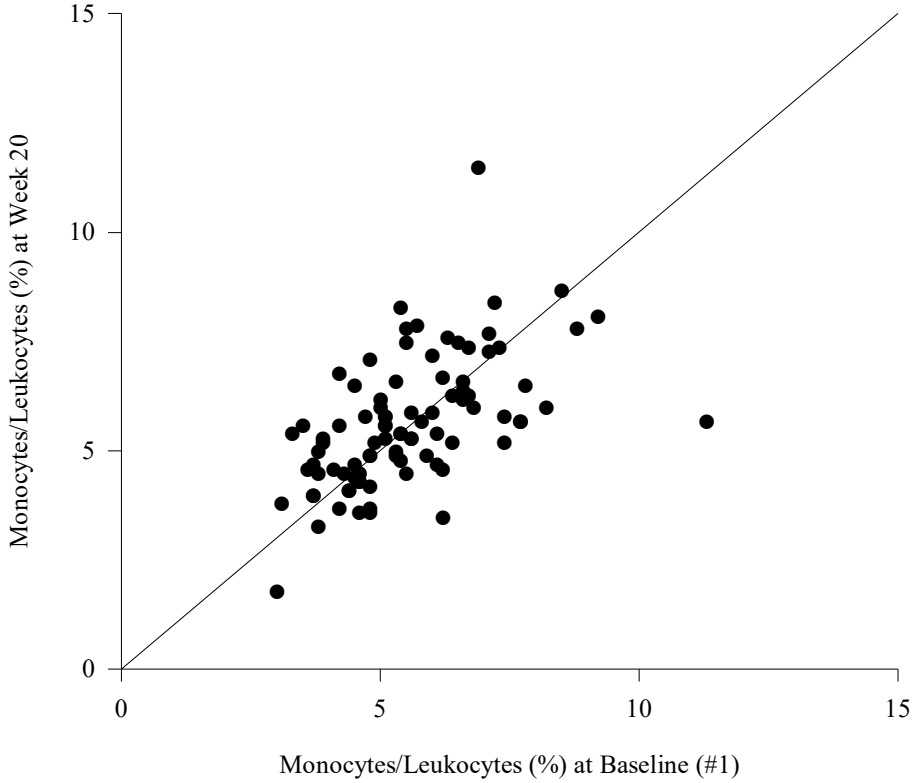


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 238 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (0%/5%)

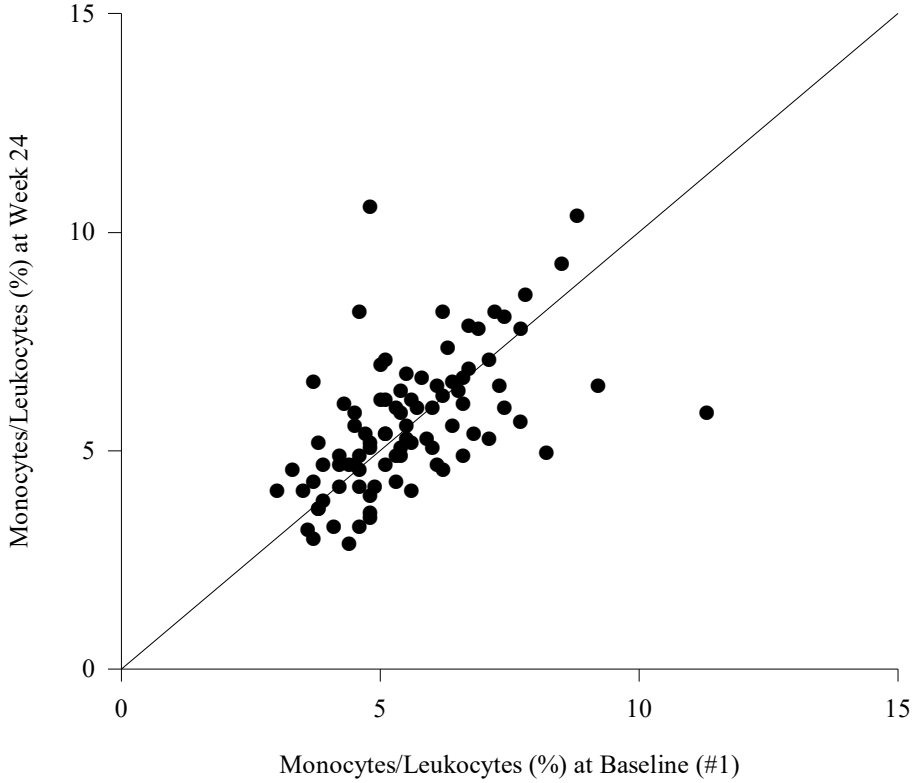


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 239 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (0%/5%)

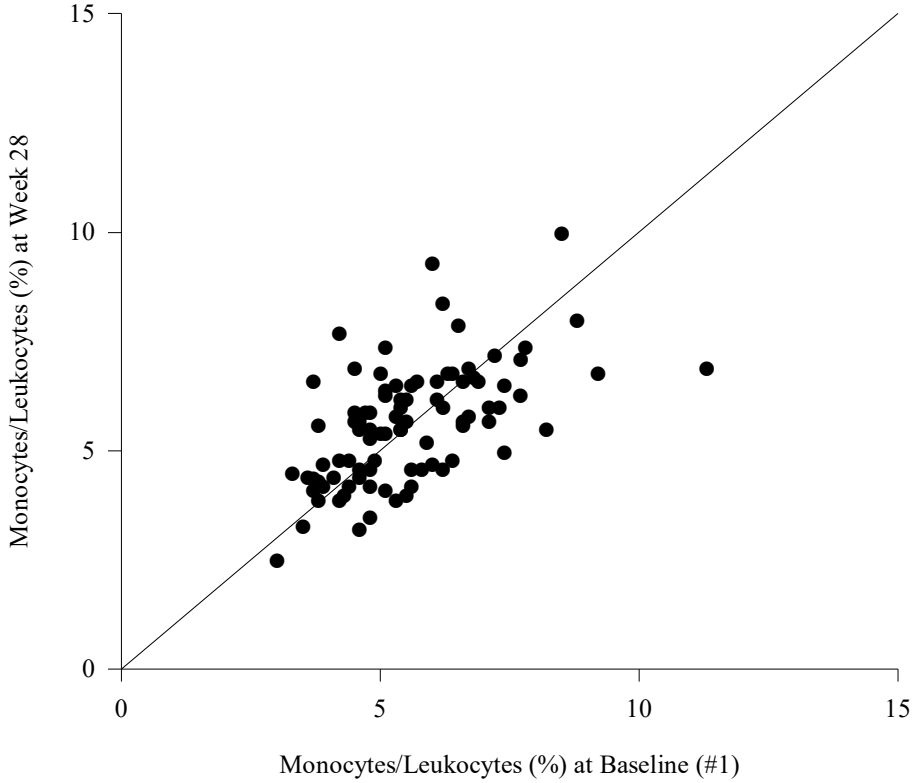


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 240 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (0%/5%)

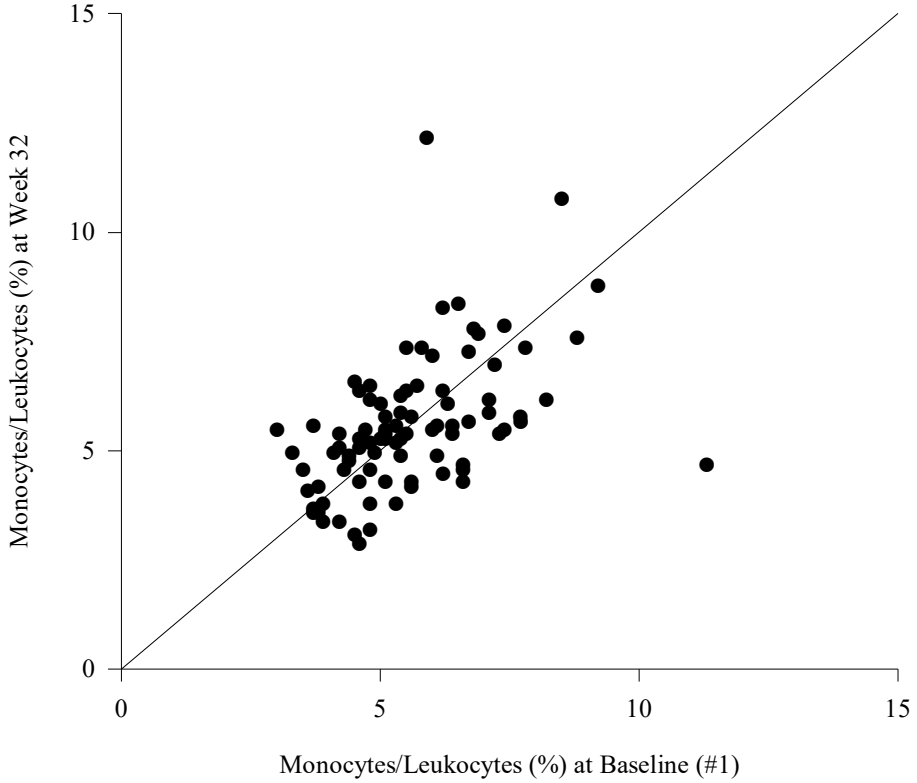


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 241 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (0%/5%)

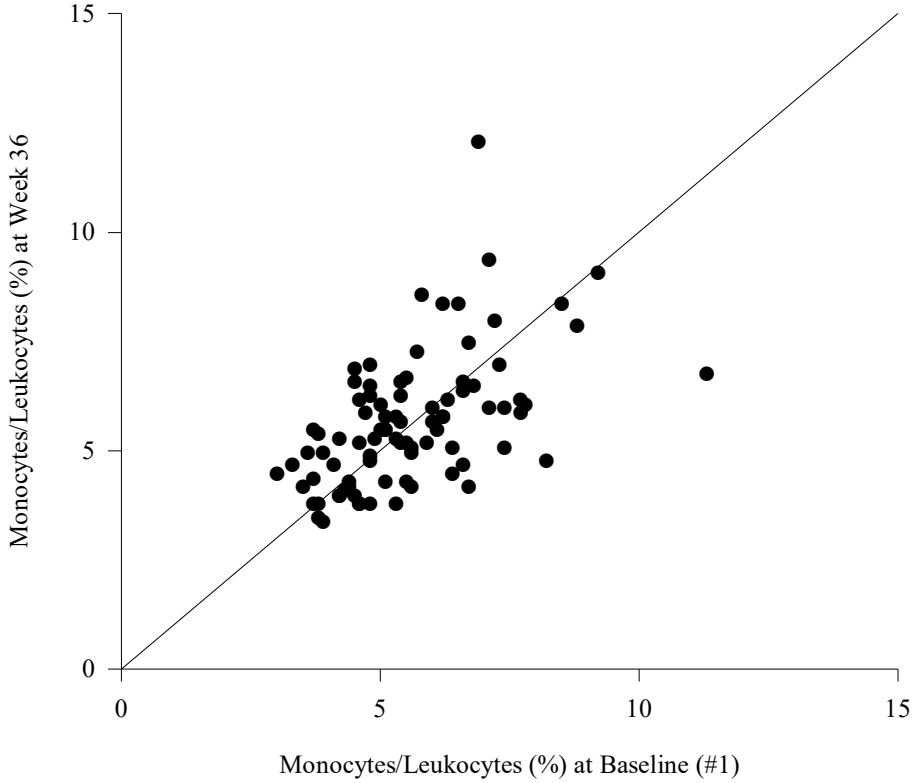


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 242 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (0%/5%)

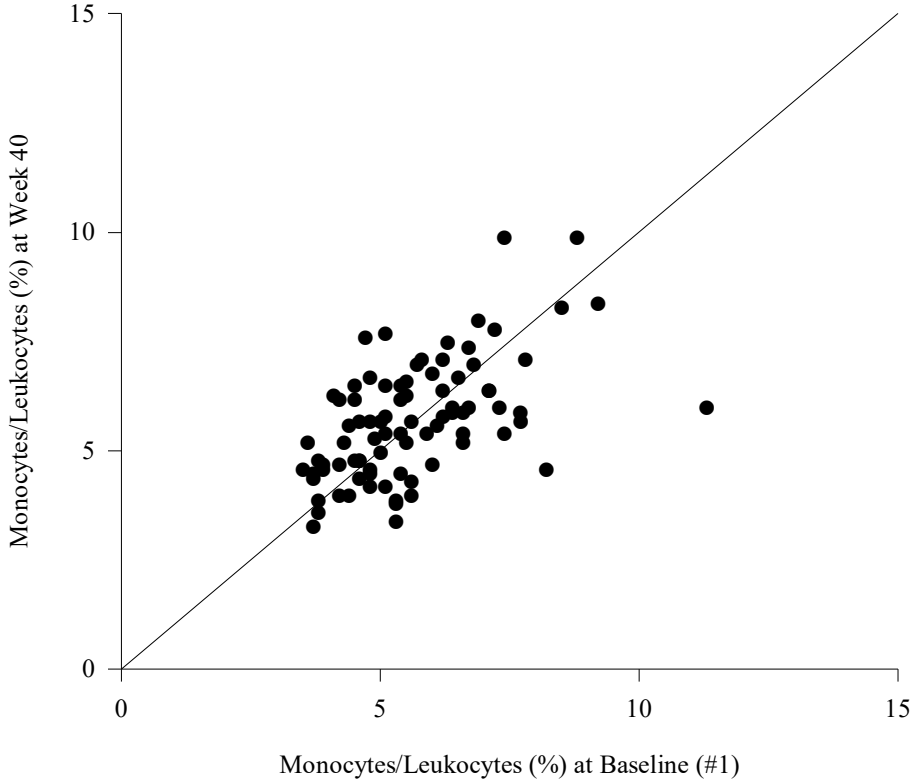


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 243 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (0%/5%)

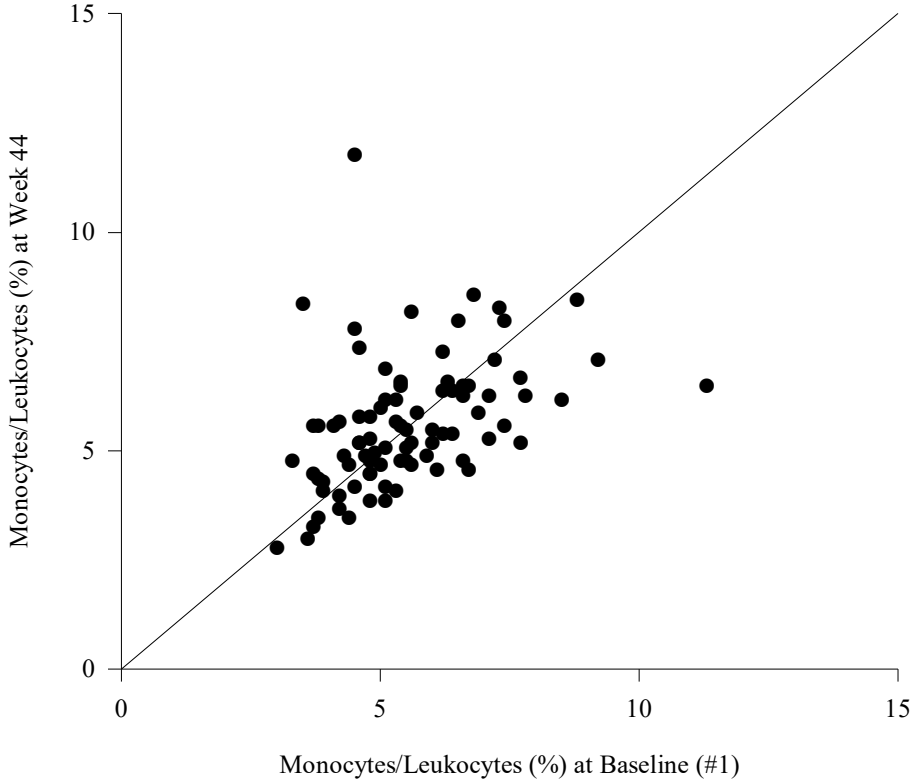


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 244 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (0%/5%)

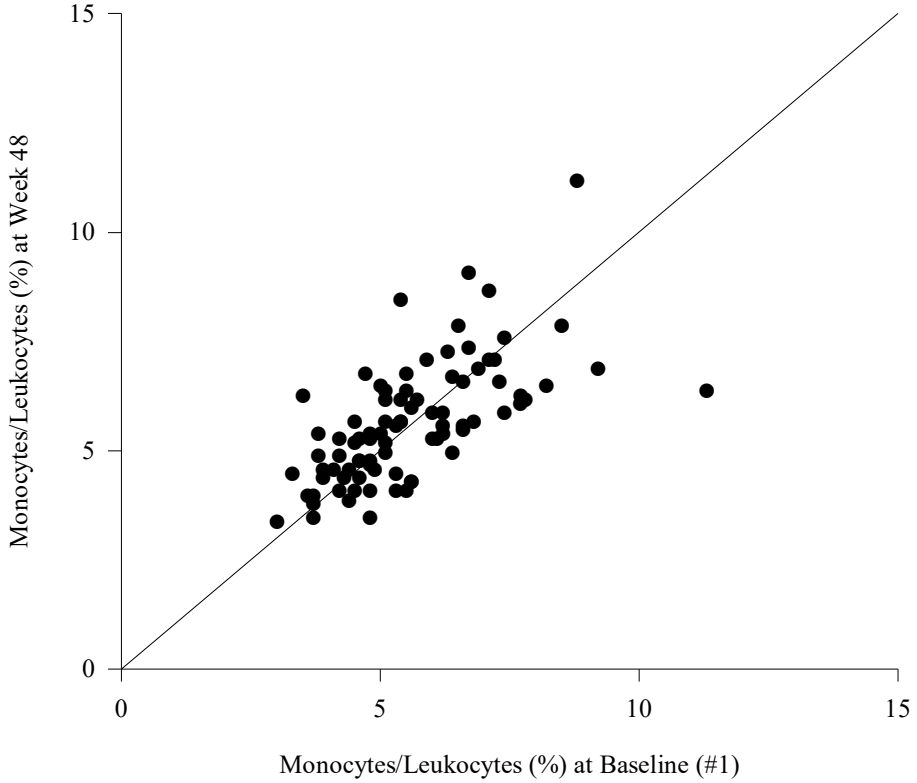


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 245 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (0%/5%)

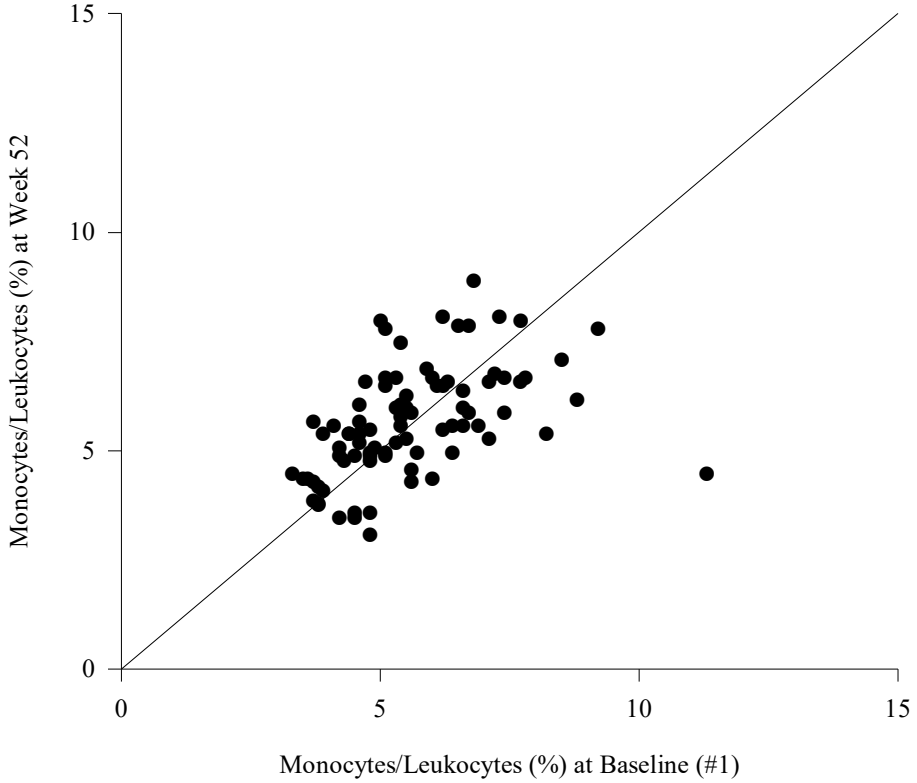


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 246 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (0%/5%)

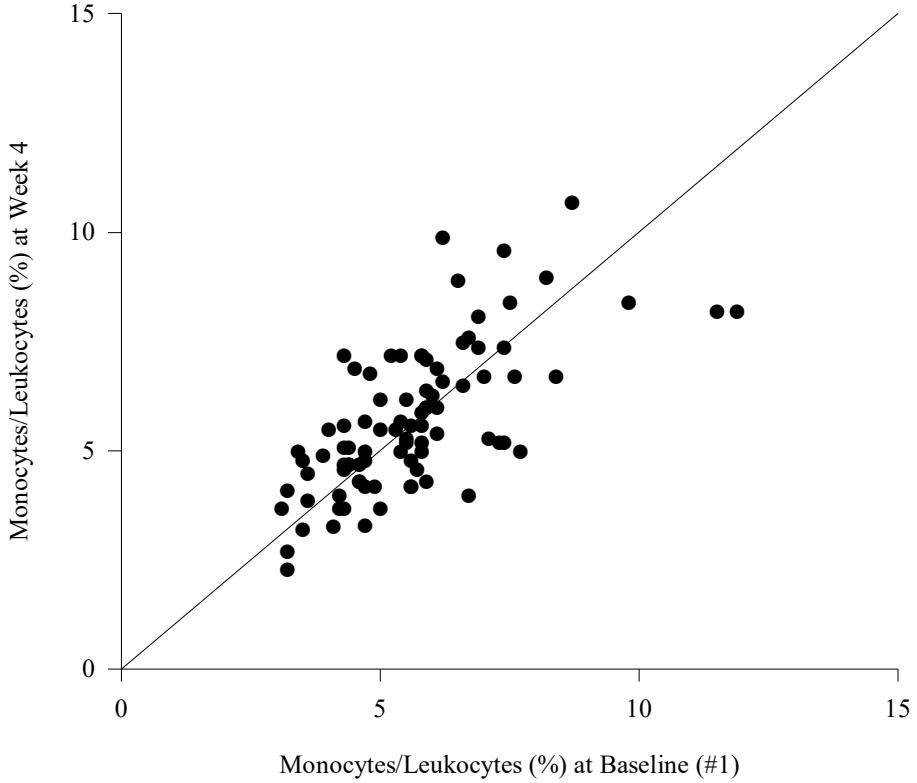


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 247 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (5%/5%)

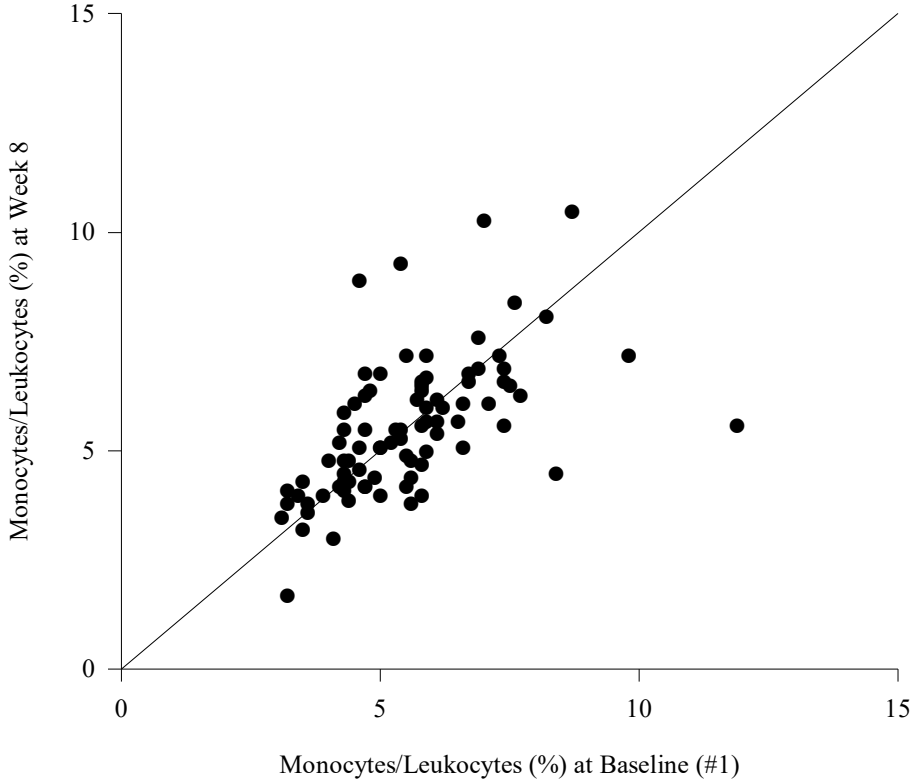


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 248 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (5%/5%)

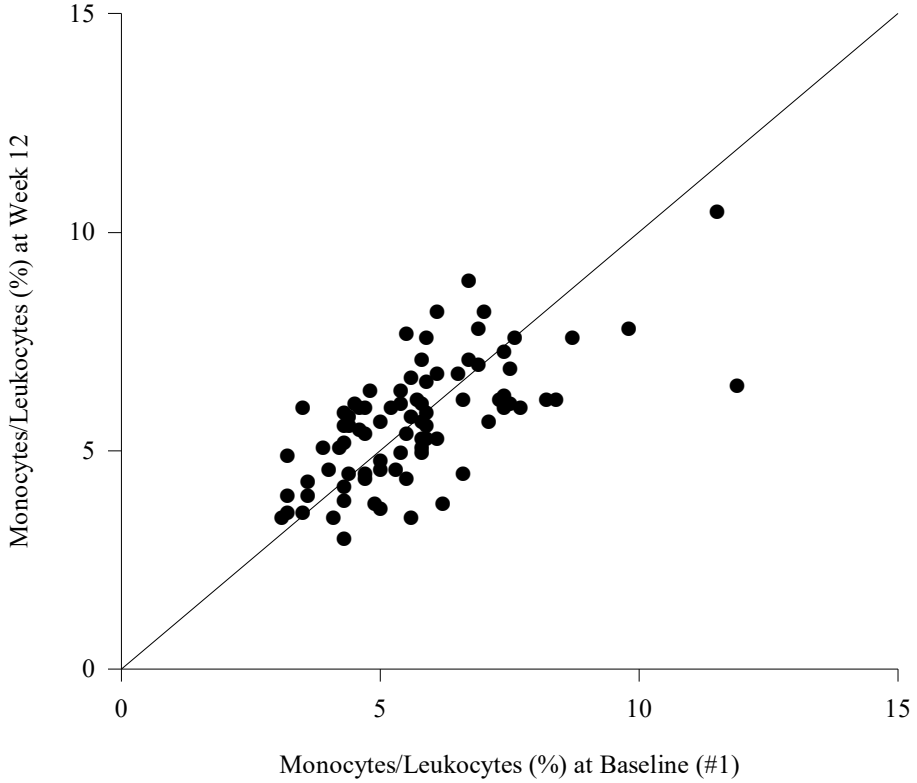


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 249 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (5%/5%)

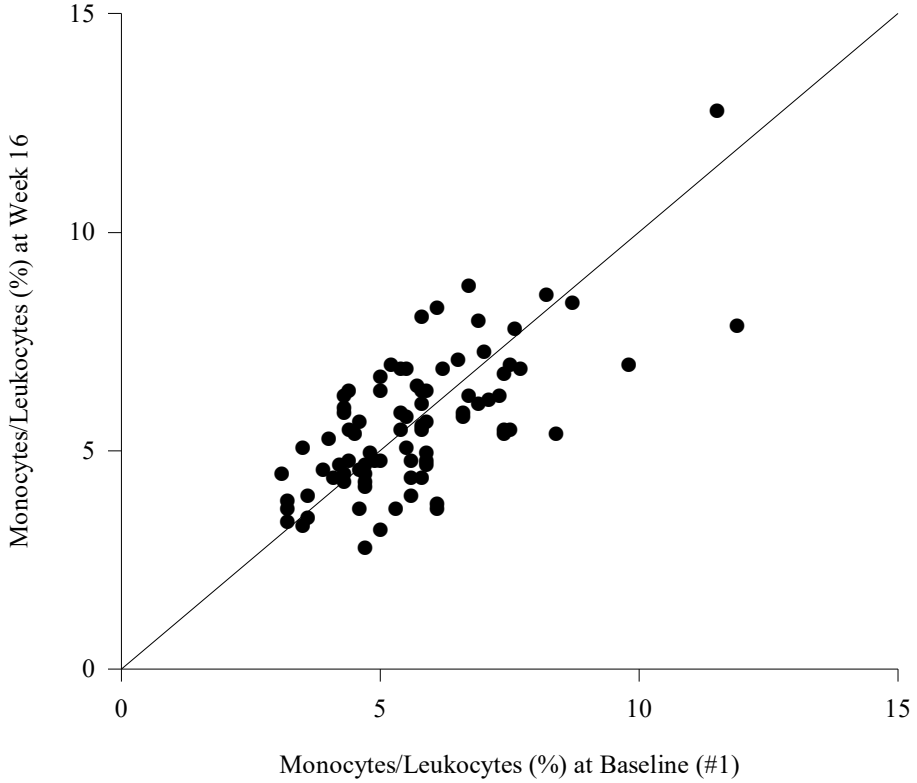


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 250 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (5%/5%)

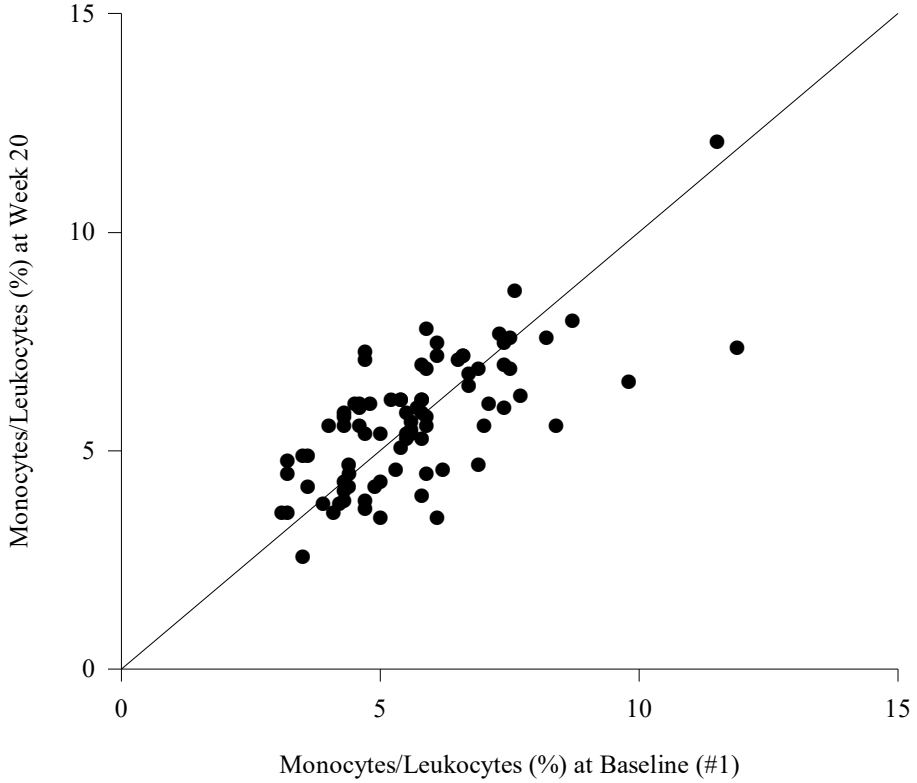


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 251 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (5%/5%)

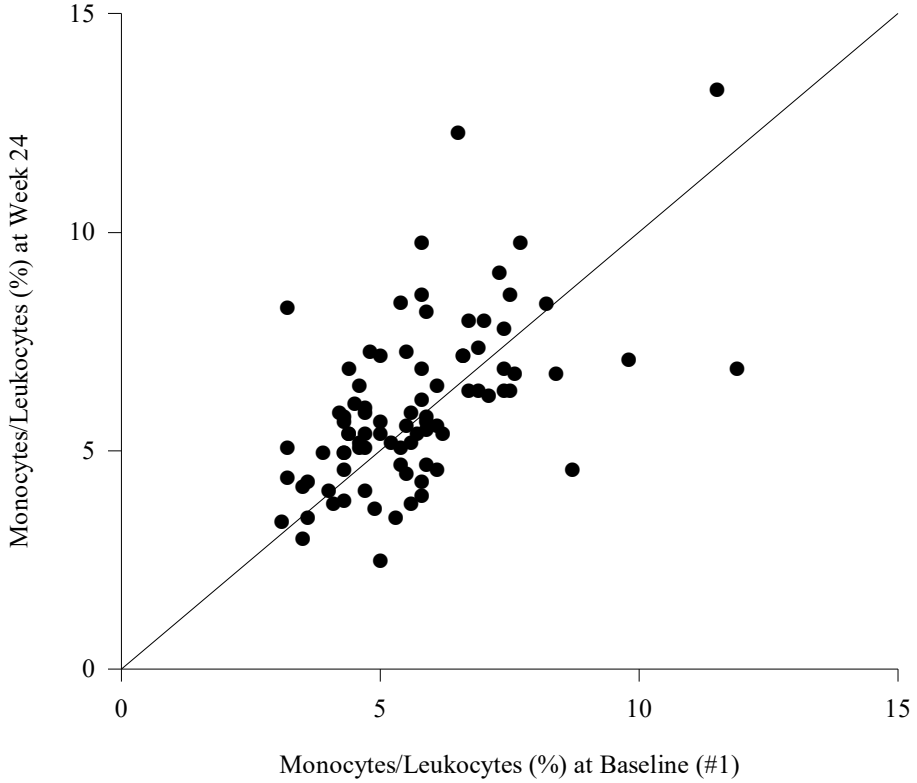


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 252 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (5%/5%)

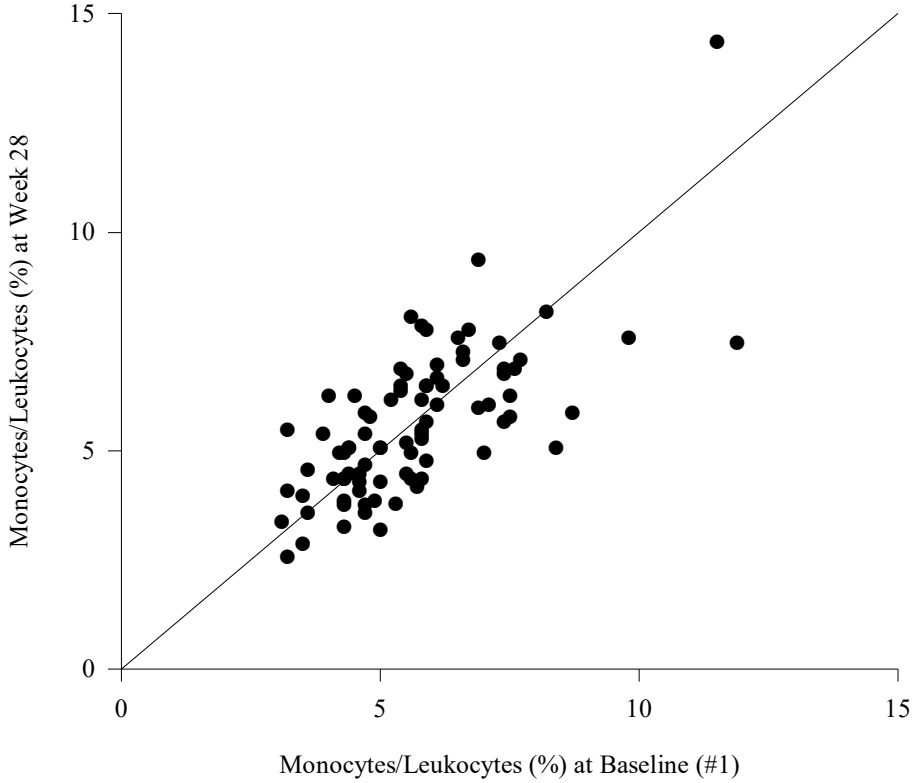


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 253 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (5%/5%)

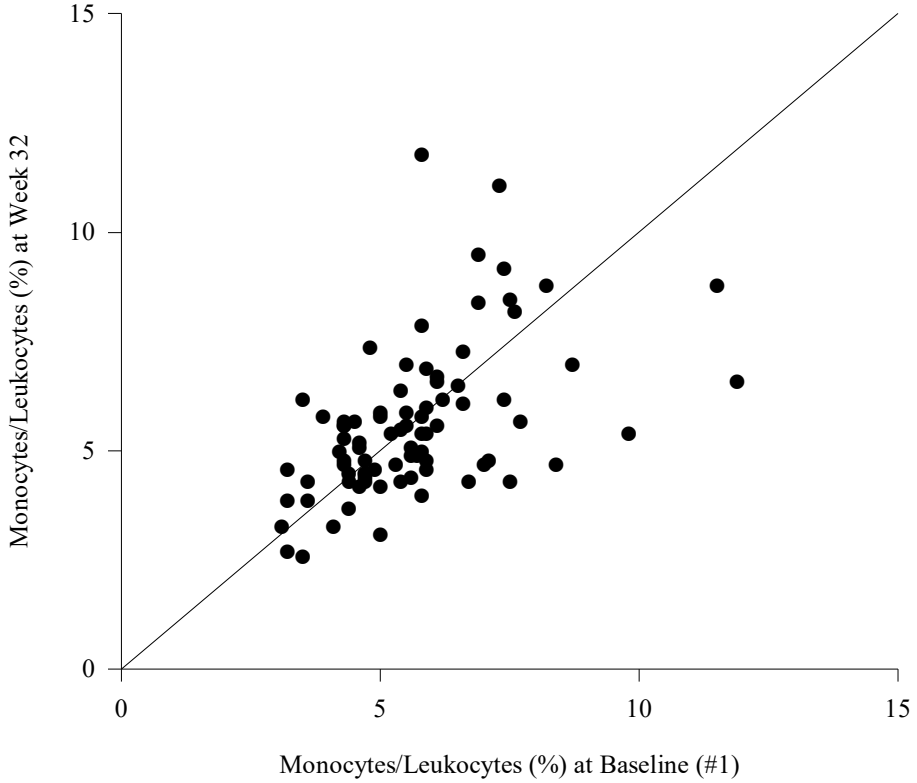


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 254 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (5%/5%)

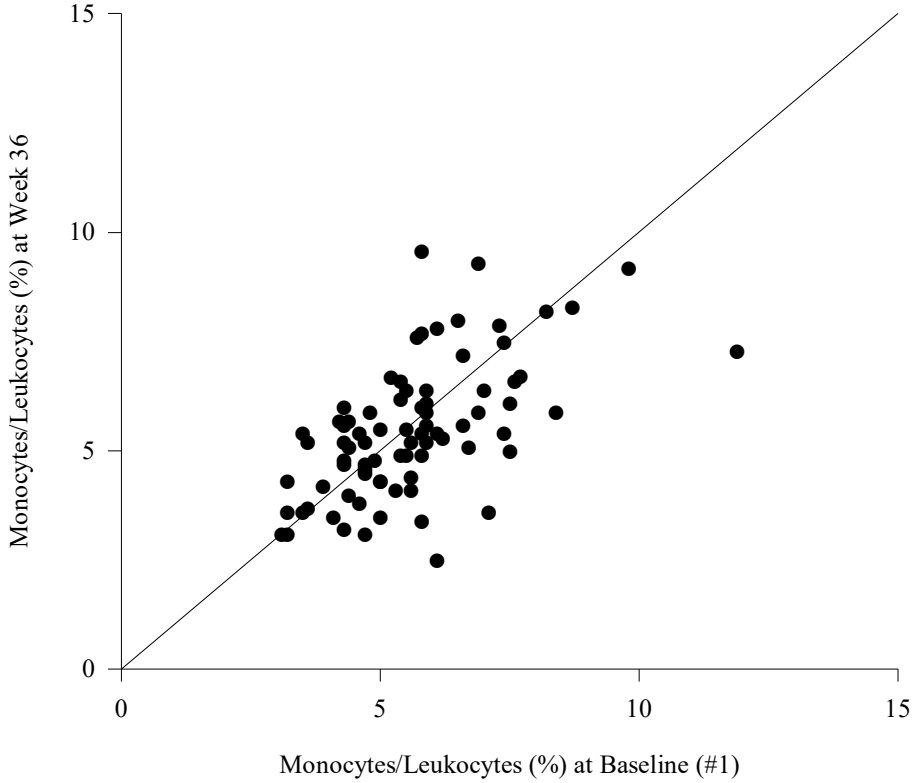


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 255 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (5%/5%)

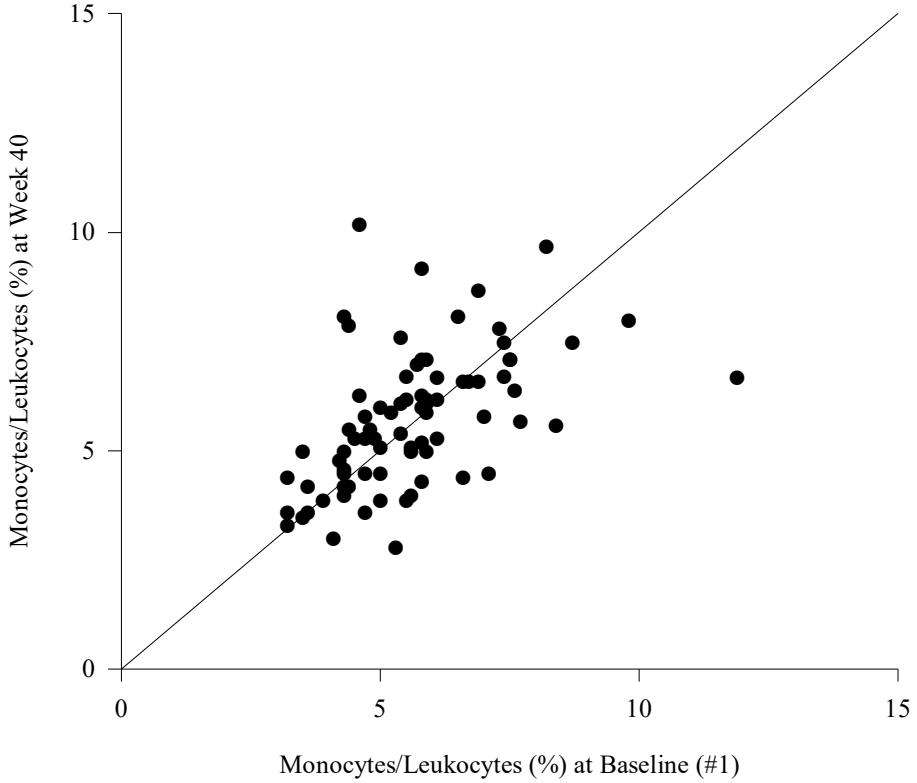


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 256 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (5%/5%)

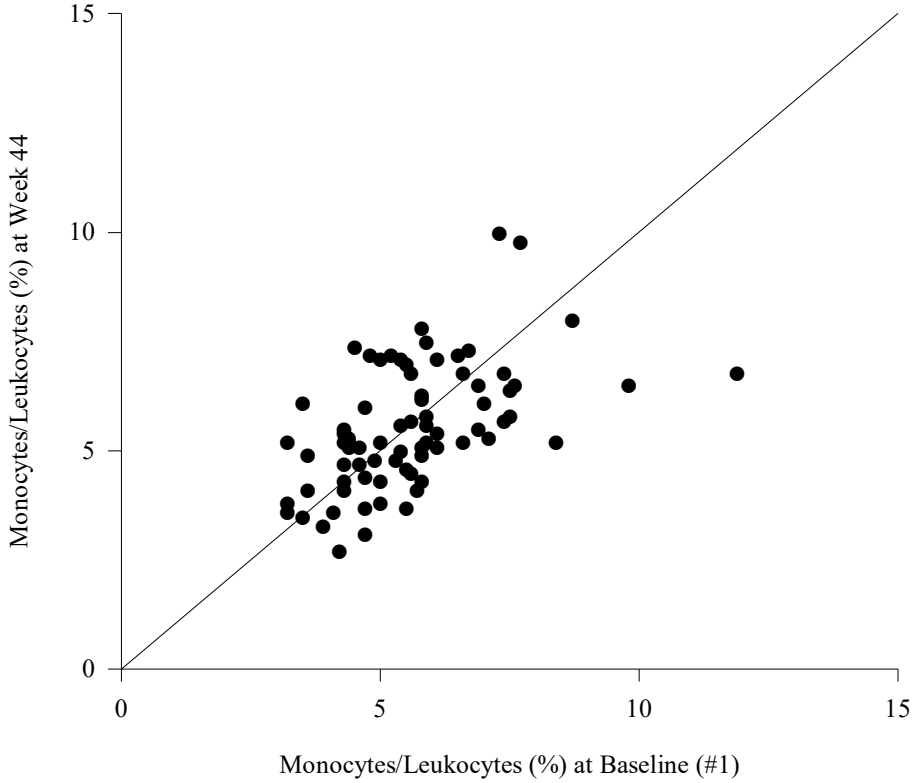


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 257 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (5%/5%)

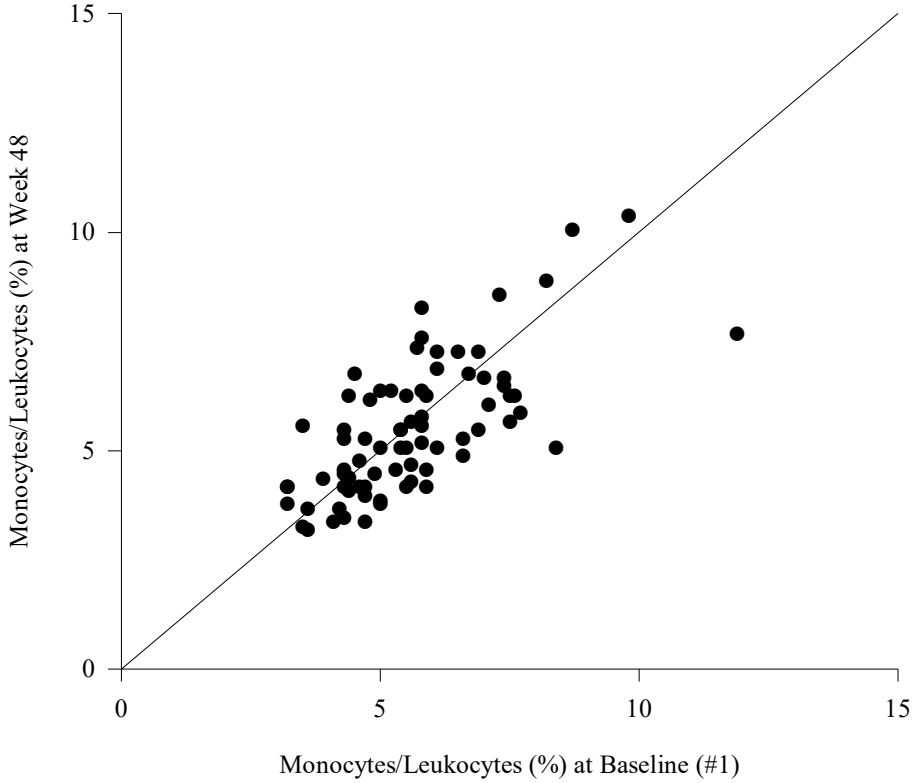


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 258 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (5%/5%)

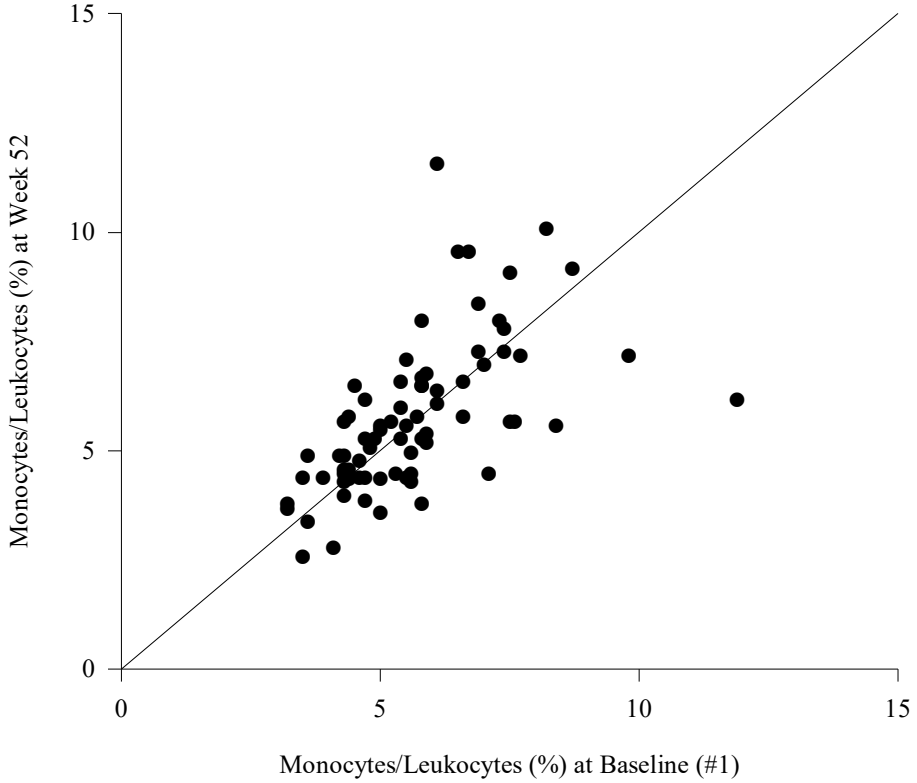


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 259 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Hematology（Safety Analysis Set）

Cohort 1 (5%/5%)

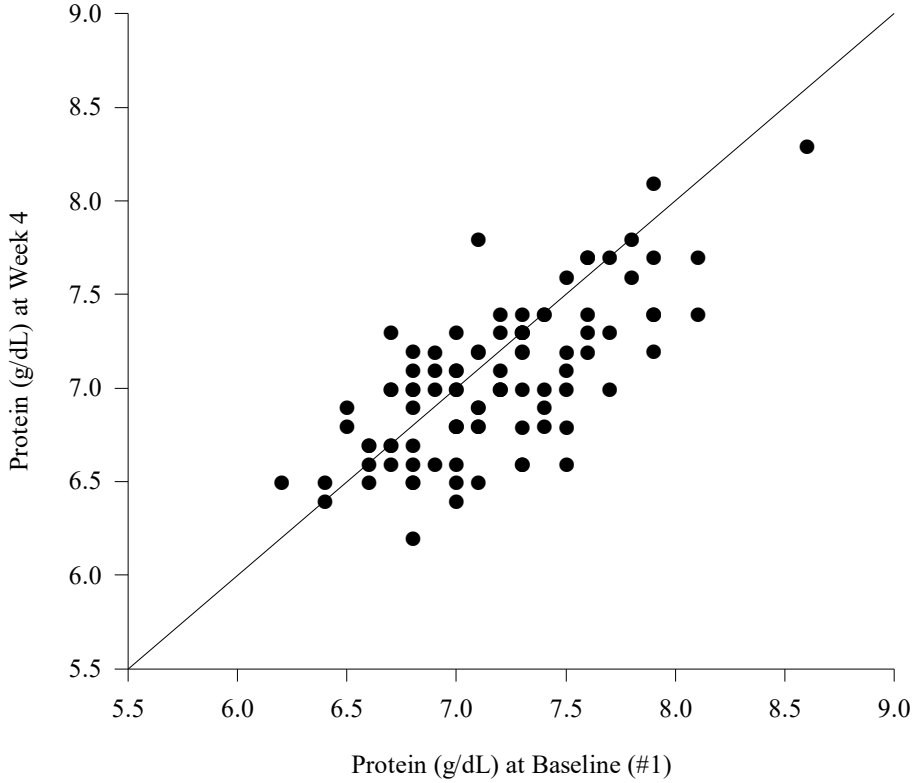


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 260 of 260
PROGRAM: f021 (OUTPUT: f14_03_04_03_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-3 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (0%/5%)

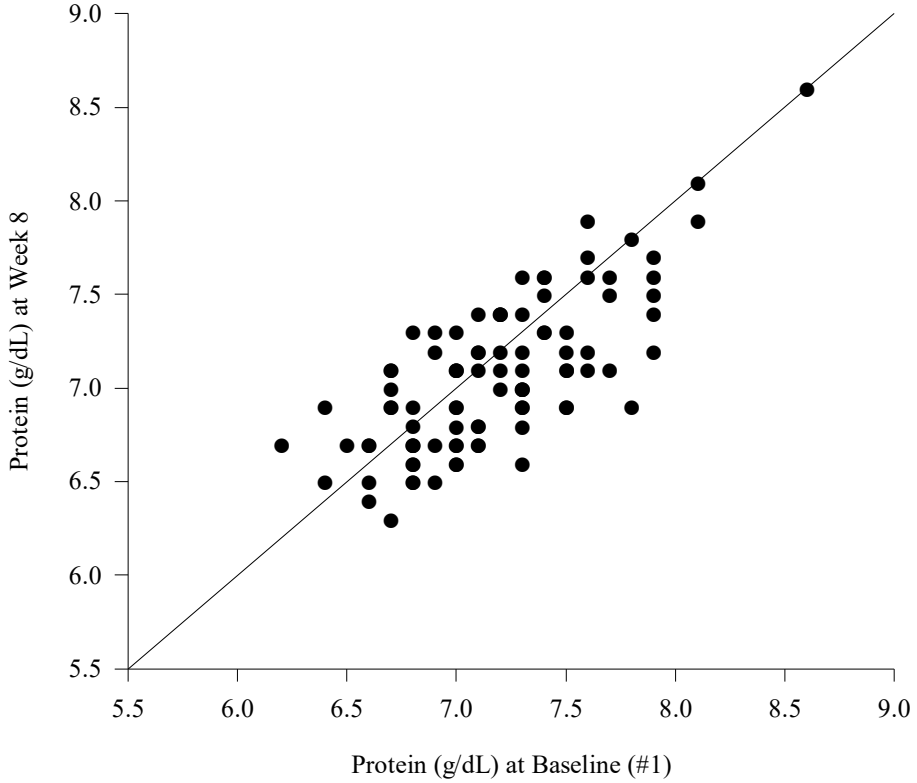


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 1 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (0%/5%)

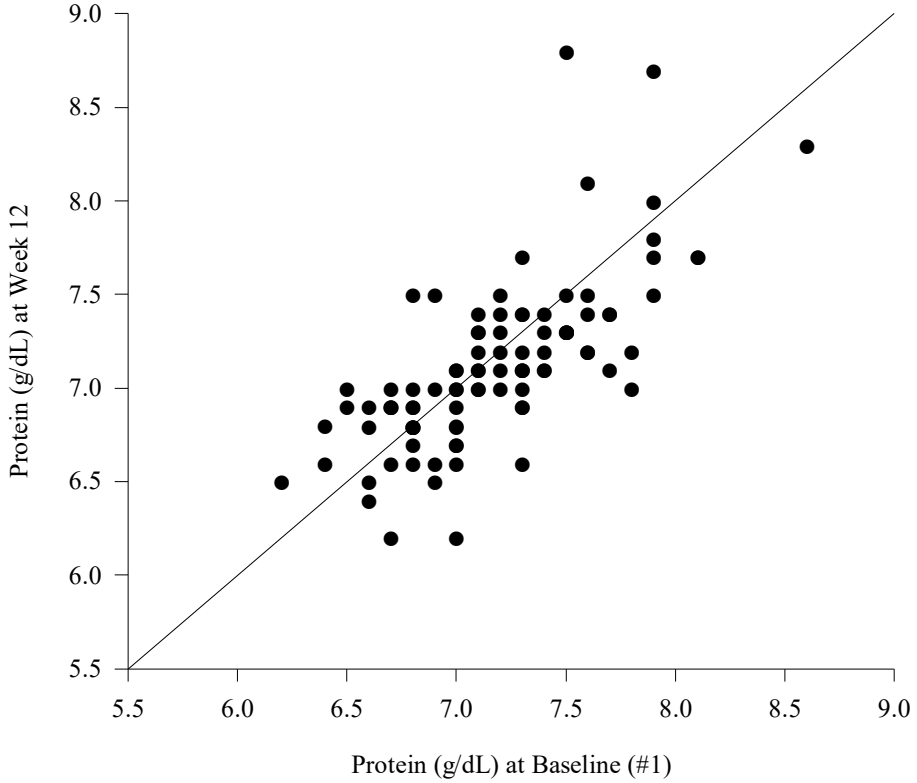


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 2 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (0%/5%)

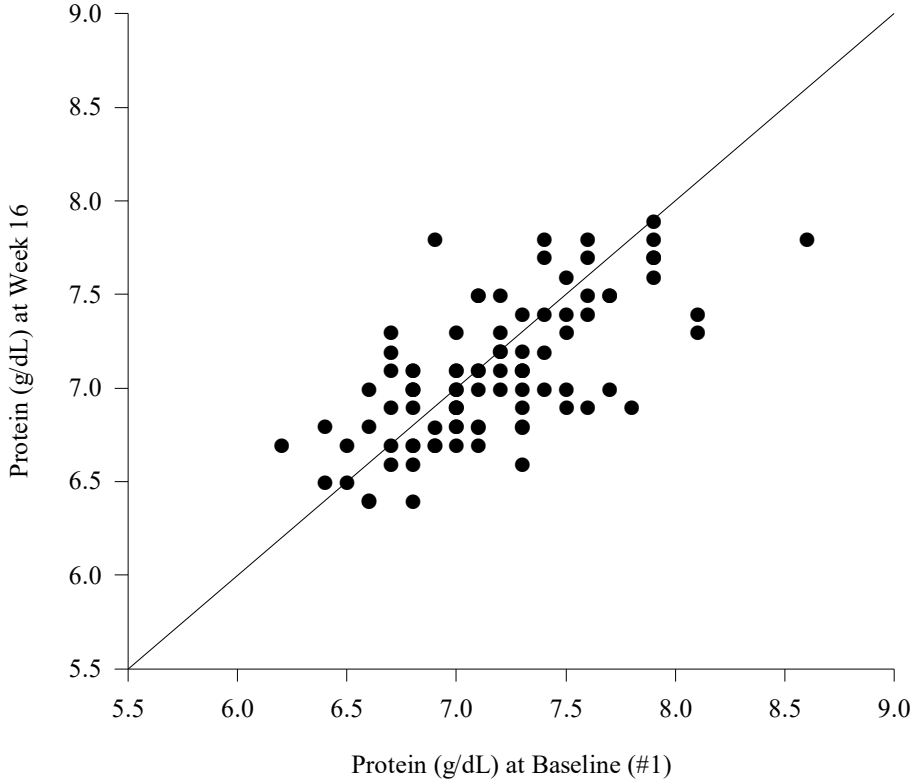


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 3 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (0%/5%)

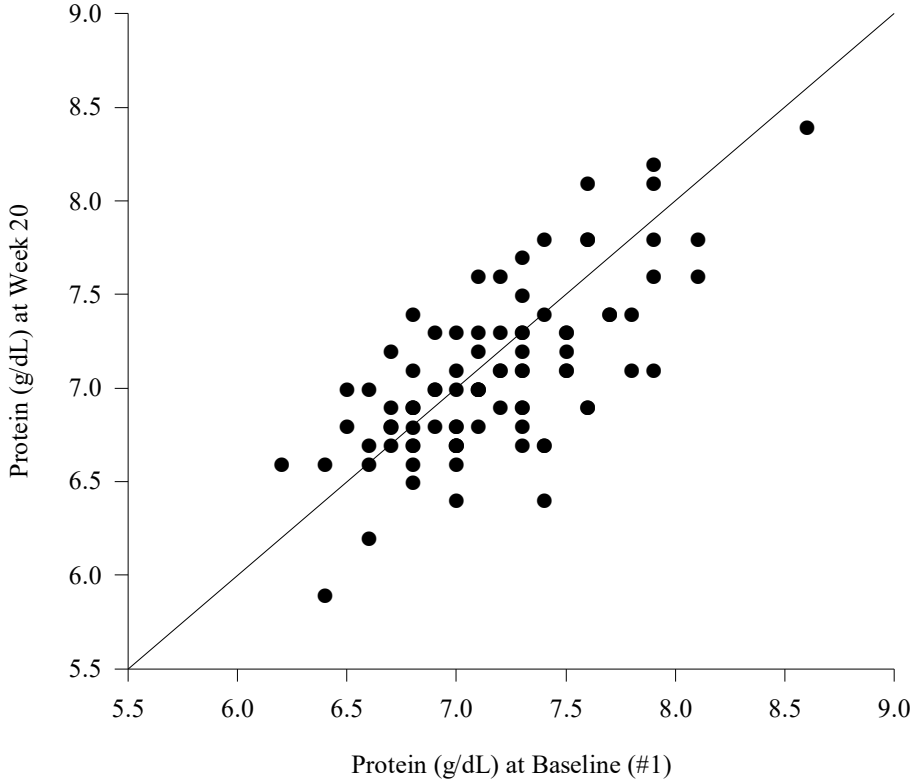


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 4 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (0%/5%)

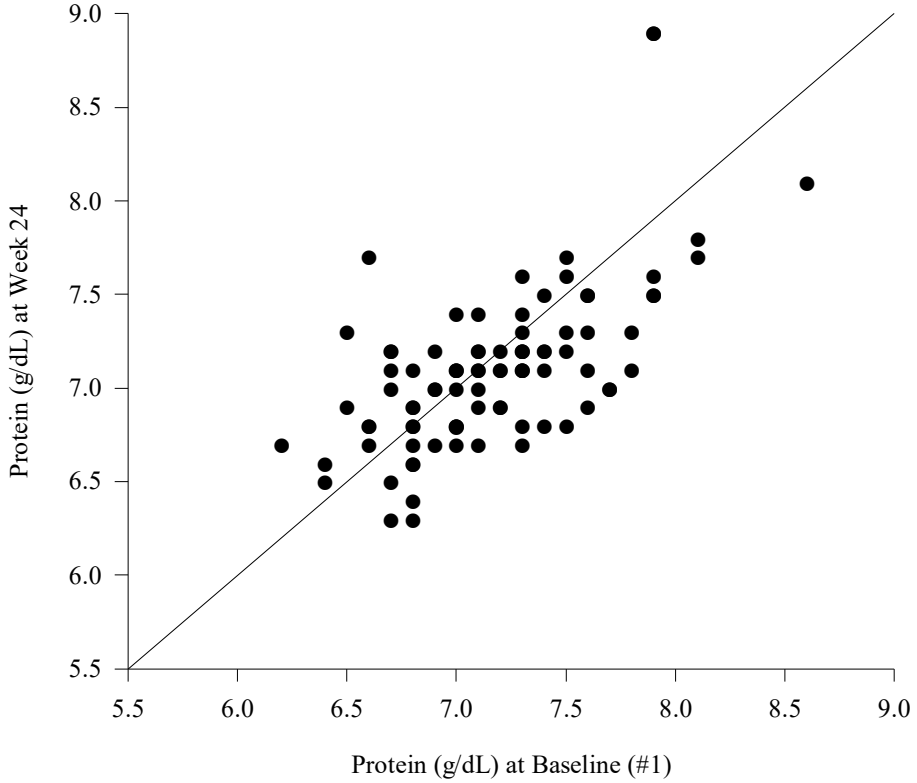


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 5 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (0%/5%)

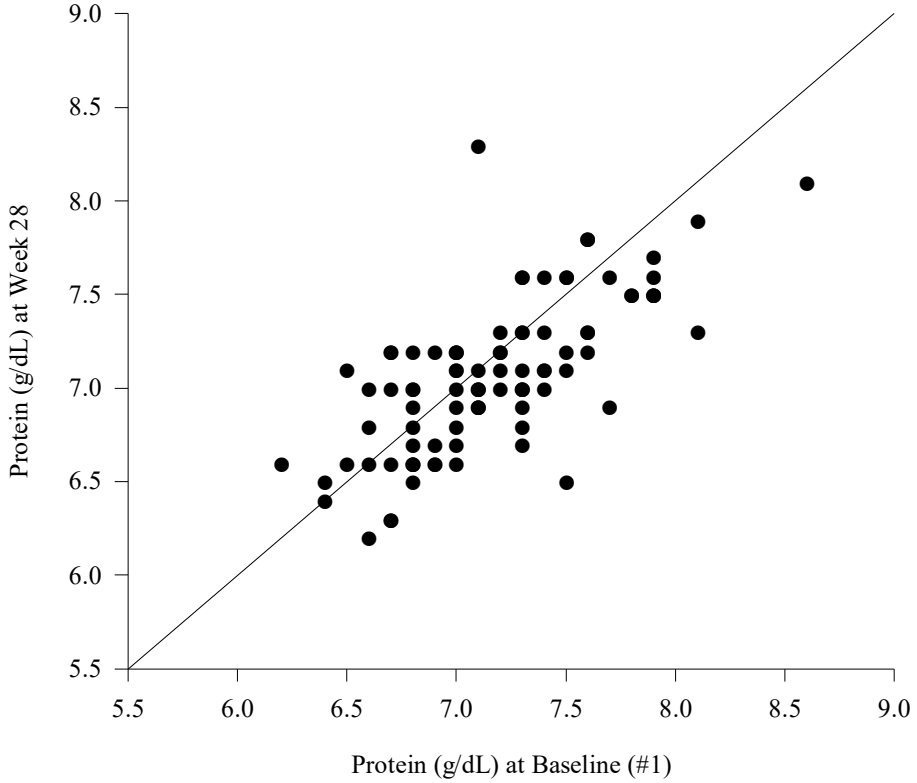


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 6 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (0%/5%)

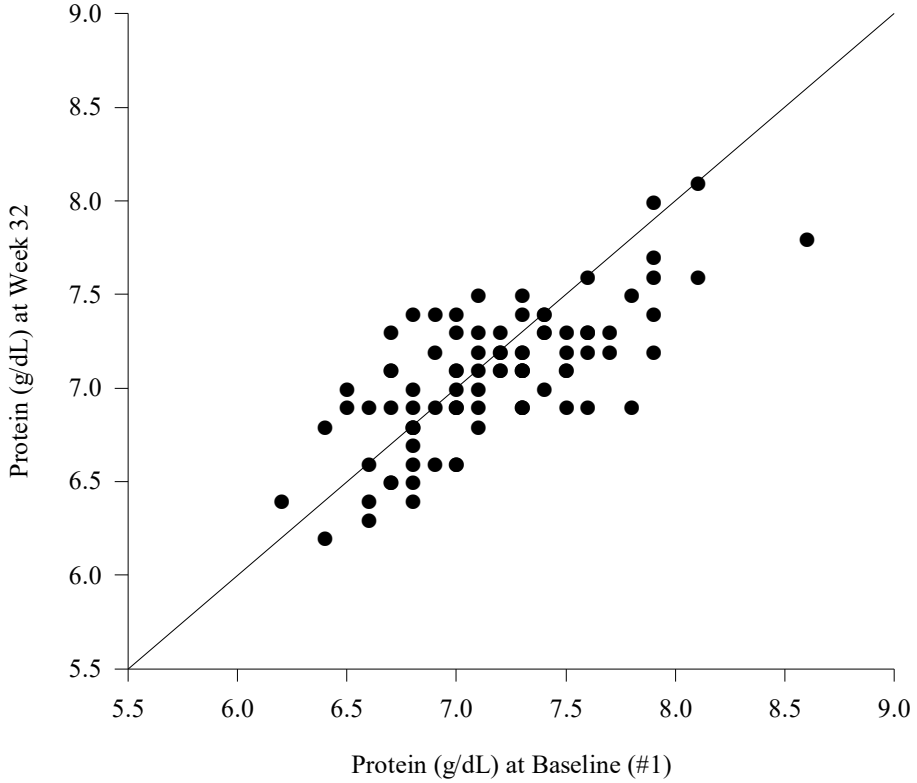


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 7 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (0%/5%)

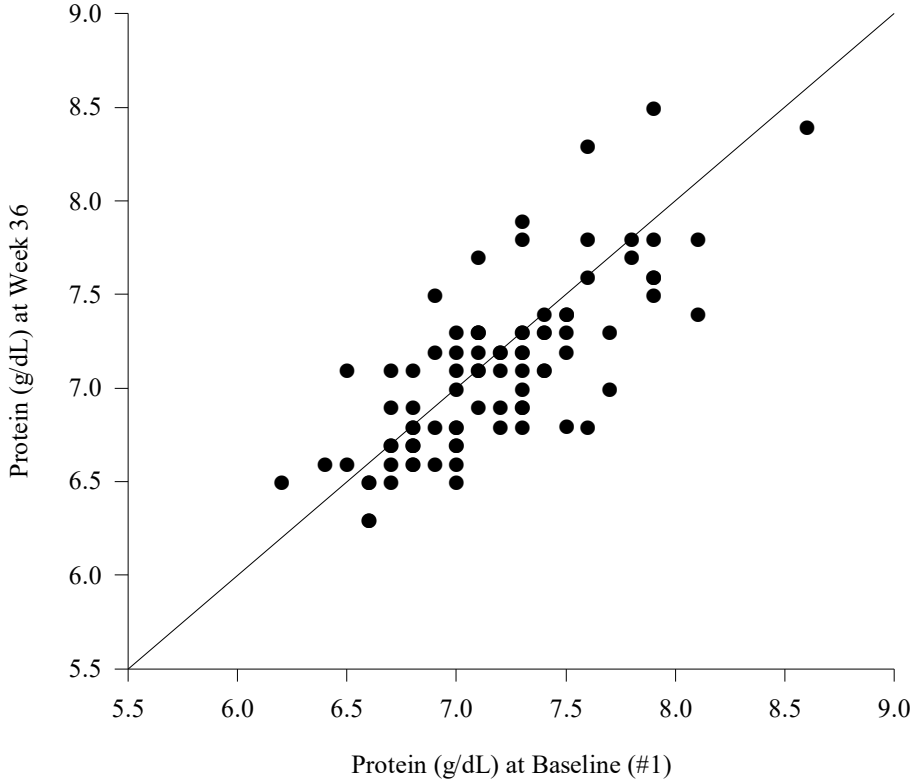


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 8 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (0%/5%)

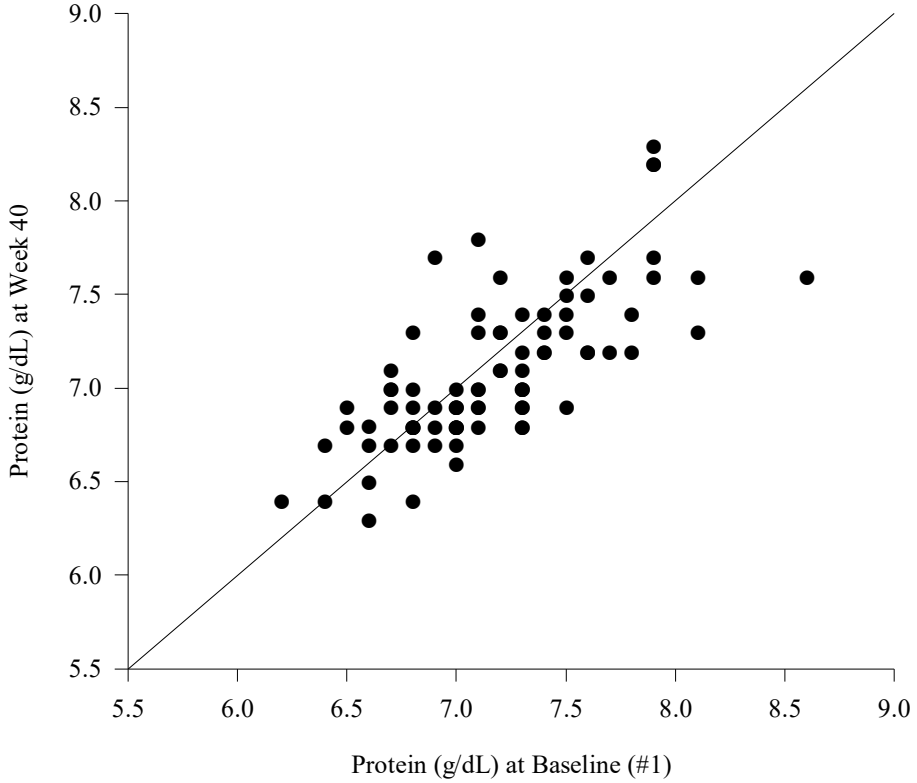


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 9 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (0%/5%)

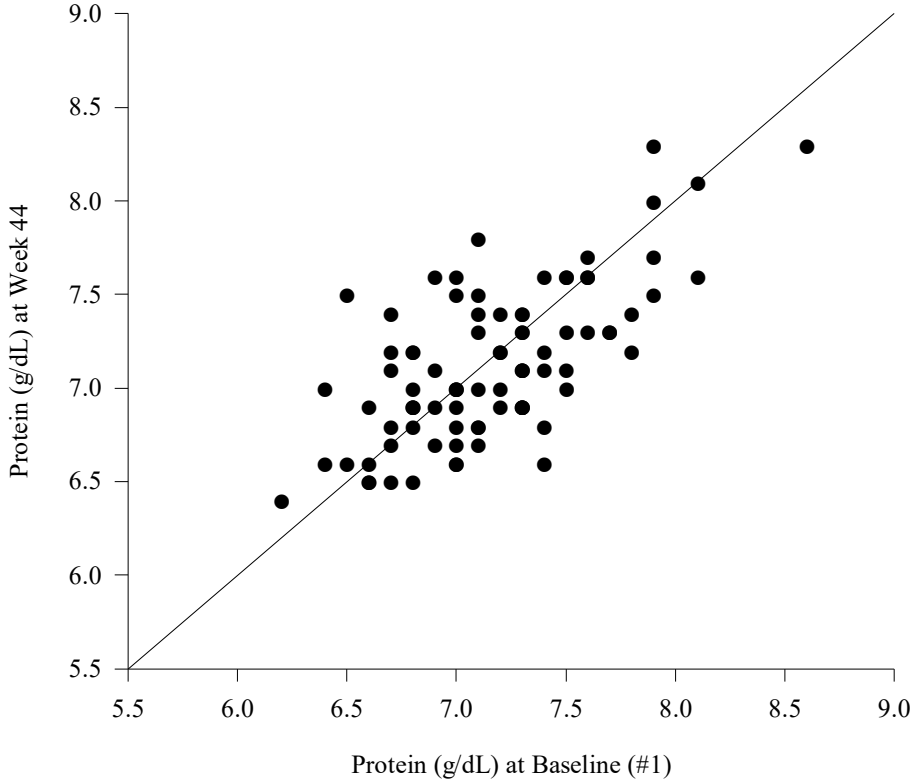


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 10 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (0%/5%)

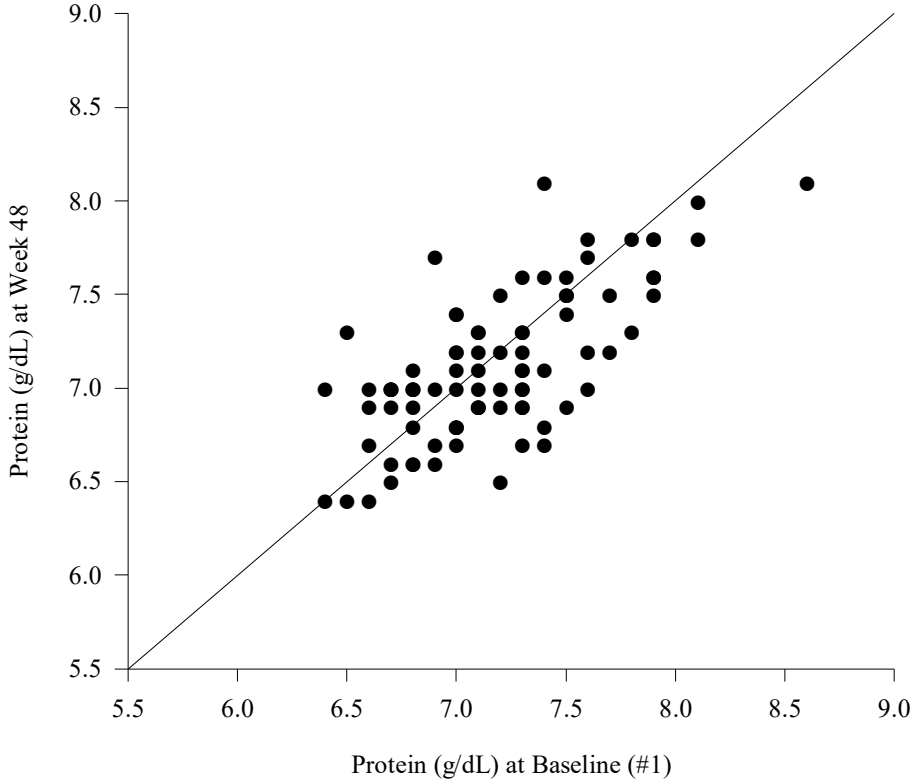


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 11 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (0%/5%)

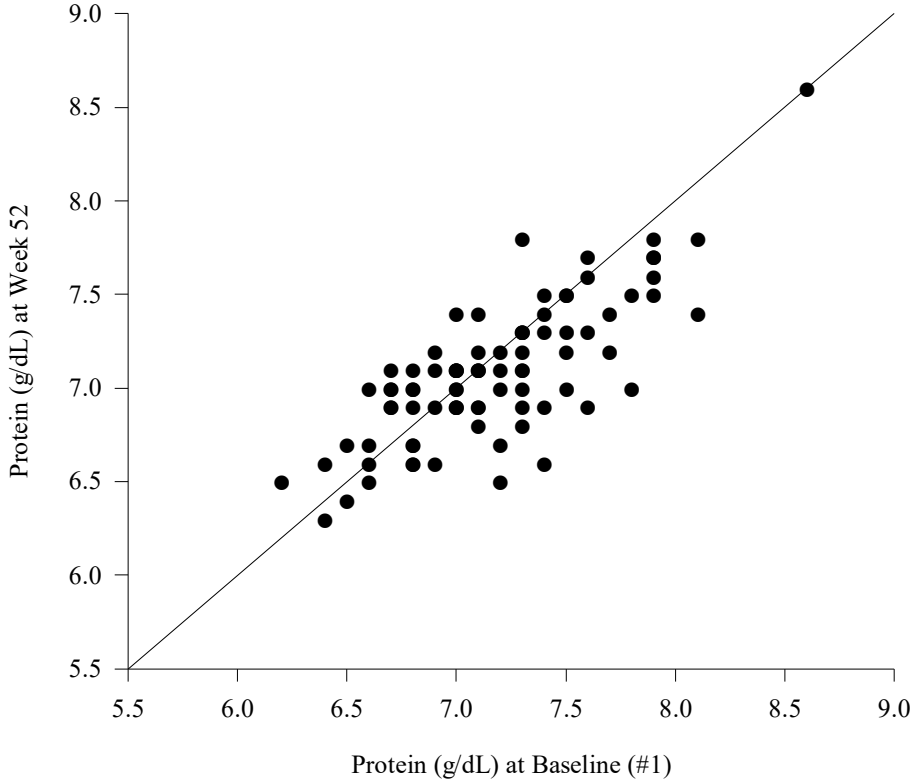


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 12 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (0%/5%)

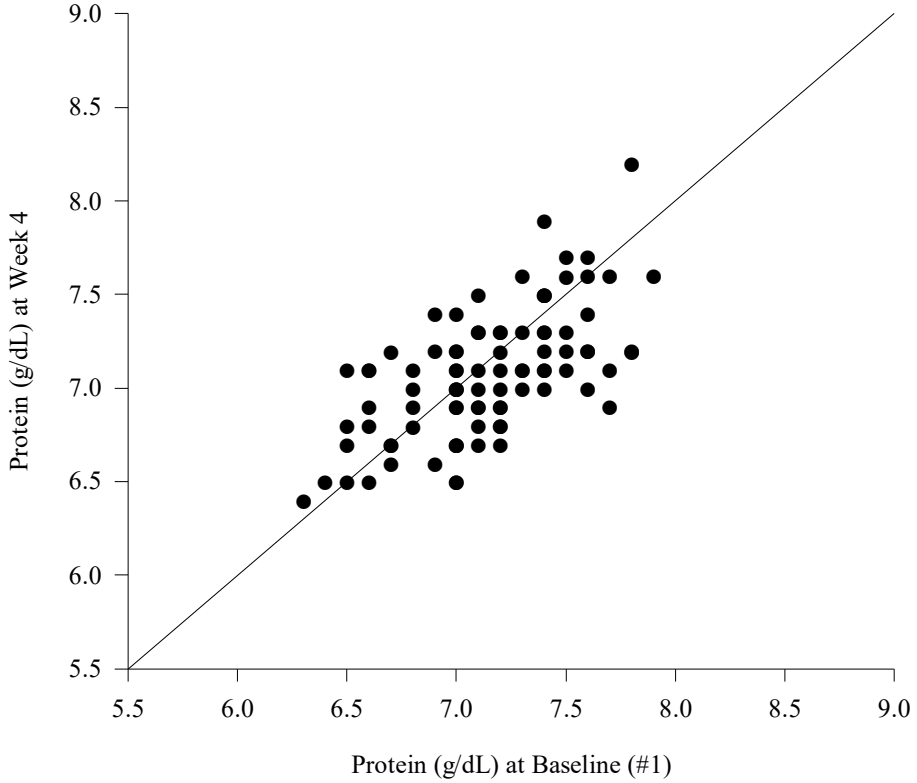


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 13 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (5%/5%)

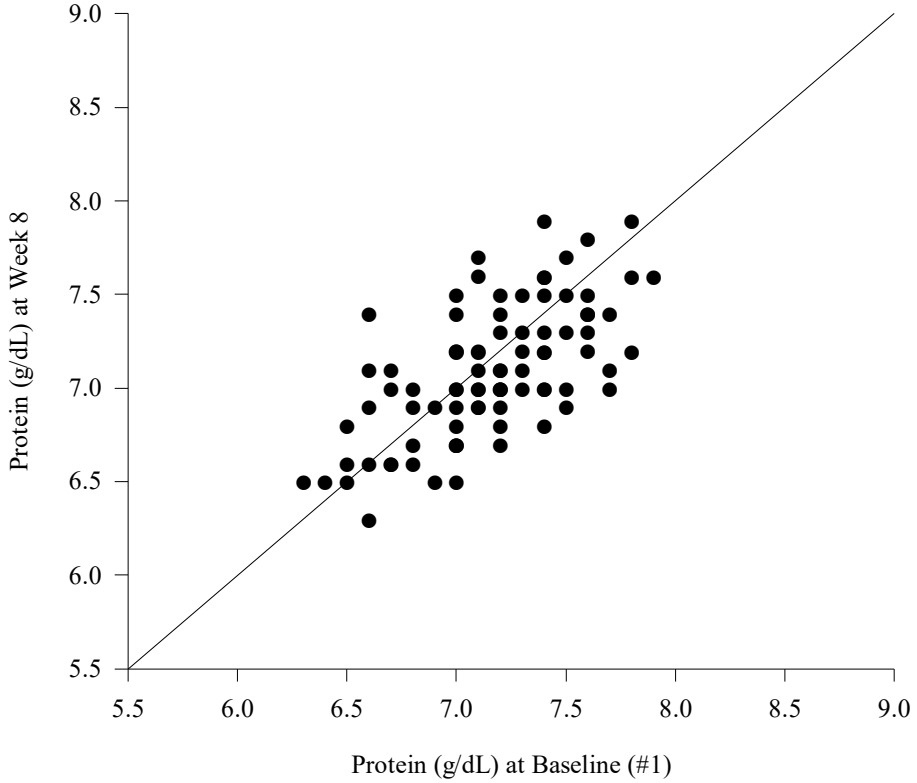


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 14 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (5%/5%)

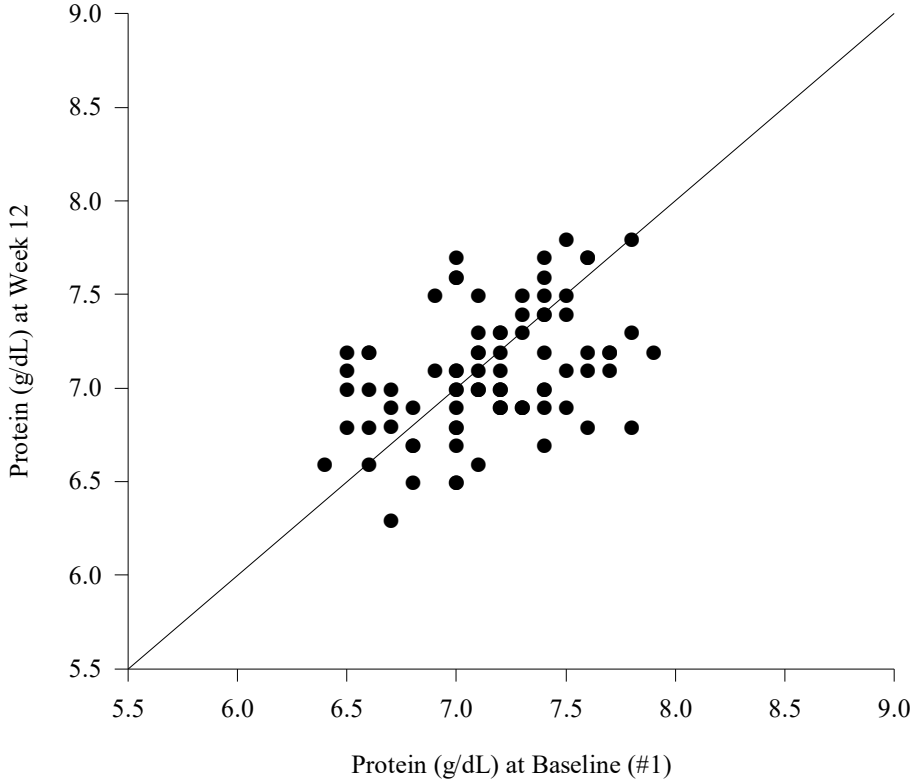


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 15 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (5%/5%)

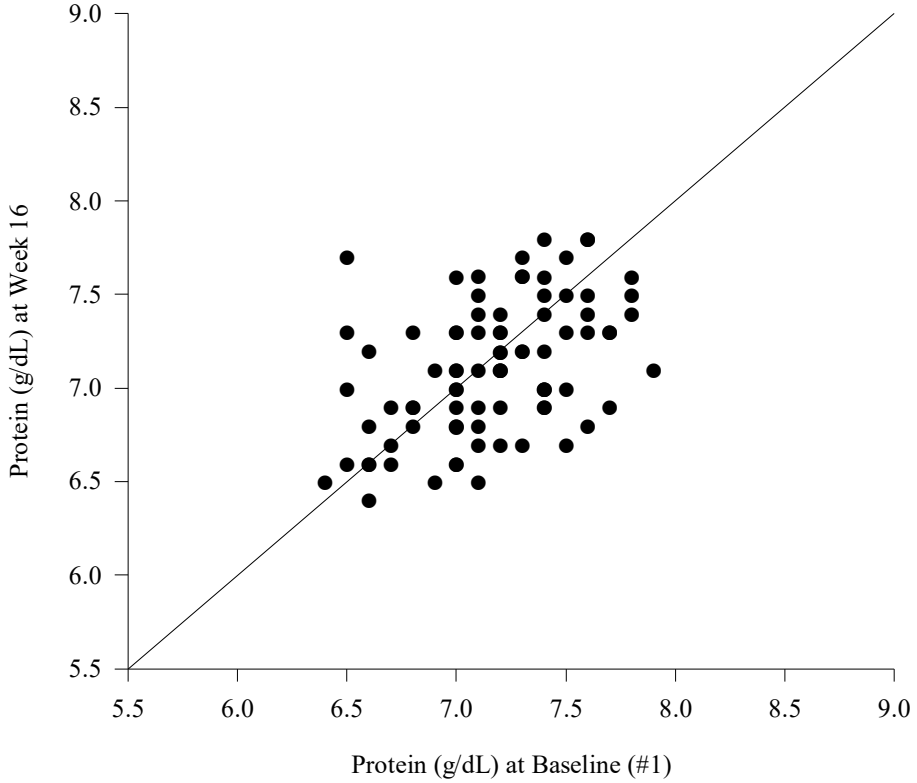


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 16 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (5%/5%)

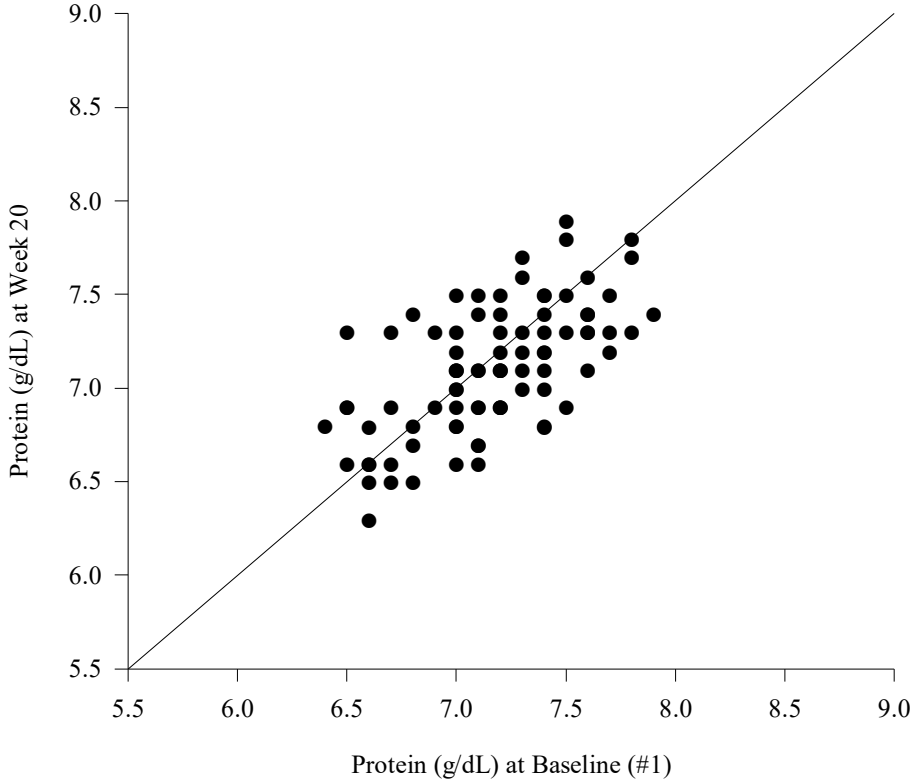


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 17 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (5%/5%)

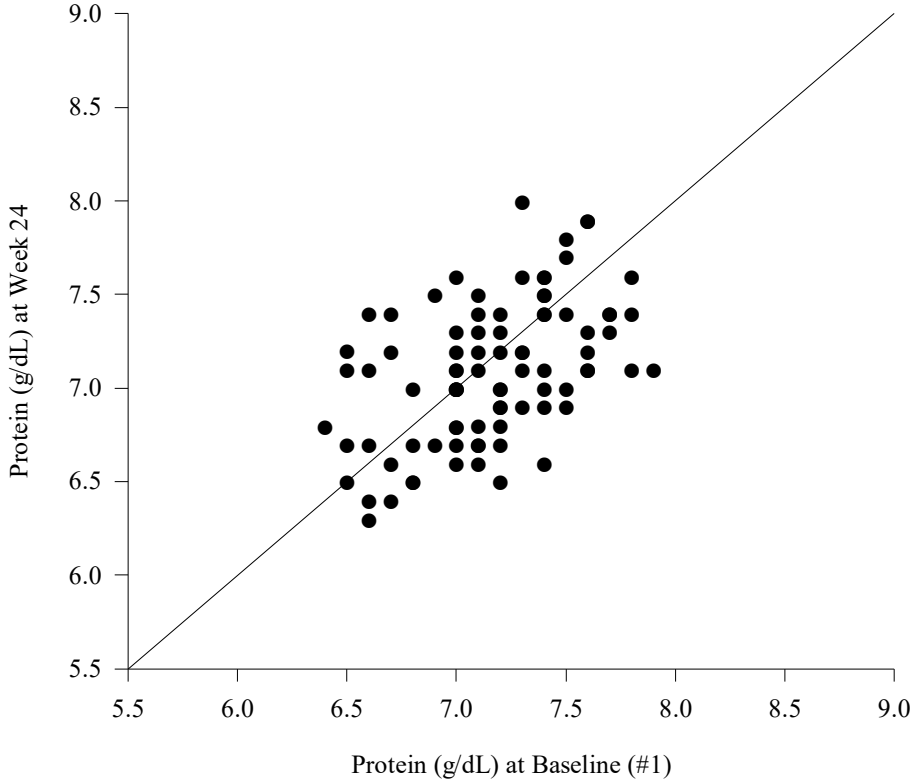


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 18 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (5%/5%)

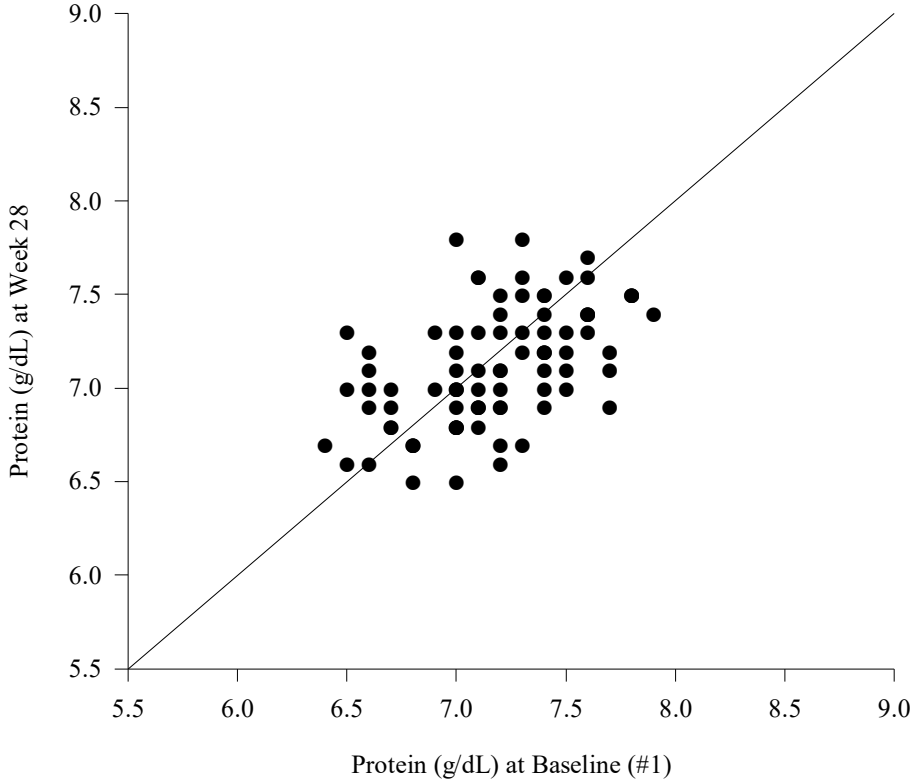


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 19 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (5%/5%)

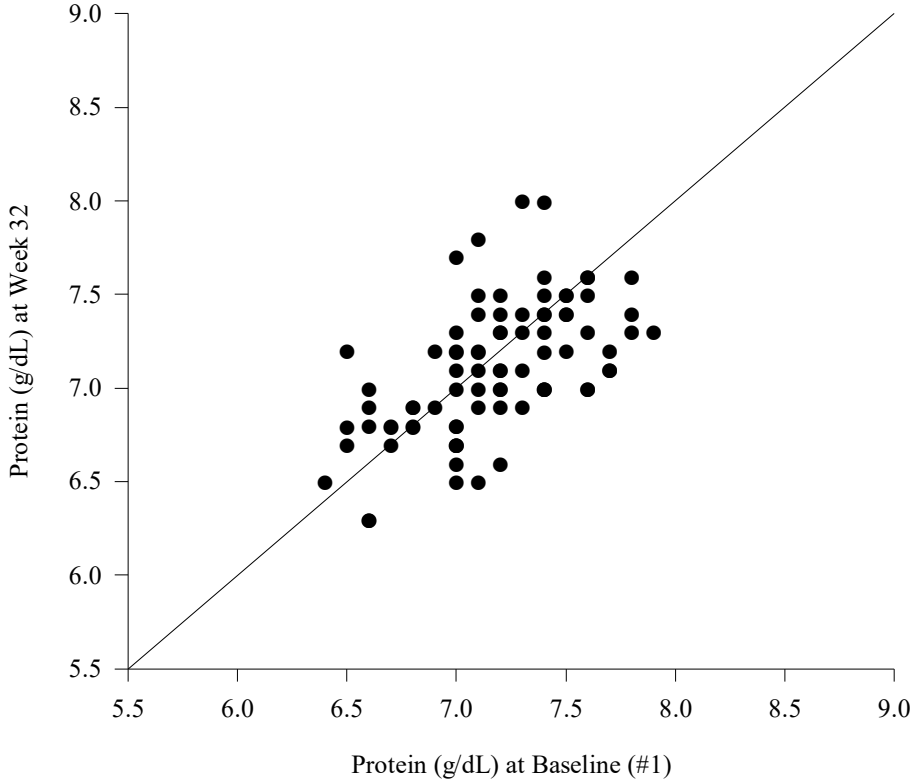


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 20 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (5%/5%)

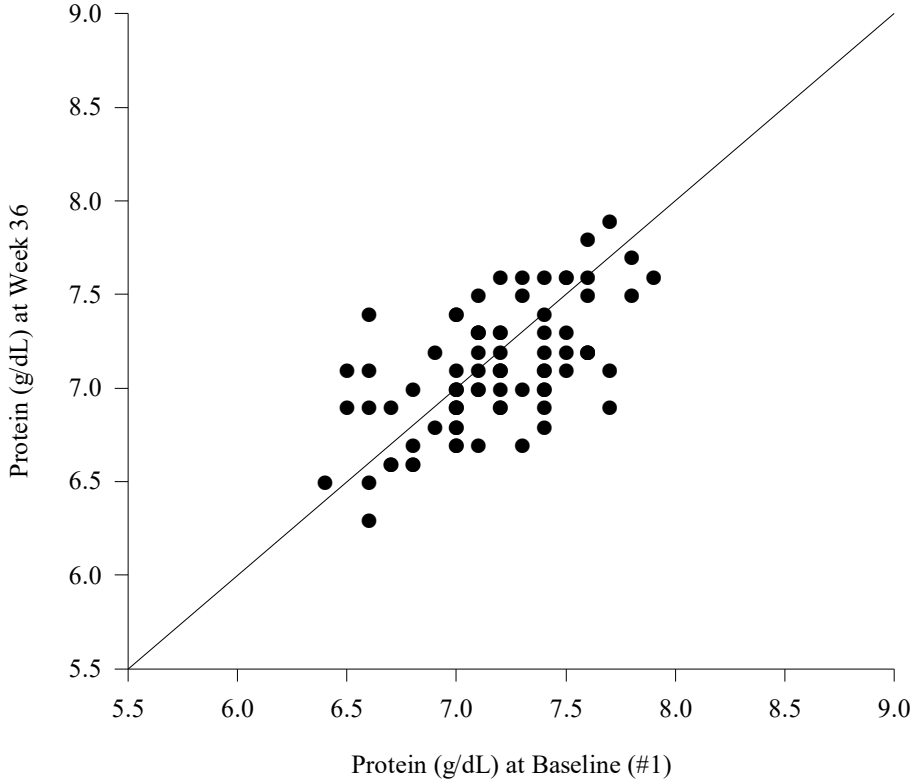


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 21 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (5%/5%)

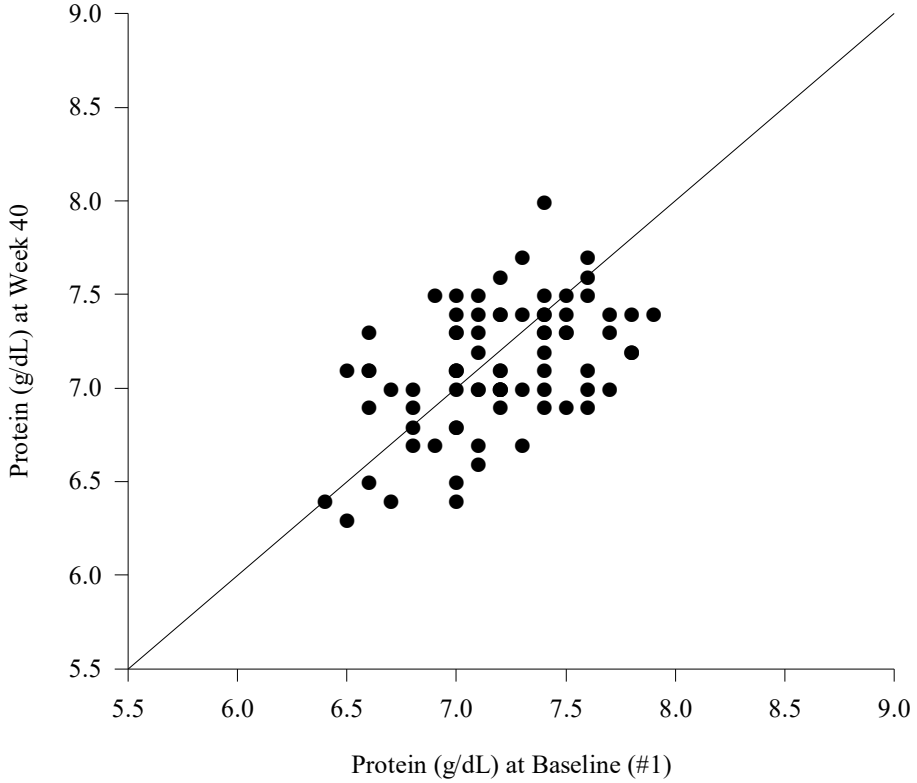


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 22 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (5%/5%)

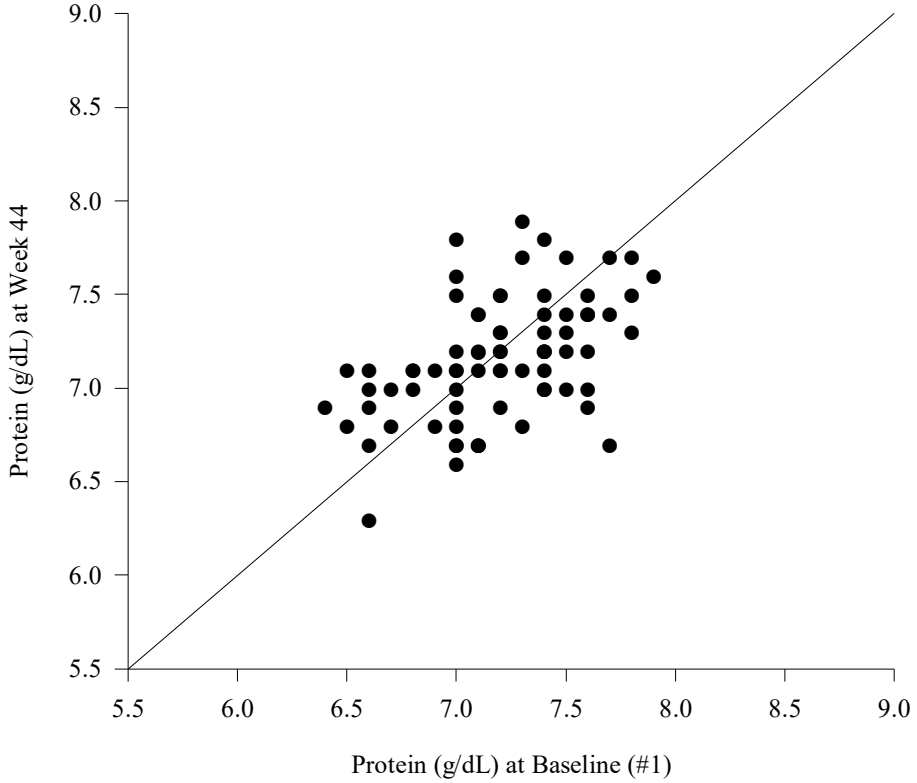


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 23 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (5%/5%)

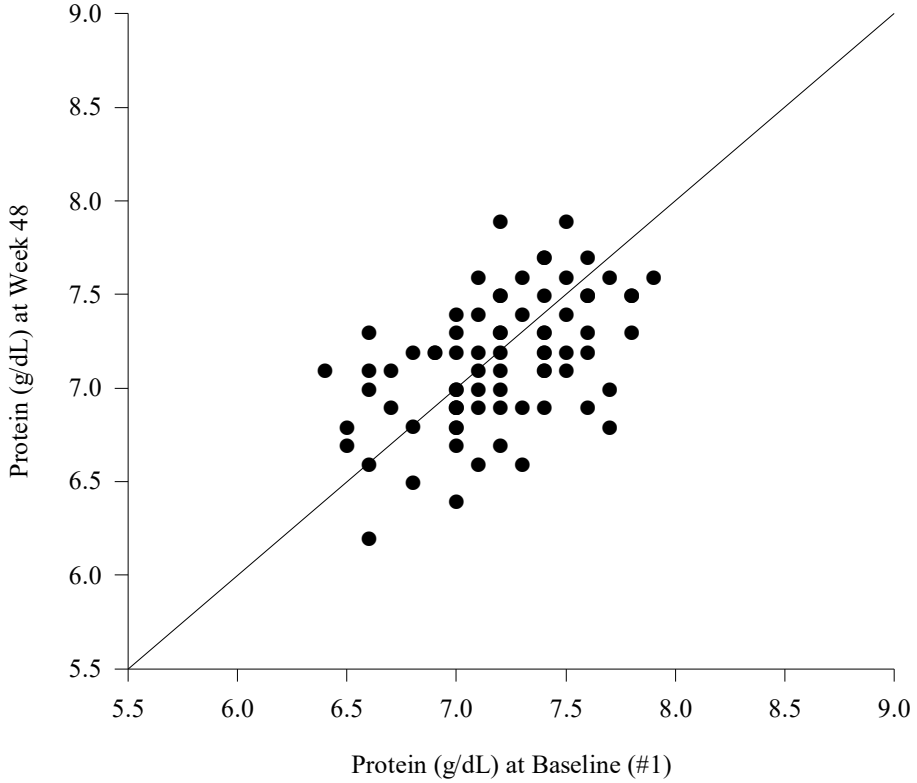


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 24 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (5%/5%)

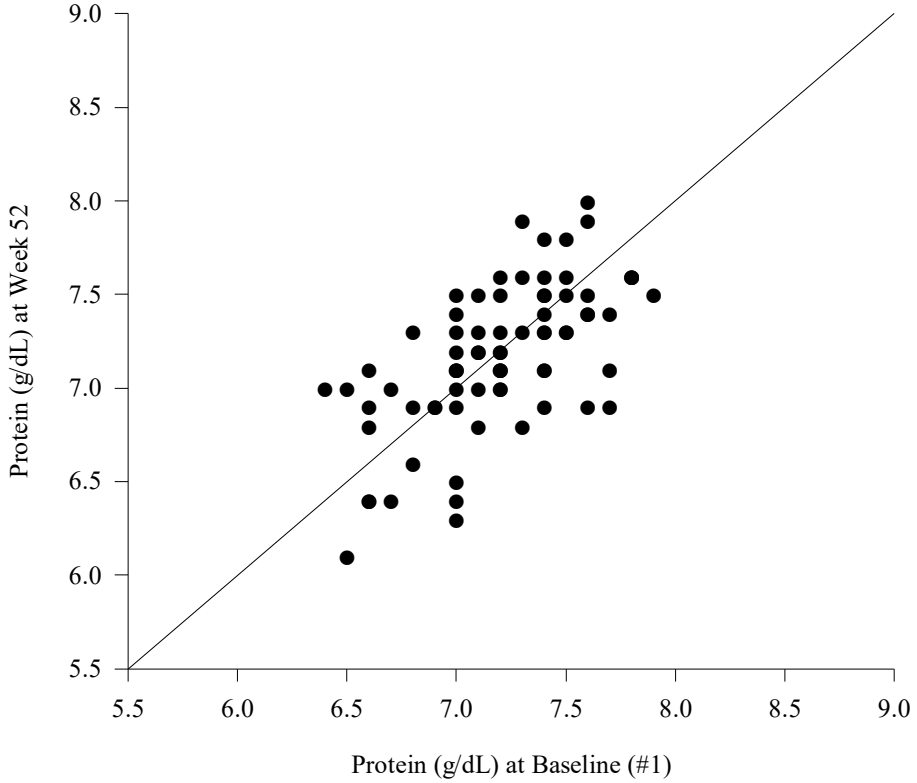


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 25 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (5%/5%)

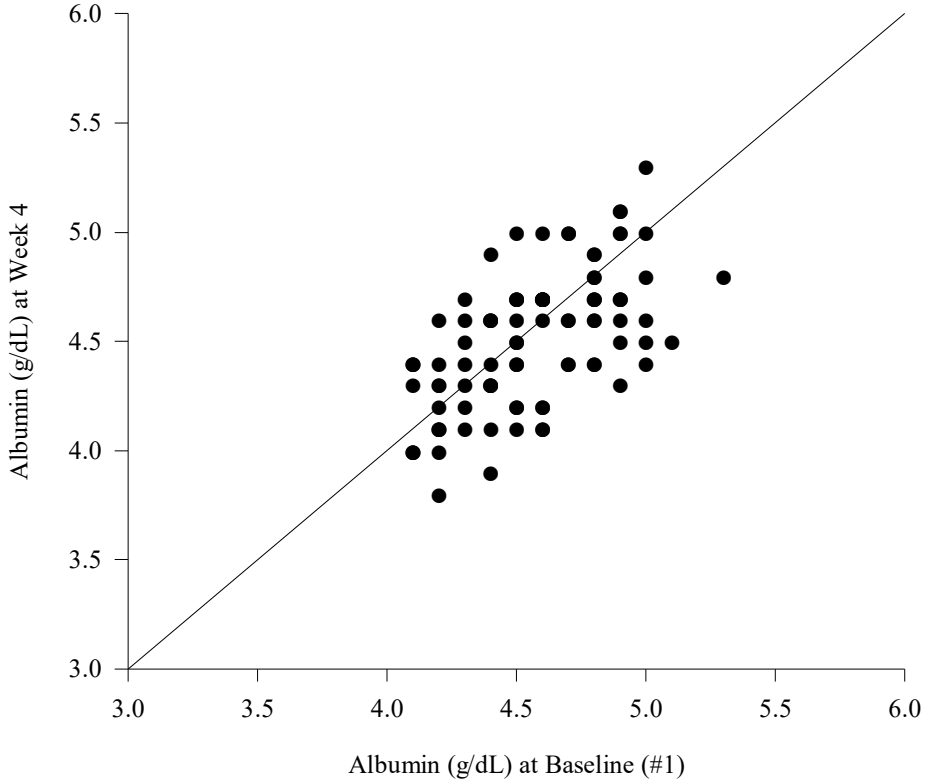


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 26 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (0%/5%)

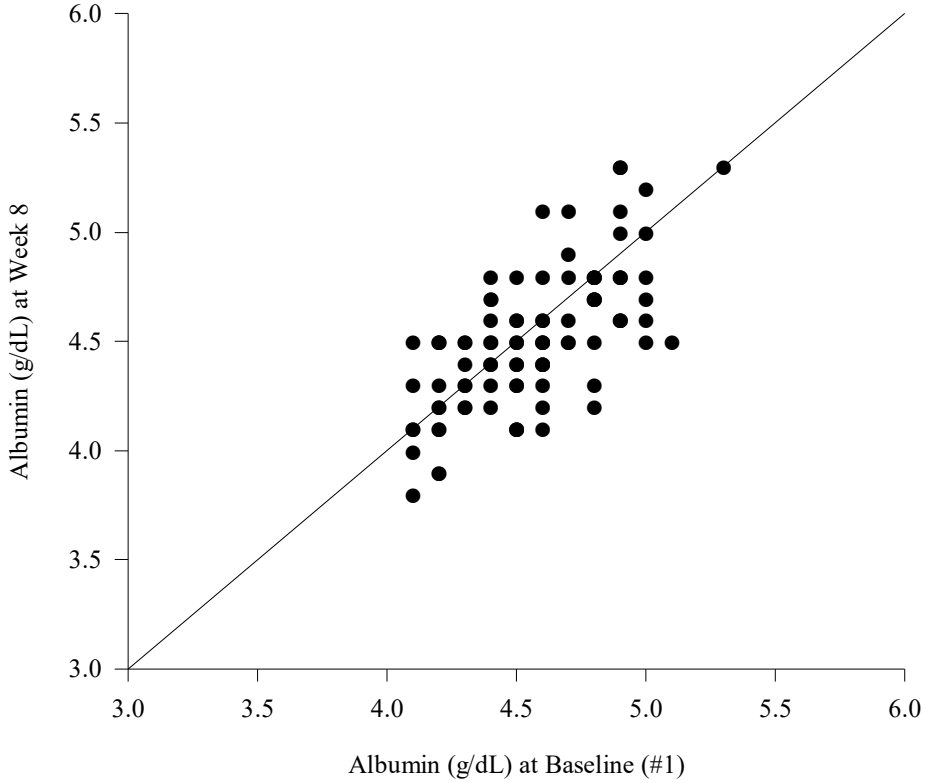


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 27 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (0%/5%)

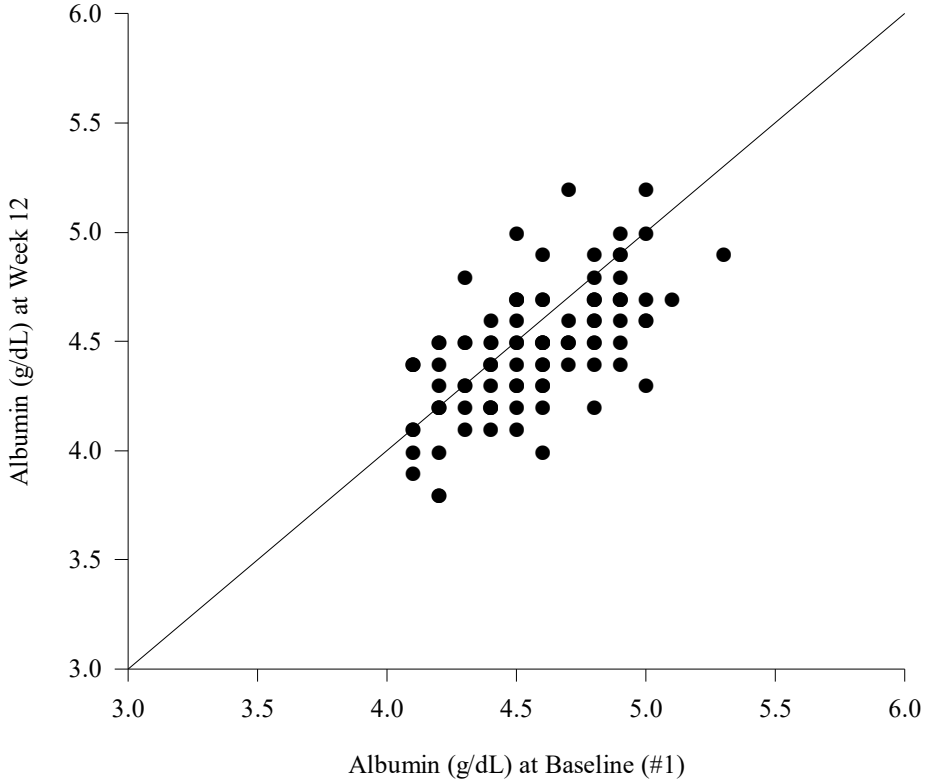


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 28 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (0%/5%)

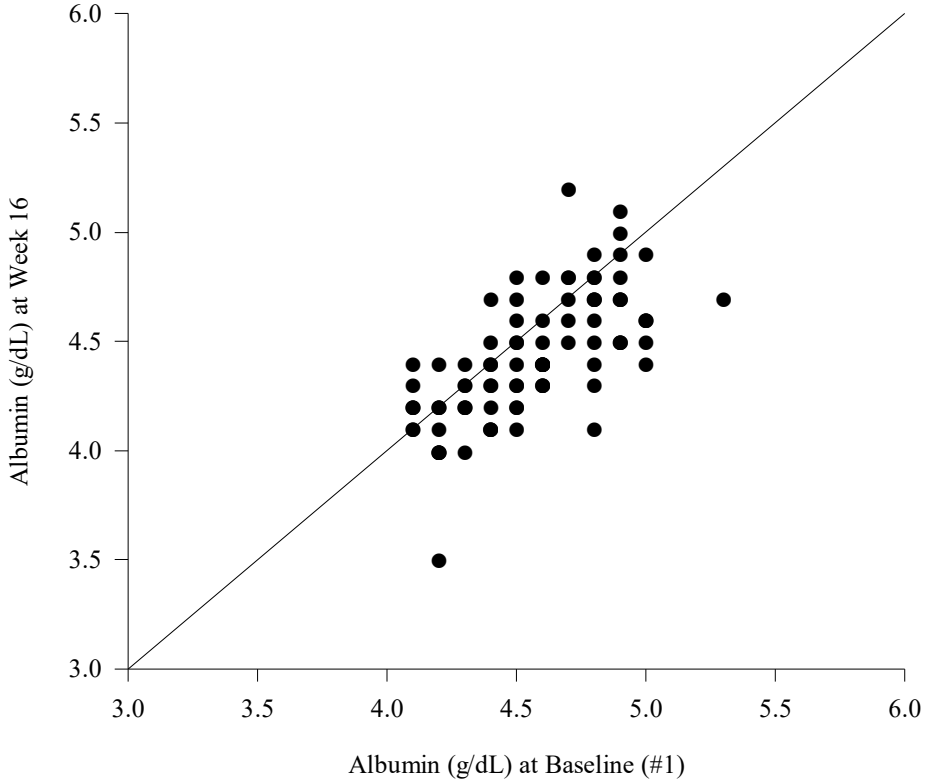


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 29 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (0%/5%)

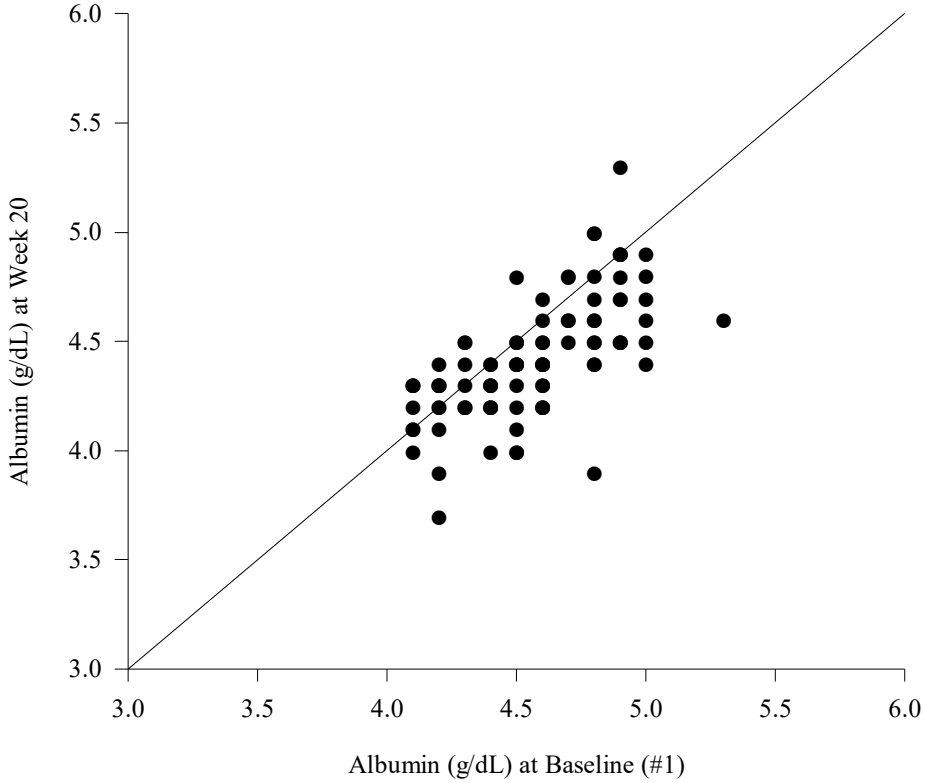


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 30 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (0%/5%)

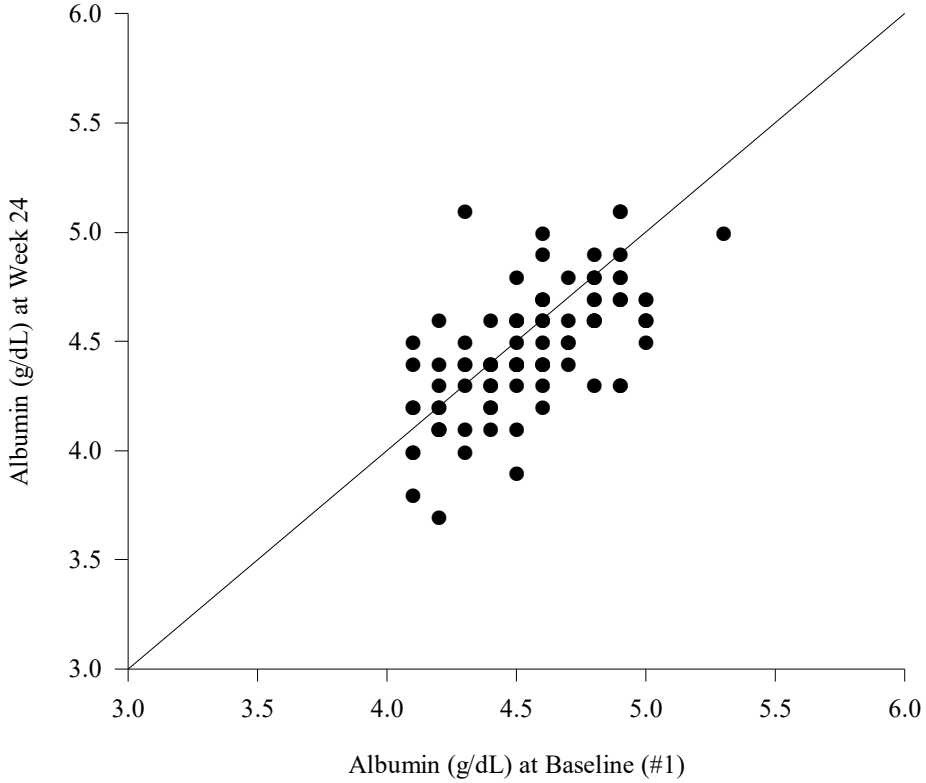


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 31 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (0%/5%)

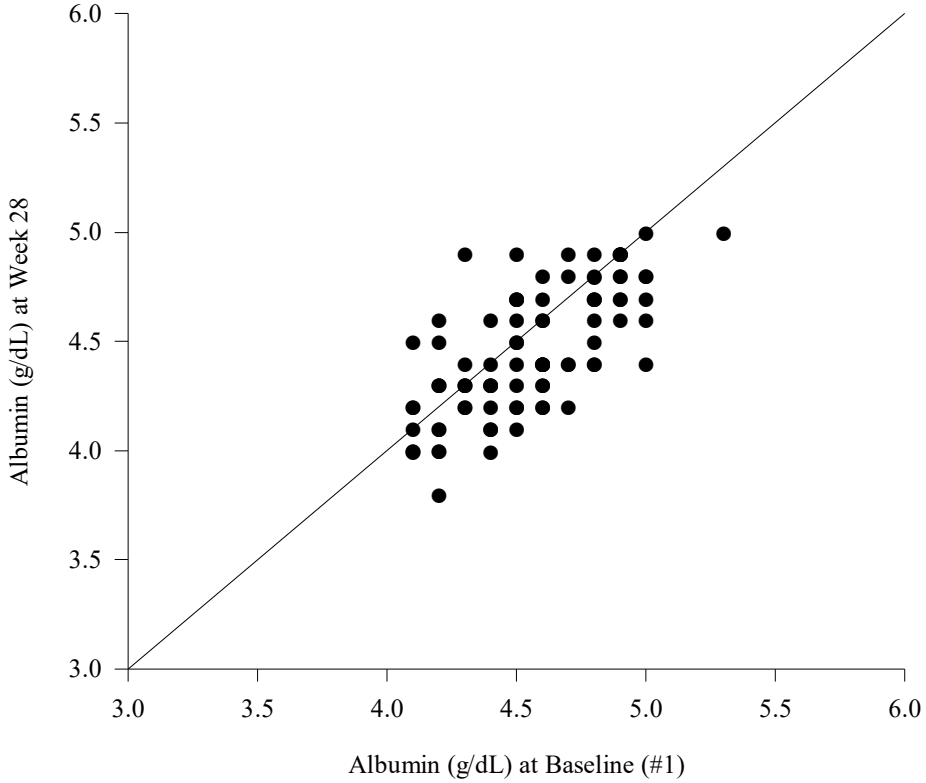


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 32 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (0%/5%)

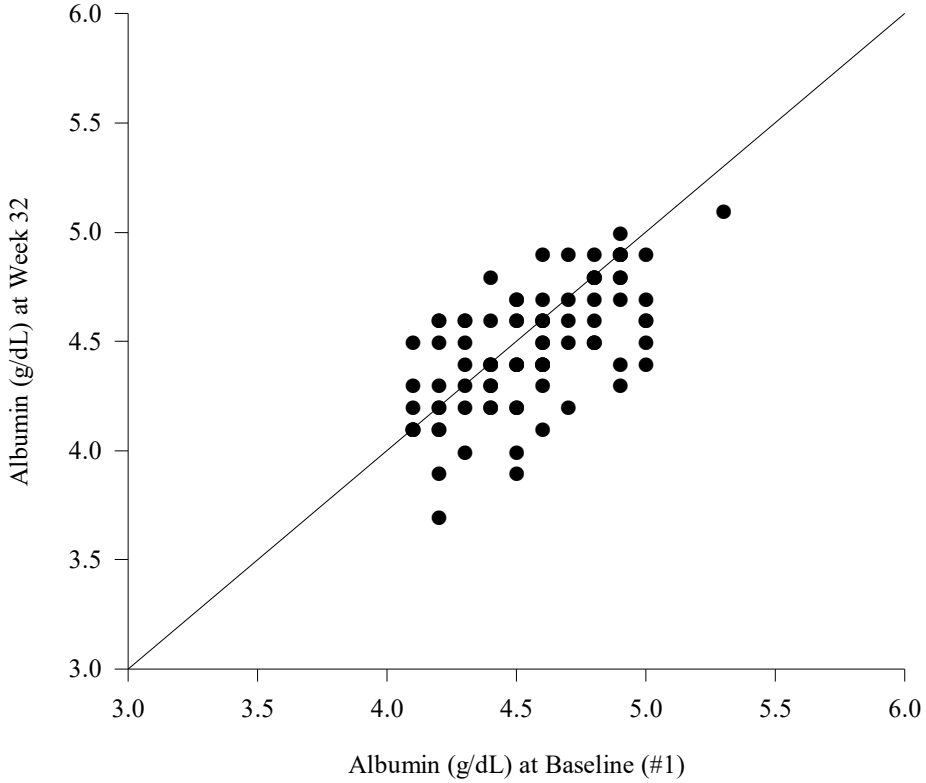


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 33 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (0%/5%)

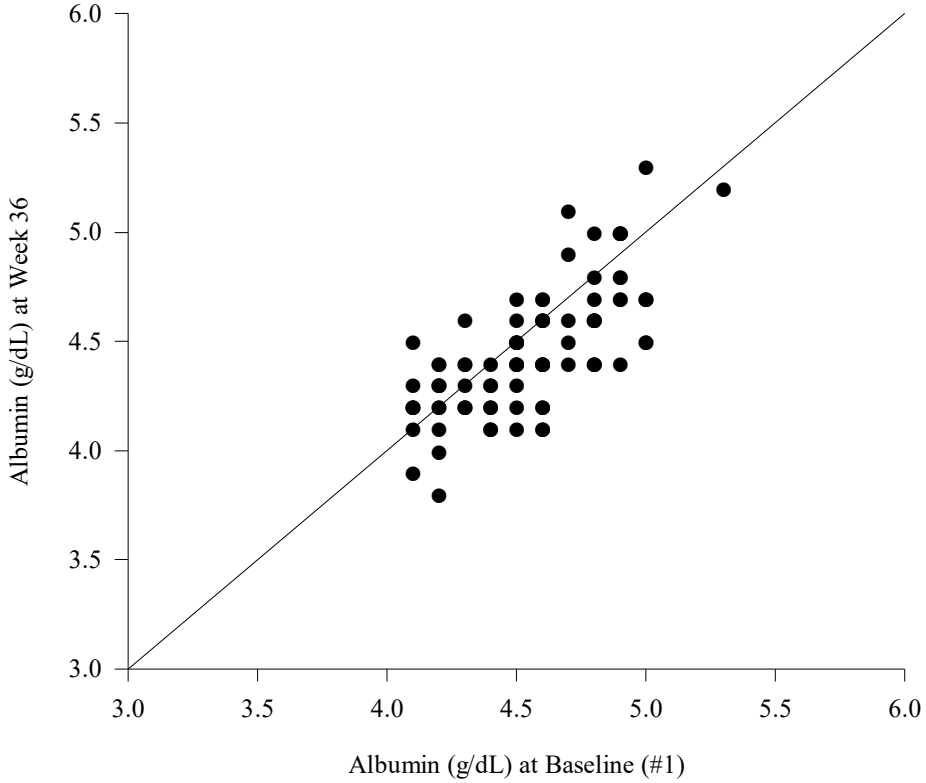


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 34 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (0%/5%)

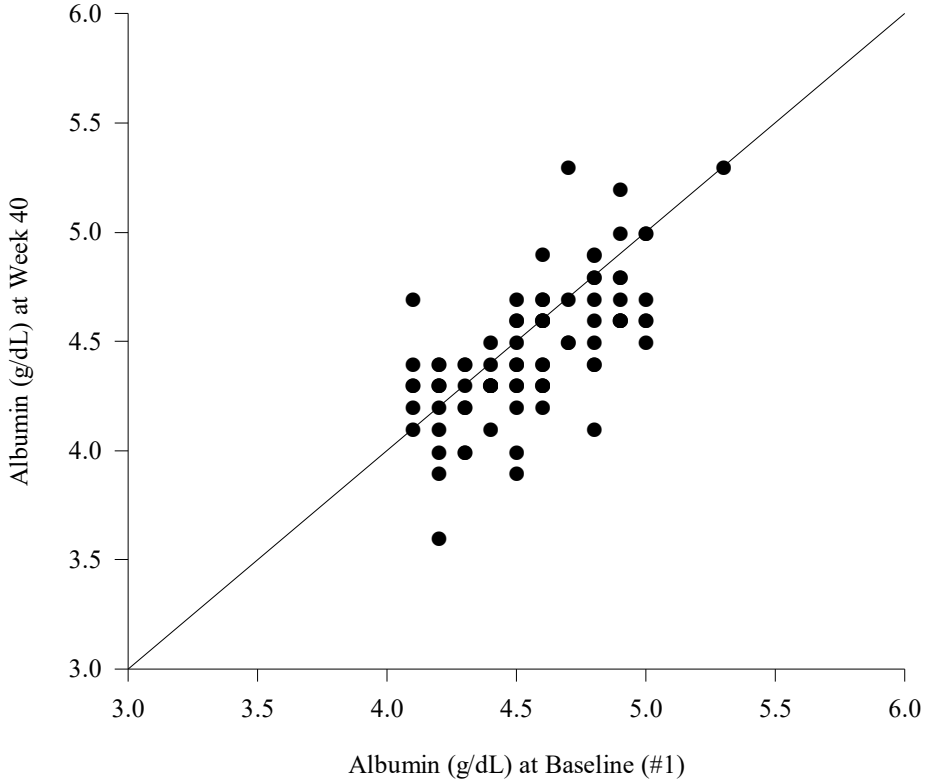


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 35 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (0%/5%)

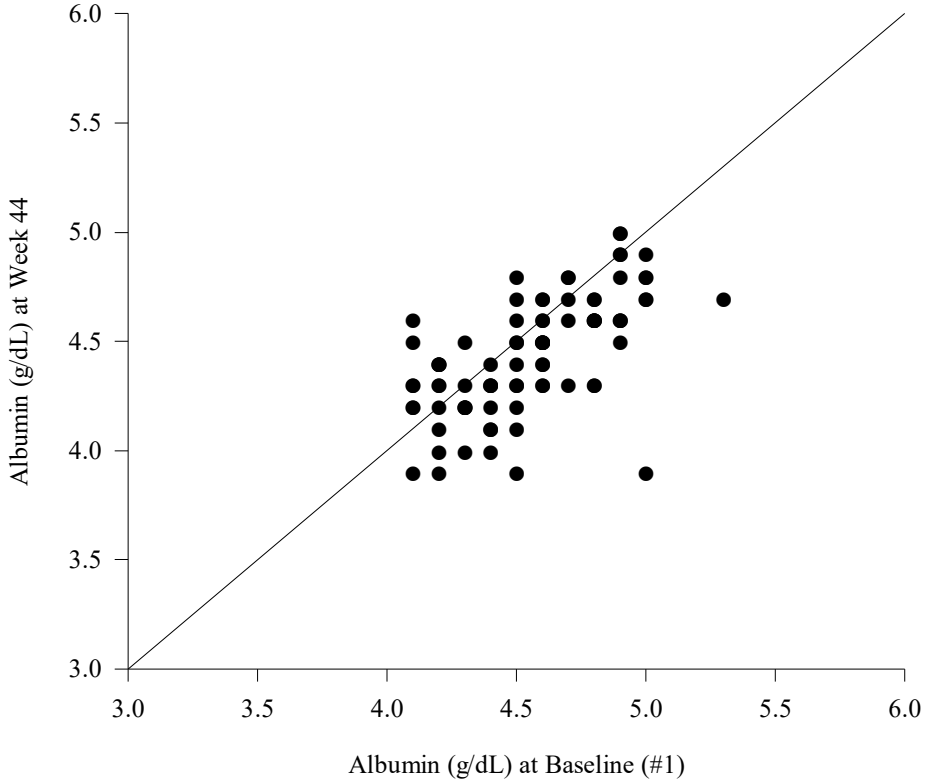


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 36 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (0%/5%)

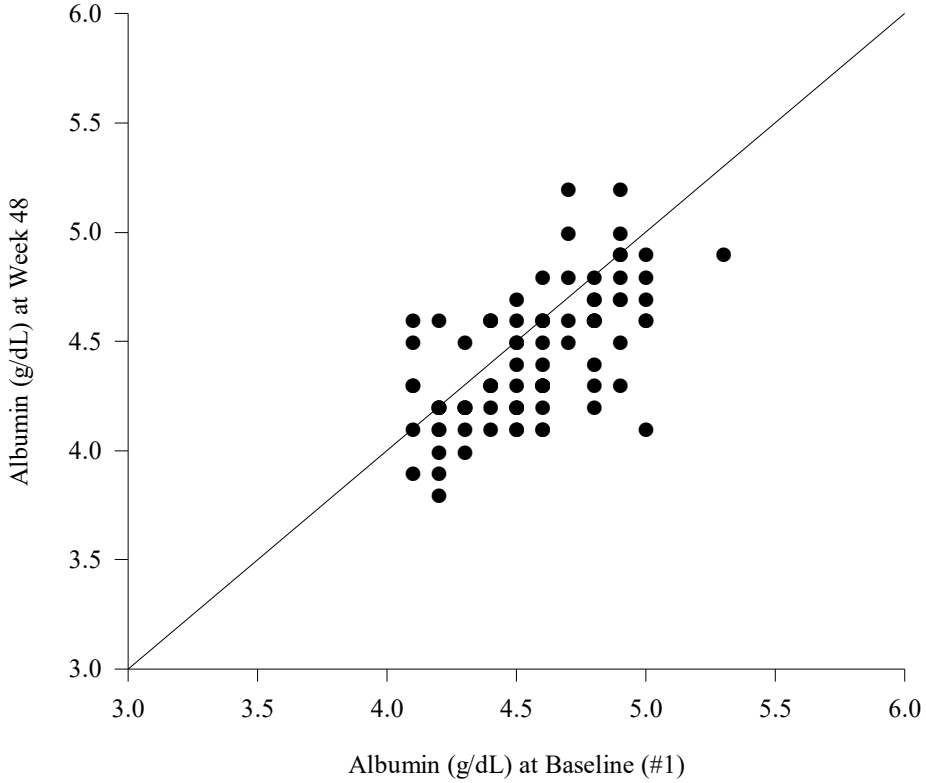


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 37 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (0%/5%)

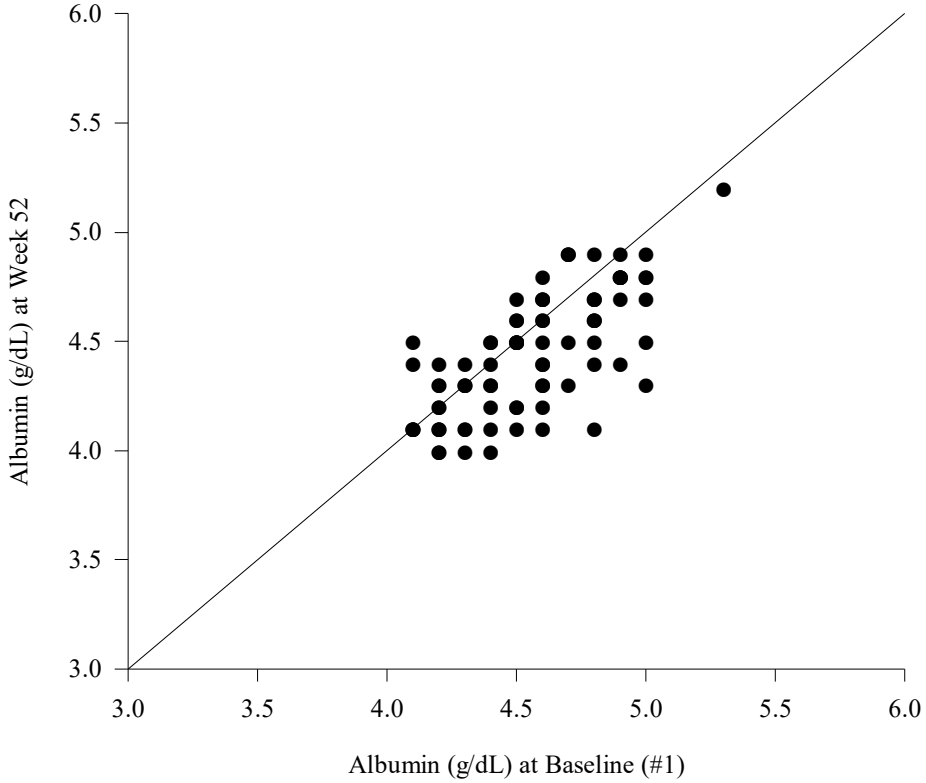


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 38 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (0%/5%)

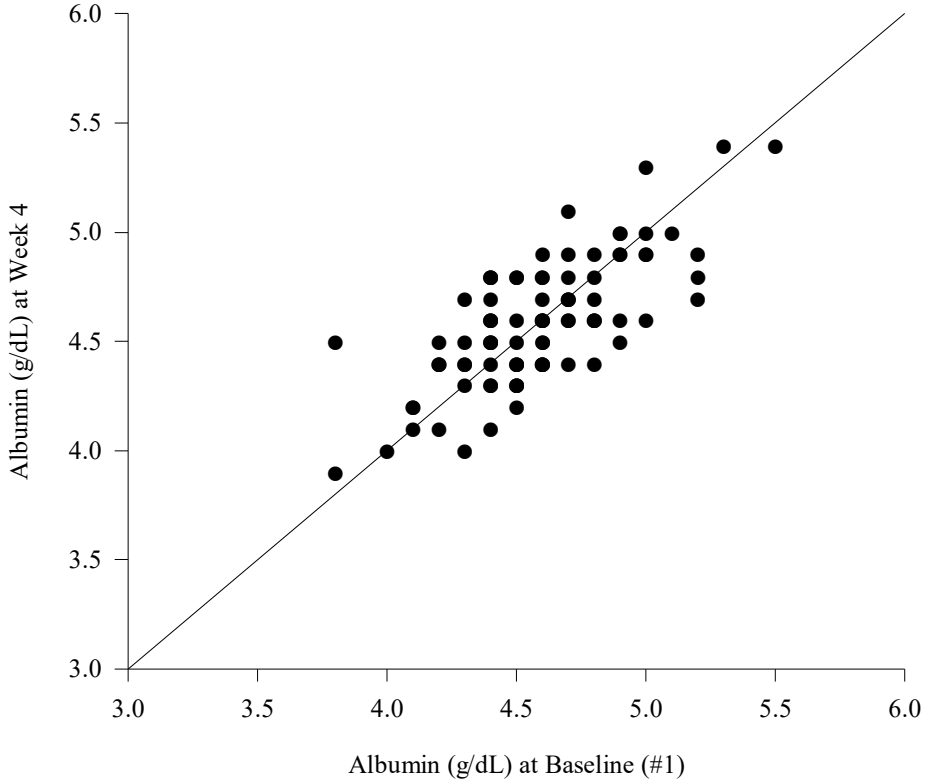


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 39 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (5%/5%)

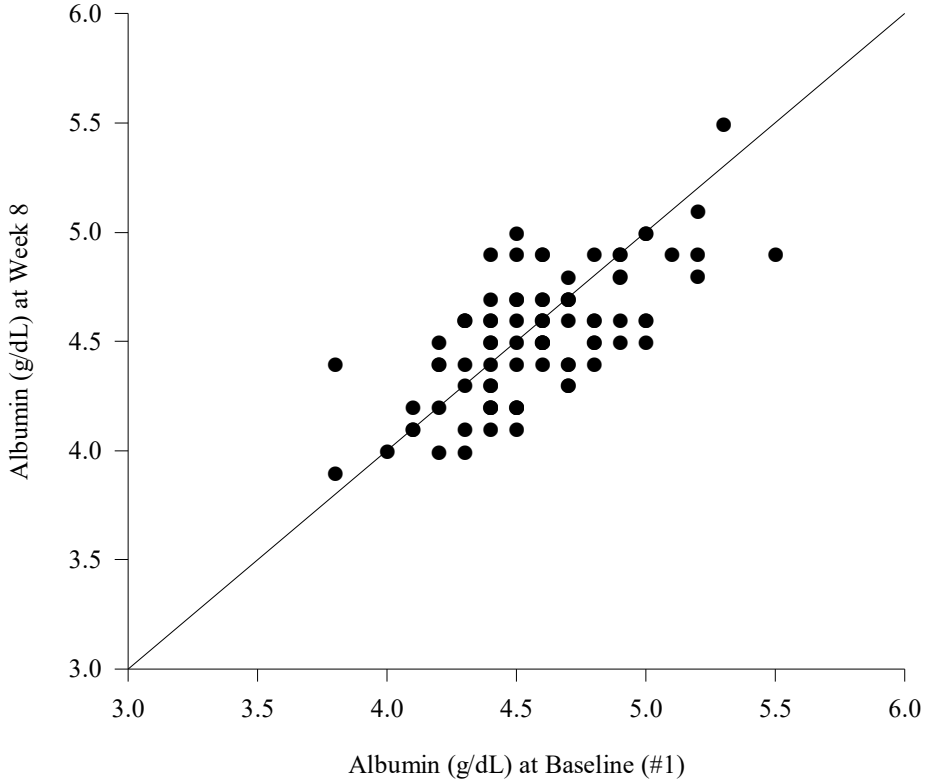


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 40 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (5%/5%)

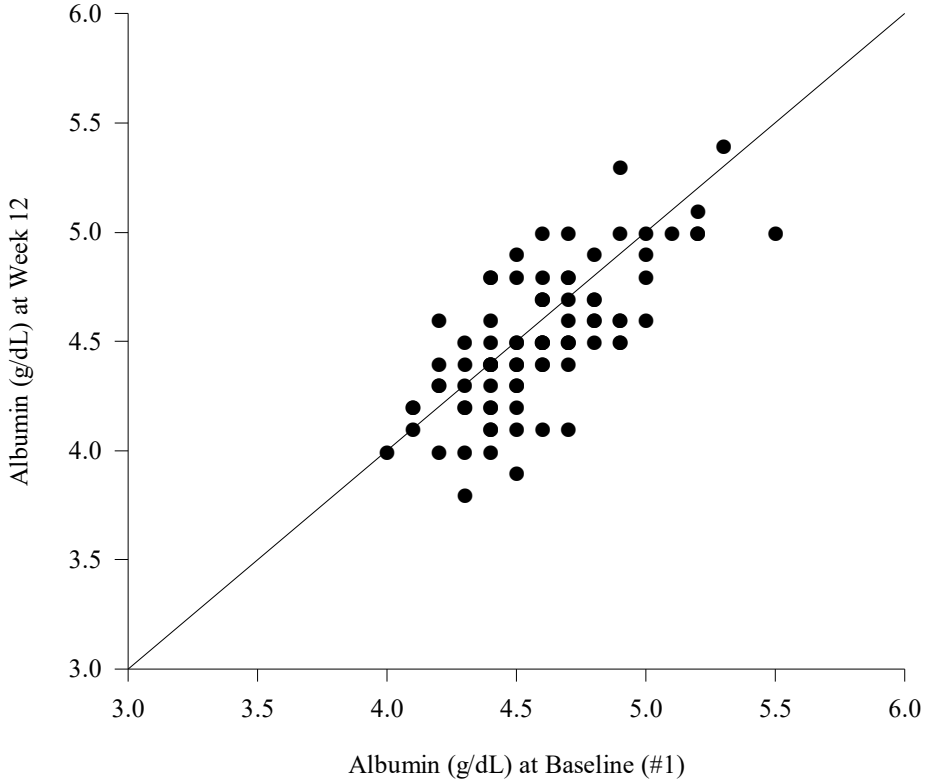


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 41 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (5%/5%)

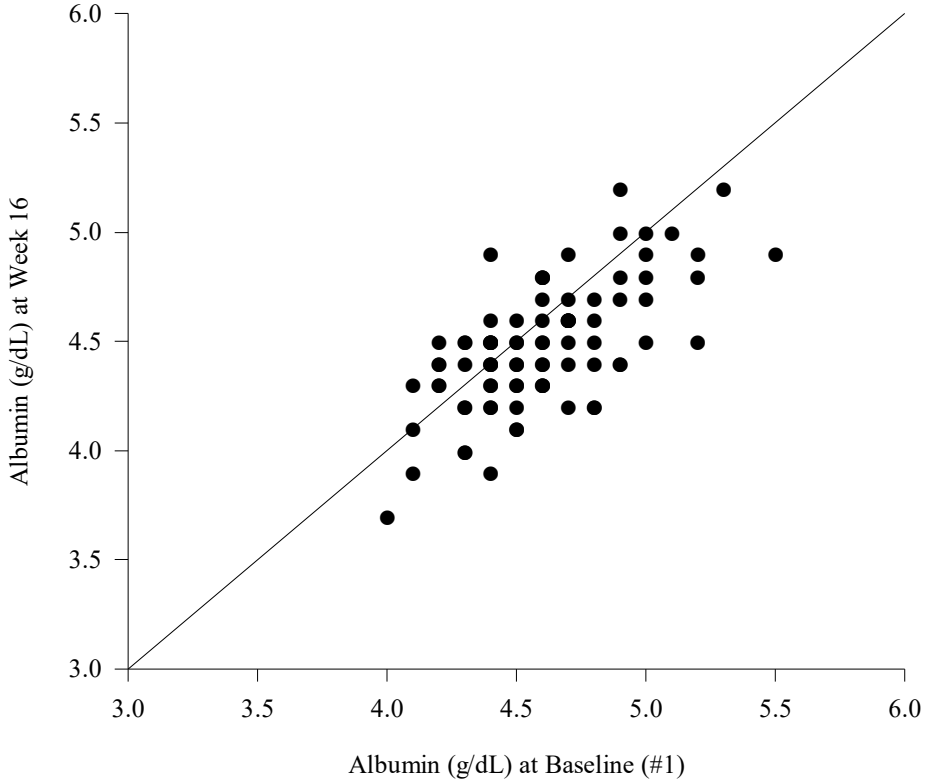


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 42 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (5%/5%)

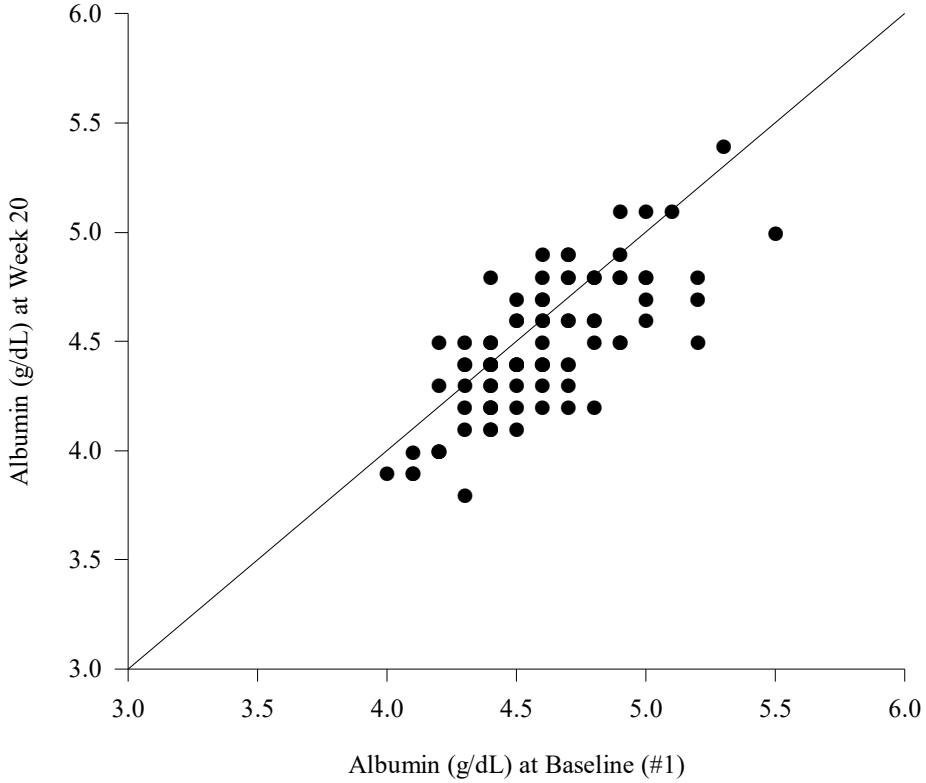


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 43 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (5%/5%)

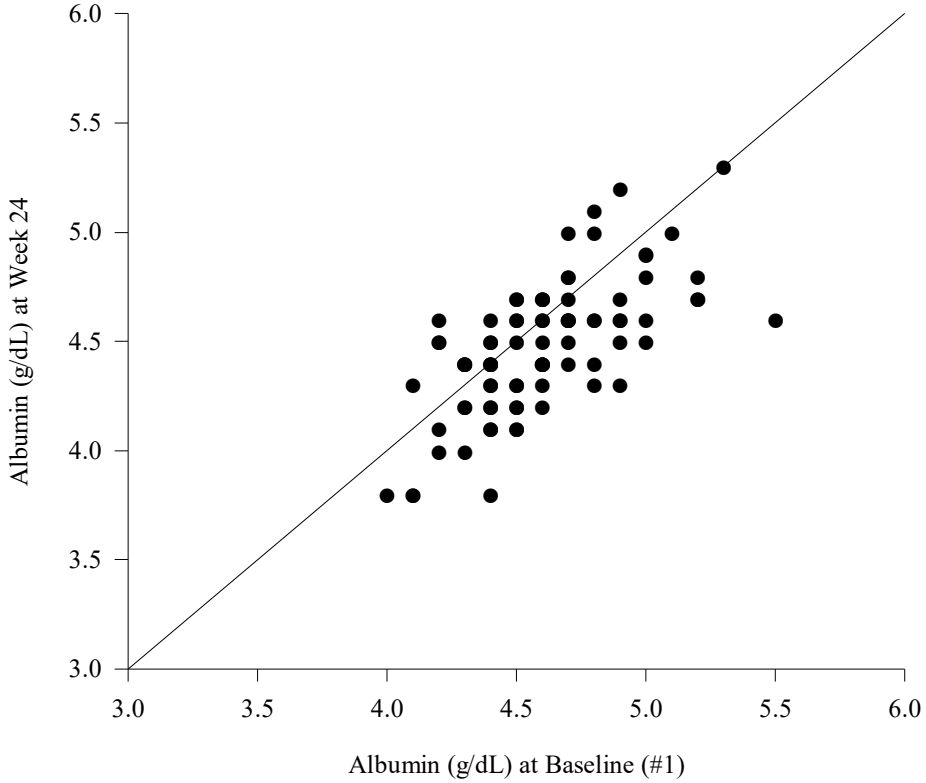


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 44 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (5%/5%)

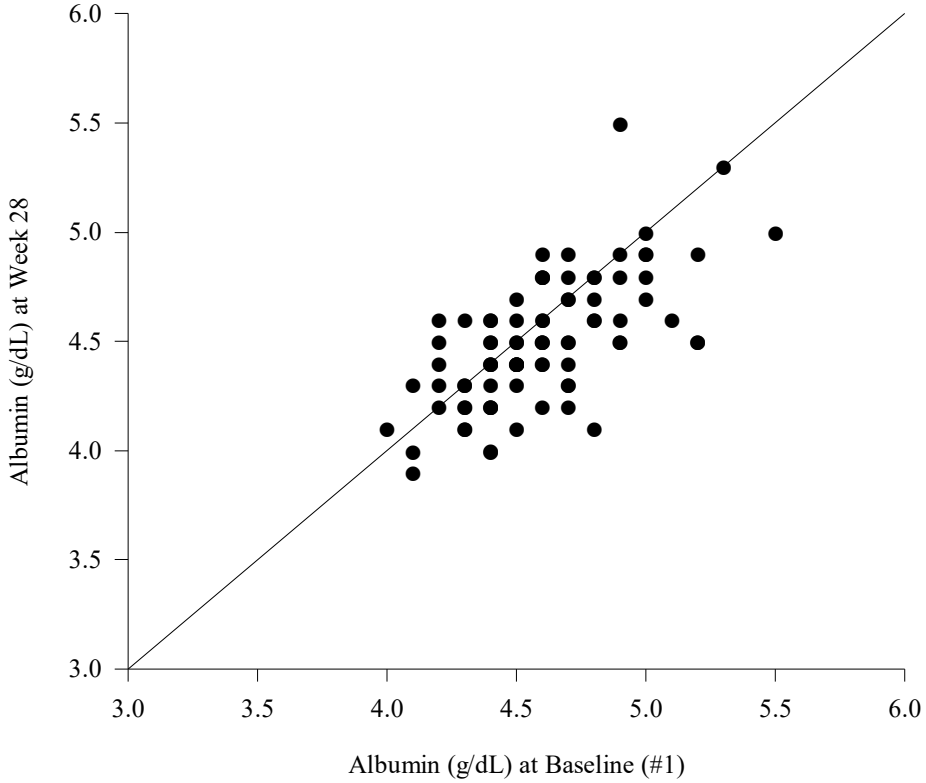


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 45 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (5%/5%)

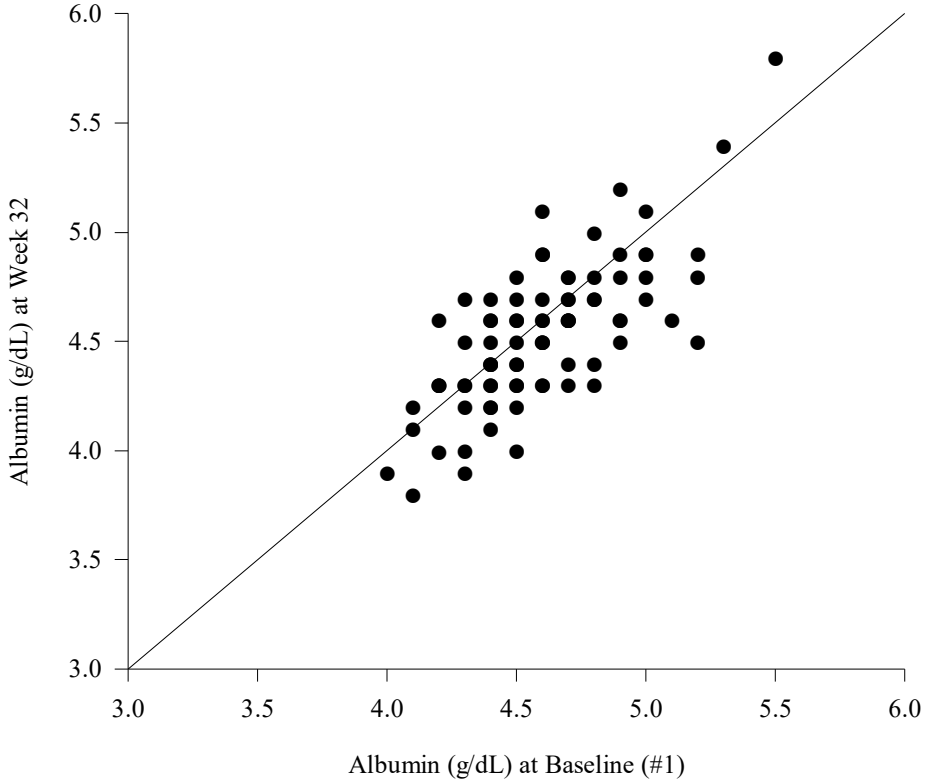


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 46 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (5%/5%)

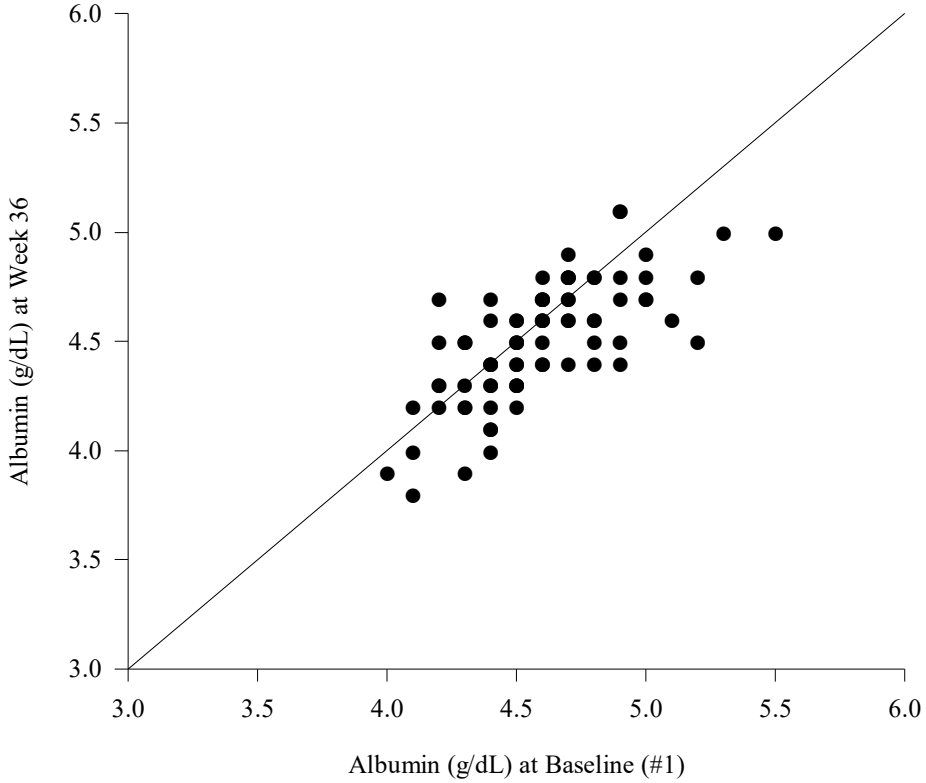


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 47 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (5%/5%)

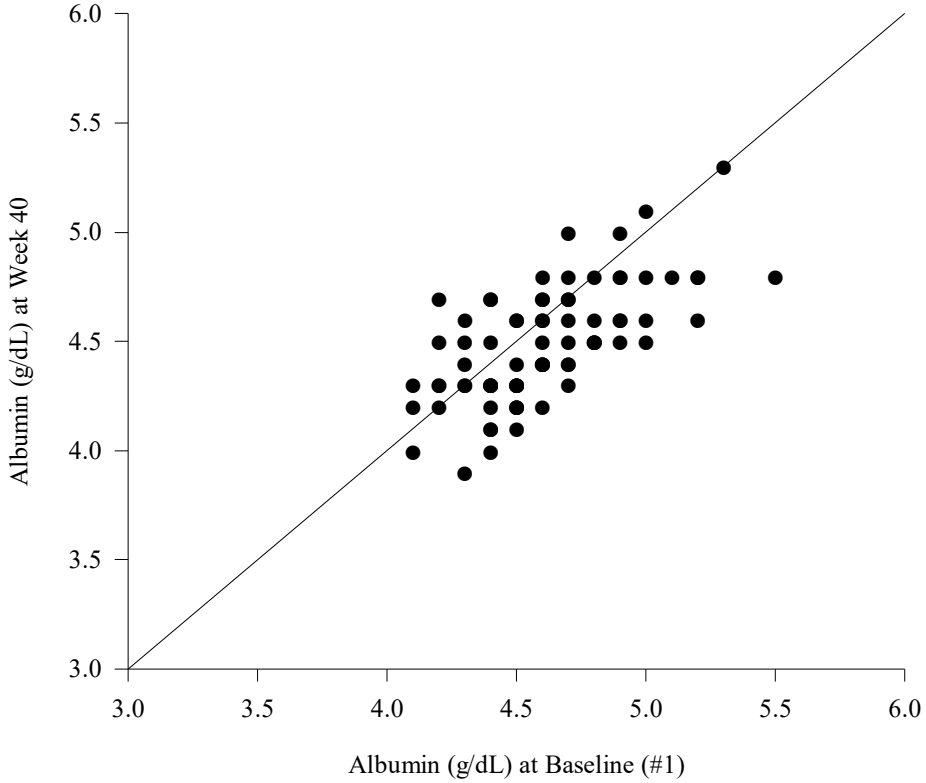


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 48 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (5%/5%)

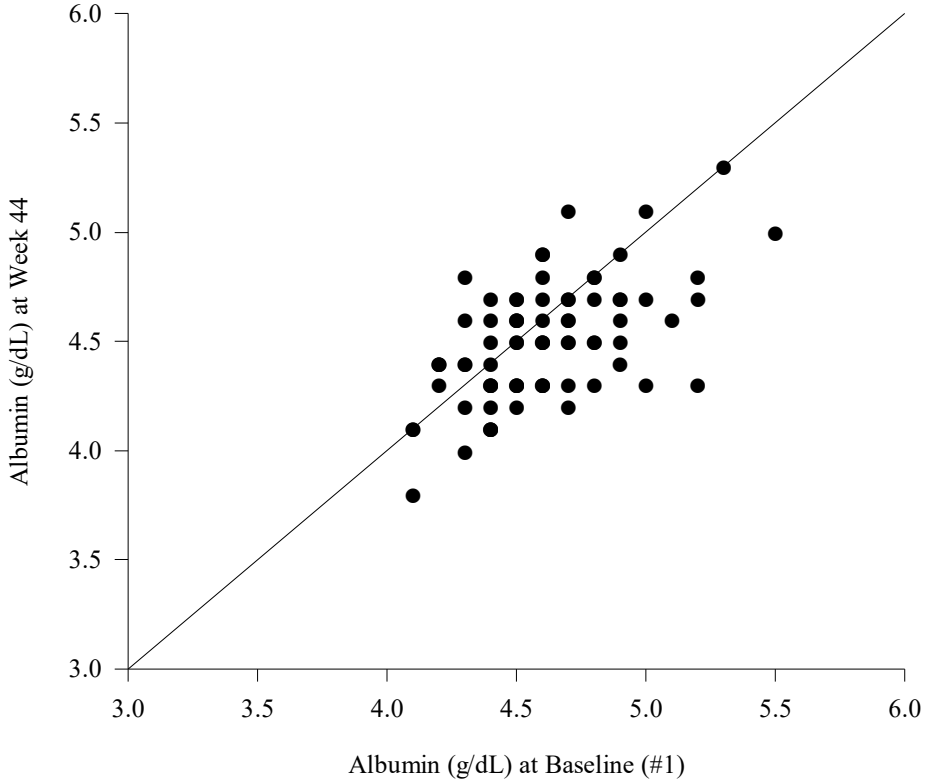


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 49 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (5%/5%)

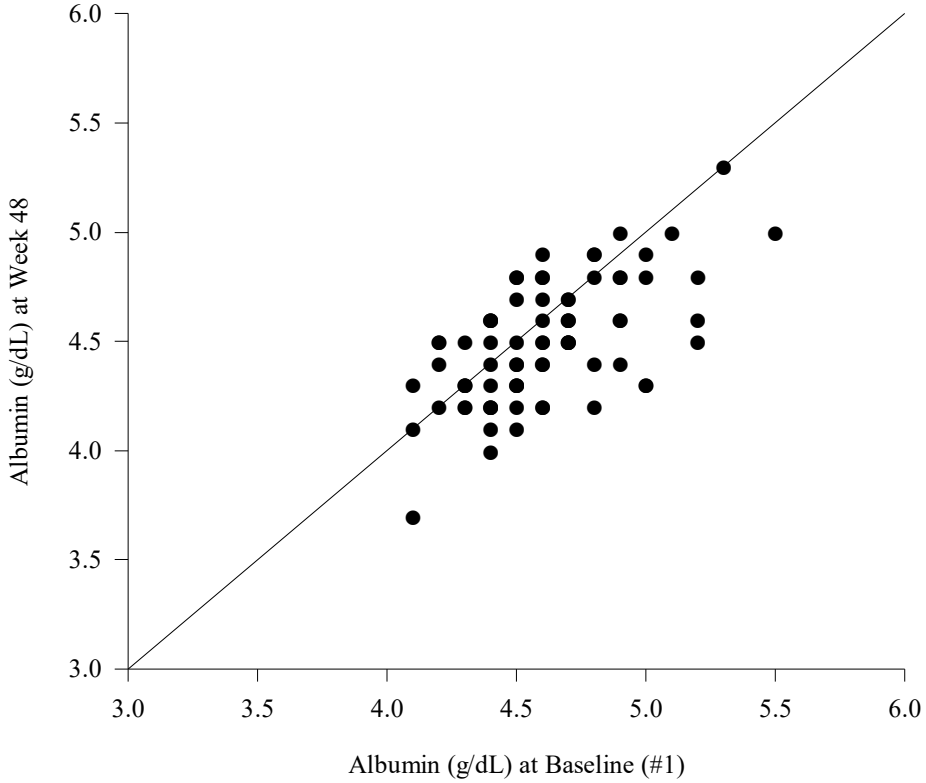


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 50 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (5%/5%)

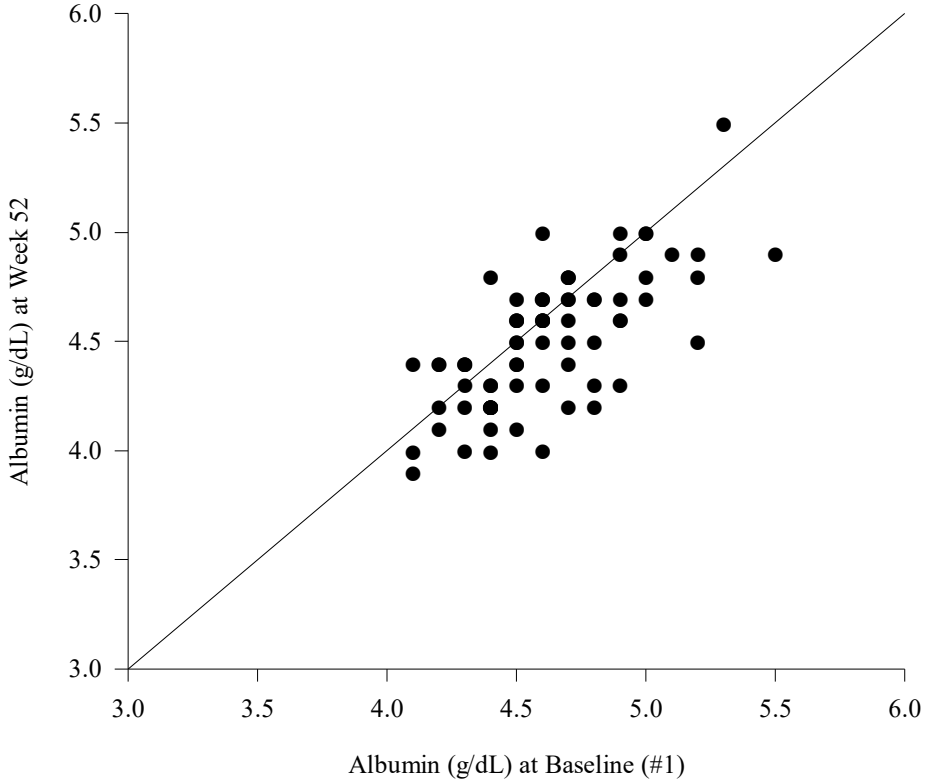


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 51 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (5%/5%)

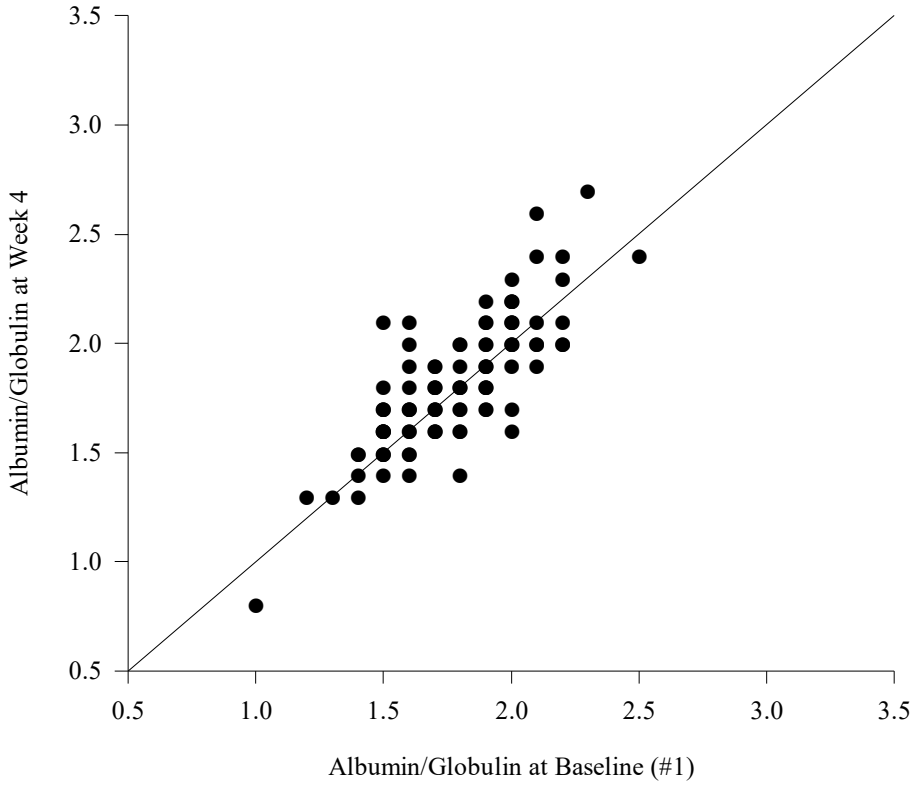


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 52 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (0%/5%)

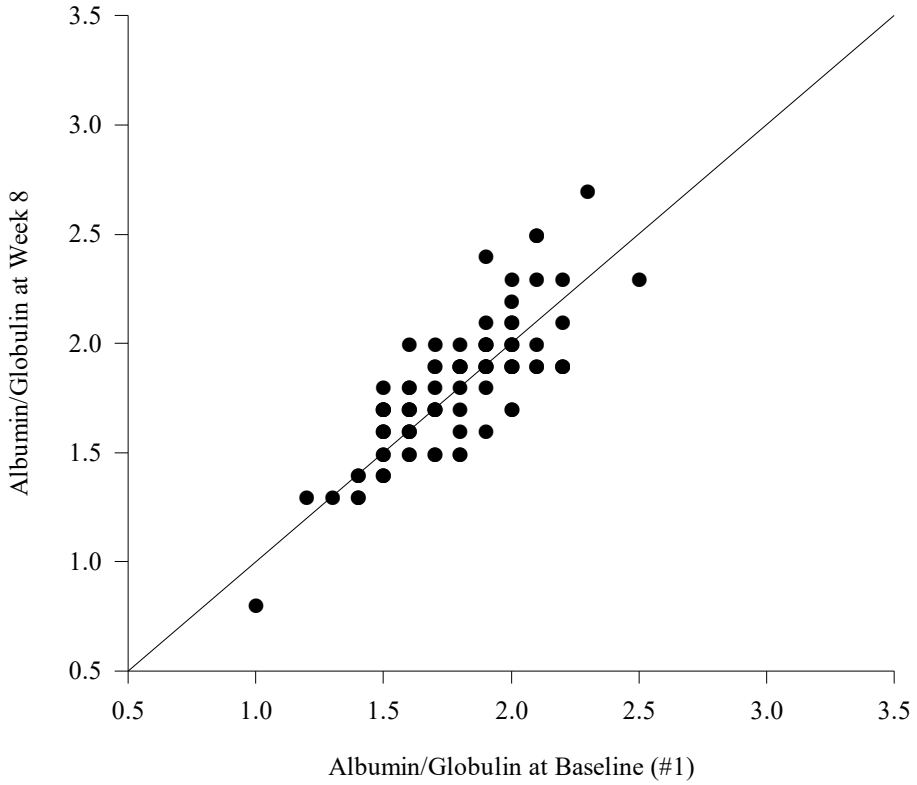


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 53 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (0%/5%)

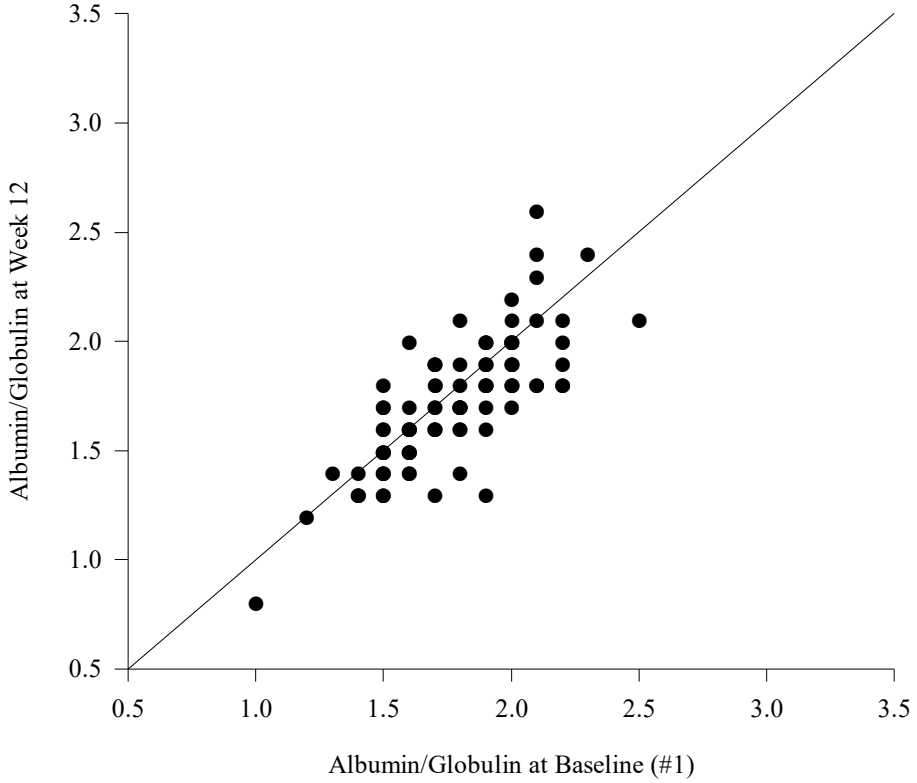


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 54 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (0%/5%)

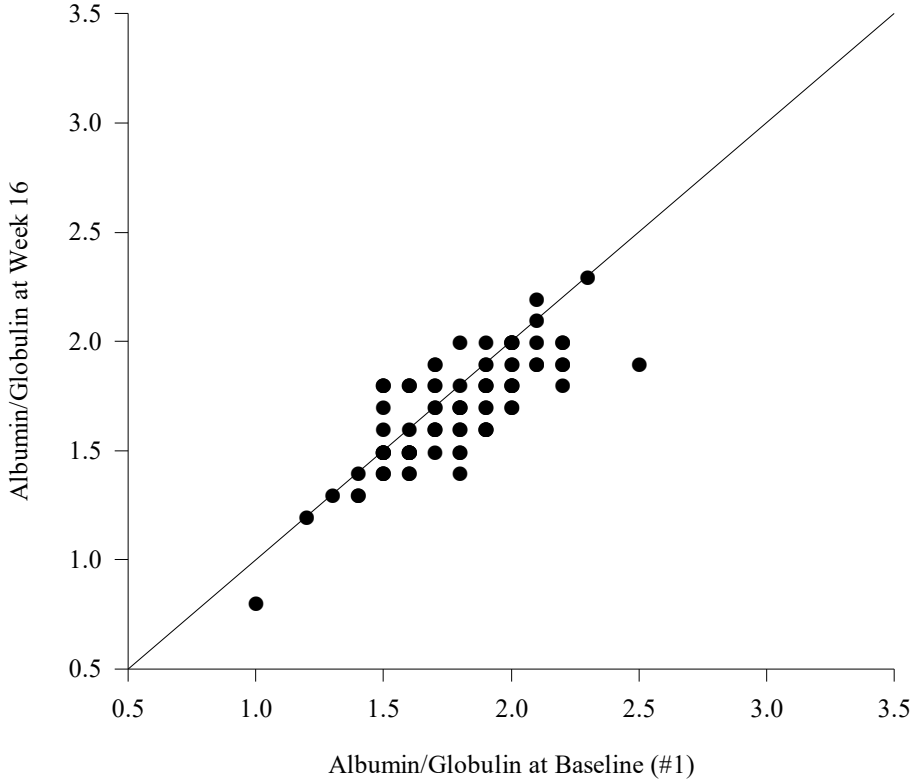


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 55 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (0%/5%)

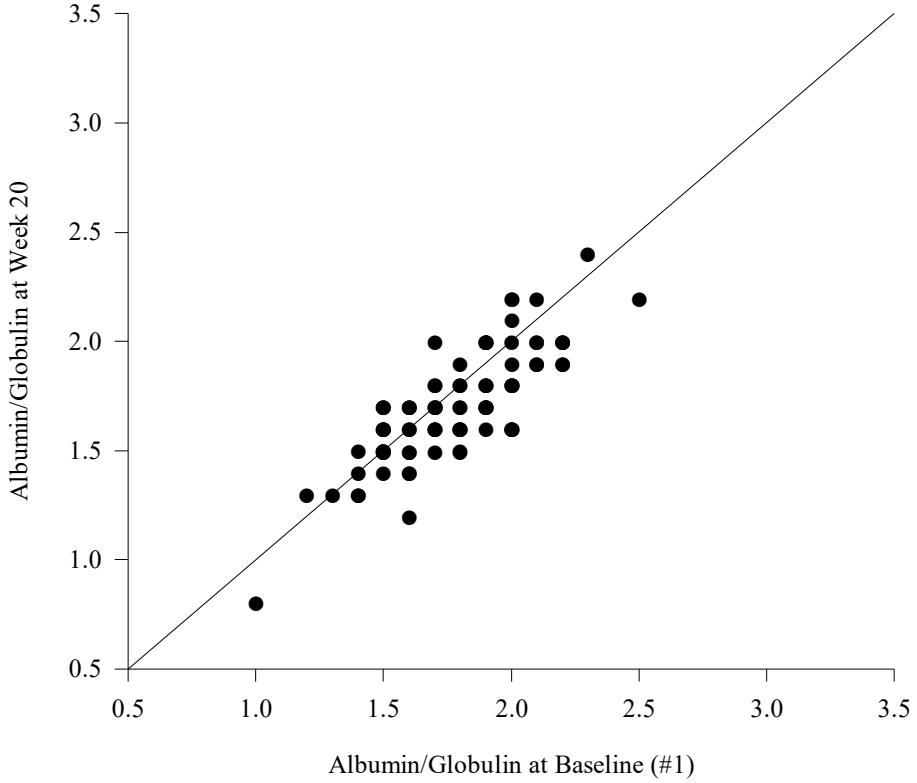


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 56 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (0%/5%)

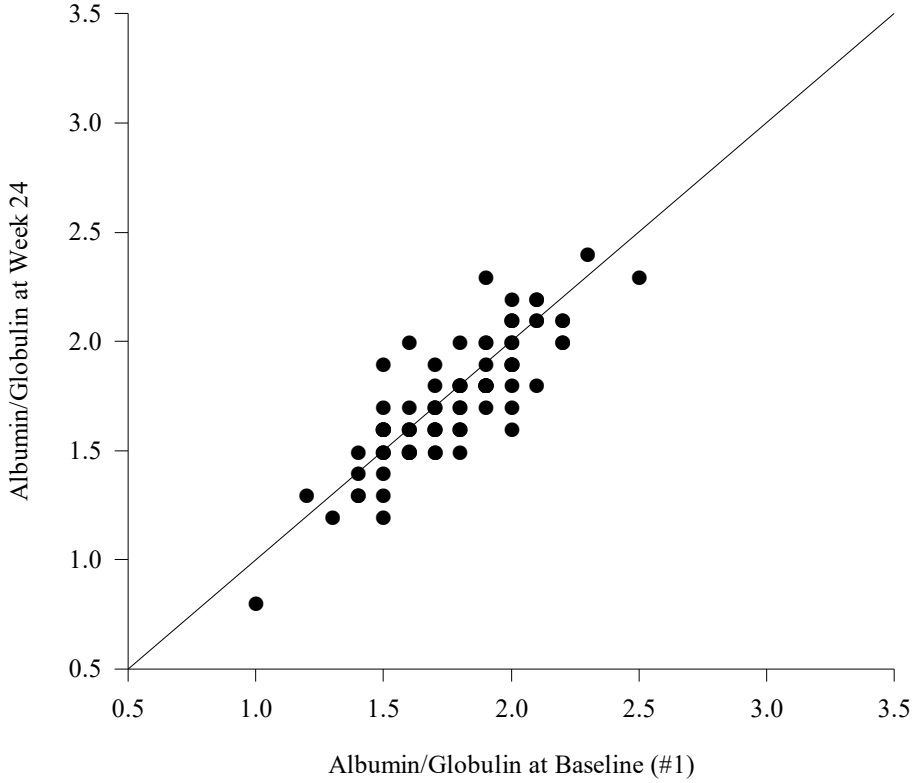


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 57 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (0%/5%)

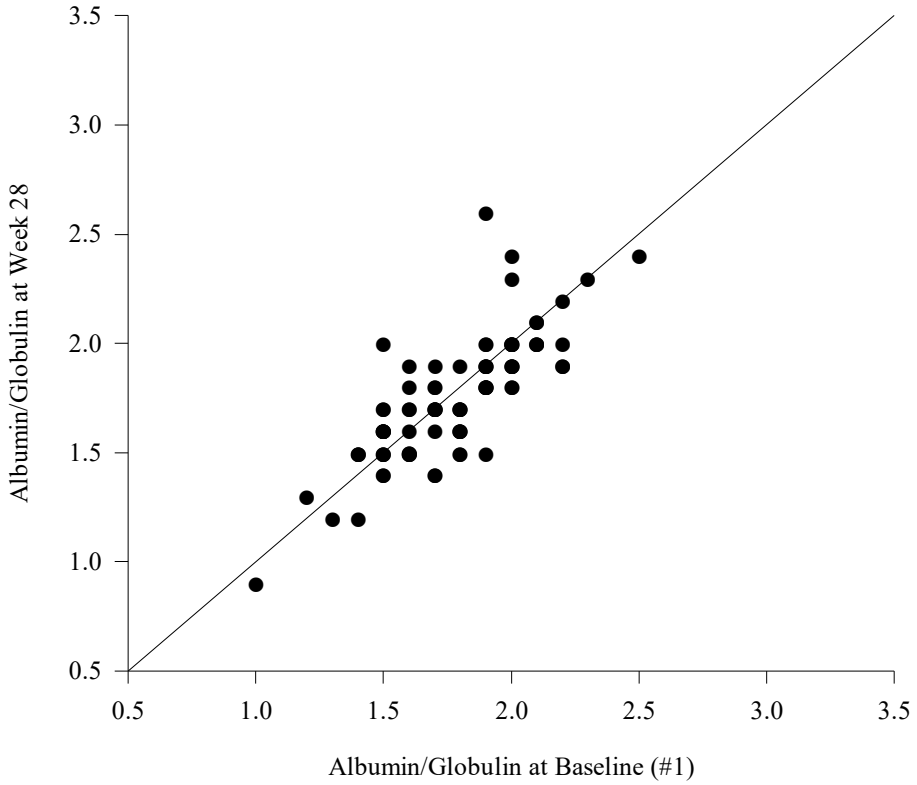


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 58 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (0%/5%)

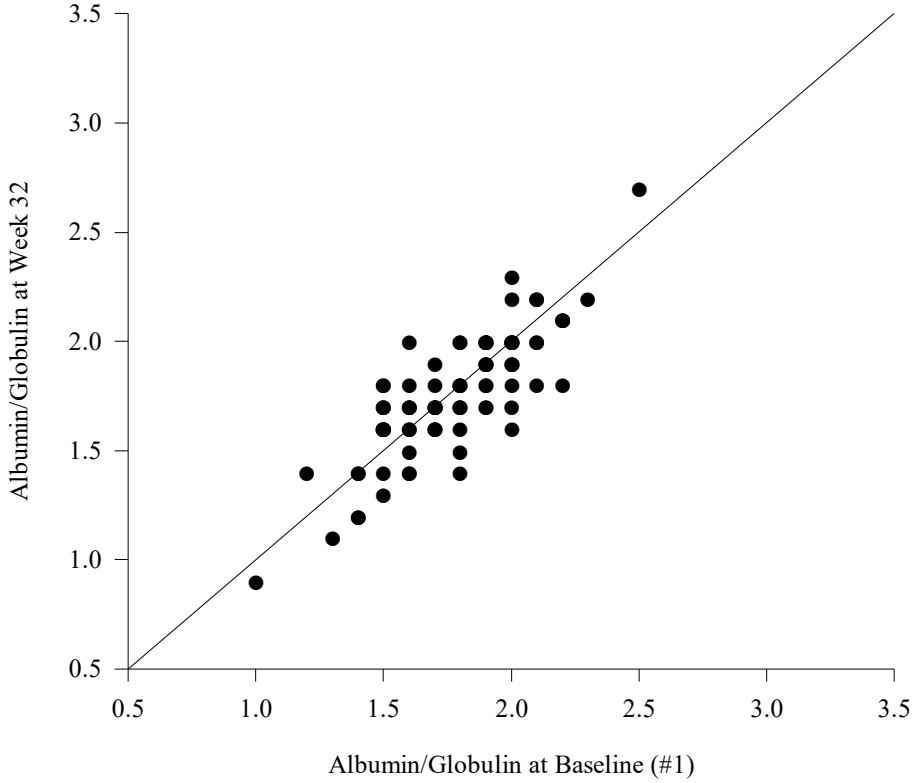


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 59 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (0%/5%)

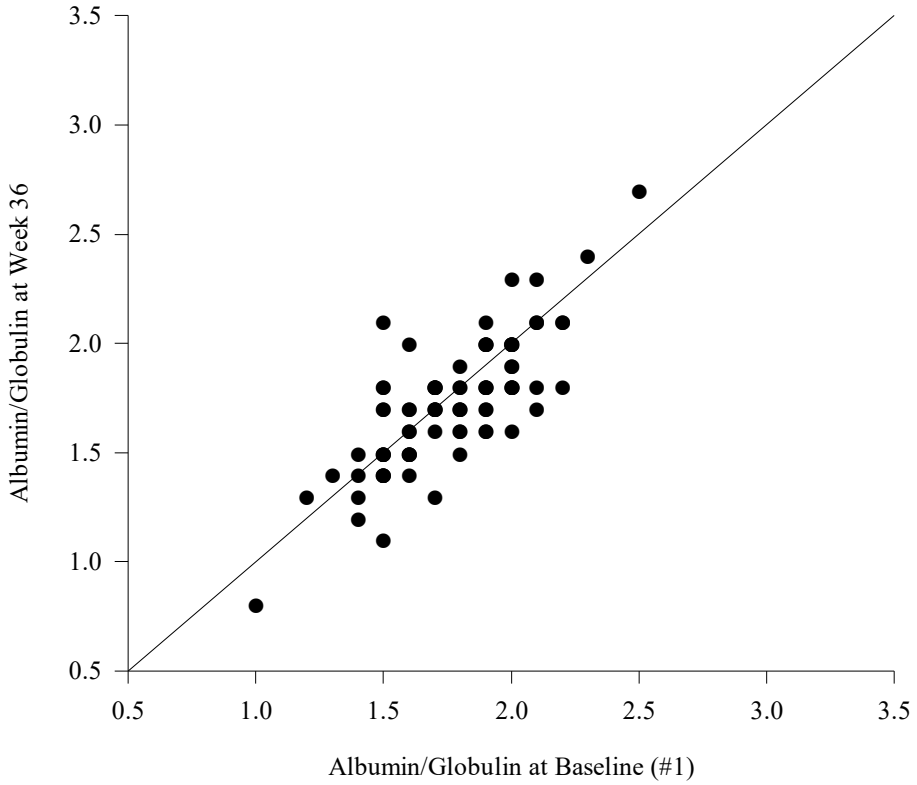


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 60 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (0%/5%)

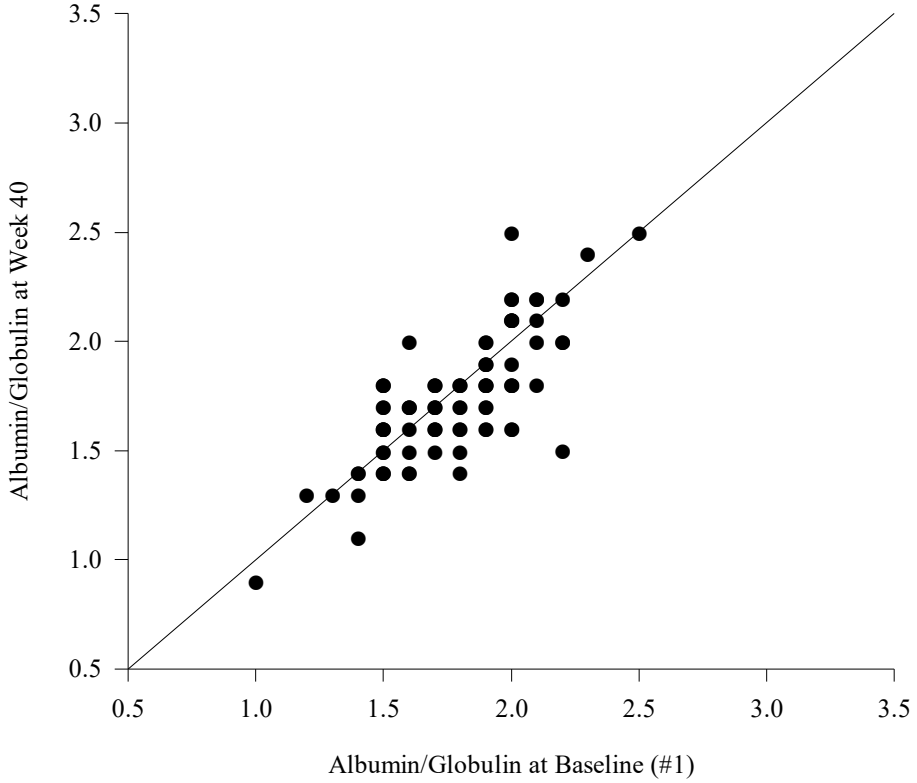


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 61 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (0%/5%)

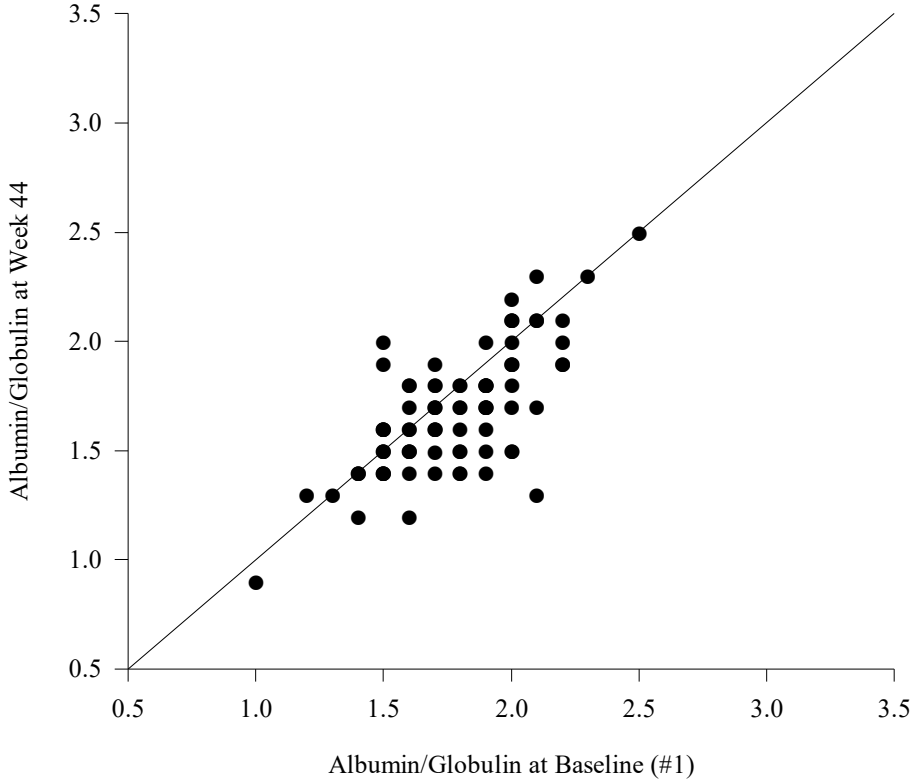


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 62 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (0%/5%)

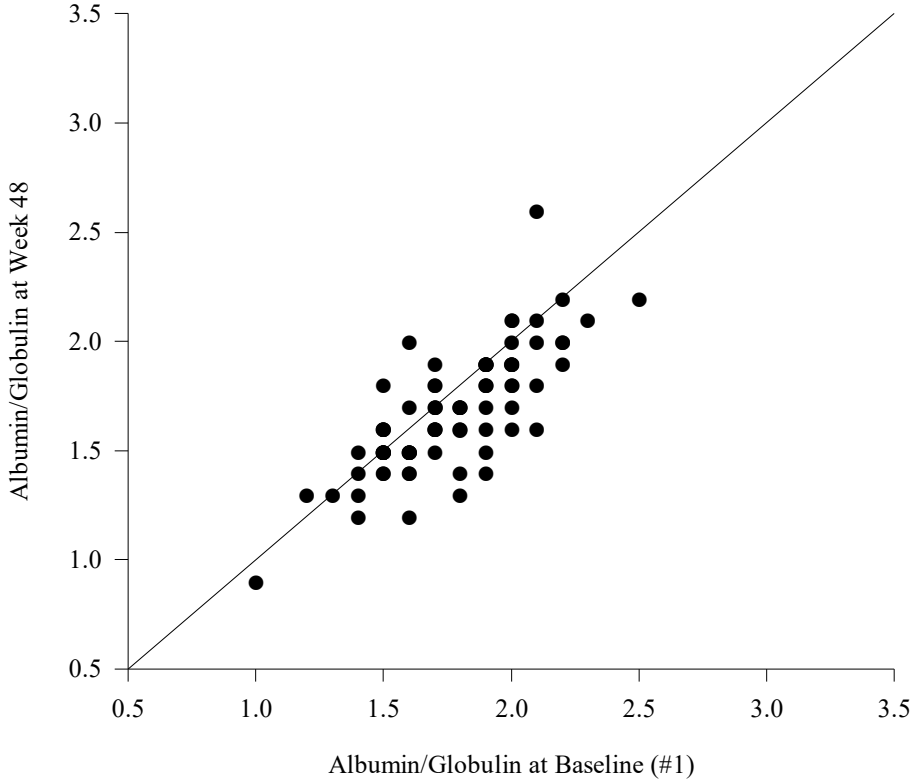


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 63 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (0%/5%)

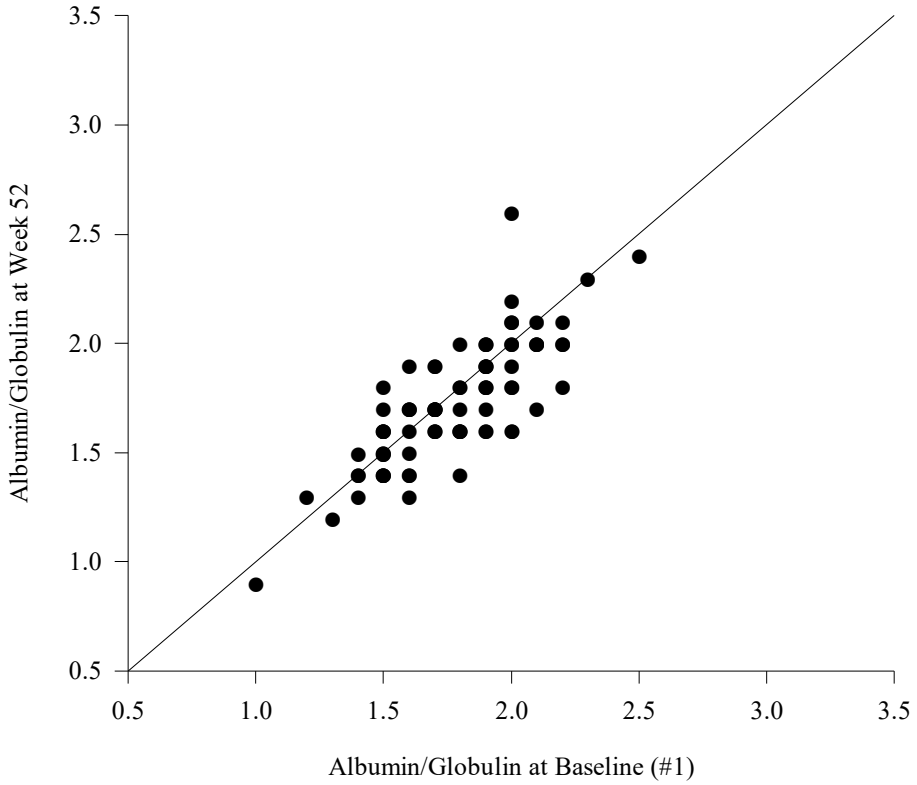


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 64 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (0%/5%)

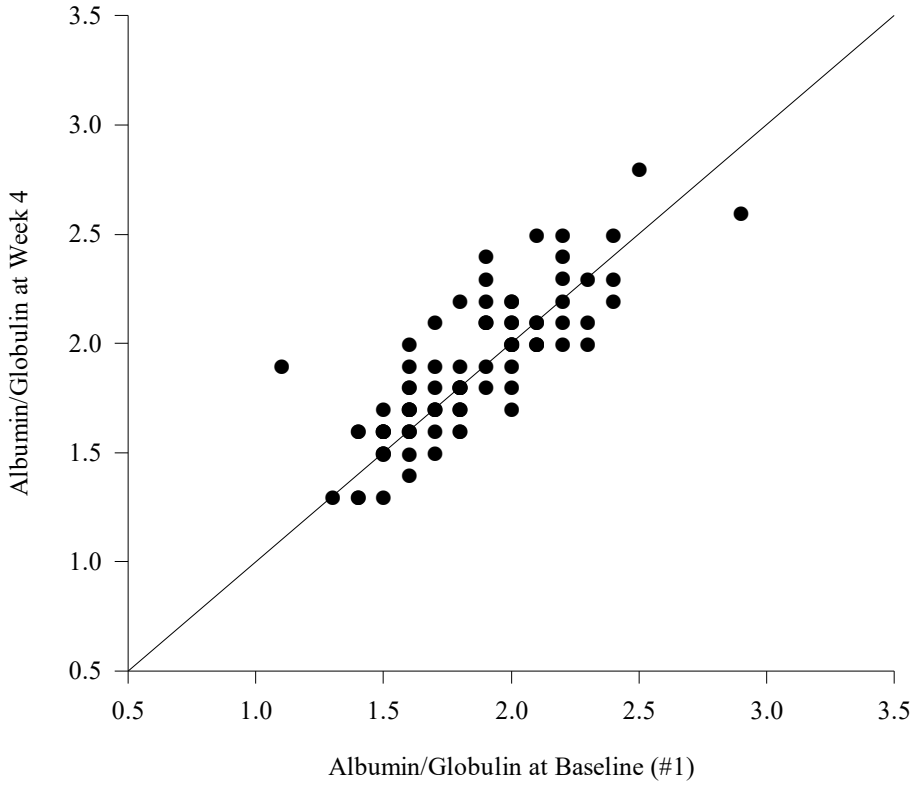


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 65 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (5%/5%)

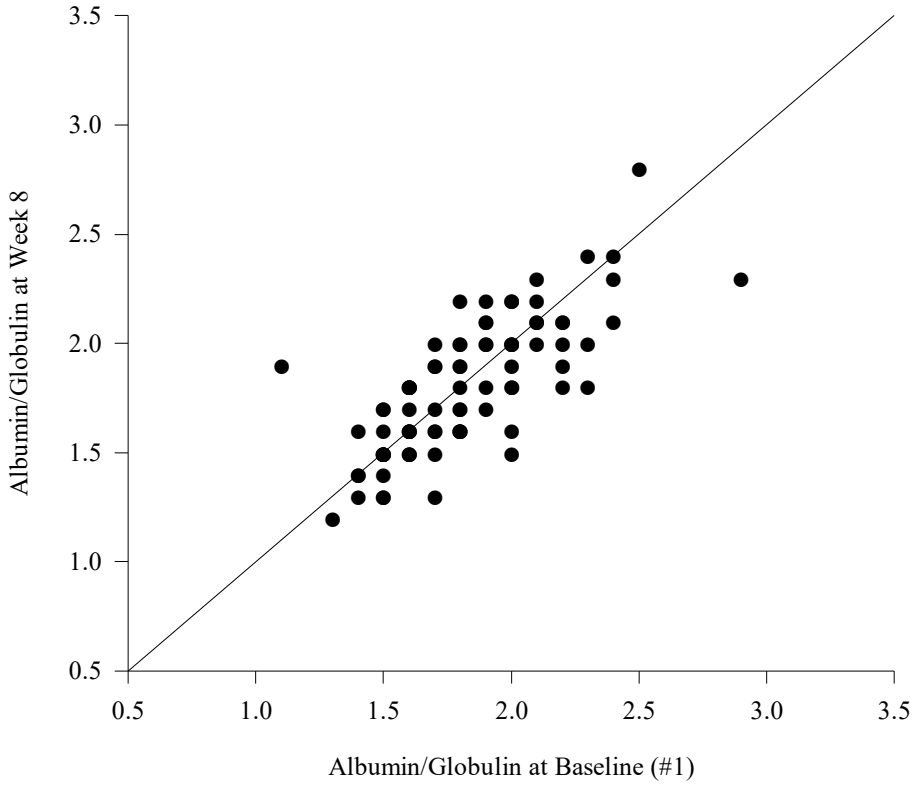


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 66 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (5%/5%)

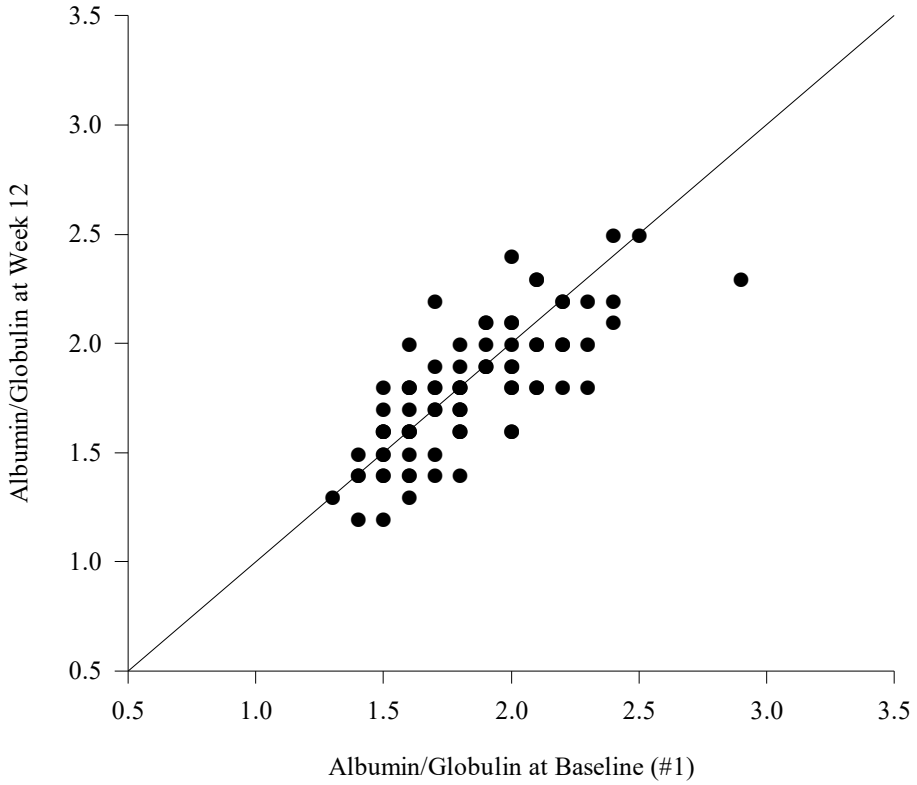


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 67 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (5%/5%)

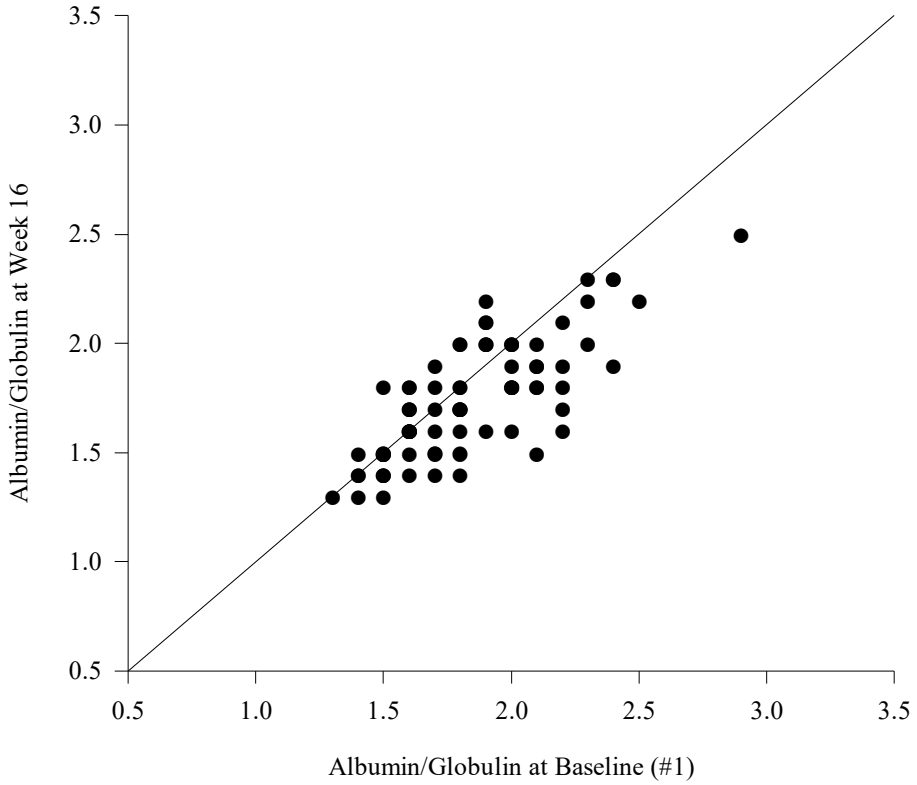


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 68 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (5%/5%)

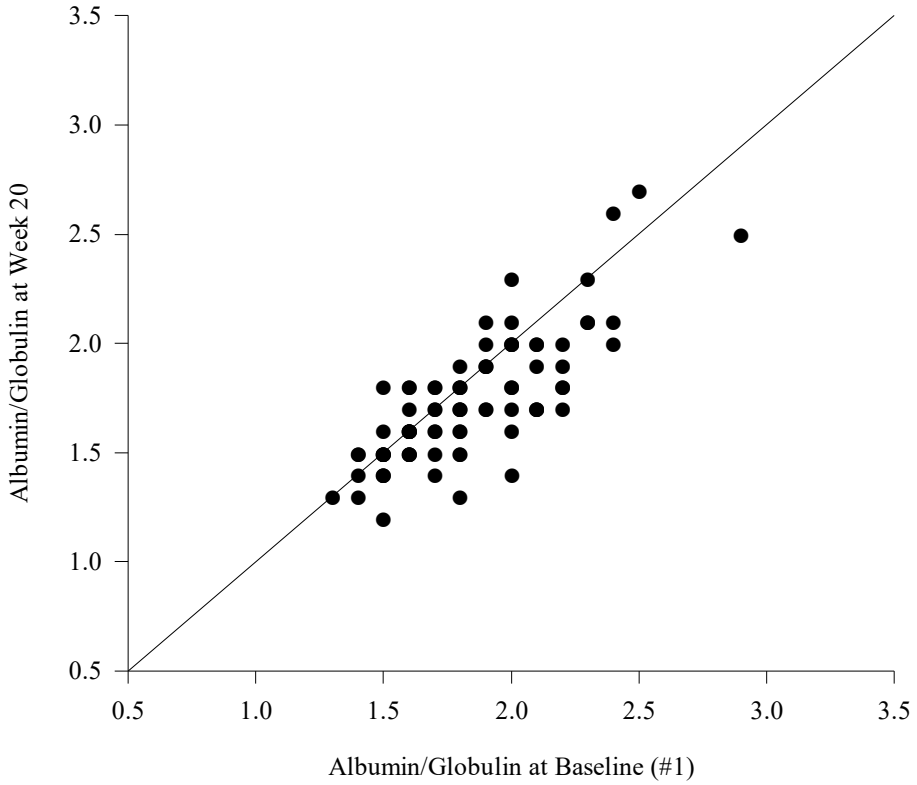


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 69 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (5%/5%)

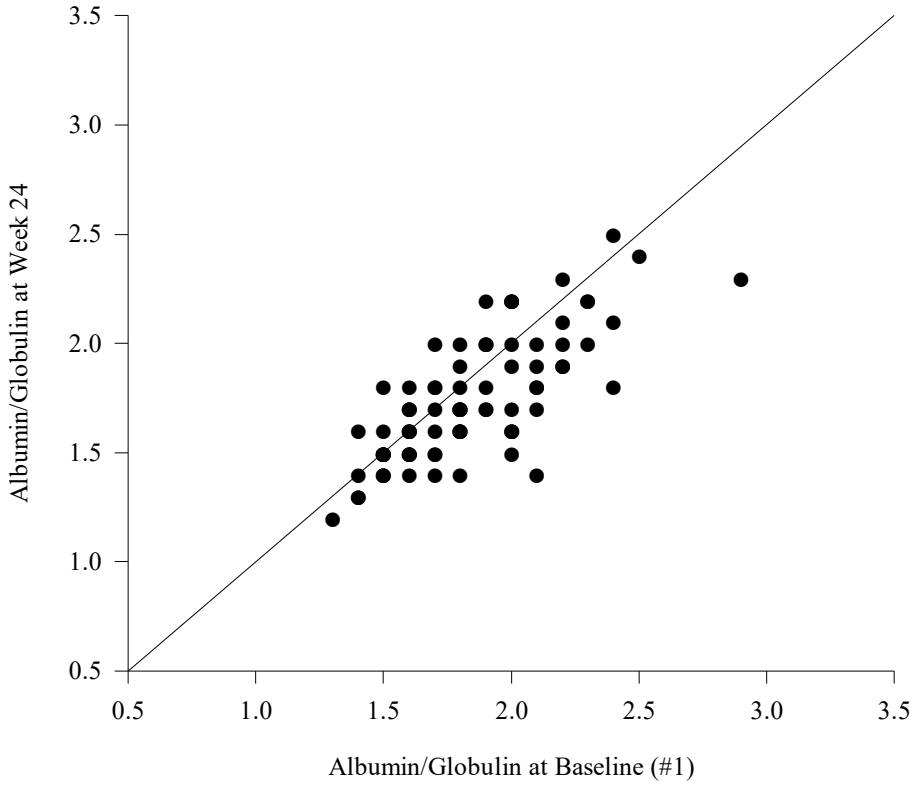


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 70 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (5%/5%)

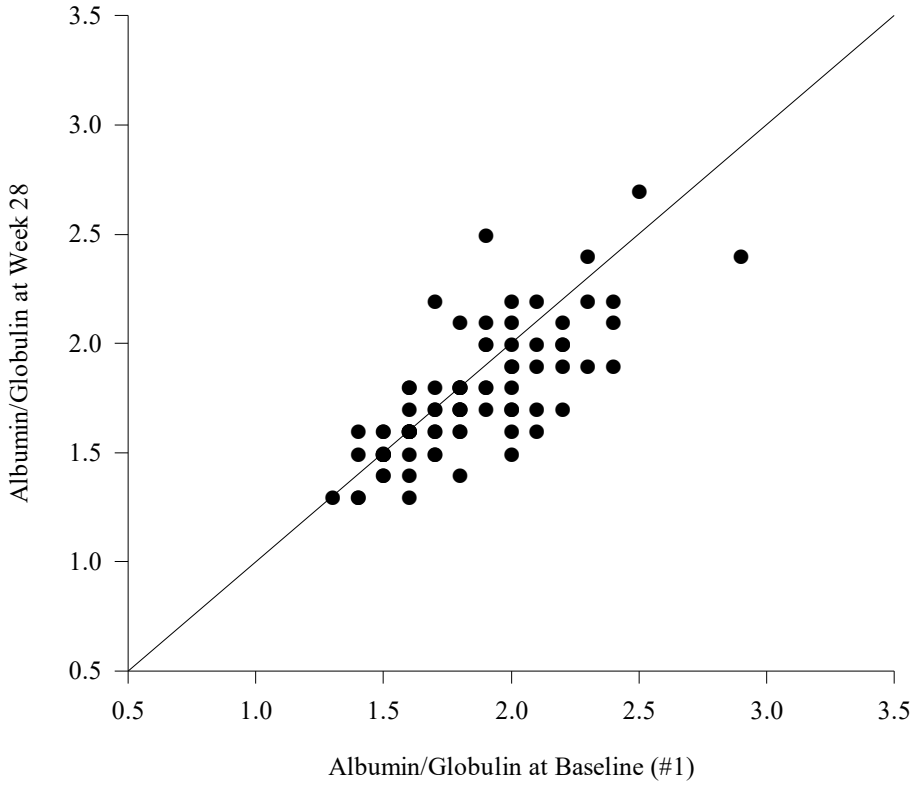


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 71 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (5%/5%)

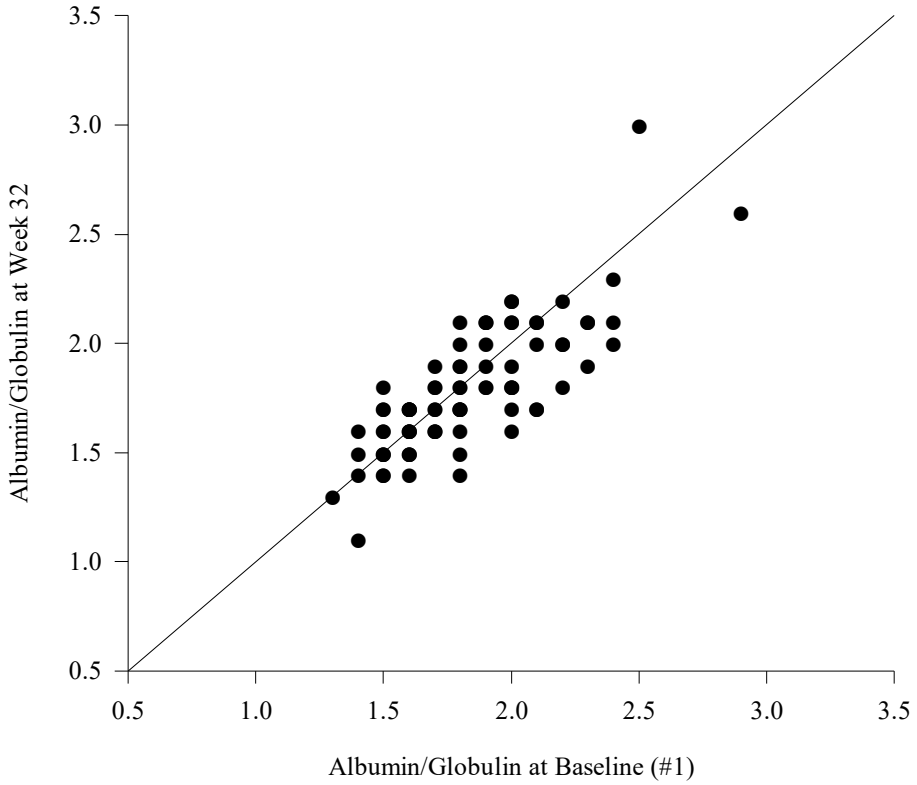


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 72 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (5%/5%)

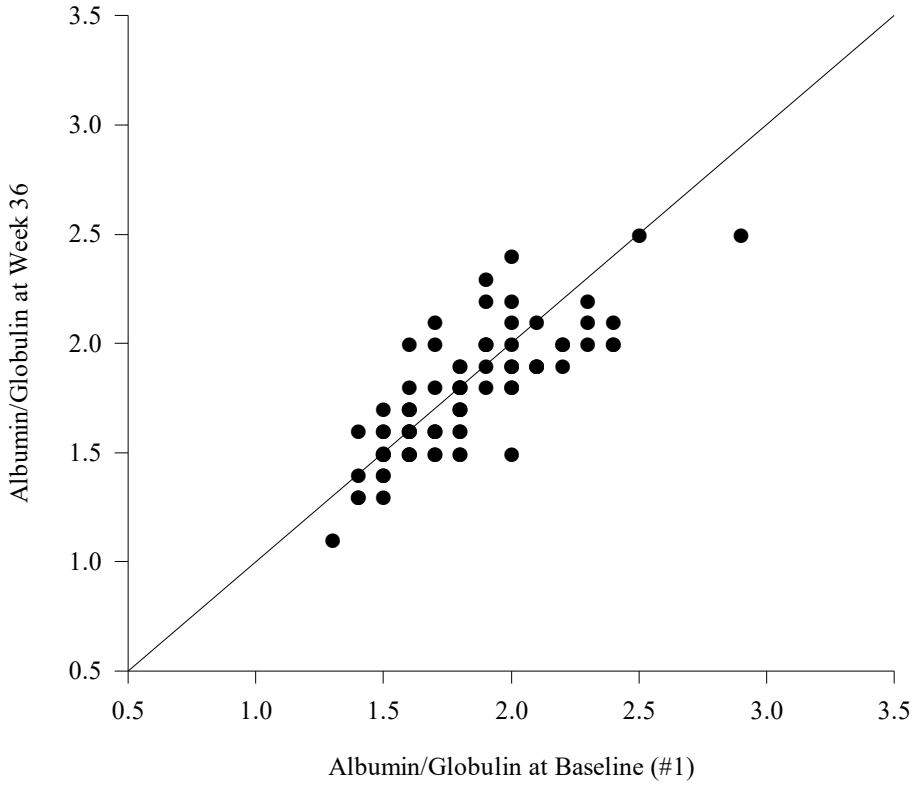


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 73 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (5%/5%)

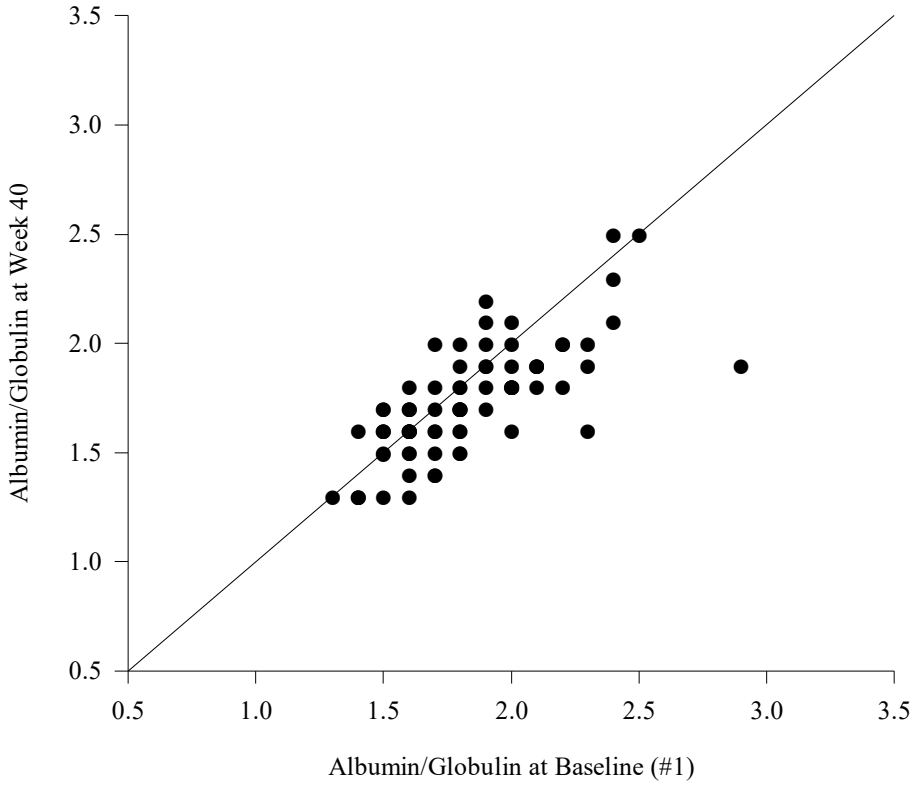


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 74 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (5%/5%)

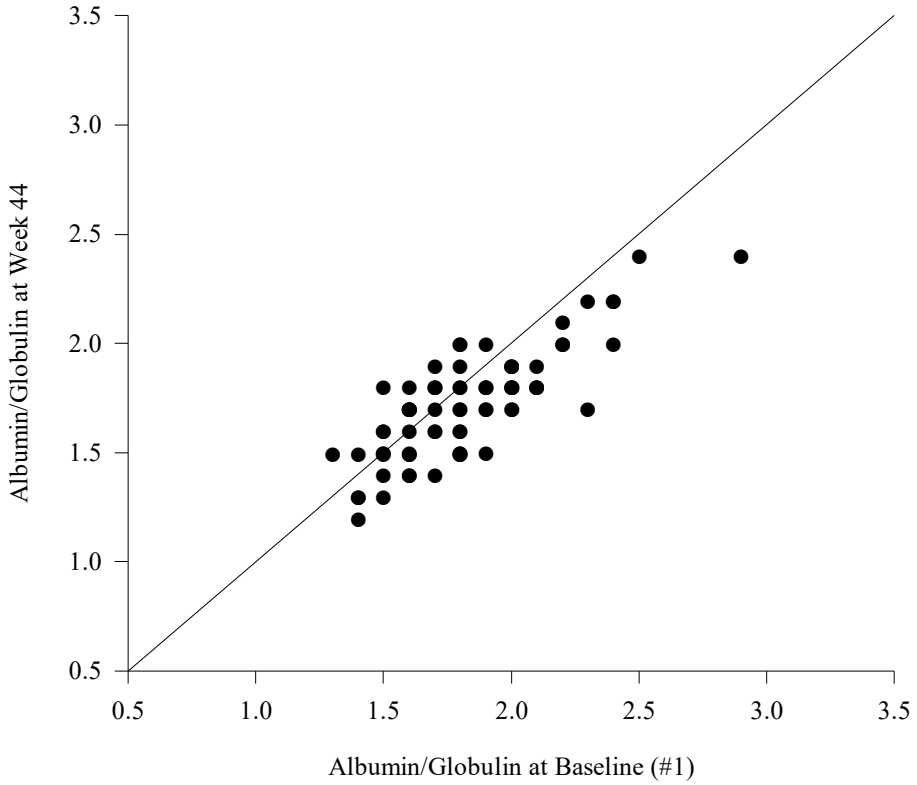


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 75 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (5%/5%)

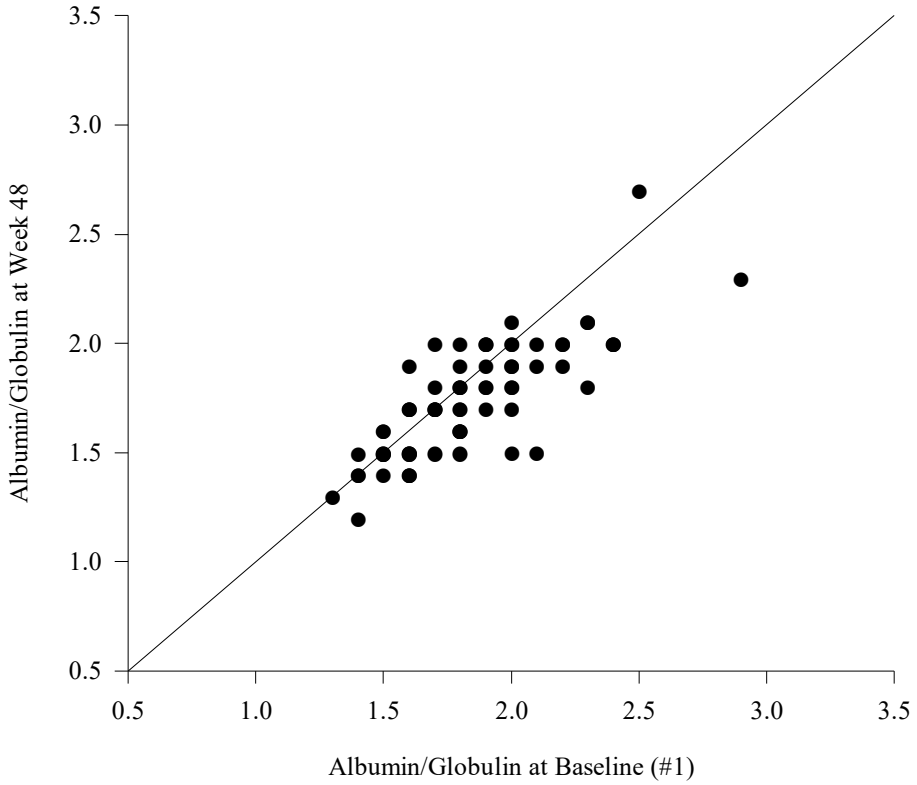


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 76 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (5%/5%)

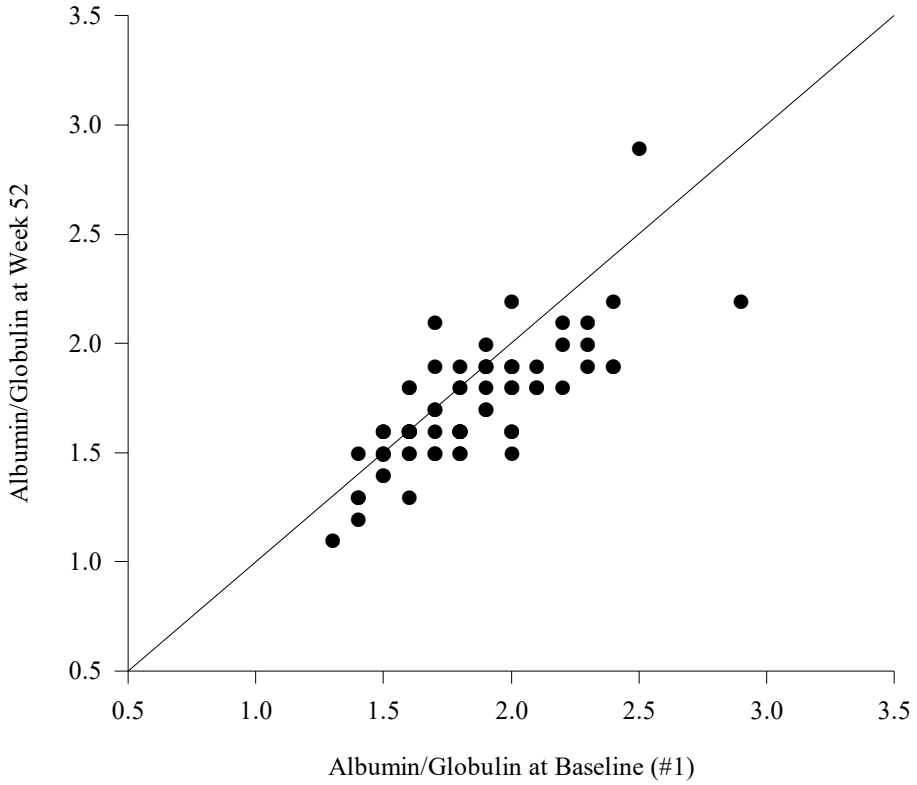


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 77 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (5%/5%)

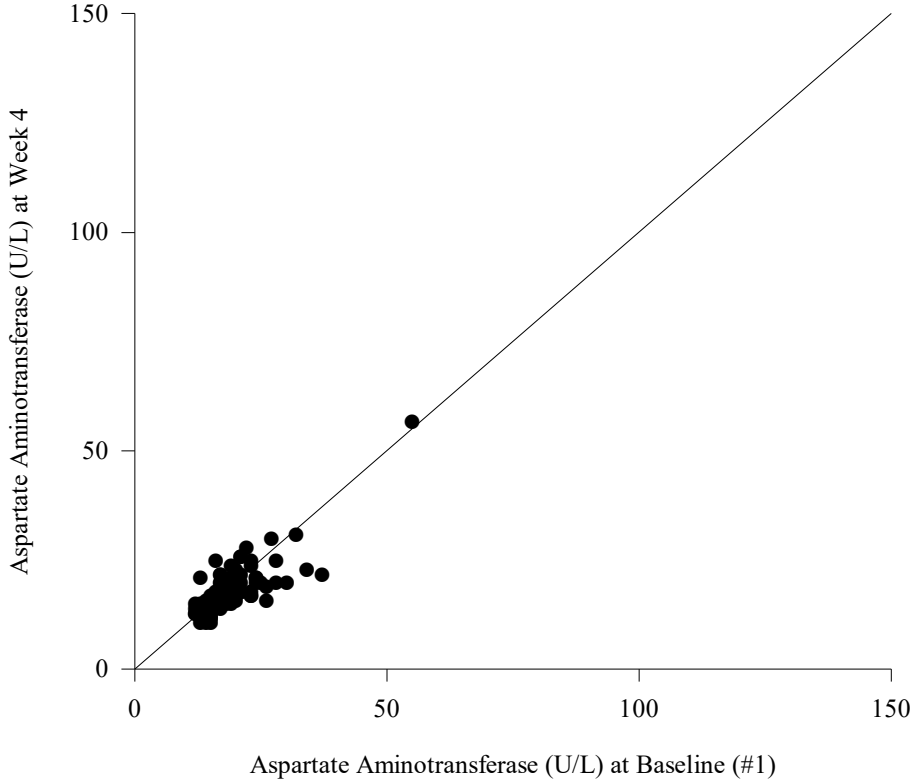


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 78 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (0%/5%)

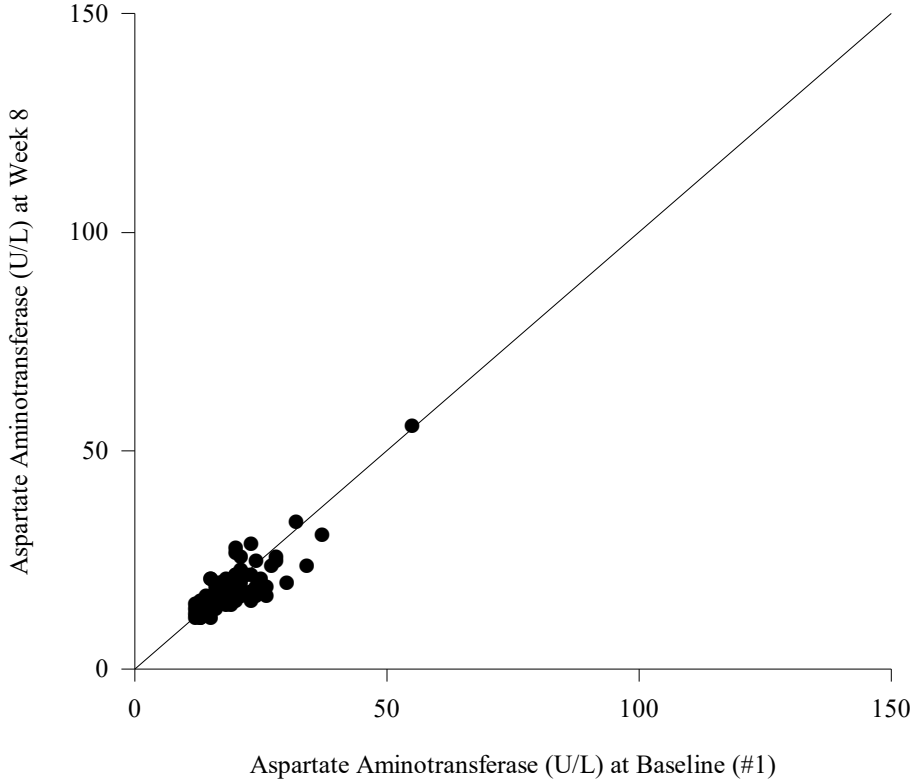


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 79 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (0%/5%)

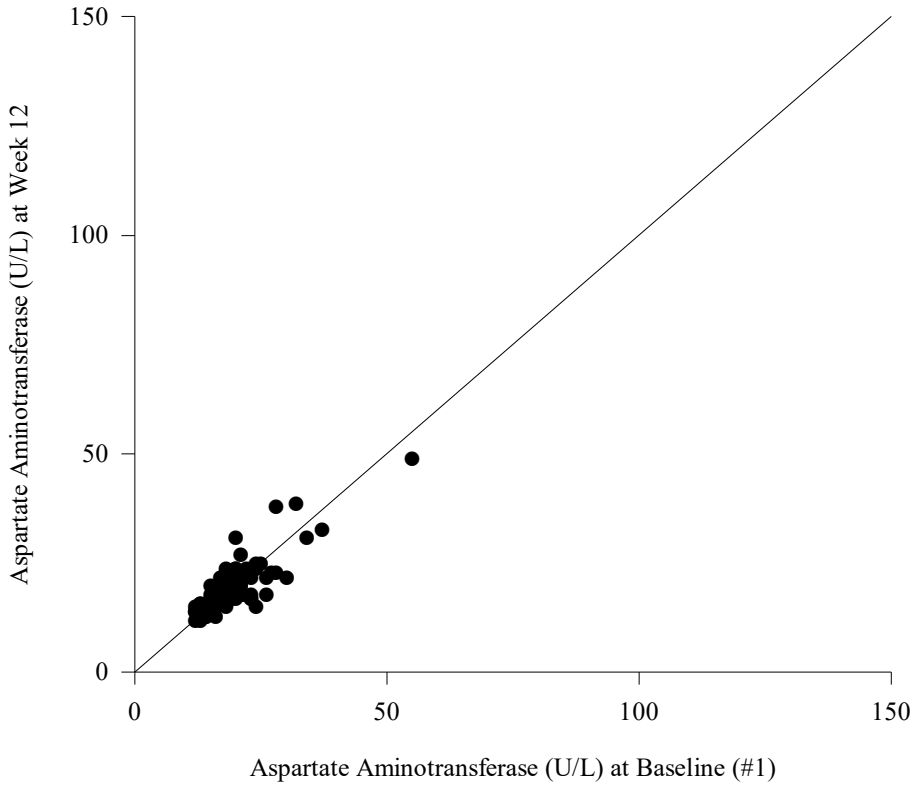


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 80 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (0%/5%)

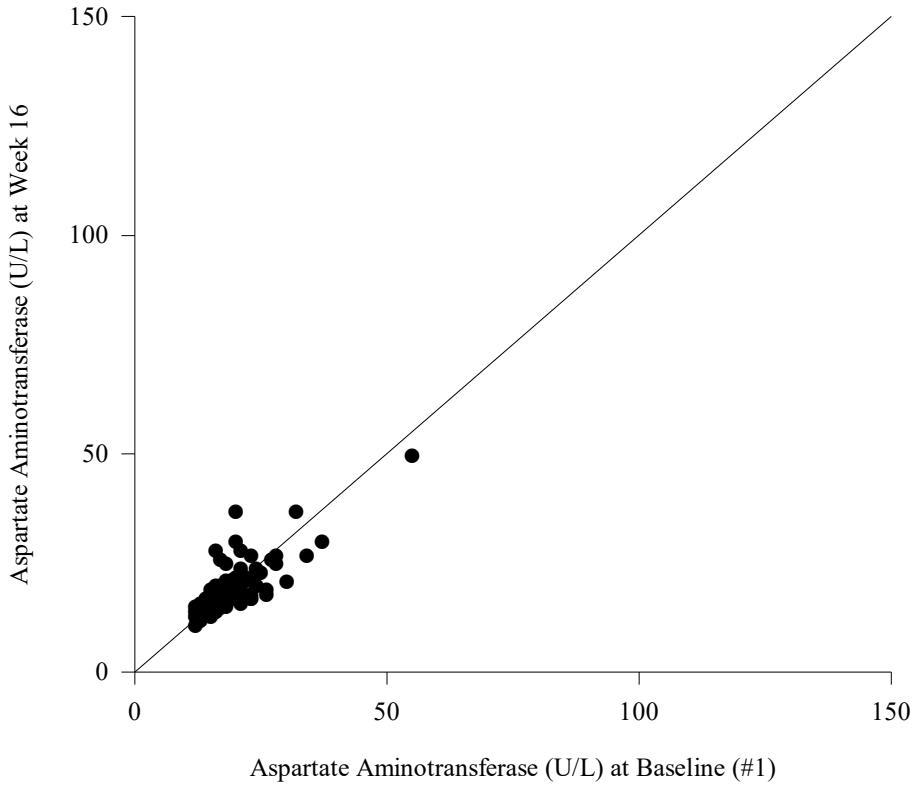


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 81 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (0%/5%)

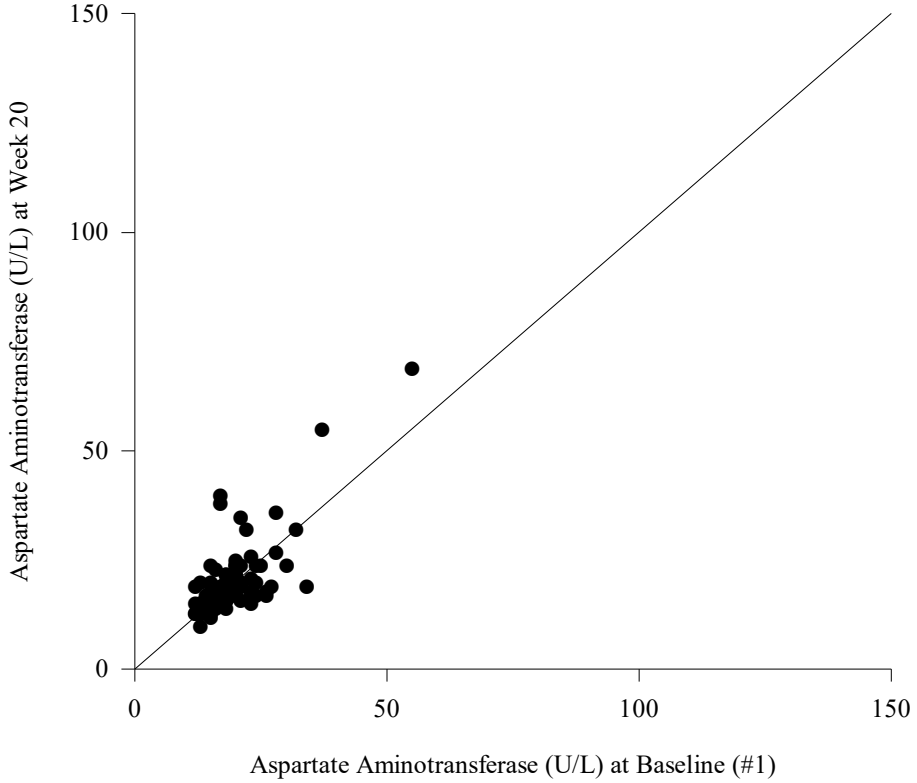


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 82 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (0%/5%)

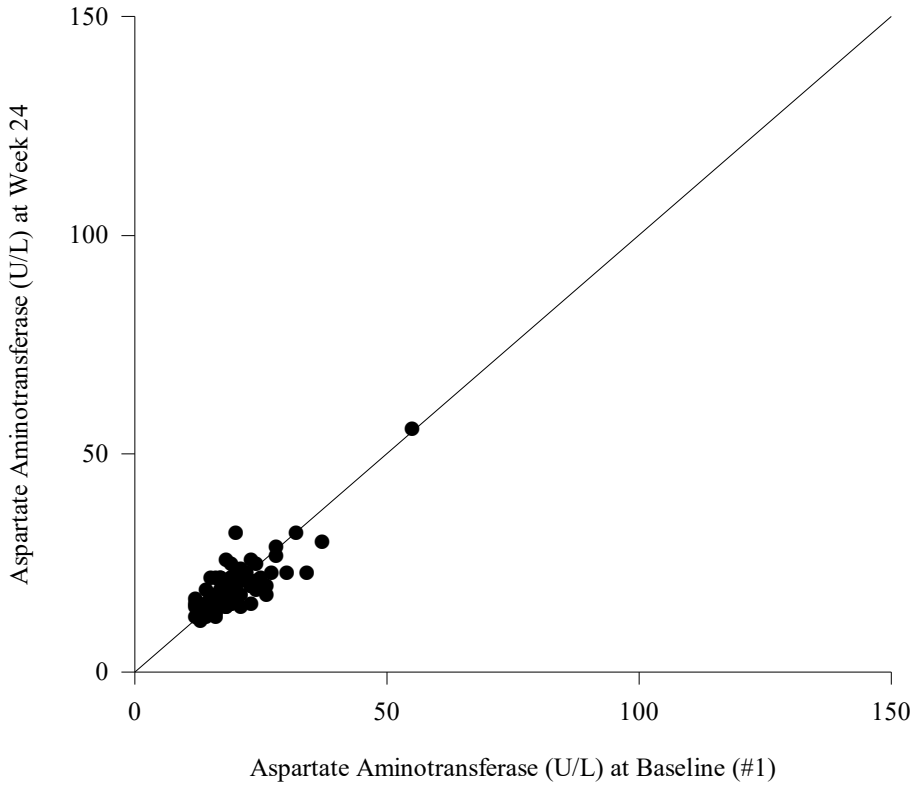


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 83 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (0%/5%)

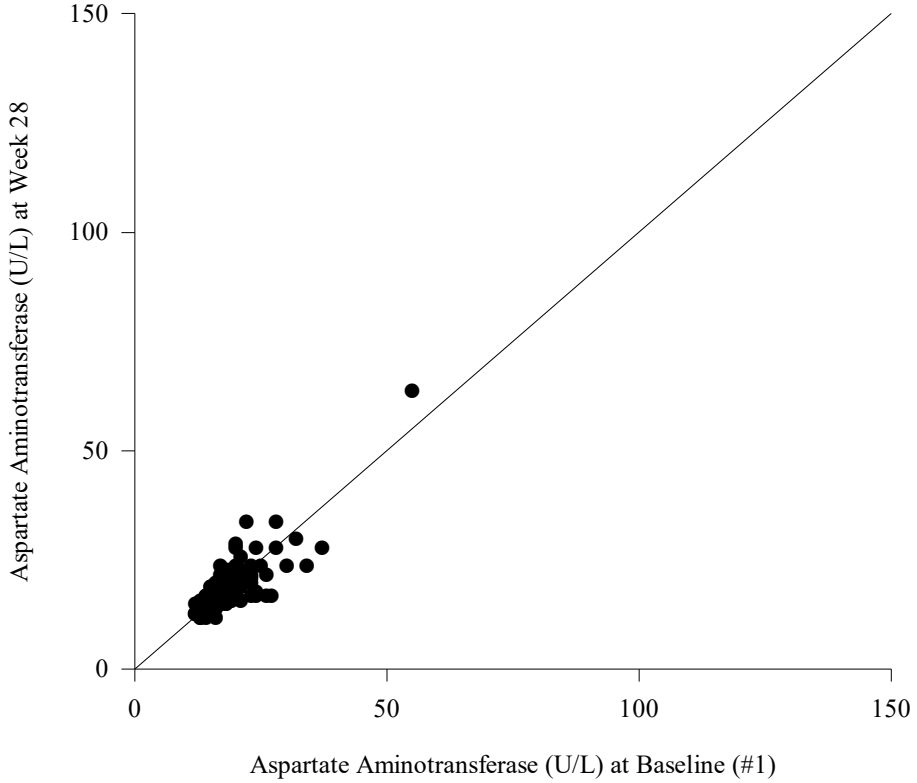


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 84 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (0%/5%)

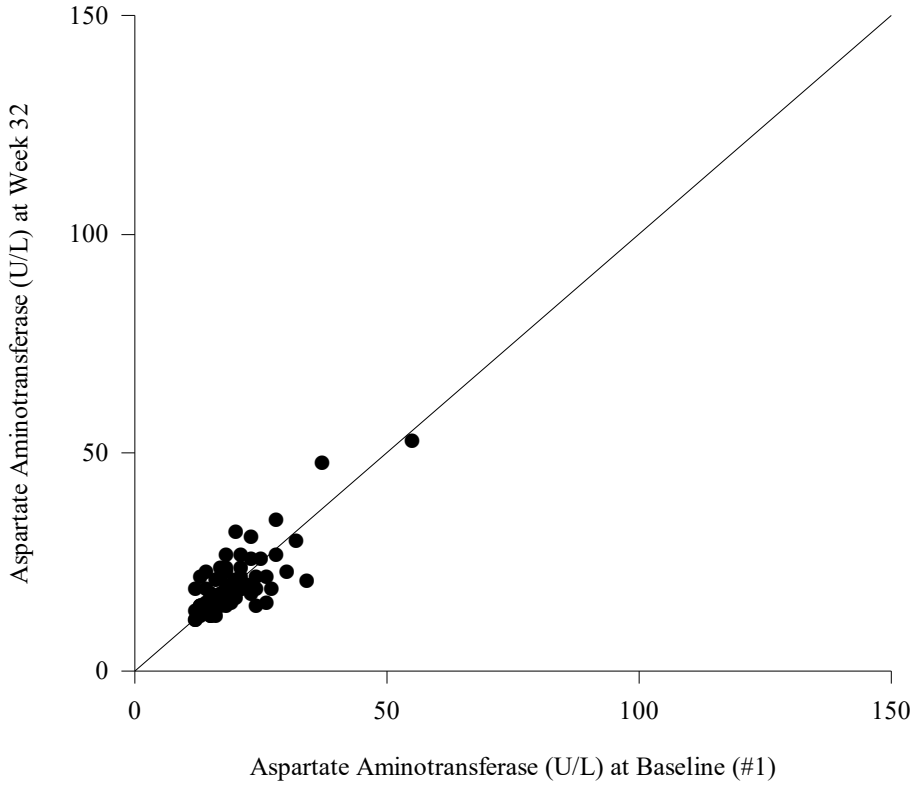


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 85 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (0%/5%)

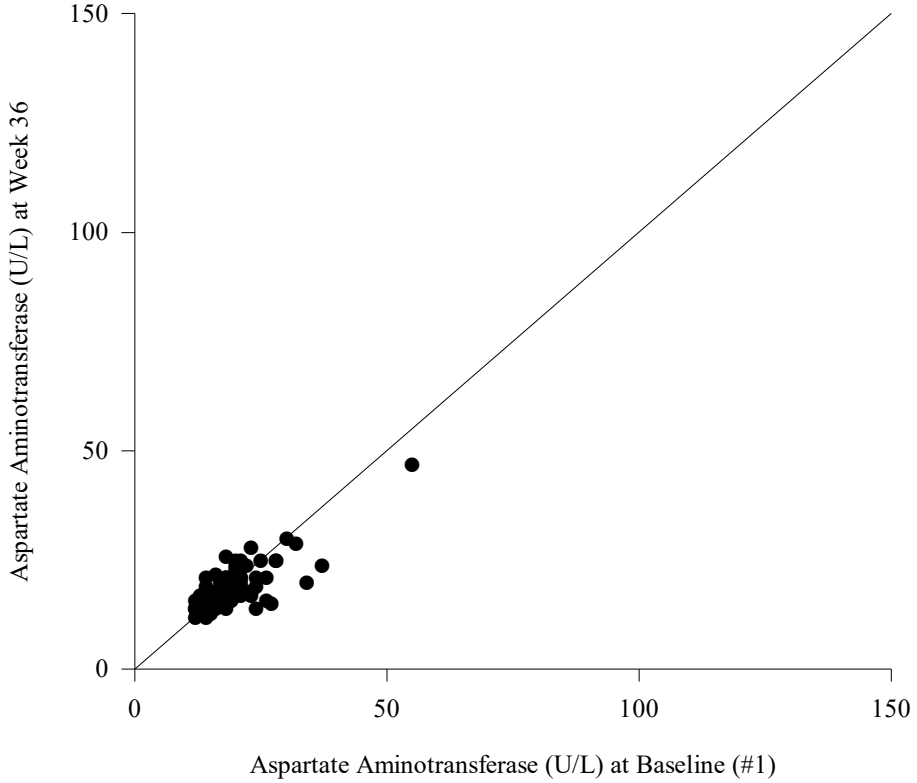


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 86 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (0%/5%)

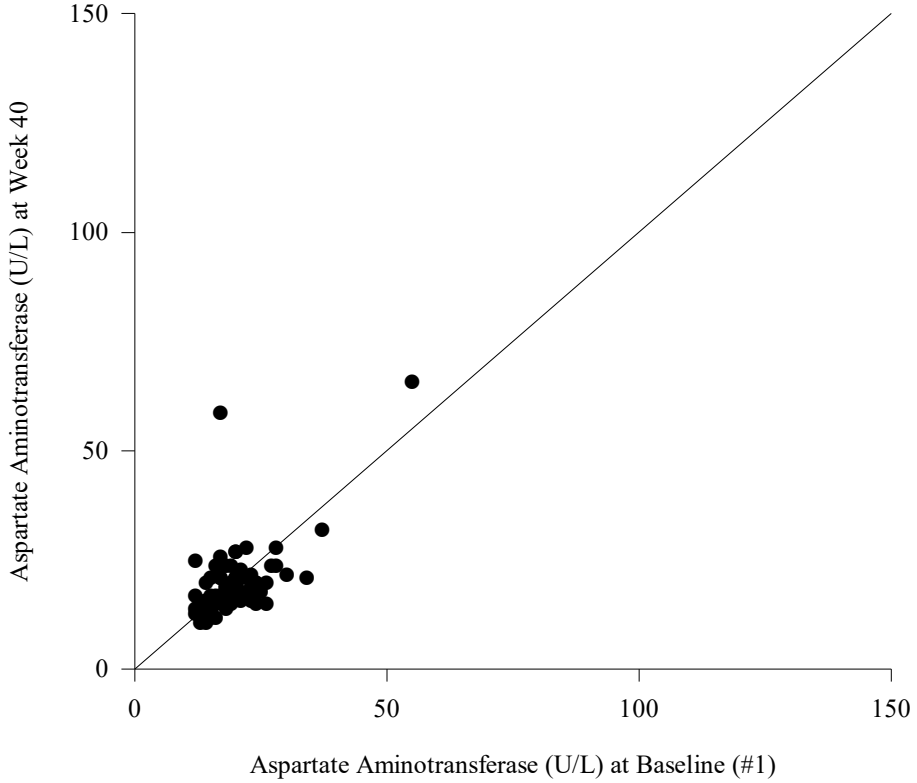


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 87 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (0%/5%)

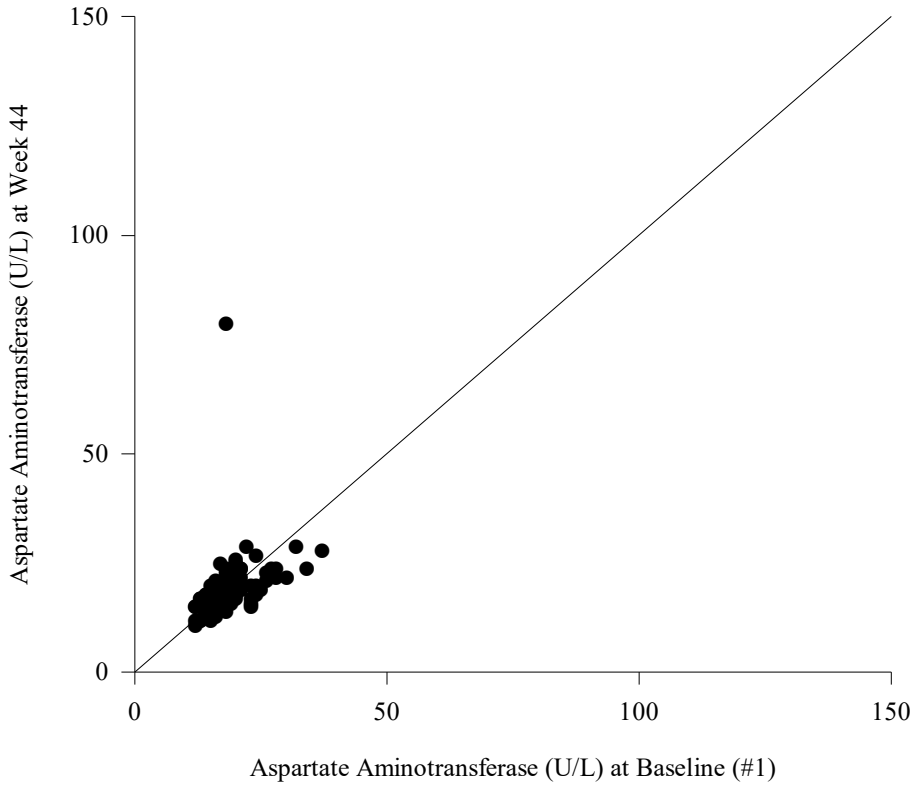


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 88 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (0%/5%)

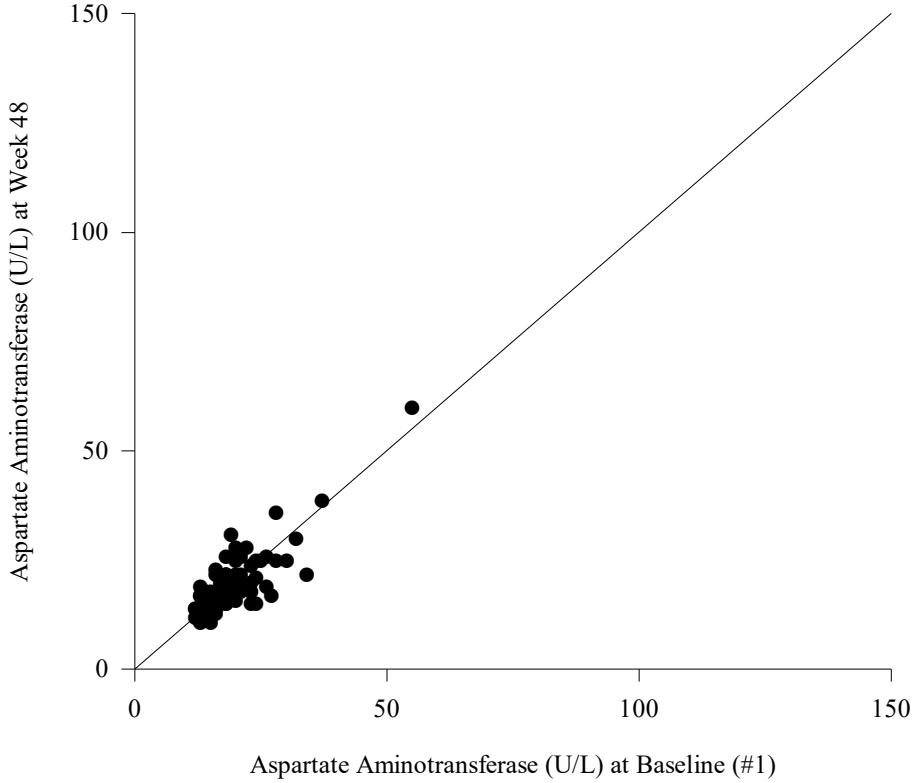


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 89 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (0%/5%)

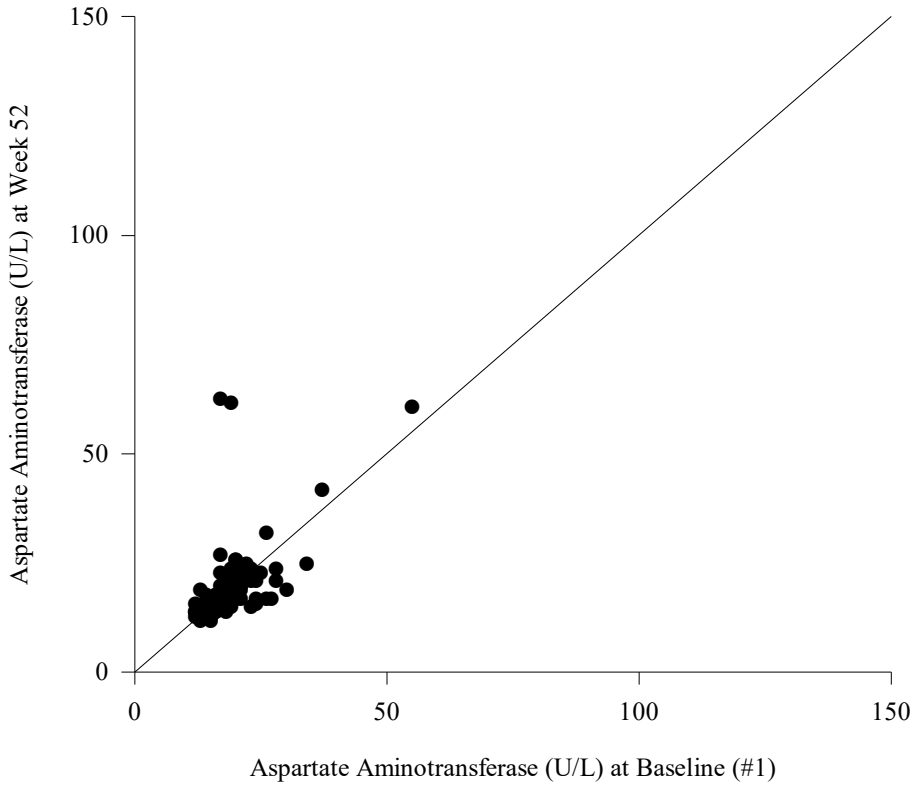


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 90 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (0%/5%)

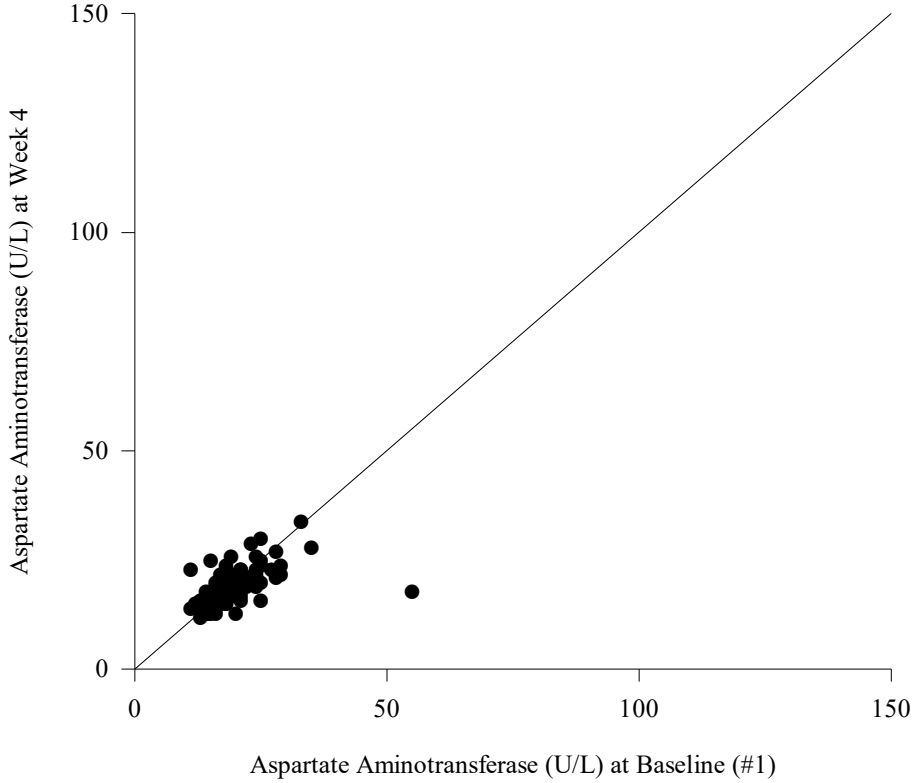


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 91 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (5%/5%)

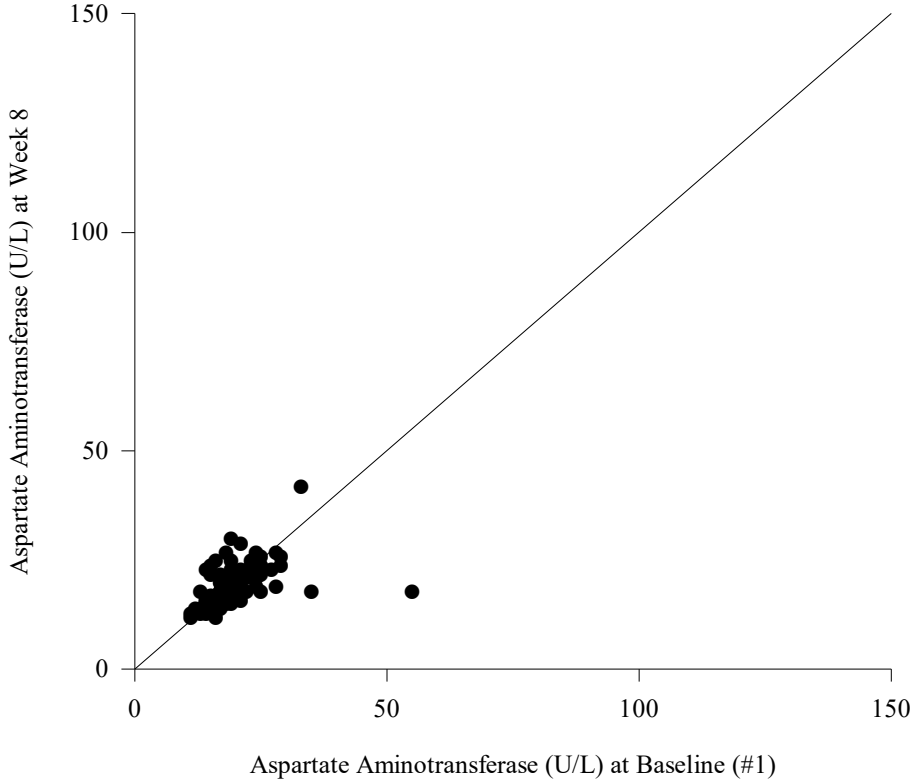


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 92 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (5%/5%)

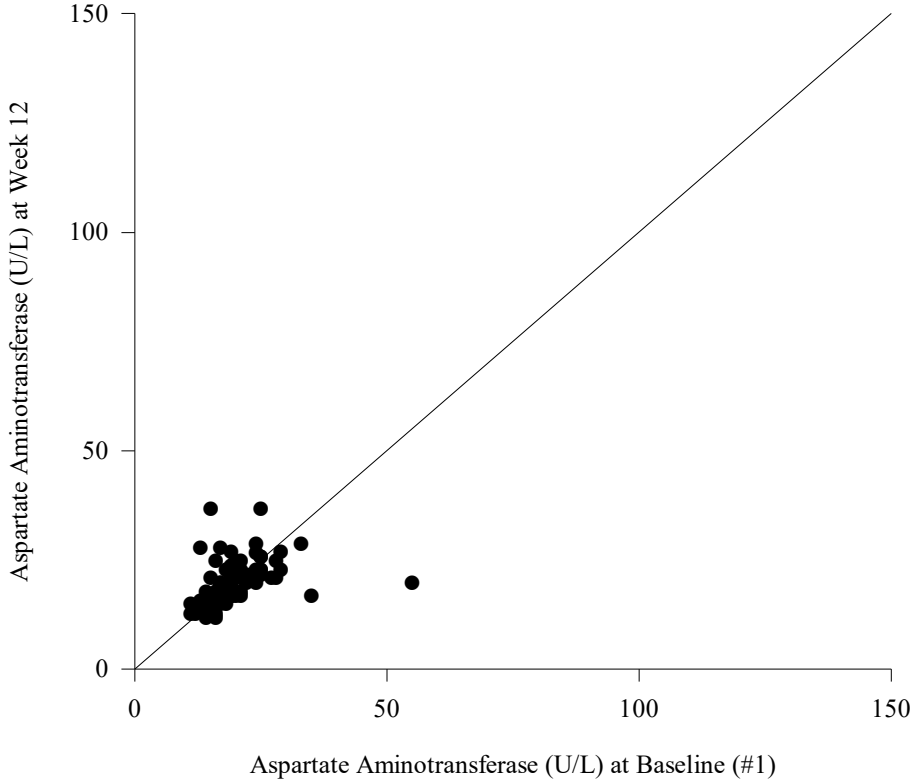


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 93 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (5%/5%)

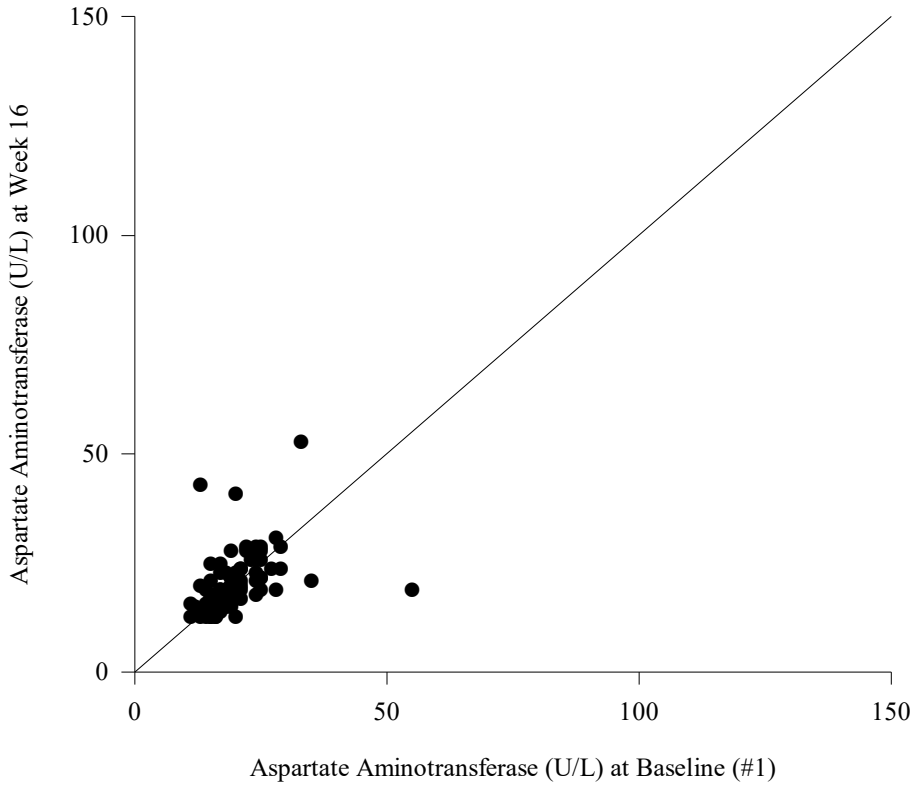


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 94 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (5%/5%)

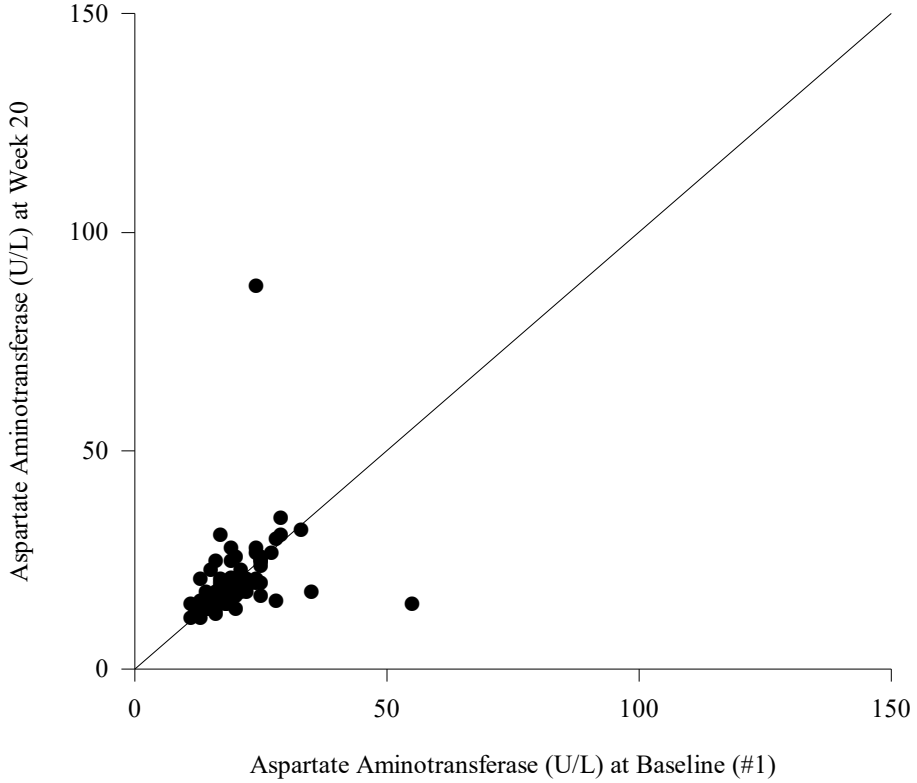


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 95 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (5%/5%)

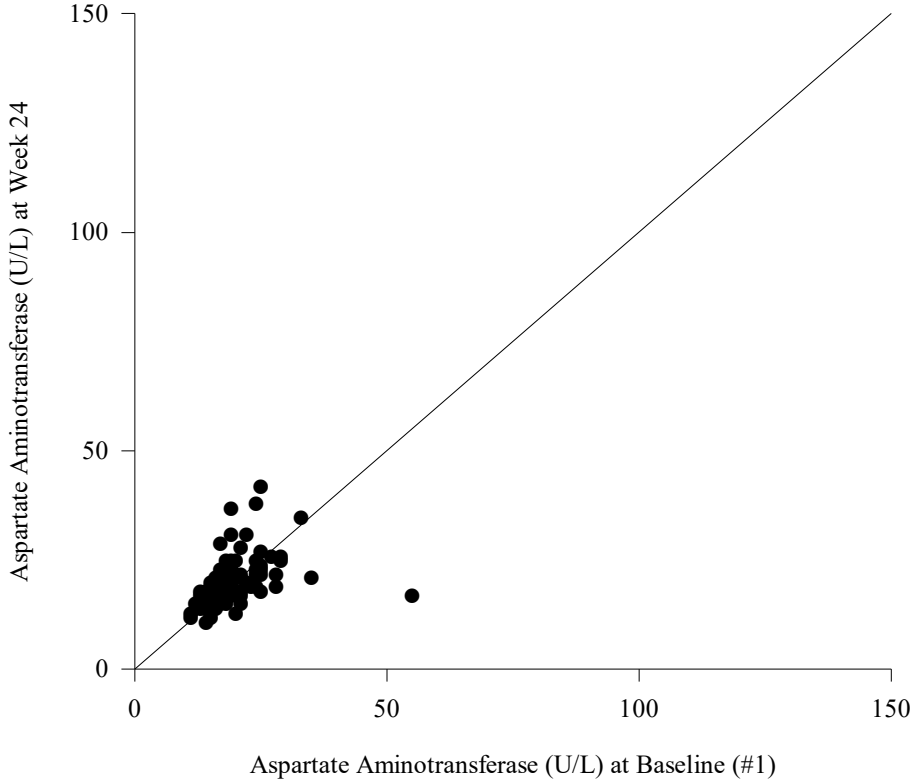


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 96 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (5%/5%)

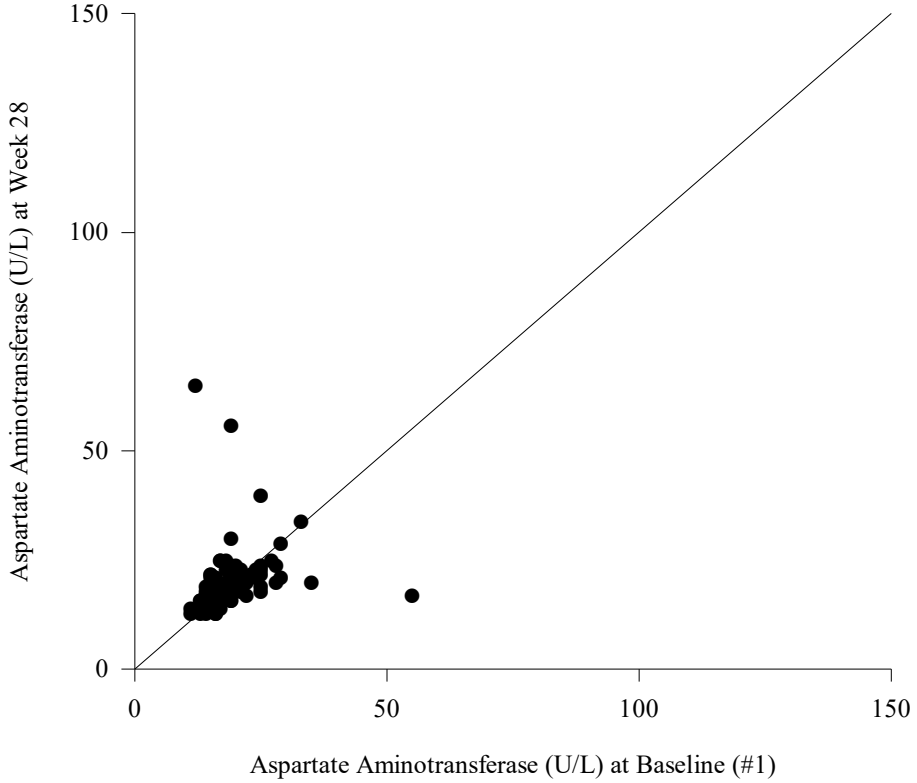


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 97 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (5%/5%)

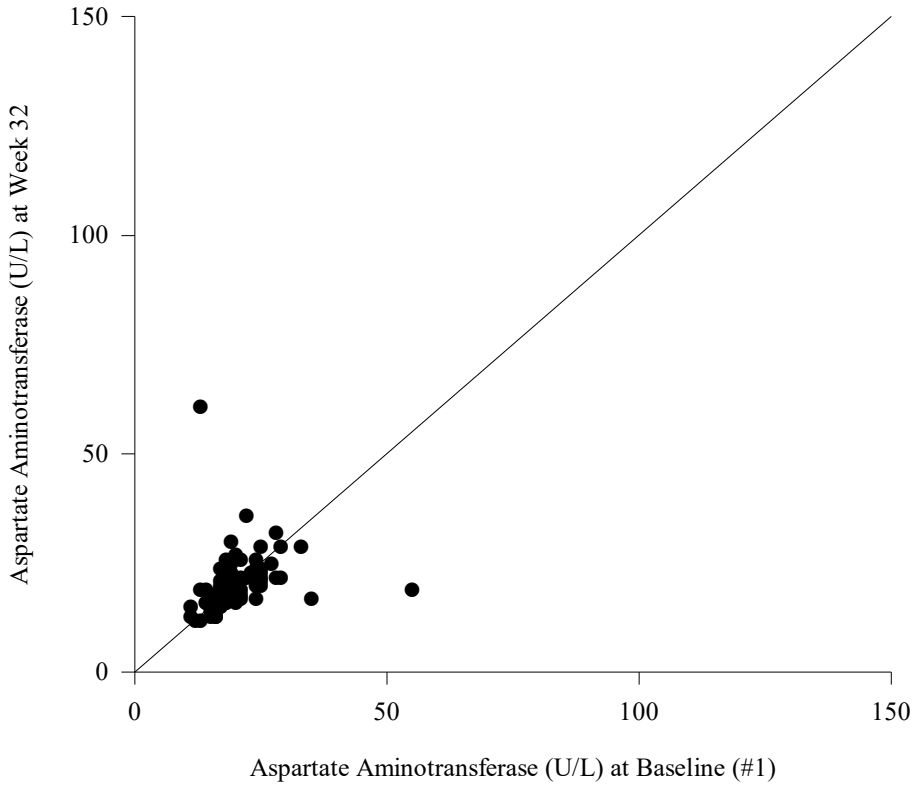


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 98 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (5%/5%)

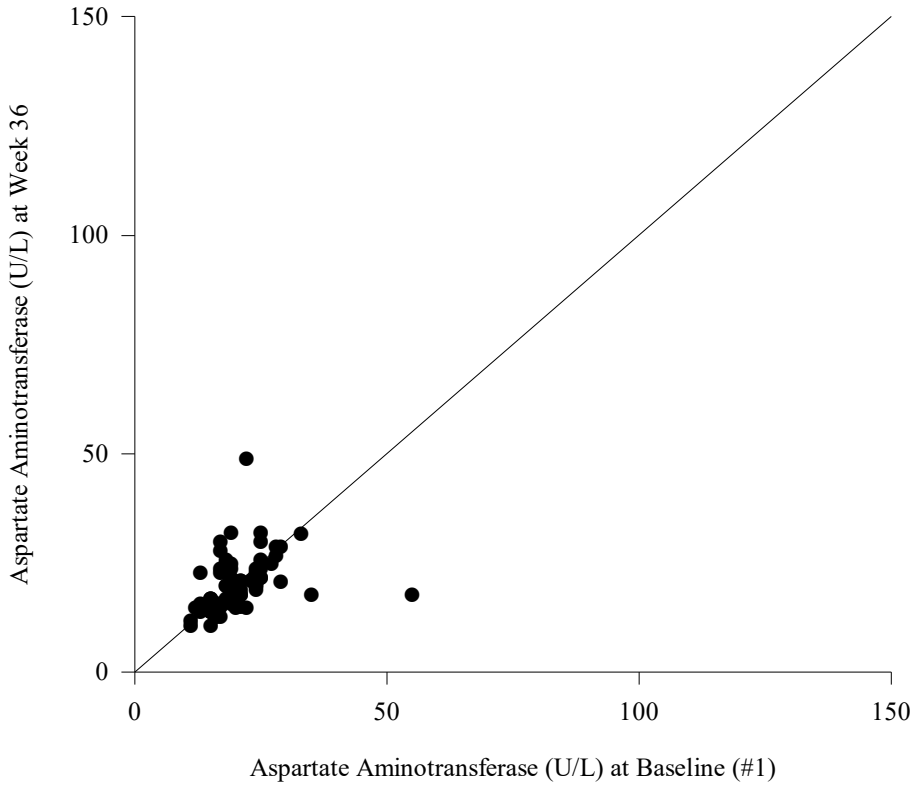


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 99 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (5%/5%)

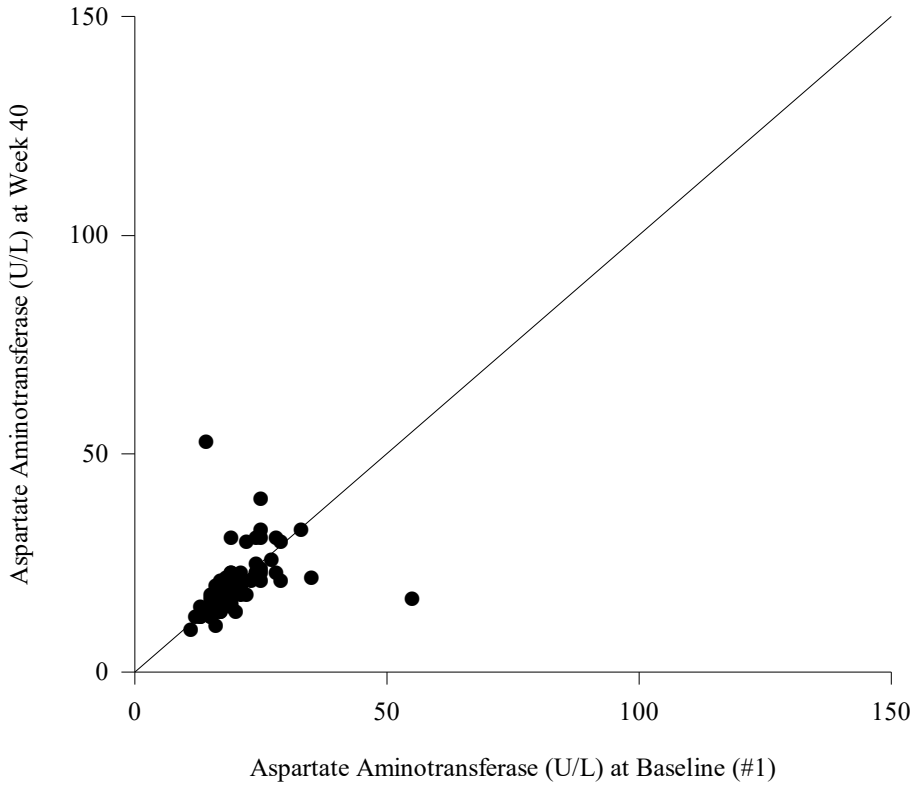


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 100 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (5%/5%)

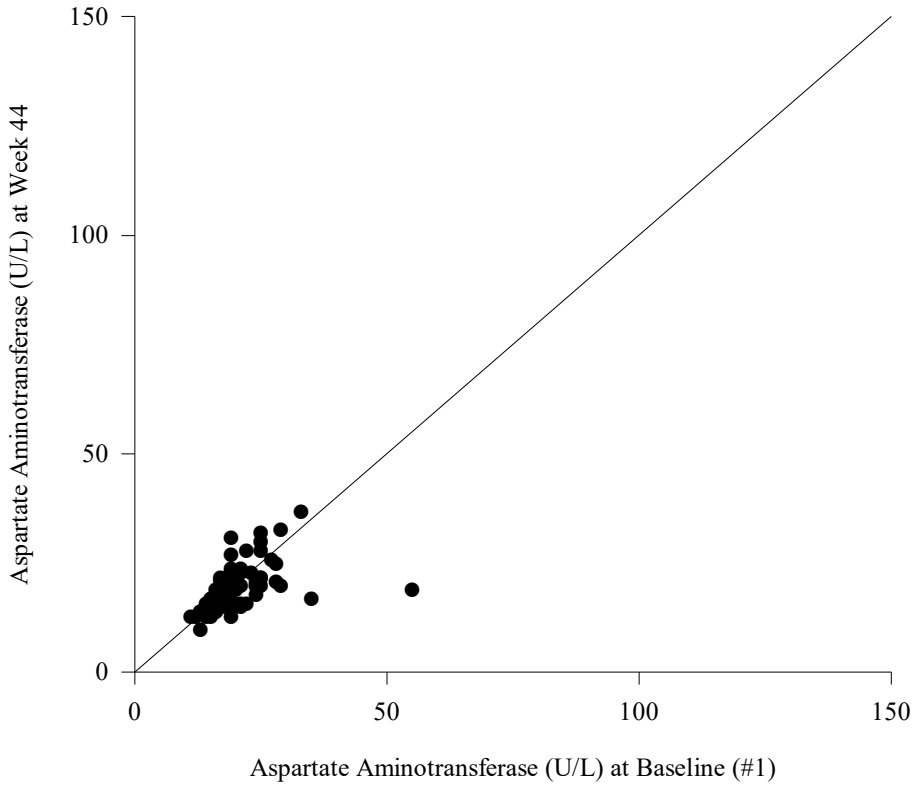


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 101 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (5%/5%)

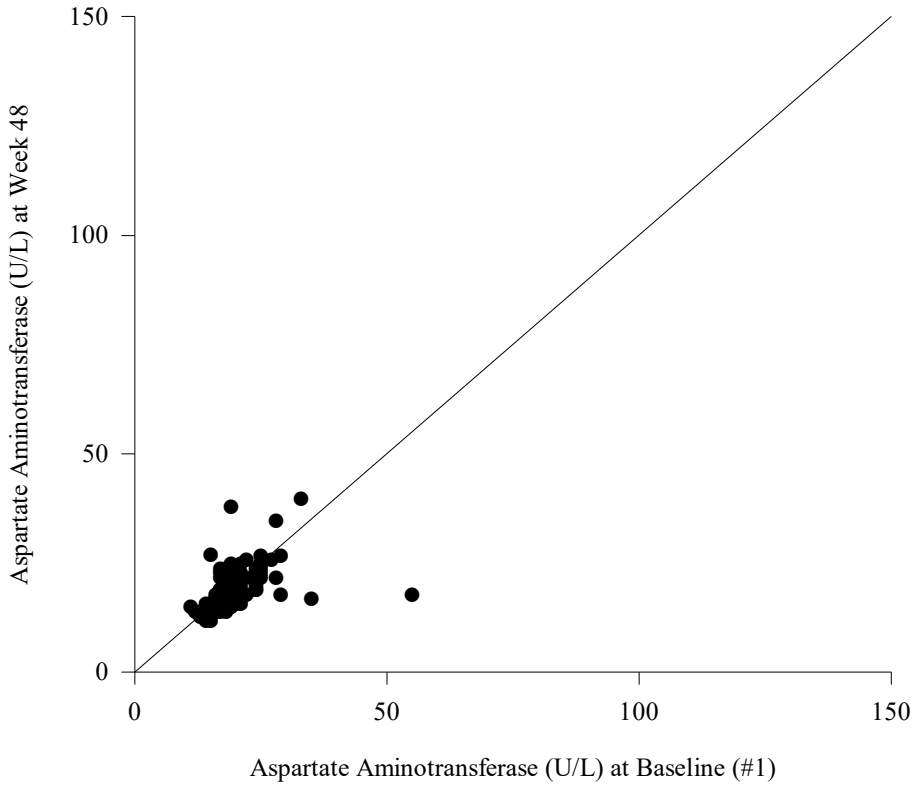


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 102 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (5%/5%)

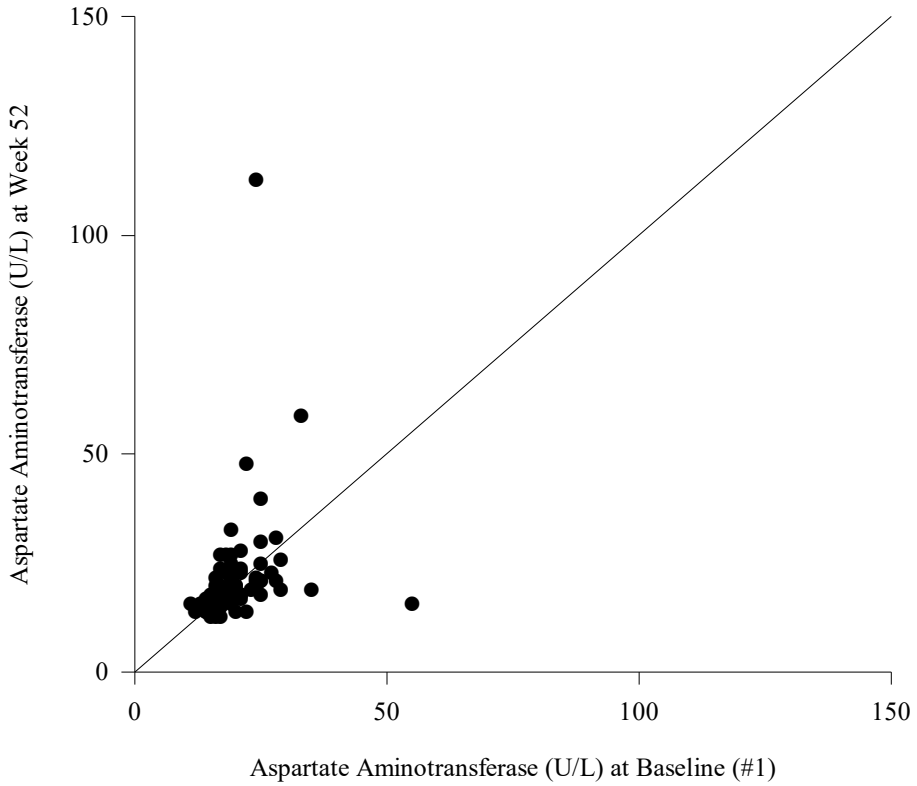


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 103 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (5%/5%)

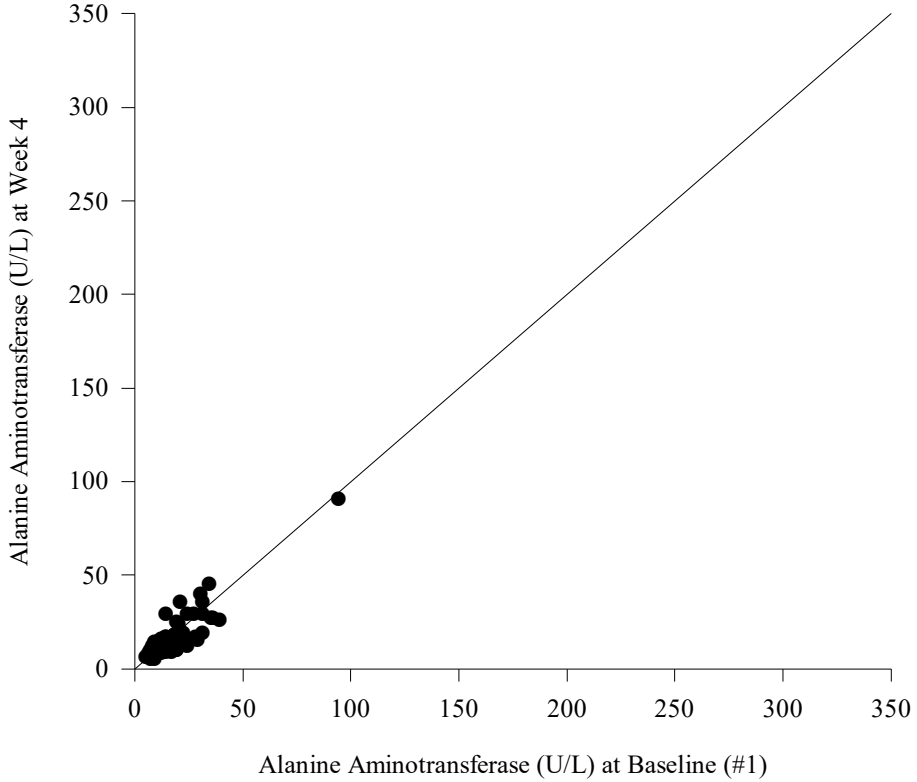


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 104 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (0%/5%)

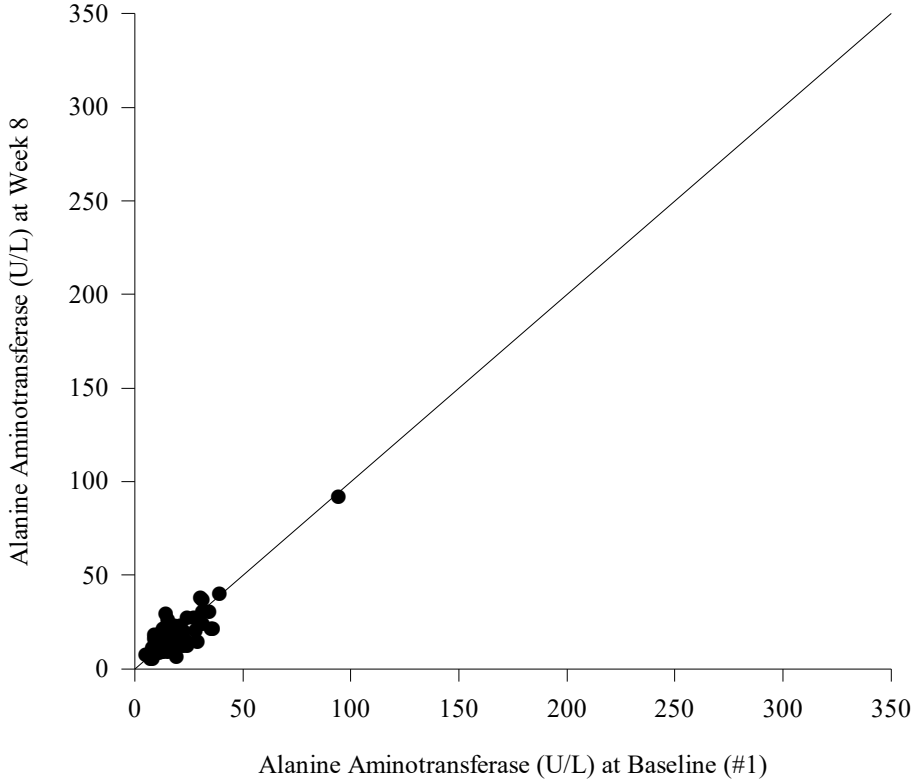


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 105 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (0%/5%)

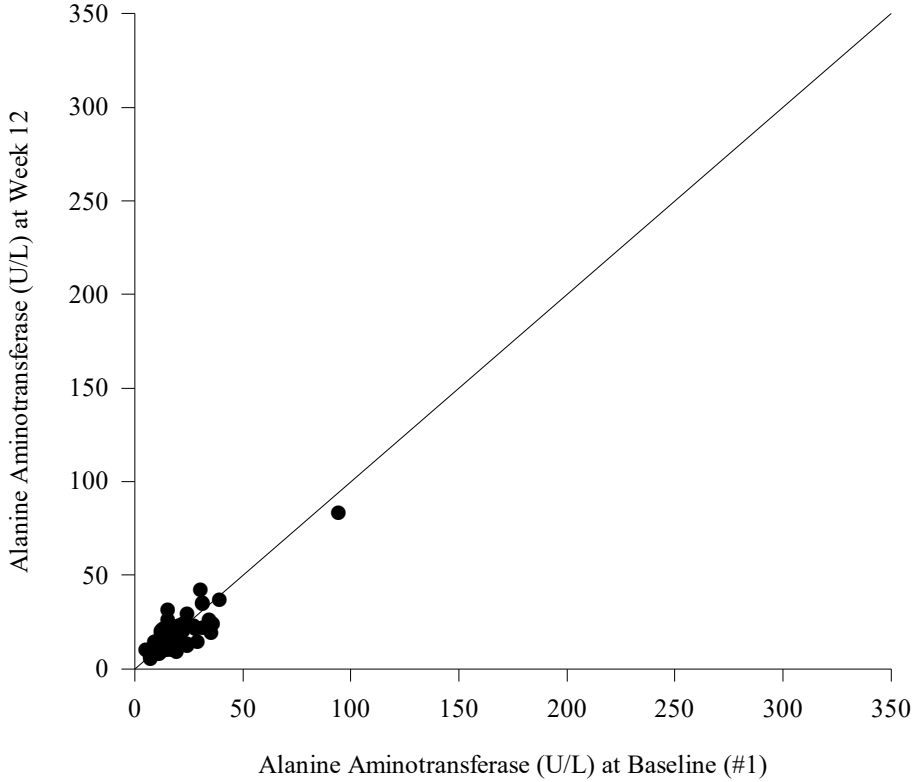


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 106 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (0%/5%)

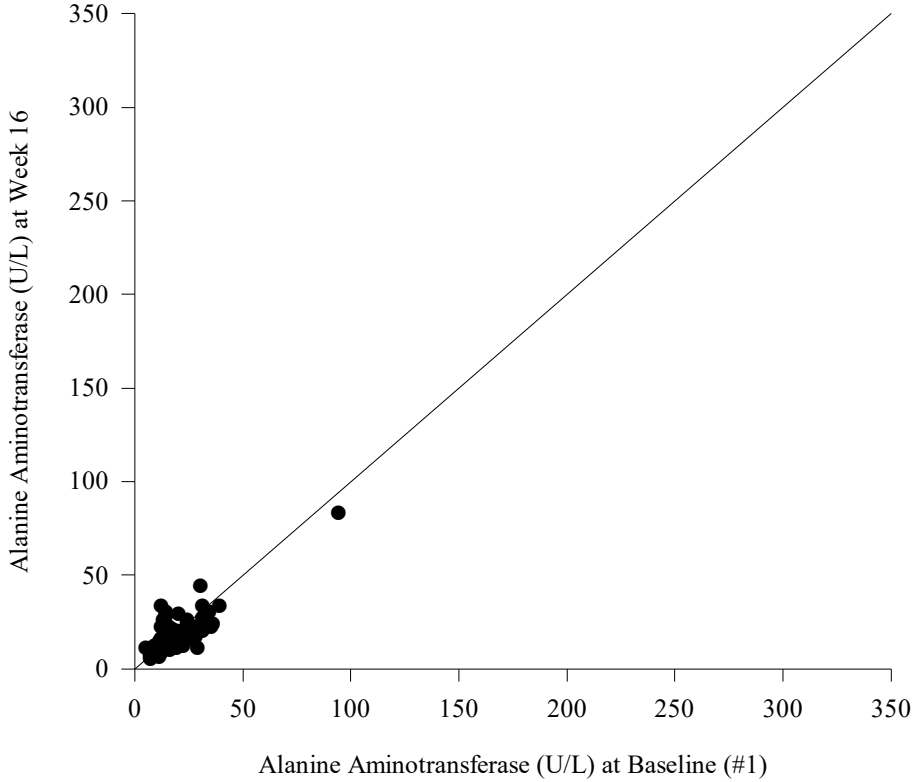


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 107 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (0%/5%)

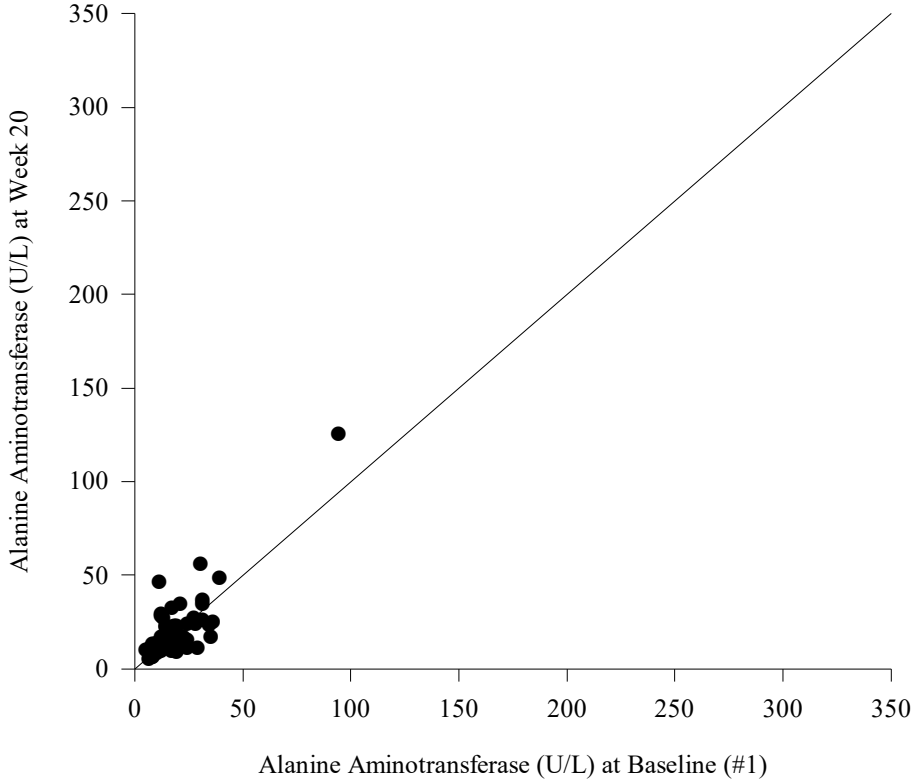


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 108 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (0%/5%)

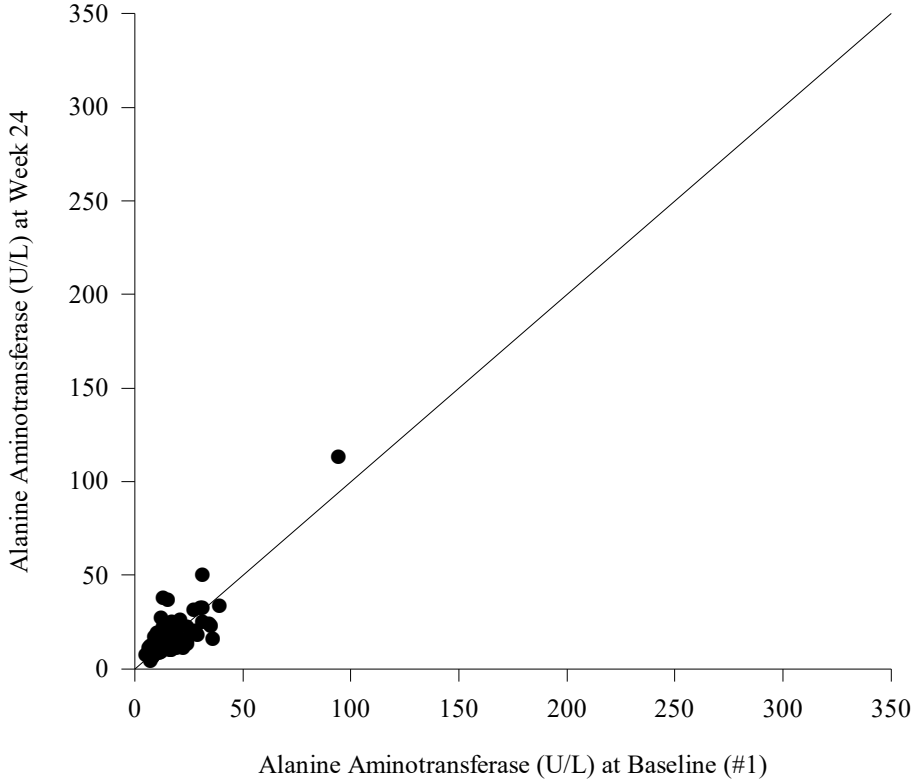


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 109 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (0%/5%)

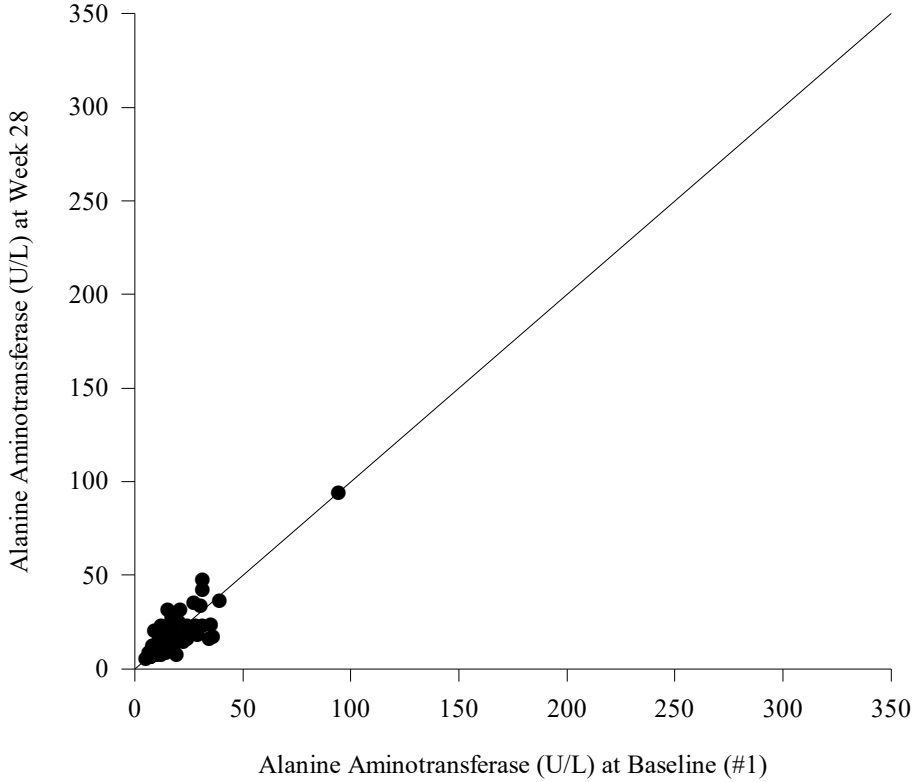


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 110 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (0%/5%)

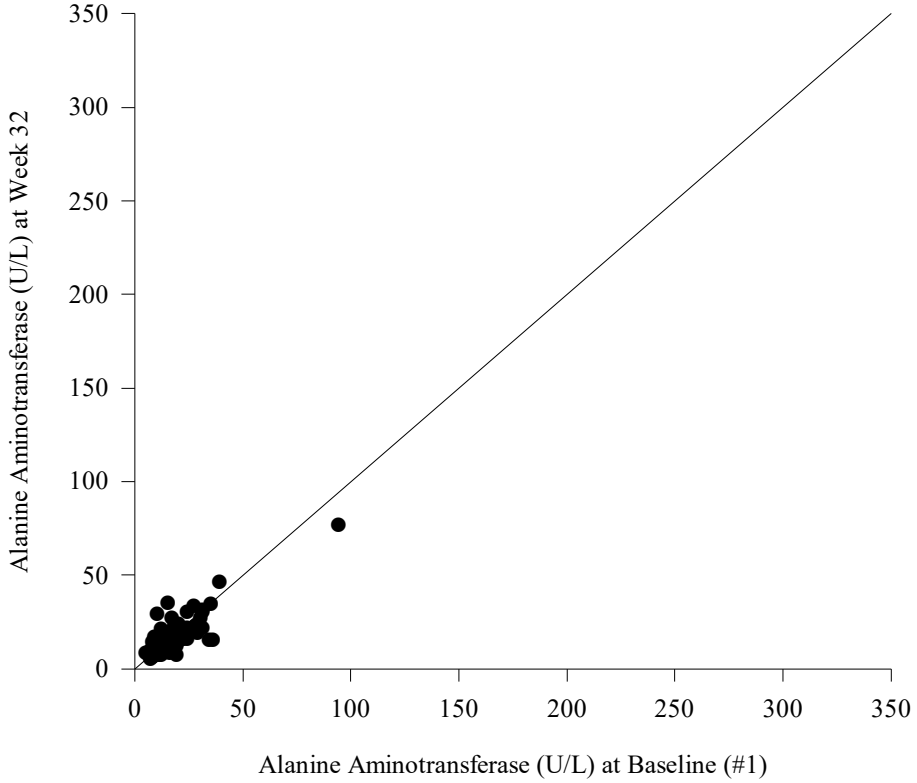


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 111 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (0%/5%)

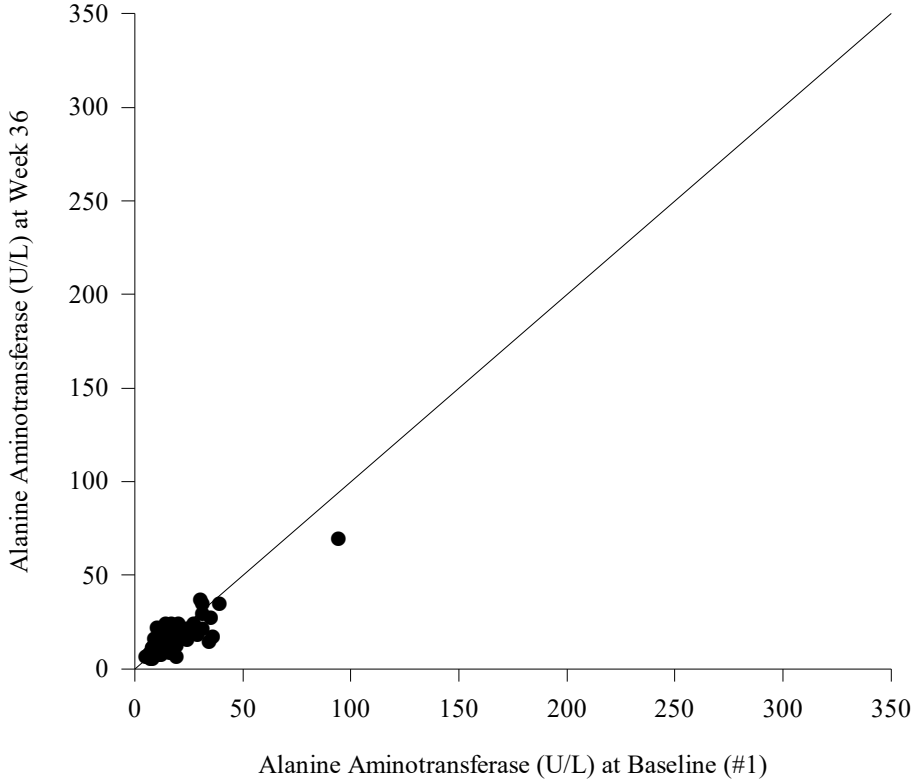


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 112 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (0%/5%)

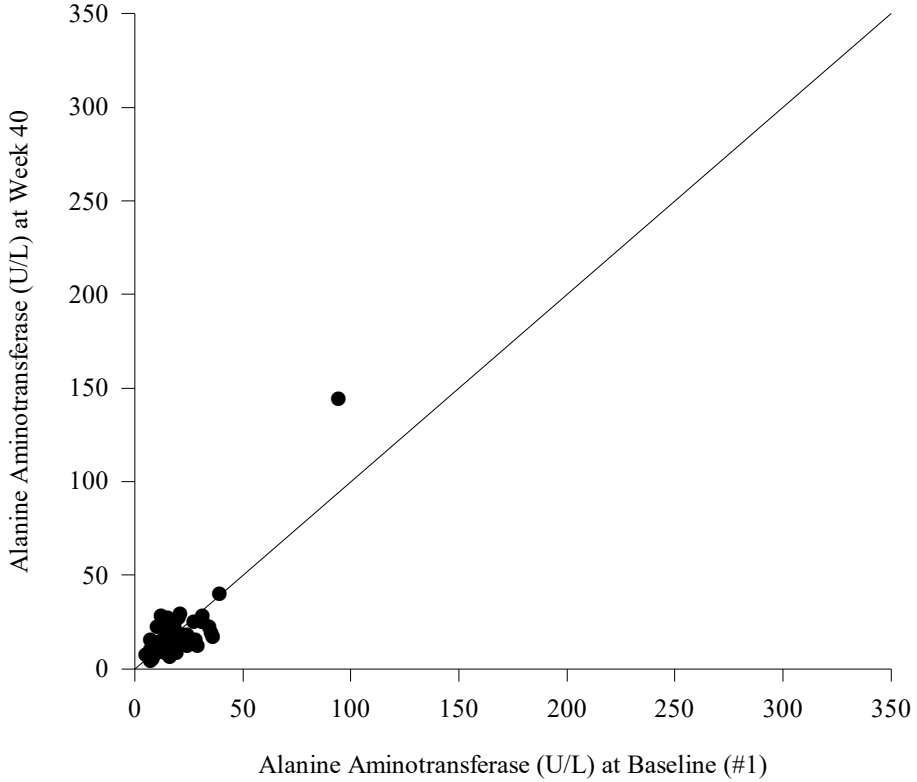


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 113 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (0%/5%)

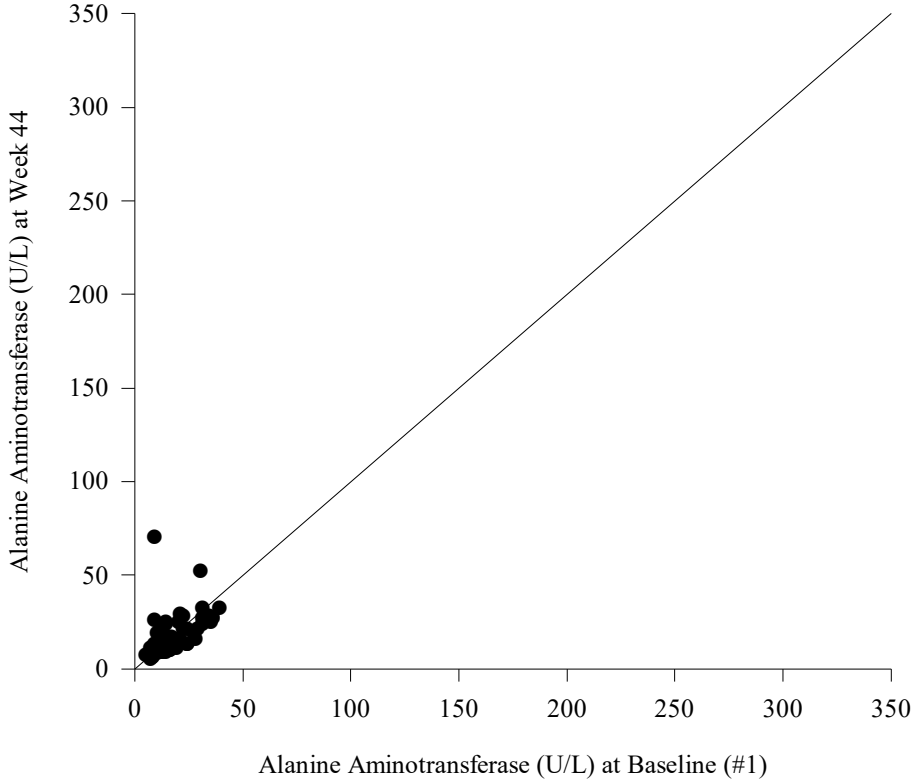


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 114 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (0%/5%)

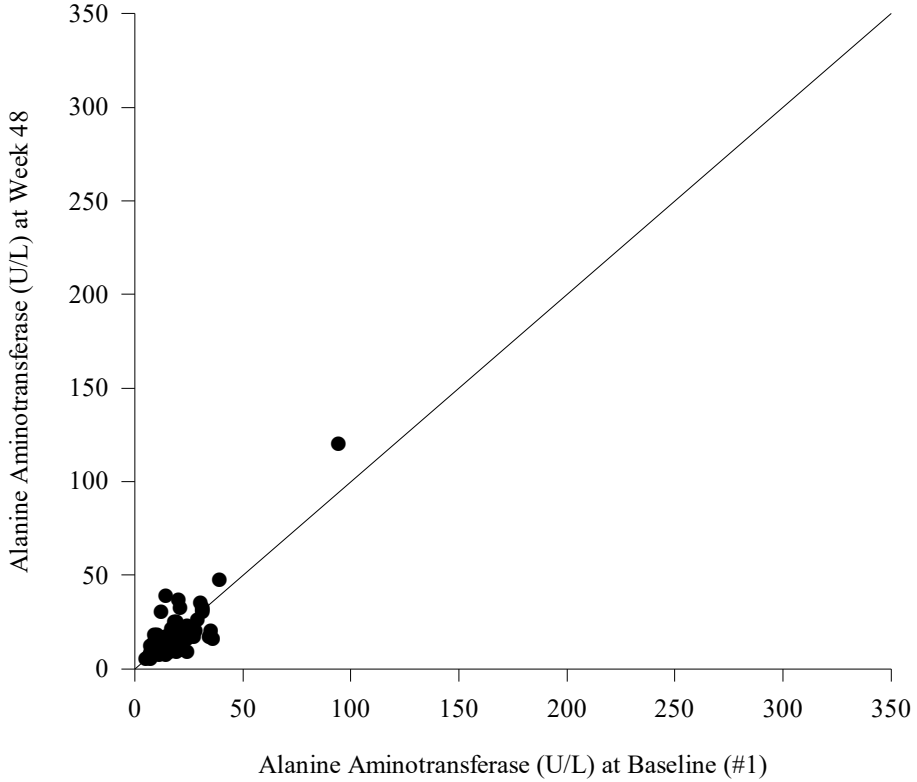


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 115 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (0%/5%)

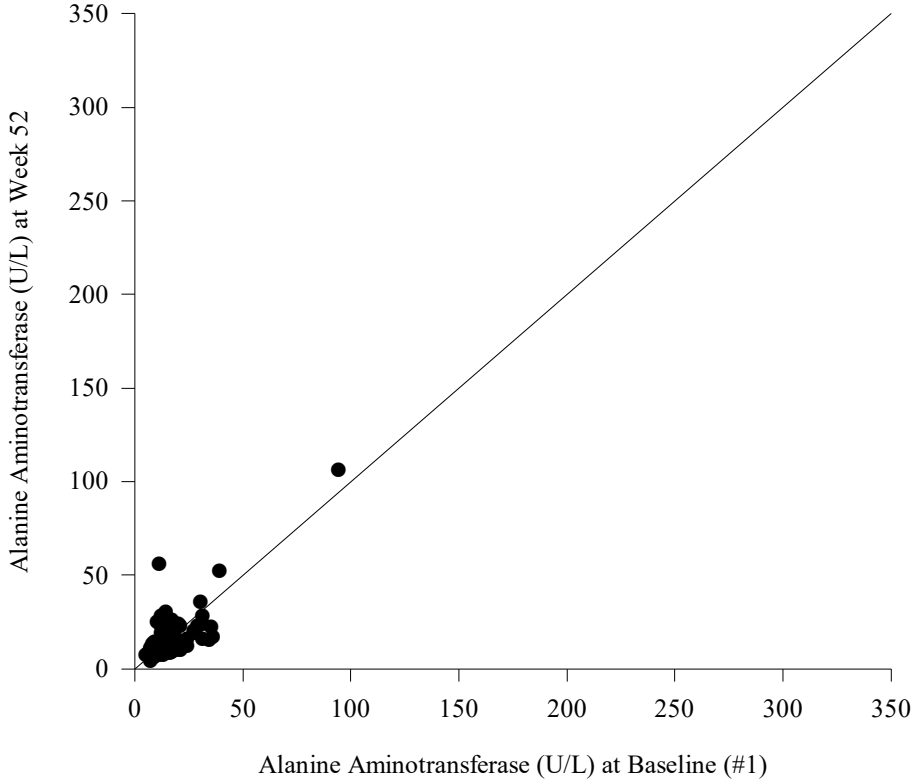


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 116 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (0%/5%)

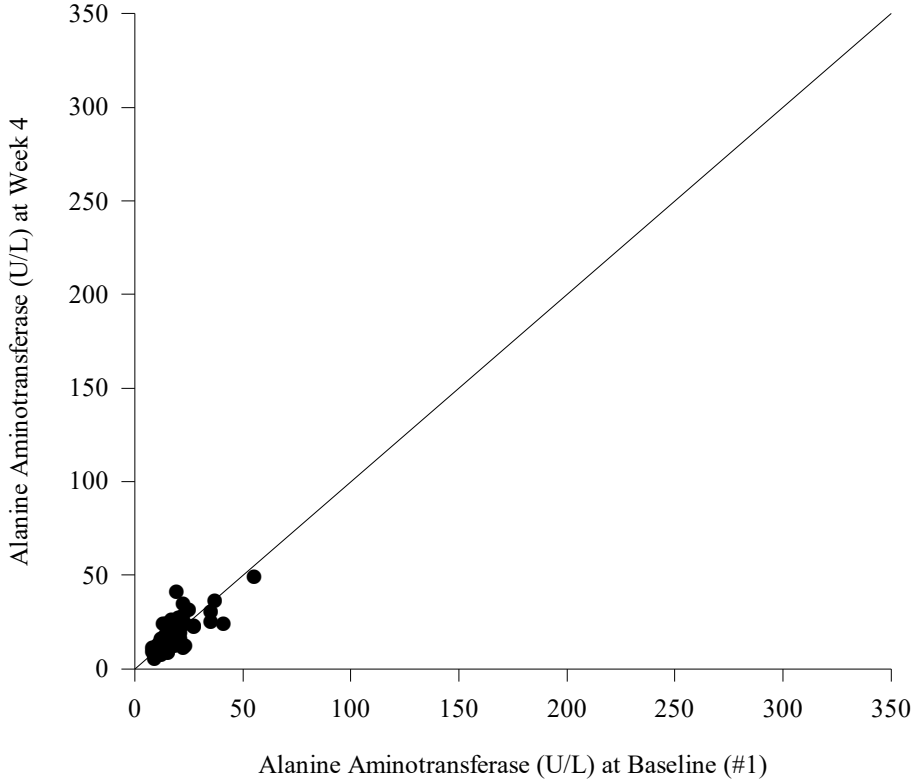


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 117 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (5%/5%)

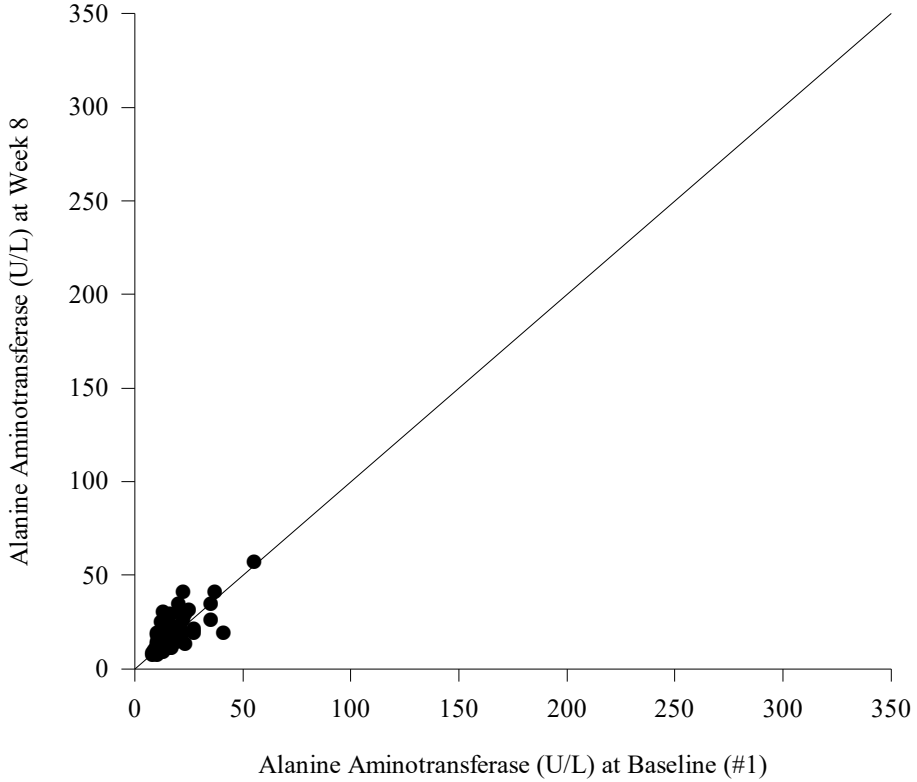


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 118 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (5%/5%)

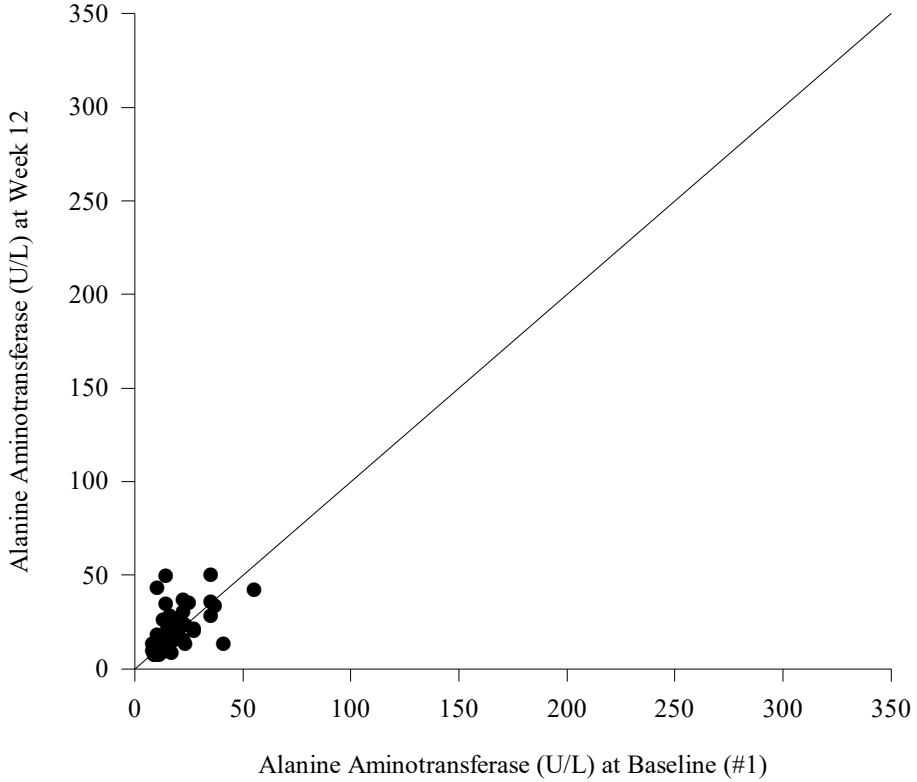


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 119 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (5%/5%)

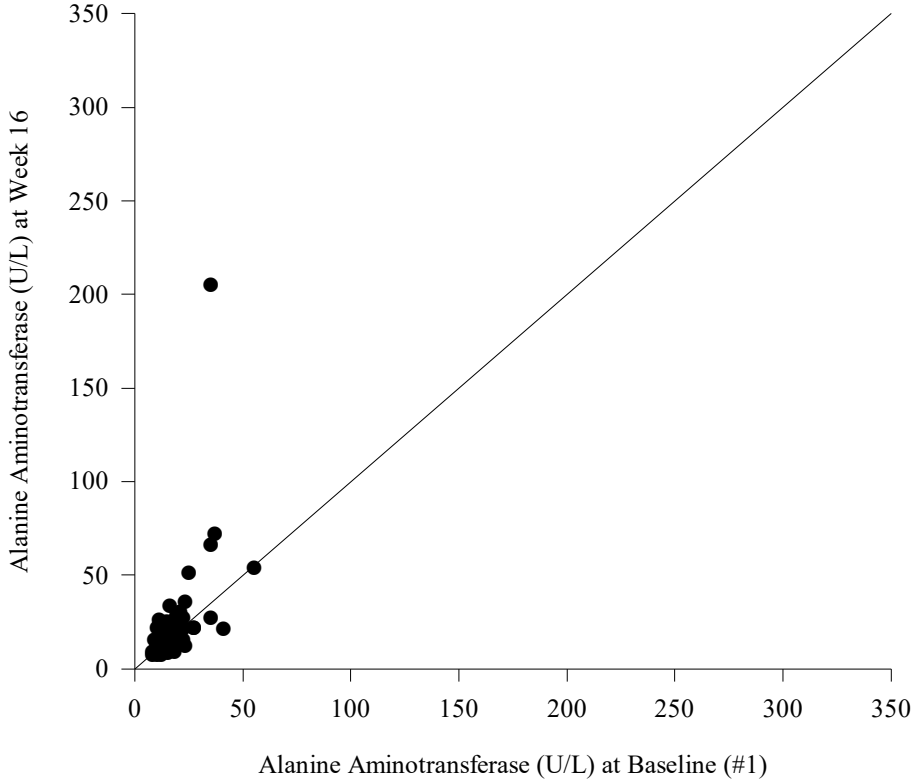


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 120 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (5%/5%)

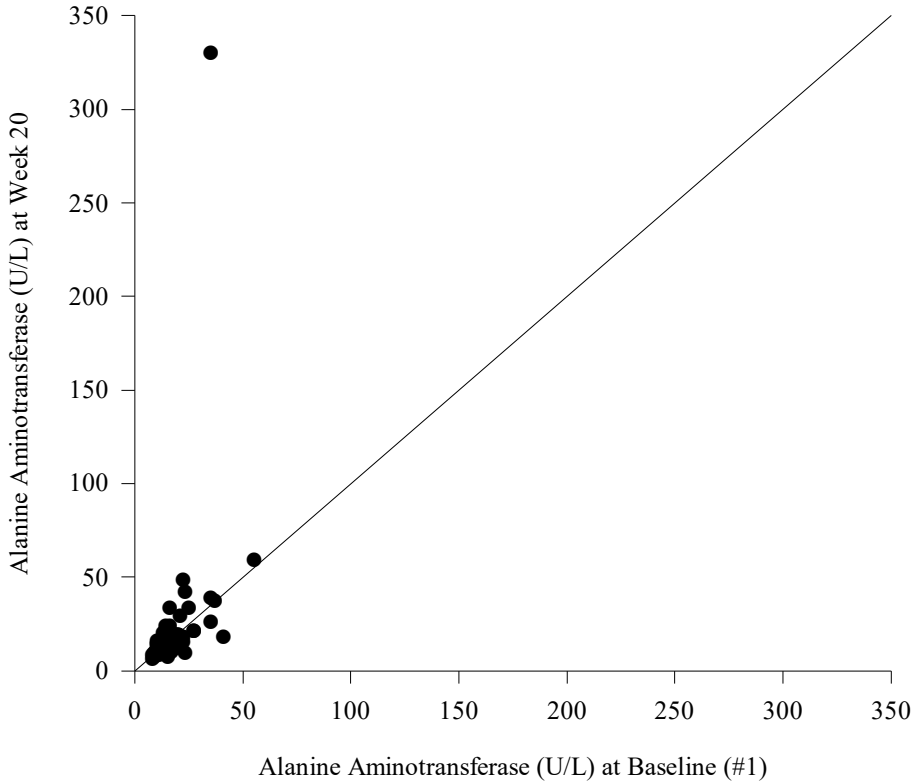


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 121 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (5%/5%)

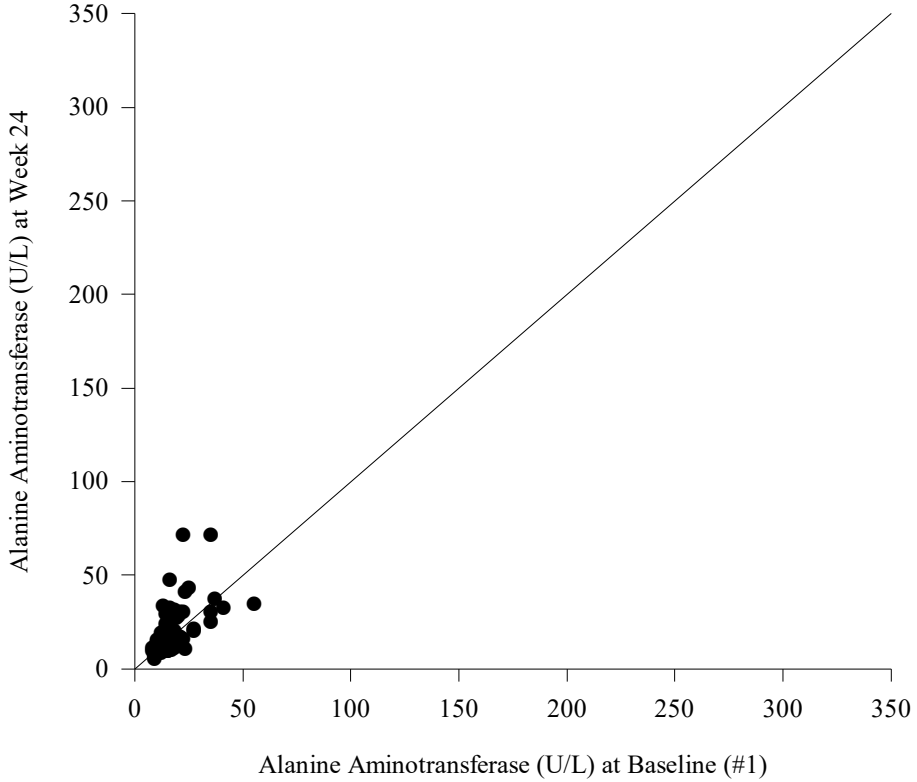


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 122 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (5%/5%)

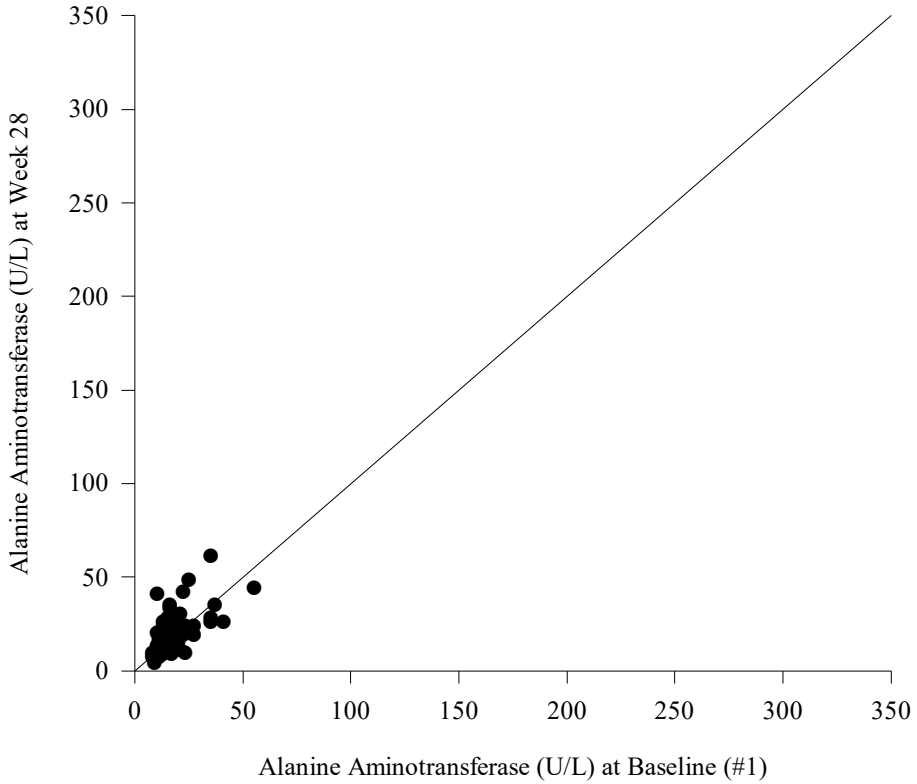


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 123 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (5%/5%)

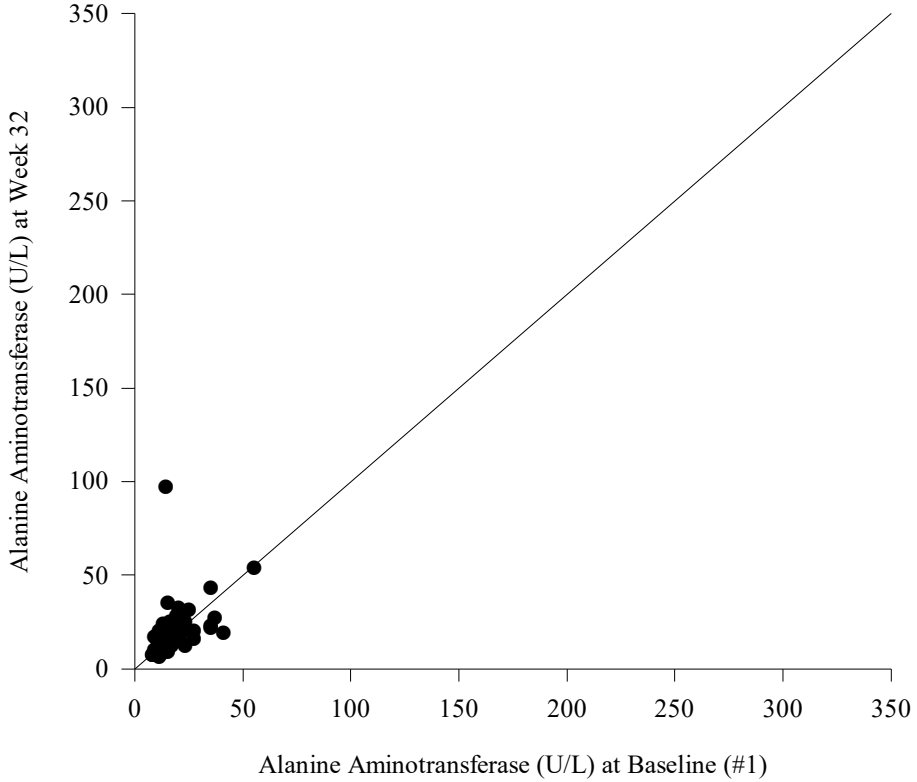


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 124 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (5%/5%)

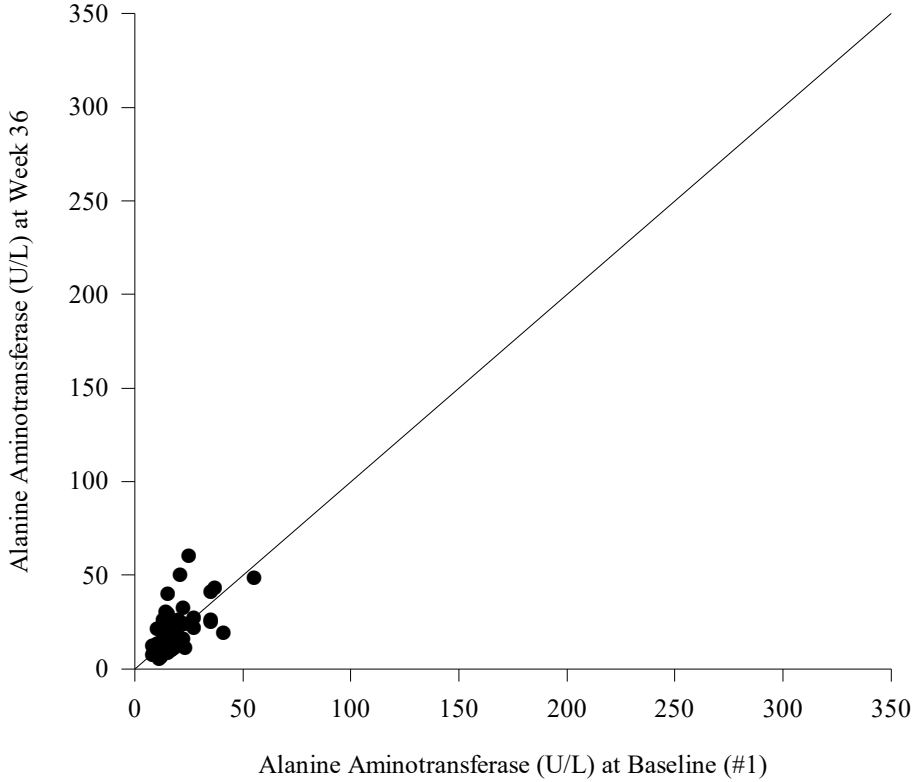


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 125 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (5%/5%)

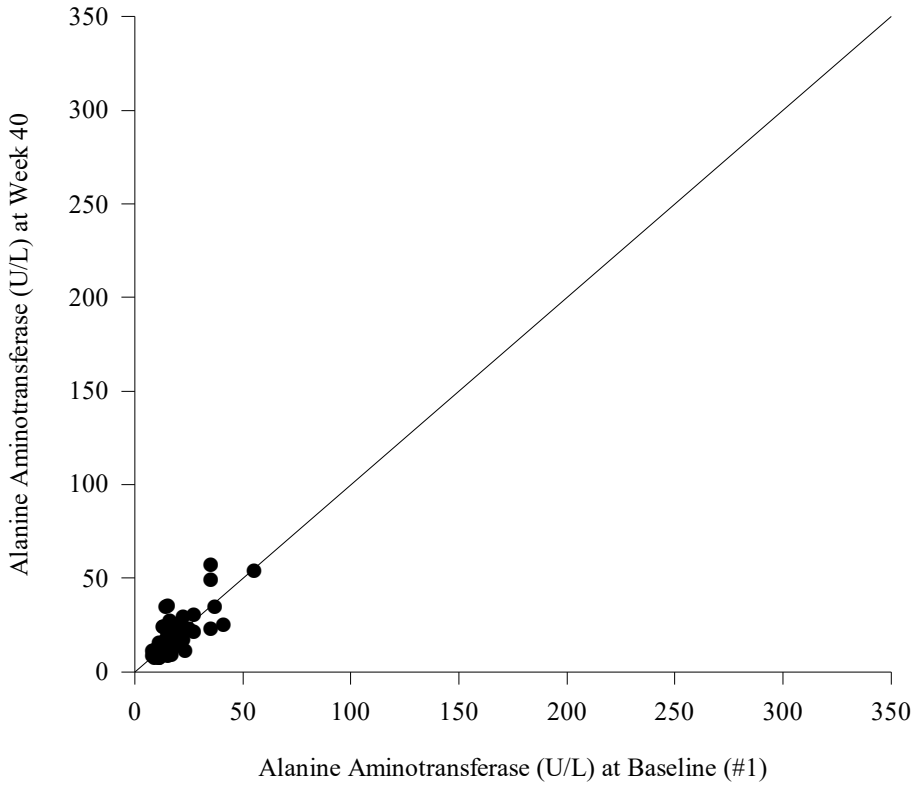


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 126 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (5%/5%)

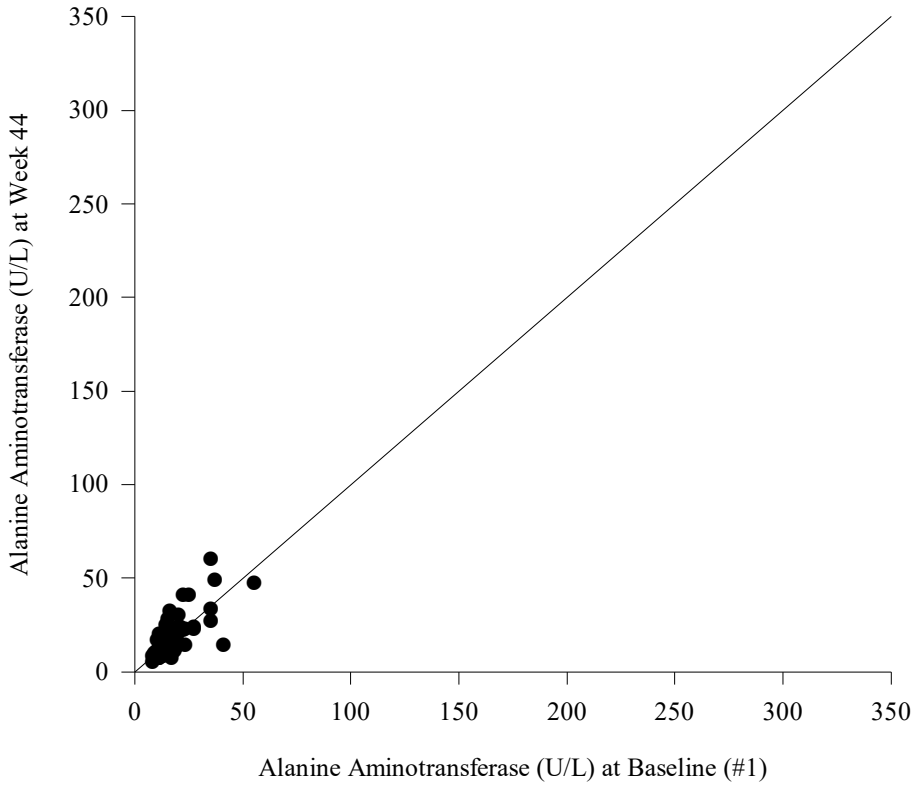


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 127 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (5%/5%)

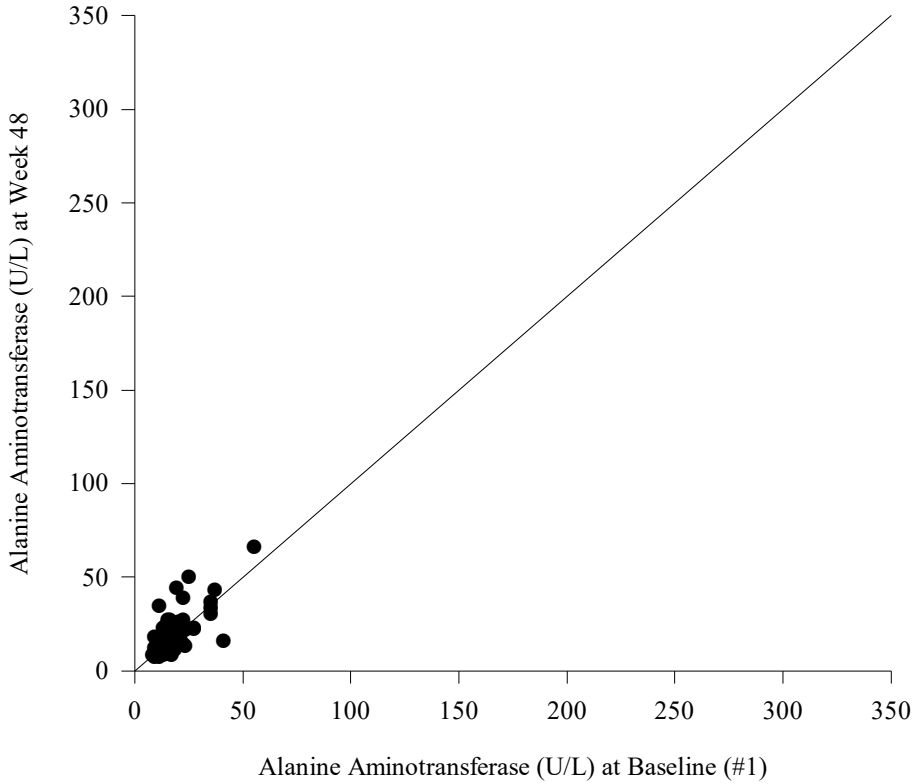


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 128 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (5%/5%)

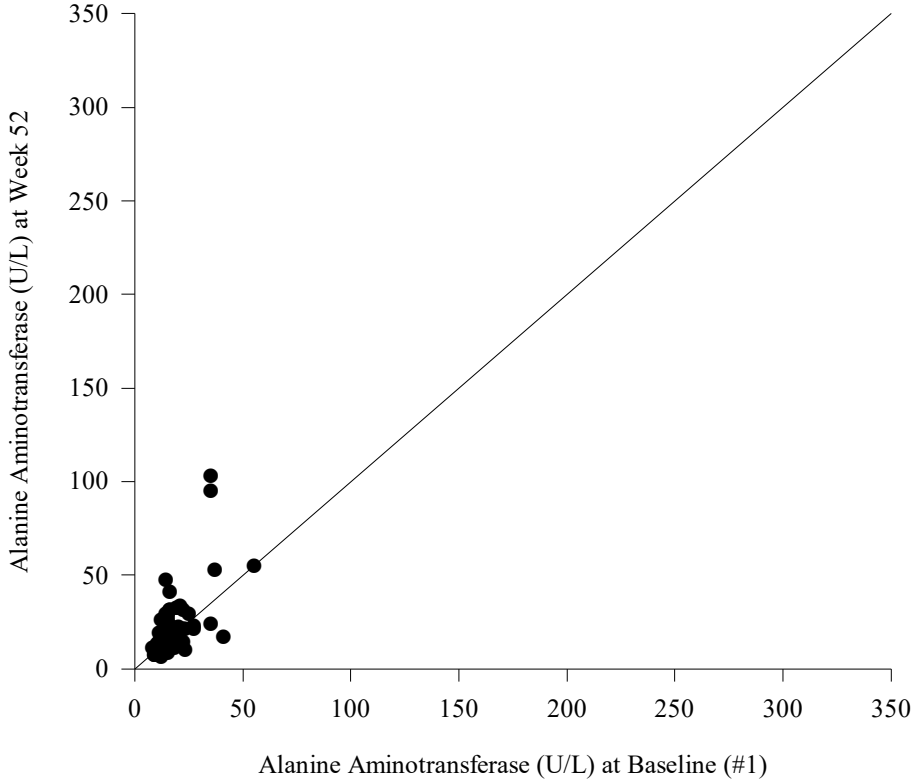


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 129 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (5%/5%)

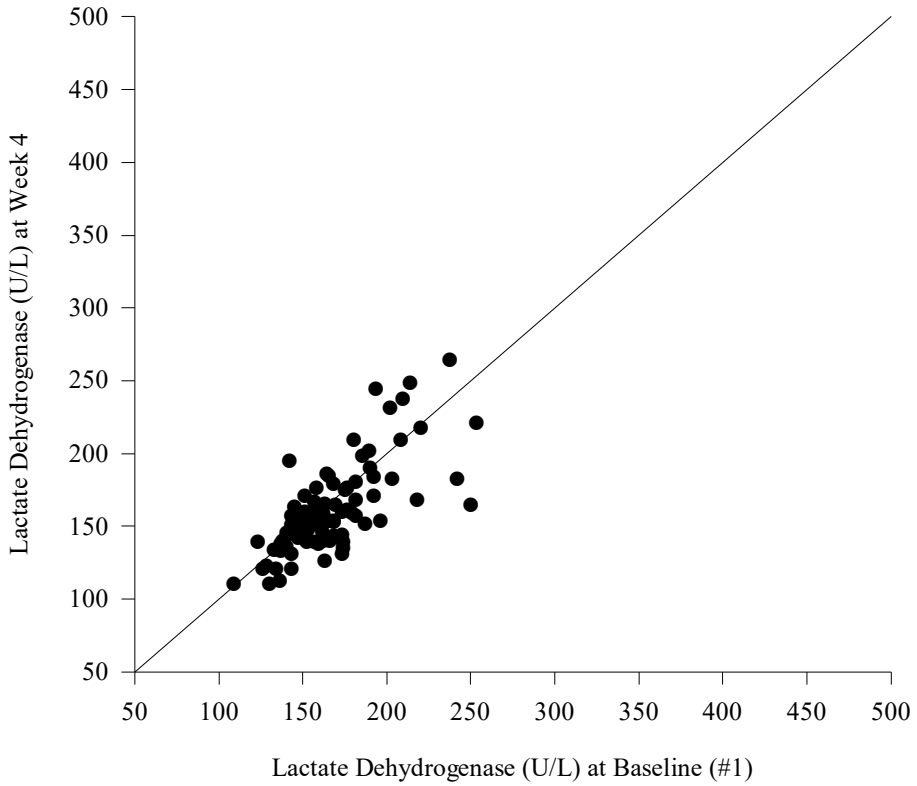


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 130 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (0%/5%)

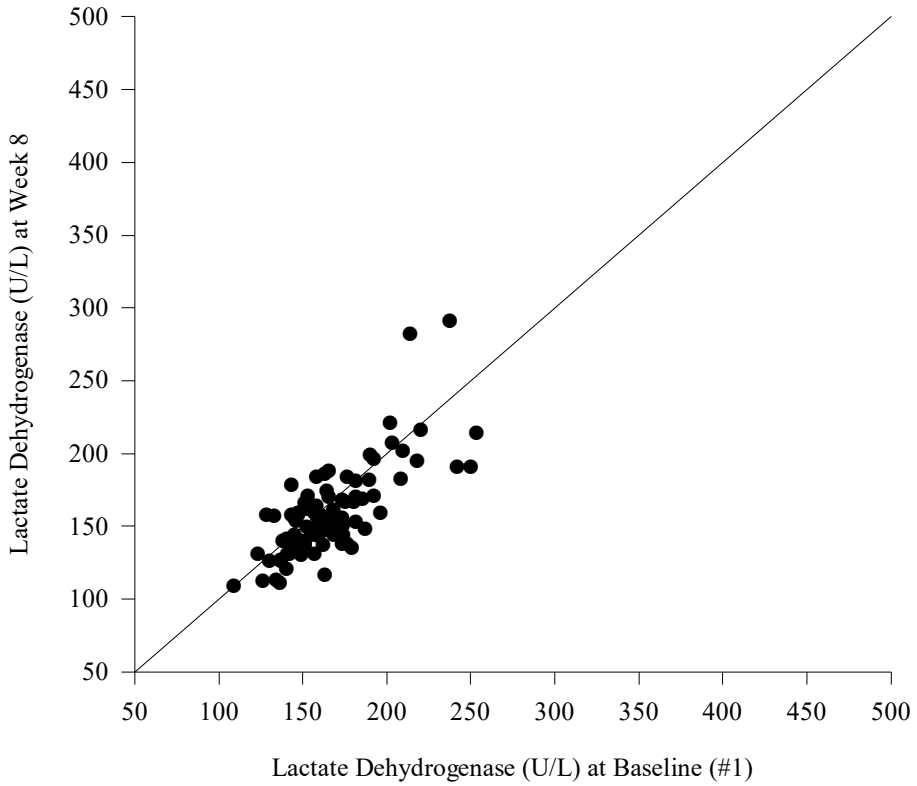


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 131 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (0%/5%)

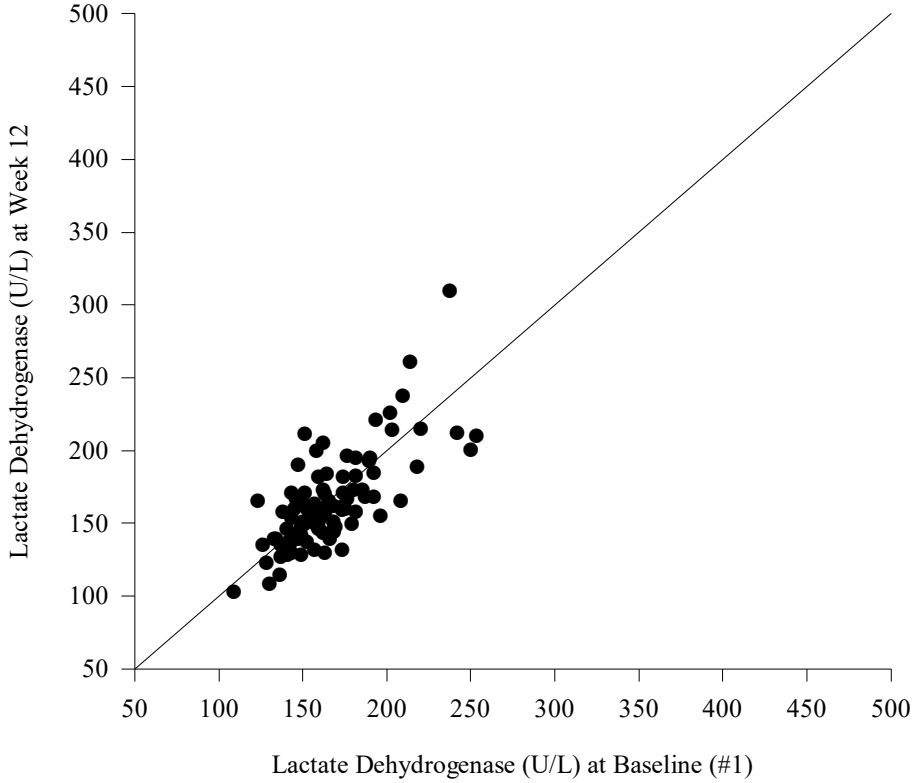


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 132 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (0%/5%)

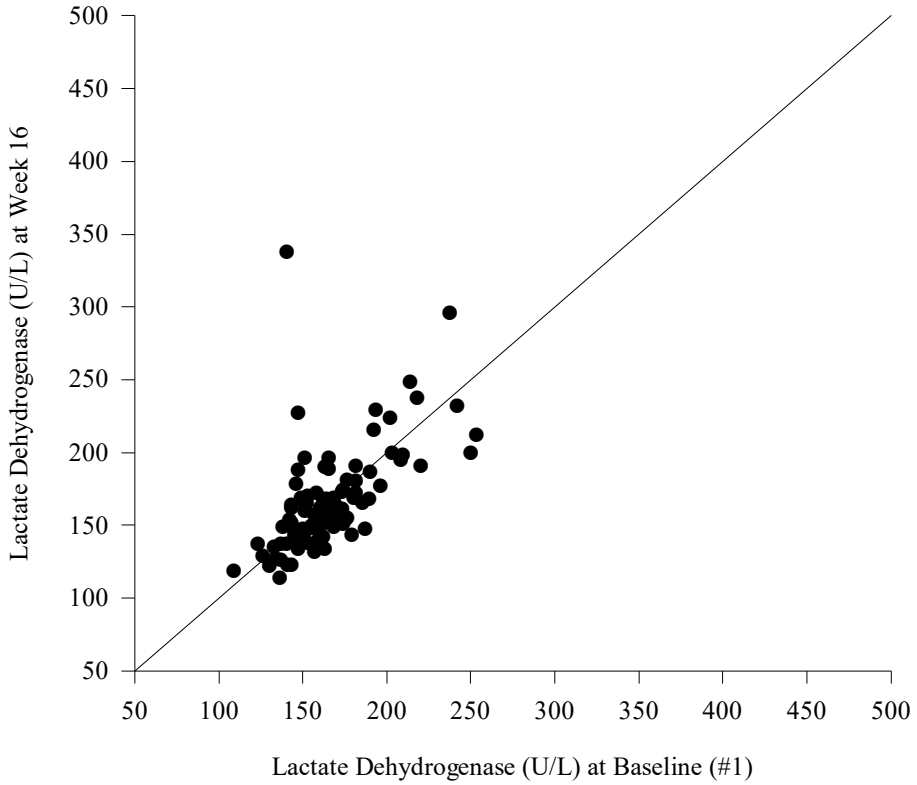


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 133 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (0%/5%)

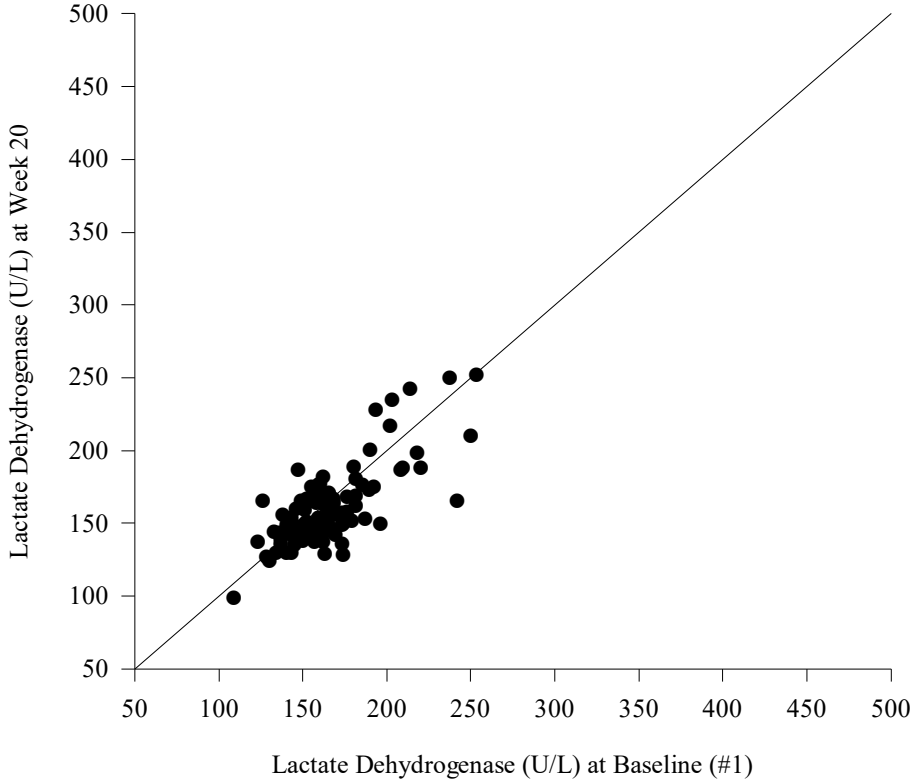


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 134 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (0%/5%)

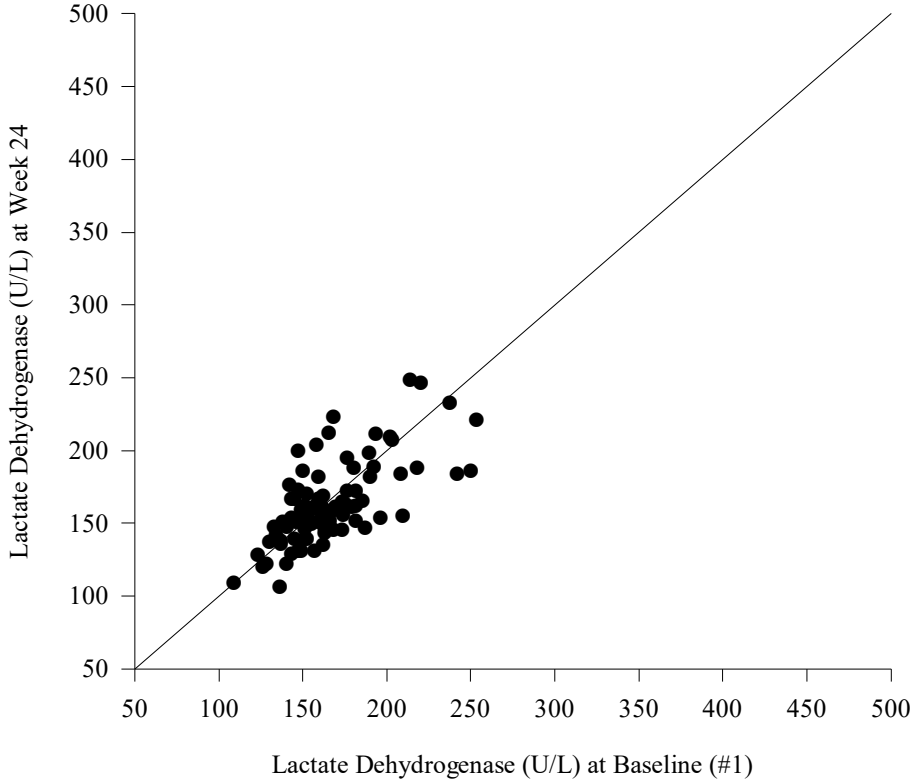


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 135 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (0%/5%)

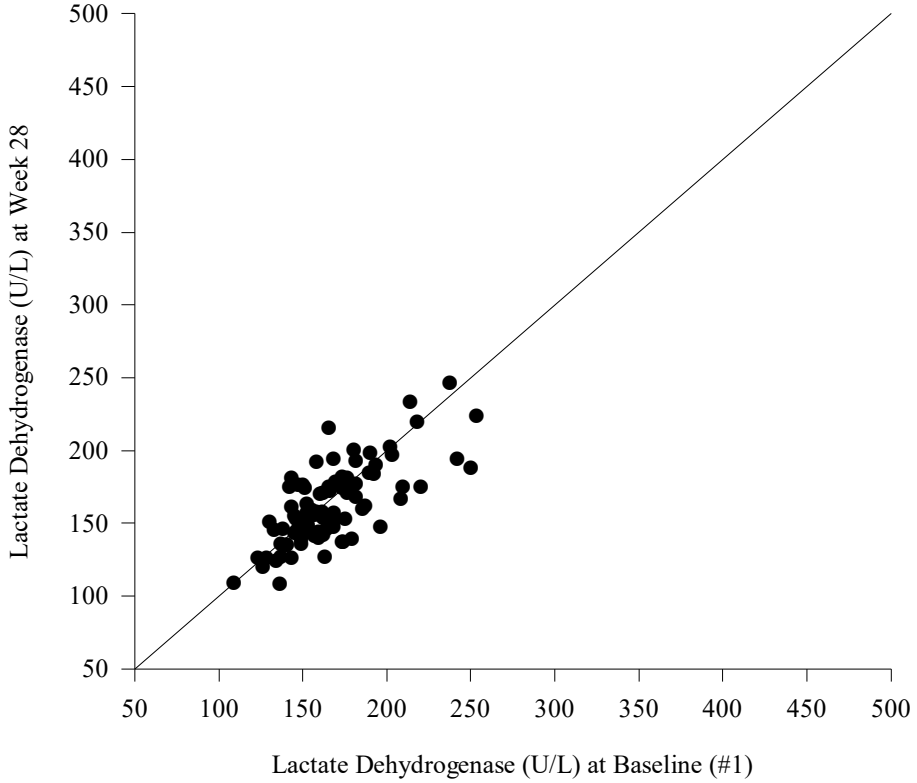


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 136 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (0%/5%)

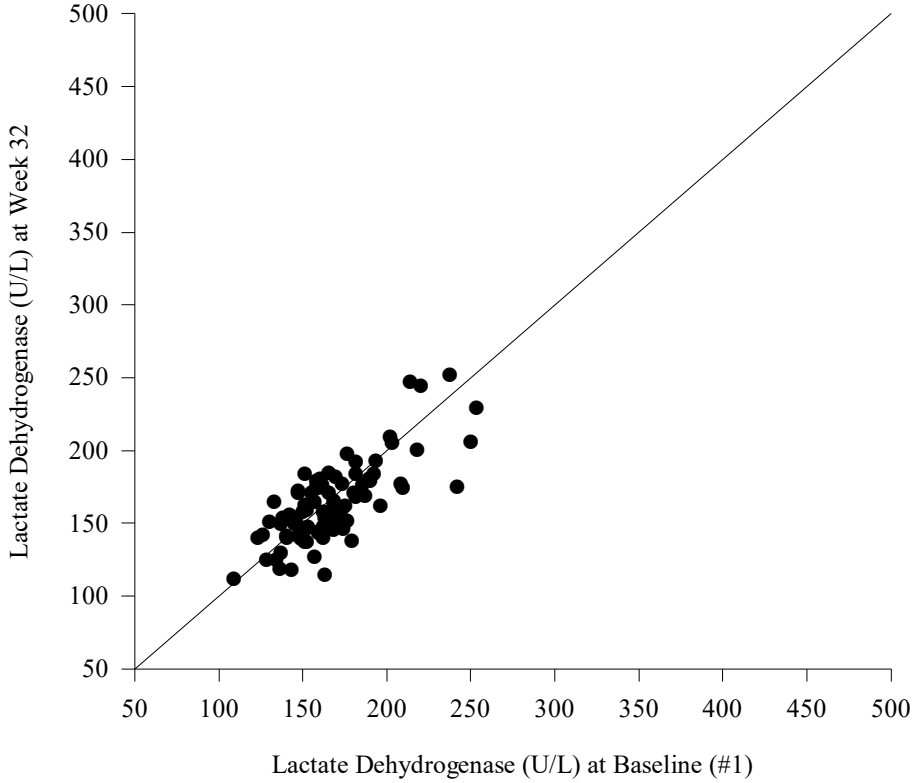


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 137 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (0%/5%)

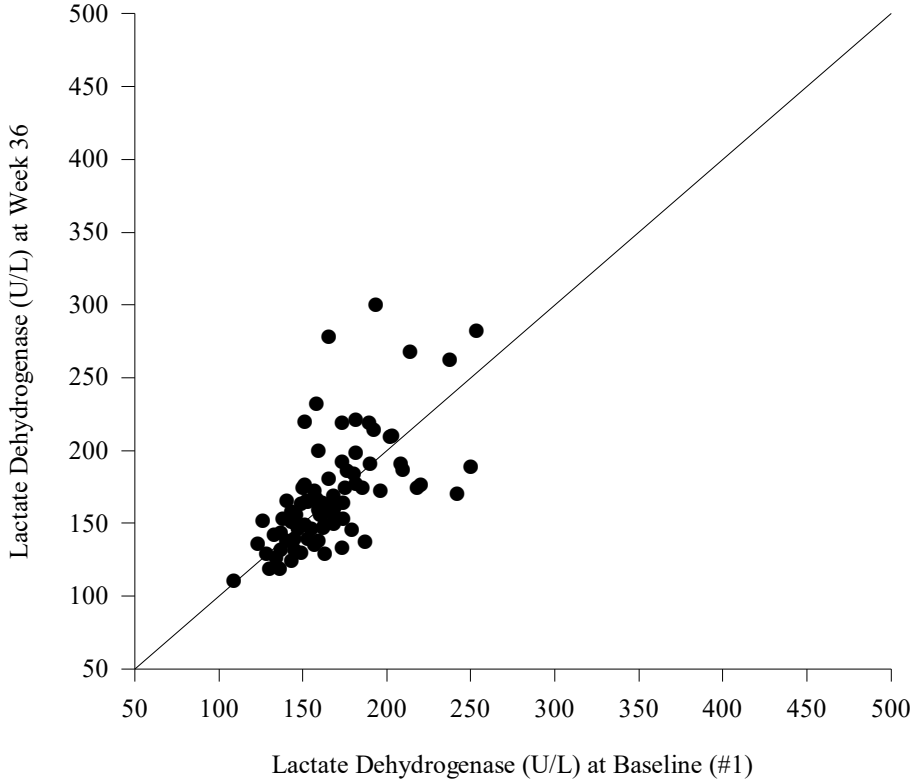


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 138 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (0%/5%)

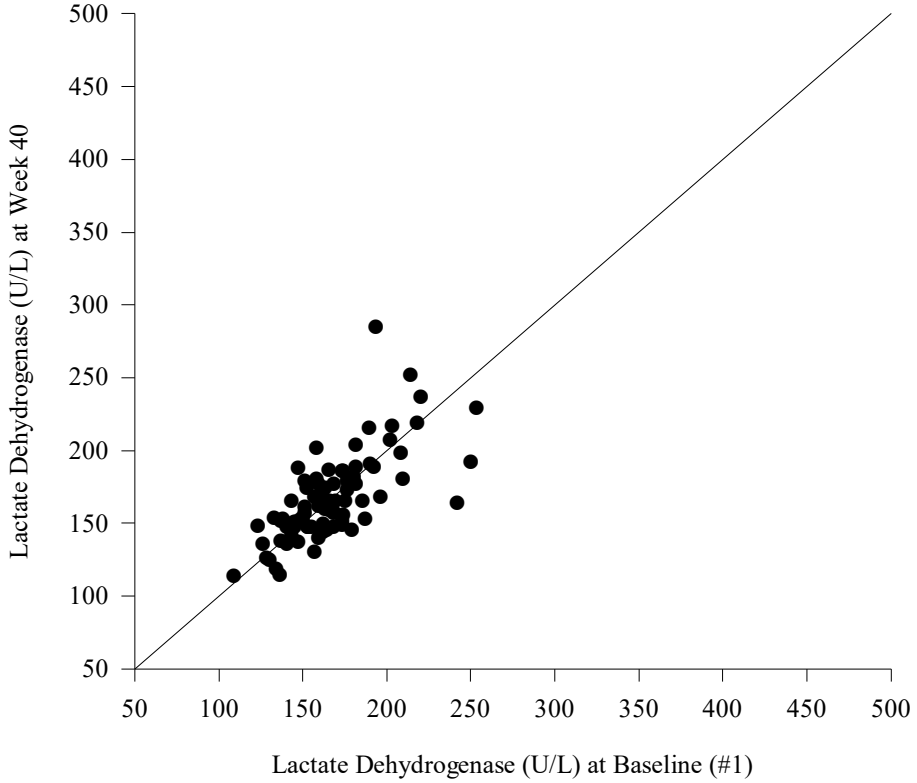


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 139 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (0%/5%)

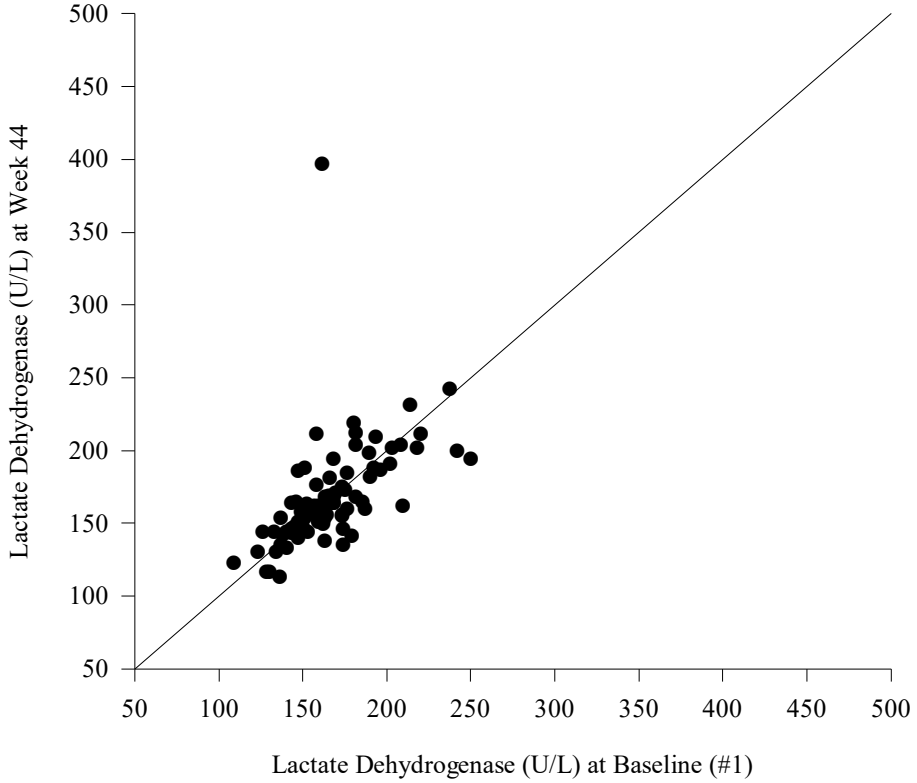


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 140 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (0%/5%)

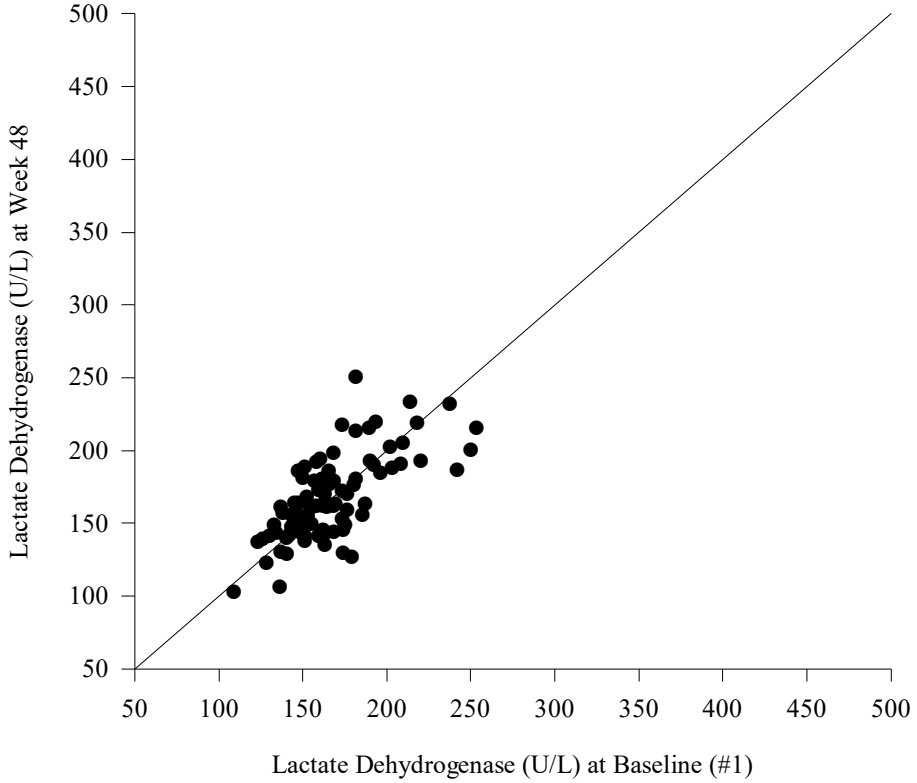


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 141 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (0%/5%)

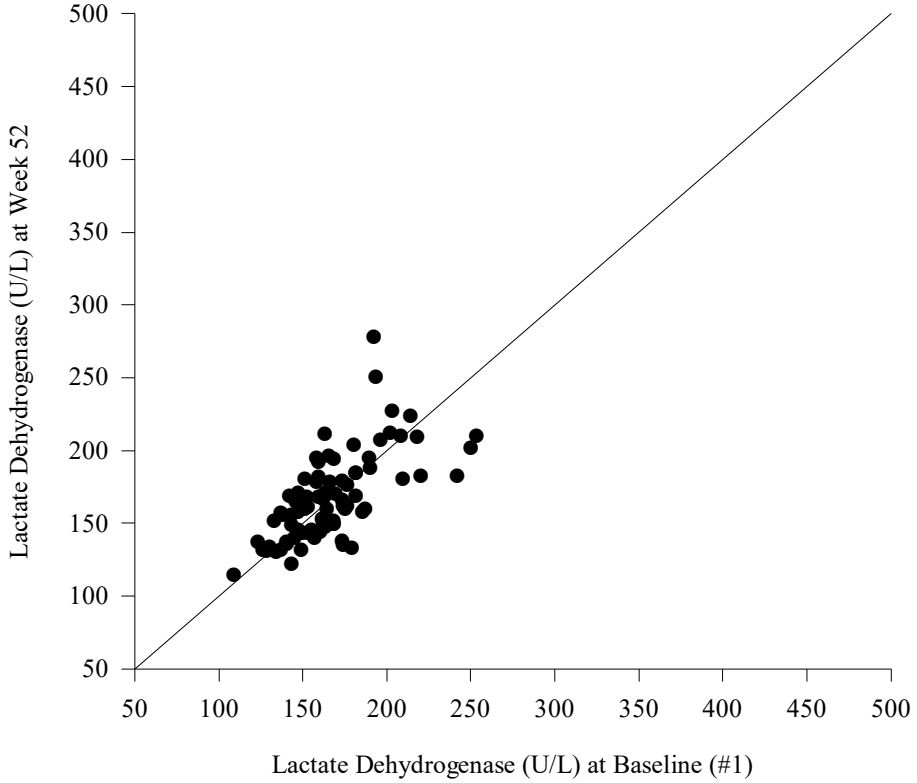


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 142 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (0%/5%)

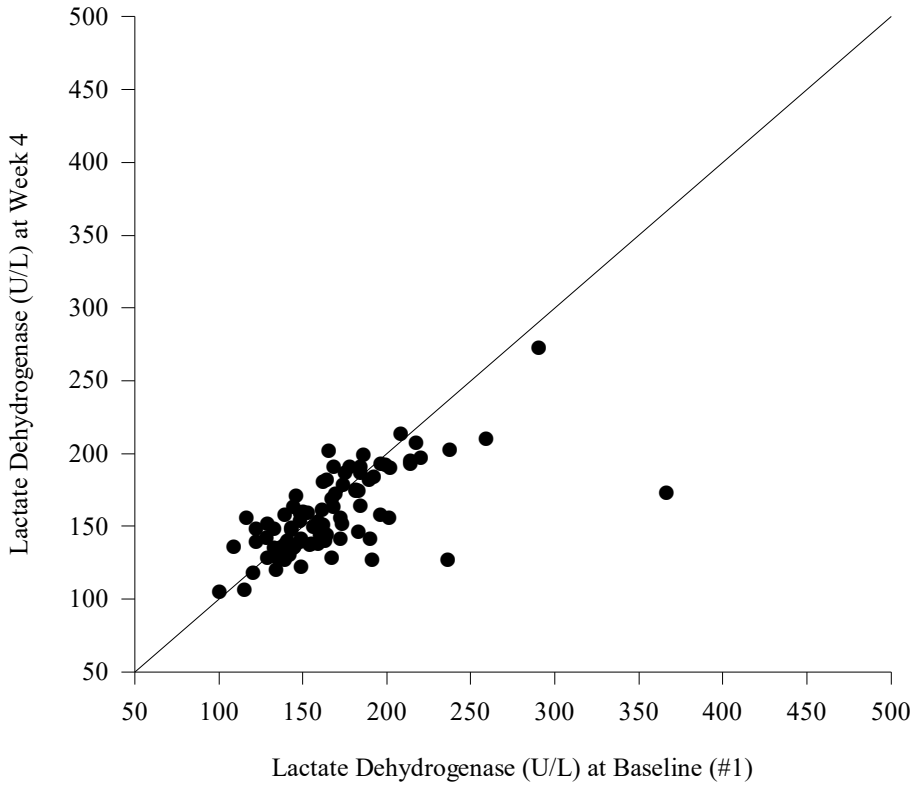


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 143 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (5%/5%)

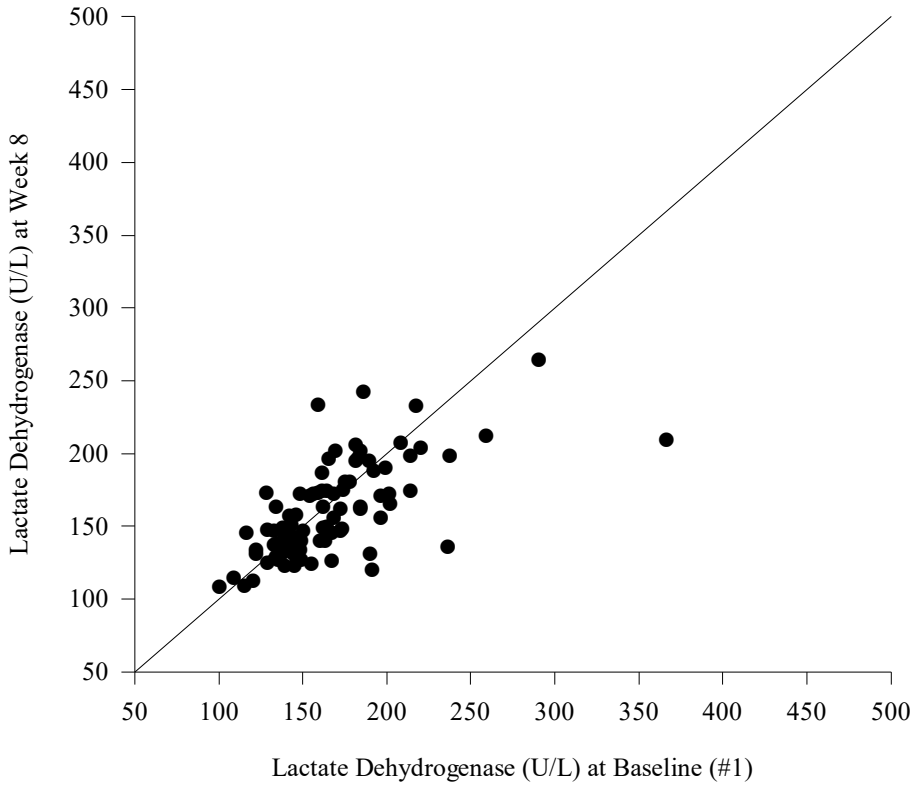


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 144 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (5%/5%)

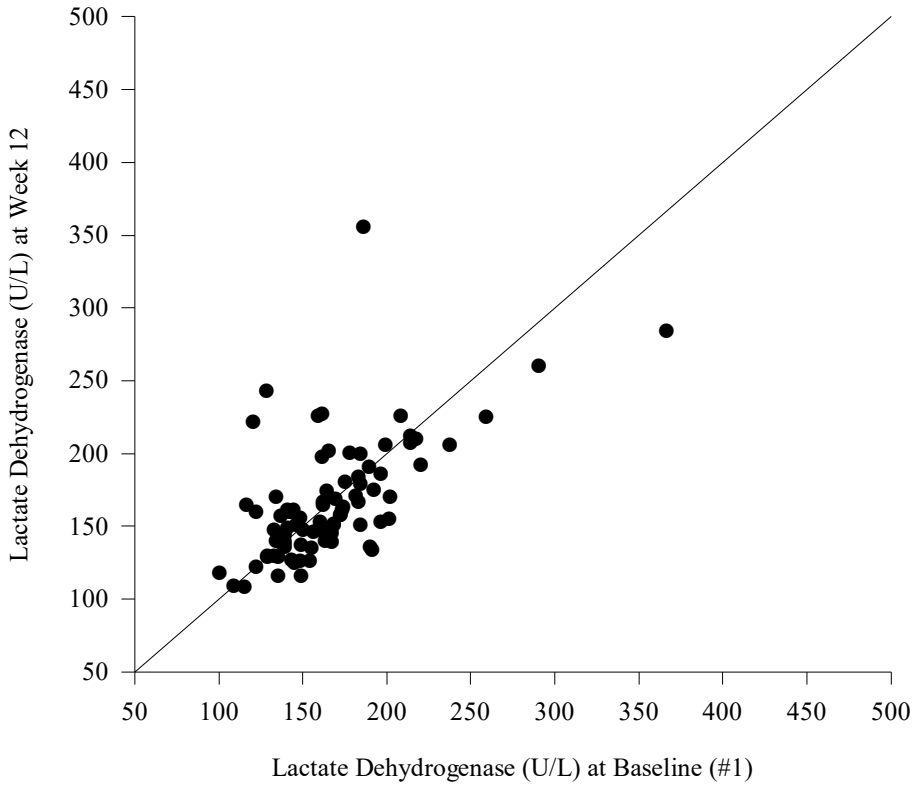


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 145 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (5%/5%)

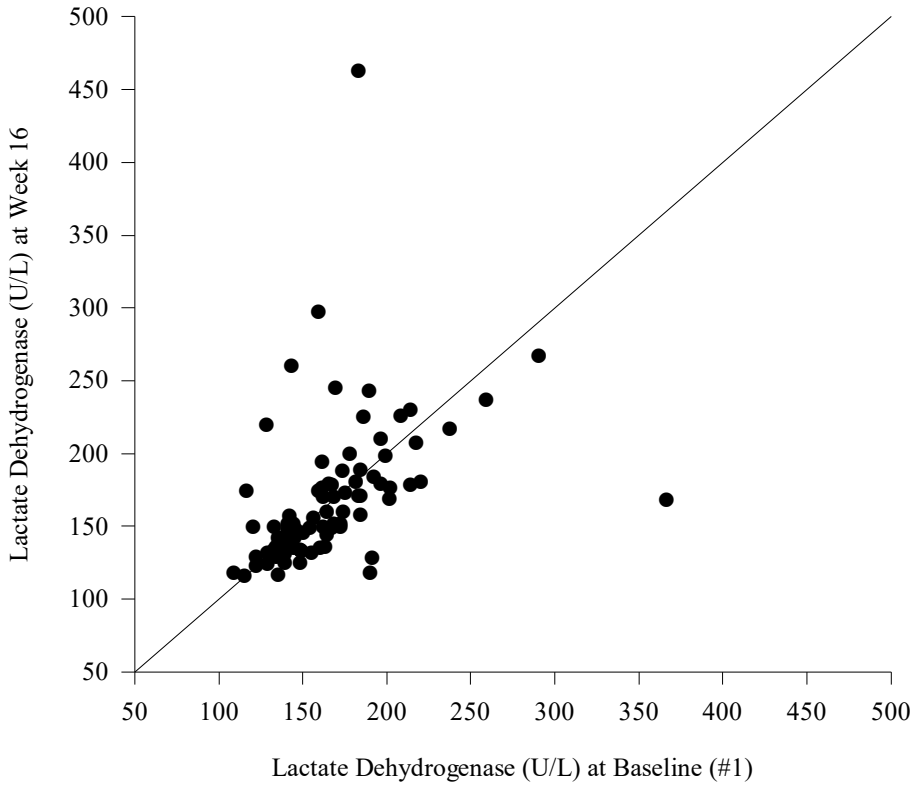


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 146 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (5%/5%)

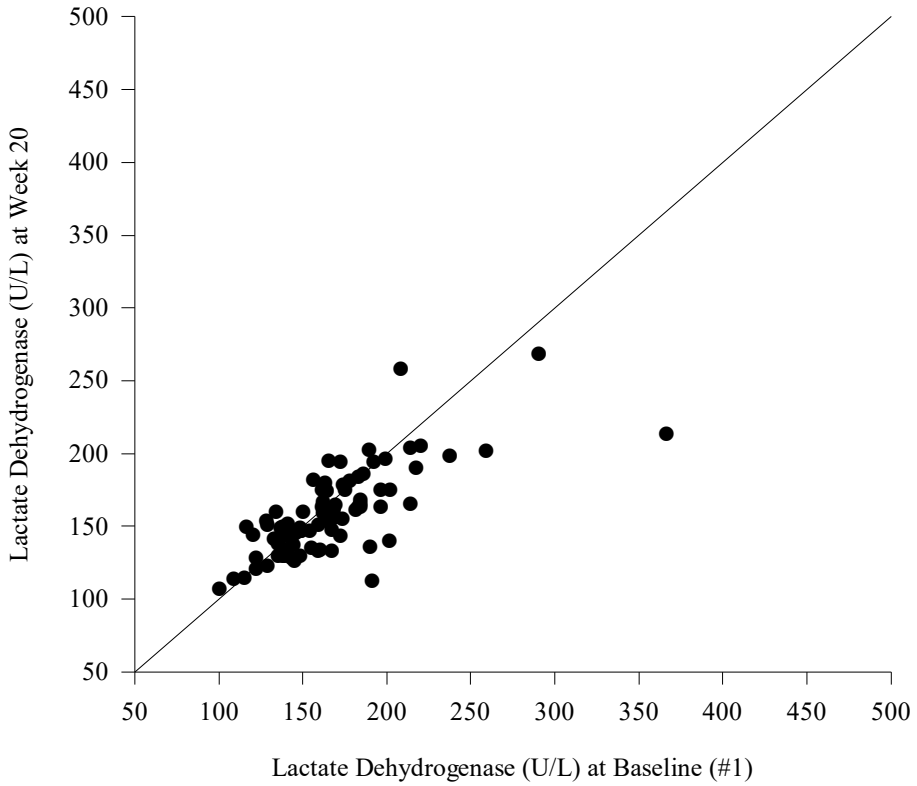


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 147 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (5%/5%)

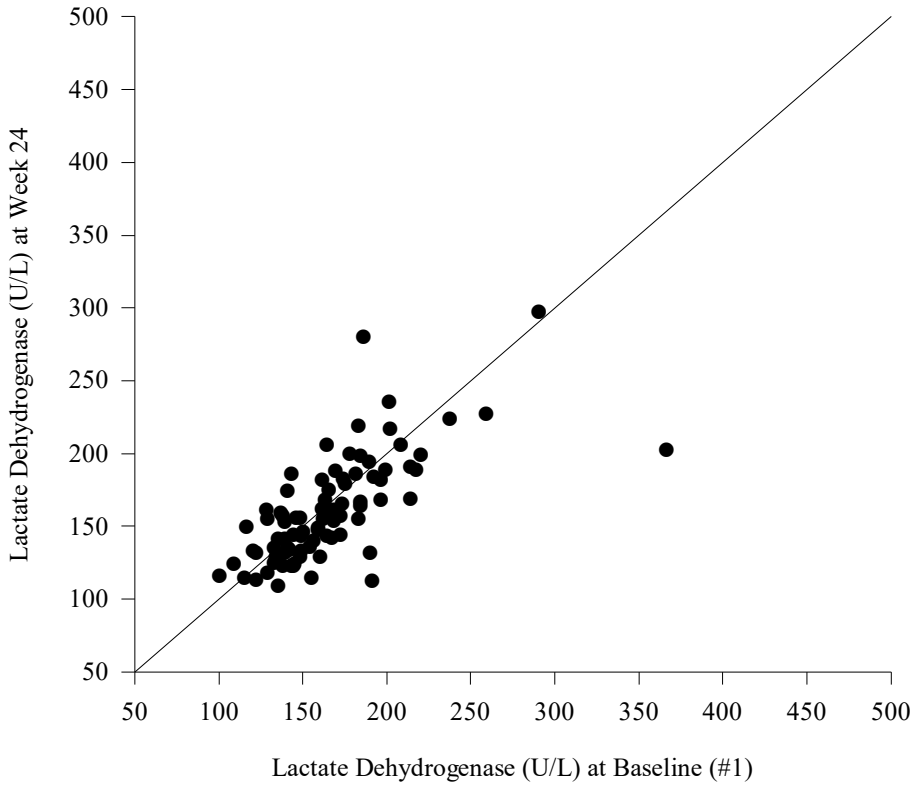


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 148 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (5%/5%)

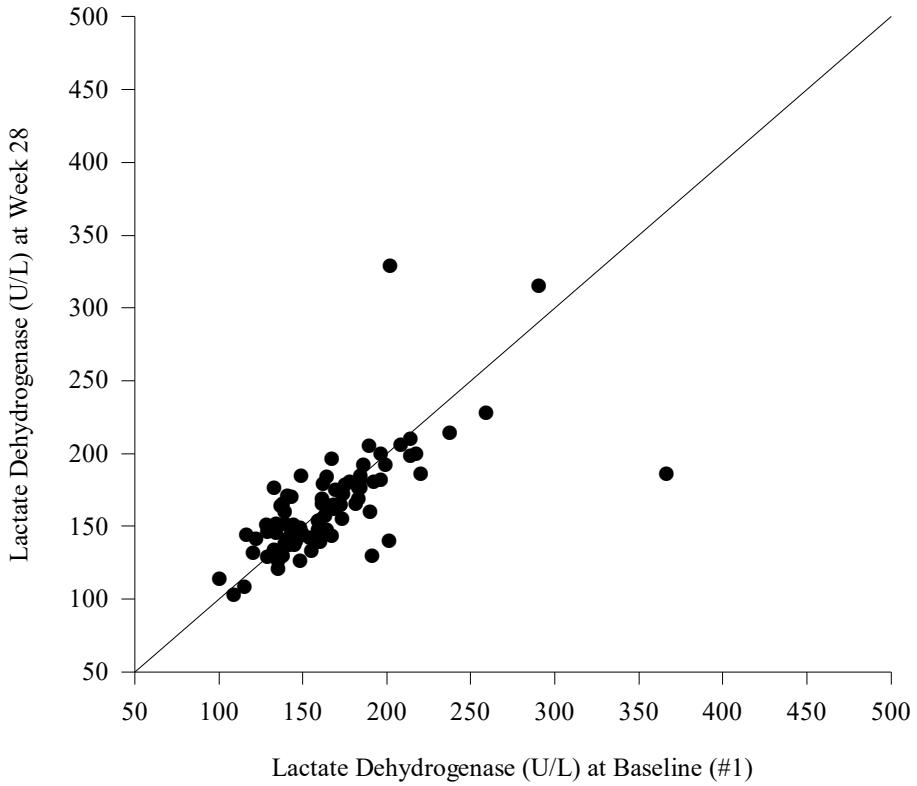


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 149 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (5%/5%)

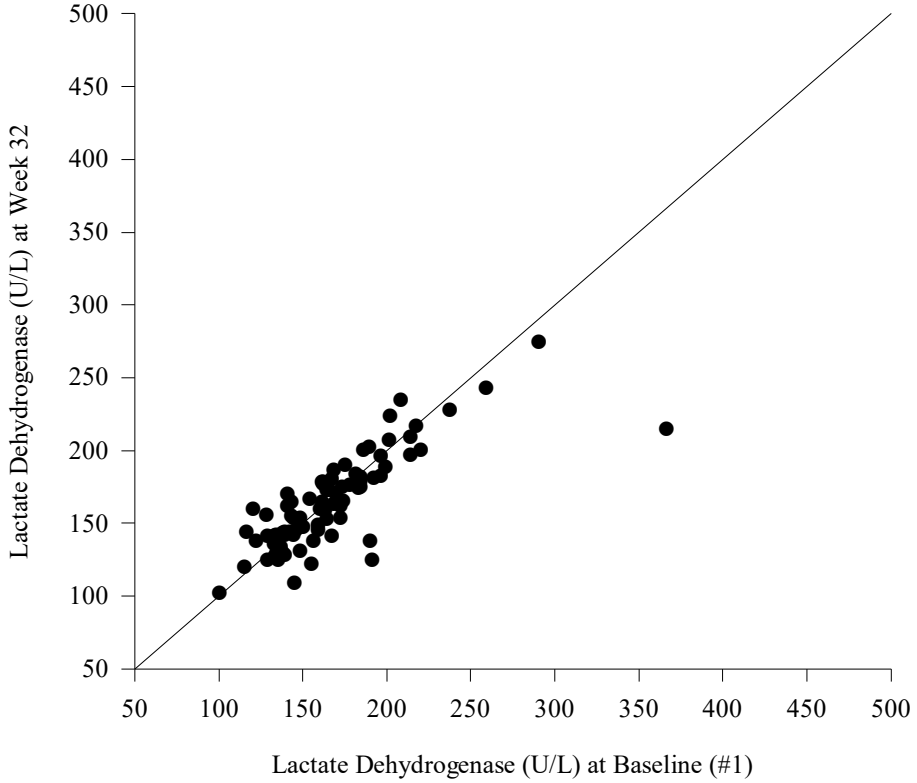


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 150 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (5%/5%)

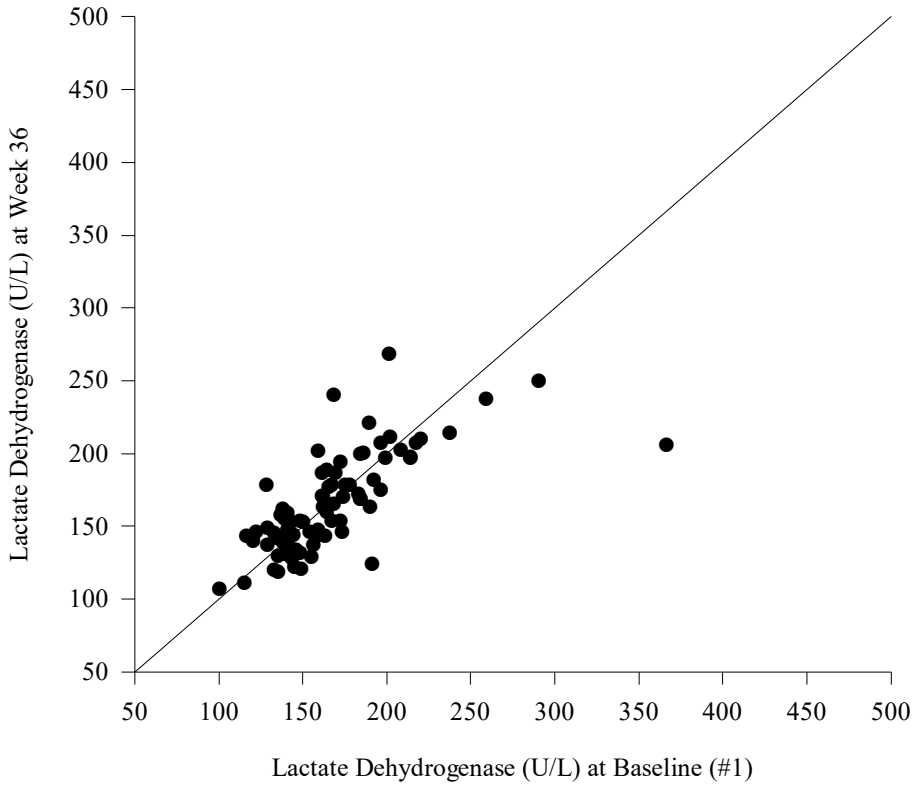


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 151 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (5%/5%)

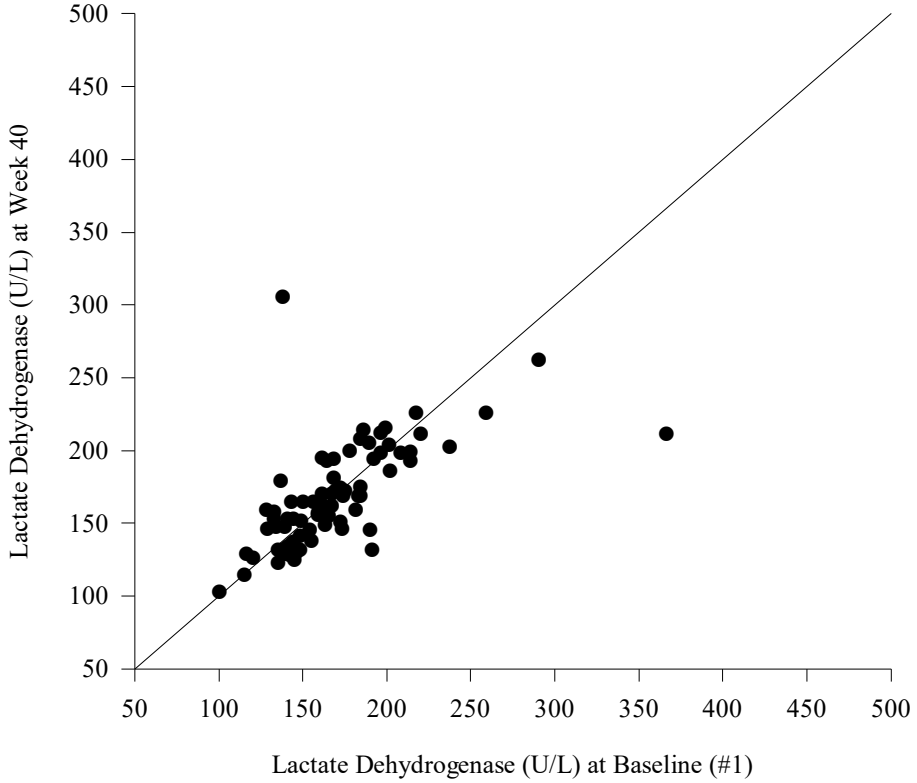


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 152 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (5%/5%)

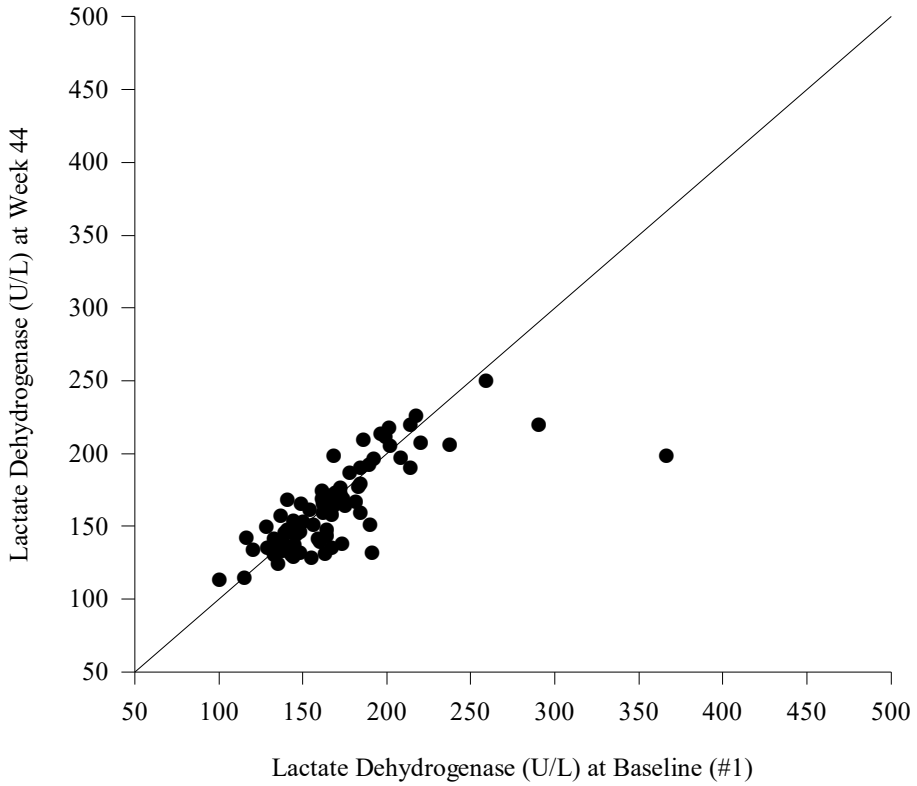


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 153 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (5%/5%)

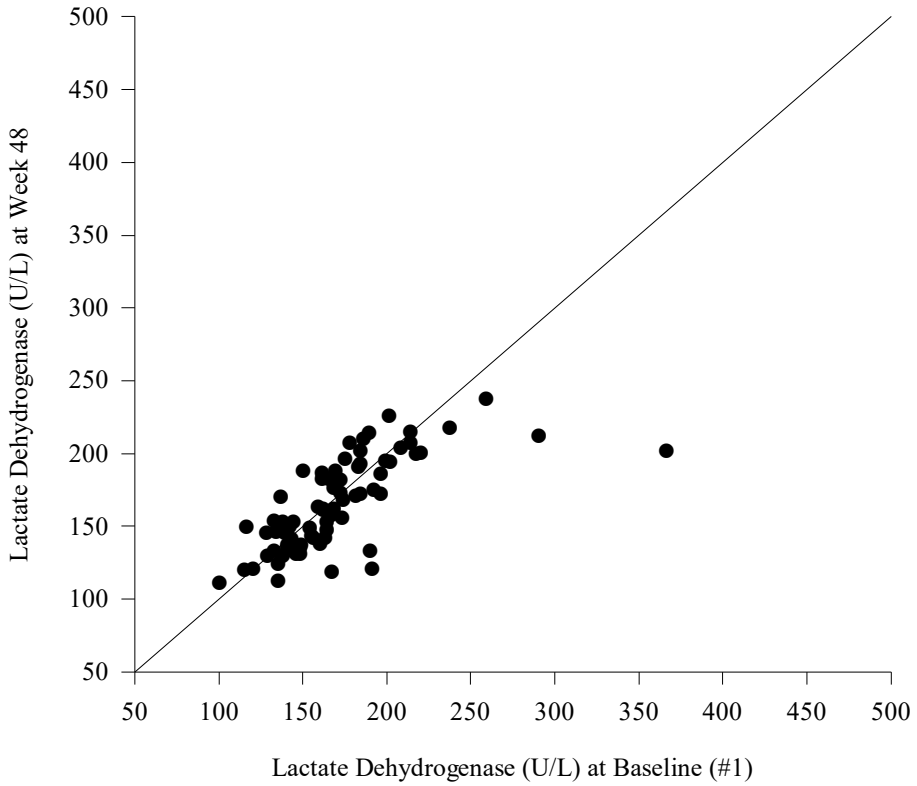


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 154 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (5%/5%)

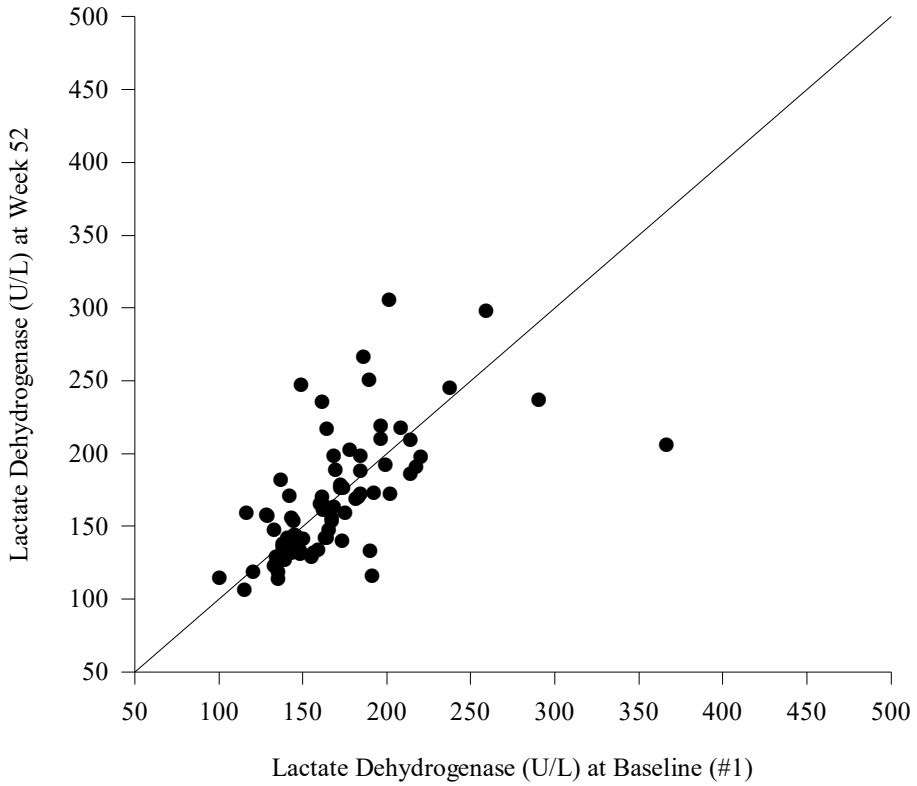


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 155 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (5%/5%)

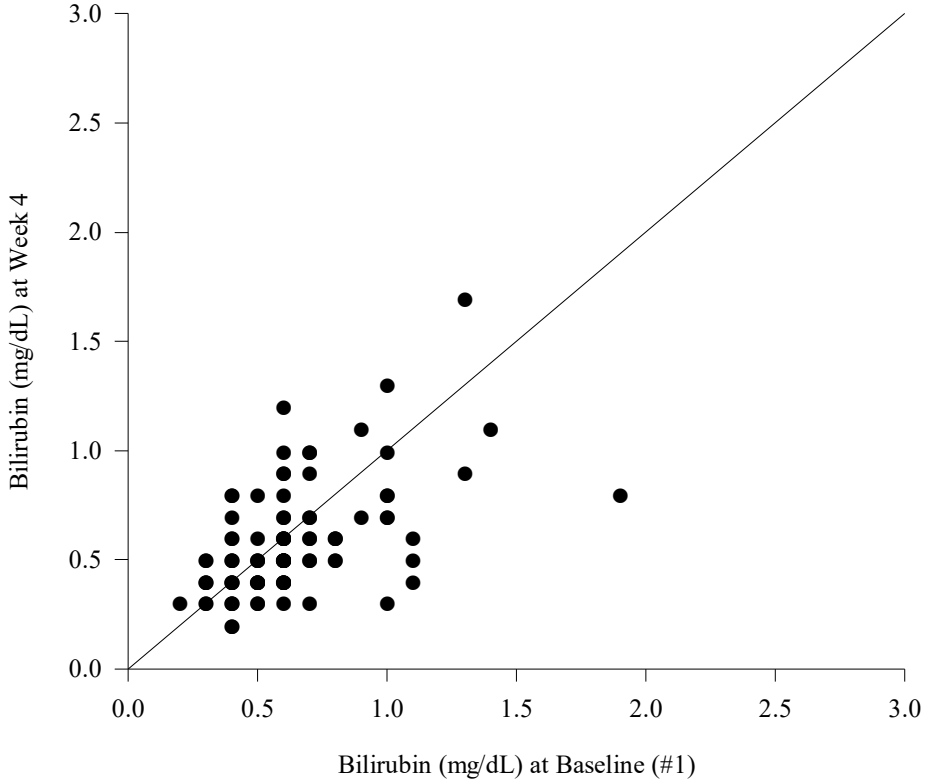


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 156 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (0%/5%)

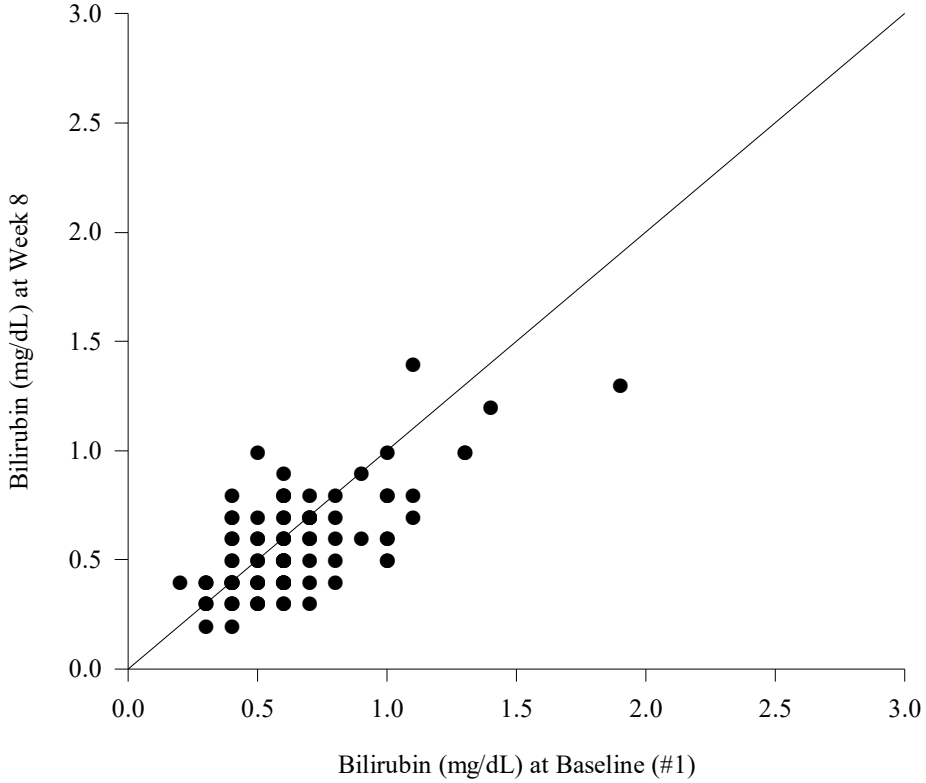


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 157 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (0%/5%)

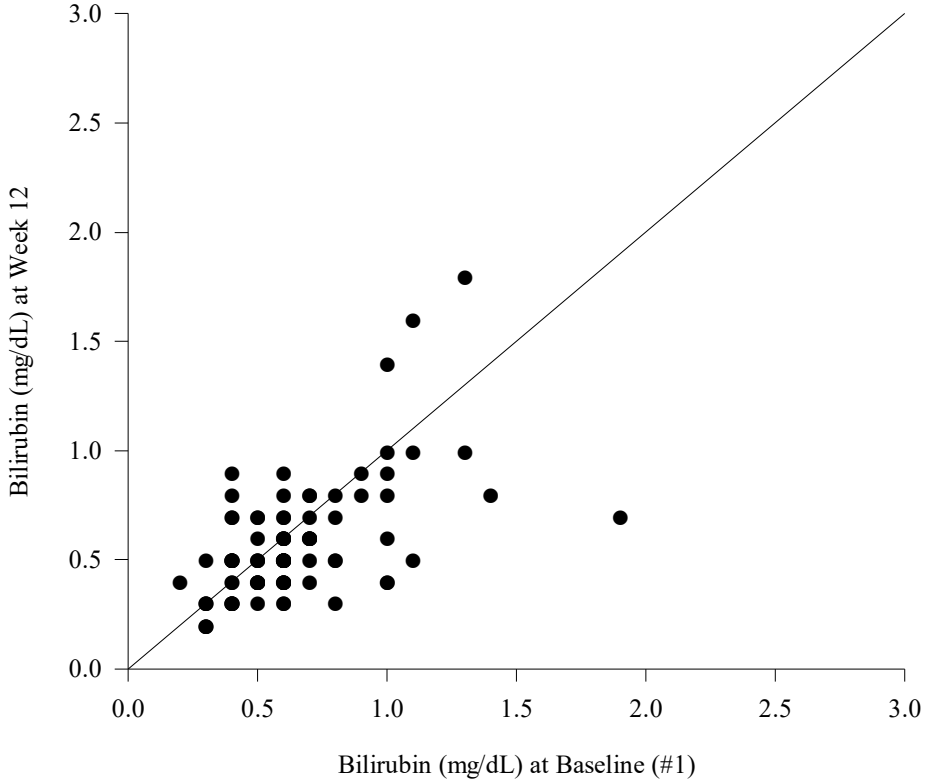


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 158 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (0%/5%)

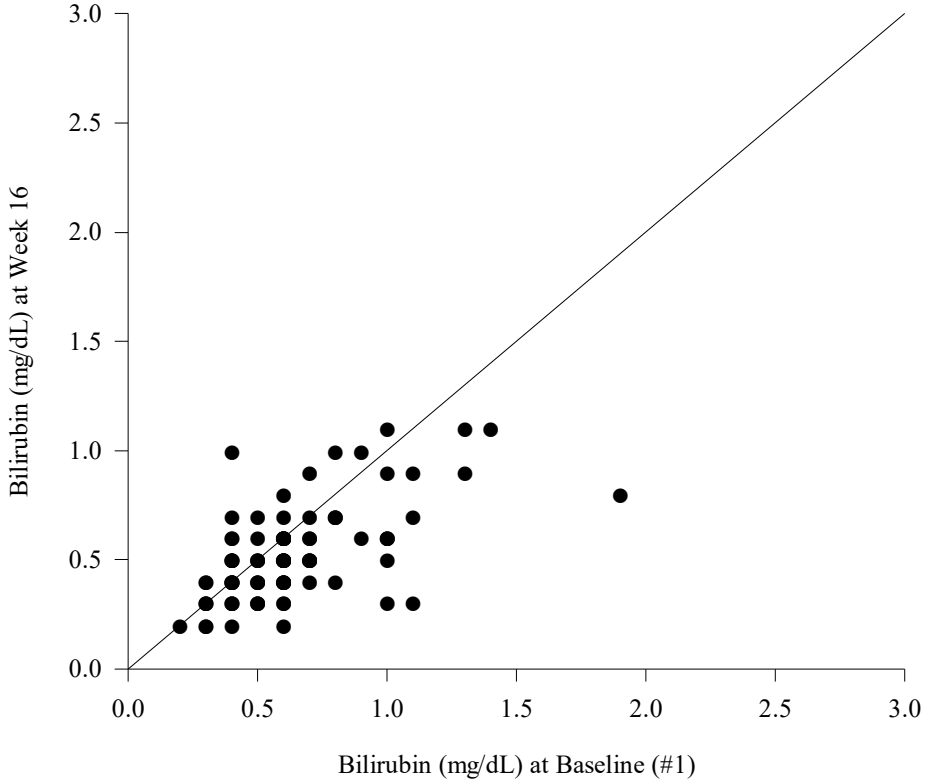


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 159 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (0%/5%)

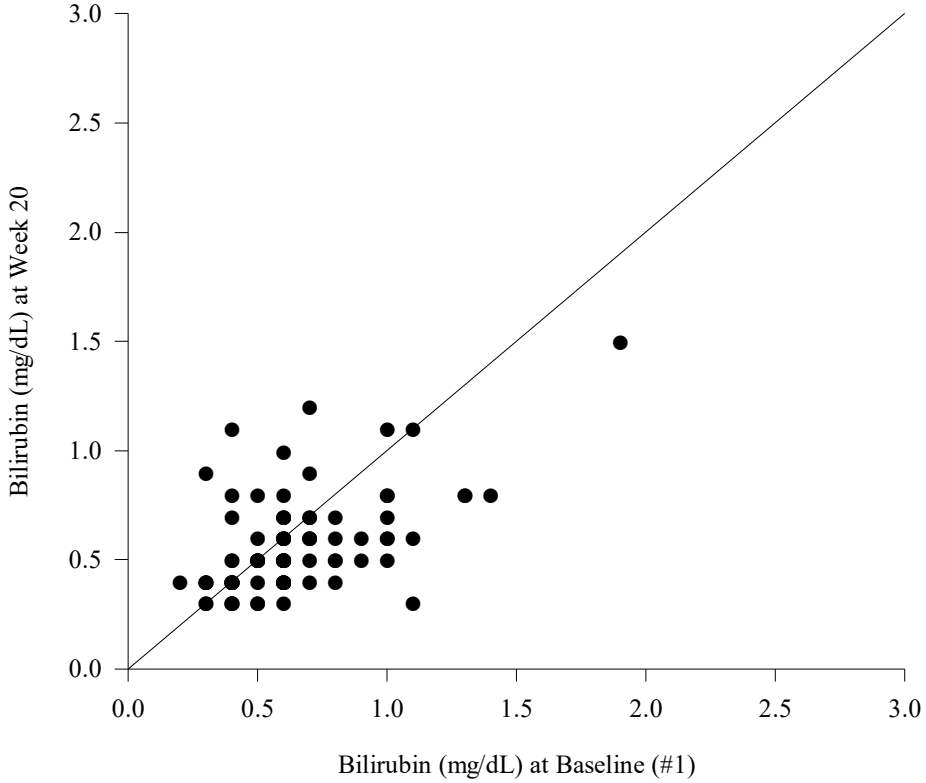


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 160 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (0%/5%)

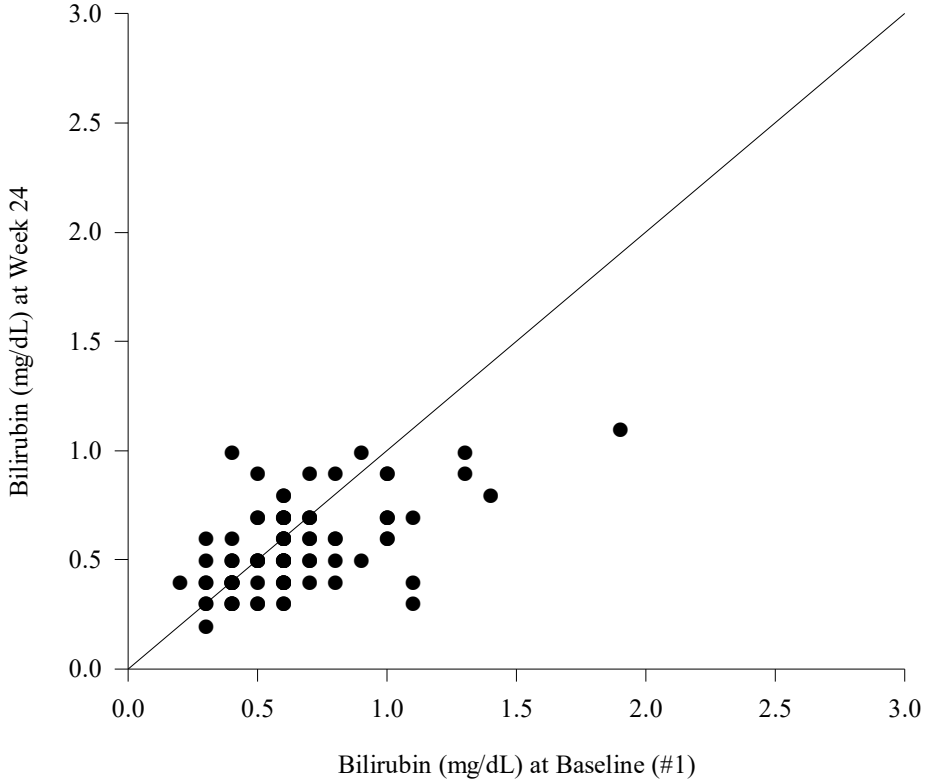


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 161 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (0%/5%)

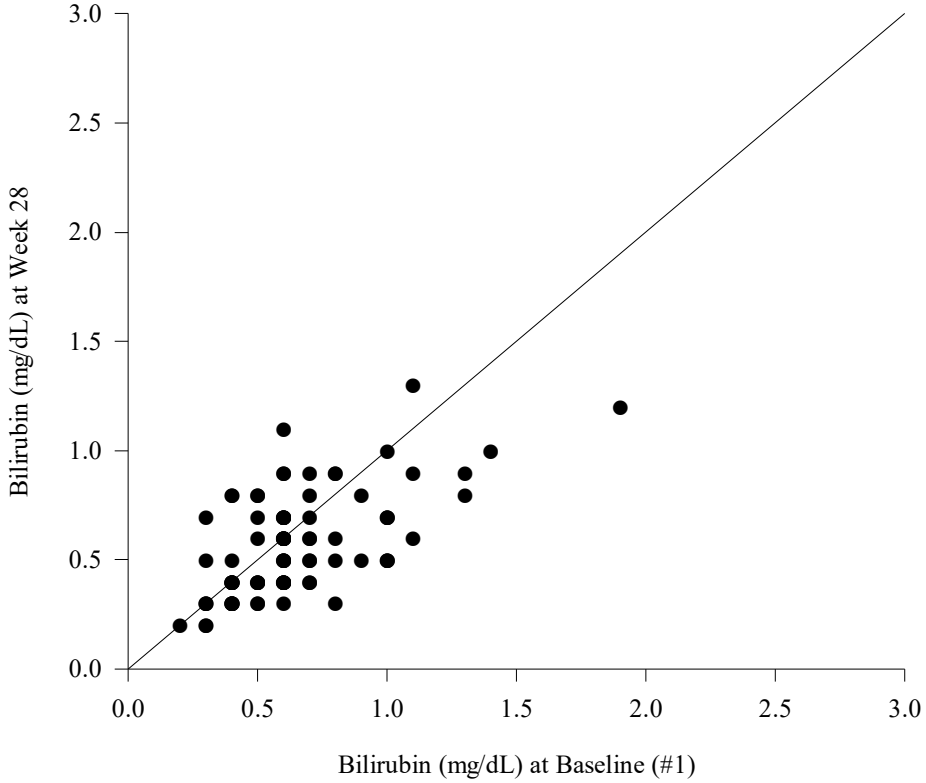


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 162 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (0%/5%)

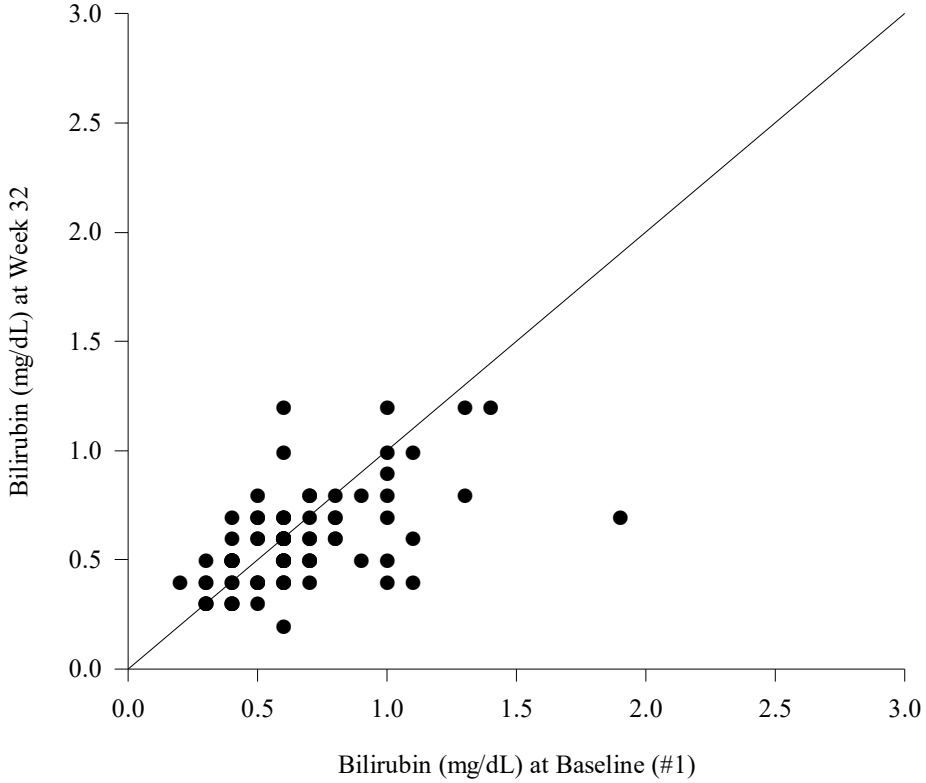


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 163 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (0%/5%)

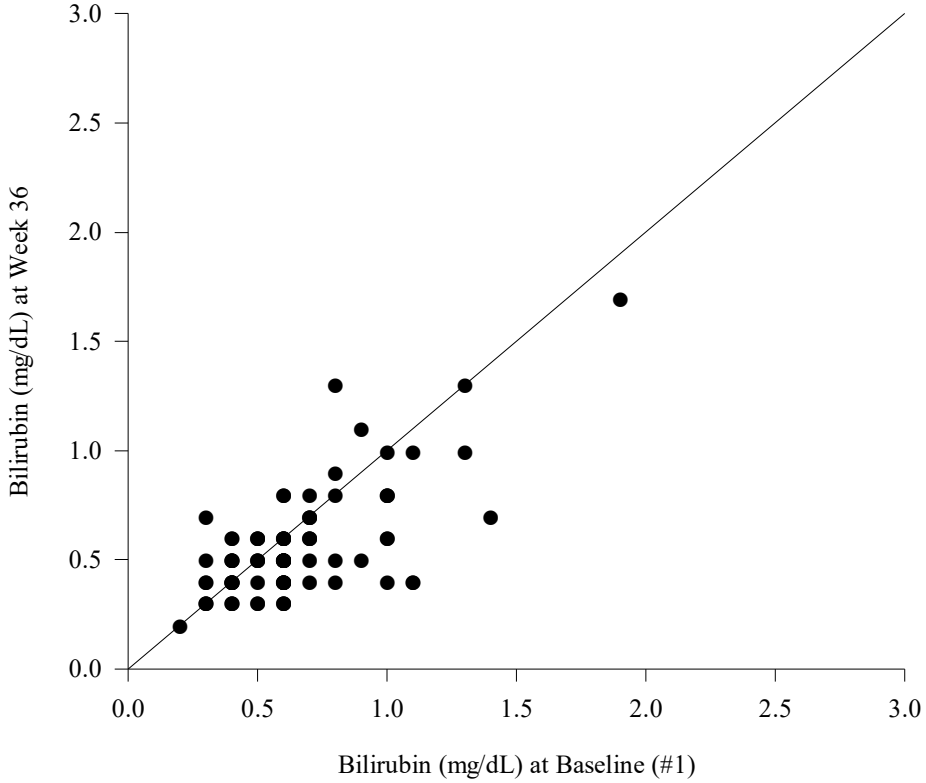


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 164 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (0%/5%)

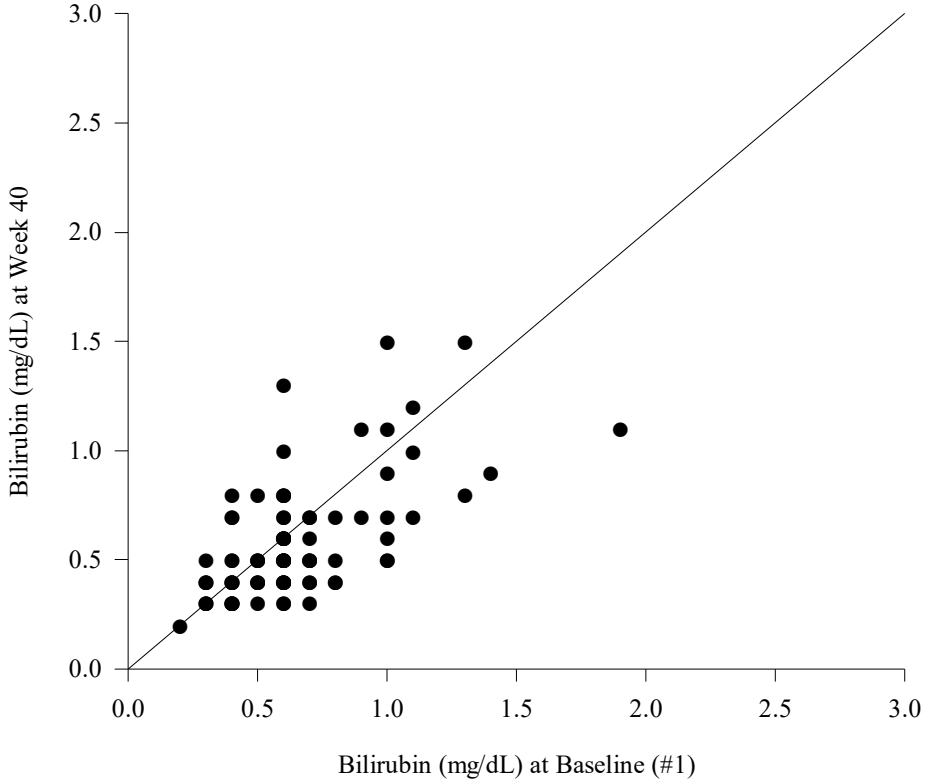


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 165 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (0%/5%)

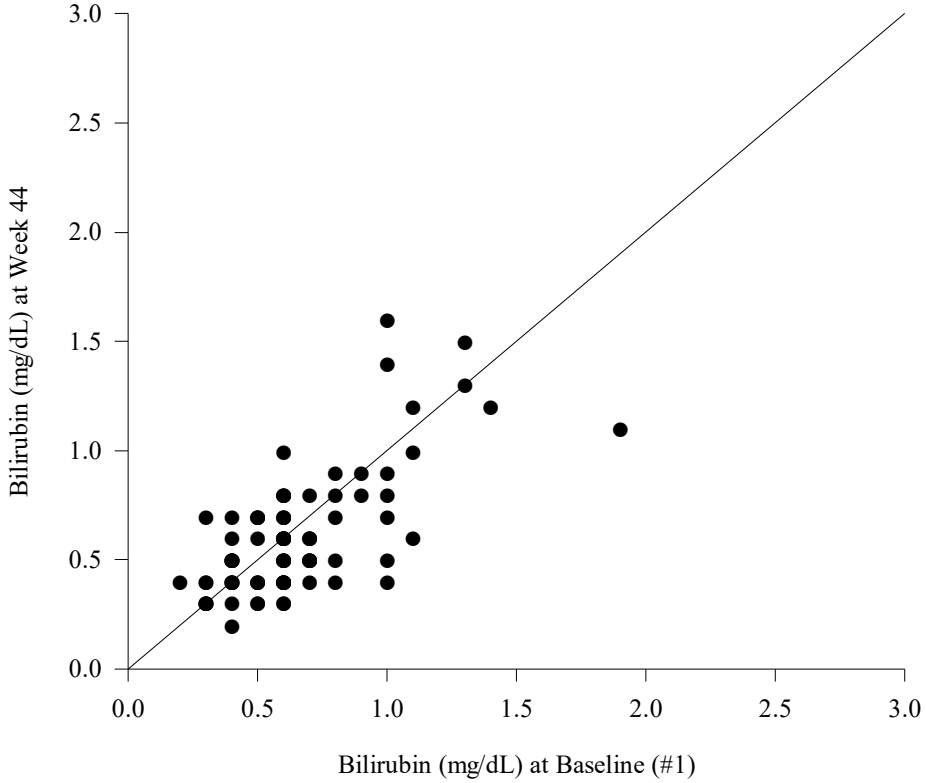


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 166 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (0%/5%)

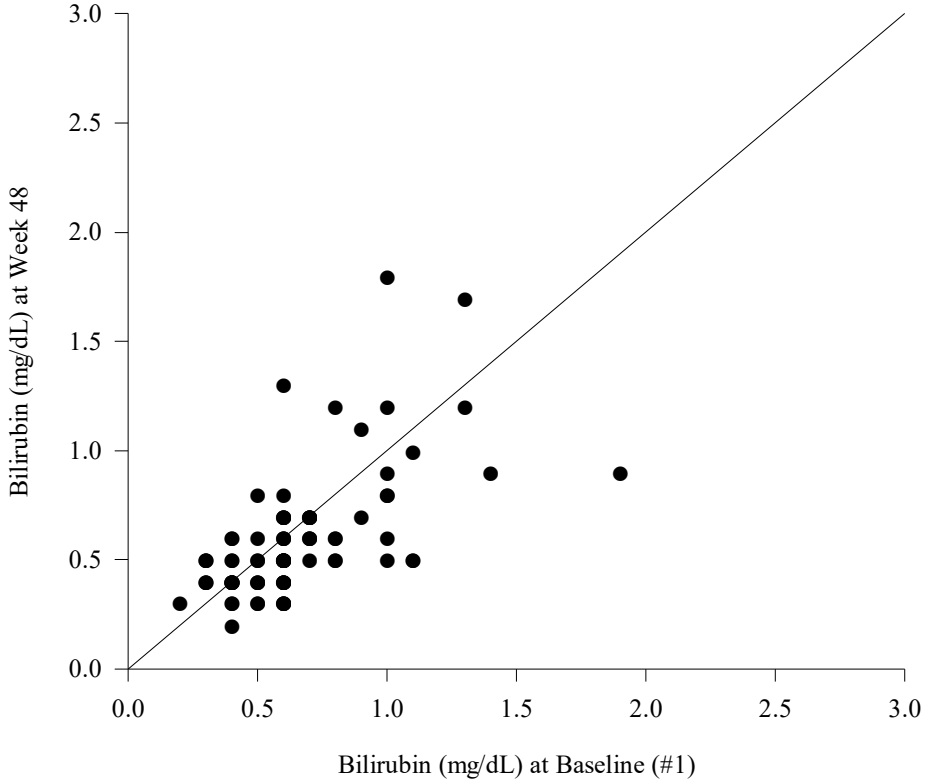


#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 167 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変

図 2.7.4-3　臨床検査値の散布図（BBI-4000-07 試験）（続き）
Biochemical（Safety Analysis Set）

Cohort 1 (0%/5%)



#1 : Baseline is defined as the value at Screening in BBI-4000-06 trial.

PAGE: 168 of 494
PROGRAM: f022 (OUTPUT: f14_03_04_04_scatter)
DATE: 2019/12/09
PROTOCOL NO: BBI-4000-07
Source：5.3.5.2-2 Figure 14.3.4-4 より改変