表 2.7.4.9－31　臨床検査値：実測値及びベースラインからの変化量（MT-6548-J03 試験）（続き）

Parameter:Bilirubin (mg/dL)

		Absolute					Change from Baseline					
Treatment Group	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean at Baseline (SD)	Mean	SD	Median	Minimum, Maximum
MT-6548	Baseline	162	0.41	0.14	0.40	(0.1, 1.0)						
	Week 2	160	0.39	0.13	0.40	(0.2, 1.0)	160	0.41 (0.14)	-0.02	0.08	0.00	(-0.4, 0.2)
	Week 4	157	0.40	0.14	0.40	(0.2, 1.0)	157	0.41 (0.14)	-0.01	0.10	0.00	(-0.4, 0.3)
	Week 6	155	0.39	0.13	0.40	(0.2, 1.0)	155	0.41 (0.14)	-0.02	0.10	0.00	(-0.4, 0.3)
	Week 8	152	0.41	0.14	0.40	(0.2, 0.9)	152	0.41 (0.14)	0.00	0.10	0.00	(-0.3, 0.3)
	Week 10	150	0.40	0.13	0.40	(0.2, 0.8)	150	0.41 (0.14)	-0.02	0.10	0.00	(-0.4, 0.4)
	Week 12	148	0.41	0.14	0.40	(0.2, 0.8)	148	0.42 (0.14)	-0.01	0.10	0.00	(-0.3, 0.4)
	Week 16	144	0.41	0.13	0.40	(0.2, 0.8)	144	0.42 (0.14)	-0.01	0.10	0.00	(-0.4, 0.3)
	Week 20	140	0.43	0.14	0.40	(0.2, 0.9)	140	0.42 (0.14)	0.01	0.11	0.00	(-0.4, 0.3)
	Week 24	138	0.41	0.14	0.40	(0.2, 1.0)	138	0.42 (0.14)	0.00	0.12	0.00	(-0.5, 0.4)
darbepoetin	Baseline	161	0.39	0.11	0.40	(0.2, 0.8)						
	Week 2	160	0.39	0.11	0.40	(0.2, 0.7)	160	0.39 (0.11)	0.01	0.09	0.00	(-0.2, 0.3)
	Week 4	159	0.40	0.12	0.40	(0.2, 0.9)	159	0.39 (0.11)	0.01	0.08	0.00	(-0.2, 0.3)
	Week 6	159	0.40	0.12	0.40	(0.2, 0.8)	159	0.39 (0.11)	0.01	0.09	0.00	(-0.3, 0.2)
	Week 8	158	0.40	0.12	0.40	(0.2, 0.8)	158	0.39 (0.11)	0.01	0.09	0.00	(-0.2, 0.3)
	Week 10	157	0.40	0.13	0.40	(0.2, 0.9)	157	0.39 (0.11)	0.01	0.10	0.00	(-0.3, 0.4)
	Week 12	157	0.39	0.12	0.40	(0.2, 0.9)	157	0.39 (0.11)	0.01	0.09	0.00	(-0.3, 0.3)
	Week 16	156	0.40	0.13	0.40	(0.2, 0.8)	156	0.39 (0.11)	0.01	0.10	0.00	(-0.2, 0.3)
	Week 20	154	0.41	0.12	0.40	(0.2, 0.9)	154	0.39 (0.11)	0.02	0.09	0.00	(-0.2, 0.3)
	Week 24	153	0.41	0.12	0.40	(0.2, 0.8)	153	0.39 (0.11)	0.02	0.09	0.00	(-0.3, 0.3)

表 2.7.4.9－31　臨床検査値：実測値及びベースラインからの変化量（MT-6548-J03 試験）（続き）

Parameter:Aspartate Aminotransferase (U/L)

		Absolute					Change from Baseline				
Treatment Group	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean at Baseline (SD)	Mean	SD	Median	Minimum, Maximum
MT-6548	Baseline	162	12.2	6.6	11.0	(3, 64)						
	Week 2	160	11.8	5.9	11.0	(3, 42)	160	12.1 (6.7)	-0.3	5.1	0.0	(-48, 18)
	Week 4	157	11.9	5.6	11.0	(3, 35)	157	12.1 (6.7)	-0.1	5.7	0.0	(-49, 22)
	Week 6	155	11.9	5.7	11.0	(3, 44)	155	12.1 (6.7)	-0.2	5.5	0.0	(-49, 20)
	Week 8	152	11.8	7.2	11.0	(3, 76)	152	12.0 (6.7)	-0.3	6.9	0.0	(-50, 52)
	Week 10	150	11.6	5.1	11.0	(3, 29)	150	12.0 (6.7)	-0.4	5.3	0.0	(-46, 16)
	Week 12	148	11.8	5.2	11.0	(3, 30)	148	12.0 (6.7)	-0.2	5.6	0.0	(-53, 12)
	Week 16	144	12.0	5.5	12.0	(3, 41)	144	11.8 (6.7)	0.1	5.9	0.0	(-47, 33)
	Week 20	140	12.4	6.6	12.0	(3, 62)	140	11.8 (6.8)	0.7	7.1	1.0	(-51, 51)
	Week 24	138	12.4	5.2	12.0	(3, 32)	138	11.8 (6.8)	0.6	5.9	1.0	(-50, 13)
darbepoetin	Baseline	161	12.4	5.6	12.0	(3, 36)						
	Week 2	160	12.1	4.8	12.0	(3, 29)	160	12.4 (5.6)	-0.3	3.6	0.0	(-22, 11)
	Week 4	159	12.2	5.7	12.0	(2, 45)	159	12.3 (5.5)	-0.1	4.8	0.0	(-18, 33)
	Week 6	159	11.6	4.8	11.0	(3, 29)	159	12.3 (5.5)	-0.7	3.5	0.0	(-17, 7)
	Week 8	158	11.8	5.0	11.5	(3, 36)	158	12.3 (5.5)	-0.5	3.9	0.0	(-23, 15)
	Week 10	157	11.6	4.7	11.0	(3, 30)	157	12.3 (5.5)	-0.7	3.7	0.0	(-17, 12)
	Week 12	157	12.2	5.7	12.0	(3, 39)	157	12.3 (5.5)	-0.1	4.1	0.0	(-17, 17)
	Week 16	156	12.8	5.6	12.0	(3, 35)	156	12.3 (5.5)	0.5	4.5	0.0	(-17, 21)
	Week 20	154	13.3	6.0	12.5	(3, 42)	154	12.3 (5.6)	0.9	5.0	1.0	(-16, 27)
	Week 24	153	14.6	16.1	13.0	(3, 197)	153	12.3 (5.6)	2.3	16.5	1.0	(-18, 193)

表 2.7.4.9－31　臨床検査値：実測値及びベースラインからの変化量（MT-6548-J03 試験）（続き）

Parameter:Alanine Aminotransferase (U/L)

		Absolute					Change from Baseline				
Treatment Group	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean at Baseline (SD)	Mean	SD	Median	Minimum, Maximum
MT-6548	Baseline	162	10.5	6.2	9.0	(3, 54)						
	Week 2	160	9.5	5.1	8.0	(3, 33)	160	10.5 (6.2)	-1.1	4.9	0.0	(-39, 13)
	Week 4	157	9.6	5.3	9.0	(2, 45)	157	10.6 (6.2)	-1.0	5.2	-1.0	(-42, 18)
	Week 6	155	9.6	6.3	8.0	(2, 50)	155	10.5 (6.2)	-1.0	6.0	-1.0	(-42, 30)
	Week 8	152	8.8	5.0	7.5	(3, 44)	152	10.4 (6.1)	-1.6	5.5	-1.0	(-42, 26)
	Week 10	150	8.5	4.3	7.5	(3, 31)	150	10.3 (6.1)	-1.8	4.8	-1.0	(-36, 13)
	Week 12	148	8.4	4.0	7.5	(3, 25)	148	10.3 (6.1)	-1.9	5.2	-1.0	(-42, 7)
	Week 16	144	8.5	3.9	8.0	(3, 26)	144	10.2 (6.1)	-1.7	5.0	-1.0	(-35, 13)
	Week 20	140	9.0	4.4	8.0	(3, 27)	140	10.3 (6.1)	-1.4	5.8	-1.0	(-44, 20)
	Week 24	138	9.1	4.3	8.0	(1, 31)	138	10.4 (6.2)	-1.3	5.6	0.0	(-41, 18)
darbepoetin	Baseline	161	10.2	5.3	9.0	(4, 41)						
	Week 2	160	9.9	4.9	9.0	(3, 28)	160	10.2 (5.4)	-0.3	3.1	0.0	(-17, 10)
	Week 4	159	10.2	5.5	9.0	(3, 38)	159	10.1 (5.3)	0.0	4.3	0.0	(-19, 25)
	Week 6	159	9.8	4.9	9.0	(3, 29)	159	10.1 (5.3)	-0.3	3.8	0.0	(-22, 13)
	Week 8	158	9.8	5.0	9.0	(3, 33)	158	10.1 (5.3)	-0.3	4.3	0.0	(-29, 18)
	Week 10	157	9.8	5.1	9.0	(3, 39)	157	10.1 (5.3)	-0.3	3.9	0.0	(-27, 16)
	Week 12	157	10.3	6.8	9.0	(3, 57)	157	10.1 (5.3)	0.3	4.2	0.0	(-10, 28)
	Week 16	156	10.7	5.8	9.0	(3, 45)	156	10.1 (5.4)	0.7	4.8	0.0	(-17, 35)
	Week 20	154	11.5	7.9	10.0	(3, 77)	154	10.1 (5.4)	1.4	7.1	0.0	(-22, 67)
	Week 24	153	12.6	17.4	10.0	(2, 211)	153	10.1 (5.4)	2.5	17.7	1.0	(-29, 206)

表 2.7.4.9－31　臨床検査値：実測値及びベースラインからの変化量（MT-6548-J03 試験）（続き）

Parameter:Alkaline Phosphatase (U/L)

		Absolute					Change from Baseline				
Treatment Group	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean at Baseline (SD)	Mean	SD	Median	Minimum, Maximum
MT-6548	Baseline	162	239.9	93.8	217.0	(73, 604)						
	Week 2	160	242.1	93.5	220.5	(69, 581)	160	240.1 (94.3)	2.0	39.7	-1.0	(-139, 157)
	Week 4	157	237.8	91.2	221.0	(77, 587)	157	237.8 (89.9)	0.0	40.5	-4.0	(-144, 193)
	Week 6	155	236.6	88.9	220.0	(72, 523)	155	237.9 (90.3)	-1.3	47.1	-2.0	(-237, 156)
	Week 8	152	232.1	89.8	213.5	(78, 573)	152	236.1 (89.5)	-4.0	48.0	-7.5	(-207, 159)
	Week 10	150	232.2	90.3	214.0	(74, 609)	150	237.0 (89.8)	-4.8	50.2	-8.0	(-165, 176)
	Week 12	148	235.8	93.7	216.5	(71, 564)	148	237.0 (89.9)	-1.3	48.0	-2.0	(-181, 156)
	Week 16	144	236.3	93.0	218.5	(78, 576)	144	237.5 (90.9)	-1.2	54.3	-4.5	(-199, 236)
	Week 20	140	228.7	84.6	218.0	(69, 639)	140	233.6 (87.2)	-4.9	55.8	-4.0	(-211, 153)
	Week 24	138	233.1	88.2	215.5	(69, 620)	138	233.2 (87.1)	-0.1	62.4	5.5	(-269, 211)
darbepoetin	Baseline	161	238.2	85.6	226.0	(81, 543)						
	Week 2	160	234.8	79.6	224.0	(74, 492)	160	236.8 (83.9)	-2.0	34.6	-3.0	(-107, 141)
	Week 4	159	231.1	76.3	227.0	(93, 478)	159	235.3 (82.1)	-4.3	31.8	-1.0	(-150, 84)
	Week 6	159	227.6	79.1	217.0	(76, 603)	159	235.3 (82.1)	-7.7	40.0	-7.0	(-167, 108)
	Week 8	158	228.3	79.1	217.0	(81, 488)	158	235.0 (82.3)	-6.7	41.2	-6.0	(-193, 121)
	Week 10	157	228.1	77.1	219.0	(74, 536)	157	235.6 (82.3)	-7.4	42.5	-7.0	(-186, 119)
	Week 12	157	230.1	78.4	217.0	(71, 549)	157	235.6 (82.3)	-5.4	42.2	-2.0	(-163, 90)
	Week 16	156	233.7	89.8	220.0	(77, 625)	156	235.7 (82.5)	-2.0	52.1	-2.0	(-160, 265)
	Week 20	154	234.0	84.4	220.5	(72, 480)	154	235.8 (83.1)	-1.8	51.9	-1.5	(-122, 214)
	Week 24	153	236.2	81.4	227.0	(73, 546)	153	236.1 (83.3)	0.1	47.8	1.0	(-113, 167)

表 2.7.4.9－31　臨床検査値：実測値及びベースラインからの変化量（MT-6548-J03 試験）（続き）

Parameter:Lactate Dehydrogenase (U/L)

		Absolute					Change from Baseline					
Treatment Group	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean at Baseline (SD)	Mean	SD	Median	Minimum, Maximum
MT-6548	Baseline	162	184.3	45.3	176.0	(99, 394)						
	Week 2	160	193.4	43.8	184.5	(116, 401)	160	184.1 (45.4)	9.3	28.3	9.5	(-148, 95)
	Week 4	157	192.6	45.0	184.0	(113, 403)	157	184.0 (45.5)	8.7	30.6	10.0	(-152, 116)
	Week 6	155	193.7	45.0	186.0	(118, 447)	155	183.3 (45.1)	10.4	29.8	10.0	(-138, 82)
	Week 8	152	193.6	56.4	183.5	(119, 614)	152	183.1 (44.3)	10.4	45.8	8.0	(-172, 397)
	Week 10	150	194.6	46.2	188.5	(109, 351)	150	183.2 (44.5)	11.4	33.6	13.5	(-179, 96)
	Week 12	148	195.1	52.8	181.0	(109, 449)	148	183.3 (44.8)	11.8	38.8	12.0	(-167, 199)
	Week 16	144	196.2	49.0	186.5	(113, 394)	144	183.5 (45.3)	12.7	40.6	14.0	(-188, 144)
	Week 20	140	202.4	49.1	196.0	(110, 401)	140	183.5 (45.5)	19.0	41.6	17.5	(-195, 157)
	Week 24	138	195.2	45.6	191.0	(118, 382)	138	183.2 (45.8)	12.0	32.4	13.0	(-127, 110)
darbepoetin	Baseline	161	182.8	42.2	176.0	(94, 373)						
	Week 2	160	183.4	44.6	177.5	(94, 426)	160	182.8 (42.3)	0.6	30.9	2.0	(-176, 152)
	Week 4	159	184.4	45.2	178.0	(79, 517)	159	182.7 (42.4)	1.8	34.0	1.0	(-181, 275)
	Week 6	159	182.3	39.7	177.0	(91, 406)	159	182.7 (42.4)	-0.4	30.3	2.0	(-175, 194)
	Week 8	158	182.7	37.8	179.0	(85, 325)	158	182.8 (42.5)	-0.1	29.2	3.5	(-162, 140)
	Week 10	157	181.1	37.4	178.0	(79, 326)	157	182.6 (42.6)	-1.5	26.8	3.0	(-172, 54)
	Week 12	157	180.3	37.3	177.0	(70, 292)	157	182.6 (42.6)	-2.3	26.9	0.0	(-163, 62)
	Week 16	156	182.1	38.1	180.0	(80, 322)	156	182.8 (42.7)	-0.7	30.0	2.0	(-163, 89)
	Week 20	154	183.6	38.2	179.0	(74, 309)	154	183.2 (42.7)	0.4	28.7	1.0	(-132, 79)
	Week 24	153	187.5	41.9	185.0	(79, 423)	153	182.2 (40.8)	5.3	37.0	6.0	(-159, 296)

表 2.7.4.9－31　臨床検査値：実測値及びベースラインからの変化量（MT-6548-J03 試験）（続き）

Parameter:Gamma Glutamyl Transferase (U/L)

		Absolute					Change from Baseline				
Treatment Group	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean at Baseline (SD)	Mean	SD	Median	Minimum, Maximum
MT-6548	Baseline	162	19.9	17.8	15.0	(6, 143)						
	Week 2	160	19.6	18.0	15.0	(6, 132)	160	19.9 (17.9)	-0.3	4.9	0.0	(-19, 45)
	Week 4	157	19.3	19.5	14.0	(5, 187)	157	20.1 (18.0)	-0.8	8.0	-1.0	(-30, 79)
	Week 6	155	19.4	20.1	14.0	(6, 189)	155	20.1 (18.1)	-0.7	8.7	-1.0	(-35, 81)
	Week 8	152	17.8	14.6	13.0	(6, 109)	152	19.5 (16.8)	-1.7	5.3	-1.0	(-34, 16)
	Week 10	150	18.2	15.8	13.0	(7, 113)	150	19.6 (16.9)	-1.4	6.3	-1.0	(-31, 36)
	Week 12	148	18.3	16.8	14.0	(7, 128)	148	19.6 (17.0)	-1.3	6.3	-1.0	(-35, 45)
	Week 16	144	17.7	16.9	13.0	(6, 121)	144	19.2 (16.3)	-1.5	6.8	-1.0	(-22, 54)
	Week 20	140	18.1	17.8	13.0	(6, 127)	140	19.2 (16.4)	-1.1	8.7	-1.0	(-42, 55)
	Week 24	138	17.7	17.4	13.0	(7, 124)	138	19.3 (16.5)	-1.6	8.4	-1.0	(-43, 56)
darbepoetin	Baseline	161	21.1	15.6	16.0	(7, 121)						
	Week 2	160	20.6	14.7	16.0	(6, 109)	160	21.2 (15.6)	-0.6	4.1	0.0	(-20, 20)
	Week 4	159	19.8	12.1	15.0	(7, 82)	159	20.7 (14.7)	-0.9	6.3	0.0	(-39, 28)
	Week 6	159	19.5	12.5	16.0	(7, 105)	159	20.7 (14.7)	-1.3	5.8	0.0	(-31, 19)
	Week 8	158	19.7	12.4	17.0	(6, 102)	158	20.8 (14.7)	-1.1	6.2	0.0	(-26, 26)
	Week 10	157	20.1	13.7	17.0	(6, 131)	157	20.8 (14.8)	-0.6	6.7	0.0	(-28, 30)
	Week 12	157	20.3	13.5	17.0	(6, 106)	157	20.8 (14.8)	-0.5	7.3	0.0	(-33, 39)
	Week 16	156	21.4	18.4	17.0	(6, 179)	156	20.8 (14.8)	0.7	12.4	0.0	(-27, 128)
	Week 20	154	22.5	16.1	18.0	(6, 97)	154	20.9 (14.8)	1.6	10.1	0.0	(-30, 58)
	Week 24	153	24.5	31.6	18.0	(6, 365)	153	20.8 (14.9)	3.7	29.1	1.0	(-38, 340)

表 2.7.4.9－31　臨床検査値：実測値及びベースラインからの変化量（MT-6548-J03 試験）（続き）

Parameter:Sodium (mEq/L)

		Absolute					Change from Baseline				
Treatment Group	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean at Baseline (SD)	Mean	SD	Median	Minimum, Maximum
MT-6548	Baseline	162	139.6	2.8	140.0	(131, 146)						
	Week 2	160	139.6	2.5	140.0	(132, 146)	160	139.6 (2.8)	-0.1	2.4	0.0	(-8, 7)
	Week 4	157	139.8	2.7	140.0	(131, 145)	157	139.6 (2.8)	0.2	2.6	0.0	(-6, 7)
	Week 6	155	139.5	3.0	140.0	(131, 147)	155	139.6 (2.8)	-0.1	2.7	0.0	(-9, 6)
	Week 8	152	139.5	2.6	139.0	(133, 147)	152	139.7 (2.8)	-0.2	2.9	0.0	(-8, 8)
	Week 10	150	139.5	2.7	139.0	(132, 148)	150	139.7 (2.8)	-0.2	2.8	0.0	(-7, 7)
	Week 12	148	139.6	2.8	139.0	(133, 146)	148	139.7 (2.8)	-0.2	2.8	0.0	(-8, 10)
	Week 16	144	140.0	2.7	140.0	(133, 147)	144	139.8 (2.8)	0.2	2.6	0.0	(-7, 10)
	Week 20	140	140.0	2.7	140.0	(133, 147)	140	139.8 (2.8)	0.2	2.7	0.5	(-7, 10)
	Week 24	138	140.2	2.5	140.0	(134, 145)	138	139.7 (2.8)	0.5	2.6	0.0	(-6, 8)
darbepoetin	Baseline	161	139.3	2.9	139.0	(130, 146)						
	Week 2	160	139.4	2.8	139.0	(132, 147)	160	139.3 (2.9)	0.1	2.7	0.0	(-6, 9)
	Week 4	159	139.3	2.7	139.0	(131, 146)	159	139.3 (2.9)	0.1	2.5	0.0	(-7, 10)
	Week 6	159	139.3	2.8	139.0	(132, 149)	159	139.3 (2.9)	0.0	2.7	0.0	(-5, 9)
	Week 8	158	139.2	2.6	139.0	(127, 146)	158	139.3 (2.9)	-0.1	2.7	0.0	(-7, 10)
	Week 10	157	139.1	2.8	139.0	(131, 148)	157	139.3 (2.9)	-0.2	2.9	0.0	(-8, 11)
	Week 12	157	139.3	2.8	139.0	(132, 146)	157	139.3 (2.9)	0.0	3.0	0.0	(-10, 7)
	Week 16	156	139.3	2.9	139.0	(127, 147)	156	139.3 (2.9)	0.0	3.1	0.0	(-17, 8)
	Week 20	154	139.3	2.8	139.0	(131, 148)	154	139.4 (2.9)	-0.1	2.9	0.0	(-7, 10)
	Week 24	153	139.4	2.6	139.0	(133, 146)	153	139.4 (2.9)	0.1	2.9	0.0	(-8, 8)

表 2.7.4.9－31　臨床検査値：実測値及びベースラインからの変化量（MT-6548-J03 試験）（続き）

Parameter:Potassium (mEq/L)

		Absolute					Change from Baseline				
Treatment Group	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean at Baseline (SD)	Mean	SD	Median	Minimum, Maximum
MT-6548	Baseline	162	4.86	0.64	4.80	(3.4, 6.7)						
	Week 2	160	4.82	0.66	4.80	(3.4, 7.6)	160	4.86 (0.64)	-0.03	0.49	-0.10	(-1.7, 1.8)
	Week 4	157	4.82	0.59	4.80	(3.4, 6.7)	157	4.86 (0.64)	-0.04	0.55	0.00	(-1.8, 1.6)
	Week 6	155	4.81	0.66	4.70	(3.5, 6.7)	155	4.85 (0.64)	-0.04	0.52	0.00	(-1.7, 1.8)
	Week 8	152	4.76	0.62	4.80	(3.2, 7.3)	152	4.85 (0.64)	-0.09	0.55	-0.10	(-1.5, 1.5)
	Week 10	150	4.76	0.66	4.70	(3.2, 7.2)	150	4.84 (0.63)	-0.08	0.56	-0.10	(-1.7, 1.9)
	Week 12	148	4.74	0.61	4.75	(3.2, 6.4)	148	4.84 (0.63)	-0.10	0.57	-0.10	(-2.0, 1.8)
	Week 16	144	4.69	0.65	4.70	(3.4, 6.9)	144	4.84 (0.64)	-0.14	0.61	-0.10	(-1.7, 2.0)
	Week 20	140	4.75	0.68	4.70	(3.2, 6.9)	140	4.85 (0.64)	-0.11	0.58	-0.10	(-1.5, 2.5)
	Week 24	138	4.80	0.76	4.80	(3.2, 8.0)	138	4.85 (0.64)	-0.05	0.64	-0.10	(-1.6, 2.7)
darbepoetin	Baseline	161	4.82	0.64	4.80	(3.3, 6.3)						
	Week 2	160	4.85	0.64	4.80	(3.5, 6.5)	160	4.81 (0.63)	0.04	0.41	0.05	(-1.3, 1.0)
	Week 4	159	4.86	0.68	4.90	(3.3, 7.4)	159	4.81 (0.63)	0.05	0.47	0.00	(-1.3, 2.1)
	Week 6	159	4.79	0.67	4.80	(3.4, 6.6)	159	4.81 (0.63)	-0.02	0.47	0.00	(-1.2, 1.7)
	Week 8	158	4.83	0.69	4.90	(3.2, 6.9)	158	4.82 (0.63)	0.02	0.51	0.00	(-2.1, 2.0)
	Week 10	157	4.80	0.68	4.80	(3.1, 6.8)	157	4.82 (0.64)	-0.02	0.55	0.00	(-1.9, 1.6)
	Week 12	157	4.78	0.66	4.80	(3.2, 6.7)	157	4.82 (0.64)	-0.04	0.53	-0.10	(-1.5, 1.7)
	Week 16	156	4.73	0.63	4.70	(3.4, 6.5)	156	4.82 (0.64)	-0.09	0.50	0.00	(-1.9, 1.5)
	Week 20	154	4.73	0.70	4.70	(3.0, 6.8)	154	4.82 (0.63)	-0.09	0.52	-0.15	(-1.6, 1.5)
	Week 24	153	4.82	0.67	4.80	(3.2, 6.4)	153	4.82 (0.64)	0.00	0.48	0.00	(-1.3, 1.5)

表 2.7.4.9－31　臨床検査値：実測値及びベースラインからの変化量（MT-6548-J03 試験）（続き）

Parameter:Chloride (mEq/L)

		Absolute					Change from Baseline				
Treatment Group	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean at Baseline (SD)	Mean	SD	Median	Minimum, Maximum
MT-6548	Baseline	162	103.4	3.1	104.0	(93, 112)						
	Week 2	160	103.1	3.0	103.0	(94, 111)	160	103.4 (3.1)	-0.3	2.2	0.0	(-7, 5)
	Week 4	157	103.3	3.1	103.0	(96, 110)	157	103.4 (3.0)	-0.1	2.5	0.0	(-7, 8)
	Week 6	155	103.4	3.5	103.0	(94, 112)	155	103.4 (3.0)	0.0	2.8	0.0	(-8, 9)
	Week 8	152	103.3	3.3	103.0	(93, 115)	152	103.4 (3.0)	-0.2	2.8	0.0	(-8, 7)
	Week 10	150	103.5	3.3	104.0	(92, 112)	150	103.4 (3.0)	0.1	2.7	0.0	(-7, 9)
	Week 12	148	103.4	3.3	103.0	(96, 114)	148	103.4 (3.0)	0.0	2.7	0.0	(-9, 7)
	Week 16	144	103.3	3.3	104.0	(92, 113)	144	103.4 (3.1)	-0.1	2.7	0.0	(-7, 8)
	Week 20	140	103.4	3.1	104.0	(94, 112)	140	103.4 (3.0)	0.0	2.6	0.0	(-8, 6)
	Week 24	138	103.4	3.1	103.0	(95, 111)	138	103.3 (3.0)	0.2	2.6	0.0	(-9, 8)
darbepoetin	Baseline	161	103.0	3.4	103.0	(90, 113)						
	Week 2	160	102.8	3.1	103.0	(90, 111)	160	102.9 (3.4)	-0.1	2.3	0.0	(-5, 9)
	Week 4	159	102.7	3.3	103.0	(89, 112)	159	102.9 (3.4)	-0.3	2.4	0.0	(-6, 11)
	Week 6	159	102.9	3.6	103.0	(86, 111)	159	102.9 (3.4)	0.0	2.7	0.0	(-5, 11)
	Week 8	158	103.3	3.3	103.0	(89, 112)	158	102.9 (3.4)	0.3	2.7	0.0	(-6, 12)
	Week 10	157	102.9	3.3	103.0	(86, 110)	157	103.0 (3.4)	-0.1	2.9	0.0	(-8, 11)
	Week 12	157	103.0	3.6	103.0	(86, 113)	157	103.0 (3.4)	0.1	3.0	0.0	(-9, 9)
	Week 16	156	103.1	4.1	103.0	(71, 111)	156	103.0 (3.5)	0.2	3.3	0.0	(-19, 10)
	Week 20	154	103.2	3.5	103.0	(85, 113)	154	103.0 (3.5)	0.2	3.0	0.0	(-10, 12)
	Week 24	153	102.9	3.2	103.0	(84, 110)	153	103.0 (3.5)	-0.2	3.0	0.0	(-8, 9)

表 2.7.4.9－31　臨床検査値：実測値及びベースラインからの変化量（MT-6548-J03 試験）（続き）

Parameter:Calcium (mg/dL)

		Absolute					Change from Baseline				
Treatment Group	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean at Baseline (SD)	Mean	SD	Median	Minimum, Maximum
MT-6548	Baseline	162	8.54	0.74	8.50	(5.8, 10.4)						
	Week 2	160	8.41	0.71	8.40	(6.2, 10.3)	160	8.53 (0.74)	-0.12	0.47	-0.10	(-1.9, 3.2)
	Week 4	157	8.46	0.72	8.40	(6.4, 10.1)	157	8.54 (0.74)	-0.08	0.54	-0.10	(-1.5, 3.6)
	Week 6	155	8.39	0.67	8.50	(6.3, 9.8)	155	8.54 (0.74)	-0.14	0.52	-0.10	(-2.0, 3.1)
	Week 8	152	8.42	0.73	8.50	(6.4, 11.0)	152	8.52 (0.73)	-0.10	0.59	-0.10	(-1.9, 3.0)
	Week 10	150	8.46	0.70	8.50	(6.6, 10.3)	150	8.52 (0.73)	-0.05	0.57	-0.05	(-2.5, 2.1)
	Week 12	148	8.53	0.69	8.60	(6.7, 10.4)	148	8.51 (0.74)	0.02	0.60	0.00	(-2.3, 2.4)
	Week 16	144	8.54	0.67	8.50	(6.7, 10.4)	144	8.53 (0.71)	0.02	0.66	0.00	(-2.5, 2.4)
	Week 20	140	8.51	0.67	8.50	(6.8, 10.3)	140	8.52 (0.71)	-0.02	0.67	0.00	(-2.1, 3.6)
	Week 24	138	8.67	0.70	8.60	(6.9, 10.8)	138	8.52 (0.72)	0.14	0.66	0.10	(-1.7, 1.9)
darbepoetin	Baseline	161	8.64	0.65	8.70	(6.7, 10.6)						
	Week 2	160	8.55	0.66	8.60	(6.7, 10.4)	160	8.65 (0.65)	-0.10	0.49	-0.10	(-2.4, 1.2)
	Week 4	159	8.58	0.63	8.60	(7.0, 10.3)	159	8.64 (0.65)	-0.06	0.47	0.00	(-2.2, 1.4)
	Week 6	159	8.54	0.65	8.50	(6.7, 10.5)	159	8.64 (0.65)	-0.10	0.51	-0.10	(-2.0, 1.7)
	Week 8	158	8.58	0.63	8.60	(6.2, 10.8)	158	8.64 (0.65)	-0.07	0.51	-0.10	(-1.6, 2.7)
	Week 10	157	8.63	0.66	8.60	(6.7, 11.0)	157	8.64 (0.65)	-0.02	0.58	-0.10	(-1.8, 2.9)
	Week 12	157	8.67	0.66	8.70	(6.8, 11.0)	157	8.64 (0.65)	0.02	0.54	0.00	(-1.7, 2.5)
	Week 16	156	8.67	0.62	8.60	(7.3, 11.1)	156	8.63 (0.64)	0.04	0.54	0.00	(-1.8, 2.0)
	Week 20	154	8.65	0.61	8.60	(6.9, 11.2)	154	8.64 (0.64)	0.01	0.52	-0.05	(-1.8, 1.8)
	Week 24	153	8.71	0.61	8.70	(7.2, 10.3)	153	8.64 (0.65)	0.07	0.58	0.00	(-2.5, 2.3)

表 2.7.4.9－31 臨床検査値：実測値及びベースラインからの変化量（MT-6548-J03 試験）（続き）

Parameter:Phosphate (mg/dL)

		Absolute					Change from Baseline				
Treatment Group	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean at Baseline (SD)	Mean	SD	Median	Minimum, Maximum
MT-6548	Baseline	162	5.37	1.17	5.30	(2.7, 9.8)						
	Week 2	160	5.43	1.21	5.40	(1.3, 10.4)	160	5.37 (1.18)	0.06	1.03	0.10	(-2.9, 3.0)
	Week 4	157	5.37	1.12	5.20	(3.0, 8.8)	157	5.38 (1.16)	-0.01	1.08	-0.10	(-3.0, 2.9)
	Week 6	155	5.46	1.38	5.30	(3.4, 11.7)	155	5.39 (1.17)	0.08	1.30	0.00	(-3.3, 3.6)
	Week 8	152	5.38	1.30	5.10	(2.9, 10.0)	152	5.40 (1.16)	-0.02	1.24	-0.10	(-2.5, 3.6)
	Week 10	150	5.27	1.28	5.20	(2.6, 10.1)	150	5.41 (1.16)	-0.14	1.15	-0.20	(-2.8, 4.4)
	Week 12	148	5.27	1.23	5.10	(2.7, 8.7)	148	5.43 (1.16)	-0.16	1.13	-0.20	(-3.4, 4.2)
	Week 16	144	5.17	1.17	5.10	(2.5, 9.3)	144	5.42 (1.17)	-0.25	1.12	-0.30	(-3.4, 2.9)
	Week 20	140	5.18	1.38	5.00	(2.7, 12.9)	140	5.42 (1.18)	-0.24	1.42	-0.40	(-2.8, 9.3)
	Week 24	138	5.28	1.23	5.20	(3.0, 10.3)	138	5.41 (1.18)	-0.13	1.28	-0.15	(-3.1, 3.4)
darbepoetin	Baseline	161	5.47	1.21	5.50	(2.2, 9.7)						
	Week 2	160	5.48	1.33	5.35	(2.2, 10.5)	160	5.47 (1.21)	0.01	1.01	-0.10	(-2.5, 3.6)
	Week 4	159	5.54	1.27	5.50	(1.8, 9.8)	159	5.46 (1.22)	0.07	0.92	0.00	(-2.3, 2.8)
	Week 6	159	5.37	1.29	5.30	(1.2, 9.6)	159	5.46 (1.22)	-0.09	1.06	0.00	(-2.9, 3.3)
	Week 8	158	5.23	1.19	5.10	(1.5, 8.3)	158	5.46 (1.22)	-0.24	1.15	-0.20	(-4.0, 3.8)
	Week 10	157	5.24	1.33	5.10	(1.8, 8.5)	157	5.47 (1.22)	-0.23	1.22	-0.30	(-4.1, 3.3)
	Week 12	157	5.17	1.24	5.20	(1.3, 9.2)	157	5.47 (1.22)	-0.30	1.16	-0.20	(-3.3, 3.3)
	Week 16	156	5.08	1.25	5.10	(1.3, 8.8)	156	5.46 (1.23)	-0.38	1.16	-0.35	(-3.7, 4.4)
	Week 20	154	5.16	1.30	5.10	(2.2, 9.9)	154	5.45 (1.22)	-0.29	1.15	-0.30	(-3.5, 2.8)
	Week 24	153	5.30	1.24	5.30	(1.7, 10.1)	153	5.45 (1.23)	-0.15	1.17	-0.10	(-3.6, 3.4)

表 2.7.4.9－31　臨床検査値：実測値及びベースラインからの変化量（MT-6548-J03 試験）（続き）

Parameter:Magnesium (mg/dL)

		Absolute					Change from Baseline				
Treatment Group	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean at Baseline (SD)	Mean	SD	Median	Minimum, Maximum
MT-6548	Baseline	162	2.39	0.32	2.40	(1.4, 3.6)						
	Week 2	160	2.31	0.29	2.30	(1.6, 3.3)	160	2.39 (0.32)	-0.08	0.17	-0.10	(-0.9, 0.3)
	Week 4	157	2.30	0.33	2.30	(1.3, 3.4)	157	2.39 (0.33)	-0.09	0.19	-0.10	(-0.7, 0.4)
	Week 6	155	2.29	0.31	2.20	(1.7, 3.2)	155	2.39 (0.33)	-0.10	0.18	-0.10	(-0.6, 0.4)
	Week 8	152	2.28	0.31	2.20	(1.5, 3.1)	152	2.38 (0.32)	-0.10	0.19	-0.10	(-0.7, 0.3)
	Week 10	150	2.30	0.34	2.25	(1.6, 3.9)	150	2.38 (0.32)	-0.08	0.21	-0.10	(-0.6, 0.7)
	Week 12	148	2.30	0.32	2.30	(1.7, 3.5)	148	2.38 (0.32)	-0.08	0.19	-0.10	(-0.7, 0.5)
	Week 16	144	2.28	0.29	2.20	(1.7, 3.1)	144	2.38 (0.33)	-0.10	0.21	-0.10	(-0.7, 0.4)
	Week 20	140	2.29	0.33	2.30	(1.6, 3.2)	140	2.38 (0.33)	-0.09	0.21	-0.10	(-0.7, 0.4)
	Week 24	138	2.31	0.35	2.30	(1.6, 3.6)	138	2.38 (0.33)	-0.07	0.23	-0.10	(-0.7, 0.8)
darbepoetin	Baseline	161	2.40	0.34	2.40	(1.6, 3.6)						
	Week 2	160	2.38	0.37	2.40	(1.5, 3.8)	160	2.40 (0.34)	-0.01	0.18	0.00	(-0.5, 0.7)
	Week 4	159	2.41	0.34	2.40	(1.5, 3.6)	159	2.40 (0.34)	0.02	0.18	0.00	(-0.5, 0.5)
	Week 6	159	2.38	0.35	2.40	(1.6, 3.6)	159	2.40 (0.34)	-0.02	0.19	0.00	(-0.5, 0.7)
	Week 8	158	2.38	0.36	2.40	(1.5, 3.8)	158	2.40 (0.34)	-0.01	0.20	0.00	(-0.7, 0.6)
	Week 10	157	2.37	0.37	2.40	(1.5, 3.7)	157	2.39 (0.34)	-0.02	0.20	0.00	(-0.6, 0.8)
	Week 12	157	2.38	0.36	2.30	(1.6, 3.9)	157	2.39 (0.34)	-0.01	0.20	0.00	(-0.5, 0.8)
	Week 16	156	2.34	0.32	2.30	(1.6, 3.5)	156	2.39 (0.33)	-0.05	0.18	0.00	(-0.5, 0.5)
	Week 20	154	2.32	0.33	2.30	(1.5, 3.5)	154	2.39 (0.33)	-0.06	0.21	-0.10	(-0.6, 0.6)
	Week 24	153	2.36	0.32	2.40	(1.6, 3.4)	153	2.39 (0.33)	-0.02	0.19	0.00	(-0.5, 0.5)

表 2.7.4.9－31　臨床検査値：実測値及びベースラインからの変化量（MT-6548-J03 試験）（続き）

Parameter:Bicarbonate (mmol/L)

		Absolute					Change from Baseline				
Treatment Group	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean at Baseline (SD)	Mean	SD	Median	Minimum, Maximum
MT-6548	Baseline	162	17.02	2.44	16.80	(11.2, 24.6)						
	Week 2	160	16.57	2.20	16.40	(11.1, 23.8)	160	17.04 (2.45)	-0.47	1.91	-0.40	(-4.9, 5.3)
	Week 4	157	16.58	2.05	16.50	(11.1, 23.0)	157	17.04 (2.47)	-0.47	1.84	-0.30	(-5.8, 4.1)
	Week 6	155	16.70	2.25	16.60	(11.3, 22.8)	155	17.04 (2.48)	-0.34	1.88	-0.30	(-5.4, 4.2)
	Week 8	152	16.80	2.14	16.90	(11.9, 22.3)	152	17.04 (2.50)	-0.24	2.12	0.10	(-6.8, 3.8)
	Week 10	150	16.81	2.28	16.65	(10.9, 22.8)	150	17.03 (2.52)	-0.22	2.09	-0.10	(-8.3, 4.9)
	Week 12	148	16.65	2.31	16.75	(10.8, 23.1)	148	17.03 (2.53)	-0.38	2.02	-0.30	(-7.6, 6.4)
	Week 16	144	17.12	2.47	17.35	(10.7, 24.2)	144	17.05 (2.56)	0.07	2.37	-0.10	(-8.4, 6.2)
	Week 20	140	16.77	2.28	16.70	(10.1, 22.3)	140	17.08 (2.58)	-0.31	2.15	0.05	(-8.3, 4.4)
	Week 24	138	17.22	2.26	17.15	(11.4, 23.5)	138	17.08 (2.60)	0.14	2.20	0.00	(-6.0, 6.7)
darbepoetin	Baseline	161	17.18	2.35	17.10	(12.3, 29.2)						
	Week 2	160	16.93	2.36	16.90	(11.0, 28.9)	160	17.19 (2.35)	-0.26	1.87	-0.20	(-6.0, 4.0)
	Week 4	159	16.71	2.37	16.70	(10.4, 29.8)	159	17.19 (2.36)	-0.48	1.79	-0.40	(-5.6, 3.8)
	Week 6	159	16.94	2.22	16.90	(10.7, 27.4)	159	17.19 (2.36)	-0.26	1.85	-0.20	(-5.0, 5.3)
	Week 8	158	16.75	2.06	16.70	(10.9, 28.3)	158	17.21 (2.36)	-0.46	1.89	-0.45	(-5.9, 5.0)
	Week 10	157	17.12	2.29	17.10	(9.5, 30.9)	157	17.21 (2.36)	-0.09	1.91	-0.20	(-6.6, 4.9)
	Week 12	157	16.91	2.41	17.10	(9.7, 29.9)	157	17.21 (2.36)	-0.30	1.96	-0.30	(-7.6, 3.9)
	Week 16	156	17.15	2.29	17.10	(11.5, 28.4)	156	17.21 (2.37)	-0.06	2.14	0.00	(-6.1, 5.0)
	Week 20	154	16.83	2.48	16.80	(7.1, 29.3)	154	17.20 (2.38)	-0.36	2.10	-0.30	(-9.4, 4.9)
	Week 24	153	17.21	2.23	17.10	(11.3, 27.1)	153	17.18 (2.37)	0.03	1.77	0.10	(-6.0, 5.9)

表 2.7.4.9－31　臨床検査値：実測値及びベースラインからの変化量（MT-6548-J03 試験）（続き）

Parameter:Total Cholesterol (mg/dL)

		Absolute					Change from Baseline				
Treatment Group	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean at Baseline (SD)	Mean	SD	Median	Minimum, Maximum
MT-6548	Baseline	162	159.1	32.3	156.0	(78, 267)						
	Week 2	160	159.0	32.5	157.0	(80, 234)	160	158.8 (32.2)	0.2	14.0	1.0	(-36, 47)
	Week 4	157	157.2	32.5	156.0	(86, 264)	157	158.4 (32.3)	-1.2	16.0	0.0	(-49, 43)
	Week 6	155	159.4	34.5	159.0	(83, 274)	155	158.1 (32.4)	1.3	18.3	1.0	(-53, 48)
	Week 8	152	158.7	35.7	156.5	(82, 284)	152	158.2 (32.6)	0.6	19.4	0.5	(-47, 55)
	Week 10	150	159.1	34.6	160.5	(80, 262)	150	157.7 (32.4)	1.4	19.9	1.0	(-41, 68)
	Week 12	148	161.5	35.3	160.5	(89, 276)	148	158.2 (32.3)	3.3	20.0	4.0	(-48, 57)
	Week 16	144	161.2	36.2	158.5	(87, 260)	144	158.0 (32.6)	3.2	22.3	4.0	(-50, 73)
	Week 20	140	166.6	35.5	164.0	(91, 284)	140	158.2 (32.6)	8.4	21.9	7.0	(-43, 99)
	Week 24	138	166.4	34.8	167.5	(91, 282)	138	158.4 (32.7)	8.0	20.0	8.5	(-41, 73)
darbepoetin	Baseline	161	158.5	33.8	153.0	(92, 265)						
	Week 2	160	157.9	33.2	155.5	(98, 299)	160	158.6 (33.9)	-0.7	12.7	0.5	(-34, 34)
	Week 4	159	158.4	33.4	155.0	(94, 295)	159	158.6 (34.0)	-0.3	13.6	0.0	(-41, 34)
	Week 6	159	157.3	34.1	153.0	(92, 300)	159	158.6 (34.0)	-1.4	13.2	-2.0	(-44, 35)
	Week 8	158	156.0	33.2	153.0	(91, 290)	158	158.8 (34.0)	-2.8	15.9	-1.0	(-67, 38)
	Week 10	157	156.0	33.7	152.0	(89, 277)	157	158.7 (34.1)	-2.7	15.5	-3.0	(-60, 45)
	Week 12	157	157.6	35.0	153.0	(90, 273)	157	158.7 (34.1)	-1.1	16.2	-1.0	(-66, 40)
	Week 16	156	157.5	35.2	154.0	(91, 306)	156	158.8 (34.2)	-1.3	17.8	1.0	(-73, 47)
	Week 20	154	158.8	35.4	156.0	(88, 296)	154	159.1 (34.2)	-0.4	18.3	1.0	(-55, 53)
	Week 24	153	162.7	37.0	159.0	(86, 288)	153	159.2 (34.4)	3.5	18.6	6.0	(-56, 64)

表 2.7.4.9－31　臨床検査値：実測値及びベースラインからの変化量（MT-6548-J03 試験）（続き）

Parameter:LDL Cholesterol (mg/dL)

		Absolute					Change from Baseline					
Treatment Group	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean at Baseline (SD)	Mean	SD	Median	Minimum, Maximum
MT-6548	Baseline	162	88.7	26.3	86.0	(33, 185)						
	Week 2	160	87.0	25.7	88.0	(33, 156)	160	88.4 (26.0)	-1.3	12.7	-1.0	(-52, 36)
	Week 4	157	86.6	26.3	89.0	(32, 171)	157	88.1 (26.0)	-1.5	13.2	-1.0	(-46, 44)
	Week 6	155	87.2	27.8	87.0	(26, 189)	155	87.8 (26.0)	-0.6	16.2	0.0	(-55, 56)
	Week 8	152	86.9	28.1	87.0	(29, 190)	152	87.8 (26.3)	-0.9	15.7	-1.0	(-48, 46)
	Week 10	150	86.7	27.7	86.0	(28, 153)	150	87.3 (25.7)	-0.6	16.6	-0.5	(-38, 69)
	Week 12	148	88.3	28.7	88.0	(31, 159)	148	87.7 (25.6)	0.6	17.2	1.5	(-42, 59)
	Week 16	144	88.7	29.5	87.0	(31, 169)	144	87.5 (25.7)	1.2	18.3	0.5	(-44, 81)
	Week 20	140	91.8	28.1	93.5	(34, 198)	140	87.4 (25.8)	4.4	16.0	4.0	(-37, 53)
	Week 24	138	89.9	27.7	93.5	(35, 164)	138	87.4 (25.9)	2.5	16.0	3.0	(-34, 60)
darbepoetin	Baseline	161	86.2	28.0	82.0	(32, 173)						
	Week 2	160	86.1	27.1	85.0	(25, 189)	160	86.2 (28.1)	-0.2	10.7	0.0	(-35, 34)
	Week 4	159	86.2	27.1	85.0	(34, 193)	159	86.4 (28.1)	-0.2	10.9	0.0	(-42, 29)
	Week 6	159	86.2	27.7	84.0	(34, 204)	159	86.4 (28.1)	-0.3	11.6	0.0	(-34, 31)
	Week 8	158	84.4	26.5	83.5	(30, 187)	158	86.5 (28.2)	-2.1	12.3	-1.0	(-59, 25)
	Week 10	157	84.7	27.8	82.0	(27, 186)	157	86.5 (28.3)	-1.7	13.8	-2.0	(-66, 52)
	Week 12	157	85.2	28.0	81.0	(36, 177)	157	86.5 (28.3)	-1.3	13.3	0.0	(-60, 39)
	Week 16	156	85.1	28.3	81.5	(31, 201)	156	86.6 (28.3)	-1.5	14.3	-1.0	(-63, 36)
	Week 20	154	85.5	28.3	85.0	(34, 191)	154	86.9 (28.4)	-1.4	14.2	-1.0	(-59, 31)
	Week 24	153	86.7	29.1	85.0	(31, 190)	153	86.9 (28.5)	-0.2	13.4	0.0	(-49, 32)

表 2.7.4.9－31　臨床検査値：実測値及びベースラインからの変化量（MT-6548-J03 試験）（続き）

Parameter:HDL Cholesterol (mg/dL)

		Absolute					Change from Baseline					
Treatment Group	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean at Baseline (SD)	Mean	SD	Median	Minimum, Maximum
MT-6548	Baseline	162	48.5	15.5	47.0	(23, 103)						
	Week 2	160	45.7	14.6	43.5	(23, 92)	160	48.5 (15.6)	-2.8	5.6	-1.5	(-23, 10)
	Week 4	157	44.4	14.4	42.0	(22, 93)	157	48.3 (15.7)	-3.9	6.4	-3.0	(-27, 11)
	Week 6	155	44.4	15.4	41.0	(21, 107)	155	48.4 (15.7)	-4.0	6.1	-4.0	(-26, 9)
	Week 8	152	44.0	14.4	41.5	(22, 102)	152	48.6 (15.7)	-4.7	6.5	-4.0	(-34, 10)
	Week 10	150	43.8	14.2	41.5	(21, 98)	150	48.7 (15.8)	-4.9	7.0	-4.0	(-28, 9)
	Week 12	148	44.3	14.7	41.0	(21, 101)	148	48.6 (15.9)	-4.3	7.0	-4.0	(-25, 9)
	Week 16	144	45.6	15.6	42.0	(20, 95)	144	48.8 (16.0)	-3.2	7.4	-3.0	(-34, 17)
	Week 20	140	47.0	15.8	44.0	(14, 102)	140	48.8 (16.1)	-1.8	6.7	-1.0	(-21, 18)
	Week 24	138	47.7	17.1	44.5	(21, 110)	138	48.9 (16.0)	-1.2	7.7	-2.0	(-22, 25)
darbepoetin	Baseline	161	51.0	16.0	49.0	(17, 99)						
	Week 2	160	50.7	15.5	50.0	(21, 99)	160	51.0 (16.1)	-0.3	4.7	0.0	(-15, 12)
	Week 4	159	49.9	15.6	48.0	(19, 98)	159	50.8 (16.0)	-1.0	5.0	-1.0	(-17, 15)
	Week 6	159	48.7	15.2	47.0	(18, 93)	159	50.8 (16.0)	-2.1	5.3	-2.0	(-23, 15)
	Week 8	158	49.3	15.2	48.0	(19, 100)	158	51.0 (16.0)	-1.6	6.4	-2.0	(-25, 23)
	Week 10	157	48.7	15.4	47.0	(20, 93)	157	50.8 (15.9)	-2.1	6.0	-2.0	(-31, 20)
	Week 12	157	50.1	16.2	48.0	(19, 100)	157	50.8 (15.9)	-0.8	6.6	-1.0	(-19, 33)
	Week 16	156	50.7	16.1	48.5	(17, 94)	156	50.7 (15.9)	0.0	7.3	0.0	(-26, 30)
	Week 20	154	50.8	15.5	49.0	(19, 100)	154	50.7 (15.9)	0.1	7.2	0.5	(-36, 20)
	Week 24	153	52.7	16.8	50.0	(22, 106)	153	50.8 (15.9)	2.0	7.7	2.0	(-18, 31)

表 2.7.4.9－31　臨床検査値：実測値及びベースラインからの変化量（MT-6548-J03 試験）（続き）

Parameter:Triglycerides (mg/dL)

		Absolute					Change from Baseline				
Treatment Group	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean at Baseline (SD)	Mean	SD	Median	Minimum, Maximum
MT-6548	Baseline	162	115.123	69.077	94.000	(29.00, 415.00)						
	Week 2	160	141.631	105.338	113.000	(21.00, 708.00)	160	115.475 (69.367)	26.156	66.893	12.000	(-91.00, 383.00)
	Week 4	157	138.605	88.507	112.000	(28.00, 723.00)	157	116.223 (69.761)	22.382	45.524	17.000	(-76.00, 308.00)
	Week 6	155	144.465	114.085	116.000	(34.00, 900.00)	155	115.600 (69.992)	28.865	70.359	18.000	(-156.00, 563.00)
	Week 8	152	146.507	109.412	123.000	(27.00, 1070.00)	152	113.803 (67.197)	32.704	72.861	22.000	(-162.00, 655.00)
	Week 10	150	148.633	100.721	118.000	(28.00, 616.00)	150	113.287 (66.815)	35.347	60.510	23.000	(-100.00, 279.00)
	Week 12	148	153.115	93.692	127.500	(44.00, 592.00)	148	114.284 (66.696)	38.831	57.719	34.000	(-143.00, 243.00)
	Week 16	144	140.618	95.982	121.500	(29.00, 795.00)	144	114.000 (66.954)	26.618	64.979	17.500	(-142.00, 458.00)
	Week 20	140	143.707	92.564	120.000	(36.00, 677.00)	140	114.536 (67.412)	29.171	70.844	19.500	(-128.00, 475.00)
	Week 24	138	141.362	101.656	115.000	(29.00, 695.00)	138	114.906 (67.631)	26.457	74.411	11.000	(-141.00, 352.00)
darbepoetin	Baseline	161	111.708	67.298	95.000	(33.00, 451.00)						
	Week 2	160	112.363	64.355	95.000	(26.00, 346.00)	160	112.013 (67.398)	0.350	40.263	3.500	(-141.00, 166.00)
	Week 4	159	116.654	66.497	100.000	(30.00, 467.00)	159	112.233 (67.553)	4.421	46.016	4.000	(-252.00, 225.00)
	Week 6	159	117.862	66.682	94.000	(31.00, 418.00)	159	112.233 (67.553)	5.629	49.466	9.000	(-166.00, 160.00)
	Week 8	158	117.196	66.309	98.500	(32.00, 432.00)	158	112.361 (67.749)	4.835	45.778	5.500	(-191.00, 190.00)
	Week 10	157	122.242	72.033	107.000	(23.00, 446.00)	157	112.471 (67.951)	9.771	53.679	7.000	(-266.00, 209.00)
	Week 12	157	118.439	69.918	100.000	(28.00, 456.00)	157	112.471 (67.951)	5.968	51.365	4.000	(-190.00, 200.00)
	Week 16	156	115.519	67.566	95.000	(25.00, 406.00)	156	112.737 (68.088)	2.782	55.798	3.500	(-208.00, 247.00)
	Week 20	154	115.156	62.976	96.000	(38.00, 371.00)	154	113.461 (68.184)	1.695	45.058	6.000	(-252.00, 111.00)
	Week 24	153	111.288	60.866	92.000	(26.00, 318.00)	153	113.033 (68.200)	-1.745	53.162	5.000	(-288.00, 161.00)

表 2.7.4.9－31　臨床検査値：実測値及びベースラインからの変化量（MT-6548-J03 試験）（続き）

Parameter:C Reactive Protein (mg/dL)

		Absolute					Change from Baseline					
Treatment Group	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean at Baseline (SD)	Mean	SD	Median	Minimum, Maximum
MT-6548	Baseline	162	0.2749	0.9101	0.0600	(0.009, 10.400)						
	Week 24	138	0.2803	0.6844	0.0600	(0.009, 5.830)	138	0.2819 (0.9733)	-0.0016	1.0498	0.0000	(-9.600, 4.570)
darbepoetin	Baseline	161	0.3152	0.8515	0.0500	(0.010, 7.130)						
	Week 24	153	0.3055	0.7072	0.0600	(0.010, 6.580)	153	0.3033 (0.8546)	0.0022	0.9239	0.0100	(-6.730, 3.430)

表 2.7.4.9－31　臨床検査値：実測値及びベースラインからの変化量（MT-6548-J03 試験）（続き）

Parameter:Vascular Endothelial Growth Factor (pg/mL)

		Absolute					Change from Baseline					
Treatment Group	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean at Baseline (SD)	Mean	SD	Median	Minimum, Maximum
MT-6548	Baseline	162	50.359	22.659	46.200	(15.59, 176.00)						
	Week 12	148	58.723	55.680	47.800	(15.59, 581.00)	148	50.546 (22.577)	8.177	51.423	0.250	(-78.50, 484.70)
	Week 24	138	53.845	41.236	46.450	(15.59, 458.00)	138	50.462 (22.374)	3.383	38.607	0.250	(-75.10, 386.50)
darbepoetin	Baseline	161	52.274	34.753	45.300	(15.59, 329.00)						
	Week 12	157	48.097	26.921	42.200	(15.59, 261.00)	157	52.178 (34.990)	-4.081	39.624	-3.200	(-291.00, 170.90)
	Week 24	153	46.171	17.704	41.500	(15.59, 119.00)	153	52.410 (35.386)	-6.238	34.912	-3.700	(-264.90, 75.00)

表 2.7.4.9－31　臨床検査値：実測値及びベースラインからの変化量（MT-6548-J03 試験）（続き）

Parameter:Dehydroepiandrosterone Sulfate (ug/dL)

		Absolute					Change from Baseline				
Treatment Group	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean at Baseline (SD)	Mean	SD	Median	Minimum, Maximum
MT-6548	Baseline	162	117.46	87.05	98.00	(3.0, 614.0)						
	Week 12	148	100.34	73.80	82.00	(4.0, 434.0)	148	116.81 (88.24)	-16.47	29.71	-9.00	(-180.0, 58.0)
	Week 24	138	99.32	74.25	80.50	(1.9, 420.0)	138	119.53 (90.57)	-20.21	35.96	-12.00	(-194.0, 81.0)
darbepoetin	Baseline	161	132.25	104.46	103.00	(10.0, 817.0)						
	Week 12	157	135.51	111.68	110.00	(6.0, 955.0)	157	133.92 (105.14)	1.59	34.15	0.00	(-162.0, 138.0)
	Week 24	158	139.07	108.37	113.00	(8.0, 696.0)	153	135.31 (106.13)	3.76	31.66	3.00	(-124.0, 131.0)

Data Source: Listing 16.2.6.1, Listing 16.2.6.2, Listing 16.2.6.3, Listing 16.2.6.4
Source: t_14_3_2_1.sas

5.3.5.1—7 表 14.3.2.1 より引用

表 2.7.4.9－32　規定した基準（臨床検査値）に該当した被験者数及び割合（MT-6548-J03 試験）

Criteria	MT-6548(N=162) n (%)	darbepoetin(N=161) n (%)
Uric Acid		
Any post-baseline value		
25% increase and >7.0 mg/dL	0 (0.0)	0 (0.0)
Potassium		
Any post-baseline value		
>6.0 - 7.0 mmol/L	25 (15.4)	25 (15.5)
>7.0 mmol/L	4 (2.5)	1 (0.6)
VEGF		
Any post-baseline value		
>= 2 x baseline and 200 pg/mL	5 (3.1)	1 (0.6)
Hb		
Any post-baseline value		
HD: > 12 g/dL	24 (14.8)	30 (18.6)
HD: > 13 g/dL	3 (1.9)	3 (1.9)
AST, ALT		
Any post-baseline value		
AST >3.0 x ULN	0 (0.0)	1 (0.6)
AST >5.0 x ULN	0 (0.0)	0 (0.0)
ALT >3.0 x ULN	0 (0.0)	1 (0.6)
ALT >5.0 x ULN	0 (0.0)	0 (0.0)
AST >3.0 x ULN + T-bil > 2.0 x ULN	0 (0.0)	0 (0.0)
ALT >3.0 x ULN + T-bil > 2.0 x ULN	0 (0.0)	0 (0.0)
AST or ALT >3.0 x ULN + ALP < 2.0 x ULN + T-bil > 2.0 x ULN	0 (0.0)	0 (0.0)

Note(s): Percentages are calculated using the number of subjects with post-baseline values as the denominator.
Source: t_14_3_7_1_1_2.sas

5.3.5.3—2 Table 14.3.7.1.1.2 より引用（一部改変）

表 2.7.4.9－33　臨床検査値：実測値及びベースラインからの変化量（ISS-1）

Parameter:Hemoglobin (g/dL)

		Absolute					Change from Baseline				
	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean	SD	Median	Minimum, Maximum
NDD	Baseline	202	10.22	0.97	10.25	(7.5, 12.5)					
	Week 2	202	10.54	0.96	10.60	(7.9, 13.8)	202	0.32	0.65	0.30	(-1.1, 2.9)
	Week 4	200	10.68	1.04	10.80	(8.0, 13.1)	200	0.45	0.91	0.40	(-2.1, 3.6)
	Week 6	199	10.86	1.04	10.90	(8.1, 13.5)	199	0.64	1.06	0.60	(-2.2, 3.8)
	Week 8	195	11.10	1.06	11.20	(8.4, 13.7)	195	0.86	1.06	0.90	(-2.4, 3.4)
	Week 10	192	11.26	0.97	11.30	(8.3, 13.6)	192	1.00	1.06	0.90	(-2.4, 4.1)
	Week 12	180	11.41	1.05	11.50	(8.1, 13.7)	180	1.11	1.19	1.10	(-2.2, 4.9)
	Week 14	34	11.00	0.78	11.10	(9.2, 12.4)	34	1.29	0.90	1.00	(-0.4, 3.1)
	Week 16	176	11.49	1.01	11.60	(8.4, 14.1)	176	1.17	1.26	1.10	(-2.6, 4.6)
	Week 20	140	11.65	1.10	11.70	(8.3, 14.6)	140	1.19	1.34	1.20	(-3.2, 4.8)
	Week 24	132	11.68	1.10	11.80	(7.4, 14.1)	132	1.21	1.32	1.20	(-2.6, 4.3)
HD	Baseline	237	10.10	1.24	10.30	(5.6, 12.6)					
	Week 2	233	10.06	1.20	10.10	(6.1, 12.9)	233	-0.07	0.57	0.00	(-1.8, 1.5)
	Week 4	223	10.06	1.07	10.10	(7.2, 12.8)	223	-0.14	0.90	-0.20	(-2.3, 2.7)
	Week 6	219	10.06	1.08	10.00	(7.2, 13.9)	219	-0.15	1.12	-0.10	(-3.2, 3.3)
	Week 8	215	10.10	1.10	10.10	(6.8, 13.0)	215	-0.09	1.31	0.00	(-3.3, 3.7)
	Week 10	213	10.21	1.11	10.30	(6.7, 13.2)	213	0.00	1.47	0.00	(-3.7, 5.4)
	Week 12	205	10.41	1.07	10.50	(7.4, 13.3)	205	0.15	1.47	0.20	(-3.9, 3.7)
	Week 14	36	10.58	0.94	10.55	(9.0, 12.4)	36	1.78	1.14	1.65	(-0.2, 3.9)
	Week 16	200	10.70	1.06	10.70	(7.5, 16.8)	200	0.45	1.62	0.30	(-4.1, 7.9)
	Week 20	161	10.73	0.88	10.80	(8.3, 13.1)	161	0.19	1.24	0.20	(-2.9, 2.7)
	Week 24	159	10.69	0.92	10.70	(8.0, 13.3)	159	0.14	1.21	0.10	(-3.6, 2.9)
PD	Baseline	42	10.90	1.10	11.10	(8.6, 13.0)					
	Week 2	40	10.96	1.32	11.15	(7.9, 13.1)	40	0.09	0.65	0.05	(-1.2, 1.6)
	Week 4	41	10.74	1.36	10.90	(7.7, 13.1)	41	-0.15	0.82	-0.10	(-2.3, 2.2)
	Week 6	39	10.61	1.60	10.60	(7.1, 13.9)	39	-0.33	1.16	-0.40	(-4.0, 1.8)
	Week 8	39	10.83	1.40	10.90	(7.6, 13.5)	39	-0.10	1.10	-0.10	(-2.4, 1.7)
	Week 10	39	10.87	1.31	10.90	(7.3, 13.6)	39	-0.07	1.10	-0.30	(-2.1, 3.0)
	Week 12	38	11.10	1.31	11.00	(7.5, 13.4)	38	0.17	1.30	-0.05	(-1.7, 3.8)
	Week 16	37	11.58	1.37	11.50	(8.4, 13.5)	37	0.58	1.35	0.20	(-1.0, 4.3)
	Week 20	37	11.61	1.38	11.80	(8.9, 14.9)	37	0.61	1.26	0.30	(-1.0, 4.9)
	Week 24	36	11.35	1.16	11.70	(8.4, 13.7)	36	0.31	0.99	0.35	(-1.8, 2.1)

表 2.7.4.9－33　臨床検査値：実測値及びベースラインからの変化量（ISS-1）（続き）

Parameter:Hemoglobin (g/dL)

		Absolute					Change from Baseline				
	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean	SD	Median	Minimum, Maximum
Total	Baseline	481	10.22	1.14	10.30	(5.6, 13.0)					
	Week 2	475	10.34	1.15	10.50	(6.1, 13.8)	475	0.11	0.64	0.10	(-1.8, 2.9)
	Week 4	464	10.39	1.13	10.40	(7.2, 13.1)	464	0.11	0.94	0.10	(-2.3, 3.6)
	Week 6	457	10.45	1.16	10.50	(7.1, 13.9)	457	0.18	1.17	0.10	(-4.0, 3.8)
	Week 8	449	10.60	1.21	10.70	(6.8, 13.7)	449	0.32	1.28	0.30	(-3.3, 3.7)
	Week 10	444	10.72	1.18	10.70	(6.7, 13.6)	444	0.43	1.37	0.50	(-3.7, 5.4)
	Week 12	423	10.90	1.18	10.90	(7.4, 13.7)	423	0.56	1.42	0.60	(-3.9, 4.9)
	Week 14	70	10.79	0.89	10.75	(9.0, 12.4)	70	1.54	1.06	1.35	(-0.4, 3.9)
	Week 16	413	11.12	1.14	11.10	(7.5, 16.8)	413	0.77	1.49	0.70	(-4.1, 7.9)
	Week 20	338	11.21	1.13	11.15	(8.3, 14.9)	338	0.65	1.36	0.60	(-3.2, 4.9)
	Week 24	327	11.16	1.12	11.20	(7.4, 14.1)	327	0.59	1.33	0.60	(-3.6, 4.3)

表 2.7.4.9－33　臨床検査値：実測値及びベースラインからの変化量（ISS-1）（続き）

Parameter:Hematocrit (%)

		Absolute					Change from Baseline				
	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean	SD	Median	Minimum, Maximum
NDD	Baseline	202	31.00	2.97	31.10	(22.6, 37.9)					
	Week 2	202	32.17	3.05	32.30	(24.1, 40.6)	202	1.16	2.24	1.00	(-4.4, 10.9)
	Week 4	200	32.51	3.33	32.95	(23.9, 41.1)	200	1.50	2.98	1.50	(-6.1, 12.9)
	Week 6	199	33.16	3.33	33.20	(25.0, 40.9)	199	2.14	3.44	1.80	(-6.4, 12.7)
	Week 8	195	33.90	3.28	34.10	(25.8, 41.5)	195	2.84	3.44	2.80	(-8.3, 10.9)
	Week 10	192	34.31	2.99	34.75	(25.2, 41.5)	192	3.19	3.40	2.85	(-8.8, 13.0)
	Week 12	180	34.74	3.28	35.20	(25.0, 41.9)	180	3.55	3.81	3.50	(-8.2, 15.5)
	Week 14	34	34.16	2.56	34.40	(29.1, 39.2)	34	4.01	2.96	3.50	(-1.1, 10.7)
	Week 16	176	34.91	3.16	35.20	(25.5, 43.0)	176	3.65	4.08	3.45	(-9.5, 14.4)
	Week 20	140	35.12	3.46	35.30	(25.0, 44.2)	140	3.62	4.19	3.55	(-11.0, 14.8)
	Week 24	132	35.17	3.40	35.55	(22.2, 42.3)	132	3.63	4.14	3.85	(-8.9, 13.4)
HD	Baseline	237	30.51	3.75	31.10	(16.7, 38.5)					
	Week 2	233	30.52	3.57	30.90	(18.7, 39.8)	233	-0.08	1.83	0.10	(-6.0, 5.2)
	Week 4	223	30.40	3.28	30.40	(21.4, 39.7)	223	-0.40	2.88	-0.50	(-7.5, 9.3)
	Week 6	219	30.44	3.37	30.30	(21.1, 43.0)	219	-0.39	3.59	-0.40	(-9.8, 11.1)
	Week 8	216	30.51	3.39	30.55	(20.3, 39.8)	216	-0.31	4.11	-0.30	(-10.7, 11.1)
	Week 10	213	30.84	3.39	30.80	(20.1, 39.9)	213	0.01	4.59	0.00	(-11.6, 16.3)
	Week 12	205	31.36	3.26	31.50	(21.4, 39.5)	205	0.36	4.59	0.40	(-12.8, 11.4)
	Week 14	36	32.24	2.94	32.05	(26.9, 38.0)	36	5.43	3.44	4.95	(-1.5, 11.7)
	Week 16	200	32.29	3.30	32.20	(22.9, 50.4)	200	1.33	5.03	0.70	(-12.1, 23.6)
	Week 20	161	32.20	2.76	32.40	(24.3, 40.2)	161	0.40	3.82	0.50	(-10.0, 8.9)
	Week 24	159	31.90	2.83	31.80	(23.5, 40.4)	159	0.09	3.75	-0.10	(-12.6, 9.4)
PD	Baseline	42	32.79	3.44	33.60	(25.0, 40.0)					
	Week 2	40	32.93	4.15	33.60	(22.6, 41.2)	40	0.25	2.10	0.15	(-4.0, 4.9)
	Week 4	41	32.34	4.22	33.00	(23.2, 40.7)	41	-0.42	2.57	-0.30	(-7.8, 6.4)
	Week 6	39	31.87	4.96	32.00	(21.1, 43.5)	39	-1.01	3.63	-1.00	(-12.6, 5.7)
	Week 8	39	32.51	4.35	32.70	(22.3, 41.9)	39	-0.38	3.47	-0.50	(-6.9, 5.7)
	Week 10	39	32.64	4.22	32.70	(21.9, 41.3)	39	-0.25	3.52	-0.60	(-6.6, 9.0)
	Week 12	38	33.29	4.10	33.05	(22.6, 40.7)	38	0.43	3.93	0.05	(-4.7, 11.0)
	Week 16	37	34.75	4.36	34.00	(24.7, 40.8)	37	1.68	4.43	0.40	(-4.3, 13.5)
	Week 20	37	34.81	4.21	35.50	(27.0, 45.0)	37	1.74	3.89	0.90	(-3.2, 14.8)
	Week 24	36	34.05	3.70	34.65	(24.7, 40.8)	36	0.82	3.26	0.85	(-6.4, 6.4)

表 2.7.4.9－33　臨床検査値：実測値及びベースラインからの変化量（ISS-1）（続き）

Parameter:Hematocrit (%)

		Absolute					Change from Baseline				
	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean	SD	Median	Minimum, Maximum
Total	Baseline	481	30.92	3.46	31.20	(16.7, 40.0)					
	Week 2	475	31.42	3.53	31.80	(18.7, 41.2)	475	0.48	2.12	0.40	(-6.0, 10.9)
	Week 4	464	31.48	3.54	31.80	(21.4, 41.1)	464	0.42	3.05	0.35	(-7.8, 12.9)
	Week 6	457	31.75	3.74	31.70	(21.1, 43.5)	457	0.66	3.76	0.60	(-12.6, 12.7)
	Week 8	450	32.15	3.80	32.55	(20.3, 41.9)	450	1.05	4.08	1.20	(-10.7, 11.1)
	Week 10	444	32.50	3.69	32.55	(20.1, 41.5)	444	1.36	4.32	1.55	(-11.6, 16.3)
	Week 12	423	32.97	3.71	33.20	(21.4, 41.9)	423	1.72	4.49	1.90	(-12.8, 15.5)
	Week 14	70	33.17	2.91	33.25	(26.9, 39.2)	70	4.74	3.27	4.25	(-1.5, 11.7)
	Week 16	413	33.63	3.59	33.70	(22.9, 50.4)	413	2.35	4.72	2.40	(-12.1, 23.6)
	Week 20	338	33.70	3.53	33.60	(24.3, 45.0)	338	1.88	4.25	1.85	(-11.0, 14.8)
	Week 24	327	33.46	3.52	33.50	(22.2, 42.3)	327	1.60	4.20	1.70	(-12.6, 13.4)

表 2.7.4.9－33　臨床検査値：実測値及びベースラインからの変化量（ISS-1）（続き）

Parameter:Erythrocytes (10^4/uL)

		Absolute					Change from Baseline				
	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean	SD	Median	Minimum, Maximum
NDD	Baseline	202	331.9	37.7	330.5	(237, 458)					
	Week 2	202	340.8	38.3	344.0	(243, 453)	202	8.9	21.2	6.5	(-44, 90)
	Week 4	200	342.8	39.3	345.0	(236, 465)	200	10.7	27.7	11.0	(-62, 109)
	Week 6	199	347.8	40.2	348.0	(222, 432)	199	15.5	33.8	14.0	(-74, 110)
	Week 8	195	355.3	40.9	354.0	(248, 461)	195	22.5	35.4	23.0	(-88, 105)
	Week 10	192	359.6	39.2	362.0	(241, 454)	192	25.9	36.6	23.5	(-93, 124)
	Week 12	180	363.9	42.3	366.0	(234, 467)	180	29.4	40.8	28.0	(-87, 139)
	Week 14	34	360.0	30.9	366.5	(296, 412)	34	39.1	31.1	36.5	(-19, 112)
	Week 16	176	366.6	42.8	365.0	(221, 480)	176	31.2	45.2	31.0	(-109, 139)
	Week 20	140	368.6	47.9	373.5	(204, 487)	140	30.4	47.4	30.5	(-133, 143)
	Week 24	132	369.3	47.5	370.0	(210, 504)	132	30.8	47.2	32.0	(-119, 148)
HD	Baseline	237	320.9	44.1	322.0	(176, 467)					
	Week 2	233	318.7	42.7	320.0	(197, 453)	233	-3.1	17.5	-2.0	(-65, 43)
	Week 4	223	316.2	39.9	317.0	(215, 424)	223	-7.2	27.0	-6.0	(-76, 72)
	Week 6	219	315.7	40.4	316.0	(212, 445)	219	-8.2	34.1	-7.0	(-103, 94)
	Week 8	216	315.6	39.9	318.5	(215, 439)	216	-8.4	39.7	-7.5	(-101, 101)
	Week 10	213	317.5	39.6	316.0	(213, 430)	213	-6.3	45.9	-4.0	(-132, 157)
	Week 12	205	322.0	39.3	322.0	(208, 432)	205	-3.5	46.9	-3.0	(-143, 107)
	Week 14	36	328.1	31.8	327.0	(268, 398)	36	46.2	35.7	46.5	(-24, 113)
	Week 16	200	331.1	39.5	332.5	(224, 519)	200	6.0	53.1	1.5	(-135, 234)
	Week 20	161	331.6	36.4	332.0	(238, 451)	161	-2.5	42.8	-3.0	(-131, 93)
	Week 24	159	329.3	34.6	327.0	(249, 445)	159	-4.9	40.2	-6.0	(-155, 91)
PD	Baseline	42	356.8	46.7	362.0	(257, 489)					
	Week 2	40	357.9	54.2	364.0	(245, 506)	40	1.7	21.2	-0.5	(-39, 43)
	Week 4	41	349.9	52.2	356.0	(231, 495)	41	-7.5	25.5	-5.0	(-81, 55)
	Week 6	39	342.3	60.2	348.0	(223, 535)	39	-15.8	38.4	-15.0	(-141, 59)
	Week 8	39	346.0	53.4	351.0	(216, 511)	39	-12.1	36.3	-8.0	(-83, 60)
	Week 10	39	344.1	52.0	350.0	(208, 492)	39	-14.0	35.3	-15.0	(-70, 59)
	Week 12	38	348.8	51.4	358.5	(217, 490)	38	-8.8	39.7	-12.0	(-70, 98)
	Week 16	37	362.5	55.6	356.0	(232, 488)	37	2.1	51.1	-20.0	(-65, 136)
	Week 20	37	362.4	49.7	361.0	(271, 462)	37	2.0	45.3	-10.0	(-92, 155)
	Week 24	36	356.0	45.7	362.5	(241, 476)	36	-5.9	36.7	-9.5	(-64, 60)

表 2.7.4.9－33　臨床検査値：実測値及びベースラインからの変化量（ISS-1）（続き）

Parameter:Erythrocytes (10^4/uL)

		Absolute					Change from Baseline				
	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean	SD	Median	Minimum, Maximum
Total	Baseline	481	328.6	42.9	328.0	(176, 489)					
	Week 2	475	331.4	44.0	332.0	(197, 506)	475	2.4	20.3	2.0	(-65, 90)
	Week 4	464	330.6	43.1	331.5	(215, 495)	464	0.5	28.5	1.0	(-81, 109)
	Week 6	457	331.9	45.0	333.0	(212, 535)	457	1.5	36.5	1.0	(-141, 110)
	Week 8	450	335.4	45.8	336.0	(215, 511)	450	4.7	40.7	7.0	(-101, 105)
	Week 10	444	338.0	45.3	340.0	(208, 492)	444	7.0	44.4	7.0	(-132, 157)
	Week 12	423	342.2	46.3	343.0	(208, 490)	423	10.0	46.8	13.0	(-143, 139)
	Week 14	70	343.6	35.1	345.5	(268, 412)	70	42.7	33.5	39.0	(-24, 113)
	Week 16	413	349.0	45.9	349.0	(221, 519)	413	16.4	51.2	18.0	(-135, 234)
	Week 20	338	350.3	46.5	348.0	(204, 487)	338	11.6	47.6	11.0	(-133, 155)
	Week 24	327	348.4	45.5	345.0	(210, 504)	327	9.4	46.2	11.0	(-155, 148)

表 2.7.4.9－33　臨床検査値：実測値及びベースラインからの変化量（ISS-1）（続き）

Parameter:Reticulocyte count (10^4/uL)

		Absolute					Change from Baseline				
	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean	SD	Median	Minimum, Maximum
NDD	Baseline	202	4.0875	1.9704	3.8040	(0.300, 11.100)					
	Week 2	202	6.5177	2.9666	5.9280	(0.400, 18.900)	202	2.4301	2.4822	2.1000	(-4.200, 11.300)
	Week 4	200	5.5017	2.1515	5.1795	(1.900, 12.408)	200	1.4108	1.8551	1.4000	(-3.900, 8.200)
	Week 6	199	5.5924	2.2189	5.3000	(1.700, 13.300)	199	1.5091	1.8915	1.5400	(-3.900, 7.700)
	Week 8	195	5.3012	2.0295	5.0000	(1.700, 10.500)	195	1.2060	1.8322	1.0000	(-4.000, 7.100)
	Week 10	192	5.2291	1.9680	4.9500	(1.548, 13.600)	192	1.1736	1.8903	1.2000	(-5.200, 6.500)
	Week 12	180	5.0141	2.0449	4.7000	(0.400, 11.200)	180	0.9936	1.9821	1.0000	(-4.800, 6.200)
	Week 14	34	4.0906	1.6258	3.9410	(1.452, 7.560)	34	0.0896	1.5871	-0.0400	(-3.363, 3.600)
	Week 16	176	4.9296	1.9843	4.7290	(1.100, 11.000)	176	0.9013	1.7982	0.8395	(-6.900, 5.900)
	Week 20	140	5.1000	2.0642	4.9500	(1.500, 11.700)	140	1.0764	1.8440	1.0000	(-3.500, 5.700)
	Week 24	132	5.4220	2.1074	5.0500	(1.100, 13.400)	132	1.3538	1.8358	1.3000	(-3.400, 5.700)
HD	Baseline	237	4.1584	1.9465	4.1000	(0.000, 11.500)					
	Week 2	233	4.8852	2.7041	4.6000	(0.300, 21.080)	233	0.7263	2.7787	0.8000	(-7.200, 16.541)
	Week 4	223	4.7318	2.2053	4.5000	(0.300, 13.000)	223	0.4934	2.3356	0.6000	(-5.600, 7.863)
	Week 6	219	5.0554	2.1313	4.8000	(1.000, 11.600)	219	0.8051	2.1610	0.8000	(-5.300, 6.300)
	Week 8	216	5.0287	2.0479	4.7000	(1.500, 11.952)	216	0.7870	2.1709	0.7000	(-4.700, 7.300)
	Week 10	213	5.2146	2.0246	4.8000	(1.600, 11.400)	213	0.9871	2.0827	1.0000	(-4.700, 9.800)
	Week 12	205	5.3159	1.9217	5.2000	(1.600, 12.300)	205	1.0485	1.7996	1.0260	(-3.900, 7.400)
	Week 14	36	5.2279	2.1050	4.9705	(1.950, 10.974)	36	1.7944	1.4062	1.9620	(-1.594, 5.564)
	Week 16	200	5.2446	1.9243	5.0000	(1.516, 11.500)	200	0.9690	1.7513	0.7575	(-3.000, 5.900)
	Week 20	161	5.1932	2.0357	4.8000	(1.400, 11.600)	161	0.7516	1.8529	0.7000	(-3.800, 6.400)
	Week 24	159	5.0151	1.9870	4.8000	(0.700, 12.100)	159	0.5566	1.8180	0.4000	(-3.700, 6.200)
PD	Baseline	42	3.1681	1.8983	2.9500	(0.300, 9.900)					
	Week 2	40	5.1975	2.5418	4.6500	(1.500, 11.100)	40	2.0825	2.2495	1.9500	(-3.000, 7.800)
	Week 4	41	4.9146	2.3338	4.6000	(0.700, 10.000)	41	1.7780	2.1117	1.7000	(-2.600, 7.700)
	Week 6	39	5.5436	2.4344	5.5000	(1.300, 10.300)	39	2.4103	2.4563	2.1000	(-4.000, 8.200)
	Week 8	39	5.4359	2.8361	5.2000	(1.500, 14.400)	39	2.3026	3.0966	1.8000	(-3.200, 12.500)
	Week 10	39	6.0051	2.8623	6.0000	(2.100, 17.100)	39	2.8718	2.8607	2.7000	(-3.800, 12.800)
	Week 12	38	5.6684	2.0374	5.2000	(2.100, 9.900)	38	2.5026	2.1933	2.6000	(-3.400, 7.300)
	Week 16	37	5.6459	2.0736	5.2000	(2.100, 10.800)	37	2.5135	1.9362	2.2000	(-2.700, 7.100)
	Week 20	37	5.5514	2.2561	5.4000	(0.900, 12.000)	37	2.4189	2.5547	2.7000	(-5.600, 8.200)
	Week 24	36	5.6444	2.2485	5.7500	(0.000, 10.900)	36	2.5528	2.3081	2.7500	(-3.100, 7.400)

表 2.7.4.9－33　臨床検査値：実測値及びベースラインからの変化量（ISS-1）（続き）

Parameter:Reticulocyte count (10^4/uL)

		Absolute					Change from Baseline				
	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean	SD	Median	Minimum, Maximum
Total	Baseline	481	4.0439	1.9666	3.9000	(0.000, 11.500)					
	Week 2	475	5.6057	2.9096	5.2380	(0.300, 21.080)	475	1.5651	2.7378	1.6000	(-7.200, 16.541)
	Week 4	464	5.0798	2.2203	4.8000	(0.300, 13.000)	464	1.0023	2.1749	1.1000	(-5.600, 8.200)
	Week 6	457	5.3309	2.2076	5.1000	(1.000, 13.300)	457	1.2486	2.1260	1.2090	(-5.300, 8.200)
	Week 8	450	5.1821	2.1193	4.9000	(1.500, 14.400)	450	1.0999	2.1671	0.9000	(-4.700, 12.500)
	Week 10	444	5.2903	2.0937	4.9000	(1.548, 17.100)	444	1.2333	2.1413	1.2000	(-5.200, 12.800)
	Week 12	423	5.2191	1.9908	5.0050	(0.400, 12.300)	423	1.1558	1.9580	1.1000	(-4.800, 7.400)
	Week 14	70	4.6755	1.9595	4.4940	(1.452, 10.974)	70	0.9664	1.7159	0.8685	(-3.363, 5.564)
	Week 16	413	5.1463	1.9708	4.9500	(1.100, 11.500)	413	1.0785	1.8403	1.0000	(-6.900, 7.100)
	Week 20	338	5.1938	2.0704	4.9500	(0.900, 12.000)	338	1.0686	1.9945	0.9000	(-5.600, 8.200)
	Week 24	327	5.2486	2.0729	5.0000	(0.000, 13.400)	327	1.0982	1.9827	1.0000	(-3.700, 7.400)

表 2.7.4.9－33　臨床検査値：実測値及びベースラインからの変化量（ISS-1）（続き）

Parameter:Reticulocytes ratio (%)

		Absolute					Change from Baseline				
	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean	SD	Median	Minimum, Maximum
NDD	Baseline	202	12.5	6.1	12.0	(1, 40)					
	Week 2	202	19.2	8.5	18.0	(1, 51)	202	6.7	6.9	6.0	(-13, 29)
	Week 4	200	16.2	6.4	15.0	(6, 39)	200	3.7	5.3	4.0	(-12, 23)
	Week 6	199	16.3	7.1	15.0	(4, 60)	199	3.9	6.2	3.0	(-12, 41)
	Week 8	195	15.1	6.0	14.0	(4, 36)	195	2.6	5.6	2.0	(-14, 22)
	Week 10	192	14.7	5.8	14.0	(4, 38)	192	2.4	5.9	2.0	(-18, 19)
	Week 12	180	14.0	5.9	13.0	(1, 35)	180	1.8	6.1	1.5	(-13, 19)
	Week 14	34	11.5	4.8	11.0	(4, 24)	34	-0.9	4.8	-1.0	(-11, 12)
	Week 16	176	13.6	5.8	13.0	(3, 42)	176	1.4	5.6	2.0	(-21, 17)
	Week 20	140	14.0	6.0	13.0	(4, 44)	140	1.9	5.6	2.0	(-15, 20)
	Week 24	132	14.9	6.4	14.0	(3, 55)	132	2.6	5.9	2.5	(-15, 22)
HD	Baseline	237	12.9	5.9	13.0	(0, 34)					
	Week 2	233	15.7	9.1	14.0	(1, 68)	233	2.8	8.8	3.0	(-20, 51)
	Week 4	223	15.2	7.3	14.0	(1, 40)	223	2.1	7.3	2.0	(-20, 24)
	Week 6	219	16.3	7.1	15.0	(3, 38)	219	3.1	6.8	3.0	(-15, 21)
	Week 8	216	16.2	7.0	15.0	(5, 41)	216	3.1	7.1	3.0	(-15, 29)
	Week 10	213	16.7	6.8	16.0	(5, 39)	213	3.6	6.9	4.0	(-14, 34)
	Week 12	205	16.8	6.4	16.0	(5, 42)	205	3.6	6.0	3.0	(-12, 24)
	Week 14	36	16.1	6.6	16.5	(6, 34)	36	3.8	5.9	4.5	(-15, 19)
	Week 16	200	16.0	6.0	15.0	(4, 35)	200	2.9	5.5	3.0	(-17, 16)
	Week 20	161	15.8	6.2	15.0	(4, 39)	161	2.5	5.6	2.0	(-13, 20)
	Week 24	159	15.3	6.1	15.0	(2, 39)	159	1.9	5.2	1.0	(-12, 18)
PD	Baseline	42	9.0	5.3	8.0	(1, 26)					
	Week 2	40	14.6	6.9	14.0	(4, 34)	40	5.8	6.1	5.0	(-7, 27)
	Week 4	41	14.0	6.5	13.0	(2, 26)	41	5.2	5.7	5.0	(-6, 20)
	Week 6	39	16.2	6.7	15.0	(5, 30)	39	7.5	6.7	8.0	(-9, 22)
	Week 8	39	15.9	8.5	15.0	(5, 46)	39	7.2	9.0	7.0	(-9, 41)
	Week 10	39	17.5	7.6	17.0	(7, 43)	39	8.7	7.6	8.0	(-8, 31)
	Week 12	38	16.3	5.5	16.0	(6, 30)	38	7.4	5.9	7.0	(-6, 18)
	Week 16	37	15.6	5.2	15.0	(7, 28)	37	6.9	5.2	7.0	(-6, 17)
	Week 20	37	15.4	6.1	15.0	(3, 27)	37	6.7	7.2	7.0	(-14, 21)
	Week 24	36	15.8	5.6	15.5	(0, 26)	36	7.3	6.2	7.5	(-8, 20)

表 2.7.4.9－33　臨床検査値：実測値及びベースラインからの変化量（ISS-1）（続き）

Parameter:Reticulocytes ratio (%)

		Absolute					Change from Baseline				
	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean	SD	Median	Minimum, Maximum
Total	Baseline	481	12.4	6.0	12.0	(0, 40)					
	Week 2	475	17.1	8.9	16.0	(1, 68)	475	4.7	8.0	5.0	(-20, 51)
	Week 4	464	15.5	6.9	14.5	(1, 40)	464	3.1	6.4	3.0	(-20, 24)
	Week 6	457	16.3	7.1	15.0	(3, 60)	457	3.8	6.6	3.0	(-15, 41)
	Week 8	450	15.7	6.7	15.0	(4, 46)	450	3.3	6.8	3.0	(-15, 41)
	Week 10	444	15.9	6.6	15.0	(4, 43)	444	3.5	6.7	3.0	(-18, 34)
	Week 12	423	15.5	6.3	15.0	(1, 42)	423	3.2	6.2	3.0	(-13, 24)
	Week 14	70	13.8	6.2	14.0	(4, 34)	70	1.5	5.9	1.0	(-15, 19)
	Week 16	413	15.0	6.0	14.0	(3, 42)	413	2.6	5.7	3.0	(-21, 17)
	Week 20	338	15.0	6.2	14.0	(3, 44)	338	2.7	5.9	2.0	(-15, 21)
	Week 24	327	15.2	6.2	15.0	(0, 55)	327	2.8	5.8	2.0	(-15, 22)

表 2.7.4.9－33　臨床検査値：実測値及びベースラインからの変化量（ISS-1）（続き）

Parameter:Ery. Mean Corpuscular Volume (fL)

		Absolute					Change from Baseline				
	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean	SD	Median	Minimum, Maximum
NDD	Baseline	202	93.71	4.87	93.85	(82.0, 119.0)					
	Week 2	202	94.71	5.07	94.45	(82.0, 118.0)	202	1.00	1.55	1.00	(-2.0, 7.6)
	Week 4	200	95.09	5.15	95.00	(83.0, 120.0)	200	1.43	1.94	1.00	(-3.2, 10.2)
	Week 6	199	95.65	5.28	95.00	(82.0, 122.0)	199	1.99	2.09	2.00	(-3.0, 10.0)
	Week 8	195	95.75	5.08	96.00	(83.0, 122.0)	195	2.13	2.14	2.00	(-3.0, 9.0)
	Week 10	192	95.74	5.17	96.00	(82.0, 124.0)	192	2.14	2.28	2.00	(-3.3, 11.0)
	Week 12	180	95.81	5.19	95.25	(83.0, 123.0)	180	2.25	2.54	2.00	(-4.6, 14.0)
	Week 14	34	95.07	3.85	94.50	(85.8, 104.8)	34	1.11	3.33	0.25	(-4.8, 10.0)
	Week 16	176	95.67	5.47	95.15	(82.0, 124.0)	176	2.14	2.92	2.00	(-5.6, 17.0)
	Week 20	140	95.87	6.02	95.00	(82.0, 128.0)	140	2.35	2.86	2.00	(-4.0, 16.0)
	Week 24	132	95.78	6.31	95.00	(82.0, 132.0)	132	2.20	3.07	2.00	(-4.0, 17.0)
HD	Baseline	237	95.41	5.28	95.00	(76.3, 111.0)					
	Week 2	233	96.12	5.27	96.00	(77.0, 110.0)	233	0.75	1.67	0.60	(-2.0, 9.8)
	Week 4	223	96.50	5.17	96.60	(78.0, 111.3)	223	0.89	2.12	1.00	(-4.0, 7.8)
	Week 6	219	96.74	5.21	97.00	(78.0, 113.0)	219	1.21	2.49	1.00	(-4.0, 9.6)
	Week 8	216	97.02	5.13	97.00	(78.0, 112.0)	216	1.54	2.62	1.00	(-4.0, 11.1)
	Week 10	213	97.39	5.06	97.30	(81.0, 112.0)	213	1.82	2.78	1.80	(-5.0, 10.0)
	Week 12	205	97.74	5.13	97.60	(81.0, 111.0)	205	2.15	2.83	2.00	(-5.0, 12.0)
	Week 14	36	98.43	4.44	97.40	(89.6, 110.0)	36	3.14	2.58	3.30	(-3.6, 7.5)
	Week 16	200	97.81	5.04	98.00	(85.0, 114.0)	200	2.29	2.89	2.00	(-5.0, 12.0)
	Week 20	161	97.47	5.13	98.00	(85.0, 113.0)	161	1.94	3.16	2.00	(-7.0, 12.0)
	Week 24	159	97.13	5.13	97.00	(84.0, 115.0)	159	1.60	3.13	1.00	(-8.0, 13.0)
PD	Baseline	42	92.40	5.85	92.00	(81.0, 109.0)					
	Week 2	40	92.45	5.79	92.00	(81.0, 111.0)	40	0.23	1.27	0.00	(-2.0, 4.0)
	Week 4	41	92.83	5.85	92.00	(82.0, 114.0)	41	0.66	1.80	0.00	(-2.0, 5.0)
	Week 6	39	93.54	5.57	93.00	(81.0, 113.0)	39	1.28	2.15	1.00	(-2.0, 7.0)
	Week 8	39	94.46	5.52	94.00	(82.0, 114.0)	39	2.21	2.71	1.00	(-2.0, 10.0)
	Week 10	39	95.23	5.48	95.00	(82.0, 112.0)	39	2.97	3.26	2.00	(-1.0, 13.0)
	Week 12	38	95.82	5.75	95.00	(82.0, 112.0)	38	3.50	3.43	3.00	(-2.0, 16.0)
	Week 16	37	96.41	5.41	96.00	(83.0, 113.0)	37	4.24	3.25	4.00	(0.0, 15.0)
	Week 20	37	96.41	6.00	96.00	(84.0, 113.0)	37	4.24	3.97	4.00	(-1.0, 20.0)
	Week 24	36	96.14	6.01	95.50	(85.0, 114.0)	36	3.89	4.33	3.50	(-3.0, 21.0)

表 2.7.4.9－33　臨床検査値：実測値及びベースラインからの変化量（ISS-1）（続き）

Parameter:Ery. Mean Corpuscular Volume (fL)

		Absolute					Change from Baseline				
	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean	SD	Median	Minimum, Maximum
Total	Baseline	481	94.43	5.25	94.00	(76.3, 119.0)					
	Week 2	475	95.21	5.33	95.00	(77.0, 118.0)	475	0.81	1.60	1.00	(-2.0, 9.8)
	Week 4	464	95.57	5.32	95.00	(78.0, 120.0)	464	1.10	2.04	1.00	(-4.0, 10.2)
	Week 6	457	95.99	5.34	96.00	(78.0, 122.0)	457	1.55	2.32	1.00	(-4.0, 10.0)
	Week 8	450	96.25	5.20	96.00	(78.0, 122.0)	450	1.85	2.44	1.95	(-4.0, 11.1)
	Week 10	444	96.49	5.21	96.20	(81.0, 124.0)	444	2.06	2.64	2.00	(-5.0, 13.0)
	Week 12	423	96.75	5.29	96.80	(81.0, 123.0)	423	2.32	2.79	2.00	(-5.0, 16.0)
	Week 14	70	96.80	4.47	96.45	(85.8, 110.0)	70	2.15	3.12	2.10	(-4.8, 10.0)
	Week 16	413	96.77	5.35	97.00	(82.0, 124.0)	413	2.40	2.98	2.00	(-5.6, 17.0)
	Week 20	338	96.69	5.65	96.50	(82.0, 128.0)	338	2.36	3.20	2.00	(-7.0, 20.0)
	Week 24	327	96.48	5.75	96.00	(82.0, 132.0)	327	2.10	3.32	2.00	(-8.0, 21.0)

表 2.7.4.9－33　臨床検査値：実測値及びベースラインからの変化量（ISS-1）（続き）

Parameter:Ery. Mean Corpuscular Hemoglobin (pg)

		Absolute					Change from Baseline				
	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean	SD	Median	Minimum, Maximum
NDD	Baseline	202	30.90	1.78	30.90	(26.2, 39.7)					
	Week 2	202	31.05	1.83	31.00	(26.7, 40.3)	202	0.15	0.53	0.20	(-1.2, 1.8)
	Week 4	200	31.25	1.83	31.20	(27.1, 40.3)	200	0.36	0.64	0.30	(-1.7, 3.5)
	Week 6	199	31.36	1.85	31.20	(27.1, 41.0)	199	0.47	0.77	0.40	(-1.5, 3.2)
	Week 8	195	31.36	1.81	31.30	(27.1, 40.7)	195	0.49	0.82	0.30	(-1.3, 3.9)
	Week 10	192	31.44	1.90	31.45	(27.1, 42.3)	192	0.58	0.94	0.50	(-1.8, 4.9)
	Week 12	180	31.49	1.93	31.40	(26.8, 42.1)	180	0.59	1.02	0.50	(-1.6, 4.8)
	Week 14	34	30.63	1.34	30.25	(28.5, 34.1)	34	0.33	1.11	0.35	(-2.2, 4.2)
	Week 16	176	31.51	2.01	31.40	(27.0, 42.5)	176	0.62	1.16	0.50	(-1.7, 7.0)
	Week 20	140	31.80	2.16	31.95	(26.8, 43.6)	140	0.74	1.30	0.50	(-1.8, 6.2)
	Week 24	132	31.84	2.25	31.60	(27.2, 45.2)	132	0.75	1.36	0.60	(-1.9, 7.0)
HD	Baseline	237	31.60	1.95	31.50	(24.0, 36.8)					
	Week 2	233	31.68	1.93	31.70	(24.4, 37.6)	233	0.09	0.56	0.10	(-1.9, 1.9)
	Week 4	223	31.94	1.82	31.90	(25.1, 38.3)	223	0.27	0.74	0.20	(-2.1, 3.5)
	Week 6	219	31.98	1.86	32.00	(25.7, 39.2)	219	0.35	0.93	0.30	(-2.8, 5.0)
	Week 8	216	32.13	1.81	32.20	(25.6, 37.9)	216	0.52	1.05	0.50	(-2.4, 5.4)
	Week 10	213	32.26	1.82	32.30	(26.7, 39.0)	213	0.61	1.09	0.60	(-1.7, 5.1)
	Week 12	205	32.45	1.83	32.40	(27.1, 39.1)	205	0.81	1.10	0.80	(-2.1, 5.1)
	Week 14	36	32.29	1.19	32.25	(29.9, 34.5)	36	1.03	0.99	1.10	(-1.1, 4.9)
	Week 16	200	32.45	1.86	32.40	(27.1, 39.4)	200	0.82	1.20	0.70	(-2.4, 5.2)
	Week 20	161	32.50	1.91	32.60	(27.9, 40.2)	161	0.81	1.28	0.80	(-2.6, 5.0)
	Week 24	159	32.56	1.95	32.60	(26.9, 41.0)	159	0.86	1.29	0.60	(-2.4, 5.6)
PD	Baseline	42	30.75	2.21	30.80	(26.2, 37.1)					
	Week 2	40	30.84	2.22	30.85	(25.9, 38.0)	40	0.14	0.68	0.15	(-1.2, 1.7)
	Week 4	41	30.88	2.19	30.70	(26.3, 38.8)	41	0.22	0.75	0.20	(-1.1, 2.3)
	Week 6	39	31.17	1.98	31.10	(26.0, 37.6)	39	0.47	0.94	0.50	(-1.3, 3.0)
	Week 8	39	31.47	2.02	31.40	(26.4, 38.2)	39	0.77	1.08	0.70	(-1.3, 3.7)
	Week 10	39	31.78	2.06	31.50	(26.4, 38.4)	39	1.08	1.28	0.70	(-0.8, 4.7)
	Week 12	38	32.01	2.02	31.95	(26.3, 37.5)	38	1.29	1.27	0.85	(-0.5, 5.5)
	Week 16	37	32.15	2.03	32.10	(26.6, 37.7)	37	1.51	1.47	1.10	(-1.0, 5.7)
	Week 20	37	32.17	2.11	32.00	(27.1, 37.8)	37	1.52	1.63	1.30	(-1.0, 7.4)
	Week 24	36	32.03	2.01	31.95	(27.5, 37.2)	36	1.36	1.73	1.20	(-2.2, 6.6)

表 2.7.4.9－33　臨床検査値：実測値及びベースラインからの変化量（ISS-1）（続き）

Parameter:Ery. Mean Corpuscular Hemoglobin (pg)

		Absolute					Change from Baseline				
	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean	SD	Median	Minimum, Maximum
Total	Baseline	481	31.23	1.94	31.30	(24.0, 39.7)					
	Week 2	475	31.34	1.94	31.30	(24.4, 40.3)	475	0.12	0.56	0.10	(-1.9, 1.9)
	Week 4	464	31.55	1.89	31.50	(25.1, 40.3)	464	0.30	0.70	0.30	(-2.1, 3.5)
	Week 6	457	31.64	1.89	31.50	(25.7, 41.0)	457	0.41	0.86	0.40	(-2.8, 5.0)
	Week 8	450	31.74	1.86	31.75	(25.6, 40.7)	450	0.53	0.96	0.40	(-2.4, 5.4)
	Week 10	444	31.87	1.91	31.90	(26.4, 42.3)	444	0.64	1.05	0.50	(-1.8, 5.1)
	Week 12	423	32.00	1.94	32.00	(26.3, 42.1)	423	0.76	1.10	0.60	(-2.1, 5.5)
	Week 14	70	31.48	1.51	31.40	(28.5, 34.5)	70	0.69	1.10	0.70	(-2.2, 4.9)
	Week 16	413	32.02	1.99	32.10	(26.6, 42.5)	413	0.80	1.23	0.60	(-2.4, 7.0)
	Week 20	338	32.17	2.06	32.10	(26.8, 43.6)	338	0.86	1.35	0.70	(-2.6, 7.4)
	Week 24	327	32.21	2.10	32.10	(26.9, 45.2)	327	0.87	1.38	0.60	(-2.4, 7.0)

表 2.7.4.9－33　臨床検査値：実測値及びベースラインからの変化量（ISS-1）（続き）

Parameter:Ery. Mean Corpuscular HGB Concentration (%)

		Absolute					Change from Baseline				
	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean	SD	Median	Minimum, Maximum
NDD	Baseline	202	32.97	0.83	33.10	(30.4, 34.5)					
	Week 2	202	32.80	0.95	33.00	(29.4, 35.1)	202	-0.17	0.60	-0.10	(-2.0, 1.2)
	Week 4	200	32.86	0.94	33.00	(29.4, 34.8)	200	-0.11	0.62	-0.10	(-2.4, 1.4)
	Week 6	199	32.78	0.90	32.90	(29.7, 34.6)	199	-0.19	0.68	-0.10	(-2.6, 1.1)
	Week 8	195	32.76	0.84	32.90	(29.1, 34.6)	195	-0.21	0.70	-0.20	(-1.9, 1.5)
	Week 10	192	32.83	0.79	32.90	(29.5, 34.3)	192	-0.14	0.65	-0.10	(-1.9, 1.7)
	Week 12	180	32.85	0.78	33.00	(30.1, 34.7)	180	-0.17	0.68	-0.20	(-2.7, 1.5)
	Week 14	34	32.23	0.92	32.30	(30.0, 34.3)	34	-0.01	0.97	0.05	(-2.0, 1.8)
	Week 16	176	32.92	0.69	32.90	(30.3, 34.8)	176	-0.09	0.70	-0.10	(-2.4, 2.2)
	Week 20	140	33.17	0.48	33.10	(31.9, 34.6)	140	-0.03	0.69	-0.10	(-1.5, 1.9)
	Week 24	132	33.22	0.52	33.20	(31.7, 34.7)	132	0.01	0.73	0.00	(-1.5, 3.2)
HD	Baseline	237	33.11	0.63	33.10	(30.5, 35.5)					
	Week 2	233	32.96	0.72	33.00	(29.3, 35.2)	233	-0.15	0.65	-0.10	(-3.5, 1.5)
	Week 4	223	33.09	0.59	33.10	(31.4, 35.2)	223	-0.03	0.57	0.00	(-2.0, 1.7)
	Week 6	219	33.05	0.67	33.00	(31.1, 35.0)	219	-0.06	0.64	0.00	(-2.3, 2.7)
	Week 8	216	33.12	0.65	33.10	(31.3, 37.1)	216	0.02	0.63	0.00	(-2.1, 3.1)
	Week 10	213	33.10	0.61	33.10	(30.2, 35.0)	213	0.00	0.60	0.00	(-2.6, 2.2)
	Week 12	205	33.20	0.60	33.20	(30.9, 35.5)	205	0.11	0.59	0.10	(-1.7, 2.6)
	Week 14	36	32.82	0.69	32.85	(30.1, 33.9)	36	0.01	0.82	0.05	(-2.1, 2.6)
	Week 16	200	33.16	0.60	33.20	(31.3, 35.2)	200	0.06	0.63	0.10	(-2.4, 2.4)
	Week 20	161	33.32	0.56	33.30	(31.8, 35.5)	161	0.16	0.57	0.10	(-2.1, 1.5)
	Week 24	159	33.50	0.61	33.40	(31.5, 35.7)	159	0.33	0.62	0.40	(-1.7, 2.1)
PD	Baseline	42	33.26	0.66	33.25	(31.5, 34.4)					
	Week 2	40	33.32	0.77	33.30	(31.7, 35.0)	40	0.04	0.65	0.10	(-1.3, 1.7)
	Week 4	41	33.24	0.52	33.10	(31.9, 34.6)	41	-0.02	0.54	0.00	(-1.2, 1.1)
	Week 6	39	33.30	0.57	33.30	(31.9, 34.8)	39	0.04	0.59	0.00	(-1.2, 1.2)
	Week 8	39	33.34	0.61	33.20	(32.2, 35.3)	39	0.08	0.58	0.20	(-1.1, 1.2)
	Week 10	39	33.33	0.71	33.20	(31.7, 35.6)	39	0.07	0.67	0.10	(-1.2, 1.6)
	Week 12	38	33.37	0.55	33.30	(32.2, 34.3)	38	0.09	0.59	0.00	(-1.0, 1.4)
	Week 16	37	33.35	0.64	33.30	(32.1, 35.7)	37	0.10	0.72	0.10	(-1.5, 1.6)
	Week 20	37	33.35	0.49	33.40	(32.1, 34.5)	37	0.11	0.61	0.10	(-1.1, 1.4)
	Week 24	36	33.35	0.48	33.35	(32.2, 34.1)	36	0.11	0.80	0.15	(-1.5, 1.5)

表 2.7.4.9－33　臨床検査値：実測値及びベースラインからの変化量（ISS-1）（続き）

Parameter:Ery. Mean Corpuscular HGB Concentration (%)

		Absolute					Change from Baseline				
	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean	SD	Median	Minimum, Maximum
Total	Baseline	481	33.06	0.73	33.10	(30.4, 35.5)					
	Week 2	475	32.92	0.84	33.00	(29.3, 35.2)	475	-0.14	0.63	-0.10	(-3.5, 1.7)
	Week 4	464	33.00	0.76	33.10	(29.4, 35.2)	464	-0.06	0.59	-0.10	(-2.4, 1.7)
	Week 6	457	32.95	0.79	33.00	(29.7, 35.0)	457	-0.11	0.66	-0.10	(-2.6, 2.7)
	Week 8	450	32.98	0.76	33.00	(29.1, 37.1)	450	-0.07	0.66	-0.10	(-2.1, 3.1)
	Week 10	444	33.00	0.72	33.10	(29.5, 35.6)	444	-0.05	0.63	0.00	(-2.6, 2.2)
	Week 12	423	33.06	0.70	33.10	(30.1, 35.5)	423	-0.01	0.64	0.00	(-2.7, 2.6)
	Week 14	70	32.53	0.86	32.60	(30.0, 34.3)	70	0.00	0.89	0.05	(-2.1, 2.6)
	Week 16	413	33.07	0.66	33.10	(30.3, 35.7)	413	0.00	0.67	0.00	(-2.4, 2.4)
	Week 20	338	33.26	0.52	33.20	(31.8, 35.5)	338	0.08	0.63	0.00	(-2.1, 1.9)
	Week 24	327	33.37	0.58	33.30	(31.5, 35.7)	327	0.18	0.70	0.20	(-1.7, 3.2)

表 2.7.4.9－33　臨床検査値：実測値及びベースラインからの変化量（ISS-1）（続き）

Parameter:Erythrocytes Distribution Width (%)

		Absolute					Change from Baseline				
	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean	SD	Median	Minimum, Maximum
NDD	Baseline	202	14.27	1.48	14.00	(12.0, 22.8)					
	Week 2	202	14.85	1.59	14.50	(12.1, 23.5)	202	0.58	0.74	0.50	(-0.9, 4.0)
	Week 4	200	15.00	1.72	14.75	(12.0, 23.7)	200	0.73	0.94	0.60	(-1.5, 5.3)
	Week 6	199	14.97	1.82	14.60	(12.3, 23.7)	199	0.70	1.07	0.60	(-1.9, 9.1)
	Week 8	195	14.74	1.65	14.40	(12.2, 21.8)	195	0.47	0.96	0.40	(-2.2, 3.8)
	Week 10	192	14.60	1.57	14.30	(11.6, 20.4)	192	0.31	1.12	0.30	(-3.3, 4.2)
	Week 12	180	14.45	1.52	14.20	(11.9, 21.3)	180	0.15	1.18	0.10	(-3.2, 4.1)
	Week 14	34	13.55	0.96	13.60	(11.9, 15.7)	34	-0.02	0.72	0.05	(-1.9, 1.4)
	Week 16	176	14.07	1.26	13.90	(11.9, 19.4)	176	-0.23	1.27	0.00	(-4.9, 3.1)
	Week 20	140	14.20	1.35	13.90	(11.4, 20.4)	140	-0.24	1.48	-0.20	(-5.6, 5.9)
	Week 24	132	14.36	1.47	14.10	(11.8, 21.8)	132	-0.04	1.47	0.00	(-5.4, 4.7)
HD	Baseline	237	14.40	1.36	14.20	(11.6, 19.9)					
	Week 2	233	14.58	1.34	14.40	(11.9, 21.1)	233	0.17	0.79	0.20	(-1.6, 3.9)
	Week 4	223	14.56	1.31	14.40	(12.1, 20.7)	223	0.16	0.98	0.00	(-2.1, 3.2)
	Week 6	219	14.57	1.28	14.40	(11.9, 20.2)	219	0.16	1.04	0.10	(-2.8, 3.8)
	Week 8	216	14.58	1.33	14.40	(12.0, 19.3)	216	0.16	1.11	0.20	(-3.1, 3.5)
	Week 10	213	14.53	1.28	14.40	(11.6, 20.0)	213	0.13	1.14	0.20	(-3.9, 4.1)
	Week 12	205	14.45	1.27	14.30	(12.1, 21.0)	205	0.06	1.24	0.10	(-4.9, 4.5)
	Week 14	36	13.36	0.89	13.35	(11.8, 15.8)	36	-0.01	0.84	0.00	(-2.0, 2.1)
	Week 16	200	14.13	1.11	14.00	(11.9, 19.5)	200	-0.24	1.22	-0.10	(-6.0, 2.5)
	Week 20	161	14.09	1.13	13.90	(12.2, 20.1)	161	-0.48	1.43	-0.40	(-6.2, 3.6)
	Week 24	159	14.11	1.18	13.90	(12.1, 19.2)	159	-0.47	1.53	-0.40	(-5.9, 3.8)
PD	Baseline	42	15.54	2.76	14.55	(12.9, 26.8)					
	Week 2	40	15.81	2.74	15.15	(13.0, 26.7)	40	0.24	0.64	0.15	(-1.6, 1.8)
	Week 4	41	15.84	2.55	15.00	(12.8, 26.0)	41	0.25	1.08	0.30	(-4.4, 2.7)
	Week 6	39	15.87	2.29	15.30	(12.7, 23.5)	39	0.28	1.56	0.40	(-6.3, 3.1)
	Week 8	39	15.74	2.07	15.40	(12.9, 20.6)	39	0.15	1.95	0.20	(-6.9, 3.7)
	Week 10	39	15.49	1.69	15.50	(12.6, 20.4)	39	-0.09	2.09	0.20	(-10.0, 2.7)
	Week 12	38	15.24	1.84	15.05	(12.5, 21.3)	38	-0.31	2.34	-0.35	(-11.1, 4.7)
	Week 16	37	14.51	1.66	14.00	(12.4, 21.0)	37	-1.04	2.63	-0.60	(-12.0, 3.4)
	Week 20	37	14.39	1.86	13.80	(12.5, 21.3)	37	-1.16	2.27	-0.70	(-11.0, 2.9)
	Week 24	36	14.30	1.62	13.90	(12.6, 20.8)	36	-1.25	2.60	-0.65	(-12.6, 1.5)

表 2.7.4.9－33　臨床検査値：実測値及びベースラインからの変化量（ISS-1）（続き）

Parameter:Erythrocytes Distribution Width (%)

		Absolute					Change from Baseline				
	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean	SD	Median	Minimum, Maximum
Total	Baseline	481	14.45	1.61	14.10	(11.6, 26.8)					
	Week 2	475	14.80	1.64	14.50	(11.9, 26.7)	475	0.35	0.78	0.30	(-1.6, 4.0)
	Week 4	464	14.86	1.67	14.55	(12.0, 26.0)	464	0.41	1.01	0.30	(-4.4, 5.3)
	Week 6	457	14.85	1.67	14.60	(11.9, 23.7)	457	0.41	1.13	0.30	(-6.3, 9.1)
	Week 8	450	14.75	1.58	14.40	(12.0, 21.8)	450	0.30	1.15	0.30	(-6.9, 3.8)
	Week 10	444	14.64	1.47	14.40	(11.6, 20.4)	444	0.19	1.25	0.20	(-10.0, 4.2)
	Week 12	423	14.52	1.45	14.30	(11.9, 21.3)	423	0.06	1.35	0.10	(-11.1, 4.7)
	Week 14	70	13.45	0.92	13.45	(11.8, 15.8)	70	-0.01	0.77	0.00	(-2.0, 2.1)
	Week 16	413	14.14	1.24	13.90	(11.9, 21.0)	413	-0.31	1.44	-0.10	(-12.0, 3.4)
	Week 20	338	14.17	1.32	13.90	(11.4, 21.3)	338	-0.46	1.58	-0.30	(-11.0, 5.9)
	Week 24	327	14.23	1.36	13.90	(11.8, 21.8)	327	-0.39	1.69	-0.20	(-12.6, 4.7)

表 2.7.4.9－33　臨床検査値：実測値及びベースラインからの変化量（ISS-1）（続き）

Parameter:Leukocytes (/uL)

		Absolute					Change from Baseline				
	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean	SD	Median	Minimum, Maximum
NDD	Baseline	202	5699.5	1825.9	5300.0	(2400, 13700)					
	Week 2	202	5798.0	2008.9	5400.0	(2500, 19700)	202	98.5	1357.9	100.0	(-5300, 11500)
	Week 4	200	5619.0	1836.9	5200.0	(2400, 12400)	200	-103.0	1168.6	-100.0	(-3700, 6600)
	Week 6	199	5717.1	1595.9	5500.0	(2800, 10900)	199	-9.0	1213.0	0.0	(-7000, 3600)
	Week 8	195	5827.2	1755.7	5500.0	(2600, 11600)	195	105.1	1157.5	100.0	(-3600, 6300)
	Week 10	192	5907.3	1796.7	5700.0	(2800, 17600)	192	171.9	1465.4	200.0	(-5700, 11400)
	Week 12	180	5606.1	1538.6	5500.0	(2800, 10900)	180	-157.2	1179.8	0.0	(-5100, 2700)
	Week 14	34	5694.1	1572.5	5600.0	(3400, 9500)	34	-264.7	1255.3	-50.0	(-4700, 1600)
	Week 16	176	5833.5	1726.5	5500.0	(2800, 14500)	176	75.6	1338.1	100.0	(-3400, 7400)
	Week 20	140	5862.9	1767.5	5600.0	(3100, 12700)	140	161.4	1624.4	100.0	(-5100, 8000)
	Week 24	132	5845.5	1856.7	5550.0	(2500, 14900)	132	120.5	1428.9	50.0	(-3600, 7800)
HD	Baseline	237	5706.3	1782.9	5400.0	(1100, 13100)					
	Week 2	233	5780.7	1808.7	5400.0	(1100, 14400)	233	53.6	982.3	-100.0	(-3000, 4600)
	Week 4	223	5763.2	1795.8	5400.0	(1200, 14600)	223	47.5	1033.7	0.0	(-3200, 3800)
	Week 6	219	5745.2	1739.8	5500.0	(1200, 12900)	219	4.1	1006.1	0.0	(-3600, 3700)
	Week 8	216	5769.4	1739.3	5500.0	(1200, 12600)	216	12.0	1158.9	0.0	(-5000, 4700)
	Week 10	213	5795.8	1853.7	5400.0	(1600, 12400)	213	48.4	1199.5	0.0	(-4100, 3400)
	Week 12	204	5707.8	1836.2	5300.0	(2800, 14100)	204	-34.3	1146.0	-100.0	(-5100, 4800)
	Week 14	36	5522.2	1531.4	5300.0	(2900, 9900)	36	130.6	1131.8	-150.0	(-1400, 2600)
	Week 16	200	5819.5	1915.5	5500.0	(2000, 14100)	200	47.5	1151.5	0.0	(-5000, 4900)
	Week 20	161	5942.2	1895.1	5600.0	(2800, 11800)	161	50.9	1026.9	0.0	(-3200, 3700)
	Week 24	159	5845.9	1944.9	5600.0	(2400, 12600)	159	-53.5	1144.9	-100.0	(-4400, 4700)
PD	Baseline	42	6095.2	2435.7	5300.0	(3100, 12000)					
	Week 2	40	6297.5	2127.8	5650.0	(3400, 12000)	40	167.5	960.6	300.0	(-2600, 2800)
	Week 4	41	6097.6	1733.1	5700.0	(3200, 9300)	41	0.0	1323.8	200.0	(-3500, 2300)
	Week 6	39	6302.6	1876.0	5800.0	(3900, 10800)	39	100.0	1218.7	300.0	(-3400, 3100)
	Week 8	39	6405.1	2031.7	5700.0	(3500, 11200)	39	202.6	1450.0	400.0	(-3900, 4000)
	Week 10	39	6274.4	2104.0	5600.0	(3200, 11100)	39	71.8	1289.0	100.0	(-3400, 4100)
	Week 12	38	6376.3	2403.6	5750.0	(2900, 14500)	38	121.1	1404.7	200.0	(-3300, 2800)
	Week 16	37	6600.0	2421.1	5700.0	(3700, 14100)	37	259.5	1165.8	300.0	(-3000, 2200)
	Week 20	37	6556.8	2038.7	5900.0	(3600, 11100)	37	216.2	1414.3	100.0	(-3200, 3500)
	Week 24	36	6636.1	2384.5	5600.0	(4000, 13200)	36	333.3	1668.5	300.0	(-3700, 5000)

表 2.7.4.9－33　臨床検査値：実測値及びベースラインからの変化量（ISS-1）（続き）

Parameter:Leukocytes (/uL)

		Absolute					Change from Baseline				
	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean	SD	Median	Minimum, Maximum
Total	Baseline	481	5737.4	1864.9	5300.0	(1100, 13700)					
	Week 2	475	5831.6	1924.9	5400.0	(1100, 19700)	475	82.3	1153.8	0.0	(-5300, 11500)
	Week 4	464	5730.6	1809.4	5400.0	(1200, 14600)	464	-21.6	1120.6	0.0	(-3700, 6600)
	Week 6	457	5780.5	1694.7	5500.0	(1200, 12900)	457	6.6	1116.9	0.0	(-7000, 3700)
	Week 8	450	5849.6	1777.6	5500.0	(1200, 12600)	450	68.9	1184.7	50.0	(-5000, 6300)
	Week 10	444	5886.0	1853.0	5600.0	(1600, 17600)	444	103.8	1326.8	100.0	(-5700, 11400)
	Week 12	422	5724.6	1794.1	5450.0	(2800, 14500)	422	-72.7	1185.6	-100.0	(-5100, 4800)
	Week 14	70	5605.7	1542.6	5350.0	(2900, 9900)	70	-61.4	1201.2	-100.0	(-4700, 2600)
	Week 16	413	5895.4	1897.2	5600.0	(2000, 14500)	413	78.5	1234.2	100.0	(-5000, 7400)
	Week 20	338	5976.6	1865.6	5600.0	(2800, 12700)	338	114.8	1344.1	100.0	(-5100, 8000)
	Week 24	327	5932.7	1925.3	5600.0	(2400, 14900)	327	59.3	1330.6	0.0	(-4400, 7800)

表 2.7.4.9－33　臨床検査値：実測値及びベースラインからの変化量（ISS-1）（続き）

Parameter:Neutrophils/Leukocytes (%)

		Absolute					Change from Baseline				
	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean	SD	Median	Minimum, Maximum
NDD	Baseline	201	64.70	9.18	65.00	(35.5, 89.0)					
	Week 2	201	64.15	9.22	64.10	(37.0, 91.5)	201	-0.55	6.57	-0.10	(-22.9, 20.0)
	Week 4	199	64.47	9.55	64.40	(36.8, 91.1)	199	-0.27	7.08	0.10	(-21.0, 33.4)
	Week 6	199	65.12	8.75	65.40	(41.0, 88.5)	198	0.43	6.26	0.85	(-16.7, 20.4)
	Week 8	194	64.64	8.98	64.70	(38.5, 91.0)	194	0.06	6.92	-0.25	(-18.6, 22.1)
	Week 10	192	64.98	8.89	64.70	(39.9, 87.5)	191	0.38	7.36	0.50	(-28.6, 20.1)
	Week 12	179	64.56	9.41	64.90	(37.2, 89.0)	179	0.14	6.71	0.10	(-23.9, 18.0)
	Week 14	34	66.11	6.39	66.65	(41.8, 81.1)	34	-0.13	5.28	-0.25	(-12.4, 9.2)
	Week 16	174	65.21	8.98	65.25	(43.1, 90.3)	174	0.72	6.78	1.15	(-15.9, 24.5)
	Week 20	139	65.62	9.93	65.50	(36.3, 90.0)	139	1.77	8.05	1.90	(-19.0, 27.6)
	Week 24	131	65.47	9.16	64.90	(35.9, 92.5)	131	1.73	8.01	1.30	(-18.6, 28.0)
HD	Baseline	237	66.61	8.29	66.70	(40.9, 88.5)					
	Week 2	232	66.51	8.08	66.55	(40.1, 88.5)	232	-0.26	5.57	-0.30	(-12.9, 18.2)
	Week 4	222	66.70	7.80	66.95	(41.0, 85.5)	222	0.05	5.87	0.45	(-18.0, 16.0)
	Week 6	218	66.58	7.18	66.55	(48.6, 86.5)	218	-0.20	6.29	-0.10	(-18.5, 17.0)
	Week 8	215	66.81	7.59	66.60	(45.1, 84.6)	215	-0.13	6.56	-0.50	(-18.1, 28.1)
	Week 10	212	66.80	8.09	67.30	(41.6, 90.5)	212	-0.17	7.14	-0.55	(-31.1, 23.0)
	Week 12	204	66.58	7.72	66.55	(45.6, 88.5)	204	-0.39	6.59	-0.75	(-29.5, 22.4)
	Week 14	36	64.89	6.98	65.80	(49.9, 76.0)	36	1.52	5.32	0.30	(-6.0, 19.2)
	Week 16	200	67.12	7.64	67.45	(45.7, 85.7)	200	0.30	6.43	0.15	(-23.2, 17.9)
	Week 20	160	68.29	8.04	68.00	(43.3, 89.0)	160	0.64	6.69	0.50	(-16.7, 26.3)
	Week 24	158	69.37	8.03	69.00	(46.0, 90.5)	158	1.70	6.53	1.00	(-15.0, 24.5)
PD	Baseline	42	65.47	7.65	65.80	(44.0, 88.0)					
	Week 2	40	64.77	7.61	65.15	(41.5, 86.0)	40	-0.58	5.37	-1.30	(-12.5, 13.7)
	Week 4	41	66.84	7.50	68.00	(43.0, 83.5)	41	1.48	5.76	0.90	(-11.0, 16.0)
	Week 6	39	66.24	9.49	66.80	(39.0, 91.0)	39	0.69	5.77	0.20	(-10.5, 20.3)
	Week 8	39	66.06	8.16	66.50	(45.5, 87.0)	39	0.51	6.56	0.30	(-13.5, 15.0)
	Week 10	39	65.51	7.45	65.00	(52.9, 87.0)	39	-0.04	6.15	-0.70	(-14.5, 15.0)
	Week 12	38	68.40	7.31	68.55	(55.2, 86.0)	38	3.24	7.26	2.00	(-8.5, 21.9)
	Week 16	37	67.81	8.18	68.00	(50.0, 86.5)	37	2.07	6.77	2.70	(-11.0, 21.0)
	Week 20	37	69.54	8.83	70.00	(51.0, 88.0)	37	3.80	9.10	2.30	(-10.0, 31.7)
	Week 24	36	68.58	8.40	69.25	(53.0, 85.5)	36	2.80	7.06	2.60	(-6.9, 18.5)

表 2.7.4.9－33　臨床検査値：実測値及びベースラインからの変化量（ISS-1）（続き）

Parameter:Neutrophils/Leukocytes (%)

		Absolute					Change from Baseline				
	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean	SD	Median	Minimum, Maximum
Total	Baseline	480	65.71	8.66	66.00	(35.5, 89.0)					
	Week 2	473	65.36	8.61	65.60	(37.0, 91.5)	473	-0.41	5.99	-0.30	(-22.9, 20.0)
	Week 4	462	65.75	8.63	65.90	(36.8, 91.1)	462	0.04	6.42	0.40	(-21.0, 33.4)
	Week 6	456	65.92	8.12	66.00	(39.0, 91.0)	455	0.15	6.23	0.20	(-18.5, 20.4)
	Week 8	448	65.81	8.31	66.00	(38.5, 91.0)	448	0.01	6.71	-0.30	(-18.6, 28.1)
	Week 10	443	65.90	8.42	66.00	(39.9, 90.5)	442	0.08	7.15	-0.10	(-31.1, 23.0)
	Week 12	421	65.89	8.52	66.00	(37.2, 89.0)	421	0.17	6.76	-0.10	(-29.5, 22.4)
	Week 14	70	65.48	7.66	66.15	(41.8, 81.1)	70	0.72	5.33	0.00	(-12.4, 19.2)
	Week 16	411	66.37	8.32	67.00	(43.1, 90.3)	411	0.64	6.61	0.50	(-23.2, 24.5)
	Week 20	336	67.33	9.05	67.00	(36.3, 90.0)	336	1.45	7.60	1.45	(-19.0, 31.7)
	Week 24	325	67.71	8.72	67.50	(35.9, 92.5)	325	1.84	7.21	1.20	(-18.6, 28.0)

表 2.7.4.9－33　臨床検査値：実測値及びベースラインからの変化量（ISS-1）（続き）

Parameter:Eosinophils/Leukocytes (%)

		Absolute					Change from Baseline				
	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean	SD	Median	Minimum, Maximum
NDD	Baseline	201	3.78	2.89	3.10	(0.0, 23.0)					
	Week 2	201	4.12	3.46	3.20	(0.0, 26.3)	201	0.34	2.08	0.10	(-5.0, 16.3)
	Week 4	199	3.98	3.32	3.10	(0.0, 23.5)	199	0.20	2.31	0.10	(-6.8, 17.5)
	Week 6	199	3.87	2.64	3.40	(0.1, 19.1)	198	0.09	1.94	0.10	(-6.4, 9.8)
	Week 8	194	4.00	2.98	3.25	(0.0, 18.5)	194	0.19	2.03	0.00	(-5.1, 7.5)
	Week 10	192	4.01	3.22	3.10	(0.0, 22.0)	191	0.20	2.53	-0.10	(-7.0, 16.0)
	Week 12	179	3.99	3.03	3.30	(0.0, 17.2)	179	0.17	2.09	0.00	(-5.8, 8.1)
	Week 14	34	3.89	2.84	3.05	(0.8, 11.4)	34	0.17	1.17	0.10	(-2.3, 3.2)
	Week 16	174	3.60	2.59	2.95	(0.0, 15.2)	174	-0.04	1.91	0.00	(-7.8, 7.0)
	Week 20	139	3.63	2.98	3.00	(0.0, 23.0)	139	-0.13	2.36	-0.10	(-7.5, 17.0)
	Week 24	131	3.69	3.21	3.00	(0.0, 25.0)	131	-0.04	2.90	0.10	(-9.5, 18.7)
HD	Baseline	237	4.99	3.54	4.00	(0.0, 23.0)					
	Week 2	232	4.84	3.44	4.15	(0.0, 27.0)	232	-0.11	2.07	0.00	(-7.0, 5.1)
	Week 4	222	4.63	3.51	4.00	(0.0, 26.5)	222	-0.32	2.35	-0.10	(-9.0, 13.8)
	Week 6	218	4.69	3.60	3.70	(0.0, 28.0)	218	-0.26	2.37	-0.10	(-7.0, 9.1)
	Week 8	215	4.81	3.55	4.10	(0.0, 30.0)	215	-0.14	2.30	-0.10	(-9.4, 7.4)
	Week 10	212	4.77	3.56	4.00	(0.0, 26.0)	212	-0.13	2.83	-0.10	(-10.2, 22.2)
	Week 12	204	4.79	3.78	3.80	(0.0, 19.6)	204	-0.15	2.76	-0.15	(-9.7, 14.6)
	Week 14	36	5.35	3.38	4.80	(0.8, 17.0)	36	-0.10	1.89	-0.05	(-4.0, 4.7)
	Week 16	200	4.72	3.75	3.55	(0.0, 22.0)	200	-0.22	2.70	-0.20	(-8.7, 10.4)
	Week 20	160	4.49	3.56	3.85	(0.4, 19.6)	160	-0.37	2.53	-0.20	(-10.4, 10.3)
	Week 24	158	4.52	3.29	3.85	(0.0, 15.9)	158	-0.33	2.34	0.00	(-7.1, 5.7)
PD	Baseline	42	5.53	3.64	4.95	(0.1, 14.2)					
	Week 2	40	5.69	4.25	4.50	(0.5, 17.7)	40	-0.03	2.47	-0.30	(-5.7, 5.9)
	Week 4	41	4.98	3.01	4.50	(1.2, 15.2)	41	-0.67	2.41	-0.40	(-9.0, 4.0)
	Week 6	39	5.50	4.46	4.20	(0.4, 20.0)	39	-0.21	3.94	-0.40	(-9.5, 14.0)
	Week 8	39	5.50	3.75	5.00	(0.5, 18.0)	39	-0.21	3.07	-0.10	(-10.3, 6.2)
	Week 10	39	5.23	3.51	4.80	(0.2, 16.2)	39	-0.49	2.93	-0.60	(-10.0, 7.6)
	Week 12	38	4.62	3.09	4.00	(0.0, 13.5)	38	-1.24	2.55	-0.90	(-8.5, 4.9)
	Week 16	37	4.76	3.09	4.20	(0.1, 15.5)	37	-1.09	3.37	-0.90	(-13.0, 6.9)
	Week 20	37	4.86	3.11	4.00	(0.0, 14.2)	37	-1.00	3.19	-0.50	(-8.0, 9.3)
	Week 24	36	5.06	3.20	3.95	(1.0, 14.5)	36	-0.83	2.70	-0.25	(-9.0, 3.5)

表 2.7.4.9－33　臨床検査値：実測値及びベースラインからの変化量（ISS-1）（続き）

Parameter:Eosinophils/Leukocytes (%)

		Absolute					Change from Baseline				
	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean	SD	Median	Minimum, Maximum
Total	Baseline	480	4.53	3.35	3.80	(0.0, 23.0)					
	Week 2	473	4.61	3.55	3.90	(0.0, 27.0)	473	0.09	2.12	0.00	(-7.0, 16.3)
	Week 4	462	4.38	3.40	3.70	(0.0, 26.5)	462	-0.13	2.35	-0.05	(-9.0, 17.5)
	Week 6	456	4.40	3.34	3.50	(0.0, 28.0)	455	-0.10	2.38	0.00	(-9.5, 14.0)
	Week 8	448	4.52	3.36	3.90	(0.0, 30.0)	448	0.00	2.27	0.00	(-10.3, 7.5)
	Week 10	443	4.48	3.43	3.70	(0.0, 26.0)	442	-0.02	2.72	-0.10	(-10.2, 22.2)
	Week 12	421	4.44	3.43	3.50	(0.0, 19.6)	421	-0.11	2.50	-0.10	(-9.7, 14.6)
	Week 14	70	4.64	3.19	4.00	(0.0, 17.0)	70	0.03	1.57	0.00	(-4.0, 4.7)
	Week 16	411	4.25	3.29	3.40	(0.0, 22.0)	411	-0.22	2.48	-0.20	(-13.0, 10.4)
	Week 20	336	4.17	3.31	3.40	(0.0, 23.0)	336	-0.34	2.55	-0.20	(-10.4, 17.0)
	Week 24	325	4.25	3.27	3.50	(0.0, 25.0)	325	-0.27	2.62	0.00	(-9.5, 18.7)

表 2.7.4.9－33　臨床検査値：実測値及びベースラインからの変化量（ISS-1）（続き）

Parameter:Monocytes/Leukocytes (%)

		Absolute					Change from Baseline				
	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean	SD	Median	Minimum, Maximum
NDD	Baseline	201	6.00	2.06	5.90	(0.9, 12.5)					
	Week 2	201	6.56	2.03	6.30	(3.0, 12.8)	201	0.56	1.72	0.40	(-4.4, 6.8)
	Week 4	199	6.61	2.25	6.40	(1.6, 12.5)	199	0.62	1.81	0.60	(-6.0, 6.0)
	Week 6	199	6.49	2.07	6.20	(1.1, 12.1)	198	0.49	1.89	0.50	(-5.8, 5.6)
	Week 8	194	6.71	2.10	6.45	(2.8, 12.6)	194	0.72	1.88	0.50	(-5.9, 10.4)
	Week 10	192	6.58	2.05	6.40	(2.4, 11.9)	191	0.57	1.79	0.60	(-7.1, 6.4)
	Week 12	179	6.61	2.19	6.50	(1.5, 13.0)	179	0.56	1.97	0.60	(-5.4, 4.7)
	Week 14	34	5.46	1.60	5.30	(2.9, 9.4)	34	0.37	1.20	0.40	(-1.6, 2.9)
	Week 16	174	6.93	2.24	6.85	(1.0, 15.0)	174	0.88	1.90	0.90	(-6.2, 6.5)
	Week 20	139	7.00	2.26	7.00	(2.0, 15.0)	139	0.64	2.13	0.70	(-4.9, 5.3)
	Week 24	131	6.97	2.18	6.90	(2.5, 14.5)	131	0.56	2.37	0.60	(-8.5, 5.7)
HD	Baseline	237	6.41	2.00	6.00	(2.0, 12.6)					
	Week 2	232	6.62	2.02	6.50	(3.0, 12.2)	232	0.21	2.01	0.30	(-5.6, 5.9)
	Week 4	222	6.54	1.93	6.40	(2.6, 12.9)	222	0.13	1.93	0.00	(-6.1, 5.4)
	Week 6	218	6.86	1.88	7.00	(1.2, 12.3)	218	0.46	2.02	0.50	(-7.8, 6.0)
	Week 8	215	6.77	2.04	6.60	(0.5, 12.9)	215	0.37	2.06	0.40	(-5.5, 7.1)
	Week 10	212	6.55	1.90	6.45	(2.0, 12.2)	212	0.16	2.18	0.10	(-7.0, 7.0)
	Week 12	204	6.75	1.97	6.50	(1.4, 12.8)	204	0.30	1.91	0.20	(-4.4, 5.6)
	Week 14	36	6.36	1.69	6.10	(3.2, 9.6)	36	0.43	1.19	0.45	(-3.0, 2.9)
	Week 16	200	6.79	2.18	6.60	(2.0, 12.6)	200	0.32	2.14	0.50	(-7.5, 7.3)
	Week 20	160	6.82	2.07	6.95	(1.8, 11.6)	160	0.25	1.99	0.20	(-6.5, 5.0)
	Week 24	158	6.72	2.30	6.75	(1.0, 12.7)	158	0.16	2.47	0.25	(-6.5, 7.3)
PD	Baseline	42	7.05	2.36	7.05	(2.1, 12.1)					
	Week 2	40	7.68	3.29	7.30	(2.0, 21.0)	40	0.71	2.86	0.25	(-4.8, 12.0)
	Week 4	41	7.15	3.08	7.00	(1.5, 18.5)	41	0.12	2.96	-0.20	(-4.9, 9.5)
	Week 6	39	7.27	2.76	7.10	(1.0, 15.5)	39	0.41	2.46	0.00	(-4.3, 6.8)
	Week 8	39	7.34	3.54	6.90	(2.9, 23.0)	39	0.48	3.23	0.00	(-4.9, 14.0)
	Week 10	39	7.01	2.13	7.00	(1.0, 13.5)	39	0.15	2.30	-0.20	(-4.0, 4.5)
	Week 12	38	7.19	2.67	7.50	(1.1, 13.5)	38	0.26	2.11	0.20	(-3.9, 4.7)
	Week 16	37	7.19	2.35	7.20	(2.0, 13.0)	37	0.31	2.34	0.20	(-3.2, 7.0)
	Week 20	37	6.66	2.25	7.00	(1.0, 11.0)	37	-0.22	2.90	0.00	(-5.7, 5.2)
	Week 24	36	7.36	2.85	6.45	(2.0, 15.5)	36	0.63	2.51	0.35	(-3.7, 9.5)

表 2.7.4.9－33　臨床検査値：実測値及びベースラインからの変化量（ISS-1）（続き）

Parameter:Monocytes/Leukocytes (%)

		Absolute					Change from Baseline				
	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean	SD	Median	Minimum, Maximum
Total	Baseline	480	6.30	2.08	6.00	(0.9, 12.6)					
	Week 2	473	6.68	2.18	6.50	(2.0, 21.0)	473	0.40	1.99	0.30	(-5.6, 12.0)
	Week 4	462	6.62	2.19	6.50	(1.5, 18.5)	462	0.34	2.00	0.30	(-6.1, 9.5)
	Week 6	456	6.73	2.06	6.65	(1.0, 15.5)	455	0.47	2.00	0.50	(-7.8, 6.8)
	Week 8	448	6.79	2.23	6.50	(0.5, 23.0)	448	0.53	2.12	0.50	(-5.9, 14.0)
	Week 10	443	6.60	1.99	6.50	(1.0, 13.5)	442	0.34	2.03	0.35	(-7.1, 7.0)
	Week 12	421	6.73	2.14	6.50	(1.1, 13.5)	421	0.41	1.96	0.40	(-5.4, 5.6)
	Week 14	70	5.93	1.69	5.80	(2.9, 9.6)	70	0.40	1.19	0.45	(-3.0, 2.9)
	Week 16	411	6.86	2.22	6.70	(1.0, 15.0)	411	0.56	2.07	0.60	(-7.5, 7.3)
	Week 20	336	6.88	2.16	7.00	(1.0, 15.0)	336	0.36	2.17	0.50	(-6.5, 5.3)
	Week 24	325	6.89	2.32	6.80	(1.0, 15.5)	325	0.37	2.44	0.40	(-8.5, 9.5)

表 2.7.4.9－33　臨床検査値：実測値及びベースラインからの変化量（ISS-1）（続き）

Parameter:Lymphocytes/Leukocytes (%)

		Absolute					Change from Baseline				
	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean	SD	Median	Minimum, Maximum
NDD	Baseline	201	25.13	8.04	24.20	(7.5, 51.2)					
	Week 2	201	24.77	8.20	24.00	(5.0, 54.5)	201	-0.37	5.27	-0.70	(-19.9, 13.7)
	Week 4	199	24.53	8.49	24.00	(5.7, 51.4)	199	-0.57	5.74	-0.10	(-30.4, 16.2)
	Week 6	199	24.09	7.91	23.90	(7.5, 48.0)	198	-1.04	4.96	-0.90	(-20.0, 12.7)
	Week 8	194	24.23	8.18	23.80	(4.0, 49.4)	194	-0.99	5.88	-0.80	(-17.4, 14.8)
	Week 10	192	24.04	7.84	23.80	(4.0, 46.8)	191	-1.15	5.74	-1.00	(-15.6, 22.8)
	Week 12	179	24.44	8.54	23.60	(7.0, 53.1)	179	-0.89	5.45	-1.00	(-15.4, 22.7)
	Week 14	34	24.12	7.91	23.05	(12.9, 48.2)	34	-0.40	5.28	-0.45	(-10.7, 12.5)
	Week 16	174	23.88	7.94	23.00	(6.5, 47.0)	174	-1.55	5.82	-1.90	(-25.4, 14.3)
	Week 20	139	23.45	8.69	22.60	(6.0, 56.5)	139	-2.22	6.71	-1.50	(-24.5, 11.7)
	Week 24	131	23.52	8.20	22.50	(2.0, 59.3)	131	-2.24	6.66	-1.50	(-20.4, 15.2)
HD	Baseline	237	21.59	6.80	21.00	(6.5, 42.3)					
	Week 2	232	21.65	6.57	21.50	(5.5, 41.4)	232	0.18	4.21	0.35	(-14.0, 10.6)
	Week 4	222	21.70	6.46	21.45	(7.5, 40.0)	222	0.12	4.41	0.15	(-13.0, 16.5)
	Week 6	218	21.50	6.15	21.15	(6.0, 37.3)	218	0.02	4.67	0.00	(-12.7, 12.0)
	Week 8	215	21.24	6.33	21.00	(7.5, 41.6)	215	-0.09	4.95	0.30	(-19.3, 11.7)
	Week 10	212	21.49	6.81	20.35	(5.0, 42.0)	212	0.15	5.51	0.40	(-19.4, 14.0)
	Week 12	204	21.48	6.46	21.00	(6.0, 39.3)	204	0.24	5.30	0.30	(-20.0, 14.9)
	Week 14	36	22.75	6.51	21.20	(14.9, 40.9)	36	-1.94	5.02	-1.10	(-16.5, 5.8)
	Week 16	200	21.02	6.30	20.60	(7.0, 39.6)	200	-0.35	5.13	-0.20	(-14.6, 13.6)
	Week 20	160	20.06	6.26	20.00	(6.5, 42.9)	160	-0.49	5.43	-0.10	(-17.2, 13.5)
	Week 24	158	19.12	6.38	19.10	(5.5, 37.1)	158	-1.43	4.91	-1.15	(-16.5, 11.5)
PD	Baseline	42	21.55	7.26	20.90	(3.0, 41.0)					
	Week 2	40	21.43	6.29	21.15	(6.0, 33.9)	40	-0.15	4.14	0.65	(-11.3, 7.0)
	Week 4	41	20.57	5.79	20.00	(8.0, 35.5)	41	-1.00	4.31	-0.80	(-13.5, 8.3)
	Week 6	39	20.52	6.62	21.00	(6.0, 31.6)	39	-0.96	5.36	-0.70	(-16.5, 8.9)
	Week 8	39	20.60	6.62	19.40	(3.0, 34.1)	39	-0.89	5.01	0.30	(-15.0, 6.0)
	Week 10	39	21.75	6.45	20.70	(6.0, 32.0)	39	0.26	4.53	0.50	(-12.0, 10.0)
	Week 12	38	19.41	5.68	19.05	(6.0, 30.8)	38	-2.23	5.91	-0.80	(-18.0, 7.5)
	Week 16	37	19.91	6.46	19.60	(5.5, 38.0)	37	-1.21	4.65	-1.00	(-11.9, 10.0)
	Week 20	37	18.55	6.38	18.40	(5.0, 35.3)	37	-2.57	6.63	-1.30	(-25.4, 8.5)
	Week 24	36	18.66	6.83	17.40	(7.5, 34.1)	36	-2.52	4.85	-2.35	(-15.2, 5.8)

表 2.7.4.9－33　臨床検査値：実測値及びベースラインからの変化量（ISS-1）（続き）

Parameter:Lymphocytes/Leukocytes (%)

		Absolute					Change from Baseline				
	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean	SD	Median	Minimum, Maximum
Total	Baseline	480	23.07	7.57	22.40	(3.0, 51.2)					
	Week 2	473	22.96	7.44	22.30	(5.0, 54.5)	473	-0.08	4.69	0.00	(-19.9, 13.7)
	Week 4	462	22.82	7.49	22.40	(5.7, 51.4)	462	-0.27	5.02	0.00	(-30.4, 16.5)
	Week 6	456	22.55	7.13	22.00	(6.0, 48.0)	455	-0.52	4.88	-0.40	(-20.0, 12.7)
	Week 8	448	22.48	7.36	22.00	(3.0, 49.4)	448	-0.55	5.39	-0.35	(-19.3, 14.8)
	Week 10	443	22.62	7.33	22.00	(4.0, 46.8)	442	-0.40	5.56	-0.30	(-19.4, 22.8)
	Week 12	421	22.55	7.54	21.60	(6.0, 53.1)	421	-0.46	5.46	-0.20	(-20.0, 22.7)
	Week 14	70	23.42	7.20	22.45	(12.9, 48.2)	70	-1.19	5.17	-0.85	(-16.5, 12.5)
	Week 16	411	22.13	7.20	21.90	(5.5, 47.0)	411	-0.94	5.41	-0.90	(-25.4, 14.3)
	Week 20	336	21.30	7.59	20.55	(5.0, 56.5)	336	-1.43	6.17	-0.90	(-25.4, 13.5)
	Week 24	325	20.85	7.52	20.50	(2.0, 59.3)	325	-1.88	5.68	-1.40	(-20.4, 15.2)

表 2.7.4.9－33　臨床検査値：実測値及びベースラインからの変化量（ISS-1）（続き）

Parameter:Basophils/Leukocytes (%)

		Absolute					Change from Baseline				
	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean	SD	Median	Minimum, Maximum
NDD	Baseline	201	0.39	0.31	0.30	(0.0, 2.0)					
	Week 2	201	0.41	0.32	0.40	(0.0, 1.2)	201	0.01	0.40	0.00	(-2.0, 1.2)
	Week 4	199	0.41	0.33	0.40	(0.0, 1.6)	199	0.01	0.40	0.00	(-1.3, 1.2)
	Week 6	199	0.43	0.35	0.40	(0.0, 2.2)	198	0.04	0.43	0.00	(-1.7, 2.0)
	Week 8	194	0.42	0.31	0.40	(0.0, 1.7)	194	0.03	0.41	0.00	(-2.0, 1.7)
	Week 10	192	0.39	0.34	0.40	(0.0, 2.0)	191	0.00	0.39	0.00	(-1.9, 1.7)
	Week 12	179	0.40	0.30	0.40	(0.0, 1.6)	179	0.02	0.35	0.00	(-1.5, 0.9)
	Week 14	34	0.42	0.20	0.40	(0.1, 0.9)	34	-0.01	0.24	0.00	(-0.5, 0.4)
	Week 16	174	0.38	0.35	0.30	(0.0, 2.5)	174	0.00	0.45	0.00	(-2.0, 2.3)
	Week 20	139	0.30	0.27	0.30	(0.0, 1.1)	139	-0.06	0.34	0.00	(-1.4, 0.9)
	Week 24	131	0.34	0.35	0.30	(0.0, 1.8)	131	-0.02	0.43	0.00	(-1.3, 1.4)
HD	Baseline	237	0.40	0.40	0.30	(0.0, 2.2)					
	Week 2	232	0.38	0.38	0.30	(0.0, 2.0)	232	-0.02	0.47	0.00	(-2.2, 2.0)
	Week 4	222	0.42	0.42	0.30	(0.0, 3.1)	222	0.02	0.49	0.00	(-2.0, 2.3)
	Week 6	218	0.36	0.36	0.30	(0.0, 2.1)	218	-0.03	0.48	0.00	(-2.2, 1.3)
	Week 8	215	0.37	0.35	0.30	(0.0, 1.7)	215	-0.02	0.48	0.00	(-1.8, 1.2)
	Week 10	212	0.39	0.36	0.40	(0.0, 1.7)	212	-0.01	0.45	0.00	(-2.0, 1.4)
	Week 12	204	0.39	0.36	0.35	(0.0, 1.6)	204	0.00	0.44	0.00	(-1.5, 1.0)
	Week 14	36	0.64	0.36	0.45	(0.2, 1.4)	36	0.09	0.27	0.00	(-0.3, 0.5)
	Week 16	200	0.35	0.35	0.30	(0.0, 1.5)	200	-0.05	0.47	0.00	(-1.5, 1.3)
	Week 20	160	0.34	0.38	0.20	(0.0, 2.0)	160	-0.03	0.55	0.00	(-2.0, 2.0)
	Week 24	158	0.27	0.32	0.20	(0.0, 1.7)	158	-0.09	0.49	0.00	(-2.2, 1.3)
PD	Baseline	42	0.35	0.29	0.30	(0.0, 1.0)					
	Week 2	40	0.39	0.37	0.30	(0.0, 1.5)	40	0.04	0.42	0.00	(-1.0, 1.0)
	Week 4	41	0.44	0.56	0.40	(0.0, 3.0)	41	0.09	0.56	0.00	(-1.0, 2.5)
	Week 6	39	0.45	0.44	0.30	(0.0, 2.0)	39	0.11	0.48	0.00	(-0.7, 1.5)
	Week 8	39	0.47	0.55	0.40	(0.0, 3.0)	39	0.12	0.59	0.00	(-1.0, 2.5)
	Week 10	39	0.48	0.52	0.40	(0.0, 2.6)	39	0.13	0.63	0.10	(-1.0, 2.5)
	Week 12	38	0.34	0.47	0.30	(0.0, 2.5)	38	-0.01	0.55	0.00	(-1.0, 2.0)
	Week 16	37	0.31	0.31	0.30	(0.0, 1.2)	37	-0.05	0.40	0.00	(-1.0, 1.0)
	Week 20	37	0.37	0.35	0.30	(0.0, 1.5)	37	0.01	0.46	0.00	(-1.0, 1.0)
	Week 24	36	0.29	0.31	0.20	(0.0, 1.5)	36	-0.07	0.43	0.00	(-1.0, 1.0)

表 2.7.4.9－33　臨床検査値：実測値及びベースラインからの変化量（ISS-1）（続き）

Parameter:Basophils/Leukocytes (%)

		Absolute					Change from Baseline				
	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean	SD	Median	Minimum, Maximum
Total	Baseline	480	0.39	0.35	0.30	(0.0, 2.2)					
	Week 2	473	0.39	0.35	0.30	(0.0, 2.0)	473	0.00	0.44	0.00	(-2.2, 2.0)
	Week 4	462	0.42	0.40	0.40	(0.0, 3.1)	462	0.03	0.46	0.00	(-2.0, 2.5)
	Week 6	456	0.40	0.36	0.30	(0.0, 2.2)	455	0.01	0.46	0.00	(-2.2, 2.0)
	Week 8	448	0.40	0.36	0.40	(0.0, 3.0)	448	0.01	0.46	0.00	(-2.0, 2.5)
	Week 10	443	0.40	0.37	0.40	(0.0, 2.6)	442	0.01	0.44	0.00	(-2.0, 2.5)
	Week 12	421	0.39	0.35	0.40	(0.0, 2.5)	421	0.01	0.42	0.00	(-1.5, 2.0)
	Week 14	70	0.53	0.31	0.40	(0.1, 1.4)	70	0.04	0.26	0.00	(-0.5, 0.5)
	Week 16	411	0.36	0.35	0.30	(0.0, 2.5)	411	-0.03	0.46	0.00	(-2.0, 2.3)
	Week 20	336	0.33	0.33	0.30	(0.0, 2.0)	336	-0.04	0.46	0.00	(-2.0, 2.0)
	Week 24	325	0.30	0.33	0.20	(0.0, 1.8)	325	-0.06	0.46	0.00	(-2.2, 1.4)

表 2.7.4.9－33　臨床検査値：実測値及びベースラインからの変化量（ISS-1）（続き）

Parameter:Platelets (10^4/uL)

		Absolute					Change from Baseline				
	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean	SD	Median	Minimum, Maximum
NDD	Baseline	202	20.12	6.24	18.90	(7.4, 41.5)					
	Week 2	202	20.92	6.48	20.00	(6.9, 42.1)	202	0.80	3.11	0.90	(-13.9, 11.2)
	Week 4	199	20.42	6.64	19.20	(7.6, 59.1)	199	0.26	3.68	0.20	(-10.7, 32.6)
	Week 6	198	20.57	6.20	19.60	(7.9, 38.7)	198	0.36	3.05	0.60	(-12.7, 12.2)
	Week 8	194	20.36	5.96	19.60	(6.9, 46.4)	194	0.17	3.09	0.00	(-8.6, 15.9)
	Week 10	192	20.11	6.14	19.15	(4.7, 40.4)	192	-0.14	3.58	0.00	(-12.9, 19.0)
	Week 12	179	20.27	5.94	19.50	(9.0, 38.1)	179	0.02	3.30	0.30	(-13.4, 8.4)
	Week 14	34	21.46	5.37	21.25	(11.9, 31.5)	34	-1.17	3.47	-1.05	(-8.6, 5.3)
	Week 16	176	20.14	5.66	19.50	(6.6, 39.5)	176	-0.10	3.26	0.10	(-13.0, 8.7)
	Week 20	138	20.08	5.91	19.50	(8.2, 40.8)	138	0.25	3.56	0.30	(-16.5, 9.8)
	Week 24	131	20.37	6.30	19.30	(5.2, 42.1)	131	0.32	3.71	0.30	(-14.5, 13.5)
HD	Baseline	236	18.32	5.36	17.60	(5.1, 38.4)					
	Week 2	229	17.72	5.29	17.40	(5.2, 35.7)	228	-0.63	2.72	-0.40	(-10.8, 10.1)
	Week 4	221	17.82	5.11	17.30	(5.7, 35.3)	220	-0.34	2.68	-0.45	(-8.3, 8.0)
	Week 6	218	17.87	5.11	17.30	(5.8, 36.9)	217	-0.45	2.67	-0.50	(-9.1, 7.7)
	Week 8	214	17.98	4.76	17.60	(6.1, 33.9)	213	-0.38	2.59	-0.40	(-8.4, 9.0)
	Week 10	211	18.26	4.99	17.60	(6.1, 37.1)	211	-0.03	2.51	0.00	(-8.0, 9.0)
	Week 12	202	18.38	4.76	17.60	(7.3, 35.1)	202	0.02	2.51	0.00	(-10.4, 8.1)
	Week 14	36	18.87	4.69	17.95	(10.3, 33.6)	36	0.47	2.33	0.70	(-3.9, 6.1)
	Week 16	198	18.45	5.15	17.80	(7.4, 35.3)	197	-0.02	2.69	-0.20	(-11.9, 8.7)
	Week 20	160	18.21	4.87	17.55	(6.4, 33.9)	159	-0.30	2.48	-0.30	(-6.3, 9.4)
	Week 24	155	18.43	4.94	18.00	(7.6, 35.5)	154	-0.23	2.78	-0.40	(-8.7, 13.1)
PD	Baseline	42	22.96	7.87	22.15	(9.6, 43.6)					
	Week 2	39	22.85	7.30	22.60	(9.1, 42.8)	39	-0.26	2.71	-0.10	(-9.6, 6.0)
	Week 4	41	22.18	7.21	20.20	(10.6, 38.8)	41	-0.75	3.37	-0.70	(-11.7, 7.5)
	Week 6	39	23.12	8.04	22.00	(10.0, 43.0)	39	0.26	2.46	0.10	(-4.5, 5.3)
	Week 8	38	23.34	8.07	22.15	(11.5, 42.9)	38	0.79	4.05	0.70	(-7.2, 14.8)
	Week 10	39	22.94	8.09	22.10	(9.9, 38.4)	39	0.08	4.41	0.10	(-10.0, 17.1)
	Week 12	38	22.76	6.84	22.70	(10.4, 35.0)	38	-0.46	3.92	0.50	(-10.7, 7.3)
	Week 16	37	23.09	8.27	21.40	(8.8, 40.6)	37	-0.32	3.97	0.30	(-10.8, 6.1)
	Week 20	37	23.58	6.94	23.90	(9.2, 36.2)	37	0.17	4.47	1.20	(-10.4, 9.1)
	Week 24	36	24.57	6.87	24.10	(9.8, 36.8)	36	1.07	4.83	0.80	(-10.7, 17.7)

表 2.7.4.9－33　臨床検査値：実測値及びベースラインからの変化量（ISS-1）（続き）

Parameter:Platelets (10^4/uL)

		Absolute					Change from Baseline				
	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean	SD	Median	Minimum, Maximum
Total	Baseline	480	19.48	6.13	18.50	(5.1, 43.6)					
	Week 2	470	19.52	6.27	18.55	(5.2, 42.8)	469	0.02	2.97	0.10	(-13.9, 11.2)
	Week 4	461	19.33	6.19	18.40	(5.7, 59.1)	460	-0.12	3.22	-0.20	(-11.7, 32.6)
	Week 6	455	19.49	6.12	18.40	(5.8, 43.0)	454	-0.03	2.84	0.00	(-12.7, 12.2)
	Week 8	446	19.48	5.86	18.50	(6.1, 46.4)	445	-0.04	2.97	-0.10	(-8.6, 15.9)
	Week 10	442	19.48	5.98	18.65	(4.7, 40.4)	442	-0.07	3.20	0.00	(-12.9, 19.6)
	Week 12	419	19.59	5.65	18.90	(7.3, 38.1)	419	-0.02	3.01	0.20	(-13.4, 8.4)
	Week 14	70	20.13	5.16	19.40	(10.3, 33.6)	70	-0.33	3.03	-0.10	(-8.6, 6.1)
	Week 16	411	19.59	5.86	18.80	(6.6, 40.6)	410	-0.06	3.07	0.00	(-13.0, 8.7)
	Week 20	335	19.57	5.80	19.00	(6.4, 40.8)	334	-0.02	3.22	0.00	(-16.5, 9.8)
	Week 24	322	19.91	6.04	19.00	(5.2, 42.1)	321	0.14	3.46	0.00	(-14.5, 17.7)

表 2.7.4.9－33　臨床検査値：実測値及びベースラインからの変化量（ISS-1）（続き）

Parameter:Protein (g/dL)

		Absolute					Change from Baseline				
	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean	SD	Median	Minimum, Maximum
NDD	Baseline	202	6.85	0.57	6.90	(5.1, 8.4)					
	Week 2	202	6.88	0.56	6.85	(5.3, 8.8)	202	0.03	0.32	0.00	(-0.9, 0.9)
	Week 4	200	6.84	0.59	6.90	(5.4, 8.8)	200	-0.02	0.33	0.00	(-1.1, 0.7)
	Week 6	199	6.84	0.60	6.90	(5.0, 8.7)	199	-0.01	0.33	0.00	(-1.2, 0.8)
	Week 8	195	6.86	0.60	6.90	(5.2, 8.4)	195	0.00	0.34	0.00	(-1.1, 0.8)
	Week 10	193	6.84	0.60	6.80	(5.3, 9.1)	193	-0.02	0.35	0.00	(-1.2, 0.9)
	Week 12	180	6.86	0.58	6.90	(5.1, 8.5)	180	0.02	0.38	0.00	(-1.2, 0.9)
	Week 14	34	7.01	0.54	7.05	(5.4, 8.0)	34	-0.10	0.32	-0.05	(-1.0, 0.5)
	Week 16	176	6.81	0.64	6.90	(4.8, 9.1)	176	-0.04	0.43	0.00	(-1.6, 0.9)
	Week 20	140	6.78	0.62	6.85	(4.9, 9.0)	140	-0.01	0.41	0.00	(-1.3, 1.0)
	Week 24	132	6.84	0.64	6.90	(5.0, 9.2)	132	0.03	0.44	0.00	(-1.1, 1.7)
HD	Baseline	237	6.33	0.45	6.30	(5.0, 7.9)					
	Week 2	233	6.36	0.45	6.30	(5.1, 7.9)	233	0.02	0.25	0.00	(-0.8, 0.7)
	Week 4	223	6.35	0.45	6.30	(5.0, 7.8)	223	0.01	0.29	0.00	(-0.8, 0.9)
	Week 6	219	6.36	0.47	6.40	(5.0, 8.0)	219	0.02	0.30	0.00	(-1.1, 0.8)
	Week 8	216	6.33	0.46	6.35	(5.2, 7.4)	216	0.00	0.30	0.00	(-0.8, 0.9)
	Week 10	213	6.33	0.45	6.30	(5.3, 7.8)	213	0.00	0.31	0.00	(-0.7, 0.9)
	Week 12	205	6.38	0.44	6.40	(5.2, 7.7)	205	0.03	0.31	0.00	(-1.1, 0.8)
	Week 14	36	6.39	0.40	6.40	(5.5, 7.2)	36	0.05	0.35	0.10	(-0.6, 0.7)
	Week 16	200	6.35	0.44	6.40	(5.1, 7.6)	200	0.01	0.32	0.00	(-0.9, 0.9)
	Week 20	161	6.36	0.44	6.30	(5.3, 7.6)	161	0.01	0.33	0.00	(-0.9, 0.8)
	Week 24	159	6.34	0.44	6.40	(5.3, 7.6)	159	-0.01	0.28	0.00	(-0.8, 0.6)
PD	Baseline	42	6.37	0.62	6.40	(4.8, 7.7)					
	Week 2	40	6.41	0.59	6.40	(5.0, 8.0)	40	0.02	0.27	0.00	(-0.6, 0.5)
	Week 4	41	6.31	0.58	6.30	(4.7, 7.8)	41	-0.08	0.35	-0.10	(-1.0, 0.7)
	Week 6	39	6.24	0.64	6.20	(4.7, 7.5)	39	-0.17	0.35	-0.20	(-1.0, 0.8)
	Week 8	39	6.33	0.63	6.30	(4.8, 7.5)	39	-0.07	0.33	-0.10	(-0.8, 0.8)
	Week 10	39	6.22	0.59	6.20	(4.9, 7.5)	39	-0.18	0.34	-0.20	(-1.0, 0.6)
	Week 12	38	6.28	0.60	6.20	(5.0, 7.6)	38	-0.14	0.40	-0.10	(-0.9, 0.9)
	Week 16	37	6.27	0.57	6.20	(4.7, 7.8)	37	-0.12	0.42	-0.10	(-1.4, 0.7)
	Week 20	37	6.35	0.63	6.40	(5.2, 7.5)	37	-0.04	0.50	0.00	(-1.1, 1.1)
	Week 24	36	6.25	0.71	6.35	(4.7, 7.7)	36	-0.14	0.55	-0.10	(-1.5, 1.1)

表 2.7.4.9－33　臨床検査値：実測値及びベースラインからの変化量（ISS-1）（続き）

Parameter:Protein (g/dL)

		Absolute					Change from Baseline				
	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean	SD	Median	Minimum, Maximum
Total	Baseline	481	6.55	0.57	6.50	(4.8, 8.4)					
	Week 2	475	6.58	0.57	6.60	(5.0, 8.8)	475	0.02	0.28	0.00	(-0.9, 0.9)
	Week 4	464	6.55	0.58	6.50	(4.7, 8.8)	464	-0.01	0.31	0.00	(-1.1, 0.9)
	Week 6	457	6.56	0.60	6.50	(4.7, 8.7)	457	-0.01	0.33	0.00	(-1.2, 0.8)
	Week 8	450	6.56	0.60	6.60	(4.8, 8.4)	450	-0.01	0.32	0.00	(-1.1, 0.9)
	Week 10	445	6.54	0.59	6.50	(4.9, 9.1)	445	-0.02	0.34	0.00	(-1.2, 0.9)
	Week 12	423	6.57	0.57	6.60	(5.0, 8.5)	423	0.01	0.35	0.00	(-1.2, 0.9)
	Week 14	70	6.69	0.56	6.70	(5.4, 8.0)	70	-0.02	0.34	0.00	(-1.0, 0.7)
	Week 16	413	6.54	0.60	6.50	(4.7, 9.1)	413	-0.03	0.38	0.00	(-1.6, 0.9)
	Week 20	338	6.53	0.58	6.60	(4.9, 9.0)	338	0.00	0.38	0.00	(-1.3, 1.1)
	Week 24	327	6.53	0.61	6.50	(4.7, 9.2)	327	-0.01	0.39	0.00	(-1.5, 1.7)

表 2.7.4.9－33　臨床検査値：実測値及びベースラインからの変化量（ISS-1）（続き）

Parameter:Albumin (g/dL)

		Absolute					Change from Baseline				
	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean	SD	Median	Minimum, Maximum
NDD	Baseline	202	3.82	0.41	3.80	(2.4, 4.7)					
	Week 2	202	3.80	0.39	3.80	(2.4, 4.9)	202	-0.02	0.21	0.00	(-0.8, 0.5)
	Week 4	200	3.75	0.41	3.80	(1.7, 4.6)	200	-0.06	0.25	-0.10	(-2.1, 0.5)
	Week 6	199	3.75	0.42	3.80	(2.0, 4.8)	199	-0.06	0.23	-0.10	(-1.1, 0.8)
	Week 8	195	3.77	0.40	3.80	(2.4, 4.8)	195	-0.05	0.23	0.00	(-1.0, 0.8)
	Week 10	193	3.72	0.37	3.70	(2.4, 4.6)	193	-0.09	0.23	-0.10	(-1.0, 0.8)
	Week 12	180	3.73	0.38	3.80	(2.1, 4.5)	180	-0.07	0.26	-0.10	(-1.0, 0.9)
	Week 14	34	3.92	0.33	3.90	(3.1, 4.5)	34	-0.09	0.21	-0.10	(-0.5, 0.3)
	Week 16	176	3.72	0.43	3.80	(2.0, 4.8)	176	-0.09	0.30	-0.10	(-1.2, 0.9)
	Week 20	140	3.67	0.45	3.80	(1.7, 4.5)	140	-0.09	0.32	-0.10	(-1.2, 0.9)
	Week 24	132	3.75	0.39	3.80	(2.5, 4.7)	132	-0.03	0.33	0.00	(-1.1, 1.2)
HD	Baseline	237	3.57	0.27	3.60	(2.6, 4.3)					
	Week 2	233	3.55	0.27	3.50	(2.6, 4.3)	233	-0.02	0.18	0.00	(-0.7, 0.6)
	Week 4	223	3.52	0.29	3.50	(2.6, 4.3)	223	-0.05	0.18	-0.10	(-0.7, 0.7)
	Week 6	219	3.51	0.29	3.50	(2.7, 4.3)	219	-0.06	0.19	-0.10	(-0.7, 0.5)
	Week 8	216	3.49	0.30	3.50	(2.6, 4.5)	216	-0.08	0.20	-0.10	(-0.6, 0.6)
	Week 10	213	3.49	0.30	3.50	(2.7, 4.5)	213	-0.08	0.22	-0.10	(-0.7, 0.6)
	Week 12	205	3.51	0.30	3.50	(2.8, 4.3)	205	-0.07	0.22	-0.10	(-0.9, 0.5)
	Week 14	36	3.72	0.23	3.70	(3.3, 4.3)	36	0.01	0.21	0.00	(-0.4, 0.5)
	Week 16	200	3.50	0.29	3.50	(2.8, 4.3)	200	-0.07	0.21	-0.10	(-0.6, 0.7)
	Week 20	161	3.48	0.30	3.50	(2.5, 4.4)	161	-0.07	0.22	-0.10	(-0.6, 0.4)
	Week 24	159	3.48	0.27	3.50	(2.5, 4.2)	159	-0.08	0.19	-0.10	(-0.5, 0.5)
PD	Baseline	42	3.36	0.41	3.30	(2.3, 4.5)					
	Week 2	40	3.35	0.41	3.30	(2.3, 4.5)	40	-0.03	0.18	0.00	(-0.4, 0.3)
	Week 4	41	3.28	0.38	3.30	(2.2, 4.2)	41	-0.09	0.20	-0.10	(-0.5, 0.2)
	Week 6	39	3.25	0.41	3.30	(2.2, 4.3)	39	-0.13	0.21	-0.10	(-0.5, 0.3)
	Week 8	39	3.27	0.44	3.20	(2.1, 4.4)	39	-0.10	0.22	-0.10	(-0.7, 0.3)
	Week 10	39	3.23	0.36	3.30	(2.3, 4.1)	39	-0.14	0.21	-0.20	(-0.6, 0.4)
	Week 12	38	3.23	0.42	3.25	(2.4, 4.3)	38	-0.13	0.30	-0.10	(-0.8, 0.6)
	Week 16	37	3.19	0.35	3.20	(2.2, 4.0)	37	-0.15	0.30	-0.10	(-1.2, 0.4)
	Week 20	37	3.24	0.38	3.20	(2.5, 3.9)	37	-0.09	0.31	-0.10	(-0.8, 0.7)
	Week 24	36	3.19	0.47	3.30	(1.7, 4.1)	36	-0.15	0.41	-0.10	(-1.3, 0.7)

表 2.7.4.9－33　臨床検査値：実測値及びベースラインからの変化量（ISS-1）（続き）

Parameter:Albumin (g/dL)

		Absolute					Change from Baseline				
	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean	SD	Median	Minimum, Maximum
Total	Baseline	481	3.66	0.37	3.60	(2.3, 4.7)					
	Week 2	475	3.64	0.37	3.60	(2.3, 4.9)	475	-0.02	0.19	0.00	(-0.8, 0.6)
	Week 4	464	3.60	0.38	3.60	(1.7, 4.6)	464	-0.06	0.22	-0.10	(-2.1, 0.7)
	Week 6	457	3.59	0.39	3.60	(2.0, 4.8)	457	-0.07	0.21	-0.10	(-1.1, 0.8)
	Week 8	450	3.59	0.39	3.60	(2.1, 4.8)	450	-0.07	0.22	-0.10	(-1.0, 0.8)
	Week 10	445	3.57	0.37	3.60	(2.3, 4.6)	445	-0.09	0.22	-0.10	(-1.0, 0.8)
	Week 12	423	3.59	0.38	3.60	(2.1, 4.5)	423	-0.06	0.24	-0.10	(-1.0, 0.9)
	Week 14	70	3.82	0.30	3.80	(3.1, 4.5)	70	-0.04	0.21	0.00	(-0.5, 0.5)
	Week 16	413	3.57	0.40	3.60	(2.0, 4.8)	413	-0.09	0.26	-0.10	(-1.2, 0.9)
	Week 20	338	3.53	0.40	3.50	(1.7, 4.5)	338	-0.08	0.28	-0.10	(-1.2, 0.9)
	Week 24	327	3.56	0.39	3.50	(1.7, 4.7)	327	-0.07	0.28	-0.10	(-1.3, 1.2)

表 2.7.4.9－33　臨床検査値：実測値及びベースラインからの変化量（ISS-1）（続き）

Parameter:Glucose (mg/dL)

		Absolute					Change from Baseline				
	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean	SD	Median	Minimum, Maximum
NDD	Baseline	202	122.3	41.9	109.0	(57, 340)					
	Week 2	202	116.7	39.6	106.5	(47, 377)	202	-5.6	38.5	-2.0	(-197, 201)
	Week 4	200	121.0	45.7	106.0	(53, 451)	200	-1.5	35.5	-1.0	(-136, 154)
	Week 6	199	116.6	36.3	105.0	(54, 262)	199	-6.0	32.9	-3.0	(-139, 118)
	Week 8	195	118.5	39.8	107.0	(43, 312)	195	-3.8	35.5	-1.0	(-135, 121)
	Week 10	193	118.1	38.5	107.0	(66, 347)	193	-4.4	33.3	-4.0	(-148, 116)
	Week 12	180	120.6	42.4	108.5	(73, 426)	180	-1.4	37.9	-1.5	(-166, 250)
	Week 14	34	118.2	34.2	109.5	(79, 239)	34	-8.9	44.9	-6.0	(-102, 152)
	Week 16	176	121.7	44.7	106.0	(71, 399)	176	-0.6	40.4	-1.5	(-213, 190)
	Week 20	140	121.2	41.9	105.0	(57, 284)	140	0.2	40.0	-1.5	(-115, 198)
	Week 24	132	110.9	31.2	102.0	(38, 275)	132	-8.0	36.8	-5.5	(-210, 198)
HD	Baseline	237	122.2	32.0	116.0	(52, 295)					
	Week 2	233	120.8	33.3	113.0	(70, 262)	233	-1.7	25.4	-3.0	(-62, 101)
	Week 4	223	121.5	33.4	113.0	(73, 273)	223	-1.6	32.3	-2.0	(-166, 194)
	Week 6	219	119.1	33.3	112.0	(68, 267)	219	-4.1	29.5	-6.0	(-107, 160)
	Week 8	216	119.2	35.0	111.0	(66, 288)	216	-3.7	30.5	-6.0	(-89, 133)
	Week 10	213	119.7	31.5	113.0	(70, 253)	213	-3.2	29.4	-4.0	(-149, 113)
	Week 12	205	121.0	36.4	110.0	(70, 271)	205	-2.0	28.0	-2.0	(-91, 166)
	Week 14	36	124.8	39.9	112.5	(72, 243)	36	-4.9	37.5	-2.0	(-135, 65)
	Week 16	200	120.5	34.5	112.0	(69, 259)	200	-2.3	29.8	-5.0	(-69, 153)
	Week 20	161	119.8	36.8	108.0	(74, 301)	161	-1.3	28.7	-5.0	(-61, 113)
	Week 24	159	118.9	31.9	110.0	(72, 238)	159	-1.9	27.5	-5.0	(-64, 149)
PD	Baseline	42	116.0	30.5	106.0	(85, 213)					
	Week 2	40	117.6	30.9	112.0	(69, 212)	40	1.7	27.4	2.0	(-118, 61)
	Week 4	41	112.5	24.9	106.0	(59, 169)	41	-2.7	28.9	0.0	(-126, 44)
	Week 6	39	110.0	29.4	99.0	(78, 200)	39	-5.2	30.2	-2.0	(-131, 57)
	Week 8	39	110.5	22.8	104.0	(66, 164)	39	-4.7	30.8	0.0	(-124, 77)
	Week 10	39	117.6	33.7	104.0	(83, 205)	39	2.5	30.6	3.0	(-100, 68)
	Week 12	38	110.1	31.9	101.5	(77, 217)	38	-4.1	30.7	-1.5	(-121, 61)
	Week 16	37	108.0	34.6	99.0	(76, 213)	37	-6.8	29.9	-6.0	(-123, 81)
	Week 20	37	116.5	42.6	99.0	(66, 296)	37	1.6	40.7	1.0	(-79, 140)
	Week 24	36	115.6	38.3	104.0	(79, 270)	36	0.4	31.5	0.5	(-72, 114)

表 2.7.4.9－33　臨床検査値：実測値及びベースラインからの変化量（ISS-1）（続き）

Parameter:Glucose (mg/dL)

		Absolute					Change from Baseline				
	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean	SD	Median	Minimum, Maximum
Total	Baseline	481	121.7	36.3	113.0	(52, 340)					
	Week 2	475	118.8	35.9	111.0	(47, 377)	475	-3.1	31.8	-2.0	(-197, 201)
	Week 4	464	120.5	38.7	109.0	(53, 451)	464	-1.6	33.4	-1.0	(-166, 194)
	Week 6	457	117.2	34.4	108.0	(54, 267)	457	-5.0	31.0	-4.0	(-139, 160)
	Week 8	450	118.1	36.3	109.0	(43, 312)	450	-3.8	32.7	-4.0	(-135, 133)
	Week 10	445	118.8	34.8	110.0	(66, 347)	445	-3.2	31.2	-3.0	(-149, 116)
	Week 12	423	119.8	38.7	109.0	(70, 426)	423	-1.9	32.7	-2.0	(-166, 250)
	Week 14	70	121.6	37.2	111.0	(72, 243)	70	-6.8	41.0	-4.0	(-135, 152)
	Week 16	413	119.9	39.3	109.0	(69, 399)	413	-2.0	34.7	-3.0	(-213, 190)
	Week 20	338	120.0	39.5	107.0	(57, 301)	338	-0.4	35.0	-3.0	(-115, 198)
	Week 24	327	115.3	32.5	107.0	(38, 275)	327	-4.1	32.1	-5.0	(-210, 198)

表 2.7.4.9－33　臨床検査値：実測値及びベースラインからの変化量（ISS-1）（続き）

Parameter:Urea Nitrogen (mg/dL)

		Absolute					Change from Baseline				
	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean	SD	Median	Minimum, Maximum
NDD	Baseline	202	44.59	19.27	42.00	(12.2, 162.4)					
	Week 2	202	44.21	17.74	41.85	(13.6, 122.7)	202	-0.37	7.54	0.10	(-39.7, 21.9)
	Week 4	200	42.99	16.03	40.65	(7.9, 114.4)	200	-1.68	8.69	-1.60	(-48.0, 21.6)
	Week 6	199	42.39	17.35	40.00	(11.3, 107.4)	199	-2.11	8.61	-1.80	(-55.0, 16.4)
	Week 8	195	42.69	17.46	41.30	(12.3, 109.9)	195	-1.50	9.34	-1.60	(-52.5, 22.9)
	Week 10	193	43.07	17.58	40.10	(14.2, 127.3)	193	-1.05	8.66	-0.80	(-35.1, 21.2)
	Week 12	180	43.01	17.48	40.10	(12.9, 126.6)	180	-1.06	9.27	-1.40	(-35.8, 36.7)
	Week 14	34	47.51	17.72	47.95	(14.9, 81.5)	34	2.73	9.31	2.65	(-22.7, 24.6)
	Week 16	176	43.90	16.27	41.55	(15.0, 132.2)	176	0.04	10.04	0.50	(-30.2, 40.4)
	Week 20	140	43.36	17.61	40.95	(11.2, 121.9)	140	0.27	9.91	0.35	(-40.5, 39.9)
	Week 24	132	42.43	18.55	39.85	(12.0, 112.2)	132	0.14	9.60	0.00	(-20.6, 56.0)
HD	Baseline	237	64.31	13.91	63.00	(19.2, 112.7)					
	Week 2	233	62.95	13.50	63.60	(18.4, 113.8)	233	-1.34	9.75	-0.90	(-27.9, 30.5)
	Week 4	223	61.43	13.91	60.10	(20.7, 103.3)	223	-2.81	11.72	-2.90	(-40.6, 46.7)
	Week 6	219	60.31	13.96	60.50	(23.3, 113.4)	219	-3.98	11.12	-4.40	(-50.0, 24.6)
	Week 8	216	59.68	12.29	60.40	(23.5, 105.0)	216	-4.52	10.69	-4.55	(-37.3, 24.8)
	Week 10	213	59.46	13.26	58.50	(26.7, 105.3)	213	-4.71	11.80	-3.80	(-41.6, 38.1)
	Week 12	205	58.88	13.54	57.90	(24.6, 105.8)	205	-5.26	11.77	-5.10	(-44.5, 38.3)
	Week 14	36	54.33	12.18	54.40	(28.1, 79.5)	36	-7.14	11.39	-7.50	(-43.3, 15.2)
	Week 16	200	58.38	13.47	57.65	(25.4, 99.3)	200	-5.58	12.81	-5.55	(-50.0, 44.7)
	Week 20	161	60.94	14.88	59.70	(28.4, 118.5)	161	-3.60	12.35	-4.10	(-29.2, 46.8)
	Week 24	159	61.58	14.59	61.60	(26.4, 108.3)	159	-3.04	12.58	-3.20	(-38.2, 50.6)
PD	Baseline	42	53.22	11.25	51.90	(31.0, 86.9)					
	Week 2	40	55.60	13.81	54.75	(30.5, 99.7)	40	1.55	8.80	2.90	(-21.9, 24.5)
	Week 4	41	53.08	12.31	52.60	(28.3, 93.0)	41	-0.68	8.14	-0.10	(-24.6, 16.6)
	Week 6	39	53.52	13.98	51.80	(28.3, 100.0)	39	-0.60	9.02	-2.30	(-18.3, 24.3)
	Week 8	39	52.73	13.58	49.70	(32.3, 106.8)	39	-1.39	9.05	-1.20	(-23.4, 19.9)
	Week 10	39	50.38	13.18	48.90	(23.0, 86.4)	39	-3.73	9.93	-3.10	(-21.5, 23.6)
	Week 12	38	50.64	13.29	47.20	(27.9, 88.2)	38	-3.09	7.20	-3.95	(-17.7, 18.3)
	Week 16	37	48.52	10.76	49.30	(28.0, 75.3)	37	-4.31	6.90	-3.70	(-17.3, 9.8)
	Week 20	37	49.16	11.31	48.50	(24.1, 78.4)	37	-3.67	7.55	-2.40	(-26.0, 8.7)
	Week 24	36	50.79	12.46	50.00	(27.3, 79.4)	36	-1.99	9.85	-1.00	(-24.8, 13.2)

表 2.7.4.9－33　臨床検査値：実測値及びベースラインからの変化量（ISS-1）（続き）

Parameter:Urea Nitrogen (mg/dL)

		Absolute					Change from Baseline				
	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean	SD	Median	Minimum, Maximum
Total	Baseline	481	55.06	18.71	55.10	(12.2, 162.4)					
	Week 2	475	54.36	17.85	54.90	(13.6, 122.7)	475	-0.69	8.81	-0.20	(-39.7, 30.5)
	Week 4	464	52.74	17.97	53.20	(7.9, 114.4)	464	-2.13	10.23	-2.00	(-48.0, 46.7)
	Week 6	457	51.92	17.71	52.50	(11.3, 113.4)	457	-2.87	9.97	-2.90	(-55.0, 24.6)
	Week 8	450	51.71	16.90	52.10	(12.3, 109.9)	450	-2.94	10.08	-2.60	(-52.5, 24.8)
	Week 10	445	51.56	17.14	52.30	(14.2, 127.3)	445	-3.03	10.51	-2.30	(-41.6, 38.1)
	Week 12	423	51.38	17.06	51.20	(12.9, 126.6)	423	-3.27	10.58	-3.20	(-44.5, 38.3)
	Week 14	70	51.02	15.41	53.35	(14.9, 81.5)	70	-2.35	11.49	-2.00	(-43.3, 24.6)
	Week 16	413	51.33	16.97	51.50	(15.0, 132.2)	413	-3.07	11.56	-3.00	(-50.0, 44.7)
	Week 20	338	52.37	17.80	51.85	(11.2, 121.9)	338	-2.01	11.08	-1.75	(-40.5, 46.8)
	Week 24	327	52.66	18.43	52.70	(12.0, 112.2)	327	-1.64	11.24	-1.80	(-38.2, 56.0)

表 2.7.4.9－33　臨床検査値：実測値及びベースラインからの変化量（ISS-1）（続き）

Parameter:Creatinine (mg/dL)

		Absolute					Change from Baseline				
	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean	SD	Median	Minimum, Maximum
NDD	Baseline	202	2.925	1.509	2.655	(0.82, 9.09)					
	Week 2	202	3.087	1.575	2.725	(0.89, 8.84)	202	0.162	0.344	0.140	(-1.48, 2.06)
	Week 4	200	3.054	1.575	2.735	(0.76, 8.47)	200	0.121	0.358	0.100	(-1.11, 1.31)
	Week 6	199	3.081	1.618	2.780	(0.88, 8.29)	199	0.152	0.445	0.120	(-1.24, 2.81)
	Week 8	195	3.097	1.633	2.820	(0.91, 8.72)	195	0.186	0.481	0.140	(-1.75, 2.60)
	Week 10	193	3.088	1.610	2.880	(0.93, 8.94)	193	0.187	0.450	0.140	(-2.33, 1.70)
	Week 12	180	3.139	1.677	2.990	(0.90, 9.60)	180	0.218	0.533	0.160	(-2.11, 2.87)
	Week 14	34	3.591	2.136	3.245	(1.02, 9.87)	34	0.341	0.777	0.150	(-0.68, 3.26)
	Week 16	176	3.208	1.853	2.880	(0.91, 10.71)	176	0.294	0.655	0.160	(-1.31, 5.05)
	Week 20	140	3.114	1.802	2.830	(0.84, 9.49)	140	0.315	0.731	0.160	(-1.56, 4.52)
	Week 24	132	3.015	1.720	2.515	(0.89, 8.60)	132	0.292	0.643	0.150	(-1.25, 3.73)
HD	Baseline	237	10.862	2.343	11.030	(3.87, 21.14)					
	Week 2	233	10.920	2.347	11.070	(4.15, 21.19)	233	0.055	0.572	0.070	(-2.49, 1.82)
	Week 4	223	10.890	2.380	11.010	(4.15, 21.26)	223	0.004	0.717	-0.010	(-2.44, 3.76)
	Week 6	219	10.898	2.399	11.060	(4.27, 21.28)	219	0.002	0.811	-0.080	(-2.33, 3.99)
	Week 8	216	10.870	2.420	10.930	(4.04, 20.39)	216	-0.003	0.850	-0.110	(-2.80, 3.35)
	Week 10	213	10.868	2.379	10.970	(4.10, 19.11)	213	-0.029	0.855	-0.080	(-3.58, 3.62)
	Week 12	205	10.809	2.427	10.790	(4.06, 19.76)	205	-0.084	0.944	-0.190	(-3.49, 3.78)
	Week 14	36	10.623	2.297	10.215	(6.69, 14.60)	36	-0.022	0.874	-0.030	(-1.48, 2.29)
	Week 16	200	10.679	2.481	10.520	(4.19, 19.77)	200	-0.212	1.100	-0.145	(-3.96, 4.25)
	Week 20	161	10.824	2.471	10.820	(4.38, 19.72)	161	-0.166	1.044	-0.170	(-3.10, 4.76)
	Week 24	159	10.801	2.488	10.870	(4.12, 19.09)	159	-0.190	1.129	-0.130	(-3.23, 4.97)
PD	Baseline	42	9.779	3.382	10.160	(2.40, 16.09)					
	Week 2	40	10.087	3.303	10.015	(3.61, 16.49)	40	0.239	0.621	0.140	(-1.31, 2.54)
	Week 4	41	10.131	3.261	10.260	(3.40, 16.99)	41	0.172	0.835	0.060	(-1.32, 2.58)
	Week 6	39	10.242	3.324	10.800	(3.75, 16.84)	39	0.293	0.799	0.320	(-1.29, 2.52)
	Week 8	39	10.371	3.429	10.600	(4.15, 18.32)	39	0.422	0.872	0.430	(-1.56, 2.79)
	Week 10	39	10.228	3.401	10.890	(3.70, 17.36)	39	0.280	0.813	0.240	(-1.42, 2.04)
	Week 12	38	10.278	3.578	10.335	(3.73, 17.96)	38	0.355	1.048	0.410	(-1.54, 3.72)
	Week 16	37	10.089	3.458	10.110	(3.64, 17.95)	37	0.241	1.110	0.130	(-2.15, 3.71)
	Week 20	37	10.078	3.502	10.020	(3.62, 18.19)	37	0.230	1.233	0.250	(-3.12, 3.95)
	Week 24	36	9.986	3.411	9.555	(3.76, 17.39)	36	0.205	1.134	0.210	(-3.72, 2.46)

表 2.7.4.9－33　臨床検査値：実測値及びベースラインからの変化量（ISS-1）（続き）

Parameter:Creatinine (mg/dL)

		Absolute					Change from Baseline				
	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean	SD	Median	Minimum, Maximum
Total	Baseline	481	7.434	4.412	7.900	(0.82, 21.14)					
	Week 2	475	7.519	4.389	7.650	(0.89, 21.19)	475	0.116	0.496	0.100	(-2.49, 2.54)
	Week 4	464	7.445	4.403	7.745	(0.76, 21.26)	464	0.069	0.605	0.075	(-2.44, 3.76)
	Week 6	457	7.438	4.418	7.580	(0.88, 21.28)	457	0.092	0.680	0.070	(-2.33, 3.99)
	Week 8	450	7.459	4.421	7.415	(0.91, 20.39)	450	0.116	0.727	0.090	(-2.80, 3.35)
	Week 10	445	7.437	4.401	7.610	(0.93, 19.11)	445	0.092	0.712	0.090	(-3.58, 3.62)
	Week 12	423	7.497	4.392	7.620	(0.90, 19.76)	423	0.084	0.822	0.100	(-3.49, 3.78)
	Week 14	70	7.207	4.170	7.430	(1.02, 14.60)	70	0.154	0.843	0.110	(-1.48, 3.26)
	Week 16	413	7.443	4.342	7.560	(0.91, 19.77)	413	0.044	0.968	0.090	(-3.96, 5.05)
	Week 20	338	7.549	4.421	7.690	(0.84, 19.72)	338	0.077	0.977	0.110	(-3.12, 4.76)
	Week 24	327	7.568	4.424	7.800	(0.89, 19.09)	327	0.048	0.988	0.070	(-3.72, 4.97)

表 2.7.4.9－33　臨床検査値：実測値及びベースラインからの変化量（ISS-1）（続き）

Parameter:Urate (mg/dL)

		Absolute					Change from Baseline				
	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean	SD	Median	Minimum, Maximum
NDD	Baseline	202	6.14	1.38	6.00	(3.1, 12.4)					
	Week 2	202	6.15	1.71	6.00	(2.3, 12.3)	202	0.01	1.19	0.05	(-6.7, 3.9)
	Week 4	200	6.00	1.72	5.95	(2.0, 12.9)	200	-0.15	1.24	-0.10	(-7.0, 3.7)
	Week 6	199	5.95	1.71	5.90	(2.0, 11.8)	199	-0.18	1.32	0.00	(-7.1, 2.9)
	Week 8	195	6.00	1.76	5.90	(1.6, 12.4)	195	-0.11	1.31	-0.10	(-7.4, 6.6)
	Week 10	193	5.95	1.78	5.90	(1.7, 11.5)	193	-0.14	1.29	-0.10	(-7.3, 3.4)
	Week 12	180	5.92	1.81	5.90	(1.4, 11.7)	180	-0.15	1.39	-0.10	(-7.6, 4.6)
	Week 14	34	6.03	1.73	6.05	(3.0, 10.1)	34	-0.09	0.95	-0.20	(-1.7, 2.1)
	Week 16	176	5.86	1.68	5.80	(1.7, 10.8)	176	-0.21	1.21	-0.10	(-7.3, 2.1)
	Week 20	140	5.88	1.68	5.80	(1.8, 12.2)	140	-0.18	1.37	-0.10	(-7.2, 4.0)
	Week 24	132	5.82	1.72	5.65	(2.1, 11.2)	132	-0.23	1.33	-0.10	(-6.9, 3.5)
HD	Baseline	237	6.78	1.46	6.80	(3.0, 13.2)					
	Week 2	233	6.74	1.54	6.90	(2.7, 11.2)	233	-0.04	0.90	0.00	(-2.4, 4.0)
	Week 4	223	6.71	1.63	6.80	(2.9, 11.8)	223	-0.09	1.06	-0.10	(-2.6, 6.7)
	Week 6	219	6.68	1.60	6.70	(2.7, 11.0)	219	-0.14	1.01	-0.20	(-2.7, 4.5)
	Week 8	216	6.69	1.56	6.80	(2.3, 10.5)	216	-0.10	0.95	-0.10	(-2.9, 3.1)
	Week 10	213	6.76	1.69	7.00	(2.8, 11.1)	213	-0.03	1.06	-0.20	(-3.5, 4.3)
	Week 12	205	6.64	1.65	6.70	(2.9, 11.8)	205	-0.17	0.98	-0.20	(-2.8, 4.7)
	Week 14	36	6.69	1.18	6.80	(4.0, 9.4)	36	-0.05	1.01	-0.20	(-1.7, 2.9)
	Week 16	200	6.68	1.62	6.90	(2.3, 10.5)	200	-0.15	1.05	-0.20	(-3.3, 3.2)
	Week 20	161	6.81	1.67	6.90	(3.1, 10.4)	161	-0.04	1.05	0.00	(-2.4, 4.7)
	Week 24	159	6.78	1.65	6.90	(3.0, 10.6)	159	-0.07	1.07	-0.10	(-2.6, 3.3)
PD	Baseline	42	5.24	1.15	5.15	(3.1, 7.8)					
	Week 2	40	5.30	1.13	4.90	(3.1, 7.7)	40	0.05	0.60	0.15	(-1.6, 1.4)
	Week 4	41	5.15	1.27	4.70	(3.2, 7.5)	41	-0.09	0.60	0.00	(-1.8, 1.1)
	Week 6	39	5.19	1.32	5.10	(2.6, 7.4)	39	-0.05	0.70	0.00	(-1.2, 2.2)
	Week 8	39	5.40	1.19	5.30	(3.4, 7.7)	39	0.16	0.75	0.10	(-1.8, 2.2)
	Week 10	39	5.39	1.19	5.40	(3.2, 7.7)	39	0.15	0.90	0.10	(-1.5, 3.1)
	Week 12	38	5.23	1.32	5.35	(3.0, 7.8)	38	-0.04	0.78	-0.15	(-1.7, 1.3)
	Week 16	37	5.25	1.32	5.60	(2.6, 7.6)	37	-0.06	0.73	-0.20	(-1.5, 2.3)
	Week 20	37	5.43	1.21	5.40	(3.2, 7.7)	37	0.12	0.93	0.10	(-2.6, 2.7)
	Week 24	36	5.27	1.35	5.25	(2.3, 8.1)	36	-0.07	0.74	-0.10	(-1.9, 1.8)

表 2.7.4.9－33　臨床検査値：実測値及びベースラインからの変化量（ISS-1）（続き）

Parameter:Urate (mg/dL)

		Absolute					Change from Baseline				
	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean	SD	Median	Minimum, Maximum
Total	Baseline	481	6.38	1.48	6.30	(3.0, 13.2)					
	Week 2	475	6.37	1.64	6.40	(2.3, 12.3)	475	-0.01	1.01	0.00	(-6.7, 4.0)
	Week 4	464	6.26	1.71	6.30	(2.0, 12.9)	464	-0.12	1.11	-0.10	(-7.0, 6.7)
	Week 6	457	6.24	1.69	6.30	(2.0, 11.8)	457	-0.15	1.13	-0.10	(-7.1, 4.5)
	Week 8	450	6.28	1.69	6.30	(1.6, 12.4)	450	-0.08	1.11	-0.10	(-7.4, 6.6)
	Week 10	445	6.29	1.75	6.40	(1.7, 11.5)	445	-0.06	1.15	-0.10	(-7.3, 4.3)
	Week 12	423	6.21	1.75	6.20	(1.4, 11.8)	423	-0.15	1.16	-0.10	(-7.6, 4.7)
	Week 14	70	6.37	1.50	6.45	(3.0, 10.1)	70	-0.07	0.97	-0.20	(-1.7, 2.9)
	Week 16	413	6.20	1.69	6.30	(1.7, 10.8)	413	-0.17	1.10	-0.20	(-7.3, 3.2)
	Week 20	338	6.27	1.71	6.30	(1.8, 12.2)	338	-0.08	1.18	0.00	(-7.2, 4.7)
	Week 24	327	6.23	1.74	6.30	(2.1, 11.2)	327	-0.14	1.15	-0.10	(-6.9, 3.5)

表 2.7.4.9－33　臨床検査値：実測値及びベースラインからの変化量（ISS-1）（続き）

Parameter:Creatine Kinase (U/L)

		Absolute					Change from Baseline				
	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean	SD	Median	Minimum, Maximum
NDD	Baseline	202	126.3	78.7	102.0	(24, 516)					
	Week 2	202	131.9	88.8	110.0	(18, 790)	202	5.6	63.4	3.5	(-194, 499)
	Week 4	200	137.4	91.7	108.0	(17, 563)	200	11.5	68.1	5.0	(-255, 412)
	Week 6	199	135.0	82.6	118.0	(24, 587)	199	8.9	63.2	8.0	(-269, 464)
	Week 8	195	145.5	117.1	109.0	(24, 922)	195	20.0	103.6	7.0	(-343, 847)
	Week 10	193	133.5	85.2	110.0	(21, 547)	193	10.0	76.1	6.0	(-318, 420)
	Week 12	180	140.4	139.6	112.0	(29, 1528)	180	15.9	129.0	8.0	(-272, 1271)
	Week 14	34	129.1	68.3	121.0	(47, 328)	34	7.7	45.2	8.5	(-131, 141)
	Week 16	176	137.9	97.2	117.0	(24, 848)	176	13.6	90.4	7.5	(-258, 622)
	Week 20	140	143.2	106.5	121.0	(24, 929)	140	17.4	106.8	7.0	(-318, 770)
	Week 24	132	147.1	132.0	106.5	(23, 1184)	132	23.2	128.7	6.5	(-262, 1009)
HD	Baseline	237	120.6	80.4	94.0	(28, 553)					
	Week 2	233	125.8	80.2	104.0	(27, 589)	233	4.9	57.5	3.0	(-397, 308)
	Week 4	223	128.0	84.6	102.0	(27, 541)	223	6.5	66.5	6.0	(-408, 330)
	Week 6	219	140.0	112.2	109.0	(32, 1019)	219	18.6	87.1	9.0	(-406, 822)
	Week 8	216	131.5	87.3	106.5	(26, 531)	216	9.3	64.5	6.0	(-387, 301)
	Week 10	213	138.4	118.9	110.0	(31, 1315)	213	16.1	98.9	8.0	(-380, 1172)
	Week 12	205	133.3	94.8	104.0	(37, 610)	205	10.7	73.2	9.0	(-358, 468)
	Week 14	36	195.8	205.6	127.0	(37, 1002)	36	43.8	141.4	9.5	(-58, 627)
	Week 16	200	136.4	116.4	111.0	(32, 1188)	200	15.2	100.6	5.5	(-267, 1078)
	Week 20	161	126.0	72.5	109.0	(40, 485)	161	8.4	51.9	9.0	(-300, 167)
	Week 24	159	124.0	80.7	99.0	(27, 502)	159	6.0	58.9	5.0	(-223, 248)
PD	Baseline	42	153.3	107.3	122.5	(31, 618)					
	Week 2	40	197.2	157.2	132.5	(35, 815)	40	40.1	137.0	9.5	(-219, 700)
	Week 4	41	174.9	145.8	131.0	(38, 747)	41	20.2	128.5	5.0	(-319, 507)
	Week 6	39	192.4	127.7	171.0	(18, 518)	39	36.3	88.7	14.0	(-142, 325)
	Week 8	39	162.5	104.7	120.0	(28, 455)	39	6.5	83.3	-1.0	(-263, 244)
	Week 10	39	153.6	88.0	125.0	(38, 318)	39	-2.5	88.9	-7.0	(-335, 160)
	Week 12	38	198.2	155.2	128.0	(34, 667)	38	41.2	132.0	26.5	(-295, 405)
	Week 16	37	196.7	139.4	146.0	(30, 609)	37	39.8	129.6	20.0	(-305, 398)
	Week 20	37	170.3	106.7	160.0	(26, 495)	37	13.4	107.0	4.0	(-308, 302)
	Week 24	36	192.9	137.6	145.0	(26, 626)	36	34.3	127.3	20.0	(-266, 364)

表 2.7.4.9－33　臨床検査値：実測値及びベースラインからの変化量（ISS-1）（続き）

Parameter:Creatine Kinase (U/L)

		Absolute					Change from Baseline				
	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean	SD	Median	Minimum, Maximum
Total	Baseline	481	125.8	82.7	101.0	(24, 618)					
	Week 2	475	134.4	94.3	108.0	(18, 815)	475	8.2	70.4	4.0	(-397, 700)
	Week 4	464	136.2	95.1	106.0	(17, 747)	464	9.9	74.5	5.5	(-408, 507)
	Week 6	457	142.3	102.8	116.0	(18, 1019)	457	15.9	77.9	9.0	(-406, 822)
	Week 8	450	140.3	102.9	109.0	(24, 922)	450	13.7	85.1	6.0	(-387, 847)
	Week 10	445	137.6	102.9	111.0	(21, 1315)	445	11.9	88.8	6.0	(-380, 1172)
	Week 12	423	142.1	122.6	109.0	(29, 1528)	423	15.6	106.1	9.0	(-358, 1271)
	Week 14	70	163.4	157.5	121.5	(37, 1002)	70	26.2	107.0	9.5	(-131, 627)
	Week 16	413	142.4	112.0	117.0	(24, 1188)	413	16.7	99.4	7.0	(-305, 1078)
	Week 20	338	138.0	92.7	118.5	(24, 929)	338	12.7	85.0	8.0	(-318, 770)
	Week 24	327	140.9	112.4	107.0	(23, 1184)	327	16.0	100.9	6.0	(-266, 1009)

表 2.7.4.9－33　臨床検査値：実測値及びベースラインからの変化量（ISS-1）（続き）

Parameter:Bilirubin (mg/dL)

		Absolute					Change from Baseline				
	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean	SD	Median	Minimum, Maximum
NDD	Baseline	202	0.50	0.20	0.50	(0.2, 1.2)					
	Week 2	202	0.48	0.18	0.50	(0.2, 1.5)	202	-0.02	0.12	0.00	(-0.5, 0.6)
	Week 4	200	0.49	0.17	0.50	(0.2, 1.1)	200	-0.01	0.13	0.00	(-0.4, 0.3)
	Week 6	199	0.48	0.19	0.50	(0.2, 1.2)	199	-0.02	0.13	0.00	(-0.4, 0.3)
	Week 8	195	0.49	0.17	0.50	(0.2, 1.1)	195	-0.01	0.13	0.00	(-0.5, 0.3)
	Week 10	193	0.49	0.20	0.40	(0.2, 1.5)	193	-0.01	0.15	0.00	(-0.7, 0.6)
	Week 12	180	0.50	0.19	0.50	(0.2, 1.0)	180	-0.01	0.14	0.00	(-0.5, 0.4)
	Week 14	34	0.36	0.14	0.30	(0.2, 0.8)	34	0.01	0.15	0.00	(-0.5, 0.3)
	Week 16	176	0.51	0.19	0.50	(0.2, 1.2)	176	0.00	0.16	0.00	(-0.7, 0.5)
	Week 20	140	0.57	0.20	0.50	(0.2, 1.6)	140	0.02	0.18	0.00	(-0.6, 0.7)
	Week 24	132	0.57	0.19	0.50	(0.2, 1.3)	132	0.02	0.16	0.00	(-0.5, 0.4)
HD	Baseline	237	0.38	0.15	0.40	(0.1, 1.0)					
	Week 2	233	0.37	0.14	0.30	(0.1, 1.0)	233	-0.01	0.08	0.00	(-0.4, 0.2)
	Week 4	223	0.38	0.14	0.40	(0.1, 1.0)	223	0.00	0.10	0.00	(-0.4, 0.3)
	Week 6	219	0.38	0.14	0.40	(0.1, 1.0)	219	-0.01	0.10	0.00	(-0.4, 0.4)
	Week 8	216	0.38	0.15	0.40	(0.1, 0.9)	216	-0.01	0.10	0.00	(-0.3, 0.4)
	Week 10	213	0.38	0.13	0.40	(0.1, 0.8)	213	-0.01	0.10	0.00	(-0.4, 0.4)
	Week 12	205	0.38	0.14	0.40	(0.1, 0.8)	205	-0.01	0.10	0.00	(-0.3, 0.4)
	Week 14	36	0.27	0.10	0.25	(0.1, 0.6)	36	-0.01	0.09	0.00	(-0.2, 0.3)
	Week 16	200	0.39	0.14	0.40	(0.1, 1.0)	200	0.00	0.11	0.00	(-0.4, 0.4)
	Week 20	161	0.43	0.14	0.40	(0.1, 0.9)	161	0.01	0.11	0.00	(-0.4, 0.3)
	Week 24	159	0.42	0.15	0.40	(0.1, 1.0)	159	0.00	0.13	0.00	(-0.5, 0.4)
PD	Baseline	42	0.41	0.13	0.40	(0.2, 0.8)					
	Week 2	40	0.38	0.12	0.30	(0.2, 0.8)	40	-0.03	0.09	0.00	(-0.2, 0.1)
	Week 4	41	0.40	0.12	0.40	(0.2, 0.7)	41	-0.01	0.10	0.00	(-0.2, 0.2)
	Week 6	39	0.41	0.15	0.40	(0.2, 1.0)	39	-0.01	0.10	0.00	(-0.2, 0.4)
	Week 8	39	0.40	0.15	0.40	(0.2, 0.9)	39	-0.01	0.11	0.00	(-0.2, 0.3)
	Week 10	39	0.41	0.14	0.40	(0.2, 0.9)	39	-0.01	0.11	0.00	(-0.2, 0.3)
	Week 12	38	0.43	0.15	0.40	(0.2, 0.8)	38	0.01	0.11	0.00	(-0.2, 0.3)
	Week 16	37	0.39	0.15	0.40	(0.2, 1.0)	37	-0.03	0.08	0.00	(-0.2, 0.2)
	Week 20	37	0.39	0.13	0.40	(0.2, 0.8)	37	-0.03	0.08	0.00	(-0.2, 0.2)
	Week 24	36	0.41	0.15	0.40	(0.1, 1.0)	36	-0.01	0.12	0.00	(-0.3, 0.2)

表 2.7.4.9－33　臨床検査値：実測値及びベースラインからの変化量（ISS-1）（続き）

Parameter:Bilirubin (mg/dL)

		Absolute					Change from Baseline				
	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean	SD	Median	Minimum, Maximum
Total	Baseline	481	0.44	0.18	0.40	(0.1, 1.2)					
	Week 2	475	0.42	0.17	0.40	(0.1, 1.5)	475	-0.02	0.10	0.00	(-0.5, 0.6)
	Week 4	464	0.43	0.16	0.40	(0.1, 1.1)	464	0.00	0.11	0.00	(-0.4, 0.3)
	Week 6	457	0.43	0.17	0.40	(0.1, 1.2)	457	-0.01	0.11	0.00	(-0.4, 0.4)
	Week 8	450	0.43	0.17	0.40	(0.1, 1.1)	450	-0.01	0.11	0.00	(-0.5, 0.4)
	Week 10	445	0.43	0.18	0.40	(0.1, 1.5)	445	-0.01	0.13	0.00	(-0.7, 0.6)
	Week 12	423	0.44	0.17	0.40	(0.1, 1.0)	423	0.00	0.12	0.00	(-0.5, 0.4)
	Week 14	70	0.31	0.13	0.30	(0.1, 0.8)	70	0.00	0.12	0.00	(-0.5, 0.3)
	Week 16	413	0.44	0.18	0.40	(0.1, 1.2)	413	0.00	0.13	0.00	(-0.7, 0.5)
	Week 20	338	0.48	0.18	0.40	(0.1, 1.6)	338	0.01	0.14	0.00	(-0.6, 0.7)
	Week 24	327	0.48	0.18	0.40	(0.1, 1.3)	327	0.01	0.14	0.00	(-0.5, 0.4)

表 2.7.4.9－33　臨床検査値：実測値及びベースラインからの変化量（ISS-1）（続き）

Parameter:Aspartate Aminotransferase (U/L)

		Absolute					Change from Baseline				
	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean	SD	Median	Minimum, Maximum
NDD	Baseline	202	19.4	8.7	18.0	(5, 86)					
	Week 2	202	17.9	8.1	17.0	(5, 84)	202	-1.5	7.7	-1.0	(-65, 65)
	Week 4	200	17.6	6.9	16.0	(4, 48)	200	-1.7	6.4	-1.0	(-65, 24)
	Week 6	199	17.8	7.9	17.0	(4, 64)	199	-1.5	6.5	-1.0	(-64, 24)
	Week 8	195	17.6	7.6	16.0	(4, 79)	195	-1.7	7.1	-1.0	(-66, 27)
	Week 10	193	17.3	6.6	17.0	(4, 47)	193	-1.7	7.1	-1.0	(-68, 29)
	Week 12	180	19.0	11.7	17.0	(4, 116)	180	-0.3	11.3	-1.0	(-69, 98)
	Week 14	34	19.2	11.2	17.5	(9, 68)	34	0.3	10.0	-1.0	(-10, 50)
	Week 16	176	18.6	8.7	17.0	(4, 80)	176	-0.6	8.7	-1.0	(-66, 50)
	Week 20	140	18.7	7.9	18.0	(3, 71)	140	-0.7	8.6	0.0	(-68, 19)
	Week 24	132	19.0	7.2	18.0	(6, 50)	132	-0.5	8.6	-0.5	(-63, 26)
HD	Baseline	237	12.3	6.2	11.0	(3, 64)					
	Week 2	233	11.7	5.5	11.0	(3, 42)	233	-0.6	4.7	0.0	(-48, 18)
	Week 4	223	11.8	5.9	11.0	(2, 52)	223	-0.3	5.4	0.0	(-49, 27)
	Week 6	219	12.0	6.4	11.0	(3, 61)	219	-0.2	5.6	0.0	(-49, 36)
	Week 8	216	11.7	6.9	11.0	(3, 76)	216	-0.4	6.2	-1.0	(-50, 52)
	Week 10	213	11.6	5.7	11.0	(3, 53)	213	-0.5	5.2	-1.0	(-46, 28)
	Week 12	205	11.6	5.3	11.0	(3, 37)	205	-0.5	5.2	0.0	(-53, 12)
	Week 14	36	12.1	5.2	11.5	(5, 30)	36	-0.9	5.4	-2.0	(-9, 24)
	Week 16	200	12.0	6.1	11.0	(3, 51)	200	-0.1	5.9	0.0	(-47, 33)
	Week 20	161	12.6	8.1	12.0	(3, 74)	161	0.9	7.8	1.0	(-51, 51)
	Week 24	159	12.6	6.8	12.0	(3, 67)	159	0.9	6.5	1.0	(-50, 42)
PD	Baseline	42	15.4	7.1	14.0	(4, 37)					
	Week 2	40	14.6	7.0	12.5	(5, 35)	40	-1.0	4.8	-1.0	(-12, 16)
	Week 4	41	13.2	5.8	13.0	(5, 29)	41	-2.1	5.2	-1.0	(-16, 10)
	Week 6	39	13.4	5.9	12.0	(5, 29)	39	-2.0	4.6	-1.0	(-13, 6)
	Week 8	39	13.6	5.4	13.0	(5, 28)	39	-1.8	6.1	-2.0	(-16, 14)
	Week 10	39	13.5	5.5	12.0	(6, 29)	39	-1.9	6.0	-2.0	(-17, 20)
	Week 12	38	13.8	6.3	12.0	(6, 37)	38	-1.6	5.0	-0.5	(-17, 8)
	Week 16	37	15.2	7.3	14.0	(6, 36)	37	0.0	5.2	1.0	(-14, 12)
	Week 20	37	14.3	5.4	14.0	(6, 25)	37	-0.9	5.0	0.0	(-14, 9)
	Week 24	36	15.3	6.4	14.0	(6, 27)	36	-0.1	5.3	1.0	(-14, 9)

表 2.7.4.9－33　臨床検査値：実測値及びベースラインからの変化量（ISS-1）（続き）

Parameter:Aspartate Aminotransferase (U/L)

		Absolute					Change from Baseline				
	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean	SD	Median	Minimum, Maximum
Total	Baseline	481	15.5	8.1	14.0	(3, 86)					
	Week 2	475	14.5	7.4	13.0	(3, 84)	475	-1.0	6.2	-1.0	(-65, 65)
	Week 4	464	14.4	6.9	13.0	(2, 52)	464	-1.0	5.9	-1.0	(-65, 27)
	Week 6	457	14.7	7.6	13.0	(3, 64)	457	-0.9	6.0	-1.0	(-64, 36)
	Week 8	450	14.4	7.6	13.0	(3, 79)	450	-1.1	6.6	-1.0	(-66, 52)
	Week 10	445	14.2	6.7	13.0	(3, 53)	445	-1.2	6.2	-1.0	(-68, 29)
	Week 12	423	14.9	9.4	13.0	(3, 116)	423	-0.5	8.3	0.0	(-69, 98)
	Week 14	70	15.5	9.3	13.0	(5, 68)	70	-0.3	8.0	-1.0	(-10, 50)
	Week 16	413	15.1	8.1	14.0	(3, 80)	413	-0.3	7.1	0.0	(-66, 50)
	Week 20	338	15.3	8.3	14.0	(3, 74)	338	0.0	7.9	0.0	(-68, 51)
	Week 24	327	15.5	7.5	14.0	(3, 67)	327	0.2	7.3	0.0	(-63, 42)

表 2.7.4.9－33　臨床検査値：実測値及びベースラインからの変化量（ISS-1）（続き）

Parameter:Alanine Aminotransferase (U/L)

		Absolute					Change from Baseline				
	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean	SD	Median	Minimum, Maximum
NDD	Baseline	202	13.6	7.0	12.0	(4, 59)					
	Week 2	202	10.9	6.8	9.0	(4, 77)	202	-2.7	5.2	-2.0	(-26, 25)
	Week 4	200	10.9	6.0	9.0	(2, 51)	200	-2.7	6.1	-2.0	(-26, 41)
	Week 6	199	10.5	5.1	9.0	(3, 34)	199	-3.2	5.4	-2.0	(-38, 15)
	Week 8	195	10.5	5.4	9.0	(3, 37)	195	-3.2	6.0	-2.0	(-48, 15)
	Week 10	193	10.7	5.9	9.0	(3, 38)	193	-2.8	6.5	-2.0	(-45, 28)
	Week 12	180	11.6	10.7	9.0	(4, 125)	180	-2.0	11.1	-2.0	(-46, 115)
	Week 14	34	14.2	14.3	10.0	(6, 90)	34	-0.8	15.4	-2.0	(-23, 80)
	Week 16	176	11.2	6.8	10.0	(2, 51)	176	-2.3	7.6	-2.0	(-47, 37)
	Week 20	140	11.0	6.1	10.0	(2, 38)	140	-2.2	7.3	-2.0	(-46, 27)
	Week 24	132	11.0	5.5	9.5	(3, 34)	132	-2.0	7.3	-1.0	(-45, 28)
HD	Baseline	237	11.3	6.3	10.0	(3, 54)					
	Week 2	233	9.7	5.1	8.0	(3, 33)	233	-1.7	4.7	-1.0	(-39, 13)
	Week 4	223	9.7	5.6	9.0	(2, 52)	223	-1.6	5.1	-1.0	(-42, 18)
	Week 6	219	9.9	7.6	8.0	(2, 80)	219	-1.3	6.3	-1.0	(-42, 39)
	Week 8	216	9.3	7.1	8.0	(3, 88)	216	-1.8	6.1	-1.5	(-42, 47)
	Week 10	213	9.0	6.1	8.0	(3, 75)	213	-2.2	5.3	-1.0	(-36, 34)
	Week 12	205	8.9	5.6	8.0	(3, 65)	205	-2.2	5.1	-1.0	(-42, 24)
	Week 14	36	10.0	3.5	9.0	(5, 23)	36	-2.7	3.8	-2.5	(-10, 4)
	Week 16	200	9.3	7.4	8.0	(3, 98)	200	-1.8	6.4	-1.0	(-35, 57)
	Week 20	161	9.6	8.6	8.0	(3, 104)	161	-1.2	7.7	-1.0	(-44, 63)
	Week 24	159	9.8	8.3	8.0	(1, 100)	159	-1.1	7.4	0.0	(-41, 59)
PD	Baseline	42	15.9	10.7	12.0	(4, 52)					
	Week 2	40	13.5	8.0	11.5	(4, 42)	40	-2.8	6.4	-1.0	(-24, 8)
	Week 4	41	11.2	4.6	10.0	(4, 26)	41	-4.9	9.2	-2.0	(-40, 5)
	Week 6	39	11.3	6.8	10.0	(1, 44)	39	-5.1	8.3	-2.0	(-39, 4)
	Week 8	39	11.7	5.2	10.0	(5, 24)	39	-4.7	10.4	-2.0	(-38, 8)
	Week 10	39	12.1	9.2	9.0	(2, 55)	39	-4.3	13.2	-2.0	(-37, 51)
	Week 12	38	10.9	8.7	9.0	(1, 58)	38	-5.4	8.5	-3.0	(-36, 6)
	Week 16	37	12.1	7.1	9.0	(5, 41)	37	-4.1	8.9	-1.0	(-33, 12)
	Week 20	37	12.0	6.5	11.0	(5, 37)	37	-4.2	8.2	-2.0	(-26, 9)
	Week 24	36	12.5	8.0	10.0	(1, 44)	36	-3.8	8.6	-1.5	(-28, 9)

表 2.7.4.9－33　臨床検査値：実測値及びベースラインからの変化量（ISS-1）（続き）

Parameter:Alanine Aminotransferase (U/L)

		Absolute					Change from Baseline				
	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean	SD	Median	Minimum, Maximum
Total	Baseline	481	12.7	7.2	11.0	(3, 59)					
	Week 2	475	10.5	6.3	9.0	(3, 77)	475	-2.2	5.1	-1.0	(-39, 25)
	Week 4	464	10.3	5.7	9.0	(2, 52)	464	-2.4	6.0	-2.0	(-42, 41)
	Week 6	457	10.3	6.5	9.0	(1, 80)	457	-2.5	6.2	-2.0	(-42, 39)
	Week 8	450	10.0	6.3	9.0	(3, 88)	450	-2.7	6.6	-2.0	(-48, 47)
	Week 10	445	10.0	6.4	9.0	(2, 75)	445	-2.7	6.8	-2.0	(-45, 51)
	Week 12	423	10.2	8.5	8.0	(1, 125)	423	-2.4	8.5	-2.0	(-46, 115)
	Week 14	70	12.6	10.4	10.0	(5, 90)	70	-1.8	11.0	-2.0	(-23, 80)
	Week 16	413	10.3	7.2	9.0	(2, 98)	413	-2.2	7.2	-1.0	(-47, 57)
	Week 20	338	10.4	7.5	9.0	(2, 104)	338	-1.9	7.6	-1.0	(-46, 63)
	Week 24	327	10.6	7.3	9.0	(1, 100)	327	-1.8	7.5	-1.0	(-45, 59)

表 2.7.4.9－33 臨床検査値：実測値及びベースラインからの変化量（ISS-1）（続き）

Parameter:Alkaline Phosphatase (U/L)

		Absolute					Change from Baseline				
	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean	SD	Median	Minimum, Maximum
NDD	Baseline	202	253.2	90.7	238.0	(98, 802)					
	Week 2	202	254.8	90.2	237.0	(112, 718)	202	1.6	33.1	3.0	(-120, 209)
	Week 4	200	257.9	112.7	238.0	(99, 1195)	200	4.9	73.9	-1.0	(-218, 872)
	Week 6	199	256.2	95.3	241.0	(101, 749)	199	3.1	39.6	2.0	(-72, 221)
	Week 8	195	256.3	96.8	243.0	(87, 787)	195	3.3	38.2	-2.0	(-87, 196)
	Week 10	193	256.0	92.8	242.0	(99, 743)	193	2.8	40.2	1.0	(-159, 123)
	Week 12	180	258.3	97.2	242.5	(92, 761)	180	4.3	48.1	1.0	(-159, 193)
	Week 14	34	272.7	80.3	262.5	(168, 517)	34	25.5	56.8	24.5	(-78, 194)
	Week 16	176	259.3	99.9	242.5	(81, 849)	176	5.9	49.8	3.0	(-158, 168)
	Week 20	140	269.4	119.4	235.5	(99, 870)	140	14.1	60.0	11.0	(-162, 232)
	Week 24	132	267.1	109.1	245.0	(98, 761)	132	11.8	60.0	9.0	(-165, 309)
HD	Baseline	237	237.6	103.2	217.0	(73, 964)					
	Week 2	233	239.9	98.2	219.0	(69, 903)	233	1.7	39.9	2.0	(-139, 157)
	Week 4	223	233.7	90.3	219.0	(73, 587)	223	1.3	40.4	-1.0	(-144, 327)
	Week 6	219	232.3	89.4	216.0	(72, 600)	219	-0.3	45.0	0.0	(-237, 156)
	Week 8	216	227.9	87.9	211.5	(73, 573)	216	-3.4	47.7	-5.0	(-207, 159)
	Week 10	213	227.4	88.2	210.0	(74, 609)	213	-4.6	50.7	-4.0	(-212, 190)
	Week 12	205	230.6	91.3	215.0	(71, 564)	205	-1.6	48.1	-2.0	(-211, 156)
	Week 14	36	235.4	79.0	219.5	(115, 441)	36	1.3	61.9	-8.5	(-184, 142)
	Week 16	200	233.2	92.0	215.5	(78, 576)	200	0.3	55.0	-2.5	(-199, 236)
	Week 20	161	226.4	86.9	215.0	(69, 639)	161	-2.3	54.9	-1.0	(-211, 153)
	Week 24	159	230.9	89.8	213.0	(69, 620)	159	2.7	61.9	7.0	(-269, 211)
PD	Baseline	42	370.5	201.8	295.0	(139, 955)					
	Week 2	40	384.3	238.8	297.5	(137, 1129)	40	19.5	78.0	8.0	(-90, 394)
	Week 4	41	377.1	236.4	276.0	(131, 1116)	41	12.4	70.5	-3.0	(-97, 253)
	Week 6	39	353.6	205.7	265.0	(141, 917)	39	-5.7	79.0	-13.0	(-138, 218)
	Week 8	39	347.5	176.0	288.0	(147, 714)	39	-11.6	86.8	-5.0	(-241, 201)
	Week 10	39	341.7	189.7	337.0	(132, 776)	39	-17.6	102.2	-12.0	(-365, 305)
	Week 12	38	328.1	176.8	286.5	(139, 754)	38	-24.8	121.0	-14.5	(-409, 275)
	Week 16	37	354.4	185.7	278.0	(142, 712)	37	-3.8	110.5	3.0	(-313, 252)
	Week 20	37	341.4	189.7	278.0	(128, 791)	37	-16.7	129.6	-9.0	(-415, 284)
	Week 24	36	360.6	212.7	256.0	(128, 856)	36	-0.6	123.4	-4.5	(-409, 315)

表 2.7.4.9－33　臨床検査値：実測値及びベースラインからの変化量（ISS-1）（続き）

Parameter:Alkaline Phosphatase (U/L)

		Absolute					Change from Baseline				
	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean	SD	Median	Minimum, Maximum
Total	Baseline	481	255.7	116.1	230.0	(73, 964)					
	Week 2	475	258.4	119.9	235.0	(69, 1129)	475	3.1	42.1	3.0	(-139, 394)
	Week 4	464	256.8	125.5	230.0	(73, 1195)	464	3.8	59.8	-1.0	(-218, 872)
	Week 6	457	253.1	111.2	229.0	(72, 917)	457	0.7	46.6	0.0	(-237, 221)
	Week 8	450	250.6	107.0	228.0	(73, 787)	450	-1.2	48.8	-3.5	(-241, 201)
	Week 10	445	249.8	107.3	228.0	(74, 776)	445	-2.6	53.4	-2.0	(-365, 305)
	Week 12	423	251.2	107.4	224.0	(71, 761)	423	-1.2	59.7	-2.0	(-409, 275)
	Week 14	70	253.5	81.3	241.0	(115, 517)	70	13.0	60.3	16.0	(-184, 194)
	Week 16	413	255.2	111.7	229.0	(78, 849)	413	2.3	59.9	0.0	(-313, 252)
	Week 20	338	256.8	120.8	228.0	(69, 870)	338	2.9	69.4	2.5	(-415, 284)
	Week 24	327	259.8	122.9	230.0	(69, 856)	327	6.0	70.5	7.0	(-409, 315)

表 2.7.4.9－33　臨床検査値：実測値及びベースラインからの変化量（ISS-1）（続き）

Parameter:Lactate Dehydrogenase (U/L)

		Absolute					Change from Baseline				
	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean	SD	Median	Minimum, Maximum
NDD	Baseline	202	199.5	37.2	197.0	(124, 304)					
	Week 2	202	204.8	40.5	200.0	(113, 334)	202	5.4	18.7	4.5	(-41, 76)
	Week 4	200	204.2	44.0	199.0	(119, 390)	200	5.0	20.4	3.5	(-43, 90)
	Week 6	199	207.4	44.4	202.0	(118, 391)	199	8.2	22.6	6.0	(-42, 96)
	Week 8	195	209.0	44.8	203.0	(116, 422)	195	10.0	25.6	5.0	(-49, 122)
	Week 10	193	208.1	44.4	201.0	(128, 380)	193	10.3	25.9	9.0	(-57, 114)
	Week 12	180	210.5	43.5	201.5	(117, 383)	180	12.4	29.4	9.5	(-59, 114)
	Week 14	34	198.5	50.4	200.0	(122, 360)	34	10.8	24.0	5.0	(-29, 88)
	Week 16	176	209.1	41.3	203.0	(126, 411)	176	11.7	30.5	11.0	(-85, 200)
	Week 20	140	216.3	44.8	208.0	(142, 377)	140	16.3	34.5	13.0	(-96, 174)
	Week 24	132	216.2	42.5	211.0	(142, 402)	132	16.9	33.8	14.5	(-86, 207)
HD	Baseline	237	181.6	42.8	176.0	(99, 394)					
	Week 2	233	190.1	41.3	180.0	(108, 401)	233	8.3	26.7	9.0	(-148, 95)
	Week 4	223	189.8	42.6	183.0	(108, 403)	223	7.9	29.0	9.0	(-152, 116)
	Week 6	219	192.4	44.5	183.0	(104, 447)	219	10.7	28.9	10.0	(-138, 114)
	Week 8	216	192.1	52.5	181.0	(102, 614)	216	10.5	41.0	9.0	(-172, 397)
	Week 10	213	193.8	45.9	187.0	(105, 351)	213	12.2	33.8	13.0	(-179, 178)
	Week 12	205	195.3	50.2	183.0	(107, 449)	205	13.1	35.6	15.0	(-167, 199)
	Week 14	36	198.1	51.2	186.5	(127, 373)	36	18.4	36.1	16.5	(-86, 122)
	Week 16	200	196.7	46.8	188.5	(100, 396)	200	14.7	40.6	15.0	(-188, 203)
	Week 20	161	202.0	49.2	195.0	(107, 401)	161	19.1	41.8	16.0	(-195, 157)
	Week 24	159	196.2	46.6	192.0	(104, 382)	159	13.5	33.1	13.0	(-127, 110)
PD	Baseline	42	226.7	66.7	212.5	(92, 490)					
	Week 2	40	240.2	64.2	218.5	(110, 450)	40	10.2	26.2	8.0	(-51, 95)
	Week 4	41	231.4	66.8	227.0	(117, 437)	41	4.0	26.0	3.0	(-55, 107)
	Week 6	39	233.9	68.4	228.0	(89, 438)	39	5.2	30.3	5.0	(-92, 71)
	Week 8	39	236.7	87.0	220.0	(90, 544)	39	8.1	47.6	2.0	(-55, 237)
	Week 10	39	234.4	80.6	212.0	(84, 473)	39	5.7	41.0	-3.0	(-63, 134)
	Week 12	38	236.5	76.8	226.0	(76, 472)	38	7.9	30.7	8.5	(-52, 88)
	Week 16	37	244.2	80.4	230.0	(88, 522)	37	16.2	33.1	11.0	(-57, 123)
	Week 20	37	245.2	83.8	237.0	(84, 527)	37	17.1	33.4	16.0	(-49, 97)
	Week 24	36	257.2	97.4	244.5	(86, 540)	36	28.8	62.6	20.0	(-176, 238)

表 2.7.4.9－33　臨床検査値：実測値及びベースラインからの変化量（ISS-1）（続き）

Parameter:Lactate Dehydrogenase (U/L)

		Absolute					Change from Baseline				
	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean	SD	Median	Minimum, Maximum
Total	Baseline	481	193.0	45.2	185.0	(92, 490)					
	Week 2	475	200.6	45.4	193.0	(108, 450)	475	7.2	23.6	7.0	(-148, 95)
	Week 4	464	199.7	47.2	192.0	(108, 437)	464	6.3	25.3	5.0	(-152, 116)
	Week 6	457	202.5	48.4	196.0	(89, 447)	457	9.1	26.4	8.0	(-138, 114)
	Week 8	450	203.3	54.8	195.0	(90, 614)	450	10.1	35.8	6.0	(-172, 397)
	Week 10	445	203.6	50.5	196.0	(84, 473)	445	10.8	31.3	9.0	(-179, 178)
	Week 12	423	205.5	51.8	196.0	(76, 472)	423	12.3	32.6	12.0	(-167, 199)
	Week 14	70	198.3	50.4	189.5	(122, 373)	70	14.7	30.8	13.0	(-86, 122)
	Week 16	413	206.2	51.2	199.0	(88, 522)	413	13.5	35.9	12.0	(-188, 203)
	Week 20	338	212.7	53.9	204.0	(84, 527)	338	17.7	37.9	15.0	(-195, 174)
	Week 24	327	211.0	56.1	200.0	(86, 540)	327	16.6	37.8	15.0	(-176, 238)

表 2.7.4.9－33　臨床検査値：実測値及びベースラインからの変化量（ISS-1）（続き）

Parameter:Gamma Glutamyl Transferase (U/L)

		Absolute					Change from Baseline				
	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean	SD	Median	Minimum, Maximum
NDD	Baseline	151	29.6	39.0	19.0	(7, 400)					
	Week 2	151	26.8	32.3	18.0	(6, 355)	151	-2.8	10.9	-1.0	(-104, 10)
	Week 4	149	25.9	31.9	18.0	(7, 326)	149	-3.7	15.1	-2.0	(-125, 59)
	Week 6	148	24.2	26.8	17.0	(6, 248)	148	-5.2	17.3	-2.0	(-152, 58)
	Week 8	145	22.5	20.4	16.0	(6, 140)	145	-4.5	12.3	-3.0	(-90, 71)
	Week 10	145	21.6	19.4	16.0	(5, 131)	145	-4.8	14.1	-2.0	(-124, 62)
	Week 12	145	22.1	19.9	16.0	(6, 123)	145	-4.9	14.7	-2.0	(-123, 54)
	Week 16	143	21.7	19.4	16.0	(5, 116)	143	-5.1	16.0	-2.0	(-120, 31)
	Week 20	140	21.4	18.6	16.0	(6, 117)	140	-5.2	18.3	-2.0	(-143, 45)
	Week 24	132	22.0	19.9	16.0	(6, 125)	132	-4.7	18.2	-2.0	(-141, 49)
HD	Baseline	186	20.8	19.4	15.5	(6, 145)					
	Week 2	183	20.2	18.5	15.0	(6, 132)	183	-0.7	5.4	-1.0	(-32, 45)
	Week 4	180	19.7	19.7	15.5	(5, 187)	180	-1.4	8.3	-1.0	(-34, 79)
	Week 6	177	19.9	21.4	15.0	(6, 189)	177	-1.1	8.8	-1.0	(-35, 81)
	Week 8	174	18.8	19.7	14.0	(6, 200)	174	-1.8	7.3	-1.0	(-34, 55)
	Week 10	172	19.4	23.5	13.5	(7, 256)	172	-1.2	10.9	-1.0	(-31, 111)
	Week 12	169	19.5	23.1	14.0	(7, 234)	169	-1.2	9.7	-1.0	(-35, 89)
	Week 16	165	19.5	25.2	14.0	(6, 263)	165	-0.9	11.7	-1.0	(-22, 118)
	Week 20	161	20.1	28.1	14.0	(6, 302)	161	-0.3	15.2	-1.0	(-42, 157)
	Week 24	159	19.5	24.7	14.0	(7, 246)	159	-1.1	11.8	-1.0	(-43, 101)
PD	Baseline	42	27.6	23.9	20.5	(8, 147)					
	Week 2	40	26.8	25.6	20.0	(8, 163)	40	-0.7	4.0	0.0	(-10, 16)
	Week 4	41	24.9	24.4	19.0	(8, 159)	41	-3.1	6.9	-2.0	(-24, 12)
	Week 6	39	23.1	20.2	17.0	(7, 122)	39	-5.3	7.3	-3.0	(-25, 10)
	Week 8	39	24.1	21.6	17.0	(7, 121)	39	-4.3	8.7	-3.0	(-26, 25)
	Week 10	39	23.9	22.9	17.0	(7, 124)	39	-4.4	9.6	-3.0	(-33, 27)
	Week 12	38	22.7	21.2	14.0	(7, 97)	38	-5.7	12.9	-3.0	(-50, 35)
	Week 16	37	22.4	20.9	14.0	(7, 103)	37	-5.6	13.2	-4.0	(-44, 38)
	Week 20	37	23.5	22.0	15.0	(7, 116)	37	-4.4	10.9	-3.0	(-33, 33)
	Week 24	36	23.3	19.8	15.0	(6, 102)	36	-5.0	11.4	-2.0	(-45, 21)

表 2.7.4.9－33　臨床検査値：実測値及びベースラインからの変化量（ISS-1）（続き）

Parameter:Gamma Glutamyl Transferase (U/L)

		Absolute					Change from Baseline				
	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean	SD	Median	Minimum, Maximum
Total	Baseline	379	25.1	29.4	18.0	(6, 400)					
	Week 2	374	23.5	25.8	17.0	(6, 355)	374	-1.6	8.1	-1.0	(-104, 45)
	Week 4	370	22.8	25.9	17.0	(5, 326)	370	-2.5	11.5	-1.0	(-125, 79)
	Week 6	364	22.0	23.7	16.0	(6, 248)	364	-3.2	13.0	-2.0	(-152, 81)
	Week 8	358	20.8	20.3	15.0	(6, 200)	358	-3.2	9.8	-2.0	(-90, 71)
	Week 10	356	20.8	21.9	15.0	(5, 256)	356	-3.0	12.3	-2.0	(-124, 111)
	Week 12	352	20.9	21.6	14.0	(6, 234)	352	-3.2	12.4	-2.0	(-123, 89)
	Week 16	345	20.7	22.5	14.0	(5, 263)	345	-3.2	13.9	-2.0	(-120, 118)
	Week 20	338	21.0	23.9	15.0	(6, 302)	338	-2.8	16.3	-2.0	(-143, 157)
	Week 24	327	20.9	22.4	15.0	(6, 246)	327	-3.0	14.8	-2.0	(-141, 101)

表 2.7.4.9－33　臨床検査値：実測値及びベースラインからの変化量（ISS-1）（続き）

Parameter:Sodium (mEq/L)

		Absolute					Change from Baseline				
	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean	SD	Median	Minimum, Maximum
NDD	Baseline	202	140.2	3.3	141.0	(128, 150)					
	Week 2	202	140.2	2.9	141.0	(129, 147)	202	0.0	2.6	0.0	(-9, 8)
	Week 4	200	140.2	3.1	140.5	(127, 149)	200	0.0	2.3	0.0	(-6, 5)
	Week 6	199	140.0	2.8	140.0	(128, 146)	199	-0.1	2.4	0.0	(-7, 8)
	Week 8	195	140.4	2.9	141.0	(127, 147)	195	0.1	2.5	0.0	(-7, 7)
	Week 10	193	140.2	3.0	141.0	(125, 146)	193	-0.1	2.5	0.0	(-8, 7)
	Week 12	180	140.3	2.9	141.0	(128, 145)	180	0.0	2.5	0.0	(-9, 10)
	Week 14	34	140.8	3.4	142.0	(129, 145)	34	0.5	2.1	0.0	(-4, 8)
	Week 16	176	140.2	3.1	140.0	(127, 149)	176	-0.1	2.6	0.0	(-8, 6)
	Week 20	140	140.4	3.4	141.0	(124, 147)	140	0.0	3.0	0.0	(-11, 11)
	Week 24	132	140.6	3.0	141.0	(126, 148)	132	0.2	2.9	0.0	(-9, 10)
HD	Baseline	237	139.7	2.8	140.0	(131, 146)					
	Week 2	233	139.8	2.7	140.0	(131, 147)	233	0.1	2.4	0.0	(-8, 7)
	Week 4	223	139.7	2.7	140.0	(130, 146)	223	0.1	2.5	0.0	(-12, 7)
	Week 6	219	139.6	3.1	140.0	(128, 147)	219	-0.1	2.8	0.0	(-9, 7)
	Week 8	216	139.6	2.7	140.0	(131, 147)	216	-0.1	2.8	0.0	(-8, 8)
	Week 10	213	139.6	2.8	140.0	(132, 148)	213	-0.1	2.8	0.0	(-10, 7)
	Week 12	205	139.7	3.0	140.0	(130, 148)	205	0.0	2.7	0.0	(-8, 10)
	Week 14	36	140.6	2.8	141.0	(133, 146)	36	0.8	2.5	1.0	(-7, 6)
	Week 16	200	139.9	2.7	140.0	(131, 147)	200	0.2	2.4	0.0	(-7, 10)
	Week 20	161	139.9	2.7	140.0	(133, 147)	161	0.2	2.7	0.0	(-7, 10)
	Week 24	159	140.2	2.6	140.0	(134, 146)	159	0.6	2.6	0.0	(-6, 8)
PD	Baseline	42	138.0	3.4	138.0	(130, 145)					
	Week 2	40	138.1	3.4	138.5	(131, 146)	40	0.2	2.4	0.0	(-4, 6)
	Week 4	41	137.6	4.2	138.0	(130, 147)	41	-0.2	2.7	0.0	(-5, 6)
	Week 6	39	137.9	3.0	138.0	(132, 144)	39	0.0	2.3	0.0	(-6, 5)
	Week 8	39	137.2	3.2	137.0	(132, 145)	39	-0.7	2.6	-1.0	(-6, 5)
	Week 10	39	137.0	3.0	137.0	(128, 144)	39	-0.9	2.5	-1.0	(-6, 5)
	Week 12	38	137.2	3.4	137.5	(129, 147)	38	-0.6	2.8	-1.0	(-7, 6)
	Week 16	37	137.0	3.6	137.0	(129, 144)	37	-0.7	2.7	0.0	(-7, 5)
	Week 20	37	138.0	3.6	138.0	(129, 145)	37	0.3	3.1	0.0	(-8, 8)
	Week 24	36	137.3	3.7	138.0	(130, 145)	36	-0.4	2.7	-1.0	(-5, 7)

表 2.7.4.9－33　臨床検査値：実測値及びベースラインからの変化量（ISS-1）（続き）

Parameter:Sodium (mEq/L)

		Absolute					Change from Baseline				
	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean	SD	Median	Minimum, Maximum
Total	Baseline	481	139.7	3.1	140.0	(128, 150)					
	Week 2	475	139.8	2.9	140.0	(129, 147)	475	0.1	2.5	0.0	(-9, 8)
	Week 4	464	139.7	3.1	140.0	(127, 149)	464	0.0	2.4	0.0	(-12, 7)
	Week 6	457	139.6	3.0	140.0	(128, 147)	457	-0.1	2.6	0.0	(-9, 8)
	Week 8	450	139.7	3.0	140.0	(127, 147)	450	0.0	2.6	0.0	(-8, 8)
	Week 10	445	139.6	3.0	140.0	(125, 148)	445	-0.1	2.7	0.0	(-10, 7)
	Week 12	423	139.7	3.1	140.0	(128, 148)	423	0.0	2.6	0.0	(-9, 10)
	Week 14	70	140.7	3.1	141.0	(129, 146)	70	0.8	2.3	1.0	(-7, 8)
	Week 16	413	139.8	3.1	140.0	(127, 149)	413	0.0	2.5	0.0	(-8, 10)
	Week 20	338	139.9	3.1	140.0	(124, 147)	338	0.2	2.9	0.0	(-11, 11)
	Week 24	327	140.0	3.1	140.0	(126, 148)	327	0.3	2.8	0.0	(-9, 10)

表 2.7.4.9－33　臨床検査値：実測値及びベースラインからの変化量（ISS-1）（続き）

Parameter:Potassium (mEq/L)

		Absolute					Change from Baseline				
	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean	SD	Median	Minimum, Maximum
NDD	Baseline	202	4.72	0.54	4.75	(3.2, 6.3)					
	Week 2	202	4.69	0.56	4.60	(3.5, 6.3)	202	-0.04	0.47	-0.10	(-1.6, 1.4)
	Week 4	200	4.69	0.55	4.60	(3.4, 6.4)	200	-0.04	0.44	-0.05	(-2.0, 1.1)
	Week 6	199	4.66	0.56	4.60	(3.5, 6.8)	199	-0.06	0.45	-0.10	(-1.4, 1.5)
	Week 8	195	4.68	0.53	4.70	(3.2, 6.2)	195	-0.05	0.49	0.00	(-1.3, 2.0)
	Week 10	193	4.65	0.55	4.60	(3.5, 6.3)	193	-0.08	0.48	-0.10	(-1.7, 1.7)
	Week 12	180	4.62	0.55	4.60	(3.3, 6.2)	180	-0.10	0.49	-0.10	(-1.6, 1.3)
	Week 14	34	4.71	0.64	4.80	(3.5, 5.9)	34	0.00	0.49	0.10	(-0.9, 1.0)
	Week 16	176	4.60	0.51	4.50	(3.6, 6.4)	176	-0.11	0.49	-0.10	(-1.8, 1.2)
	Week 20	140	4.59	0.54	4.60	(3.4, 6.8)	140	-0.11	0.53	-0.10	(-1.6, 2.0)
	Week 24	132	4.57	0.55	4.50	(3.3, 6.1)	132	-0.13	0.54	0.00	(-2.3, 1.2)
HD	Baseline	237	4.78	0.65	4.80	(2.7, 6.7)					
	Week 2	233	4.74	0.67	4.70	(2.8, 7.6)	233	-0.03	0.46	0.00	(-1.7, 1.8)
	Week 4	223	4.74	0.62	4.70	(2.8, 6.7)	223	-0.04	0.54	0.00	(-1.8, 1.6)
	Week 6	219	4.76	0.67	4.70	(2.8, 6.7)	219	-0.01	0.52	0.00	(-1.7, 1.8)
	Week 8	216	4.73	0.64	4.70	(3.1, 7.3)	216	-0.03	0.57	0.00	(-1.5, 1.9)
	Week 10	213	4.73	0.68	4.70	(3.0, 7.2)	213	-0.03	0.58	0.00	(-1.7, 1.9)
	Week 12	205	4.73	0.63	4.70	(3.2, 6.4)	205	-0.03	0.58	-0.10	(-2.0, 2.1)
	Week 14	36	4.67	0.72	4.75	(3.4, 6.4)	36	-0.04	0.60	-0.10	(-1.1, 2.1)
	Week 16	200	4.67	0.67	4.70	(3.2, 6.9)	200	-0.09	0.61	-0.10	(-1.7, 2.0)
	Week 20	161	4.71	0.69	4.70	(3.2, 6.9)	161	-0.07	0.57	-0.10	(-1.5, 2.5)
	Week 24	159	4.75	0.76	4.70	(3.2, 8.0)	159	-0.03	0.63	-0.10	(-1.6, 2.7)
PD	Baseline	42	4.27	0.55	4.20	(3.2, 5.6)					
	Week 2	40	4.22	0.53	4.25	(3.2, 5.5)	40	-0.04	0.44	-0.10	(-0.9, 0.9)
	Week 4	41	4.16	0.55	4.00	(3.1, 5.7)	41	-0.10	0.37	-0.10	(-1.0, 0.7)
	Week 6	39	4.12	0.60	4.00	(3.2, 5.4)	39	-0.16	0.36	-0.20	(-1.2, 0.6)
	Week 8	39	4.08	0.60	4.00	(2.9, 5.4)	39	-0.19	0.46	-0.20	(-2.0, 0.9)
	Week 10	39	4.15	0.62	4.00	(2.9, 6.0)	39	-0.12	0.47	-0.20	(-0.9, 1.8)
	Week 12	38	4.12	0.68	4.05	(3.1, 5.8)	38	-0.16	0.52	-0.30	(-1.0, 1.4)
	Week 16	37	4.09	0.68	4.10	(2.7, 5.5)	37	-0.15	0.59	-0.20	(-1.4, 1.3)
	Week 20	37	4.16	0.71	4.00	(2.6, 6.7)	37	-0.08	0.60	-0.20	(-1.1, 1.6)
	Week 24	36	4.14	0.70	4.00	(2.5, 5.9)	36	-0.11	0.61	-0.15	(-1.2, 1.7)

表 2.7.4.9－33　臨床検査値：実測値及びベースラインからの変化量（ISS-1）（続き）

Parameter:Potassium (mEq/L)

		Absolute					Change from Baseline				
	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean	SD	Median	Minimum, Maximum
Total	Baseline	481	4.71	0.61	4.70	(2.7, 6.7)					
	Week 2	475	4.67	0.63	4.60	(2.8, 7.6)	475	-0.04	0.46	-0.10	(-1.7, 1.8)
	Week 4	464	4.67	0.61	4.70	(2.8, 6.7)	464	-0.04	0.48	0.00	(-2.0, 1.6)
	Week 6	457	4.66	0.64	4.60	(2.8, 6.8)	457	-0.04	0.48	0.00	(-1.7, 1.8)
	Week 8	450	4.65	0.62	4.60	(2.9, 7.3)	450	-0.05	0.53	0.00	(-2.0, 2.0)
	Week 10	445	4.65	0.64	4.60	(2.9, 7.2)	445	-0.06	0.53	-0.10	(-1.7, 1.9)
	Week 12	423	4.63	0.63	4.60	(3.1, 6.4)	423	-0.07	0.54	-0.10	(-2.0, 2.1)
	Week 14	70	4.69	0.68	4.75	(3.4, 6.4)	70	-0.02	0.54	0.05	(-1.1, 2.1)
	Week 16	413	4.59	0.63	4.50	(2.7, 6.9)	413	-0.10	0.56	-0.10	(-1.8, 2.0)
	Week 20	338	4.60	0.65	4.60	(2.6, 6.9)	338	-0.09	0.56	-0.10	(-1.6, 2.5)
	Week 24	327	4.61	0.70	4.50	(2.5, 8.0)	327	-0.08	0.59	-0.10	(-2.3, 2.7)

表 2.7.4.9－33　臨床検査値：実測値及びベースラインからの変化量（ISS-1）（続き）

Parameter:Chloride (mEq/L)

		Absolute					Change from Baseline				
	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean	SD	Median	Minimum, Maximum
NDD	Baseline	202	105.7	4.1	106.0	(91, 116)					
	Week 2	202	106.1	4.0	106.0	(92, 118)	202	0.3	2.8	0.0	(-7, 9)
	Week 4	200	106.2	4.0	107.0	(90, 116)	200	0.5	2.9	0.5	(-7, 11)
	Week 6	199	106.0	4.2	106.0	(91, 115)	199	0.3	3.0	0.0	(-6, 11)
	Week 8	195	106.2	3.9	106.0	(92, 117)	195	0.4	2.9	1.0	(-7, 10)
	Week 10	193	105.8	3.9	106.0	(91, 118)	193	-0.1	3.1	0.0	(-12, 9)
	Week 12	180	105.7	3.6	106.0	(93, 117)	180	-0.3	3.1	-1.0	(-8, 9)
	Week 14	34	105.4	4.0	106.0	(94, 113)	34	0.7	2.5	1.0	(-5, 6)
	Week 16	176	105.5	4.2	105.0	(87, 118)	176	-0.4	3.1	-1.0	(-11, 9)
	Week 20	140	105.8	4.4	106.0	(87, 121)	140	-0.4	3.3	0.0	(-11, 8)
	Week 24	132	106.0	3.9	106.0	(88, 114)	132	-0.2	3.5	0.0	(-10, 9)
HD	Baseline	237	103.1	3.1	103.0	(93, 112)					
	Week 2	233	102.8	3.2	103.0	(93, 111)	233	-0.2	2.4	0.0	(-7, 5)
	Week 4	223	103.0	3.2	103.0	(92, 110)	223	-0.1	2.7	0.0	(-10, 8)
	Week 6	219	103.1	3.6	103.0	(91, 112)	219	0.1	2.9	0.0	(-8, 9)
	Week 8	216	103.0	3.4	103.0	(93, 115)	216	0.0	3.0	0.0	(-8, 8)
	Week 10	213	103.3	3.3	103.0	(92, 112)	213	0.2	3.0	0.0	(-11, 9)
	Week 12	205	103.0	3.4	103.0	(93, 114)	205	0.0	2.8	0.0	(-9, 7)
	Week 14	36	102.9	2.8	103.0	(96, 108)	36	0.7	2.6	1.0	(-6, 7)
	Week 16	200	103.1	3.4	103.0	(92, 113)	200	0.1	2.7	0.0	(-7, 8)
	Week 20	161	103.3	3.2	104.0	(94, 112)	161	0.1	2.6	0.0	(-8, 6)
	Week 24	159	103.4	3.1	103.0	(95, 111)	159	0.4	2.7	0.0	(-9, 8)
PD	Baseline	42	98.0	4.0	98.0	(88, 106)					
	Week 2	40	97.7	3.9	98.0	(88, 105)	40	-0.3	1.9	0.0	(-4, 4)
	Week 4	41	97.8	4.3	98.0	(90, 107)	41	0.0	2.6	0.0	(-6, 6)
	Week 6	39	97.8	3.6	98.0	(90, 104)	39	-0.1	2.6	0.0	(-6, 6)
	Week 8	39	96.9	4.2	96.0	(90, 104)	39	-0.9	2.8	-1.0	(-10, 4)
	Week 10	39	97.1	3.5	98.0	(89, 103)	39	-0.7	2.1	-1.0	(-6, 4)
	Week 12	38	97.6	3.8	98.0	(90, 105)	38	-0.4	2.4	-0.5	(-7, 3)
	Week 16	37	97.5	4.2	97.0	(89, 106)	37	-0.4	2.8	0.0	(-5, 6)
	Week 20	37	98.1	4.1	98.0	(90, 106)	37	0.3	2.9	0.0	(-7, 6)
	Week 24	36	97.3	4.7	97.5	(90, 108)	36	-0.5	3.3	-1.0	(-9, 6)

表 2.7.4.9－33　臨床検査値：実測値及びベースラインからの変化量（ISS-1）（続き）

Parameter:Chloride (mEq/L)

		Absolute					Change from Baseline			
	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean	SD	Median	Minimum, Maximum
Total	Baseline	481	103.8	4.2	104.0	(88, 116)					
	Week 2	475	103.8	4.3	104.0	(88, 118)	475	0.0	2.6	0.0	(-7, 9)
	Week 4	464	103.9	4.4	104.0	(90, 116)	464	0.2	2.8	0.0	(-10, 11)
	Week 6	457	103.9	4.5	104.0	(90, 115)	457	0.1	2.9	0.0	(-8, 11)
	Week 8	450	103.9	4.5	104.0	(90, 117)	450	0.1	2.9	0.0	(-10, 10)
	Week 10	445	103.8	4.3	104.0	(89, 118)	445	0.0	3.0	0.0	(-12, 9)
	Week 12	423	103.7	4.2	104.0	(90, 117)	423	-0.1	2.9	0.0	(-9, 9)
	Week 14	70	104.1	3.6	104.0	(94, 113)	70	0.7	2.5	1.0	(-6, 7)
	Week 16	413	103.6	4.4	104.0	(87, 118)	413	-0.2	2.9	0.0	(-11, 9)
	Week 20	338	103.7	4.5	104.0	(87, 121)	338	-0.1	3.0	0.0	(-11, 8)
	Week 24	327	103.8	4.4	104.0	(88, 114)	327	0.1	3.1	0.0	(-10, 9)

表 2.7.4.9－33　臨床検査値：実測値及びベースラインからの変化量（ISS-1）（続き）

Parameter:Calcium (mg/dL)

		Absolute					Change from Baseline				
	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean	SD	Median	Minimum, Maximum
NDD	Baseline	202	8.79	0.58	8.80	(6.0, 10.8)					
	Week 2	202	8.64	0.53	8.65	(6.7, 10.9)	202	-0.15	0.36	-0.10	(-1.3, 1.7)
	Week 4	200	8.62	0.54	8.70	(6.7, 10.3)	200	-0.17	0.35	-0.20	(-1.2, 1.4)
	Week 6	199	8.62	0.53	8.60	(6.7, 10.8)	199	-0.17	0.39	-0.20	(-1.7, 1.5)
	Week 8	195	8.65	0.54	8.60	(6.7, 10.5)	195	-0.13	0.39	-0.10	(-2.0, 1.5)
	Week 10	193	8.61	0.53	8.60	(6.6, 11.0)	193	-0.17	0.43	-0.20	(-2.0, 2.0)
	Week 12	180	8.65	0.54	8.70	(6.5, 11.4)	180	-0.15	0.39	-0.15	(-2.2, 1.8)
	Week 14	34	8.67	0.53	8.70	(7.3, 9.7)	34	-0.10	0.27	-0.10	(-0.8, 0.5)
	Week 16	176	8.64	0.54	8.70	(7.2, 10.1)	176	-0.17	0.48	-0.20	(-2.5, 2.0)
	Week 20	140	8.67	0.60	8.70	(6.4, 10.5)	140	-0.15	0.48	-0.10	(-2.2, 1.8)
	Week 24	132	8.81	0.57	8.90	(6.7, 10.4)	132	-0.03	0.46	0.00	(-1.9, 1.3)
HD	Baseline	237	8.54	0.78	8.50	(5.8, 11.1)					
	Week 2	233	8.42	0.74	8.40	(5.8, 10.8)	233	-0.12	0.45	-0.10	(-1.9, 3.2)
	Week 4	223	8.49	0.77	8.50	(5.9, 11.3)	223	-0.07	0.51	-0.10	(-1.5, 3.6)
	Week 6	219	8.43	0.73	8.50	(5.8, 10.7)	219	-0.12	0.49	-0.10	(-2.0, 3.1)
	Week 8	216	8.44	0.76	8.40	(5.6, 11.2)	216	-0.09	0.54	-0.10	(-1.9, 3.0)
	Week 10	213	8.50	0.74	8.50	(5.8, 11.0)	213	-0.03	0.52	0.00	(-2.5, 2.1)
	Week 12	205	8.55	0.75	8.60	(6.2, 11.9)	205	0.01	0.56	0.00	(-2.3, 2.4)
	Week 14	36	8.63	1.09	8.45	(6.2, 11.7)	36	0.12	0.50	0.10	(-1.5, 1.4)
	Week 16	200	8.60	0.72	8.60	(6.3, 10.9)	200	0.05	0.61	0.00	(-2.5, 2.4)
	Week 20	161	8.55	0.67	8.50	(6.8, 10.3)	161	0.00	0.67	0.00	(-2.1, 3.6)
	Week 24	159	8.69	0.70	8.70	(6.9, 10.8)	159	0.14	0.64	0.10	(-1.7, 1.9)
PD	Baseline	42	8.40	0.62	8.50	(6.5, 9.5)					
	Week 2	40	8.25	0.64	8.20	(6.3, 9.6)	40	-0.13	0.35	-0.10	(-1.1, 0.5)
	Week 4	41	8.29	0.72	8.40	(6.1, 9.6)	41	-0.12	0.45	-0.10	(-1.3, 0.9)
	Week 6	39	8.23	0.72	8.30	(6.1, 10.1)	39	-0.16	0.37	-0.20	(-1.2, 0.6)
	Week 8	39	8.37	0.78	8.30	(6.2, 10.2)	39	-0.01	0.47	-0.10	(-0.7, 1.6)
	Week 10	39	8.28	0.69	8.30	(6.9, 9.5)	39	-0.11	0.40	-0.10	(-1.3, 0.9)
	Week 12	38	8.37	0.66	8.30	(7.3, 9.6)	38	-0.01	0.41	-0.05	(-0.6, 1.2)
	Week 16	37	8.34	0.58	8.30	(7.1, 9.6)	37	-0.04	0.46	0.00	(-1.1, 1.3)
	Week 20	37	8.49	0.69	8.40	(6.9, 9.9)	37	0.11	0.49	0.20	(-1.2, 0.9)
	Week 24	36	8.44	0.68	8.50	(6.6, 9.6)	36	0.06	0.54	0.10	(-1.4, 1.0)

表 2.7.4.9－33　臨床検査値：実測値及びベースラインからの変化量（ISS-1）（続き）

Parameter:Calcium (mg/dL)

		Absolute					Change from Baseline				
	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean	SD	Median	Minimum, Maximum
Total	Baseline	481	8.63	0.70	8.70	(5.8, 11.1)					
	Week 2	475	8.50	0.66	8.50	(5.8, 10.9)	475	-0.13	0.40	-0.10	(-1.9, 3.2)
	Week 4	464	8.53	0.68	8.60	(5.9, 11.3)	464	-0.12	0.44	-0.10	(-1.5, 3.6)
	Week 6	457	8.49	0.66	8.50	(5.8, 10.8)	457	-0.14	0.44	-0.10	(-2.0, 3.1)
	Week 8	450	8.53	0.68	8.50	(5.6, 11.2)	450	-0.10	0.47	-0.10	(-2.0, 3.0)
	Week 10	445	8.53	0.66	8.60	(5.8, 11.0)	445	-0.10	0.48	-0.10	(-2.5, 2.1)
	Week 12	423	8.58	0.66	8.60	(6.2, 11.9)	423	-0.06	0.49	-0.10	(-2.3, 2.4)
	Week 14	70	8.65	0.86	8.65	(6.2, 11.7)	70	0.01	0.42	0.00	(-1.5, 1.4)
	Week 16	413	8.59	0.64	8.60	(6.3, 10.9)	413	-0.05	0.56	-0.10	(-2.5, 2.4)
	Week 20	338	8.59	0.64	8.60	(6.4, 10.5)	338	-0.05	0.58	0.00	(-2.2, 3.6)
	Week 24	327	8.71	0.66	8.70	(6.6, 10.8)	327	0.06	0.57	0.10	(-1.9, 1.9)

表 2.7.4.9－33　臨床検査値：実測値及びベースラインからの変化量（ISS-1）（続き）

Parameter:Phosphate (mg/dL)

		Absolute					Change from Baseline				
	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean	SD	Median	Minimum, Maximum
NDD	Baseline	202	3.96	0.83	3.90	(2.2, 10.8)					
	Week 2	202	4.03	0.78	4.00	(2.0, 6.7)	202	0.07	0.63	0.00	(-4.1, 2.6)
	Week 4	200	3.99	0.76	3.90	(2.0, 6.8)	200	0.03	0.64	0.00	(-4.5, 1.5)
	Week 6	199	3.96	0.78	3.80	(2.1, 7.8)	199	0.00	0.68	0.00	(-4.8, 3.0)
	Week 8	195	3.98	0.77	3.80	(1.8, 7.5)	195	0.03	0.66	0.00	(-4.3, 3.0)
	Week 10	193	3.95	0.83	3.90	(2.2, 6.9)	193	-0.02	0.71	0.00	(-4.0, 2.0)
	Week 12	180	3.93	0.77	3.80	(2.3, 7.2)	180	-0.05	0.69	0.00	(-4.1, 2.8)
	Week 14	34	4.02	0.80	4.10	(2.2, 6.0)	34	0.17	0.62	0.20	(-1.2, 2.3)
	Week 16	176	3.94	0.81	3.80	(2.0, 7.6)	176	-0.03	0.69	-0.05	(-3.2, 3.6)
	Week 20	140	3.97	0.94	3.85	(2.3, 10.7)	140	-0.02	0.84	-0.05	(-3.7, 5.6)
	Week 24	132	3.88	0.77	3.80	(1.4, 7.0)	132	-0.05	0.59	0.00	(-2.5, 1.6)
HD	Baseline	237	5.29	1.19	5.20	(2.6, 9.8)					
	Week 2	233	5.39	1.22	5.40	(1.3, 10.4)	233	0.09	1.06	0.10	(-3.5, 3.0)
	Week 4	223	5.38	1.18	5.20	(2.7, 8.8)	223	0.05	1.13	0.00	(-3.0, 4.4)
	Week 6	219	5.47	1.41	5.30	(2.8, 11.7)	219	0.14	1.22	0.10	(-3.3, 3.6)
	Week 8	216	5.43	1.27	5.30	(2.8, 10.0)	216	0.09	1.19	0.00	(-2.5, 3.6)
	Week 10	213	5.32	1.26	5.20	(2.6, 10.1)	213	-0.03	1.21	-0.10	(-3.2, 4.7)
	Week 12	205	5.33	1.22	5.20	(2.7, 9.6)	205	-0.03	1.18	-0.10	(-3.4, 4.2)
	Week 14	36	5.74	1.34	5.55	(3.7, 9.4)	36	0.62	1.61	0.40	(-2.6, 6.3)
	Week 16	200	5.22	1.19	5.20	(2.5, 9.3)	200	-0.13	1.18	-0.10	(-3.4, 2.9)
	Week 20	161	5.23	1.34	5.10	(2.7, 12.9)	161	-0.17	1.43	-0.30	(-2.9, 9.3)
	Week 24	159	5.29	1.20	5.20	(3.0, 10.3)	159	-0.11	1.36	-0.20	(-3.1, 3.8)
PD	Baseline	42	5.46	1.12	5.35	(3.6, 8.0)					
	Week 2	40	5.42	1.07	5.25	(3.8, 8.6)	40	-0.04	0.98	0.05	(-2.6, 2.0)
	Week 4	41	5.27	0.98	5.00	(3.1, 8.2)	41	-0.22	0.85	-0.20	(-2.8, 1.8)
	Week 6	39	5.29	0.92	5.10	(3.4, 7.4)	39	-0.27	0.98	-0.10	(-2.4, 1.8)
	Week 8	39	5.22	1.10	5.20	(3.2, 8.7)	39	-0.34	1.06	-0.20	(-2.8, 2.3)
	Week 10	39	5.21	0.80	5.20	(3.9, 7.5)	39	-0.34	1.03	-0.10	(-3.2, 1.6)
	Week 12	38	5.25	0.99	5.30	(3.9, 7.7)	38	-0.32	0.78	-0.35	(-1.9, 1.3)
	Week 16	37	5.29	0.94	5.30	(3.4, 7.3)	37	-0.25	0.83	-0.20	(-2.2, 2.2)
	Week 20	37	5.05	1.01	5.00	(2.9, 7.1)	37	-0.50	1.12	-0.50	(-3.8, 1.4)
	Week 24	36	5.12	0.95	5.30	(2.9, 6.7)	36	-0.42	1.01	-0.15	(-3.0, 1.6)

表 2.7.4.9－33　臨床検査値：実測値及びベースラインからの変化量（ISS-1）（続き）

Parameter:Phosphate (mg/dL)

		Absolute					Change from Baseline				
	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean	SD	Median	Minimum, Maximum
Total	Baseline	481	4.75	1.24	4.50	(2.2, 10.8)					
	Week 2	475	4.81	1.24	4.60	(1.3, 10.4)	475	0.07	0.89	0.10	(-4.1, 3.0)
	Week 4	464	4.77	1.21	4.70	(2.0, 8.8)	464	0.02	0.92	0.00	(-4.5, 4.4)
	Week 6	457	4.80	1.36	4.60	(2.1, 11.7)	457	0.04	1.00	0.00	(-4.8, 3.6)
	Week 8	450	4.78	1.28	4.60	(1.8, 10.0)	450	0.02	0.99	0.00	(-4.3, 3.6)
	Week 10	445	4.71	1.25	4.50	(2.2, 10.1)	445	-0.05	1.01	-0.10	(-4.0, 4.7)
	Week 12	423	4.72	1.24	4.50	(2.3, 9.6)	423	-0.06	0.97	-0.10	(-4.1, 4.2)
	Week 14	70	4.90	1.40	4.55	(2.2, 9.4)	70	0.40	1.24	0.30	(-2.6, 6.3)
	Week 16	413	4.68	1.20	4.60	(2.0, 9.3)	413	-0.10	0.97	-0.10	(-3.4, 3.6)
	Week 20	338	4.69	1.30	4.45	(2.3, 12.9)	338	-0.14	1.19	-0.20	(-3.8, 9.3)
	Week 24	327	4.70	1.22	4.50	(1.4, 10.3)	327	-0.12	1.08	-0.10	(-3.1, 3.8)

表 2.7.4.9－33　臨床検査値：実測値及びベースラインからの変化量（ISS-1）（続き）

Parameter:Magnesium (mg/dL)

		Absolute					Change from Baseline				
	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean	SD	Median	Minimum, Maximum
NDD	Baseline	151	2.00	0.30	2.00	(1.3, 2.9)					
	Week 2	151	2.02	0.29	2.00	(1.4, 3.3)	151	0.02	0.16	0.00	(-0.4, 0.5)
	Week 4	149	2.00	0.32	2.00	(1.2, 3.2)	149	0.00	0.16	0.00	(-0.4, 0.5)
	Week 6	148	2.00	0.30	2.00	(1.3, 3.4)	148	0.01	0.17	0.00	(-0.3, 0.5)
	Week 8	145	2.03	0.31	2.00	(1.4, 3.5)	145	0.03	0.18	0.00	(-0.4, 0.8)
	Week 10	145	2.00	0.30	2.00	(1.3, 3.2)	145	0.00	0.18	0.00	(-0.4, 0.5)
	Week 12	145	2.01	0.29	2.00	(1.3, 3.0)	145	0.01	0.18	0.00	(-0.4, 0.6)
	Week 16	143	1.99	0.29	2.00	(1.3, 3.0)	143	-0.01	0.19	0.00	(-0.5, 0.6)
	Week 20	140	2.04	0.32	2.00	(1.2, 3.2)	140	0.04	0.18	0.00	(-0.3, 0.5)
	Week 24	132	2.03	0.30	2.10	(1.2, 2.9)	132	0.02	0.19	0.00	(-0.8, 0.5)
HD	Baseline	186	2.38	0.33	2.40	(1.4, 3.6)					
	Week 2	183	2.30	0.31	2.30	(1.6, 3.3)	183	-0.08	0.17	-0.10	(-0.9, 0.3)
	Week 4	180	2.30	0.33	2.30	(1.3, 3.4)	180	-0.08	0.18	-0.10	(-0.7, 0.4)
	Week 6	177	2.29	0.32	2.20	(1.5, 3.4)	177	-0.09	0.19	-0.10	(-0.6, 0.7)
	Week 8	174	2.28	0.32	2.25	(1.4, 3.1)	174	-0.09	0.19	-0.10	(-0.7, 0.3)
	Week 10	172	2.30	0.35	2.30	(1.4, 3.9)	172	-0.07	0.21	-0.10	(-0.6, 0.7)
	Week 12	169	2.30	0.33	2.30	(1.5, 3.5)	169	-0.07	0.20	-0.10	(-0.7, 0.5)
	Week 16	165	2.29	0.31	2.30	(1.6, 3.1)	165	-0.08	0.21	-0.10	(-0.7, 0.4)
	Week 20	161	2.29	0.34	2.30	(1.6, 3.3)	161	-0.08	0.20	-0.10	(-0.7, 0.4)
	Week 24	159	2.31	0.35	2.30	(1.5, 3.6)	159	-0.06	0.22	-0.10	(-0.7, 0.8)
PD	Baseline	42	2.14	0.38	2.10	(1.6, 3.5)					
	Week 2	40	2.08	0.37	2.05	(1.6, 3.2)	40	-0.05	0.13	-0.10	(-0.3, 0.3)
	Week 4	41	2.02	0.36	1.90	(1.6, 3.2)	41	-0.10	0.17	-0.10	(-0.5, 0.2)
	Week 6	39	1.99	0.37	1.90	(1.5, 3.2)	39	-0.16	0.18	-0.10	(-0.8, 0.2)
	Week 8	39	2.03	0.37	2.00	(1.4, 3.2)	39	-0.11	0.22	-0.10	(-0.9, 0.2)
	Week 10	39	2.02	0.34	2.00	(1.4, 2.9)	39	-0.13	0.22	-0.10	(-0.9, 0.2)
	Week 12	38	2.03	0.38	1.90	(1.5, 3.1)	38	-0.11	0.20	-0.10	(-0.4, 0.4)
	Week 16	37	1.95	0.32	1.90	(1.5, 2.8)	37	-0.19	0.22	-0.20	(-0.7, 0.2)
	Week 20	37	1.96	0.37	1.90	(1.5, 3.3)	37	-0.15	0.18	-0.20	(-0.6, 0.2)
	Week 24	36	1.98	0.35	1.90	(1.4, 3.0)	36	-0.16	0.21	-0.15	(-0.6, 0.2)

表 2.7.4.9－33　臨床検査値：実測値及びベースラインからの変化量（ISS-1）（続き）

Parameter:Magnesium (mg/dL)

		Absolute					Change from Baseline				
	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean	SD	Median	Minimum, Maximum
Total	Baseline	379	2.20	0.37	2.20	(1.3, 3.6)					
	Week 2	374	2.16	0.34	2.10	(1.4, 3.3)	374	-0.03	0.17	0.00	(-0.9, 0.5)
	Week 4	370	2.15	0.36	2.10	(1.2, 3.4)	370	-0.05	0.18	-0.05	(-0.7, 0.5)
	Week 6	364	2.14	0.35	2.10	(1.3, 3.4)	364	-0.05	0.19	-0.10	(-0.8, 0.7)
	Week 8	358	2.15	0.34	2.10	(1.4, 3.5)	358	-0.04	0.20	0.00	(-0.9, 0.8)
	Week 10	356	2.15	0.36	2.10	(1.3, 3.9)	356	-0.05	0.20	-0.05	(-0.9, 0.7)
	Week 12	352	2.15	0.35	2.10	(1.3, 3.5)	352	-0.04	0.20	0.00	(-0.7, 0.6)
	Week 16	345	2.13	0.34	2.10	(1.3, 3.1)	345	-0.06	0.21	-0.10	(-0.7, 0.6)
	Week 20	338	2.15	0.36	2.10	(1.2, 3.3)	338	-0.04	0.20	0.00	(-0.7, 0.5)
	Week 24	327	2.16	0.36	2.10	(1.2, 3.6)	327	-0.04	0.21	0.00	(-0.8, 0.8)

表 2.7.4.9－33　臨床検査値：実測値及びベースラインからの変化量（ISS-1）（続き）

Parameter:Bicarbonate (mmol/L)

		Absolute					Change from Baseline				
	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean	SD	Median	Minimum, Maximum
NDD	Baseline	202	19.80	3.23	20.00	(7.2, 27.0)					
	Week 2	202	18.75	3.56	19.00	(7.2, 26.0)	202	-1.05	1.86	-0.95	(-8.3, 3.5)
	Week 4	200	18.87	3.36	19.00	(5.5, 26.4)	200	-0.94	1.78	-0.95	(-6.2, 3.6)
	Week 6	199	18.85	3.42	19.00	(6.3, 26.0)	199	-0.94	1.80	-1.00	(-7.0, 4.0)
	Week 8	195	18.87	3.58	19.00	(7.5, 26.0)	195	-0.95	2.13	-1.00	(-7.2, 5.1)
	Week 10	193	18.94	3.51	19.10	(7.2, 25.7)	193	-0.91	2.41	-1.00	(-8.2, 6.7)
	Week 12	180	19.03	3.57	19.30	(7.0, 27.0)	180	-0.67	2.35	-0.60	(-7.4, 5.8)
	Week 14	34	19.65	2.88	20.00	(12.0, 25.0)	34	-0.85	1.71	-1.00	(-5.0, 3.0)
	Week 16	176	19.18	3.18	19.20	(8.0, 27.1)	176	-0.53	2.27	-0.70	(-7.7, 8.2)
	Week 20	140	19.09	3.41	19.10	(3.2, 25.9)	140	-0.57	2.45	-0.50	(-7.0, 6.9)
	Week 24	132	19.02	3.17	18.80	(11.2, 26.8)	132	-0.69	2.63	-0.55	(-8.0, 7.4)
HD	Baseline	237	17.42	2.48	17.10	(11.2, 25.0)					
	Week 2	233	16.96	2.31	17.00	(10.9, 24.0)	233	-0.49	1.81	-0.50	(-4.9, 5.3)
	Week 4	223	16.89	2.17	16.70	(11.1, 24.0)	223	-0.56	1.83	-0.50	(-5.8, 4.1)
	Week 6	219	16.91	2.22	16.90	(11.3, 22.8)	219	-0.55	1.82	-0.50	(-5.4, 4.2)
	Week 8	216	16.89	2.14	17.00	(11.6, 22.3)	216	-0.57	2.05	-0.60	(-6.8, 3.8)
	Week 10	213	16.89	2.25	16.90	(8.8, 22.8)	213	-0.56	2.11	-0.30	(-8.3, 4.9)
	Week 12	205	16.82	2.26	17.00	(10.6, 23.1)	205	-0.62	1.97	-0.60	(-7.6, 6.4)
	Week 14	36	17.06	1.74	17.00	(13.0, 21.0)	36	-1.56	1.73	-1.50	(-6.0, 2.0)
	Week 16	200	17.10	2.40	17.00	(10.7, 24.2)	200	-0.35	2.38	-0.35	(-8.4, 6.2)
	Week 20	161	16.77	2.32	16.70	(10.1, 22.6)	161	-0.46	2.16	-0.10	(-8.3, 4.4)
	Week 24	159	17.19	2.22	17.10	(11.4, 23.5)	159	-0.04	2.24	-0.10	(-6.0, 6.7)
PD	Baseline	42	22.10	2.26	21.70	(18.2, 27.3)					
	Week 2	40	21.05	2.34	20.70	(17.0, 27.3)	40	-1.01	1.57	-0.80	(-5.3, 2.2)
	Week 4	41	21.30	2.68	20.80	(15.2, 26.5)	41	-0.79	1.95	-0.50	(-7.5, 2.5)
	Week 6	39	20.99	2.17	20.70	(16.0, 26.0)	39	-1.08	1.76	-1.30	(-6.3, 2.5)
	Week 8	39	21.36	2.71	20.80	(16.3, 28.7)	39	-0.72	1.89	-0.60	(-5.7, 3.1)
	Week 10	39	21.46	2.21	21.40	(16.4, 28.1)	39	-0.61	1.56	-0.60	(-3.9, 2.1)
	Week 12	38	21.43	1.87	21.05	(17.9, 27.3)	38	-0.55	1.69	-0.80	(-3.9, 2.7)
	Week 16	37	21.45	2.54	21.00	(17.6, 27.4)	37	-0.56	1.66	-0.60	(-4.5, 2.5)
	Week 20	37	21.45	2.36	21.10	(16.2, 26.7)	37	-0.56	1.76	-0.60	(-5.0, 3.4)
	Week 24	36	21.84	2.25	21.60	(18.1, 27.8)	36	-0.26	1.82	-0.40	(-3.3, 3.6)

表 2.7.4.9－33　臨床検査値：実測値及びベースラインからの変化量（ISS-1）（続き）

Parameter:Bicarbonate (mmol/L)

		Absolute					Change from Baseline				
	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean	SD	Median	Minimum, Maximum
Total	Baseline	481	18.83	3.18	18.70	(7.2, 27.3)					
	Week 2	475	18.07	3.16	18.00	(7.2, 27.3)	475	-0.77	1.83	-0.80	(-8.3, 5.3)
	Week 4	464	18.13	3.10	17.95	(5.5, 26.5)	464	-0.74	1.82	-0.70	(-7.5, 4.1)
	Week 6	457	18.10	3.08	17.90	(6.3, 26.0)	457	-0.77	1.81	-0.90	(-7.0, 4.2)
	Week 8	450	18.14	3.20	18.00	(7.5, 28.7)	450	-0.75	2.08	-0.80	(-7.2, 5.1)
	Week 10	445	18.18	3.19	18.00	(7.2, 28.1)	445	-0.72	2.21	-0.50	(-8.3, 6.7)
	Week 12	423	18.18	3.23	18.00	(7.0, 27.3)	423	-0.64	2.12	-0.60	(-7.6, 6.4)
	Week 14	70	18.31	2.68	18.00	(12.0, 25.0)	70	-1.21	1.74	-1.00	(-6.0, 3.0)
	Week 16	413	18.38	3.09	18.20	(8.0, 27.4)	413	-0.45	2.28	-0.50	(-8.4, 8.2)
	Week 20	338	18.24	3.23	18.15	(3.2, 26.7)	338	-0.52	2.24	-0.40	(-8.3, 6.9)
	Week 24	327	18.44	3.02	18.10	(11.2, 27.8)	327	-0.33	2.38	-0.30	(-8.0, 7.4)

表 2.7.4.9－33　臨床検査値：実測値及びベースラインからの変化量（ISS-1）（続き）

Parameter:Cholesterol (mg/dL)

		Absolute					Change from Baseline				
	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean	SD	Median	Minimum, Maximum
NDD	Baseline	202	178.3	36.4	175.5	(99, 282)					
	Week 2	202	177.8	40.2	175.0	(80, 313)	202	-0.4	16.7	2.5	(-58, 47)
	Week 4	200	173.3	40.3	166.5	(88, 321)	200	-4.7	19.4	-5.0	(-65, 98)
	Week 6	199	173.7	40.1	170.0	(97, 345)	199	-4.4	21.9	-4.0	(-92, 88)
	Week 8	195	175.9	40.9	171.0	(92, 359)	195	-1.4	23.4	-3.0	(-132, 85)
	Week 10	193	174.0	39.6	172.0	(94, 330)	193	-2.6	24.3	-3.0	(-131, 59)
	Week 12	180	177.8	40.5	170.0	(103, 350)	180	-0.4	26.8	0.5	(-134, 97)
	Week 14	34	171.2	25.7	166.0	(126, 241)	34	-3.6	18.4	-2.0	(-54, 25)
	Week 16	176	180.4	41.4	174.0	(104, 368)	176	2.1	28.6	1.5	(-154, 94)
	Week 20	140	182.1	42.4	178.5	(96, 308)	140	2.3	30.7	0.5	(-126, 106)
	Week 24	132	184.7	40.6	181.0	(98, 289)	132	4.8	28.3	4.0	(-134, 80)
HD	Baseline	237	158.2	31.9	156.0	(78, 267)					
	Week 2	233	158.9	31.6	157.0	(80, 234)	233	0.9	13.0	2.0	(-36, 47)
	Week 4	223	156.9	32.0	156.0	(86, 264)	223	-1.2	15.6	1.0	(-52, 43)
	Week 6	219	158.6	33.6	158.0	(83, 274)	219	0.4	18.1	0.0	(-54, 48)
	Week 8	216	158.6	34.3	157.0	(82, 284)	216	0.3	18.1	0.0	(-52, 55)
	Week 10	213	158.8	34.3	159.0	(80, 262)	213	0.8	19.8	2.0	(-72, 68)
	Week 12	205	160.9	34.5	160.0	(89, 276)	205	2.4	19.9	4.0	(-57, 57)
	Week 14	36	159.9	36.0	159.0	(97, 252)	36	1.4	21.1	-0.5	(-34, 61)
	Week 16	200	161.7	35.6	158.5	(87, 260)	200	3.3	21.2	4.0	(-50, 73)
	Week 20	161	166.2	35.7	164.0	(91, 284)	161	7.7	21.5	6.0	(-43, 99)
	Week 24	159	166.2	35.3	166.0	(91, 282)	159	7.5	19.7	8.0	(-41, 73)
PD	Baseline	42	184.4	34.3	191.5	(113, 249)					
	Week 2	40	186.2	36.6	189.0	(109, 259)	40	2.0	16.5	1.0	(-32, 41)
	Week 4	41	186.9	42.4	198.0	(85, 287)	41	3.7	21.2	4.0	(-34, 54)
	Week 6	39	181.9	41.7	190.0	(99, 251)	39	-0.1	21.4	-4.0	(-42, 53)
	Week 8	39	183.2	39.3	191.0	(102, 259)	39	1.2	23.0	4.0	(-46, 53)
	Week 10	39	182.6	39.5	192.0	(97, 241)	39	0.6	26.0	-1.0	(-81, 50)
	Week 12	38	182.1	41.7	188.5	(97, 251)	38	-1.6	29.1	0.0	(-69, 55)
	Week 16	37	176.7	36.1	176.0	(109, 236)	37	-7.2	21.3	-6.0	(-78, 27)
	Week 20	37	186.3	40.2	195.0	(115, 269)	37	2.4	27.7	2.0	(-59, 57)
	Week 24	36	187.4	44.8	195.5	(85, 280)	36	2.0	27.6	1.0	(-63, 58)

表 2.7.4.9－33　臨床検査値：実測値及びベースラインからの変化量（ISS-1）（続き）

Parameter:Cholesterol (mg/dL)

		Absolute					Change from Baseline				
	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean	SD	Median	Minimum, Maximum
Total	Baseline	481	168.9	35.6	164.0	(78, 282)					
	Week 2	475	169.2	37.3	167.0	(80, 313)	475	0.4	14.9	2.0	(-58, 47)
	Week 4	464	166.6	38.0	163.0	(85, 321)	464	-2.3	18.0	-2.0	(-65, 98)
	Week 6	457	167.2	38.2	164.0	(83, 345)	457	-1.7	20.2	-2.0	(-92, 88)
	Week 8	450	168.2	38.8	166.0	(82, 359)	450	-0.4	20.9	-1.0	(-132, 85)
	Week 10	445	167.5	38.1	165.0	(80, 330)	445	-0.7	22.4	0.0	(-131, 68)
	Week 12	423	170.0	38.8	166.0	(89, 350)	423	0.8	23.9	1.0	(-134, 97)
	Week 14	70	165.4	31.7	165.0	(97, 252)	70	-1.0	19.9	-1.0	(-54, 61)
	Week 16	413	171.0	39.2	167.0	(87, 368)	413	1.8	24.7	2.0	(-154, 94)
	Week 20	338	175.0	39.9	170.5	(91, 308)	338	4.9	26.4	4.0	(-126, 106)
	Week 24	327	176.0	39.7	174.0	(85, 289)	327	5.8	24.4	6.0	(-134, 80)

表 2.7.4.9－33　臨床検査値：実測値及びベースラインからの変化量（ISS-1）（続き）

Parameter:LDL Cholesterol (mg/dL)

		Absolute					Change from Baseline				
	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean	SD	Median	Minimum, Maximum
NDD	Baseline	151	100.4	29.7	95.0	(45, 205)					
	Week 2	151	99.5	32.2	94.0	(43, 222)	151	-0.9	14.2	-1.0	(-57, 40)
	Week 4	149	97.4	31.6	90.0	(38, 213)	149	-2.9	15.8	-3.0	(-51, 51)
	Week 6	148	96.5	31.6	90.5	(34, 254)	148	-3.9	17.7	-4.0	(-89, 70)
	Week 8	145	98.7	32.8	94.0	(35, 269)	145	-1.4	20.7	-1.0	(-130, 85)
	Week 10	145	98.5	32.5	92.0	(33, 201)	145	-1.9	21.4	-4.0	(-129, 64)
	Week 12	145	99.8	33.5	94.0	(33, 220)	145	-0.4	21.6	-2.0	(-130, 63)
	Week 16	143	101.2	36.7	94.0	(39, 264)	143	0.9	24.5	1.0	(-148, 80)
	Week 20	140	100.4	33.7	93.5	(34, 199)	140	-0.6	24.1	-1.0	(-129, 69)
	Week 24	132	101.1	32.8	96.5	(36, 196)	132	0.3	23.0	0.0	(-125, 60)
HD	Baseline	186	88.1	26.7	84.5	(33, 185)					
	Week 2	183	86.7	26.1	86.0	(33, 156)	183	-1.3	12.5	-1.0	(-52, 36)
	Week 4	180	86.2	26.8	88.0	(32, 171)	180	-1.5	13.0	-1.0	(-46, 44)
	Week 6	177	86.8	27.8	87.0	(26, 189)	177	-0.9	16.0	-1.0	(-55, 56)
	Week 8	174	87.0	28.2	87.0	(29, 190)	174	-0.7	15.3	-1.0	(-48, 46)
	Week 10	172	86.8	27.9	85.5	(28, 153)	172	-0.4	16.0	0.0	(-38, 69)
	Week 12	169	88.4	28.9	89.0	(31, 159)	169	0.6	16.6	1.0	(-42, 59)
	Week 16	165	89.1	29.9	87.0	(31, 169)	165	1.6	17.5	1.0	(-44, 81)
	Week 20	161	91.6	28.5	93.0	(34, 198)	161	4.1	15.9	4.0	(-37, 53)
	Week 24	159	89.7	28.2	92.0	(35, 164)	159	2.2	15.8	3.0	(-34, 60)
PD	Baseline	42	104.2	28.8	108.0	(48, 159)					
	Week 2	40	102.8	30.0	108.5	(43, 160)	40	-1.2	15.2	-1.0	(-31, 30)
	Week 4	41	107.0	34.6	113.0	(33, 186)	41	3.6	17.6	2.0	(-47, 46)
	Week 6	39	103.8	34.5	114.0	(38, 176)	39	0.9	16.1	1.0	(-37, 35)
	Week 8	39	102.6	29.9	106.0	(43, 155)	39	-0.2	19.1	2.0	(-39, 40)
	Week 10	39	102.6	32.1	103.0	(38, 152)	39	-0.3	19.8	2.0	(-38, 46)
	Week 12	38	102.2	34.0	105.5	(35, 155)	38	-1.9	25.8	1.5	(-67, 43)
	Week 16	37	98.4	31.1	101.0	(47, 156)	37	-6.3	19.9	-2.0	(-55, 26)
	Week 20	37	103.9	33.7	100.0	(48, 170)	37	-0.8	23.8	-1.0	(-53, 49)
	Week 24	36	105.5	36.5	113.0	(33, 168)	36	-0.3	20.9	0.0	(-60, 40)

表 2.7.4.9－33　臨床検査値：実測値及びベースラインからの変化量（ISS-1）（続き）

Parameter:LDL Cholesterol (mg/dL)

		Absolute					Change from Baseline				
	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean	SD	Median	Minimum, Maximum
Total	Baseline	379	94.8	28.8	91.0	(33, 205)					
	Week 2	374	93.6	29.8	90.0	(33, 222)	374	-1.1	13.5	-1.0	(-57, 40)
	Week 4	370	93.1	30.5	90.0	(32, 213)	370	-1.5	14.8	-1.5	(-51, 51)
	Week 6	364	92.5	30.7	89.0	(26, 254)	364	-1.9	16.8	-2.0	(-89, 70)
	Week 8	358	93.4	30.9	91.5	(29, 269)	358	-0.9	18.0	-1.0	(-130, 85)
	Week 10	356	93.3	30.9	90.0	(28, 201)	356	-1.0	18.7	-1.5	(-129, 69)
	Week 12	352	94.6	31.9	93.0	(31, 220)	352	-0.1	19.8	0.0	(-130, 63)
	Week 16	345	95.1	33.4	91.0	(31, 264)	345	0.5	21.0	0.0	(-148, 81)
	Week 20	338	96.6	31.6	94.0	(34, 199)	338	1.6	20.6	1.0	(-129, 69)
	Week 24	327	96.0	31.6	95.0	(33, 196)	327	1.2	19.5	1.0	(-125, 60)

表 2.7.4.9－33　臨床検査値：実測値及びベースラインからの変化量（ISS-1）（続き）

Parameter:HDL Cholesterol (mg/dL)

		Absolute					Change from Baseline				
	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean	SD	Median	Minimum, Maximum
NDD	Baseline	151	54.5	16.8	51.0	(24, 111)					
	Week 2	151	50.2	16.4	48.0	(22, 102)	151	-4.3	5.9	-4.0	(-21, 11)
	Week 4	149	50.0	15.9	48.0	(22, 114)	149	-4.2	6.1	-5.0	(-20, 23)
	Week 6	148	49.1	16.1	47.0	(22, 129)	148	-5.2	7.1	-5.5	(-36, 38)
	Week 8	145	49.2	15.1	47.0	(22, 105)	145	-5.1	8.3	-5.0	(-46, 22)
	Week 10	145	48.8	14.2	48.0	(23, 86)	145	-5.2	9.3	-6.0	(-68, 26)
	Week 12	145	49.3	15.2	47.0	(21, 115)	145	-4.6	9.7	-5.0	(-75, 24)
	Week 16	143	49.8	15.3	48.0	(25, 119)	143	-4.3	11.3	-5.0	(-77, 30)
	Week 20	140	51.5	16.2	49.0	(24, 122)	140	-2.4	9.2	-2.5	(-22, 31)
	Week 24	132	53.2	16.5	50.5	(25, 115)	132	-1.2	10.0	-2.0	(-25, 45)
HD	Baseline	186	48.5	16.0	46.5	(23, 112)					
	Week 2	183	45.8	15.0	45.0	(22, 107)	183	-2.6	5.5	-1.0	(-23, 10)
	Week 4	180	44.8	15.1	42.5	(22, 117)	180	-3.5	6.3	-3.0	(-27, 11)
	Week 6	177	44.6	16.0	41.0	(21, 107)	177	-3.8	6.3	-4.0	(-26, 15)
	Week 8	174	44.2	15.1	41.5	(21, 109)	174	-4.4	6.6	-4.0	(-34, 11)
	Week 10	172	44.1	15.2	41.0	(21, 118)	172	-4.6	6.9	-4.0	(-28, 9)
	Week 12	169	44.5	15.3	41.0	(21, 109)	169	-4.2	7.0	-3.0	(-25, 12)
	Week 16	165	45.7	16.1	42.0	(20, 111)	165	-3.1	7.4	-2.0	(-34, 17)
	Week 20	161	47.1	16.8	44.0	(14, 124)	161	-1.8	6.8	-2.0	(-21, 18)
	Week 24	159	47.8	17.8	44.0	(21, 122)	159	-1.1	7.7	-2.0	(-22, 25)
PD	Baseline	42	51.1	17.1	47.0	(22, 111)					
	Week 2	40	47.2	15.5	46.0	(21, 92)	40	-4.3	6.9	-5.0	(-19, 10)
	Week 4	41	45.3	14.0	42.0	(23, 78)	41	-5.9	7.3	-4.0	(-33, 4)
	Week 6	39	45.5	13.4	45.0	(22, 80)	39	-5.7	8.0	-4.0	(-31, 17)
	Week 8	39	43.7	12.4	41.0	(23, 69)	39	-7.6	9.5	-7.0	(-47, 10)
	Week 10	39	42.5	12.0	41.0	(20, 64)	39	-8.8	11.8	-7.0	(-70, 5)
	Week 12	38	44.4	12.5	43.5	(19, 63)	38	-7.3	10.6	-6.0	(-51, 10)
	Week 16	37	46.7	15.5	42.0	(21, 83)	37	-5.4	10.6	-6.0	(-28, 24)
	Week 20	37	47.1	14.9	45.0	(21, 91)	37	-4.9	13.2	-5.0	(-55, 38)
	Week 24	36	48.0	15.7	44.5	(19, 86)	36	-4.6	11.8	-3.5	(-40, 16)

表 2.7.4.9－33　臨床検査値：実測値及びベースラインからの変化量（ISS-1）（続き）

Parameter:HDL Cholesterol (mg/dL)

		Absolute					Change from Baseline				
	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean	SD	Median	Minimum, Maximum
Total	Baseline	379	51.2	16.7	50.0	(22, 112)					
	Week 2	374	47.7	15.7	46.0	(21, 107)	374	-3.5	5.9	-3.0	(-23, 11)
	Week 4	370	46.9	15.5	45.0	(22, 117)	370	-4.1	6.4	-4.0	(-33, 23)
	Week 6	364	46.5	15.9	44.0	(21, 129)	364	-4.6	6.8	-5.0	(-36, 38)
	Week 8	358	46.2	15.0	44.0	(21, 109)	358	-5.0	7.7	-5.0	(-48, 22)
	Week 10	356	45.8	14.7	44.0	(20, 118)	356	-5.3	8.6	-5.0	(-70, 26)
	Week 12	352	46.5	15.1	44.0	(19, 115)	352	-4.7	8.7	-4.0	(-75, 24)
	Week 16	345	47.5	15.8	45.0	(20, 119)	345	-3.8	9.5	-4.0	(-77, 30)
	Week 20	338	48.9	16.4	46.0	(14, 124)	338	-2.4	8.7	-2.0	(-55, 38)
	Week 24	327	50.0	17.2	46.0	(19, 122)	327	-1.6	9.2	-2.0	(-40, 45)

表 2.7.4.9－33　臨床検査値：実測値及びベースラインからの変化量（ISS-1）（続き）

Parameter:Triglycerides (mg/dL)

		Absolute					Change from Baseline				
	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean	SD	Median	Minimum, Maximum
NDD	Baseline	151	142.4	78.3	126.0	(56, 509)					
	Week 2	151	165.4	78.5	158.0	(50, 502)	151	23.0	58.3	21.0	(-180, 161)
	Week 4	149	160.0	90.7	143.0	(23, 568)	149	17.1	62.1	10.0	(-153, 265)
	Week 6	148	169.9	94.9	149.0	(44, 616)	148	27.1	67.8	27.0	(-186, 279)
	Week 8	145	171.1	108.0	149.0	(39, 825)	145	28.9	83.7	19.0	(-148, 662)
	Week 10	145	169.1	82.0	151.0	(40, 446)	145	27.4	65.2	27.0	(-218, 281)
	Week 12	145	165.4	94.7	154.0	(34, 771)	145	22.8	74.9	13.0	(-163, 392)
	Week 16	143	173.1	97.3	148.0	(33, 688)	143	30.6	71.4	26.0	(-253, 278)
	Week 20	140	163.5	92.6	137.5	(30, 616)	140	19.8	77.5	17.5	(-248, 453)
	Week 24	132	169.6	134.4	142.5	(29, 1339)	132	26.2	113.9	16.0	(-301, 966)
HD	Baseline	186	115.4	68.6	95.5	(29, 415)					
	Week 2	183	140.5	102.2	112.0	(21, 708)	183	24.7	64.9	12.0	(-91, 383)
	Week 4	180	137.7	87.7	111.5	(28, 723)	180	21.3	46.0	15.0	(-76, 308)
	Week 6	177	144.8	111.6	117.0	(34, 900)	177	28.4	69.8	18.0	(-156, 563)
	Week 8	174	144.6	105.0	123.0	(27, 1070)	174	29.8	70.9	21.0	(-162, 655)
	Week 10	172	145.9	96.4	119.0	(28, 616)	172	31.5	60.5	22.0	(-143, 279)
	Week 12	169	152.8	92.1	127.0	(43, 592)	169	37.4	57.7	32.0	(-143, 243)
	Week 16	165	141.8	94.1	123.0	(29, 795)	165	26.7	62.4	18.0	(-142, 458)
	Week 20	161	141.5	89.3	121.0	(36, 677)	161	25.9	68.6	18.0	(-128, 475)
	Week 24	159	139.7	97.3	115.0	(29, 695)	159	23.7	71.6	10.0	(-141, 352)
PD	Baseline	42	158.1	82.3	149.0	(37, 334)					
	Week 2	40	203.9	124.7	179.0	(52, 619)	40	46.4	81.5	31.5	(-84, 307)
	Week 4	41	190.0	130.3	161.0	(51, 857)	41	34.7	93.3	20.0	(-129, 523)
	Week 6	39	176.1	115.7	149.0	(51, 715)	39	24.5	77.2	14.0	(-95, 381)
	Week 8	39	194.8	93.8	185.0	(49, 412)	39	43.3	69.3	31.0	(-104, 201)
	Week 10	39	201.1	125.4	163.0	(73, 764)	39	49.5	82.8	41.0	(-125, 430)
	Week 12	38	193.5	95.5	181.5	(47, 401)	38	41.3	73.7	32.5	(-182, 228)
	Week 16	37	170.6	100.2	151.0	(43, 545)	37	21.8	69.8	21.0	(-145, 211)
	Week 20	37	197.5	122.6	179.0	(56, 665)	37	48.6	89.9	36.0	(-153, 353)
	Week 24	36	177.8	84.4	164.0	(41, 367)	36	28.6	54.0	34.5	(-98, 142)

表 2.7.4.9－33　臨床検査値：実測値及びベースラインからの変化量（ISS-1）（続き）

Parameter:Triglycerides (mg/dL)

		Absolute					Change from Baseline				
	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean	SD	Median	Minimum, Maximum
Total	Baseline	379	130.9	75.7	113.0	(29, 509)					
	Week 2	374	157.3	96.0	133.0	(21, 708)	374	26.3	64.5	16.0	(-180, 383)
	Week 4	370	152.5	95.7	133.0	(23, 857)	370	21.1	59.5	15.0	(-153, 523)
	Week 6	364	158.3	106.1	131.0	(34, 900)	364	27.4	69.6	20.5	(-186, 563)
	Week 8	358	160.8	106.2	139.0	(27, 1070)	358	30.9	76.1	22.0	(-162, 662)
	Week 10	356	161.4	95.9	142.0	(28, 764)	356	31.8	65.3	25.0	(-218, 430)
	Week 12	352	162.4	94.1	139.5	(34, 771)	352	31.8	67.3	24.5	(-182, 392)
	Week 16	345	157.9	97.1	137.0	(29, 795)	345	27.8	66.9	22.0	(-253, 458)
	Week 20	338	156.7	96.1	129.5	(30, 677)	338	25.9	75.1	19.0	(-248, 475)
	Week 24	327	156.0	113.4	133.0	(29, 1339)	327	25.3	89.5	14.0	(-301, 966)

表 2.7.4.9－33　臨床検査値：実測値及びベースラインからの変化量（ISS-1）（続き）

Parameter:C Reactive Protein (mg/dL)

		Absolute					Change from Baseline				
	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean	SD	Median	Minimum, Maximum
NDD	Baseline	202	0.2526	0.6211	0.0600	(0.009, 5.390)					
	Week 6	37	0.2054	0.3375	0.0800	(0.020, 1.360)	37	-0.0835	0.6136	0.0000	(-3.270, 1.060)
	Week 10	13	0.2754	0.5168	0.1100	(0.020, 1.930)	13	0.0792	0.5831	0.0000	(-0.520, 1.890)
	Week 16	33	0.1555	0.2673	0.0700	(0.020, 1.380)	33	0.0027	0.3234	0.0000	(-0.720, 1.360)
	Week 24	132	0.2183	0.6149	0.0400	(0.010, 5.610)	132	-0.0249	0.7376	0.0000	(-3.550, 5.360)
HD	Baseline	237	0.2521	0.7788	0.0600	(0.009, 10.400)					
	Week 6	37	0.2386	0.3064	0.0800	(0.020, 1.080)	37	-0.0219	0.3442	0.0000	(-1.560, 0.730)
	Week 10	5	0.1400	0.1859	0.0700	(0.020, 0.470)	5	0.0840	0.1998	0.0000	(-0.030, 0.440)
	Week 16	35	0.2469	0.3448	0.0800	(0.020, 1.430)	35	0.0091	0.4262	0.0000	(-1.610, 1.110)
	Week 24	159	0.2724	0.6532	0.0600	(0.009, 5.830)	159	0.0136	0.9888	0.0000	(-9.600, 4.570)
PD	Baseline	42	0.2738	0.4533	0.0750	(0.010, 2.280)					
	Week 24	36	0.5344	1.6231	0.1000	(0.010, 7.680)	36	0.2525	1.4166	-0.0050	(-0.900, 6.370)
Total	Baseline	481	0.2542	0.6909	0.0600	(0.009, 10.400)					
	Week 6	74	0.2220	0.3205	0.0800	(0.020, 1.360)	74	-0.0527	0.4950	0.0000	(-3.270, 1.060)
	Week 10	18	0.2378	0.4479	0.0750	(0.020, 1.930)	18	0.0806	0.4994	0.0000	(-0.520, 1.890)
	Week 16	68	0.2025	0.3108	0.0700	(0.020, 1.430)	68	0.0060	0.3770	0.0000	(-1.610, 1.360)
	Week 24	327	0.2794	0.8064	0.0500	(0.009, 7.680)	327	0.0243	0.9564	0.0000	(-9.600, 6.370)

表 2.7.4.9－33　臨床検査値：実測値及びベースラインからの変化量（ISS-1）（続き）

Parameter:Vascular Endothelial Growth Factor (pg/mL)

		Absolute					Change from Baseline				
	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean	SD	Median	Minimum, Maximum
NDD	Baseline	200	37.213	45.441	26.550	(15.59, 549.00)					
	Week 6	37	46.919	41.815	38.000	(20.00, 251.00)	37	7.270	32.247	2.000	(-34.00, 178.00)
	Week 10	13	33.538	29.268	23.000	(20.00, 128.00)	13	-1.692	8.567	-2.000	(-10.00, 23.00)
	Week 12	145	41.207	58.818	29.200	(15.59, 557.00)	143	4.741	26.046	0.000	(-53.10, 230.00)
	Week 16	33	37.424	20.509	30.000	(20.00, 99.00)	33	-2.424	15.603	-1.000	(-47.00, 38.00)
	Week 24	132	43.164	49.223	31.250	(15.59, 413.00)	130	6.197	31.065	3.300	(-136.00, 187.80)
HD	Baseline	237	50.087	26.829	44.700	(15.59, 307.00)					
	Week 6	37	44.432	12.801	40.000	(24.00, 90.00)	37	-7.216	43.224	0.000	(-251.00, 30.00)
	Week 10	5	35.800	9.230	41.000	(23.00, 43.00)	5	6.000	8.860	7.000	(-8.00, 14.00)
	Week 12	169	57.963	52.572	48.200	(15.59, 581.00)	169	7.621	48.294	0.800	(-78.50, 484.70)
	Week 16	35	44.600	13.423	42.000	(20.00, 84.00)	35	-8.229	46.192	0.000	(-262.00, 28.00)
	Week 24	159	53.862	39.486	47.000	(15.59, 458.00)	159	3.606	37.051	0.100	(-75.10, 386.50)
PD	Baseline	42	43.524	18.553	39.150	(17.90, 117.00)					
	Week 12	38	51.400	26.373	47.300	(15.59, 135.00)	38	7.552	24.362	4.400	(-28.20, 109.70)
	Week 24	36	47.622	23.949	44.050	(15.59, 122.00)	36	3.511	17.893	-0.050	(-21.50, 83.10)
Total	Baseline	479	44.136	35.808	38.300	(15.59, 549.00)					
	Week 6	74	45.676	30.735	40.000	(20.00, 251.00)	74	0.027	38.566	1.000	(-251.00, 178.00)
	Week 10	18	34.167	25.016	27.500	(20.00, 128.00)	18	0.444	9.102	-1.000	(-10.00, 23.00)
	Week 12	352	50.352	53.647	40.700	(15.59, 581.00)	350	6.437	38.258	0.950	(-78.50, 484.70)
	Week 16	68	41.118	17.475	37.500	(20.00, 99.00)	68	-5.412	34.750	-0.500	(-262.00, 38.00)
	Week 24	327	48.856	42.619	40.600	(15.59, 458.00)	325	4.632	33.013	1.500	(-136.00, 386.50)

表 2.7.4.9－33　臨床検査値：実測値及びベースラインからの変化量（ISS-1）（続き）

Parameter:Dehydroepiandrosterone Sulfate (ug/dL)

		Absolute					Change from Baseline				
	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean	SD	Median	Minimum, Maximum
NDD	Baseline	149	90.38	66.82	74.00	(4.0, 361.0)					
	Week 12	145	84.81	64.42	67.00	(5.0, 333.0)	143	-5.87	19.20	-4.00	(-69.0, 50.0)
	Week 24	132	89.36	69.80	74.50	(5.0, 348.0)	130	-1.85	24.58	-2.00	(-87.0, 91.0)
HD	Baseline	162	117.46	87.05	98.00	(3.0, 614.0)					
	Week 12	148	100.34	73.80	82.00	(4.0, 434.0)	148	-16.47	29.71	-9.00	(-180.0, 58.0)
	Week 24	138	99.32	74.25	80.50	(1.9, 420.0)	138	-20.21	35.96	-12.00	(-194.0, 81.0)
Total	Baseline	311	104.49	79.06	84.00	(3.0, 614.0)					
	Week 12	293	92.66	69.64	75.00	(4.0, 434.0)	291	-11.26	25.61	-6.00	(-180.0, 58.0)
	Week 24	270	94.45	72.15	76.00	(1.9, 420.0)	268	-11.31	32.25	-6.00	(-194.0, 91.0)

表 2.7.4.9－33　臨床検査値：実測値及びベースラインからの変化量（ISS-1）（続き）

Parameter:Estimated GFR (mL/min/1.73m2)

		Absolute					Change from Baseline				
	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean	SD	Median	Minimum, Maximum
NDD	Baseline	202	20.64	11.36	17.70	(4.9, 53.1)					
	Week 2	202	19.33	10.57	16.30	(5.1, 48.5)	202	-1.31	2.82	-1.00	(-13.4, 10.1)
	Week 4	200	19.93	11.41	17.00	(5.3, 57.7)	200	-0.67	3.46	-0.80	(-11.0, 26.7)
	Week 6	199	19.67	10.95	16.60	(4.0, 50.7)	199	-0.96	3.08	-1.00	(-10.2, 16.4)
	Week 8	195	19.59	10.88	16.10	(5.0, 47.4)	195	-1.15	2.74	-1.00	(-8.4, 11.0)
	Week 10	193	19.44	10.56	17.00	(4.9, 44.8)	193	-1.36	3.03	-1.10	(-10.5, 9.8)
	Week 12	180	19.29	10.89	15.85	(4.7, 51.0)	180	-1.39	2.85	-1.00	(-10.9, 8.2)
	Week 14	34	18.03	11.70	13.50	(5.0, 47.0)	34	-0.41	2.49	-1.00	(-6.0, 8.0)
	Week 16	176	19.31	11.05	14.90	(4.0, 46.5)	176	-1.46	3.51	-1.10	(-11.3, 13.2)
	Week 20	140	20.00	11.46	16.40	(3.8, 51.7)	140	-1.58	3.45	-1.45	(-10.2, 13.7)
	Week 24	132	20.41	11.33	17.40	(5.7, 48.5)	132	-1.56	3.19	-1.45	(-10.9, 13.3)
Total	Baseline	202	20.64	11.36	17.70	(4.9, 53.1)					
	Week 2	202	19.33	10.57	16.30	(5.1, 48.5)	202	-1.31	2.82	-1.00	(-13.4, 10.1)
	Week 4	200	19.93	11.41	17.00	(5.3, 57.7)	200	-0.67	3.46	-0.80	(-11.0, 26.7)
	Week 6	199	19.67	10.95	16.60	(4.0, 50.7)	199	-0.96	3.08	-1.00	(-10.2, 16.4)
	Week 8	195	19.59	10.88	16.10	(5.0, 47.4)	195	-1.15	2.74	-1.00	(-8.4, 11.0)
	Week 10	193	19.44	10.56	17.00	(4.9, 44.8)	193	-1.36	3.03	-1.10	(-10.5, 9.8)
	Week 12	180	19.29	10.89	15.85	(4.7, 51.0)	180	-1.39	2.85	-1.00	(-10.9, 8.2)
	Week 14	34	18.03	11.70	13.50	(5.0, 47.0)	34	-0.41	2.49	-1.00	(-6.0, 8.0)
	Week 16	176	19.31	11.05	14.90	(4.0, 46.5)	176	-1.46	3.51	-1.10	(-11.3, 13.2)
	Week 20	140	20.00	11.46	16.40	(3.8, 51.7)	140	-1.58	3.45	-1.45	(-10.2, 13.7)
	Week 24	132	20.41	11.33	17.40	(5.7, 48.5)	132	-1.56	3.19	-1.45	(-10.9, 13.3)

Source: t_14_3_2.sas

5.3.5.3—2 Table 14.3.2 より引用

表 2.7.4.9－34　規定した基準（臨床検査値）に該当した被験者数及び割合（ISS-1）

Criteria	MT-6548 NDD (N=202) n (%)	HD (N=237) n (%)	PD (N=42) n (%)	Total (N=481) n (%)
Uric Acid				
Any post-baseline value				
25% increase and >7.0 mg/dL	10 (5.0)	8 (3.4)	0 (0.0)	18 (3.7)
Potassium				
Any post-baseline value				
>6.0 - 7.0 mmol/L	15 (7.4)	30 (12.7)	1 (2.4)	46 (9.6)
>7.0 mmol/L	0 (0.0)	4 (1.7)	0 (0.0)	4 (0.8)
VEGF				
Any post-baseline value				
>= 2 x baseline and 200 pg/mL	4 (2.0)	5 (2.1)	0 (0.0)	9 (1.9)
Hb				
Any post-baseline value				
NDD, PD: > 13 g/dL HD: > 12 g/dL	30 (14.9)	39 (16.5)	10 (23.8)	79 (16.4)
NDD, PD: > 14 g/dL HD: > 13 g/dL	3 (1.5)	7 (3.0)	3 (7.1)	13 (2.7)
NDD, PD: change from baseline > 2 g/dL and > 13 g/dL HD: change from baseline > 2 g/dL and > 12 g/dL	26 (12.9)	19 (8.0)	7 (16.7)	52 (10.8)
NDD, PD: change from baseline > 2 g/dL and > 14 g/dL HD: change from baseline > 2 g/dL and > 13 g/dL	3 (1.5)	6 (2.5)	2 (4.8)	11 (2.3)
eGFR				
Any post-baseline value				
NDD：30% decrease from BL	20 (9.9)	-	-	20 (9.9)
AST, ALT				
Any post-baseline value				
AST >3.0 x ULN	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
AST >5.0 x ULN	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
ALT >3.0 x ULN	1 (0.5)	0 (0.0)	0 (0.0)	1 (0.2)
ALT >5.0 x ULN	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
AST >3.0 x ULN + T-bil > 2.0 x ULN	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
ALT >3.0 x ULN + T-bil > 2.0 x ULN	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
AST or ALT >3.0 x ULN + ALP < 2.0 x ULN + T-bil > 2.0 x ULN	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

Note(s): Percentages are calculated using the number of subjects with post-baseline values as the denominator.
Source: t_14_3_7_1_2.sas

5.3.5.3—2 Table 14.3.7.1.2 より引用

表 2.7.4.9－35 バイタルサイン：実測値及びベースラインからの変化量（MT-6548-J01 試験）

Parameter:Systolic Blood Pressure (mmHg)

		Absolute					Change from Baseline				
Treatment Group	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean at Baseline (SD)	Mean	SD	Median	Minimum, Maximum
MT-6548	Baseline	151	132.6	15.6	132.0	(91, 175)						
	Week 2	151	129.0	16.3	128.0	(80, 171)	151	132.6 (15.6)	-3.6	13.6	-4.0	(-39, 40)
	Week 4	149	129.8	17.2	128.0	(90, 198)	149	132.8 (15.6)	-3.1	15.2	-5.0	(-43, 50)
	Week 6	148	127.9	18.1	128.5	(79, 198)	148	132.9 (15.6)	-4.9	15.0	-4.5	(-38, 56)
	Week 8	145	129.2	17.2	128.0	(81, 189)	145	133.0 (15.6)	-3.8	17.2	-6.0	(-50, 67)
	Week 10	145	128.8	16.8	128.0	(94, 201)	145	133.0 (15.5)	-4.2	16.0	-5.0	(-40, 65)
	Week 12	145	129.3	16.7	128.0	(94, 194)	145	133.2 (15.6)	-3.9	17.0	-5.0	(-52, 51)
	Week 16	143	130.0	18.0	128.0	(90, 217)	143	133.0 (15.6)	-3.0	18.4	-6.0	(-46, 75)
	Week 20	140	131.3	17.0	130.5	(93, 187)	140	133.0 (15.4)	-1.7	16.5	-3.5	(-45, 51)
	Week 24	132	133.2	16.1	133.5	(93, 180)	132	133.2 (14.8)	0.0	15.9	0.0	(-44, 41)
darbepoetin	Baseline	153	133.3	17.9	133.0	(90, 179)						
	Week 2	153	132.6	18.0	133.0	(91, 175)	153	133.3 (17.9)	-0.7	12.5	-1.0	(-46, 42)
	Week 4	153	133.2	19.1	133.0	(85, 189)	153	133.3 (17.9)	-0.2	14.2	-1.0	(-45, 63)
	Week 6	152	130.4	17.3	130.0	(88, 178)	152	133.0 (17.7)	-2.6	12.3	-2.0	(-38, 30)
	Week 8	151	132.8	20.6	134.0	(83, 205)	151	133.0 (17.7)	-0.2	15.3	-1.0	(-62, 47)
	Week 10	150	132.3	19.8	131.0	(82, 185)	150	132.9 (17.4)	-0.6	15.9	-1.0	(-50, 41)
	Week 12	148	131.4	19.7	129.5	(82, 183)	148	133.0 (17.3)	-1.6	16.2	0.0	(-51, 68)
	Week 16	148	132.9	18.7	134.0	(89, 185)	148	132.6 (17.5)	0.3	16.2	0.0	(-38, 50)
	Week 20	145	132.9	19.3	133.0	(87, 188)	145	132.5 (17.5)	0.4	16.5	0.0	(-39, 44)
	Week 24	140	134.4	18.0	133.5	(92, 192)	140	132.4 (17.7)	2.0	15.6	2.0	(-36, 52)

表 2.7.4.9－35　バイタルサイン：実測値及びベースラインからの変化量（MT-6548-J01 試験）（続き）

Parameter:Diastolic Blood Pressure (mmHg)

		Absolute					Change from Baseline				
Treatment Group	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean at Baseline (SD)	Mean	SD	Median	Minimum, Maximum
MT-6548	Baseline	151	71.0	11.2	71.0	(40, 102)						
	Week 2	151	68.9	11.9	68.0	(41, 100)	151	71.0 (11.2)	-2.2	9.2	-3.0	(-40, 28)
	Week 4	149	69.0	11.1	70.0	(41, 98)	149	71.0 (11.3)	-2.1	8.9	-2.0	(-38, 30)
	Week 6	148	68.7	11.9	67.5	(39, 99)	148	71.1 (11.3)	-2.4	8.9	-2.0	(-35, 30)
	Week 8	145	68.1	11.7	69.0	(30, 96)	145	71.1 (11.4)	-3.0	9.1	-3.0	(-33, 23)
	Week 10	145	69.1	10.9	69.0	(44, 97)	145	71.1 (11.4)	-2.0	7.9	-2.0	(-17, 25)
	Week 12	145	69.3	11.7	70.0	(40, 99)	145	71.1 (11.4)	-1.8	8.9	-2.0	(-25, 26)
	Week 16	143	69.9	12.0	69.0	(46, 104)	143	71.1 (11.4)	-1.2	10.5	-2.0	(-30, 52)
	Week 20	140	70.8	12.5	72.0	(43, 99)	140	71.3 (11.5)	-0.5	10.0	-2.0	(-27, 33)
	Week 24	132	71.4	12.0	71.5	(41, 104)	132	71.5 (11.4)	-0.1	10.9	0.0	(-31, 39)
darbepoetin	Baseline	153	71.1	11.4	71.0	(43, 108)						
	Week 2	153	70.8	12.2	70.0	(43, 104)	153	71.1 (11.4)	-0.3	8.6	0.0	(-27, 21)
	Week 4	153	70.2	11.5	70.0	(45, 106)	153	71.1 (11.4)	-0.9	9.2	-1.0	(-31, 27)
	Week 6	152	70.8	11.8	70.0	(40, 106)	152	70.9 (11.3)	-0.1	9.3	0.5	(-33, 21)
	Week 8	151	72.0	12.0	70.0	(40, 106)	151	70.9 (11.3)	1.1	9.6	2.0	(-38, 27)
	Week 10	150	73.1	12.3	72.0	(44, 109)	150	70.8 (11.3)	2.3	9.4	2.0	(-25, 34)
	Week 12	148	72.0	12.0	71.0	(43, 106)	148	70.9 (11.3)	1.1	10.9	0.0	(-39, 33)
	Week 16	148	71.8	11.1	71.0	(47, 98)	148	70.8 (11.3)	1.0	10.5	0.0	(-26, 29)
	Week 20	145	71.8	12.6	71.0	(43, 106)	145	70.7 (11.4)	1.1	10.7	1.0	(-29, 27)
	Week 24	140	72.2	11.7	72.5	(46, 106)	140	70.7 (11.4)	1.5	10.1	1.0	(-29, 23)

表 2.7.4.9－35　バイタルサイン：実測値及びベースラインからの変化量（MT-6548-J01 試験）（続き）

Parameter:Pulse Rate (beats/min)

		Absolute					Change from Baseline				
Treatment Group	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean at Baseline (SD)	Mean	SD	Median	Minimum, Maximum
MT-6548	Baseline	151	75.4	11.9	75.0	(52, 116)						
	Week 2	151	77.1	13.1	76.0	(42, 114)	151	75.4 (11.9)	1.7	8.5	2.0	(-24, 29)
	Week 4	149	76.2	11.9	75.0	(45, 114)	149	75.4 (12.0)	0.7	7.2	0.0	(-22, 18)
	Week 6	148	76.1	11.6	76.0	(44, 104)	148	75.5 (12.0)	0.6	8.8	1.0	(-38, 26)
	Week 8	145	75.3	11.5	74.0	(46, 105)	145	75.2 (11.5)	0.1	8.0	0.0	(-26, 23)
	Week 10	145	75.9	11.5	75.0	(51, 107)	145	75.2 (11.5)	0.8	7.6	1.0	(-17, 26)
	Week 12	145	75.4	12.3	74.0	(40, 110)	145	75.1 (11.5)	0.3	9.0	1.0	(-28, 26)
	Week 16	143	75.8	10.9	75.0	(52, 104)	143	75.1 (11.6)	0.7	8.4	0.0	(-27, 25)
	Week 20	140	75.7	12.4	76.0	(48, 117)	140	74.8 (11.5)	1.0	9.0	1.0	(-26, 28)
	Week 24	132	74.3	11.7	74.0	(40, 106)	132	74.5 (11.5)	-0.2	8.6	0.0	(-31, 23)
darbepoetin	Baseline	153	74.7	11.0	75.0	(49, 106)						
	Week 2	153	74.5	11.1	75.0	(44, 106)	153	74.7 (11.0)	-0.2	6.6	0.0	(-22, 20)
	Week 4	153	73.5	11.4	72.0	(44, 110)	153	74.7 (11.0)	-1.2	8.8	-1.0	(-36, 21)
	Week 6	152	74.4	11.6	74.5	(45, 121)	152	74.6 (10.9)	-0.2	8.8	-1.0	(-23, 44)
	Week 8	151	74.0	12.6	71.0	(51, 128)	151	74.5 (10.9)	-0.5	9.4	0.0	(-30, 51)
	Week 10	150	73.3	11.9	73.0	(46, 128)	150	74.5 (11.0)	-1.3	9.3	-2.0	(-33, 51)
	Week 12	148	73.4	10.1	73.0	(52, 101)	148	74.7 (10.9)	-1.3	8.2	-2.0	(-25, 20)
	Week 16	148	73.2	10.8	73.0	(49, 104)	148	74.7 (11.0)	-1.5	8.6	-2.0	(-36, 18)
	Week 20	145	74.5	11.1	74.0	(51, 109)	145	74.6 (11.1)	0.0	9.0	0.0	(-30, 32)
	Week 24	140	74.6	10.8	73.0	(48, 101)	140	74.5 (11.1)	0.1	8.9	1.0	(-21, 24)

Data Source: Listing 16.2.7.3
Source: t_14_3_5.sas

5.3.5.1—6 表 14.3.5 より引用

表 2.7.4.9－36　規定した基準（バイタルサイン）に該当した被験者数及び割合（MT-6548-J01 試験）

Criteria	MT-6548(N=151) n (%)	darbepoetin(N=153) n (%)
SBP		
Any post-baseline value		
NDD: change from baseline >20 mmHg and > 180 mmHg	2 (1.3)	7 (4.6)
DBP		
Any post-baseline value		
Change from baseline > 15 mmHg and > 110 mmHg	0 (0.0)	0 (0.0)

Source: t_14_3_7_2_1_1.sas

5.3.5.3—2 Table 14.3.7.2.1.1 より引用

表 2.7.4.9－37 バイタルサイン：実測値及びベースラインからの変化量（MT-6548-J03 試験）

Parameter:Systolic Blood Pressure (mmHg)

		Absolute					Change from Baseline					
Treatment Group	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean at Baseline (SD)	Mean	SD	Median	Minimum, Maximum
MT-6548	Baseline	162	148.6	19.7	149.0	(95, 187)						
	Week 2	160	145.6	18.5	147.0	(102, 201)	160	148.6 (19.8)	-3.0	17.4	-3.0	(-58, 61)
	Week 4	157	144.6	19.2	145.0	(98, 185)	157	148.5 (19.9)	-3.9	18.3	-5.0	(-56, 55)
	Week 6	155	145.1	20.7	146.0	(95, 201)	155	148.5 (19.9)	-3.5	18.1	-4.0	(-50, 71)
	Week 8	152	144.1	19.6	142.5	(97, 197)	152	148.4 (19.9)	-4.3	18.2	-5.0	(-49, 44)
	Week 10	150	143.0	20.6	141.5	(95, 208)	150	148.4 (20.0)	-5.4	17.6	-5.5	(-56, 52)
	Week 12	148	145.2	21.0	143.0	(93, 207)	148	148.4 (20.1)	-3.2	20.2	-5.0	(-56, 84)
	Week 16	144	143.5	19.2	143.0	(101, 199)	144	148.0 (20.1)	-4.6	19.0	-5.0	(-63, 40)
	Week 20	140	146.9	19.4	145.0	(97, 198)	140	147.8 (20.1)	-0.9	19.9	-1.0	(-57, 71)
	Week 24	138	148.5	21.8	146.5	(97, 226)	138	147.9 (20.0)	0.6	22.8	-1.0	(-48, 61)
darbepoetin	Baseline	161	146.4	18.3	147.0	(88, 180)						
	Week 2	160	145.8	19.7	147.0	(84, 196)	160	146.4 (18.4)	-0.6	15.2	-1.0	(-48, 35)
	Week 4	159	144.7	21.5	145.0	(84, 241)	159	146.4 (18.5)	-1.6	17.4	-2.0	(-48, 66)
	Week 6	159	143.8	20.7	144.0	(91, 190)	159	146.4 (18.5)	-2.5	15.6	-3.0	(-63, 35)
	Week 8	158	146.1	20.3	144.5	(86, 197)	158	146.4 (18.5)	-0.3	17.5	0.5	(-56, 44)
	Week 10	157	144.1	20.8	144.0	(90, 190)	157	146.3 (18.5)	-2.2	18.0	-2.0	(-53, 38)
	Week 12	157	145.2	19.5	145.0	(100, 186)	157	146.3 (18.5)	-1.1	16.5	-1.0	(-47, 45)
	Week 16	156	145.8	20.5	144.5	(88, 218)	156	146.3 (18.6)	-0.5	19.1	-1.0	(-49, 54)
	Week 20	154	147.8	20.8	147.0	(99, 225)	154	146.2 (18.7)	1.5	18.8	-1.0	(-42, 67)
	Week 24	153	150.1	21.1	148.0	(97, 211)	153	146.3 (18.7)	3.8	21.0	3.0	(-49, 65)

表 2.7.4.9－37　バイタルサイン：実測値及びベースラインからの変化量（MT-6548-J03 試験）（続き）

Parameter:Diastolic Blood Pressure (mmHg)

		Absolute					Change from Baseline				
Treatment Group	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean at Baseline (SD)	Mean	SD	Median	Minimum, Maximum
MT-6548	Baseline	162	81.3	11.8	82.0	(52, 108)						
	Week 2	160	78.7	12.6	79.0	(39, 110)	160	81.4 (11.8)	-2.7	10.5	-1.0	(-49, 30)
	Week 4	157	78.0	11.9	80.0	(50, 107)	157	81.1 (11.6)	-3.1	10.1	-2.0	(-35, 22)
	Week 6	155	77.8	11.7	77.0	(52, 106)	155	81.1 (11.6)	-3.2	10.4	-4.0	(-36, 25)
	Week 8	152	77.1	11.6	77.5	(49, 116)	152	80.9 (11.6)	-3.7	10.7	-4.0	(-32, 35)
	Week 10	150	77.0	12.1	77.5	(47, 123)	150	80.9 (11.6)	-3.8	11.1	-4.5	(-37, 41)
	Week 12	148	78.6	13.6	77.5	(47, 132)	148	80.9 (11.5)	-2.4	13.5	-3.5	(-46, 66)
	Week 16	144	77.8	10.9	78.0	(51, 114)	144	80.9 (11.6)	-3.0	11.3	-4.0	(-30, 30)
	Week 20	140	78.8	10.9	79.0	(53, 106)	140	80.7 (11.7)	-1.9	11.0	-1.0	(-42, 23)
	Week 24	138	79.9	11.9	79.0	(52, 114)	138	80.9 (11.6)	-1.0	12.1	-2.0	(-23, 29)
darbepoetin	Baseline	161	78.8	12.6	79.0	(43, 107)						
	Week 2	160	78.5	12.3	78.0	(47, 108)	160	78.9 (12.6)	-0.4	8.3	-1.0	(-23, 25)
	Week 4	159	78.1	13.1	79.0	(48, 107)	159	78.8 (12.6)	-0.7	9.2	0.0	(-34, 24)
	Week 6	159	78.2	12.5	78.0	(44, 109)	159	78.8 (12.6)	-0.6	8.5	0.0	(-24, 24)
	Week 8	158	79.2	12.5	80.0	(50, 113)	158	79.0 (12.4)	0.3	9.4	1.0	(-29, 26)
	Week 10	157	77.7	13.8	78.0	(50, 114)	157	79.0 (12.5)	-1.3	9.9	-2.0	(-39, 20)
	Week 12	157	78.8	12.2	79.0	(51, 108)	157	79.0 (12.5)	-0.1	8.8	0.0	(-32, 29)
	Week 16	156	78.7	13.3	77.5	(55, 120)	156	78.9 (12.5)	-0.2	10.1	-1.0	(-27, 25)
	Week 20	154	79.4	12.8	80.0	(47, 108)	154	78.9 (12.5)	0.6	10.5	0.0	(-27, 38)
	Week 24	153	80.6	12.8	81.0	(51, 114)	153	78.8 (12.5)	1.8	10.7	2.0	(-22, 31)

表 2.7.4.9－37　バイタルサイン：実測値及びベースラインからの変化量（MT-6548-J03 試験）（続き）

Parameter:Pulse Rate (beats/min)

		Absolute					Change from Baseline				
Treatment Group	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean at Baseline (SD)	Mean	SD	Median	Minimum, Maximum
MT-6548	Baseline	162	74.3	12.0	74.0	(33, 108)						
	Week 2	160	76.5	11.8	76.0	(52, 114)	160	74.3 (12.0)	2.2	10.5	2.0	(-34, 58)
	Week 4	157	75.3	11.3	76.0	(52, 109)	157	74.0 (11.9)	1.3	9.2	2.0	(-37, 35)
	Week 6	155	75.9	10.7	76.0	(51, 110)	155	74.1 (12.0)	1.9	9.4	2.0	(-34, 37)
	Week 8	152	76.3	10.7	76.5	(56, 104)	152	73.9 (12.0)	2.4	8.6	1.0	(-32, 24)
	Week 10	150	76.7	11.4	77.0	(53, 109)	150	73.9 (12.1)	2.8	8.7	3.0	(-32, 34)
	Week 12	148	76.4	12.3	76.0	(48, 112)	148	73.9 (12.2)	2.5	8.4	2.0	(-17, 29)
	Week 16	144	75.6	12.2	74.0	(43, 127)	144	74.0 (12.2)	1.6	10.7	2.0	(-38, 36)
	Week 20	140	75.6	11.0	75.0	(52, 107)	140	73.8 (12.1)	1.8	8.5	1.0	(-26, 42)
	Week 24	138	76.1	13.2	74.0	(30, 112)	138	73.9 (12.0)	2.2	9.0	1.5	(-38, 31)
darbepoetin	Baseline	161	74.0	10.5	73.0	(53, 109)						
	Week 2	160	74.3	10.6	74.0	(47, 102)	160	74.1 (10.5)	0.2	7.2	0.0	(-18, 23)
	Week 4	159	74.1	10.4	74.0	(49, 104)	159	74.1 (10.6)	-0.1	7.6	1.0	(-24, 25)
	Week 6	159	74.4	10.9	74.0	(49, 110)	159	74.1 (10.6)	0.3	7.9	0.0	(-24, 29)
	Week 8	158	74.7	11.3	74.5	(50, 104)	158	74.2 (10.6)	0.5	8.7	0.0	(-28, 34)
	Week 10	157	74.4	11.2	73.0	(46, 111)	157	74.3 (10.5)	0.1	8.3	0.0	(-27, 26)
	Week 12	157	75.2	10.6	75.0	(51, 104)	157	74.3 (10.5)	1.0	7.6	1.0	(-22, 31)
	Week 16	156	73.9	10.8	73.0	(51, 110)	156	74.3 (10.6)	-0.3	9.1	0.0	(-24, 33)
	Week 20	154	74.4	11.0	74.0	(51, 104)	154	74.2 (10.6)	0.3	8.5	0.0	(-34, 24)
	Week 24	153	74.5	11.6	73.0	(45, 113)	153	74.1 (10.6)	0.4	8.2	0.0	(-24, 24)

Data Source: Listing 16.2.7.3
Source: t_14_3_5_1.sas

5.3.5.1—7 表 14.3.5.1 より引用

表 2.7.4.9－38　規定した基準（バイタルサイン）に該当した被験者数及び割合（MT-6548-J03 試験）

Criteria	MT-6548(N=162) n (%)	darbepoetin(N=161) n (%)
SBP		
Any post-baseline value		
HD: change from baseline >20 mmHg and > 190 mmHg	12 (7.4)	14 (8.7)
DBP		
Any post-baseline value		
Change from baseline > 15 mmHg and > 110 mmHg	6 (3.7)	2 (1.2)

Source: t_14_3_7_2_1_2.sas

5.3.5.3—2 Table 14.3.7.2.1.2 より引用

表 2.7.4.9－39　バイタルサイン：実測値及びベースラインからの変化量（ISS-1）

Parameter:Systolic Blood Pressure (mmHg)

		Absolute					Change from Baseline				
MT-6548	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean	SD	Median	Minimum, Maximum
NDD	Baseline	202	134.4	15.5	134.0	(91, 175)					
	Week 2	202	130.7	16.1	131.0	(80, 171)	202	-3.6	14.1	-4.0	(-39, 40)
	Week 4	200	131.8	17.2	131.0	(90, 193)	200	-2.8	15.7	-4.5	(-43, 50)
	Week 6	199	131.1	17.4	132.0	(79, 198)	199	-3.5	15.0	-4.0	(-38, 56)
	Week 8	195	131.2	16.5	131.0	(81, 189)	195	-3.6	16.5	-5.0	(-50, 67)
	Week 10	193	130.7	16.0	132.0	(94, 201)	193	-3.9	16.1	-5.0	(-44, 65)
	Week 12	180	131.5	16.9	130.5	(94, 194)	180	-3.5	16.7	-4.0	(-52, 51)
	Week 14	34	139.5	12.0	137.0	(120, 171)	34	-2.5	14.1	-1.0	(-38, 21)
	Week 16	176	131.3	17.9	129.5	(90, 217)	176	-3.2	17.7	-5.0	(-46, 75)
	Week 20	140	131.3	17.0	130.5	(93, 187)	140	-1.7	16.5	-3.5	(-45, 51)
	Week 24	132	133.2	16.1	133.5	(93, 180)	132	0.0	15.9	0.0	(-44, 41)
HD	Baseline	237	147.4	19.5	147.0	(95, 188)					
	Week 2	233	145.6	19.0	147.0	(99, 201)	233	-2.0	16.3	-1.0	(-58, 61)
	Week 4	223	144.6	19.0	144.0	(98, 194)	223	-2.4	17.8	-2.0	(-56, 55)
	Week 6	219	144.2	20.5	144.0	(95, 201)	219	-2.7	17.3	-4.0	(-50, 71)
	Week 8	216	144.1	19.5	144.0	(97, 197)	216	-2.7	17.3	-3.0	(-49, 44)
	Week 10	213	143.3	20.4	142.0	(95, 208)	213	-3.4	17.6	-4.0	(-56, 52)
	Week 12	205	145.8	21.8	143.0	(93, 214)	205	-0.9	19.2	-1.0	(-56, 84)
	Week 14	36	151.6	16.5	150.0	(113, 193)	36	7.9	15.2	10.0	(-25, 40)
	Week 16	200	144.9	20.7	143.5	(101, 216)	200	-1.5	19.3	-1.0	(-63, 54)
	Week 20	161	146.6	19.8	145.0	(97, 198)	161	-0.2	20.1	-1.0	(-57, 71)
	Week 24	159	148.0	21.7	146.0	(97, 226)	159	1.1	22.1	1.0	(-48, 61)
PD	Baseline	42	138.0	18.4	138.5	(104, 179)					
	Week 2	40	138.8	19.4	141.5	(102, 185)	40	0.4	14.2	1.0	(-47, 37)
	Week 4	41	138.3	20.4	138.0	(108, 197)	41	-0.1	17.3	-2.0	(-31, 58)
	Week 6	39	135.2	17.2	137.0	(96, 166)	39	-3.8	14.9	-2.0	(-51, 25)
	Week 8	39	130.4	18.9	130.0	(83, 173)	39	-8.6	14.3	-6.0	(-48, 13)
	Week 10	39	133.8	17.3	135.0	(93, 171)	39	-5.2	13.7	-3.0	(-34, 16)
	Week 12	38	131.4	19.2	129.5	(95, 185)	38	-7.2	16.7	-3.5	(-41, 21)
	Week 16	37	136.7	15.7	135.0	(107, 175)	37	-1.8	15.7	-5.0	(-34, 37)
	Week 20	37	136.1	16.4	131.0	(111, 183)	37	-2.4	17.7	-2.0	(-38, 34)
	Week 24	36	137.4	19.6	138.0	(91, 196)	36	-0.1	17.6	2.0	(-36, 33)

表 2.7.4.9－39　バイタルサイン：実測値及びベースラインからの変化量（ISS-1）（続き）

Parameter:Systolic Blood Pressure (mmHg)

		Absolute					Change from Baseline				
MT-6548	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean	SD	Median	Minimum, Maximum
Total	Baseline	481	141.1	18.9	140.0	(91, 188)					
	Week 2	475	138.7	19.2	139.0	(80, 201)	475	-2.5	15.3	-3.0	(-58, 61)
	Week 4	464	138.5	19.3	138.0	(90, 197)	464	-2.3	16.9	-3.5	(-56, 58)
	Week 6	457	137.7	19.9	137.0	(79, 201)	457	-3.1	16.1	-4.0	(-51, 71)
	Week 8	450	137.3	19.3	136.0	(81, 197)	450	-3.6	16.8	-4.0	(-50, 67)
	Week 10	445	137.0	19.3	136.0	(93, 208)	445	-3.8	16.6	-4.0	(-56, 65)
	Week 12	423	138.4	20.8	136.0	(93, 214)	423	-2.6	18.0	-3.0	(-56, 84)
	Week 14	70	145.7	15.6	145.0	(113, 193)	70	2.9	15.5	4.0	(-38, 40)
	Week 16	413	138.4	20.2	136.0	(90, 217)	413	-2.3	18.3	-4.0	(-63, 75)
	Week 20	338	139.1	19.7	139.0	(93, 198)	338	-1.1	18.4	-2.0	(-57, 71)
	Week 24	327	140.9	20.6	139.0	(91, 226)	327	0.5	19.3	0.0	(-48, 61)

表 2.7.4.9－39　バイタルサイン：実測値及びベースラインからの変化量（ISS-1）（続き）

Parameter:Diastolic Blood Pressure (mmHg)

		Absolute					Change from Baseline				
MT-6548	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean	SD	Median	Minimum, Maximum
NDD	Baseline	202	72.2	11.8	72.0	(40, 106)					
	Week 2	202	69.6	11.9	69.0	(41, 100)	202	-2.6	9.3	-3.0	(-40, 26)
	Week 4	200	70.4	11.9	70.0	(41, 109)	200	-1.8	9.2	-2.0	(-38, 30)
	Week 6	199	70.2	12.1	70.0	(39, 107)	199	-2.1	9.3	-2.0	(-35, 30)
	Week 8	195	69.7	11.9	70.0	(30, 104)	195	-2.5	9.6	-3.0	(-33, 23)
	Week 10	193	70.4	11.5	70.0	(41, 98)	193	-1.7	8.1	-2.0	(-23, 26)
	Week 12	180	70.2	12.3	71.0	(40, 99)	180	-2.2	9.5	-3.0	(-29, 26)
	Week 14	34	75.9	12.3	76.5	(44, 99)	34	-2.0	11.4	-4.0	(-27, 25)
	Week 16	176	70.7	12.1	70.0	(46, 104)	176	-1.7	10.2	-2.0	(-30, 52)
	Week 20	140	70.8	12.5	72.0	(43, 99)	140	-0.5	10.0	-2.0	(-27, 33)
	Week 24	132	71.4	12.0	71.5	(41, 104)	132	-0.1	10.9	0.0	(-31, 39)
HD	Baseline	237	80.0	11.9	79.0	(41, 108)					
	Week 2	233	78.4	12.5	78.0	(39, 110)	233	-1.7	9.9	-1.0	(-49, 30)
	Week 4	223	77.6	11.6	78.0	(41, 107)	223	-2.1	10.1	-1.0	(-35, 24)
	Week 6	219	77.3	12.1	77.0	(52, 106)	219	-2.3	10.1	-2.0	(-36, 25)
	Week 8	216	76.9	12.0	77.0	(48, 116)	216	-2.6	10.8	-3.0	(-39, 35)
	Week 10	213	77.0	12.6	76.0	(47, 123)	213	-2.4	10.9	-3.0	(-37, 41)
	Week 12	205	78.3	13.8	78.0	(47, 132)	205	-1.1	12.6	-2.0	(-46, 66)
	Week 14	36	78.6	13.0	79.0	(51, 104)	36	4.3	8.9	5.5	(-13, 19)
	Week 16	200	78.2	11.7	78.0	(48, 114)	200	-1.2	11.2	-1.0	(-30, 32)
	Week 20	161	78.8	10.8	79.0	(53, 106)	161	-1.5	11.0	-1.0	(-42, 25)
	Week 24	159	80.0	11.7	79.0	(52, 114)	159	-0.4	12.2	-2.0	(-23, 40)
PD	Baseline	42	79.6	11.3	81.5	(54, 108)					
	Week 2	40	79.0	13.2	76.5	(44, 108)	40	-0.9	9.4	-0.5	(-26, 26)
	Week 4	41	78.2	13.6	80.0	(46, 110)	41	-2.1	10.7	-2.0	(-26, 21)
	Week 6	39	76.7	12.8	76.0	(49, 99)	39	-3.5	10.1	-3.0	(-25, 24)
	Week 8	39	74.6	13.1	74.0	(40, 105)	39	-5.5	8.9	-4.0	(-30, 19)
	Week 10	39	76.8	11.8	78.0	(53, 99)	39	-3.4	9.1	-3.0	(-22, 15)
	Week 12	38	77.5	13.4	77.0	(56, 109)	38	-2.6	11.3	0.0	(-37, 15)
	Week 16	37	77.6	12.1	77.0	(52, 104)	37	-2.5	12.1	-2.0	(-29, 32)
	Week 20	37	79.3	12.7	79.0	(46, 115)	37	-0.9	11.6	1.0	(-26, 21)
	Week 24	36	79.5	13.3	80.5	(52, 115)	36	-0.3	10.9	1.5	(-26, 21)

表 2.7.4.9－39　バイタルサイン：実測値及びベースラインからの変化量（ISS-1）（続き）

Parameter:Diastolic Blood Pressure (mmHg)

		Absolute					Change from Baseline				
MT-6548	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean	SD	Median	Minimum, Maximum
Total	Baseline	481	76.7	12.4	77.0	(40, 108)					
	Week 2	475	74.7	13.0	75.0	(39, 110)	475	-2.0	9.6	-2.0	(-49, 30)
	Week 4	464	74.5	12.5	75.0	(41, 110)	464	-2.0	9.7	-2.0	(-38, 30)
	Week 6	457	74.1	12.6	74.0	(39, 107)	457	-2.3	9.7	-2.0	(-36, 30)
	Week 8	450	73.6	12.5	74.0	(30, 116)	450	-2.8	10.2	-3.0	(-39, 35)
	Week 10	445	74.1	12.5	74.0	(41, 123)	445	-2.2	9.6	-2.0	(-37, 41)
	Week 12	423	74.8	13.7	75.0	(40, 132)	423	-1.7	11.2	-2.0	(-46, 66)
	Week 14	70	77.3	12.6	78.0	(44, 104)	70	1.3	10.6	0.5	(-27, 25)
	Week 16	413	74.9	12.5	75.0	(46, 114)	413	-1.5	10.8	-2.0	(-30, 52)
	Week 20	338	75.6	12.4	77.0	(43, 115)	338	-1.0	10.6	-1.0	(-42, 33)
	Week 24	327	76.5	12.6	77.0	(41, 115)	327	-0.3	11.5	0.0	(-31, 40)

表 2.7.4.9－39　バイタルサイン：実測値及びベースラインからの変化量（ISS-1）（続き）

Parameter:Pulse Rate (beats/min)

		Absolute					Change from Baseline				
MT-6548	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean	SD	Median	Minimum, Maximum
NDD	Baseline	202	76.4	13.1	76.0	(48, 135)					
	Week 2	202	77.4	12.8	76.0	(42, 114)	202	1.0	9.3	2.0	(-32, 34)
	Week 4	200	76.6	12.8	75.0	(45, 129)	200	0.1	8.5	0.0	(-39, 41)
	Week 6	199	76.2	12.0	75.0	(44, 116)	199	-0.3	9.8	0.0	(-51, 26)
	Week 8	195	75.9	12.4	75.0	(40, 112)	195	-0.4	9.2	0.0	(-49, 26)
	Week 10	193	76.0	12.8	76.0	(45, 120)	193	-0.1	8.7	0.0	(-44, 26)
	Week 12	180	75.6	13.0	74.0	(32, 113)	180	-0.5	9.9	0.5	(-50, 26)
	Week 14	34	78.7	13.7	78.0	(55, 110)	34	-1.8	12.2	0.0	(-51, 20)
	Week 16	176	76.0	11.9	75.0	(35, 105)	176	-0.2	9.3	0.0	(-42, 25)
	Week 20	140	75.7	12.4	76.0	(48, 117)	140	1.0	9.0	1.0	(-26, 28)
	Week 24	132	74.3	11.7	74.0	(40, 106)	132	-0.2	8.6	0.0	(-31, 23)
HD	Baseline	237	75.3	12.3	75.0	(33, 117)					
	Week 2	233	77.2	12.4	76.0	(50, 115)	233	1.9	10.2	2.0	(-34, 58)
	Week 4	223	76.3	11.9	76.0	(52, 113)	223	1.5	9.8	2.0	(-37, 46)
	Week 6	219	76.4	11.3	75.0	(51, 110)	219	1.4	9.2	1.0	(-34, 37)
	Week 8	216	76.6	11.1	76.0	(50, 106)	216	1.7	8.8	1.0	(-32, 24)
	Week 10	213	77.2	11.9	77.0	(53, 118)	213	2.3	8.9	2.0	(-32, 34)
	Week 12	205	76.9	12.7	76.0	(44, 119)	205	2.0	8.8	1.0	(-24, 29)
	Week 14	36	78.7	11.5	77.5	(58, 105)	36	2.1	9.1	1.0	(-13, 22)
	Week 16	200	76.5	12.7	75.5	(43, 127)	200	1.5	10.1	2.0	(-38, 36)
	Week 20	161	76.1	11.6	75.0	(45, 107)	161	1.7	8.4	1.0	(-26, 42)
	Week 24	159	76.5	13.1	75.0	(30, 112)	159	2.0	8.8	1.0	(-38, 31)
PD	Baseline	42	80.4	11.9	77.0	(58, 108)					
	Week 2	40	80.8	12.2	78.0	(53, 119)	40	0.4	9.1	-2.0	(-17, 25)
	Week 4	41	79.3	11.7	78.0	(62, 114)	41	-1.1	10.2	0.0	(-33, 21)
	Week 6	39	80.8	12.9	78.0	(61, 119)	39	0.3	10.5	-2.0	(-27, 29)
	Week 8	39	79.0	12.5	79.0	(54, 106)	39	-1.6	8.3	-2.0	(-19, 18)
	Week 10	39	79.7	11.5	80.0	(60, 108)	39	-0.9	9.6	0.0	(-35, 23)
	Week 12	38	78.6	11.6	78.0	(58, 107)	38	-1.7	9.5	-2.0	(-29, 16)
	Week 16	37	78.3	11.3	79.0	(60, 108)	37	-2.4	9.1	-1.0	(-29, 13)
	Week 20	37	77.8	10.4	76.0	(61, 100)	37	-2.9	12.2	-2.0	(-34, 21)
	Week 24	36	80.6	14.2	79.5	(51, 118)	36	0.4	11.4	1.5	(-28, 28)

表 2.7.4.9－39　バイタルサイン：実測値及びベースラインからの変化量（ISS-1）（続き）

Parameter:Pulse Rate (beats/min)

		Absolute					Change from Baseline				
MT-6548	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean	SD	Median	Minimum, Maximum
Total	Baseline	481	76.2	12.6	76.0	(33, 135)					
	Week 2	475	77.6	12.6	77.0	(42, 119)	475	1.4	9.7	2.0	(-34, 58)
	Week 4	464	76.7	12.3	76.0	(45, 129)	464	0.6	9.3	1.0	(-39, 46)
	Week 6	457	76.7	11.8	75.0	(44, 119)	457	0.5	9.6	1.0	(-51, 37)
	Week 8	450	76.5	11.8	76.0	(40, 112)	450	0.5	9.0	0.0	(-49, 26)
	Week 10	445	76.9	12.3	77.0	(45, 120)	445	1.0	9.0	1.0	(-44, 34)
	Week 12	423	76.5	12.7	76.0	(32, 119)	423	0.6	9.4	1.0	(-50, 29)
	Week 14	70	78.7	12.5	78.0	(55, 110)	70	0.2	10.8	1.0	(-51, 22)
	Week 16	413	76.4	12.2	76.0	(35, 127)	413	0.4	9.8	1.0	(-42, 36)
	Week 20	338	76.1	11.8	76.0	(45, 117)	338	0.9	9.2	1.0	(-34, 42)
	Week 24	327	76.1	12.8	76.0	(30, 118)	327	0.9	9.1	1.0	(-38, 31)

Note(s): Heart Rate was used in CI-0021 and CI-0021 for Pulse Rate.
Source: t_14_3_4.sas

5.3.5.3—2 Table 14.3.4 より引用

表 2.7.4.9－40　規定した基準（バイタルサイン）に該当した被験者数及び割合（ISS-1）

Criteria	MT-6548 NDD (N=202) n (%)	HD (N=237) n (%)	PD (N=42) n (%)	Total (N=481) n (%)
SBP				
Any post-baseline value				
NDD, PD: change from baseline >20 mmHg and > 180 mmHg HD: change from baseline >20 mmHg and > 190 mmHg	2 (1.0)	16 (6.8)	4 (9.5)	22 (4.6)
DBP				
Any post-baseline value				
Change from baseline > 15 mmHg and > 110 mmHg	0 (0.0)	6 (2.5)	1 (2.4)	7 (1.5)

Source: t_14_3_7_2_2.sas

5.3.5.3—2 Table 14.3.7.2.2 より引用

表 2.7.4.9－41 眼底検査所見（MT-6548-J01 試験）

Visit	MT-6548(N=151) N*	Normal n (%)	Abnormal, NCS n (%)	Abnormal, CS Total n (%)	Retinal Hemorrhage Yes n (%)	Retinal Hemorrhage No n (%)	Retinal Hemorrhage uneval uable n (%)	Retinal Edema Yes n (%)	Retinal Edema No n (%)	Retinal Edema uneval uable n (%)	darbepoetin(N=153) N*	Normal n (%)	Abnormal, NCS n (%)	Abnormal, CS Total n (%)	Retinal Hemorrhage Yes n (%)	Retinal Hemorrhage No n (%)	Retinal Hemorrhage uneval uable n (%)	Retinal Edema Yes n (%)	Retinal Edema No n (%)	Retinal Edema uneval uable n (%)
Screening	151	81 (53.6)	49 (32.5)	21 (13.9)	11 (7.3)	10 (6.6)	0 (0.0)	4 (2.6)	17 (11.3)	0 (0.0)	153	87 (56.9)	46 (30.1)	20 (13.1)	10 (6.5)	10 (6.5)	0 (0.0)	1 (0.7)	19 (12.4)	0 (0.0)
Week 20 - Week 24	137	76 (55.5)	42 (30.7)	19 (13.9)	10 (7.3)	9 (6.6)	0 (0.0)	4 (2.9)	15 (10.9)	0 (0.0)	145	82 (56.6)	45 (31.0)	18 (12.4)	13 (9.0)	5 (3.4)	0 (0.0)	0 (0.0)	18 (12.4)	0 (0.0)

Note(s): Abnormal, NCS: abnormal not clinically significant; Abnormal, CS: abnormal clinically significant.
Data Source: Listing 16.2.7.4
Source: t_14_3_6_1.sas

5.3.5.1—6 表 14.3.6.1 より引用

表 2.7.4.9－42 眼底検査所見（MT-6548-J03 試験）

	MT-6548(N=162)										darbepoetin(N=161)									
		Normal	Abnormal, NCS	Abnormal, CS								Normal	Abnormal, NCS	Abnormal, CS						
					Retinal Hemorrhage			Retinal Edema							Retinal Hemorrhage			Retinal Edema		
Visit	N*	n (%)	n (%)	Total n (%)	Yes n (%)	No n (%)	uneval uable n (%)	Yes n (%)	No n (%)	uneval uable n (%)	N*	n (%)	n (%)	Total n (%)	Yes n (%)	No n (%)	uneval uable n (%)	Yes n (%)	No n (%)	uneval uable n (%)
Screening	162	93 (57.4)	43 (26.5)	26 (16.0)	8 (4.9)	18 (11.1)	0 (0.0)	1 (0.6)	24 (14.8)	1 (0.6)	161	81 (50.3)	47 (29.2)	33 (20.5)	19 (11.8)	14 (8.7)	0 (0.0)	2 (1.2)	31 (19.3)	0 (0.0)
Week 20 - Week 24	140	73 (52.1)	43 (30.7)	24 (17.1)	13 (9.3)	11 (7.9)	0 (0.0)	2 (1.4)	22 (15.7)	0 (0.0)	154	72 (46.8)	45 (29.2)	37 (24.0)	23 (14.9)	14 (9.1)	0 (0.0)	3 (1.9)	33 (21.4)	1 (0.6)

Note(s): Abnormal, NCS: abnormal not clinically significant; Abnormal, CS: abnormal clinically significant.
Data Source: Listing 16.2.7.4
Source: t_14_3_6_1.sas

5.3.5.1—7 表 14.3.6.1 より引用

表 2.7.4.9－43 眼底検査所見（ISS-1）

			MT-6548								
			Normal	Abnormal, NCS	Abnormal, CS						
						Retinal Hemorrhage			Retinal Edema		
	Visit	N1	n (%)	n (%)	Total n (%)	Yes n (%)	No n (%)	unevaluable n (%)	Yes n (%)	No n (%)	unevaluable n (%)
NDD(N=151)	Screening	151	81 (53.6)	49 (32.5)	21 (13.9)	11 (7.3)	10 (6.6)	0 (0.0)	4 (2.6)	17 (11.3)	0 (0.0)
	Week 20 - Week 24	137	76 (55.5)	42 (30.7)	19 (13.9)	10 (7.3)	9 (6.6)	0 (0.0)	4 (2.9)	15 (10.9)	0 (0.0)
HD(N=186)	Screening	186	101 (54.3)	50 (26.9)	35 (18.8)	14 (7.5)	21 (11.3)	0 (0.0)	2 (1.1)	32 (17.2)	1 (0.5)
	Week 20 - Week 24	161	81 (50.3)	50 (31.1)	30 (18.6)	17 (10.6)	13 (8.1)	0 (0.0)	3 (1.9)	27 (16.8)	0 (0.0)
PD(N=42)	Screening	42	31 (73.8)	7 (16.7)	4 (9.5)	2 (4.8)	2 (4.8)	0 (0.0)	0 (0.0)	4 (9.5)	0 (0.0)
	Week 20 - Week 24	37	22 (59.5)	10 (27.0)	5 (13.5)	3 (8.1)	2 (5.4)	0 (0.0)	0 (0.0)	5 (13.5)	0 (0.0)
Total(N=379)	Screening	379	213 (56.2)	106 (28.0)	60 (15.8)	27 (7.1)	33 (8.7)	0 (0.0)	6 (1.6)	53 (14.0)	1 (0.3)
	Week 20 - Week 24	335	179 (53.4)	102 (30.4)	54 (16.1)	30 (9.0)	24 (7.2)	0 (0.0)	7 (2.1)	47 (14.0)	0 (0.0)

Note(s): Abnormal, NCS: abnormal not clinically significant; Abnormal, CS: abnormal clinically significant.
Note(s): Percentages are based on the number of subjects at each visit in each disease stage (N1).
Note(s): Clinical Findings of Ophthalmic Test is measured only in MT-6548-J01, MT-6548-J02, MT-6548-J03 and MT-6548-J04.
Source: t_14_3_5.sas

5.3.5.3—2 Table 14.3.5 より引用

表 2.7.4.9－44　安静時標準 12 誘導心電図所見（MT-6548-J01 試験）

Visit	MT-6548(N=151)				darbepoetin(N=153)			
	N*	Normal n (%)	Abnormal, NCS n (%)	Abnormal, CS n (%)	N*	Normal n (%)	Abnormal, NCS n (%)	Abnormal, CS n (%)
Baseline	151	89(58.9)	60(39.7)	2(1.3)	153	88(57.5)	62(40.5)	3(2.0)
Week 24	132	70(53.0)	61(46.2)	1(0.8)	140	82(58.6)	55(39.3)	3(2.1)

Note(s): Abnormal, NCS: abnormal not clinically significant; Abnormal, CS: abnormal clinically significant.
Data Source: Listing 16.2.7.1
Source: t_14_3_3_1.sas

5.3.5.1―6 表 14.3.3.1 より引用

表 2.7.4.9－45　QT 延長に関連する有害事象の内訳（MT-6548-J01 試験）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 (N=151) n(%)	darbepoetin (N=153) n(%)
Subjects with at least one adverse event related to QT prolongation		0(0.0)	0(0.0)

Note(s): MedDRA Version 21.1 and MedDRA/J Version 21.1.
Source: t_14_3_1_23_1_1.sas

5.3.5.3—2 Table 14.3.1.23.1.1 より引用

表 2.7.4.9－46　安静時標準 12 誘導心電図所見（MT-6548-J03 試験）

Visit	MT-6548(N=162) N*	Normal n (%)	Abnormal, NCS n (%)	Abnormal, CS n (%)	darbepoetin(N=161) N*	Normal n (%)	Abnormal, NCS n (%)	Abnormal, CS n (%)
Baseline	162	82(50.6)	76(46.9)	4(2.5)	161	77(47.8)	82(50.9)	2(1.2)
Week 24	138	72(52.2)	62(44.9)	4(2.9)	153	69(45.1)	81(52.9)	3(2.0)

Note(s): Abnormal, NCS: abnormal not clinically significant; Abnormal, CS: abnormal clinically significant.
Data Source: Listing 16.2.7.1
Source: t_14_3_3_1.sas

5.3.5.1―7 表 14.3.3.1 より引用

表 2.7.4.9－47　QT 延長に関連する有害事象の内訳（MT-6548-J03 試験）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 (N=162) n(%)	darbepoetin (N=161) n(%)
Subjects with at least one adverse event related to QT prolongation		0(0.0)	3(1.9)
Nervous system disorders	神経系障害	0(0.0)	1(0.6)
Loss of consciousness	意識消失	0(0.0)	1(0.6)
Investigations	臨床検査	0(0.0)	2(1.2)
Electrocardiogram QT prolonged	心電図ＱＴ延長	0(0.0)	2(1.2)

Note(s): MedDRA Version 21.1 and MedDRA/J Version 21.1.
Source: t_14_3_1_23_1_2.sas

5.3.5.3—2 Table 14.3.1.23.1.2 より引用

表 2.7.4.9－48 安静時標準 12 誘導心電図所見（ISS-1）

	Visit		MT-6548 Normal n (%)	MT-6548 Abnormal, NCS n (%)	MT-6548 Abnormal, CS n (%)
		N1			
NDD(N=151)	Baseline	151	89(58.9)	60(39.7)	2(1.3)
	Week 24	132	70(53.0)	61(46.2)	1(0.8)
HD(N=186)	Baseline	186	91(48.9)	90(48.4)	5(2.7)
	Week 24	159	79(49.7)	76(47.8)	4(2.5)
PD(N=42)	Baseline	42	21(50.0)	20(47.6)	1(2.4)
	Week 24	36	20(55.6)	16(44.4)	0(0.0)
Total(N=379)	Baseline	379	201(53.0)	170(44.9)	8(2.1)
	Week 24	327	169(51.7)	153(46.8)	5(1.5)

Note(s): The subjects in CI-0021 and CI-0022 were not included in this table.
Note(s): Abnormal, NCS: abnormal not clinically significant; Abnormal, CS: abnormal clinically significant.
Note(s): Percentages are based on the number of subjects at each visit in each disease stage (N1).
Source: t_14_3_3.sas

5.3.5.3—2 Table 14.3.3 より引用

表 2.7.4.9－49　QT 延長に関連する有害事象の内訳（ISS-1）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 NDD (N=202) n(%)	HD (N=237) n(%)	PD (N=42) n(%)	Total (N=481) n(%)
Subjects with at least one adverse event related to QT prolongation		1(0.5)	0(0.0)	0(0.0)	1(0.2)
Nervous system disorders	神経系障害	1(0.5)	0(0.0)	0(0.0)	1(0.2)
Loss of consciousness	意識消失	1(0.5)	0(0.0)	0(0.0)	1(0.2)

Note(s): MedDRA Version 21.1 and MedDRA/J Version 21.1.
Source: t_14_3_1_23_2.sas

5.3.5.3—2 Table 14.3.1.23.2 より引用

表 2.7.4.9－50　胸部 X 線検査所見（MT-6548-J01 試験）

Visit	MT-6548(N=151) N*	Normal n (%)	Abnormal, NCS n (%)	Abnormal, CS n (%)	darbepoetin(N=153) N*	Normal n (%)	Abnormal, NCS n (%)	Abnormal, CS n (%)
Screening	151	123(81.5)	27(17.9)	1(0.7)	153	114(74.5)	37(24.2)	2(1.3)
Week 20 - Week 24	139	105(75.5)	29(20.9)	5(3.6)	144	106(73.6)	35(24.3)	3(2.1)

Note(s): Abnormal, NCS: abnormal not clinically significant; Abnormal, CS: abnormal clinically significant.
Data Source: Listing 16.2.7.5
Source: t_14_3_7_1.sas

5.3.5.1―6 表 14.3.7.1 より引用

表 2.7.4.9－51　胸部 X 線検査所見（MT-6548-J03 試験）

Visit	MT-6548(N=162)				darbepoetin(N=161)			
	N*	Normal n (%)	Abnormal, NCS n (%)	Abnormal, CS n (%)	N*	Normal n (%)	Abnormal, NCS n (%)	Abnormal, CS n (%)
Screening	162	134(82.7)	28(17.3)	0(0.0)	161	129(80.1)	31(19.3)	1(0.6)
Week 20 - Week 24	139	114(82.0)	24(17.3)	1(0.7)	154	125(81.2)	28(18.2)	1(0.6)

Note(s): Abnormal, NCS: abnormal not clinically significant; Abnormal, CS: abnormal clinically significant.
Data Source: Listing 16.2.7.5
Source: t_14_3_7_1.sas

5.3.5.1―7 表 14.3.7.1 より引用

表 2.7.4.9－52 胸部 X 線検査所見（ISS-1）

	Visit		MT-6548		
		N1	Normal n (%)	Abnormal, NCS n (%)	Abnormal, CS n (%)
NDD(N=151)	Screening	151	123(81.5)	27(17.9)	1(0.7)
	Week 20 - Week 24	139	105(75.5)	29(20.9)	5(3.6)
HD(N=186)	Screening	186	151(81.2)	35(18.8)	0(0.0)
	Week 20 - Week 24	160	129(80.6)	30(18.8)	1(0.6)
PD(N=42)	Screening	42	31(73.8)	10(23.8)	1(2.4)
	Week 20 - Week 24	37	29(78.4)	7(18.9)	1(2.7)
Total(N=379)	Screening	379	305(80.5)	72(19.0)	2(0.5)
	Week 20 - Week 24	336	263(78.3)	66(19.6)	7(2.1)

Note(s): Abnormal, NCS: abnormal not clinically significant; Abnormal, CS: abnormal clinically significant.
Note(s): Percentages are based on the number of subjects at each visit in each disease stage (N1).
Note(s): Clinical Findings of chest X-ray test is measured only in MT-6548-J01, MT-6548-J02, MT-6548-J03 and MT-6548-J04.
Source: t_14_3_6.sas

5.3.5.3—2 Table 14.3.6 より引用

表 2.7.4.9－53　有害事象の内訳（MT-6548-J01 試験／52 週）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548(N=151) n (%)	darbepoetin(N=153) n (%)
Subjects with at least one adverse event		136(90.1)	141(92.2)
Infections and infestations	感染症および寄生虫症	74(49.0)	76(49.7)
Nasopharyngitis	上咽頭炎	37(24.5)	43(28.1)
Conjunctivitis	結膜炎	7(4.6)	4(2.6)
Influenza	インフルエンザ	7(4.6)	2(1.3)
Cystitis	膀胱炎	6(4.0)	9(5.9)
Urinary tract infection	尿路感染	6(4.0)	4(2.6)
Bronchitis	気管支炎	5(3.3)	4(2.6)
Pneumonia	肺炎	4(2.6)	3(2.0)
Gastroenteritis	胃腸炎	4(2.6)	1(0.7)
Cellulitis	蜂巣炎	3(2.0)	0(0.0)
Otitis media	中耳炎	2(1.3)	2(1.3)
Periodontitis	歯周炎	2(1.3)	2(1.3)
Pharyngitis	咽頭炎	2(1.3)	2(1.3)
Upper respiratory tract infection	上気道感染	2(1.3)	1(0.7)
Renal cyst infection	腎嚢胞感染	2(1.3)	1(0.7)
Rhinitis	鼻炎	2(1.3)	0(0.0)
Sinusitis	副鼻腔炎	2(1.3)	0(0.0)
Dermatophytosis of nail	爪の皮膚糸状菌症	1(0.7)	4(2.6)
Herpes zoster	帯状疱疹	1(0.7)	4(2.6)
Body tinea	体部白癬	1(0.7)	1(0.7)
Diverticulitis	憩室炎	1(0.7)	1(0.7)
Aspergilloma	アスペルギローマ	1(0.7)	0(0.0)

表 2.7.4.9－53　有害事象の内訳（MT-6548-J01 試験／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548(N=151) n (%)	darbepoetin(N=153) n (%)
Gingivitis	歯肉炎	1(0.7)	0(0.0)
Herpes simplex	単純ヘルペス	1(0.7)	0(0.0)
Mediastinal abscess	縦隔洞膿瘍	1(0.7)	0(0.0)
Osteomyelitis	骨髄炎	1(0.7)	0(0.0)
Pneumonia chlamydial	クラミジア性肺炎	1(0.7)	0(0.0)
Pyelonephritis	腎盂腎炎	1(0.7)	0(0.0)
Pyelonephritis acute	急性腎盂腎炎	1(0.7)	0(0.0)
Tinea cruris	股部白癬	1(0.7)	0(0.0)
Tonsillitis	扁桃炎	1(0.7)	0(0.0)
Abscess limb	四肢膿瘍	1(0.7)	0(0.0)
Hordeolum	麦粒腫	0(0.0)	2(1.3)
Folliculitis	毛包炎	0(0.0)	1(0.7)
Genital herpes	陰部ヘルペス	0(0.0)	1(0.7)
Laryngitis	喉頭炎	0(0.0)	1(0.7)
Paronychia	爪囲炎	0(0.0)	1(0.7)
Pneumonia pneumococcal	肺炎球菌性肺炎	0(0.0)	1(0.7)
Rash pustular	膿疱性皮疹	0(0.0)	1(0.7)
Tinea pedis	足部白癬	0(0.0)	1(0.7)
Urethritis	尿道炎	0(0.0)	1(0.7)
Vaginal infection	膣感染	0(0.0)	1(0.7)
Gingival abscess	歯肉膿瘍	0(0.0)	1(0.7)
Helicobacter infection	ヘリコバクター感染	0(0.0)	1(0.7)
Asymptomatic bacteriuria	無症候性細菌尿	0(0.0)	1(0.7)

表 2.7.4.9－53　有害事象の内訳（MT-6548-J01 試験／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548(N=151) n (%)	darbepoetin(N=153) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	2(1.3)	6(3.9)
Colon adenoma	大腸腺腫	1(0.7)	0(0.0)
Oral papilloma	口腔乳頭腫	1(0.7)	0(0.0)
Basal cell carcinoma	基底細胞癌	0(0.0)	1(0.7)
Gastric cancer	胃癌	0(0.0)	1(0.7)
Keratoacanthoma	ケラトアカントーマ	0(0.0)	1(0.7)
Renal cancer	腎癌	0(0.0)	1(0.7)
Seborrhoeic keratosis	脂漏性角化症	0(0.0)	1(0.7)
Skin papilloma	皮膚乳頭腫	0(0.0)	1(0.7)
Renal cancer metastatic	遠隔転移を伴う腎癌	0(0.0)	1(0.7)
Kidney angiomyolipoma	腎血管筋脂肪腫	0(0.0)	1(0.7)
Blood and lymphatic system disorders	血液およびリンパ系障害	2(1.3)	8(5.2)
Iron deficiency anaemia	鉄欠乏性貧血	2(1.3)	6(3.9)
Eosinophilia	好酸球増加症	0(0.0)	1(0.7)
Immune thrombocytopenic purpura	免疫性血小板減少性紫斑病	0(0.0)	1(0.7)
Immune system disorders	免疫系障害	3(2.0)	1(0.7)
Seasonal allergy	季節性アレルギー	1(0.7)	1(0.7)
Allergy to arthropod sting	節足動物刺傷アレルギー	1(0.7)	0(0.0)
Allergy to arthropod bite	節足動物咬傷アレルギー	1(0.7)	0(0.0)
Endocrine disorders	内分泌障害	0(0.0)	3(2.0)
Hypothyroidism	甲状腺機能低下症	0(0.0)	2(1.3)
Hypoparathyroidism secondary	続発性副甲状腺機能低下症	0(0.0)	1(0.7)

表 2.7.4.9－53　有害事象の内訳（MT-6548-J01 試験／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548(N=151) n (%)	darbepoetin(N=153) n (%)
Metabolism and nutrition disorders	代謝および栄養障害	22(14.6)	34(22.2)
Hyperuricaemia	高尿酸血症	5(3.3)	4(2.6)
Decreased appetite	食欲減退	3(2.0)	1(0.7)
Metabolic acidosis	代謝性アシドーシス	2(1.3)	6(3.9)
Dehydration	脱水	2(1.3)	4(2.6)
Hyperphosphataemia	高リン酸塩血症	2(1.3)	4(2.6)
Diabetes mellitus	糖尿病	2(1.3)	2(1.3)
Hyperkalaemia	高カリウム血症	1(0.7)	5(3.3)
Hypoglycaemia	低血糖	1(0.7)	2(1.3)
Hyponatraemia	低ナトリウム血症	1(0.7)	2(1.3)
Fluid retention	体液貯留	1(0.7)	1(0.7)
Hypocalcaemia	低カルシウム血症	1(0.7)	1(0.7)
Dyslipidaemia	脂質異常症	1(0.7)	1(0.7)
Type 2 diabetes mellitus	2型糖尿病	1(0.7)	1(0.7)
Hypoalbuminaemia	低アルブミン血症	1(0.7)	0(0.0)
Hypoproteinaemia	低蛋白血症	1(0.7)	0(0.0)
Hyperlipidaemia	高脂血症	1(0.7)	0(0.0)
Hyperamylasaemia	高アミラーゼ血症	1(0.7)	0(0.0)
Hypercalcaemia	高カルシウム血症	0(0.0)	1(0.7)
Hypermagnesaemia	高マグネシウム血症	0(0.0)	1(0.7)
Hypokalaemia	低カリウム血症	0(0.0)	1(0.7)

表 2.7.4.9－53　有害事象の内訳（MT-6548-J01 試験／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548(N=151) n (%)	darbepoetin(N=153) n (%)
Psychiatric disorders	精神障害	7(4.6)	8(5.2)
Insomnia	不眠症	6(4.0)	5(3.3)
Depression	うつ病	1(0.7)	1(0.7)
Anxiety	不安	1(0.7)	0(0.0)
Neurosis	神経症	0(0.0)	1(0.7)
Schizophrenia	統合失調症	0(0.0)	1(0.7)
Tic	チック	0(0.0)	1(0.7)

表 2.7.4.9－53　有害事象の内訳（MT-6548-J01 試験／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548(N=151) n (%)	darbepoetin(N=153) n (%)
Nervous system disorders	神経系障害	10(6.6)	16(10.5)
Headache	頭痛	5(3.3)	7(4.6)
Dizziness	浮動性めまい	2(1.3)	1(0.7)
Intracranial aneurysm	頭蓋内動脈瘤	1(0.7)	1(0.7)
Somnolence	傾眠	1(0.7)	1(0.7)
Hypoaesthesia	感覚鈍麻	1(0.7)	0(0.0)
Hypoglycaemic coma	低血糖昏睡	1(0.7)	0(0.0)
Neuropathy peripheral	末梢性ニューロパチー	1(0.7)	0(0.0)
Presyncope	失神寸前の状態	1(0.7)	0(0.0)
Lacunar infarction	ラクナ梗塞	0(0.0)	2(1.3)
Cerebral infarction	脳梗塞	0(0.0)	1(0.7)
Dementia Alzheimer's type	アルツハイマー型認知症	0(0.0)	1(0.7)
Dizziness postural	体位性めまい	0(0.0)	1(0.7)
Loss of consciousness	意識消失	0(0.0)	1(0.7)
Sciatica	坐骨神経痛	0(0.0)	1(0.7)
Tension headache	緊張性頭痛	0(0.0)	1(0.7)
Tremor	振戦	0(0.0)	1(0.7)
Cognitive disorder	認知障害	0(0.0)	1(0.7)

表 2.7.4.9－53　有害事象の内訳（MT-6548-J01 試験／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548(N=151) n (%)	darbepoetin(N=153) n (%)
Eye disorders	眼障害	18(11.9)	27(17.6)
Cataract	白内障	4(2.6)	3(2.0)
Dry eye	眼乾燥	4(2.6)	0(0.0)
Blepharitis	眼瞼炎	3(2.0)	2(1.3)
Retinal haemorrhage	網膜出血	2(1.3)	5(3.3)
Conjunctival haemorrhage	結膜出血	2(1.3)	2(1.3)
Glaucoma	緑内障	1(0.7)	1(0.7)
Eczema eyelids	眼瞼湿疹	1(0.7)	0(0.0)
Macular oedema	黄斑浮腫	1(0.7)	0(0.0)
Retinal exudates	網膜滲出物	1(0.7)	0(0.0)
Retinal vein occlusion	網膜静脈閉塞	1(0.7)	0(0.0)
Age-related macular degeneration	加齢黄斑変性	1(0.7)	0(0.0)
Conjunctivitis allergic	アレルギー性結膜炎	0(0.0)	4(2.6)
Diabetic retinopathy	糖尿病網膜症	0(0.0)	3(2.0)
Eye pruritus	眼そう痒症	0(0.0)	2(1.3)
Asthenopia	眼精疲労	0(0.0)	1(0.7)
Diplopia	複視	0(0.0)	1(0.7)
Eye swelling	眼部腫脹	0(0.0)	1(0.7)
Pinguecula	瞼裂斑	0(0.0)	1(0.7)
Scintillating scotoma	閃輝暗点	0(0.0)	1(0.7)
Vitreous floaters	硝子体浮遊物	0(0.0)	1(0.7)
Conjunctival hyperaemia	結膜充血	0(0.0)	1(0.7)
Dacryostenosis acquired	後天性涙道狭窄	0(0.0)	1(0.7)

表 2.7.4.9－53　有害事象の内訳（MT-6548-J01 試験／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548(N=151) n (%)	darbepoetin(N=153) n (%)
Retinal aneurysm	網膜血管瘤	0(0.0)	1(0.7)
Macular fibrosis	黄斑線維症	0(0.0)	1(0.7)
Ear and labyrinth disorders	耳および迷路障害	4(2.6)	5(3.3)
Vertigo	回転性めまい	2(1.3)	4(2.6)
Vertigo positional	頭位性回転性めまい	2(1.3)	0(0.0)
Ear congestion	耳閉	1(0.7)	0(0.0)
Meniere's disease	メニエール病	0(0.0)	1(0.7)
Cardiac disorders	心臓障害	11(7.3)	7(4.6)
Cardiac failure chronic	慢性心不全	3(2.0)	0(0.0)
Atrial fibrillation	心房細動	2(1.3)	0(0.0)
Cardiac failure congestive	うっ血性心不全	2(1.3)	0(0.0)
Atrial flutter	心房粗動	1(0.7)	0(0.0)
Bradycardia	徐脈	1(0.7)	0(0.0)
Cardiac failure	心不全	1(0.7)	0(0.0)
Myocardial ischaemia	心筋虚血	1(0.7)	0(0.0)
Palpitations	動悸	1(0.7)	0(0.0)
Ventricular tachycardia	心室性頻脈	1(0.7)	0(0.0)
Cardiac failure acute	急性心不全	0(0.0)	2(1.3)
Ventricular extrasystoles	心室性期外収縮	0(0.0)	2(1.3)
Acute myocardial infarction	急性心筋梗塞	0(0.0)	1(0.7)
Cardiac hypertrophy	心肥大	0(0.0)	1(0.7)
Cardiac valve disease	心臓弁膜疾患	0(0.0)	1(0.7)

表 2.7.4.9－53　有害事象の内訳（MT-6548-J01 試験／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548(N=151) n (%)	darbepoetin(N=153) n (%)
Vascular disorders	血管障害	8(5.3)	16(10.5)
Hypertension	高血圧	2(1.3)	11(7.2)
Internal haemorrhage	内出血	1(0.7)	2(1.3)
Aortic aneurysm	大動脈瘤	1(0.7)	0(0.0)
Hypotension	低血圧	1(0.7)	0(0.0)
Varicose vein	静脈瘤	1(0.7)	0(0.0)
Vasculitis	血管炎	1(0.7)	0(0.0)
Vascular rupture	血管破裂	1(0.7)	0(0.0)
Arteriosclerosis	動脈硬化症	0(0.0)	1(0.7)
Orthostatic hypotension	起立性低血圧	0(0.0)	1(0.7)
Peripheral artery aneurysm	末梢動脈瘤	0(0.0)	1(0.7)
Hot flush	ほてり	0(0.0)	1(0.7)
Respiratory, thoracic and mediastinal disorders	呼吸器、胸郭および縦隔障害	12(7.9)	16(10.5)
Cough	咳嗽	4(2.6)	4(2.6)
Pleural effusion	胸水	2(1.3)	3(2.0)
Rhinitis allergic	アレルギー性鼻炎	2(1.3)	3(2.0)
Pulmonary congestion	肺うっ血	2(1.3)	0(0.0)
Epistaxis	鼻出血	1(0.7)	2(1.3)
Rhinorrhoea	鼻漏	1(0.7)	0(0.0)
Upper respiratory tract inflammation	上気道の炎症	0(0.0)	2(1.3)
Chronic obstructive pulmonary disease	慢性閉塞性肺疾患	0(0.0)	1(0.7)
Pulmonary embolism	肺塞栓症	0(0.0)	1(0.7)
Oropharyngeal discomfort	口腔咽頭不快感	0(0.0)	1(0.7)

表 2.7.4.9－53　有害事象の内訳（MT-6548-J01 試験／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548(N=151) n (%)	darbepoetin(N=153) n (%)
Gastrointestinal disorders	胃腸障害	59(39.1)	56(36.6)
Diarrhoea	下痢	18(11.9)	8(5.2)
Constipation	便秘	14(9.3)	11(7.2)
Vomiting	嘔吐	10(6.6)	3(2.0)
Nausea	悪心	6(4.0)	5(3.3)
Dental caries	齲歯	4(2.6)	4(2.6)
Abdominal pain upper	上腹部痛	3(2.0)	2(1.3)
Gastrooesophageal reflux disease	胃食道逆流性疾患	3(2.0)	2(1.3)
Abdominal pain	腹痛	3(2.0)	0(0.0)
Abdominal discomfort	腹部不快感	2(1.3)	3(2.0)
Stomatitis	口内炎	2(1.3)	3(2.0)
Chronic gastritis	慢性胃炎	2(1.3)	2(1.3)
Gastritis	胃炎	2(1.3)	1(0.7)
Periodontal disease	歯周病	1(0.7)	3(2.0)
Large intestine polyp	大腸ポリープ	1(0.7)	3(2.0)
Haemorrhoids	痔核	1(0.7)	2(1.3)
Gastrointestinal disorder	胃腸障害	1(0.7)	1(0.7)
Faeces soft	軟便	1(0.7)	1(0.7)
Abdominal distension	腹部膨満	1(0.7)	0(0.0)
Diverticulum intestinal	腸憩室	1(0.7)	0(0.0)
Gingival bleeding	歯肉出血	1(0.7)	0(0.0)
Mouth haemorrhage	口腔内出血	1(0.7)	0(0.0)
Oesophageal achalasia	食道アカラシア	1(0.7)	0(0.0)

表 2.7.4.9－53　有害事象の内訳（MT-6548-J01 試験／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548(N=151) n (%)	darbepoetin(N=153) n (%)
Gastrointestinal polyp haemorrhage	胃腸ポリープ出血	1(0.7)	0(0.0)
Inguinal hernia	鼠径ヘルニア	0(0.0)	2(1.3)
Aphthous ulcer	アフタ性潰瘍	0(0.0)	1(0.7)
Colitis ischaemic	虚血性大腸炎	0(0.0)	1(0.7)
Diverticulum intestinal haemorrhagic	出血性腸憩室	0(0.0)	1(0.7)
Dry mouth	口内乾燥	0(0.0)	1(0.7)
Duodenal polyp	十二指腸ポリープ	0(0.0)	1(0.7)
Enterocolitis	腸炎	0(0.0)	1(0.7)
Faeces discoloured	変色便	0(0.0)	1(0.7)
Gastric ulcer haemorrhage	出血性胃潰瘍	0(0.0)	1(0.7)
Gingival swelling	歯肉腫脹	0(0.0)	1(0.7)
Pancreatic mass	膵腫瘤	0(0.0)	1(0.7)
Anal haemorrhage	肛門出血	0(0.0)	1(0.7)
Ischaemic enteritis	虚血性小腸炎	0(0.0)	1(0.7)

表 2.7.4.9－53　有害事象の内訳（MT-6548-J01 試験／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548(N=151) n (%)	darbepoetin(N=153) n (%)
Hepatobiliary disorders	肝胆道系障害	8(5.3)	5(3.3)
Hepatic function abnormal	肝機能異常	3(2.0)	2(1.3)
Bile duct stone	胆管結石	1(0.7)	1(0.7)
Cholecystitis	胆嚢炎	1(0.7)	0(0.0)
Cholelithiasis	胆石症	1(0.7)	0(0.0)
Hepatic cirrhosis	肝硬変	1(0.7)	0(0.0)
Drug-induced liver injury	薬物性肝障害	1(0.7)	0(0.0)
Cholecystitis acute	急性胆嚢炎	0(0.0)	1(0.7)
Hepatic steatosis	脂肪肝	0(0.0)	1(0.7)
Liver disorder	肝障害	0(0.0)	1(0.7)

表 2.7.4.9－53　有害事象の内訳（MT-6548-J01 試験／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548(N=151) n (%)	darbepoetin(N=153) n (%)
Skin and subcutaneous tissue disorders	皮膚および皮下組織障害	35(23.2)	42(27.5)
Pruritus	そう痒症	7(4.6)	8(5.2)
Eczema	湿疹	5(3.3)	8(5.2)
Dermatitis contact	接触皮膚炎	4(2.6)	4(2.6)
Haemorrhage subcutaneous	皮下出血	3(2.0)	3(2.0)
Rash	発疹	3(2.0)	2(1.3)
Eczema asteatotic	皮脂欠乏性湿疹	3(2.0)	1(0.7)
Skin ulcer	皮膚潰瘍	3(2.0)	1(0.7)
Dry skin	皮膚乾燥	3(2.0)	0(0.0)
Urticaria	蕁麻疹	2(1.3)	2(1.3)
Skin erosion	皮膚びらん	2(1.3)	0(0.0)
Decubitus ulcer	褥瘡性潰瘍	1(0.7)	2(1.3)
Drug eruption	薬疹	1(0.7)	1(0.7)
Xeroderma	乾皮症	1(0.7)	1(0.7)
Dermal cyst	皮膚嚢腫	1(0.7)	0(0.0)
Dermatomyositis	皮膚筋炎	1(0.7)	0(0.0)
Prurigo	痒疹	1(0.7)	0(0.0)
Seborrhoeic dermatitis	脂漏性皮膚炎	1(0.7)	0(0.0)
Pruritus generalised	全身性そう痒症	1(0.7)	0(0.0)
Reactive perforating collagenosis	反応性穿孔性膠原線維症	1(0.7)	0(0.0)
Asteatosis	皮脂欠乏症	0(0.0)	2(1.3)
Dermatitis	皮膚炎	0(0.0)	1(0.7)
Dermatitis allergic	アレルギー性皮膚炎	0(0.0)	1(0.7)

表 2.7.4.9－53　有害事象の内訳（MT-6548-J01 試験／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548(N=151) n (%)	darbepoetin(N=153) n (%)
Hyperkeratosis	過角化	0(0.0)	1(0.7)
Ingrowing nail	嵌入爪	0(0.0)	1(0.7)
Miliaria	汗疹	0(0.0)	1(0.7)
Palmoplantar keratoderma	掌蹠角皮症	0(0.0)	1(0.7)
Psoriasis	乾癬	0(0.0)	1(0.7)
Stasis dermatitis	うっ滞性皮膚炎	0(0.0)	1(0.7)
Hand dermatitis	手皮膚炎	0(0.0)	1(0.7)

表 2.7.4.9－53　有害事象の内訳（MT-6548-J01 試験／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548(N=151) n (%)	darbepoetin(N=153) n (%)
Musculoskeletal and connective tissue disorders	筋骨格系および結合組織障害	31(20.5)	35(22.9)
Back pain	背部痛	6(4.0)	5(3.3)
Muscle spasms	筋痙縮	4(2.6)	7(4.6)
Arthritis	関節炎	4(2.6)	2(1.3)
Arthralgia	関節痛	3(2.0)	3(2.0)
Osteoporosis	骨粗鬆症	3(2.0)	1(0.7)
Spinal osteoarthritis	変形性脊椎症	3(2.0)	1(0.7)
Myalgia	筋肉痛	3(2.0)	0(0.0)
Pain in extremity	四肢痛	2(1.3)	2(1.3)
Synovial cyst	滑液嚢腫	2(1.3)	0(0.0)
Musculoskeletal pain	筋骨格痛	1(0.7)	4(2.6)
Osteoarthritis	変形性関節症	1(0.7)	4(2.6)
Neck pain	頚部痛	1(0.7)	2(1.3)
Intervertebral disc protrusion	椎間板突出	1(0.7)	2(1.3)
Lumbar spinal stenosis	腰部脊柱管狭窄症	1(0.7)	1(0.7)
Spondylolisthesis	脊椎すべり症	1(0.7)	1(0.7)
Bursitis	滑液包炎	1(0.7)	0(0.0)
Rotator cuff syndrome	肩回旋筋腱板症候群	1(0.7)	0(0.0)
Temporomandibular joint syndrome	顎関節症候群	1(0.7)	0(0.0)
Tenosynovitis	腱鞘炎	1(0.7)	0(0.0)
Trigger finger	弾発指	1(0.7)	0(0.0)
Muscle disorder	筋障害	0(0.0)	1(0.7)
Periarthritis	関節周囲炎	0(0.0)	1(0.7)

表 2.7.4.9－53　有害事象の内訳（MT-6548-J01 試験／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548(N=151) n (%)	darbepoetin(N=153) n (%)
Tendonitis	腱炎	0(0.0)	1(0.7)
Musculoskeletal stiffness	筋骨格硬直	0(0.0)	1(0.7)
Tendon pain	腱痛	0(0.0)	1(0.7)
Renal and urinary disorders	腎および尿路障害	25(16.6)	31(20.3)
Chronic kidney disease	慢性腎臓病	9(6.0)	14(9.2)
Renal impairment	腎機能障害	8(5.3)	8(5.2)
End stage renal disease	末期腎疾患	3(2.0)	1(0.7)
Renal failure	腎不全	2(1.3)	1(0.7)
Hypertonic bladder	緊張性膀胱	2(1.3)	0(0.0)
Haematuria	血尿	1(0.7)	1(0.7)
Oliguria	乏尿	1(0.7)	0(0.0)
Urinary retention	尿閉	1(0.7)	0(0.0)
Azotaemia	高窒素血症	0(0.0)	1(0.7)
Dysuria	排尿困難	0(0.0)	1(0.7)
Neurogenic bladder	神経因性膀胱	0(0.0)	1(0.7)
Nocturia	夜間頻尿	0(0.0)	1(0.7)
Diabetic nephropathy	糖尿病性腎症	0(0.0)	1(0.7)
Acute kidney injury	急性腎障害	0(0.0)	1(0.7)
Ureterolithiasis	尿管結石症	0(0.0)	1(0.7)

表 2.7.4.9－53　有害事象の内訳（MT-6548-J01 試験／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548(N=151) n (%)	darbepoetin(N=153) n (%)
Reproductive system and breast disorders	生殖系および乳房障害	5(3.3)	2(1.3)
Benign prostatic hyperplasia	良性前立腺肥大症	3(2.0)	0(0.0)
Menstruation irregular	不規則月経	1(0.7)	0(0.0)
Nipple pain	乳頭痛	1(0.7)	0(0.0)
Pruritus genital	陰部そう痒症	0(0.0)	1(0.7)
Vulvar erosion	外陰部びらん	0(0.0)	1(0.7)
General disorders and administration site conditions	一般・全身障害および投与部位の状態	25(16.6)	16(10.5)
Oedema peripheral	末梢性浮腫	11(7.3)	5(3.3)
Pyrexia	発熱	8(5.3)	1(0.7)
Malaise	倦怠感	5(3.3)	1(0.7)
Chest pain	胸痛	2(1.3)	1(0.7)
Oedema due to renal disease	腎疾患による浮腫	2(1.3)	1(0.7)
Oedema	浮腫	1(0.7)	2(1.3)
Chills	悪寒	1(0.7)	0(0.0)
Face oedema	顔面浮腫	1(0.7)	0(0.0)
Thirst	口渇	1(0.7)	0(0.0)
Vessel puncture site haemorrhage	血管穿刺部位出血	1(0.7)	0(0.0)
Asthenia	無力症	0(0.0)	1(0.7)
Fatigue	疲労	0(0.0)	1(0.7)
Feeling abnormal	異常感	0(0.0)	1(0.7)
Injection site haematoma	注射部位血腫	0(0.0)	1(0.7)
Injection site pain	注射部位疼痛	0(0.0)	1(0.7)
Injection site rash	注射部位発疹	0(0.0)	1(0.7)

表 2.7.4.9－53　有害事象の内訳（MT-6548-J01 試験／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548(N=151) n (%)	darbepoetin(N=153) n (%)
Investigations	臨床検査	13(8.6)	12(7.8)
Blood creatinine increased	血中クレアチニン増加	3(2.0)	2(1.3)
Blood creatine phosphokinase increased	血中クレアチンホスホキナーゼ増加	2(1.3)	3(2.0)
Blood pressure increased	血圧上昇	2(1.3)	1(0.7)
Blood uric acid increased	血中尿酸増加	2(1.3)	0(0.0)
Blood triglycerides increased	血中トリグリセリド増加	1(0.7)	1(0.7)
Blood potassium decreased	血中カリウム減少	1(0.7)	0(0.0)
C-reactive protein increased	Ｃ－反応性蛋白増加	1(0.7)	0(0.0)
Haemoglobin decreased	ヘモグロビン減少	1(0.7)	0(0.0)
Prostatic specific antigen increased	前立腺特異性抗原増加	1(0.7)	0(0.0)
Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	1(0.7)	0(0.0)
Blood iron decreased	血中鉄減少	0(0.0)	1(0.7)
Blood pressure decreased	血圧低下	0(0.0)	1(0.7)
Gamma-glutamyltransferase increased	γ－グルタミルトランスフェラーゼ増加	0(0.0)	1(0.7)
Intraocular pressure increased	眼圧上昇	0(0.0)	1(0.7)
Weight decreased	体重減少	0(0.0)	1(0.7)
Platelet count increased	血小板数増加	0(0.0)	1(0.7)

表 2.7.4.9－53　有害事象の内訳（MT-6548-J01 試験／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548(N=151) n (%)	darbepoetin(N=153) n (%)
Injury, poisoning and procedural complications	傷害、中毒および処置合併症	30(19.9)	26(17.0)
Contusion	挫傷	11(7.3)	7(4.6)
Skin abrasion	皮膚擦過傷	4(2.6)	2(1.3)
Spinal compression fracture	脊椎圧迫骨折	3(2.0)	2(1.3)
Rib fracture	肋骨骨折	2(1.3)	0(0.0)
Shunt stenosis	シャント狭窄	2(1.3)	0(0.0)
Limb injury	四肢損傷	2(1.3)	0(0.0)
Femoral neck fracture	大腿骨頚部骨折	1(0.7)	1(0.7)
Thermal burn	熱傷	1(0.7)	1(0.7)
Animal scratch	動物による引っかき傷	1(0.7)	0(0.0)
Clavicle fracture	鎖骨骨折	1(0.7)	0(0.0)
Hand fracture	手骨折	1(0.7)	0(0.0)
Head injury	頭部損傷	1(0.7)	0(0.0)
Laceration	裂傷	1(0.7)	0(0.0)
Seroma	漿液腫	1(0.7)	0(0.0)
Subarachnoid haemorrhage	くも膜下出血	1(0.7)	0(0.0)
Tendon rupture	腱断裂	1(0.7)	0(0.0)
Excoriation	擦過傷	1(0.7)	0(0.0)
Lumbar vertebral fracture	腰椎骨折	1(0.7)	0(0.0)
Procedural pain	処置による疼痛	1(0.7)	0(0.0)
Nail injury	爪損傷	1(0.7)	0(0.0)
Eye contusion	眼挫傷	1(0.7)	0(0.0)
Heat illness	熱中症	0(0.0)	3(2.0)

表 2.7.4.9－53　有害事象の内訳（MT-6548-J01 試験／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548(N=151) n (%)	darbepoetin(N=153) n (%)
Arthropod bite	節足動物咬傷	0 (0.0)	2 (1.3)
Chillblains	凍瘡	0 (0.0)	2 (1.3)
Ligament sprain	靱帯捻挫	0 (0.0)	2 (1.3)
Femur fracture	大腿骨骨折	0 (0.0)	1 (0.7)
Hip fracture	股関節部骨折	0 (0.0)	1 (0.7)
Humerus fracture	上腕骨骨折	0 (0.0)	1 (0.7)
Injury	損傷	0 (0.0)	1 (0.7)
Radius fracture	橈骨骨折	0 (0.0)	1 (0.7)
Shunt occlusion	シャント閉塞	0 (0.0)	1 (0.7)
Wrist fracture	手首関節骨折	0 (0.0)	1 (0.7)
Wound	創傷	0 (0.0)	1 (0.7)
Tooth fracture	歯牙破折	0 (0.0)	1 (0.7)
Bone contusion	骨挫傷	0 (0.0)	1 (0.7)

Note(s): MedDRA Version 20.1 and MedDRA/J Version 20.1.
Data Source: Listing 16.2.5.1
Source: t_14_3_1_2_1.sas

5.3.5.1—8 表 12.2.3—1 より引用

表 2.7.4.9－54　副作用の内訳（MT-6548-J01 試験／52 週）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548(N=151) n (%)	darbepoetin(N=153) n (%)
Subjects with at least one adverse drug reaction		20(13.2)	7(4.6)
Nervous system disorders	神経系障害	1(0.7)	1(0.7)
Somnolence	傾眠	1(0.7)	0(0.0)
Dizziness	浮動性めまい	0(0.0)	1(0.7)
Eye disorders	眼障害	1(0.7)	0(0.0)
Retinal haemorrhage	網膜出血	1(0.7)	0(0.0)
Ear and labyrinth disorders	耳および迷路障害	1(0.7)	0(0.0)
Vertigo	回転性めまい	1(0.7)	0(0.0)
Cardiac disorders	心臓障害	1(0.7)	0(0.0)
Palpitations	動悸	1(0.7)	0(0.0)
Vascular disorders	血管障害	1(0.7)	2(1.3)
Hypertension	高血圧	1(0.7)	2(1.3)
Hot flush	ほてり	0(0.0)	1(0.7)
Gastrointestinal disorders	胃腸障害	11(7.3)	1(0.7)
Diarrhoea	下痢	6(4.0)	0(0.0)
Nausea	悪心	3(2.0)	0(0.0)
Abdominal discomfort	腹部不快感	2(1.3)	1(0.7)
Gastritis	胃炎	1(0.7)	0(0.0)
Faeces soft	軟便	1(0.7)	0(0.0)
Hepatobiliary disorders	肝胆道系障害	1(0.7)	0(0.0)
Hepatic function abnormal	肝機能異常	1(0.7)	0(0.0)

表 2.7.4.9－54　副作用の内訳（MT-6548-J01 試験／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548(N=151) n (%)	darbepoetin(N=153) n (%)
Skin and subcutaneous tissue disorders	皮膚および皮下組織障害	3(2.0)	1(0.7)
Drug eruption	薬疹	1(0.7)	0(0.0)
Eczema	湿疹	1(0.7)	0(0.0)
Pruritus	そう痒症	1(0.7)	0(0.0)
Haemorrhage subcutaneous	皮下出血	0(0.0)	1(0.7)
Reproductive system and breast disorders	生殖系および乳房障害	1(0.7)	0(0.0)
Nipple pain	乳頭痛	1(0.7)	0(0.0)
General disorders and administration site conditions	一般・全身障害および投与部位の状態	2(1.3)	1(0.7)
Malaise	倦怠感	1(0.7)	0(0.0)
Oedema peripheral	末梢性浮腫	1(0.7)	0(0.0)
Injection site pain	注射部位疼痛	0(0.0)	1(0.7)
Investigations	臨床検査	1(0.7)	1(0.7)
Blood creatinine increased	血中クレアチニン増加	1(0.7)	1(0.7)

Note(s): MedDRA Version 20.1 and MedDRA/J Version 20.1.
Data Source: Listing 16.2.5.1
Source: t_14_3_1_3_1.sas

5.3.5.1—8 表 12.2.3—2 より引用

表 2.7.4.9－55　有害事象の内訳（MT-6548-J03 試験／52 週）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548(N=162) n (%)	darbepoetin(N=161) n (%)
Subjects with at least one adverse event		154(95.1)	158(98.1)
Infections and infestations	感染症および寄生虫症	107(66.0)	111(68.9)
Nasopharyngitis	上咽頭炎	74(45.7)	73(45.3)
Gastroenteritis	胃腸炎	12(7.4)	1(0.6)
Conjunctivitis	結膜炎	11(6.8)	4(2.5)
Influenza	インフルエンザ	9(5.6)	12(7.5)
Upper respiratory tract infection	上気道感染	7(4.3)	8(5.0)
Pneumonia	肺炎	7(4.3)	2(1.2)
Bronchitis	気管支炎	5(3.1)	6(3.7)
Hordeolum	麦粒腫	4(2.5)	1(0.6)
Pharyngitis	咽頭炎	3(1.9)	7(4.3)
Periodontitis	歯周炎	3(1.9)	5(3.1)
Cystitis	膀胱炎	3(1.9)	1(0.6)
Tinea pedis	足部白癬	2(1.2)	6(3.7)
Shunt infection	シャント感染	2(1.2)	5(3.1)
Dermatophytosis of nail	爪の皮膚糸状菌症	2(1.2)	2(1.2)
Herpes zoster	帯状疱疹	2(1.2)	2(1.2)
Skin infection	皮膚感染	2(1.2)	1(0.6)
Infected dermal cyst	感染性皮膚嚢腫	2(1.2)	1(0.6)
Otitis media	中耳炎	2(1.2)	0(0.0)
Enteritis infectious	感染性腸炎	2(1.2)	0(0.0)
Oral herpes	口腔ヘルペス	1(0.6)	3(1.9)
Angular cheilitis	口角口唇炎	1(0.6)	2(1.2)
Chronic sinusitis	慢性副鼻腔炎	1(0.6)	1(0.6)

表 2.7.4.9－55　有害事象の内訳（MT-6548-J03 試験／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548(N=162) n (%)	darbepoetin(N=161) n (%)
Pyelonephritis	腎盂腎炎	1(0.6)	1(0.6)
Cellulitis	蜂巣炎	1(0.6)	0(0.0)
Dermatitis infected	感染性皮膚炎	1(0.6)	0(0.0)
Furuncle	せつ	1(0.6)	0(0.0)
Gastroenteritis viral	ウイルス性胃腸炎	1(0.6)	0(0.0)
Hydrocele male infected	感染性陰嚢水瘤	1(0.6)	0(0.0)
Osteomyelitis	骨髄炎	1(0.6)	0(0.0)
Otitis media chronic	慢性中耳炎	1(0.6)	0(0.0)
Paronychia	爪囲炎	1(0.6)	0(0.0)
Sinusitis	副鼻腔炎	1(0.6)	0(0.0)
Hepatic cyst infection	肝嚢胞感染	1(0.6)	0(0.0)
Upper respiratory tract infection bacterial	細菌性上気道感染	1(0.6)	0(0.0)
Bacterial infection	細菌感染	1(0.6)	0(0.0)
Device related infection	医療機器関連感染	1(0.6)	0(0.0)
Folliculitis	毛包炎	0(0.0)	2(1.2)
Gingivitis	歯肉炎	0(0.0)	2(1.2)
Pericoronitis	歯冠周囲炎	0(0.0)	2(1.2)
Catheter site infection	カテーテル留置部位感染	0(0.0)	2(1.2)
Vessel puncture site infection	血管穿刺部位感染	0(0.0)	2(1.2)
Acute sinusitis	急性副鼻腔炎	0(0.0)	1(0.6)
Chronic tonsillitis	慢性扁桃炎	0(0.0)	1(0.6)
Diverticulitis	憩室炎	0(0.0)	1(0.6)
Otitis media acute	急性中耳炎	0(0.0)	1(0.6)
Peritonitis	腹膜炎	0(0.0)	1(0.6)

表 2.7.4.9－55　有害事象の内訳（MT-6548-J03 試験／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548(N=162) n (%)	darbepoetin(N=161) n (%)
Pulpitis dental	歯髄炎	0(0.0)	1(0.6)
Rash pustular	膿疱性皮疹	0(0.0)	1(0.6)
Subcutaneous abscess	皮下組織膿瘍	0(0.0)	1(0.6)
Tinea cruris	股部白癬	0(0.0)	1(0.6)
Urinary tract infection	尿路感染	0(0.0)	1(0.6)
Urinary tract infection fungal	真菌性尿路感染	0(0.0)	1(0.6)
Gingival abscess	歯肉膿瘍	0(0.0)	1(0.6)
Skin bacterial infection	皮膚細菌感染	0(0.0)	1(0.6)
Abdominal infection	腹部感染	0(0.0)	1(0.6)
Staphylococcal infection	ブドウ球菌感染	0(0.0)	1(0.6)
Pneumonia bacterial	細菌性肺炎	0(0.0)	1(0.6)
Purulence	化膿	0(0.0)	1(0.6)
Mycotic endophthalmitis	真菌性眼内炎	0(0.0)	1(0.6)

表 2.7.4.9－55　有害事象の内訳（MT-6548-J03 試験／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548(N=162) n (%)	darbepoetin(N=161) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	7(4.3)	9(5.6)
Breast cancer	乳癌	1(0.6)	1(0.6)
Gastric cancer	胃癌	1(0.6)	1(0.6)
Seborrhoeic keratosis	脂漏性角化症	1(0.6)	1(0.6)
Cholesteatoma	真珠腫	1(0.6)	0(0.0)
Laryngeal papilloma	喉頭乳頭腫	1(0.6)	0(0.0)
Squamous cell carcinoma of skin	皮膚有棘細胞癌	1(0.6)	0(0.0)
Uterine leiomyoma	子宮平滑筋腫	1(0.6)	0(0.0)
Pyogenic granuloma	化膿性肉芽腫	0(0.0)	1(0.6)
Thymoma	胸腺腫	0(0.0)	1(0.6)
Prostate cancer	前立腺癌	0(0.0)	1(0.6)
Pancreatic neoplasm	膵新生物	0(0.0)	1(0.6)
Urethral neoplasm	尿道新生物	0(0.0)	1(0.6)
Renal cell carcinoma	腎細胞癌	0(0.0)	1(0.6)
Gastrointestinal submucosal tumour	消化管粘膜下腫瘍	0(0.0)	1(0.6)

表 2.7.4.9－55　有害事象の内訳（MT-6548-J03 試験／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548(N=162) n (%)	darbepoetin(N=161) n (%)
Blood and lymphatic system disorders	血液およびリンパ系障害	9(5.6)	2(1.2)
Anaemia	貧血	2(1.2)	0(0.0)
Anaemia macrocytic	大球性貧血	1(0.6)	0(0.0)
Eosinophilia	好酸球増加症	1(0.6)	0(0.0)
Lymphadenitis	リンパ節炎	1(0.6)	0(0.0)
Lymphadenopathy	リンパ節症	1(0.6)	0(0.0)
Polycythaemia	赤血球増加症	1(0.6)	0(0.0)
Haemorrhagic anaemia	出血性貧血	1(0.6)	0(0.0)
Nephrogenic anaemia	腎性貧血	1(0.6)	0(0.0)
Aplastic anaemia	再生不良性貧血	0(0.0)	1(0.6)
Iron deficiency anaemia	鉄欠乏性貧血	0(0.0)	1(0.6)
Immune system disorders	免疫系障害	4(2.5)	14(8.7)
Seasonal allergy	季節性アレルギー	4(2.5)	12(7.5)
Drug hypersensitivity	薬物過敏症	0(0.0)	1(0.6)
Dialysis amyloidosis	透析アミロイドーシス	0(0.0)	1(0.6)
Endocrine disorders	内分泌障害	3(1.9)	4(2.5)
Hyperparathyroidism secondary	続発性副甲状腺機能亢進症	2(1.2)	2(1.2)
Hypothyroidism	甲状腺機能低下症	1(0.6)	2(1.2)
Goitre	甲状腺腫	0(0.0)	1(0.6)
Hyperparathyroidism	副甲状腺機能亢進症	0(0.0)	1(0.6)

表 2.7.4.9－55　有害事象の内訳（MT-6548-J03 試験／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548(N=162) n (%)	darbepoetin(N=161) n (%)
Metabolism and nutrition disorders	代謝および栄養障害	19(11.7)	21(13.0)
Decreased appetite	食欲減退	9(5.6)	4(2.5)
Hypocarnitinaemia	低カルニチン血症	4(2.5)	2(1.2)
Hyperphosphataemia	高リン酸塩血症	2(1.2)	2(1.2)
Hypoglycaemia	低血糖	1(0.6)	2(1.2)
Hypercalcaemia	高カルシウム血症	1(0.6)	1(0.6)
Hyperkalaemia	高カリウム血症	1(0.6)	1(0.6)
Hypoalbuminaemia	低アルブミン血症	1(0.6)	1(0.6)
Dyslipidaemia	脂質異常症	1(0.6)	0(0.0)
Zinc deficiency	亜鉛欠乏	0(0.0)	3(1.9)
Type 2 diabetes mellitus	２型糖尿病	0(0.0)	2(1.2)
Dehydration	脱水	0(0.0)	1(0.6)
Diabetes mellitus inadequate control	コントロール不良の糖尿病	0(0.0)	1(0.6)
Hyperuricaemia	高尿酸血症	0(0.0)	1(0.6)
Hypophosphataemia	低リン酸血症	0(0.0)	1(0.6)
Psychiatric disorders	精神障害	7(4.3)	7(4.3)
Insomnia	不眠症	6(3.7)	6(3.7)
Depression	うつ病	1(0.6)	0(0.0)
Abnormal behaviour	異常行動	1(0.6)	0(0.0)
Sleep disorder	睡眠障害	0(0.0)	1(0.6)

表 2.7.4.9－55　有害事象の内訳（MT-6548-J03 試験／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548(N=162) n (%)	darbepoetin(N=161) n (%)
Nervous system disorders	神経系障害	36(22.2)	24(14.9)
Headache	頭痛	13(8.0)	5(3.1)
Dizziness	浮動性めまい	8(4.9)	5(3.1)
Carpal tunnel syndrome	手根管症候群	2(1.2)	0(0.0)
Facial paralysis	顔面麻痺	2(1.2)	0(0.0)
Cerebral infarction	脳梗塞	1(0.6)	5(3.1)
Carotid artery stenosis	頸動脈狭窄	1(0.6)	1(0.6)
Cerebellar infarction	小脳梗塞	1(0.6)	1(0.6)
Neuralgia	神経痛	1(0.6)	1(0.6)
Dizziness postural	体位性めまい	1(0.6)	0(0.0)
Hypoaesthesia	感覚鈍麻	1(0.6)	0(0.0)
Intracranial aneurysm	頭蓋内動脈瘤	1(0.6)	0(0.0)
Myelopathy	脊髄症	1(0.6)	0(0.0)
Myoclonus	ミオクローヌス	1(0.6)	0(0.0)
Sciatica	坐骨神経痛	1(0.6)	0(0.0)
Somnolence	傾眠	1(0.6)	0(0.0)
Tremor	振戦	1(0.6)	0(0.0)
Intercostal neuralgia	肋間神経痛	1(0.6)	0(0.0)
Cervical radiculopathy	頸髄神経根障害	1(0.6)	0(0.0)
Lacunar infarction	ラクナ梗塞	1(0.6)	0(0.0)
Restless legs syndrome	下肢静止不能症候群	1(0.6)	0(0.0)
Thrombotic cerebral infarction	血栓性脳梗塞	1(0.6)	0(0.0)
Loss of consciousness	意識消失	0(0.0)	2(1.2)
Trigeminal neuralgia	三叉神経痛	0(0.0)	2(1.2)

表 2.7.4.9－55　有害事象の内訳（MT-6548-J03 試験／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548(N=162) n (%)	darbepoetin(N=161) n (%)
Cervicobrachial syndrome	頚腕症候群	0(0.0)	1(0.6)
Dysgeusia	味覚異常	0(0.0)	1(0.6)
Head discomfort	頭部不快感	0(0.0)	1(0.6)
Seizure	痙攣発作	0(0.0)	1(0.6)
Tension headache	緊張性頭痛	0(0.0)	1(0.6)
Vocal cord paralysis	声帯麻痺	0(0.0)	1(0.6)
Cervicogenic headache	頚原性頭痛	0(0.0)	1(0.6)

表 2.7.4.9－55　有害事象の内訳（MT-6548-J03 試験／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548(N=162) n (%)	darbepoetin(N=161) n (%)
Eye disorders	眼障害	35(21.6)	35(21.7)
Retinal haemorrhage	網膜出血	16(9.9)	10(6.2)
Conjunctival haemorrhage	結膜出血	4(2.5)	3(1.9)
Diabetic retinopathy	糖尿病網膜症	2(1.2)	1(0.6)
Dry eye	眼乾燥	2(1.2)	1(0.6)
Cataract	白内障	1(0.6)	3(1.9)
Conjunctivitis allergic	アレルギー性結膜炎	1(0.6)	3(1.9)
Macular oedema	黄斑浮腫	1(0.6)	3(1.9)
Blepharitis	眼瞼炎	1(0.6)	2(1.2)
Glaucoma	緑内障	1(0.6)	1(0.6)
Ocular hyperaemia	眼充血	1(0.6)	1(0.6)
Optic disc haemorrhage	視神経乳頭出血	1(0.6)	1(0.6)
Eye pruritus	眼そう痒症	1(0.6)	1(0.6)
Diplopia	複視	1(0.6)	0(0.0)
Keratitis	角膜炎	1(0.6)	0(0.0)
Punctate keratitis	点状角膜炎	1(0.6)	0(0.0)
Retinal oedema	網膜浮腫	1(0.6)	0(0.0)
Retinal vein occlusion	網膜静脈閉塞	1(0.6)	0(0.0)
Trichiasis	睫毛乱生	1(0.6)	0(0.0)
Vitreous floaters	硝子体浮遊物	1(0.6)	0(0.0)
Cystoid macular oedema	嚢胞様黄斑浮腫	1(0.6)	0(0.0)
Chorioretinopathy	網脈絡膜症	1(0.6)	0(0.0)
Eyelid haematoma	眼瞼血腫	1(0.6)	0(0.0)
Chalazion	霰粒腫	0(0.0)	1(0.6)

表 2.7.4.9－55　有害事象の内訳（MT-6548-J03 試験／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548(N=162) n (%)	darbepoetin(N=161) n (%)
Eye discharge	眼脂	0 (0.0)	1 (0.6)
Eyelid oedema	眼瞼浮腫	0 (0.0)	1 (0.6)
Posterior capsule opacification	後嚢部混濁	0 (0.0)	1 (0.6)
Retinal detachment	網膜剥離	0 (0.0)	1 (0.6)
Retinal vascular disorder	網膜血管障害	0 (0.0)	1 (0.6)
Vitreous detachment	硝子体剥離	0 (0.0)	1 (0.6)
Vitreous haemorrhage	硝子体出血	0 (0.0)	1 (0.6)
Conjunctival hyperaemia	結膜充血	0 (0.0)	1 (0.6)
Retinal aneurysm	網膜血管瘤	0 (0.0)	1 (0.6)
Age-related macular degeneration	加齢黄斑変性	0 (0.0)	1 (0.6)
Ear and labyrinth disorders	耳および迷路障害	8 (4.9)	6 (3.7)
Vertigo	回転性めまい	5 (3.1)	2 (1.2)
Vertigo positional	頭位性回転性めまい	1 (0.6)	1 (0.6)
Deafness	難聴	1 (0.6)	0 (0.0)
Sudden hearing loss	突発性難聴	1 (0.6)	0 (0.0)
Eustachian tube stenosis	耳管狭窄	1 (0.6)	0 (0.0)
Tinnitus	耳鳴	0 (0.0)	2 (1.2)
Ear pruritus	耳そう痒症	0 (0.0)	1 (0.6)

表 2.7.4.9－55　有害事象の内訳（MT-6548-J03 試験／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548(N=162) n (%)	darbepoetin(N=161) n (%)
Cardiac disorders	心臓障害	13(8.0)	21(13.0)
Cardiac failure congestive	うっ血性心不全	2(1.2)	0(0.0)
Tachycardia paroxysmal	発作性頻脈	2(1.2)	0(0.0)
Angina pectoris	狭心症	1(0.6)	3(1.9)
Coronary artery stenosis	冠動脈狭窄	1(0.6)	2(1.2)
Myocardial ischaemia	心筋虚血	1(0.6)	1(0.6)
Cardiac dysfunction	心機能障害	1(0.6)	1(0.6)
Angina unstable	不安定狭心症	1(0.6)	0(0.0)
Aortic valve incompetence	大動脈弁閉鎖不全症	1(0.6)	0(0.0)
Arrhythmia	不整脈	1(0.6)	0(0.0)
Arteriosclerosis coronary artery	冠動脈硬化症	1(0.6)	0(0.0)
Cardiac failure	心不全	1(0.6)	0(0.0)
Mitral valve incompetence	僧帽弁閉鎖不全症	1(0.6)	0(0.0)
Mitral valve stenosis	僧帽弁狭窄症	1(0.6)	0(0.0)
Palpitations	動悸	1(0.6)	0(0.0)
Paroxysmal arrhythmia	発作性不整脈	1(0.6)	0(0.0)
Atrial fibrillation	心房細動	0(0.0)	4(2.5)
Bradycardia	徐脈	0(0.0)	3(1.9)
Aortic valve stenosis	大動脈弁狭窄	0(0.0)	1(0.6)
Pericarditis	心膜炎	0(0.0)	1(0.6)
Tachycardia	頻脈	0(0.0)	1(0.6)
Ventricular extrasystoles	心室性期外収縮	0(0.0)	1(0.6)
Left ventricular dysfunction	左室機能不全	0(0.0)	1(0.6)
Coronary artery perforation	冠動脈穿孔	0(0.0)	1(0.6)

表 2.7.4.9－55　有害事象の内訳（MT-6548-J03 試験／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548(N=162) n (%)	darbepoetin(N=161) n (%)
Cardiac valve disease	心臓弁膜疾患	0(0.0)	1(0.6)
Supraventricular tachyarrhythmia	上室性頻脈性不整脈	0(0.0)	1(0.6)
Vascular disorders	血管障害	20(12.3)	22(13.7)
Hypertension	高血圧	6(3.7)	6(3.7)
Hypotension	低血圧	5(3.1)	3(1.9)
Internal haemorrhage	内出血	3(1.9)	4(2.5)
Peripheral arterial occlusive disease	末梢動脈閉塞性疾患	3(1.9)	3(1.9)
Orthostatic hypotension	起立性低血圧	1(0.6)	3(1.9)
Vascular pain	血管痛	1(0.6)	0(0.0)
Vascular insufficiency	血行不全	1(0.6)	0(0.0)
Haemorrhage	出血	1(0.6)	0(0.0)
Extravasation blood	血液溢出	0(0.0)	1(0.6)
Haematoma	血腫	0(0.0)	1(0.6)
Thrombophlebitis	血栓性静脈炎	0(0.0)	1(0.6)
Peripheral artery occlusion	末梢動脈閉塞	0(0.0)	1(0.6)
Artery dissection	動脈解離	0(0.0)	1(0.6)
Steal syndrome	スチール症候群	0(0.0)	1(0.6)
Peripheral artery aneurysm rupture	末梢動脈瘤破裂	0(0.0)	1(0.6)

表 2.7.4.9－55　有害事象の内訳（MT-6548-J03 試験／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548(N=162) n (%)	darbepoetin(N=161) n (%)
Respiratory, thoracic and mediastinal disorders	呼吸器、胸郭および縦隔障害	21(13.0)	31(19.3)
Rhinitis allergic	アレルギー性鼻炎	5(3.1)	2(1.2)
Epistaxis	鼻出血	4(2.5)	2(1.2)
Upper respiratory tract inflammation	上気道の炎症	4(2.5)	2(1.2)
Oropharyngeal pain	口腔咽頭痛	2(1.2)	2(1.2)
Pulmonary oedema	肺水腫	2(1.2)	1(0.6)
Hiccups	しゃっくり	1(0.6)	4(2.5)
Sleep apnoea syndrome	睡眠時無呼吸症候群	1(0.6)	3(1.9)
Pleural effusion	胸水	1(0.6)	2(1.2)
Asthma	喘息	1(0.6)	0(0.0)
Haemoptysis	喀血	1(0.6)	0(0.0)
Pneumonia aspiration	誤嚥性肺炎	1(0.6)	0(0.0)
Cough	咳嗽	0(0.0)	3(1.9)
Rhinorrhoea	鼻漏	0(0.0)	2(1.2)
Bronchitis chronic	慢性気管支炎	0(0.0)	1(0.6)
Dyspnoea	呼吸困難	0(0.0)	1(0.6)
Mediastinal mass	縦隔腫瘤	0(0.0)	1(0.6)
Nasal inflammation	鼻の炎症	0(0.0)	1(0.6)
Pleurisy	胸膜炎	0(0.0)	1(0.6)
Allergic bronchitis	アレルギー性気管支炎	0(0.0)	1(0.6)
Laryngeal discomfort	喉頭不快感	0(0.0)	1(0.6)
Pulmonary mass	肺腫瘤	0(0.0)	1(0.6)
Oropharyngeal discomfort	口腔咽頭不快感	0(0.0)	1(0.6)

表 2.7.4.9－55　有害事象の内訳（MT-6548-J03 試験／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548(N=162) n (%)	darbepoetin(N=161) n (%)
Gastrointestinal disorders	胃腸障害	66(40.7)	81(50.3)
Diarrhoea	下痢	25(15.4)	24(14.9)
Vomiting	嘔吐	10(6.2)	17(10.6)
Nausea	悪心	10(6.2)	2(1.2)
Constipation	便秘	7(4.3)	12(7.5)
Gastrooesophageal reflux disease	胃食道逆流性疾患	5(3.1)	6(3.7)
Dental caries	齲歯	5(3.1)	5(3.1)
Haemorrhoids	痔核	4(2.5)	3(1.9)
Abdominal discomfort	腹部不快感	4(2.5)	2(1.2)
Large intestine polyp	大腸ポリープ	3(1.9)	5(3.1)
Toothache	歯痛	3(1.9)	1(0.6)
Gastric ulcer	胃潰瘍	3(1.9)	0(0.0)
Stomatitis	口内炎	2(1.2)	4(2.5)
Abdominal pain	腹痛	2(1.2)	3(1.9)
Chronic gastritis	慢性胃炎	2(1.2)	2(1.2)
Dyspepsia	消化不良	2(1.2)	2(1.2)
Gastritis	胃炎	2(1.2)	2(1.2)
Enterocolitis	腸炎	2(1.2)	1(0.6)
Duodenal ulcer	十二指腸潰瘍	2(1.2)	0(0.0)
Faeces soft	軟便	1(0.6)	3(1.9)
Gastric polyps	胃ポリープ	1(0.6)	1(0.6)
Abdominal distension	腹部膨満	1(0.6)	0(0.0)
Abdominal pain lower	下腹部痛	1(0.6)	0(0.0)
Barrett's oesophagus	バレット食道	1(0.6)	0(0.0)

表 2.7.4.9－55　有害事象の内訳（MT-6548-J03 試験／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548(N=162) n (%)	darbepoetin(N=161) n (%)
Diverticulum intestinal	腸憩室	1(0.6)	0(0.0)
Dry mouth	口内乾燥	1(0.6)	0(0.0)
Duodenal polyp	十二指腸ポリープ	1(0.6)	0(0.0)
Food poisoning	食中毒	1(0.6)	0(0.0)
Gastritis erosive	びらん性胃炎	1(0.6)	0(0.0)
Gastritis haemorrhagic	出血性胃炎	1(0.6)	0(0.0)
Glossitis	舌炎	1(0.6)	0(0.0)
Melaena	メレナ	1(0.6)	0(0.0)
Pancreatitis	膵炎	1(0.6)	0(0.0)
Rectal ulcer	直腸潰瘍	1(0.6)	0(0.0)
Gastric disorder	胃障害	1(0.6)	0(0.0)
Gastrointestinal motility disorder	消化管運動障害	1(0.6)	0(0.0)
Loose tooth	弛緩歯	1(0.6)	0(0.0)
Abdominal pain upper	上腹部痛	0(0.0)	4(2.5)
Periodontal disease	歯周病	0(0.0)	4(2.5)
Anal fissure	裂肛	0(0.0)	2(1.2)
Hiatus hernia	裂孔ヘルニア	0(0.0)	2(1.2)
Haemorrhoidal haemorrhage	痔出血	0(0.0)	2(1.2)
Anal fistula	痔瘻	0(0.0)	1(0.6)
Enteritis	小腸炎	0(0.0)	1(0.6)
Gastrointestinal disorder	胃腸障害	0(0.0)	1(0.6)
Gingival pain	歯肉痛	0(0.0)	1(0.6)
Inguinal hernia	鼠径ヘルニア	0(0.0)	1(0.6)
Lip dry	口唇乾燥	0(0.0)	1(0.6)

表 2.7.4.9－55　有害事象の内訳（MT-6548-J03 試験／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548(N=162) n (%)	darbepoetin(N=161) n (%)
Oral discomfort	口腔内不快感	0 (0.0)	1 (0.6)
Tooth loss	歯の脱落	0 (0.0)	1 (0.6)
Upper gastrointestinal haemorrhage	上部消化管出血	0 (0.0)	1 (0.6)
Hepatobiliary disorders	肝胆道系障害	4 (2.5)	3 (1.9)
Cholelithiasis	胆石症	3 (1.9)	1 (0.6)
Hepatic function abnormal	肝機能異常	1 (0.6)	2 (1.2)
Cholangitis	胆管炎	1 (0.6)	0 (0.0)
Cholecystitis	胆嚢炎	1 (0.6)	0 (0.0)

表 2.7.4.9－55　有害事象の内訳（MT-6548-J03 試験／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548(N=162) n (%)	darbepoetin(N=161) n (%)
Skin and subcutaneous tissue disorders	皮膚および皮下組織障害	56(34.6)	37(23.0)
Pruritus	そう痒症	12(7.4)	9(5.6)
Eczema	湿疹	10(6.2)	8(5.0)
Haemorrhage subcutaneous	皮下出血	7(4.3)	2(1.2)
Dermatitis contact	接触皮膚炎	5(3.1)	3(1.9)
Skin exfoliation	皮膚剥脱	5(3.1)	2(1.2)
Rash	発疹	5(3.1)	0(0.0)
Drug eruption	薬疹	4(2.5)	0(0.0)
Ingrowing nail	嵌入爪	4(2.5)	0(0.0)
Dermatitis	皮膚炎	3(1.9)	4(2.5)
Xeroderma	乾皮症	3(1.9)	4(2.5)
Hyperkeratosis	過角化	3(1.9)	2(1.2)
Blister	水疱	2(1.2)	0(0.0)
Cold sweat	冷汗	2(1.2)	0(0.0)
Eczema asteatotic	皮脂欠乏性湿疹	2(1.2)	0(0.0)
Dermal cyst	皮膚嚢腫	1(0.6)	3(1.9)
Acne	ざ瘡	1(0.6)	2(1.2)
Erythema	紅斑	1(0.6)	2(1.2)
Alopecia	脱毛症	1(0.6)	1(0.6)
Skin disorder	皮膚障害	1(0.6)	0(0.0)
Skin mass	皮膚腫瘤	1(0.6)	0(0.0)
Nail disorder	爪の障害	0(0.0)	1(0.6)
Palmoplantar keratoderma	掌蹠角皮症	0(0.0)	1(0.6)
Petechiae	点状出血	0(0.0)	1(0.6)

表 2.7.4.9－55　有害事象の内訳（MT-6548-J03 試験／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548(N=162) n (%)	darbepoetin(N=161) n (%)
Skin ulcer	皮膚潰瘍	0(0.0)	1(0.6)
Urticaria	蕁麻疹	0(0.0)	1(0.6)
Onychomadesis	爪甲脱落症	0(0.0)	1(0.6)
Hand dermatitis	手皮膚炎	0(0.0)	1(0.6)

表 2.7.4.9－55　有害事象の内訳（MT-6548-J03 試験／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548(N=162) n (%)	darbepoetin(N=161) n (%)
Musculoskeletal and connective tissue disorders	筋骨格系および結合組織障害	66(40.7)	56(34.8)
Back pain	背部痛	15(9.3)	11(6.8)
Pain in extremity	四肢痛	13(8.0)	4(2.5)
Arthralgia	関節痛	10(6.2)	11(6.8)
Myalgia	筋肉痛	9(5.6)	5(3.1)
Musculoskeletal pain	筋骨格痛	7(4.3)	8(5.0)
Periarthritis	関節周囲炎	7(4.3)	5(3.1)
Muscle spasms	筋痙縮	7(4.3)	4(2.5)
Osteoarthritis	変形性関節症	7(4.3)	2(1.2)
Neck pain	頸部痛	4(2.5)	5(3.1)
Spinal osteoarthritis	変形性脊椎症	4(2.5)	3(1.9)
Lumbar spinal stenosis	腰部脊柱管狭窄症	4(2.5)	1(0.6)
Trigger finger	弾発指	2(1.2)	3(1.9)
Tenosynovitis	腱鞘炎	2(1.2)	1(0.6)
Osteoporosis	骨粗鬆症	2(1.2)	0(0.0)
Musculoskeletal chest pain	筋骨格系胸痛	1(0.6)	1(0.6)
Bursitis	滑液包炎	1(0.6)	0(0.0)
Haemarthrosis	出血性関節症	1(0.6)	0(0.0)
Joint swelling	関節腫脹	1(0.6)	0(0.0)
Rotator cuff syndrome	肩回旋筋腱板症候群	1(0.6)	0(0.0)
Intervertebral disc protrusion	椎間板突出	1(0.6)	0(0.0)
Musculoskeletal discomfort	筋骨格不快感	1(0.6)	0(0.0)
Arthritis	関節炎	0(0.0)	2(1.2)
Spondylolisthesis	脊椎すべり症	0(0.0)	2(1.2)

表 2.7.4.9－55　有害事象の内訳（MT-6548-J03 試験／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548(N=162) n (%)	darbepoetin(N=161) n (%)
Bone pain	骨痛	0(0.0)	1(0.6)
Groin pain	鼠径部痛	0(0.0)	1(0.6)
Muscular weakness	筋力低下	0(0.0)	1(0.6)
Spinal column stenosis	脊柱管狭窄症	0(0.0)	1(0.6)
Synovial cyst	滑液嚢腫	0(0.0)	1(0.6)
Tendonitis	腱炎	0(0.0)	1(0.6)
Musculoskeletal stiffness	筋骨格硬直	0(0.0)	1(0.6)
Muscle contracture	筋拘縮	0(0.0)	1(0.6)
Amyloid arthropathy	アミロイド関節症	0(0.0)	1(0.6)
Limb mass	四肢腫瘤	0(0.0)	1(0.6)
Renal and urinary disorders	腎および尿路障害	6(3.7)	5(3.1)
Renal cyst	腎嚢胞	2(1.2)	0(0.0)
Haematuria	血尿	1(0.6)	1(0.6)
Ureterolithiasis	尿管結石症	1(0.6)	1(0.6)
Pollakiuria	頻尿	1(0.6)	0(0.0)
Chronic kidney disease	慢性腎臓病	1(0.6)	0(0.0)
Hypertonic bladder	緊張性膀胱	0(0.0)	1(0.6)
Urethral haemorrhage	尿道出血	0(0.0)	1(0.6)
Renal mass	腎腫瘤	0(0.0)	1(0.6)

表 2.7.4.9－55　有害事象の内訳（MT-6548-J03 試験／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548(N=162) n (%)	darbepoetin(N=161) n (%)
Reproductive system and breast disorders	生殖系および乳房障害	5(3.1)	4(2.5)
Benign prostatic hyperplasia	良性前立腺肥大症	2(1.2)	0(0.0)
Acquired hydrocele	後天性陰嚢水瘤	1(0.6)	0(0.0)
Prostatitis	前立腺炎	1(0.6)	0(0.0)
Erectile dysfunction	勃起不全	1(0.6)	0(0.0)
Endometrial hyperplasia	子宮内膜増殖症	0(0.0)	1(0.6)
Menorrhagia	月経過多	0(0.0)	1(0.6)
Polycystic ovaries	多嚢胞性卵巣	0(0.0)	1(0.6)
Scrotal pain	陰嚢痛	0(0.0)	1(0.6)

表 2.7.4.9－55　有害事象の内訳（MT-6548-J03 試験／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548(N=162) n (%)	darbepoetin(N=161) n (%)
General disorders and administration site conditions	一般・全身障害および投与部位の状態	18(11.1)	18(11.2)
Pyrexia	発熱	5(3.1)	3(1.9)
Oedema peripheral	末梢性浮腫	5(3.1)	0(0.0)
Chest discomfort	胸部不快感	2(1.2)	2(1.2)
Vessel puncture site bruise	血管穿刺部位内出血	2(1.2)	0(0.0)
Feeling abnormal	異常感	1(0.6)	1(0.6)
Puncture site haemorrhage	穿刺部位出血	1(0.6)	1(0.6)
Puncture site pain	穿刺部位疼痛	1(0.6)	1(0.6)
Fatigue	疲労	1(0.6)	0(0.0)
Injection site reaction	注射部位反応	1(0.6)	0(0.0)
Peripheral swelling	末梢腫脹	1(0.6)	0(0.0)
Application site pruritus	適用部位そう痒感	0(0.0)	2(1.2)
Chest pain	胸痛	0(0.0)	1(0.6)
Hyperthermia	高熱	0(0.0)	1(0.6)
Injection site bruising	注射部位内出血	0(0.0)	1(0.6)
Injection site rash	注射部位発疹	0(0.0)	1(0.6)
Swelling	腫脹	0(0.0)	1(0.6)
Catheter site pain	カテーテル留置部位疼痛	0(0.0)	1(0.6)
Puncture site reaction	穿刺部位反応	0(0.0)	1(0.6)
Catheter site bruise	カテーテル留置部位内出血	0(0.0)	1(0.6)
Mucosal hyperaemia	粘膜充血	0(0.0)	1(0.6)

表 2.7.4.9－55　有害事象の内訳（MT-6548-J03 試験／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548(N=162) n (%)	darbepoetin(N=161) n (%)
Investigations	臨床検査	14(8.6)	23(14.3)
Blood pressure decreased	血圧低下	5(3.1)	7(4.3)
Blood pressure increased	血圧上昇	3(1.9)	6(3.7)
Haemoglobin decreased	ヘモグロビン減少	1(0.6)	2(1.2)
Aspartate aminotransferase increased	アスパラギン酸アミノトランスフェラーゼ増加	1(0.6)	0(0.0)
Blood urea increased	血中尿素増加	1(0.6)	0(0.0)
C-reactive protein increased	Ｃ－反応性蛋白増加	1(0.6)	0(0.0)
Prostatic specific antigen increased	前立腺特異性抗原増加	1(0.6)	0(0.0)
Serum ferritin decreased	血清フェリチン減少	1(0.6)	0(0.0)
Transferrin saturation decreased	トランスフェリン飽和度低下	1(0.6)	0(0.0)
Salmonella test positive	サルモネラ検査陽性	1(0.6)	0(0.0)
Blood parathyroid hormone increased	血中副甲状腺ホルモン増加	0(0.0)	2(1.2)
Electrocardiogram QT prolonged	心電図ＱＴ延長	0(0.0)	2(1.2)
Gamma-glutamyltransferase increased	γ－グルタミルトランスフェラーゼ増加	0(0.0)	2(1.2)
Blood calcium decreased	血中カルシウム減少	0(0.0)	1(0.6)
Carnitine decreased	カルニチン減少	0(0.0)	1(0.6)
Haemoglobin increased	ヘモグロビン増加	0(0.0)	1(0.6)
Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	0(0.0)	1(0.6)
Medication residue present	残留薬剤存在	0(0.0)	1(0.6)
Liver function test increased	肝機能検査値上昇	0(0.0)	1(0.6)

表 2.7.4.9－55　有害事象の内訳（MT-6548-J03 試験／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548(N=162) n (%)	darbepoetin(N=161) n (%)
Injury, poisoning and procedural complications	傷害、中毒および処置合併症	75(46.3)	87(54.0)
Shunt stenosis	シャント狭窄	23(14.2)	26(16.1)
Contusion	挫傷	21(13.0)	19(11.8)
Wound	創傷	10(6.2)	7(4.3)
Skin abrasion	皮膚擦過傷	9(5.6)	15(9.3)
Thermal burn	熱傷	7(4.3)	3(1.9)
Procedural hypotension	処置による低血圧	5(3.1)	6(3.7)
Shunt occlusion	シャント閉塞	4(2.5)	4(2.5)
Foot fracture	足骨折	2(1.2)	3(1.9)
Rib fracture	肋骨骨折	2(1.2)	3(1.9)
Laceration	裂傷	2(1.2)	2(1.2)
Limb injury	四肢損傷	2(1.2)	2(1.2)
Animal bite	動物咬傷	2(1.2)	0(0.0)
Joint injury	関節損傷	2(1.2)	0(0.0)
Procedural hypertension	処置による高血圧	2(1.2)	0(0.0)
Dental restoration failure	歯科修復不成功	2(1.2)	0(0.0)
Tooth fracture	歯牙破折	1(0.6)	4(2.5)
Subcutaneous haematoma	皮下血腫	1(0.6)	2(1.2)
Femoral neck fracture	大腿骨頚部骨折	1(0.6)	1(0.6)
Ligament sprain	靭帯捻挫	1(0.6)	1(0.6)
Scratch	引っかき傷	1(0.6)	1(0.6)
Heat illness	熱中症	1(0.6)	1(0.6)
Skin wound	皮膚創傷	1(0.6)	1(0.6)
Chillblains	凍瘡	1(0.6)	0(0.0)

表 2.7.4.9－55　有害事象の内訳（MT-6548-J03 試験／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548(N=162) n (%)	darbepoetin(N=161) n (%)
Foreign body in eye	眼内異物	1(0.6)	0(0.0)
Muscle injury	筋損傷	1(0.6)	0(0.0)
Scrotal haematoma	陰嚢血腫	1(0.6)	0(0.0)
Spinal compression fracture	脊椎圧迫骨折	1(0.6)	0(0.0)
Subdural haematoma	硬膜下血腫	1(0.6)	0(0.0)
Tibia fracture	脛骨骨折	1(0.6)	0(0.0)
Tooth injury	歯牙損傷	1(0.6)	0(0.0)
Wound complication	創合併症	1(0.6)	0(0.0)
Arteriovenous fistula site haemorrhage	動静脈瘻部位出血	1(0.6)	0(0.0)
Shunt thrombosis	シャント血栓症	1(0.6)	0(0.0)
Vascular access complication	血管確保合併症	1(0.6)	0(0.0)
Post procedural inflammation	処置後炎症	1(0.6)	0(0.0)
Shunt blood flow excessive	シャント血流過剰	1(0.6)	0(0.0)
Pubis fracture	恥骨骨折	1(0.6)	0(0.0)
Eye contusion	眼挫傷	1(0.6)	0(0.0)
Vascular access site inflammation	血管確保部位炎症	1(0.6)	0(0.0)
Arthropod sting	節足動物刺傷	0(0.0)	3(1.9)
Arteriovenous fistula site complication	動静脈瘻部位合併症	0(0.0)	3(1.9)
Radius fracture	橈骨骨折	0(0.0)	2(1.2)
Procedural pain	処置による疼痛	0(0.0)	2(1.2)
Arteriovenous fistula thrombosis	動静脈瘻血栓症	0(0.0)	1(0.6)
Arthropod bite	節足動物咬傷	0(0.0)	1(0.6)
Epicondylitis	上顆炎	0(0.0)	1(0.6)
Femur fracture	大腿骨骨折	0(0.0)	1(0.6)

表 2.7.4.9－55　有害事象の内訳（MT-6548-J03 試験／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548(N=162) n (%)	darbepoetin(N=161) n (%)
Fractured ischium	坐骨骨折	0(0.0)	1(0.6)
Hand fracture	手骨折	0(0.0)	1(0.6)
Head injury	頭部損傷	0(0.0)	1(0.6)
Joint dislocation	関節脱臼	0(0.0)	1(0.6)
Nail avulsion	爪裂離	0(0.0)	1(0.6)
Subarachnoid haemorrhage	くも膜下出血	0(0.0)	1(0.6)
Postoperative ileus	術後イレウス	0(0.0)	1(0.6)
Arteriovenous graft site stenosis	動静脈グラフト部位狭窄	0(0.0)	1(0.6)
Coronary artery restenosis	冠動脈再狭窄	0(0.0)	1(0.6)
Upper limb fracture	上肢骨折	0(0.0)	1(0.6)
Ear abrasion	耳擦過傷	0(0.0)	1(0.6)
Shunt malfunction	シャント機能不全	0(0.0)	1(0.6)
Post-traumatic pain	外傷後疼痛	0(0.0)	1(0.6)
Procedural headache	処置による頭痛	0(0.0)	1(0.6)
Haemodialysis complication	血液透析合併症	0(0.0)	1(0.6)
Dialysis related complication	透析関連合併症	0(0.0)	1(0.6)
Closed globe injury	閉鎖性眼球損傷	0(0.0)	1(0.6)
Surgical and medical procedures	外科および内科処置	0(0.0)	2(1.2)
Renal transplant	腎移植	0(0.0)	2(1.2)

Note(s): MedDRA Version 20.1 and MedDRA/J Version 20.1.
Data Source: Listing 16.2.5.1
Source: t_14_3_1_2_1.sas

5.3.5.1—9 表 12.2.3—1 より引用

表 2.7.4.9－56　副作用の内訳（MT-6548-J03 試験／52 週）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548(N=162) n (%)	darbepoetin(N=161) n (%)
Subjects with at least one adverse drug reaction		18(11.1)	6(3.7)
Infections and infestations	感染症および寄生虫症	1(0.6)	0(0.0)
Gastroenteritis	胃腸炎	1(0.6)	0(0.0)
Blood and lymphatic system disorders	血液およびリンパ系障害	1(0.6)	0(0.0)
Polycythaemia	赤血球増加症	1(0.6)	0(0.0)
Vascular disorders	血管障害	2(1.2)	0(0.0)
Hypertension	高血圧	2(1.2)	0(0.0)
Gastrointestinal disorders	胃腸障害	10(6.2)	2(1.2)
Diarrhoea	下痢	4(2.5)	2(1.2)
Nausea	悪心	3(1.9)	0(0.0)
Abdominal discomfort	腹部不快感	2(1.2)	0(0.0)
Vomiting	嘔吐	2(1.2)	0(0.0)
Stomatitis	口内炎	1(0.6)	0(0.0)
Hepatobiliary disorders	肝胆道系障害	0(0.0)	2(1.2)
Hepatic function abnormal	肝機能異常	0(0.0)	2(1.2)
Skin and subcutaneous tissue disorders	皮膚および皮下組織障害	4(2.5)	0(0.0)
Alopecia	脱毛症	1(0.6)	0(0.0)
Cold sweat	冷汗	1(0.6)	0(0.0)
Drug eruption	薬疹	1(0.6)	0(0.0)
Pruritus	そう痒症	1(0.6)	0(0.0)
Renal and urinary disorders	腎および尿路障害	1(0.6)	0(0.0)
Pollakiuria	頻尿	1(0.6)	0(0.0)
General disorders and administration site conditions	一般・全身障害および投与部位の状態	1(0.6)	0(0.0)
Chest discomfort	胸部不快感	1(0.6)	0(0.0)

表 2.7.4.9－56　副作用の内訳（MT-6548-J03 試験／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548(N=162) n (%)	darbepoetin(N=161) n (%)
Investigations	臨床検査	2(1.2)	2(1.2)
Aspartate aminotransferase increased	アスパラギン酸アミノトランスフェラーゼ増加	1(0.6)	0(0.0)
Serum ferritin decreased	血清フェリチン減少	1(0.6)	0(0.0)
Transferrin saturation decreased	トランスフェリン飽和度低下	1(0.6)	0(0.0)
Gamma-glutamyltransferase increased	γ－グルタミルトランスフェラーゼ増加	0(0.0)	1(0.6)
Haemoglobin increased	ヘモグロビン増加	0(0.0)	1(0.6)

Note(s): MedDRA Version 20.1 and MedDRA/J Version 20.1.
Data Source: Listing 16.2.5.1
Source: t_14_3_1_3_1.sas

5.3.5.1—9 表 12.2.3—2 より引用

表 2.7.4.9－57　有害事象の内訳（ISS-1／52 週）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 NDD (N=202) n(%)	MT-6548 HD (N=237) n(%)	MT-6548 PD (N=42) n(%)	MT-6548 Total (N=481) n(%)
Subjects with at least one adverse event		177(87.6)	218(92.0)	38(90.5)	433(90.0)
Infections and infestations	感染症および寄生虫症	90(44.6)	138(58.2)	22(52.4)	250(52.0)
Nasopharyngitis	上咽頭炎	42(20.8)	91(38.4)	6(14.3)	139(28.9)
Influenza	インフルエンザ	11(5.4)	9(3.8)	0(0.0)	20(4.2)
Conjunctivitis	結膜炎	7(3.5)	12(5.1)	1(2.4)	20(4.2)
Gastroenteritis	胃腸炎	4(2.0)	13(5.5)	0(0.0)	17(3.5)
Pneumonia	肺炎	4(2.0)	10(4.2)	1(2.4)	15(3.1)
Upper respiratory tract infection	上気道感染	3(1.5)	8(3.4)	2(4.8)	13(2.7)
Bronchitis	気管支炎	5(2.5)	6(2.5)	1(2.4)	12(2.5)
Cystitis	膀胱炎	7(3.5)	3(1.3)	0(0.0)	10(2.1)
Catheter site infection	カテーテル留置部位感染	0(0.0)	0(0.0)	10(23.8)	10(2.1)
Urinary tract infection	尿路感染	7(3.5)	0(0.0)	0(0.0)	7(1.5)
Herpes zoster	帯状疱疹	2(1.0)	5(2.1)	0(0.0)	7(1.5)
Periodontitis	歯周炎	2(1.0)	4(1.7)	0(0.0)	6(1.2)
Cellulitis	蜂巣炎	3(1.5)	1(0.4)	1(2.4)	5(1.0)
Pharyngitis	咽頭炎	2(1.0)	3(1.3)	0(0.0)	5(1.0)
Hordeolum	麦粒腫	0(0.0)	5(2.1)	0(0.0)	5(1.0)
Peritonitis	腹膜炎	0(0.0)	0(0.0)	5(11.9)	5(1.0)
Otitis media	中耳炎	2(1.0)	2(0.8)	0(0.0)	4(0.8)
Sinusitis	副鼻腔炎	2(1.0)	1(0.4)	0(0.0)	3(0.6)
Dermatophytosis of nail	爪の皮膚糸状菌症	1(0.5)	2(0.8)	0(0.0)	3(0.6)
Shunt infection	シャント感染	0(0.0)	3(1.3)	0(0.0)	3(0.6)
Enteritis infectious	感染性腸炎	0(0.0)	3(1.3)	0(0.0)	3(0.6)

表 2.7.4.9－57　有害事象の内訳（ISS-1／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 NDD (N=202) n(%)	MT-6548 HD (N=237) n(%)	MT-6548 PD (N=42) n(%)	MT-6548 Total (N=481) n(%)
Herpes simplex	単純ヘルペス	2(1.0)	0(0.0)	0(0.0)	2(0.4)
Rhinitis	鼻炎	2(1.0)	0(0.0)	0(0.0)	2(0.4)
Renal cyst infection	腎嚢胞感染	2(1.0)	0(0.0)	0(0.0)	2(0.4)
Gingivitis	歯肉炎	1(0.5)	1(0.4)	0(0.0)	2(0.4)
Osteomyelitis	骨髄炎	1(0.5)	1(0.4)	0(0.0)	2(0.4)
Paronychia	爪囲炎	1(0.5)	1(0.4)	0(0.0)	2(0.4)
Pyelonephritis	腎盂腎炎	1(0.5)	1(0.4)	0(0.0)	2(0.4)
Upper respiratory tract infection bacterial	細菌性上気道感染	1(0.5)	1(0.4)	0(0.0)	2(0.4)
Body tinea	体部白癬	1(0.5)	0(0.0)	1(2.4)	2(0.4)
Diverticulitis	憩室炎	1(0.5)	0(0.0)	1(2.4)	2(0.4)
Otitis media chronic	慢性中耳炎	0(0.0)	2(0.8)	0(0.0)	2(0.4)
Skin infection	皮膚感染	0(0.0)	2(0.8)	0(0.0)	2(0.4)
Tinea pedis	足部白癬	0(0.0)	2(0.8)	0(0.0)	2(0.4)
Infected dermal cyst	感染性皮膚嚢腫	0(0.0)	2(0.8)	0(0.0)	2(0.4)
Aspergilloma	アスペルギローマ	1(0.5)	0(0.0)	0(0.0)	1(0.2)
Mediastinal abscess	縦隔洞膿瘍	1(0.5)	0(0.0)	0(0.0)	1(0.2)
Otitis externa	外耳炎	1(0.5)	0(0.0)	0(0.0)	1(0.2)
Pneumonia chlamydial	クラミジア性肺炎	1(0.5)	0(0.0)	0(0.0)	1(0.2)
Pyelonephritis acute	急性腎盂腎炎	1(0.5)	0(0.0)	0(0.0)	1(0.2)
Tinea cruris	股部白癬	1(0.5)	0(0.0)	0(0.0)	1(0.2)
Tonsillitis	扁桃炎	1(0.5)	0(0.0)	0(0.0)	1(0.2)
Abscess limb	四肢膿瘍	1(0.5)	0(0.0)	0(0.0)	1(0.2)
Lung infection	肺感染	1(0.5)	0(0.0)	0(0.0)	1(0.2)

表 2.7.4.9－57　有害事象の内訳（ISS-1／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 NDD (N=202) n(%)	MT-6548 HD (N=237) n(%)	MT-6548 PD (N=42) n(%)	MT-6548 Total (N=481) n(%)
Chronic sinusitis	慢性副鼻腔炎	0(0.0)	1(0.4)	0(0.0)	1(0.2)
Dermatitis infected	感染性皮膚炎	0(0.0)	1(0.4)	0(0.0)	1(0.2)
Epididymitis	精巣上体炎	0(0.0)	1(0.4)	0(0.0)	1(0.2)
Furuncle	せつ	0(0.0)	1(0.4)	0(0.0)	1(0.2)
Gastroenteritis viral	ウイルス性胃腸炎	0(0.0)	1(0.4)	0(0.0)	1(0.2)
Hydrocele male infected	感染性陰嚢水瘤	0(0.0)	1(0.4)	0(0.0)	1(0.2)
Tracheobronchitis	気管気管支炎	0(0.0)	1(0.4)	0(0.0)	1(0.2)
Hepatic cyst infection	肝嚢胞感染	0(0.0)	1(0.4)	0(0.0)	1(0.2)
Bacterial infection	細菌感染	0(0.0)	1(0.4)	0(0.0)	1(0.2)
Oral herpes	口腔ヘルペス	0(0.0)	1(0.4)	0(0.0)	1(0.2)
Vascular device infection	血管デバイス感染	0(0.0)	1(0.4)	0(0.0)	1(0.2)
Folliculitis	毛包炎	0(0.0)	0(0.0)	1(2.4)	1(0.2)
Sepsis	敗血症	0(0.0)	0(0.0)	1(2.4)	1(0.2)
Helicobacter infection	ヘリコバクター感染	0(0.0)	0(0.0)	1(2.4)	1(0.2)

表 2.7.4.9－57　有害事象の内訳（ISS-1／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 NDD (N=202) n(%)	MT-6548 HD (N=237) n(%)	MT-6548 PD (N=42) n(%)	MT-6548 Total (N=481) n(%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	2(1.0)	8(3.4)	0(0.0)	10(2.1)
Colon adenoma	大腸腺腫	1(0.5)	0(0.0)	0(0.0)	1(0.2)
Oral papilloma	口腔乳頭腫	1(0.5)	0(0.0)	0(0.0)	1(0.2)
Breast cancer	乳癌	0(0.0)	1(0.4)	0(0.0)	1(0.2)
Cholesteatoma	真珠腫	0(0.0)	1(0.4)	0(0.0)	1(0.2)
Gastric cancer	胃癌	0(0.0)	1(0.4)	0(0.0)	1(0.2)
Laryngeal papilloma	喉頭乳頭腫	0(0.0)	1(0.4)	0(0.0)	1(0.2)
Seborrhoeic keratosis	脂漏性角化症	0(0.0)	1(0.4)	0(0.0)	1(0.2)
Skin papilloma	皮膚乳頭腫	0(0.0)	1(0.4)	0(0.0)	1(0.2)
Squamous cell carcinoma of skin	皮膚有棘細胞癌	0(0.0)	1(0.4)	0(0.0)	1(0.2)
Uterine leiomyoma	子宮平滑筋腫	0(0.0)	1(0.4)	0(0.0)	1(0.2)
Blood and lymphatic system disorders	血液およびリンパ系障害	2(1.0)	10(4.2)	2(4.8)	14(2.9)
Anaemia	貧血	0(0.0)	2(0.8)	1(2.4)	3(0.6)
Iron deficiency anaemia	鉄欠乏性貧血	2(1.0)	0(0.0)	0(0.0)	2(0.4)
Anaemia macrocytic	大球性貧血	0(0.0)	2(0.8)	0(0.0)	2(0.4)
Nephrogenic anaemia	腎性貧血	0(0.0)	1(0.4)	1(2.4)	2(0.4)
Eosinophilia	好酸球増加症	0(0.0)	1(0.4)	0(0.0)	1(0.2)
Lymphadenitis	リンパ節炎	0(0.0)	1(0.4)	0(0.0)	1(0.2)
Lymphadenopathy	リンパ節症	0(0.0)	1(0.4)	0(0.0)	1(0.2)
Polycythaemia	赤血球増加症	0(0.0)	1(0.4)	0(0.0)	1(0.2)
Blood loss anaemia	失血性貧血	0(0.0)	1(0.4)	0(0.0)	1(0.2)

表 2.7.4.9－57　有害事象の内訳（ISS-1／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 NDD (N=202) n(%)	MT-6548 HD (N=237) n(%)	MT-6548 PD (N=42) n(%)	MT-6548 Total (N=481) n(%)
Immune system disorders	免疫系障害	3(1.5)	4(1.7)	0(0.0)	7(1.5)
Seasonal allergy	季節性アレルギー	1(0.5)	4(1.7)	0(0.0)	5(1.0)
Allergy to arthropod sting	節足動物刺傷アレルギー	1(0.5)	0(0.0)	0(0.0)	1(0.2)
Allergy to arthropod bite	節足動物咬傷アレルギー	1(0.5)	0(0.0)	0(0.0)	1(0.2)
Endocrine disorders	内分泌障害	2(1.0)	3(1.3)	0(0.0)	5(1.0)
Hypothyroidism	甲状腺機能低下症	1(0.5)	1(0.4)	0(0.0)	2(0.4)
Hyperparathyroidism secondary	続発性副甲状腺機能亢進症	0(0.0)	2(0.8)	0(0.0)	2(0.4)
Parathyroid gland enlargement	副甲状腺肥大	1(0.5)	0(0.0)	0(0.0)	1(0.2)

表 2.7.4.9－57　有害事象の内訳（ISS-1／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 NDD (N=202) n(%)	HD (N=237) n(%)	PD (N=42) n(%)	Total (N=481) n(%)
Metabolism and nutrition disorders	代謝および栄養障害	29(14.4)	20(8.4)	5(11.9)	54(11.2)
Decreased appetite	食欲減退	3(1.5)	9(3.8)	3(7.1)	15(3.1)
Hyperkalaemia	高カリウム血症	5(2.5)	1(0.4)	0(0.0)	6(1.2)
Hyperphosphataemia	高リン酸塩血症	3(1.5)	2(0.8)	1(2.4)	6(1.2)
Hyperuricaemia	高尿酸血症	5(2.5)	0(0.0)	0(0.0)	5(1.0)
Dehydration	脱水	3(1.5)	0(0.0)	1(2.4)	4(0.8)
Hypocarnitinaemia	低カルニチン血症	0(0.0)	4(1.7)	0(0.0)	4(0.8)
Metabolic acidosis	代謝性アシドーシス	3(1.5)	0(0.0)	0(0.0)	3(0.6)
Hypoglycaemia	低血糖	2(1.0)	1(0.4)	0(0.0)	3(0.6)
Hypoalbuminaemia	低アルブミン血症	1(0.5)	1(0.4)	1(2.4)	3(0.6)
Diabetes mellitus	糖尿病	2(1.0)	0(0.0)	0(0.0)	2(0.4)
Hypocalcaemia	低カルシウム血症	1(0.5)	1(0.4)	0(0.0)	2(0.4)
Dyslipidaemia	脂質異常症	1(0.5)	1(0.4)	0(0.0)	2(0.4)
Fluid retention	体液貯留	1(0.5)	0(0.0)	0(0.0)	1(0.2)
Hyponatraemia	低ナトリウム血症	1(0.5)	0(0.0)	0(0.0)	1(0.2)
Hypoproteinaemia	低蛋白血症	1(0.5)	0(0.0)	0(0.0)	1(0.2)
Hyperlipidaemia	高脂血症	1(0.5)	0(0.0)	0(0.0)	1(0.2)
Hyperamylasaemia	高アミラーゼ血症	1(0.5)	0(0.0)	0(0.0)	1(0.2)
Type 2 diabetes mellitus	2型糖尿病	1(0.5)	0(0.0)	0(0.0)	1(0.2)
Hypercalcaemia	高カルシウム血症	0(0.0)	1(0.4)	0(0.0)	1(0.2)
Fluid overload	水分過負荷	0(0.0)	0(0.0)	1(2.4)	1(0.2)
Hypokalaemia	低カリウム血症	0(0.0)	0(0.0)	1(2.4)	1(0.2)

表 2.7.4.9－57　有害事象の内訳（ISS-1／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 NDD (N=202) n(%)	HD (N=237) n(%)	PD (N=42) n(%)	Total (N=481) n(%)
Psychiatric disorders	精神障害	9(4.5)	10(4.2)	3(7.1)	22(4.6)
Insomnia	不眠症	6(3.0)	8(3.4)	2(4.8)	16(3.3)
Delirium	譫妄	2(1.0)	0(0.0)	0(0.0)	2(0.4)
Anxiety	不安	1(0.5)	1(0.4)	0(0.0)	2(0.4)
Depression	うつ病	1(0.5)	1(0.4)	0(0.0)	2(0.4)
Abnormal behaviour	異常行動	0(0.0)	1(0.4)	0(0.0)	1(0.2)
Sleep disorder	睡眠障害	0(0.0)	0(0.0)	1(2.4)	1(0.2)

表 2.7.4.9－57　有害事象の内訳（ISS-1／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 NDD (N=202) n(%)	HD (N=237) n(%)	PD (N=42) n(%)	Total (N=481) n(%)
Nervous system disorders	神経系障害	13(6.4)	47(19.8)	5(11.9)	65(13.5)
Headache	頭痛	6(3.0)	20(8.4)	0(0.0)	26(5.4)
Dizziness	浮動性めまい	3(1.5)	8(3.4)	1(2.4)	12(2.5)
Hypoaesthesia	感覚鈍麻	1(0.5)	1(0.4)	0(0.0)	2(0.4)
Intracranial aneurysm	頭蓋内動脈瘤	1(0.5)	1(0.4)	0(0.0)	2(0.4)
Somnolence	傾眠	1(0.5)	1(0.4)	0(0.0)	2(0.4)
Neuropathy peripheral	末梢性ニューロパチー	1(0.5)	0(0.0)	1(2.4)	2(0.4)
Carpal tunnel syndrome	手根管症候群	0(0.0)	2(0.8)	0(0.0)	2(0.4)
Facial paralysis	顔面麻痺	0(0.0)	2(0.8)	0(0.0)	2(0.4)
Restless legs syndrome	下肢静止不能症候群	0(0.0)	2(0.8)	0(0.0)	2(0.4)
Cerebral infarction	脳梗塞	0(0.0)	1(0.4)	1(2.4)	2(0.4)
Hypoglycaemic coma	低血糖昏睡	1(0.5)	0(0.0)	0(0.0)	1(0.2)
Loss of consciousness	意識消失	1(0.5)	0(0.0)	0(0.0)	1(0.2)
Presyncope	失神寸前の状態	1(0.5)	0(0.0)	0(0.0)	1(0.2)
Subarachnoid haemorrhage	くも膜下出血	1(0.5)	0(0.0)	0(0.0)	1(0.2)
Carotid artery stenosis	頸動脈狭窄	0(0.0)	1(0.4)	0(0.0)	1(0.2)
Cerebellar infarction	小脳梗塞	0(0.0)	1(0.4)	0(0.0)	1(0.2)
Cerebral haemorrhage	脳出血	0(0.0)	1(0.4)	0(0.0)	1(0.2)
Diabetic neuropathy	糖尿病性ニューロパチー	0(0.0)	1(0.4)	0(0.0)	1(0.2)
Dizziness postural	体位性めまい	0(0.0)	1(0.4)	0(0.0)	1(0.2)
Myelopathy	脊髄症	0(0.0)	1(0.4)	0(0.0)	1(0.2)
Myoclonus	ミオクローヌス	0(0.0)	1(0.4)	0(0.0)	1(0.2)
Neuralgia	神経痛	0(0.0)	1(0.4)	0(0.0)	1(0.2)

表 2.7.4.9－57　有害事象の内訳（ISS-1／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 NDD (N=202) n(%)	MT-6548 HD (N=237) n(%)	MT-6548 PD (N=42) n(%)	MT-6548 Total (N=481) n(%)
Post herpetic neuralgia	ヘルペス後神経痛	0(0.0)	1(0.4)	0(0.0)	1(0.2)
Sciatica	坐骨神経痛	0(0.0)	1(0.4)	0(0.0)	1(0.2)
Toxic encephalopathy	中毒性脳症	0(0.0)	1(0.4)	0(0.0)	1(0.2)
Tremor	振戦	0(0.0)	1(0.4)	0(0.0)	1(0.2)
Intercostal neuralgia	肋間神経痛	0(0.0)	1(0.4)	0(0.0)	1(0.2)
Cervical radiculopathy	頚髄神経根障害	0(0.0)	1(0.4)	0(0.0)	1(0.2)
Lacunar infarction	ラクナ梗塞	0(0.0)	1(0.4)	0(0.0)	1(0.2)
Thrombotic cerebral infarction	血栓性脳梗塞	0(0.0)	1(0.4)	0(0.0)	1(0.2)
Dizziness exertional	労作性めまい	0(0.0)	0(0.0)	1(2.4)	1(0.2)
Dysgeusia	味覚異常	0(0.0)	0(0.0)	1(2.4)	1(0.2)

表 2.7.4.9－57　有害事象の内訳（ISS-1／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 NDD (N=202) n(%)	HD (N=237) n(%)	PD (N=42) n(%)	Total (N=481) n(%)
Eye disorders	眼障害	19(9.4)	37(15.6)	6(14.3)	62(12.9)
Retinal haemorrhage	網膜出血	2(1.0)	16(6.8)	2(4.8)	20(4.2)
Dry eye	ドライアイ	4(2.0)	2(0.8)	1(2.4)	7(1.5)
Conjunctival haemorrhage	結膜出血	3(1.5)	4(1.7)	0(0.0)	7(1.5)
Cataract	白内障	4(2.0)	2(0.8)	0(0.0)	6(1.2)
Blepharitis	眼瞼炎	3(1.5)	1(0.4)	0(0.0)	4(0.8)
Retinal vein occlusion	網膜静脈閉塞	1(0.5)	1(0.4)	1(2.4)	3(0.6)
Diabetic retinopathy	糖尿病網膜症	0(0.0)	3(1.3)	0(0.0)	3(0.6)
Glaucoma	緑内障	1(0.5)	1(0.4)	0(0.0)	2(0.4)
Macular oedema	黄斑浮腫	1(0.5)	1(0.4)	0(0.0)	2(0.4)
Eczema eyelids	眼瞼湿疹	1(0.5)	0(0.0)	0(0.0)	1(0.2)
Retinal exudates	網膜滲出物	1(0.5)	0(0.0)	0(0.0)	1(0.2)
Age-related macular degeneration	加齢黄斑変性	1(0.5)	0(0.0)	0(0.0)	1(0.2)
Conjunctivitis allergic	アレルギー性結膜炎	0(0.0)	1(0.4)	0(0.0)	1(0.2)
Diplopia	複視	0(0.0)	1(0.4)	0(0.0)	1(0.2)
Keratitis	角膜炎	0(0.0)	1(0.4)	0(0.0)	1(0.2)
Ocular hyperaemia	眼充血	0(0.0)	1(0.4)	0(0.0)	1(0.2)
Optic disc haemorrhage	視神経乳頭出血	0(0.0)	1(0.4)	0(0.0)	1(0.2)
Punctate keratitis	点状角膜炎	0(0.0)	1(0.4)	0(0.0)	1(0.2)
Retinal oedema	網膜浮腫	0(0.0)	1(0.4)	0(0.0)	1(0.2)
Trichiasis	睫毛乱生	0(0.0)	1(0.4)	0(0.0)	1(0.2)
Vitreous floaters	硝子体浮遊物	0(0.0)	1(0.4)	0(0.0)	1(0.2)
Eye pruritus	眼そう痒症	0(0.0)	1(0.4)	0(0.0)	1(0.2)

表 2.7.4.9－57　有害事象の内訳（ISS-1／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 NDD (N=202) n(%)	MT-6548 HD (N=237) n(%)	MT-6548 PD (N=42) n(%)	MT-6548 Total (N=481) n(%)
Cystoid macular oedema	嚢胞様黄斑浮腫	0(0.0)	1(0.4)	0(0.0)	1(0.2)
Chorioretinopathy	網脈絡膜症	0(0.0)	1(0.4)	0(0.0)	1(0.2)
Eyelid haematoma	眼瞼血腫	0(0.0)	1(0.4)	0(0.0)	1(0.2)
Macular degeneration	黄斑変性	0(0.0)	0(0.0)	1(2.4)	1(0.2)
Meibomian gland dysfunction	マイボーム腺機能不全	0(0.0)	0(0.0)	1(2.4)	1(0.2)
Macular fibrosis	黄斑線維症	0(0.0)	0(0.0)	1(2.4)	1(0.2)
Ear and labyrinth disorders	耳および迷路障害	4(2.0)	9(3.8)	0(0.0)	13(2.7)
Vertigo	回転性めまい	2(1.0)	6(2.5)	0(0.0)	8(1.7)
Vertigo positional	頭位性回転性めまい	2(1.0)	1(0.4)	0(0.0)	3(0.6)
Ear congestion	耳閉	1(0.5)	0(0.0)	0(0.0)	1(0.2)
Deafness	難聴	0(0.0)	1(0.4)	0(0.0)	1(0.2)
Sudden hearing loss	突発性難聴	0(0.0)	1(0.4)	0(0.0)	1(0.2)
Eustachian tube stenosis	耳管狭窄	0(0.0)	1(0.4)	0(0.0)	1(0.2)

表 2.7.4.9－57　有害事象の内訳（ISS-1／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 NDD (N=202) n(%)	MT-6548 HD (N=237) n(%)	MT-6548 PD (N=42) n(%)	MT-6548 Total (N=481) n(%)
Cardiac disorders	心臓障害	11(5.4)	17(7.2)	2(4.8)	30(6.2)
Cardiac failure chronic	慢性心不全	3(1.5)	1(0.4)	1(2.4)	5(1.0)
Cardiac failure congestive	うっ血性心不全	2(1.0)	2(0.8)	0(0.0)	4(0.8)
Atrial fibrillation	心房細動	2(1.0)	1(0.4)	0(0.0)	3(0.6)
Myocardial ischaemia	心筋虚血	1(0.5)	1(0.4)	1(2.4)	3(0.6)
Cardiac failure	心不全	1(0.5)	1(0.4)	0(0.0)	2(0.4)
Palpitations	動悸	1(0.5)	1(0.4)	0(0.0)	2(0.4)
Tachycardia paroxysmal	発作性頻脈	0(0.0)	2(0.8)	0(0.0)	2(0.4)
Cardiac dysfunction	心機能障害	0(0.0)	2(0.8)	0(0.0)	2(0.4)
Atrial flutter	心房粗動	1(0.5)	0(0.0)	0(0.0)	1(0.2)
Bradycardia	徐脈	1(0.5)	0(0.0)	0(0.0)	1(0.2)
Ventricular tachycardia	心室性頻脈	1(0.5)	0(0.0)	0(0.0)	1(0.2)
Angina pectoris	狭心症	0(0.0)	1(0.4)	0(0.0)	1(0.2)
Angina unstable	不安定狭心症	0(0.0)	1(0.4)	0(0.0)	1(0.2)
Aortic valve incompetence	大動脈弁閉鎖不全症	0(0.0)	1(0.4)	0(0.0)	1(0.2)
Arrhythmia	不整脈	0(0.0)	1(0.4)	0(0.0)	1(0.2)
Arteriosclerosis coronary artery	冠動脈硬化症	0(0.0)	1(0.4)	0(0.0)	1(0.2)
Coronary artery stenosis	冠動脈狭窄	0(0.0)	1(0.4)	0(0.0)	1(0.2)
Mitral valve incompetence	僧帽弁閉鎖不全症	0(0.0)	1(0.4)	0(0.0)	1(0.2)
Mitral valve stenosis	僧帽弁狭窄症	0(0.0)	1(0.4)	0(0.0)	1(0.2)
Pericarditis	心膜炎	0(0.0)	1(0.4)	0(0.0)	1(0.2)
Paroxysmal arrhythmia	発作性不整脈	0(0.0)	1(0.4)	0(0.0)	1(0.2)

表 2.7.4.9－57　有害事象の内訳（ISS-1／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 NDD (N=202) n(%)	HD (N=237) n(%)	PD (N=42) n(%)	Total (N=481) n(%)
Vascular disorders	血管障害	14(6.9)	23(9.7)	6(14.3)	43(8.9)
Hypertension	高血圧	7(3.5)	6(2.5)	0(0.0)	13(2.7)
Hypotension	低血圧	1(0.5)	5(2.1)	1(2.4)	7(1.5)
Peripheral arterial occlusive disease	末梢動脈閉塞性疾患	0(0.0)	4(1.7)	2(4.8)	6(1.2)
Internal haemorrhage	内出血	1(0.5)	3(1.3)	0(0.0)	4(0.8)
Orthostatic hypotension	起立性低血圧	1(0.5)	1(0.4)	1(2.4)	3(0.6)
Haemorrhage	出血	0(0.0)	2(0.8)	0(0.0)	2(0.4)
Arteriosclerosis	動脈硬化症	0(0.0)	0(0.0)	2(4.8)	2(0.4)
Aortic aneurysm	大動脈瘤	1(0.5)	0(0.0)	0(0.0)	1(0.2)
Varicose vein	静脈瘤	1(0.5)	0(0.0)	0(0.0)	1(0.2)
Vasculitis	血管炎	1(0.5)	0(0.0)	0(0.0)	1(0.2)
Vascular rupture	血管破裂	1(0.5)	0(0.0)	0(0.0)	1(0.2)
Aneurysm	動脈瘤	0(0.0)	1(0.4)	0(0.0)	1(0.2)
Vascular pain	血管痛	0(0.0)	1(0.4)	0(0.0)	1(0.2)
Vascular insufficiency	血行不全	0(0.0)	1(0.4)	0(0.0)	1(0.2)

表 2.7.4.9－57　有害事象の内訳（ISS-1／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 NDD (N=202) n(%)	MT-6548 HD (N=237) n(%)	MT-6548 PD (N=42) n(%)	MT-6548 Total (N=481) n(%)
Respiratory, thoracic and mediastinal disorders	呼吸器、胸郭および縦隔障害	16(7.9)	28(11.8)	3(7.1)	47(9.8)
Cough	咳嗽	4(2.0)	3(1.3)	2(4.8)	9(1.9)
Rhinitis allergic	アレルギー性鼻炎	2(1.0)	6(2.5)	0(0.0)	8(1.7)
Upper respiratory tract inflammation	上気道の炎症	0(0.0)	5(2.1)	1(2.4)	6(1.2)
Epistaxis	鼻出血	1(0.5)	4(1.7)	0(0.0)	5(1.0)
Pleural effusion	胸水	2(1.0)	1(0.4)	0(0.0)	3(0.6)
Asthma	喘息	1(0.5)	2(0.8)	0(0.0)	3(0.6)
Pulmonary congestion	肺うっ血	2(1.0)	0(0.0)	0(0.0)	2(0.4)
Haemoptysis	喀血	1(0.5)	1(0.4)	0(0.0)	2(0.4)
Pulmonary oedema	肺水腫	0(0.0)	2(0.8)	0(0.0)	2(0.4)
Sleep apnoea syndrome	睡眠時無呼吸症候群	0(0.0)	2(0.8)	0(0.0)	2(0.4)
Oropharyngeal pain	口腔咽頭痛	0(0.0)	2(0.8)	0(0.0)	2(0.4)
Interstitial lung disease	間質性肺疾患	1(0.5)	0(0.0)	0(0.0)	1(0.2)
Pulmonary hypertension	肺高血圧症	1(0.5)	0(0.0)	0(0.0)	1(0.2)
Rhinorrhoea	鼻漏	1(0.5)	0(0.0)	0(0.0)	1(0.2)
Reflux laryngitis	逆流性喉頭炎	1(0.5)	0(0.0)	0(0.0)	1(0.2)
Hiccups	しゃっくり	0(0.0)	1(0.4)	0(0.0)	1(0.2)
Pneumonia aspiration	誤嚥性肺炎	0(0.0)	1(0.4)	0(0.0)	1(0.2)
Sputum increased	喀痰増加	0(0.0)	1(0.4)	0(0.0)	1(0.2)

表 2.7.4.9－57　有害事象の内訳（ISS-1／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 NDD (N=202) n(%)	MT-6548 HD (N=237) n(%)	MT-6548 PD (N=42) n(%)	MT-6548 Total (N=481) n(%)
Gastrointestinal disorders	胃腸障害	74(36.6)	89(37.6)	18(42.9)	181(37.6)
Diarrhoea	下痢	21(10.4)	36(15.2)	8(19.0)	65(13.5)
Vomiting	嘔吐	11(5.4)	13(5.5)	4(9.5)	28(5.8)
Constipation	便秘	17(8.4)	9(3.8)	1(2.4)	27(5.6)
Nausea	悪心	9(4.5)	12(5.1)	3(7.1)	24(5.0)
Dental caries	齲歯	6(3.0)	5(2.1)	1(2.4)	12(2.5)
Gastrooesophageal reflux disease	胃食道逆流性疾患	4(2.0)	6(2.5)	0(0.0)	10(2.1)
Abdominal pain	腹痛	4(2.0)	4(1.7)	0(0.0)	8(1.7)
Abdominal discomfort	腹部不快感	2(1.0)	4(1.7)	2(4.8)	8(1.7)
Stomatitis	口内炎	3(1.5)	3(1.3)	0(0.0)	6(1.2)
Abdominal pain upper	上腹部痛	3(1.5)	0(0.0)	3(7.1)	6(1.2)
Enterocolitis	腸炎	1(0.5)	3(1.3)	2(4.8)	6(1.2)
Gastritis	胃炎	2(1.0)	3(1.3)	0(0.0)	5(1.0)
Haemorrhoids	痔核	1(0.5)	4(1.7)	0(0.0)	5(1.0)
Abdominal distension	腹部膨満	3(1.5)	1(0.4)	0(0.0)	4(0.8)
Chronic gastritis	慢性胃炎	2(1.0)	2(0.8)	0(0.0)	4(0.8)
Large intestine polyp	大腸ポリープ	1(0.5)	3(1.3)	0(0.0)	4(0.8)
Faeces soft	軟便	1(0.5)	2(0.8)	0(0.0)	3(0.6)
Gastric ulcer	胃潰瘍	0(0.0)	3(1.3)	0(0.0)	3(0.6)
Toothache	歯痛	0(0.0)	3(1.3)	0(0.0)	3(0.6)
Gastric polyps	胃ポリープ	0(0.0)	1(0.4)	2(4.8)	3(0.6)
Periodontal disease	歯周病	2(1.0)	0(0.0)	0(0.0)	2(0.4)
Angular cheilitis	口角口唇炎	1(0.5)	1(0.4)	0(0.0)	2(0.4)

表 2.7.4.9－57　有害事象の内訳（ISS-1／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 NDD (N=202) n(%)	HD (N=237) n(%)	PD (N=42) n(%)	Total (N=481) n(%)
Diverticulum intestinal	腸憩室	1(0.5)	1(0.4)	0(0.0)	2(0.4)
Duodenal ulcer haemorrhage	出血性十二指腸潰瘍	1(0.5)	1(0.4)	0(0.0)	2(0.4)
Mouth haemorrhage	口腔内出血	1(0.5)	1(0.4)	0(0.0)	2(0.4)
Gingival bleeding	歯肉出血	1(0.5)	0(0.0)	1(2.4)	2(0.4)
Duodenal ulcer	十二指腸潰瘍	0(0.0)	2(0.8)	0(0.0)	2(0.4)
Dyspepsia	消化不良	0(0.0)	2(0.8)	0(0.0)	2(0.4)
Gastrointestinal disorder	胃腸障害	1(0.5)	0(0.0)	0(0.0)	1(0.2)
Oesophageal achalasia	食道アカラシア	1(0.5)	0(0.0)	0(0.0)	1(0.2)
Tooth loss	歯の脱落	1(0.5)	0(0.0)	0(0.0)	1(0.2)
Gastrointestinal polyp haemorrhage	胃腸ポリープ出血	1(0.5)	0(0.0)	0(0.0)	1(0.2)
Abdominal pain lower	下腹部痛	0(0.0)	1(0.4)	0(0.0)	1(0.2)
Barrett's oesophagus	バレット食道	0(0.0)	1(0.4)	0(0.0)	1(0.2)
Dry mouth	口内乾燥	0(0.0)	1(0.4)	0(0.0)	1(0.2)
Duodenal polyp	十二指腸ポリープ	0(0.0)	1(0.4)	0(0.0)	1(0.2)
Food poisoning	食中毒	0(0.0)	1(0.4)	0(0.0)	1(0.2)
Gastric ulcer haemorrhage	出血性胃潰瘍	0(0.0)	1(0.4)	0(0.0)	1(0.2)
Gastritis erosive	びらん性胃炎	0(0.0)	1(0.4)	0(0.0)	1(0.2)
Gastritis haemorrhagic	出血性胃炎	0(0.0)	1(0.4)	0(0.0)	1(0.2)
Glossitis	舌炎	0(0.0)	1(0.4)	0(0.0)	1(0.2)
Melaena	メレナ	0(0.0)	1(0.4)	0(0.0)	1(0.2)
Pancreatitis	膵炎	0(0.0)	1(0.4)	0(0.0)	1(0.2)
Rectal ulcer	直腸潰瘍	0(0.0)	1(0.4)	0(0.0)	1(0.2)
Gastric disorder	胃障害	0(0.0)	1(0.4)	0(0.0)	1(0.2)

表 2.7.4.9－57　有害事象の内訳（ISS-1／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 NDD (N=202) n(%)	MT-6548 HD (N=237) n(%)	MT-6548 PD (N=42) n(%)	MT-6548 Total (N=481) n(%)
Gastrointestinal motility disorder	消化管運動障害	0(0.0)	1(0.4)	0(0.0)	1(0.2)
Loose tooth	弛緩歯	0(0.0)	1(0.4)	0(0.0)	1(0.2)
Hiatus hernia	裂孔ヘルニア	0(0.0)	0(0.0)	1(2.4)	1(0.2)
Inguinal hernia	鼠径ヘルニア	0(0.0)	0(0.0)	1(2.4)	1(0.2)
Traumatic occlusion	外傷性咬合	0(0.0)	0(0.0)	1(2.4)	1(0.2)
Hepatobiliary disorders	肝胆道系障害	9(4.5)	6(2.5)	0(0.0)	15(3.1)
Hepatic function abnormal	肝機能異常	4(2.0)	1(0.4)	0(0.0)	5(1.0)
Cholelithiasis	胆石症	1(0.5)	4(1.7)	0(0.0)	5(1.0)
Cholecystitis	胆嚢炎	1(0.5)	1(0.4)	0(0.0)	2(0.4)
Bile duct stone	胆管結石	1(0.5)	0(0.0)	0(0.0)	1(0.2)
Hepatic cirrhosis	肝硬変	1(0.5)	0(0.0)	0(0.0)	1(0.2)
Drug-induced liver injury	薬物性肝障害	1(0.5)	0(0.0)	0(0.0)	1(0.2)
Cholangitis	胆管炎	0(0.0)	1(0.4)	0(0.0)	1(0.2)
Cholecystitis acute	急性胆嚢炎	0(0.0)	1(0.4)	0(0.0)	1(0.2)

表 2.7.4.9－57　有害事象の内訳（ISS-1／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 NDD (N=202) n(%)	HD (N=237) n(%)	PD (N=42) n(%)	Total (N=481) n(%)
Skin and subcutaneous tissue disorders	皮膚および皮下組織障害	37(18.3)	65(27.4)	5(11.9)	107(22.2)
Pruritus	そう痒症	7(3.5)	14(5.9)	0(0.0)	21(4.4)
Eczema	湿疹	6(3.0)	11(4.6)	0(0.0)	17(3.5)
Dermatitis contact	接触皮膚炎	4(2.0)	5(2.1)	2(4.8)	11(2.3)
Haemorrhage subcutaneous	皮下出血	3(1.5)	7(3.0)	0(0.0)	10(2.1)
Rash	発疹	3(1.5)	6(2.5)	1(2.4)	10(2.1)
Eczema asteatotic	皮脂欠乏性湿疹	4(2.0)	2(0.8)	0(0.0)	6(1.2)
Drug eruption	薬疹	1(0.5)	4(1.7)	0(0.0)	5(1.0)
Ingrowing nail	嵌入爪	0(0.0)	5(2.1)	0(0.0)	5(1.0)
Skin exfoliation	皮膚剥脱	0(0.0)	5(2.1)	0(0.0)	5(1.0)
Xeroderma	乾皮症	1(0.5)	3(1.3)	0(0.0)	4(0.8)
Dermatitis	皮膚炎	0(0.0)	3(1.3)	1(2.4)	4(0.8)
Dry skin	皮膚乾燥	3(1.5)	0(0.0)	0(0.0)	3(0.6)
Skin ulcer	皮膚潰瘍	3(1.5)	0(0.0)	0(0.0)	3(0.6)
Dermal cyst	皮膚嚢腫	1(0.5)	2(0.8)	0(0.0)	3(0.6)
Hyperkeratosis	過角化	0(0.0)	3(1.3)	0(0.0)	3(0.6)
Skin erosion	皮膚びらん	2(1.0)	0(0.0)	0(0.0)	2(0.4)
Urticaria	蕁麻疹	2(1.0)	0(0.0)	0(0.0)	2(0.4)
Seborrhoeic dermatitis	脂漏性皮膚炎	1(0.5)	1(0.4)	0(0.0)	2(0.4)
Blister	水疱	0(0.0)	2(0.8)	0(0.0)	2(0.4)
Cold sweat	冷汗	0(0.0)	2(0.8)	0(0.0)	2(0.4)
Decubitus ulcer	褥瘡性潰瘍	1(0.5)	0(0.0)	0(0.0)	1(0.2)
Dermatomyositis	皮膚筋炎	1(0.5)	0(0.0)	0(0.0)	1(0.2)

表 2.7.4.9－57　有害事象の内訳（ISS-1／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 NDD (N=202) n(%)	MT-6548 HD (N=237) n(%)	MT-6548 PD (N=42) n(%)	MT-6548 Total (N=481) n(%)
Prurigo	痒疹	1(0.5)	0(0.0)	0(0.0)	1(0.2)
Pruritus generalised	全身性そう痒症	1(0.5)	0(0.0)	0(0.0)	1(0.2)
Reactive perforating collagenosis	反応性穿孔性膠原線維症	1(0.5)	0(0.0)	0(0.0)	1(0.2)
Acne	ざ瘡	0(0.0)	1(0.4)	0(0.0)	1(0.2)
Alopecia	脱毛症	0(0.0)	1(0.4)	0(0.0)	1(0.2)
Dermatitis acneiform	ざ瘡様皮膚炎	0(0.0)	1(0.4)	0(0.0)	1(0.2)
Erythema	紅斑	0(0.0)	1(0.4)	0(0.0)	1(0.2)
Neurodermatitis	神経皮膚炎	0(0.0)	1(0.4)	0(0.0)	1(0.2)
Rash pruritic	そう痒性皮疹	0(0.0)	1(0.4)	0(0.0)	1(0.2)
Skin disorder	皮膚障害	0(0.0)	1(0.4)	0(0.0)	1(0.2)
Skin mass	皮膚腫瘤	0(0.0)	1(0.4)	0(0.0)	1(0.2)
Hand dermatitis	手皮膚炎	0(0.0)	0(0.0)	1(2.4)	1(0.2)

表 2.7.4.9－57　有害事象の内訳（ISS-1／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 NDD (N=202) n(%)	MT-6548 HD (N=237) n(%)	MT-6548 PD (N=42) n(%)	MT-6548 Total (N=481) n(%)
Musculoskeletal and connective tissue disorders	筋骨格系および結合組織障害	35(17.3)	77(32.5)	4(9.5)	116(24.1)
Back pain	背部痛	9(4.5)	17(7.2)	2(4.8)	28(5.8)
Pain in extremity	四肢痛	3(1.5)	14(5.9)	0(0.0)	17(3.5)
Arthralgia	関節痛	3(1.5)	12(5.1)	1(2.4)	16(3.3)
Muscle spasms	筋痙縮	5(2.5)	10(4.2)	0(0.0)	15(3.1)
Myalgia	筋肉痛	3(1.5)	10(4.2)	0(0.0)	13(2.7)
Musculoskeletal pain	筋骨格痛	1(0.5)	8(3.4)	0(0.0)	9(1.9)
Osteoarthritis	変形性関節症	1(0.5)	7(3.0)	0(0.0)	8(1.7)
Spinal osteoarthritis	変形性脊椎症	3(1.5)	4(1.7)	0(0.0)	7(1.5)
Periarthritis	関節周囲炎	0(0.0)	7(3.0)	0(0.0)	7(1.5)
Arthritis	関節炎	4(2.0)	0(0.0)	1(2.4)	5(1.0)
Osteoporosis	骨粗鬆症	3(1.5)	2(0.8)	0(0.0)	5(1.0)
Lumbar spinal stenosis	腰部脊柱管狭窄症	1(0.5)	4(1.7)	0(0.0)	5(1.0)
Neck pain	頚部痛	1(0.5)	4(1.7)	0(0.0)	5(1.0)
Tenosynovitis	腱鞘炎	1(0.5)	3(1.3)	0(0.0)	4(0.8)
Trigger finger	弾発指	1(0.5)	2(0.8)	0(0.0)	3(0.6)
Synovial cyst	滑液嚢腫	2(1.0)	0(0.0)	0(0.0)	2(0.4)
Bursitis	滑液包炎	1(0.5)	1(0.4)	0(0.0)	2(0.4)
Rotator cuff syndrome	肩回旋筋腱板症候群	1(0.5)	1(0.4)	0(0.0)	2(0.4)
Intervertebral disc protrusion	椎間板突出	1(0.5)	1(0.4)	0(0.0)	2(0.4)
Temporomandibular joint syndrome	顎関節症候群	1(0.5)	0(0.0)	0(0.0)	1(0.2)
Spondylolisthesis	脊椎すべり症	1(0.5)	0(0.0)	0(0.0)	1(0.2)
Chondrocalcinosis pyrophosphate	ピロリン酸カルシウム結晶性軟骨石灰化症	0(0.0)	1(0.4)	0(0.0)	1(0.2)

表 2.7.4.9－57　有害事象の内訳（ISS-1／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 NDD (N=202) n(%)	MT-6548 HD (N=237) n(%)	MT-6548 PD (N=42) n(%)	MT-6548 Total (N=481) n(%)
Haemarthrosis	出血性関節症	0(0.0)	1(0.4)	0(0.0)	1(0.2)
Joint swelling	関節腫脹	0(0.0)	1(0.4)	0(0.0)	1(0.2)
Musculoskeletal chest pain	筋骨格系胸痛	0(0.0)	1(0.4)	0(0.0)	1(0.2)
Musculoskeletal stiffness	筋骨格硬直	0(0.0)	1(0.4)	0(0.0)	1(0.2)
Musculoskeletal discomfort	筋骨格不快感	0(0.0)	1(0.4)	0(0.0)	1(0.2)
Renal and urinary disorders	腎および尿路障害	34(16.8)	6(2.5)	3(7.1)	43(8.9)
Renal impairment	腎機能障害	11(5.4)	0(0.0)	1(2.4)	12(2.5)
Chronic kidney disease	慢性腎臓病	10(5.0)	1(0.4)	0(0.0)	11(2.3)
End stage renal disease	末期腎疾患	4(2.0)	0(0.0)	0(0.0)	4(0.8)
Haematuria	血尿	1(0.5)	1(0.4)	1(2.4)	3(0.6)
Hypertonic bladder	緊張性膀胱	2(1.0)	0(0.0)	0(0.0)	2(0.4)
Renal failure	腎不全	2(1.0)	0(0.0)	0(0.0)	2(0.4)
Pollakiuria	頻尿	1(0.5)	1(0.4)	0(0.0)	2(0.4)
Renal cyst	腎嚢胞	0(0.0)	2(0.8)	0(0.0)	2(0.4)
Oliguria	乏尿	1(0.5)	0(0.0)	0(0.0)	1(0.2)
Urinary retention	尿閉	1(0.5)	0(0.0)	0(0.0)	1(0.2)
Hypertensive nephropathy	高血圧性腎症	1(0.5)	0(0.0)	0(0.0)	1(0.2)
Diabetic nephropathy	糖尿病性腎症	1(0.5)	0(0.0)	0(0.0)	1(0.2)
Acute kidney injury	急性腎障害	1(0.5)	0(0.0)	0(0.0)	1(0.2)
Ureterolithiasis	尿管結石症	0(0.0)	1(0.4)	0(0.0)	1(0.2)
Azotaemia	高窒素血症	0(0.0)	0(0.0)	1(2.4)	1(0.2)

表 2.7.4.9－57　有害事象の内訳（ISS-1／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 NDD (N=202) n(%)	HD (N=237) n(%)	PD (N=42) n(%)	Total (N=481) n(%)
Reproductive system and breast disorders	生殖系および乳房障害	6(3.0)	5(2.1)	1(2.4)	12(2.5)
Benign prostatic hyperplasia	良性前立腺肥大症	4(2.0)	2(0.8)	0(0.0)	6(1.2)
Acquired hydrocele	後天性陰嚢水瘤	0(0.0)	1(0.4)	1(2.4)	2(0.4)
Menstruation irregular	不規則月経	1(0.5)	0(0.0)	0(0.0)	1(0.2)
Nipple pain	乳頭痛	1(0.5)	0(0.0)	0(0.0)	1(0.2)
Prostatitis	前立腺炎	0(0.0)	1(0.4)	0(0.0)	1(0.2)
Erectile dysfunction	勃起不全	0(0.0)	1(0.4)	0(0.0)	1(0.2)

表 2.7.4.9－57　有害事象の内訳（ISS-1／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 NDD (N=202) n(%)	HD (N=237) n(%)	PD (N=42) n(%)	Total (N=481) n(%)
General disorders and administration site conditions	一般・全身障害および投与部位の状態	29(14.4)	20(8.4)	6(14.3)	55(11.4)
Oedema peripheral	末梢性浮腫	13(6.4)	5(2.1)	0(0.0)	18(3.7)
Pyrexia	発熱	8(4.0)	7(3.0)	2(4.8)	17(3.5)
Malaise	倦怠感	5(2.5)	0(0.0)	0(0.0)	5(1.0)
Oedema due to renal disease	腎疾患による浮腫	4(2.0)	0(0.0)	1(2.4)	5(1.0)
Chest pain	胸痛	2(1.0)	0(0.0)	1(2.4)	3(0.6)
Chest discomfort	胸部不快感	0(0.0)	2(0.8)	0(0.0)	2(0.4)
Vessel puncture site bruise	血管穿刺部位内出血	0(0.0)	2(0.8)	0(0.0)	2(0.4)
Chills	悪寒	1(0.5)	0(0.0)	0(0.0)	1(0.2)
Face oedema	顔面浮腫	1(0.5)	0(0.0)	0(0.0)	1(0.2)
Oedema	浮腫	1(0.5)	0(0.0)	0(0.0)	1(0.2)
Thirst	口渇	1(0.5)	0(0.0)	0(0.0)	1(0.2)
Vessel puncture site haemorrhage	血管穿刺部位出血	1(0.5)	0(0.0)	0(0.0)	1(0.2)
Fatigue	疲労	0(0.0)	1(0.4)	0(0.0)	1(0.2)
Feeling abnormal	異常感	0(0.0)	1(0.4)	0(0.0)	1(0.2)
Injection site reaction	注射部位反応	0(0.0)	1(0.4)	0(0.0)	1(0.2)
Peripheral swelling	末梢腫脹	0(0.0)	1(0.4)	0(0.0)	1(0.2)
Puncture site haemorrhage	穿刺部位出血	0(0.0)	1(0.4)	0(0.0)	1(0.2)
Puncture site pain	穿刺部位疼痛	0(0.0)	1(0.4)	0(0.0)	1(0.2)
Catheter site haemorrhage	カテーテル留置部位出血	0(0.0)	0(0.0)	1(2.4)	1(0.2)
Catheter site granuloma	カテーテル留置部位肉芽腫	0(0.0)	0(0.0)	1(2.4)	1(0.2)

表 2.7.4.9－57　有害事象の内訳（ISS-1／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 NDD (N=202) n(%)	HD (N=237) n(%)	PD (N=42) n(%)	Total (N=481) n(%)
Investigations	臨床検査	14(6.9)	19(8.0)	3(7.1)	36(7.5)
Blood pressure increased	血圧上昇	2(1.0)	4(1.7)	0(0.0)	6(1.2)
Blood pressure decreased	血圧低下	0(0.0)	5(2.1)	0(0.0)	5(1.0)
Blood creatinine increased	血中クレアチニン増加	3(1.5)	0(0.0)	0(0.0)	3(0.6)
Haemoglobin decreased	ヘモグロビン減少	1(0.5)	2(0.8)	0(0.0)	3(0.6)
C-reactive protein increased	C－反応性蛋白増加	1(0.5)	1(0.4)	1(2.4)	3(0.6)
Blood creatine phosphokinase increased	血中クレアチンホスホキナーゼ増加	2(1.0)	0(0.0)	0(0.0)	2(0.4)
Blood uric acid increased	血中尿酸増加	2(1.0)	0(0.0)	0(0.0)	2(0.4)
Aspartate aminotransferase increased	アスパラギン酸アミノトランスフェラーゼ増加	1(0.5)	1(0.4)	0(0.0)	2(0.4)
Prostatic specific antigen increased	前立腺特異性抗原増加	1(0.5)	1(0.4)	0(0.0)	2(0.4)
Blood potassium decreased	血中カリウム減少	1(0.5)	0(0.0)	1(2.4)	2(0.4)
Blood triglycerides increased	血中トリグリセリド増加	1(0.5)	0(0.0)	0(0.0)	1(0.2)
Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	1(0.5)	0(0.0)	0(0.0)	1(0.2)
Blood parathyroid hormone increased	血中副甲状腺ホルモン増加	0(0.0)	1(0.4)	0(0.0)	1(0.2)
Blood urea increased	血中尿素増加	0(0.0)	1(0.4)	0(0.0)	1(0.2)
Blood uric acid decreased	血中尿酸減少	0(0.0)	1(0.4)	0(0.0)	1(0.2)
Blood urine present	尿中血陽性	0(0.0)	1(0.4)	0(0.0)	1(0.2)
Serum ferritin decreased	血清フェリチン減少	0(0.0)	1(0.4)	0(0.0)	1(0.2)
Transferrin saturation decreased	トランスフェリン飽和度低下	0(0.0)	1(0.4)	0(0.0)	1(0.2)
Salmonella test positive	サルモネラ検査陽性	0(0.0)	1(0.4)	0(0.0)	1(0.2)
Weight decreased	体重減少	0(0.0)	0(0.0)	1(2.4)	1(0.2)
Optic nerve cup/disc ratio increased	視神経乳頭陥凹／乳頭比増加	0(0.0)	0(0.0)	1(2.4)	1(0.2)

表 2.7.4.9－57　有害事象の内訳（ISS-1／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 NDD (N=202) n(%)	MT-6548 HD (N=237) n(%)	MT-6548 PD (N=42) n(%)	MT-6548 Total (N=481) n(%)
Injury, poisoning and procedural complications	傷害、中毒および処置合併症	35(17.3)	99(41.8)	6(14.3)	140(29.1)
Contusion	挫傷	14(6.9)	25(10.5)	1(2.4)	40(8.3)
Shunt stenosis	シャント狭窄	2(1.0)	32(13.5)	0(0.0)	34(7.1)
Skin abrasion	皮膚擦過傷	5(2.5)	14(5.9)	0(0.0)	19(4.0)
Wound	創傷	1(0.5)	11(4.6)	0(0.0)	12(2.5)
Thermal burn	熱傷	1(0.5)	8(3.4)	0(0.0)	9(1.9)
Spinal compression fracture	脊椎圧迫骨折	5(2.5)	1(0.4)	0(0.0)	6(1.2)
Procedural hypotension	処置による低血圧	0(0.0)	5(2.1)	0(0.0)	5(1.0)
Shunt occlusion	シャント閉塞	0(0.0)	4(1.7)	1(2.4)	5(1.0)
Rib fracture	肋骨骨折	2(1.0)	2(0.8)	0(0.0)	4(0.8)
Skin laceration	皮膚裂傷	2(1.0)	2(0.8)	0(0.0)	4(0.8)
Limb injury	四肢損傷	2(1.0)	2(0.8)	0(0.0)	4(0.8)
Tooth fracture	歯牙破折	1(0.5)	1(0.4)	1(2.4)	3(0.6)
Arteriovenous fistula site complication	動静脈瘻部位合併症	0(0.0)	3(1.3)	0(0.0)	3(0.6)
Clavicle fracture	鎖骨骨折	1(0.5)	1(0.4)	0(0.0)	2(0.4)
Femoral neck fracture	大腿骨頚部骨折	1(0.5)	1(0.4)	0(0.0)	2(0.4)
Eye contusion	眼挫傷	1(0.5)	1(0.4)	0(0.0)	2(0.4)
Animal bite	動物咬傷	0(0.0)	2(0.8)	0(0.0)	2(0.4)
Foot fracture	足骨折	0(0.0)	2(0.8)	0(0.0)	2(0.4)
Ligament sprain	靱帯捻挫	0(0.0)	2(0.8)	0(0.0)	2(0.4)
Subcutaneous haematoma	皮下血腫	0(0.0)	2(0.8)	0(0.0)	2(0.4)
Joint injury	関節損傷	0(0.0)	2(0.8)	0(0.0)	2(0.4)
Procedural hypertension	処置による高血圧	0(0.0)	2(0.8)	0(0.0)	2(0.4)

表 2.7.4.9－57　有害事象の内訳（ISS-1／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 NDD (N=202) n(%)	HD (N=237) n(%)	PD (N=42) n(%)	Total (N=481) n(%)
Shunt blood flow excessive	シャント血流過剰	0(0.0)	2(0.8)	0(0.0)	2(0.4)
Dental restoration failure	歯科修復不成功	0(0.0)	2(0.8)	0(0.0)	2(0.4)
Animal scratch	動物による引っかき傷	1(0.5)	0(0.0)	0(0.0)	1(0.2)
Fall	転倒	1(0.5)	0(0.0)	0(0.0)	1(0.2)
Hand fracture	手骨折	1(0.5)	0(0.0)	0(0.0)	1(0.2)
Head injury	頭部損傷	1(0.5)	0(0.0)	0(0.0)	1(0.2)
Injury	損傷	1(0.5)	0(0.0)	0(0.0)	1(0.2)
Seroma	漿液腫	1(0.5)	0(0.0)	0(0.0)	1(0.2)
Sternal fracture	胸骨骨折	1(0.5)	0(0.0)	0(0.0)	1(0.2)
Tendon rupture	腱断裂	1(0.5)	0(0.0)	0(0.0)	1(0.2)
Lumbar vertebral fracture	腰椎骨折	1(0.5)	0(0.0)	0(0.0)	1(0.2)
Procedural pain	処置による疼痛	1(0.5)	0(0.0)	0(0.0)	1(0.2)
Nail injury	爪損傷	1(0.5)	0(0.0)	0(0.0)	1(0.2)
Chillblains	凍瘡	0(0.0)	1(0.4)	0(0.0)	1(0.2)
Foreign body in eye	眼内異物	0(0.0)	1(0.4)	0(0.0)	1(0.2)
Muscle injury	筋損傷	0(0.0)	1(0.4)	0(0.0)	1(0.2)
Scratch	引っかき傷	0(0.0)	1(0.4)	0(0.0)	1(0.2)
Scrotal haematoma	陰嚢血腫	0(0.0)	1(0.4)	0(0.0)	1(0.2)
Subdural haematoma	硬膜下血腫	0(0.0)	1(0.4)	0(0.0)	1(0.2)
Tibia fracture	脛骨骨折	0(0.0)	1(0.4)	0(0.0)	1(0.2)
Tooth injury	歯牙損傷	0(0.0)	1(0.4)	0(0.0)	1(0.2)
Wound complication	創合併症	0(0.0)	1(0.4)	0(0.0)	1(0.2)
Arteriovenous fistula site haemorrhage	動静脈瘻部位出血	0(0.0)	1(0.4)	0(0.0)	1(0.2)

表 2.7.4.9－57　有害事象の内訳（ISS-1／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 NDD (N=202) n(%)	MT-6548 HD (N=237) n(%)	MT-6548 PD (N=42) n(%)	MT-6548 Total (N=481) n(%)
Arteriovenous graft site stenosis	動静脈グラフト部位狭窄	0(0.0)	1(0.4)	0(0.0)	1(0.2)
Arteriovenous fistula occlusion	動静脈瘻閉塞	0(0.0)	1(0.4)	0(0.0)	1(0.2)
Shunt thrombosis	シャント血栓症	0(0.0)	1(0.4)	0(0.0)	1(0.2)
Pelvic fracture	骨盤骨折	0(0.0)	1(0.4)	0(0.0)	1(0.2)
Vascular access complication	血管確保合併症	0(0.0)	1(0.4)	0(0.0)	1(0.2)
Post procedural inflammation	処置後炎症	0(0.0)	1(0.4)	0(0.0)	1(0.2)
Heat illness	熱中症	0(0.0)	1(0.4)	0(0.0)	1(0.2)
Pubis fracture	恥骨骨折	0(0.0)	1(0.4)	0(0.0)	1(0.2)
Skin wound	皮膚創傷	0(0.0)	1(0.4)	0(0.0)	1(0.2)
Vascular access site inflammation	血管確保部位炎症	0(0.0)	1(0.4)	0(0.0)	1(0.2)
Vascular access malfunction	血管アクセス機能不全	0(0.0)	1(0.4)	0(0.0)	1(0.2)
Soft tissue foreign body	軟部組織内異物	0(0.0)	1(0.4)	0(0.0)	1(0.2)
Heat stroke	熱射病	0(0.0)	0(0.0)	1(2.4)	1(0.2)
Peritoneal dialysis complication	腹膜透析合併症	0(0.0)	0(0.0)	1(2.4)	1(0.2)
Traumatic haemothorax	外傷性血胸	0(0.0)	0(0.0)	1(2.4)	1(0.2)
Surgical and medical procedures	外科および内科処置	3(1.5)	0(0.0)	0(0.0)	3(0.6)
Arteriovenous fistula operation	動静脈瘻手術	3(1.5)	0(0.0)	0(0.0)	3(0.6)

Note(s): MedDRA Version 22.0 and MedDRA/J Version 22.0.
Source: t_14_3_1_2_1.sas

5.3.5.3—4 Table 14.3.1.2.1 より引用

表 2.7.4.9－58　副作用の内訳（ISS-1／52 週）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 NDD (N=202) n(%)	MT-6548 HD (N=237) n(%)	MT-6548 PD (N=42) n(%)	MT-6548 Total (N=481) n(%)
Subjects with at least one adverse drug reaction		30(14.9)	26(11.0)	5(11.9)	61(12.7)
Infections and infestations	感染症および寄生虫症	0(0.0)	1(0.4)	0(0.0)	1(0.2)
Gastroenteritis	胃腸炎	0(0.0)	1(0.4)	0(0.0)	1(0.2)
Blood and lymphatic system disorders	血液およびリンパ系障害	0(0.0)	1(0.4)	0(0.0)	1(0.2)
Polycythaemia	赤血球増加症	0(0.0)	1(0.4)	0(0.0)	1(0.2)
Psychiatric disorders	精神障害	0(0.0)	0(0.0)	1(2.4)	1(0.2)
Sleep disorder	睡眠障害	0(0.0)	0(0.0)	1(2.4)	1(0.2)
Nervous system disorders	神経系障害	1(0.5)	0(0.0)	0(0.0)	1(0.2)
Somnolence	傾眠	1(0.5)	0(0.0)	0(0.0)	1(0.2)
Eye disorders	眼障害	1(0.5)	0(0.0)	1(2.4)	2(0.4)
Retinal haemorrhage	網膜出血	1(0.5)	0(0.0)	1(2.4)	2(0.4)
Ear and labyrinth disorders	耳および迷路障害	1(0.5)	0(0.0)	0(0.0)	1(0.2)
Vertigo	回転性めまい	1(0.5)	0(0.0)	0(0.0)	1(0.2)
Cardiac disorders	心臓障害	1(0.5)	0(0.0)	1(2.4)	2(0.4)
Palpitations	動悸	1(0.5)	0(0.0)	0(0.0)	1(0.2)
Myocardial ischaemia	心筋虚血	0(0.0)	0(0.0)	1(2.4)	1(0.2)
Vascular disorders	血管障害	5(2.5)	2(0.8)	0(0.0)	7(1.5)
Hypertension	高血圧	5(2.5)	2(0.8)	0(0.0)	7(1.5)

表 2.7.4.9－58　副作用の内訳（ISS-1／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 NDD (N=202) n(%)	HD (N=237) n(%)	PD (N=42) n(%)	Total (N=481) n(%)
Gastrointestinal disorders	胃腸障害	15(7.4)	18(7.6)	2(4.8)	35(7.3)
Diarrhoea	下痢	7(3.5)	10(4.2)	2(4.8)	19(4.0)
Nausea	悪心	5(2.5)	3(1.3)	0(0.0)	8(1.7)
Abdominal discomfort	腹部不快感	2(1.0)	2(0.8)	0(0.0)	4(0.8)
Vomiting	嘔吐	1(0.5)	3(1.3)	0(0.0)	4(0.8)
Faeces soft	軟便	1(0.5)	1(0.4)	0(0.0)	2(0.4)
Gastritis	胃炎	1(0.5)	0(0.0)	0(0.0)	1(0.2)
Stomatitis	口内炎	0(0.0)	1(0.4)	0(0.0)	1(0.2)
Hepatobiliary disorders	肝胆道系障害	2(1.0)	0(0.0)	0(0.0)	2(0.4)
Hepatic function abnormal	肝機能異常	2(1.0)	0(0.0)	0(0.0)	2(0.4)
Skin and subcutaneous tissue disorders	皮膚および皮下組織障害	3(1.5)	4(1.7)	0(0.0)	7(1.5)
Drug eruption	薬疹	1(0.5)	1(0.4)	0(0.0)	2(0.4)
Pruritus	そう痒症	1(0.5)	1(0.4)	0(0.0)	2(0.4)
Eczema	湿疹	1(0.5)	0(0.0)	0(0.0)	1(0.2)
Alopecia	脱毛症	0(0.0)	1(0.4)	0(0.0)	1(0.2)
Cold sweat	冷汗	0(0.0)	1(0.4)	0(0.0)	1(0.2)
Renal and urinary disorders	腎および尿路障害	1(0.5)	1(0.4)	0(0.0)	2(0.4)
Pollakiuria	頻尿	1(0.5)	1(0.4)	0(0.0)	2(0.4)
Reproductive system and breast disorders	生殖系および乳房障害	1(0.5)	0(0.0)	0(0.0)	1(0.2)
Nipple pain	乳頭痛	1(0.5)	0(0.0)	0(0.0)	1(0.2)

表 2.7.4.9－58　副作用の内訳（ISS-1／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 NDD (N=202) n(%)	MT-6548 HD (N=237) n(%)	MT-6548 PD (N=42) n(%)	MT-6548 Total (N=481) n(%)
General disorders and administration site conditions	一般・全身障害および投与部位の状態	2(1.0)	1(0.4)	0(0.0)	3(0.6)
Malaise	倦怠感	1(0.5)	0(0.0)	0(0.0)	1(0.2)
Oedema peripheral	末梢性浮腫	1(0.5)	0(0.0)	0(0.0)	1(0.2)
Chest discomfort	胸部不快感	0(0.0)	1(0.4)	0(0.0)	1(0.2)
Investigations	臨床検査	2(1.0)	2(0.8)	0(0.0)	4(0.8)
Aspartate aminotransferase increased	アスパラギン酸アミノトランスフェラーゼ増加	1(0.5)	1(0.4)	0(0.0)	2(0.4)
Blood creatinine increased	血中クレアチニン増加	1(0.5)	0(0.0)	0(0.0)	1(0.2)
Serum ferritin decreased	血清フェリチン減少	0(0.0)	1(0.4)	0(0.0)	1(0.2)
Transferrin saturation decreased	トランスフェリン飽和度低下	0(0.0)	1(0.4)	0(0.0)	1(0.2)

Note(s): MedDRA Version 22.0 and MedDRA/J Version 22.0.
Source: t_14_3_1_2_2.sas

5.3.5.3—4 Table 14.3.1.2.2 より引用

表 2.7.4.9－59　程度別の有害事象の内訳（MT-6548-J01 試験／52 週）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548(N=151) Mild n (%)	 Moderate n (%)	 Severe n (%)	darbepoetin(N=153) Mild n (%)	 Moderate n (%)	 Severe n (%)
Subjects with at least one adverse event		81(53.6)	44(29.1)	11(7.3)	90(58.8)	42(27.5)	9(5.9)
Infections and infestations	感染症および寄生虫症	58(38.4)	15(9.9)	1(0.7)	66(43.1)	9(5.9)	1(0.7)
Nasopharyngitis	上咽頭炎	37(24.5)	0(0.0)	0(0.0)	43(28.1)	0(0.0)	0(0.0)
Conjunctivitis	結膜炎	7(4.6)	0(0.0)	0(0.0)	4(2.6)	0(0.0)	0(0.0)
Influenza	インフルエンザ	5(3.3)	2(1.3)	0(0.0)	2(1.3)	0(0.0)	0(0.0)
Cystitis	膀胱炎	4(2.6)	2(1.3)	0(0.0)	8(5.2)	1(0.7)	0(0.0)
Urinary tract infection	尿路感染	4(2.6)	2(1.3)	0(0.0)	4(2.6)	0(0.0)	0(0.0)
Bronchitis	気管支炎	5(3.3)	0(0.0)	0(0.0)	4(2.6)	0(0.0)	0(0.0)
Pneumonia	肺炎	2(1.3)	2(1.3)	0(0.0)	0(0.0)	2(1.3)	1(0.7)
Gastroenteritis	胃腸炎	3(2.0)	1(0.7)	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Cellulitis	蜂巣炎	1(0.7)	1(0.7)	1(0.7)	0(0.0)	0(0.0)	0(0.0)
Otitis media	中耳炎	2(1.3)	0(0.0)	0(0.0)	2(1.3)	0(0.0)	0(0.0)
Periodontitis	歯周炎	1(0.7)	1(0.7)	0(0.0)	1(0.7)	1(0.7)	0(0.0)
Pharyngitis	咽頭炎	2(1.3)	0(0.0)	0(0.0)	2(1.3)	0(0.0)	0(0.0)
Upper respiratory tract infection	上気道感染	2(1.3)	0(0.0)	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Renal cyst infection	腎嚢胞感染	1(0.7)	1(0.7)	0(0.0)	0(0.0)	1(0.7)	0(0.0)
Rhinitis	鼻炎	2(1.3)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Sinusitis	副鼻腔炎	2(1.3)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Dermatophytosis of nail	爪の皮膚糸状菌症	1(0.7)	0(0.0)	0(0.0)	4(2.6)	0(0.0)	0(0.0)
Herpes zoster	帯状疱疹	1(0.7)	0(0.0)	0(0.0)	3(2.0)	1(0.7)	0(0.0)
Body tinea	体部白癬	1(0.7)	0(0.0)	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Diverticulitis	憩室炎	0(0.0)	1(0.7)	0(0.0)	0(0.0)	1(0.7)	0(0.0)
Aspergilloma	アスペルギローマ	1(0.7)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Gingivitis	歯肉炎	1(0.7)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)

表 2.7.4.9－59　程度別の有害事象の内訳（MT-6548-J01 試験／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548(N=151) Mild n (%)	 Moderate n (%)	 Severe n (%)	darbepoetin(N=153) Mild n (%)	 Moderate n (%)	 Severe n (%)
Herpes simplex	単純ヘルペス	1(0.7)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Mediastinal abscess	縦隔洞膿瘍	0(0.0)	1(0.7)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Osteomyelitis	骨髄炎	0(0.0)	0(0.0)	1(0.7)	0(0.0)	0(0.0)	0(0.0)
Pneumonia chlamydial	クラミジア性肺炎	0(0.0)	1(0.7)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Pyelonephritis	腎盂腎炎	0(0.0)	1(0.7)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Pyelonephritis acute	急性腎盂腎炎	0(0.0)	1(0.7)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Tinea cruris	股部白癬	1(0.7)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Tonsillitis	扁桃炎	1(0.7)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Abscess limb	四肢膿瘍	1(0.7)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Hordeolum	麦粒腫	0(0.0)	0(0.0)	0(0.0)	2(1.3)	0(0.0)	0(0.0)
Folliculitis	毛包炎	0(0.0)	0(0.0)	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Genital herpes	陰部ヘルペス	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.7)	0(0.0)
Laryngitis	喉頭炎	0(0.0)	0(0.0)	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Paronychia	爪囲炎	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.7)	0(0.0)
Pneumonia pneumococcal	肺炎球菌性肺炎	0(0.0)	0(0.0)	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Rash pustular	膿疱性皮疹	0(0.0)	0(0.0)	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Tinea pedis	足部白癬	0(0.0)	0(0.0)	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Urethritis	尿道炎	0(0.0)	0(0.0)	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Vaginal infection	膣感染	0(0.0)	0(0.0)	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Gingival abscess	歯肉膿瘍	0(0.0)	0(0.0)	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Helicobacter infection	ヘリコバクター感染	0(0.0)	0(0.0)	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Asymptomatic bacteriuria	無症候性細菌尿	0(0.0)	0(0.0)	0(0.0)	1(0.7)	0(0.0)	0(0.0)

表 2.7.4.9－59　程度別の有害事象の内訳（MT-6548-J01 試験／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548(N=151) Mild n (%)	 Moderate n (%)	 Severe n (%)	darbepoetin(N=153) Mild n (%)	 Moderate n (%)	 Severe n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	2(1.3)	0(0.0)	0(0.0)	5(3.3)	1(0.7)	0(0.0)
Colon adenoma	大腸腺腫	1(0.7)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Oral papilloma	口腔乳頭腫	1(0.7)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Basal cell carcinoma	基底細胞癌	0(0.0)	0(0.0)	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Gastric cancer	胃癌	0(0.0)	0(0.0)	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Keratoacanthoma	ケラトアカントーマ	0(0.0)	0(0.0)	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Renal cancer	腎癌	0(0.0)	0(0.0)	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Seborrhoeic keratosis	脂漏性角化症	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.7)	0(0.0)
Skin papilloma	皮膚乳頭腫	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.7)	0(0.0)
Renal cancer metastatic	遠隔転移を伴う腎癌	0(0.0)	0(0.0)	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Kidney angiomyolipoma	腎血管筋脂肪腫	0(0.0)	0(0.0)	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Blood and lymphatic system disorders	血液およびリンパ系障害	2(1.3)	0(0.0)	0(0.0)	7(4.6)	1(0.7)	0(0.0)
Iron deficiency anaemia	鉄欠乏性貧血	2(1.3)	0(0.0)	0(0.0)	6(3.9)	0(0.0)	0(0.0)
Eosinophilia	好酸球増加症	0(0.0)	0(0.0)	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Immune thrombocytopenic purpura	免疫性血小板減少性紫斑病	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.7)	0(0.0)
Immune system disorders	免疫系障害	3(2.0)	0(0.0)	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Seasonal allergy	季節性アレルギー	1(0.7)	0(0.0)	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Allergy to arthropod sting	節足動物刺傷アレルギー	1(0.7)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Allergy to arthropod bite	節足動物咬傷アレルギー	1(0.7)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Endocrine disorders	内分泌障害	0(0.0)	0(0.0)	0(0.0)	3(2.0)	0(0.0)	0(0.0)
Hypothyroidism	甲状腺機能低下症	0(0.0)	0(0.0)	0(0.0)	2(1.3)	0(0.0)	0(0.0)
Hypoparathyroidism secondary	続発性副甲状腺機能低下症	0(0.0)	0(0.0)	0(0.0)	1(0.7)	0(0.0)	0(0.0)

表 2.7.4.9－59　程度別の有害事象の内訳（MT-6548-J01 試験／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548(N=151) Mild n (%)	 Moderate n (%)	 Severe n (%)	darbepoetin(N=153) Mild n (%)	 Moderate n (%)	 Severe n (%)
Metabolism and nutrition disorders	代謝および栄養障害	19(12.6)	3(2.0)	0(0.0)	26(17.0)	6(3.9)	2(1.3)
Hyperuricaemia	高尿酸血症	5(3.3)	0(0.0)	0(0.0)	4(2.6)	0(0.0)	0(0.0)
Decreased appetite	食欲減退	3(2.0)	0(0.0)	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Metabolic acidosis	代謝性アシドーシス	2(1.3)	0(0.0)	0(0.0)	5(3.3)	1(0.7)	0(0.0)
Dehydration	脱水	1(0.7)	1(0.7)	0(0.0)	0(0.0)	4(2.6)	0(0.0)
Hyperphosphataemia	高リン酸塩血症	2(1.3)	0(0.0)	0(0.0)	4(2.6)	0(0.0)	0(0.0)
Diabetes mellitus	糖尿病	1(0.7)	1(0.7)	0(0.0)	2(1.3)	0(0.0)	0(0.0)
Hyperkalaemia	高カリウム血症	1(0.7)	0(0.0)	0(0.0)	4(2.6)	1(0.7)	0(0.0)
Hypoglycaemia	低血糖	1(0.7)	0(0.0)	0(0.0)	2(1.3)	0(0.0)	0(0.0)
Hyponatraemia	低ナトリウム血症	0(0.0)	1(0.7)	0(0.0)	1(0.7)	0(0.0)	1(0.7)
Fluid retention	体液貯留	0(0.0)	1(0.7)	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Hypocalcaemia	低カルシウム血症	1(0.7)	0(0.0)	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Dyslipidaemia	脂質異常症	1(0.7)	0(0.0)	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Type 2 diabetes mellitus	2型糖尿病	1(0.7)	0(0.0)	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Hypoalbuminaemia	低アルブミン血症	1(0.7)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Hypoproteinaemia	低蛋白血症	0(0.0)	1(0.7)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Hyperlipidaemia	高脂血症	1(0.7)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Hyperamylasaemia	高アミラーゼ血症	1(0.7)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Hypercalcaemia	高カルシウム血症	0(0.0)	0(0.0)	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Hypermagnesaemia	高マグネシウム血症	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.7)
Hypokalaemia	低カリウム血症	0(0.0)	0(0.0)	0(0.0)	1(0.7)	0(0.0)	0(0.0)

表 2.7.4.9－59　程度別の有害事象の内訳（MT-6548-J01 試験／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548(N=151) Mild n (%)	 Moderate n (%)	 Severe n (%)	darbepoetin(N=153) Mild n (%)	 Moderate n (%)	 Severe n (%)
Psychiatric disorders	精神障害	7(4.6)	0(0.0)	0(0.0)	8(5.2)	0(0.0)	0(0.0)
Insomnia	不眠症	6(4.0)	0(0.0)	0(0.0)	5(3.3)	0(0.0)	0(0.0)
Depression	うつ病	1(0.7)	0(0.0)	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Anxiety	不安	1(0.7)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Neurosis	神経症	0(0.0)	0(0.0)	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Schizophrenia	統合失調症	0(0.0)	0(0.0)	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Tic	チック	0(0.0)	0(0.0)	0(0.0)	1(0.7)	0(0.0)	0(0.0)

表 2.7.4.9－59　程度別の有害事象の内訳（MT-6548-J01 試験／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548(N=151) Mild n (%)	 Moderate n (%)	 Severe n (%)	darbepoetin(N=153) Mild n (%)	 Moderate n (%)	 Severe n (%)
Nervous system disorders	神経系障害	7(4.6)	3(2.0)	0(0.0)	11(7.2)	5(3.3)	0(0.0)
Headache	頭痛	4(2.6)	1(0.7)	0(0.0)	4(2.6)	3(2.0)	0(0.0)
Dizziness	浮動性めまい	2(1.3)	0(0.0)	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Intracranial aneurysm	頭蓋内動脈瘤	0(0.0)	1(0.7)	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Somnolence	傾眠	1(0.7)	0(0.0)	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Hypoaesthesia	感覚鈍麻	1(0.7)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Hypoglycaemic coma	低血糖昏睡	0(0.0)	1(0.7)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Neuropathy peripheral	末梢性ニューロパチー	1(0.7)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Presyncope	失神寸前の状態	1(0.7)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Lacunar infarction	ラクナ梗塞	0(0.0)	0(0.0)	0(0.0)	2(1.3)	0(0.0)	0(0.0)
Cerebral infarction	脳梗塞	0(0.0)	0(0.0)	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Dementia Alzheimer's type	アルツハイマー型認知症	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.7)	0(0.0)
Dizziness postural	体位性めまい	0(0.0)	0(0.0)	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Loss of consciousness	意識消失	0(0.0)	0(0.0)	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Sciatica	坐骨神経痛	0(0.0)	0(0.0)	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Tension headache	緊張性頭痛	0(0.0)	0(0.0)	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Tremor	振戦	0(0.0)	0(0.0)	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Cognitive disorder	認知障害	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.7)	0(0.0)

表 2.7.4.9－59　程度別の有害事象の内訳（MT-6548-J01 試験／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548(N=151) Mild n (%)	 Moderate n (%)	 Severe n (%)	darbepoetin(N=153) Mild n (%)	 Moderate n (%)	 Severe n (%)
Eye disorders	眼障害	14(9.3)	4(2.6)	0(0.0)	27(17.6)	0(0.0)	0(0.0)
Cataract	白内障	0(0.0)	4(2.6)	0(0.0)	3(2.0)	0(0.0)	0(0.0)
Dry eye	眼乾燥	4(2.6)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Blepharitis	眼瞼炎	3(2.0)	0(0.0)	0(0.0)	2(1.3)	0(0.0)	0(0.0)
Retinal haemorrhage	網膜出血	2(1.3)	0(0.0)	0(0.0)	5(3.3)	0(0.0)	0(0.0)
Conjunctival haemorrhage	結膜出血	2(1.3)	0(0.0)	0(0.0)	2(1.3)	0(0.0)	0(0.0)
Glaucoma	緑内障	1(0.7)	0(0.0)	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Eczema eyelids	眼瞼湿疹	1(0.7)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Macular oedema	黄斑浮腫	1(0.7)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Retinal exudates	網膜滲出物	1(0.7)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Retinal vein occlusion	網膜静脈閉塞	1(0.7)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Age-related macular degeneration	加齢黄斑変性	1(0.7)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Conjunctivitis allergic	アレルギー性結膜炎	0(0.0)	0(0.0)	0(0.0)	4(2.6)	0(0.0)	0(0.0)
Diabetic retinopathy	糖尿病網膜症	0(0.0)	0(0.0)	0(0.0)	3(2.0)	0(0.0)	0(0.0)
Eye pruritus	眼そう痒症	0(0.0)	0(0.0)	0(0.0)	2(1.3)	0(0.0)	0(0.0)
Asthenopia	眼精疲労	0(0.0)	0(0.0)	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Diplopia	複視	0(0.0)	0(0.0)	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Eye swelling	眼部腫脹	0(0.0)	0(0.0)	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Pinguecula	瞼裂斑	0(0.0)	0(0.0)	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Scintillating scotoma	閃輝暗点	0(0.0)	0(0.0)	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Vitreous floaters	硝子体浮遊物	0(0.0)	0(0.0)	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Conjunctival hyperaemia	結膜充血	0(0.0)	0(0.0)	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Dacryostenosis acquired	後天性涙道狭窄	0(0.0)	0(0.0)	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Retinal aneurysm	網膜血管瘤	0(0.0)	0(0.0)	0(0.0)	1(0.7)	0(0.0)	0(0.0)

表 2.7.4.9－59　程度別の有害事象の内訳（MT-6548-J01 試験／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548(N=151) Mild n (%)	 Moderate n (%)	 Severe n (%)	darbepoetin(N=153) Mild n (%)	 Moderate n (%)	 Severe n (%)
Macular fibrosis	黄斑線維症	0(0.0)	0(0.0)	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Ear and labyrinth disorders	耳および迷路障害	4(2.6)	0(0.0)	0(0.0)	5(3.3)	0(0.0)	0(0.0)
Vertigo	回転性めまい	2(1.3)	0(0.0)	0(0.0)	4(2.6)	0(0.0)	0(0.0)
Vertigo positional	頭位性回転性めまい	2(1.3)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Ear congestion	耳閉	1(0.7)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Meniere's disease	メニエール病	0(0.0)	0(0.0)	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Cardiac disorders	心臓障害	6(4.0)	4(2.6)	1(0.7)	4(2.6)	0(0.0)	3(2.0)
Cardiac failure chronic	慢性心不全	2(1.3)	1(0.7)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Atrial fibrillation	心房細動	2(1.3)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Cardiac failure congestive	うっ血性心不全	0(0.0)	2(1.3)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Atrial flutter	心房粗動	1(0.7)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Bradycardia	徐脈	1(0.7)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Cardiac failure	心不全	0(0.0)	1(0.7)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Myocardial ischaemia	心筋虚血	0(0.0)	0(0.0)	1(0.7)	0(0.0)	0(0.0)	0(0.0)
Palpitations	動悸	1(0.7)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Ventricular tachycardia	心室性頻脈	0(0.0)	1(0.7)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Cardiac failure acute	急性心不全	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	2(1.3)
Ventricular extrasystoles	心室性期外収縮	0(0.0)	0(0.0)	0(0.0)	2(1.3)	0(0.0)	0(0.0)
Acute myocardial infarction	急性心筋梗塞	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.7)
Cardiac hypertrophy	心肥大	0(0.0)	0(0.0)	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Cardiac valve disease	心臓弁膜疾患	0(0.0)	0(0.0)	0(0.0)	1(0.7)	0(0.0)	0(0.0)

表 2.7.4.9－59　程度別の有害事象の内訳（MT-6548-J01 試験／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548(N=151) Mild n (%)	 Moderate n (%)	 Severe n (%)	darbepoetin(N=153) Mild n (%)	 Moderate n (%)	 Severe n (%)
Vascular disorders	血管障害	6(4.0)	2(1.3)	0(0.0)	15(9.8)	1(0.7)	0(0.0)
Hypertension	高血圧	2(1.3)	0(0.0)	0(0.0)	11(7.2)	0(0.0)	0(0.0)
Internal haemorrhage	内出血	1(0.7)	0(0.0)	0(0.0)	2(1.3)	0(0.0)	0(0.0)
Aortic aneurysm	大動脈瘤	1(0.7)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Hypotension	低血圧	1(0.7)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Varicose vein	静脈瘤	0(0.0)	1(0.7)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Vasculitis	血管炎	1(0.7)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Vascular rupture	血管破裂	0(0.0)	1(0.7)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Arteriosclerosis	動脈硬化症	0(0.0)	0(0.0)	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Orthostatic hypotension	起立性低血圧	0(0.0)	0(0.0)	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Peripheral artery aneurysm	末梢動脈瘤	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.7)	0(0.0)
Hot flush	ほてり	0(0.0)	0(0.0)	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Respiratory, thoracic and mediastinal disorders	呼吸器、胸郭および縦隔障害	11(7.3)	1(0.7)	0(0.0)	14(9.2)	2(1.3)	0(0.0)
Cough	咳嗽	4(2.6)	0(0.0)	0(0.0)	4(2.6)	0(0.0)	0(0.0)
Pleural effusion	胸水	2(1.3)	0(0.0)	0(0.0)	3(2.0)	0(0.0)	0(0.0)
Rhinitis allergic	アレルギー性鼻炎	2(1.3)	0(0.0)	0(0.0)	3(2.0)	0(0.0)	0(0.0)
Pulmonary congestion	肺うっ血	1(0.7)	1(0.7)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Epistaxis	鼻出血	1(0.7)	0(0.0)	0(0.0)	2(1.3)	0(0.0)	0(0.0)
Rhinorrhoea	鼻漏	1(0.7)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Upper respiratory tract inflammation	上気道の炎症	0(0.0)	0(0.0)	0(0.0)	2(1.3)	0(0.0)	0(0.0)
Chronic obstructive pulmonary disease	慢性閉塞性肺疾患	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.7)	0(0.0)
Pulmonary embolism	肺塞栓症	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.7)	0(0.0)
Oropharyngeal discomfort	口腔咽頭不快感	0(0.0)	0(0.0)	0(0.0)	1(0.7)	0(0.0)	0(0.0)

表 2.7.4.9－59　程度別の有害事象の内訳（MT-6548-J01 試験／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548(N=151) Mild n (%)	 Moderate n (%)	 Severe n (%)	darbepoetin(N=153) Mild n (%)	 Moderate n (%)	 Severe n (%)
Gastrointestinal disorders	胃腸障害	52(34.4)	6(4.0)	1(0.7)	52(34.0)	4(2.6)	0(0.0)
Diarrhoea	下痢	16(10.6)	2(1.3)	0(0.0)	8(5.2)	0(0.0)	0(0.0)
Constipation	便秘	14(9.3)	0(0.0)	0(0.0)	10(6.5)	1(0.7)	0(0.0)
Vomiting	嘔吐	8(5.3)	2(1.3)	0(0.0)	2(1.3)	1(0.7)	0(0.0)
Nausea	悪心	6(4.0)	0(0.0)	0(0.0)	4(2.6)	1(0.7)	0(0.0)
Dental caries	齲歯	4(2.6)	0(0.0)	0(0.0)	4(2.6)	0(0.0)	0(0.0)
Abdominal pain upper	上腹部痛	3(2.0)	0(0.0)	0(0.0)	2(1.3)	0(0.0)	0(0.0)
Gastrooesophageal reflux disease	胃食道逆流性疾患	3(2.0)	0(0.0)	0(0.0)	2(1.3)	0(0.0)	0(0.0)
Abdominal pain	腹痛	3(2.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Abdominal discomfort	腹部不快感	1(0.7)	1(0.7)	0(0.0)	3(2.0)	0(0.0)	0(0.0)
Stomatitis	口内炎	2(1.3)	0(0.0)	0(0.0)	3(2.0)	0(0.0)	0(0.0)
Chronic gastritis	慢性胃炎	2(1.3)	0(0.0)	0(0.0)	2(1.3)	0(0.0)	0(0.0)
Gastritis	胃炎	1(0.7)	0(0.0)	1(0.7)	1(0.7)	0(0.0)	0(0.0)
Periodontal disease	歯周病	1(0.7)	0(0.0)	0(0.0)	3(2.0)	0(0.0)	0(0.0)
Large intestine polyp	大腸ポリープ	1(0.7)	0(0.0)	0(0.0)	3(2.0)	0(0.0)	0(0.0)
Haemorrhoids	痔核	1(0.7)	0(0.0)	0(0.0)	2(1.3)	0(0.0)	0(0.0)
Gastrointestinal disorder	胃腸障害	1(0.7)	0(0.0)	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Faeces soft	軟便	1(0.7)	0(0.0)	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Abdominal distension	腹部膨満	1(0.7)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Diverticulum intestinal	腸憩室	1(0.7)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Gingival bleeding	歯肉出血	1(0.7)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Mouth haemorrhage	口腔内出血	1(0.7)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Oesophageal achalasia	食道アカラシア	0(0.0)	1(0.7)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Gastrointestinal polyp haemorrhage	胃腸ポリープ出血	0(0.0)	1(0.7)	0(0.0)	0(0.0)	0(0.0)	0(0.0)

表 2.7.4.9－59　程度別の有害事象の内訳（MT-6548-J01 試験／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548(N=151) Mild n (%)	 Moderate n (%)	 Severe n (%)	darbepoetin(N=153) Mild n (%)	 Moderate n (%)	 Severe n (%)
Inguinal hernia	鼠径ヘルニア	0(0.0)	0(0.0)	0(0.0)	2(1.3)	0(0.0)	0(0.0)
Aphthous ulcer	アフタ性潰瘍	0(0.0)	0(0.0)	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Colitis ischaemic	虚血性大腸炎	0(0.0)	0(0.0)	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Diverticulum intestinal haemorrhagic	出血性腸憩室	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.7)	0(0.0)
Dry mouth	口内乾燥	0(0.0)	0(0.0)	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Duodenal polyp	十二指腸ポリープ	0(0.0)	0(0.0)	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Enterocolitis	腸炎	0(0.0)	0(0.0)	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Faeces discoloured	変色便	0(0.0)	0(0.0)	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Gastric ulcer haemorrhage	出血性胃潰瘍	0(0.0)	0(0.0)	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Gingival swelling	歯肉腫脹	0(0.0)	0(0.0)	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Pancreatic mass	膵腫瘤	0(0.0)	0(0.0)	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Anal haemorrhage	肛門出血	0(0.0)	0(0.0)	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Ischaemic enteritis	虚血性小腸炎	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.7)	0(0.0)
Hepatobiliary disorders	肝胆道系障害	3(2.0)	5(3.3)	0(0.0)	4(2.6)	1(0.7)	0(0.0)
Hepatic function abnormal	肝機能異常	2(1.3)	1(0.7)	0(0.0)	1(0.7)	1(0.7)	0(0.0)
Bile duct stone	胆管結石	0(0.0)	1(0.7)	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Cholecystitis	胆嚢炎	0(0.0)	1(0.7)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Cholelithiasis	胆石症	0(0.0)	1(0.7)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Hepatic cirrhosis	肝硬変	0(0.0)	1(0.7)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Drug-induced liver injury	薬物性肝障害	1(0.7)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Cholecystitis acute	急性胆嚢炎	0(0.0)	0(0.0)	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Hepatic steatosis	脂肪肝	0(0.0)	0(0.0)	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Liver disorder	肝障害	0(0.0)	0(0.0)	0(0.0)	1(0.7)	0(0.0)	0(0.0)

表 2.7.4.9－59　程度別の有害事象の内訳（MT-6548-J01 試験／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548(N=151) Mild n (%)	 Moderate n (%)	 Severe n (%)	darbepoetin(N=153) Mild n (%)	 Moderate n (%)	 Severe n (%)
Skin and subcutaneous tissue disorders	皮膚および皮下組織障害	34(22.5)	1(0.7)	0(0.0)	41(26.8)	1(0.7)	0(0.0)
Pruritus	そう痒症	7(4.6)	0(0.0)	0(0.0)	8(5.2)	0(0.0)	0(0.0)
Eczema	湿疹	5(3.3)	0(0.0)	0(0.0)	8(5.2)	0(0.0)	0(0.0)
Dermatitis contact	接触皮膚炎	4(2.6)	0(0.0)	0(0.0)	3(2.0)	1(0.7)	0(0.0)
Haemorrhage subcutaneous	皮下出血	3(2.0)	0(0.0)	0(0.0)	3(2.0)	0(0.0)	0(0.0)
Rash	発疹	3(2.0)	0(0.0)	0(0.0)	2(1.3)	0(0.0)	0(0.0)
Eczema asteatotic	皮脂欠乏性湿疹	3(2.0)	0(0.0)	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Skin ulcer	皮膚潰瘍	3(2.0)	0(0.0)	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Dry skin	皮膚乾燥	3(2.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Urticaria	蕁麻疹	2(1.3)	0(0.0)	0(0.0)	2(1.3)	0(0.0)	0(0.0)
Skin erosion	皮膚びらん	2(1.3)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Decubitus ulcer	褥瘡性潰瘍	1(0.7)	0(0.0)	0(0.0)	2(1.3)	0(0.0)	0(0.0)
Drug eruption	薬疹	1(0.7)	0(0.0)	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Xeroderma	乾皮症	1(0.7)	0(0.0)	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Dermal cyst	皮膚嚢腫	1(0.7)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Dermatomyositis	皮膚筋炎	0(0.0)	1(0.7)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Prurigo	痒疹	1(0.7)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Seborrhoeic dermatitis	脂漏性皮膚炎	1(0.7)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Pruritus generalised	全身性そう痒症	1(0.7)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Reactive perforating collagenosis	反応性穿孔性膠原線維症	1(0.7)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Asteatosis	皮脂欠乏症	0(0.0)	0(0.0)	0(0.0)	2(1.3)	0(0.0)	0(0.0)
Dermatitis	皮膚炎	0(0.0)	0(0.0)	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Dermatitis allergic	アレルギー性皮膚炎	0(0.0)	0(0.0)	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Hyperkeratosis	過角化	0(0.0)	0(0.0)	0(0.0)	1(0.7)	0(0.0)	0(0.0)

表 2.7.4.9－59　程度別の有害事象の内訳（MT-6548-J01 試験／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548(N=151) Mild n (%)	 Moderate n (%)	 Severe n (%)	darbepoetin(N=153) Mild n (%)	 Moderate n (%)	 Severe n (%)
Ingrowing nail	嵌入爪	0(0.0)	0(0.0)	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Miliaria	汗疹	0(0.0)	0(0.0)	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Palmoplantar keratoderma	掌蹠角皮症	0(0.0)	0(0.0)	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Psoriasis	乾癬	0(0.0)	0(0.0)	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Stasis dermatitis	うっ滞性皮膚炎	0(0.0)	0(0.0)	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Hand dermatitis	手皮膚炎	0(0.0)	0(0.0)	0(0.0)	1(0.7)	0(0.0)	0(0.0)

表 2.7.4.9－59　程度別の有害事象の内訳（MT-6548-J01 試験／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548(N=151) Mild n (%)	 Moderate n (%)	 Severe n (%)	darbepoetin(N=153) Mild n (%)	 Moderate n (%)	 Severe n (%)
Musculoskeletal and connective tissue disorders	筋骨格系および結合組織障害	25(16.6)	5(3.3)	1(0.7)	30(19.6)	4(2.6)	1(0.7)
Back pain	背部痛	4(2.6)	2(1.3)	0(0.0)	4(2.6)	1(0.7)	0(0.0)
Muscle spasms	筋痙縮	4(2.6)	0(0.0)	0(0.0)	7(4.6)	0(0.0)	0(0.0)
Arthritis	関節炎	3(2.0)	1(0.7)	0(0.0)	2(1.3)	0(0.0)	0(0.0)
Arthralgia	関節痛	3(2.0)	0(0.0)	0(0.0)	2(1.3)	1(0.7)	0(0.0)
Osteoporosis	骨粗鬆症	2(1.3)	1(0.7)	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Spinal osteoarthritis	変形性脊椎症	3(2.0)	0(0.0)	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Myalgia	筋肉痛	3(2.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Pain in extremity	四肢痛	2(1.3)	0(0.0)	0(0.0)	2(1.3)	0(0.0)	0(0.0)
Synovial cyst	滑液嚢腫	2(1.3)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Musculoskeletal pain	筋骨格痛	1(0.7)	0(0.0)	0(0.0)	4(2.6)	0(0.0)	0(0.0)
Osteoarthritis	変形性関節症	1(0.7)	0(0.0)	0(0.0)	3(2.0)	1(0.7)	0(0.0)
Neck pain	頚部痛	1(0.7)	0(0.0)	0(0.0)	2(1.3)	0(0.0)	0(0.0)
Intervertebral disc protrusion	椎間板突出	0(0.0)	1(0.7)	0(0.0)	1(0.7)	1(0.7)	0(0.0)
Lumbar spinal stenosis	腰部脊柱管狭窄症	0(0.0)	1(0.7)	0(0.0)	0(0.0)	0(0.0)	1(0.7)
Spondylolisthesis	脊椎すべり症	1(0.7)	0(0.0)	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Bursitis	滑液包炎	1(0.7)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Rotator cuff syndrome	肩回旋筋腱板症候群	0(0.0)	0(0.0)	1(0.7)	0(0.0)	0(0.0)	0(0.0)
Temporomandibular joint syndrome	顎関節症候群	1(0.7)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Tenosynovitis	腱鞘炎	1(0.7)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Trigger finger	弾発指	1(0.7)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Muscle disorder	筋障害	0(0.0)	0(0.0)	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Periarthritis	関節周囲炎	0(0.0)	0(0.0)	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Tendonitis	腱炎	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.7)	0(0.0)

表 2.7.4.9－59　程度別の有害事象の内訳（MT-6548-J01 試験／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548(N=151) Mild n (%)	 Moderate n (%)	 Severe n (%)	darbepoetin(N=153) Mild n (%)	 Moderate n (%)	 Severe n (%)
Musculoskeletal stiffness	筋骨格硬直	0(0.0)	0(0.0)	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Tendon pain	腱痛	0(0.0)	0(0.0)	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Renal and urinary disorders	腎および尿路障害	5(3.3)	15(9.9)	5(3.3)	10(6.5)	18(11.8)	3(2.0)
Chronic kidney disease	慢性腎臓病	2(1.3)	4(2.6)	3(2.0)	4(2.6)	9(5.9)	1(0.7)
Renal impairment	腎機能障害	1(0.7)	6(4.0)	1(0.7)	3(2.0)	5(3.3)	0(0.0)
End stage renal disease	末期腎疾患	0(0.0)	2(1.3)	1(0.7)	0(0.0)	0(0.0)	1(0.7)
Renal failure	腎不全	0(0.0)	2(1.3)	0(0.0)	0(0.0)	0(0.0)	1(0.7)
Hypertonic bladder	緊張性膀胱	2(1.3)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Haematuria	血尿	1(0.7)	0(0.0)	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Oliguria	乏尿	1(0.7)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Urinary retention	尿閉	0(0.0)	1(0.7)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Azotaemia	高窒素血症	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.7)	0(0.0)
Dysuria	排尿困難	0(0.0)	0(0.0)	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Neurogenic bladder	神経因性膀胱	0(0.0)	0(0.0)	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Nocturia	夜間頻尿	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.7)	0(0.0)
Diabetic nephropathy	糖尿病性腎症	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.7)	0(0.0)
Acute kidney injury	急性腎障害	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.7)	0(0.0)
Ureterolithiasis	尿管結石症	0(0.0)	0(0.0)	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Reproductive system and breast disorders	生殖系および乳房障害	5(3.3)	0(0.0)	0(0.0)	2(1.3)	0(0.0)	0(0.0)
Benign prostatic hyperplasia	良性前立腺肥大症	3(2.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Menstruation irregular	不規則月経	1(0.7)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Nipple pain	乳頭痛	1(0.7)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Pruritus genital	陰部そう痒症	0(0.0)	0(0.0)	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Vulvar erosion	外陰部びらん	0(0.0)	0(0.0)	0(0.0)	1(0.7)	0(0.0)	0(0.0)

表 2.7.4.9－59　程度別の有害事象の内訳（MT-6548-J01 試験／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548(N=151) Mild n (%)	 Moderate n (%)	 Severe n (%)	darbepoetin(N=153) Mild n (%)	 Moderate n (%)	 Severe n (%)
General disorders and administration site conditions	一般・全身障害および投与部位の状態	21(13.9)	4(2.6)	0(0.0)	14(9.2)	2(1.3)	0(0.0)
Oedema peripheral	末梢性浮腫	9(6.0)	2(1.3)	0(0.0)	3(2.0)	2(1.3)	0(0.0)
Pyrexia	発熱	7(4.6)	1(0.7)	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Malaise	倦怠感	4(2.6)	1(0.7)	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Chest pain	胸痛	2(1.3)	0(0.0)	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Oedema due to renal disease	腎疾患による浮腫	2(1.3)	0(0.0)	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Oedema	浮腫	1(0.7)	0(0.0)	0(0.0)	2(1.3)	0(0.0)	0(0.0)
Chills	悪寒	1(0.7)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Face oedema	顔面浮腫	1(0.7)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Thirst	口渇	1(0.7)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Vessel puncture site haemorrhage	血管穿刺部位出血	1(0.7)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Asthenia	無力症	0(0.0)	0(0.0)	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Fatigue	疲労	0(0.0)	0(0.0)	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Feeling abnormal	異常感	0(0.0)	0(0.0)	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Injection site haematoma	注射部位血腫	0(0.0)	0(0.0)	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Injection site pain	注射部位疼痛	0(0.0)	0(0.0)	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Injection site rash	注射部位発疹	0(0.0)	0(0.0)	0(0.0)	1(0.7)	0(0.0)	0(0.0)

表 2.7.4.9－59　程度別の有害事象の内訳（MT-6548-J01 試験／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548(N=151) Mild n (%)	 Moderate n (%)	 Severe n (%)	darbepoetin(N=153) Mild n (%)	 Moderate n (%)	 Severe n (%)
Investigations	臨床検査	11(7.3)	2(1.3)	0(0.0)	11(7.2)	1(0.7)	0(0.0)
Blood creatinine increased	血中クレアチニン増加	2(1.3)	1(0.7)	0(0.0)	2(1.3)	0(0.0)	0(0.0)
Blood creatine phosphokinase increased	血中クレアチンホスホキナーゼ増加	2(1.3)	0(0.0)	0(0.0)	3(2.0)	0(0.0)	0(0.0)
Blood pressure increased	血圧上昇	2(1.3)	0(0.0)	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Blood uric acid increased	血中尿酸増加	2(1.3)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Blood triglycerides increased	血中トリグリセリド増加	1(0.7)	0(0.0)	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Blood potassium decreased	血中カリウム減少	1(0.7)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
C-reactive protein increased	Ｃ－反応性蛋白増加	1(0.7)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Haemoglobin decreased	ヘモグロビン減少	0(0.0)	1(0.7)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Prostatic specific antigen increased	前立腺特異性抗原増加	1(0.7)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	1(0.7)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Blood iron decreased	血中鉄減少	0(0.0)	0(0.0)	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Blood pressure decreased	血圧低下	0(0.0)	0(0.0)	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Gamma-glutamyltransferase increased	γ－グルタミルトランスフェラーゼ増加	0(0.0)	0(0.0)	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Intraocular pressure increased	眼圧上昇	0(0.0)	0(0.0)	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Weight decreased	体重減少	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.7)	0(0.0)
Platelet count increased	血小板数増加	0(0.0)	0(0.0)	0(0.0)	1(0.7)	0(0.0)	0(0.0)

表 2.7.4.9－59　程度別の有害事象の内訳（MT-6548-J01 試験／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548(N=151) Mild n (%)	 Moderate n (%)	 Severe n (%)	darbepoetin(N=153) Mild n (%)	 Moderate n (%)	 Severe n (%)
Injury, poisoning and procedural complications	傷害、中毒および処置合併症	21(13.9)	7(4.6)	2(1.3)	16(10.5)	8(5.2)	2(1.3)
Contusion	挫傷	10(6.6)	1(0.7)	0(0.0)	7(4.6)	0(0.0)	0(0.0)
Skin abrasion	皮膚擦過傷	4(2.6)	0(0.0)	0(0.0)	2(1.3)	0(0.0)	0(0.0)
Spinal compression fracture	脊椎圧迫骨折	0(0.0)	2(1.3)	1(0.7)	0(0.0)	2(1.3)	0(0.0)
Rib fracture	肋骨骨折	2(1.3)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Shunt stenosis	シャント狭窄	0(0.0)	2(1.3)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Limb injury	四肢損傷	2(1.3)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Femoral neck fracture	大腿骨頚部骨折	0(0.0)	0(0.0)	1(0.7)	0(0.0)	1(0.7)	0(0.0)
Thermal burn	熱傷	1(0.7)	0(0.0)	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Animal scratch	動物による引っかき傷	1(0.7)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Clavicle fracture	鎖骨骨折	1(0.7)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Hand fracture	手骨折	0(0.0)	1(0.7)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Head injury	頭部損傷	1(0.7)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Laceration	裂傷	1(0.7)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Seroma	漿液腫	0(0.0)	1(0.7)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Subarachnoid haemorrhage	くも膜下出血	0(0.0)	1(0.7)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Tendon rupture	腱断裂	1(0.7)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Excoriation	擦過傷	1(0.7)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Lumbar vertebral fracture	腰椎骨折	1(0.7)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Procedural pain	処置による疼痛	1(0.7)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Nail injury	爪損傷	1(0.7)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Eye contusion	眼挫傷	1(0.7)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Heat illness	熱中症	0(0.0)	0(0.0)	0(0.0)	2(1.3)	1(0.7)	0(0.0)
Arthropod bite	節足動物咬傷	0(0.0)	0(0.0)	0(0.0)	2(1.3)	0(0.0)	0(0.0)

表 2.7.4.9－59　程度別の有害事象の内訳（MT-6548-J01 試験／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548(N=151) Mild n (%)	 Moderate n (%)	 Severe n (%)	darbepoetin(N=153) Mild n (%)	 Moderate n (%)	 Severe n (%)
Chillblains	凍瘡	0(0.0)	0(0.0)	0(0.0)	2(1.3)	0(0.0)	0(0.0)
Ligament sprain	靱帯捻挫	0(0.0)	0(0.0)	0(0.0)	2(1.3)	0(0.0)	0(0.0)
Femur fracture	大腿骨骨折	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.7)	0(0.0)
Hip fracture	股関節部骨折	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.7)
Humerus fracture	上腕骨骨折	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.7)	0(0.0)
Injury	損傷	0(0.0)	0(0.0)	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Radius fracture	橈骨骨折	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.7)	0(0.0)
Shunt occlusion	シャント閉塞	0(0.0)	0(0.0)	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Wrist fracture	手首関節骨折	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.7)	0(0.0)
Wound	創傷	0(0.0)	0(0.0)	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Tooth fracture	歯牙破折	0(0.0)	0(0.0)	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Bone contusion	骨挫傷	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.7)

Note(s): MedDRA Version 20.1 and MedDRA/J Version 20.1.
Data Source: Listing 16.2.5.1
Source: t_14_3_1_11_1.sas

5.3.5.1—8 表 14.3.1.11.1 より引用

表 2.7.4.9－60　程度別の副作用の内訳（MT-6548-J01 試験／52 週）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548(N=151) Mild n (%)	 Moderate n (%)	 Severe n (%)	darbepoetin(N=153) Mild n (%)	 Moderate n (%)	 Severe n (%)
Subjects with at least one adverse drug reaction		17(11.3)	2(1.3)	1(0.7)	7(4.6)	0(0.0)	0(0.0)
Nervous system disorders	神経系障害	1(0.7)	0(0.0)	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Somnolence	傾眠	1(0.7)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Dizziness	浮動性めまい	0(0.0)	0(0.0)	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Eye disorders	眼障害	1(0.7)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Retinal haemorrhage	網膜出血	1(0.7)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Ear and labyrinth disorders	耳および迷路障害	1(0.7)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Vertigo	回転性めまい	1(0.7)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Cardiac disorders	心臓障害	1(0.7)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Palpitations	動悸	1(0.7)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Vascular disorders	血管障害	1(0.7)	0(0.0)	0(0.0)	2(1.3)	0(0.0)	0(0.0)
Hypertension	高血圧	1(0.7)	0(0.0)	0(0.0)	2(1.3)	0(0.0)	0(0.0)
Hot flush	ほてり	0(0.0)	0(0.0)	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Gastrointestinal disorders	胃腸障害	8(5.3)	2(1.3)	1(0.7)	1(0.7)	0(0.0)	0(0.0)
Diarrhoea	下痢	4(2.6)	2(1.3)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Nausea	悪心	3(2.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Abdominal discomfort	腹部不快感	1(0.7)	1(0.7)	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Gastritis	胃炎	0(0.0)	0(0.0)	1(0.7)	0(0.0)	0(0.0)	0(0.0)
Faeces soft	軟便	1(0.7)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Hepatobiliary disorders	肝胆道系障害	1(0.7)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Hepatic function abnormal	肝機能異常	1(0.7)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)

表 2.7.4.9－60　程度別の副作用の内訳（MT-6548-J01 試験／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548(N=151) Mild n (%)	 Moderate n (%)	 Severe n (%)	darbepoetin(N=153) Mild n (%)	 Moderate n (%)	 Severe n (%)
Skin and subcutaneous tissue disorders	皮膚および皮下組織障害	3(2.0)	0(0.0)	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Drug eruption	薬疹	1(0.7)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Eczema	湿疹	1(0.7)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Pruritus	そう痒症	1(0.7)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Haemorrhage subcutaneous	皮下出血	0(0.0)	0(0.0)	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Reproductive system and breast disorders	生殖系および乳房障害	1(0.7)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Nipple pain	乳頭痛	1(0.7)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
General disorders and administration site conditions	一般・全身障害および投与部位の状態	1(0.7)	1(0.7)	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Malaise	倦怠感	0(0.0)	1(0.7)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Oedema peripheral	末梢性浮腫	1(0.7)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Injection site pain	注射部位疼痛	0(0.0)	0(0.0)	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Investigations	臨床検査	1(0.7)	0(0.0)	0(0.0)	1(0.7)	0(0.0)	0(0.0)
Blood creatinine increased	血中クレアチニン増加	1(0.7)	0(0.0)	0(0.0)	1(0.7)	0(0.0)	0(0.0)

Note(s): MedDRA Version 20.1 and MedDRA/J Version 20.1.
Data Source: Listing 16.2.5.1
Source: t_14_3_1_12_1.sas

5.3.5.1—8 表 14.3.1.12.1 より引用

表 2.7.4.9－61　程度別の有害事象の内訳（MT-6548-J03 試験／52 週）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548(N=162) Mild n (%)	 Moderate n (%)	 Severe n (%)	darbepoetin(N=161) Mild n (%)	 Moderate n (%)	 Severe n (%)
Subjects with at least one adverse event		95(58.6)	49(30.2)	10(6.2)	110(68.3)	39(24.2)	9(5.6)
Infections and infestations	感染症および寄生虫症	93(57.4)	11(6.8)	3(1.9)	100(62.1)	9(5.6)	2(1.2)
Nasopharyngitis	上咽頭炎	72(44.4)	2(1.2)	0(0.0)	73(45.3)	0(0.0)	0(0.0)
Gastroenteritis	胃腸炎	11(6.8)	1(0.6)	0(0.0)	1(0.6)	0(0.0)	0(0.0)
Conjunctivitis	結膜炎	11(6.8)	0(0.0)	0(0.0)	4(2.5)	0(0.0)	0(0.0)
Influenza	インフルエンザ	7(4.3)	2(1.2)	0(0.0)	7(4.3)	5(3.1)	0(0.0)
Upper respiratory tract infection	上気道感染	7(4.3)	0(0.0)	0(0.0)	8(5.0)	0(0.0)	0(0.0)
Pneumonia	肺炎	2(1.2)	3(1.9)	2(1.2)	2(1.2)	0(0.0)	0(0.0)
Bronchitis	気管支炎	5(3.1)	0(0.0)	0(0.0)	6(3.7)	0(0.0)	0(0.0)
Hordeolum	麦粒腫	4(2.5)	0(0.0)	0(0.0)	1(0.6)	0(0.0)	0(0.0)
Pharyngitis	咽頭炎	3(1.9)	0(0.0)	0(0.0)	7(4.3)	0(0.0)	0(0.0)
Periodontitis	歯周炎	3(1.9)	0(0.0)	0(0.0)	4(2.5)	1(0.6)	0(0.0)
Cystitis	膀胱炎	3(1.9)	0(0.0)	0(0.0)	0(0.0)	1(0.6)	0(0.0)
Tinea pedis	足部白癬	2(1.2)	0(0.0)	0(0.0)	6(3.7)	0(0.0)	0(0.0)
Shunt infection	シャント感染	1(0.6)	1(0.6)	0(0.0)	5(3.1)	0(0.0)	0(0.0)
Dermatophytosis of nail	爪の皮膚糸状菌症	2(1.2)	0(0.0)	0(0.0)	2(1.2)	0(0.0)	0(0.0)
Herpes zoster	帯状疱疹	2(1.2)	0(0.0)	0(0.0)	1(0.6)	1(0.6)	0(0.0)
Skin infection	皮膚感染	2(1.2)	0(0.0)	0(0.0)	1(0.6)	0(0.0)	0(0.0)
Infected dermal cyst	感染性皮膚嚢腫	2(1.2)	0(0.0)	0(0.0)	1(0.6)	0(0.0)	0(0.0)
Otitis media	中耳炎	2(1.2)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Enteritis infectious	感染性腸炎	1(0.6)	1(0.6)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Oral herpes	口腔ヘルペス	1(0.6)	0(0.0)	0(0.0)	3(1.9)	0(0.0)	0(0.0)
Angular cheilitis	口角口唇炎	1(0.6)	0(0.0)	0(0.0)	2(1.2)	0(0.0)	0(0.0)
Chronic sinusitis	慢性副鼻腔炎	1(0.6)	0(0.0)	0(0.0)	1(0.6)	0(0.0)	0(0.0)

表 2.7.4.9－61　程度別の有害事象の内訳（MT-6548-J03 試験／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548(N=162) Mild n (%)	 Moderate n (%)	 Severe n (%)	darbepoetin(N=161) Mild n (%)	 Moderate n (%)	 Severe n (%)
Pyelonephritis	腎盂腎炎	1(0.6)	0(0.0)	0(0.0)	1(0.6)	0(0.0)	0(0.0)
Cellulitis	蜂巣炎	1(0.6)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Dermatitis infected	感染性皮膚炎	1(0.6)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Furuncle	せつ	1(0.6)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Gastroenteritis viral	ウイルス性胃腸炎	1(0.6)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Hydrocele male infected	感染性陰嚢水瘤	0(0.0)	1(0.6)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Osteomyelitis	骨髄炎	1(0.6)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Otitis media chronic	慢性中耳炎	1(0.6)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Paronychia	爪囲炎	1(0.6)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Sinusitis	副鼻腔炎	1(0.6)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Hepatic cyst infection	肝嚢胞感染	0(0.0)	0(0.0)	1(0.6)	0(0.0)	0(0.0)	0(0.0)
Upper respiratory tract infection bacterial	細菌性上気道感染	1(0.6)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Bacterial infection	細菌感染	0(0.0)	1(0.6)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Device related infection	医療機器関連感染	0(0.0)	1(0.6)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Folliculitis	毛包炎	0(0.0)	0(0.0)	0(0.0)	2(1.2)	0(0.0)	0(0.0)
Gingivitis	歯肉炎	0(0.0)	0(0.0)	0(0.0)	2(1.2)	0(0.0)	0(0.0)
Pericoronitis	歯冠周囲炎	0(0.0)	0(0.0)	0(0.0)	2(1.2)	0(0.0)	0(0.0)
Catheter site infection	カテーテル留置部位感染	0(0.0)	0(0.0)	0(0.0)	2(1.2)	0(0.0)	0(0.0)
Vessel puncture site infection	血管穿刺部位感染	0(0.0)	0(0.0)	0(0.0)	2(1.2)	0(0.0)	0(0.0)
Acute sinusitis	急性副鼻腔炎	0(0.0)	0(0.0)	0(0.0)	1(0.6)	0(0.0)	0(0.0)
Chronic tonsillitis	慢性扁桃炎	0(0.0)	0(0.0)	0(0.0)	1(0.6)	0(0.0)	0(0.0)
Diverticulitis	憩室炎	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.6)	0(0.0)
Otitis media acute	急性中耳炎	0(0.0)	0(0.0)	0(0.0)	1(0.6)	0(0.0)	0(0.0)
Peritonitis	腹膜炎	0(0.0)	0(0.0)	0(0.0)	1(0.6)	0(0.0)	0(0.0)

表 2.7.4.9－61　程度別の有害事象の内訳（MT-6548-J03 試験／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548(N=162) Mild n (%)	 Moderate n (%)	 Severe n (%)	darbepoetin(N=161) Mild n (%)	 Moderate n (%)	 Severe n (%)
Pulpitis dental	歯髄炎	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
Rash pustular	膿疱性皮疹	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
Subcutaneous abscess	皮下組織膿瘍	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
Tinea cruris	股部白癬	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
Urinary tract infection	尿路感染	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
Urinary tract infection fungal	真菌性尿路感染	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)
Gingival abscess	歯肉膿瘍	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
Skin bacterial infection	皮膚細菌感染	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
Abdominal infection	腹部感染	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
Staphylococcal infection	ブドウ球菌感染	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
Pneumonia bacterial	細菌性肺炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.6)
Purulence	化膿	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
Mycotic endophthalmitis	真菌性眼内炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.6)

表 2.7.4.9－61　程度別の有害事象の内訳（MT-6548-J03 試験／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548(N=162) Mild n (%)	 Moderate n (%)	 Severe n (%)	darbepoetin(N=161) Mild n (%)	 Moderate n (%)	 Severe n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	6(3.7)	0(0.0)	1(0.6)	6(3.7)	1(0.6)	2(1.2)
Breast cancer	乳癌	0(0.0)	0(0.0)	1(0.6)	0(0.0)	0(0.0)	1(0.6)
Gastric cancer	胃癌	1(0.6)	0(0.0)	0(0.0)	1(0.6)	0(0.0)	0(0.0)
Seborrhoeic keratosis	脂漏性角化症	1(0.6)	0(0.0)	0(0.0)	1(0.6)	0(0.0)	0(0.0)
Cholesteatoma	真珠腫	1(0.6)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Laryngeal papilloma	喉頭乳頭腫	1(0.6)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Squamous cell carcinoma of skin	皮膚有棘細胞癌	1(0.6)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Uterine leiomyoma	子宮平滑筋腫	1(0.6)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Pyogenic granuloma	化膿性肉芽腫	0(0.0)	0(0.0)	0(0.0)	1(0.6)	0(0.0)	0(0.0)
Thymoma	胸腺腫	0(0.0)	0(0.0)	0(0.0)	1(0.6)	0(0.0)	0(0.0)
Prostate cancer	前立腺癌	0(0.0)	0(0.0)	0(0.0)	1(0.6)	0(0.0)	0(0.0)
Pancreatic neoplasm	膵新生物	0(0.0)	0(0.0)	0(0.0)	1(0.6)	0(0.0)	0(0.0)
Urethral neoplasm	尿道新生物	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.6)	0(0.0)
Renal cell carcinoma	腎細胞癌	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.6)
Gastrointestinal submucosal tumour	消化管粘膜下腫瘍	0(0.0)	0(0.0)	0(0.0)	1(0.6)	0(0.0)	0(0.0)

表 2.7.4.9－61　程度別の有害事象の内訳（MT-6548-J03 試験／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548(N=162) Mild n (%)	 Moderate n (%)	 Severe n (%)	darbepoetin(N=161) Mild n (%)	 Moderate n (%)	 Severe n (%)
Blood and lymphatic system disorders	血液およびリンパ系障害	6(3.7)	3(1.9)	0(0.0)	1(0.6)	0(0.0)	1(0.6)
Anaemia	貧血	1(0.6)	1(0.6)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Anaemia macrocytic	大球性貧血	1(0.6)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Eosinophilia	好酸球増加症	1(0.6)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Lymphadenitis	リンパ節炎	0(0.0)	1(0.6)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Lymphadenopathy	リンパ節症	1(0.6)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Polycythaemia	赤血球増加症	1(0.6)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Haemorrhagic anaemia	出血性貧血	1(0.6)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Nephrogenic anaemia	腎性貧血	0(0.0)	1(0.6)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Aplastic anaemia	再生不良性貧血	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.6)
Iron deficiency anaemia	鉄欠乏性貧血	0(0.0)	0(0.0)	0(0.0)	1(0.6)	0(0.0)	0(0.0)
Immune system disorders	免疫系障害	4(2.5)	0(0.0)	0(0.0)	14(8.7)	0(0.0)	0(0.0)
Seasonal allergy	季節性アレルギー	4(2.5)	0(0.0)	0(0.0)	12(7.5)	0(0.0)	0(0.0)
Drug hypersensitivity	薬物過敏症	0(0.0)	0(0.0)	0(0.0)	1(0.6)	0(0.0)	0(0.0)
Dialysis amyloidosis	透析アミロイドーシス	0(0.0)	0(0.0)	0(0.0)	1(0.6)	0(0.0)	0(0.0)
Endocrine disorders	内分泌障害	3(1.9)	0(0.0)	0(0.0)	4(2.5)	0(0.0)	0(0.0)
Hyperparathyroidism secondary	続発性副甲状腺機能亢進症	2(1.2)	0(0.0)	0(0.0)	2(1.2)	0(0.0)	0(0.0)
Hypothyroidism	甲状腺機能低下症	1(0.6)	0(0.0)	0(0.0)	2(1.2)	0(0.0)	0(0.0)
Goitre	甲状腺腫	0(0.0)	0(0.0)	0(0.0)	1(0.6)	0(0.0)	0(0.0)
Hyperparathyroidism	副甲状腺機能亢進症	0(0.0)	0(0.0)	0(0.0)	1(0.6)	0(0.0)	0(0.0)

表 2.7.4.9－61　程度別の有害事象の内訳（MT-6548-J03 試験／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548(N=162) Mild n (%)	 Moderate n (%)	 Severe n (%)	darbepoetin(N=161) Mild n (%)	 Moderate n (%)	 Severe n (%)
Metabolism and nutrition disorders	代謝および栄養障害	16(9.9)	3(1.9)	0(0.0)	21(13.0)	0(0.0)	0(0.0)
Decreased appetite	食欲減退	7(4.3)	2(1.2)	0(0.0)	4(2.5)	0(0.0)	0(0.0)
Hypocarnitinaemia	低カルニチン血症	4(2.5)	0(0.0)	0(0.0)	2(1.2)	0(0.0)	0(0.0)
Hyperphosphataemia	高リン酸塩血症	2(1.2)	0(0.0)	0(0.0)	2(1.2)	0(0.0)	0(0.0)
Hypoglycaemia	低血糖	1(0.6)	0(0.0)	0(0.0)	2(1.2)	0(0.0)	0(0.0)
Hypercalcaemia	高カルシウム血症	1(0.6)	0(0.0)	0(0.0)	1(0.6)	0(0.0)	0(0.0)
Hyperkalaemia	高カリウム血症	0(0.0)	1(0.6)	0(0.0)	1(0.6)	0(0.0)	0(0.0)
Hypoalbuminaemia	低アルブミン血症	1(0.6)	0(0.0)	0(0.0)	1(0.6)	0(0.0)	0(0.0)
Dyslipidaemia	脂質異常症	1(0.6)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Zinc deficiency	亜鉛欠乏	0(0.0)	0(0.0)	0(0.0)	3(1.9)	0(0.0)	0(0.0)
Type 2 diabetes mellitus	2型糖尿病	0(0.0)	0(0.0)	0(0.0)	2(1.2)	0(0.0)	0(0.0)
Dehydration	脱水	0(0.0)	0(0.0)	0(0.0)	1(0.6)	0(0.0)	0(0.0)
Diabetes mellitus inadequate control	コントロール不良の糖尿病	0(0.0)	0(0.0)	0(0.0)	1(0.6)	0(0.0)	0(0.0)
Hyperuricaemia	高尿酸血症	0(0.0)	0(0.0)	0(0.0)	1(0.6)	0(0.0)	0(0.0)
Hypophosphataemia	低リン酸血症	0(0.0)	0(0.0)	0(0.0)	1(0.6)	0(0.0)	0(0.0)
Psychiatric disorders	精神障害	7(4.3)	0(0.0)	0(0.0)	7(4.3)	0(0.0)	0(0.0)
Insomnia	不眠症	6(3.7)	0(0.0)	0(0.0)	6(3.7)	0(0.0)	0(0.0)
Depression	うつ病	1(0.6)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Abnormal behaviour	異常行動	1(0.6)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Sleep disorder	睡眠障害	0(0.0)	0(0.0)	0(0.0)	1(0.6)	0(0.0)	0(0.0)

表 2.7.4.9－61　程度別の有害事象の内訳（MT-6548-J03 試験／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548(N=162) Mild n (%)	 Moderate n (%)	 Severe n (%)	darbepoetin(N=161) Mild n (%)	 Moderate n (%)	 Severe n (%)
Nervous system disorders	神経系障害	29(17.9)	6(3.7)	1(0.6)	20(12.4)	3(1.9)	1(0.6)
Headache	頭痛	13(8.0)	0(0.0)	0(0.0)	5(3.1)	0(0.0)	0(0.0)
Dizziness	浮動性めまい	8(4.9)	0(0.0)	0(0.0)	5(3.1)	0(0.0)	0(0.0)
Carpal tunnel syndrome	手根管症候群	2(1.2)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Facial paralysis	顔面麻痺	0(0.0)	2(1.2)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Cerebral infarction	脳梗塞	0(0.0)	0(0.0)	1(0.6)	2(1.2)	2(1.2)	1(0.6)
Carotid artery stenosis	頚動脈狭窄	1(0.6)	0(0.0)	0(0.0)	1(0.6)	0(0.0)	0(0.0)
Cerebellar infarction	小脳梗塞	0(0.0)	1(0.6)	0(0.0)	0(0.0)	1(0.6)	0(0.0)
Neuralgia	神経痛	1(0.6)	0(0.0)	0(0.0)	1(0.6)	0(0.0)	0(0.0)
Dizziness postural	体位性めまい	1(0.6)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Hypoaesthesia	感覚鈍麻	1(0.6)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Intracranial aneurysm	頭蓋内動脈瘤	1(0.6)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Myelopathy	脊髄症	0(0.0)	1(0.6)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Myoclonus	ミオクローヌス	1(0.6)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Sciatica	坐骨神経痛	1(0.6)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Somnolence	傾眠	1(0.6)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Tremor	振戦	1(0.6)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Intercostal neuralgia	肋間神経痛	1(0.6)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Cervical radiculopathy	頚髄神経根障害	0(0.0)	1(0.6)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Lacunar infarction	ラクナ梗塞	1(0.6)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Restless legs syndrome	下肢静止不能症候群	1(0.6)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Thrombotic cerebral infarction	血栓性脳梗塞	0(0.0)	1(0.6)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Loss of consciousness	意識消失	0(0.0)	0(0.0)	0(0.0)	2(1.2)	0(0.0)	0(0.0)
Trigeminal neuralgia	三叉神経痛	0(0.0)	0(0.0)	0(0.0)	2(1.2)	0(0.0)	0(0.0)

表 2.7.4.9－61　程度別の有害事象の内訳（MT-6548-J03 試験／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548(N=162) Mild n (%)	 Moderate n (%)	 Severe n (%)	darbepoetin(N=161) Mild n (%)	 Moderate n (%)	 Severe n (%)
Cervicobrachial syndrome	頚腕症候群	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
Dysgeusia	味覚異常	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
Head discomfort	頭部不快感	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
Seizure	痙攣発作	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
Tension headache	緊張性頭痛	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
Vocal cord paralysis	声帯麻痺	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
Cervicogenic headache	頚原性頭痛	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)

表 2.7.4.9－61　程度別の有害事象の内訳（MT-6548-J03 試験／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548(N=162) Mild n (%)	 Moderate n (%)	 Severe n (%)	darbepoetin(N=161) Mild n (%)	 Moderate n (%)	 Severe n (%)
Eye disorders	眼障害	34(21.0)	1(0.6)	0(0.0)	34(21.1)	0(0.0)	1(0.6)
Retinal haemorrhage	網膜出血	16(9.9)	0(0.0)	0(0.0)	10(6.2)	0(0.0)	0(0.0)
Conjunctival haemorrhage	結膜出血	4(2.5)	0(0.0)	0(0.0)	3(1.9)	0(0.0)	0(0.0)
Diabetic retinopathy	糖尿病網膜症	2(1.2)	0(0.0)	0(0.0)	1(0.6)	0(0.0)	0(0.0)
Dry eye	眼乾燥	2(1.2)	0(0.0)	0(0.0)	1(0.6)	0(0.0)	0(0.0)
Cataract	白内障	0(0.0)	1(0.6)	0(0.0)	3(1.9)	0(0.0)	0(0.0)
Conjunctivitis allergic	アレルギー性結膜炎	1(0.6)	0(0.0)	0(0.0)	3(1.9)	0(0.0)	0(0.0)
Macular oedema	黄斑浮腫	1(0.6)	0(0.0)	0(0.0)	3(1.9)	0(0.0)	0(0.0)
Blepharitis	眼瞼炎	1(0.6)	0(0.0)	0(0.0)	2(1.2)	0(0.0)	0(0.0)
Glaucoma	緑内障	1(0.6)	0(0.0)	0(0.0)	1(0.6)	0(0.0)	0(0.0)
Ocular hyperaemia	眼充血	1(0.6)	0(0.0)	0(0.0)	1(0.6)	0(0.0)	0(0.0)
Optic disc haemorrhage	視神経乳頭出血	1(0.6)	0(0.0)	0(0.0)	1(0.6)	0(0.0)	0(0.0)
Eye pruritus	眼そう痒症	1(0.6)	0(0.0)	0(0.0)	1(0.6)	0(0.0)	0(0.0)
Diplopia	複視	1(0.6)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Keratitis	角膜炎	1(0.6)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Punctate keratitis	点状角膜炎	1(0.6)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Retinal oedema	網膜浮腫	1(0.6)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Retinal vein occlusion	網膜静脈閉塞	1(0.6)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Trichiasis	睫毛乱生	1(0.6)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Vitreous floaters	硝子体浮遊物	1(0.6)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Cystoid macular oedema	嚢胞様黄斑浮腫	1(0.6)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Chorioretinopathy	網脈絡膜症	1(0.6)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Eyelid haematoma	眼瞼血腫	1(0.6)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Chalazion	霰粒腫	0(0.0)	0(0.0)	0(0.0)	1(0.6)	0(0.0)	0(0.0)

表 2.7.4.9－61　程度別の有害事象の内訳（MT-6548-J03 試験／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 (N=162) Mild n (%)	 Moderate n (%)	 Severe n (%)	darbepoetin (N=161) Mild n (%)	 Moderate n (%)	 Severe n (%)
Eye discharge	眼脂	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
Eyelid oedema	眼瞼浮腫	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
Posterior capsule opacification	後嚢部混濁	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
Retinal detachment	網膜剥離	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.6)
Retinal vascular disorder	網膜血管障害	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
Vitreous detachment	硝子体剥離	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
Vitreous haemorrhage	硝子体出血	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
Conjunctival hyperaemia	結膜充血	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
Retinal aneurysm	網膜血管瘤	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
Age-related macular degeneration	加齢黄斑変性	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
Ear and labyrinth disorders	耳および迷路障害	7 (4.3)	1 (0.6)	0 (0.0)	6 (3.7)	0 (0.0)	0 (0.0)
Vertigo	回転性めまい	5 (3.1)	0 (0.0)	0 (0.0)	2 (1.2)	0 (0.0)	0 (0.0)
Vertigo positional	頭位性回転性めまい	0 (0.0)	1 (0.6)	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
Deafness	難聴	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Sudden hearing loss	突発性難聴	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Eustachian tube stenosis	耳管狭窄	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Tinnitus	耳鳴	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.2)	0 (0.0)	0 (0.0)
Ear pruritus	耳そう痒症	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)

表 2.7.4.9－61　程度別の有害事象の内訳（MT-6548-J03 試験／52 週）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548(N=162) Mild n (%)	 Moderate n (%)	 Severe n (%)	darbepoetin(N=161) Mild n (%)	 Moderate n (%)	 Severe n (%)
Cardiac disorders	心臓障害	5(3.1)	6(3.7)	2(1.2)	13(8.1)	8(5.0)	0(0.0)
Cardiac failure congestive	うっ血性心不全	0(0.0)	1(0.6)	1(0.6)	0(0.0)	0(0.0)	0(0.0)
Tachycardia paroxysmal	発作性頻脈	2(1.2)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Angina pectoris	狭心症	0(0.0)	1(0.6)	0(0.0)	2(1.2)	1(0.6)	0(0.0)
Coronary artery stenosis	冠動脈狭窄	1(0.6)	0(0.0)	0(0.0)	1(0.6)	1(0.6)	0(0.0)
Myocardial ischaemia	心筋虚血	0(0.0)	1(0.6)	0(0.0)	0(0.0)	1(0.6)	0(0.0)
Cardiac dysfunction	心機能障害	1(0.6)	0(0.0)	0(0.0)	0(0.0)	1(0.6)	0(0.0)
Angina unstable	不安定狭心症	0(0.0)	1(0.6)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Aortic valve incompetence	大動脈弁閉鎖不全症	0(0.0)	1(0.6)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Arrhythmia	不整脈	1(0.6)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Arteriosclerosis coronary artery	冠動脈硬化症	0(0.0)	1(0.6)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Cardiac failure	心不全	0(0.0)	0(0.0)	1(0.6)	0(0.0)	0(0.0)	0(0.0)
Mitral valve incompetence	僧帽弁閉鎖不全症	0(0.0)	1(0.6)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Mitral valve stenosis	僧帽弁狭窄症	0(0.0)	1(0.6)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Palpitations	動悸	0(0.0)	1(0.6)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Paroxysmal arrhythmia	発作性不整脈	1(0.6)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Atrial fibrillation	心房細動	0(0.0)	0(0.0)	0(0.0)	3(1.9)	1(0.6)	0(0.0)
Bradycardia	徐脈	0(0.0)	0(0.0)	0(0.0)	3(1.9)	0(0.0)	0(0.0)
Aortic valve stenosis	大動脈弁狭窄	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.6)	0(0.0)
Pericarditis	心膜炎	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.6)	0(0.0)
Tachycardia	頻脈	0(0.0)	0(0.0)	0(0.0)	1(0.6)	0(0.0)	0(0.0)
Ventricular extrasystoles	心室性期外収縮	0(0.0)	0(0.0)	0(0.0)	1(0.6)	0(0.0)	0(0.0)
Left ventricular dysfunction	左室機能不全	0(0.0)	0(0.0)	0(0.0)	1(0.6)	0(0.0)	0(0.0)
Coronary artery perforation	冠動脈穿孔	0(0.0)	0(0.0)	0(0.0)	1(0.6)	0(0.0)	0(0.0)