表 2.7.4.7-26. 初回発現時期別の有害事象：613/1031 試験

器官別大分類		Placebo N=220		SI-613 30 mg N=220	
基本語	Timing of first onset	n	(%)	n	(%)
評価例数	Week 0 - Week 4	220		220	
	Week 4 - Week 12	214		216	
	Post Week 12	212		207	
全ての有害事象	Week 0 - Week 4	54	(24.5)	53	(24.1)
	Week 4 - Week 12	42	(19.6)	53	(24.5)
	Post Week 12	30	(14.2)	28	(13.5)
感染症および寄生虫症	Week 0 - Week 4	15	(6.8)	17	(7.7)
	Week 4 - Week 12	20	(9.3)	19	(8.8)
	Post Week 12	20	(9.4)	13	(6.3)
アデノウイルス感染	Week 0 - Week 4	0		0	
	Week 4 - Week 12	0		0	
	Post Week 12	0		1	(0.5)
気管支炎	Week 0 - Week 4	0		0	
	Week 4 - Week 12	0		1	(0.5)
	Post Week 12	1	(0.5)	0	
結膜炎	Week 0 - Week 4	1	(0.5)	2	(0.9)
	Week 4 - Week 12	0		0	
	Post Week 12	1	(0.5)	0	
膀胱炎	Week 0 - Week 4	2	(0.9)	0	
	Week 4 - Week 12	1	(0.5)	0	
	Post Week 12	1	(0.5)	0	
感染性腸炎	Week 0 - Week 4	1	(0.5)	0	
	Week 4 - Week 12	0		0	
	Post Week 12	0		0	
真菌感染	Week 0 - Week 4	0		0	
	Week 4 - Week 12	0		0	
	Post Week 12	1	(0.5)	0	
せつ	Week 0 - Week 4	0		0	
	Week 4 - Week 12	0		0	
	Post Week 12	0		1	(0.5)
胃腸炎	Week 0 - Week 4	0		0	
	Week 4 - Week 12	2	(0.9)	1	(0.5)
	Post Week 12	1	(0.5)	1	(0.5)
歯肉炎	Week 0 - Week 4	1	(0.5)	1	(0.5)
	Week 4 - Week 12	1	(0.5)	0	
	Post Week 12	0		0	
単純ヘルペス	Week 0 - Week 4	0		0	
	Week 4 - Week 12	0		0	
	Post Week 12	0		2	(1.0)
帯状疱疹	Week 0 - Week 4	0		0	
	Week 4 - Week 12	0		1	(0.5)
	Post Week 12	0		0	
インフルエンザ	Week 0 - Week 4	1	(0.5)	0	
	Week 4 - Week 12	1	(0.5)	1	(0.5)
	Post Week 12	2	(0.9)	1	(0.5)
上咽頭炎	Week 0 - Week 4	7	(3.2)	12	(5.5)
	Week 4 - Week 12	11	(5.1)	15	(6.9)
	Post Week 12	12	(5.7)	10	(4.8)
口腔ヘルペス	Week 0 - Week 4	0		0	
	Week 4 - Week 12	0		0	
	Post Week 12	1	(0.5)	0	

器官別大分類		Placebo N=220		SI-613 30 mg N=220	
基本語	Timing of first onset	n	(%)	n	(%)
外耳炎	Week 0 - Week 4	0		0	
	Week 4 - Week 12	0		0	
	Post Week 12	1	(0.5)	0	
中耳炎	Week 0 - Week 4	1	(0.5)	0	
	Week 4 - Week 12	0		1	(0.5)
	Post Week 12	1	(0.5)	0	
爪囲炎	Week 0 - Week 4	0		0	
	Week 4 - Week 12	0		0	
	Post Week 12	1	(0.5)	0	
歯冠周囲炎	Week 0 - Week 4	1	(0.5)	0	
	Week 4 - Week 12	0		0	
	Post Week 12	0		0	
歯周炎	Week 0 - Week 4	0		1	(0.5)
	Week 4 - Week 12	1	(0.5)	0	
	Post Week 12	0		1	(0.5)
咽頭炎	Week 0 - Week 4	0		0	
	Week 4 - Week 12	1	(0.5)	0	
	Post Week 12	0		0	
歯髄炎	Week 0 - Week 4	0		1	(0.5)
	Week 4 - Week 12	0		0	
	Post Week 12	0		0	
鼻炎	Week 0 - Week 4	0		0	
	Week 4 - Week 12	0		0	
	Post Week 12	0		1	(0.5)
副鼻腔炎	Week 0 - Week 4	0		0	
	Week 4 - Week 12	1	(0.5)	0	
	Post Week 12	0		1	(0.5)
皮膚細菌感染	Week 0 - Week 4	0		1	(0.5)
	Week 4 - Week 12	0		0	
	Post Week 12	0		0	
股部白癬	Week 0 - Week 4	0		0	
	Week 4 - Week 12	0		1	(0.5)
	Post Week 12	0		0	
足部白癬	Week 0 - Week 4	0		0	
	Week 4 - Week 12	0		0	
	Post Week 12	0		1	(0.5)
トリコフィトン感染症	Week 0 - Week 4	0		0	
	Week 4 - Week 12	1	(0.5)	0	
	Post Week 12	0		0	
上気道感染	Week 0 - Week 4	1	(0.5)	0	
	Week 4 - Week 12	0		0	
	Post Week 12	0		0	
外陰部腟カンジダ症	Week 0 - Week 4	1	(0.5)	0	
	Week 4 - Week 12	1	(0.5)	0	
	Post Week 12	0		0	
血液およびリンパ系障害	Week 0 - Week 4	0		0	
	Week 4 - Week 12	0		0	
	Post Week 12	1	(0.5)	0	
脾腫	Week 0 - Week 4	0		0	
	Week 4 - Week 12	0		0	
	Post Week 12	1	(0.5)	0	
免疫系障害	Week 0 - Week 4	0		2	(0.9)
	Week 4 - Week 12	0		2	(0.9)

器官別大分類 基本語	Timing of first onset	Placebo N=220 n	(%)	SI-613 30 mg N=220 n	(%)
	Post Week 12	0		0	
節足動物刺傷アレルギー	Week 0 - Week 4	0		0	
	Week 4 - Week 12	0		1	(0.5)
	Post Week 12	0		0	
アナフィラキシー反応	Week 0 - Week 4	0		1	(0.5)
	Week 4 - Week 12	0		0	
	Post Week 12	0		0	
アナフィラキシーショック	Week 0 - Week 4	0		1	(0.5)
	Week 4 - Week 12	0		0	
	Post Week 12	0		0	
季節性アレルギー	Week 0 - Week 4	0		0	
	Week 4 - Week 12	0		1	(0.5)
	Post Week 12	0		0	
内分泌障害	Week 0 - Week 4	0		0	
	Week 4 - Week 12	1	(0.5)	0	
	Post Week 12	0		0	
甲状腺腫	Week 0 - Week 4	0		0	
	Week 4 - Week 12	1	(0.5)	0	
	Post Week 12	0		0	
代謝および栄養障害	Week 0 - Week 4	1	(0.5)	2	(0.9)
	Week 4 - Week 12	0		2	(0.9)
	Post Week 12	2	(0.9)	1	(0.5)
糖尿病	Week 0 - Week 4	0		0	
	Week 4 - Week 12	0		0	
	Post Week 12	1	(0.5)	1	(0.5)
脂質異常症	Week 0 - Week 4	0		1	(0.5)
	Week 4 - Week 12	0		0	
	Post Week 12	0		0	
耐糖能障害	Week 0 - Week 4	0		0	
	Week 4 - Week 12	0		1	(0.5)
	Post Week 12	1	(0.5)	0	
高尿酸血症	Week 0 - Week 4	1	(0.5)	1	(0.5)
	Week 4 - Week 12	0		1	(0.5)
	Post Week 12	0		0	
精神障害	Week 0 - Week 4	0		0	
	Week 4 - Week 12	1	(0.5)	0	
	Post Week 12	0		0	
身体疾患による睡眠障害、不眠症型	Week 0 - Week 4	0		0	
	Week 4 - Week 12	1	(0.5)	0	
	Post Week 12	0		0	
神経系障害	Week 0 - Week 4	0		5	(2.3)
	Week 4 - Week 12	2	(0.9)	5	(2.3)
	Post Week 12	0		4	(1.9)
自律神経発作	Week 0 - Week 4	0		0	
	Week 4 - Week 12	0		1	(0.5)
	Post Week 12	0		0	
頚腕症候群	Week 0 - Week 4	0		0	
	Week 4 - Week 12	1	(0.5)	1	(0.5)
	Post Week 12	0		0	
浮動性めまい	Week 0 - Week 4	0		1	(0.5)
	Week 4 - Week 12	0		0	
	Post Week 12	0		2	(1.0)
味覚異常	Week 0 - Week 4	0		0	

器官別大分類		Placebo N=220		SI-613 30 mg N=220	
基本語	Timing of first onset	n	(%)	n	(%)
	Week 4 - Week 12	0		1	(0.5)
	Post Week 12	0		0	
頭痛	Week 0 - Week 4	0		2	(0.9)
	Week 4 - Week 12	0		0	
	Post Week 12	0		1	(0.5)
片頭痛	Week 0 - Week 4	0		0	
	Week 4 - Week 12	0		1	(0.5)
	Post Week 12	0		0	
錯感覚	Week 0 - Week 4	0		0	
	Week 4 - Week 12	0		1	(0.5)
	Post Week 12	0		0	
坐骨神経痛	Week 0 - Week 4	0		2	(0.9)
	Week 4 - Week 12	1	(0.5)	0	
	Post Week 12	0		1	(0.5)
眼障害	Week 0 - Week 4	0		2	(0.9)
	Week 4 - Week 12	0		3	(1.4)
	Post Week 12	1	(0.5)	1	(0.5)
白内障	Week 0 - Week 4	0		1	(0.5)
	Week 4 - Week 12	0		0	
	Post Week 12	0		1	(0.5)
結膜充血	Week 0 - Week 4	0		0	
	Week 4 - Week 12	0		0	
	Post Week 12	1	(0.5)	0	
アレルギー性結膜炎	Week 0 - Week 4	0		0	
	Week 4 - Week 12	0		1	(0.5)
	Post Week 12	0		0	
ドライアイ	Week 0 - Week 4	0		0	
	Week 4 - Week 12	0		1	(0.5)
	Post Week 12	0		0	
眼の炎症	Week 0 - Week 4	0		0	
	Week 4 - Week 12	0		1	(0.5)
	Post Week 12	0		0	
流涙増加	Week 0 - Week 4	0		1	(0.5)
	Week 4 - Week 12	0		0	
	Post Week 12	0		0	
耳および迷路障害	Week 0 - Week 4	0		0	
	Week 4 - Week 12	0		1	(0.5)
	Post Week 12	1	(0.5)	1	(0.5)
感音性難聴	Week 0 - Week 4	0		0	
	Week 4 - Week 12	0		1	(0.5)
	Post Week 12	0		0	
回転性めまい	Week 0 - Week 4	0		0	
	Week 4 - Week 12	0		0	
	Post Week 12	1	(0.5)	0	
頭位性回転性めまい	Week 0 - Week 4	0		0	
	Week 4 - Week 12	0		0	
	Post Week 12	0		1	(0.5)
心臓障害	Week 0 - Week 4	0		1	(0.5)
	Week 4 - Week 12	0		0	
	Post Week 12	0		1	(0.5)
不安定狭心症	Week 0 - Week 4	0		1	(0.5)
	Week 4 - Week 12	0		0	
	Post Week 12	0		0	

器官別大分類 基本語	Timing of first onset	Placebo N=220 n	(%)	SI-613 30 mg N=220 n	(%)
不整脈	Week 0 - Week 4	0		0	
	Week 4 - Week 12	0		0	
	Post Week 12	0		1	(0.5)
血管障害	Week 0 - Week 4	1	(0.5)	0	
	Week 4 - Week 12	1	(0.5)	2	(0.9)
	Post Week 12	0		1	(0.5)
高血圧	Week 0 - Week 4	0		0	
	Week 4 - Week 12	1	(0.5)	1	(0.5)
	Post Week 12	0		0	
蒼白	Week 0 - Week 4	1	(0.5)	0	
	Week 4 - Week 12	0		0	
	Post Week 12	0		0	
末梢静脈疾患	Week 0 - Week 4	0		0	
	Week 4 - Week 12	0		1	(0.5)
	Post Week 12	0		0	
静脈瘤	Week 0 - Week 4	0		0	
	Week 4 - Week 12	0		0	
	Post Week 12	0		1	(0.5)
呼吸器、胸郭および縦隔障害	Week 0 - Week 4	2	(0.9)	1	(0.5)
	Week 4 - Week 12	3	(1.4)	0	
	Post Week 12	1	(0.5)	2	(1.0)
咳嗽	Week 0 - Week 4	1	(0.5)	0	
	Week 4 - Week 12	0		0	
	Post Week 12	0		0	
鼻出血	Week 0 - Week 4	0		0	
	Week 4 - Week 12	1	(0.5)	0	
	Post Week 12	0		0	
喉頭痛	Week 0 - Week 4	0		0	
	Week 4 - Week 12	0		0	
	Post Week 12	0		1	(0.5)
口腔咽頭痛	Week 0 - Week 4	0		0	
	Week 4 - Week 12	0		0	
	Post Week 12	1	(0.5)	1	(0.5)
上気道の炎症	Week 0 - Week 4	1	(0.5)	1	(0.5)
	Week 4 - Week 12	2	(0.9)	0	
	Post Week 12	0		0	
胃腸障害	Week 0 - Week 4	5	(2.3)	4	(1.8)
	Week 4 - Week 12	8	(3.7)	7	(3.2)
	Post Week 12	3	(1.4)	3	(1.4)
腹痛	Week 0 - Week 4	1	(0.5)	0	
	Week 4 - Week 12	0		0	
	Post Week 12	0		0	
上腹部痛	Week 0 - Week 4	0		0	
	Week 4 - Week 12	0		1	(0.5)
	Post Week 12	0		1	(0.5)
口唇炎	Week 0 - Week 4	0		0	
	Week 4 - Week 12	0		1	(0.5)
	Post Week 12	0		0	
慢性胃炎	Week 0 - Week 4	0		0	
	Week 4 - Week 12	1	(0.5)	1	(0.5)
	Post Week 12	0		0	
齲歯	Week 0 - Week 4	0		0	
	Week 4 - Week 12	1	(0.5)	1	(0.5)

器官別大分類 基本語	Timing of first onset	Placebo N=220 n	(%)	SI-613 30 mg N=220 n	(%)
	Post Week 12	1	(0.5)	0	
下痢	Week 0 - Week 4	1	(0.5)	2	(0.9)
	Week 4 - Week 12	2	(0.9)	1	(0.5)
	Post Week 12	0		0	
胃潰瘍	Week 0 - Week 4	0		0	
	Week 4 - Week 12	0		1	(0.5)
	Post Week 12	0		0	
胃炎	Week 0 - Week 4	0		1	(0.5)
	Week 4 - Week 12	0		0	
	Post Week 12	0		2	(1.0)
胃食道逆流性疾患	Week 0 - Week 4	0		0	
	Week 4 - Week 12	3	(1.4)	0	
	Post Week 12	0		0	
痔核	Week 0 - Week 4	1	(0.5)	0	
	Week 4 - Week 12	0		0	
	Post Week 12	1	(0.5)	0	
過敏性腸症候群	Week 0 - Week 4	1	(0.5)	0	
	Week 4 - Week 12	0		0	
	Post Week 12	0		0	
悪心	Week 0 - Week 4	0		1	(0.5)
	Week 4 - Week 12	2	(0.9)	0	
	Post Week 12	0		0	
膵嚢胞	Week 0 - Week 4	0		0	
	Week 4 - Week 12	0		0	
	Post Week 12	1	(0.5)	0	
口内炎	Week 0 - Week 4	1	(0.5)	0	
	Week 4 - Week 12	0		0	
	Post Week 12	0		0	
歯痛	Week 0 - Week 4	0		0	
	Week 4 - Week 12	0		1	(0.5)
	Post Week 12	0		0	
嘔吐	Week 0 - Week 4	1	(0.5)	0	
	Week 4 - Week 12	2	(0.9)	0	
	Post Week 12	0		0	
肝胆道系障害	Week 0 - Week 4	0		1	(0.5)
	Week 4 - Week 12	0		1	(0.5)
	Post Week 12	1	(0.5)	1	(0.5)
胆嚢ポリープ	Week 0 - Week 4	0		0	
	Week 4 - Week 12	0		0	
	Post Week 12	1	(0.5)	0	
肝機能異常	Week 0 - Week 4	0		1	(0.5)
	Week 4 - Week 12	0		1	(0.5)
	Post Week 12	0		1	(0.5)
脂肪肝	Week 0 - Week 4	0		0	
	Week 4 - Week 12	0		0	
	Post Week 12	1	(0.5)	0	
皮膚および皮下組織障害	Week 0 - Week 4	3	(1.4)	2	(0.9)
	Week 4 - Week 12	7	(3.3)	3	(1.4)
	Post Week 12	3	(1.4)	3	(1.4)
ざ瘡	Week 0 - Week 4	0		0	
	Week 4 - Week 12	1	(0.5)	0	
	Post Week 12	0		0	
冷汗	Week 0 - Week 4	1	(0.5)	0	

器官別大分類 基本語	Timing of first onset	Placebo N=220 n	(%)	SI-613 30 mg N=220 n	(%)
	Week 4 - Week 12	0		0	
	Post Week 12	0		0	
皮膚嚢腫	Week 0 - Week 4	0		0	
	Week 4 - Week 12	1	(0.5)	0	
	Post Week 12	1	(0.5)	0	
皮膚炎	Week 0 - Week 4	0		0	
	Week 4 - Week 12	0		0	
	Post Week 12	1	(0.5)	0	
アレルギー性皮膚炎	Week 0 - Week 4	1	(0.5)	0	
	Week 4 - Week 12	0		0	
	Post Week 12	0		0	
皮膚乾燥	Week 0 - Week 4	0		0	
	Week 4 - Week 12	0		0	
	Post Week 12	1	(0.5)	0	
湿疹	Week 0 - Week 4	0		0	
	Week 4 - Week 12	1	(0.5)	2	(0.9)
	Post Week 12	1	(0.5)	3	(1.4)
汗疹	Week 0 - Week 4	0		0	
	Week 4 - Week 12	0		1	(0.5)
	Post Week 12	0		0	
そう痒症	Week 0 - Week 4	0		0	
	Week 4 - Week 12	1	(0.5)	0	
	Post Week 12	0		0	
発疹	Week 0 - Week 4	1	(0.5)	0	
	Week 4 - Week 12	2	(0.9)	0	
	Post Week 12	1	(0.5)	0	
蕁麻疹	Week 0 - Week 4	0		2	(0.9)
	Week 4 - Week 12	1	(0.5)	0	
	Post Week 12	0		0	
筋骨格系および結合組織障害	Week 0 - Week 4	19	(8.6)	9	(4.1)
	Week 4 - Week 12	14	(6.5)	24	(11.1)
	Post Week 12	17	(8.0)	14	(6.8)
関節痛	Week 0 - Week 4	3	(1.4)	1	(0.5)
	Week 4 - Week 12	2	(0.9)	3	(1.4)
	Post Week 12	2	(0.9)	6	(2.9)
関節炎	Week 0 - Week 4	0		0	
	Week 4 - Week 12	1	(0.5)	1	(0.5)
	Post Week 12	1	(0.5)	0	
背部痛	Week 0 - Week 4	1	(0.5)	2	(0.9)
	Week 4 - Week 12	3	(1.4)	3	(1.4)
	Post Week 12	3	(1.4)	2	(1.0)
ピロリン酸カルシウム結晶性軟骨石灰化症	Week 0 - Week 4	0		0	
	Week 4 - Week 12	1	(0.5)	0	
	Post Week 12	0		0	
腱付着部症	Week 0 - Week 4	1	(0.5)	0	
	Week 4 - Week 12	0		0	
	Post Week 12	0		0	
出血性関節症	Week 0 - Week 4	0		0	
	Week 4 - Week 12	1	(0.5)	0	
	Post Week 12	0		0	
椎間板変性症	Week 0 - Week 4	0		0	
	Week 4 - Week 12	0		0	
	Post Week 12	1	(0.5)	0	

器官別大分類		Placebo N=220		SI-613 30 mg N=220	
基本語	Timing of first onset	n	(%)	n	(%)
椎間板障害	Week 0 - Week 4	0		0	
	Week 4 - Week 12	0		0	
	Post Week 12	0		1	(0.5)
関節滲出液	Week 0 - Week 4	1	(0.5)	0	
	Week 4 - Week 12	0		0	
	Post Week 12	0		0	
関節硬直	Week 0 - Week 4	1	(0.5)	0	
	Week 4 - Week 12	0		0	
	Post Week 12	0		0	
関節腫脹	Week 0 - Week 4	1	(0.5)	0	
	Week 4 - Week 12	0		0	
	Post Week 12	0		0	
四肢不快感	Week 0 - Week 4	1	(0.5)	0	
	Week 4 - Week 12	0		1	(0.5)
	Post Week 12	0		0	
腰部脊柱管狭窄症	Week 0 - Week 4	0		0	
	Week 4 - Week 12	1	(0.5)	1	(0.5)
	Post Week 12	0		1	(0.5)
筋痙縮	Week 0 - Week 4	1	(0.5)	1	(0.5)
	Week 4 - Week 12	0		0	
	Post Week 12	2	(0.9)	0	
筋骨格痛	Week 0 - Week 4	0		0	
	Week 4 - Week 12	1	(0.5)	2	(0.9)
	Post Week 12	0		0	
筋骨格硬直	Week 0 - Week 4	1	(0.5)	0	
	Week 4 - Week 12	0		1	(0.5)
	Post Week 12	0		0	
筋肉痛	Week 0 - Week 4	0		1	(0.5)
	Week 4 - Week 12	1	(0.5)	2	(0.9)
	Post Week 12	0		2	(1.0)
筋筋膜炎	Week 0 - Week 4	2	(0.9)	0	
	Week 4 - Week 12	0		1	(0.5)
	Post Week 12	0		0	
頚部痛	Week 0 - Week 4	0		1	(0.5)
	Week 4 - Week 12	0		0	
	Post Week 12	0		0	
変形性関節症	Week 0 - Week 4	5	(2.3)	2	(0.9)
	Week 4 - Week 12	0		3	(1.4)
	Post Week 12	3	(1.4)	2	(1.0)
骨壊死	Week 0 - Week 4	0		0	
	Week 4 - Week 12	0		1	(0.5)
	Post Week 12	0		0	
四肢痛	Week 0 - Week 4	1	(0.5)	1	(0.5)
	Week 4 - Week 12	0		1	(0.5)
	Post Week 12	2	(0.9)	0	
関節周囲炎	Week 0 - Week 4	1	(0.5)	0	
	Week 4 - Week 12	1	(0.5)	3	(1.4)
	Post Week 12	1	(0.5)	0	
肩回旋筋腱板症候群	Week 0 - Week 4	0		0	
	Week 4 - Week 12	1	(0.5)	0	
	Post Week 12	0		0	
変形性脊椎症	Week 0 - Week 4	1	(0.5)	0	
	Week 4 - Week 12	1	(0.5)	0	

器官別大分類 基本語	Timing of first onset	Placebo N=220 n	(%)	SI-613 30 mg N=220 n	(%)
	Post Week 12	2	(0.9)	2	(1.0)
脊椎すべり症	Week 0 - Week 4	0		0	
	Week 4 - Week 12	0		0	
	Post Week 12	1	(0.5)	0	
滑液嚢腫	Week 0 - Week 4	0		0	
	Week 4 - Week 12	0		0	
	Post Week 12	1	(0.5)	0	
滑膜炎	Week 0 - Week 4	0		0	
	Week 4 - Week 12	0		0	
	Post Week 12	1	(0.5)	0	
腱炎	Week 0 - Week 4	0		0	
	Week 4 - Week 12	0		2	(0.9)
	Post Week 12	1	(0.5)	0	
腱鞘炎	Week 0 - Week 4	0		1	(0.5)
	Week 4 - Week 12	0		2	(0.9)
	Post Week 12	1	(0.5)	0	
弾発指	Week 0 - Week 4	0		0	
	Week 4 - Week 12	0		1	(0.5)
	Post Week 12	0		0	
腎および尿路障害	Week 0 - Week 4	0		0	
	Week 4 - Week 12	1	(0.5)	1	(0.5)
	Post Week 12	1	(0.5)	0	
緊張性膀胱	Week 0 - Week 4	0		0	
	Week 4 - Week 12	1	(0.5)	0	
	Post Week 12	0		0	
腎嚢胞	Week 0 - Week 4	0		0	
	Week 4 - Week 12	0		0	
	Post Week 12	1	(0.5)	0	
腎機能障害	Week 0 - Week 4	0		0	
	Week 4 - Week 12	0		1	(0.5)
	Post Week 12	0		0	
生殖系および乳房障害	Week 0 - Week 4	1	(0.5)	1	(0.5)
	Week 4 - Week 12	0		1	(0.5)
	Post Week 12	0		0	
子宮頚管ポリープ	Week 0 - Week 4	1	(0.5)	0	
	Week 4 - Week 12	0		0	
	Post Week 12	0		0	
前立腺炎	Week 0 - Week 4	0		1	(0.5)
	Week 4 - Week 12	0		0	
	Post Week 12	0		0	
外陰腟そう痒症	Week 0 - Week 4	0		0	
	Week 4 - Week 12	0		1	(0.5)
	Post Week 12	0		0	
一般・全身障害および投与部位の状態	Week 0 - Week 4	7	(3.2)	2	(0.9)
	Week 4 - Week 12	2	(0.9)	6	(2.8)
	Post Week 12	5	(2.4)	3	(1.4)
胸痛	Week 0 - Week 4	1	(0.5)	0	
	Week 4 - Week 12	0		0	
	Post Week 12	1	(0.5)	1	(0.5)
悪寒	Week 0 - Week 4	0		0	
	Week 4 - Week 12	0		1	(0.5)
	Post Week 12	0		0	
異常感	Week 0 - Week 4	1	(0.5)	0	

器官別大分類 基本語	Timing of first onset	Placebo N=220 n	(%)	SI-613 30 mg N=220 n	(%)
	Week 4 - Week 12	0		0	
	Post Week 12	0		0	
炎症	Week 0 - Week 4	0		0	
	Week 4 - Week 12	0		1	(0.5)
	Post Week 12	0		0	
注射部位関節不快感	Week 0 - Week 4	1	(0.5)	0	
	Week 4 - Week 12	0		0	
	Post Week 12	0		0	
注射部位関節痛	Week 0 - Week 4	2	(0.9)	2	(0.9)
	Week 4 - Week 12	2	(0.9)	3	(1.4)
	Post Week 12	2	(0.9)	1	(0.5)
注射部位関節腫脹	Week 0 - Week 4	1	(0.5)	0	
	Week 4 - Week 12	0		0	
	Post Week 12	0		0	
注射部位疼痛	Week 0 - Week 4	0		0	
	Week 4 - Week 12	0		0	
	Post Week 12	2	(0.9)	0	
倦怠感	Week 0 - Week 4	0		0	
	Week 4 - Week 12	0		0	
	Post Week 12	0		1	(0.5)
末梢性浮腫	Week 0 - Week 4	1	(0.5)	0	
	Week 4 - Week 12	0		1	(0.5)
	Post Week 12	0		0	
発熱	Week 0 - Week 4	1	(0.5)	0	
	Week 4 - Week 12	0		1	(0.5)
	Post Week 12	0		0	
臨床検査	Week 0 - Week 4	0		8	(3.6)
	Week 4 - Week 12	4	(1.9)	6	(2.8)
	Post Week 12	3	(1.4)	4	(1.9)
アラニンアミノトランスフェラーゼ増加	Week 0 - Week 4	0		0	
	Week 4 - Week 12	0		0	
	Post Week 12	1	(0.5)	0	
アスパラギン酸アミノトランスフェラーゼ増加	Week 0 - Week 4	0		0	
	Week 4 - Week 12	0		0	
	Post Week 12	1	(0.5)	0	
血中アルカリホスファターゼ増加	Week 0 - Week 4	0		0	
	Week 4 - Week 12	0		2	(0.9)
	Post Week 12	0		0	
血中クレアチンホスホキナーゼ増加	Week 0 - Week 4	0		4	(1.8)
	Week 4 - Week 12	1	(0.5)	0	
	Post Week 12	1	(0.5)	0	
血中クレアチニン増加	Week 0 - Week 4	0		0	
	Week 4 - Week 12	1	(0.5)	0	
	Post Week 12	0		0	
外来血圧上昇	Week 0 - Week 4	0		0	
	Week 4 - Week 12	0		1	(0.5)
	Post Week 12	0		0	
血圧上昇	Week 0 - Week 4	0		0	
	Week 4 - Week 12	1	(0.5)	0	
	Post Week 12	0		1	(0.5)
血中尿酸増加	Week 0 - Week 4	0		1	(0.5)
	Week 4 - Week 12	0		0	
	Post Week 12	0		0	

器官別大分類		Placebo N=220		SI-613 30 mg N=220	
基本語	Timing of first onset	n	(%)	n	(%)
血中亜鉛減少	Week 0 - Week 4	0		0	
	Week 4 - Week 12	0		1	(0.5)
	Post Week 12	0		0	
Ｃ－反応性蛋白増加	Week 0 - Week 4	0		0	
	Week 4 - Week 12	0		0	
	Post Week 12	1	(0.5)	0	
γ－グルタミルトランスフェラーゼ増加	Week 0 - Week 4	0		0	
	Week 4 - Week 12	0		1	(0.5)
	Post Week 12	0		0	
尿中ブドウ糖	Week 0 - Week 4	0		1	(0.5)
	Week 4 - Week 12	0		0	
	Post Week 12	0		0	
尿中ブドウ糖陽性	Week 0 - Week 4	0		0	
	Week 4 - Week 12	1	(0.5)	1	(0.5)
	Post Week 12	0		2	(1.0)
グリコヘモグロビン増加	Week 0 - Week 4	0		0	
	Week 4 - Week 12	0		0	
	Post Week 12	1	(0.5)	0	
肝機能検査異常	Week 0 - Week 4	0		1	(0.5)
	Week 4 - Week 12	0		1	(0.5)
	Post Week 12	0		0	
肝機能検査値上昇	Week 0 - Week 4	0		1	(0.5)
	Week 4 - Week 12	0		1	(0.5)
	Post Week 12	0		1	(0.5)
白血球数増加	Week 0 - Week 4	0		1	(0.5)
	Week 4 - Week 12	0		0	
	Post Week 12	0		0	
傷害、中毒および処置合併症	Week 0 - Week 4	5	(2.3)	7	(3.2)
	Week 4 - Week 12	9	(4.2)	9	(4.2)
	Post Week 12	1	(0.5)	9	(4.3)
動物咬傷	Week 0 - Week 4	0		0	
	Week 4 - Week 12	0		1	(0.5)
	Post Week 12	0		0	
節足動物咬傷	Week 0 - Week 4	0		0	
	Week 4 - Week 12	1	(0.5)	1	(0.5)
	Post Week 12	1	(0.5)	1	(0.5)
節足動物刺傷	Week 0 - Week 4	0		1	(0.5)
	Week 4 - Week 12	0		0	
	Post Week 12	0		0	
剥離骨折	Week 0 - Week 4	0		0	
	Week 4 - Week 12	0		1	(0.5)
	Post Week 12	0		0	
挫傷	Week 0 - Week 4	1	(0.5)	2	(0.9)
	Week 4 - Week 12	4	(1.9)	0	
	Post Week 12	0		2	(1.0)
上顆炎	Week 0 - Week 4	0		1	(0.5)
	Week 4 - Week 12	0		0	
	Post Week 12	0		0	
眼瞼挫傷	Week 0 - Week 4	0		1	(0.5)
	Week 4 - Week 12	0		0	
	Post Week 12	0		0	
転倒	Week 0 - Week 4	0		0	
	Week 4 - Week 12	2	(0.9)	0	

器官別大分類 基本語	Timing of first onset	Placebo N=220 n	(%)	SI-613 30 mg N=220 n	(%)
	Post Week 12	0		2	(1.0)
足骨折	Week 0 - Week 4	0		0	
	Week 4 - Week 12	0		1	(0.5)
	Post Week 12	0		0	
気道内異物	Week 0 - Week 4	0		1	(0.5)
	Week 4 - Week 12	0		0	
	Post Week 12	0		0	
手骨折	Week 0 - Week 4	0		0	
	Week 4 - Week 12	0		1	(0.5)
	Post Week 12	0		0	
注入に伴う反応	Week 0 - Week 4	1	(0.5)	0	
	Week 4 - Week 12	0		0	
	Post Week 12	0		0	
関節損傷	Week 0 - Week 4	1	(0.5)	0	
	Week 4 - Week 12	0		0	
	Post Week 12	0		0	
靱帯損傷	Week 0 - Week 4	0		0	
	Week 4 - Week 12	0		0	
	Post Week 12	0		1	(0.5)
靱帯捻挫	Week 0 - Week 4	1	(0.5)	0	
	Week 4 - Week 12	0		4	(1.9)
	Post Week 12	0		3	(1.4)
四肢損傷	Week 0 - Week 4	1	(0.5)	0	
	Week 4 - Week 12	0		0	
	Post Week 12	0		0	
皮膚擦過傷	Week 0 - Week 4	0		1	(0.5)
	Week 4 - Week 12	1	(0.5)	0	
	Post Week 12	0		0	
皮膚創傷	Week 0 - Week 4	0		0	
	Week 4 - Week 12	0		1	(0.5)
	Post Week 12	0		0	
脊椎圧迫骨折	Week 0 - Week 4	0		0	
	Week 4 - Week 12	1	(0.5)	0	
	Post Week 12	0		0	
刺創	Week 0 - Week 4	0		0	
	Week 4 - Week 12	1	(0.5)	0	
	Post Week 12	0		0	
熱傷	Week 0 - Week 4	0		0	
	Week 4 - Week 12	0		0	
	Post Week 12	0		1	(0.5)
歯牙破折	Week 0 - Week 4	0		0	
	Week 4 - Week 12	0		0	
	Post Week 12	1	(0.5)	1	(0.5)
創傷	Week 0 - Week 4	0		0	
	Week 4 - Week 12	1	(0.5)	1	(0.5)
	Post Week 12	0		0	
外科および内科処置	Week 0 - Week 4	0		0	
	Week 4 - Week 12	0		0	
	Post Week 12	0		1	(0.5)
斜視矯正術	Week 0 - Week 4	0		0	
	Week 4 - Week 12	0		0	
	Post Week 12	0		1	(0.5)
社会環境	Week 0 - Week 4	1	(0.5)	0	

器官別大分類		Placebo N=220		SI-613 30 mg N=220	
基本語	Timing of first onset	n	(%)	n	(%)
	Week 4 - Week 12	0		0	
	Post Week 12	0		0	
過労	Week 0 - Week 4	1	(0.5)	0	
	Week 4 - Week 12	0		0	
	Post Week 12	0		0	
製品の問題	Week 0 - Week 4	0		0	
	Week 4 - Week 12	0		1	(0.5)
	Post Week 12	0		1	(0.5)
医療機器破損	Week 0 - Week 4	0		0	
	Week 4 - Week 12	0		1	(0.5)
	Post Week 12	0		1	(0.5)

MedDRA/J Version 21.1
〔5.3.5.1-3 Table 14.3.1-10 改編〕

表 2.7.4.7-27. 初回発現時期別の副作用：613/1031 試験

器官別大分類		Placebo N=220		SI-613 30 mg N=220	
基本語	Timing of first onset	n	(%)	n	(%)
評価例数	Week 0 - Week 4	220		220	
	Week 4 - Week 12	214		216	
	Post Week 12	212		207	
全ての副作用	Week 0 - Week 4	4	(1.8)	3	(1.4)
	Week 4 - Week 12	1	(0.5)	4	(1.9)
	Post Week 12	1	(0.5)	1	(0.5)
免疫系障害	Week 0 - Week 4	0		2	(0.9)
	Week 4 - Week 12	0		0	
	Post Week 12	0		0	
アナフィラキシー反応	Week 0 - Week 4	0		1	(0.5)
	Week 4 - Week 12	0		0	
	Post Week 12	0		0	
アナフィラキシーショック	Week 0 - Week 4	0		1	(0.5)
	Week 4 - Week 12	0		0	
	Post Week 12	0		0	
筋骨格系および結合組織障害	Week 0 - Week 4	2	(0.9)	0	
	Week 4 - Week 12	1	(0.5)	1	(0.5)
	Post Week 12	0		0	
関節痛	Week 0 - Week 4	0		0	
	Week 4 - Week 12	1	(0.5)	0	
	Post Week 12	0		0	
関節滲出液	Week 0 - Week 4	1	(0.5)	0	
	Week 4 - Week 12	0		0	
	Post Week 12	0		0	
関節硬直	Week 0 - Week 4	1	(0.5)	0	
	Week 4 - Week 12	0		0	
	Post Week 12	0		0	
四肢不快感	Week 0 - Week 4	0		0	
	Week 4 - Week 12	0		1	(0.5)
	Post Week 12	0		0	
一般・全身障害および投与部位の状態	Week 0 - Week 4	2	(0.9)	1	(0.5)
	Week 4 - Week 12	0		2	(0.9)
	Post Week 12	2	(0.9)	1	(0.5)
注射部位関節不快感	Week 0 - Week 4	1	(0.5)	0	

器官別大分類		Placebo N=220		SI-613 30 mg N=220	
基本語	Timing of first onset	n	(%)	n	(%)
	Week 4 - Week 12	0		0	
	Post Week 12	0		0	
注射部位関節痛	Week 0 - Week 4	2	(0.9)	1	(0.5)
	Week 4 - Week 12	0		2	(0.9)
	Post Week 12	1	(0.5)	1	(0.5)
注射部位疼痛	Week 0 - Week 4	0		0	
	Week 4 - Week 12	0		0	
	Post Week 12	1	(0.5)	0	
臨床検査	Week 0 - Week 4	0		0	
	Week 4 - Week 12	0		2	(0.9)
	Post Week 12	0		0	
γーグルタミルトランスフェラーゼ増加	Week 0 - Week 4	0		0	
	Week 4 - Week 12	0		1	(0.5)
	Post Week 12	0		0	
肝機能検査異常	Week 0 - Week 4	0		0	
	Week 4 - Week 12	0		1	(0.5)
	Post Week 12	0		0	

MedDRA/J Version 21.1
〔5.3.5.1-3 Table 14.3.1-11 改編〕

表 2.7.4.7-28. 初回発現時期別の関節ごとの有害事象：613/1032 試験

器官別大分類		Knee N=126		Shoulder N=15		Elbow N=8		Hip N=9		Ankle N=8		Total N=166	
基本語	Timing of first onset	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
評価例数	Week 0 - Week 4	126		15		8		9		8		166	
	Week 4 - Week 12	125		15		8		9		8		165	
	Week 12 - Week 24	123		14		8		7		8		160	
	Week 24 - Week 36	121		14		8		7		8		158	
	Post Week 36	120		14		8		7		8		157	
全ての有害事象	Week 0 - Week 4	20	(15.9)	3	(20.0)	2	(25.0)	3	(33.3)	2	(25.0)	30	(18.1)
	Week 4 - Week 12	29	(23.2)	3	(20.0)	0		2	(22.2)	0		34	(20.6)
	Week 12 - Week 24	22	(17.9)	2	(14.3)	2	(25.0)	4	(57.1)	3	(37.5)	33	(20.6)
	Week 24 - Week 36	14	(11.6)	2	(14.3)	1	(12.5)	0		0		17	(10.8)
	Post Week 36	9	(7.5)	3	(21.4)	0		0		0		12	(7.6)
感染症および寄生虫症	Week 0 - Week 4	5	(4.0)	0		1	(12.5)	0		0		6	(3.6)
	Week 4 - Week 12	7	(5.6)	1	(6.7)	1	(12.5)	1	(11.1)	0		10	(6.1)
	Week 12 - Week 24	13	(10.6)	0		0		1	(14.3)	2	(25.0)	16	(10.0)
	Week 24 - Week 36	13	(10.7)	1	(7.1)	1	(12.5)	3	(42.9)	0		18	(11.4)
	Post Week 36	9	(7.5)	1	(7.1)	0		0		0		10	(6.4)
虫垂炎	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	3	(2.4)	0		0		0		0		3	(1.8)
	Week 12 - Week 24	0		0		0		0		0		0	
	Week 24 - Week 36	0		0		0		0		0		0	
	Post Week 36	0		0		0		0		0		0	
気管支炎	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	1	(0.8)	0		0		0		0		1	(0.6)
	Week 24 - Week 36	0		0		0		0		0		0	
	Post Week 36	0		0		0		0		0		0	
カンピロバクター感染	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Week 24 - Week 36	0		0		0		0		0		0	

器官別大分類		Knee N=126		Shoulder N=15		Elbow N=8		Hip N=9		Ankle N=8		Total N=166	
基本語	Timing of first onset	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
	Post Week 36	1	(0.8)	0		0		0		0		1	(0.6)
蜂巣炎	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Week 24 - Week 36	0		1	(7.1)	0		0		0		1	(0.6)
	Post Week 36	1	(0.8)	0		0		0		0		1	(0.6)
膀胱炎	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	3	(2.4)	0		0		0		0		3	(1.9)
	Week 24 - Week 36	0		0		0		0		0		0	
	Post Week 36	0		0		0		0		0		0	
胃腸炎	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Week 24 - Week 36	0		0		1	(12.5)	0		0		1	(0.6)
	Post Week 36	1	(0.8)	0		0		0		0		1	(0.6)
歯肉炎	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Week 24 - Week 36	1	(0.8)	0		0		0		0		1	(0.6)
	Post Week 36	2	(1.7)	0		0		0		0		2	(1.3)
帯状疱疹	Week 0 - Week 4	1	(0.8)	0		0		0		0		1	(0.6)
	Week 4 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	1	(0.8)	0		0		0		0		1	(0.6)
	Week 24 - Week 36	0		0		0		0		0		0	
	Post Week 36	1	(0.8)	0		0		0		0		1	(0.6)
麦粒腫	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Week 24 - Week 36	0		0		0		0		0		0	
	Post Week 36	1	(0.8)	0		0		0		0		1	(0.6)
咬傷感染	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	1	(0.8)	0		0		0		0		1	(0.6)
	Week 12 - Week 24	0		0		0		0		0		0	
	Week 24 - Week 36	0		0		0		0		0		0	
	Post Week 36	0		0		0		0		0		0	
インフルエンザ	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Week 24 - Week 36	1	(0.8)	0		0		1	(14.3)	0		2	(1.3)
	Post Week 36	3	(2.5)	0		1	(12.5)	0		0		4	(2.5)
上咽頭炎	Week 0 - Week 4	3	(2.4)	0		1	(12.5)	0		0		4	(2.4)
	Week 4 - Week 12	3	(2.4)	1	(6.7)	0		1	(11.1)	0		5	(3.0)
	Week 12 - Week 24	9	(7.3)	0		0		1	(14.3)	2	(25.0)	12	(7.5)
	Week 24 - Week 36	10	(8.3)	1	(7.1)	1	(12.5)	2	(28.6)	0		14	(8.9)
	Post Week 36	5	(4.2)	1	(7.1)	0		0		0		6	(3.8)
中耳炎	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Week 24 - Week 36	0		0		0		0		0		0	
	Post Week 36	1	(0.8)	0		0		0		0		1	(0.6)
爪囲炎	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	

器官別大分類		Knee N=126		Shoulder N=15		Elbow N=8		Hip N=9		Ankle N=8		Total N=166	
基本語	Timing of first onset	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
	Week 24 - Week 36	1	(0.8)	0		0		0		0		1	(0.6)
	Post Week 36	0		0		0		0		0		0	
歯周炎	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	1	(0.8)	0		0		0		0		1	(0.6)
	Week 24 - Week 36	0		0		0		0		0		0	
	Post Week 36	0		0		0		0		0		0	
咽頭炎	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	0		0		1	(12.5)	0		0		1	(0.6)
	Week 12 - Week 24	2	(1.6)	0		0		0		0		2	(1.3)
	Week 24 - Week 36	1	(0.8)	0		0		0		0		1	(0.6)
	Post Week 36	0		0		0		0		1	(12.5)	1	(0.6)
白癬感染	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	1	(0.8)	0		0		0		0		1	(0.6)
	Week 24 - Week 36	0		0		0		0		0		0	
	Post Week 36	0		0		0		0		0		0	
足部白癬	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	1	(0.8)	0		0		0		0		1	(0.6)
	Week 12 - Week 24	0		0		0		0		0		0	
	Week 24 - Week 36	0		0		0		0		0		0	
	Post Week 36	0		0		0		0		0		0	
上気道感染	Week 0 - Week 4	1	(0.8)	0		0		0		0		1	(0.6)
	Week 4 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Week 24 - Week 36	1	(0.8)	0		0		0		0		1	(0.6)
	Post Week 36	1	(0.8)	0		0		0		0		1	(0.6)
外陰部炎	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Week 24 - Week 36	1	(0.8)	0		0		0		0		1	(0.6)
	Post Week 36	0		0		0		0		0		0	
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）	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	2	(1.6)	0		0		0		0		2	(1.2)
	Week 12 - Week 24	1	(0.8)	0		0		0		0		1	(0.6)
	Week 24 - Week 36	0		0		0		0		0		0	
	Post Week 36	0		1	(7.1)	0		0		0		1	(0.6)
乳癌	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	1	(0.8)	0		0		0		0		1	(0.6)
	Week 12 - Week 24	0		0		0		0		0		0	
	Week 24 - Week 36	0		0		0		0		0		0	
	Post Week 36	0		0		0		0		0		0	
類腱腫	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Week 24 - Week 36	0		0		0		0		0		0	
	Post Week 36	0		1	(7.1)	0		0		0		1	(0.6)
脂肪腫	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	1	(0.8)	0		0		0		0		1	(0.6)
	Week 24 - Week 36	0		0		0		0		0		0	
	Post Week 36	0		0		0		0		0		0	
皮膚乳頭腫	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	1	(0.8)	0		0		0		0		1	(0.6)

器官別大分類		Knee N=126		Shoulder N=15		Elbow N=8		Hip N=9		Ankle N=8		Total N=166	
基本語	Timing of first onset	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
	Week 12 - Week 24	0		0		0		0		0		0	
	Week 24 - Week 36	0		0		0		0		0		0	
	Post Week 36	0		0		0		0		0		0	
血液およびリンパ系障害	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	1	(0.8)	0		0		0		0		1	(0.6)
	Week 24 - Week 36	0		0		0		0		0		0	
	Post Week 36	0		0		0		0		0		0	
貧血	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	1	(0.8)	0		0		0		0		1	(0.6)
	Week 24 - Week 36	0		0		0		0		0		0	
	Post Week 36	0		0		0		0		0		0	
免疫系障害	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Week 24 - Week 36	0		0		0		0		0		0	
	Post Week 36	1	(0.8)	0		0		0		0		1	(0.6)
季節性アレルギー	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Week 24 - Week 36	0		0		0		0		0		0	
	Post Week 36	1	(0.8)	0		0		0		0		1	(0.6)
代謝および栄養障害	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Week 24 - Week 36	0		0		0		0		0		0	
	Post Week 36	4	(3.3)	0		0		0		0		4	(2.5)
糖尿病	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Week 24 - Week 36	0		0		0		0		0		0	
	Post Week 36	1	(0.8)	0		0		0		0		1	(0.6)
高コレステロール血症	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Week 24 - Week 36	0		0		0		0		0		0	
	Post Week 36	1	(0.8)	0		0		0		0		1	(0.6)
高カリウム血症	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Week 24 - Week 36	0		0		0		0		0		0	
	Post Week 36	1	(0.8)	0		0		0		0		1	(0.6)
ビタミンD欠乏	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Week 24 - Week 36	0		0		0		0		0		0	
	Post Week 36	2	(1.7)	0		0		0		0		2	(1.3)
精神障害	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Week 24 - Week 36	0		0		0		1	(14.3)	0		1	(0.6)
	Post Week 36	0		0		0		0		0		0	
不眠症	Week 0 - Week 4	0		0		0		0		0		0	

器官別大分類		Knee N=126		Shoulder N=15		Elbow N=8		Hip N=9		Ankle N=8		Total N=166	
基本語	Timing of first onset	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
	Week 4 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Week 24 - Week 36	0		0		0		1	(14.3)	0		1	(0.6)
	Post Week 36	0		0		0		0		0		0	
神経系障害	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	2	(1.6)	0		0		1	(11.1)	0		3	(1.8)
	Week 12 - Week 24	2	(1.6)	1	(7.1)	0		1	(14.3)	0		4	(2.5)
	Week 24 - Week 36	6	(5.0)	0		0		0		0		6	(3.8)
	Post Week 36	5	(4.2)	0		0		0		2	(25.0)	7	(4.5)
脳梗塞	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Week 24 - Week 36	1	(0.8)	0		0		0		0		1	(0.6)
	Post Week 36	0		0		0		0		0		0	
頚腕症候群	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Week 24 - Week 36	0		0		0		0		0		0	
	Post Week 36	1	(0.8)	0		0		0		0		1	(0.6)
浮動性めまい	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	1	(0.8)	0		0		0		0		1	(0.6)
	Week 12 - Week 24	0		0		0		1	(14.3)	0		1	(0.6)
	Week 24 - Week 36	2	(1.7)	0		0		0		0		2	(1.3)
	Post Week 36	0		0		0		0		1	(12.5)	1	(0.6)
頭痛	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	1	(0.8)	0		0		1	(11.1)	0		2	(1.2)
	Week 12 - Week 24	0		1	(7.1)	0		0		0		1	(0.6)
	Week 24 - Week 36	0		0		0		0		0		0	
	Post Week 36	1	(0.8)	0		0		0		1	(12.5)	2	(1.3)
感覚異常性大腿神経痛	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	1	(0.8)	0		0		0		0		1	(0.6)
	Week 24 - Week 36	0		0		0		0		0		0	
	Post Week 36	0		0		0		0		0		0	
ミオクローヌス	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Week 24 - Week 36	0		0		0		0		0		0	
	Post Week 36	1	(0.8)	0		0		0		0		1	(0.6)
神経痛	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Week 24 - Week 36	1	(0.8)	0		0		0		0		1	(0.6)
	Post Week 36	0		0		0		0		0		0	
錯感覚	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	1	(0.8)	0		0		0		0		1	(0.6)
	Week 24 - Week 36	0		0		0		0		0		0	
	Post Week 36	0		0		0		0		0		0	
坐骨神経痛	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Week 24 - Week 36	1	(0.8)	0		0		0		0		1	(0.6)
	Post Week 36	1	(0.8)	0		0		0		0		1	(0.6)

器官別大分類		Knee N=126		Shoulder N=15		Elbow N=8		Hip N=9		Ankle N=8		Total N=166	
基本語	Timing of first onset	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
鎮静	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Week 24 - Week 36	0		0		0		0		0		0	
	Post Week 36	1	(0.8)	0		0		0		0		1	(0.6)
傾眠	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Week 24 - Week 36	1	(0.8)	0		0		0		0		1	(0.6)
	Post Week 36	0		0		0		0		0		0	
眼障害	Week 0 - Week 4	1	(0.8)	0		0		0		0		1	(0.6)
	Week 4 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Week 24 - Week 36	4	(3.3)	0		0		0		0		4	(2.5)
	Post Week 36	4	(3.3)	2	(14.3)	0		0		0		6	(3.8)
眼精疲労	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Week 24 - Week 36	0		0		0		0		0		0	
	Post Week 36	0		1	(7.1)	0		0		0		1	(0.6)
眼瞼炎	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Week 24 - Week 36	2	(1.7)	0		0		0		0		2	(1.3)
	Post Week 36	0		0		0		0		0		0	
霰粒腫	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Week 24 - Week 36	0		0		0		0		0		0	
	Post Week 36	1	(0.8)	0		0		0		0		1	(0.6)
アレルギー性結膜炎	Week 0 - Week 4	1	(0.8)	0		0		0		0		1	(0.6)
	Week 4 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Week 24 - Week 36	0		0		0		0		0		0	
	Post Week 36	1	(0.8)	0		0		0		0		1	(0.6)
後天性涙道狭窄	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Week 24 - Week 36	0		0		0		0		0		0	
	Post Week 36	1	(0.8)	0		0		0		0		1	(0.6)
ドライアイ	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Week 24 - Week 36	2	(1.7)	0		0		0		0		2	(1.3)
	Post Week 36	1	(0.8)	0		0		0		0		1	(0.6)
高眼圧症	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Week 24 - Week 36	0		0		0		0		0		0	
	Post Week 36	1	(0.8)	0		0		0		0		1	(0.6)
網膜出血	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Week 24 - Week 36	0		0		0		0		0		0	

器官別大分類		Knee N=126		Shoulder N=15		Elbow N=8		Hip N=9		Ankle N=8		Total N=166	
基本語	Timing of first onset	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
	Post Week 36	0		1	(7.1)	0		0		0		1	(0.6)
耳および迷路障害	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	1	(0.8)	0		0		0		0		1	(0.6)
	Week 24 - Week 36	0		1	(7.1)	0		0		0		1	(0.6)
	Post Week 36	2	(1.7)	0		1	(12.5)	0		0		3	(1.9)
耳垢栓塞	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Week 24 - Week 36	0		0		0		0		0		0	
	Post Week 36	0		0		1	(12.5)	0		0		1	(0.6)
突発性難聴	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Week 24 - Week 36	0		0		0		0		0		0	
	Post Week 36	1	(0.8)	0		0		0		0		1	(0.6)
耳鳴	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Week 24 - Week 36	0		1	(7.1)	0		0		0		1	(0.6)
	Post Week 36	0		0		0		0		0		0	
回転性めまい	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	1	(0.8)	0		0		0		0		1	(0.6)
	Week 24 - Week 36	0		0		0		0		0		0	
	Post Week 36	1	(0.8)	0		0		0		0		1	(0.6)
心臓障害	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	0		0		0		1	(11.1)	0		1	(0.6)
	Week 12 - Week 24	1	(0.8)	0		0		0		0		1	(0.6)
	Week 24 - Week 36	1	(0.8)	0		0		0		0		1	(0.6)
	Post Week 36	2	(1.7)	0		0		0		0		2	(1.3)
急性心筋梗塞	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Week 24 - Week 36	1	(0.8)	0		0		0		0		1	(0.6)
	Post Week 36	0		0		0		0		0		0	
不安定狭心症	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Week 24 - Week 36	0		0		0		0		0		0	
	Post Week 36	1	(0.8)	0		0		0		0		1	(0.6)
心房細動	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	1	(0.8)	0		0		0		0		1	(0.6)
	Week 24 - Week 36	0		0		0		0		0		0	
	Post Week 36	0		0		0		0		0		0	
動悸	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	0		0		0		1	(11.1)	0		1	(0.6)
	Week 12 - Week 24	0		0		0		0		0		0	
	Week 24 - Week 36	0		0		0		0		0		0	
	Post Week 36	1	(0.8)	0		0		0		0		1	(0.6)
血管障害	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	1	(0.8)	0		0		0		0		1	(0.6)
	Week 12 - Week 24	0		0		0		0		0		0	

器官別大分類		Knee N=126		Shoulder N=15		Elbow N=8		Hip N=9		Ankle N=8		Total N=166	
基本語	Timing of first onset	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
	Week 24 - Week 36	0		0		0		0		0		0	
	Post Week 36	1	(0.8)	0		0		0		0		1	(0.6)
高血圧	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	1	(0.8)	0		0		0		0		1	(0.6)
	Week 12 - Week 24	0		0		0		0		0		0	
	Week 24 - Week 36	0		0		0		0		0		0	
	Post Week 36	1	(0.8)	0		0		0		0		1	(0.6)
呼吸器、胸郭および縦隔障害	Week 0 - Week 4	2	(1.6)	0		0		0		0		2	(1.2)
	Week 4 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	1	(0.8)	0		0		0		0		1	(0.6)
	Week 24 - Week 36	2	(1.7)	1	(7.1)	0		0		0		3	(1.9)
	Post Week 36	1	(0.8)	0		1	(12.5)	0		0		2	(1.3)
喘息	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Week 24 - Week 36	0		0		0		0		0		0	
	Post Week 36	0		0		1	(12.5)	0		0		1	(0.6)
慢性気管支炎	Week 0 - Week 4	1	(0.8)	0		0		0		0		1	(0.6)
	Week 4 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Week 24 - Week 36	1	(0.8)	0		0		0		0		1	(0.6)
	Post Week 36	0		0		0		0		0		0	
鼻出血	Week 0 - Week 4	1	(0.8)	0		0		0		0		1	(0.6)
	Week 4 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Week 24 - Week 36	0		1	(7.1)	0		0		0		1	(0.6)
	Post Week 36	0		0		0		0		0		0	
鼻痂皮	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Week 24 - Week 36	1	(0.8)	0		0		0		0		1	(0.6)
	Post Week 36	0		0		0		0		0		0	
口腔咽頭痛	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	1	(0.8)	0		0		0		0		1	(0.6)
	Week 24 - Week 36	0		0		0		0		0		0	
	Post Week 36	1	(0.8)	0		0		0		0		1	(0.6)
胃腸障害	Week 0 - Week 4	2	(1.6)	1	(6.7)	0		1	(11.1)	0		4	(2.4)
	Week 4 - Week 12	4	(3.2)	0		0		0		0		4	(2.4)
	Week 12 - Week 24	4	(3.3)	3	(21.4)	2	(25.0)	1	(14.3)	0		10	(6.3)
	Week 24 - Week 36	5	(4.1)	0		0		0		0		5	(3.2)
	Post Week 36	5	(4.2)	0		0		0		0		5	(3.2)
腹部膨満	Week 0 - Week 4	1	(0.8)	0		0		0		0		1	(0.6)
	Week 4 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Week 24 - Week 36	0		0		0		0		0		0	
	Post Week 36	2	(1.7)	0		0		0		0		2	(1.3)
腹痛	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Week 24 - Week 36	0		0		0		1	(14.3)	0		1	(0.6)
	Post Week 36	0		0		0		0		0		0	
上腹部痛	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	1	(0.8)	0		0		0		0		1	(0.6)

器官別大分類		Knee N=126		Shoulder N=15		Elbow N=8		Hip N=9		Ankle N=8		Total N=166	
基本語	Timing of first onset	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
	Week 12 - Week 24	0		0		1	(12.5)	0		0		1	(0.6)
	Week 24 - Week 36	0		0		0		0		0		0	
	Post Week 36	0		0		0		0		0		0	
肛門ポリープ	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Week 24 - Week 36	0		0		0		0		0		0	
	Post Week 36	1	(0.8)	0		0		0		0		1	(0.6)
慢性胃炎	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	1	(0.8)	0		0		0		0		1	(0.6)
	Week 12 - Week 24	0		0		0		0		0		0	
	Week 24 - Week 36	0		0		0		0		0		0	
	Post Week 36	0		0		0		0		0		0	
便秘	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		1	(7.1)	0		0		0		1	(0.6)
	Week 24 - Week 36	0		0		0		0		0		0	
	Post Week 36	1	(0.8)	0		0		0		0		1	(0.6)
齲歯	Week 0 - Week 4	1	(0.8)	0		0		1	(11.1)	0		2	(1.2)
	Week 4 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	1	(0.8)	0		0		0		0		1	(0.6)
	Week 24 - Week 36	0		0		0		0		0		0	
	Post Week 36	0		0		0		0		0		0	
食中毒	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		1	(7.1)	0		0		0		1	(0.6)
	Week 24 - Week 36	0		0		0		0		0		0	
	Post Week 36	0		0		0		0		0		0	
胃ポリープ	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	1	(0.8)	0		0		0		0		1	(0.6)
	Week 12 - Week 24	0		0		0		0		0		0	
	Week 24 - Week 36	0		0		0		0		0		0	
	Post Week 36	0		0		0		0		0		0	
胃潰瘍	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	1	(0.8)	0		0		0		0		1	(0.6)
	Week 12 - Week 24	0		0		0		0		0		0	
	Week 24 - Week 36	0		0		0		0		0		0	
	Post Week 36	0		0		0		0		0		0	
胃炎	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Week 24 - Week 36	1	(0.8)	0		0		0		0		1	(0.6)
	Post Week 36	0		0		0		0		0		0	
びらん性胃炎	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Week 24 - Week 36	1	(0.8)	0		0		0		0		1	(0.6)
	Post Week 36	0		0		0		0		0		0	
胃食道逆流性疾患	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	1	(0.8)	0		0		0		0		1	(0.6)
	Week 12 - Week 24	1	(0.8)	0		0		0		0		1	(0.6)
	Week 24 - Week 36	1	(0.8)	0		0		0		0		1	(0.6)
	Post Week 36	1	(0.8)	0		0		0		0		1	(0.6)
歯肉肥厚	Week 0 - Week 4	0		0		0		0		0		0	

器官別大分類		Knee N=126		Shoulder N=15		Elbow N=8		Hip N=9		Ankle N=8		Total N=166	
基本語	Timing of first onset	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
	Week 4 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Week 24 - Week 36	1	(0.8)	0		0		0		0		1	(0.6)
	Post Week 36	0		0		0		0		0		0	
歯肉痛	Week 0 - Week 4	0		1	(6.7)	0		0		0		1	(0.6)
	Week 4 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Week 24 - Week 36	0		0		0		0		0		0	
	Post Week 36	0		0		0		0		0		0	
鼠径ヘルニア	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Week 24 - Week 36	0		0		1	(12.5)	0		0		1	(0.6)
	Post Week 36	0		0		0		0		0		0	
過敏性腸症候群	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		1	(12.5)	0		0		1	(0.6)
	Week 24 - Week 36	0		0		0		0		0		0	
	Post Week 36	0		0		0		0		0		0	
大腸ポリープ	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	1	(0.8)	0		0		0		0		1	(0.6)
	Week 12 - Week 24	0		0		0		0		0		0	
	Week 24 - Week 36	0		0		0		0		0		0	
	Post Week 36	1	(0.8)	0		0		0		0		1	(0.6)
悪心	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	1	(0.8)	0		0		1	(14.3)	0		2	(1.3)
	Week 24 - Week 36	1	(0.8)	0		0		0		0		1	(0.6)
	Post Week 36	0		0		0		0		0		0	
口内炎	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		1	(7.1)	0		0		0		1	(0.6)
	Week 24 - Week 36	2	(1.7)	0		0		0		0		2	(1.3)
	Post Week 36	0		0		0		0		0		0	
嘔吐	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	1	(0.8)	0		0		0		0		1	(0.6)
	Week 24 - Week 36	0		0		0		0		0		0	
	Post Week 36	0		0		0		0		0		0	
肝胆道系障害	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	2	(1.6)	0		0		0		0		2	(1.3)
	Week 24 - Week 36	0		0		0		0		0		0	
	Post Week 36	1	(0.8)	0		1	(12.5)	0		0		2	(1.3)
肝機能異常	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	2	(1.6)	0		0		0		0		2	(1.3)
	Week 24 - Week 36	0		0		0		0		0		0	
	Post Week 36	1	(0.8)	0		1	(12.5)	0		0		2	(1.3)
皮膚および皮下組織障害	Week 0 - Week 4	1	(0.8)	0		0		0		0		1	(0.6)
	Week 4 - Week 12	5	(4.0)	2	(13.3)	0		0		0		7	(4.2)
	Week 12 - Week 24	2	(1.6)	0		0		2	(28.6)	0		4	(2.5)
	Week 24 - Week 36	3	(2.5)	1	(7.1)	0		0		0		4	(2.5)
	Post Week 36	3	(2.5)	3	(21.4)	0		0		0		6	(3.8)

器官別大分類		Knee N=126		Shoulder N=15		Elbow N=8		Hip N=9		Ankle N=8		Total N=166	
基本語	Timing of first onset	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
ざ瘡	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Week 24 - Week 36	1	(0.8)	0		0		0		0		1	(0.6)
	Post Week 36	0		0		0		0		0		0	
皮膚嚢腫	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	1	(0.8)	0		0		0		0		1	(0.6)
	Week 24 - Week 36	0		0		0		0		0		0	
	Post Week 36	0		0		0		0		0		0	
皮膚炎	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	1	(0.8)	1	(6.7)	0		0		0		2	(1.2)
	Week 12 - Week 24	0		0		0		0		0		0	
	Week 24 - Week 36	0		0		0		0		0		0	
	Post Week 36	0		0		0		0		0		0	
接触皮膚炎	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Week 24 - Week 36	1	(0.8)	0		0		0		0		1	(0.6)
	Post Week 36	0		0		0		0		0		0	
薬疹	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Week 24 - Week 36	0		0		0		0		0		0	
	Post Week 36	1	(0.8)	0		0		0		0		1	(0.6)
皮膚乾燥	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Week 24 - Week 36	0		1	(7.1)	0		0		0		1	(0.6)
	Post Week 36	0		0		0		0		0		0	
湿疹	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	2	(1.6)	0		0		0		0		2	(1.2)
	Week 12 - Week 24	1	(0.8)	0		0		2	(28.6)	0		3	(1.9)
	Week 24 - Week 36	1	(0.8)	1	(7.1)	0		0		0		2	(1.3)
	Post Week 36	2	(1.7)	1	(7.1)	0		0		0		3	(1.9)
紅斑	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	1	(0.8)	0		0		0		0		1	(0.6)
	Week 12 - Week 24	0		0		0		0		0		0	
	Week 24 - Week 36	0		0		0		0		0		0	
	Post Week 36	0		1	(7.1)	0		0		0		1	(0.6)
嵌入爪	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Week 24 - Week 36	1	(0.8)	0		0		0		0		1	(0.6)
	Post Week 36	0		1	(7.1)	0		0		0		1	(0.6)
汗疹	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	0		1	(6.7)	0		0		0		1	(0.6)
	Week 12 - Week 24	0		0		0		0		0		0	
	Week 24 - Week 36	0		0		0		0		0		0	
	Post Week 36	0		0		0		0		0		0	
老人性そう痒症	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Week 24 - Week 36	0		0		0		0		0		0	

器官別大分類		Knee N=126		Shoulder N=15		Elbow N=8		Hip N=9		Ankle N=8		Total N=166	
基本語	Timing of first onset	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
	Post Week 36	0		1	(7.1)	0		0		0		1	(0.6)
蕁麻疹	Week 0 - Week 4	1	(0.8)	0		0		0		0		1	(0.6)
	Week 4 - Week 12	1	(0.8)	0		0		0		0		1	(0.6)
	Week 12 - Week 24	0		0		0		0		0		0	
	Week 24 - Week 36	0		0		0		0		0		0	
	Post Week 36	0		0		0		0		0		0	
筋骨格系および結合組織障害	Week 0 - Week 4	5	(4.0)	1	(6.7)	0		0		0		6	(3.6)
	Week 4 - Week 12	5	(4.0)	0		0		1	(11.1)	0		6	(3.6)
	Week 12 - Week 24	8	(6.5)	0		2	(25.0)	0		2	(25.0)	12	(7.5)
	Week 24 - Week 36	7	(5.8)	1	(7.1)	0		1	(14.3)	0		9	(5.7)
	Post Week 36	11	(9.2)	3	(21.4)	1	(12.5)	1	(14.3)	0		16	(10.2)
関節痛	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	1	(0.8)	0		0		0		0		1	(0.6)
	Week 12 - Week 24	1	(0.8)	0		0		0		0		1	(0.6)
	Week 24 - Week 36	0		1	(7.1)	0		0		0		1	(0.6)
	Post Week 36	1	(0.8)	0		0		0		0		1	(0.6)
関節炎	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	1	(0.8)	0		0		0		0		1	(0.6)
	Week 24 - Week 36	1	(0.8)	0		0		0		0		1	(0.6)
	Post Week 36	0		1	(7.1)	0		0		0		1	(0.6)
関節障害	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		1	(7.1)	0		0		0		1	(0.6)
	Week 24 - Week 36	0		0		0		0		0		0	
	Post Week 36	0		0		0		0		0		0	
背部痛	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	0		0		0		1	(11.1)	0		1	(0.6)
	Week 12 - Week 24	1	(0.8)	0		0		0		0		1	(0.6)
	Week 24 - Week 36	1	(0.8)	0		0		0		0		1	(0.6)
	Post Week 36	4	(3.3)	0		0		0		0		4	(2.5)
滑液包炎	Week 0 - Week 4	1	(0.8)	0		0		0		0		1	(0.6)
	Week 4 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Week 24 - Week 36	0		0		0		0		0		0	
	Post Week 36	0		0		0		0		0		0	
ピロリン酸カルシウム結晶性軟骨石灰化症	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Week 24 - Week 36	1	(0.8)	0		0		0		0		1	(0.6)
	Post Week 36	0		0		0		0		0		0	
尾骨痛	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	1	(0.8)	0		0		0		0		1	(0.6)
	Week 24 - Week 36	0		0		0		0		0		0	
	Post Week 36	0		0		0		0		0		0	
椎間板障害	Week 0 - Week 4	1	(0.8)	0		0		0		0		1	(0.6)
	Week 4 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		1	(12.5)	0		0		1	(0.6)
	Week 24 - Week 36	0		0		0		0		0		0	
	Post Week 36	0		0		0		0		0		0	
椎間板突出	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	1	(0.8)	0		0		0		0		1	(0.6)

器官別大分類		Knee N=126		Shoulder N=15		Elbow N=8		Hip N=9		Ankle N=8		Total N=166	
基本語	Timing of first onset	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
	Week 24 - Week 36	0		0		0		0		0		0	
	Post Week 36	0		0		0		0		0		0	
関節ロック	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Week 24 - Week 36	1	(0.8)	0		0		0		0		1	(0.6)
	Post Week 36	0		0		0		0		0		0	
筋痙縮	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	1	(0.8)	0		0		0		0		1	(0.6)
	Week 24 - Week 36	1	(0.8)	0		0		0		0		1	(0.6)
	Post Week 36	2	(1.7)	0		0		0		0		2	(1.3)
筋骨格痛	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	1	(0.8)	0		0		0		0		1	(0.6)
	Week 24 - Week 36	0		0		0		0		0		0	
	Post Week 36	0		0		0		0		0		0	
筋骨格硬直	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	1	(0.8)	0		1	(12.5)	0		0		2	(1.3)
	Week 24 - Week 36	1	(0.8)	0		0		0		0		1	(0.6)
	Post Week 36	0		0		0		0		0		0	
筋筋膜炎	Week 0 - Week 4	0		1	(6.7)	0		0		0		1	(0.6)
	Week 4 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	1	(0.8)	0		0		0		0		1	(0.6)
	Week 24 - Week 36	0		0		0		0		0		0	
	Post Week 36	0		2	(14.3)	0		0		0		2	(1.3)
結節性変形性関節症	Week 0 - Week 4	1	(0.8)	0		0		0		0		1	(0.6)
	Week 4 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Week 24 - Week 36	0		0		0		0		0		0	
	Post Week 36	0		0		0		1	(14.3)	0		1	(0.6)
変形性関節症	Week 0 - Week 4	1	(0.8)	0		0		0		0		1	(0.6)
	Week 4 - Week 12	1	(0.8)	0		0		0		0		1	(0.6)
	Week 12 - Week 24	2	(1.6)	0		0		0		1	(12.5)	3	(1.9)
	Week 24 - Week 36	4	(3.3)	0		0		0		0		4	(2.5)
	Post Week 36	3	(2.5)	0		0		0		1	(12.5)	4	(2.5)
骨壊死	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Week 24 - Week 36	1	(0.8)	0		0		0		0		1	(0.6)
	Post Week 36	0		0		0		0		0		0	
四肢痛	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	2	(1.6)	0		0		0		0		2	(1.2)
	Week 12 - Week 24	0		0		0		0		0		0	
	Week 24 - Week 36	1	(0.8)	0		0		0		0		1	(0.6)
	Post Week 36	0		0		0		0		0		0	
関節周囲炎	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	2	(1.6)	0		0		0		0		2	(1.2)
	Week 12 - Week 24	0		0		0		0		0		0	
	Week 24 - Week 36	1	(0.8)	0		0		1	(14.3)	0		2	(1.3)
	Post Week 36	0		0		0		0		0		0	
関節リウマチ	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	0		0		0		0		0		0	

器官別大分類		Knee N=126		Shoulder N=15		Elbow N=8		Hip N=9		Ankle N=8		Total N=166	
基本語	Timing of first onset	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
	Week 12 - Week 24	0		0		0		0		0		0	
	Week 24 - Week 36	0		0		0		0		0		0	
	Post Week 36	1	(0.8)	0		0		0		0		1	(0.6)
変形性脊椎症	Week 0 - Week 4	1	(0.8)	0		0		0		0		1	(0.6)
	Week 4 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		1	(12.5)	1	(0.6)
	Week 24 - Week 36	0		0		0		0		0		0	
	Post Week 36	3	(2.5)	0		0		0		0		3	(1.9)
滑液嚢腫	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Week 24 - Week 36	0		0		0		0		0		0	
	Post Week 36	0		0		1	(12.5)	0		0		1	(0.6)
腱鞘炎	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	1	(0.8)	0		0		0		0		1	(0.6)
	Week 24 - Week 36	0		0		0		0		0		0	
	Post Week 36	0		0		0		0		0		0	
狭窄性腱鞘炎	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	1	(0.8)	0		0		0		0		1	(0.6)
	Week 12 - Week 24	0		0		0		0		0		0	
	Week 24 - Week 36	0		0		0		0		0		0	
	Post Week 36	0		0		0		0		0		0	
弾発指	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	1	(0.8)	0		0		0		0		1	(0.6)
	Week 12 - Week 24	0		0		0		0		0		0	
	Week 24 - Week 36	0		0		0		0		0		0	
	Post Week 36	0		0		0		0		0		0	
腎および尿路障害	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Week 24 - Week 36	1	(0.8)	1	(7.1)	0		0		0		2	(1.3)
	Post Week 36	1	(0.8)	0		0		0		0		1	(0.6)
緊張性膀胱	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Week 24 - Week 36	1	(0.8)	0		0		0		0		1	(0.6)
	Post Week 36	1	(0.8)	0		0		0		0		1	(0.6)
尿管結石症	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Week 24 - Week 36	0		1	(7.1)	0		0		0		1	(0.6)
	Post Week 36	0		0		0		0		0		0	
一般・全身障害および投与部位の状態	Week 0 - Week 4	3	(2.4)	1	(6.7)	2	(25.0)	0		1	(12.5)	7	(4.2)
	Week 4 - Week 12	4	(3.2)	1	(6.7)	0		2	(22.2)	0		7	(4.2)
	Week 12 - Week 24	2	(1.6)	1	(7.1)	0		2	(28.6)	0		5	(3.1)
	Week 24 - Week 36	2	(1.7)	0		0		0		0		2	(1.3)
	Post Week 36	4	(3.3)	0		0		0		0		4	(2.5)
腋窩痛	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Week 24 - Week 36	0		0		0		0		0		0	
	Post Week 36	0		1	(7.1)	0		0		0		1	(0.6)
胸部不快感	Week 0 - Week 4	0		0		0		0		0		0	

器官別大分類		Knee N=126		Shoulder N=15		Elbow N=8		Hip N=9		Ankle N=8		Total N=166	
基本語	Timing of first onset	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
	Week 4 - Week 12	0		0		0		1	(11.1)	0		1	(0.6)
	Week 12 - Week 24	0		0		0		0		0		0	
	Week 24 - Week 36	0		0		0		0		0		0	
	Post Week 36	0		0		0		0		0		0	
炎症	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	1	(0.8)	0		0		0		0		1	(0.6)
	Week 12 - Week 24	0		0		0		0		0		0	
	Week 24 - Week 36	0		0		0		0		0		0	
	Post Week 36	0		0		0		0		0		0	
注射部位損傷	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Week 24 - Week 36	0		0		0		0		0		0	
	Post Week 36	1	(0.8)	0		0		0		0		1	(0.6)
注射部位関節滲出液	Week 0 - Week 4	1	(0.8)	0		0		0		0		1	(0.6)
	Week 4 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Week 24 - Week 36	0		0		0		0		0		0	
	Post Week 36	0		0		0		0		0		0	
注射部位関節痛	Week 0 - Week 4	1	(0.8)	1	(6.7)	2	(25.0)	0		1	(12.5)	5	(3.0)
	Week 4 - Week 12	1	(0.8)	0		0		0		0		1	(0.6)
	Week 12 - Week 24	2	(1.6)	1	(7.1)	0		0		0		3	(1.9)
	Week 24 - Week 36	2	(1.7)	0		0		0		0		2	(1.3)
	Post Week 36	3	(2.5)	0		0		0		0		3	(1.9)
注射部位関節腫脹	Week 0 - Week 4	1	(0.8)	0		0		0		0		1	(0.6)
	Week 4 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Week 24 - Week 36	0		0		0		0		0		0	
	Post Week 36	0		0		0		0		0		0	
注射部位浮腫	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Week 24 - Week 36	0		0		0		0		0		0	
	Post Week 36	1	(0.8)	0		0		0		0		1	(0.6)
倦怠感	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	1	(0.8)	0		0		0		0		1	(0.6)
	Week 12 - Week 24	0		0		0		0		0		0	
	Week 24 - Week 36	0		0		0		0		0		0	
	Post Week 36	0		0		0		0		0		0	
浮腫	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	1	(0.8)	0		0		0		0		1	(0.6)
	Week 12 - Week 24	0		0		0		0		0		0	
	Week 24 - Week 36	0		0		0		0		0		0	
	Post Week 36	0		0		0		0		0		0	
発熱	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	0		1	(6.7)	0		2	(22.2)	0		3	(1.8)
	Week 12 - Week 24	0		0		0		2	(28.6)	0		2	(1.3)
	Week 24 - Week 36	0		0		0		0		0		0	
	Post Week 36	0		0		0		0		0		0	
臨床検査	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	3	(2.4)	0		0		0		0		3	(1.8)
	Week 12 - Week 24	1	(0.8)	0		0		0		0		1	(0.6)
	Week 24 - Week 36	1	(0.8)	0		0		0		0		1	(0.6)
	Post Week 36	3	(2.5)	0		0		0		1	(12.5)	4	(2.5)

器官別大分類		Knee N=126		Shoulder N=15		Elbow N=8		Hip N=9		Ankle N=8		Total N=166	
基本語	Timing of first onset	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
血中アルカリホスファターゼ増加	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Week 24 - Week 36	0		0		0		0		0		0	
	Post Week 36	1	(0.8)	0		0		0		1	(12.5)	2	(1.3)
血中クレアチンホスホキナーゼ増加	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	1	(0.8)	0		0		0		0		1	(0.6)
	Week 12 - Week 24	0		0		0		0		0		0	
	Week 24 - Week 36	0		0		0		0		0		0	
	Post Week 36	0		0		0		0		0		0	
血中クレアチニン増加	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	1	(0.8)	0		0		0		0		1	(0.6)
	Week 12 - Week 24	0		0		0		0		0		0	
	Week 24 - Week 36	0		0		0		0		0		0	
	Post Week 36	0		0		0		0		0		0	
血圧上昇	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	1	(0.8)	0		0		0		0		1	(0.6)
	Week 12 - Week 24	1	(0.8)	0		0		0		0		1	(0.6)
	Week 24 - Week 36	1	(0.8)	0		0		0		0		1	(0.6)
	Post Week 36	1	(0.8)	0		0		0		0		1	(0.6)
Ｃ－反応性蛋白増加	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	1	(0.8)	0		0		0		0		1	(0.6)
	Week 12 - Week 24	0		0		0		0		0		0	
	Week 24 - Week 36	0		0		0		0		0		0	
	Post Week 36	0		0		0		0		0		0	
γ－グルタミルトランスフェラーゼ増加	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Week 24 - Week 36	0		0		0		0		0		0	
	Post Week 36	1	(0.8)	0		0		0		0		1	(0.6)
グリコヘモグロビン増加	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Week 24 - Week 36	0		0		0		0		0		0	
	Post Week 36	0		0		0		0		1	(12.5)	1	(0.6)
眼圧上昇	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	1	(0.8)	0		0		0		0		1	(0.6)
	Week 24 - Week 36	0		0		0		0		0		0	
	Post Week 36	0		0		0		0		0		0	
肝機能検査異常	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	1	(0.8)	0		0		0		0		1	(0.6)
	Week 12 - Week 24	0		0		0		0		0		0	
	Week 24 - Week 36	0		0		0		0		0		0	
	Post Week 36	0		0		0		0		0		0	
尿中蛋白陽性	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	1	(0.8)	0		0		0		0		1	(0.6)
	Week 12 - Week 24	0		0		0		0		0		0	
	Week 24 - Week 36	0		0		0		0		0		0	
	Post Week 36	0		0		0		0		0		0	
赤血球数減少	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Week 24 - Week 36	0		0		0		0		0		0	

器官別大分類		Knee N=126		Shoulder N=15		Elbow N=8		Hip N=9		Ankle N=8		Total N=166	
基本語	Timing of first onset	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
	Post Week 36	1	(0.8)	0		0		0		0		1	(0.6)
傷害、中毒および処置合併症	Week 0 - Week 4	4	(3.2)	0		0		1	(11.1)	1	(12.5)	6	(3.6)
	Week 4 - Week 12	8	(6.4)	1	(6.7)	0		0		0		9	(5.5)
	Week 12 - Week 24	9	(7.3)	0		0		0		1	(12.5)	10	(6.3)
	Week 24 - Week 36	6	(5.0)	0		2	(25.0)	0		0		8	(5.1)
	Post Week 36	6	(5.0)	0		0		0		0		6	(3.8)
節足動物刺傷	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	1	(0.8)	0		0		0		0		1	(0.6)
	Week 12 - Week 24	0		0		0		0		0		0	
	Week 24 - Week 36	0		0		0		0		0		0	
	Post Week 36	0		0		0		0		0		0	
骨挫傷	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	0		1	(6.7)	0		0		0		1	(0.6)
	Week 12 - Week 24	0		0		0		0		0		0	
	Week 24 - Week 36	0		0		0		0		0		0	
	Post Week 36	1	(0.8)	0		0		0		0		1	(0.6)
凍瘡	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Week 24 - Week 36	0		0		0		0		0		0	
	Post Week 36	1	(0.8)	0		0		0		0		1	(0.6)
挫傷	Week 0 - Week 4	0		0		0		0		1	(12.5)	1	(0.6)
	Week 4 - Week 12	4	(3.2)	1	(6.7)	0		0		0		5	(3.0)
	Week 12 - Week 24	4	(3.3)	0		0		0		1	(12.5)	5	(3.1)
	Week 24 - Week 36	1	(0.8)	0		1	(12.5)	0		0		2	(1.3)
	Post Week 36	4	(3.3)	0		0		0		0		4	(2.5)
上顆炎	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		1	(7.1)	0		0		0		1	(0.6)
	Week 24 - Week 36	0		0		0		0		0		0	
	Post Week 36	0		0		1	(12.5)	0		0		1	(0.6)
足骨折	Week 0 - Week 4	1	(0.8)	0		0		0		0		1	(0.6)
	Week 4 - Week 12	1	(0.8)	0		0		0		0		1	(0.6)
	Week 12 - Week 24	0		0		0		0		0		0	
	Week 24 - Week 36	0		0		0		0		0		0	
	Post Week 36	1	(0.8)	0		0		0		0		1	(0.6)
手骨折	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	1	(0.8)	0		0		0		0		1	(0.6)
	Week 24 - Week 36	0		0		0		0		0		0	
	Post Week 36	0		0		0		0		0		0	
熱中症	Week 0 - Week 4	0		0		0		1	(11.1)	0		1	(0.6)
	Week 4 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	1	(0.8)	0		0		0		0		1	(0.6)
	Week 24 - Week 36	0		0		0		0		0		0	
	Post Week 36	0		0		0		0		0		0	
上腕骨骨折	Week 0 - Week 4	1	(0.8)	0		0		0		0		1	(0.6)
	Week 4 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Week 24 - Week 36	0		0		0		0		0		0	
	Post Week 36	0		0		0		0		0		0	
靭帯損傷	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	1	(0.8)	0		0		0		0		1	(0.6)

器官別大分類		Knee N=126		Shoulder N=15		Elbow N=8		Hip N=9		Ankle N=8		Total N=166	
基本語	Timing of first onset	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
	Week 24 - Week 36	0		0		0		0		0		0	
	Post Week 36	0		0		0		0		0		0	
靭帯捻挫	Week 0 - Week 4	0		0		0		0		1	(12.5)	1	(0.6)
	Week 4 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	4	(3.3)	0		0		0		0		4	(2.5)
	Week 24 - Week 36	1	(0.8)	0		0		0		0		1	(0.6)
	Post Week 36	0		0		0		0		0		0	
肉離れ	Week 0 - Week 4	1	(0.8)	0		0		0		0		1	(0.6)
	Week 4 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Week 24 - Week 36	1	(0.8)	0		0		0		0		1	(0.6)
	Post Week 36	0		0		0		0		0		0	
橈骨神経損傷	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	1	(0.8)	0		0		0		0		1	(0.6)
	Week 12 - Week 24	0		0		0		0		0		0	
	Week 24 - Week 36	0		0		0		0		0		0	
	Post Week 36	0		0		0		0		0		0	
橈骨骨折	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Week 24 - Week 36	0		0		0		0		0		0	
	Post Week 36	1	(0.8)	0		0		0		0		1	(0.6)
肋骨骨折	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	1	(0.8)	0		0		0		0		1	(0.6)
	Week 12 - Week 24	0		0		0		0		0		0	
	Week 24 - Week 36	0		0		0		0		0		0	
	Post Week 36	0		0		0		0		0		0	
皮膚擦過傷	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Week 24 - Week 36	0		0		1	(12.5)	0		0		1	(0.6)
	Post Week 36	0		0		0		0		0		0	
脊椎圧迫骨折	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Week 24 - Week 36	1	(0.8)	0		0		0		0		1	(0.6)
	Post Week 36	0		0		0		0		0		0	
皮下血腫	Week 0 - Week 4	1	(0.8)	0		0		0		0		1	(0.6)
	Week 4 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Week 24 - Week 36	0		0		0		0		0		0	
	Post Week 36	0		0		0		0		0		0	
腱断裂	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Week 24 - Week 36	1	(0.8)	0		0		0		0		1	(0.6)
	Post Week 36	0		0		0		0		0		0	
熱傷	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Week 24 - Week 36	1	(0.8)	0		0		0		0		1	(0.6)
	Post Week 36	1	(0.8)	0		0		0		0		1	(0.6)
創傷	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	1	(0.8)	0		0		0		0		1	(0.6)

器官別大分類		Knee N=126		Shoulder N=15		Elbow N=8		Hip N=9		Ankle N=8		Total N=166	
基本語	Timing of first onset	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
	Week 12 - Week 24	1	(0.8)	0		0		0		0		1	(0.6)
	Week 24 - Week 36	0		0		1	(12.5)	0		0		1	(0.6)
	Post Week 36	0		0		0		0		0		0	
外科および内科処置	Week 0 - Week 4	0		0		0		1	(11.1)	0		1	(0.6)
	Week 4 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Week 24 - Week 36	0		0		0		0		0		0	
	Post Week 36	1	(0.8)	0		0		0		0		1	(0.6)
抜歯	Week 0 - Week 4	0		0		0		1	(11.1)	0		1	(0.6)
	Week 4 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Week 24 - Week 36	0		0		0		0		0		0	
	Post Week 36	0		0		0		0		0		0	
智歯抜歯	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Week 24 - Week 36	0		0		0		0		0		0	
	Post Week 36	1	(0.8)	0		0		0		0		1	(0.6)

MedDRA/J Version 22.0
〔5.3.5.2-1 Table 14.3.1-10 改編〕

表 2.7.4.7-29. 初回発現時期別の関節ごとの副作用：613/1032 試験

器官別大分類		Knee N=126		Shoulder N=15		Elbow N=8		Hip N=9		Ankle N=8		Total N=166	
基本語	Timing of first onset	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
評価例数	Week 0 - Week 4	126		15		8		9		8		166	
	Week 4 - Week 12	125		15		8		9		8		165	
	Week 12 - Week 24	123		14		8		7		8		160	
	Week 24 - Week 36	121		14		8		7		8		158	
	Post Week 36	120		14		8		7		8		157	
全ての副作用	Week 0 - Week 4	1	(0.8)	1	(6.7)	2	(25.0)	0		1	(12.5)	5	(3.0)
	Week 4 - Week 12	2	(1.6)	0		0		1	(11.1)	0		3	(1.8)
	Week 12 - Week 24	2	(1.6)	1	(7.1)	0		0		0		3	(1.9)
	Week 24 - Week 36	2	(1.7)	0		0		0		0		2	(1.3)
	Post Week 36	2	(1.7)	0		0		0		0		2	(1.3)
神経系障害	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	1	(0.8)	0		0		0		0		1	(0.6)
	Week 12 - Week 24	0		0		0		0		0		0	
	Week 24 - Week 36	0		0		0		0		0		0	
	Post Week 36	0		0		0		0		0		0	
頭痛	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	1	(0.8)	0		0		0		0		1	(0.6)
	Week 12 - Week 24	0		0		0		0		0		0	
	Week 24 - Week 36	0		0		0		0		0		0	
	Post Week 36	0		0		0		0		0		0	
心臓障害	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	0		0		0		1	(11.1)	0		1	(0.6)
	Week 12 - Week 24	0		0		0		0		0		0	
	Week 24 - Week 36	0		0		0		0		0		0	
	Post Week 36	0		0		0		0		0		0	
動悸	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	0		0		0		1	(11.1)	0		1	(0.6)

器官別大分類		Knee N=126		Shoulder N=15		Elbow N=8		Hip N=9		Ankle N=8		Total N=166	
基本語	Timing of first onset	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
	Week 12 - Week 24	0		0		0		0		0		0	
	Week 24 - Week 36	0		0		0		0		0		0	
	Post Week 36	0		0		0		0		0		0	
胃腸障害	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	1	(0.8)	0		0		0		0		1	(0.6)
	Week 24 - Week 36	0		0		0		0		0		0	
	Post Week 36	0		0		0		0		0		0	
嘔吐	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	1	(0.8)	0		0		0		0		1	(0.6)
	Week 24 - Week 36	0		0		0		0		0		0	
	Post Week 36	0		0		0		0		0		0	
一般・全身障害および投与部位の状態	Week 0 - Week 4	1	(0.8)	1	(6.7)	2	(25.0)	0		1	(12.5)	5	(3.0)
	Week 4 - Week 12	2	(1.6)	0		0		0		0		2	(1.2)
	Week 12 - Week 24	2	(1.6)	1	(7.1)	0		0		0		3	(1.9)
	Week 24 - Week 36	2	(1.7)	0		0		0		0		2	(1.3)
	Post Week 36	2	(1.7)	0		0		0		0		2	(1.3)
注射部位関節痛	Week 0 - Week 4	1	(0.8)	1	(6.7)	2	(25.0)	0		1	(12.5)	5	(3.0)
	Week 4 - Week 12	1	(0.8)	0		0		0		0		1	(0.6)
	Week 12 - Week 24	2	(1.6)	1	(7.1)	0		0		0		3	(1.9)
	Week 24 - Week 36	2	(1.7)	0		0		0		0		2	(1.3)
	Post Week 36	2	(1.7)	0		0		0		0		2	(1.3)
倦怠感	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 12	1	(0.8)	0		0		0		0		1	(0.6)
	Week 12 - Week 24	0		0		0		0		0		0	
	Week 24 - Week 36	0		0		0		0		0		0	
	Post Week 36	0		0		0		0		0		0	

MedDRA/J Version 22.0
〔5.3.5.2-1 Table 14.3.1-11 改編〕

表 2.7.4.7-30. 発現時期別の有害事象：613/1022 試験

器官別大分類	Placebo N=89								SI-613 30 mg N=87							
	(A)		(B)		(C)		(D)		(A)		(B)		(C)		(D)	
基本語	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
評価例数	89		83		83		81		87		86		85		84	
全ての有害事象	21	(23.6)	12	(14.5)	15	(18.1)	16	(19.8)	19	(21.8)	18	(20.9)	11	(12.9)	22	(26.2)
感染症および寄生虫症	8	(9.0)	5	(6.0)	2	(2.4)	2	(2.5)	6	(6.9)	10	(11.6)	6	(7.1)	7	(8.3)
結膜炎	0		0		0		0		0		0		0		1	(1.2)
胃腸炎	0		0		0		0		0		1	(1.2)	0		0	
インフルエンザ	1	(1.1)	1	(1.2)	0		0		0		0		0		0	
鼻咽頭炎	5	(5.6)	4	(4.8)	2	(2.4)	2	(2.5)	6	(6.9)	7	(8.1)	5	(5.9)	6	(7.1)
爪囲炎	0		0		0		0		0		0		0		1	(1.2)
歯周炎	0		0		0		0		0		2	(2.3)	0		1	(1.2)
咽頭炎	1	(1.1)	0		0		0		0		0		0		0	
肺炎	0		1	(1.2)	0		0		0		0		0		0	
鼻炎	1	(1.1)	0		0		0		0		0		0		0	
足部白癬	0		0		0		0		0		0		1	(1.2)	0	
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）	0		0		0		1	(1.2)	0		0		0		0	

	Placebo N=89								SI-613 30 mg N=87							
器官別大分類	(A)		(B)		(C)		(D)		(A)		(B)		(C)		(D)	
基本語	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
乳癌	0		0		0		1	(1.2)	0		0		0		0	
代謝および栄養障害	0		0		0		0		0		0		1	(1.2)	0	
高尿酸血症	0		0		0		0		0		0		1	(1.2)	0	
精神障害	0		0		0		0		0		0		0		1	(1.2)
不安	0		0		0		0		0		0		0		1	(1.2)
神経系障害	0		0		0		2	(2.5)	0		1	(1.2)	0		2	(2.4)
頭痛	0		0		0		2	(2.5)	0		1	(1.2)	0		0	
片頭痛	0		0		0		0		0		0		0		1	(1.2)
小発作てんかん	0		0		0		0		0		0		0		1	(1.2)
第７脳神経麻痺	0		0		0		0		0		0		0		1	(1.2)
眼障害	1	(1.1)	0		0		1	(1.2)	2	(2.3)	1	(1.2)	0		1	(1.2)
白内障	0		0		0		0		1	(1.1)	1	(1.2)	0		0	
霰粒腫	0		0		0		0		1	(1.1)	0		0		0	
アレルギー性結膜炎	0		0		0		1	(1.2)	0		0		0		0	
眼乾燥	1	(1.1)	0		0		0		0		0		0		0	
網膜出血	0		0		0		0		0		0		0		1	(1.2)
耳および迷路障害	0		0		0		1	(1.2)	0		0		0		0	
回転性めまい	0		0		0		1	(1.2)	0		0		0		0	
心臓障害	1	(1.1)	0		0		0		1	(1.1)	0		0		1	(1.2)
心障害	0		0		0		0		0		0		0		1	(1.2)
動悸	0		0		0		0		1	(1.1)	0		0		0	
頻脈	1	(1.1)	0		0		0		0		0		0		0	
血管障害	0		1	(1.2)	1	(1.2)	1	(1.2)	0		0		0		0	
高血圧	0		1	(1.2)	0		1	(1.2)	0		0		0		0	
内出血	0		0		1	(1.2)	0		0		0		0		0	
呼吸器、胸郭および縦隔障害	1	(1.1)	2	(2.4)	0		0		1	(1.1)	1	(1.2)	0		0	
咳嗽	0		2	(2.4)	0		0		0		0		0		0	
口腔咽頭痛	0		0		0		0		1	(1.1)	0		0		0	
副鼻腔嚢胞	0		0		0		0		0		1	(1.2)	0		0	
上気道の炎症	1	(1.1)	0		0		0		0		0		0		0	
胃腸障害	1	(1.1)	1	(1.2)	1	(1.2)	3	(3.7)	1	(1.1)	2	(2.3)	1	(1.2)	2	(2.4)
腹部膨満	0		0		0		0		0		0		0		1	(1.2)
腹痛	0		0		0		0		0		0		1	(1.2)	0	
下腹部痛	0		0		0		0		0		0		0		1	(1.2)
便秘	0		1	(1.2)	0		1	(1.2)	0		0		0		0	
下痢	1	(1.1)	0		1	(1.2)	0		0		0		0		0	
変色便	0		0		0		1	(1.2)	0		0		0		0	
痔核	0		0		0		0		0		1	(1.2)	0		0	
悪心	0		0		0		0		1	(1.1)	0		0		0	
口内炎	0		0		0		0		0		1	(1.2)	0		1	(1.2)
嘔吐	0		0		0		1	(1.2)	0		0		0		1	(1.2)
皮膚および皮下組織障害	2	(2.2)	0		1	(1.2)	0		2	(2.3)	0		0		1	(1.2)
接触性皮膚炎	1	(1.1)	0		1	(1.2)	0		0		0		0		0	
皮下出血	1	(1.1)	0		0		0		0		0		0		1	(1.2)
発疹	0		0		0		0		1	(1.1)	0		0		0	
蕁麻疹	0		0		0		0		1	(1.1)	0		0		0	
筋骨格系および結合組織障害	3	(3.4)	4	(4.8)	5	(6.0)	9	(11.1)	4	(4.6)	4	(4.7)	3	(3.5)	6	(7.1)
関節痛	0		1	(1.2)	1	(1.2)	0		1	(1.1)	0		0		1	(1.2)
背部痛	1	(1.1)	0		1	(1.2)	1	(1.2)	0		0		0		0	
椎間板変性症	0		0		0		0		0		0		0		1	(1.2)
椎間板障害	0		0		0		0		0		0		0		1	(1.2)
腰部脊柱管狭窄症	0		0		0		0		0		0		0		1	(1.2)
筋痙縮	0		0		0		1	(1.2)	1	(1.1)	0		0		0	

器官別大分類	Placebo N=89								SI-613 30 mg N=87							
	(A)		(B)		(C)		(D)		(A)		(B)		(C)		(D)	
基本語	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
筋骨格痛	0		0		0		0		0		0		0		1	(1.2)
頚部痛	0		0		0		0		0		1	(1.2)	0		0	
結節性変形性関節症	0		0		0		0		0		1	(1.2)	0		0	
変形性関節症	0		1	(1.2)	1	(1.2)	4	(4.9)	1	(1.1)	2	(2.3)	0		2	(2.4)
骨粗鬆症性骨折	0		0		1	(1.2)	0		0		0		0		0	
関節周囲炎	0		0		0		1	(1.2)	0		0		1	(1.2)	0	
変形性脊椎症	1	(1.1)	1	(1.2)	0		0		1	(1.1)	1	(1.2)	0		0	
脊椎すべり症	0		0		1	(1.2)	0		0		0		0		1	(1.2)
滑液嚢腫	0		0		0		2	(2.5)	0		0		0		0	
腱鞘炎	1	(1.1)	0		0		0		0		0		1	(1.2)	0	
弾発指	0		1	(1.2)	0		0		0		0		1	(1.2)	0	
腎および尿路障害	0		0		1	(1.2)	0		0		0		0		0	
血尿	0		0		1	(1.2)	0		0		0		0		0	
一般・全身障害および投与部位の状態	0		0		2	(2.4)	0		0		1	(1.2)	0		1	(1.2)
胸痛	0		0		0		0		0		0		0		1	(1.2)
注射部位関節の炎症	0		0		0		0		0		1	(1.2)	0		0	
末梢性浮腫	0		0		1	(1.2)	0		0		0		0		0	
末梢腫脹	0		0		1	(1.2)	0		0		0		0		0	
臨床検査	1	(1.1)	2	(2.4)	2	(2.4)	1	(1.2)	1	(1.1)	0		2	(2.4)	1	(1.2)
アスパラギン酸アミノトランスフェラーゼ増加	1	(1.1)	0		0		0		0		0		0		0	
血中クレアチンホスホキナーゼ増加	0		2	(2.4)	0		1	(1.2)	0		0		0		0	
血中クレアチニン増加	0		0		0		0		0		0		1	(1.2)	0	
血圧上昇	0		0		0		0		0		0		0		1	(1.2)
血中トリグリセリド増加	0		0		1	(1.2)	0		0		0		0		0	
尿中ブドウ糖陽性	0		0		0		0		1	(1.1)	0		1	(1.2)	0	
白血球数減少	0		0		1	(1.2)	0		0		0		0		0	
傷害、中毒および処置合併症	5	(5.6)	0		2	(2.4)	1	(1.2)	2	(2.3)	1	(1.2)	0		1	(1.2)
足関節部骨折	1	(1.1)	0		0		0		0		0		0		0	
挫傷	2	(2.2)	0		1	(1.2)	0		1	(1.1)	1	(1.2)	0		1	(1.2)
上顆炎	0		0		0		1	(1.2)	0		0		0		0	
擦過傷	1	(1.1)	0		0		0		0		0		0		0	
靭帯捻挫	1	(1.1)	0		1	(1.2)	0		1	(1.1)	0		0		0	

MedDRA/J Version 18.0
(A):Post 1st injection to 2nd injection; (B):Post 2nd injection to 3rd injection; (C):Post 3rd injection to Week 12; (D):Post Week 12.
〔5.3.5.1-1 Table 14.4.1-7 改編〕

表 2.7.4.7-31. 発現時期別の有害事象：613/1031 試験

器官別大分類		Placebo N=220		SI-613 30 mg N=220	
基本語	Timing of onset	n	(%)	n	(%)
評価例数	Week 0 - Week 4	220		220	
	Week 4 - Week 8	214		216	
	Week 8 - Week 12	214		214	
	Week 12 - Week 16	212		207	
	Week 16 - Week 20	210		206	
	Post Week 20	209		206	
全ての有害事象	Week 0 - Week 4	54	(24.5)	53	(24.1)
	Week 4 - Week 8	35	(16.4)	44	(20.4)

器官別大分類		Placebo N=220		SI-613 30 mg N=220	
基本語	Timing of onset	n	(%)	n	(%)
	Week 8 - Week 12	29	(13.6)	44	(20.6)
	Week 12 - Week 16	26	(12.3)	27	(13.0)
	Week 16 - Week 20	24	(11.4)	19	(9.2)
	Post Week 20	20	(9.6)	28	(13.6)
感染症および寄生虫症	Week 0 - Week 4	15	(6.8)	17	(7.7)
	Week 4 - Week 8	11	(5.1)	12	(5.6)
	Week 8 - Week 12	11	(5.1)	12	(5.6)
	Week 12 - Week 16	8	(3.8)	7	(3.4)
	Week 16 - Week 20	11	(5.2)	8	(3.9)
	Post Week 20	5	(2.4)	9	(4.4)
アデノウイルス感染	Week 0 - Week 4	0		0	
	Week 4 - Week 8	0		0	
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		1	(0.5)
	Post Week 20	0		0	
気管支炎	Week 0 - Week 4	0		0	
	Week 4 - Week 8	0		0	
	Week 8 - Week 12	0		1	(0.5)
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	1	(0.5)	0	
	Post Week 20	0		0	
結膜炎	Week 0 - Week 4	1	(0.5)	2	(0.9)
	Week 4 - Week 8	0		0	
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	1	(0.5)	0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		0	
膀胱炎	Week 0 - Week 4	2	(0.9)	0	
	Week 4 - Week 8	0		0	
	Week 8 - Week 12	1	(0.5)	0	
	Week 12 - Week 16	1	(0.5)	0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		0	
感染性腸炎	Week 0 - Week 4	1	(0.5)	0	
	Week 4 - Week 8	0		0	
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		0	
真菌感染	Week 0 - Week 4	0		0	
	Week 4 - Week 8	0		0	
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	1	(0.5)	0	
	Post Week 20	0		0	
せつ	Week 0 - Week 4	0		0	
	Week 4 - Week 8	0		0	
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	0		1	(0.5)
	Week 16 - Week 20	0		0	
	Post Week 20	0		0	
胃腸炎	Week 0 - Week 4	0		0	
	Week 4 - Week 8	2	(0.9)	1	(0.5)

器官別大分類		Placebo N=220		SI-613 30 mg N=220	
基本語	Timing of onset	n	(%)	n	(%)
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		0	
	Post Week 20	1	(0.5)	1	(0.5)
歯肉炎	Week 0 - Week 4	1	(0.5)	1	(0.5)
	Week 4 - Week 8	0		0	
	Week 8 - Week 12	1	(0.5)	0	
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		0	
単純ヘルペス	Week 0 - Week 4	0		0	
	Week 4 - Week 8	0		0	
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		1	(0.5)
	Post Week 20	0		1	(0.5)
帯状疱疹	Week 0 - Week 4	0		0	
	Week 4 - Week 8	0		1	(0.5)
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		0	
インフルエンザ	Week 0 - Week 4	1	(0.5)	0	
	Week 4 - Week 8	1	(0.5)	1	(0.5)
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	2	(0.9)	1	(0.5)
	Week 16 - Week 20	0		0	
	Post Week 20	0		0	
上咽頭炎	Week 0 - Week 4	7	(3.2)	12	(5.5)
	Week 4 - Week 8	6	(2.8)	8	(3.7)
	Week 8 - Week 12	7	(3.3)	10	(4.7)
	Week 12 - Week 16	2	(0.9)	4	(1.9)
	Week 16 - Week 20	7	(3.3)	5	(2.4)
	Post Week 20	4	(1.9)	7	(3.4)
口腔ヘルペス	Week 0 - Week 4	0		0	
	Week 4 - Week 8	0		0	
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	1	(0.5)	0	
	Post Week 20	0		0	
外耳炎	Week 0 - Week 4	0		0	
	Week 4 - Week 8	0		0	
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	1	(0.5)	0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		0	
中耳炎	Week 0 - Week 4	1	(0.5)	0	
	Week 4 - Week 8	0		0	
	Week 8 - Week 12	0		1	(0.5)
	Week 12 - Week 16	1	(0.5)	0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		0	
爪囲炎	Week 0 - Week 4	0		0	
	Week 4 - Week 8	0		0	

器官別大分類		Placebo N=220		SI-613 30 mg N=220	
基本語	Timing of onset	n	(%)	n	(%)
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	1	(0.5)	0	
	Post Week 20	0		0	
歯冠周囲炎	Week 0 - Week 4	1	(0.5)	0	
	Week 4 - Week 8	0		0	
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		0	
歯周炎	Week 0 - Week 4	0		1	(0.5)
	Week 4 - Week 8	1	(0.5)	0	
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	0		1	(0.5)
	Week 16 - Week 20	0		0	
	Post Week 20	0		0	
咽頭炎	Week 0 - Week 4	0		0	
	Week 4 - Week 8	0		0	
	Week 8 - Week 12	1	(0.5)	0	
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		0	
歯髄炎	Week 0 - Week 4	0		1	(0.5)
	Week 4 - Week 8	0		0	
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		0	
鼻炎	Week 0 - Week 4	0		0	
	Week 4 - Week 8	0		0	
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		1	(0.5)
	Post Week 20	0		0	
副鼻腔炎	Week 0 - Week 4	0		0	
	Week 4 - Week 8	0		0	
	Week 8 - Week 12	1	(0.5)	0	
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		1	(0.5)
皮膚細菌感染	Week 0 - Week 4	0		1	(0.5)
	Week 4 - Week 8	0		0	
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		0	
股部白癬	Week 0 - Week 4	0		0	
	Week 4 - Week 8	0		1	(0.5)
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		0	
足部白癬	Week 0 - Week 4	0		0	
	Week 4 - Week 8	0		0	

器官別大分類		Placebo N=220		SI-613 30 mg N=220	
基本語	Timing of onset	n	(%)	n	(%)
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		1	(0.5)
トリコフィトン感染症	Week 0 - Week 4	0		0	
	Week 4 - Week 8	0		0	
	Week 8 - Week 12	1	(0.5)	0	
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		0	
上気道感染	Week 0 - Week 4	1	(0.5)	0	
	Week 4 - Week 8	0		0	
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		0	
外陰部腟カンジダ症	Week 0 - Week 4	1	(0.5)	0	
	Week 4 - Week 8	1	(0.5)	0	
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		0	
血液およびリンパ系障害	Week 0 - Week 4	0		0	
	Week 4 - Week 8	0		0	
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	1	(0.5)	0	
	Post Week 20	0		0	
脾腫	Week 0 - Week 4	0		0	
	Week 4 - Week 8	0		0	
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	1	(0.5)	0	
	Post Week 20	0		0	
免疫系障害	Week 0 - Week 4	0		2	(0.9)
	Week 4 - Week 8	0		1	(0.5)
	Week 8 - Week 12	0		1	(0.5)
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		0	
節足動物刺傷アレルギー	Week 0 - Week 4	0		0	
	Week 4 - Week 8	0		1	(0.5)
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		0	
アナフィラキシー反応	Week 0 - Week 4	0		1	(0.5)
	Week 4 - Week 8	0		0	
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		0	
アナフィラキシーショック	Week 0 - Week 4	0		1	(0.5)
	Week 4 - Week 8	0		0	

器官別大分類		Placebo N=220		SI-613 30 mg N=220	
基本語	Timing of onset	n	(%)	n	(%)
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		0	
季節性アレルギー	Week 0 - Week 4	0		0	
	Week 4 - Week 8	0		0	
	Week 8 - Week 12	0		1	(0.5)
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		0	
内分泌障害	Week 0 - Week 4	0		0	
	Week 4 - Week 8	1	(0.5)	0	
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		0	
甲状腺腫	Week 0 - Week 4	0		0	
	Week 4 - Week 8	1	(0.5)	0	
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		0	
代謝および栄養障害	Week 0 - Week 4	1	(0.5)	2	(0.9)
	Week 4 - Week 8	0		0	
	Week 8 - Week 12	0		2	(0.9)
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		1	(0.5)
	Post Week 20	2	(1.0)	0	
糖尿病	Week 0 - Week 4	0		0	
	Week 4 - Week 8	0		0	
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		1	(0.5)
	Post Week 20	1	(0.5)	0	
脂質異常症	Week 0 - Week 4	0		1	(0.5)
	Week 4 - Week 8	0		0	
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		0	
耐糖能障害	Week 0 - Week 4	0		0	
	Week 4 - Week 8	0		0	
	Week 8 - Week 12	0		1	(0.5)
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		0	
	Post Week 20	1	(0.5)	0	
高尿酸血症	Week 0 - Week 4	1	(0.5)	1	(0.5)
	Week 4 - Week 8	0		0	
	Week 8 - Week 12	0		1	(0.5)
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		0	
精神障害	Week 0 - Week 4	0		0	
	Week 4 - Week 8	1	(0.5)	0	

器官別大分類		Placebo N=220		SI-613 30 mg N=220	
基本語	Timing of onset	n	(%)	n	(%)
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		0	
身体疾患による睡眠障害、不眠症型	Week 0 - Week 4	0		0	
	Week 4 - Week 8	1	(0.5)	0	
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		0	
神経系障害	Week 0 - Week 4	0		5	(2.3)
	Week 4 - Week 8	0		2	(0.9)
	Week 8 - Week 12	2	(0.9)	3	(1.4)
	Week 12 - Week 16	0		1	(0.5)
	Week 16 - Week 20	0		1	(0.5)
	Post Week 20	0		2	(1.0)
自律神経発作	Week 0 - Week 4	0		0	
	Week 4 - Week 8	0		0	
	Week 8 - Week 12	0		1	(0.5)
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		0	
頚腕症候群	Week 0 - Week 4	0		0	
	Week 4 - Week 8	0		0	
	Week 8 - Week 12	1	(0.5)	1	(0.5)
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		0	
浮動性めまい	Week 0 - Week 4	0		1	(0.5)
	Week 4 - Week 8	0		0	
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	0		1	(0.5)
	Week 16 - Week 20	0		1	(0.5)
	Post Week 20	0		0	
味覚異常	Week 0 - Week 4	0		0	
	Week 4 - Week 8	0		0	
	Week 8 - Week 12	0		1	(0.5)
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		0	
頭痛	Week 0 - Week 4	0		2	(0.9)
	Week 4 - Week 8	0		0	
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		1	(0.5)
片頭痛	Week 0 - Week 4	0		0	
	Week 4 - Week 8	0		1	(0.5)
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		0	
錯感覚	Week 0 - Week 4	0		0	
	Week 4 - Week 8	0		1	(0.5)

器官別大分類		Placebo N=220		SI-613 30 mg N=220	
基本語	Timing of onset	n	(%)	n	(%)
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		0	
坐骨神経痛	Week 0 - Week 4	0		2	(0.9)
	Week 4 - Week 8	0		0	
	Week 8 - Week 12	1	(0.5)	0	
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		1	(0.5)
眼障害	Week 0 - Week 4	0		2	(0.9)
	Week 4 - Week 8	0		1	(0.5)
	Week 8 - Week 12	0		2	(0.9)
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		1	(0.5)
	Post Week 20	1	(0.5)	0	
白内障	Week 0 - Week 4	0		1	(0.5)
	Week 4 - Week 8	0		0	
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		1	(0.5)
	Post Week 20	0		0	
結膜充血	Week 0 - Week 4	0		0	
	Week 4 - Week 8	0		0	
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		0	
	Post Week 20	1	(0.5)	0	
アレルギー性結膜炎	Week 0 - Week 4	0		0	
	Week 4 - Week 8	0		1	(0.5)
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		0	
ドライアイ	Week 0 - Week 4	0		0	
	Week 4 - Week 8	0		0	
	Week 8 - Week 12	0		1	(0.5)
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		0	
眼の炎症	Week 0 - Week 4	0		0	
	Week 4 - Week 8	0		0	
	Week 8 - Week 12	0		1	(0.5)
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		0	
流涙増加	Week 0 - Week 4	0		1	(0.5)
	Week 4 - Week 8	0		0	
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		0	
耳および迷路障害	Week 0 - Week 4	0		0	
	Week 4 - Week 8	0		1	(0.5)

器官別大分類		Placebo N=220		SI-613 30 mg N=220	
基本語	Timing of onset	n	(%)	n	(%)
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	1	(0.5)	0	
	Week 16 - Week 20	0		1	(0.5)
	Post Week 20	0		0	
感音性難聴	Week 0 - Week 4	0		0	
	Week 4 - Week 8	0		1	(0.5)
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		0	
回転性めまい	Week 0 - Week 4	0		0	
	Week 4 - Week 8	0		0	
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	1	(0.5)	0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		0	
頭位性回転性めまい	Week 0 - Week 4	0		0	
	Week 4 - Week 8	0		0	
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		1	(0.5)
	Post Week 20	0		0	
心臓障害	Week 0 - Week 4	0		1	(0.5)
	Week 4 - Week 8	0		0	
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		1	(0.5)
不安定狭心症	Week 0 - Week 4	0		1	(0.5)
	Week 4 - Week 8	0		0	
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		0	
不整脈	Week 0 - Week 4	0		0	
	Week 4 - Week 8	0		0	
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		1	(0.5)
血管障害	Week 0 - Week 4	1	(0.5)	0	
	Week 4 - Week 8	1	(0.5)	1	(0.5)
	Week 8 - Week 12	0		1	(0.5)
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		1	(0.5)
高血圧	Week 0 - Week 4	0		0	
	Week 4 - Week 8	1	(0.5)	1	(0.5)
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		0	
蒼白	Week 0 - Week 4	1	(0.5)	0	
	Week 4 - Week 8	0		0	

器官別大分類		Placebo N=220		SI-613 30 mg N=220	
基本語	Timing of onset	n	(%)	n	(%)
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		0	
末梢静脈疾患	Week 0 - Week 4	0		0	
	Week 4 - Week 8	0		0	
	Week 8 - Week 12	0		1	(0.5)
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		0	
静脈瘤	Week 0 - Week 4	0		0	
	Week 4 - Week 8	0		0	
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		1	(0.5)
呼吸器、胸郭および縦隔障害	Week 0 - Week 4	2	(0.9)	1	(0.5)
	Week 4 - Week 8	2	(0.9)	0	
	Week 8 - Week 12	1	(0.5)	0	
	Week 12 - Week 16	0		1	(0.5)
	Week 16 - Week 20	1	(0.5)	1	(0.5)
	Post Week 20	0		0	
咳嗽	Week 0 - Week 4	1	(0.5)	0	
	Week 4 - Week 8	0		0	
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		0	
鼻出血	Week 0 - Week 4	0		0	
	Week 4 - Week 8	0		0	
	Week 8 - Week 12	1	(0.5)	0	
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		0	
喉頭痛	Week 0 - Week 4	0		0	
	Week 4 - Week 8	0		0	
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		1	(0.5)
	Post Week 20	0		0	
口腔咽頭痛	Week 0 - Week 4	0		0	
	Week 4 - Week 8	0		0	
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	0		1	(0.5)
	Week 16 - Week 20	1	(0.5)	0	
	Post Week 20	0		0	
上気道の炎症	Week 0 - Week 4	1	(0.5)	1	(0.5)
	Week 4 - Week 8	2	(0.9)	0	
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		0	
胃腸障害	Week 0 - Week 4	5	(2.3)	4	(1.8)
	Week 4 - Week 8	5	(2.3)	3	(1.4)

器官別大分類		Placebo N=220		SI-613 30 mg N=220	
基本語	Timing of onset	n	(%)	n	(%)
	Week 8 - Week 12	3	(1.4)	4	(1.9)
	Week 12 - Week 16	1	(0.5)	1	(0.5)
	Week 16 - Week 20	2	(1.0)	2	(1.0)
	Post Week 20	1	(0.5)	0	
腹痛	Week 0 - Week 4	1	(0.5)	0	
	Week 4 - Week 8	0		0	
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		0	
上腹部痛	Week 0 - Week 4	0		0	
	Week 4 - Week 8	0		0	
	Week 8 - Week 12	0		1	(0.5)
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		1	(0.5)
	Post Week 20	0		0	
口唇炎	Week 0 - Week 4	0		0	
	Week 4 - Week 8	0		1	(0.5)
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		0	
慢性胃炎	Week 0 - Week 4	0		0	
	Week 4 - Week 8	1	(0.5)	0	
	Week 8 - Week 12	0		1	(0.5)
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		0	
齲歯	Week 0 - Week 4	0		0	
	Week 4 - Week 8	1	(0.5)	0	
	Week 8 - Week 12	0		1	(0.5)
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		0	
	Post Week 20	1	(0.5)	0	
下痢	Week 0 - Week 4	1	(0.5)	2	(0.9)
	Week 4 - Week 8	1	(0.5)	0	
	Week 8 - Week 12	1	(0.5)	1	(0.5)
	Week 12 - Week 16	1	(0.5)	0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		0	
胃潰瘍	Week 0 - Week 4	0		0	
	Week 4 - Week 8	0		1	(0.5)
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		0	
胃炎	Week 0 - Week 4	0		1	(0.5)
	Week 4 - Week 8	0		0	
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	0		1	(0.5)
	Week 16 - Week 20	0		1	(0.5)
	Post Week 20	0		0	
胃食道逆流性疾患	Week 0 - Week 4	0		0	
	Week 4 - Week 8	3	(1.4)	0	

器官別大分類		Placebo N=220		SI-613 30 mg N=220	
基本語	Timing of onset	n	(%)	n	(%)
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		0	
痔核	Week 0 - Week 4	1	(0.5)	0	
	Week 4 - Week 8	0		0	
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	1	(0.5)	0	
	Post Week 20	0		0	
過敏性腸症候群	Week 0 - Week 4	1	(0.5)	0	
	Week 4 - Week 8	0		0	
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		0	
悪心	Week 0 - Week 4	0		1	(0.5)
	Week 4 - Week 8	0		0	
	Week 8 - Week 12	2	(0.9)	0	
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		0	
膵嚢胞	Week 0 - Week 4	0		0	
	Week 4 - Week 8	0		0	
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	1	(0.5)	0	
	Post Week 20	0		0	
口内炎	Week 0 - Week 4	1	(0.5)	0	
	Week 4 - Week 8	0		0	
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		0	
歯痛	Week 0 - Week 4	0		0	
	Week 4 - Week 8	0		1	(0.5)
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		0	
嘔吐	Week 0 - Week 4	1	(0.5)	0	
	Week 4 - Week 8	0		0	
	Week 8 - Week 12	2	(0.9)	0	
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		0	
肝胆道系障害	Week 0 - Week 4	0		1	(0.5)
	Week 4 - Week 8	0		0	
	Week 8 - Week 12	0		1	(0.5)
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	1	(0.5)	0	
	Post Week 20	0		1	(0.5)
胆嚢ポリープ	Week 0 - Week 4	0		0	
	Week 4 - Week 8	0		0	

器官別大分類		Placebo N=220		SI-613 30 mg N=220	
基本語	Timing of onset	n	(%)	n	(%)
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	1	(0.5)	0	
	Post Week 20	0		0	
肝機能異常	Week 0 - Week 4	0		1	(0.5)
	Week 4 - Week 8	0		0	
	Week 8 - Week 12	0		1	(0.5)
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		1	(0.5)
脂肪肝	Week 0 - Week 4	0		0	
	Week 4 - Week 8	0		0	
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	1	(0.5)	0	
	Post Week 20	0		0	
皮膚および皮下組織障害	Week 0 - Week 4	3	(1.4)	2	(0.9)
	Week 4 - Week 8	4	(1.9)	3	(1.4)
	Week 8 - Week 12	3	(1.4)	0	
	Week 12 - Week 16	5	(2.4)	2	(1.0)
	Week 16 - Week 20	1	(0.5)	0	
	Post Week 20	0		1	(0.5)
ざ瘡	Week 0 - Week 4	0		0	
	Week 4 - Week 8	0		0	
	Week 8 - Week 12	1	(0.5)	0	
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		0	
冷汗	Week 0 - Week 4	1	(0.5)	0	
	Week 4 - Week 8	0		0	
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		0	
皮膚嚢腫	Week 0 - Week 4	0		0	
	Week 4 - Week 8	1	(0.5)	0	
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	1	(0.5)	0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		0	
皮膚炎	Week 0 - Week 4	0		0	
	Week 4 - Week 8	0		0	
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	1	(0.5)	0	
	Post Week 20	0		0	
アレルギー性皮膚炎	Week 0 - Week 4	1	(0.5)	0	
	Week 4 - Week 8	0		0	
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		0	
皮膚乾燥	Week 0 - Week 4	0		0	
	Week 4 - Week 8	0		0	

器官別大分類		Placebo N=220		SI-613 30 mg N=220	
基本語	Timing of onset	n	(%)	n	(%)
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	1	(0.5)	0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		0	
湿疹	Week 0 - Week 4	0		0	
	Week 4 - Week 8	0		2	(0.9)
	Week 8 - Week 12	1	(0.5)	0	
	Week 12 - Week 16	2	(0.9)	2	(1.0)
	Week 16 - Week 20	0		0	
	Post Week 20	0		1	(0.5)
汗疹	Week 0 - Week 4	0		0	
	Week 4 - Week 8	0		1	(0.5)
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		0	
そう痒症	Week 0 - Week 4	0		0	
	Week 4 - Week 8	1	(0.5)	0	
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		0	
発疹	Week 0 - Week 4	1	(0.5)	0	
	Week 4 - Week 8	2	(0.9)	0	
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	1	(0.5)	0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		0	
蕁麻疹	Week 0 - Week 4	0		2	(0.9)
	Week 4 - Week 8	0		0	
	Week 8 - Week 12	1	(0.5)	0	
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		0	
筋骨格系および結合組織障害	Week 0 - Week 4	19	(8.6)	9	(4.1)
	Week 4 - Week 8	10	(4.7)	14	(6.5)
	Week 8 - Week 12	4	(1.9)	14	(6.5)
	Week 12 - Week 16	6	(2.8)	6	(2.9)
	Week 16 - Week 20	8	(3.8)	5	(2.4)
	Post Week 20	8	(3.8)	6	(2.9)
関節痛	Week 0 - Week 4	3	(1.4)	1	(0.5)
	Week 4 - Week 8	2	(0.9)	2	(0.9)
	Week 8 - Week 12	0		1	(0.5)
	Week 12 - Week 16	1	(0.5)	2	(1.0)
	Week 16 - Week 20	1	(0.5)	2	(1.0)
	Post Week 20	1	(0.5)	2	(1.0)
関節炎	Week 0 - Week 4	0		0	
	Week 4 - Week 8	0		1	(0.5)
	Week 8 - Week 12	1	(0.5)	0	
	Week 12 - Week 16	1	(0.5)	0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		0	
背部痛	Week 0 - Week 4	1	(0.5)	2	(0.9)
	Week 4 - Week 8	3	(1.4)	2	(0.9)

器官別大分類		Placebo N=220		SI-613 30 mg N=220	
基本語	Timing of onset	n	(%)	n	(%)
	Week 8 - Week 12	0		1	(0.5)
	Week 12 - Week 16	2	(0.9)	2	(1.0)
	Week 16 - Week 20	1	(0.5)	0	
	Post Week 20	0		0	
ピロリン酸カルシウム結晶性軟骨石灰化症	Week 0 - Week 4	0		0	
	Week 4 - Week 8	1	(0.5)	0	
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		0	
腱付着部症	Week 0 - Week 4	1	(0.5)	0	
	Week 4 - Week 8	0		0	
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		0	
出血性関節症	Week 0 - Week 4	0		0	
	Week 4 - Week 8	0		0	
	Week 8 - Week 12	1	(0.5)	0	
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		0	
椎間板変性症	Week 0 - Week 4	0		0	
	Week 4 - Week 8	0		0	
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	1	(0.5)	0	
	Post Week 20	0		0	
椎間板障害	Week 0 - Week 4	0		0	
	Week 4 - Week 8	0		0	
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		1	(0.5)
	Post Week 20	0		0	
関節滲出液	Week 0 - Week 4	1	(0.5)	0	
	Week 4 - Week 8	0		0	
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		0	
関節硬直	Week 0 - Week 4	1	(0.5)	0	
	Week 4 - Week 8	0		0	
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		0	
関節腫脹	Week 0 - Week 4	1	(0.5)	0	
	Week 4 - Week 8	0		0	
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		0	
四肢不快感	Week 0 - Week 4	1	(0.5)	0	
	Week 4 - Week 8	0		1	(0.5)

器官別大分類		Placebo N=220		SI-613 30 mg N=220	
基本語	Timing of onset	n	(%)	n	(%)
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		0	
腰部脊柱管狭窄症	Week 0 - Week 4	0		0	
	Week 4 - Week 8	0		0	
	Week 8 - Week 12	1	(0.5)	1	(0.5)
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		1	(0.5)
筋痙縮	Week 0 - Week 4	1	(0.5)	1	(0.5)
	Week 4 - Week 8	0		1	(0.5)
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	1	(0.5)	0	
	Week 16 - Week 20	0		0	
	Post Week 20	1	(0.5)	0	
筋骨格痛	Week 0 - Week 4	0		0	
	Week 4 - Week 8	0		1	(0.5)
	Week 8 - Week 12	1	(0.5)	1	(0.5)
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		0	
筋骨格硬直	Week 0 - Week 4	1	(0.5)	0	
	Week 4 - Week 8	0		1	(0.5)
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		0	
筋肉痛	Week 0 - Week 4	0		1	(0.5)
	Week 4 - Week 8	1	(0.5)	1	(0.5)
	Week 8 - Week 12	0		1	(0.5)
	Week 12 - Week 16	0		1	(0.5)
	Week 16 - Week 20	0		1	(0.5)
	Post Week 20	0		0	
筋筋膜炎	Week 0 - Week 4	2	(0.9)	0	
	Week 4 - Week 8	0		0	
	Week 8 - Week 12	0		1	(0.5)
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		0	
頚部痛	Week 0 - Week 4	0		1	(0.5)
	Week 4 - Week 8	0		0	
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		0	
変形性関節症	Week 0 - Week 4	5	(2.3)	2	(0.9)
	Week 4 - Week 8	0		0	
	Week 8 - Week 12	0		3	(1.4)
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	1	(0.5)	0	
	Post Week 20	2	(1.0)	3	(1.5)
骨壊死	Week 0 - Week 4	0		0	
	Week 4 - Week 8	0		1	(0.5)

器官別大分類		Placebo N=220		SI-613 30 mg N=220	
基本語	Timing of onset	n	(%)	n	(%)
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		0	
四肢痛	Week 0 - Week 4	1	(0.5)	1	(0.5)
	Week 4 - Week 8	0		1	(0.5)
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	1	(0.5)	0	
	Post Week 20	1	(0.5)	0	
関節周囲炎	Week 0 - Week 4	1	(0.5)	0	
	Week 4 - Week 8	1	(0.5)	1	(0.5)
	Week 8 - Week 12	0		2	(0.9)
	Week 12 - Week 16	1	(0.5)	0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		0	
肩回旋筋腱板症候群	Week 0 - Week 4	0		0	
	Week 4 - Week 8	1	(0.5)	0	
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		0	
変形性脊椎症	Week 0 - Week 4	1	(0.5)	0	
	Week 4 - Week 8	1	(0.5)	0	
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	0		1	(0.5)
	Week 16 - Week 20	1	(0.5)	1	(0.5)
	Post Week 20	1	(0.5)	0	
脊椎すべり症	Week 0 - Week 4	0		0	
	Week 4 - Week 8	0		0	
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	1	(0.5)	0	
	Post Week 20	0		0	
滑液嚢腫	Week 0 - Week 4	0		0	
	Week 4 - Week 8	0		0	
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	1	(0.5)	0	
	Post Week 20	0		0	
滑膜炎	Week 0 - Week 4	0		0	
	Week 4 - Week 8	0		0	
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		0	
	Post Week 20	1	(0.5)	0	
腱炎	Week 0 - Week 4	0		0	
	Week 4 - Week 8	0		0	
	Week 8 - Week 12	0		2	(0.9)
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		0	
	Post Week 20	1	(0.5)	0	
腱鞘炎	Week 0 - Week 4	0		1	(0.5)
	Week 4 - Week 8	0		1	(0.5)

器官別大分類		Placebo N=220		SI-613 30 mg N=220	
基本語	Timing of onset	n	(%)	n	(%)
	Week 8 - Week 12	0		1	(0.5)
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	1	(0.5)	0	
	Post Week 20	0		0	
弾発指	Week 0 - Week 4	0		0	
	Week 4 - Week 8	0		1	(0.5)
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		0	
腎および尿路障害	Week 0 - Week 4	0		0	
	Week 4 - Week 8	1	(0.5)	0	
	Week 8 - Week 12	0		1	(0.5)
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	1	(0.5)	0	
	Post Week 20	0		0	
緊張性膀胱	Week 0 - Week 4	0		0	
	Week 4 - Week 8	1	(0.5)	0	
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		0	
腎嚢胞	Week 0 - Week 4	0		0	
	Week 4 - Week 8	0		0	
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	1	(0.5)	0	
	Post Week 20	0		0	
腎機能障害	Week 0 - Week 4	0		0	
	Week 4 - Week 8	0		0	
	Week 8 - Week 12	0		1	(0.5)
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		0	
生殖系および乳房障害	Week 0 - Week 4	1	(0.5)	1	(0.5)
	Week 4 - Week 8	0		0	
	Week 8 - Week 12	0		1	(0.5)
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		1	(0.5)
子宮頚管ポリープ	Week 0 - Week 4	1	(0.5)	0	
	Week 4 - Week 8	0		0	
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		0	
前立腺炎	Week 0 - Week 4	0		1	(0.5)
	Week 4 - Week 8	0		0	
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		0	
外陰腟そう痒症	Week 0 - Week 4	0		0	
	Week 4 - Week 8	0		0	

器官別大分類		Placebo N=220		SI-613 30 mg N=220	
基本語	Timing of onset	n	(%)	n	(%)
	Week 8 - Week 12	0		1	(0.5)
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		1	(0.5)
一般・全身障害および投与部位の状態	Week 0 - Week 4	7	(3.2)	2	(0.9)
	Week 4 - Week 8	0		4	(1.9)
	Week 8 - Week 12	2	(0.9)	2	(0.9)
	Week 12 - Week 16	3	(1.4)	2	(1.0)
	Week 16 - Week 20	1	(0.5)	1	(0.5)
	Post Week 20	2	(1.0)	2	(1.0)
胸痛	Week 0 - Week 4	1	(0.5)	0	
	Week 4 - Week 8	0		0	
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	1	(0.5)	0	
	Week 16 - Week 20	0		1	(0.5)
	Post Week 20	0		0	
悪寒	Week 0 - Week 4	0		0	
	Week 4 - Week 8	0		1	(0.5)
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		0	
異常感	Week 0 - Week 4	1	(0.5)	0	
	Week 4 - Week 8	0		0	
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		0	
炎症	Week 0 - Week 4	0		0	
	Week 4 - Week 8	0		1	(0.5)
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		0	
注射部位関節不快感	Week 0 - Week 4	1	(0.5)	0	
	Week 4 - Week 8	0		0	
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		0	
注射部位関節痛	Week 0 - Week 4	2	(0.9)	2	(0.9)
	Week 4 - Week 8	0		2	(0.9)
	Week 8 - Week 12	2	(0.9)	1	(0.5)
	Week 12 - Week 16	0		1	(0.5)
	Week 16 - Week 20	1	(0.5)	0	
	Post Week 20	2	(1.0)	2	(1.0)
注射部位関節腫脹	Week 0 - Week 4	1	(0.5)	0	
	Week 4 - Week 8	0		0	
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		0	
注射部位疼痛	Week 0 - Week 4	0		0	
	Week 4 - Week 8	0		0	

器官別大分類		Placebo N=220		SI-613 30 mg N=220	
基本語	Timing of onset	n	(%)	n	(%)
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	2	(0.9)	0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		0	
倦怠感	Week 0 - Week 4	0		0	
	Week 4 - Week 8	0		0	
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	0		1	(0.5)
	Week 16 - Week 20	0		0	
	Post Week 20	0		0	
末梢性浮腫	Week 0 - Week 4	1	(0.5)	0	
	Week 4 - Week 8	0		0	
	Week 8 - Week 12	0		1	(0.5)
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		0	
発熱	Week 0 - Week 4	1	(0.5)	0	
	Week 4 - Week 8	0		1	(0.5)
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		0	
臨床検査	Week 0 - Week 4	0		8	(3.6)
	Week 4 - Week 8	0		2	(0.9)
	Week 8 - Week 12	4	(1.9)	6	(2.8)
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		1	(0.5)
	Post Week 20	3	(1.4)	4	(1.9)
アラニンアミノトランスフェラーゼ増加	Week 0 - Week 4	0		0	
	Week 4 - Week 8	0		0	
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		0	
	Post Week 20	1	(0.5)	0	
アスパラギン酸アミノトランスフェラーゼ増加	Week 0 - Week 4	0		0	
	Week 4 - Week 8	0		0	
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		0	
	Post Week 20	1	(0.5)	0	
血中アルカリホスファターゼ増加	Week 0 - Week 4	0		0	
	Week 4 - Week 8	0		0	
	Week 8 - Week 12	0		2	(0.9)
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		0	
血中クレアチンホスホキナーゼ増加	Week 0 - Week 4	0		4	(1.8)
	Week 4 - Week 8	0		0	
	Week 8 - Week 12	1	(0.5)	0	
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		0	
	Post Week 20	1	(0.5)	1	(0.5)
血中クレアチニン増加	Week 0 - Week 4	0		0	
	Week 4 - Week 8	0		0	

器官別大分類		Placebo N=220		SI-613 30 mg N=220	
基本語	Timing of onset	n	(%)	n	(%)
	Week 8 - Week 12	1	(0.5)	0	
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		0	
外来血圧上昇	Week 0 - Week 4	0		0	
	Week 4 - Week 8	0		1	(0.5)
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		0	
血圧上昇	Week 0 - Week 4	0		0	
	Week 4 - Week 8	0		0	
	Week 8 - Week 12	1	(0.5)	0	
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		1	(0.5)
	Post Week 20	0		0	
血中尿酸増加	Week 0 - Week 4	0		1	(0.5)
	Week 4 - Week 8	0		0	
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		0	
血中亜鉛減少	Week 0 - Week 4	0		0	
	Week 4 - Week 8	0		1	(0.5)
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		0	
Ｃ－反応性蛋白増加	Week 0 - Week 4	0		0	
	Week 4 - Week 8	0		0	
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		0	
	Post Week 20	1	(0.5)	0	
γ－グルタミルトランスフェラーゼ増加	Week 0 - Week 4	0		0	
	Week 4 - Week 8	0		0	
	Week 8 - Week 12	0		1	(0.5)
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		0	
尿中ブドウ糖	Week 0 - Week 4	0		1	(0.5)
	Week 4 - Week 8	0		0	
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		0	
尿中ブドウ糖陽性	Week 0 - Week 4	0		0	
	Week 4 - Week 8	0		0	
	Week 8 - Week 12	1	(0.5)	1	(0.5)
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		2	(1.0)
グリコヘモグロビン増加	Week 0 - Week 4	0		0	
	Week 4 - Week 8	0		0	

器官別大分類		Placebo N=220		SI-613 30 mg N=220	
基本語	Timing of onset	n	(%)	n	(%)
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		0	
	Post Week 20	1	(0.5)	0	
肝機能検査異常	Week 0 - Week 4	0		1	(0.5)
	Week 4 - Week 8	0		0	
	Week 8 - Week 12	0		1	(0.5)
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		0	
肝機能検査値上昇	Week 0 - Week 4	0		1	(0.5)
	Week 4 - Week 8	0		0	
	Week 8 - Week 12	0		1	(0.5)
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		1	(0.5)
白血球数増加	Week 0 - Week 4	0		1	(0.5)
	Week 4 - Week 8	0		0	
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		0	
傷害、中毒および処置合併症	Week 0 - Week 4	5	(2.3)	7	(3.2)
	Week 4 - Week 8	6	(2.8)	6	(2.8)
	Week 8 - Week 12	3	(1.4)	4	(1.9)
	Week 12 - Week 16	2	(0.9)	6	(2.9)
	Week 16 - Week 20	0		0	
	Post Week 20	0		4	(1.9)
動物咬傷	Week 0 - Week 4	0		0	
	Week 4 - Week 8	0		1	(0.5)
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		0	
節足動物咬傷	Week 0 - Week 4	0		0	
	Week 4 - Week 8	1	(0.5)	0	
	Week 8 - Week 12	0		1	(0.5)
	Week 12 - Week 16	1	(0.5)	0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		1	(0.5)
節足動物刺傷	Week 0 - Week 4	0		1	(0.5)
	Week 4 - Week 8	0		0	
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		0	
剥離骨折	Week 0 - Week 4	0		0	
	Week 4 - Week 8	0		1	(0.5)
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		0	
挫傷	Week 0 - Week 4	1	(0.5)	2	(0.9)
	Week 4 - Week 8	3	(1.4)	0	

器官別大分類		Placebo N=220		SI-613 30 mg N=220	
基本語	Timing of onset	n	(%)	n	(%)
	Week 8 - Week 12	1	(0.5)	0	
	Week 12 - Week 16	0		1	(0.5)
	Week 16 - Week 20	0		0	
	Post Week 20	0		1	(0.5)
上顎炎	Week 0 - Week 4	0		1	(0.5)
	Week 4 - Week 8	0		0	
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		0	
眼瞼挫傷	Week 0 - Week 4	0		1	(0.5)
	Week 4 - Week 8	0		0	
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		0	
転倒	Week 0 - Week 4	0		0	
	Week 4 - Week 8	1	(0.5)	0	
	Week 8 - Week 12	1	(0.5)	0	
	Week 12 - Week 16	0		2	(1.0)
	Week 16 - Week 20	0		0	
	Post Week 20	0		0	
足骨折	Week 0 - Week 4	0		0	
	Week 4 - Week 8	0		0	
	Week 8 - Week 12	0		1	(0.5)
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		0	
気道内異物	Week 0 - Week 4	0		1	(0.5)
	Week 4 - Week 8	0		0	
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		0	
手骨折	Week 0 - Week 4	0		0	
	Week 4 - Week 8	0		1	(0.5)
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		0	
注入に伴う反応	Week 0 - Week 4	1	(0.5)	0	
	Week 4 - Week 8	0		0	
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		0	
関節損傷	Week 0 - Week 4	1	(0.5)	0	
	Week 4 - Week 8	0		0	
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		0	
靭帯損傷	Week 0 - Week 4	0		0	
	Week 4 - Week 8	0		0	

器官別大分類		Placebo N=220		SI-613 30 mg N=220	
基本語	Timing of onset	n	(%)	n	(%)
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	0		1	(0.5)
	Week 16 - Week 20	0		0	
	Post Week 20	0		0	
靭帯捻挫	Week 0 - Week 4	1	(0.5)	0	
	Week 4 - Week 8	0		2	(0.9)
	Week 8 - Week 12	0		2	(0.9)
	Week 12 - Week 16	0		1	(0.5)
	Week 16 - Week 20	0		0	
	Post Week 20	0		2	(1.0)
四肢損傷	Week 0 - Week 4	1	(0.5)	0	
	Week 4 - Week 8	0		0	
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		0	
皮膚擦過傷	Week 0 - Week 4	0		1	(0.5)
	Week 4 - Week 8	0		0	
	Week 8 - Week 12	1	(0.5)	0	
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		0	
皮膚創傷	Week 0 - Week 4	0		0	
	Week 4 - Week 8	0		1	(0.5)
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		0	
脊椎圧迫骨折	Week 0 - Week 4	0		0	
	Week 4 - Week 8	1	(0.5)	0	
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		0	
刺創	Week 0 - Week 4	0		0	
	Week 4 - Week 8	1	(0.5)	0	
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		0	
熱傷	Week 0 - Week 4	0		0	
	Week 4 - Week 8	0		0	
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	0		1	(0.5)
	Week 16 - Week 20	0		0	
	Post Week 20	0		0	
歯牙破折	Week 0 - Week 4	0		0	
	Week 4 - Week 8	0		0	
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	1	(0.5)	1	(0.5)
	Week 16 - Week 20	0		0	
	Post Week 20	0		0	
創傷	Week 0 - Week 4	0		0	
	Week 4 - Week 8	0		1	(0.5)

器官別大分類		Placebo N=220		SI-613 30 mg N=220	
基本語	Timing of onset	n	(%)	n	(%)
	Week 8 - Week 12	1	(0.5)	0	
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		0	
外科および内科処置	Week 0 - Week 4	0		0	
	Week 4 - Week 8	0		0	
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		1	(0.5)
	Post Week 20	0		0	
斜視矯正術	Week 0 - Week 4	0		0	
	Week 4 - Week 8	0		0	
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		1	(0.5)
	Post Week 20	0		0	
社会環境	Week 0 - Week 4	1	(0.5)	0	
	Week 4 - Week 8	0		0	
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		0	
過労	Week 0 - Week 4	1	(0.5)	0	
	Week 4 - Week 8	0		0	
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		0	
製品の問題	Week 0 - Week 4	0		0	
	Week 4 - Week 8	0		1	(0.5)
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	0		1	(0.5)
	Week 16 - Week 20	0		0	
	Post Week 20	0		0	
医療機器破損	Week 0 - Week 4	0		0	
	Week 4 - Week 8	0		1	(0.5)
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	0		1	(0.5)
	Week 16 - Week 20	0		0	
	Post Week 20	0		0	

MedDRA/J Version 21.1
〔5.3.5.1-3 Table 14.3.1-8 改編〕

表 2.7.4.7-32. 発現時期別の副作用：613/1022 試験

器官別大分類	Placebo N=89								SI-613 30 mg N=87							
基本語	(A)		(B)		(C)		(D)		(A)		(B)		(C)		(D)	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
評価例数	89		83		83		81		87		86		85		84	
全ての副作用	0		0		0		0		0		1	(1.2)	0		0	
一般・全身障害および投与部位の状態	0		0		0		0		0		1	(1.2)	0		0	
注射部位関節の炎症	0		0		0		0		0		1	(1.2)	0		0	

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(A):Post 1st injection to 2nd injection; (B):Post 2nd injection to 3rd injection; (C):Post 3rd injection to Week 12; (D):Post Week 12.
〔5.3.5.1-2 Table 14.3.1-8 改編〕

表 2.7.4.7-33. 発現時期別の副作用：613/1031 試験

器官別大分類		Placebo N=220		SI-613 30 mg N=220	
基本語	Timing of onset	n	(%)	n	(%)
評価例数	Week 0 - Week 4	220		220	
	Week 4 - Week 8	214		216	
	Week 8 - Week 12	214		214	
	Week 12 - Week 16	212		207	
	Week 16 - Week 20	210		206	
	Post Week 20	209		206	
全ての副作用	Week 0 - Week 4	4	(1.8)	3	(1.4)
	Week 4 - Week 8	1	(0.5)	3	(1.4)
	Week 8 - Week 12	0		2	(0.9)
	Week 12 - Week 16	1	(0.5)	1	(0.5)
	Week 16 - Week 20	1	(0.5)	0	
	Post Week 20	1	(0.5)	2	(1.0)
免疫系障害	Week 0 - Week 4	0		2	(0.9)
	Week 4 - Week 8	0		0	
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		0	
アナフィラキシー反応	Week 0 - Week 4	0		1	(0.5)
	Week 4 - Week 8	0		0	
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		0	
アナフィラキシーショック	Week 0 - Week 4	0		1	(0.5)
	Week 4 - Week 8	0		0	
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		0	
筋骨格系および結合組織障害	Week 0 - Week 4	2	(0.9)	0	
	Week 4 - Week 8	1	(0.5)	1	(0.5)
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		0	

器官別大分類		Placebo N=220		SI-613 30 mg N=220	
基本語	Timing of onset	n	(%)	n	(%)
関節痛	Week 0 - Week 4	0		0	
	Week 4 - Week 8	1	(0.5)	0	
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		0	
関節滲出液	Week 0 - Week 4	1	(0.5)	0	
	Week 4 - Week 8	0		0	
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		0	
関節硬直	Week 0 - Week 4	1	(0.5)	0	
	Week 4 - Week 8	0		0	
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		0	
四肢不快感	Week 0 - Week 4	0		0	
	Week 4 - Week 8	0		1	(0.5)
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		0	
一般・全身障害および投与部位の状態	Week 0 - Week 4	2	(0.9)	1	(0.5)
	Week 4 - Week 8	0		2	(0.9)
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	1	(0.5)	1	(0.5)
	Week 16 - Week 20	1	(0.5)	0	
	Post Week 20	1	(0.5)	2	(1.0)
注射部位関節不快感	Week 0 - Week 4	1	(0.5)	0	
	Week 4 - Week 8	0		0	
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		0	
注射部位関節痛	Week 0 - Week 4	2	(0.9)	1	(0.5)
	Week 4 - Week 8	0		2	(0.9)
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	0		1	(0.5)
	Week 16 - Week 20	1	(0.5)	0	
	Post Week 20	1	(0.5)	2	(1.0)
注射部位疼痛	Week 0 - Week 4	0		0	
	Week 4 - Week 8	0		0	
	Week 8 - Week 12	0		0	
	Week 12 - Week 16	1	(0.5)	0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		0	
臨床検査	Week 0 - Week 4	0		0	
	Week 4 - Week 8	0		0	
	Week 8 - Week 12	0		2	(0.9)
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		0	

器官別大分類 基本語	Timing of onset	Placebo N=220 n	(%)	SI-613 30 mg N=220 n	(%)
	Post Week 20	0		0	
γ－グルタミルトランスフェラーゼ増加	Week 0 - Week 4	0		0	
	Week 4 - Week 8	0		0	
	Week 8 - Week 12	0		1	(0.5)
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		0	
肝機能検査異常	Week 0 - Week 4	0		0	
	Week 4 - Week 8	0		0	
	Week 8 - Week 12	0		1	(0.5)
	Week 12 - Week 16	0		0	
	Week 16 - Week 20	0		0	
	Post Week 20	0		0	

MedDRA/J Version 21.1
〔5.3.5.1-3 Table 14.3.1-9 改編〕

表 2.7.4.7-34. 発現時期別の関節ごとの有害事象：613/1033 試験

		Shoulder				Elbow				Hip				Ankle				Total			
		Placebo		SI-613 30 mg		Placebo		SI-613 30 mg		Placebo		SI-613 30 mg		Placebo		SI-613 30 mg		Placebo		SI-613 30 mg	
器官別大分類		N=45		N=45		N=25		N=25		N=44		N=46		N=30		N=30		N=144		N=146	
基本語	Timing of onset	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
評価例数	Week 0 - Week 4	45		45		25		25		44		46		30		30		144		146	
	Week 4 - Week 8	44		45		25		25		43		46		30		29		142		145	
	Post Week 8	44		45		25		25		42		45		29		29		140		144	
全ての有害事象	Week 0 - Week 4	4	(8.9)	12	(26.7)	6	(24.0)	5	(20.0)	9	(20.5)	11	(23.9)	5	(16.7)	9	(30.0)	24	(16.7)	37	(25.3)
	Week 4 - Week 8	6	(13.6)	10	(22.2)	2	(8.0)	2	(8.0)	7	(16.3)	14	(30.4)	4	(13.3)	11	(37.9)	19	(13.4)	37	(25.5)
	Post Week 8	9	(20.5)	5	(11.1)	2	(8.0)	5	(20.0)	3	(7.1)	7	(15.6)	4	(13.8)	6	(20.7)	18	(12.9)	23	(16.0)
感染症および寄生虫症	Week 0 - Week 4	1	(2.2)	4	(8.9)	1	(4.0)	2	(8.0)	4	(9.1)	1	(2.2)	1	(3.3)	3	(10.0)	7	(4.9)	10	(6.8)
	Week 4 - Week 8	3	(6.8)	4	(8.9)	1	(4.0)	0		1	(2.3)	5	(10.9)	2	(6.7)	4	(13.8)	7	(4.9)	13	(9.0)
	Post Week 8	4	(9.1)	0		0		1	(4.0)	1	(2.4)	3	(6.7)	1	(3.4)	1	(3.4)	6	(4.3)	5	(3.5)
気管支炎	Week 0 - Week 4	0		0		0		0		0		0		0		0		0		0	
	Week 4 - Week 8	0		1	(2.2)	0		0		0		0		0		0		0		1	(0.7)
	Post Week 8	0		0		0		0		0		0		0		0		0		0	
結膜炎	Week 0 - Week 4	0		1	(2.2)	0		0		0		0		0		0		0		1	(0.7)
	Week 4 - Week 8	0		0		0		0		0		0		0		0		0		0	
	Post Week 8	0		0		0		0		0		0		0		0		0		0	
膀胱炎	Week 0 - Week 4	0		0		0		1	(4.0)	0		0		0		0		0		1	(0.7)
	Week 4 - Week 8	0		0		0		0		0		0		0		0		0		0	
	Post Week 8	0		0		0		0		0		0		0		0		0		0	
胃腸炎	Week 0 - Week 4	0		0		0		0		0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0		0		1	(3.4)	0		1	(0.7)
	Post Week 8	0		0		0		0		0		0		0		0		0		0	
上咽頭炎	Week 0 - Week 4	1	(2.2)	2	(4.4)	1	(4.0)	1	(4.0)	3	(6.8)	1	(2.2)	0		3	(10.0)	5	(3.5)	7	(4.8)
	Week 4 - Week 8	1	(2.3)	3	(6.7)	1	(4.0)	0		1	(2.3)	5	(10.9)	2	(6.7)	3	(10.3)	5	(3.5)	11	(7.6)
	Post Week 8	3	(6.8)	0		0		1	(4.0)	1	(2.4)	3	(6.7)	0		1	(3.4)	4	(2.9)	5	(3.5)
口腔ヘルペス	Week 0 - Week 4	0		0		0		0		0		0		1	(3.3)	0		1	(0.7)	0	
	Week 4 - Week 8	0		0		0		0		0		0		0		0		0		0	
	Post Week 8	0		0		0		0		0		0		0		0		0		0	
爪囲炎	Week 0 - Week 4	0		0		0		0		1	(2.3)	0		0		0		1	(0.7)	0	
	Week 4 - Week 8	0		0		0		0		0		0		0		0		0		0	
	Post Week 8	0		0		0		0		0		0		0		0		0		0	

器官別大分類		Shoulder				Elbow				Hip				Ankle				Total			
		Placebo		SI-613 30 mg		Placebo		SI-613 30 mg		Placebo		SI-613 30 mg		Placebo		SI-613 30 mg		Placebo		SI-613 30 mg	
		N=45		N=45		N=25		N=25		N=44		N=46		N=30		N=30		N=144		N=146	
基本語	Timing of onset	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
歯周炎	Week 0 - Week 4	0		1	(2.2)	0		0		0		0		0		0		0		1	(0.7)
	Week 4 - Week 8	1	(2.3)	0		0		0		0		0		0		0		1	(0.7)	0	
	Post Week 8	0		0		0		0		0		0		0		0		0		0	
咽頭炎	Week 0 - Week 4	0		1	(2.2)	0		0		0		0		0		0		0		1	(0.7)
	Week 4 - Week 8	0		0		0		0		0		0		0		0		0		0	
	Post Week 8	0		0		0		0		0		0		0		0		0		0	
肺炎	Week 0 - Week 4	0		0		0		0		0		0		0		0		0		0	
	Week 4 - Week 8	1	(2.3)	0		0		0		0		0		0		0		1	(0.7)	0	
	Post Week 8	1	(2.3)	0		0		0		0		0		0		0		1	(0.7)	0	
上気道感染	Week 0 - Week 4	0		0		0		0		0		0		0		0		0		0	
	Week 4 - Week 8	1	(2.3)	0		0		0		0		0		0		0		1	(0.7)	0	
	Post Week 8	0		0		0		0		0		0		1	(3.4)	0		1	(0.7)	0	
免疫系障害	Week 0 - Week 4	0		1	(2.2)	0		0		0		0		0		0		0		1	(0.7)
	Week 4 - Week 8	0		0		0		0		0		0		0		0		0		0	
	Post Week 8	0		0		0		0		0		0		0		0		0		0	
季節性アレルギー	Week 0 - Week 4	0		1	(2.2)	0		0		0		0		0		0		0		1	(0.7)
	Week 4 - Week 8	0		0		0		0		0		0		0		0		0		0	
	Post Week 8	0		0		0		0		0		0		0		0		0		0	
代謝および栄養障害	Week 0 - Week 4	0		0		0		1	(4.0)	0		0		0		0		0		1	(0.7)
	Week 4 - Week 8	0		0		0		0		0		0		0		0		0		0	
	Post Week 8	0		0		0		0		0		0		0		0		0		0	
２型糖尿病	Week 0 - Week 4	0		0		0		1	(4.0)	0		0		0		0		0		1	(0.7)
	Week 4 - Week 8	0		0		0		0		0		0		0		0		0		0	
	Post Week 8	0		0		0		0		0		0		0		0		0		0	
神経系障害	Week 0 - Week 4	0		1	(2.2)	0		0		3	(6.8)	1	(2.2)	0		1	(3.3)	3	(2.1)	3	(2.1)
	Week 4 - Week 8	0		1	(2.2)	0		0		1	(2.3)	2	(4.3)	0		1	(3.4)	1	(0.7)	4	(2.8)
	Post Week 8	0		0		1	(4.0)	0		0		0		0		1	(3.4)	1	(0.7)	1	(0.7)
小脳出血	Week 0 - Week 4	0		0		0		0		0		0		0		0		0		0	
	Week 4 - Week 8	0		1	(2.2)	0		0		0		0		0		0		0		1	(0.7)
	Post Week 8	0		0		0		0		0		0		0		0		0		0	
肘部管症候群	Week 0 - Week 4	0		0		0		0		0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0		0		0		0		0	
	Post Week 8	0		0		1	(4.0)	0		0		0		0		0		1	(0.7)	0	
浮動性めまい	Week 0 - Week 4	0		0		0		0		2	(4.5)	0		0		0		2	(1.4)	0	

器官別大分類		Shoulder				Elbow				Hip				Ankle				Total			
		Placebo		SI-613 30 mg		Placebo		SI-613 30 mg		Placebo		SI-613 30 mg		Placebo		SI-613 30 mg		Placebo		SI-613 30 mg	
		N=45		N=45		N=25		N=25		N=44		N=46		N=30		N=30		N=144		N=146	
基本語	Timing of onset	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
	Week 4 - Week 8	0		0		0		0		0		0		0		0		0		0	
	Post Week 8	0		0		0		0		0		0		0		0		0		0	
頭痛	Week 0 - Week 4	0		0		0		0		0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0		0		0		0		0	
	Post Week 8	0		0		0		0		0		0		0		1	(3.4)	0		1	(0.7)
感覚鈍麻	Week 0 - Week 4	0		0		0		0		0		1	(2.2)	0		1	(3.3)	0		2	(1.4)
	Week 4 - Week 8	0		0		0		0		1	(2.3)	0		0		0		1	(0.7)	0	
	Post Week 8	0		0		0		0		0		0		0		0		0		0	
失神寸前の状態	Week 0 - Week 4	0		0		0		0		0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		1	(2.2)	0		0		0		1	(0.7)
	Post Week 8	0		0		0		0		0		0		0		0		0		0	
振戦	Week 0 - Week 4	0		0		0		0		0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		1	(2.2)	0		0		0		1	(0.7)
	Post Week 8	0		0		0		0		0		0		0		0		0		0	
迷走神経障害	Week 0 - Week 4	0		1	(2.2)	0		0		1	(2.3)	0		0		0		1	(0.7)	1	(0.7)
	Week 4 - Week 8	0		0		0		0		0		0		0		1	(3.4)	0		1	(0.7)
	Post Week 8	0		0		0		0		0		0		0		0		0		0	
眼障害	Week 0 - Week 4	0		1	(2.2)	0		0		0		0		0		0		0		1	(0.7)
	Week 4 - Week 8	0		0		0		0		0		0		1	(3.3)	0		1	(0.7)	0	
	Post Week 8	1	(2.3)	0		0		0		0		0		1	(3.4)	0		2	(1.4)	0	
白内障	Week 0 - Week 4	0		0		0		0		0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0		0		0		0		0	
	Post Week 8	1	(2.3)	0		0		0		0		0		0		0		1	(0.7)	0	
脈絡膜血管新生	Week 0 - Week 4	0		1	(2.2)	0		0		0		0		0		0		0		1	(0.7)
	Week 4 - Week 8	0		0		0		0		0		0		0		0		0		0	
	Post Week 8	0		0		0		0		0		0		0		0		0		0	
ドライアイ	Week 0 - Week 4	0		0		0		0		0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0		1	(3.3)	0		1	(0.7)	0	
	Post Week 8	1	(2.3)	0		0		0		0		0		0		0		1	(0.7)	0	
眼の炎症	Week 0 - Week 4	0		0		0		0		0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0		0		0		0		0	
	Post Week 8	0		0		0		0		0		0		1	(3.4)	0		1	(0.7)	0	
耳および迷路障害	Week 0 - Week 4	1	(2.2)	0		1	(4.0)	0		0		0		0		0		2	(1.4)	0	
	Week 4 - Week 8	0		0		0		0		0		0		0		0		0		0	

器官別大分類		Shoulder				Elbow				Hip				Ankle				Total			
		Placebo		SI-613 30 mg		Placebo		SI-613 30 mg		Placebo		SI-613 30 mg		Placebo		SI-613 30 mg		Placebo		SI-613 30 mg	
		N=45		N=45		N=25		N=25		N=44		N=46		N=30		N=30		N=144		N=146	
基本語	Timing of onset	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
	Post Week 8	0		0		0		0		0		0		0		0		0		0	
感音性難聴	Week 0 - Week 4	0		0		1	(4.0)	0		0		0		0		0		1	(0.7)	0	
	Week 4 - Week 8	0		0		0		0		0		0		0		0		0		0	
	Post Week 8	0		0		0		0		0		0		0		0		0		0	
回転性めまい	Week 0 - Week 4	1	(2.2)	0		0		0		0		0		0		0		1	(0.7)	0	
	Week 4 - Week 8	0		0		0		0		0		0		0		0		0		0	
	Post Week 8	0		0		0		0		0		0		0		0		0		0	
心臓障害	Week 0 - Week 4	0		1	(2.2)	0		0		0		0		0		0		0		1	(0.7)
	Week 4 - Week 8	0		0		0		0		0		2	(4.3)	0		0		0		2	(1.4)
	Post Week 8	0		0		0		0		0		0		0		0		0		0	
動悸	Week 0 - Week 4	0		1	(2.2)	0		0		0		0		0		0		0		1	(0.7)
	Week 4 - Week 8	0		0		0		0		0		2	(4.3)	0		0		0		2	(1.4)
	Post Week 8	0		0		0		0		0		0		0		0		0		0	
血管障害	Week 0 - Week 4	0		0		0		0		0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0		0		0		0		0	
	Post Week 8	0		1	(2.2)	0		1	(4.0)	0		0		0		0		0		2	(1.4)
高血圧	Week 0 - Week 4	0		0		0		0		0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0		0		0		0		0	
	Post Week 8	0		1	(2.2)	0		1	(4.0)	0		0		0		0		0		2	(1.4)
呼吸器、胸郭および縦隔障害	Week 0 - Week 4	0		0		0		0		0		1	(2.2)	0		2	(6.7)	0		3	(2.1)
	Week 4 - Week 8	0		0		0		0		0		1	(2.2)	0		1	(3.4)	0		2	(1.4)
	Post Week 8	0		0		1	(4.0)	1	(4.0)	0		1	(2.2)	0		0		1	(0.7)	2	(1.4)
喘息	Week 0 - Week 4	0		0		0		0		0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0		0		1	(3.4)	0		1	(0.7)
	Post Week 8	0		0		0		0		0		1	(2.2)	0		0		0		1	(0.7)
咳嗽	Week 0 - Week 4	0		0		0		0		0		1	(2.2)	0		0		0		1	(0.7)
	Week 4 - Week 8	0		0		0		0		0		0		0		0		0		0	
	Post Week 8	0		0		0		0		0		0		0		0		0		0	
呼吸困難	Week 0 - Week 4	0		0		0		0		0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		1	(2.2)	0		0		0		1	(0.7)
	Post Week 8	0		0		0		0		0		0		0		0		0		0	
鼻出血	Week 0 - Week 4	0		0		0		0		0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0		0		0		0		0	
	Post Week 8	0		0		0		1	(4.0)	0		0		0		0		0		1	(0.7)

器官別大分類		Shoulder				Elbow				Hip				Ankle				Total			
		Placebo		SI-613 30 mg		Placebo		SI-613 30 mg		Placebo		SI-613 30 mg		Placebo		SI-613 30 mg		Placebo		SI-613 30 mg	
		N=45		N=45		N=25		N=25		N=44		N=46		N=30		N=30		N=144		N=146	
基本語	Timing of onset	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
口腔咽頭痛	Week 0 - Week 4	0		0		0		0		0		0		0		1	(3.3)	0		1	(0.7)
	Week 4 - Week 8	0		0		0		0		0		0		0		0		0		0	
	Post Week 8	0		0		0		0		0		0		0		0		0		0	
上気道の炎症	Week 0 - Week 4	0		0		0		0		0		0		0		1	(3.3)	0		1	(0.7)
	Week 4 - Week 8	0		0		0		0		0		0		0		0		0		0	
	Post Week 8	0		0		0		0		0		0		0		0		0		0	
声帯白斑症	Week 0 - Week 4	0		0		0		0		0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0		0		0		0		0	
	Post Week 8	0		0		1	(4.0)	0		0		0		0		0		1	(0.7)	0	
胃腸障害	Week 0 - Week 4	1	(2.2)	1	(2.2)	1	(4.0)	0		0		4	(8.7)	0		0		2	(1.4)	5	(3.4)
	Week 4 - Week 8	1	(2.3)	1	(2.2)	0		0		1	(2.3)	3	(6.5)	0		1	(3.4)	2	(1.4)	5	(3.4)
	Post Week 8	0		1	(2.2)	0		1	(4.0)	0		1	(2.2)	0		0		0		3	(2.1)
腹部不快感	Week 0 - Week 4	0		0		0		0		0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0		0		0		0		0	
	Post Week 8	0		1	(2.2)	0		0		0		0		0		0		0		1	(0.7)
腹部膨満	Week 0 - Week 4	0		0		0		0		0		1	(2.2)	0		0		0		1	(0.7)
	Week 4 - Week 8	0		0		0		0		0		0		0		0		0		0	
	Post Week 8	0		0		0		0		0		0		0		0		0		0	
腹痛	Week 0 - Week 4	0		0		0		0		0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0		0		1	(3.4)	0		1	(0.7)
	Post Week 8	0		0		0		0		0		0		0		0		0		0	
上腹部痛	Week 0 - Week 4	0		0		0		0		0		0		0		0		0		0	
	Week 4 - Week 8	0		1	(2.2)	0		0		0		0		0		0		0		1	(0.7)
	Post Week 8	0		0		0		1	(4.0)	0		0		0		0		0		1	(0.7)
虚血性大腸炎	Week 0 - Week 4	0		0		0		0		0		1	(2.2)	0		0		0		1	(0.7)
	Week 4 - Week 8	0		0		0		0		0		0		0		0		0		0	
	Post Week 8	0		0		0		0		0		0		0		0		0		0	
齲歯	Week 0 - Week 4	0		1	(2.2)	0		0		0		0		0		0		0		1	(0.7)
	Week 4 - Week 8	0		0		0		0		1	(2.3)	0		0		0		1	(0.7)	0	
	Post Week 8	0		0		0		0		0		0		0		0		0		0	
消化不良	Week 0 - Week 4	0		0		0		0		0		1	(2.2)	0		0		0		1	(0.7)
	Week 4 - Week 8	0		0		0		0		0		0		0		0		0		0	
	Post Week 8	0		0		0		0		0		0		0		0		0		0	
大腸ポリープ	Week 0 - Week 4	0		0		1	(4.0)	0		0		0		0		0		1	(0.7)	0	

器官別大分類		Shoulder				Elbow				Hip				Ankle				Total			
		Placebo N=45		SI-613 30 mg N=45		Placebo N=25		SI-613 30 mg N=25		Placebo N=44		SI-613 30 mg N=46		Placebo N=30		SI-613 30 mg N=30		Placebo N=144		SI-613 30 mg N=146	
基本語	Timing of onset	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
	Week 4 - Week 8	0		0		0		0		0		0		0		0		0		0	
	Post Week 8	0		0		0		0		0		0		0		0		0		0	
悪心	Week 0 - Week 4	0		0		0		0		0		1	(2.2)	0		0		0		1	(0.7)
	Week 4 - Week 8	0		0		0		0		0		3	(6.5)	0		1	(3.4)	0		4	(2.8)
	Post Week 8	0		0		0		0		0		1	(2.2)	0		0		0		1	(0.7)
口内炎	Week 0 - Week 4	0		0		0		0		0		0		0		0		0		0	
	Week 4 - Week 8	1	(2.3)	0		0		0		0		0		0		0		1	(0.7)	0	
	Post Week 8	0		0		0		0		0		0		0		0		0		0	
嘔吐	Week 0 - Week 4	1	(2.2)	0		0		0		0		1	(2.2)	0		0		1	(0.7)	1	(0.7)
	Week 4 - Week 8	0		0		0		0		0		0		0		0		0		0	
	Post Week 8	0		0		0		0		0		0		0		0		0		0	
皮膚および皮下組織障害	Week 0 - Week 4	0		1	(2.2)	1	(4.0)	0		0		1	(2.2)	0		0		1	(0.7)	2	(1.4)
	Week 4 - Week 8	2	(4.5)	1	(2.2)	0		0		0		2	(4.3)	0		1	(3.4)	2	(1.4)	4	(2.8)
	Post Week 8	0		0		0		0		0		0		0		0		0		0	
冷汗	Week 0 - Week 4	0		0		0		0		0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		1	(2.2)	0		0		0		1	(0.7)
	Post Week 8	0		0		0		0		0		0		0		0		0		0	
皮下出血	Week 0 - Week 4	0		0		0		0		0		1	(2.2)	0		0		0		1	(0.7)
	Week 4 - Week 8	0		0		0		0		0		0		0		0		0		0	
	Post Week 8	0		0		0		0		0		0		0		0		0		0	
多汗症	Week 0 - Week 4	0		0		0		0		0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		1	(2.2)	0		0		0		1	(0.7)
	Post Week 8	0		0		0		0		0		0		0		0		0		0	
そう痒症	Week 0 - Week 4	0		1	(2.2)	0		0		0		0		0		0		0		1	(0.7)
	Week 4 - Week 8	1	(2.3)	0		0		0		0		0		0		0		1	(0.7)	0	
	Post Week 8	0		0		0		0		0		0		0		0		0		0	
発疹	Week 0 - Week 4	0		0		0		0		0		0		0		0		0		0	
	Week 4 - Week 8	1	(2.3)	0		0		0		0		0		0		0		1	(0.7)	0	
	Post Week 8	0		0		0		0		0		0		0		0		0		0	
瘢痕痛	Week 0 - Week 4	0		0		0		0		0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0		0		1	(3.4)	0		1	(0.7)
	Post Week 8	0		0		0		0		0		0		0		0		0		0	
老人性そう痒症	Week 0 - Week 4	0		0		0		0		0		0		0		0		0		0	
	Week 4 - Week 8	0		1	(2.2)	0		0		0		0		0		0		0		1	(0.7)

器官別大分類		Shoulder				Elbow				Hip				Ankle				Total			
		Placebo		SI-613 30 mg		Placebo		SI-613 30 mg		Placebo		SI-613 30 mg		Placebo		SI-613 30 mg		Placebo		SI-613 30 mg	
		N=45		N=45		N=25		N=25		N=44		N=46		N=30		N=30		N=144		N=146	
基本語	Timing of onset	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
	Post Week 8	0		0		0		0		0		0		0		0		0		0	
蕁麻疹	Week 0 - Week 4	0		0		1	(4.0)	0		0		0		0		0		1	(0.7)	0	
	Week 4 - Week 8	0		0		0		0		0		0		0		0		0		0	
	Post Week 8	0		0		0		0		0		0		0		0		0		0	
筋骨格系および結合組織障害	Week 0 - Week 4	2	(4.4)	1	(2.2)	1	(4.0)	0		1	(2.3)	2	(4.3)	1	(3.3)	1	(3.3)	5	(3.5)	4	(2.7)
	Week 4 - Week 8	1	(2.3)	1	(2.2)	0		2	(8.0)	3	(7.0)	1	(2.2)	0		2	(6.9)	4	(2.8)	6	(4.1)
	Post Week 8	2	(4.5)	1	(2.2)	0		0		0		0		1	(3.4)	1	(3.4)	3	(2.1)	2	(1.4)
関節痛	Week 0 - Week 4	1	(2.2)	0		0		0		0		0		1	(3.3)	1	(3.3)	2	(1.4)	1	(0.7)
	Week 4 - Week 8	1	(2.3)	0		0		0		0		0		0		0		1	(0.7)	0	
	Post Week 8	0		0		0		0		0		0		1	(3.4)	0		1	(0.7)	0	
背部痛	Week 0 - Week 4	0		0		0		0		0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0		0		1	(3.4)	0		1	(0.7)
	Post Week 8	0		0		0		0		0		0		0		0		0		0	
関節裂隙狭小化	Week 0 - Week 4	0		0		0		0		0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0		0		0		0		0	
	Post Week 8	0		1	(2.2)	0		0		0		0		0		0		0		1	(0.7)
靭帯炎	Week 0 - Week 4	0		0		0		0		0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0		0		0		0		0	
	Post Week 8	0		0		0		0		0		0		0		1	(3.4)	0		1	(0.7)
筋痙縮	Week 0 - Week 4	0		0		0		0		0		1	(2.2)	0		0		0		1	(0.7)
	Week 4 - Week 8	0		0		0		0		0		0		0		0		0		0	
	Post Week 8	0		0		0		0		0		0		0		0		0		0	
筋骨格痛	Week 0 - Week 4	1	(2.2)	1	(2.2)	0		0		0		0		0		0		1	(0.7)	1	(0.7)
	Week 4 - Week 8	0		1	(2.2)	0		0		0		0		0		0		0		1	(0.7)
	Post Week 8	1	(2.3)	0		0		0		0		0		0		0		1	(0.7)	0	
筋肉痛	Week 0 - Week 4	0		0		0		0		0		1	(2.2)	0		0		0		1	(0.7)
	Week 4 - Week 8	0		0		0		0		0		1	(2.2)	0		0		0		1	(0.7)
	Post Week 8	0		0		0		0		0		0		0		0		0		0	
変形性関節症	Week 0 - Week 4	0		0		0		0		0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		1	(2.3)	0		0		0		1	(0.7)	0	
	Post Week 8	0		0		0		0		0		0		0		0		0		0	
四肢痛	Week 0 - Week 4	0		0		0		0		0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		1	(4.0)	0		0		0		0		0		1	(0.7)
	Post Week 8	0		0		0		0		0		0		0		0		0		0	

器官別大分類		Shoulder				Elbow				Hip				Ankle				Total			
		Placebo		SI-613 30 mg		Placebo		SI-613 30 mg		Placebo		SI-613 30 mg		Placebo		SI-613 30 mg		Placebo		SI-613 30 mg	
		N=45		N=45		N=25		N=25		N=44		N=46		N=30		N=30		N=144		N=146	
基本語	Timing of onset	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
関節周囲炎	Week 0 - Week 4	0		0		0		0		0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		1	(4.0)	1	(2.3)	0		0		0		1	(0.7)	1	(0.7)
	Post Week 8	0		0		0		0		0		0		0		0		0		0	
多発性関節炎	Week 0 - Week 4	0		0		0		0		0		0		0		0		0		0	
	Week 4 - Week 8	1	(2.3)	0		0		0		0		0		0		0		1	(0.7)	0	
	Post Week 8	0		0		0		0		0		0		0		0		0		0	
肩回旋筋腱板症候群	Week 0 - Week 4	0		0		1	(4.0)	0		1	(2.3)	0		0		0		2	(1.4)	0	
	Week 4 - Week 8	0		0		0		0		0		0		0		0		0		0	
	Post Week 8	0		0		0		0		0		0		0		0		0		0	
滑液嚢腫	Week 0 - Week 4	1	(2.2)	0		0		0		0		0		0		0		1	(0.7)	0	
	Week 4 - Week 8	0		0		0		0		0		0		0		1	(3.4)	0		1	(0.7)
	Post Week 8	0		0		0		0		0		0		0		0		0		0	
腱炎	Week 0 - Week 4	0		0		0		0		0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0		0		0		0		0	
	Post Week 8	1	(2.3)	0		0		0		0		0		0		0		1	(0.7)	0	
弾発指	Week 0 - Week 4	0		0		0		0		0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		1	(2.3)	0		0		0		1	(0.7)	0	
	Post Week 8	0		0		0		0		0		0		0		0		0		0	
一般・全身障害および投与部位の状態	Week 0 - Week 4	0		1	(2.2)	0		0		1	(2.3)	2	(4.3)	2	(6.7)	2	(6.7)	3	(2.1)	5	(3.4)
	Week 4 - Week 8	0		1	(2.2)	1	(4.0)	0		0		5	(10.9)	1	(3.3)	4	(13.8)	2	(1.4)	10	(6.9)
	Post Week 8	0		1	(2.2)	0		0		1	(2.4)	2	(4.4)	1	(3.4)	3	(10.3)	2	(1.4)	6	(4.2)
悪寒	Week 0 - Week 4	0		0		0		0		0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0		0		1	(3.4)	0		1	(0.7)
	Post Week 8	0		0		0		0		0		0		0		0		0		0	
注射部位内出血	Week 0 - Week 4	0		0		0		0		0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0		0		0		0		0	
	Post Week 8	0		0		0		0		1	(2.4)	0		0		0		1	(0.7)	0	
注射部位湿疹	Week 0 - Week 4	0		0		0		0		0		0		1	(3.3)	0		1	(0.7)	0	
	Week 4 - Week 8	0		0		0		0		0		0		0		0		0		0	
	Post Week 8	0		0		0		0		0		0		0		0		0		0	
注射部位知覚低下	Week 0 - Week 4	0		0		0		0		0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0		0		1	(3.4)	0		1	(0.7)
	Post Week 8	0		0		0		0		0		0		0		0		0		0	
注射部位損傷	Week 0 - Week 4	0		0		0		0		0		0		0		0		0		0	

器官別大分類		Shoulder				Elbow				Hip				Ankle				Total			
		Placebo		SI-613 30 mg		Placebo		SI-613 30 mg		Placebo		SI-613 30 mg		Placebo		SI-613 30 mg		Placebo		SI-613 30 mg	
		N=45		N=45		N=25		N=25		N=44		N=46		N=30		N=30		N=144		N=146	
基本語	Timing of onset	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
	Week 4 - Week 8	0		0		1	(4.0)	0		0		0		0		0		1	(0.7)	0	
	Post Week 8	0		0		0		0		0		0		0		0		0		0	
注射部位関節痛	Week 0 - Week 4	0		1	(2.2)	0		0		1	(2.3)	2	(4.3)	1	(3.3)	2	(6.7)	2	(1.4)	5	(3.4)
	Week 4 - Week 8	0		1	(2.2)	0		0		0		3	(6.5)	1	(3.3)	1	(3.4)	1	(0.7)	5	(3.4)
	Post Week 8	0		1	(2.2)	0		0		0		0		1	(3.4)	2	(6.9)	1	(0.7)	3	(2.1)
注射部位関節腫脹	Week 0 - Week 4	0		0		0		0		0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0		0		1	(3.4)	0		1	(0.7)
	Post Week 8	0		0		0		0		0		0		0		1	(3.4)	0		1	(0.7)
倦怠感	Week 0 - Week 4	0		0		0		0		0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		2	(4.3)	0		0		0		2	(1.4)
	Post Week 8	0		0		0		0		0		1	(2.2)	0		0		0		1	(0.7)
発熱	Week 0 - Week 4	0		0		0		0		0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		1	(2.2)	0		0		0		1	(0.7)
	Post Week 8	0		0		0		0		0		2	(4.4)	0		0		0		2	(1.4)
臨床検査	Week 0 - Week 4	0		0		1	(4.0)	1	(4.0)	1	(2.3)	0		0		0		2	(1.4)	1	(0.7)
	Week 4 - Week 8	0		0		0		0		0		0		1	(3.3)	0		1	(0.7)	0	
	Post Week 8	2	(4.5)	1	(2.2)	0		0		1	(2.4)	1	(2.2)	0		0		3	(2.1)	2	(1.4)
アラニンアミノトランスフェラーゼ増加	Week 0 - Week 4	0		0		0		0		0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0		0		0		0		0	
	Post Week 8	0		0		0		0		1	(2.4)	0		0		0		1	(0.7)	0	
アスパラギン酸アミノトランスフェラーゼ増加	Week 0 - Week 4	0		0		0		0		0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0		0		0		0		0	
	Post Week 8	0		0		0		0		1	(2.4)	0		0		0		1	(0.7)	0	
血圧低下	Week 0 - Week 4	0		0		1	(4.0)	0		0		0		0		0		1	(0.7)	0	
	Week 4 - Week 8	0		0		0		0		0		0		0		0		0		0	
	Post Week 8	0		0		0		0		0		0		0		0		0		0	
血圧上昇	Week 0 - Week 4	0		0		0		0		0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0		1	(3.3)	0		1	(0.7)	0	
	Post Week 8	0		0		0		0		0		0		0		0		0		0	
血中トリグリセリド増加	Week 0 - Week 4	0		0		0		1	(4.0)	1	(2.3)	0		0		0		1	(0.7)	1	(0.7)
	Week 4 - Week 8	0		0		0		0		0		0		0		0		0		0	
	Post Week 8	1	(2.3)	0		0		0		0		1	(2.2)	0		0		1	(0.7)	1	(0.7)
Ｃ－反応性蛋白増加	Week 0 - Week 4	0		0		0		0		0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0		0		0		0		0	

器官別大分類		Shoulder				Elbow				Hip				Ankle				Total			
		Placebo		SI-613 30 mg		Placebo		SI-613 30 mg		Placebo		SI-613 30 mg		Placebo		SI-613 30 mg		Placebo		SI-613 30 mg	
		N=45		N=45		N=25		N=25		N=44		N=46		N=30		N=30		N=144		N=146	
基本語	Timing of onset	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
	Post Week 8	1	(2.3)	0		0		0		0		0		0		0		1	(0.7)	0	
尿中ブドウ糖陽性	Week 0 - Week 4	0		0		0		1	(4.0)	0		0		0		0		0		1	(0.7)
	Week 4 - Week 8	0		0		0		0		0		0		0		0		0		0	
	Post Week 8	0		0		0		0		0		0		0		0		0		0	
尿中蛋白陽性	Week 0 - Week 4	0		0		0		0		0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0		0		0		0		0	
	Post Week 8	0		1	(2.2)	0		0		0		0		0		0		0		1	(0.7)
傷害、中毒および処置合併症	Week 0 - Week 4	0		1	(2.2)	0		1	(4.0)	0		0		1	(3.3)	1	(3.3)	1	(0.7)	3	(2.1)
	Week 4 - Week 8	1	(2.3)	1	(2.2)	0		0		1	(2.3)	0		0		0		2	(1.4)	1	(0.7)
	Post Week 8	0		0		0		2	(8.0)	0		2	(4.4)	1	(3.4)	0		1	(0.7)	4	(2.8)
動物咬傷	Week 0 - Week 4	0		0		0		0		0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0		0		0		0		0	
	Post Week 8	0		0		0		0		0		1	(2.2)	0		0		0		1	(0.7)
挫傷	Week 0 - Week 4	0		0		0		1	(4.0)	0		0		1	(3.3)	0		1	(0.7)	1	(0.7)
	Week 4 - Week 8	0		0		0		0		0		0		0		0		0		0	
	Post Week 8	0		0		0		0		0		1	(2.2)	1	(3.4)	0		1	(0.7)	1	(0.7)
靭帯捻挫	Week 0 - Week 4	0		0		0		0		0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		1	(2.3)	0		0		0		1	(0.7)	0	
	Post Week 8	0		0		0		0		0		0		0		0		0		0	
つち指	Week 0 - Week 4	0		0		0		0		0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0		0		0		0		0	
	Post Week 8	0		0		0		1	(4.0)	0		0		0		0		0		1	(0.7)
橈骨骨折	Week 0 - Week 4	0		0		0		0		0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0		0		0		0		0	
	Post Week 8	0		0		0		1	(4.0)	0		0		0		0		0		1	(0.7)
肋骨骨折	Week 0 - Week 4	0		0		0		0		0		0		0		0		0		0	
	Week 4 - Week 8	0		1	(2.2)	0		0		0		0		0		0		0		1	(0.7)
	Post Week 8	0		0		0		0		0		0		0		0		0		0	
硬膜下血腫	Week 0 - Week 4	0		0		0		0		0		0		0		0		0		0	
	Week 4 - Week 8	1	(2.3)	0		0		0		0		0		0		0		1	(0.7)	0	
	Post Week 8	0		0		0		0		0		0		0		0		0		0	

		Shoulder				Elbow				Hip				Ankle				Total			
		Placebo		SI-613 30 mg		Placebo		SI-613 30 mg		Placebo		SI-613 30 mg		Placebo		SI-613 30 mg		Placebo		SI-613 30 mg	
器官別大分類		N=45		N=45		N=25		N=25		N=44		N=46		N=30		N=30		N=144		N=146	
基本語	Timing of onset	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
熱傷	Week 0 - Week 4	0		1	(2.2)	0		0		0		0		0		1	(3.3)	0		2	(1.4)
	Week 4 - Week 8	0		0		0		0		0		0		0		0		0		0	
	Post Week 8	0		0		0		0		0		0		0		0		0		0	

Percentages are based on the number of subjects analyzed at each timepoint.
MedDRA/J Version 22.0
〔5.3.5.1-4 Tables 14.3.1-11 改編〕

表 2.7.4.7-35. 発現時期別の関節ごとの副作用：613/1033 試験

		Shoulder				Elbow				Hip				Ankle				Total			
		Placebo		SI-613 30 mg		Placebo		SI-613 30 mg		Placebo		SI-613 30 mg		Placebo		SI-613 30 mg		Placebo		SI-613 30 mg	
器官別大分類		N=45		N=45		N=25		N=25		N=44		N=46		N=30		N=30		N=144		N=146	
基本語	Timing of onset	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
評価例数	Week 0 - Week 4	45		45		25		25		44		46		30		30		144		146	
	Week 4 - Week 8	44		45		25		25		43		46		30		29		142		145	
	Post Week 8	44		45		25		25		42		45		29		29		140		144	
全ての副作用	Week 0 - Week 4	0		2	(4.4)	0		0		1	(2.3)	0		0		0		1	(0.7)	2	(1.4)
	Week 4 - Week 8	0		0		0		0		0		3	(6.5)	0		1	(3.4)	0		4	(2.8)
	Post Week 8	0		0		0		0		0		1	(2.2)	0		1	(3.4)	0		2	(1.4)
神経系障害	Week 0 - Week 4	0		0		0		0		0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		1	(2.2)	0		0		0		1	(0.7)
	Post Week 8	0		0		0		0		0		0		0		0		0		0	
振戦	Week 0 - Week 4	0		0		0		0		0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		1	(2.2)	0		0		0		1	(0.7)
	Post Week 8	0		0		0		0		0		0		0		0		0		0	
心臓障害	Week 0 - Week 4	0		1	(2.2)	0		0		0		0		0		0		0		1	(0.7)
	Week 4 - Week 8	0		0		0		0		0		0		0		0		0		0	
	Post Week 8	0		0		0		0		0		0		0		0		0		0	
動悸	Week 0 - Week 4	0		1	(2.2)	0		0		0		0		0		0		0		1	(0.7)
	Week 4 - Week 8	0		0		0		0		0		0		0		0		0		0	
	Post Week 8	0		0		0		0		0		0		0		0		0		0	
呼吸器、胸郭および縦隔障害	Week 0 - Week 4	0		0		0		0		0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		1	(2.2)	0		0		0		1	(0.7)

器官別大分類		Shoulder				Elbow				Hip				Ankle				Total			
		Placebo		SI-613 30 mg		Placebo		SI-613 30 mg		Placebo		SI-613 30 mg		Placebo		SI-613 30 mg		Placebo		SI-613 30 mg	
		N=45		N=45		N=25		N=25		N=44		N=46		N=30		N=30		N=144		N=146	
基本語	Timing of onset	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
	Post Week 8	0		0		0		0		0		0		0		0		0		0	
呼吸困難	Week 0 - Week 4	0		0		0		0		0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		1	(2.2)	0		0		0		1	(0.7)
	Post Week 8	0		0		0		0		0		0		0		0		0		0	
胃腸障害	Week 0 - Week 4	0		0		0		0		0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		1	(2.2)	0		0		0		1	(0.7)
	Post Week 8	0		0		0		0		0		0		0		0		0		0	
悪心	Week 0 - Week 4	0		0		0		0		0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		1	(2.2)	0		0		0		1	(0.7)
	Post Week 8	0		0		0		0		0		0		0		0		0		0	
筋骨格系および結合組織障害	Week 0 - Week 4	0		1	(2.2)	0		0		0		0		0		0		0		1	(0.7)
	Week 4 - Week 8	0		0		0		0		0		1	(2.2)	0		0		0		1	(0.7)
	Post Week 8	0		0		0		0		0		0		0		0		0		0	
筋骨格痛	Week 0 - Week 4	0		1	(2.2)	0		0		0		0		0		0		0		1	(0.7)
	Week 4 - Week 8	0		0		0		0		0		0		0		0		0		0	
	Post Week 8	0		0		0		0		0		0		0		0		0		0	
筋肉痛	Week 0 - Week 4	0		0		0		0		0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		1	(2.2)	0		0		0		1	(0.7)
	Post Week 8	0		0		0		0		0		0		0		0		0		0	
一般・全身障害および投与部位の状態	Week 0 - Week 4	0		0		0		0		1	(2.3)	0		0		0		1	(0.7)	0	
	Week 4 - Week 8	0		0		0		0		0		2	(4.3)	0		1	(3.4)	0		3	(2.1)
	Post Week 8	0		0		0		0		0		1	(2.2)	0		1	(3.4)	0		2	(1.4)
注射部位関節痛	Week 0 - Week 4	0		0		0		0		1	(2.3)	0		0		0		1	(0.7)	0	
	Week 4 - Week 8	0		0		0		0		0		0		0		0		0		0	
	Post Week 8	0		0		0		0		0		0		0		0		0		0	
注射部位関節腫脹	Week 0 - Week 4	0		0		0		0		0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0		0		1	(3.4)	0		1	(0.7)
	Post Week 8	0		0		0		0		0		0		0		1	(3.4)	0		1	(0.7)
倦怠感	Week 0 - Week 4	0		0		0		0		0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		2	(4.3)	0		0		0		2	(1.4)
	Post Week 8	0		0		0		0		0		1	(2.2)	0		0		0		1	(0.7)

器官別大分類		Shoulder				Elbow				Hip				Ankle				Total			
		Placebo		SI-613 30 mg		Placebo		SI-613 30 mg		Placebo		SI-613 30 mg		Placebo		SI-613 30 mg		Placebo		SI-613 30 mg	
		N=45		N=45		N=25		N=25		N=44		N=46		N=30		N=30		N=144		N=146	
基本語	Timing of onset	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
発熱	Week 0 - Week 4	0		0		0		0		0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		1	(2.2)	0		0		0		1	(0.7)
	Post Week 8	0		0		0		0		0		1	(2.2)	0		0		0		1	(0.7)

Percentages are based on the number of subjects analyzed at each timepoint.
MedDRA/J Version 22.0
〔5.3.5.1-4 Table 14.3.1-12 改編〕

表 2.7.4.7-36. 発現時期別の関節ごとの有害事象：613/1032 試験

器官別大分類		Knee N=126		Shoulder N=15		Elbow N=8		Hip N=9		Ankle N=8		Total N=166	
基本語	Timing of onset	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
評価例数	Week 0 - Week 4	126		15		8		9		8		166	
	Week 4 - Week 8	125		15		8		9		8		165	
	Week 8 - Week 12	123		15		8		9		8		163	
	Week 12 - Week 24	123		14		8		7		8		160	
	Post Week 24	121		14		8		7		8		158	
全ての有害事象	Week 0 - Week 4	20	(15.9)	3	(20.0)	2	(25.0)	3	(33.3)	2	(25.0)	30	(18.1)
	Week 4 - Week 8	23	(18.4)	3	(20.0)	1	(12.5)	3	(33.3)	0		30	(18.2)
	Week 8 - Week 12	17	(13.8)	4	(26.7)	1	(12.5)	2	(22.2)	0		24	(14.7)
	Week 12 - Week 24	46	(37.4)	6	(42.9)	4	(50.0)	5	(71.4)	4	(50.0)	65	(40.6)
	Post Week 24	77	(63.6)	8	(57.1)	4	(50.0)	4	(57.1)	4	(50.0)	97	(61.4)
感染症および寄生虫症	Week 0 - Week 4	5	(4.0)	0		1	(12.5)	0		0		6	(3.6)
	Week 4 - Week 8	5	(4.0)	0		1	(12.5)	1	(11.1)	0		7	(4.2)
	Week 8 - Week 12	3	(2.4)	1	(6.7)	0		0		0		4	(2.5)
	Week 12 - Week 24	16	(13.0)	0		0		1	(14.3)	2	(25.0)	19	(11.9)
	Post Week 24	32	(26.4)	2	(14.3)	2	(25.0)	4	(57.1)	1	(12.5)	41	(25.9)
虫垂炎	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	2	(1.6)	0		0		0		0		2	(1.2)
	Week 8 - Week 12	1	(0.8)	0		0		0		0		1	(0.6)
	Week 12 - Week 24	0		0		0		0		0		0	
	Post Week 24	0		0		0		0		0		0	
気管支炎	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	1	(0.8)	0		0		0		0		1	(0.6)
	Post Week 24	0		0		0		0		0		0	
カンピロバクター感染	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Post Week 24	1	(0.8)	0		0		0		0		1	(0.6)
蜂巣炎	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Post Week 24	1	(0.8)	1	(7.1)	0		0		0		2	(1.3)
膀胱炎	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	3	(2.4)	0		0		0		0		3	(1.9)
	Post Week 24	0		0		0		0		0		0	
胃腸炎	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Post Week 24	1	(0.8)	0		1	(12.5)	0		0		2	(1.3)
歯肉炎	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Post Week 24	3	(2.5)	0		0		0		0		3	(1.9)
帯状疱疹	Week 0 - Week 4	1	(0.8)	0		0		0		0		1	(0.6)
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	0		0		0		0		0		0	

器官別大分類		Knee N=126		Shoulder N=15		Elbow N=8		Hip N=9		Ankle N=8		Total N=166	
基本語	Timing of onset	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
	Week 12 - Week 24	1	(0.8)	0		0		0		0		1	(0.6)
	Post Week 24	1	(0.8)	0		0		0		0		1	(0.6)
麦粒腫	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Post Week 24	1	(0.8)	0		0		0		0		1	(0.6)
咬傷感染	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	1	(0.8)	0		0		0		0		1	(0.6)
	Week 12 - Week 24	0		0		0		0		0		0	
	Post Week 24	0		0		0		0		0		0	
インフルエンザ	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Post Week 24	4	(3.3)	0		1	(12.5)	1	(14.3)	0		6	(3.8)
上咽頭炎	Week 0 - Week 4	3	(2.4)	0		1	(12.5)	0		0		4	(2.4)
	Week 4 - Week 8	2	(1.6)	0		0		1	(11.1)	0		3	(1.8)
	Week 8 - Week 12	1	(0.8)	1	(6.7)	0		0		0		2	(1.2)
	Week 12 - Week 24	9	(7.3)	0		0		1	(14.3)	2	(25.0)	12	(7.5)
	Post Week 24	19	(15.7)	2	(14.3)	1	(12.5)	3	(42.9)	0		25	(15.8)
中耳炎	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Post Week 24	1	(0.8)	0		0		0		0		1	(0.6)
爪囲炎	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Post Week 24	1	(0.8)	0		0		0		0		1	(0.6)
歯周炎	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	1	(0.8)	0		0		0		0		1	(0.6)
	Post Week 24	0		0		0		0		0		0	
咽頭炎	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	0		0		1	(12.5)	0		0		1	(0.6)
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	2	(1.6)	0		0		0		0		2	(1.3)
	Post Week 24	2	(1.7)	0		0		0		1	(12.5)	3	(1.9)
白癬感染	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	1	(0.8)	0		0		0		0		1	(0.6)
	Post Week 24	0		0		0		0		0		0	
足部白癬	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	1	(0.8)	0		0		0		0		1	(0.6)
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Post Week 24	0		0		0		0		0		0	
上気道感染	Week 0 - Week 4	1	(0.8)	0		0		0		0		1	(0.6)
	Week 4 - Week 8	0		0		0		0		0		0	

器官別大分類		Knee N=126		Shoulder N=15		Elbow N=8		Hip N=9		Ankle N=8		Total N=166	
基本語	Timing of onset	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	1	(0.8)	0		0		0		0		1	(0.6)
	Post Week 24	2	(1.7)	0		0		0		0		2	(1.3)
外陰部炎	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Post Week 24	1	(0.8)	0		0		0		0		1	(0.6)
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）	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	2	(1.6)	0		0		0		0		2	(1.2)
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	1	(0.8)	0		0		0		0		1	(0.6)
	Post Week 24	0		1	(7.1)	0		0		0		1	(0.6)
乳癌	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	1	(0.8)	0		0		0		0		1	(0.6)
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Post Week 24	0		0		0		0		0		0	
類腱腫	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Post Week 24	0		1	(7.1)	0		0		0		1	(0.6)
脂肪腫	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	1	(0.8)	0		0		0		0		1	(0.6)
	Post Week 24	0		0		0		0		0		0	
皮膚乳頭腫	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	1	(0.8)	0		0		0		0		1	(0.6)
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Post Week 24	0		0		0		0		0		0	
血液およびリンパ系障害	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	1	(0.8)	0		0		0		0		1	(0.6)
	Post Week 24	0		0		0		0		0		0	
貧血	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	1	(0.8)	0		0		0		0		1	(0.6)
	Post Week 24	0		0		0		0		0		0	
免疫系障害	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Post Week 24	1	(0.8)	0		0		0		0		1	(0.6)
季節性アレルギー	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Post Week 24	1	(0.8)	0		0		0		0		1	(0.6)
代謝および栄養障害	Week 0 - Week 4	0		0		0		0		0		0	

器官別大分類		Knee N=126		Shoulder N=15		Elbow N=8		Hip N=9		Ankle N=8		Total N=166	
基本語	Timing of onset	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Post Week 24	4	(3.3)	0		0		0		0		4	(2.5)
糖尿病	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Post Week 24	1	(0.8)	0		0		0		0		1	(0.6)
高コレステロール血症	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Post Week 24	1	(0.8)	0		0		0		0		1	(0.6)
高カリウム血症	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Post Week 24	1	(0.8)	0		0		0		0		1	(0.6)
ビタミンD欠乏	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Post Week 24	2	(1.7)	0		0		0		0		2	(1.3)
精神障害	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Post Week 24	0		0		0		1	(14.3)	0		1	(0.6)
不眠症	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Post Week 24	0		0		0		1	(14.3)	0		1	(0.6)
神経系障害	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		1	(11.1)	0		1	(0.6)
	Week 8 - Week 12	2	(1.6)	0		0		0		0		2	(1.2)
	Week 12 - Week 24	2	(1.6)	1	(7.1)	0		1	(14.3)	0		4	(2.5)
	Post Week 24	11	(9.1)	0		0		0		2	(25.0)	13	(8.2)
脳梗塞	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Post Week 24	1	(0.8)	0		0		0		0		1	(0.6)
頚腕症候群	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Post Week 24	1	(0.8)	0		0		0		0		1	(0.6)
浮動性めまい	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	1	(0.8)	0		0		0		0		1	(0.6)
	Week 12 - Week 24	0		0		0		1	(14.3)	0		1	(0.6)
	Post Week 24	2	(1.7)	0		0		0		1	(12.5)	3	(1.9)

器官別大分類		Knee N=126		Shoulder N=15		Elbow N=8		Hip N=9		Ankle N=8		Total N=166	
基本語	Timing of onset	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
頭痛	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		1	(11.1)	0		1	(0.6)
	Week 8 - Week 12	1	(0.8)	0		0		0		0		1	(0.6)
	Week 12 - Week 24	0		1	(7.1)	0		0		0		1	(0.6)
	Post Week 24	1	(0.8)	0		0		0		1	(12.5)	2	(1.3)
感覚異常性大腿神経痛	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	1	(0.8)	0		0		0		0		1	(0.6)
	Post Week 24	0		0		0		0		0		0	
ミオクローヌス	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Post Week 24	1	(0.8)	0		0		0		0		1	(0.6)
神経痛	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Post Week 24	1	(0.8)	0		0		0		0		1	(0.6)
錯感覚	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	1	(0.8)	0		0		0		0		1	(0.6)
	Post Week 24	0		0		0		0		0		0	
坐骨神経痛	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Post Week 24	2	(1.7)	0		0		0		0		2	(1.3)
鎮静	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Post Week 24	1	(0.8)	0		0		0		0		1	(0.6)
傾眠	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Post Week 24	1	(0.8)	0		0		0		0		1	(0.6)
眼障害	Week 0 - Week 4	1	(0.8)	0		0		0		0		1	(0.6)
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Post Week 24	9	(7.4)	2	(14.3)	0		0		0		11	(7.0)
眼精疲労	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Post Week 24	0		1	(7.1)	0		0		0		1	(0.6)
眼瞼炎	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	

器官別大分類		Knee N=126		Shoulder N=15		Elbow N=8		Hip N=9		Ankle N=8		Total N=166	
基本語	Timing of onset	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
	Post Week 24	2	(1.7)	0		0		0		0		2	(1.3)
霰粒腫	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Post Week 24	1	(0.8)	0		0		0		0		1	(0.6)
アレルギー性結膜炎	Week 0 - Week 4	1	(0.8)	0		0		0		0		1	(0.6)
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Post Week 24	1	(0.8)	0		0		0		0		1	(0.6)
後天性涙道狭窄	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Post Week 24	1	(0.8)	0		0		0		0		1	(0.6)
ドライアイ	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Post Week 24	3	(2.5)	0		0		0		0		3	(1.9)
高眼圧症	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Post Week 24	1	(0.8)	0		0		0		0		1	(0.6)
網膜出血	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Post Week 24	0		1	(7.1)	0		0		0		1	(0.6)
耳および迷路障害	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	1	(0.8)	0		0		0		0		1	(0.6)
	Post Week 24	2	(1.7)	1	(7.1)	1	(12.5)	0		0		4	(2.5)
耳垢栓塞	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Post Week 24	0		0		1	(12.5)	0		0		1	(0.6)
突発性難聴	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Post Week 24	1	(0.8)	0		0		0		0		1	(0.6)
耳鳴	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Post Week 24	0		1	(7.1)	0		0		0		1	(0.6)
回転性めまい	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	0		0		0		0		0		0	

器官別大分類		Knee N=126		Shoulder N=15		Elbow N=8		Hip N=9		Ankle N=8		Total N=166	
基本語	Timing of onset	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
	Week 12 - Week 24	1	(0.8)	0		0		0		0		1	(0.6)
	Post Week 24	1	(0.8)	0		0		0		0		1	(0.6)
心臓障害	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		1	(11.1)	0		1	(0.6)
	Week 8 - Week 12	0		0		0		1	(11.1)	0		1	(0.6)
	Week 12 - Week 24	1	(0.8)	0		0		0		0		1	(0.6)
	Post Week 24	3	(2.5)	0		0		0		0		3	(1.9)
急性心筋梗塞	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Post Week 24	1	(0.8)	0		0		0		0		1	(0.6)
不安定狭心症	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Post Week 24	1	(0.8)	0		0		0		0		1	(0.6)
心房細動	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	1	(0.8)	0		0		0		0		1	(0.6)
	Post Week 24	0		0		0		0		0		0	
動悸	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		1	(11.1)	0		1	(0.6)
	Week 8 - Week 12	0		0		0		1	(11.1)	0		1	(0.6)
	Week 12 - Week 24	0		0		0		0		0		0	
	Post Week 24	1	(0.8)	0		0		0		0		1	(0.6)
血管障害	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	1	(0.8)	0		0		0		0		1	(0.6)
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Post Week 24	1	(0.8)	0		0		0		0		1	(0.6)
高血圧	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	1	(0.8)	0		0		0		0		1	(0.6)
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Post Week 24	1	(0.8)	0		0		0		0		1	(0.6)
呼吸器、胸郭および縦隔障害	Week 0 - Week 4	2	(1.6)	0		0		0		0		2	(1.2)
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	1	(0.8)	0		0		0		0		1	(0.6)
	Post Week 24	3	(2.5)	1	(7.1)	1	(12.5)	0		0		5	(3.2)
喘息	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Post Week 24	0		0		1	(12.5)	0		0		1	(0.6)
慢性気管支炎	Week 0 - Week 4	1	(0.8)	0		0		0		0		1	(0.6)
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Post Week 24	1	(0.8)	0		0		0		0		1	(0.6)
鼻出血	Week 0 - Week 4	1	(0.8)	0		0		0		0		1	(0.6)
	Week 4 - Week 8	0		0		0		0		0		0	

器官別大分類		Knee N=126		Shoulder N=15		Elbow N=8		Hip N=9		Ankle N=8		Total N=166	
基本語	Timing of onset	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Post Week 24	0		1	(7.1)	0		0		0		1	(0.6)
鼻痂皮	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Post Week 24	1	(0.8)	0		0		0		0		1	(0.6)
口腔咽頭痛	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	1	(0.8)	0		0		0		0		1	(0.6)
	Post Week 24	1	(0.8)	0		0		0		0		1	(0.6)
胃腸障害	Week 0 - Week 4	2	(1.6)	1	(6.7)	0		1	(11.1)	0		4	(2.4)
	Week 4 - Week 8	3	(2.4)	0		0		0		0		3	(1.8)
	Week 8 - Week 12	1	(0.8)	0		0		0		0		1	(0.6)
	Week 12 - Week 24	4	(3.3)	3	(21.4)	2	(25.0)	1	(14.3)	0		10	(6.3)
	Post Week 24	13	(10.7)	0		1	(12.5)	1	(14.3)	0		15	(9.5)
腹部膨満	Week 0 - Week 4	1	(0.8)	0		0		0		0		1	(0.6)
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Post Week 24	3	(2.5)	0		0		0		0		3	(1.9)
腹痛	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Post Week 24	0		0		0		1	(14.3)	0		1	(0.6)
上腹部痛	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	1	(0.8)	0		0		0		0		1	(0.6)
	Week 12 - Week 24	0		0		1	(12.5)	0		0		1	(0.6)
	Post Week 24	0		0		0		0		0		0	
肛門ポリープ	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Post Week 24	1	(0.8)	0		0		0		0		1	(0.6)
慢性胃炎	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	1	(0.8)	0		0		0		0		1	(0.6)
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Post Week 24	0		0		0		0		0		0	
便秘	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		1	(7.1)	0		0		0		1	(0.6)
	Post Week 24	1	(0.8)	0		0		0		0		1	(0.6)
齲歯	Week 0 - Week 4	1	(0.8)	0		0		1	(11.1)	0		2	(1.2)
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	1	(0.8)	0		0		0		0		1	(0.6)
	Post Week 24	0		0		0		0		0		0	
食中毒	Week 0 - Week 4	0		0		0		0		0		0	

器官別大分類		Knee N=126		Shoulder N=15		Elbow N=8		Hip N=9		Ankle N=8		Total N=166	
基本語	Timing of onset	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		1	(7.1)	0		0		0		1	(0.6)
	Post Week 24	0		0		0		0		0		0	
胃ポリープ	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	1	(0.8)	0		0		0		0		1	(0.6)
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Post Week 24	0		0		0		0		0		0	
胃潰瘍	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	1	(0.8)	0		0		0		0		1	(0.6)
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Post Week 24	0		0		0		0		0		0	
胃炎	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Post Week 24	1	(0.8)	0		0		0		0		1	(0.6)
びらん性胃炎	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Post Week 24	1	(0.8)	0		0		0		0		1	(0.6)
胃食道逆流性疾患	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	1	(0.8)	0		0		0		0		1	(0.6)
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	1	(0.8)	0		0		0		0		1	(0.6)
	Post Week 24	3	(2.5)	0		0		0		0		3	(1.9)
歯肉肥厚	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Post Week 24	1	(0.8)	0		0		0		0		1	(0.6)
歯肉痛	Week 0 - Week 4	0		1	(6.7)	0		0		0		1	(0.6)
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Post Week 24	0		0		0		0		0		0	
鼠径ヘルニア	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Post Week 24	0		0		1	(12.5)	0		0		1	(0.6)
過敏性腸症候群	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		1	(12.5)	0		0		1	(0.6)
	Post Week 24	0		0		0		0		0		0	
大腸ポリープ	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	1	(0.8)	0		0		0		0		1	(0.6)
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Post Week 24	1	(0.8)	0		0		0		0		1	(0.6)

器官別大分類		Knee N=126		Shoulder N=15		Elbow N=8		Hip N=9		Ankle N=8		Total N=166	
基本語	Timing of onset	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
悪心	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	1	(0.8)	0		0		1	(14.3)	0		2	(1.3)
	Post Week 24	1	(0.8)	0		0		0		0		1	(0.6)
口内炎	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		1	(7.1)	0		0		0		1	(0.6)
	Post Week 24	2	(1.7)	0		0		0		0		2	(1.3)
嘔吐	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	1	(0.8)	0		0		0		0		1	(0.6)
	Post Week 24	0		0		0		0		0		0	
肝胆道系障害	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	2	(1.6)	0		0		0		0		2	(1.3)
	Post Week 24	1	(0.8)	0		1	(12.5)	0		0		2	(1.3)
肝機能異常	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	2	(1.6)	0		0		0		0		2	(1.3)
	Post Week 24	1	(0.8)	0		1	(12.5)	0		0		2	(1.3)
皮膚および皮下組織障害	Week 0 - Week 4	1	(0.8)	0		0		0		0		1	(0.6)
	Week 4 - Week 8	4	(3.2)	1	(6.7)	0		0		0		5	(3.0)
	Week 8 - Week 12	1	(0.8)	1	(6.7)	0		0		0		2	(1.2)
	Week 12 - Week 24	2	(1.6)	0		0		2	(28.6)	0		4	(2.5)
	Post Week 24	7	(5.8)	5	(35.7)	0		0		0		12	(7.6)
ざ瘡	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Post Week 24	1	(0.8)	0		0		0		0		1	(0.6)
皮膚嚢腫	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	1	(0.8)	0		0		0		0		1	(0.6)
	Post Week 24	0		0		0		0		0		0	
皮膚炎	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	1	(0.8)	1	(6.7)	0		0		0		2	(1.2)
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Post Week 24	0		0		0		0		0		0	
接触皮膚炎	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Post Week 24	1	(0.8)	0		0		0		0		1	(0.6)
薬疹	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	

器官別大分類		Knee N=126		Shoulder N=15		Elbow N=8		Hip N=9		Ankle N=8		Total N=166	
基本語	Timing of onset	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
	Post Week 24	1	(0.8)	0		0		0		0		1	(0.6)
皮膚乾燥	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Post Week 24	0		1	(7.1)	0		0		0		1	(0.6)
湿疹	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	2	(1.6)	0		0		0		0		2	(1.2)
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	1	(0.8)	0		0		2	(28.6)	0		3	(1.9)
	Post Week 24	3	(2.5)	2	(14.3)	0		0		0		5	(3.2)
紅斑	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	1	(0.8)	0		0		0		0		1	(0.6)
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Post Week 24	0		1	(7.1)	0		0		0		1	(0.6)
嵌入爪	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Post Week 24	1	(0.8)	1	(7.1)	0		0		0		2	(1.3)
汗疹	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	0		1	(6.7)	0		0		0		1	(0.6)
	Week 12 - Week 24	0		0		0		0		0		0	
	Post Week 24	0		0		0		0		0		0	
老人性そう痒症	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Post Week 24	0		1	(7.1)	0		0		0		1	(0.6)
蕁麻疹	Week 0 - Week 4	1	(0.8)	0		0		0		0		1	(0.6)
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	1	(0.8)	0		0		0		0		1	(0.6)
	Week 12 - Week 24	0		0		0		0		0		0	
	Post Week 24	0		0		0		0		0		0	
筋骨格系および結合組織障害	Week 0 - Week 4	5	(4.0)	1	(6.7)	0		0		0		6	(3.6)
	Week 4 - Week 8	3	(2.4)	0		0		1	(11.1)	0		4	(2.4)
	Week 8 - Week 12	5	(4.1)	0		0		1	(11.1)	0		6	(3.7)
	Week 12 - Week 24	10	(8.1)	1	(7.1)	2	(25.0)	0		2	(25.0)	15	(9.4)
	Post Week 24	24	(19.8)	4	(28.6)	2	(25.0)	2	(28.6)	1	(12.5)	33	(20.9)
関節痛	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	1	(0.8)	0		0		0		0		1	(0.6)
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	1	(0.8)	0		0		0		0		1	(0.6)
	Post Week 24	1	(0.8)	1	(7.1)	0		0		0		2	(1.3)
関節炎	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	1	(0.8)	0		0		0		0		1	(0.6)
	Post Week 24	1	(0.8)	1	(7.1)	0		0		0		2	(1.3)
関節障害	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	0		0		0		0		0		0	

器官別大分類		Knee N=126		Shoulder N=15		Elbow N=8		Hip N=9		Ankle N=8		Total N=166	
基本語	Timing of onset	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
	Week 12 - Week 24	0		1	(7.1)	0		0		0		1	(0.6)
	Post Week 24	0		0		0		0		0		0	
背部痛	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		1	(11.1)	0		1	(0.6)
	Week 8 - Week 12	0		0		0		1	(11.1)	0		1	(0.6)
	Week 12 - Week 24	1	(0.8)	0		0		0		0		1	(0.6)
	Post Week 24	5	(4.1)	0		0		0		0		5	(3.2)
滑液包炎	Week 0 - Week 4	1	(0.8)	0		0		0		0		1	(0.6)
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Post Week 24	0		0		0		0		0		0	
ピロリン酸カルシウム	Week 0 - Week 4	0		0		0		0		0		0	
結晶性軟骨石灰化症	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Post Week 24	1	(0.8)	0		0		0		0		1	(0.6)
尾骨痛	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	1	(0.8)	0		0		0		0		1	(0.6)
	Post Week 24	0		0		0		0		0		0	
椎間板障害	Week 0 - Week 4	1	(0.8)	0		0		0		0		1	(0.6)
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		1	(12.5)	0		0		1	(0.6)
	Post Week 24	0		0		0		0		0		0	
椎間板突出	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	1	(0.8)	0		0		0		0		1	(0.6)
	Post Week 24	0		0		0		0		0		0	
関節ロック	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Post Week 24	1	(0.8)	0		0		0		0		1	(0.6)
筋痙縮	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	1	(0.8)	0		0		0		0		1	(0.6)
	Post Week 24	3	(2.5)	0		0		0		0		3	(1.9)
筋骨格痛	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	1	(0.8)	0		0		0		0		1	(0.6)
	Post Week 24	0		0		0		0		0		0	
筋骨格硬直	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	1	(0.8)	0		1	(12.5)	0		0		2	(1.3)
	Post Week 24	1	(0.8)	0		1	(12.5)	0		0		2	(1.3)
筋筋膜炎	Week 0 - Week 4	0		1	(6.7)	0		0		0		1	(0.6)
	Week 4 - Week 8	0		0		0		0		0		0	

器官別大分類		Knee N=126		Shoulder N=15		Elbow N=8		Hip N=9		Ankle N=8		Total N=166	
基本語	Timing of onset	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	1	(0.8)	0		0		0		0		1	(0.6)
	Post Week 24	0		2	(14.3)	0		0		0		2	(1.3)
結節性変形性関節症	Week 0 - Week 4	1	(0.8)	0		0		0		0		1	(0.6)
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Post Week 24	0		0		0		1	(14.3)	0		1	(0.6)
変形性関節症	Week 0 - Week 4	1	(0.8)	0		0		0		0		1	(0.6)
	Week 4 - Week 8	1	(0.8)	0		0		0		0		1	(0.6)
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	2	(1.6)	0		0		0		1	(12.5)	3	(1.9)
	Post Week 24	7	(5.8)	0		0		0		1	(12.5)	8	(5.1)
骨壊死	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Post Week 24	1	(0.8)	0		0		0		0		1	(0.6)
四肢痛	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	1	(0.8)	0		0		0		0		1	(0.6)
	Week 8 - Week 12	1	(0.8)	0		0		0		0		1	(0.6)
	Week 12 - Week 24	0		0		0		0		0		0	
	Post Week 24	1	(0.8)	0		0		0		0		1	(0.6)
関節周囲炎	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	2	(1.6)	0		0		0		0		2	(1.2)
	Week 12 - Week 24	0		0		0		0		0		0	
	Post Week 24	1	(0.8)	0		0		1	(14.3)	0		2	(1.3)
関節リウマチ	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Post Week 24	1	(0.8)	0		0		0		0		1	(0.6)
変形性脊椎症	Week 0 - Week 4	1	(0.8)	0		0		0		0		1	(0.6)
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		1	(12.5)	1	(0.6)
	Post Week 24	3	(2.5)	0		0		0		0		3	(1.9)
滑液嚢腫	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Post Week 24	0		0		1	(12.5)	0		0		1	(0.6)
腱鞘炎	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	1	(0.8)	0		0		0		0		1	(0.6)
	Post Week 24	0		0		0		0		0		0	
狭窄性腱鞘炎	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	1	(0.8)	0		0		0		0		1	(0.6)
	Week 12 - Week 24	0		0		0		0		0		0	
	Post Week 24	0		0		0		0		0		0	
弾発指	Week 0 - Week 4	0		0		0		0		0		0	

器官別大分類		Knee N=126		Shoulder N=15		Elbow N=8		Hip N=9		Ankle N=8		Total N=166	
基本語	Timing of onset	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	1	(0.8)	0		0		0		0		1	(0.6)
	Week 12 - Week 24	0		0		0		0		0		0	
	Post Week 24	0		0		0		0		0		0	
腎および尿路障害	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Post Week 24	2	(1.7)	1	(7.1)	0		0		0		3	(1.9)
緊張性膀胱	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Post Week 24	2	(1.7)	0		0		0		0		2	(1.3)
尿管結石症	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Post Week 24	0		1	(7.1)	0		0		0		1	(0.6)
一般・全身障害および投与部位の状態	Week 0 - Week 4	3	(2.4)	1	(6.7)	2	(25.0)	0		1	(12.5)	7	(4.2)
	Week 4 - Week 8	4	(3.2)	1	(6.7)	1	(12.5)	2	(22.2)	0		8	(4.8)
	Week 8 - Week 12	3	(2.4)	2	(13.3)	1	(12.5)	1	(11.1)	0		7	(4.3)
	Week 12 - Week 24	5	(4.1)	2	(14.3)	1	(12.5)	2	(28.6)	0		10	(6.3)
	Post Week 24	9	(7.4)	1	(7.1)	2	(25.0)	0		0		12	(7.6)
腋窩痛	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Post Week 24	0		1	(7.1)	0		0		0		1	(0.6)
胸部不快感	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		1	(11.1)	0		1	(0.6)
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Post Week 24	0		0		0		0		0		0	
炎症	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	1	(0.8)	0		0		0		0		1	(0.6)
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Post Week 24	1	(0.8)	0		0		0		0		1	(0.6)
注射部位損傷	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Post Week 24	1	(0.8)	0		0		0		0		1	(0.6)
注射部位関節滲出液	Week 0 - Week 4	1	(0.8)	0		0		0		0		1	(0.6)
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Post Week 24	0		0		0		0		0		0	
注射部位関節痛	Week 0 - Week 4	1	(0.8)	1	(6.7)	2	(25.0)	0		1	(12.5)	5	(3.0)
	Week 4 - Week 8	2	(1.6)	1	(6.7)	1	(12.5)	0		0		4	(2.4)
	Week 8 - Week 12	2	(1.6)	1	(6.7)	1	(12.5)	0		0		4	(2.5)
	Week 12 - Week 24	4	(3.3)	2	(14.3)	1	(12.5)	0		0		7	(4.4)
	Post Week 24	7	(5.8)	1	(7.1)	2	(25.0)	0		0		10	(6.3)

器官別大分類		Knee N=126		Shoulder N=15		Elbow N=8		Hip N=9		Ankle N=8		Total N=166	
基本語	Timing of onset	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
注射部位関節腫脹	Week 0 - Week 4	1	(0.8)	0		0		0		0		1	(0.6)
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Post Week 24	0		0		0		0		0		0	
注射部位浮腫	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Post Week 24	1	(0.8)	0		0		0		0		1	(0.6)
倦怠感	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	1	(0.8)	0		0		0		0		1	(0.6)
	Week 12 - Week 24	1	(0.8)	0		0		0		0		1	(0.6)
	Post Week 24	0		0		0		0		0		0	
浮腫	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	1	(0.8)	0		0		0		0		1	(0.6)
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Post Week 24	0		0		0		0		0		0	
発熱	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		2	(22.2)	0		2	(1.2)
	Week 8 - Week 12	0		1	(6.7)	0		1	(11.1)	0		2	(1.2)
	Week 12 - Week 24	0		0		0		2	(28.6)	0		2	(1.3)
	Post Week 24	0		0		0		0		0		0	
臨床検査	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	3	(2.4)	0		0		0		0		3	(1.8)
	Week 12 - Week 24	2	(1.6)	0		0		0		0		2	(1.3)
	Post Week 24	6	(5.0)	0		0		0		1	(12.5)	7	(4.4)
血中アルカリホス	Week 0 - Week 4	0		0		0		0		0		0	
ファターゼ増加	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Post Week 24	1	(0.8)	0		0		0		1	(12.5)	2	(1.3)
血中クレアチンホス	Week 0 - Week 4	0		0		0		0		0		0	
ホキナーゼ増加	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	1	(0.8)	0		0		0		0		1	(0.6)
	Week 12 - Week 24	0		0		0		0		0		0	
	Post Week 24	0		0		0		0		0		0	
血中クレアチニン増加	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	1	(0.8)	0		0		0		0		1	(0.6)
	Week 12 - Week 24	0		0		0		0		0		0	
	Post Week 24	0		0		0		0		0		0	
血圧上昇	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	1	(0.8)	0		0		0		0		1	(0.6)
	Week 12 - Week 24	1	(0.8)	0		0		0		0		1	(0.6)
	Post Week 24	4	(3.3)	0		0		0		0		4	(2.5)
Ｃ－反応性蛋白増加	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	1	(0.8)	0		0		0		0		1	(0.6)
	Week 12 - Week 24	0		0		0		0		0		0	

器官別大分類		Knee N=126		Shoulder N=15		Elbow N=8		Hip N=9		Ankle N=8		Total N=166	
基本語	Timing of onset	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
	Post Week 24	0		0		0		0		0		0	
γ－グルタミルトランスフェラーゼ増加	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Post Week 24	1	(0.8)	0		0		0		0		1	(0.6)
グリコヘモグロビン増加	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Post Week 24	0		0		0		0		1	(12.5)	1	(0.6)
眼圧上昇	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	1	(0.8)	0		0		0		0		1	(0.6)
	Post Week 24	0		0		0		0		0		0	
肝機能検査異常	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	1	(0.8)	0		0		0		0		1	(0.6)
	Week 12 - Week 24	1	(0.8)	0		0		0		0		1	(0.6)
	Post Week 24	0		0		0		0		0		0	
尿中蛋白陽性	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	1	(0.8)	0		0		0		0		1	(0.6)
	Week 12 - Week 24	0		0		0		0		0		0	
	Post Week 24	0		0		0		0		0		0	
赤血球数減少	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Post Week 24	1	(0.8)	0		0		0		0		1	(0.6)
傷害、中毒および処置合併症	Week 0 - Week 4	4	(3.2)	0		0		1	(11.1)	1	(12.5)	6	(3.6)
	Week 4 - Week 8	3	(2.4)	1	(6.7)	0		0		0		4	(2.4)
	Week 8 - Week 12	5	(4.1)	0		0		0		0		5	(3.1)
	Week 12 - Week 24	11	(8.9)	1	(7.1)	0		0		1	(12.5)	13	(8.1)
	Post Week 24	16	(13.2)	1	(7.1)	2	(25.0)	0		0		19	(12.0)
節足動物刺傷	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	1	(0.8)	0		0		0		0		1	(0.6)
	Week 12 - Week 24	0		0		0		0		0		0	
	Post Week 24	0		0		0		0		0		0	
骨挫傷	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	0		1	(6.7)	0		0		0		1	(0.6)
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Post Week 24	1	(0.8)	0		0		0		0		1	(0.6)
凍瘡	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Post Week 24	1	(0.8)	0		0		0		0		1	(0.6)
挫傷	Week 0 - Week 4	0		0		0		0		1	(12.5)	1	(0.6)
	Week 4 - Week 8	3	(2.4)	1	(6.7)	0		0		0		4	(2.4)
	Week 8 - Week 12	1	(0.8)	0		0		0		0		1	(0.6)

器官別大分類		Knee N=126		Shoulder N=15		Elbow N=8		Hip N=9		Ankle N=8		Total N=166	
基本語	Timing of onset	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
	Week 12 - Week 24	5	(4.1)	0		0		0		1	(12.5)	6	(3.8)
	Post Week 24	6	(5.0)	0		1	(12.5)	0		0		7	(4.4)
上顆炎	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		1	(7.1)	0		0		0		1	(0.6)
	Post Week 24	0		1	(7.1)	1	(12.5)	0		0		2	(1.3)
足骨折	Week 0 - Week 4	1	(0.8)	0		0		0		0		1	(0.6)
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	1	(0.8)	0		0		0		0		1	(0.6)
	Week 12 - Week 24	0		0		0		0		0		0	
	Post Week 24	1	(0.8)	0		0		0		0		1	(0.6)
手骨折	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	1	(0.8)	0		0		0		0		1	(0.6)
	Post Week 24	0		0		0		0		0		0	
熱中症	Week 0 - Week 4	0		0		0		1	(11.1)	0		1	(0.6)
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	1	(0.8)	0		0		0		0		1	(0.6)
	Post Week 24	0		0		0		0		0		0	
上腕骨骨折	Week 0 - Week 4	1	(0.8)	0		0		0		0		1	(0.6)
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Post Week 24	0		0		0		0		0		0	
靭帯損傷	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	1	(0.8)	0		0		0		0		1	(0.6)
	Post Week 24	0		0		0		0		0		0	
靭帯捻挫	Week 0 - Week 4	0		0		0		0		1	(12.5)	1	(0.6)
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	4	(3.3)	0		0		0		0		4	(2.5)
	Post Week 24	1	(0.8)	0		0		0		0		1	(0.6)
肉離れ	Week 0 - Week 4	1	(0.8)	0		0		0		0		1	(0.6)
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Post Week 24	1	(0.8)	0		0		0		0		1	(0.6)
橈骨神経損傷	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	1	(0.8)	0		0		0		0		1	(0.6)
	Week 12 - Week 24	0		0		0		0		0		0	
	Post Week 24	0		0		0		0		0		0	
橈骨骨折	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Post Week 24	1	(0.8)	0		0		0		0		1	(0.6)
肋骨骨折	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0	

器官別大分類		Knee N=126		Shoulder N=15		Elbow N=8		Hip N=9		Ankle N=8		Total N=166	
基本語	Timing of onset	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
	Week 8 - Week 12	1	(0.8)	0		0		0		0		1	(0.6)
	Week 12 - Week 24	0		0		0		0		0		0	
	Post Week 24	0		0		0		0		0		0	
皮膚擦過傷	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Post Week 24	0		0		1	(12.5)	0		0		1	(0.6)
脊椎圧迫骨折	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Post Week 24	1	(0.8)	0		0		0		0		1	(0.6)
皮下血腫	Week 0 - Week 4	1	(0.8)	0		0		0		0		1	(0.6)
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Post Week 24	0		0		0		0		0		0	
腱断裂	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Post Week 24	1	(0.8)	0		0		0		0		1	(0.6)
熱傷	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Post Week 24	2	(1.7)	0		0		0		0		2	(1.3)
創傷	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	1	(0.8)	0		0		0		0		1	(0.6)
	Week 12 - Week 24	1	(0.8)	0		0		0		0		1	(0.6)
	Post Week 24	0		0		1	(12.5)	0		0		1	(0.6)
外科および内科処置	Week 0 - Week 4	0		0		0		1	(11.1)	0		1	(0.6)
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Post Week 24	1	(0.8)	0		0		0		0		1	(0.6)
抜歯	Week 0 - Week 4	0		0		0		1	(11.1)	0		1	(0.6)
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Post Week 24	0		0		0		0		0		0	
智歯抜歯	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	0		0		0		0		0		0	
	Post Week 24	1	(0.8)	0		0		0		0		1	(0.6)

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〔5.3.5.2-1 Table 14.3.1-8 改編〕

表 2.7.4.7-37. 発現時期別の関節ごとの副作用：613/1032 試験

器官別大分類		Knee N=126		Shoulder N=15		Elbow N=8		Hip N=9		Ankle N=8		Total N=166	
基本語	Timing of onset	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
評価例数	Week 0 - Week 4	126		15		8		9		8		166	
	Week 4 - Week 8	125		15		8		9		8		165	
	Week 8 - Week 12	123		15		8		9		8		163	
	Week 12 - Week 24	123		14		8		7		8		160	
	Post Week 24	121		14		8		7		8		158	
全ての副作用	Week 0 - Week 4	1	(0.8)	1	(6.7)	2	(25.0)	0		1	(12.5)	5	(3.0)
	Week 4 - Week 8	2	(1.6)	1	(6.7)	1	(12.5)	1	(11.1)	0		5	(3.0)
	Week 8 - Week 12	3	(2.4)	1	(6.7)	1	(12.5)	1	(11.1)	0		6	(3.7)
	Week 12 - Week 24	5	(4.1)	2	(14.3)	1	(12.5)	0		0		8	(5.0)
	Post Week 24	6	(5.0)	1	(7.1)	2	(25.0)	0		0		9	(5.7)
神経系障害	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	1	(0.8)	0		0		0		0		1	(0.6)
	Week 12 - Week 24	0		0		0		0		0		0	
	Post Week 24	0		0		0		0		0		0	
頭痛	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	1	(0.8)	0		0		0		0		1	(0.6)
	Week 12 - Week 24	0		0		0		0		0		0	
	Post Week 24	0		0		0		0		0		0	
心臓障害	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		1	(11.1)	0		1	(0.6)
	Week 8 - Week 12	0		0		0		1	(11.1)	0		1	(0.6)
	Week 12 - Week 24	0		0		0		0		0		0	
	Post Week 24	0		0		0		0		0		0	
動悸	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		1	(11.1)	0		1	(0.6)
	Week 8 - Week 12	0		0		0		1	(11.1)	0		1	(0.6)
	Week 12 - Week 24	0		0		0		0		0		0	
	Post Week 24	0		0		0		0		0		0	
胃腸障害	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	1	(0.8)	0		0		0		0		1	(0.6)
	Post Week 24	0		0		0		0		0		0	
嘔吐	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	0		0		0		0		0		0	
	Week 12 - Week 24	1	(0.8)	0		0		0		0		1	(0.6)
	Post Week 24	0		0		0		0		0		0	
一般・全身障害および投与部位の状態	Week 0 - Week 4	1	(0.8)	1	(6.7)	2	(25.0)	0		1	(12.5)	5	(3.0)
	Week 4 - Week 8	2	(1.6)	1	(6.7)	1	(12.5)	0		0		4	(2.4)
	Week 8 - Week 12	3	(2.4)	1	(6.7)	1	(12.5)	0		0		5	(3.1)
	Week 12 - Week 24	5	(4.1)	2	(14.3)	1	(12.5)	0		0		8	(5.0)
	Post Week 24	6	(5.0)	1	(7.1)	2	(25.0)	0		0		9	(5.7)
注射部位関節痛	Week 0 - Week 4	1	(0.8)	1	(6.7)	2	(25.0)	0		1	(12.5)	5	(3.0)
	Week 4 - Week 8	2	(1.6)	1	(6.7)	1	(12.5)	0		0		4	(2.4)
	Week 8 - Week 12	2	(1.6)	1	(6.7)	1	(12.5)	0		0		4	(2.5)
	Week 12 - Week 24	4	(3.3)	2	(14.3)	1	(12.5)	0		0		7	(4.4)
	Post Week 24	6	(5.0)	1	(7.1)	2	(25.0)	0		0		9	(5.7)
倦怠感	Week 0 - Week 4	0		0		0		0		0		0	
	Week 4 - Week 8	0		0		0		0		0		0	
	Week 8 - Week 12	1	(0.8)	0		0		0		0		1	(0.6)

器官別大分類		Knee N=126		Shoulder N=15		Elbow N=8		Hip N=9		Ankle N=8		Total N=166	
基本語	Timing of onset	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
	Week 12 - Week 24	1	(0.8)	0		0		0		0		1	(0.6)
	Post Week 24	0		0		0		0		0		0	

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〔5.3.5.2-1 Table 14.3.1-9 改編〕

表 2.7.4.7-38. 投与当日に発現した有害事象：613/1021 試験

器官別大分類	Placebo N=40				SI-613 15 mg N=40				SI-613 30 mg N=41			
基本語	1日以内[a]		2日以降		1日以内[a]		2日以降		1日以内[a]		2日以降	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
全ての有害事象	3	(7.5)	16	(40.0)	2	(5.0)	17	(42.5)	5	(12.2)	24	(58.5)
感染症および寄生虫症			4	(10.0)			1	(2.5)			7	(17.1)
慢性副鼻腔炎			1	(2.5)								
膀胱炎											1	(2.4)
麦粒腫											1	(2.4)
鼻咽頭炎			3	(7.5)			1	(2.5)			5	(12.2)
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	(5.0)							1	(2.4)
結腸癌			1	(2.5)								
皮膚乳頭腫			1	(2.5)								
肺の悪性新生物											1	(2.4)
代謝および栄養障害							2	(5.0)			1	(2.4)
高尿酸血症											1	(2.4)
低カリウム血症							1	(2.5)				
脂質異常症							1	(2.5)				
神経系障害			1	(2.5)			1	(2.5)				
頚腕症候群			1	(2.5)			1	(2.5)				
眼障害			2	(5.0)							3	(7.3)
白内障			1	(2.5)								
結膜出血											1	(2.4)
結膜炎			1	(2.5)								
アレルギー性結膜炎											1	(2.4)
睫毛乱生			1	(2.5)								
硝子体浮遊物											1	(2.4)
黄斑線維症			1	(2.5)								
心臓障害									1	(2.4)	1	(2.4)
不整脈											1	(2.4)
動悸									1	(2.4)		
血管障害											1	(2.4)
高血圧											1	(2.4)
呼吸器、胸郭および縦隔障害											1	(2.4)
上気道の炎症											1	(2.4)
胃腸障害			3	(7.5)							5	(12.2)
腹部不快感											1	(2.4)
上腹部痛			1	(2.5)							1	(2.4)
下痢			1	(2.5)							1	(2.4)
びらん性胃炎											1	(2.4)
歯の脱落			1	(2.5)								
口の感覚鈍麻											1	(2.4)
肝胆道系障害			1	(2.5)								
肝機能異常			1	(2.5)								
皮膚および皮下組織障害			2	(5.0)			3	(7.5)	1	(2.4)	2	(4.9)

器官別大分類	Placebo N=40				SI-613 15 mg N=40				SI-613 30 mg N=41			
基本語	1日以内[a]		2日以降		1日以内[a]		2日以降		1日以内[a]		2日以降	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
湿疹			2	(5.0)			1	(2.5)	1	(2.4)	1	(2.4)
過角化							1	(2.5)				
丘疹							1	(2.5)				
日光皮膚炎											1	(2.4)
筋骨格系および結合組織障害	1	(2.5)	4	(10.0)	1	(2.5)	7	(17.5)	2	(4.9)	7	(17.1)
関節痛	1	(2.5)									1	(2.4)
関節炎							1	(2.5)				
背部痛			1	(2.5)							1	(2.4)
外骨腫											1	(2.4)
関節硬直									1	(2.4)		
腰部脊柱管狭窄症							1	(2.5)				
筋骨格痛			1	(2.5)								
筋肉痛									1	(2.4)		
変形性関節症			1	(2.5)							1	(2.4)
四肢痛							1	(2.5)			2	(4.9)
関節周囲炎											1	(2.4)
足底筋膜炎											1	(2.4)
重感					1	(2.5)						
脊柱管狭窄症							1	(2.5)				
滑液嚢腫							1	(2.5)				
筋緊張							1	(2.5)				
筋骨格硬直			1	(2.5)								
脊椎すべり症							1	(2.5)				
一般・全身障害および投与部位の状態	2	(5.0)			1	(2.5)			2	(4.9)	1	(2.4)
注射部位疼痛									1	(2.4)		
注射部位関節腫脹	1	(2.5)										
注射部位関節疼痛	1	(2.5)			1	(2.5)			1	(2.4)		
注射部位関節滲出液											1	(2.4)
臨床検査			3	(7.5)			5	(12.5)			6	(14.6)
血中ビリルビン増加							1	(2.5)				
血中クレアチンホスホキナーゼ増加			1	(2.5)			2	(5.0)			1	(2.4)
血中トリグリセリド増加			1	(2.5)							1	(2.4)
血中尿酸増加							1	(2.5)				
尿中ブドウ糖陽性							1	(2.5)			3	(7.3)
肝機能検査異常			1	(2.5)								
尿中蛋白陽性											1	(2.4)
腎機能検査異常											1	(2.4)
傷害、中毒および処置合併症			2	(5.0)			1	(2.5)			5	(12.2)
動物咬傷							1	(2.5)				
手骨折			1	(2.5)								
靱帯捻挫			1	(2.5)							1	(2.4)
挫傷											4	(9.8)

MedDRA/J version 16.1
a: 治験薬投与翌日までに発現した事象を 1 日以内として集計した。
〔5.3.5.1-1 表 12.2-6 改編〕

表 2.7.4.7-39. 投与当日に発現した有害事象：613/1022 試験

器官別大分類	Placebo N=89						SI-613 30 mg N=87					
	1st injection		2nd injection		3rd injection		1st injection		2nd injection		3rd injection	
基本語	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
評価例数	89		83		83		87		86		85	
全ての有害事象	0		0		0		2	(2.3)	2	(2.3)	1	(1.2)
感染症および寄生虫症	0		0		0		1	(1.1)	0		0	
鼻咽頭炎	0		0		0		1	(1.1)	0		0	
眼障害	0		0		0		1	(1.1)	1	(1.2)	0	
白内障	0		0		0		0		1	(1.2)	0	
霰粒腫	0		0		0		1	(1.1)	0		0	
筋骨格系および結合組織障害	0		0		0		0		0		1	(1.2)
関節周囲炎	0		0		0		0		0		1	(1.2)
一般・全身障害および投与部位の状態	0		0		0		0		1	(1.2)	0	
注射部位関節の炎症	0		0		0		0		1	(1.2)	0	

MedDRA/J Version 18.0
〔5.3.5.1-2 Table14.3.1-9 改編〕

表 2.7.4.7-40. 投与当日に発現した有害事象：613/1031 試験

器官別大分類		Placebo N=220		SI-613 30 mg N=220	
基本語	Injection	n	(%)	n	(%)
評価例数	Week 0	220		220	
	Week 4	212		216	
	Week 8	213		213	
	Week 12	211		207	
	Week 16	209		205	
	Week 20	209		204	
	Either period	220		220	
全ての有害事象	Week 0	5	(2.3)	6	(2.7)
	Week 4	1	(0.5)	3	(1.4)
	Week 8	2	(0.9)	4	(1.9)
	Week 12	3	(1.4)	2	(1.0)
	Week 16	1	(0.5)	1	(0.5)
	Week 20	2	(1.0)	4	(2.0)
	Either period	13	(5.9)	17	(7.7)
感染症および寄生虫症	Week 0	0		0	
	Week 4	0		0	
	Week 8	0		0	
	Week 12	1	(0.5)	0	
	Week 16	0		0	
	Week 20	0		1	(0.5)
	Either period	1	(0.5)	1	(0.5)
膀胱炎	Week 0	0		0	
	Week 4	0		0	
	Week 8	0		0	
	Week 12	1	(0.5)	0	
	Week 16	0		0	
	Week 20	0		0	
	Either period	1	(0.5)	0	
副鼻腔炎	Week 0	0		0	
	Week 4	0		0	
	Week 8	0		0	

器官別大分類		Placebo N=220		SI-613 30 mg N=220	
基本語	Injection	n	(%)	n	(%)
	Week 12	0		0	
	Week 16	0		0	
	Week 20	0		1	(0.5)
	Either period	0		1	(0.5)
免疫系障害	Week 0	0		2	(0.9)
	Week 4	0		0	
	Week 8	0		0	
	Week 12	0		0	
	Week 16	0		0	
	Week 20	0		0	
	Either period	0		2	(0.9)
アナフィラキシー反応	Week 0	0		1	(0.5)
	Week 4	0		0	
	Week 8	0		0	
	Week 12	0		0	
	Week 16	0		0	
	Week 20	0		0	
	Either period	0		1	(0.5)
アナフィラキシーショック	Week 0	0		1	(0.5)
	Week 4	0		0	
	Week 8	0		0	
	Week 12	0		0	
	Week 16	0		0	
	Week 20	0		0	
	Either period	0		1	(0.5)
代謝および栄養障害	Week 0	0		0	
	Week 4	0		0	
	Week 8	0		1	(0.5)
	Week 12	0		0	
	Week 16	0		0	
	Week 20	0		0	
	Either period	0		1	(0.5)
高尿酸血症	Week 0	0		0	
	Week 4	0		0	
	Week 8	0		1	(0.5)
	Week 12	0		0	
	Week 16	0		0	
	Week 20	0		0	
	Either period	0		1	(0.5)
神経系障害	Week 0	0		2	(0.9)
	Week 4	0		0	
	Week 8	0		1	(0.5)
	Week 12	0		0	
	Week 16	0		0	
	Week 20	0		0	
	Either period	0		3	(1.4)
自律神経発作	Week 0	0		0	
	Week 4	0		0	
	Week 8	0		1	(0.5)
	Week 12	0		0	
	Week 16	0		0	
	Week 20	0		0	
	Either period	0		1	(0.5)
浮動性めまい	Week 0	0		1	(0.5)

器官別大分類		Placebo N=220		SI-613 30 mg N=220	
基本語	Injection	n	(%)	n	(%)
	Week 4	0		0	
	Week 8	0		0	
	Week 12	0		0	
	Week 16	0		0	
	Week 20	0		0	
	Either period	0		1	(0.5)
頭痛	Week 0	0		1	(0.5)
	Week 4	0		0	
	Week 8	0		0	
	Week 12	0		0	
	Week 16	0		0	
	Week 20	0		0	
	Either period	0		1	(0.5)
眼障害	Week 0	0		1	(0.5)
	Week 4	0		0	
	Week 8	0		0	
	Week 12	0		0	
	Week 16	0		0	
	Week 20	0		0	
	Either period	0		1	(0.5)
白内障	Week 0	0		1	(0.5)
	Week 4	0		0	
	Week 8	0		0	
	Week 12	0		0	
	Week 16	0		0	
	Week 20	0		0	
	Either period	0		1	(0.5)
血管障害	Week 0	1	(0.5)	0	
	Week 4	0		0	
	Week 8	0		0	
	Week 12	0		0	
	Week 16	0		0	
	Week 20	0		0	
	Either period	1	(0.5)	0	
蒼白	Week 0	1	(0.5)	0	
	Week 4	0		0	
	Week 8	0		0	
	Week 12	0		0	
	Week 16	0		0	
	Week 20	0		0	
	Either period	1	(0.5)	0	
胃腸障害	Week 0	0		1	(0.5)
	Week 4	0		0	
	Week 8	1	(0.5)	0	
	Week 12	0		0	
	Week 16	0		0	
	Week 20	0		0	
	Either period	1	(0.5)	1	(0.5)
下痢	Week 0	0		1	(0.5)
	Week 4	0		0	
	Week 8	0		0	
	Week 12	0		0	
	Week 16	0		0	
	Week 20	0		0	

器官別大分類		Placebo N=220		SI-613 30 mg N=220	
基本語	Injection	n	(%)	n	(%)
	Either period	0		1	(0.5)
悪心	Week 0	0		0	
	Week 4	0		0	
	Week 8	1	(0.5)	0	
	Week 12	0		0	
	Week 16	0		0	
	Week 20	0		0	
	Either period	1	(0.5)	0	
皮膚および皮下組織障害	Week 0	1	(0.5)	0	
	Week 4	0		0	
	Week 8	0		0	
	Week 12	0		0	
	Week 16	0		0	
	Week 20	0		0	
	Either period	1	(0.5)	0	
冷汗	Week 0	1	(0.5)	0	
	Week 4	0		0	
	Week 8	0		0	
	Week 12	0		0	
	Week 16	0		0	
	Week 20	0		0	
	Either period	1	(0.5)	0	
筋骨格系および結合組織障害	Week 0	0		0	
	Week 4	1	(0.5)	1	(0.5)
	Week 8	0		0	
	Week 12	0		0	
	Week 16	0		1	(0.5)
	Week 20	0		1	(0.5)
	Either period	1	(0.5)	3	(1.4)
関節痛	Week 0	0		0	
	Week 4	1	(0.5)	0	
	Week 8	0		0	
	Week 12	0		0	
	Week 16	0		1	(0.5)
	Week 20	0		1	(0.5)
	Either period	1	(0.5)	2	(0.9)
四肢不快感	Week 0	0		0	
	Week 4	0		1	(0.5)
	Week 8	0		0	
	Week 12	0		0	
	Week 16	0		0	
	Week 20	0		0	
	Either period	0		1	(0.5)
一般・全身障害および投与部位の状態	Week 0	4	(1.8)	2	(0.9)
	Week 4	0		2	(0.9)
	Week 8	2	(0.9)	2	(0.9)
	Week 12	2	(0.9)	2	(1.0)
	Week 16	1	(0.5)	0	
	Week 20	2	(1.0)	2	(1.0)
	Either period	10	(4.5)	8	(3.6)
悪寒	Week 0	0		0	
	Week 4	0		1	(0.5)
	Week 8	0		0	
	Week 12	0		0	

器官別大分類		Placebo N=220		SI-613 30 mg N=220	
基本語	Injection	n	(%)	n	(%)
	Week 16	0		0	
	Week 20	0		0	
	Either period	0		1	(0.5)
異常感	Week 0	1	(0.5)	0	
	Week 4	0		0	
	Week 8	0		0	
	Week 12	0		0	
	Week 16	0		0	
	Week 20	0		0	
	Either period	1	(0.5)	0	
注射部位関節不快感	Week 0	1	(0.5)	0	
	Week 4	0		0	
	Week 8	0		0	
	Week 12	0		0	
	Week 16	0		0	
	Week 20	0		0	
	Either period	1	(0.5)	0	
注射部位関節痛	Week 0	1	(0.5)	2	(0.9)
	Week 4	0		2	(0.9)
	Week 8	2	(0.9)	1	(0.5)
	Week 12	0		1	(0.5)
	Week 16	1	(0.5)	0	
	Week 20	2	(1.0)	2	(1.0)
	Either period	5	(2.3)	6	(2.7)
注射部位関節腫脹	Week 0	1	(0.5)	0	
	Week 4	0		0	
	Week 8	0		0	
	Week 12	0		0	
	Week 16	0		0	
	Week 20	0		0	
	Either period	1	(0.5)	0	
注射部位疼痛	Week 0	0		0	
	Week 4	0		0	
	Week 8	0		0	
	Week 12	2	(0.9)	0	
	Week 16	0		0	
	Week 20	0		0	
	Either period	2	(0.9)	0	
倦怠感	Week 0	0		0	
	Week 4	0		0	
	Week 8	0		0	
	Week 12	0		1	(0.5)
	Week 16	0		0	
	Week 20	0		0	
	Either period	0		1	(0.5)
末梢性浮腫	Week 0	0		0	
	Week 4	0		0	
	Week 8	0		1	(0.5)
	Week 12	0		0	
	Week 16	0		0	
	Week 20	0		0	
	Either period	0		1	(0.5)
傷害、中毒および処置合併症	Week 0	1	(0.5)	0	
	Week 4	0		0	

器官別大分類		Placebo N=220		SI-613 30 mg N=220	
基本語	Injection	n	(%)	n	(%)
	Week 8	0		0	
	Week 12	0		0	
	Week 16	0		0	
	Week 20	0		0	
	Either period	1	(0.5)	0	
注入に伴う反応	Week 0	1	(0.5)	0	
	Week 4	0		0	
	Week 8	0		0	
	Week 12	0		0	
	Week 16	0		0	
	Week 20	0		0	
	Either period	1	(0.5)	0	

MedDRA/J Version 21.1
〔5.3.5.1-3 Table 14.3.1-12 改編〕

表 2.7.4.7-41. 投与当日に発現した副作用：613/1021 試験

器官別大分類	Placebo N=40			SI-613 15 mg N=40			SI-613 30 mg N=41		
基本語	1 日以内 [a]		2 日以降	1 日以内 [a]		2 日以降	1 日以内 [a]		2 日以降
全ての副作用	3	(7.5)		2	(5.0)		2	(4.9)	
筋骨格系および結合組織障害	1	(2.5)		1	(2.5)		1	(2.4)	
関節痛	1	(2.5)							
関節硬直							1	(2.4)	
重感				1	(2.5)				
一般・全身障害および投与部位の状態	2	(5.0)		1	(2.5)		2	(4.9)	
注射部位疼痛							1	(2.4)	
注射部位関節腫脹	1	(2.5)							
注射部位関節疼痛	1	(2.5)		1	(2.5)		1	(2.4)	

n(%)
MedDRA/J Version 16.1
a: 治験薬投与翌日までに発現した事象を 1 日以内として集計した。
〔5.3.5.1-1 表 12.2-7 改編〕

表 2.7.4.7-42. 投与当日に発現した副作用：613/1022 試験

	Placebo N=89						SI-613 30 mg N=87					
器官別大分類	1st injection		2nd injection		3rd injection		1st injection		2nd injection		3rd injection	
基本語	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
評価例数	89		83		83		87		86		85	
全ての副作用	0		0		0		0		1	(1.2)	0	
一般・全身障害および投与部位の状態	0		0		0		0		1	(1.2)	0	
注射部位関節の炎症	0		0		0		0		1	(1.2)	0	

MedDRA/J Version 18.0
〔5.3.5.1-2 Table 14.3.1-10 改編〕

表 2.7.4.7-43. 投与当日に発現した副作用：613/1031 試験

器官別大分類		Placebo N=220		SI-613 30 mg N=220	
基本語	Injection	n	(%)	n	(%)
評価例数	Week 0	220		220	
	Week 4	212		216	
	Week 8	213		213	
	Week 12	211		207	
	Week 16	209		205	
	Week 20	209		204	
	Either period	220		220	
全ての副作用	Week 0	2	(0.9)	3	(1.4)
	Week 4	1	(0.5)	3	(1.4)
	Week 8	0		0	
	Week 12	1	(0.5)	1	(0.5)
	Week 16	1	(0.5)	0	
	Week 20	1	(0.5)	2	(1.0)
	Either period	5	(2.3)	7	(3.2)
免疫系障害	Week 0	0		2	(0.9)
	Week 4	0		0	
	Week 8	0		0	
	Week 12	0		0	
	Week 16	0		0	
	Week 20	0		0	
	Either period	0		2	(0.9)
アナフィラキシー反応	Week 0	0		1	(0.5)
	Week 4	0		0	
	Week 8	0		0	
	Week 12	0		0	
	Week 16	0		0	
	Week 20	0		0	
	Either period	0		1	(0.5)
アナフィラキシーショック	Week 0	0		1	(0.5)
	Week 4	0		0	
	Week 8	0		0	
	Week 12	0		0	
	Week 16	0		0	
	Week 20	0		0	
	Either period	0		1	(0.5)
筋骨格系および結合組織障害	Week 0	0		0	
	Week 4	1	(0.5)	1	(0.5)
	Week 8	0		0	
	Week 12	0		0	
	Week 16	0		0	
	Week 20	0		0	
	Either period	1	(0.5)	1	(0.5)
関節痛	Week 0	0		0	
	Week 4	1	(0.5)	0	
	Week 8	0		0	
	Week 12	0		0	
	Week 16	0		0	
	Week 20	0		0	
	Either period	1	(0.5)	0	
四肢不快感	Week 0	0		0	
	Week 4	0		1	(0.5)
	Week 8	0		0	
	Week 12	0		0	

器官別大分類		Placebo N=220		SI-613 30 mg N=220	
基本語	Injection	n	(%)	n	(%)
	Week 16	0		0	
	Week 20	0		0	
	Either period	0		1	(0.5)
一般・全身障害および投与部位の状態	Week 0	2	(0.9)	1	(0.5)
	Week 4	0		2	(0.9)
	Week 8	0		0	
	Week 12	1	(0.5)	1	(0.5)
	Week 16	1	(0.5)	0	
	Week 20	1	(0.5)	2	(1.0)
	Either period	4	(1.8)	4	(1.8)
注射部位関節不快感	Week 0	1	(0.5)	0	
	Week 4	0		0	
	Week 8	0		0	
	Week 12	0		0	
	Week 16	0		0	
	Week 20	0		0	
	Either period	1	(0.5)	0	
注射部位関節痛	Week 0	1	(0.5)	1	(0.5)
	Week 4	0		2	(0.9)
	Week 8	0		0	
	Week 12	0		1	(0.5)
	Week 16	1	(0.5)	0	
	Week 20	1	(0.5)	2	(1.0)
	Either period	2	(0.9)	4	(1.8)
注射部位疼痛	Week 0	0		0	
	Week 4	0		0	
	Week 8	0		0	
	Week 12	1	(0.5)	0	
	Week 16	0		0	
	Week 20	0		0	
	Either period	1	(0.5)	0	

MedDRA/J Version 21.1
〔5.3.5.1-3 Table 14.3.1-13 改編〕

表 2.7.4.7-44. 投与当日に発現した関節ごとの有害事象：613/1033 試験

器官別大分類		Shoulder				Elbow				Hip				Ankle				Total			
		Placebo		SI-613 30 mg		Placebo		SI-613 30 mg		Placebo		SI-613 30 mg		Placebo		SI-613 30 mg		Placebo		SI-613 30 mg	
		N=45		N=45		N=25		N=25		N=44		N=46		N=30		N=30		N=144		N=146	
基本語	Injection	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
評価例数	Week 0	45		45		25		25		44		46		30		30		144		146	
	Week 4	44		45		25		25		43		46		30		29		142		145	
	Week 8	44		44		25		25		42		44		29		29		140		142	
	Either period	45		45		25		25		44		46		30		30		144		146	
全ての有害事象	Week 0	1	(2.2)	3	(6.7)	1	(4.0)	0		2	(4.5)	3	(6.5)	1	(3.3)	3	(10.0)	5	(3.5)	9	(6.2)
	Week 4	0		1	(2.2)	0		0		0		10	(21.7)	2	(6.7)	5	(17.2)	2	(1.4)	16	(11.0)
	Week 8	0		1	(2.3)	1	(4.0)	1	(4.0)	0		3	(6.8)	1	(3.4)	4	(13.8)	2	(1.4)	9	(6.3)
	Either period	1	(2.2)	3	(6.7)	2	(8.0)	1	(4.0)	2	(4.5)	11	(23.9)	3	(10.0)	7	(23.3)	8	(5.6)	22	(15.1)
感染症および寄生虫症	Week 0	0		0		0		0		0		0		0		0		0		0	
	Week 4	0		0		0		0		0		1	(2.2)	0		0		0		1	(0.7)
	Week 8	0		0		0		0		0		0		0		0		0		0	
	Either period	0		0		0		0		0		1	(2.2)	0		0		0		1	(0.7)
上咽頭炎	Week 0	0		0		0		0		0		0		0		0		0		0	
	Week 4	0		0		0		0		0		1	(2.2)	0		0		0		1	(0.7)
	Week 8	0		0		0		0		0		0		0		0		0		0	
	Either period	0		0		0		0		0		1	(2.2)	0		0		0		1	(0.7)
神経系障害	Week 0	0		1	(2.2)	0		0		1	(2.3)	0		0		1	(3.3)	1	(0.7)	2	(1.4)
	Week 4	0		0		0		0		0		2	(4.3)	0		1	(3.4)	0		3	(2.1)
	Week 8	0		0		0		0		0		0		0		1	(3.4)	0		1	(0.7)
	Either period	0		1	(2.2)	0		0		1	(2.3)	2	(4.3)	0		3	(10.0)	1	(0.7)	6	(4.1)
浮動性めまい	Week 0	0		0		0		0		1	(2.3)	0		0		0		1	(0.7)	0	
	Week 4	0		0		0		0		0		0		0		0		0		0	
	Week 8	0		0		0		0		0		0		0		0		0		0	
	Either period	0		0		0		0		1	(2.3)	0		0		0		1	(0.7)	0	
頭痛	Week 0	0		0		0		0		0		0		0		0		0		0	
	Week 4	0		0		0		0		0		0		0		0		0		0	
	Week 8	0		0		0		0		0		0		0		1	(3.4)	0		1	(0.7)
	Either period	0		0		0		0		0		0		0		1	(3.3)	0		1	(0.7)
感覚鈍麻	Week 0	0		0		0		0		0		0		0		1	(3.3)	0		1	(0.7)
	Week 4	0		0		0		0		0		0		0		0		0		0	
	Week 8	0		0		0		0		0		0		0		0		0		0	
	Either period	0		0		0		0		0		0		0		1	(3.3)	0		1	(0.7)

器官別大分類		Shoulder				Elbow				Hip				Ankle				Total			
		Placebo		SI-613 30 mg		Placebo		SI-613 30 mg		Placebo		SI-613 30 mg		Placebo		SI-613 30 mg		Placebo		SI-613 30 mg	
		N=45		N=45		N=25		N=25		N=44		N=46		N=30		N=30		N=144		N=146	
基本語	Injection	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
失神寸前の状態	Week 0	0		0		0		0		0		0		0		0		0		0	
	Week 4	0		0		0		0		0		1	(2.2)	0		0		0		1	(0.7)
	Week 8	0		0		0		0		0		0		0		0		0		0	
	Either period	0		0		0		0		0		1	(2.2)	0		0		0		1	(0.7)
振戦	Week 0	0		0		0		0		0		0		0		0		0		0	
	Week 4	0		0		0		0		0		1	(2.2)	0		0		0		1	(0.7)
	Week 8	0		0		0		0		0		0		0		0		0		0	
	Either period	0		0		0		0		0		1	(2.2)	0		0		0		1	(0.7)
迷走神経障害	Week 0	0		1	(2.2)	0		0		0		0		0		0		0		1	(0.7)
	Week 4	0		0		0		0		0		0		0		1	(3.4)	0		1	(0.7)
	Week 8	0		0		0		0		0		0		0		0		0		0	
	Either period	0		1	(2.2)	0		0		0		0		0		1	(3.3)	0		2	(1.4)
心臓障害	Week 0	0		1	(2.2)	0		0		0		0		0		0		0		1	(0.7)
	Week 4	0		0		0		0		0		2	(4.3)	0		0		0		2	(1.4)
	Week 8	0		0		0		0		0		0		0		0		0		0	
	Either period	0		1	(2.2)	0		0		0		2	(4.3)	0		0		0		3	(2.1)
動悸	Week 0	0		1	(2.2)	0		0		0		0		0		0		0		1	(0.7)
	Week 4	0		0		0		0		0		2	(4.3)	0		0		0		2	(1.4)
	Week 8	0		0		0		0		0		0		0		0		0		0	
	Either period	0		1	(2.2)	0		0		0		2	(4.3)	0		0		0		3	(2.1)
呼吸器、胸郭および縦隔障害	Week 0	0		0		0		0		0		0		0		0		0		0	
	Week 4	0		0		0		0		0		1	(2.2)	0		0		0		1	(0.7)
	Week 8	0		0		1	(4.0)	1	(4.0)	0		0		0		0		1	(0.7)	1	(0.7)
	Either period	0		0		1	(4.0)	1	(4.0)	0		1	(2.2)	0		0		1	(0.7)	2	(1.4)
呼吸困難	Week 0	0		0		0		0		0		0		0		0		0		0	
	Week 4	0		0		0		0		0		1	(2.2)	0		0		0		1	(0.7)
	Week 8	0		0		0		0		0		0		0		0		0		0	
	Either period	0		0		0		0		0		1	(2.2)	0		0		0		1	(0.7)
鼻出血	Week 0	0		0		0		0		0		0		0		0		0		0	
	Week 4	0		0		0		0		0		0		0		0		0		0	
	Week 8	0		0		0		1	(4.0)	0		0		0		0		0		1	(0.7)
	Either period	0		0		0		1	(4.0)	0		0		0		0		0		1	(0.7)
声帯白斑症	Week 0	0		0		0		0		0		0		0		0		0		0	
	Week 4	0		0		0		0		0		0		0		0		0		0	

器官別大分類		Shoulder				Elbow				Hip				Ankle				Total			
		Placebo		SI-613 30 mg		Placebo		SI-613 30 mg		Placebo		SI-613 30 mg		Placebo		SI-613 30 mg		Placebo		SI-613 30 mg	
		N=45		N=45		N=25		N=25		N=44		N=46		N=30		N=30		N=144		N=146	
基本語	Injection	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
	Week 8	0		0		1	(4.0)	0		0		0		0		0		1	(0.7)	0	
	Either period	0		0		1	(4.0)	0		0		0		0		0		1	(0.7)	0	
胃腸障害	Week 0	1	(2.2)	0		0		0		0		1	(2.2)	0		0		1	(0.7)	1	(0.7)
	Week 4	0		0		0		0		0		3	(6.5)	0		1	(3.4)	0		4	(2.8)
	Week 8	0		0		0		0		0		1	(2.3)	0		0		0		1	(0.7)
	Either period	1	(2.2)	0		0		0		0		4	(8.7)	0		1	(3.3)	1	(0.7)	5	(3.4)
腹痛	Week 0	0		0		0		0		0		0		0		0		0		0	
	Week 4	0		0		0		0		0		0		0		1	(3.4)	0		1	(0.7)
	Week 8	0		0		0		0		0		0		0		0		0		0	
	Either period	0		0		0		0		0		0		0		1	(3.3)	0		1	(0.7)
悪心	Week 0	0		0		0		0		0		1	(2.2)	0		0		0		1	(0.7)
	Week 4	0		0		0		0		0		3	(6.5)	0		1	(3.4)	0		4	(2.8)
	Week 8	0		0		0		0		0		1	(2.3)	0		0		0		1	(0.7)
	Either period	0		0		0		0		0		4	(8.7)	0		1	(3.3)	0		5	(3.4)
嘔吐	Week 0	1	(2.2)	0		0		0		0		0		0		0		1	(0.7)	0	
	Week 4	0		0		0		0		0		0		0		0		0		0	
	Week 8	0		0		0		0		0		0		0		0		0		0	
	Either period	1	(2.2)	0		0		0		0		0		0		0		1	(0.7)	0	
皮膚および皮下組織障害	Week 0	0		0		0		0		0		0		0		0		0		0	
	Week 4	0		0		0		0		0		2	(4.3)	0		0		0		2	(1.4)
	Week 8	0		0		0		0		0		0		0		0		0		0	
	Either period	0		0		0		0		0		2	(4.3)	0		0		0		2	(1.4)
冷汗	Week 0	0		0		0		0		0		0		0		0		0		0	
	Week 4	0		0		0		0		0		1	(2.2)	0		0		0		1	(0.7)
	Week 8	0		0		0		0		0		0		0		0		0		0	
	Either period	0		0		0		0		0		1	(2.2)	0		0		0		1	(0.7)
多汗症	Week 0	0		0		0		0		0		0		0		0		0		0	
	Week 4	0		0		0		0		0		1	(2.2)	0		0		0		1	(0.7)
	Week 8	0		0		0		0		0		0		0		0		0		0	
	Either period	0		0		0		0		0		1	(2.2)	0		0		0		1	(0.7)
筋骨格系および結合組織障害	Week 0	0		0		0		0		0		0		0		0		0		0	
	Week 4	0		0		0		0		0		0		0		1	(3.4)	0		1	(0.7)
	Week 8	0		0		0		0		0		0		0		0		0		0	
	Either period	0		0		0		0		0		0		0		1	(3.3)	0		1	(0.7)

器官別大分類		Shoulder				Elbow				Hip				Ankle				Total			
		Placebo		SI-613 30 mg		Placebo		SI-613 30 mg		Placebo		SI-613 30 mg		Placebo		SI-613 30 mg		Placebo		SI-613 30 mg	
		N=45		N=45		N=25		N=25		N=44		N=46		N=30		N=30		N=144		N=146	
基本語	Injection	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
背部痛	Week 0	0		0		0		0		0		0		0		0		0		0	
	Week 4	0		0		0		0		0		0		0		1	(3.4)	0		1	(0.7)
	Week 8	0		0		0		0		0		0		0		0		0		0	
	Either period	0		0		0		0		0		0		0		1	(3.3)	0		1	(0.7)
一般・全身障害および投与部位の状態	Week 0	0		1	(2.2)	0		0		1	(2.3)	2	(4.3)	1	(3.3)	2	(6.7)	2	(1.4)	5	(3.4)
	Week 4	0		1	(2.2)	0		0		0		4	(8.7)	1	(3.3)	3	(10.3)	1	(0.7)	8	(5.5)
	Week 8	0		1	(2.3)	0		0		0		2	(4.5)	1	(3.4)	3	(10.3)	1	(0.7)	6	(4.2)
	Either period	0		1	(2.2)	0		0		1	(2.3)	5	(10.9)	2	(6.7)	4	(13.3)	3	(2.1)	10	(6.8)
悪寒	Week 0	0		0		0		0		0		0		0		0		0		0	
	Week 4	0		0		0		0		0		0		0		1	(3.4)	0		1	(0.7)
	Week 8	0		0		0		0		0		0		0		0		0		0	
	Either period	0		0		0		0		0		0		0		1	(3.3)	0		1	(0.7)
注射部位関節痛	Week 0	0		1	(2.2)	0		0		1	(2.3)	2	(4.3)	1	(3.3)	2	(6.7)	2	(1.4)	5	(3.4)
	Week 4	0		1	(2.2)	0		0		0		3	(6.5)	1	(3.3)	1	(3.4)	1	(0.7)	5	(3.4)
	Week 8	0		1	(2.3)	0		0		0		0		1	(3.4)	2	(6.9)	1	(0.7)	3	(2.1)
	Either period	0		1	(2.2)	0		0		1	(2.3)	3	(6.5)	2	(6.7)	2	(6.7)	3	(2.1)	6	(4.1)
注射部位関節腫脹	Week 0	0		0		0		0		0		0		0		0		0		0	
	Week 4	0		0		0		0		0		0		0		1	(3.4)	0		1	(0.7)
	Week 8	0		0		0		0		0		0		0		1	(3.4)	0		1	(0.7)
	Either period	0		0		0		0		0		0		0		1	(3.3)	0		1	(0.7)
倦怠感	Week 0	0		0		0		0		0		0		0		0		0		0	
	Week 4	0		0		0		0		0		1	(2.2)	0		0		0		1	(0.7)
	Week 8	0		0		0		0		0		1	(2.3)	0		0		0		1	(0.7)
	Either period	0		0		0		0		0		1	(2.2)	0		0		0		1	(0.7)
発熱	Week 0	0		0		0		0		0		0		0		0		0		0	
	Week 4	0		0		0		0		0		1	(2.2)	0		0		0		1	(0.7)
	Week 8	0		0		0		0		0		2	(4.5)	0		0		0		2	(1.4)
	Either period	0		0		0		0		0		2	(4.3)	0		0		0		2	(1.4)
臨床検査	Week 0	0		0		1	(4.0)	0		0		0		0		0		1	(0.7)	0	
	Week 4	0		0		0		0		0		0		1	(3.3)	0		1	(0.7)	0	
	Week 8	0		0		0		0		0		0		0		0		0		0	
	Either period	0		0		1	(4.0)	0		0		0		1	(3.3)	0		2	(1.4)	0	
血圧低下	Week 0	0		0		1	(4.0)	0		0		0		0		0		1	(0.7)	0	
	Week 4	0		0		0		0		0		0		0		0		0		0	

器官別大分類		Shoulder				Elbow				Hip				Ankle				Total			
		Placebo		SI-613 30 mg		Placebo		SI-613 30 mg		Placebo		SI-613 30 mg		Placebo		SI-613 30 mg		Placebo		SI-613 30 mg	
		N=45		N=45		N=25		N=25		N=44		N=46		N=30		N=30		N=144		N=146	
基本語	Injection	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
	Week 8	0		0		0		0		0		0		0		0		0		0	
	Either period	0		0		1	(4.0)	0		0		0		0		0		1	(0.7)	0	
血圧上昇	Week 0	0		0		0		0		0		0		0		0		0		0	
	Week 4	0		0		0		0		0		0		1	(3.3)	0		1	(0.7)	0	
	Week 8	0		0		0		0		0		0		0		0		0		0	
	Either period	0		0		0		0		0		0		1	(3.3)	0		1	(0.7)	0	

Percentages are based on the number of subjects analyzed at each timepoint.
MedDRA/J Version 22.0
〔5.3.5.1-4 Table 14.3.1-13 改編〕

表 2.7.4.7-45. 投与当日に発現した関節ごとの副作用：613/1033 試験

		Shoulder				Elbow				Hip				Ankle				Total			
		Placebo		SI-613 30 mg		Placebo		SI-613 30 mg		Placebo		SI-613 30 mg		Placebo		SI-613 30 mg		Placebo		SI-613 30 mg	
器官別大分類		N=45		N=45		N=25		N=25		N=44		N=46		N=30		N=30		N=144		N=146	
基本語	Injection	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
評価例数	Week 0	45		45		25		25		44		46		30		30		144		146	
	Week 4	44		45		25		25		43		46		30		29		142		145	
	Week 8	44		44		25		25		42		44		29		29		140		142	
	Either period	45		45		25		25		44		46		30		30		144		146	
全ての副作用	Week 0	0		1	(2.2)	0		0		1	(2.3)	0		0		0		1	(0.7)	1	(0.7)
	Week 4	0		0		0		0		0		2	(4.3)	0		1	(3.4)	0		3	(2.1)
	Week 8	0		0		0		0		0		1	(2.3)	0		1	(3.4)	0		2	(1.4)
	Either period	0		1	(2.2)	0		0		1	(2.3)	2	(4.3)	0		1	(3.3)	1	(0.7)	4	(2.7)
神経系障害	Week 0	0		0		0		0		0		0		0		0		0		0	
	Week 4	0		0		0		0		0		1	(2.2)	0		0		0		1	(0.7)
	Week 8	0		0		0		0		0		0		0		0		0		0	
	Either period	0		0		0		0		0		1	(2.2)	0		0		0		1	(0.7)
振戦	Week 0	0		0		0		0		0		0		0		0		0		0	
	Week 4	0		0		0		0		0		1	(2.2)	0		0		0		1	(0.7)
	Week 8	0		0		0		0		0		0		0		0		0		0	
	Either period	0		0		0		0		0		1	(2.2)	0		0		0		1	(0.7)
心臓障害	Week 0	0		1	(2.2)	0		0		0		0		0		0		0		1	(0.7)
	Week 4	0		0		0		0		0		0		0		0		0		0	
	Week 8	0		0		0		0		0		0		0		0		0		0	
	Either period	0		1	(2.2)	0		0		0		0		0		0		0		1	(0.7)
動悸	Week 0	0		1	(2.2)	0		0		0		0		0		0		0		1	(0.7)
	Week 4	0		0		0		0		0		0		0		0		0		0	
	Week 8	0		0		0		0		0		0		0		0		0		0	
	Either period	0		1	(2.2)	0		0		0		0		0		0		0		1	(0.7)
呼吸器、胸郭および縦隔障害	Week 0	0		0		0		0		0		0		0		0		0		0	
	Week 4	0		0		0		0		0		1	(2.2)	0		0		0		1	(0.7)
	Week 8	0		0		0		0		0		0		0		0		0		0	
	Either period	0		0		0		0		0		1	(2.2)	0		0		0		1	(0.7)
呼吸困難	Week 0	0		0		0		0		0		0		0		0		0		0	
	Week 4	0		0		0		0		0		1	(2.2)	0		0		0		1	(0.7)
	Week 8	0		0		0		0		0		0		0		0		0		0	
	Either period	0		0		0		0		0		1	(2.2)	0		0		0		1	(0.7)

器官別大分類		Shoulder				Elbow				Hip				Ankle				Total			
		Placebo		SI-613 30 mg		Placebo		SI-613 30 mg		Placebo		SI-613 30 mg		Placebo		SI-613 30 mg		Placebo		SI-613 30 mg	
		N=45		N=45		N=25		N=25		N=44		N=46		N=30		N=30		N=144		N=146	
基本語	Injection	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
胃腸障害	Week 0	0		0		0		0		0		0		0		0		0		0	
	Week 4	0		0		0		0		0		1	(2.2)	0		0		0		1	(0.7)
	Week 8	0		0		0		0		0		0		0		0		0		0	
	Either period	0		0		0		0		0		1	(2.2)	0		0		0		1	(0.7)
悪心	Week 0	0		0		0		0		0		0		0		0		0		0	
	Week 4	0		0		0		0		0		1	(2.2)	0		0		0		1	(0.7)
	Week 8	0		0		0		0		0		0		0		0		0		0	
	Either period	0		0		0		0		0		1	(2.2)	0		0		0		1	(0.7)
一般・全身障害および投与局所様態	Week 0	0		0		0		0		1	(2.3)	0		0		0		1	(0.7)	0	
	Week 4	0		0		0		0		0		1	(2.2)	0		1	(3.4)	0		2	(1.4)
	Week 8	0		0		0		0		0		1	(2.3)	0		1	(3.4)	0		2	(1.4)
	Either period	0		0		0		0		1	(2.3)	1	(2.2)	0		1	(3.3)	1	(0.7)	2	(1.4)
注射部位関節痛	Week 0	0		0		0		0		1	(2.3)	0		0		0		1	(0.7)	0	
	Week 4	0		0		0		0		0		0		0		0		0		0	
	Week 8	0		0		0		0		0		0		0		0		0		0	
	Either period	0		0		0		0		1	(2.3)	0		0		0		1	(0.7)	0	
注射部位関節腫脹	Week 0	0		0		0		0		0		0		0		0		0		0	
	Week 4	0		0		0		0		0		0		0		1	(3.4)	0		1	(0.7)
	Week 8	0		0		0		0		0		0		0		1	(3.4)	0		1	(0.7)
	Either period	0		0		0		0		0		0		0		1	(3.3)	0		1	(0.7)
倦怠感	Week 0	0		0		0		0		0		0		0		0		0		0	
	Week 4	0		0		0		0		0		1	(2.2)	0		0		0		1	(0.7)
	Week 8	0		0		0		0		0		1	(2.3)	0		0		0		1	(0.7)
	Either period	0		0		0		0		0		1	(2.2)	0		0		0		1	(0.7)
発熱	Week 0	0		0		0		0		0		0		0		0		0		0	
	Week 4	0		0		0		0		0		1	(2.2)	0		0		0		1	(0.7)
	Week 8	0		0		0		0		0		1	(2.3)	0		0		0		1	(0.7)
	Either period	0		0		0		0		0		1	(2.2)	0		0		0		1	(0.7)

Percentages are based on the number of subjects analyzed at each timepoint.
MedDRA/J Version 22.0
〔5.3.5.1-4 Table 14.3.1-14 改編〕

表 2.7.4.7-46. 治験薬投与部位に発現した副作用：613/1031 試験

器官別大分類	Placebo N=220		SI-613 30 mg N=220	
基本語	n	(%)	n	(%)
全ての副作用	7	(3.2)	7	(3.2)
免疫系障害	0		2	(0.9)
アナフィラキシー反応	0		1	(0.5)
アナフィラキシーショック	0		1	(0.5)
筋骨格系および結合組織障害	3	(1.4)	1	(0.5)
関節痛	1	(0.5)	0	
関節滲出液	1	(0.5)	0	
関節硬直	1	(0.5)	0	
四肢不快感	0		1	(0.5)
一般・全身障害および投与部位の状態	4	(1.8)	4	(1.8)
注射部位関節不快感	1	(0.5)	0	
注射部位関節痛	3	(1.4)	4	(1.8)
注射部位疼痛	1	(0.5)	0	

MedDRA/J Version 21.1
〔5.3.5.1-3 Table 14.3.1-23 改編〕

表 2.7.4.7-47. 治験薬投与部位に発現した関節ごとの有害事象：613/1033 試験

器官別大分類	Shoulder		Elbow		Hip		Ankle		Total	
	Placebo	SI-613 30 mg	Placebo	SI-613 30 mg	Placebo	SI-613 30 mg	Placebo	SI-613 30 mg	Placebo	SI-613 30 mg
基本語	N=45	N=45	N=25	N=25	N=44	N=46	N=30	N=30	N=144	N=146
全ての有害事象	0	3 (6.7)	2 (8.0)	0	2 (4.5)	3 (6.5)	3 (10.0)	4 (13.3)	7 (4.9)	10 (6.8)
神経系障害	0	0	1 (4.0)	0	0	0	0	0	1 (0.7)	0
肘部管症候群	0	0	1 (4.0)	0	0	0	0	0	1 (0.7)	0
筋骨格系および結合組織障害	0	2 (4.4)	0	0	0	0	0	0	0	2 (1.4)
関節裂隙狭小化	0	1 (2.2)	0	0	0	0	0	0	0	1 (0.7)
筋骨格痛	0	1 (2.2)	0	0	0	0	0	0	0	1 (0.7)
一般・全身障害および投与部位の状態	0	1 (2.2)	1 (4.0)	0	2 (4.5)	3 (6.5)	3 (10.0)	4 (13.3)	6 (4.2)	8 (5.5)
注射部位内出血	0	0	0	0	1 (2.3)	0	0	0	1 (0.7)	0
注射部位湿疹	0	0	0	0	0	0	1 (3.3)	0	1 (0.7)	0
注射部位知覚低下	0	0	0	0	0	0	0	1 (3.3)	0	1 (0.7)
注射部位損傷	0	0	1 (4.0)	0	0	0	0	0	1 (0.7)	0
注射部位関節痛	0	1 (2.2)	0	0	1 (2.3)	3 (6.5)	2 (6.7)	2 (6.7)	3 (2.1)	6 (4.1)
注射部位関節腫脹	0	0	0	0	0	0	0	1 (3.3)	0	1 (0.7)

n (%)
MedDRA/J Version 22.0
〔5.3.5.1-4 Table 14.3.1-29 改編〕

表 2.7.4.7-48. 治験薬投与部位に発現した関節ごとの副作用：613/1033 試験

	Shoulder				Elbow				Hip				Ankle				Total			
	Placebo		SI-613 30 mg		Placebo		SI-613 30 mg		Placebo		SI-613 30 mg		Placebo		SI-613 30 mg		Placebo		SI-613 30 mg	
器官別大分類	N=45		N=45		N=25		N=25		N=44		N=46		N=30		N=30		N=144		N=146	
基本語	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
全ての副作用	0		1	(2.2)	0		0		1	(2.3)	0		0		1	(3.3)	1	(0.7)	2	(1.4)
筋骨格系および結合組織障害	0		1	(2.2)	0		0		0		0		0		0		0		1	(0.7)
筋骨格痛	0		1	(2.2)	0		0		0		0		0		0		0		1	(0.7)
一般・全身障害および投与部位の状態	0		0		0		0		1	(2.3)	0		0		1	(3.3)	1	(0.7)	1	(0.7)
注射部位関節痛	0		0		0		0		1	(2.3)	0		0		0		1	(0.7)	0	
注射部位関節腫脹	0		0		0		0		0		0		0		1	(3.3)	0		1	(0.7)

MedDRA/J Version 22.0

〔5.3.5.1-4 Table 14.3.1-31 改編〕

表 2.7.4.7-49. 治験薬投与部位に発現した副作用：613/1032 試験

	Knee		Except for knee		Total	
器官別大分類	N=126		N=40		N=166	
基本語	n	(%)	n	(%)	n	(%)
全ての副作用	8	(6.3)	5	(12.5)	13	(7.8)
一般・全身障害および投与部位の状態	8	(6.3)	5	(12.5)	13	(7.8)
注射部位関節痛	8	(6.3)	5	(12.5)	13	(7.8)

MedDRA/J Version 22.0

〔5.3.5.2-1 Table 14.3.1-21 改編〕

表 2.7.4.7-50. 治験薬投与部位に発現した関節ごとの有害事象：613/1032 試験

	Knee		Shoulder		Elbow		Hip		Ankle		Total	
器官別大分類	N=126		N=15		N=8		N=9		N=8		N=166	
基本語	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
全ての有害事象	12	(9.5)	2	(13.3)	3	(37.5)	0		1	(12.5)	18	(10.8)
筋骨格系および結合組織障害	2	(1.6)	0		0		0		0		2	(1.2)
関節ロック	1	(0.8)	0		0		0		0		1	(0.6)
変形性関節症	1	(0.8)	0		0		0		0		1	(0.6)
一般・全身障害および投与部位の状態	11	(8.7)	2	(13.3)	2	(25.0)	0		1	(12.5)	16	(9.6)
注射部位関節滲出液	1	(0.8)	0		0		0		0		1	(0.6)
注射部位関節痛	9	(7.1)	2	(13.3)	2	(25.0)	0		1	(12.5)	14	(8.4)
注射部位関節腫脹	1	(0.8)	0		0		0		0		1	(0.6)
注射部位浮腫	1	(0.8)	0		0		0		0		1	(0.6)
傷害、中毒および処置合併症	0		0		1	(12.5)	0		0		1	(0.6)
上顆炎	0		0		1	(12.5)	0		0		1	(0.6)

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〔5.3.5.2-1 Table 14.3.1-20 改編〕

表 2.7.4.7-51. 治験薬投与部位に発現した関節ごとの副作用：613/1032 試験

器官別大分類	Knee N=126		Shoulder N=15		Elbow N=8		Hip N=9		Ankle N=8		Total N=166	
基本語	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
全ての副作用	8	(6.3)	2	(13.3)	2	(25.0)	0		1	(12.5)	13	(7.8)
一般・全身障害および投与部位の状態	8	(6.3)	2	(13.3)	2	(25.0)	0		1	(12.5)	13	(7.8)
注射部位関節痛	8	(6.3)	2	(13.3)	2	(25.0)	0		1	(12.5)	13	(7.8)

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〔5.3.5.2-1 Table 14.3.1-21 改編〕

表 2.7.4.7-52. 消化管障害に関連する関節ごとの有害事象：613/1033 試験

器官別大分類	Shoulder		Elbow		Hip		Ankle		Total	
	Placebo	SI-613 30 mg	Placebo	SI-613 30 mg	Placebo	SI-613 30 mg	Placebo	SI-613 30 mg	Placebo	SI-613 30 mg
基本語	N=45	N=45	N=25	N=25	N=44	N=46	N=30	N=30	N=144	N=146
全ての有害事象	0	1 (2.2)	0	0	0	0	0	0	0	1 (0.7)
胃腸障害	0	1 (2.2)	0	0	0	0	0	0	0	1 (0.7)
腹部不快感	0	1 (2.2)	0	0	0	0	0	0	0	1 (0.7)

n (%)
MedDRA/J Version 22.0
〔5.3.5.1-4 Table 14.3.1-33 改編〕

表 2.7.4.7-53. 消化管障害に関連する関節ごとの有害事象：613/1032 試験

器官別大分類	Knee N=126		Shoulder N=15		Elbow N=8		Hip N=9		Ankle N=8		Total N=166	
基本語	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
全ての有害事象	2	(1.6)	0		0		0		0		2	(1.2)
胃腸障害	2	(1.6)	0		0		0		0		2	(1.2)
胃潰瘍	1	(0.8)	0		0		0		0		1	(0.6)
びらん性胃炎	1	(0.8)	0		0		0		0		1	(0.6)

MedDRA/J Version 22.0
〔5.3.5.2-1 Table 14.3.1-22 改編〕

表 2.7.4.7-54. アナフィラキシーに関連する副作用：613/1031 試験

器官別大分類	Placebo N=220		SI-613 30 mg N=220	
基本語	n	(%)	n	(%)
全ての副作用	0		2	(0.9)
免疫系障害	0		2	(0.9)
アナフィラキシー反応	0		1	(0.5)
アナフィラキシーショック	0		1	(0.5)

MedDRA/J Version 21.1
〔5.3.5.1-3 Table 14.3.1-19 改編〕

表 2.7.4.7-55. アナフィラキシーに関連する関節ごとの有害事象：613/1033 試験

器官別大分類	Shoulder		Elbow		Hip		Ankle		Total	
	Placebo	SI-613 30 mg	Placebo	SI-613 30 mg	Placebo	SI-613 30 mg	Placebo	SI-613 30 mg	Placebo	SI-613 30 mg
基本語	N=45	N=45	N=25	N=25	N=44	N=46	N=30	N=30	N=144	N=146
全ての有害事象	2 (4.4)	1 (2.2)	2 (8.0)	0	0	3 (6.5)	0	1 (3.3)	4 (2.8)	5 (3.4)
呼吸器、胸郭および縦隔障害	0	0	0	0	0	3 (6.5)	0	1 (3.3)	0	4 (2.7)
喘息	0	0	0	0	0	1 (2.2)	0	1 (3.3)	0	2 (1.4)
咳嗽	0	0	0	0	0	1 (2.2)	0	0	0	1 (0.7)
呼吸困難	0	0	0	0	0	1 (2.2)	0	0	0	1 (0.7)
皮膚および皮下組織障害	2 (4.4)	1 (2.2)	1 (4.0)	0	0	0	0	0	3 (2.1)	1 (0.7)
そう痒症	1 (2.2)	1 (2.2)	0	0	0	0	0	0	1 (0.7)	1 (0.7)
発疹	1 (2.2)	0	0	0	0	0	0	0	1 (0.7)	0
蕁麻疹	0	0	1 (4.0)	0	0	0	0	0	1 (0.7)	0
臨床検査	0	0	1 (4.0)	0	0	0	0	0	1 (0.7)	0
血圧低下	0	0	1 (4.0)	0	0	0	0	0	1 (0.7)	0

n (%)
MedDRA/J Version 22.0
〔5.3.5.1-4 Table 14.3.1-41 改編〕

表 2.7.4.7-56. アナフィラキシーに関連する関節ごとの副作用：613/1033 試験

器官別大分類	Shoulder		Elbow		Hip		Ankle		Total	
	Placebo	SI-613 30 mg	Placebo	SI-613 30 mg	Placebo	SI-613 30 mg	Placebo	SI-613 30 mg	Placebo	SI-613 30 mg
基本語	N=45	N=45	N=25	N=25	N=44	N=46	N=30	N=30	N=144	N=146
全ての副作用	0	0	0	0	0	1 (2.2)	0	0	0	1 (0.7)
呼吸器、胸郭および縦隔障害	0	0	0	0	0	1 (2.2)	0	0	0	1 (0.7)
呼吸困難	0	0	0	0	0	1 (2.2)	0	0	0	1 (0.7)

n (%)
MedDRA/J Version 22.0
〔5.3.5.1-4 Table 14.3.1-43 改編〕

表 2.7.4.7-57. アナフィラキシーに関連する関節ごとの有害事象：613/1032 試験

器官別大分類	Knee N=126		Shoulder N=15		Elbow N=8		Hip N=9		Ankle N=8		Total N=166	
基本語	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
全ての有害事象	4	(3.2)	1	(6.7)	1	(12.5)	1	(11.1)	0		7	(4.2)
呼吸器、胸郭および縦隔障害	0		0		1	(12.5)	0		0		1	(0.6)
喘息	0		0		1	(12.5)	0		0		1	(0.6)
皮膚および皮下組織障害	3	(2.4)	1	(6.7)	0		0		0		4	(2.4)
紅斑	1	(0.8)	1	(6.7)	0		0		0		2	(1.2)
蕁麻疹	2	(1.6)	0		0		0		0		2	(1.2)
一般・全身障害および投与部位の状態	1	(0.8)	0		0		1	(11.1)	0		2	(1.2)
胸部不快感	0		0		0		1	(11.1)	0		1	(0.6)
浮腫	1	(0.8)	0		0		0		0		1	(0.6)

MedDRA/J Version 22.0
〔5.3.5.2-1 Table 14.3.1-26 改編〕

表 2.7.4.7-58. 過敏症に関連する副作用：613/1031 試験

器官別大分類	Placebo N=220		SI-613 30 mg N=220	
基本語	n	(%)	n	(%)
全ての副作用	0		2	(0.9)
免疫系障害	0		2	(0.9)
アナフィラキシー反応	0		1	(0.5)
アナフィラキシーショック	0		1	(0.5)

MedDRA/J Version 21.1
〔5.3.5.1-3 Table 14.3.1-27 改編〕

表 2.7.4.7-59. 過敏症に関連する関節ごとの有害事象：613/1033 試験

器官別大分類	Shoulder		Elbow		Hip		Ankle		Total	
	Placebo	SI-613 30 mg	Placebo	SI-613 30 mg	Placebo	SI-613 30 mg	Placebo	SI-613 30 mg	Placebo	SI-613 30 mg
基本語	N=45	N=45	N=25	N=25	N=44	N=46	N=30	N=30	N=144	N=146
全ての有害事象	3 (6.7)	3 (6.7)	1 (4.0)	0	0	1 (2.2)	1 (3.3)	1 (3.3)	5 (3.5)	5 (3.4)
感染症および寄生虫症	0	1 (2.2)	0	0	0	0	0	0	0	1 (0.7)
結膜炎	0	1 (2.2)	0	0	0	0	0	0	0	1 (0.7)
免疫系障害	0	1 (2.2)	0	0	0	0	0	0	0	1 (0.7)
季節性アレルギー	0	1 (2.2)	0	0	0	0	0	0	0	1 (0.7)
呼吸器、胸郭および縦隔障害	0	0	0	0	0	1 (2.2)	0	1 (3.3)	0	2 (1.4)
喘息	0	0	0	0	0	1 (2.2)	0	1 (3.3)	0	2 (1.4)
胃腸障害	1 (2.2)	0	0	0	0	0	0	0	1 (0.7)	0
口内炎	1 (2.2)	0	0	0	0	0	0	0	1 (0.7)	0
皮膚および皮下組織障害	2 (4.4)	1 (2.2)	1 (4.0)	0	0	0	0	0	3 (2.1)	1 (0.7)
そう痒症	1 (2.2)	1 (2.2)	0	0	0	0	0	0	1 (0.7)	1 (0.7)
発疹	1 (2.2)	0	0	0	0	0	0	0	1 (0.7)	0
蕁麻疹	0	0	1 (4.0)	0	0	0	0	0	1 (0.7)	0
一般・全身障害および投与部位の状態	0	0	0	0	0	0	1 (3.3)	0	1 (0.7)	0
注射部位湿疹	0	0	0	0	0	0	1 (3.3)	0	1 (0.7)	0

n (%)
MedDRA/J Version 22.0
〔5.3.5.1-4 Table 14.3.1-37 改編〕

表 2.7.4.7-60. 過敏症に関連する関節ごとの有害事象：613/1032 試験

器官別大分類	Knee N=126		Shoulder N=15		Elbow N=8		Hip N=9		Ankle N=8		Total N=166	
基本語	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
全ての有害事象	16	(12.7)	4	(26.7)	1	(12.5)	2	(22.2)	0		23	(13.9)
免疫系障害	1	(0.8)	0		0		0		0		1	(0.6)
季節性アレルギー	1	(0.8)	0		0		0		0		1	(0.6)
眼障害	2	(1.6)	0		0		0		0		2	(1.2)
アレルギー性結膜炎	2	(1.6)	0		0		0		0		2	(1.2)
呼吸器、胸郭および縦隔障害	0		0		1	(12.5)	0		0		1	(0.6)
喘息	0		0		1	(12.5)	0		0		1	(0.6)
胃腸障害	2	(1.6)	1	(6.7)	0		0		0		3	(1.8)
口内炎	2	(1.6)	1	(6.7)	0		0		0		3	(1.8)
皮膚および皮下組織障害	11	(8.7)	4	(26.7)	0		2	(22.2)	0		17	(10.2)
皮膚炎	1	(0.8)	1	(6.7)	0		0		0		2	(1.2)
接触皮膚炎	1	(0.8)	0		0		0		0		1	(0.6)
薬疹	1	(0.8)	0		0		0		0		1	(0.6)
湿疹	6	(4.8)	2	(13.3)	0		2	(22.2)	0		10	(6.0)
紅斑	1	(0.8)	1	(6.7)	0		0		0		2	(1.2)
蕁麻疹	2	(1.6)	0		0		0		0		2	(1.2)

MedDRA/J Version 22.0
〔5.3.5.2-1 Table 14.3.1-24 改編〕

表 2.7.4.7-61. 腎機能に関連する関節ごとの有害事象：613/1033 試験

	Shoulder				Elbow				Hip				Ankle				Total			
器官別大分類	Placebo N=45		SI-613 30 mg N=45		Placebo N=25		SI-613 30 mg N=25		Placebo N=44		SI-613 30 mg N=46		Placebo N=30		SI-613 30 mg N=30		Placebo N=144		SI-613 30 mg N=146	
基本語	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
全ての有害事象	0		1	(2.2)	0		0		0		0		0		0		0		1	(0.7)
臨床検査	0		1	(2.2)	0		0		0		0		0		0		0		1	(0.7)
尿中蛋白陽性	0		1	(2.2)	0		0		0		0		0		0		0		1	(0.7)

MedDRA/J Version 22.0
〔5.3.5.1-4 Table 14.3.1-5 改編〕

表 2.7.4.7-62. 腎機能に関連する関節ごとの有害事象：613/1032 試験

器官別大分類	Knee N=126		Shoulder N=15		Elbow N=8		Hip N=9		Ankle N=8		Total N=166	
基本語	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
全ての有害事象	2	(1.6)	0		0		0		0		2	(1.6)
代謝および栄養障害	1	(0.8)	0		0		0		0		1	(0.6)
高カリウム血症	1	(0.8)	0		0		0		0		1	(0.6)
臨床検査	1	(0.8)	0		0		0		0		1	(0.6)
血中クレアチニン増加	1	(0.8)	0		0		0		0		1	(0.6)
尿中蛋白陽性	1	(0.8)	0		0		0		0		1	(0.6)

MedDRA/J Version 22.0
〔5.3.5.2-1 Table 14.3.1-4 改編〕

表 2.7.4.7-63. 心臓血管系に関連する関節ごとの有害事象：613/1033 試験

	Shoulder				Elbow				Hip				Ankle				Total			
	Placebo		SI-613 30 mg		Placebo		SI-613 30 mg		Placebo		SI-613 30 mg		Placebo		SI-613 30 mg		Placebo		SI-613 30 mg	
器官別大分類	N=45		N=45		N=25		N=25		N=44		N=46		N=30		N=30		N=144		N=146	
基本語	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
全ての有害事象	0		1	(2.2)	0		0		0		2	(4.3)	0		0		0		3	(2.1)
心臓障害	0		1	(2.2)	0		0		0		2	(4.3)	0		0		0		3	(2.1)
動悸	0		1	(2.2)	0		0		0		2	(4.3)	0		0		0		3	(2.1)

MedDRA/J Version 22.0
〔5.3.5.1-4 Table 14.3.1-5 改編〕

表 2.7.4.7-64. 心臓血管系に関連する関節ごとの副作用：613/1033 試験

	Shoulder				Elbow				Hip				Ankle				Total			
	Placebo		SI-613 30 mg		Placebo		SI-613 30 mg		Placebo		SI-613 30 mg		Placebo		SI-613 30 mg		Placebo		SI-613 30 mg	
器官別大分類	N=45		N=45		N=25		N=25		N=44		N=46		N=30		N=30		N=144		N=146	
基本語	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
全ての副作用	0		1	(2.2)	0		0		0		0		0		0		0		1	(0.7)
心臓障害	0		1	(2.2)	0		0		0		0		0		0		0		1	(0.7)
動悸	0		1	(2.2)	0		0		0		0		0		0		0		1	(0.7)

MedDRA/J Version 22.0
〔5.3.5.1-4 Table 14.3.1-7 改編〕

表 2.7.4.7-65. 心臓血管系に関連する関節ごとの有害事象：613/1032 試験

	Knee		Shoulder		Elbow		Hip		Ankle		Total	
器官別大分類	N=126		N=15		N=8		N=9		N=8		N=166	
基本語	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
全ての有害事象	6	(4.8)	0		0		1	(11.1)	0		7	(4.2)
心臓障害	4	(3.2)	0		0		1	(11.1)	0		5	(3.0)
急性心筋梗塞	1	(0.8)	0		0		0		0		1	(0.6)
不安定狭心症	1	(0.8)	0		0		0		0		1	(0.6)
心房細動	1	(0.8)	0		0		0		0		1	(0.6)
動悸	1	(0.8)	0		0		1	(11.1)	0		2	(1.2)
一般・全身障害および投与部位の状態	1	(0.8)	0		0		0		0		1	(0.6)
浮腫	1	(0.8)	0		0		0		0		1	(0.6)
臨床検査	1	(0.8)	0		0		0		0		1	(0.6)
血中クレアチンホスホキナーゼ増加	1	(0.8)	0		0		0		0		1	(0.6)

MedDRA/J Version 22.0
〔5.3.5.2-1 Table 14.3.1-4 改編〕

表 2.7.4.7-66. 心臓血管系に関連する関節ごとの副作用：613/1032 試験

	Knee		Shoulder		Elbow		Hip		Ankle		Total	
器官別大分類	N=126		N=15		N=8		N=9		N=8		N=166	
基本語	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
全ての副作用	0		0		0		1	(11.1)	0		1	(0.6)
心臓障害	0		0		0		1	(11.1)	0		1	(0.6)
動悸	0		0		0		1	(11.1)	0		1	(0.6)

MedDRA/J Version 22.0
〔5.3.5.2-1 Table 14.3.1-5 改編〕

表 2.7.4.7-67. 臨床検査値の中央測定で採用した基準値：613/1021 試験、613/1022 試験、613/1031 試験、613/1033 試験、613/1032 試験

分類	項目名	基準値	単位
血液学的検査	白血球数	3300～9000	/μL
	白血球分画		
	好中球	40.0～75.0	%
	リンパ球	18.0～49.0	%
	単球	2.0～10.0	%
	好酸球	0.0～8.0	%
	好塩基球	0.0～2.0	%
	赤血球数	Male：430～570 Female：380～500	10^4/μL
	ヘモグロビン	Male：13.5～17.5 Female：11.5～15.0	g/dL
	ヘマトクリット	Male：39.7～52.4 Female：34.8～45.0	g/dL
	血小板数	14.0～34.0	10^4/μL
血液生化学的検査	総蛋白	6.7～8.3	g/dL
	アルブミン	3.8～5.3	g/dL
	総ビリルビン	0.2～1.2	mg/dL
	直接ビリルビン	0.0～0.3	mg/dL
	AST	10～40	U/L
	ALT	5～45	U/L
	LDH	120～240	U/L
	ALP	100～325	U/L
	γ-GTP	Male：80 以下 Female：30 以下	U/L
	尿酸	Male：3.8～7.0 Female：2.5～7.0	mg/dL
	尿素窒素	8～23	mg/dL
	クレアチニン	Male：0.61～1.04 Female：0.47～0.79	mg/dL
	総コレステロール	120～219	mg/dL
	中性脂肪	30～149	mg/dL
	CRP	0.5 以下	mg/dL
	Na	137～147	mEq/L
	K	3.5～5.0	mEq/L
	Cl	98～108	mEq/L
	Ca	8.4～10.4	mg/dL
	クレアチンキナーゼ	Male：60～270 Female：40～150	U/L
	HbA1c	4.6～6.2	%
免疫学的検査	HCV 抗体		
	判定	(-)	なし
	カットオフインデックス	1.0 未満	なし
	HBs 抗原		
	判定	(-)	なし
	濃度	0.05 未満	IU/mL
尿検査 （定性検査）	尿蛋白	(-)	なし
	尿糖	(-)	なし
	ウロビリノゲン	(±)	なし

表 2.7.4.7-68. 臨床検査値の各項目の平均値と中央値：613/1021 試験

			Placebo		SI-613 15 mg		SI-613 30 mg	
			N=40		N=40		N=41	
Parameters		Time point	n	Value at timepoint	n	Value at timepoint	n	Value at timepoint
白血球数 (/uL)	Mean (SD)	Baseline	40	5732.5 (1181.1)	40	6127.5 (1266.9)	41	5546.3 (1399.5)
		Week 1	39	5497.4 (1090.3)	40	5835.0 (1266.6)	41	5514.6 (1587.9)
		Week 2	40	5542.5 (1255.3)	38	5760.5 (1327.8)	39	5582.1 (1331.2)
		Week 4	40	5565.0 (916.1)	38	5673.7 (1282.9)	40	5670.0 (1555.2)
		Week 12	38	5628.9 (866.8)	37	5675.7 (1256.8)	38	5471.1 (1327.4)
	Median	Baseline	40	5550.0 (4700.0, 6650.0)	40	5800.0 (5500.0, 6850.0)	41	5500.0 (4600.0, 6200.0)
	(25%, 75%)	Week 1	39	5600.0 (4800.0, 6200.0)	40	5900.0 (5050.0, 6750.0)	41	5200.0 (4300.0, 7100.0)
		Week 2	40	5400.0 (4800.0, 6000.0)	38	5750.0 (4800.0, 6700.0)	39	5300.0 (4800.0, 6600.0)
		Week 4	40	5350.0 (4900.0, 6350.0)	38	5700.0 (4900.0, 6700.0)	40	5650.0 (4500.0, 6600.0)
		Week 12	38	5600.0 (5000.0, 6100.0)	37	5600.0 (5000.0, 6500.0)	38	5350.0 (4600.0, 6200.0)
好中球 (%)	Mean (SD)	Baseline	40	57.6 (7.3)	40	56.8 (7.4)	41	54.5 (8.4)
		Week 1	39	57.0 (8.3)	40	55.6 (7.4)	41	55.7 (8.6)
		Week 2	40	56.2 (8.8)	38	55.4 (7.5)	39	55.4 (8.4)
		Week 4	40	56.9 (7.9)	38	54.9 (6.2)	40	56.3 (8.3)
		Week 12	38	57.1 (8.4)	37	55.2 (7.5)	38	55.3 (7.6)
	Median	Baseline	40	59.2 (52.5, 63.2)	40	57.9 (50.8, 61.8)	41	54.5 (49.0, 59.8)
	(25%, 75%)	Week 1	39	57.2 (49.9, 62.9)	40	56.3 (50.9, 60.1)	41	55.3 (48.7, 61.0)
		Week 2	40	57.1 (48.9, 63.9)	38	55.3 (50.5, 60.7)	39	51.8 (49.1, 63.0)
		Week 4	40	57.1 (49.5, 62.8)	38	55.2 (50.3, 59.0)	40	55.7 (50.3, 62.1)
		Week 12	38	57.5 (50.4, 63.8)	37	55.4 (49.9, 60.1)	38	54.9 (50.2, 60.7)
リンパ球(%)	Mean (SD)	Baseline	40	31.71 (7.41)	40	32.42 (6.72)	41	34.77 (7.53)
		Week 1	39	32.76 (7.89)	40	33.71 (6.66)	41	33.93 (8.16)
		Week 2	40	33.24 (8.02)	38	33.69 (7.03)	39	34.23 (7.79)
		Week 4	40	32.99 (7.42)	38	34.49 (6.44)	40	33.89 (7.99)
		Week 12	38	32.35 (7.79)	37	34.03 (7.03)	38	34.61 (7.70)
	Median	Baseline	40	29.85 (26.50, 38.40)	40	32.65 (27.65, 35.20)	41	36.00 (28.90, 39.40)
	(25%, 75%)	Week 1	39	32.50 (26.50, 39.60)	40	33.60 (29.35, 36.65)	41	33.40 (28.60, 40.60)
		Week 2	40	31.65 (28.25, 39.70)	38	33.90 (30.10, 38.30)	39	34.00 (27.50, 40.40)
		Week 4	40	31.55 (28.30, 38.80)	38	34.20 (30.20, 38.60)	40	33.25 (27.00, 41.50)
		Week 12	38	32.30 (27.50, 36.80)	37	32.80 (30.00, 38.00)	38	35.30 (29.4 , 40.30)
単球 (%)	Mean (SD)	Baseline	40	7.10 (2.07)	40	7.29 (1.59)	41	6.85 (1.32)
		Week 1	39	7.00 (1.90)	40	7.43 (1.79)	41	6.99 (1.39)
		Week 2	40	7.07 (1.95)	38	7.63 (2.08)	39	7.09 (1.76)
		Week 4	40	6.68 (1.74)	38	7.29 (1.73)	40	6.85 (1.42)
		Week 12	38	7.31 (1.93)	37	7.50 (1.68)	38	7.06 (1.61)
	Median	Baseline	40	6.65 (5.80, 7.95)	40	7.25 (6.20, 8.70)	41	6.90 (5.80, 7.80)
	(25%, 75%)	Week 1	39	6.70 (6.00, 8.00)	40	7.00 (6.35, 8.10)	41	6.90 (6.20, 7.90)
		Week 2	40	6.60 (5.60, 8.50)	38	7.50 (6.40, 8.40)	39	6.80 (5.70, 8.30)
		Week 4	40	6.30 (5.35, 8.00)	38	7.00 (6.20, 8.70)	40	6.80 (6.00, 7.85)
		Week 12	38	7.25 (5.80, 8.30)	37	7.40 (6.70, 8.10)	38	7.05 (6.20, 7.90)
好酸球(%)	Mean (SD)	Baseline	40	3.08 (1.66)	40	3.05 (2.86)	41	3.36 (2.41)
		Week 1	39	2.79 (1.59)	40	2.87 (2.00)	41	2.94 (2.02)
		Week 2	40	3.00 (1.78)	38	2.80 (1.63)	39	2.80 (2.04)
		Week 4	40	3.02 (1.46)	38	2.93 (1.80)	40	2.52 (1.90)
		Week 12	38	2.83 (1.71)	37	2.86 (1.64)	38	2.56 (1.62)
	Median	Baseline	40	2.95 (1.80, 3.90)	40	2.15 (1.55, 3.80)	41	2.30 (1.40, 5.50)
	(25%, 75%)	Week 1	39	2.70 (1.70, 4.10)	40	2.55 (1.35, 3.85)	41	2.30 (1.70, 3.70)
		Week 2	40	2.60 (1.75, 3.95)	38	2.20 (1.60, 4.20)	39	2.00 (1.30, 4.20)
		Week 4	40	2.75 (1.90, 4.05)	38	2.65 (1.30, 4.00)	40	2.10 (1.05, 3.35)
		Week 12	38	2.65 (1.60, 3.40)	37	2.50 (1.60, 3.90)	38	2.15 (1.30, 3.30)
好塩基球 (%)	Mean (SD)	Baseline	40	0.48 (0.29)	40	0.46 (0.26)	41	0.52 (0.30)

			Placebo		SI-613 15 mg		SI-613 30 mg	
			N=40		N=40		N=41	
Parameters		Time point	n	Value at timepoint	n	Value at timepoint	n	Value at timepoint
		Week 1	39	0.46 (0.27)	40	0.37 (0.19)	41	0.49 (0.41)
		Week 2	40	0.47 (0.25)	38	0.45 (0.26)	39	0.45 (0.22)
		Week 4	40	0.45 (0.23)	38	0.43 (0.22)	40	0.48 (0.28)
		Week 12	38	0.44 (0.24)	37	0.39 (0.21)	38	0.43 (0.23)
	Median	Baseline	40	0.40 (0.30, 0.60)	40	0.40 (0.30, 0.55)	41	0.50 (0.30, 0.60)
	(25%, 75%)	Week 1	39	0.40 (0.30, 0.60)	40	0.40 (0.30, 0.50)	41	0.40 (0.20, 0.60)
		Week 2	40	0.40 (0.30, 0.60)	38	0.40 (0.30, 0.50)	39	0.40 (0.30, 0.60)
		Week 4	40	0.40 (0.35, 0.50)	38	0.40 (0.30, 0.50) ()	40	0.45 (0.30, 0.60)
		Week 12	38	0.40 (0.30, 0.60)	37	0.40 (0.30, 0.50) ()	38	0.40 (0.30, 0.60)
赤血球数 (× 10^4/μL)	Mean (SD)	Baseline	40	421.0 (41.2)	40	436.3 (32.5)	41	427.3 (31.9)
		Week 1	39	420.3 (41.7)	40	435.2 (32.1)	41	424.5 (32.1)
		Week 2	40	413.0 (39.0)	38	434.0 (33.0)	39	423.0 (31.3)
		Week 4	40	418.1 (43.0)	38	434.0 (34.2)	40	422.8 (33.3)
		Week 12	38	417.4 (41.1)	37	436.0 (31.6)	38	421.8 (31.0)
	Median	Baseline	40	424.0 (383.5, 455.5)	40	434.5 (421.0, 446.5)	41	432.0 (409.0, 444.0)
	(25%, 75%)	Week 1	39	427.0 (392.0, 446.0)	40	437.5 (416.0, 457.0)	41	421.0 (408.0, 445.0)
		Week 2	40	410.0 (388.5, 438.0)	38	433.5 (412.0, 452.0)	39	420.0 (400.0, 447.0)
		Week 4	40	425.0 (381.0, 456.5)	38	434.5 (410.0, 456.0)	40	422.0 (397.0, 443.0)
		Week 12	38	413.5 (389.0, 445.0)	37	432.0 (412.0, 455.0)	38	424.0 (401.0, 440.0)
ヘモグロビン (g/dL)	Mean (SD)	Baseline	40	13.11 (1.23)	40	13.64 (1.09)	41	13.35 (1.18)
		Week 1	39	13.05 (1.17)	40	13.59 (1.14)	41	13.26 (1.17)
		Week 2	40	12.84 (1.13)	38	13.57 (1.12)	39	13.19 (1.12)
		Week 4	40	12.98 (1.23)	38	13.51 (1.10)	40	13.16 (1.17)
		Week 12	38	12.99 (1.17)	37	13.50 (1.11)	38	13.14 (1.01)
	Median	Baseline	40	12.90 (12.10, 13.95)	40	13.55 (12.75, 14.40)	41	13.20 (12.60, 14.10)
	(25%, 75%)	Week 1	39	13.00 (12.30, 13.80)	40	13.55 (12.80, 14.35)	41	13.20 (12.60, 13.90)
		Week 2	40	12.60 (12.00, 13.45)	38	13.70 (12.80, 14.50)	39	13.20 (12.30, 13.70)
		Week 4	40	12.85 (12.05, 13.90)	38	13.35 (12.60, 14.30)	40	13.15 (12.45, 13.70)
		Week 12	38	12.80 (12.20, 14.00)	37	13.60 (12.60, 14.00)	38	13.25 (12.40, 13.70)
ヘマトクリット (%)	Mean (SD)	Baseline	40	39.22 (3.53)	40	40.82 (3.22)	41	40.02 (3.33)
		Week 1	39	39.12 (3.35)	40	40.70 (3.21)	41	39.74 (3.35)
		Week 2	40	38.52 (3.32)	38	40.74 (3.31)	39	39.58 (3.25)
		Week 4	40	38.94 (3.52)	38	40.46 (3.19)	40	39.50 (3.31)
		Week 12	38	38.66 (3.60)	37	40.28 (3.01)	38	39.20 (2.88)
	Median	Baseline	40	38.55 (36.45, 41.80)	40	40.45 (38.80, 42.65)	41	40.00 (38.00, 41.60)
	(25%, 75%)	Week 1	39	38.50 (36.40, 41.20)	40	40.80 (38.35, 42.75)	41	39.60 (38.00, 41.60)
		Week 2	40	37.80 (36.00, 40.35)	38	40.85 (38.40, 43.50)	39	39.20 (37.00, 41.00)
		Week 4	40	38.50 (36.30, 41.75)	38	40.30 (37.60, 42.60)	40	39.15 (37.15, 41.25)
		Week 12	38	37.90 (36.40, 41.40)	37	40.30 (37.90, 42.00)	38	39.55 (37.20, 40.70)
血小板数 (× 10^4/μL)	Mean (SD)	Baseline	40	22.28 (3.28)	39	23.55 (4.34)	41	21.80 (4.85)
		Week 1	39	22.41 (3.47)	40	23.15 (3.96)	41	21.82 (4.66)
		Week 2	40	21.85 (3.01)	38	22.56 (3.55)	39	22.29 (5.05)
		Week 4	40	21.74 (3.18)	38	23.10 (3.98)	40	22.23 (5.30)
		Week 12	38	22.43 (2.91)	37	22.31 (3.61)	38	21.30 (4.66)
	Median	Baseline	40	22.20 (19.90, 25.15)	39	23.20 (20.50, 26.00)	41	22.00 (18.60, 25.20)
	(25%, 75%)	Week 1	39	22.15 (20.00, 25.00)	40	22.85 (20.30, 25.70)	41	22.20 (18.90, 25.30)
		Week 2	40	21.70 (19.40, 24.20)	38	22.40 (20.00, 24.60)	39	23.10 (19.40, 26.10)
		Week 4	40	22.10 (19.40, 23.90)	38	23.25 (20.70, 24.80)	40	22.40 (18.90, 26.85)
		Week 12	38	21.90 (20.20, 25.20)	37	22.70 (19.40, 24.00)	38	21.95 (18.40, 24.80)
総タンパク (g/dL)	Mean (SD)	Baseline	40	7.23 (0.43)	40	7.19 (0.34)	41	7.24 (0.39)
		Week 1	39	7.24 (0.38)	40	7.14 (0.33)	41	7.17 (0.37)
		Week 2	40	7.10 (0.35)	38	7.13 (0.31)	39	7.16 (0.38)

			Placebo		SI-613 15 mg		SI-613 30 mg	
			N=40		N=40		N=41	
Parameters		Time point	n	Value at timepoint	n	Value at timepoint	n	Value at timepoint
		Week 4	40	7.18 (0.34)	38	7.09 (0.35)	40	7.16 (0.39)
		Week 12	38	7.13 (0.36)	37	7.08 (0.34)	38	7.17 (0.37)
	Median	Baseline	40	7.20 (6.90, 7.50)	40	7.20 (7.00, 7.40)	41	7.20 (6.90, 7.50)
	(25%, 75%)	Week 1	39	7.20 (7.00, 7.50)	40	7.15 (6.95, 7.35)	41	7.20 (6.90, 7.40)
		Week 2	40	7.10 (6.85, 7.30)	38	7.15 (7.00, 7.30)	39	7.10 (6.90, 7.40)
		Week 4	40	7.20 (6.95, 7.30)	38	7.10 (6.90, 7.30)	40	7.20 (6.80, 7.45)
		Week 12	38	7.10 (6.80, 7.30)	37	7.10 (6.80, 7.30)	38	7.20 (6.90, 7.30)
アルブミン (g/dL)	Mean (SD)	Baseline	40	4.38 (0.26)	40	4.41 (0.19)	41	4.40 (0.20)
		Week 1	39	4.36 (0.23)	40	4.40 (0.23)	41	4.37 (0.20)
		Week 2	40	4.27 (0.21)	38	4.39 (0.24)	39	4.30 (0.25)
		Week 4	40	4.34 (0.22)	38	4.37 (0.21)	40	4.33 (0.25)
		Week 12	38	4.34 (0.23)	37	4.37 (0.26)	38	4.37 (0.19)
	Median	Baseline	40	4.40 (4.20, 4.55)	40	4.40 (4.30, 4.50)	41	4.40 (4.30, 4.50)
	(25%, 75%)	Week 1	39	4.40 (4.20, 4.50)	40	4.40 (4.20, 4.60)	41	4.40 (4.30, 4.50)
		Week 2	40	4.30 (4.10, 4.40)	38	4.40 (4.30, 4.50)	39	4.30 (4.10, 4.50)
		Week 4	40	4.30 (4.25, 4.50)	38	4.40 (4.20 , 4.50)	40	4.30 (4.20, 4.50)
		Week 12	38	4.40 (4.20, 4.50)	37	4.40 (4.20, 4.50)	38	4.40 (4.20, 4.50)
総ビリルビン	Mean (SD)	Baseline	40	0.61 (0.19)	40	0.70 (0.32)	41	0.72 (0.28)
(mg/dL)		Week 1	39	0.61 (0.16)	40	0.71 (0.37)	41	0.67 (0.28)
		Week 2	40	0.62 (0.21)	38	0.72 (0.27)	39	0.63 (0.20)
		Week 4	40	0.65 (0.18)	38	0.72 (0.29)	40	0.69 (0.25)
		Week 12	38	0.63 (0.18)	37	0.71 (0.30)	38	0.68 (0.25)
	Median	Baseline	40	0.60 (0.50, 0.80)	40	0.60 (0.50, 0.85)	41	0.60 (0.50, 0.90)
	(25%, 75%)	Week 1	39	0.60 (0.50, 0.70)	40	0.60 (0.50, 0.80)	41	0.60 (0.50, 0.80)
		Week 2	40	0.60 (0.50, 0.70)	38	0.65 (0.50, 0.80)	39	0.60 (0.50, 0.70)
		Week 4	40	0.60 (0.50, 0.80)	38	0.65 (0.50, 0.90)	40	0.60 (0.50, 0.80)
		Week 12	38	0.60 (0.50, 0.70)	37	0.70 (0.50, 0.80)	38	0.65 (0.50, 0.80)
直接ビリルビン	Mean (SD)	Baseline	40	0.11 (0.03)	40	0.12 (0.06)	41	0.13 (0.06)
(g/dL)		Week 1	39	0.11 (0.04)	40	0.12 (0.08)	41	0.12 (0.06)
		Week 2	40	0.11 (0.03)	38	0.12 (0.06)	39	0.11 (0.03)
		Week 4	40	0.11 (0.03)	38	0.13 (0.06)	40	0.13 (0.06)
		Week 12	38	0.11 (0.03)	37	0.12 (0.06)	38	0.12 (0.05)
	Median	Baseline	40	0.10 (0.10, 0.10)	40	0.10 (0.10, 0.10)	41	0.10 (0.20, 0.10)
	(25%, 75%)	Week 1	39	0.10 (0.10, 0.10)	40	0.10 (0.10, 0.10)	41	0.10 (0.10, 0.10)
		Week 2	40	0.10 (0.10, 0.10)	38	0.10 (0.10, 0.20)	39	0.10 (0.10, 0.10)
		Week 4	40	0.10 (0.10, 0.10)	38	0.10 (0.10, 0.10)	40	0.10 (0.10, 0.15)
		Week 12	38	0.10 (0.10, 0.10)	37	0.10 (0.10, 0.10)	38	0.10 (0.10, 0.10)
AST (U/L)	Mean (SD)	Baseline	40	24.0 (6.1)	40	22.9 (5.4)	41	25.7 (5.9)
		Week 1	39	24.3 (8.2)	40	23.1 (5.4)	41	26.5 (8.3)
		Week 2	40	24.6 (9.2)	38	23.0 (5.0)	39	25.8 (7.5)
		Week 4	40	23.9 (6.8)	38	23.1 (5.9)	40	26.2 (8.9)
		Week 12	38	25.7 (11.2)	36	22.3 (6.4)	38	26.6 (8.1)
	Median	Baseline	40	24.0 (20.0, 26.5)	40	21.5 (19.0, 26.0)	41	25.0 (21.0, 28.0)
	(25%, 75%)	Week 1	39	23.0 (19.0, 27.0)	40	22.0 (19.0, 26.5)	41	25.0 (22.0, 30.0)
		Week 2	40	25.0 (19.5, 26.0)	38	22.5 (19.0, 27.0)	39	24.0 (21.0, 27.0)
		Week 4	40	24.0 (19.0, 26.0)	38	22.5 (19.0, 27.0)	40	23.5 (20.5, 29.0)
		Week 12	38	23.0 (19.0, 26.0)	36	21.0 (18.0, 26.0)	38	24.5 (21.0, 29.0)
ALT(U/L)	Mean (SD)	Baseline	40	21.1 (9.9)	40	19.3 (7.2)	41	22.7 (8.9)
		Week 1	39	20.1 (8.5)	40	19.2 (7.7)	41	22.7 (9.3)
		Week 2	40	20.6 (10.6)	38	19.2 (7.2)	39	21.7 (9.4)
		Week 4	40	19.7 (8.3)	38	18.9 (8.0)	40	22.0 (9.7)
		Week 12	38	23.1 (13.1)	37	18.8 (8.9)	38	23.8 (12.9)

			Placebo		SI-613 15 mg		SI-613 30 mg	
			N=40		N=40		N=41	
Parameters		Time point	n	Value at timepoint	n	Value at timepoint	n	Value at timepoint
	Median	Baseline	40	18.0 (15.0, 22.0)	40	17.5 (14.0, 23.0)	41	21.0 (17.0, 29.0)
	(25%, 75%)	Week 1	39	18.0 (14.0, 22.0)	40	18.0 (15.0, 21.5)	41	21.0 (16.0, 28.0)
		Week 2	40	18.0 (14.5, 20.5)	38	18.0 (14.0, 22.0)	39	19.0 (14.0, 28.0)
		Week 4	40	17.5 (14.0, 22.0)	38	18.0 (13.0, 22.0)	40	21.0 (14.5, 25.5)
		Week 12	38	19.5 (16.0, 25.0)	37	17.0 (12.0, 21.0)	38	19.5 (16.0, 27.0)
LDH (U/L)	Mean (SD)	Baseline	40	193.0 (31.6)	40	187.9 (25.5)	41	202.3 (57.2)
		Week 1	39	189.5 (29.5)	40	183.6 (22.7)	41	203.6 (69.6)
		Week 2	40	187.8 (30.0)	38	186.5 (27.3)	39	202.7 (74.4)
		Week 4	40	193.3 (29.7)	38	184.6 (25.5)	40	208.3 (91.9)
		Week 12	38	193.4 (32.1)	36	182.1 (22.9)	38	193.2 (37.1)
	Median	Baseline	40	196.5 (167.5, 208.5)	40	189.5 (170.0, 209.5)	41	196.0 (175.0, 218.0)
	(25%, 75%)	Week 1	39	192.0 (167.0, 219.0)	40	187.0 (167.5, 198.0)	41	198.0 (179.0, 213.0)
		Week 2	40	184.5 (162.5, 206.0)	38	188.0 (169.0, 209.0)	39	193.0 (170.0, 211.0)
		Week 4	40	193.5 (170.5, 211.5)	38	187.0 (170.0, 206.0)	40	190.5 (174.5, 217.5)
		Week 12	38	185.0 (169.0, 211.0)	36	185.5 (167.0, 202.0)	38	189.0 (172.0, 210.0)
ALP (U/L)	Mean (SD)	Baseline	40	236.8 (68.7)	40	244.4 (58.0)	41	238.3 (64.2)
		Week 1	39	234.1 (74.9)	40	250.8 (64.9)	41	241.9 (66.0)
		Week 2	40	230.1 (63.2)	38	249.8 (63.1)	39	238.9 (64.5)
		Week 4	40	230.2 (67.8)	38	241.1 (65.6)	40	235.4 (64.3)
		Week 12	38	239.2 (74.3)	37	239.5 (59.4)	38	236.3 (61.7)
	Median	Baseline	40	226.0 (198.0, 258.5)	40	247.0 (199.0, 285.5)	41	227.0 (191.0, 276.0)
	(25%, 75%)	Week 1	39	220.0 (186.0, 260.0)	40	248.5 (198.0, 282.5)	41	233.0 (198.0, 281.0)
		Week 2	40	222.0 (193.0, 249.0)	38	251.0 (208.0, 294.0)	39	238.0 (194.0, 279.0)
		Week 4	40	229.0 (192.0, 252.0)	38	240.0 (188.0, 280.0)	40	229.5 (178.5, 267.5)
		Week 12	38	231.0 (197.0, 258.0)	37	238.0 (203.0, 283.0)	38	228.0 (188.0, 278.0)
γ-GTP (U/L)	Mean (SD)	Baseline	40	26.4 (21.7)	40	26.0 (15.2)	41	32.2 (27.9)
		Week 1	39	25.8 (19.7)	40	25.2 (14.0)	41	30.8 (25.5)
		Week 2	40	25.8 (20.4)	38	25.7 (15.7)	39	31.4 (29.6)
		Week 4	40	25.7 (19.7)	38	24.9 (13.9)	40	31.5 (26.7)
		Week 12	38	30.6 (25.5)	37	25.9 (15.4)	38	32.8 (32.5)
	Median	Baseline	40	17.5 (15.0, 27.0)	40	21.5 (16.0, 29.0)	41	23.0 (18.0, 33.0)
	(25%, 75%)	Week 1	39	17.0 (14.0, 25.0)	40	22.0 (17.0, 28.0)	41	25.0 (17.0, 30.0)
		Week 2	40	17.5 (14.0, 23.5)	38	22.0 (16.0, 28.0)	39	21.0 (16.0, 30.0)
		Week 4	40	18.0 (14.0, 24.0)	38	21.5 (17.0, 30.0)	40	26.0 (16.5, 32.0)
		Week 12	38	20.0 (14.0, 44.0)	37	22.0 (17.0, 27.0)	38	21.5 (16.0, 30.0)
尿酸 (mg/dL)	Mean (SD)	Baseline	40	4.95 (1.38)	40	5.21 (1.12)	41	5.05 (1.36)
		Week 1	39	4.85 (1.36)	40	5.11 (1.06)	41	4.99 (1.29)
		Week 2	40	5.02 (1.25)	38	5.21 (1.06)	39	4.97 (1.31)
		Week 4	40	4.95 (1.34)	38	5.14 (1.06)	40	5.06 (1.41)
		Week 12	38	4.99 (1.30)	37	5.23 (1.14)	38	5.11 (1.60)
	Median	Baseline	40	4.85 (4.00, 5.60)	40	5.10 (4.45, 5.90)	41	4.80 (4.30, 5.70)
	(25%, 75%)	Week 1	39	4.90 (4.10, 5.70)	40	5.05 (4.35, 5.75)	41	5.10 (4.30, 6.10)
		Week 2	40	5.05 (4.25, 5.55)	38	5.20 (4.60, 5.60)	39	4.80 (4.30, 5.80)
		Week 4	40	5.00 (4.10, 5.85)	38	5.05 (4.50, 5.60)	40	5.10 (4.20, 6.15)
		Week 12	38	5.05 (4.30, 5.60)	37	5.00 (4.40 6.10)	38	4.95 (4.10, 6.10)
尿素窒素 (mg/dL)	Mean (SD)	Baseline	40	15.2 (3.7)	40	15.5 (3.6)	41	15.8 (4.1)
		Week 1	39	15.1 (3.7)	40	14.6 (3.5)	41	15.4 (4.3)
		Week 2	40	15.6 (3.7)	38	15.2 (3.5)	39	15.0 (3.8)
		Week 4	40	15.0 (4.3)	38	14.7 (3.9)	40	14.9 (4.0)
		Week 12	38	15.6 (4.4)	37	15.6 (3.7)	38	16.2 (5.0)
	Median	Baseline	40	14.5 (12.0, 17.0)	40	16.0 (13.0, 17.0)	41	15.0 (12.0, 19.0)
	(25%, 75%)	Week 1	39	15.0 (12.0, 18.0)	40	15.0 (12.0, 17.0)	41	15.0 (13.0, 17.0)

			Placebo		SI-613 15 mg		SI-613 30 mg	
			N=40		N=40		N=41	
Parameters		Time point	n	Value at timepoint	n	Value at timepoint	n	Value at timepoint
		Week 2	40	14.5 (12.5, 19.0)	38	14.5 (13.0, 17.0)	39	15.0 (12.0, 17.0)
		Week 4	40	15.0 (11.0, 17.5)	38	15.0 (11.0, 17.0)	40	14.5 (13.0, 17.0)
		Week 12	38	15.0 (12.0, 19.0)	37	16.0 (13.0, 18.0)	38	15.0 (13.0, 19.0)
クレアチニン (mg/dL)	Mean (SD)	Baseline	40	0.639 (0.119)	40	0.679 (0.187)	41	0.630 (0.141)
		Week 1	39	0.621 (0.123)	40	0.681 (0.176)	41	0.634 (0.144)
		Week 2	40	0.631 (0.126)	38	0.681 (0.174)	39	0.635 (0.139)
		Week 4	40	0.637 (0.123)	38	0.689 (0.166)	40	0.636 (0.144)
		Week 12	38	0.637 (0.123)	37	0.690 (0.164)	38	0.653 (0.165)
	Median (25%, 75%)	Baseline	40	0.600 (0.555, 0.730)	40	0.645 (0.545, 0.755)	41	0.610 (0.520, 0.720)
		Week 1	39	0.590 (0.530, 0.710)	40	0.640 (0.570, 0.705)	41	0.620 (0.530, 0.710)
		Week 2	40	0.600 (0.550, 0.730)	38	0.630 (0.560, 0.740)	39	0.630 (0.530, 0.700)
		Week 4	40	0.600 (0.560, 0.715)	38	0.660 (0.570, 0.750)	40	0.600 (0.530, 0.720)
		Week 12	38	0.610 (0.550, 0.730)	37	0.650 (0.580, 0.750)	38	0.605 (0.550, 0.720)
総コレステロール (mg/dL)	Mean (SD)	Baseline	40	218.9 (40.6)	40	218.0 (35.4)	41	214.2 (33.8)
		Week 1	39	216.7 (40.1)	40	217.0 (32.2)	41	210.7 (34.5)
		Week 2	40	217.0 (42.2)	38	217.1 (31.6)	39	207.6 (34.2)
		Week 4	40	218.6 (42.4)	38	213.8 (31.7)	40	210.0 (35.0)
		Week 12	38	217.6 (35.2)	37	211.6 (28.6)	38	213.6 (32.2)
	Median (25%, 75%)	Baseline	40	210.5 (191.5, 244.0)	40	218.0 (192.0, 232.5)	41	215.0 (195.0, 236.0)
		Week 1	39	212.0 (186.0, 243.0)	40	215.5 (193.5, 234.5)	41	206.0 (189.0, 233.0)
		Week 2	40	209.5 (191.0, 240.0)	38	219.5 (193.0, 241.0)	39	208.0 (182.0, 231.0)
		Week 4	40	216.0 (195.0, 235.5)	38	217.5 (195.0, 234.0)	40	207.5 (192.0, 228.0)
		Week 12	38	216.5 (193.0, 234.0)	37	215.0 (197.0, 222.0)	38	211.5 (190.0, 230.0)
中性脂肪 (mg/dL)	Mean (SD)	Baseline	40	156.4 (78.2)	40	154.6 (62.7)	41	128.3 (87.6)
		Week 1	39	154.6 (93.3)	40	180.2 (84.8)	41	160.9 (145.4)
		Week 2	40	153.7 (76.9)	38	183.7 (96.8)	39	160.1 (99.8)
		Week 4	40	149.7 (63.5)	38	154.8 (63.1)	40	157.1 (136.1)
		Week 12	38	155.7 (78.7)	37	148.0 (62.2)	38	151.7 (74.4)
	Median (25%, 75%)	Baseline	40	129.5 (98.0, 197.0)	40	146.5 (108.0, 190.5)	41	107.0 (74.0, 151.0)
		Week 1	39	116.0 (86.0, 207.0)	40	155.0 (117.5, 210.5)	41	126.0 (80.0, 189.0)
		Week 2	40	137.5 (90.0, 207.5)	38	152.0 (114.0, 247.0)	39	144.0 (86.0, 194.0)
		Week 4	40	143.5 (104.5, 188.0)	38	141.0 (116.0, 178.0)	40	132.5 (89.0, 189.5)
		Week 12	38	132.5 (103.0, 187.0)	37	123.0 (105.0, 182.0)	38	138.0 (102.0, 179.0)
CRP (mg/dL)	Mean (SD)	Baseline	40	0.08 (0.10)	40	0.24 (0.87)	41	0.14 (0.23)
		Week 1	39	0.15 (0.57)	40	0.09 (0.08)	41	0.13 (0.31)
		Week 2	40	0.08 (0.11)	38	0.13 (0.13)	39	0.15 (0.32)
		Week 4	40	0.09 (0.18)	38	0.09 (0.09)	40	0.29 (0.75)
		Week 12	38	0.07 (0.07)	37	0.11 (0.18)	38	0.09 (0.09)
	Median (25%, 75%)	Baseline	40	0.00 (0.00, 0.10)	40	0.10 (0.00, 0.15)	41	0.10 (0.00, 0.10)
		Week 1	39	0.00 (0.00, 0.10)	40	0.10 (0.00, 0.10)	41	0.10 (0.00, 0.10)
		Week 2	40	0.00 (0.00, 0.10)	38	0.10 (0.00, 0.10)	39	0.10 (0.00, 0.10)
		Week 4	40	0.10 (0.00, 0.10)	38	0.10 (0.00, 0.10)	40	0.10 (0.00, 0.10)
		Week 12	38	0.10 (0.00, 0.10)	37	0.10 (0.00, 0.10)	38	0.10 (0.00, 0.10)
Na (mEq/L)	Mean (SD)	Baseline	40	141.9 (1.5)	40	142.2 (1.8)	41	141.9 (1.7)
		Week 1	39	141.6 (1.5)	40	141.9 (1.6)	41	142.2 (1.9)
		Week 2	40	141.5 (1.7)	38	142.1 (1.5)	39	141.8 (1.8)
		Week 4	40	141.8 (1.7)	38	141.8 (1.9)	40	142.3 (2.0)
		Week 12	38	141.8 (1.9)	37	141.7 (1.8)	38	142.1 (1.7)
	Median (25%, 75%)	Baseline	40	142.0 (141.0, 143.0)	40	142.0 (141.0, 143.0)	41	142.0 (141.0, 143.0)
		Week 1	39	142.0 (140.0, 142.0)	40	142.0 (141.0, 143.0)	41	142.0 (141.0, 143.0)
		Week 2	40	141.5 (140.0, 142.5)	38	142.0 (141.0, 143.0)	39	142.0 (141.0, 143.0)
		Week 4	40	142.0 (141.0, 143.0)	38	142.0 (141.0, 143.0)	40	142.0 (141.0, 143.0)

			Placebo		SI-613 15 mg		SI-613 30 mg	
			N=40		N=40		N=41	
Parameters		Time point	n	Value at timepoint	n	Value at timepoint	n	Value at timepoint
		Week 12	38	142.0 (141.0, 143.0)	37	142.0 (141.0, 143.0)	38	142.0 (141.0, 143.0)
K (mEq/L)	Mean (SD)	Baseline	40	4.17 (0.34)	40	4.20 (0.35)	41	4.13 (0.33)
		Week 1	39	4.15 (0.31)	40	4.08 (0.35)	41	4.27 (0.37)
		Week 2	40	4.12 (0.29)	38	4.07 (0.39)	39	4.22 (0.40)
		Week 4	40	4.23 (0.44)	38	4.06 (0.38)	40	4.24 (0.45)
		Week 12	38	4.20 (0.41)	36	4.10 (0.42)	38	4.19 (0.36)
	Median (25%, 75%)	Baseline	40	4.20 (3.90, 4.40)	40	4.15 (4.00, 4.50)	41	4.10 (3.90, 4.20)
		Week 1	39	4.10 (3.90, 4.40)	40	4.10 (3.90, 4.20)	41	4.20 (4.00, 4.50)
		Week 2	40	4.10 (3.90, 4.30)	38	4.10 (3.80, 4.30)	39	4.10 (4.00, 4.40)
		Week 4	40	4.20 (3.90, 4.50)	38	4.10 (3.90, 4.30)	40	4.10 (4.00, 4.50)
		Week 12	38	4.20 (3.90, 4.50)	36	4.10 (3.95, 4.30)	38	4.10 (4.00, 4.40)
Cl (mEq/L)	Mean (SD)	Baseline	40	103.7 (1.7)	40	103.8 (2.0)	41	103.7 (1.8)
		Week 1	39	103.3 (1.8)	40	103.6 (2.0)	41	104.4 (1.8)
		Week 2	40	103.5 (2.1)	38	103.6 (2.2)	39	104.0 (1.6)
		Week 4	40	103.5 (1.8)	38	103.8 (1.9)	40	104.5 (2.1)
		Week 12	38	104.1 (1.8)	37	103.7 (2.1)	38	104.2 (2.0)
	Median (25%, 75%)	Baseline	40	104.0 (102.5, 105.0)	40	104.0 (102.5, 105.0)	41	104.0 (103.0, 105.0)
		Week 1	39	103.0 (102.5, 105.0)	40	104.0 (102.5, 105.0)	41	104.0 (103.0, 106.0)
		Week 2	40	103.0 (102.5, 105.0)	38	104.0 (102.0, 105.0)	39	104.0 (103.0, 105.0)
		Week 4	40	103.0 (102.5, 104.0)	38	104.0 (103.0, 105.0)	40	104.5 (103.0, 106.0)
		Week 12	38	104.0 (103.0, 105.0)	37	104.0 (102.0, 105.0)	38	104.0 (103.0, 106.0)
Ca (mg/L)	Mean (SD)	Baseline	40	9.37 (0.29)	40	9.39 (0.27)	41	9.37 (0.35)
		Week 1	39	9.39 (0.29)	40	9.41 (0.37)	41	9.41 (0.41)
		Week 2	40	9.25 (0.30)	38	9.38 (0.36)	39	9.39 (0.35)
		Week 4	40	9.37 (0.37)	38	9.32 (0.32)	40	9.41 (0.40)
		Week 12	38	9.32 (0.33)	37	9.39 (0.39)	38	9.34 (0.34)
	Median (25%, 75%)	Baseline	40	9.40 (9.10, 9.55)	40	9.30 (9.15, 9.65)	41	9.40 (9.20, 9.60)
		Week 1	39	9.40 (9.30, 9.60)	40	9.35 (9.20, 9.70)	41	9.40 (9.20, 9.60)
		Week 2	40	9.20 (9.10, 9.40)	38	9.40 (9.10, 9.60)	39	9.40 (9.20, 9.70)
		Week 4	40	9.40 (9.05, 9.55)	38	9.30 (9.10, 9.50)	40	9.40 (9.20, 9.60)
		Week 12	38	9.30 (9.10, 9.50)	37	9.30 (9.10, 9.60)	38	9.40 (9.10, 9.50)
クレアチンキナーゼ (U/L)	Mean (SD)	Baseline	40	125.6 (53.8)	40	119.1 (64.2)	41	123.3 (69.2)
		Week 1	39	121.6 (50.2)	40	120.9 (65.7)	41	122.9 (70.9)
		Week 2	40	131.5 (85.4)	38	120.6 (67.6)	39	118.0 (66.0)
		Week 4	40	131.3 (52.4)	38	129.2 (75.4)	40	118.4 (77.1)
		Week 12	38	133.6 (67.1)	37	118.4 (56.6)	38	117.6 (60.0)
	Median (25%, 75%)	Baseline	40	116.0 (91.0, 146.0)	40	101.5 (80.5, 131.0)	41	102.0 (83.0, 131.0)
		Week 1	39	115.0 (86.0, 144.0)	40	98.0 (78.5, 153.5)	41	104.0 (82.0, 136.0)
		Week 2	40	116.5 (87.0, 146.5)	38	105.0 (80.0, 145.0)	39	96.0 (79.0, 136.0)
		Week 4	40	127.5 (92.0, 164.0)	38	108.0 (78.0, 165.0)	40	100.0 (74.0, 127.5)
		Week 12	38	120.0 (94.0, 155.0)	37	95.0 (83.0, 137.0)	38	104.0 (78.0, 129.0)
HbA1c (%)	Mean (SD)	Baseline	40	5.85 (0.40)	40	5.90 (0.54)	41	5.76 (0.46)
		Week 1	39	5.82 (0.38)	40	5.88 (0.58)	41	5.75 (0.43)
		Week 2	40	5.79 (0.37)	38	5.86 (0.56)	39	5.78 (0.44)
		Week 4	40	5.81 (0.34)	38	5.87 (0.55)	40	5.74 (0.47)
		Week 12	38	5.79 (0.40)	37	5.84 (0.55)	38	5.71 (0.51)
	Median (25%, 75%)	Baseline	40	5.80 (5.60 , 6.00)	40	5.90 (5.50 , 6.10)	41	5.60 (5.50 , 5.90)
		Week 1	39	5.70 (5.60 , 6.10)	40	5.80 (5.60 , 6.10)	41	5.70 (5.50 , 6.00)
		Week 2	40	5.70 (5.50 , 5.90)	38	5.80 (5.60 , 6.10)	39	5.70 (5.50 , 6.00)
		Week 4	40	5.75 (5.50 , 5.95)	38	5.90 (5.50 , 6.10)	40	5.60 (5.50 , 5.95)
		Week 12	38	5.70 (5.50 , 6.00)	37	5.80 (5.50 , 6.00)	38	5.60 (5.40 , 5.80)

表 2.7.4.7-69. 臨床検査値の各項目の平均値と中央値：613/1022 試験

			Placebo N=89			SI-613 30 mg N=87		
Parameters		Timepoint	n	Value at timepoint	Change from baseline	n	Value at timepoint	Change from baseline
Leukocytes (/uL)	Mean (SD)	Baseline	89	5966.3 (1293.1)	-	87	6235.6 (1603.1)	-
		Week 2	85	5763.5 (1310.2)	-231.8 (794.2)	87	6106.9 (1547.2)	-128.7 (926.6)
		Week 4	83	5834.9 (1426.3)	-166.3 (1154.4)	86	6069.8 (1584.8)	-181.4 (966.4)
		Week 8	83	5769.9 (1338.3)	-231.3 (1021.8)	85	6020.0 (1643.7)	-252.9 (941.2)
		Week 12	81	5624.7 (1329.2)	-371.6 (911.5)	84	5920.2 (1400.2)	-351.2 (913.0)
		Week 24	81	5745.7 (1308.2)	-250.6 (950.4)	82	6086.6 (1637.9)	-184.1 (1073.2)
	Median (25%, 75%)	Baseline	89	6000.0 (5100.0, 6800.0)	-	87	6000.0 (5200.0, 6900.0)	-
		Week 2	85	5600.0 (4800.0, 6600.0)	-300.0 (-700.0, 300.0)	87	5900.0 (5100.0, 6800.0)	-100.0 (-600.0, 300.0)
		Week 4	83	5700.0 (5000.0, 6600.0)	-300.0 (-900.0, 600.0)	86	6100.0 (5100.0, 6900.0)	-200.0 (-700.0, 400.0)
		Week 8	83	5600.0 (5000.0, 6600.0)	-300.0 (-800.0, 300.0)	85	5900.0 (4900.0, 6800.0)	-200.0 (-900.0, 200.0)
		Week 12	81	5500.0 (4700.0, 6400.0)	-400.0 (-800.0, 0.0)	84	5800.0 (4950.0, 6750.0)	-300.0 (-850.0, 200.0)
		Week 24	81	5600.0 (4800.0, 6800.0)	-400.0 (-800.0, 300.0)	82	5800.0 (5100.0, 6700.0)	-200.0 (-700.0, 300.0)
Neutrophils/Leukocytes (%)	Mean (SD)	Baseline	89	56.84 (7.46)	-	87	57.09 (8.99)	-
		Week 2	85	55.43 (7.20)	-1.44 (5.07)	87	56.60 (8.19)	-0.49 (6.96)
		Week 4	83	54.83 (7.17)	-2.12 (5.72)	86	57.87 (7.87)	0.84 (7.49)
		Week 8	83	56.66 (7.58)	-0.29 (6.54)	85	56.27 (8.08)	-0.85 (6.88)
		Week 12	81	55.25 (6.99)	-1.77 (6.04)	84	56.50 (8.62)	-0.55 (7.02)
		Week 24	81	55.08 (7.21)	-1.95 (6.69)	82	56.56 (8.51)	-0.37 (7.30)
	Median (25%, 75%)	Baseline	89	58.00 (51.60, 62.60)	-	87	57.60 (52.50, 62.90)	-
		Week 2	85	55.50 (50.40, 59.90)	-0.70 (-4.10, 2.70)	87	56.50 (50.90, 61.90)	-0.70 (-5.60, 3.80)
		Week 4	83	54.30 (49.70, 61.00)	-2.10 (-5.00, 1.90)	86	58.50 (52.40, 63.40)	-0.25 (-3.10, 4.00)
		Week 8	83	56.90 (50.80, 61.20)	0.00 (-4.80, 4.60)	85	56.70 (50.40, 61.90)	-0.10 (-4.00, 2.60)
		Week 12	81	55.30 (49.60, 59.60)	-2.40 (-6.00, 2.80)	84	57.40 (50.00, 63.10)	-1.00 (-5.50, 4.45)
		Week 24	81	56.10 (50.30, 60.00)	-2.10 (-5.20, 2.20)	82	57.10 (50.80, 62.50)	0.10 (-3.80, 3.50)
Lymphocytes/Leukocytes (%)	Mean (SD)	Baseline	89	32.41 (6.99)	-	87	32.42 (8.47)	-
		Week 2	85	33.40 (6.57)	1.00 (4.49)	87	32.91 (7.90)	0.48 (6.02)
		Week 4	83	34.03 (6.40)	1.68 (4.89)	86	31.66 (7.40)	-0.91 (6.31)
		Week 8	83	32.47 (7.01)	0.12 (5.43)	85	32.97 (7.87)	0.47 (5.71)
		Week 12	81	33.82 (6.65)	1.55 (5.39)	84	33.05 (8.05)	0.50 (5.94)
		Week 24	81	33.62 (6.68)	1.36 (5.98)	82	33.03 (8.42)	0.41 (6.22)
	Median (25%, 75%)	Baseline	89	31.70 (27.20, 37.70)	-	87	33.10 (27.20, 37.00)	-
		Week 2	85	32.80 (28.60, 39.00)	0.40 (-1.70, 3.30)	87	32.60 (28.00, 38.10)	0.80 (-3.10, 4.30)
		Week 4	83	34.20 (29.10, 39.40)	1.80 (-1.70, 3.30)	86	31.10 (26.40, 37.40)	-0.60 (-3.70, 3.20)
		Week 8	83	32.40 (27.30, 38.00)	-0.30 (-3.30, 3.40)	85	33.00 (27.60, 37.00)	0.20 (-2.50, 3.80)
		Week 12	81	34.00 (29.20, 38.90)	1.40 (-2.50, 5.30)	84	31.45 (27.20, 38.65)	0.90 (-3.40, 4.50)
		Week 24	81	33.50 (28.50, 38.20)	0.60 (-1.40, 4.80)	82	32.00 (27.10, 38.00)	0.10 (-3.30, 3.40)
Monocytes/Leukocytes (%)	Mean (SD)	Baseline	89	7.18 (2.06)	-	87	7.30 (1.71)	-
		Week 2	85	7.26 (2.26)	0.16 (1.68)	87	7.03 (1.84)	-0.27 (1.38)
		Week 4	83	7.23 (2.09)	0.14 (1.49)	86	7.15 (1.94)	-0.10 (1.62)
		Week 8	83	7.08 (1.93)	-0.01 (1.31)	85	7.27 (1.92)	0.04 (1.49)
		Week 12	81	7.18 (2.05)	0.11 (1.68)	84	6.94 (1.99)	-0.31 (1.68)
		Week 24	81	7.46 (2.14)	0.39 (1.28)	82	7.27 (1.85)	-0.01 (1.53)
	Median (25%, 75%)	Baseline	89	7.00 (5.80, 8.60)	-	87	7.20 (5.80, 8.60)	-
		Week 2	85	6.90 (5.70, 8.40)	-0.10 (-0.90, 1.10)	87	7.00 (5.70, 8.00)	-0.20 (-1.20, 0.70)
		Week 4	83	7.00 (6.00, 8.30)	0.20 (-0.60, 0.90)	86	6.95 (5.70, 8.30)	-0.10 (-1.10, 0.80)
		Week 8	83	6.90 (6.00, 8.10)	-0.10 (-0.80, 0.90)	85	7.00 (6.00, 8.60)	0.00 (-0.80, 1.10)

Parameters		Timepoint	Placebo N=89 n	Value at timepoint	Change from baseline	SI-613 30 mg N=87 n	Value at timepoint	Change from baseline
		Week 12	81	6.90 (5.80, 8.40)	0.00 (-0.90, 1.20)	84	6.80 (5.50, 8.30)	-0.30 (-1.45, 0.90)
		Week 24	81	7.20 (6.20, 8.40)	0.40 (-0.60, 1.10)	82	7.10 (6.00, 8.40)	0.00 (-1.00, 1.10)
Eosinophils/Leukocytes (%)	Mean (SD)	Baseline	89	3.16 (2.13)	-	87	2.78 (2.21)	-
		Week 2	85	3.45 (2.68)	0.23 (1.51)	87	3.05 (2.57)	0.27 (1.32)
		Week 4	83	3.48 (2.59)	0.29 (1.78)	86	2.91 (2.63)	0.16 (1.58)
		Week 8	83	3.35 (2.44)	0.15 (1.79)	85	3.05 (2.37)	0.31 (1.56)
		Week 12	81	3.29 (2.41)	0.06 (1.69)	84	3.06 (2.33)	0.32 (1.36)
		Week 24	81	3.40 (2.21)	0.16 (1.63)	82	2.73 (2.18)	-0.04 (1.26)
	Median (25%, 75%)	Baseline	89	2.40 (1.70, 4.60)	-	87	2.20 (1.30, 3.20)	-
		Week 2	85	2.60 (1.70, 4.50)	0.00 (-0.60, 0.70)	87	2.30 (1.30, 3.90)	0.10 (-0.40, 0.90)
		Week 4	83	2.80 (1.70, 4.80)	0.10 (-0.50, 1.00)	86	2.05 (1.30, 3.70)	0.05 (-0.50, 0.60)
		Week 8	83	2.60 (1.70, 4.30)	0.10 (-0.80, 0.80)	85	2.50 (1.40, 4.00)	0.10 (-0.40, 1.00)
		Week 12	81	2.80 (1.90, 4.00)	0.00 (-0.90, 1.00)	84	2.55 (1.40, 4.05)	0.20 (-0.40, 1.00)
		Week 24	81	3.00 (2.00, 3.90)	0.30 (-0.60, 0.90)	82	2.00 (1.30, 3.20)	0.00 (-0.70, 0.50)
Basophils/Leukocytes (%)	Mean (SD)	Baseline	89	0.41 (0.23)	-	87	0.41 (0.30)	-
		Week 2	85	0.46 (0.28)	0.05 (0.35)	87	0.41 (0.30)	0.00 (0.42)
		Week 4	83	0.43 (0.23)	0.02 (0.33)	86	0.42 (0.22)	0.00 (0.40)
		Week 8	83	0.44 (0.26)	0.03 (0.32)	85	0.44 (0.20)	0.03 (0.37)
		Week 12	81	0.45 (0.40)	0.05 (0.44)	84	0.44 (0.26)	0.04 (0.40)
		Week 24	81	0.45 (0.30)	0.04 (0.34)	82	0.41 (0.22)	0.01 (0.37)
	Median (25%, 75%)	Baseline	89	0.40 (0.30, 0.50)	-	87	0.40 (0.20, 0.50)	-
		Week 2	85	0.40 (0.30, 0.50)	0.00 (-0.10, 0.20)	87	0.30 (0.20, 0.50)	0.00 (-0.20, 0.20)
		Week 4	83	0.40 (0.30, 0.50)	0.00 (-0.20, 0.20)	86	0.40 (0.30, 0.50)	0.10 (-0.20, 0.20)
		Week 8	83	0.40 (0.30, 0.50)	0.00 (-0.20, 0.20)	85	0.40 (0.30, 0.50)	0.10 (-0.10, 0.20)
		Week 12	81	0.40 (0.20, 0.60)	0.00 (-0.20, 0.20)	84	0.40 (0.30, 0.50)	0.00 (-0.15, 0.20)
		Week 24	81	0.40 (0.30, 0.60)	0.10 (-0.10, 0.20)	82	0.40 (0.30, 0.50)	0.10 (-0.10, 0.20)
Erythrocytes (10^4/uL)	Mean (SD)	Baseline	89	428.6 (42.0)	-	87	442.1 (40.8)	-
		Week 2	85	430.7 (39.7)	0.0 (18.8)	87	442.3 (39.9)	0.3 (17.6)
		Week 4	83	430.6 (41.9)	-0.3 (17.2)	86	438.8 (41.3)	-3.4 (17.5)
		Week 8	83	428.0 (40.0)	-2.8 (18.7)	85	436.5 (39.7)	-5.9 (18.9)
		Week 12	81	428.0 (41.8)	-2.9 (17.9)	84	437.0 (39.0)	-5.5 (17.8)
		Week 24	81	425.6 (42.1)	-5.2 (19.2)	82	439.6 (39.3)	-3.2 (21.7)
	Median (25%, 75%)	Baseline	89	431.0 (404.0, 448.0)	-	87	437.0 (411.0, 471.0)	-
		Week 2	85	431.0 (407.0, 451.0)	-2.0 (-10.0, 9.0)	87	436.0 (408.0, 473.0)	-1.0 (-12.0, 10.0)
		Week 4	83	434.0 (402.0, 451.0)	-1.0 (-10.0, 8.0)	86	431.0 (404.0, 473.0)	-6.0 (-14.0, 6.0)
		Week 8	83	430.0 (400.0, 449.0)	-3.0 (-15.0, 7.0)	85	436.0 (406.0, 466.0)	-8.0 (-17.0, 5.0)
		Week 12	81	430.0 (403.0, 447.0)	-2.0 (-14.0, 8.0)	84	433.0 (404.0, 470.0)	-5.0 (-18.0, 4.5)
		Week 24	81	425.0 (402.0, 455.0)	-6.0 (-19.0, 5.0)	82	433.0 (409.0, 472.0)	-4.0 (-16.0, 9.0)
Hemoglobin (g/dL)	Mean (SD)	Baseline	89	13.34 (1.26)	-	87	13.55 (1.30)	-
		Week 2	85	13.38 (1.19)	-0.02 (0.60)	87	13.54 (1.28)	-0.02 (0.56)
		Week 4	83	13.38 (1.23)	-0.02 (0.54)	86	13.42 (1.31)	-0.14 (0.53)
		Week 8	83	13.30 (1.18)	-0.10 (0.59)	85	13.36 (1.27)	-0.20 (0.56)
		Week 12	81	13.25 (1.21)	-0.15 (0.59)	84	13.35 (1.28)	-0.22 (0.50)
		Week 24	81	13.18 (1.22)	-0.22 (0.60)	82	13.46 (1.32)	-0.10 (0.67)
	Median (25%, 75%)	Baseline	89	13.30 (12.70, 14.00)	-	87	13.50 (12.70, 14.50)	-
		Week 2	85	13.40 (12.50, 14.00)	-0.10 (-0.30, 0.30)	87	13.40 (12.70, 14.40)	-0.10 (-0.40, 0.30)
		Week 4	83	13.20 (12.50, 14.10)	0.00 (-0.40, 0.30)	86	13.30 (12.60, 14.30)	-0.20 (-0.50, 0.20)
		Week 8	83	13.20 (12.50, 13.90)	-0.10 (-0.40, 0.20)	85	13.30 (12.60, 14.10)	-0.20 (-0.60, 0.10)
		Week 12	81	13.10 (12.60, 13.80)	-0.20 (-0.50, 0.30)	84	13.30 (12.40, 14.20)	-0.20 (-0.60, 0.10)
		Week 24	81	13.00 (12.50, 13.90)	-0.30 (-0.70, 0.10)	82	13.45 (12.60, 14.30)	-0.10 (-0.60, 0.30)
Hematocrit (%)	Mean (SD)	Baseline	89	39.69 (3.63)	-	87	40.27 (3.69)	-
		Week 2	85	39.79 (3.33)	-0.08 (1.62)	87	40.30 (3.65)	0.02 (1.60)
		Week 4	83	39.78 (3.53)	-0.12 (1.61)	86	39.94 (3.68)	-0.35 (1.67)

Parameters		Timepoint	Placebo N=89 n	Value at timepoint	Change from baseline	SI-613 30 mg N=87 n	Value at timepoint	Change from baseline
		Week 8	83	39.59 (3.38)	-0.31 (1.74)	85	39.75 (3.60)	-0.56 (1.61)
		Week 12	81	39.64 (3.52)	-0.25 (1.59)	84	39.90 (3.71)	-0.41 (1.56)
		Week 24	81	39.66 (3.58)	-0.23 (1.81)	82	40.35 (3.82)	0.03 (1.98)
	Median	Baseline	89	39.40 (37.80, 41.50)	-	87	39.80 (37.60, 42.70)	-
	(25%, 75%)	Week 2	85	39.50 (37.30, 41.90)	-0.10 (-1.00, 0.70)	87	39.80 (37.80, 43.00)	-0.20 (-1.00, 1.00)
		Week 4	83	39.40 (37.50, 41.70)	-0.40 (-1.10, 0.90)	86	39.30 (37.30, 42.50)	-0.50 (-1.50, 0.50)
		Week 8	83	39.40 (37.40, 41.30)	-0.20 (-1.50, 0.70)	85	39.50 (37.10, 41.80)	-0.80 (-1.50, 0.30)
		Week 12	81	39.50 (37.70, 41.10)	-0.40 (-1.50, 0.80)	84	39.35 (37.40, 42.00)	-0.50 (-1.55, 0.70)
		Week 24	81	39.30 (37.50, 41.40)	-0.40 (-1.40, 0.80)	82	40.45 (37.70, 42.90)	-0.05 (-1.00, 1.00)
Platelets	Mean (SD)	Baseline	88	22.56 (5.13)	-	87	23.45 (5.18)	-
(10^4/uL)		Week 2	85	22.23 (4.74)	-0.45 (2.52)	87	23.12 (5.70)	-0.33 (3.38)
		Week 4	83	22.58 (4.86)	-0.15 (2.36)	86	23.03 (5.04)	-0.46 (2.90)
		Week 8	83	22.33 (5.01)	-0.39 (2.69)	85	22.88 (4.94)	-0.55 (3.05)
		Week 12	81	22.44 (4.77)	-0.33 (2.34)	84	22.78 (4.89)	-0.58 (2.81)
		Week 24	81	22.52 (4.79)	-0.25 (2.57)	82	22.91 (5.08)	-0.37 (3.14)
	Median	Baseline	88	22.10 (18.75, 25.75)	-	87	22.80 (19.70, 26.80)	-
	(25%, 75%)	Week 2	85	21.80 (19.00, 26.10)	-0.45 (-1.65, 0.70)	87	22.10 (19.20, 26.00)	0.20 (-1.80, 0.90)
		Week 4	83	22.10 (19.20, 26.10)	0.00 (-1.80, 1.50)	86	22.80 (18.70, 26.30)	0.05 (-1.90, 1.40)
		Week 8	83	21.80 (18.80, 25.90)	-0.65 (-1.80, 1.00)	85	22.40 (19.20, 26.50)	-0.20 (-2.00, 1.00)
		Week 12	81	22.20 (19.10, 26.20)	-0.40 (-1.55, 0.60)	84	22.60 (19.40, 25.70)	-0.25 (-2.10, 1.15)
		Week 24	81	22.30 (19.20, 26.10)	0.05 (-2.05, 1.10)	82	22.70 (19.30, 26.00)	0.00 (-1.80, 1.70)
Protein (g/dL)	Mean (SD)	Baseline	89	7.12 (0.36)	-	87	7.08 (0.39)	-
		Week 2	85	7.06 (0.35)	-0.05 (0.27)	87	7.06 (0.34)	-0.02 (0.27)
		Week 4	83	7.08 (0.38)	-0.03 (0.30)	86	7.02 (0.37)	-0.06 (0.27)
		Week 8	83	7.05 (0.32)	-0.06 (0.27)	85	6.99 (0.38)	-0.10 (0.30)
		Week 12	81	7.04 (0.34)	-0.07 (0.24)	84	6.99 (0.33)	-0.10 (0.28)
		Week 24	81	6.98 (0.36)	-0.13 (0.31)	82	7.06 (0.38)	-0.04 (0.35)
	Median	Baseline	89	7.10 (6.90, 7.30)	-	87	7.00 (6.70, 7.30)	-
	(25%, 75%)	Week 2	85	7.00 (6.80, 7.30)	0.00 (-0.20, 0.10)	87	7.00 (6.80, 7.30)	0.00 (-0.20, 0.20)
		Week 4	83	7.00 (6.80, 7.40)	0.00 (-0.20, 0.20)	86	7.05 (6.80, 7.30)	-0.10 (-0.20, 0.10)
		Week 8	83	7.10 (6.90, 7.20)	0.00 (-0.20, 0.10)	85	7.00 (6.70, 7.20)	-0.10 (-0.30, 0.00)
		Week 12	81	7.10 (6.80, 7.30)	-0.10 (-0.20, 0.10)	84	6.95 (6.80, 7.20)	-0.10 (-0.30, 0.05)
		Week 24	81	6.90 (6.80, 7.30)	-0.20 (-0.40, 0.10)	82	7.00 (6.80, 7.40)	0.00 (-0.20, 0.10)
Albumin (g/dL)	Mean (SD)	Baseline	89	4.34 (0.24)	-	87	4.38 (0.22)	-
		Week 2	85	4.34 (0.24)	-0.01 (0.19)	87	4.38 (0.23)	0.00 (0.15)
		Week 4	83	4.34 (0.24)	0.00 (0.19)	86	4.35 (0.21)	-0.03 (0.19)
		Week 8	83	4.33 (0.24)	-0.01 (0.20)	85	4.34 (0.23)	-0.04 (0.19)
		Week 12	81	4.30 (0.23)	-0.03 (0.19)	84	4.33 (0.20)	-0.05 (0.18)
		Week 24	81	4.27 (0.22)	-0.07 (0.18)	82	4.31 (0.22)	-0.07 (0.19)
	Median	Baseline	89	4.40 (4.10, 4.50)	-	87	4.40 (4.20, 4.50)	-
	(25%, 75%)	Week 2	85	4.30 (4.20, 4.50)	0.00 (-0.10, 0.10)	87	4.40 (4.30, 4.60)	0.00 (-0.10, 0.10)
		Week 4	83	4.30 (4.20, 4.50)	0.00 (-0.10, 0.10)	86	4.30 (4.20, 4.50)	0.00 (-0.20, 0.10)
		Week 8	83	4.40 (4.20, 4.50)	0.00 (-0.10, 0.10)	85	4.30 (4.20, 4.50)	-0.10 (-0.20, 0.10)
		Week 12	81	4.30 (4.10, 4.50)	-0.10 (-0.10, 0.10)	84	4.30 (4.20, 4.50)	-0.10 (-0.15, 0.00)
		Week 24	81	4.30 (4.10, 4.40)	-0.10 (-0.20, 0.10)	82	4.30 (4.20, 4.50)	-0.10 (-0.20, 0.00)
Bilirubin (mg/dL)	Mean (SD)	Baseline	89	0.65 (0.19)	-	87	0.71 (0.42)	-
		Week 2	85	0.65 (0.23)	0.00 (0.18)	87	0.71 (0.28)	0.00 (0.30)
		Week 4	83	0.65 (0.23)	0.01 (0.18)	86	0.72 (0.36)	0.00 (0.26)
		Week 8	83	0.66 (0.22)	0.02 (0.19)	85	0.73 (0.35)	0.01 (0.22)
		Week 12	81	0.68 (0.23)	0.04 (0.19)	84	0.72 (0.47)	0.00 (0.20)
		Week 24	81	0.66 (0.21)	0.02 (0.22)	82	0.74 (0.35)	0.01 (0.23)
	Median	Baseline	89	0.60 (0.50, 0.80)	-	87	0.60 (0.50, 0.80)	-
	(25%, 75%)	Week 2	85	0.60 (0.50, 0.70)	0.00 (-0.10, 0.10)	87	0.70 (0.50, 0.80)	0.00 (-0.10, 0.10)

Parameters		Timepoint	Placebo N=89 n	Value at timepoint	Change from baseline	SI-613 30 mg N=87 n	Value at timepoint	Change from baseline
		Week 4	83	0.60 (0.50, 0.80)	0.00 (-0.10, 0.10)	86	0.70 (0.50, 0.80)	0.00 (-0.10, 0.10)
		Week 8	83	0.60 (0.50, 0.80)	0.00 (-0.10, 0.10)	85	0.60 (0.50, 0.90)	0.00 (-0.10, 0.10)
		Week 12	81	0.70 (0.50, 0.80)	0.00 (-0.10, 0.10)	84	0.60 (0.50, 0.80)	0.00 (-0.10, 0.10)
		Week 24	81	0.60 (0.50, 0.80)	0.00 (-0.10, 0.10)	82	0.70 (0.50, 0.90)	0.00 (-0.10, 0.10)
Direct Bilirubin (mg/dL)	Mean (SD)	Baseline	89	0.10 (0.06)	-	87	0.12 (0.07)	-
		Week 2	85	0.10 (0.05)	0.01 (0.05)	87	0.11 (0.06)	0.00 (0.06)
		Week 4	83	0.11 (0.05)	0.01 (0.05)	86	0.12 (0.08)	0.00 (0.06)
		Week 8	83	0.10 (0.05)	0.01 (0.05)	85	0.12 (0.07)	0.00 (0.05)
		Week 12	81	0.11 (0.05)	0.01 (0.05)	84	0.13 (0.09)	0.01 (0.06)
		Week 24	81	0.10 (0.05)	0.01 (0.06)	82	0.12 (0.06)	0.00 (0.05)
	Median (25%, 75%)	Baseline	89	0.10 (0.10, 0.10)	-	87	0.10 (0.10, 0.10)	-
		Week 2	85	0.10 (0.10, 0.10)	0.00 (0.00, 0.00)	87	0.10 (0.10, 0.10)	0.00 (0.00, 0.00)
		Week 4	83	0.10 (0.10, 0.10)	0.00 (0.00, 0.00)	86	0.10 (0.10, 0.10)	0.00 (0.00, 0.00)
		Week 8	83	0.10 (0.10, 0.10)	0.00 (0.00, 0.00)	85	0.10 (0.10, 0.10)	0.00 (0.00, 0.00)
		Week 12	81	0.10 (0.10, 0.10)	0.00 (0.00, 0.00)	84	0.10 (0.10, 0.10)	0.00 (0.00, 0.00)
		Week 24	81	0.10 (0.10, 0.10)	0.00 (0.00, 0.00)	82	0.10 (0.10, 0.10)	0.00 (0.00, 0.00)
Aspartate Aminotransferase (U/L)	Mean (SD)	Baseline	89	24.7 (9.6)	-	87	23.9 (7.9)	-
		Week 2	85	24.2 (10.6)	0.3 (6.5)	87	23.2 (6.7)	-0.8 (4.9)
		Week 4	83	23.4 (6.1)	-0.6 (3.6)	86	23.4 (7.5)	-0.4 (4.8)
		Week 8	83	23.1 (5.3)	-0.8 (4.4)	85	22.8 (6.4)	-1.0 (4.9)
		Week 12	81	23.2 (5.1)	-0.9 (5.0)	84	23.0 (7.0)	-0.8 (5.8)
		Week 24	81	23.4 (5.7)	-0.7 (6.1)	82	23.9 (7.3)	0.1 (4.8)
	Median (25%, 75%)	Baseline	89	22.0 (20.0, 27.0)	-	87	22.0 (19.0, 26.0)	-
		Week 2	85	23.0 (20.0, 26.0)	-1.0 (-2.0, 1.0)	87	22.0 (19.0, 26.0)	0.0 (-2.0, 2.0)
		Week 4	83	22.0 (20.0, 25.0)	0.0 (-2.0, 1.0)	86	22.0 (19.0, 26.0)	-0.5 (-2.0, 2.0)
		Week 8	83	22.0 (20.0, 25.0)	0.0 (-2.0, 1.0)	85	22.0 (19.0, 25.0)	0.0 (-3.0, 1.0)
		Week 12	81	22.0 (20.0, 26.0)	-1.0 (-3.0, 2.0)	84	22.0 (19.0, 24.0)	-0.5 (-2.0, 2.0)
		Week 24	81	22.0 (20.0, 26.0)	0.0 (-3.0, 2.0)	82	22.5 (19.0, 26.0)	1.0 (-2.0, 3.0)
Alanine Aminotransferase (U/L)	Mean (SD)	Baseline	89	20.6 (12.8)	-	87	20.2 (12.0)	-
		Week 2	85	19.4 (10.2)	-0.5 (5.1)	87	19.5 (11.0)	-0.7 (6.2)
		Week 4	83	19.8 (10.5)	-0.1 (6.8)	86	19.8 (12.2)	-0.4 (6.9)
		Week 8	83	19.7 (10.4)	-0.2 (6.5)	85	18.7 (11.1)	-1.5 (6.4)
		Week 12	81	19.6 (9.1)	-0.5 (7.3)	84	18.9 (10.0)	-1.3 (7.1)
		Week 24	81	19.5 (10.3)	-0.6 (7.8)	82	20.1 (12.2)	0.0 (6.8)
	Median (25%, 75%)	Baseline	89	17.0 (14.0, 22.0)	-	87	17.0 (13.0, 23.0)	-
		Week 2	85	17.0 (13.0, 22.0)	0.0 (-2.0, 2.0)	87	17.0 (14.0, 22.0)	0.0 (-2.0, 2.0)
		Week 4	83	17.0 (13.0, 23.0)	0.0 (-2.0, 1.0)	86	17.0 (13.0, 20.0)	0.0 (-3.0, 3.0)
		Week 8	83	17.0 (13.0, 23.0)	-1.0 (-2.0, 1.0)	85	17.0 (13.0, 21.0)	0.0 (-3.0, 2.0)
		Week 12	81	18.0 (14.0, 22.0)	0.0 (-3.0, 2.0)	84	17.0 (14.0, 21.0)	0.0 (-3.0, 1.5)
		Week 24	81	18.0 (14.0, 22.0)	0.0 (-2.0, 2.0)	82	17.5 (14.0, 22.0)	0.0 (-3.0, 4.0)
Lactate Dehydrogenase (U/L)	Mean (SD)	Baseline	89	185.2 (32.8)	-	87	188.0 (29.3)	-
		Week 2	85	182.0 (30.3)	-1.4 (16.2)	87	188.6 (29.5)	0.6 (17.1)
		Week 4	83	183.1 (30.8)	-0.3 (17.5)	86	186.9 (30.1)	-1.1 (17.4)
		Week 8	83	183.1 (29.3)	-0.4 (16.1)	85	187.8 (32.6)	-0.2 (25.1)
		Week 12	81	181.2 (28.6)	-2.5 (15.2)	84	185.6 (28.3)	-1.7 (16.8)
		Week 24	81	182.3 (30.8)	-1.4 (17.2)	82	187.8 (31.3)	0.9 (18.6)
	Median (25%, 75%)	Baseline	89	181.0 (160.0, 205.0)	-	87	189.0 (169.0, 204.0)	-
		Week 2	85	177.0 (159.0, 203.0)	-3.0 (-10.0, 4.0)	87	187.0 (170.0, 208.0)	2.0 (-9.0, 12.0)
		Week 4	83	178.0 (162.0, 199.0)	-3.0 (-10.0, 11.0)	86	184.0 (168.0, 203.0)	0.0 (-13.0, 8.0)
		Week 8	83	178.0 (160.0, 202.0)	0.0 (-11.0, 7.0)	85	186.0 (169.0, 206.0)	-2.0 (-13.0, 8.0)
		Week 12	81	179.0 (160.0, 198.0)	-1.0 (-13.0, 6.0)	84	184.0 (168.5, 202.0)	-1.0 (-12.0, 10.0)
		Week 24	81	181.0 (159.0, 197.0)	-2.0 (-12.0, 9.0)	82	185.0 (169.0, 211.0)	0.5 (-11.0, 10.0)
	Mean (SD)	Baseline	89	236.5 (76.0)	-	87	233.5 (66.2)	-

Parameters		Timepoint	Placebo N=89 n	Placebo N=89 Value at timepoint	Placebo N=89 Change from baseline	SI-613 30 mg N=87 n	SI-613 30 mg N=87 Value at timepoint	SI-613 30 mg N=87 Change from baseline
Alkaline		Week 2	85	236.4 (70.0)	-1.0 (33.3)	87	233.7 (60.4)	0.2 (32.2)
Phosphatase (U/L)		Week 4	83	234.3 (69.4)	-4.0 (30.0)	86	228.3 (66.9)	-3.6 (30.5)
		Week 8	83	236.5 (80.4)	-1.8 (37.3)	85	226.6 (62.8)	-5.9 (29.1)
		Week 12	81	234.3 (74.8)	-5.6 (33.1)	84	227.7 (60.6)	-4.7 (30.1)
		Week 24	81	235.1 (82.7)	-4.8 (46.2)	82	231.3 (60.9)	-2.1 (38.9)
	Median	Baseline	89	227.0 (184.0, 280.0)	-	87	222.0 (181.0, 283.0)	-
	(25%, 75%)	Week 2	85	226.0 (188.0, 268.0)	0.0 (-15.0, 21.0)	87	229.0 (182.0, 275.0)	0.0 (-13.0, 10.0)
		Week 4	83	228.0 (174.0, 272.0)	-4.0 (-20.0, 13.0)	86	221.5 (174.0, 259.0)	-0.5 (-15.0, 5.0)
		Week 8	83	231.0 (165.0, 284.0)	-1.0 (-21.0, 15.0)	85	217.0 (182.0, 268.0)	-2.0 (-22.0, 10.0)
		Week 12	81	226.0 (181.0, 272.0)	2.0 (-23.0, 12.0)	84	219.5 (178.5, 265.5)	-0.5 (-20.0, 10.5)
		Week 24	81	231.0 (176.0, 271.0)	0.0 (-26.0, 18.0)	82	233.0 (185.0, 272.0)	-3.5 (-19.0, 18.0)
Gamma Glutamyl	Mean (SD)	Baseline	89	42.8 (169.1)	-	87	30.0 (20.7)	-
Transferase (U/L)		Week 2	85	24.6 (17.5)	-0.8 (8.7)	87	29.3 (19.2)	-0.7 (8.5)
		Week 4	83	25.4 (19.2)	0.0 (8.9)	86	28.9 (19.4)	-0.7 (9.6)
		Week 8	83	25.9 (20.2)	0.4 (8.6)	85	30.3 (26.4)	0.5 (15.1)
		Week 12	81	24.5 (18.7)	-1.0 (8.9)	84	28.8 (17.6)	-1.2 (12.8)
		Week 24	81	25.7 (23.0)	0.2 (12.6)	82	28.9 (17.7)	-1.1 (16.7)
	Median	Baseline	89	19.0 (13.0, 30.0)	-	87	23.0 (18.0, 35.0)	-
	(25%, 75%)	Week 2	85	20.0 (13.0, 27.0)	0.0 (-2.0, 2.0)	87	23.0 (17.0, 33.0)	0.0 (-3.0, 2.0)
		Week 4	83	19.0 (14.0, 29.0)	0.0 (-2.0, 2.0)	86	22.5 (17.0, 34.0)	-1.0 (-4.0, 3.0)
		Week 8	83	19.0 (13.0, 29.0)	0.0 (-2.0, 2.0)	85	23.0 (17.0, 32.0)	0.0 (-3.0, 3.0)
		Week 12	81	19.0 (13.0, 29.0)	0.0 (-2.0, 1.0)	84	24.5 (17.0, 32.5)	0.0 (-4.0, 2.5)
		Week 24	81	19.0 (13.0, 29.0)	0.0 (-2.0, 2.0)	82	24.5 (17.0, 32.0)	0.0 (-4.0, 4.0)
Urate (mg/dL)	Mean (SD)	Baseline	89	5.06 (1.27)	-	87	5.03 (1.19)	-
		Week 2	85	5.08 (1.24)	-0.02 (0.50)	87	5.15 (1.25)	0.12 (0.64)
		Week 4	83	5.17 (1.36)	0.04 (0.65)	86	5.07 (1.16)	0.01 (0.62)
		Week 8	83	5.15 (1.25)	0.02 (0.64)	85	5.10 (1.08)	0.04 (0.55)
		Week 12	81	5.20 (1.35)	0.10 (0.75)	84	5.08 (1.18)	0.02 (0.78)
		Week 24	81	5.26 (1.28)	0.16 (0.69)	82	5.33 (1.38)	0.25 (0.87)
	Median	Baseline	89	4.70 (4.20, 5.70)	-	87	4.90 (4.30, 5.80)	-
	(25%, 75%)	Week 2	85	4.80 (4.40, 5.80)	0.00 (-0.30, 0.30)	87	5.10 (4.30, 6.00)	0.10 (-0.20, 0.60)
		Week 4	83	5.00 (4.20, 5.80)	0.00 (-0.40, 0.40)	86	4.95 (4.30, 5.80)	0.05 (-0.40, 0.30)
		Week 8	83	4.90 (4.30, 5.90)	0.00 (-0.30, 0.30)	85	5.00 (4.50, 5.70)	0.10 (-0.30, 0.40)
		Week 12	81	5.00 (4.30, 5.70)	0.10 (-0.20, 0.50)	84	4.85 (4.20, 5.85)	0.10 (-0.50, 0.60)
		Week 24	81	5.00 (4.40, 6.10)	0.20 (-0.30, 0.50)	82	5.10 (4.40, 5.80)	0.30 (-0.30, 0.60)
Blood Urea	Mean (SD)	Baseline	89	15.5 (3.3)	-	87	15.1 (4.1)	-
Nitrogen (mg/dL)		Week 2	85	15.8 (3.5)	0.3 (2.9)	87	15.3 (3.6)	0.2 (3.5)
		Week 4	83	15.8 (3.3)	0.2 (3.4)	86	15.0 (3.9)	-0.2 (3.1)
		Week 8	83	15.9 (3.4)	0.3 (3.2)	85	15.2 (3.7)	0.0 (2.9)
		Week 12	81	15.5 (3.2)	0.0 (3.1)	84	15.4 (3.6)	0.3 (3.2)
		Week 24	81	15.7 (3.1)	0.2 (2.8)	82	15.3 (3.9)	0.2 (3.4)
	Median	Baseline	89	15.0 (14.0, 17.0)	-	87	15.0 (12.0, 17.0)	-
	(25%, 75%)	Week 2	85	16.0 (14.0, 18.0)	0.0 (-1.0, 2.0)	87	15.0 (13.0, 17.0)	0.0 (-2.0, 3.0)
		Week 4	83	16.0 (14.0, 18.0)	0.0 (-2.0, 3.0)	86	14.0 (13.0, 18.0)	0.0 (-2.0, 2.0)
		Week 8	83	16.0 (14.0, 18.0)	1.0 (-2.0, 2.0)	85	15.0 (12.0, 17.0)	0.0 (-1.0, 2.0)
		Week 12	81	16.0 (13.0, 17.0)	0.0 (-2.0, 2.0)	84	15.0 (12.5, 18.0)	1.0 (-2.0, 2.0)
		Week 24	81	15.0 (14.0, 18.0)	0.0 (-1.0, 2.0)	82	15.0 (13.0, 17.0)	0.0 (-2.0, 2.0)
Creatinine	Mean (SD)	Baseline	89	0.662 (0.131)	-	87	0.681 (0.155)	-
(mg/dL)		Week 2	85	0.665 (0.127)	0.002 (0.049)	87	0.689 (0.145)	0.008 (0.073)
		Week 4	83	0.668 (0.131)	0.001 (0.051)	86	0.687 (0.153)	0.003 (0.070)
		Week 8	83	0.668 (0.133)	0.002 (0.058)	85	0.688 (0.142)	0.003 (0.058)
		Week 12	81	0.674 (0.123)	0.012 (0.055)	84	0.690 (0.153)	0.003 (0.073)
		Week 24	81	0.675 (0.127)	0.013 (0.052)	82	0.697 (0.154)	0.010 (0.084)

Parameters		Timepoint	Placebo N=89 n	Value at timepoint	Change from baseline	SI-613 30 mg N=87 n	Value at timepoint	Change from baseline
	Median	Baseline	89	0.660 (0.570, 0.740)	-	87	0.660 (0.560, 0.780)	-
	(25%, 75%)	Week 2	85	0.660 (0.580, 0.750)	0.010 (-0.030, 0.030)	87	0.660 (0.590, 0.760)	0.000 (-0.020, 0.050)
		Week 4	83	0.650 (0.580, 0.750)	0.000 (-0.020, 0.030)	86	0.660 (0.570, 0.780)	0.000 (-0.030, 0.040)
		Week 8	83	0.650 (0.580, 0.740)	0.000 (-0.040, 0.030)	85	0.660 (0.590, 0.780)	0.000 (-0.030, 0.040)
		Week 12	81	0.680 (0.600, 0.730)	0.010 (-0.020, 0.050)	84	0.670 (0.580, 0.755)	0.010 (-0.030, 0.050)
		Week 24	81	0.660 (0.600, 0.750)	0.020 (-0.020, 0.040)	82	0.675 (0.570, 0.790)	0.010 (-0.030, 0.050)
Cholesterol	Mean (SD)	Baseline	89	213.1 (35.0)	-	87	210.0 (35.6)	-
(mg/dL)		Week 2	85	212.7 (33.8)	-1.2 (18.0)	87	208.4 (32.0)	-1.6 (19.5)
		Week 4	83	215.7 (35.3)	1.0 (21.4)	86	207.8 (29.4)	-2.7 (22.3)
		Week 8	83	210.0 (33.6)	-4.7 (20.7)	85	207.3 (30.6)	-3.0 (21.2)
		Week 12	81	212.2 (31.8)	-2.6 (20.7)	84	209.2 (27.7)	-1.3 (23.8)
		Week 24	81	209.0 (34.1)	-5.9 (20.6)	82	212.0 (34.5)	2.0 (20.4)
	Median	Baseline	89	208.0 (190.0, 229.0)	-	87	205.0 (189.0, 230.0)	-
	(25%, 75%)	Week 2	85	208.0 (191.0, 232.0)	-4.0 (-13.0, 10.0)	87	203.0 (185.0, 225.0)	1.0 (-14.0, 12.0)
		Week 4	83	215.0 (192.0, 232.0)	0.0 (-11.0, 12.0)	86	205.5 (188.0, 227.0)	-2.0 (-12.0, 9.0)
		Week 8	83	205.0 (184.0, 233.0)	-5.0 (-21.0, 10.0)	85	204.0 (187.0, 225.0)	-1.0 (-14.0, 10.0)
		Week 12	81	215.0 (195.0, 228.0)	-4.0 (-14.0, 11.0)	84	209.0 (188.5, 228.0)	0.0 (-13.5, 10.5)
		Week 24	81	206.0 (183.0, 227.0)	-8.0 (-19.0, 8.0)	82	202.0 (188.0, 238.0)	0.0 (-13.0, 12.0)
Triglycerides	Mean (SD)	Baseline	89	152.1 (96.4)	-	87	156.5 (111.7)	-
(mg/dL)		Week 2	85	154.3 (90.7)	0.5 (93.4)	87	161.2 (102.6)	4.7 (81.3)
		Week 4	83	142.8 (79.7)	-12.1 (70.4)	86	163.3 (129.7)	5.5 (73.7)
		Week 8	83	146.8 (90.0)	-8.1 (78.2)	85	148.5 (92.5)	-7.3 (65.0)
		Week 12	81	152.5 (84.2)	-1.2 (79.9)	84	170.5 (115.7)	13.3 (86.0)
		Week 24	81	150.1 (74.3)	-3.6 (71.3)	82	176.5 (134.6)	18.6 (89.4)
	Median	Baseline	89	129.0 (92.0, 188.0)	-	87	126.0 (86.0, 181.0)	-
	(25%, 75%)	Week 2	85	137.0 (99.0, 184.0)	5.0 (-26.0, 37.0)	87	129.0 (89.0, 199.0)	6.0 (-26.0, 38.0)
		Week 4	83	126.0 (83.0, 182.0)	-7.0 (-29.0, 22.0)	86	127.5 (87.0, 183.0)	-5.5 (-28.0, 45.0)
		Week 8	83	126.0 (85.0, 172.0)	-4.0 (-36.0, 29.0)	85	128.0 (91.0, 160.0)	-3.0 (-33.0, 34.0)
		Week 12	81	129.0 (96.0, 189.0)	1.0 (-25.0, 30.0)	84	135.0 (98.0, 190.0)	7.0 (-26.0, 47.5)
		Week 24	81	134.0 (94.0, 175.0)	3.0 (-30.0, 24.0)	82	129.0 (99.0, 215.0)	17.0 (-33.0, 65.0)
C Reactive	Mean (SD)	Baseline	89	0.21 (0.49)	-	87	0.13 (0.24)	-
Protein (mg/dL)		Week 2	85	0.12 (0.18)	-0.09 (0.47)	87	0.11 (0.15)	-0.02 (0.27)
		Week 4	83	0.13 (0.29)	-0.08 (0.32)	86	0.10 (0.12)	-0.03 (0.25)
		Week 8	83	0.15 (0.19)	-0.06 (0.44)	85	0.13 (0.20)	-0.01 (0.29)
		Week 12	81	0.11 (0.18)	-0.10 (0.43)	84	0.13 (0.26)	-0.01 (0.35)
		Week 24	81	0.13 (0.17)	-0.08 (0.47)	82	0.13 (0.17)	-0.01 (0.29)
	Median	Baseline	89	0.10 (0.00, 0.20)	-	87	0.10 (0.00, 0.10)	-
	(25%, 75%)	Week 2	85	0.10 (0.00, 0.10)	0.00 (-0.10, 0.00)	87	0.10 (0.00, 0.20)	0.00 (0.00, 0.10)
		Week 4	83	0.10 (0.00, 0.10)	0.00 (-0.10, 0.00)	86	0.10 (0.00, 0.20)	0.00 (0.00, 0.00)
		Week 8	83	0.10 (0.00, 0.20)	0.00 (0.00, 0.00)	85	0.10 (0.00, 0.10)	0.00 (0.00, 0.00)
		Week 12	81	0.10 (0.00, 0.10)	0.00 (-0.10, 0.00)	84	0.10 (0.00, 0.10)	0.00 (-0.10, 0.00)
		Week 24	81	0.10 (0.00, 0.10)	0.00 (0.00, 0.00)	82	0.10 (0.00, 0.10)	0.00 (0.00, 0.10)
Sodium (mEq/L)	Mean (SD)	Baseline	89	142.2 (2.1)	-	87	142.5 (2.2)	-
		Week 2	85	141.9 (2.0)	-0.3 (2.2)	87	142.1 (1.9)	-0.4 (2.2)
		Week 4	83	141.9 (1.7)	-0.3 (2.0)	86	141.9 (1.8)	-0.6 (2.1)
		Week 8	83	141.9 (1.7)	-0.4 (1.7)	85	141.9 (1.6)	-0.6 (2.0)
		Week 12	81	141.6 (1.6)	-0.6 (1.7)	84	142.0 (1.5)	-0.5 (2.1)
		Week 24	81	141.7 (1.9)	-0.6 (1.9)	82	141.5 (1.5)	-1.0 (1.8)
	Median	Baseline	89	142.0 (141.0, 143.0)	-	87	142.0 (141.0, 144.0)	-
	(25%, 75%)	Week 2	85	142.0 (141.0, 143.0)	0.0 (-1.0, 1.0)	87	142.0 (141.0, 143.0)	0.0 (-1.0, 1.0)
		Week 4	83	142.0 (141.0, 143.0)	0.0 (-1.0, 1.0)	86	142.0 (141.0, 143.0)	0.0 (-2.0, 1.0)
		Week 8	83	142.0 (141.0, 143.0)	0.0 (-1.0, 1.0)	85	142.0 (141.0, 143.0)	-1.0 (-2.0, 1.0)
		Week 12	81	142.0 (141.0, 142.0)	0.0 (-2.0, 1.0)	84	142.0 (141.0, 143.0)	0.0 (-2.0, 1.0)

Parameters		Timepoint	Placebo N=89 n	Value at timepoint	Change from baseline	SI-613 30 mg N=87 n	Value at timepoint	Change from baseline
		Week 24	81	141.0 (141.0, 143.0)	-1.0 (-2.0, 1.0)	82	141.0 (140.0, 142.0)	-1.0 (-2.0, 0.0)
Potassium (mEq/L)	Mean (SD)	Baseline	89	4.19 (0.35)	-	87	4.15 (0.33)	-
		Week 2	85	4.18 (0.33)	-0.02 (0.31)	87	4.13 (0.35)	-0.02 (0.24)
		Week 4	83	4.17 (0.37)	-0.03 (0.33)	86	4.12 (0.34)	-0.03 (0.28)
		Week 8	83	4.19 (0.36)	-0.01 (0.38)	85	4.13 (0.33)	-0.02 (0.28)
		Week 12	81	4.19 (0.31)	0.00 (0.31)	84	4.09 (0.34)	-0.06 (0.34)
		Week 24	81	4.17 (0.37)	-0.02 (0.36)	82	4.11 (0.33)	-0.03 (0.29)
	Median (25%, 75%)	Baseline	89	4.10 (4.00, 4.30)	-	87	4.10 (3.90, 4.40)	-
		Week 2	85	4.20 (4.00, 4.40)	0.00 (-0.20, 0.20)	87	4.10 (3.90, 4.30)	0.00 (-0.20, 0.10)
		Week 4	83	4.10 (3.90, 4.40)	0.00 (-0.20, 0.10)	86	4.10 (3.90, 4.30)	0.00 (-0.20, 0.20)
		Week 8	83	4.20 (3.90, 4.40)	-0.10 (-0.30, 0.20)	85	4.10 (3.90, 4.30)	0.00 (-0.20, 0.20)
		Week 12	81	4.20 (4.00, 4.30)	0.00 (-0.20, 0.20)	84	4.10 (3.90, 4.30)	0.00 (-0.30, 0.10)
		Week 24	81	4.20 (4.00, 4.40)	0.00 (-0.20, 0.20)	82	4.10 (3.90, 4.30)	-0.05 (-0.20, 0.20)
Chloride (mEq/L)	Mean (SD)	Baseline	89	104.3 (1.9)	-	87	104.5 (2.4)	-
		Week 2	85	104.0 (2.1)	-0.3 (2.0)	87	104.1 (1.9)	-0.4 (2.0)
		Week 4	83	104.0 (2.0)	-0.3 (1.8)	86	104.2 (2.2)	-0.3 (2.0)
		Week 8	83	104.0 (1.9)	-0.3 (1.9)	85	104.2 (1.9)	-0.3 (2.1)
		Week 12	81	103.7 (1.9)	-0.7 (1.7)	84	104.2 (1.9)	-0.3 (2.1)
		Week 24	81	104.0 (1.9)	-0.3 (2.0)	82	103.5 (2.0)	-0.9 (1.9)
	Median (25%, 75%)	Baseline	89	105.0 (103.0, 106.0)	-	87	104.0 (103.0, 106.0)	-
		Week 2	85	104.0 (103.0, 106.0)	0.0 (-2.0, 1.0)	87	104.0 (103.0, 105.0)	0.0 (-2.0, 1.0)
		Week 4	83	104.0 (102.0, 106.0)	0.0 (-1.0, 1.0)	86	104.0 (102.0, 106.0)	0.0 (-1.0, 1.0)
		Week 8	83	104.0 (103.0, 105.0)	0.0 (-1.0, 1.0)	85	104.0 (103.0, 105.0)	0.0 (-1.0, 1.0)
		Week 12	81	104.0 (102.0, 105.0)	-1.0 (-2.0, 0.0)	84	104.0 (103.0, 105.0)	0.0 (-1.5, 1.0)
		Week 24	81	105.0 (102.0, 105.0)	0.0 (-1.0, 1.0)	82	103.0 (102.0, 105.0)	-1.0 (-2.0, 0.0)
Calcium (mg/dL)	Mean (SD)	Baseline	89	9.20 (0.31)	-	87	9.22 (0.34)	-
		Week 2	85	9.19 (0.33)	-0.01 (0.26)	87	9.26 (0.37)	0.05 (0.32)
		Week 4	83	9.22 (0.35)	0.01 (0.29)	86	9.22 (0.33)	-0.01 (0.29)
		Week 8	83	9.21 (0.33)	0.00 (0.30)	85	9.22 (0.31)	-0.01 (0.30)
		Week 12	81	9.21 (0.38)	0.01 (0.31)	84	9.21 (0.29)	-0.02 (0.25)
		Week 24	81	9.18 (0.33)	-0.02 (0.31)	82	9.24 (0.36)	0.01 (0.32)
	Median (25%, 75%)	Baseline	89	9.20 (9.00, 9.40)	-	87	9.20 (9.00, 9.40)	-
		Week 2	85	9.20 (9.00, 9.50)	0.00 (-0.20, 0.20)	87	9.20 (9.00, 9.50)	0.00 (-0.20, 0.20)
		Week 4	83	9.20 (9.00, 9.50)	0.00 (-0.20, 0.20)	86	9.20 (9.00, 9.40)	0.00 (-0.20, 0.20)
		Week 8	83	9.20 (9.00, 9.40)	0.00 (-0.20, 0.20)	85	9.20 (9.00, 9.30)	0.00 (-0.20, 0.20)
		Week 12	81	9.20 (9.00, 9.40)	0.00 (-0.20, 0.10)	84	9.20 (9.10, 9.40)	0.00 (-0.20, 0.10)
		Week 24	81	9.20 (8.90, 9.40)	0.00 (-0.20, 0.20)	82	9.20 (9.00, 9.40)	0.00 (-0.20, 0.20)
Creatine Kinase (U/L)	Mean (SD)	Baseline	89	115.6 (68.3)	-	87	120.2 (60.7)	-
		Week 2	85	111.4 (59.8)	-2.1 (45.8)	87	125.0 (69.8)	4.8 (62.3)
		Week 4	83	111.3 (67.4)	-2.2 (46.0)	86	120.9 (67.2)	0.2 (49.4)
		Week 8	83	118.4 (84.8)	5.0 (74.0)	85	121.3 (56.5)	0.0 (52.1)
		Week 12	81	104.8 (54.4)	-9.4 (35.7)	84	120.0 (68.9)	-0.7 (57.0)
		Week 24	81	114.2 (68.6)	0.0 (43.5)	82	114.8 (52.5)	-5.2 (43.5)
	Median (25%, 75%)	Baseline	89	97.0 (77.0, 129.0)	-	87	100.0 (75.0, 150.0)	-
		Week 2	85	99.0 (72.0, 128.0)	-2.0 (-17.0, 10.0)	87	106.0 (77.0, 161.0)	3.0 (-8.0, 19.0)
		Week 4	83	95.0 (68.0, 135.0)	-5.0 (-19.0, 10.0)	86	102.5 (77.0, 147.0)	2.5 (-13.0, 14.0)
		Week 8	83	98.0 (71.0, 133.0)	1.0 (-16.0, 18.0)	85	109.0 (79.0, 153.0)	1.0 (-19.0, 16.0)
		Week 12	81	88.0 (70.0, 118.0)	-5.0 (-19.0, 6.0)	84	94.5 (77.0, 160.5)	-2.5 (-19.5, 16.5)
		Week 24	81	99.0 (72.0, 129.0)	-2.0 (-15.0, 13.0)	82	104.0 (81.0, 137.0)	-0.5 (-22.0, 17.0)
Hemoglobin A1C/Hemoglobin (%)	Mean (SD)	Baseline	89	5.76 (0.81)	-	87	5.72 (0.75)	-
		Week 2	85	5.73 (0.78)	0.00 (0.14)	87	5.75 (0.74)	0.03 (0.18)
		Week 4	83	5.73 (0.76)	0.02 (0.17)	86	5.76 (0.73)	0.03 (0.18)
		Week 8	83	5.74 (0.72)	0.03 (0.21)	85	5.75 (0.75)	0.01 (0.25)

Parameters		Timepoint	Placebo N=89 n	Value at timepoint	Change from baseline	SI-613 30 mg N=87 n	Value at timepoint	Change from baseline
		Week 12	81	5.70 (0.65)	-0.01 (0.27)	84	5.72 (0.72)	-0.01 (0.29)
		Week 24	81	5.68 (0.59)	-0.03 (0.32)	82	5.71 (0.70)	-0.02 (0.51)
	Median	Baseline	89	5.50 (5.30, 5.90)	-	87	5.50 (5.30, 5.90)	-
	(25%, 75%)	Week 2	85	5.50 (5.30, 5.90)	0.00 (-0.10, 0.10)	87	5.60 (5.30, 5.90)	0.00 (-0.10, 0.20)
		Week 4	83	5.50 (5.30, 6.00)	0.00 (-0.10, 0.10)	86	5.60 (5.30, 5.90)	0.00 (-0.10, 0.10)
		Week 8	83	5.50 (5.40, 5.80)	0.00 (-0.10, 0.20)	85	5.60 (5.40, 5.90)	0.00 (-0.10, 0.10)
		Week 12	81	5.50 (5.30, 5.90)	0.00 (-0.10, 0.20)	84	5.50 (5.35, 5.90)	0.00 (-0.20, 0.10)
		Week 24	81	5.50 (5.30, 5.90)	0.00 (-0.10, 0.10)	82	5.60 (5.40, 5.90)	0.00 (-0.10, 0.10)

〔5.3.5.1-2 Table 14.3.4-1 改編〕

表 2.7.4.7-70. 臨床検査値の各項目の平均値と中央値：613/1031 試験

Parameters		Timepoint	Placebo N=220 n	Value at timepoint	Change from baseline	SI-613 30 mg N=220 n	Value at timepoint	Change from baseline
Leukocytes (/uL)	Mean (SD)	Baseline	220	6075.5 (1489.9)	-	220	6159.1 (1646.8)	-
		Week 2	215	5854.9 (1418.2)	-222.3 (1102.6)	218	5949.1 (1600.2)	-220.2 (1247.5)
		Week 12	213	5972.8 (1444.2)	-95.8 (1144.6)	211	5928.4 (1515.2)	-246.9 (1172.6)
		Week 24	209	5805.7 (1284.4)	-249.3 (1116.4)	206	5983.5 (1653.3)	-193.2 (1298.9)
	Median (25%, 75%)	Baseline	220	5900.0 (4950.0, 6900.0)	-	220	6000.0 (4900.0, 7150.0)	-
		Week 2	215	5700.0 (4900.0, 6600.0)	-300.0 (-800.0, 200.0)	218	5750.0 (4800.0, 6800.0)	-200.0 (-800.0, 400.0)
		Week 12	213	5800.0 (5100.0, 6700.0)	0.0 (-700.0, 500.0)	211	5700.0 (4900.0, 6700.0)	-200.0 (-800.0, 400.0)
		Week 24	209	5700.0 (4900.0, 6500.0)	-100.0 (-800.0, 300.0)	206	5750.0 (4800.0, 6800.0)	-100.0 (-700.0, 500.0)
Neutrophils/Leukocytes (%)	Mean (SD)	Baseline	220	57.56 (8.67)	-	220	58.50 (8.20)	-
		Week 2	215	57.30 (8.29)	-0.37 (6.87)	218	57.96 (8.09)	-0.55 (7.26)
		Week 12	213	57.60 (8.40)	-0.16 (6.78)	211	57.79 (7.93)	-0.74 (6.77)
		Week 24	209	58.00 (8.19)	0.27 (7.72)	206	57.90 (8.32)	-0.61 (7.90)
	Median	Baseline	220	58.30 (52.50, 64.00)	-	220	58.60 (52.50, 64.40)	-
	(25%, 75%)	Week 2	215	58.10 (52.10, 63.00)	-1.00 (-4.90, 3.40)	218	58.30 (52.70, 63.90)	-0.05 (-4.60, 3.90)
		Week 12	213	58.30 (52.10, 63.30)	-0.50 (-4.50, 3.40)	211	58.00 (52.90, 63.00)	-0.50 (-4.20, 3.70)
		Week 24	209	58.80 (52.20, 64.00)	-0.50 (-4.10, 5.00)	206	57.45 (52.40, 63.00)	0.10 (-4.60, 3.90)
Lymphocytes/Leukocytes (%)	Mean (SD)	Baseline	220	32.09 (8.05)	-	220	31.22 (7.47)	-
		Week 2	215	32.21 (7.72)	0.22 (6.07)	218	31.95 (7.47)	0.74 (6.21)
		Week 12	213	31.99 (7.77)	0.08 (6.03)	211	31.73 (7.26)	0.61 (5.73)
		Week 24	209	31.54 (7.46)	-0.36 (6.83)	206	31.79 (7.65)	0.59 (6.80)
	Median	Baseline	220	31.45 (26.25, 36.60)	-	220	30.85 (25.65, 37.00)	-
	(25%, 75%)	Week 2	215	31.00 (27.10, 37.40)	0.90 (-3.40, 3.80)	218	31.60 (26.90, 36.70)	0.60 (-3.30, 4.10)
		Week 12	213	32.10 (26.70, 36.70)	0.50 (-3.60, 4.10)	211	31.80 (26.30, 36.50)	0.40 (-3.50, 4.00)
		Week 24	209	31.00 (26.10, 36.50)	0.30 (-4.80, 3.90)	206	31.40 (26.50, 37.10)	0.10 (-3.80, 4.50)
Monocytes/Leukocytes (%)	Mean (SD)	Baseline	220	6.92 (1.83)	-	220	6.95 (1.86)	-
		Week 2	215	7.05 (1.71)	0.12 (1.59)	218	6.76 (1.65)	-0.19 (1.65)
		Week 12	213	7.02 (1.70)	0.09 (1.61)	211	6.95 (1.81)	-0.02 (1.63)
		Week 24	209	6.97 (1.82)	0.03 (1.64)	206	6.93 (1.77)	-0.01 (1.71)
	Median	Baseline	220	6.85 (5.70, 7.90)	-	220	6.90 (5.80, 8.10)	-
	(25%, 75%)	Week 2	215	6.90 (6.00, 8.10)	0.20 (-0.90, 1.10)	218	6.70 (5.70, 8.00)	-0.15 (-1.30, 0.70)
		Week 12	213	6.90 (5.80, 8.10)	0.10 (-0.80, 1.10)	211	7.00 (5.80, 8.00)	0.00 (-0.80, 0.90)
		Week 24	209	6.80 (5.80, 8.00)	0.00 (-0.80, 0.90)	206	6.90 (5.70, 8.20)	-0.10 (-0.90, 0.90)
	Mean (SD)	Baseline	220	2.99 (1.97)	-	220	2.93 (2.21)	-

Parameters		Timepoint	Placebo N=220 n	Placebo N=220 Value at timepoint	Placebo N=220 Change from baseline	SI-613 30 mg N=220 n	SI-613 30 mg N=220 Value at timepoint	SI-613 30 mg N=220 Change from baseline
Eosinophils/Leukocytes (%)		Week 2	215	3.01 (2.04)	0.05 (1.17)	218	2.91 (2.00)	-0.01 (1.49)
		Week 12	213	2.99 (2.19)	0.03 (1.47)	211	3.10 (2.52)	0.14 (2.33)
		Week 24	209	3.09 (2.05)	0.11 (1.50)	206	2.97 (1.98)	0.02 (1.66)
	Median (25%, 75%)	Baseline	220	2.40 (1.80, 3.80)	-	220	2.50 (1.50, 3.85)	-
		Week 2	215	2.60 (1.80, 3.70)	0.00 (-0.50, 0.80)	218	2.40 (1.50, 3.60)	0.05 (-0.40, 0.60)
		Week 12	213	2.50 (1.50, 3.80)	0.00 (-0.70, 0.70)	211	2.50 (1.60, 3.70)	0.10 (-0.70, 0.80)
		Week 24	209	2.60 (1.60, 4.00)	0.10 (-0.70, 0.80)	206	2.50 (1.50, 4.00)	0.05 (-0.70, 0.80)
Basophils/Leukocytes (%)	Mean (SD)	Baseline	220	0.44 (0.29)	-	220	0.40 (0.29)	-
		Week 2	215	0.42 (0.27)	-0.02 (0.35)	218	0.41 (0.25)	0.01 (0.36)
		Week 12	213	0.40 (0.28)	-0.04 (0.39)	211	0.42 (0.29)	0.01 (0.37)
		Week 24	209	0.39 (0.29)	-0.05 (0.36)	206	0.41 (0.31)	0.01 (0.42)
	Median (25%, 75%)	Baseline	220	0.40 (0.30, 0.60)	-	220	0.40 (0.20, 0.50)	-
		Week 2	215	0.40 (0.30, 0.50)	0.00 (-0.20, 0.20)	218	0.40 (0.30, 0.50)	0.00 (-0.10, 0.20)
		Week 12	213	0.40 (0.20, 0.50)	0.00 (-0.20, 0.20)	211	0.40 (0.30, 0.50)	0.00 (-0.10, 0.20)
		Week 24	209	0.40 (0.30, 0.50)	0.00 (-0.20, 0.10)	206	0.40 (0.30, 0.50)	0.00 (-0.20, 0.20)
Erythrocytes (10^4/uL)	Mean (SD)	Baseline	220	444.1 (40.0)	-	220	446.5 (43.0)	-
		Week 2	215	439.1 (40.3)	-4.9 (15.9)	218	440.1 (42.7)	-6.3 (17.3)
		Week 12	213	440.2 (41.3)	-4.7 (22.0)	211	441.7 (43.1)	-5.4 (18.7)
		Week 24	209	442.4 (40.6)	-2.5 (17.6)	206	443.5 (41.3)	-4.2 (21.0)
	Median (25%, 75%)	Baseline	220	441.5 (420.0, 469.0)	-	220	447.0 (417.0, 473.0)	-
		Week 2	215	439.0 (411.0, 463.0)	-4.0 (-15.0, 5.0)	218	441.0 (408.0, 470.0)	-5.0 (-17.0, 4.0)
		Week 12	213	439.0 (414.0, 465.0)	-6.0 (-16.0, 8.0)	211	441.0 (411.0, 470.0)	-6.0 (-17.0, 6.0)
		Week 24	209	439.0 (416.0, 470.0)	-3.0 (-13.0, 10.0)	206	444.5 (414.0, 471.0)	-2.0 (-17.0, 10.0)
Hemoglobin (g/dL)	Mean (SD)	Baseline	220	13.60 (1.28)	-	220	13.70 (1.31)	-
		Week 2	215	13.45 (1.26)	-0.17 (0.50)	218	13.52 (1.29)	-0.18 (0.53)
		Week 12	213	13.49 (1.17)	-0.14 (0.78)	211	13.59 (1.23)	-0.13 (0.64)
		Week 24	209	13.57 (1.20)	-0.06 (0.67)	206	13.69 (1.24)	-0.04 (0.68)
	Median (25%, 75%)	Baseline	220	13.40 (12.70, 14.60)	-	220	13.70 (12.95, 14.50)	-
		Week 2	215	13.40 (12.60, 14.30)	-0.20 (-0.50, 0.20)	218	13.50 (12.60, 14.50)	-0.20 (-0.50, 0.10)
		Week 12	213	13.60 (12.60, 14.20)	-0.20 (-0.50, 0.20)	211	13.60 (12.70, 14.40)	-0.10 (-0.50, 0.20)
		Week 24	209	13.60 (12.70, 14.40)	-0.10 (-0.40, 0.30)	206	13.60 (12.70, 14.40)	0.00 (-0.50, 0.30)
Hematocrit (%)	Mean (SD)	Baseline	220	40.34 (3.67)	-	220	40.66 (3.74)	-
		Week 2	215	39.96 (3.64)	-0.39 (1.48)	218	40.13 (3.72)	-0.53 (1.56)
		Week 12	213	40.20 (3.43)	-0.23 (2.28)	211	40.41 (3.54)	-0.29 (1.86)
		Week 24	209	40.38 (3.49)	-0.05 (1.82)	206	40.61 (3.47)	-0.12 (1.96)
	Median (25%, 75%)	Baseline	220	39.85 (37.70, 42.75)	-	220	40.60 (38.30, 43.00)	-
		Week 2	215	39.80 (37.60, 42.30)	-0.30 (-1.30, 0.50)	218	40.25 (37.50, 42.60)	-0.45 (-1.50, 0.40)
		Week 12	213	40.40 (37.70, 42.60)	-0.30 (-1.50, 0.80)	211	40.30 (38.10, 42.50)	-0.40 (-1.30, 0.80)
		Week 24	209	40.10 (37.90, 42.60)	-0.20 (-1.20, 0.90)	206	40.60 (37.90, 42.80)	-0.05 (-1.30, 1.00)
Platelets (10^4/uL)	Mean (SD)	Baseline	219	23.72 (5.22)	-	220	23.69 (5.75)	-
		Week 2	215	23.62 (5.32)	-0.07 (2.28)	218	23.31 (6.04)	-0.34 (2.54)
		Week 12	213	23.93 (5.36)	0.31 (2.61)	211	23.79 (6.00)	0.11 (2.25)
		Week 24	208	24.12 (5.38)	0.54 (2.80)	206	23.83 (5.82)	0.19 (2.34)
	Median (25%, 75%)	Baseline	220	22.80 (20.00, 26.90)	-	220	23.00 (19.80, 26.60)	-
		Week 2	215	23.20 (19.60, 27.00)	0.00 (-1.50, 1.20)	218	22.30 (19.30, 26.10)	-0.30 (-1.60, 0.90)
		Week 12	212	23.60 (20.10, 27.70)	0.40 (-1.30, 1.45)	211	22.70 (19.90, 26.60)	0.20 (-1.10, 1.30)
		Week 24	208	23.35 (20.20, 27.75)	0.30 (-1.00, 1.70)	206	23.50 (19.90, 27.00)	0.40 (-1.30, 1.70)
Protein (g/dL)	Mean (SD)	Baseline	220	7.14 (0.39)	-	220	7.20 (0.38)	-
		Week 2	215	7.06 (0.36)	-0.08 (0.29)	218	7.08 (0.38)	-0.12 (0.29)
		Week 12	213	7.08 (0.37)	-0.06 (0.31)	211	7.09 (0.36)	-0.11 (0.30)
		Week 24	209	7.12 (0.40)	-0.03 (0.32)	206	7.12 (0.38)	-0.08 (0.31)
	Median (25%, 75%)	Baseline	220	7.15 (6.90, 7.40)	-	220	7.20 (6.90, 7.45)	-
		Week 2	215	7.10 (6.80, 7.30)	-0.10 (-0.20, 0.10)	218	7.10 (6.80, 7.30)	-0.10 (-0.30, 0.10)

Parameters		Timepoint	Placebo N=220 n	Placebo N=220 Value at timepoint	Placebo N=220 Change from baseline	SI-613 30 mg N=220 n	SI-613 30 mg N=220 Value at timepoint	SI-613 30 mg N=220 Change from baseline
		Week 12	213	7.10 (6.80, 7.40)	0.00 (-0.30, 0.10)	211	7.00 (6.80, 7.30)	-0.10 (-0.30, 0.10)
		Week 24	209	7.10 (6.80, 7.40)	0.00 (-0.20, 0.20)	206	7.10 (6.90, 7.40)	-0.10 (-0.30, 0.20)
Albumin (g/dL)	Mean (SD)	Baseline	220	4.45 (0.23)	-	220	4.47 (0.24)	-
		Week 2	215	4.40 (0.22)	-0.05 (0.19)	218	4.40 (0.24)	-0.07 (0.20)
		Week 12	213	4.40 (0.23)	-0.06 (0.21)	211	4.41 (0.23)	-0.06 (0.20)
		Week 24	209	4.41 (0.23)	-0.04 (0.23)	206	4.40 (0.22)	-0.07 (0.20)
	Median (25%, 75%)	Baseline	220	4.50 (4.30, 4.60)	-	220	4.50 (4.30, 4.60)	-
		Week 2	215	4.40 (4.20, 4.60)	0.00 (-0.20, 0.10)	218	4.40 (4.30, 4.60)	-0.05 (-0.20, 0.10)
		Week 12	213	4.40 (4.30, 4.60)	-0.10 (-0.20, 0.10)	211	4.40 (4.30, 4.60)	-0.10 (-0.20, 0.10)
		Week 24	209	4.40 (4.30, 4.60)	0.00 (-0.20, 0.10)	206	4.40 (4.30, 4.60)	-0.10 (-0.20, 0.10)
Bilirubin (mg/dL)	Mean (SD)	Baseline	220	0.66 (0.26)	-	220	0.71 (0.27)	-
		Week 2	215	0.67 (0.27)	0.01 (0.18)	218	0.72 (0.28)	0.00 (0.24)
		Week 12	213	0.65 (0.27)	-0.01 (0.20)	211	0.70 (0.28)	-0.02 (0.23)
		Week 24	209	0.65 (0.24)	-0.02 (0.20)	206	0.70 (0.28)	-0.02 (0.27)
	Median (25%, 75%)	Baseline	220	0.60 (0.50, 0.70)	-	220	0.70 (0.50, 0.90)	-
		Week 2	215	0.60 (0.50, 0.80)	0.00 (-0.10, 0.10)	218	0.70 (0.50, 0.90)	0.00 (-0.10, 0.10)
		Week 12	213	0.60 (0.50, 0.80)	0.00 (-0.10, 0.10)	211	0.70 (0.50, 0.80)	0.00 (-0.10, 0.10)
		Week 24	209	0.60 (0.50, 0.80)	0.00 (-0.10, 0.10)	206	0.70 (0.50, 0.80)	0.00 (-0.10, 0.10)
Direct Bilirubin (mg/dL)	Mean (SD)	Baseline	220	0.12 (0.07)	-	220	0.12 (0.06)	-
		Week 2	215	0.12 (0.07)	0.00 (0.06)	218	0.12 (0.06)	0.00 (0.06)
		Week 12	213	0.12 (0.06)	0.00 (0.05)	211	0.13 (0.06)	0.00 (0.06)
		Week 24	209	0.11 (0.06)	-0.01 (0.06)	206	0.12 (0.06)	-0.01 (0.07)
	Median (25%, 75%)	Baseline	220	0.10 (0.10, 0.10)	-	220	0.10 (0.10, 0.10)	-
		Week 2	215	0.10 (0.10, 0.10)	0.00 (0.00, 0.00)	218	0.10 (0.10, 0.10)	0.00 (0.00, 0.00)
		Week 12	213	0.10 (0.10, 0.10)	0.00 (0.00, 0.00)	211	0.10 (0.10, 0.10)	0.00 (0.00, 0.00)
		Week 24	209	0.10 (0.10, 0.10)	0.00 (0.00, 0.00)	206	0.10 (0.10, 0.10)	0.00 (0.00, 0.00)
Aspartate Aminotransferase (U/L)	Mean (SD)	Baseline	220	24.8 (8.4)	-	220	24.5 (7.4)	-
		Week 2	215	25.0 (8.9)	0.1 (4.3)	218	24.4 (7.9)	-0.1 (5.8)
		Week 12	213	25.1 (9.0)	0.1 (5.5)	211	25.1 (11.4)	0.4 (10.0)
		Week 24	209	25.2 (8.9)	0.3 (6.2)	206	25.5 (8.9)	0.7 (7.0)
	Median (25%, 75%)	Baseline	220	22.5 (20.0, 27.0)	-	220	23.0 (20.0, 27.0)	-
		Week 2	215	23.0 (20.0, 27.0)	0.0 (-2.0, 2.0)	218	22.0 (20.0, 27.0)	0.0 (-2.0, 2.0)
		Week 12	213	23.0 (20.0, 27.0)	0.0 (-2.0, 2.0)	211	22.0 (20.0, 27.0)	0.0 (-3.0, 2.0)
		Week 24	209	23.0 (20.0, 27.0)	0.0 (-2.0, 2.0)	206	23.0 (20.0, 29.0)	0.0 (-3.0, 3.0)
Alanine Aminotransferase (U/L)	Mean (SD)	Baseline	220	22.1 (11.4)	-	220	22.0 (10.8)	-
		Week 2	215	22.8 (12.1)	0.4 (5.0)	218	22.3 (11.3)	0.2 (5.9)
		Week 12	213	23.2 (13.1)	0.7 (7.7)	211	24.0 (22.6)	1.8 (19.9)
		Week 24	209	23.2 (13.7)	0.7 (9.1)	206	24.2 (14.1)	1.9 (10.1)
	Median (25%, 75%)	Baseline	220	19.0 (15.0, 25.5)	-	220	19.0 (15.0, 26.0)	-
		Week 2	215	20.0 (15.0, 26.0)	0.0 (-2.0, 3.0)	218	19.0 (15.0, 27.0)	0.0 (-3.0, 2.0)
		Week 12	213	20.0 (16.0, 26.0)	0.0 (-3.0, 3.0)	211	19.0 (15.0, 28.0)	0.0 (-3.0, 3.0)
		Week 24	209	20.0 (15.0, 26.0)	0.0 (-3.0, 4.0)	206	20.5 (15.0, 29.0)	1.0 (-2.0, 4.0)
Lactate Dehydrogenase (U/L)	Mean (SD)	Baseline	220	194.0 (36.0)	-	220	189.2 (28.8)	-
		Week 2	215	191.8 (36.7)	-2.3 (17.7)	218	187.1 (30.1)	-1.9 (16.5)
		Week 12	213	193.2 (42.7)	-1.0 (22.1)	211	188.5 (30.6)	-0.8 (18.3)
		Week 24	209	192.7 (34.4)	-1.6 (20.7)	206	187.3 (30.7)	-1.8 (18.8)
	Median (25%, 75%)	Baseline	220	188.5 (172.5, 211.0)	-	220	186.0 (171.5, 206.0)	-
		Week 2	215	186.0 (169.0, 210.0)	-3.0 (-11.0, 8.0)	218	184.0 (167.0, 205.0)	-3.0 (-11.0, 7.0)
		Week 12	213	186.0 (168.0, 212.0)	-2.0 (-11.0, 9.0)	211	185.0 (170.0, 207.0)	-1.0 (-10.0, 8.0)
		Week 24	209	189.0 (170.0, 211.0)	-2.0 (-14.0, 9.0)	206	187.0 (170.0, 202.0)	-3.0 (-13.0, 8.0)
Alkaline Phosphatase (U/L)	Mean (SD)	Baseline	220	249.9 (76.0)	-	220	237.4 (71.2)	-
		Week 2	215	250.7 (77.2)	1.2 (37.5)	218	237.6 (70.7)	-0.6 (32.7)
		Week 12	213	250.1 (75.1)	1.7 (38.7)	211	239.7 (69.6)	0.4 (37.4)

Parameters		Timepoint	Placebo N=220 n	Placebo N=220 Value at timepoint	Placebo N=220 Change from baseline	SI-613 30 mg N=220 n	SI-613 30 mg N=220 Value at timepoint	SI-613 30 mg N=220 Change from baseline
		Week 24	209	249.5 (73.9)	1.6 (33.7)	206	238.8 (67.5)	-0.1 (35.2)
	Median	Baseline	220	237.0 (197.5, 286.5)	-	220	222.0 (195.0, 275.5)	-
	(25%, 75%)	Week 2	215	238.0 (198.0, 290.0)	2.0 (-14.0, 15.0)	218	225.0 (188.0, 280.0)	-3.0 (-17.0, 13.0)
		Week 12	213	241.0 (200.0, 284.0)	2.0 (-15.0, 19.0)	211	232.0 (193.0, 277.0)	-1.0 (-15.0, 18.0)
		Week 24	209	236.0 (200.0, 288.0)	2.0 (-12.0, 19.0)	206	231.5 (194.0, 274.0)	0.0 (-19.0, 20.0)
Gamma Glutamyl Transferase (U/L)	Mean (SD)	Baseline	220	33.7 (31.9)	-	220	35.6 (37.6)	-
		Week 2	215	35.0 (34.7)	1.5 (12.4)	218	34.9 (32.2)	-0.8 (12.6)
		Week 12	213	35.8 (35.9)	2.1 (20.1)	211	39.2 (49.2)	3.0 (34.6)
		Week 24	209	33.6 (30.5)	0.4 (18.7)	206	37.9 (37.8)	1.3 (15.0)
	Median	Baseline	220	23.0 (16.0, 38.0)	-	220	24.0 (15.5, 38.0)	-
	(25%, 75%)	Week 2	215	23.0 (16.0, 42.0)	1.0 (-2.0, 3.0)	218	25.0 (15.0, 42.0)	0.0 (-3.0, 3.0)
		Week 12	213	25.0 (17.0, 41.0)	1.0 (-2.0, 5.0)	211	25.0 (16.0, 43.0)	0.0 (-4.0, 5.0)
		Week 24	209	24.0 (16.0, 39.0)	0.0 (-3.0, 4.0)	206	25.0 (15.0, 46.0)	1.0 (-3.0, 4.0)
Urate (mg/dL)	Mean (SD)	Baseline	220	5.16 (1.25)	-	220	5.33 (1.27)	-
		Week 2	215	5.25 (1.28)	0.09 (0.60)	218	5.45 (1.35)	0.12 (0.69)
		Week 12	213	5.24 (1.18)	0.07 (0.75)	211	5.38 (1.21)	0.04 (0.70)
		Week 24	209	5.17 (1.16)	-0.01 (0.72)	206	5.45 (1.26)	0.10 (0.72)
	Median	Baseline	220	5.00 (4.40, 5.80)	-	220	5.20 (4.40, 6.25)	-
	(25%, 75%)	Week 2	215	5.20 (4.40, 5.90)	0.10 (-0.30, 0.50)	218	5.30 (4.50, 6.40)	0.10 (-0.30, 0.40)
		Week 12	213	5.20 (4.50, 5.90)	0.10 (-0.30, 0.50)	211	5.40 (4.40, 6.30)	0.10 (-0.30, 0.40)
		Week 24	209	5.10 (4.40, 5.90)	0.00 (-0.30, 0.40)	206	5.30 (4.50, 6.30)	0.10 (-0.40, 0.60)
Blood Urea Nitrogen (mg/dL)	Mean (SD)	Baseline	220	15.3 (3.8)	-	220	15.3 (4.1)	-
		Week 2	215	15.3 (3.7)	-0.1 (2.9)	218	15.5 (3.9)	0.2 (2.8)
		Week 12	213	15.7 (3.9)	0.3 (3.1)	211	15.2 (3.6)	-0.1 (3.2)
		Week 24	209	15.3 (3.8)	-0.1 (3.0)	206	15.2 (3.9)	-0.1 (3.2)
	Median	Baseline	220	15.0 (13.0, 18.0)	-	220	14.0 (13.0, 18.0)	-
	(25%, 75%)	Week 2	215	15.0 (13.0, 17.0)	0.0 (-2.0, 1.0)	218	15.0 (12.0, 18.0)	0.0 (-2.0, 2.0)
		Week 12	213	16.0 (13.0, 18.0)	0.0 (-2.0, 2.0)	211	15.0 (13.0, 17.0)	0.0 (-2.0, 2.0)
		Week 24	209	15.0 (13.0, 17.0)	0.0 (-2.0, 2.0)	206	14.5 (13.0, 17.0)	0.0 (-2.0, 1.0)
Creatinine (mg/dL)	Mean (SD)	Baseline	220	0.669 (0.150)	-	220	0.692 (0.159)	-
		Week 2	215	0.681 (0.154)	0.011 (0.057)	218	0.696 (0.158)	0.004 (0.063)
		Week 12	213	0.675 (0.158)	0.003 (0.064)	211	0.695 (0.158)	0.002 (0.059)
		Week 24	209	0.676 (0.162)	0.002 (0.067)	206	0.697 (0.158)	0.001 (0.065)
	Median	Baseline	220	0.650 (0.560, 0.770)	-	220	0.650 (0.580, 0.780)	-
	(25%, 75%)	Week 2	215	0.670 (0.570, 0.780)	0.010 (-0.030, 0.050)	218	0.670 (0.590, 0.780)	0.000 (-0.030, 0.040)
		Week 12	213	0.650 (0.550, 0.790)	0.000 (-0.030, 0.040)	211	0.660 (0.590, 0.770)	0.000 (-0.030, 0.040)
		Week 24	209	0.650 (0.560, 0.800)	0.000 (-0.030, 0.040)	206	0.670 (0.570, 0.780)	0.000 (-0.040, 0.040)
Cholesterol (mg/dL)	Mean (SD)	Baseline	220	209.9 (33.0)	-	220	217.6 (35.4)	-
		Week 2	215	207.8 (32.0)	-2.2 (18.3)	218	213.5 (35.2)	-3.9 (17.9)
		Week 12	213	208.2 (32.0)	-1.9 (22.0)	211	214.0 (35.4)	-3.3 (20.9)
		Week 24	209	208.8 (31.3)	-0.9 (22.9)	206	216.3 (37.3)	-1.3 (21.0)
	Median	Baseline	220	209.0 (192.0, 227.5)	-	220	214.0 (192.5, 239.5)	-
	(25%, 75%)	Week 2	215	204.0 (187.0, 226.0)	-2.0 (-13.0, 8.0)	218	211.0 (190.0, 235.0)	-2.0 (-13.0, 6.0)
		Week 12	213	207.0 (190.0, 228.0)	-3.0 (-14.0, 10.0)	211	214.0 (189.0, 238.0)	-5.0 (-16.0, 11.0)
		Week 24	209	206.0 (189.0, 229.0)	-3.0 (-14.0, 13.0)	206	213.5 (190.0, 237.0)	-1.0 (-14.0, 10.0)
Triglycerides (mg/dL)	Mean (SD)	Baseline	220	150.2 (92.9)	-	220	150.4 (91.4)	-
		Week 2	215	155.2 (89.9)	5.7 (84.3)	218	154.0 (91.0)	3.9 (80.0)
		Week 12	213	157.9 (92.7)	7.9 (89.6)	211	156.0 (114.2)	5.4 (98.6)
		Week 24	209	151.9 (91.6)	1.8 (83.3)	206	160.7 (104.5)	8.8 (87.6)
	Median	Baseline	220	129.0 (82.5, 189.0)	-	220	125.5 (87.0, 185.5)	-
	(25%, 75%)	Week 2	215	133.0 (91.0, 193.0)	14.0 (-26.0, 40.0)	218	135.0 (88.0, 190.0)	1.5 (-30.0, 44.0)
		Week 12	213	136.0 (86.0, 195.0)	4.0 (-31.0, 51.0)	211	126.0 (91.0, 194.0)	8.0 (-25.0, 39.0)
		Week 24	209	126.0 (86.0, 188.0)	-1.0 (-37.0, 34.0)	206	128.0 (89.0, 198.0)	8.5 (-29.0, 42.0)

Parameters		Timepoint	Placebo N=220 n	Placebo N=220 Value at timepoint	Placebo N=220 Change from baseline	SI-613 30 mg N=220 n	SI-613 30 mg N=220 Value at timepoint	SI-613 30 mg N=220 Change from baseline
C Reactive Protein (mg/dL)	Mean (SD)	Baseline	220	0.14 (0.20)	-	220	0.17 (0.37)	-
		Week 2	215	0.16 (0.29)	0.02 (0.32)	218	0.15 (0.32)	-0.02 (0.46)
		Week 12	213	0.17 (0.61)	0.03 (0.59)	211	0.14 (0.19)	-0.03 (0.39)
		Week 24	209	0.15 (0.29)	0.01 (0.32)	206	0.15 (0.23)	-0.02 (0.36)
	Median (25%, 75%)	Baseline	220	0.10 (0.00, 0.10)	-	220	0.10 (0.00, 0.20)	-
		Week 2	215	0.10 (0.00, 0.20)	0.00 (0.00, 0.00)	218	0.10 (0.00, 0.20)	0.00 (-0.10, 0.00)
		Week 12	213	0.10 (0.00, 0.20)	0.00 (0.00, 0.10)	211	0.10 (0.00, 0.20)	0.00 (-0.10, 0.00)
		Week 24	209	0.10 (0.00, 0.10)	0.00 (0.00, 0.00)	206	0.10 (0.00, 0.20)	0.00 (0.00, 0.10)
Sodium (mEq/L)	Mean (SD)	Baseline	220	142.1 (1.7)	-	220	141.9 (1.8)	-
		Week 2	215	142.0 (1.9)	-0.1 (1.7)	218	142.0 (1.8)	0.1 (1.8)
		Week 12	213	142.1 (2.1)	0.1 (2.0)	211	142.0 (1.8)	0.1 (1.9)
		Week 24	209	142.1 (1.9)	0.0 (1.8)	206	142.0 (1.9)	0.2 (1.8)
	Median (25%, 75%)	Baseline	220	142.0 (141.0, 143.0)	-	220	142.0 (141.0, 143.0)	-
		Week 2	215	142.0 (141.0, 143.0)	0.0 (-1.0, 1.0)	218	142.0 (141.0, 143.0)	0.0 (-1.0, 1.0)
		Week 12	213	142.0 (141.0, 143.0)	0.0 (-1.0, 1.0)	211	142.0 (141.0, 143.0)	0.0 (-1.0, 2.0)
		Week 24	209	142.0 (141.0, 143.0)	0.0 (-1.0, 1.0)	206	142.0 (141.0, 143.0)	0.0 (-1.0, 1.0)
Potassium (mEq/L)	Mean (SD)	Baseline	220	4.17 (0.33)	-	220	4.20 (0.33)	-
		Week 2	215	4.18 (0.38)	0.01 (0.35)	218	4.18 (0.34)	-0.03 (0.32)
		Week 12	213	4.18 (0.35)	0.01 (0.32)	211	4.14 (0.32)	-0.06 (0.28)
		Week 24	209	4.19 (0.32)	0.02 (0.32)	206	4.15 (0.30)	-0.05 (0.29)
	Median (25%, 75%)	Baseline	220	4.10 (3.90, 4.40)	-	220	4.20 (4.00, 4.40)	-
		Week 2	215	4.20 (3.90, 4.40)	0.00 (-0.20, 0.20)	218	4.10 (4.00, 4.40)	-0.05 (-0.20, 0.10)
		Week 12	213	4.20 (3.90, 4.40)	0.00 (-0.20, 0.20)	211	4.10 (4.00, 4.30)	-0.10 (-0.20, 0.10)
		Week 24	209	4.20 (4.00, 4.40)	0.00 (-0.20, 0.20)	206	4.20 (3.90, 4.30)	-0.10 (-0.30, 0.10)
Chloride (mEq/L)	Mean (SD)	Baseline	220	103.9 (2.0)	-	220	103.9 (2.0)	-
		Week 2	215	104.1 (2.0)	0.2 (1.9)	218	104.0 (2.0)	0.1 (1.9)
		Week 12	213	104.1 (2.0)	0.2 (2.1)	211	103.9 (2.0)	0.1 (2.0)
		Week 24	209	103.6 (1.8)	-0.2 (1.9)	206	103.6 (2.0)	-0.2 (2.1)
	Median (25%, 75%)	Baseline	220	104.0 (103.0, 105.0)	-	220	104.0 (103.0, 105.0)	-
		Week 2	215	104.0 (103.0, 105.0)	0.0 (-1.0, 1.0)	218	104.0 (103.0, 105.0)	0.0 (-1.0, 1.0)
		Week 12	213	104.0 (103.0, 105.0)	0.0 (-1.0, 1.0)	211	104.0 (103.0, 105.0)	0.0 (-1.0, 1.0)
		Week 24	209	104.0 (102.0, 105.0)	0.0 (-2.0, 1.0)	206	104.0 (102.0, 105.0)	0.0 (-2.0, 1.0)
Calcium (mg/dL)	Mean (SD)	Baseline	220	9.00 (0.30)	-	220	9.07 (0.32)	-
		Week 2	215	8.98 (0.29)	-0.03 (0.27)	218	9.02 (0.31)	-0.04 (0.28)
		Week 12	213	8.97 (0.28)	-0.03 (0.29)	211	9.00 (0.35)	-0.06 (0.30)
		Week 24	209	8.98 (0.29)	-0.02 (0.28)	206	8.99 (0.33)	-0.08 (0.30)
	Median (25%, 75%)	Baseline	220	9.00 (8.80, 9.20)	-	220	9.10 (8.80, 9.30)	-
		Week 2	215	9.00 (8.80, 9.20)	-0.10 (-0.20, 0.10)	218	9.00 (8.80, 9.20)	0.00 (-0.20, 0.10)
		Week 12	213	9.00 (8.80, 9.10)	-0.10 (-0.20, 0.20)	211	9.00 (8.80, 9.20)	0.00 (-0.30, 0.20)
		Week 24	209	9.00 (8.80, 9.20)	0.00 (-0.20, 0.20)	206	9.00 (8.80, 9.20)	-0.10 (-0.30, 0.20)
Creatine Kinase (U/L)	Mean (SD)	Baseline	220	131.5 (97.0)	-	220	129.0 (96.3)	-
		Week 2	215	134.7 (93.4)	2.4 (78.5)	218	138.6 (224.4)	9.7 (195.0)
		Week 12	213	138.5 (115.4)	5.6 (90.3)	211	122.1 (72.8)	-7.4 (75.8)
		Week 24	209	127.6 (68.2)	-6.3 (72.6)	206	119.3 (67.5)	-11.1 (78.2)
	Median (25%, 75%)	Baseline	220	106.0 (80.0, 146.0)	-	220	103.0 (74.5, 144.5)	-
		Week 2	215	109.0 (82.0, 161.0)	0.0 (-17.0, 18.0)	218	101.0 (75.0, 144.0)	2.0 (-20.0, 18.0)
		Week 12	213	108.0 (81.0, 147.0)	2.0 (-15.0, 23.0)	211	106.0 (76.0, 144.0)	-2.0 (-23.0, 16.0)
		Week 24	209	115.0 (86.0, 146.0)	1.0 (-21.0, 19.0)	206	104.0 (75.0, 146.0)	-2.0 (-24.0, 15.0)
Hemoglobin A1C/Hemoglobin (%)	Mean (SD)	Baseline	219	5.85 (0.69)	-	220	5.76 (0.55)	-
		Week 2	214	5.84 (0.67)	-0.01 (0.16)	218	5.77 (0.54)	0.00 (0.17)
		Week 12	212	5.82 (0.63)	-0.02 (0.27)	211	5.80 (0.56)	0.04 (0.23)
		Week 24	208	5.87 (0.60)	0.02 (0.29)	206	5.81 (0.55)	0.04 (0.28)
		Baseline	219	5.70 (5.50, 6.00)	-	220	5.70 (5.40, 5.90)	-

Parameters		Timepoint	Placebo N=220 n	Placebo N=220 Value at timepoint	Placebo N=220 Change from baseline	SI-613 30 mg N=220 n	SI-613 30 mg N=220 Value at timepoint	SI-613 30 mg N=220 Change from baseline
	Median	Week 2	214	5.70 (5.40, 6.00)	0.00 (-0.10, 0.10)	218	5.70 (5.50, 5.90)	0.00 (-0.10, 0.10)
	(25%, 75%)	Week 12	212	5.70 (5.50, 6.00)	0.00 (-0.10, 0.10)	211	5.70 (5.50, 6.00)	0.00 (-0.10, 0.20)
		Week 24	208	5.70 (5.50, 6.10)	0.00 (-0.10, 0.20)	206	5.70 (5.50, 6.00)	0.00 (-0.10, 0.20)

〔5.3.5.1-3 Table 14.3.4-1 改編〕

表 2.7.4.7-71. 臨床検査値の各項目の平均値と中央値：613/1033 試験

Parameters		Timepoint	Placebo N=144 n	Placebo N=144 Value at timepoint	Placebo N=144 Change from baseline	SI-613 30 mg N=146 n	SI-613 30 mg N=146 Value at timepoint	SI-613 30 mg N=146 Change from baseline
Leukocytes (/uL)	Mean (SD)	Baseline	144	5875.0 (1278.5)	-	146	6182.9 (1523.0)	-
		Week 2	143	5746.2 (1284.5)	-128.0 (1064.4)	146	6035.6 (1459.0)	-147.3 (1121.2)
		Week 12	138	5787.0 (1329.7)	-104.3 (1069.7)	143	5935.7 (1395.8)	-272.0 (1219.3)
	Median (25%, 75%)	Baseline	144	5700.0 (4900.0, 6800.0)	-	146	5900.0 (4900.0, 7300.0)	-
		Week 2	143	5700.0 (4800.0, 6700.0)	0.0 (-600.0, 500.0)	146	5900.0 (4900.0, 7100.0)	-100.0 (-700.0, 500.0)
		Week 12	138	5650.0 (4700.0, 6700.0)	0.0 (-700.0, 500.0)	143	5500.0 (4900.0, 7100.0)	-300.0 (-900.0, 300.0)
Neutrophils /Leukocytes (%)	Mean (SD)	Baseline	144	59.09 (7.72)	-	146	60.44 (8.34)	-
		Week 2	143	58.84 (8.29)	-0.26 (7.00)	146	58.74 (8.96)	-1.70 (6.60)
		Week 12	138	57.33 (8.23)	-1.70 (7.21)	143	59.17 (8.71)	-1.30 (7.08)
	Median	Baseline	144	58.55 (54.45, 64.10)	-	146	60.55 (54.90, 65.60)	-
	(25%, 75%)	Week 2	143	58.00 (52.70, 64.90)	-0.50 (-4.70, 4.00)	146	59.90 (51.80, 65.00)	-1.85 (-5.50, 2.00)
		Week 12	138	57.30 (51.20, 62.50)	-1.55 (-5.80, 2.00)	143	60.10 (53.00, 64.90)	-1.00 (-4.80, 3.30)
Lymphocytes /Leukocytes (%)	Mean (SD)	Baseline	144	31.21 (7.04)	-	146	29.73 (7.80)	-
		Week 2	143	31.25 (7.39)	0.01 (5.96)	146	31.05 (8.67)	1.32 (5.75)
		Week 12	138	32.26 (7.78)	0.97 (6.21)	143	30.43 (7.87)	0.67 (6.19)
	Median	Baseline	144	30.95 (26.50, 35.60)	-	146	29.25 (24.90, 34.20)	-
	(25%, 75%)	Week 2	143	31.70 (25.80, 36.70)	0.60 (-3.20, 3.80)	146	30.10 (25.20, 36.60)	1.75 (-1.60, 4.10)
		Week 12	138	32.00 (27.00, 37.40)	0.85 (-2.30, 4.70)	143	29.40 (25.00, 36.00)	0.10 (-2.60, 4.60)
Monocytes /Leukocytes (%)	Mean (SD)	Baseline	144	6.72 (1.64)	-	146	6.74 (1.96)	-
		Week 2	143	6.84 (1.89)	0.10 (1.55)	146	6.75 (1.93)	0.01 (1.81)
		Week 12	138	6.83 (1.99)	0.13 (1.68)	143	6.95 (2.04)	0.27 (1.79)
	Median	Baseline	144	6.85 (5.35, 7.85)	-	146	6.80 (5.30, 8.00)	-
	(25%, 75%)	Week 2	143	6.70 (5.50, 8.00)	0.10 (-0.90, 1.00)	146	6.65 (5.50, 8.00)	-0.05 (-1.00, 0.90)
		Week 12	138	6.50 (5.60, 8.10)	0.10 (-0.90, 1.20)	143	6.80 (5.50, 8.00)	0.20 (-0.70, 1.30)
Eosinophils /Leukocytes (%)	Mean (SD)	Baseline	144	2.63 (1.88)	-	146	2.71 (2.00)	-
		Week 2	143	2.69 (1.86)	0.11 (1.09)	146	3.04 (2.31)	0.33 (1.25)
		Week 12	138	3.19 (2.46)	0.55 (2.12)	143	3.03 (2.15)	0.32 (1.61)
	Median	Baseline	144	2.20 (1.35, 3.15)	-	146	2.30 (1.20, 3.60)	-
	(25%, 75%)	Week 2	143	2.30 (1.40, 3.50)	0.10 (-0.50, 0.70)	146	2.50 (1.50, 3.90)	0.25 (-0.40, 0.90)
		Week 12	138	2.60 (1.50, 4.00)	0.20 (-0.40, 1.10)	143	2.40 (1.60, 4.00)	0.20 (-0.40, 1.00)
Basophils /Leukocytes (%)	Mean (SD)	Baseline	144	0.35 (0.24)	-	146	0.37 (0.27)	-
		Week 2	143	0.38 (0.29)	0.04 (0.35)	146	0.41 (0.31)	0.04 (0.38)
		Week 12	138	0.38 (0.26)	0.05 (0.30)	143	0.41 (0.25)	0.04 (0.35)
	Median	Baseline	144	0.40 (0.20, 0.50)	-	146	0.30 (0.20, 0.50)	-
	(25%, 75%)	Week 2	143	0.30 (0.20, 0.50)	0.00 (-0.20, 0.20)	146	0.35 (0.20, 0.50)	0.00 (-0.20, 0.20)
		Week 12	138	0.40 (0.30, 0.50)	0.00 (-0.10, 0.20)	143	0.40 (0.30, 0.50)	0.00 (-0.10, 0.20)
Erythrocytes (10^4/uL)	Mean (SD)	Baseline	144	436.2 (38.6)	-	146	447.3 (42.2)	-
		Week 2	143	433.3 (38.7)	-3.1 (18.0)	146	443.0 (44.0)	-4.3 (16.6)

Parameters		Timepoint	Placebo N=144 n	Placebo N=144 Value at timepoint	Placebo N=144 Change from baseline	SI-613 30 mg N=146 n	SI-613 30 mg N=146 Value at timepoint	SI-613 30 mg N=146 Change from baseline
		Week 12	138	436.4 (38.9)	0.3 (19.7)	143	444.0 (45.5)	-3.2 (20.2)
	Median	Baseline	144	438.0 (411.0, 463.5)	-	146	444.0 (423.0, 474.0)	-
	(25%, 75%)	Week 2	143	437.0 (404.0, 462.0)	-2.0 (-13.0, 6.0)	146	441.0 (414.0, 477.0)	-3.0 (-14.0, 5.0)
		Week 12	138	436.0 (410.0, 462.0)	-1.5 (-12.0, 13.0)	143	443.0 (416.0, 475.0)	-4.0 (-18.0, 12.0)
Hemoglobin	Mean (SD)	Baseline	144	13.47 (1.20)	-	146	13.70 (1.35)	-
(g/dL)		Week 2	144	13.37 (1.21)	-0.10 (0.54)	146	13.57 (1.39)	-0.12 (0.52)
		Week 12	138	13.48 (1.18)	0.00 (0.61)	143	13.62 (1.41)	-0.10 (0.64)
	Median	Baseline	144	13.60 (12.60, 14.30)	-	146	13.65 (12.80, 14.60)	-
	(25%, 75%)	Week 2	144	13.40 (12.55, 14.40)	-0.10 (-0.40, 0.20)	146	13.60 (12.60, 14.50)	-0.10 (-0.40, 0.20)
		Week 12	138	13.55 (12.60, 14.30)	0.00 (-0.40, 0.40)	143	13.70 (12.70, 14.60)	-0.10 (-0.50, 0.30)
Hematocrit (%)	Mean (SD)	Baseline	144	40.07 (3.47)	-	146	40.81 (3.84)	-
		Week 2	143	39.77 (3.49)	-0.31 (1.67)	146	40.42 (3.98)	-0.39 (1.49)
		Week 12	138	40.09 (3.30)	0.00 (1.78)	143	40.58 (4.04)	-0.28 (1.85)
	Median	Baseline	144	40.40 (37.60, 42.50)	-	146	40.85 (38.20, 43.40)	-
	(25%, 75%)	Week 2	143	39.80 (37.30, 42.90)	-0.40 (-1.30, 0.70)	146	40.25 (37.90, 43.20)	-0.30 (-1.30, 0.50)
		Week 12	138	40.05 (37.50, 42.70)	0.00 (-1.10, 0.90)	143	40.50 (38.00, 43.30)	-0.40 (-1.60, 1.30)
Platelets (10^4/uL)	Mean (SD)	Baseline	143	24.08 (5.28)	-	146	25.04 (7.10)	-
		Week 2	142	24.07 (5.41)	-0.01 (2.37)	146	24.25 (6.78)	-0.79 (2.50)
		Week 12	138	24.56 (5.89)	0.46 (3.32)	143	24.76 (6.22)	-0.36 (2.68)
	Median	Baseline	143	23.90 (20.80, 27.20)	-	146	24.00 (20.80, 28.00)	-
	(25%, 75%)	Week 2	142	24.30 (19.70, 27.30)	-0.10 (-1.20, 1.40)	146	23.20 (20.10, 26.80)	-0.60 (-2.00, 0.50)
		Week 12	138	24.50 (20.00, 28.40)	0.40 (-1.20, 2.00)	143	23.80 (20.20, 28.50)	0.00 (-1.60, 1.20)
Protein (g/dL)	Mean (SD)	Baseline	144	7.14 (0.44)	-	146	7.23 (0.47)	-
		Week 2	144	7.03 (0.42)	-0.10 (0.35)	146	7.13 (0.44)	-0.10 (0.32)
		Week 12	138	7.11 (0.42)	-0.02 (0.34)	143	7.14 (0.42)	-0.09 (0.34)
	Median	Baseline	144	7.20 (6.90, 7.40)	-	146	7.20 (6.90, 7.50)	-
	(25%, 75%)	Week 2	144	7.10 (6.80, 7.30)	-0.10 (-0.30, 0.20)	146	7.00 (6.80, 7.30)	-0.10 (-0.30, 0.20)
		Week 12	138	7.10 (6.90, 7.40)	-0.05 (-0.20, 0.20)	143	7.10 (6.90, 7.40)	-0.10 (-0.30, 0.20)
Albumin (g/dL)	Mean (SD)	Baseline	144	4.26 (0.27)	-	146	4.30 (0.28)	-
		Week 2	144	4.20 (0.29)	-0.06 (0.23)	146	4.25 (0.28)	-0.05 (0.21)
		Week 12	138	4.24 (0.29)	-0.02 (0.26)	143	4.25 (0.26)	-0.05 (0.24)
	Median	Baseline	144	4.30 (4.10, 4.45)	-	146	4.30 (4.10, 4.50)	-
	(25%, 75%)	Week 2	144	4.20 (4.00, 4.40)	-0.10 (-0.20, 0.10)	146	4.20 (4.10, 4.40)	-0.05 (-0.20, 0.10)
		Week 12	138	4.30 (4.10, 4.40)	0.00 (-0.20, 0.10)	143	4.30 (4.10, 4.40)	0.00 (-0.20, 0.10)
Bilirubin (mg/dL)	Mean (SD)	Baseline	144	0.70 (0.24)	-	146	0.72 (0.27)	-
		Week 2	144	0.70 (0.23)	0.00 (0.18)	146	0.73 (0.28)	0.02 (0.21)
		Week 12	138	0.68 (0.23)	-0.01 (0.19)	143	0.72 (0.23)	0.00 (0.18)
	Median	Baseline	144	0.70 (0.50, 0.80)	-	146	0.70 (0.50, 0.80)	-
	(25%, 75%)	Week 2	144	0.70 (0.50, 0.80)	0.00 (-0.10, 0.10)	146	0.70 (0.60, 0.90)	0.00 (-0.10, 0.10)
		Week 12	138	0.60 (0.50, 0.80)	0.00 (-0.10, 0.10)	143	0.70 (0.60, 0.80)	0.00 (-0.10, 0.10)
Direct Bilirubin	Mean (SD)	Baseline	144	0.07 (0.05)	-	146	0.08 (0.05)	-
(mg/dL)		Week 2	144	0.07 (0.05)	0.00 (0.05)	146	0.08 (0.05)	0.00 (0.05)
		Week 12	138	0.08 (0.05)	0.01 (0.05)	143	0.08 (0.05)	0.00 (0.05)
	Median	Baseline	144	0.10 (0.00, 0.10)	-	146	0.10 (0.00, 0.10)	-
	(25%, 75%)	Week 2	144	0.10 (0.00, 0.10)	0.00 (0.00, 0.00)	146	0.10 (0.00, 0.10)	0.00 (0.00, 0.00)
		Week 12	138	0.10 (0.00, 0.10)	0.00 (0.00, 0.00)	143	0.10 (0.00, 0.10)	0.00 (0.00, 0.00)
Aspartate	Mean (SD)	Baseline	144	22.6 (6.6)	-	146	23.5 (9.8)	-
Aminotransferase		Week 2	144	22.9 (6.8)	0.3 (4.5)	146	23.9 (10.3)	0.4 (5.5)
(U/L)		Week 12	138	22.4 (6.5)	-0.2 (5.5)	143	23.7 (10.6)	0.2 (5.7)
	Median	Baseline	144	21.0 (18.0, 25.5)	-	146	22.0 (18.0, 26.0)	-
	(25%, 75%)	Week 2	144	22.0 (18.0, 25.5)	0.0 (-2.0, 2.5)	146	21.0 (18.0, 26.0)	0.0 (-2.0, 2.0)
		Week 12	138	21.0 (18.0, 25.0)	0.0 (-3.0, 2.0)	143	21.0 (18.0, 25.0)	0.0 (-2.0, 2.0)
	Mean (SD)	Baseline	144	20.2 (9.7)	-	146	22.7 (22.4)	-

Parameters		Timepoint	Placebo N=144 n	Placebo N=144 Value at timepoint	Placebo N=144 Change from baseline	SI-613 30 mg N=146 n	SI-613 30 mg N=146 Value at timepoint	SI-613 30 mg N=146 Change from baseline
Alanine Aminotransferase (U/L)		Week 2	144	20.3 (9.3)	0.1 (6.0)	146	23.3 (23.7)	0.6 (7.2)
		Week 12	138	19.8 (9.4)	-0.5 (7.2)	143	23.1 (23.0)	0.4 (8.3)
	Median (25%, 75%)	Baseline	144	17.5 (14.0, 23.0)	-	146	17.0 (13.0, 25.0)	-
		Week 2	144	17.5 (14.0, 24.0)	0.0 (-2.5, 3.0)	146	17.5 (13.0, 25.0)	0.0 (-2.0, 2.0)
		Week 12	138	17.0 (14.0, 22.0)	-1.0 (-3.0, 3.0)	143	18.0 (13.0, 25.0)	0.0 (-3.0, 3.0)
Lactate Dehydrogenase (U/L)	Mean (SD)	Baseline	144	196.4 (34.4)	-	146	193.2 (34.1)	-
		Week 2	144	192.9 (33.9)	-3.5 (17.6)	146	191.4 (32.7)	-1.8 (22.8)
		Week 12	138	197.9 (38.6)	1.1 (26.0)	143	192.1 (34.6)	-1.1 (27.8)
	Median (25%, 75%)	Baseline	144	195.0 (172.0, 217.5)	-	146	193.0 (170.0, 215.0)	-
		Week 2	144	189.0 (169.0, 213.0)	-4.0 (-14.5, 8.0)	146	190.5 (170.0, 213.0)	0.0 (-13.0, 9.0)
		Week 12	138	192.0 (169.0, 218.0)	0.0 (-13.0, 11.0)	143	187.0 (167.0, 216.0)	-3.0 (-12.0, 11.0)
Alkaline Phosphatase (U/L)	Mean (SD)	Baseline	144	238.9 (70.1)	-	146	247.8 (74.4)	-
		Week 2	144	235.1 (69.5)	-3.8 (28.7)	146	243.7 (70.7)	-4.1 (29.9)
		Week 12	138	239.0 (76.1)	0.0 (40.6)	143	252.6 (73.2)	3.5 (33.3)
	Median (25%, 75%)	Baseline	144	238.5 (196.5, 276.0)	-	146	234.0 (195.0, 300.0)	-
		Week 2	144	233.5 (185.5, 279.0)	-4.0 (-19.5, 13.5)	146	233.5 (192.0, 296.0)	-1.0 (-21.0, 10.0)
		Week 12	138	229.5 (196.0, 275.0)	0.0 (-25.0, 16.0)	143	239.0 (204.0, 299.0)	1.0 (-14.0, 19.0)
Gamma Glutamyl Transferase (U/L)	Mean (SD)	Baseline	144	31.8 (29.3)	-	146	35.2 (31.4)	-
		Week 2	144	32.7 (30.9)	0.9 (9.8)	146	34.5 (29.9)	-0.7 (9.0)
		Week 12	138	32.1 (28.4)	-0.2 (12.3)	143	35.9 (35.2)	0.5 (15.9)
	Median (25%, 75%)	Baseline	144	22.0 (16.0, 33.0)	-	146	24.0 (17.0, 38.0)	-
		Week 2	144	23.5 (16.0, 37.0)	0.0 (-1.5, 3.0)	146	23.0 (17.0, 37.0)	0.0 (-2.0, 2.0)
		Week 12	138	24.0 (16.0, 36.0)	0.0 (-2.0, 3.0)	143	25.0 (18.0, 38.0)	0.0 (-2.0, 5.0)
Urate (mg/dL)	Mean (SD)	Baseline	144	5.06 (1.32)	-	146	5.33 (1.19)	-
		Week 2	144	5.15 (1.27)	0.09 (0.75)	146	5.36 (1.25)	0.02 (0.56)
		Week 12	138	5.08 (1.27)	0.00 (0.88)	143	5.37 (1.22)	0.00 (0.73)
	Median (25%, 75%)	Baseline	144	4.80 (4.25, 5.85)	-	146	5.20 (4.40, 6.20)	-
		Week 2	144	4.90 (4.30, 5.70)	0.00 (-0.30, 0.50)	146	5.20 (4.40, 6.10)	0.05 (-0.40, 0.40)
		Week 12	138	4.80 (4.20, 5.80)	0.00 (-0.40, 0.50)	143	5.30 (4.50, 6.10)	0.00 (-0.40, 0.50)
Blood Urea Nitrogen (mg/dL)	Mean (SD)	Baseline	144	16.28 (4.23)	-	146	15.96 (4.05)	-
		Week 2	144	16.33 (4.38)	0.04 (2.93)	146	15.55 (3.60)	-0.40 (3.01)
		Week 12	138	16.49 (4.27)	0.22 (3.50)	143	15.69 (4.00)	-0.28 (3.48)
	Median (25%, 75%)	Baseline	144	15.30 (13.10, 19.30)	-	146	15.25 (13.30, 18.20)	-
		Week 2	144	15.90 (13.00, 18.95)	0.15 (-1.75, 1.65)	146	15.20 (13.10, 18.10)	-0.35 (-2.50, 1.50)
		Week 12	138	15.90 (13.60, 18.70)	0.30 (-2.20, 2.40)	143	14.70 (12.90, 18.20)	-0.30 (-2.20, 1.50)
Creatinine (mg/dL)	Mean (SD)	Baseline	144	0.697 (0.153)	-	146	0.702 (0.153)	-
		Week 2	144	0.690 (0.143)	-0.007 (0.062)	146	0.696 (0.158)	-0.006 (0.061)
		Week 12	138	0.701 (0.156)	0.002 (0.071)	143	0.708 (0.158)	0.004 (0.075)
	Median (25%, 75%)	Baseline	144	0.685 (0.590, 0.800)	-	146	0.675 (0.580, 0.810)	-
		Week 2	144	0.680 (0.585, 0.780)	-0.010 (-0.040, 0.030)	146	0.665 (0.580, 0.810)	-0.010 (-0.040, 0.020)
		Week 12	138	0.700 (0.580, 0.800)	0.000 (-0.050, 0.050)	143	0.670 (0.580, 0.830)	0.000 (-0.040, 0.050)
Cholesterol (mg/dL)	Mean (SD)	Baseline	144	213.7 (34.1)	-	146	210.6 (34.1)	-
		Week 2	144	212.3 (32.9)	-1.4 (18.8)	146	208.9 (33.6)	-1.7 (18.4)
		Week 12	138	214.4 (34.3)	1.1 (23.3)	143	210.7 (37.0)	0.5 (21.5)
	Median (25%, 75%)	Baseline	144	212.0 (194.5, 234.5)	-	146	207.0 (187.0, 232.0)	-
		Week 2	144	213.0 (188.0, 238.0)	-1.0 (-13.0, 11.5)	146	206.0 (185.0, 228.0)	-2.0 (-11.0, 9.0)
		Week 12	138	215.5 (190.0, 236.0)	3.0 (-13.0, 15.0)	143	207.0 (186.0, 233.0)	1.0 (-13.0, 13.0)
Triglycerides (mg/dL)	Mean (SD)	Baseline	144	143.7 (84.8)	-	146	162.5 (103.2)	-
		Week 2	144	144.4 (106.2)	0.7 (73.6)	146	165.0 (97.2)	2.6 (90.2)
		Week 12	138	151.3 (100.6)	7.3 (90.9)	143	160.9 (91.6)	-2.6 (77.4)
	Median (25%, 75%)	Baseline	144	123.5 (87.5, 177.5)	-	146	140.0 (106.0, 201.0)	-
		Week 2	144	115.5 (85.5, 174.0)	-2.5 (-35.5, 35.0)	146	133.5 (99.0, 200.0)	1.0 (-27.0, 35.0)
		Week 12	138	124.0 (90.0, 182.0)	-3.0 (-30.0, 37.0)	143	139.0 (103.0, 194.0)	0.0 (-32.0, 36.0)

Parameters		Timepoint	Placebo N=144 n	Placebo N=144 Value at timepoint	Placebo N=144 Change from baseline	SI-613 30 mg N=146 n	SI-613 30 mg N=146 Value at timepoint	SI-613 30 mg N=146 Change from baseline
C Reactive Protein (mg/dL)	Mean (SD)	Baseline	144	0.095 (0.219)	-	145	0.175 (0.446)	-
		Week 2	143	0.125 (0.545)	0.030 (0.580)	145	0.171 (0.460)	-0.004 (0.333)
		Week 12	137	0.177 (0.887)	0.080 (0.859)	143	0.164 (0.313)	-0.010 (0.286)
	Median (25%, 75%)	Baseline	144	0.040 (0.020, 0.080)	-	145	0.060 (0.030, 0.150)	-
		Week 2	143	0.030 (0.020, 0.070)	0.000 (-0.020, 0.020)	145	0.050 (0.020, 0.120)	0.000 (-0.050, 0.020)
		Week 12	135	0.030 (0.020, 0.090)	0.000 (-0.010, 0.020)	143	0.050 (0.030, 0.150)	0.000 (-0.030, 0.030)
Sodium (mEq/L)	Mean (SD)	Baseline	144	141.8 (2.1)	-	146	141.6 (2.0)	-
		Week 2	144	141.7 (2.1)	-0.2 (2.3)	146	141.6 (2.2)	-0.1 (2.2)
		Week 12	138	141.9 (2.2)	0.1 (2.5)	143	141.4 (2.6)	-0.3 (2.3)
	Median (25%, 75%)	Baseline	144	142.0 (140.0, 143.0)	-	146	142.0 (140.0, 143.0)	-
		Week 2	144	142.0 (140.0, 143.0)	0.0 (-2.0, 1.0)	146	142.0 (140.0, 143.0)	0.0 (-2.0, 1.0)
		Week 12	138	142.0 (140.0, 143.0)	0.0 (-2.0, 2.0)	143	141.0 (140.0, 143.0)	0.0 (-2.0, 1.0)
Potassium (mEq/L)	Mean (SD)	Baseline	144	4.29 (0.33)	-	146	4.25 (0.35)	-
		Week 2	144	4.27 (0.36)	-0.02 (0.35)	146	4.20 (0.32)	-0.04 (0.33)
		Week 12	138	4.25 (0.33)	-0.06 (0.36)	143	4.25 (0.37)	0.00 (0.39)
	Median (25%, 75%)	Baseline	144	4.30 (4.10, 4.50)	-	146	4.20 (4.00, 4.50)	-
		Week 2	144	4.20 (4.00, 4.50)	0.00 (-0.20, 0.20)	146	4.20 (4.00, 4.40)	0.00 (-0.20, 0.10)
		Week 12	138	4.20 (4.00, 4.50)	0.00 (-0.30, 0.20)	143	4.20 (4.00, 4.50)	0.00 (-0.20, 0.20)
Chloride (mEq/L)	Mean (SD)	Baseline	144	104.0 (2.3)	-	146	103.7 (2.1)	-
		Week 2	144	104.2 (2.3)	0.2 (2.2)	146	104.0 (2.1)	0.2 (2.2)
		Week 12	138	104.0 (2.4)	0.1 (2.2)	143	103.9 (2.5)	0.2 (2.0)
	Median (25%, 75%)	Baseline	144	104.0 (103.0, 105.0)	-	146	104.0 (102.0, 105.0)	-
		Week 2	144	104.0 (102.0, 106.0)	0.0 (-1.0, 2.0)	146	104.0 (103.0, 105.0)	0.0 (-1.0, 2.0)
		Week 12	138	104.0 (103.0, 105.0)	0.0 (-1.0, 2.0)	143	104.0 (103.0, 105.0)	0.0 (-1.0, 2.0)
Calcium (mg/dL)	Mean (SD)	Baseline	144	9.31 (0.38)	-	146	9.34 (0.36)	-
		Week 2	144	9.29 (0.38)	-0.02 (0.34)	146	9.33 (0.33)	-0.01 (0.32)
		Week 12	138	9.33 (0.39)	0.02 (0.38)	143	9.33 (0.34)	-0.02 (0.37)
	Median (25%, 75%)	Baseline	144	9.30 (9.10, 9.50)	-	146	9.30 (9.10, 9.60)	-
		Week 2	144	9.25 (9.00, 9.50)	0.00 (-0.20, 0.20)	146	9.30 (9.10, 9.50)	0.00 (-0.20, 0.20)
		Week 12	138	9.30 (9.10, 9.50)	0.00 (-0.20, 0.30)	143	9.30 (9.10, 9.60)	0.00 (-0.30, 0.30)
Creatine Kinase (U/L)	Mean (SD)	Baseline	144	122.2 (65.2)	-	146	115.9 (83.3)	-
		Week 2	144	125.6 (77.4)	3.4 (60.8)	146	112.5 (68.0)	-3.5 (66.5)
		Week 12	138	117.6 (57.0)	-5.0 (50.3)	143	114.1 (73.9)	-2.5 (70.3)
	Median (25%, 75%)	Baseline	144	104.0 (76.5, 141.5)	-	146	92.0 (68.0, 138.0)	-
		Week 2	144	106.0 (78.5, 146.0)	0.5 (-18.0, 17.5)	146	95.5 (67.0, 134.0)	1.5 (-13.0, 14.0)
		Week 12	138	99.5 (77.0, 140.0)	-0.5 (-18.0, 16.0)	143	95.0 (68.0, 131.0)	0.0 (-13.0, 14.0)
Hemoglobin A1C/Hemoglobin (%)	Mean (SD)	Baseline	144	5.86 (0.53)	-	146	5.83 (0.51)	-
		Week 2	144	5.86 (0.50)	0.00 (0.14)	146	5.83 (0.51)	-0.01 (0.15)
		Week 12	138	5.93 (0.58)	0.06 (0.22)	143	5.87 (0.57)	0.03 (0.23)
	Median (25%, 75%)	Baseline	144	5.80 (5.50, 6.00)	-	146	5.70 (5.50, 6.00)	-
		Week 2	144	5.70 (5.60, 6.00)	0.00 (-0.10, 0.10)	146	5.70 (5.50, 6.00)	0.00 (-0.10, 0.10)
		Week 12	138	5.80 (5.60, 6.10)	0.10 (-0.10, 0.10)	143	5.70 (5.50, 6.00)	0.00 (-0.10, 0.10)

〔5.3.5.1-4 Table 14.3.4-1 改編〕

表 2.7.4.7-72. 臨床検査値の各項目の平均値と中央値：613/1032 試験

			Knee N=126			Except for knee N=40			Total N=166		
Parameters		Timepoint	n	Value at timepoint	Change from baseline	n	Value at timepoint	Change from baseline	n	Value at timepoint	Change from baseline
Leukocytes (/uL)	Mean (SD)	Baseline	126	6423.8 (1608.6)	-	40	6362.5 (1743.5)	-	166	6409.0 (1637.0)	-
		Week 2	126	6090.5 (1550.6)	-333.3 (1041.4)	38	6244.7 (1821.0)	-110.5 (1470.4)	164	6126.2 (1612.7)	-281.7 (1153.8)
		Week 12	122	6012.3 (1478.3)	-378.7 (1099.9)	40	6087.5 (1646.6)	-275.0 (1309.5)	162	6030.9 (1516.7)	-353.1 (1151.8)
		Week 24	121	6077.7 (1554.4)	-310.7 (1243.0)	37	5783.8 (1537.0)	-516.2 (1323.6)	158	6008.9 (1550.5)	-358.9 (1261.0)
		Week 36	120	6109.2 (1483.7)	-281.7 (1314.3)	37	5810.8 (1756.1)	-489.2 (1240.5)	157	6038.9 (1551.5)	-330.6 (1296.4)
		Week 52	119	5911.8 (1334.9)	-462.2 (1099.5)	37	5859.5 (1700.6)	-440.5 (1533.4)	156	5899.4 (1424.4)	-457.1 (1211.0)
	Median	Baseline	126	6300.0 (5100.0, 7300.0)	-	40	6150.0 (5000.0, 7050.0)	-	166	6300.0 (5100.0, 7300.0)	-
	(25%, 75%)	Week 2	126	5900.0 (5100.0, 6900.0)	-300.0 (-800.0, 300.0)	38	5750.0 (4900.0, 7500.0)	0.0 (-800.0, 700.0)	164	5900.0 (5050.0, 7100.0)	-250.0 (-800.0, 300.0)
		Week 12	122	5800.0 (5000.0, 6700.0)	-300.0 (-800.0, 300.0)	40	6050.0 (4700.0, 7350.0)	-300.0 (-650.0, 300.0)	162	5900.0 (4900.0, 6700.0)	-300.0 (-800.0, 300.0)
		Week 24	121	5800.0 (5200.0, 6800.0)	-500.0 (-1000.0, 300.0)	37	5400.0 (4900.0, 6400.0)	-400.0 (-1000.0, 300.0)	158	5700.0 (5100.0, 6700.0)	-400.0 (-1000.0, 300.0)
		Week 36	120	5900.0 (5200.0, 6800.0)	-300.0 (-900.0, 300.0)	37	5500.0 (4700.0, 6900.0)	-500.0 (-1200.0, 200.0)	157	5800.0 (5100.0, 6800.0)	-300.0 (-1000.0, 300.0)
		Week 52	119	5800.0 (5100.0, 6700.0)	-500.0 (-900.0, 100.0)	37	5600.0 (5100.0, 6200.0)	-200.0 (-1200.0, 500.0)	156	5700.0 (5100.0, 6550.0)	-450.0 (-900.0, 200.0)
Neutrophils /Leukocytes (%)	Mean (SD)	Baseline	126	59.17 (8.69)	-	40	57.51 (9.38)	-	166	58.77 (8.86)	-
		Week 2	126	57.70 (8.14)	-1.47 (6.99)	38	58.53 (8.56)	1.36 (7.58)	164	57.89 (8.22)	-0.81 (7.21)
		Week 12	122	57.89 (8.01)	-1.28 (6.76)	40	57.60 (7.85)	0.09 (7.37)	162	57.82 (7.95)	-0.94 (6.92)
		Week 24	121	58.49 (8.31)	-0.74 (8.21)	37	57.66 (7.77)	0.08 (7.85)	158	58.30 (8.17)	-0.54 (8.11)
		Week 36	120	60.10 (9.12)	0.88 (8.23)	37	57.36 (9.73)	-0.21 (9.35)	157	59.45 (9.31)	0.62 (8.49)
		Week 52	119	58.14 (8.53)	-0.99 (7.24)	37	58.31 (7.75)	0.73 (8.28)	156	58.18 (8.33)	-0.59 (7.51)
	Median	Baseline	126	58.95 (52.90, 65.90)	-	40	56.10 (52.40, 61.55)	-	166	57.90 (52.80, 64.90)	-
	(25%, 75%)	Week 2	126	56.85 (52.60, 62.60)	-1.25 (-5.50, 2.50)	38	58.50 (52.70, 63.40)	1.05 (-3.60, 8.80)	164	57.90 (52.65, 63.20)	-0.85 (-5.25, 3.70)
		Week 12	122	57.20 (52.10, 63.70)	-1.05 (-5.40, 3.20)	40	58.10 (52.10, 61.90)	-0.65 (-5.25, 4.85)	162	57.45 (52.10, 63.20)	-0.90 (-5.40, 3.90)
		Week 24	121	59.80 (53.10, 63.40)	-0.70 (-4.70, 4.30)	37	57.90 (53.50, 63.20)	0.40 (-2.50, 4.30)	158	58.95 (53.10, 63.40)	-0.55 (-4.10, 4.30)
		Week 36	120	58.35 (53.35, 66.90)	0.55 (-3.75, 5.65)	37	58.30 (51.30, 64.80)	1.20 (-4.80, 5.10)	157	58.30 (53.10, 65.90)	0.80 (-4.20, 5.60)
		Week 52	119	58.70 (51.10, 64.50)	-1.80 (-5.30, 3.50)	37	59.10 (53.50, 63.50)	1.10 (-1.80, 5.00)	156	59.00 (52.00, 64.20)	-0.65 (-5.05, 3.65)
Lymphocytes /Leukocytes (%)	Mean (SD)	Baseline	126	30.26 (7.23)	-	40	32.19 (7.80)	-	166	30.72 (7.39)	-
		Week 2	126	31.53 (7.27)	1.27 (5.73)	38	30.66 (7.08)	-1.76 (6.67)	164	31.33 (7.21)	0.57 (6.08)
		Week 12	122	31.63 (7.26)	1.33 (5.63)	40	31.86 (7.16)	-0.33 (6.49)	162	31.69 (7.21)	0.92 (5.88)
		Week 24	121	31.00 (7.54)	0.73 (6.61)	37	31.87 (5.68)	0.04 (6.33)	158	31.20 (7.14)	0.57 (6.53)
		Week 36	120	29.74 (8.07)	-0.54 (7.04)	37	31.62 (8.09)	-0.21 (7.52)	157	30.18 (8.09)	-0.46 (7.13)
		Week 52	119	31.19 (7.63)	0.85 (6.03)	37	30.93 (6.36)	-0.89 (7.06)	156	31.13 (7.33)	0.43 (6.31)
	Median	Baseline	126	30.10 (25.30, 35.90)	-	40	33.75 (27.95, 37.85)	-	166	31.00 (25.50, 36.40)	-
	(25%, 75%)	Week 2	126	30.95 (26.70, 36.70)	1.65 (-1.80, 4.10)	38	30.75 (26.00, 34.50)	-0.80 (-6.40, 2.50)	164	30.90 (26.55, 36.40)	1.45 (-2.90, 3.60)
		Week 12	122	31.70 (26.40, 37.00)	0.85 (-2.10, 4.50)	40	31.95 (27.50, 36.45)	-0.45 (-4.10, 4.40)	162	31.70 (27.00, 36.90)	0.45 (-2.70, 4.50)
		Week 24	121	30.30 (26.10, 35.30)	0.90 (-3.10, 3.50)	37	32.50 (27.90, 36.20)	0.40 (-3.50, 3.00)	158	30.95 (26.30, 35.60)	0.70 (-3.20, 3.50)

Parameters		Timepoint	Knee N=126 n	Knee N=126 Value at timepoint	Knee N=126 Change from baseline	Except for knee N=40 n	Except for knee N=40 Value at timepoint	Except for knee N=40 Change from baseline	Total N=166 n	Total N=166 Value at timepoint	Total N=166 Change from baseline
		Week 36	120	29.55 (23.30, 35.65)	-0.15 (-3.80, 3.50)	37	30.50 (24.80, 37.20)	-1.10 (-4.60, 4.10)	157	30.50 (23.50, 36.00)	-0.30 (-4.30, 3.50)
		Week 52	119	30.00 (26.00, 36.50)	1.10 (-2.90, 4.30)	37	30.50 (25.80, 34.40)	-1.10 (-3.70, 2.00)	156	30.05 (25.80, 35.60)	0.40 (-3.40, 4.00)
Monocytes /Leukocytes (%)	Mean (SD)	Baseline	126	7.10 (2.13)	-	40	6.89 (2.27)	-	166	7.05 (2.16)	-
		Week 2	126	7.17 (1.82)	0.07 (1.76)	38	7.12 (1.97)	0.20 (1.78)	164	7.16 (1.85)	0.10 (1.76)
		Week 12	122	7.05 (1.95)	-0.03 (1.79)	40	7.25 (1.55)	0.37 (1.95)	162	7.10 (1.86)	0.07 (1.83)
		Week 24	121	7.27 (1.87)	0.18 (1.90)	37	7.03 (1.82)	-0.01 (2.04)	158	7.21 (1.85)	0.14 (1.93)
		Week 36	120	6.85 (1.86)	-0.23 (1.81)	37	7.51 (1.77)	0.47 (1.88)	157	7.00 (1.86)	-0.07 (1.84)
		Week 52	119	7.38 (1.92)	0.27 (1.95)	37	7.08 (2.19)	0.04 (2.23)	156	7.31 (1.98)	0.22 (2.01)
	Median (25%, 75%)	Baseline	126	7.00 (5.50, 8.60)	-	40	6.85 (5.45, 8.00)	-	166	7.00 (5.50, 8.40)	-
		Week 2	126	7.00 (6.00, 8.40)	0.10 (-1.00, 1.10)	38	6.95 (6.00, 8.00)	-0.10 (-1.00, 1.50)	164	7.00 (6.00, 8.30)	0.00 (-1.00, 1.10)
		Week 12	122	7.00 (6.00, 8.10)	0.05 (-1.10, 1.00)	40	7.15 (6.05, 8.35)	0.40 (-1.15, 1.15)	162	7.00 (6.00, 8.20)	0.20 (-1.10, 1.00)
		Week 24	121	7.00 (5.90, 8.50)	-0.10 (-1.20, 1.60)	37	6.80 (5.90, 8.00)	0.20 (-1.00, 1.10)	158	7.00 (5.90, 8.40)	0.10 (-1.10, 1.40)
		Week 36	120	6.80 (5.40, 7.70)	0.00 (-1.20, 0.65)	37	7.10 (6.60, 8.30)	0.40 (-1.00, 1.40)	157	7.00 (5.70, 7.80)	0.00 (-1.10, 0.80)
		Week 52	119	7.30 (5.90, 8.90)	0.40 (-0.70, 1.50)	37	7.00 (5.60, 8.60)	-0.20 (-1.00, 1.00)	156	7.25 (5.90, 8.70)	0.30 (-0.85, 1.30)
Eosinophils /Leukocytes (%)	Mean (SD)	Baseline	126	3.08 (2.53)	-	40	3.10 (2.61)	-	166	3.08 (2.54)	-
		Week 2	126	3.14 (1.98)	0.07 (1.66)	38	3.31 (2.99)	0.14 (2.10)	164	3.18 (2.25)	0.09 (1.76)
		Week 12	122	3.00 (1.88)	-0.05 (1.69)	40	2.83 (2.22)	-0.27 (2.19)	162	2.96 (1.96)	-0.10 (1.82)
		Week 24	121	2.83 (1.80)	-0.20 (1.98)	37	3.06 (2.66)	-0.16 (1.25)	158	2.89 (2.02)	-0.19 (1.83)
		Week 36	120	2.92 (1.95)	-0.12 (2.08)	37	3.13 (2.57)	-0.09 (1.63)	157	2.97 (2.11)	-0.11 (1.98)
		Week 52	119	2.90 (1.68)	-0.13 (1.84)	37	3.33 (2.63)	0.10 (1.11)	156	3.00 (1.95)	-0.07 (1.69)
	Median (25%, 75%)	Baseline	126	2.40 (1.60, 3.90)	-	40	2.40 (1.50, 3.70)	-	166	2.40 (1.50, 3.90)	-
		Week 2	126	2.50 (1.70, 4.30)	0.00 (-0.60, 0.80)	38	2.20 (1.80, 4.30)	-0.20 (-0.70, 0.40)	164	2.45 (1.75, 4.30)	0.00 (-0.60, 0.70)
		Week 12	122	2.50 (1.60, 4.10)	0.20 (-0.60, 0.80)	40	2.35 (1.50, 3.65)	-0.15 (-1.20, 0.40)	162	2.45 (1.60, 3.80)	0.10 (-0.70, 0.70)
		Week 24	121	2.40 (1.50, 3.70)	0.00 (-0.80, 0.80)	37	2.30 (1.70, 3.50)	-0.10 (-0.80, 0.40)	158	2.40 (1.60, 3.70)	0.00 (-0.80, 0.70)
		Week 36	120	2.40 (1.65, 4.00)	-0.10 (-0.70, 0.70)	37	2.00 (1.60, 3.90)	0.20 (-0.90, 0.70)	157	2.30 (1.60, 4.00)	0.00 (-0.70, 0.70)
		Week 52	119	2.50 (1.70, 3.70)	0.00 (-0.80, 0.70)	37	2.50 (1.60, 4.10)	-0.10 (-0.70, 0.60)	156	2.50 (1.70, 3.85)	0.00 (-0.70, 0.70)
Basophils /Leukocytes (%)	Mean (SD)	Baseline	126	0.39 (0.28)	-	40	0.33 (0.19)	-	166	0.38 (0.27)	-
		Week 2	126	0.45 (0.29)	0.06 (0.40)	38	0.38 (0.21)	0.06 (0.28)	164	0.44 (0.28)	0.06 (0.37)
		Week 12	122	0.42 (0.29)	0.03 (0.36)	40	0.47 (0.29)	0.14 (0.29)	162	0.43 (0.29)	0.06 (0.35)
		Week 24	121	0.41 (0.26)	0.02 (0.36)	37	0.38 (0.22)	0.05 (0.25)	158	0.40 (0.25)	0.03 (0.34)
		Week 36	120	0.39 (0.31)	0.01 (0.35)	37	0.38 (0.26)	0.05 (0.28)	157	0.39 (0.30)	0.02 (0.34)
		Week 52	119	0.39 (0.25)	0.00 (0.31)	37	0.36 (0.24)	0.03 (0.33)	156	0.38 (0.24)	0.01 (0.32)
	Median (25%, 75%)	Baseline	126	0.30 (0.30, 0.50)	-	40	0.30 (0.25, 0.40)	-	166	0.30 (0.30, 0.50)	-
		Week 2	126	0.40 (0.30, 0.50)	0.05 (-0.10, 0.20)	38	0.35 (0.30, 0.50)	0.00 (-0.10, 0.20)	164	0.40 (0.30, 0.50)	0.00 (-0.10, 0.20)
		Week 12	122	0.40 (0.30, 0.50)	0.00 (-0.10, 0.20)	40	0.40 (0.30, 0.60)	0.10 (0.00, 0.20)	162	0.40 (0.30, 0.60)	0.00 (-0.10, 0.20)

Parameters		Timepoint	Knee N=126 n	Knee N=126 Value at timepoint	Knee N=126 Change from baseline	Except for knee N=40 n	Except for knee N=40 Value at timepoint	Except for knee N=40 Change from baseline	Total N=166 n	Total N=166 Value at timepoint	Total N=166 Change from baseline
		Week 24	121	0.40 (0.30, 0.50)	0.10 (-0.10, 0.20)	37	0.30 (0.30, 0.50)	0.00 (-0.10, 0.10)	158	0.40 (0.30, 0.50)	0.05 (-0.10, 0.20)
		Week 36	120	0.30 (0.25, 0.50)	0.00 (-0.15, 0.15)	37	0.30 (0.30, 0.50)	0.00 (-0.10, 0.10)	157	0.30 (0.30, 0.50)	0.00 (-0.10, 0.10)
		Week 52	119	0.40 (0.30, 0.50)	0.00 (-0.10, 0.20)	37	0.30 (0.30, 0.50)	0.00 (-0.20, 0.10)	156	0.40 (0.30, 0.50)	0.00 (-0.10, 0.20)
Erythrocytes (10^4/uL)	Mean (SD)	Baseline	126	432.2 (41.2)	-	40	441.5 (40.1)	-	166	434.4 (41.0)	-
		Week 2	126	424.2 (41.2)	-8.0 (15.9)	38	439.3 (36.4)	-4.4 (16.1)	164	427.7 (40.6)	-7.1 (15.9)
		Week 12	122	427.5 (42.6)	-4.7 (18.8)	40	436.0 (41.2)	-5.5 (14.9)	162	429.6 (42.3)	-4.9 (17.9)
		Week 24	121	429.5 (44.4)	-3.0 (20.0)	37	436.2 (42.7)	-5.1 (17.9)	158	431.1 (44.0)	-3.5 (19.5)
		Week 36	120	430.1 (42.1)	-2.2 (18.7)	37	441.9 (44.5)	0.6 (18.3)	157	432.9 (42.8)	-1.5 (18.6)
		Week 52	119	424.4 (42.7)	-8.6 (19.7)	37	431.4 (36.5)	-9.9 (18.7)	156	426.1 (41.3)	-8.9 (19.4)
	Median (25%, 75%)	Baseline	126	431.5 (407.0, 461.0)	-	40	441.5 (414.0, 466.5)	-	166	435.5 (409.0, 463.0)	-
		Week 2	126	426.5 (397.0, 453.0)	-7.0 (-21.0, 4.0)	38	440.0 (422.0, 470.0)	-5.5 (-14.0, 6.0)	164	430.0 (400.0, 457.0)	-7.0 (-20.0, 4.0)
		Week 12	122	432.0 (399.0, 457.0)	-5.0 (-19.0, 8.0)	40	436.0 (408.5, 462.5)	-6.0 (-14.5, 0.0)	162	433.0 (402.0, 459.0)	-5.0 (-17.0, 5.0)
		Week 24	121	430.0 (402.0, 463.0)	-3.0 (-18.0, 8.0)	37	428.0 (413.0, 464.0)	-3.0 (-17.0, 8.0)	158	430.0 (405.0, 464.0)	-3.0 (-17.0, 8.0)
		Week 36	120	434.0 (401.0, 462.5)	-1.5 (-13.0, 12.5)	37	439.0 (420.0, 475.0)	1.0 (-9.0, 14.0)	157	434.0 (407.0, 465.0)	-1.0 (-12.0, 13.0)
		Week 52	119	425.0 (399.0, 458.0)	-8.0 (-20.0, 4.0)	37	435.0 (416.0, 454.0)	-9.0 (-23.0, 1.0)	156	427.0 (402.0, 456.5)	-9.0 (-20.0, 2.5)
Hemoglobin (g/dL)	Mean (SD)	Baseline	126	13.39 (1.25)	-	40	13.47 (1.39)	-	166	13.41 (1.28)	-
		Week 2	126	13.15 (1.25)	-0.24 (0.47)	40	13.33 (1.32)	-0.14 (0.45)	166	13.20 (1.27)	-0.21 (0.47)
		Week 12	122	13.24 (1.32)	-0.16 (0.59)	40	13.36 (1.47)	-0.11 (0.44)	162	13.27 (1.35)	-0.15 (0.56)
		Week 24	121	13.36 (1.37)	-0.04 (0.61)	37	13.53 (1.61)	0.01 (0.55)	158	13.40 (1.42)	-0.03 (0.59)
		Week 36	120	13.42 (1.27)	0.02 (0.58)	37	13.70 (1.59)	0.18 (0.54)	157	13.48 (1.35)	0.05 (0.57)
		Week 52	119	13.27 (1.28)	-0.14 (0.62)	37	13.50 (1.39)	-0.03 (0.54)	156	13.32 (1.31)	-0.12 (0.60)
	Median (25%, 75%)	Baseline	126	13.30 (12.60, 14.20)	-	40	13.35 (12.50, 14.55)	-	166	13.30 (12.60, 14.20)	-
		Week 2	126	13.10 (12.30, 14.00)	-0.20 (-0.60, 0.10)	40	13.15 (12.65, 14.50)	-0.10 (-0.50, 0.20)	166	13.10 (12.30, 14.00)	-0.10 (-0.60, 0.10)
		Week 12	122	13.25 (12.40, 14.20)	-0.20 (-0.60, 0.20)	40	13.25 (12.35, 14.50)	-0.20 (-0.40, 0.00)	162	13.25 (12.40, 14.20)	-0.20 (-0.50, 0.20)
		Week 24	121	13.30 (12.60, 14.30)	0.00 (-0.50, 0.30)	37	13.30 (12.70, 14.70)	0.00 (-0.30, 0.40)	158	13.30 (12.60, 14.40)	0.00 (-0.50, 0.30)
		Week 36	120	13.30 (12.60, 14.40)	0.00 (-0.30, 0.40)	37	13.40 (12.80, 15.20)	0.10 (-0.20, 0.60)	157	13.40 (12.60, 14.50)	0.00 (-0.30, 0.40)
		Week 52	119	13.30 (12.40, 14.10)	-0.10 (-0.50, 0.20)	37	13.30 (12.60, 14.60)	-0.10 (-0.50, 0.40)	156	13.30 (12.45, 14.20)	-0.10 (-0.50, 0.25)
Hematocrit (%)	Mean (SD)	Baseline	126	39.87 (3.67)	-	40	40.24 (3.91)	-	166	39.96 (3.72)	-
		Week 2	126	39.25 (3.60)	-0.62 (1.50)	38	39.98 (3.58)	-0.36 (1.41)	164	39.42 (3.60)	-0.56 (1.48)
		Week 12	122	39.63 (3.84)	-0.26 (1.75)	40	40.05 (4.21)	-0.19 (1.28)	162	39.73 (3.93)	-0.24 (1.65)
		Week 24	121	39.82 (3.95)	-0.09 (1.86)	37	40.27 (4.47)	-0.10 (1.61)	158	39.92 (4.07)	-0.09 (1.80)
		Week 36	120	39.84 (3.57)	-0.04 (1.71)	37	40.63 (4.48)	0.26 (1.62)	157	40.03 (3.80)	0.03 (1.69)
		Week 52	119	39.29 (3.66)	-0.65 (1.84)	37	39.82 (3.81)	-0.55 (1.58)	156	39.42 (3.69)	-0.63 (1.78)
	Median (25%, 75%)	Baseline	126	39.65 (37.40, 42.00)	-	40	40.20 (36.95, 43.10)	-	166	39.85 (37.30, 42.40)	-
		Week 2	126	39.20 (36.90, 41.60)	-0.55 (-1.90, 0.60)	38	39.30 (38.40, 42.70)	-0.45 (-1.50, 0.70)	164	39.30 (37.10, 41.95)	-0.50 (-1.65, 0.60)

Parameters		Timepoint	Knee N=126 n	Knee N=126 Value at timepoint	Knee N=126 Change from baseline	Except for knee N=40 n	Except for knee N=40 Value at timepoint	Except for knee N=40 Change from baseline	Total N=166 n	Total N=166 Value at timepoint	Total N=166 Change from baseline
		Week 12	122	39.75 (37.20, 42.60)	-0.30 (-1.50, 0.90)	40	39.85 (37.05, 42.90)	-0.15 (-0.90, 0.40)	162	39.80 (37.20, 42.60)	-0.30 (-1.20, 0.70)
		Week 24	121	39.90 (37.30, 42.30)	-0.10 (-1.40, 0.90)	37	39.20 (38.00, 43.60)	-0.10 (-1.10, 1.10)	158	39.85 (37.30, 42.80)	-0.10 (-1.40, 1.00)
		Week 36	120	39.90 (37.25, 42.80)	-0.15 (-1.00, 1.05)	37	40.20 (38.00, 44.30)	0.30 (-1.10, 1.30)	157	39.90 (37.50, 42.90)	-0.10 (-1.00, 1.10)
		Week 52	119	39.30 (36.50, 41.70)	-0.70 (-1.80, 0.50)	37	39.50 (37.60, 42.70)	-0.70 (-1.80, 0.70)	156	39.35 (36.80, 42.00)	-0.70 (-1.80, 0.50)
Platelets (10^4/uL)	Mean (SD)	Baseline	126	23.99 (6.12)	-	40	25.36 (6.99)	-	166	24.32 (6.34)	-
		Week 2	126	23.49 (5.77)	-0.49 (2.99)	38	24.85 (5.69)	-0.60 (3.23)	164	23.81 (5.76)	-0.52 (3.04)
		Week 12	122	23.32 (6.04)	-0.67 (2.98)	40	25.13 (6.33)	-0.24 (2.67)	162	23.77 (6.14)	-0.56 (2.90)
		Week 24	121	23.44 (5.73)	-0.57 (2.85)	35	25.05 (6.42)	-0.56 (3.63)	156	23.80 (5.91)	-0.56 (3.03)
		Week 36	120	24.14 (6.16)	0.04 (3.46)	37	24.88 (6.22)	-0.12 (3.46)	157	24.31 (6.16)	0.00 (3.45)
		Week 52	119	23.72 (5.91)	-0.13 (4.01)	37	25.08 (6.35)	0.07 (4.45)	156	24.04 (6.02)	-0.08 (4.10)
	Median	Baseline	126	23.00 (20.30, 26.90)	-	40	23.80 (19.55, 29.60)	-	166	23.20 (20.20, 27.60)	-
	(25%, 75%)	Week 2	126	22.95 (19.70, 26.30)	-0.65 (-1.70, 1.00)	38	24.35 (20.30, 27.80)	-0.55 (-3.00, 1.70)	164	23.10 (19.70, 26.65)	-0.60 (-1.85, 1.20)
		Week 12	122	22.75 (19.00, 27.00)	-0.60 (-2.10, 1.10)	40	23.10 (20.35, 28.90)	-0.10 (-1.40, 1.80)	162	22.95 (19.30, 27.20)	-0.45 (-2.00, 1.30)
		Week 24	121	23.00 (19.50, 26.50)	-0.60 (-1.90, 1.30)	35	23.70 (19.80, 28.70)	-0.80 (-2.00, 1.40)	156	23.10 (19.55, 27.35)	-0.60 (-1.90, 1.35)
		Week 36	120	23.30 (19.80, 27.05)	0.10 (-1.25, 1.60)	37	23.40 (19.60, 29.20)	-0.40 (-2.00, 2.40)	157	23.30 (19.70, 27.60)	0.10 (-1.60, 1.70)
		Week 52	119	23.00 (19.70, 27.50)	-0.20 (-1.50, 1.20)	37	23.00 (20.70, 30.50)	0.90 (-2.10, 2.50)	156	23.00 (19.80, 27.70)	-0.10 (-1.65, 1.55)
Protein (g/dL)	Mean (SD)	Baseline	126	7.11 (0.41)	-	39	7.18 (0.38)	-	165	7.12 (0.41)	-
		Week 2	126	6.99 (0.43)	-0.12 (0.30)	40	7.04 (0.45)	-0.14 (0.32)	166	7.00 (0.43)	-0.12 (0.30)
		Week 12	122	7.03 (0.39)	-0.08 (0.29)	40	7.07 (0.28)	-0.11 (0.28)	162	7.04 (0.36)	-0.09 (0.29)
		Week 24	121	7.05 (0.41)	-0.05 (0.33)	37	7.09 (0.37)	-0.06 (0.30)	158	7.06 (0.40)	-0.05 (0.32)
		Week 36	120	7.06 (0.39)	-0.04 (0.32)	37	7.16 (0.39)	0.01 (0.33)	157	7.08 (0.39)	-0.03 (0.32)
		Week 52	120	7.01 (0.40)	-0.09 (0.32)	37	7.11 (0.42)	-0.06 (0.28)	157	7.03 (0.41)	-0.09 (0.31)
	Median	Baseline	126	7.10 (6.80, 7.40)	-	39	7.20 (6.90, 7.50)	-	165	7.10 (6.80, 7.40)	-
	(25%, 75%)	Week 2	126	7.00 (6.70, 7.30)	-0.10 (-0.30, 0.10)	40	7.00 (6.70, 7.50)	-0.20 (-0.40, 0.10)	166	7.00 (6.70, 7.30)	-0.10 (-0.30, 0.10)
		Week 12	122	7.00 (6.80, 7.20)	-0.10 (-0.30, 0.10)	40	7.00 (6.90, 7.30)	-0.10 (-0.30, 0.10)	162	7.00 (6.80, 7.30)	-0.10 (-0.30, 0.10)
		Week 24	121	7.10 (6.80, 7.30)	0.00 (-0.20, 0.20)	37	7.10 (6.80, 7.30)	-0.10 (-0.15, 0.10)	158	7.10 (6.80, 7.30)	-0.10 (-0.20, 0.20)
		Week 36	120	7.00 (6.80, 7.35)	-0.05 (-0.30, 0.20)	37	7.10 (6.80, 7.30)	0.10 (-0.20, 0.20)	157	7.10 (6.80, 7.30)	0.00 (-0.25, 0.20)
		Week 52	120	7.00 (6.80, 7.30)	-0.10 (-0.30, 0.10)	37	7.10 (6.80, 7.40)	0.00 (-0.25, 0.10)	157	7.00 (6.80, 7.30)	-0.10 (-0.30, 0.10)
Albumin (g/dL)	Mean (SD)	Baseline	126	4.23 (0.28)	-	39	4.21 (0.36)	-	165	4.23 (0.30)	-
		Week 2	126	4.15 (0.28)	-0.08 (0.22)	40	4.15 (0.31)	-0.05 (0.22)	166	4.15 (0.28)	-0.08 (0.22)
		Week 12	122	4.18 (0.28)	-0.06 (0.20)	40	4.16 (0.30)	-0.04 (0.23)	162	4.18 (0.28)	-0.06 (0.21)
		Week 24	121	4.20 (0.28)	-0.03 (0.24)	37	4.20 (0.36)	-0.01 (0.23)	158	4.20 (0.30)	-0.03 (0.24)
		Week 36	120	4.21 (0.31)	-0.02 (0.23)	37	4.22 (0.34)	0.01 (0.23)	157	4.21 (0.31)	-0.02 (0.23)
		Week 52	120	4.19 (0.26)	-0.05 (0.24)	37	4.19 (0.39)	-0.03 (0.22)	157	4.19 (0.29)	-0.04 (0.23)
		Baseline	126	4.20 (4.00, 4.40)	-	39	4.20 (3.90, 4.50)	-	165	4.20 (4.00, 4.40)	-

Parameters		Timepoint	Knee N=126 n	Knee N=126 Value at timepoint	Knee N=126 Change from baseline	Except for knee N=40 n	Except for knee N=40 Value at timepoint	Except for knee N=40 Change from baseline	Total N=166 n	Total N=166 Value at timepoint	Total N=166 Change from baseline
	Median	Week 2	126	4.10 (3.90, 4.30)	-0.10 (-0.20, 0.10)	40	4.20 (3.95, 4.40)	0.00 (-0.20, 0.10)	166	4.15 (3.90, 4.40)	-0.10 (-0.20, 0.10)
	(25%, 75%)	Week 12	122	4.20 (4.00, 4.40)	-0.10 (-0.20, 0.10)	40	4.10 (4.00, 4.40)	0.00 (-0.20, 0.10)	162	4.10 (4.00, 4.40)	-0.10 (-0.20, 0.10)
		Week 24	121	4.20 (4.00, 4.40)	-0.10 (-0.20, 0.10)	37	4.20 (4.00, 4.50)	0.00 (-0.20, 0.20)	158	4.20 (4.00, 4.40)	0.00 (-0.20, 0.10)
		Week 36	120	4.20 (4.00, 4.40)	0.00 (-0.20, 0.10)	37	4.20 (4.10, 4.40)	0.00 (-0.10, 0.15)	157	4.20 (4.00, 4.40)	0.00 (-0.20, 0.10)
		Week 52	120	4.20 (4.05, 4.30)	0.00 (-0.20, 0.10)	37	4.10 (4.00, 4.40)	-0.05 (-0.20, 0.10)	157	4.20 (4.00, 4.40)	0.00 (-0.20, 0.10)
Bilirubin (mg/dL)	Mean (SD)	Baseline	126	0.71 (0.25)	-	39	0.72 (0.21)	-	165	0.72 (0.24)	-
		Week 2	126	0.72 (0.27)	0.00 (0.18)	40	0.68 (0.22)	-0.04 (0.18)	166	0.71 (0.26)	-0.01 (0.19)
		Week 12	122	0.71 (0.25)	-0.01 (0.18)	40	0.72 (0.23)	-0.01 (0.22)	162	0.71 (0.25)	-0.01 (0.19)
		Week 24	121	0.70 (0.26)	-0.02 (0.18)	37	0.72 (0.20)	-0.02 (0.20)	158	0.70 (0.25)	-0.02 (0.19)
		Week 36	120	0.67 (0.22)	-0.04 (0.18)	37	0.70 (0.17)	-0.04 (0.18)	157	0.68 (0.21)	-0.04 (0.18)
		Week 52	120	0.68 (0.26)	-0.04 (0.22)	37	0.72 (0.23)	-0.03 (0.21)	157	0.69 (0.25)	-0.04 (0.22)
	Median	Baseline	126	0.70 (0.50, 0.80)	-	39	0.70 (0.60, 0.90)	-	165	0.70 (0.50, 0.80)	-
	(25%, 75%)	Week 2	126	0.70 (0.50, 0.80)	0.00 (-0.10, 0.10)	40	0.70 (0.50, 0.80)	0.00 (-0.20, 0.10)	166	0.70 (0.50, 0.80)	0.00 (-0.10, 0.10)
		Week 12	122	0.70 (0.60, 0.80)	0.00 (-0.10, 0.10)	40	0.70 (0.50, 0.90)	0.00 (-0.10, 0.10)	162	0.70 (0.60, 0.80)	0.00 (-0.10, 0.10)
		Week 24	121	0.70 (0.50, 0.80)	0.00 (-0.10, 0.10)	37	0.70 (0.60, 0.80)	0.00 (-0.15, 0.05)	158	0.70 (0.50, 0.80)	0.00 (-0.10, 0.10)
		Week 36	120	0.60 (0.50, 0.80)	0.00 (-0.10, 0.10)	37	0.70 (0.60, 0.80)	0.00 (-0.20, 0.10)	157	0.70 (0.50, 0.80)	0.00 (-0.10, 0.10)
		Week 52	120	0.60 (0.50, 0.80)	0.00 (-0.10, 0.10)	37	0.70 (0.60, 0.80)	-0.05 (-0.10, 0.05)	157	0.60 (0.50, 0.80)	0.00 (-0.10, 0.10)
Direct Bilirubin (mg/dL)	Mean (SD)	Baseline	126	0.08 (0.06)	-	39	0.08 (0.05)	-	165	0.08 (0.05)	-
		Week 2	126	0.08 (0.05)	0.00 (0.06)	40	0.07 (0.05)	-0.02 (0.05)	166	0.08 (0.05)	-0.01 (0.06)
		Week 12	122	0.08 (0.05)	0.00 (0.06)	40	0.09 (0.05)	0.01 (0.04)	162	0.09 (0.05)	0.00 (0.05)
		Week 24	121	0.08 (0.05)	0.00 (0.06)	37	0.09 (0.05)	0.00 (0.05)	158	0.08 (0.05)	0.00 (0.06)
		Week 36	120	0.07 (0.05)	-0.01 (0.06)	37	0.09 (0.05)	0.00 (0.05)	157	0.08 (0.05)	-0.01 (0.06)
		Week 52	120	0.06 (0.06)	-0.02 (0.06)	37	0.08 (0.06)	0.00 (0.06)	157	0.07 (0.06)	-0.02 (0.06)
	Median	Baseline	126	0.10 (0.00, 0.10)	-	39	0.10 (0.10, 0.10)	-	165	0.10 (0.10, 0.10)	-
	(25%, 75%)	Week 2	126	0.10 (0.00, 0.10)	0.00 (0.00, 0.00)	40	0.10 (0.00, 0.10)	0.00 (0.00, 0.00)	166	0.10 (0.00, 0.10)	0.00 (0.00, 0.00)
		Week 12	122	0.10 (0.10, 0.10)	0.00 (0.00, 0.00)	40	0.10 (0.10, 0.10)	0.00 (0.00, 0.00)	162	0.10 (0.10, 0.10)	0.00 (0.00, 0.00)
		Week 24	121	0.10 (0.10, 0.10)	0.00 (0.00, 0.00)	37	0.10 (0.10, 0.10)	0.00 (0.00, 0.00)	158	0.10 (0.10, 0.10)	0.00 (0.00, 0.00)
		Week 36	120	0.10 (0.00, 0.10)	0.00 (0.00, 0.00)	37	0.10 (0.10, 0.10)	0.00 (0.00, 0.00)	157	0.10 (0.00, 0.10)	0.00 (0.00, 0.00)
		Week 52	120	0.10 (0.00, 0.10)	0.00 (-0.10, 0.00)	37	0.10 (0.10, 0.10)	0.00 (0.00, 0.00)	157	0.10 (0.00, 0.10)	0.00 (-0.10, 0.00)
Aspartate Aminotransferase (U/L)	Mean (SD)	Baseline	126	23.5 (9.6)	-	39	22.2 (8.9)	-	165	23.2 (9.4)	-
		Week 2	126	22.7 (7.9)	-0.8 (5.7)	40	21.7 (9.0)	-0.3 (3.8)	166	22.5 (8.2)	-0.7 (5.3)
		Week 12	122	24.0 (13.5)	0.4 (9.4)	40	22.1 (7.8)	0.0 (4.9)	162	23.5 (12.3)	0.3 (8.5)
		Week 24	121	25.7 (11.2)	2.0 (8.7)	37	23.9 (9.6)	1.8 (4.5)	158	25.3 (10.8)	1.9 (7.9)
		Week 36	120	23.9 (9.5)	0.4 (9.1)	37	23.3 (7.9)	1.1 (5.6)	157	23.8 (9.1)	0.5 (8.4)
		Week 52	120	23.3 (8.4)	-0.4 (7.9)	37	24.7 (21.4)	2.3 (22.0)	157	23.7 (12.6)	0.3 (12.6)

Parameters		Timepoint	Knee N=126 n	Knee N=126 Value at timepoint	Knee N=126 Change from baseline	Except for knee N=40 n	Except for knee N=40 Value at timepoint	Except for knee N=40 Change from baseline	Total N=166 n	Total N=166 Value at timepoint	Total N=166 Change from baseline
	Median	Baseline	126	20.5 (18.0, 27.0)	-	39	19.0 (17.0, 24.0)	-	165	20.0 (18.0, 26.0)	-
	(25%, 75%)	Week 2	126	21.0 (17.0, 26.0)	-1.0 (-2.0, 1.0)	40	20.0 (16.0, 24.0)	0.0 (-2.0, 1.0)	166	21.0 (17.0, 26.0)	-1.0 (-2.0, 1.0)
		Week 12	122	21.0 (18.0, 26.0)	0.0 (-2.0, 2.0)	40	20.0 (17.5, 24.5)	0.0 (-2.0, 3.0)	162	21.0 (18.0, 26.0)	0.0 (-2.0, 2.0)
		Week 24	121	22.0 (19.0, 28.0)	1.0 (-1.0, 4.0)	37	22.0 (17.0, 26.0)	1.0 (-0.5, 4.0)	158	22.0 (19.0, 28.0)	1.0 (-1.0, 4.0)
		Week 36	120	22.0 (18.0, 26.5)	0.0 (-2.0, 3.0)	37	22.0 (17.0, 25.0)	1.0 (-1.0, 4.0)	157	22.0 (18.0, 26.0)	1.0 (-2.0, 3.0)
		Week 52	120	21.0 (18.0, 27.0)	0.0 (-2.5, 2.0)	37	20.0 (16.0, 24.0)	-1.0 (-3.0, 2.5)	157	21.0 (17.0, 26.0)	-0.5 (-3.0, 2.0)
Alanine Aminotransferase (U/L)	Mean (SD)	Baseline	126	22.8 (16.1)	-	39	20.1 (13.8)	-	165	22.2 (15.6)	-
		Week 2	126	22.3 (14.3)	-0.5 (6.9)	40	20.0 (14.3)	0.2 (4.5)	166	21.8 (14.3)	-0.3 (6.4)
		Week 12	122	23.3 (15.8)	0.3 (10.1)	40	19.7 (13.1)	-0.2 (6.2)	162	22.4 (15.2)	0.2 (9.3)
		Week 24	121	25.2 (19.1)	2.1 (13.4)	37	21.9 (14.9)	2.0 (6.2)	158	24.4 (18.2)	2.1 (12.1)
		Week 36	120	22.6 (16.7)	-0.2 (12.4)	37	20.6 (11.8)	0.7 (9.1)	157	22.2 (15.7)	0.0 (11.7)
		Week 52	120	21.7 (15.0)	-1.3 (13.3)	37	20.0 (15.9)	-0.2 (16.6)	157	21.3 (15.2)	-1.1 (14.1)
	Median	Baseline	126	18.0 (14.0, 25.0)	-	39	16.0 (12.0, 23.0)	-	165	18.0 (13.0, 24.0)	-
	(25%, 75%)	Week 2	126	18.0 (14.0, 25.0)	0.0 (-2.0, 2.0)	40	15.5 (12.0, 24.5)	0.0 (-2.0, 2.0)	166	17.5 (13.0, 25.0)	0.0 (-2.0, 2.0)
		Week 12	122	18.5 (14.0, 27.0)	0.0 (-2.0, 3.0)	40	17.0 (12.0, 22.0)	0.0 (-3.0, 2.0)	162	18.0 (14.0, 25.0)	0.0 (-2.0, 3.0)
		Week 24	121	20.0 (14.0, 28.0)	1.0 (-2.0, 4.0)	37	17.0 (13.0, 26.0)	2.0 (-1.0, 4.5)	158	19.5 (14.0, 28.0)	1.0 (-2.0, 4.0)
		Week 36	120	18.5 (13.0, 25.0)	0.0 (-3.0, 3.0)	37	17.0 (14.0, 25.0)	0.0 (-4.0, 4.0)	157	18.0 (13.0, 25.0)	0.0 (-3.5, 3.0)
		Week 52	120	19.0 (13.0, 25.0)	0.0 (-4.0, 2.5)	37	14.0 (12.0, 22.0)	-1.0 (-5.0, 4.5)	157	18.0 (13.0, 24.0)	0.0 (-4.0, 3.0)
Lactate Dehydrogenase (U/L)	Mean (SD)	Baseline	126	196.1 (35.3)	-	39	185.8 (35.6)	-	165	193.7 (35.5)	-
		Week 2	126	191.5 (33.6)	-4.6 (16.0)	40	184.4 (38.8)	-1.5 (18.5)	166	189.8 (34.9)	-3.9 (16.6)
		Week 12	122	195.1 (36.1)	-1.5 (23.2)	40	182.8 (35.7)	-2.8 (16.1)	162	192.0 (36.3)	-1.8 (21.7)
		Week 24	121	193.6 (35.3)	-2.8 (18.6)	37	184.7 (35.5)	-0.3 (18.3)	158	191.5 (35.5)	-2.2 (18.5)
		Week 36	120	191.9 (34.1)	-3.9 (19.6)	37	183.6 (34.8)	-1.5 (18.7)	157	189.9 (34.4)	-3.3 (19.4)
		Week 52	120	193.7 (37.9)	-2.8 (20.8)	37	188.6 (52.5)	3.3 (46.5)	157	192.5 (41.7)	-1.4 (28.8)
	Median	Baseline	126	196.0 (173.0, 218.0)	-	39	180.0 (158.0, 208.0)	-	165	194.0 (169.0, 217.0)	-
	(25%, 75%)	Week 2	126	191.5 (170.0, 213.0)	-4.0 (-16.0, 4.0)	40	186.0 (158.5, 203.0)	0.0 (-11.0, 9.0)	166	188.0 (165.0, 213.0)	-3.0 (-14.0, 5.0)
		Week 12	122	192.0 (171.0, 215.0)	-4.0 (-12.0, 7.0)	40	180.5 (155.5, 204.0)	-2.0 (-15.0, 9.0)	162	189.5 (167.0, 211.0)	-3.0 (-12.0, 7.0)
		Week 24	121	189.0 (168.0, 218.0)	-3.0 (-12.0, 7.0)	37	174.0 (166.0, 212.0)	2.0 (-7.0, 9.0)	158	187.0 (167.0, 217.0)	-1.0 (-11.0, 8.0)
		Week 36	120	191.0 (170.5, 211.5)	-1.0 (-16.0, 7.5)	37	174.0 (162.0, 205.0)	-2.0 (-13.0, 14.0)	157	189.0 (166.0, 209.0)	-1.5 (-15.0, 9.0)
		Week 52	120	190.0 (169.5, 215.5)	-3.0 (-14.0, 8.5)	37	176.0 (157.0, 205.0)	-2.0 (-15.5, 12.5)	157	190.0 (165.0, 215.0)	-3.0 (-14.0, 9.5)
Alkaline Phosphatase (U/L)	Mean (SD)	Baseline	126	232.1 (67.2)	-	39	212.9 (58.3)	-	165	227.6 (65.5)	-
		Week 2	126	230.1 (65.4)	-2.0 (26.6)	40	223.4 (74.8)	11.9 (33.7)	166	228.5 (67.6)	1.3 (29.0)
		Week 12	122	229.9 (68.3)	-2.3 (29.1)	40	221.0 (62.0)	9.9 (28.2)	162	227.7 (66.8)	0.6 (29.3)
		Week 24	121	234.8 (67.4)	2.5 (30.7)	37	218.0 (59.7)	10.8 (33.4)	158	230.9 (65.9)	4.4 (31.4)
		Week 36	120	239.4 (73.2)	7.9 (45.4)	37	239.1 (104.1)	31.6 (85.6)	157	239.3 (81.1)	13.3 (57.8)

Parameters		Timepoint	Knee N=126 n	Knee N=126 Value at timepoint	Knee N=126 Change from baseline	Except for knee N=40 n	Except for knee N=40 Value at timepoint	Except for knee N=40 Change from baseline	Total N=166 n	Total N=166 Value at timepoint	Total N=166 Change from baseline
		Week 52	120	237.1 (76.6)	5.4 (45.8)	37	231.4 (89.6)	22.4 (63.6)	157	235.7 (79.6)	9.3 (50.7)
	Median	Baseline	126	222.0 (181.0, 270.0)	-	39	210.0 (171.0, 256.0)	-	165	220.0 (179.0, 267.0)	-
	(25%, 75%)	Week 2	126	221.5 (181.0, 280.0)	-7.0 (-17.0, 10.0)	40	213.0 (164.0, 269.5)	2.0 (-5.0, 26.0)	166	220.5 (177.0, 278.0)	-3.0 (-15.0, 12.0)
		Week 12	122	217.0 (182.0, 277.0)	-3.5 (-22.0, 21.0)	40	220.0 (177.5, 257.0)	6.0 (-9.0, 28.0)	162	218.0 (181.0, 277.0)	-2.0 (-17.0, 22.0)
		Week 24	121	228.0 (184.0, 277.0)	2.0 (-19.0, 23.0)	37	221.0 (172.0, 257.0)	9.0 (-8.5, 30.5)	158	226.0 (179.0, 275.0)	4.0 (-18.0, 24.0)
		Week 36	120	228.0 (193.0, 275.5)	6.5 (-12.0, 24.5)	37	218.0 (181.0, 275.0)	13.5 (0.0, 31.0)	157	226.0 (192.0, 275.0)	10.0 (-11.5, 28.0)
		Week 52	120	222.5 (190.0, 289.0)	1.0 (-22.5, 25.0)	37	223.0 (180.0, 272.0)	12.0 (-4.5, 36.0)	157	223.0 (183.0, 282.0)	3.5 (-18.0, 28.5)
Gamma Glutamyl Transferase (U/L)	Mean (SD)	Baseline	126	32.1 (28.6)	-	39	30.3 (19.5)	-	165	31.7 (26.7)	-
		Week 2	126	30.8 (26.6)	-1.3 (6.6)	40	29.7 (20.5)	-0.3 (5.4)	166	30.5 (25.3)	-1.1 (6.4)
		Week 12	122	33.1 (29.8)	0.9 (11.0)	40	32.2 (23.6)	2.4 (10.1)	162	32.9 (28.3)	1.3 (10.8)
		Week 24	121	34.9 (36.5)	2.6 (15.0)	37	32.9 (33.0)	3.2 (21.1)	158	34.4 (35.6)	2.7 (16.5)
		Week 36	120	32.7 (29.0)	0.5 (16.2)	37	32.9 (30.0)	3.2 (20.6)	157	32.8 (29.1)	1.1 (17.3)
		Week 52	120	33.9 (39.1)	1.6 (28.2)	37	47.6 (121.0)	18.3 (113.9)	157	37.1 (67.7)	5.4 (59.9)
	Median	Baseline	126	23.0 (15.0, 37.0)	-	39	21.0 (15.0, 44.0)	-	165	23.0 (15.0, 38.0)	-
	(25%, 75%)	Week 2	126	22.0 (15.0, 34.0)	-1.0 (-3.0, 1.0)	40	20.0 (15.5, 38.5)	-1.0 (-2.0, 2.0)	166	22.0 (15.0, 35.0)	-1.0 (-2.0, 1.0)
		Week 12	122	23.5 (14.0, 39.0)	0.0 (-2.0, 3.0)	40	20.5 (15.5, 46.5)	1.0 (-2.0, 5.0)	162	23.0 (14.0, 41.0)	0.0 (-2.0, 3.0)
		Week 24	121	25.0 (15.0, 39.0)	1.0 (-2.0, 3.0)	37	21.0 (16.0, 42.0)	0.0 (-2.0, 2.0)	158	24.0 (15.0, 40.0)	0.0 (-2.0, 3.0)
		Week 36	120	23.0 (15.0, 38.0)	0.0 (-2.5, 3.5)	37	24.0 (16.0, 41.0)	0.5 (-4.0, 3.0)	157	23.0 (15.0, 38.0)	0.0 (-3.0, 3.0)
		Week 52	120	22.0 (14.0, 36.5)	-0.5 (-4.5, 2.0)	37	20.0 (15.0, 35.0)	0.0 (-3.5, 2.0)	157	22.0 (15.0, 36.0)	0.0 (-4.0, 2.0)
Urate (mg/dL)	Mean (SD)	Baseline	126	5.26 (1.18)	-	39	5.24 (1.23)	-	165	5.26 (1.19)	-
		Week 2	126	5.22 (1.21)	-0.05 (0.57)	40	5.29 (1.12)	0.06 (0.85)	166	5.23 (1.18)	-0.02 (0.64)
		Week 12	122	5.39 (1.30)	0.17 (0.81)	40	5.17 (1.00)	-0.10 (0.81)	162	5.34 (1.24)	0.11 (0.82)
		Week 24	121	5.30 (1.21)	0.07 (0.71)	37	5.18 (1.24)	0.00 (0.97)	158	5.27 (1.21)	0.05 (0.77)
		Week 36	120	5.16 (1.09)	-0.09 (0.73)	37	5.18 (1.21)	-0.01 (1.04)	157	5.17 (1.11)	-0.07 (0.81)
		Week 52	120	5.07 (1.13)	-0.18 (0.74)	37	5.31 (1.20)	0.14 (1.03)	157	5.12 (1.15)	-0.10 (0.82)
	Median	Baseline	126	5.20 (4.50, 6.00)	-	39	5.10 (4.30, 5.90)	-	165	5.20 (4.30, 5.90)	-
	(25%, 75%)	Week 2	126	5.15 (4.40, 5.80)	-0.10 (-0.40, 0.40)	40	5.15 (4.35, 6.10)	0.10 (-0.30, 0.40)	166	5.15 (4.40, 5.90)	-0.10 (-0.40, 0.40)
		Week 12	122	5.25 (4.70, 6.10)	0.10 (-0.30, 0.40)	40	5.25 (4.40, 5.80)	0.00 (-0.40, 0.40)	162	5.25 (4.60, 6.10)	0.00 (-0.30, 0.40)
		Week 24	121	5.40 (4.50, 6.00)	0.10 (-0.40, 0.50)	37	5.20 (4.30, 5.90)	0.15 (-0.40, 0.50)	158	5.30 (4.50, 6.00)	0.10 (-0.40, 0.50)
		Week 36	120	5.15 (4.50, 5.95)	-0.10 (-0.50, 0.40)	37	5.30 (4.10, 5.80)	0.00 (-0.40, 0.45)	157	5.20 (4.40, 5.90)	-0.10 (-0.50, 0.40)
		Week 52	120	5.00 (4.30, 5.90)	-0.30 (-0.60, 0.30)	37	5.30 (4.30, 5.80)	0.05 (-0.25, 0.80)	157	5.10 (4.30, 5.90)	-0.20 (-0.55, 0.30)
Blood Urea Nitrogen (mg/dL)	Mean (SD)	Baseline	126	16.81 (4.38)	-	39	15.91 (4.97)	-	165	16.60 (4.53)	-
		Week 2	126	16.72 (4.48)	-0.09 (3.41)	40	16.11 (4.32)	0.34 (3.67)	166	16.57 (4.44)	0.01 (3.47)
		Week 12	122	17.44 (4.57)	0.70 (4.03)	40	16.48 (5.16)	0.58 (2.46)	162	17.20 (4.72)	0.67 (3.70)
		Week 24	121	16.84 (4.55)	0.12 (3.61)	37	16.06 (4.23)	0.51 (3.22)	158	16.66 (4.47)	0.21 (3.51)

Parameters		Timepoint	Knee N=126 n	Knee N=126 Value at timepoint	Knee N=126 Change from baseline	Except for knee N=40 n	Except for knee N=40 Value at timepoint	Except for knee N=40 Change from baseline	Total N=166 n	Total N=166 Value at timepoint	Total N=166 Change from baseline
		Week 36	120	16.31 (4.00)	-0.44 (3.54)	37	15.88 (4.14)	0.20 (3.74)	157	16.21 (4.03)	-0.29 (3.58)
		Week 52	120	16.58 (4.12)	-0.16 (3.76)	37	16.33 (4.74)	0.69 (3.63)	157	16.52 (4.26)	0.04 (3.73)
	Median	Baseline	126	16.10 (13.50, 19.30)	-	39	14.60 (13.00, 18.60)	-	165	15.80 (13.40, 18.90)	-
	(25%, 75%)	Week 2	126	16.60 (13.90, 18.80)	-0.45 (-2.20, 2.10)	40	15.60 (13.30, 19.30)	0.70 (-1.10, 2.60)	166	16.45 (13.70, 19.00)	-0.20 (-2.00, 2.40)
		Week 12	122	16.45 (14.20, 20.70)	0.25 (-1.50, 2.90)	40	16.10 (13.10, 19.10)	0.30 (-1.00, 2.50)	162	16.30 (14.00, 20.20)	0.30 (-1.50, 2.60)
		Week 24	121	16.30 (13.50, 19.50)	0.40 (-2.20, 2.10)	37	16.10 (13.40, 18.90)	1.05 (-1.15, 2.40)	158	16.10 (13.40, 19.30)	0.50 (-2.10, 2.20)
		Week 36	120	15.70 (14.00, 19.25)	-0.40 (-3.00, 1.95)	37	15.30 (12.90, 18.80)	0.20 (-1.30, 1.75)	157	15.70 (13.80, 19.10)	-0.20 (-2.70, 1.85)
		Week 52	120	15.80 (13.65, 19.00)	-0.25 (-2.60, 2.20)	37	16.10 (13.00, 19.00)	0.20 (-1.35, 2.65)	157	15.90 (13.50, 19.00)	-0.10 (-2.25, 2.25)
Creatinine (mg/dL)	Mean (SD)	Baseline	126	0.701 (0.161)	-	39	0.702 (0.162)	-	165	0.701 (0.160)	-
		Week 2	126	0.690 (0.156)	-0.011 (0.059)	40	0.702 (0.159)	0.004 (0.069)	166	0.693 (0.156)	-0.007 (0.061)
		Week 12	122	0.722 (0.194)	0.021 (0.125)	40	0.715 (0.155)	0.016 (0.068)	162	0.720 (0.185)	0.020 (0.114)
		Week 24	121	0.709 (0.170)	0.008 (0.077)	37	0.708 (0.167)	0.008 (0.064)	158	0.709 (0.169)	0.008 (0.074)
		Week 36	120	0.693 (0.157)	-0.009 (0.072)	37	0.715 (0.170)	0.016 (0.082)	157	0.698 (0.160)	-0.003 (0.075)
		Week 52	120	0.722 (0.164)	0.019 (0.070)	37	0.752 (0.166)	0.054 (0.089)	157	0.729 (0.164)	0.027 (0.076)
	Median	Baseline	126	0.670 (0.610, 0.760)	-	39	0.670 (0.580, 0.780)	-	165	0.670 (0.600, 0.760)	-
	(25%, 75%)	Week 2	126	0.670 (0.600, 0.740)	-0.005 (-0.040, 0.030)	40	0.665 (0.580, 0.795)	0.010 (-0.030, 0.050)	166	0.670 (0.600, 0.750)	0.000 (-0.040, 0.030)
		Week 12	122	0.690 (0.610, 0.790)	0.010 (-0.020, 0.050)	40	0.680 (0.600, 0.830)	0.020 (-0.020, 0.060)	162	0.690 (0.610, 0.800)	0.010 (-0.020, 0.050)
		Week 24	121	0.680 (0.590, 0.780)	0.010 (-0.030, 0.050)	37	0.680 (0.560, 0.840)	0.010 (-0.030, 0.055)	158	0.680 (0.590, 0.790)	0.010 (-0.030, 0.050)
		Week 36	120	0.680 (0.590, 0.755)	-0.010 (-0.050, 0.030)	37	0.680 (0.590, 0.810)	0.020 (-0.030, 0.055)	157	0.680 (0.590, 0.760)	-0.005 (-0.045, 0.035)
		Week 52	120	0.700 (0.620, 0.775)	0.020 (-0.020, 0.060)	37	0.700 (0.650, 0.840)	0.050 (-0.030, 0.085)	157	0.700 (0.630, 0.790)	0.030 (-0.020, 0.070)
Cholesterol (mg/dL)	Mean (SD)	Baseline	126	213.6 (35.3)	-	39	209.3 (33.4)	-	165	212.6 (34.8)	-
		Week 2	126	206.8 (32.9)	-6.8 (19.2)	40	204.3 (34.3)	-3.5 (16.0)	166	206.2 (33.1)	-6.1 (18.5)
		Week 12	122	209.7 (36.8)	-4.1 (22.0)	40	201.8 (38.4)	-6.2 (22.7)	162	207.8 (37.3)	-4.6 (22.1)
		Week 24	121	214.3 (37.9)	0.4 (25.6)	37	212.3 (39.2)	5.2 (23.9)	158	213.8 (38.1)	1.5 (25.2)
		Week 36	120	215.5 (35.8)	1.6 (28.6)	37	213.3 (37.8)	5.6 (24.2)	157	215.0 (36.2)	2.5 (27.6)
		Week 52	120	210.5 (35.2)	-3.2 (26.7)	37	209.2 (38.8)	0.9 (22.7)	157	210.2 (35.9)	-2.2 (25.8)
	Median	Baseline	126	210.5 (190.0, 234.0)	-	39	204.0 (187.0, 231.0)	-	165	210.0 (190.0, 233.0)	-
	(25%, 75%)	Week 2	126	206.0 (187.0, 227.0)	-7.5 (-20.0, 7.0)	40	201.0 (178.5, 228.0)	-2.0 (-15.0, 8.0)	166	204.0 (182.0, 227.0)	-5.0 (-17.0, 7.0)
		Week 12	122	208.5 (185.0, 231.0)	-5.5 (-20.0, 9.0)	40	205.0 (173.0, 218.5)	-5.0 (-17.0, 7.0)	162	207.0 (184.0, 227.0)	-5.0 (-18.0, 8.0)
		Week 24	121	214.0 (189.0, 239.0)	0.0 (-13.0, 17.0)	37	210.0 (182.0, 239.0)	6.0 (-9.0, 14.5)	158	212.0 (188.0, 239.0)	4.0 (-12.0, 17.0)
		Week 36	120	216.5 (186.0, 240.5)	2.5 (-12.5, 17.0)	37	214.0 (189.0, 231.0)	6.5 (-5.5, 19.0)	157	215.0 (186.0, 240.0)	3.0 (-10.0, 17.5)
		Week 52	120	206.5 (183.0, 233.0)	0.0 (-16.5, 15.5)	37	204.0 (178.0, 231.0)	3.0 (-10.0, 14.0)	157	205.0 (181.0, 231.0)	0.0 (-15.0, 14.0)
Triglycerides (mg/dL)	Mean (SD)	Baseline	126	162.1 (95.8)	-	39	162.1 (80.8)	-	165	162.1 (92.3)	-
		Week 2	126	164.3 (103.1)	2.2 (86.7)	40	162.7 (77.1)	2.5 (59.3)	166	163.9 (97.3)	2.3 (80.9)
		Week 12	122	161.7 (99.1)	0.0 (90.1)	40	168.6 (94.1)	8.1 (58.8)	162	163.4 (97.6)	2.0 (83.5)

Parameters		Timepoint	Knee N=126 n	Knee N=126 Value at timepoint	Knee N=126 Change from baseline	Except for knee N=40 n	Except for knee N=40 Value at timepoint	Except for knee N=40 Change from baseline	Total N=166 n	Total N=166 Value at timepoint	Total N=166 Change from baseline
		Week 24	121	152.6 (91.5)	-9.1 (90.1)	37	163.2 (110.4)	4.5 (84.4)	158	155.1 (96.0)	-6.0 (88.8)
		Week 36	120	165.1 (130.5)	2.7 (130.7)	37	159.2 (88.5)	0.1 (62.4)	157	163.7 (121.7)	2.1 (118.3)
		Week 52	120	156.3 (108.4)	-6.0 (96.4)	37	166.2 (115.0)	4.2 (85.1)	157	158.7 (109.7)	-3.6 (93.8)
	Median	Baseline	126	139.0 (100.0, 194.0)	-	39	147.0 (97.0, 219.0)	-	165	141.0 (98.0, 200.0)	-
	(25%, 75%)	Week 2	126	140.0 (95.0, 201.0)	4.5 (-39.0, 40.0)	40	149.5 (105.0, 193.0)	8.0 (-27.0, 52.0)	166	144.0 (100.0, 200.0)	5.0 (-33.0, 42.0)
		Week 12	122	139.0 (92.0, 200.0)	-6.5 (-38.0, 42.0)	40	148.5 (95.0, 227.5)	-1.0 (-35.0, 56.0)	162	140.0 (92.0, 204.0)	-4.0 (-38.0, 44.0)
		Week 24	121	136.0 (90.0, 187.0)	-6.0 (-43.0, 37.0)	37	118.0 (88.0, 203.0)	-2.5 (-38.5, 34.5)	158	134.5 (89.0, 187.0)	-5.0 (-43.0, 37.0)
		Week 36	120	131.5 (95.5, 192.0)	-5.5 (-42.0, 33.0)	37	137.0 (86.0, 210.0)	-4.5 (-28.0, 28.0)	157	133.0 (94.0, 195.0)	-5.5 (-41.0, 31.0)
		Week 52	120	135.5 (86.5, 183.0)	-5.5 (-49.0, 35.5)	37	140.0 (94.0, 200.0)	-6.5 (-55.0, 65.5)	157	137.0 (88.0, 190.0)	-5.5 (-50.0, 43.0)
C Reactive Protein	Mean (SD)	Baseline	126	0.138 (0.236)	-	39	0.224 (0.779)	-	165	0.158 (0.429)	-
(mg/dL)		Week 2	126	0.140 (0.281)	0.002 (0.343)	40	0.233 (0.553)	0.013 (0.381)	166	0.162 (0.366)	0.005 (0.351)
		Week 12	122	0.113 (0.200)	-0.023 (0.262)	40	0.268 (0.622)	0.051 (0.409)	162	0.151 (0.358)	-0.005 (0.305)
		Week 24	121	0.123 (0.188)	-0.013 (0.261)	37	0.181 (0.502)	-0.031 (0.384)	158	0.137 (0.292)	-0.017 (0.293)
		Week 36	120	0.131 (0.226)	-0.005 (0.296)	37	0.332 (1.195)	0.124 (1.271)	157	0.178 (0.613)	0.025 (0.659)
		Week 52	120	0.181 (0.498)	0.045 (0.545)	37	0.191 (0.355)	-0.021 (0.565)	157	0.183 (0.467)	0.030 (0.548)
	Median	Baseline	126	0.060 (0.030, 0.130)	-	39	0.050 (0.030, 0.120)	-	165	0.060 (0.030, 0.130)	-
	(25%, 75%)	Week 2	126	0.050 (0.020, 0.120)	0.000 (-0.040, 0.020)	40	0.060 (0.025, 0.135)	0.000 (-0.010, 0.030)	166	0.050 (0.020, 0.120)	0.000 (-0.030, 0.020)
		Week 12	122	0.050 (0.020, 0.130)	0.000 (-0.030, 0.020)	40	0.060 (0.020, 0.175)	0.000 (-0.010, 0.050)	162	0.050 (0.020, 0.140)	0.000 (-0.030, 0.030)
		Week 24	121	0.050 (0.030, 0.130)	0.000 (-0.030, 0.030)	37	0.040 (0.020, 0.100)	0.000 (-0.015, 0.020)	158	0.045 (0.020, 0.120)	0.000 (-0.020, 0.020)
		Week 36	120	0.055 (0.030, 0.120)	0.000 (-0.040, 0.020)	37	0.060 (0.020, 0.120)	0.010 (-0.010, 0.040)	157	0.060 (0.030, 0.120)	0.000 (-0.025, 0.035)
		Week 52	120	0.070 (0.030, 0.160)	0.010 (-0.010, 0.050)	37	0.060 (0.030, 0.160)	0.010 (-0.010, 0.065)	157	0.070 (0.030, 0.160)	0.010 (-0.010, 0.050)
Sodium (mEq/L)	Mean (SD)	Baseline	126	142.1 (2.3)	-	39	141.5 (2.1)	-	165	141.9 (2.2)	-
		Week 2	126	141.7 (2.0)	-0.3 (2.1)	40	141.3 (1.9)	-0.2 (2.0)	166	141.6 (1.9)	-0.3 (2.0)
		Week 12	122	141.6 (2.0)	-0.5 (2.3)	40	141.0 (1.8)	-0.5 (2.4)	162	141.5 (2.0)	-0.5 (2.3)
		Week 24	121	142.3 (2.2)	0.2 (2.3)	37	141.6 (1.6)	0.2 (1.6)	158	142.1 (2.1)	0.2 (2.2)
		Week 36	120	141.9 (2.2)	-0.1 (2.3)	37	141.5 (1.9)	0.0 (1.8)	157	141.8 (2.1)	-0.1 (2.2)
		Week 52	120	141.7 (2.1)	-0.4 (2.2)	37	141.2 (2.1)	-0.3 (2.5)	157	141.6 (2.1)	-0.3 (2.2)
	Median	Baseline	126	142.0 (141.0, 143.0)	-	39	142.0 (140.0, 143.0)	-	165	142.0 (141.0, 143.0)	-
	(25%, 75%)	Week 2	126	142.0 (140.0, 143.0)	0.0 (-2.0, 1.0)	40	141.0 (140.0, 142.5)	0.0 (-1.0, 1.0)	166	142.0 (140.0, 143.0)	0.0 (-2.0, 1.0)
		Week 12	122	141.0 (140.0, 143.0)	0.0 (-2.0, 1.0)	40	141.0 (140.0, 142.0)	-1.0 (-2.0, 1.0)	162	141.0 (140.0, 143.0)	0.0 (-2.0, 1.0)
		Week 24	121	142.0 (141.0, 143.0)	0.0 (-1.0, 1.0)	37	142.0 (141.0, 143.0)	0.0 (-1.0, 1.0)	158	142.0 (141.0, 143.0)	0.0 (-1.0, 1.0)
		Week 36	120	142.0 (141.0, 143.0)	0.0 (-2.0, 1.0)	37	141.0 (140.0, 143.0)	0.0 (-2.0, 1.0)	157	142.0 (140.0, 143.0)	0.0 (-2.0, 1.0)
		Week 52	120	142.0 (140.5, 143.0)	0.0 (-2.0, 1.0)	37	141.0 (140.0, 142.0)	-1.0 (-2.0, 2.0)	157	142.0 (140.0, 143.0)	0.0 (-2.0, 1.0)
Potassium (mEq/L)	Mean (SD)	Baseline	126	4.31 (0.37)	-	39	4.23 (0.32)	-	165	4.29 (0.36)	-
		Week 2	126	4.18 (0.34)	-0.13 (0.33)	40	4.23 (0.29)	-0.01 (0.33)	166	4.19 (0.33)	-0.10 (0.33)

Parameters		Timepoint	Knee N=126 n	Knee N=126 Value at timepoint	Knee N=126 Change from baseline	Except for knee N=40 n	Except for knee N=40 Value at timepoint	Except for knee N=40 Change from baseline	Total N=166 n	Total N=166 Value at timepoint	Total N=166 Change from baseline
		Week 12	122	4.24 (0.34)	-0.09 (0.36)	40	4.23 (0.30)	0.00 (0.31)	162	4.23 (0.33)	-0.07 (0.35)
		Week 24	121	4.28 (0.37)	-0.04 (0.33)	37	4.25 (0.26)	0.01 (0.36)	158	4.27 (0.34)	-0.03 (0.34)
		Week 36	120	4.26 (0.37)	-0.07 (0.32)	37	4.34 (0.29)	0.10 (0.31)	157	4.28 (0.35)	-0.03 (0.32)
		Week 52	120	4.19 (0.39)	-0.14 (0.38)	37	4.18 (0.24)	-0.06 (0.33)	157	4.19 (0.36)	-0.12 (0.37)
	Median	Baseline	126	4.30 (4.00, 4.50)	-	39	4.10 (4.00, 4.40)	-	165	4.30 (4.00, 4.50)	-
	(25%, 75%)	Week 2	126	4.20 (4.00, 4.40)	-0.10 (-0.30, 0.10)	40	4.20 (4.05, 4.40)	0.00 (-0.20, 0.20)	166	4.20 (4.00, 4.40)	-0.10 (-0.30, 0.10)
		Week 12	122	4.20 (4.00, 4.40)	-0.10 (-0.30, 0.10)	40	4.25 (4.00, 4.45)	0.00 (-0.20, 0.20)	162	4.20 (4.00, 4.40)	0.00 (-0.30, 0.10)
		Week 24	121	4.30 (4.00, 4.50)	0.00 (-0.20, 0.10)	37	4.20 (4.00, 4.50)	0.05 (-0.20, 0.30)	158	4.20 (4.00, 4.50)	0.00 (-0.20, 0.10)
		Week 36	120	4.20 (4.00, 4.50)	-0.10 (-0.30, 0.10)	37	4.30 (4.10, 4.50)	0.10 (-0.10, 0.30)	157	4.30 (4.00, 4.50)	0.00 (-0.20, 0.20)
		Week 52	120	4.20 (3.90, 4.40)	-0.10 (-0.40, 0.10)	37	4.20 (4.00, 4.40)	0.00 (-0.30, 0.10)	157	4.20 (4.00, 4.40)	-0.10 (-0.40, 0.10)
Chloride (mEq/L)	Mean (SD)	Baseline	126	104.2 (2.1)	-	39	103.9 (2.2)	-	165	104.2 (2.1)	-
		Week 2	126	104.5 (2.4)	0.3 (2.0)	40	104.3 (2.4)	0.4 (2.0)	166	104.5 (2.4)	0.3 (2.0)
		Week 12	122	104.5 (2.5)	0.3 (2.3)	40	104.2 (2.4)	0.3 (2.5)	162	104.4 (2.5)	0.3 (2.4)
		Week 24	121	104.6 (2.4)	0.4 (2.3)	37	104.4 (2.6)	0.5 (2.5)	158	104.6 (2.4)	0.4 (2.4)
		Week 36	120	104.4 (2.6)	0.2 (2.1)	37	104.0 (2.2)	0.0 (1.9)	157	104.3 (2.5)	0.1 (2.1)
		Week 52	120	104.7 (2.5)	0.4 (2.1)	37	104.1 (2.6)	0.2 (2.4)	157	104.5 (2.5)	0.4 (2.2)
	Median	Baseline	126	104.0 (103.0, 105.0)	-	39	104.0 (102.0, 105.0)	-	165	104.0 (103.0, 105.0)	-
	(25%, 75%)	Week 2	126	104.0 (103.0, 106.0)	0.0 (-1.0, 1.0)	40	104.5 (103.0, 106.0)	0.0 (-1.0, 2.0)	166	104.0 (103.0, 106.0)	0.0 (-1.0, 1.0)
		Week 12	122	104.0 (103.0, 106.0)	0.0 (-1.0, 2.0)	40	104.0 (102.5, 106.0)	0.0 (-1.0, 2.0)	162	104.0 (103.0, 106.0)	0.0 (-1.0, 2.0)
		Week 24	121	105.0 (103.0, 106.0)	1.0 (-1.0, 2.0)	37	105.0 (102.0, 106.0)	0.5 (-1.0, 2.0)	158	105.0 (103.0, 106.0)	1.0 (-1.0, 2.0)
		Week 36	120	104.0 (103.0, 106.0)	0.0 (-1.0, 2.0)	37	104.0 (103.0, 106.0)	0.0 (-1.0, 1.5)	157	104.0 (103.0, 106.0)	0.0 (-1.0, 2.0)
		Week 52	120	105.0 (103.0, 106.0)	0.0 (-1.0, 2.0)	37	105.0 (103.0, 106.0)	1.0 (-1.0, 2.0)	157	105.0 (103.0, 106.0)	0.0 (-1.0, 2.0)
Calcium (mg/dL)	Mean (SD)	Baseline	126	9.28 (0.34)	-	39	9.32 (0.35)	-	165	9.29 (0.34)	-
		Week 2	126	9.18 (0.39)	-0.10 (0.33)	40	9.19 (0.41)	-0.13 (0.36)	166	9.18 (0.40)	-0.11 (0.33)
		Week 12	122	9.20 (0.35)	-0.08 (0.30)	40	9.24 (0.32)	-0.08 (0.30)	162	9.21 (0.34)	-0.08 (0.29)
		Week 24	121	9.33 (0.38)	0.05 (0.39)	37	9.28 (0.40)	-0.04 (0.39)	158	9.32 (0.39)	0.03 (0.39)
		Week 36	120	9.35 (0.37)	0.08 (0.32)	37	9.41 (0.34)	0.08 (0.33)	157	9.36 (0.36)	0.08 (0.32)
		Week 52	120	9.31 (0.36)	0.04 (0.31)	37	9.34 (0.38)	0.01 (0.28)	157	9.32 (0.37)	0.03 (0.30)
	Median	Baseline	126	9.30 (9.00, 9.50)	-	39	9.30 (9.10, 9.60)	-	165	9.30 (9.10, 9.50)	-
	(25%, 75%)	Week 2	126	9.10 (8.90, 9.40)	-0.10 (-0.30, 0.10)	40	9.10 (8.90, 9.40)	-0.20 (-0.40, 0.10)	166	9.10 (8.90, 9.40)	-0.10 (-0.30, 0.10)
		Week 12	122	9.20 (9.00, 9.40)	-0.10 (-0.30, 0.10)	40	9.30 (9.10, 9.40)	-0.10 (-0.30, 0.10)	162	9.20 (9.00, 9.40)	-0.10 (-0.30, 0.10)
		Week 24	121	9.30 (9.10, 9.50)	0.00 (-0.20, 0.30)	37	9.30 (9.00, 9.50)	-0.20 (-0.35, 0.20)	158	9.30 (9.00, 9.50)	0.00 (-0.30, 0.20)
		Week 36	120	9.30 (9.10, 9.50)	0.10 (-0.10, 0.30)	37	9.40 (9.20, 9.60)	0.05 (-0.20, 0.30)	157	9.30 (9.10, 9.60)	0.10 (-0.10, 0.30)
		Week 52	120	9.30 (9.10, 9.50)	0.10 (-0.20, 0.20)	37	9.40 (9.10, 9.50)	0.00 (-0.20, 0.20)	157	9.30 (9.10, 9.50)	0.10 (-0.20, 0.20)
	Mean (SD)	Baseline	126	118.9 (67.4)	-	39	118.2 (87.4)	-	165	118.8 (72.3)	-

Parameters		Timepoint	Knee N=126 n	Knee N=126 Value at timepoint	Knee N=126 Change from baseline	Except for knee N=40 n	Except for knee N=40 Value at timepoint	Except for knee N=40 Change from baseline	Total N=166 n	Total N=166 Value at timepoint	Total N=166 Change from baseline
Creatine Kinase		Week 2	126	117.3 (64.2)	-1.6 (43.0)	40	111.8 (65.5)	-5.6 (45.6)	166	116.0 (64.3)	-2.6 (43.5)
(U/L)		Week 12	122	119.0 (66.6)	-0.9 (44.4)	40	115.1 (81.1)	-3.4 (47.9)	162	118.0 (70.2)	-1.5 (45.1)
		Week 24	121	125.3 (67.0)	5.2 (46.5)	37	115.4 (70.1)	-4.1 (47.8)	158	123.0 (67.7)	3.1 (46.8)
		Week 36	120	125.2 (92.0)	5.3 (72.0)	37	108.1 (53.5)	-11.8 (48.7)	157	121.2 (84.7)	1.4 (67.6)
		Week 52	120	126.8 (81.5)	6.4 (58.2)	37	135.5 (138.0)	16.9 (138.2)	157	128.9 (97.3)	8.8 (83.3)
	Median	Baseline	126	101.5 (74.0, 144.0)	-	39	104.0 (65.0, 147.0)	-	165	102.0 (72.0, 145.0)	-
	(25%, 75%)	Week 2	126	105.0 (75.0, 140.0)	-1.0 (-16.0, 17.0)	40	96.5 (64.5, 137.0)	0.0 (-16.0, 8.0)	166	105.0 (73.0, 140.0)	-1.0 (-16.0, 14.0)
		Week 12	122	108.0 (77.0, 142.0)	-3.5 (-18.0, 18.0)	40	83.5 (65.0, 141.0)	-3.0 (-24.0, 14.0)	162	104.5 (70.0, 142.0)	-3.0 (-18.0, 17.0)
		Week 24	121	108.0 (80.0, 148.0)	4.0 (-10.0, 18.0)	37	100.0 (75.0, 143.0)	-1.0 (-13.5, 11.0)	158	107.5 (79.0, 148.0)	3.0 (-12.0, 18.0)
		Week 36	120	105.0 (77.0, 137.5)	-2.0 (-23.5, 21.0)	37	99.0 (66.0, 136.0)	-1.5 (-18.0, 16.0)	157	104.0 (75.0, 137.0)	-2.0 (-22.0, 16.0)
		Week 52	120	103.0 (79.5, 148.5)	0.5 (-14.5, 18.5)	37	92.0 (69.0, 142.0)	0.5 (-21.5, 16.5)	157	101.0 (78.0, 148.0)	0.5 (-15.5, 17.5)
Hemoglobin A1C	Mean (SD)	Baseline	126	5.92 (0.54)	-	39	5.78 (0.55)	-	165	5.88 (0.55)	-
/Hemoglobin (%)		Week 2	126	5.87 (0.54)	-0.05 (0.14)	40	5.83 (0.59)	0.01 (0.16)	166	5.86 (0.55)	-0.04 (0.15)
		Week 12	122	5.90 (0.52)	-0.02 (0.20)	40	5.78 (0.63)	-0.03 (0.23)	162	5.87 (0.55)	-0.02 (0.21)
		Week 24	121	5.95 (0.52)	0.03 (0.25)	37	5.88 (0.73)	0.09 (0.25)	158	5.93 (0.57)	0.04 (0.25)
		Week 36	120	6.00 (0.55)	0.08 (0.26)	37	5.99 (1.17)	0.21 (0.89)	157	6.00 (0.74)	0.11 (0.48)
		Week 52	120	5.98 (0.52)	0.06 (0.24)	37	5.84 (0.65)	0.03 (0.25)	157	5.95 (0.56)	0.06 (0.24)
	Median	Baseline	126	5.80 (5.50, 6.20)	-	39	5.70 (5.40, 6.10)	-	165	5.80 (5.50, 6.20)	-
	(25%, 75%)	Week 2	126	5.70 (5.50, 6.10)	-0.10 (-0.20, 0.00)	40	5.75 (5.40, 6.10)	0.00 (-0.10, 0.10)	166	5.70 (5.50, 6.10)	0.00 (-0.10, 0.10)
		Week 12	122	5.80 (5.50, 6.10)	0.00 (-0.10, 0.10)	40	5.65 (5.40, 6.00)	0.00 (-0.20, 0.10)	162	5.70 (5.50, 6.10)	0.00 (-0.10, 0.10)
		Week 24	121	5.80 (5.60, 6.20)	0.00 (-0.10, 0.20)	37	5.80 (5.40, 6.10)	0.00 (-0.10, 0.20)	158	5.80 (5.60, 6.20)	0.00 (-0.10, 0.20)
		Week 36	120	5.90 (5.60, 6.30)	0.10 (-0.10, 0.20)	37	5.70 (5.50, 6.10)	0.10 (0.00, 0.20)	157	5.90 (5.60, 6.30)	0.10 (0.00, 0.20)
		Week 52	120	5.90 (5.60, 6.30)	0.10 (0.00, 0.20)	37	5.80 (5.40, 6.10)	0.00 (-0.10, 0.15)	157	5.80 (5.60, 6.20)	0.10 (0.00, 0.20)

〔5.3.5.2-1 Table 14.3.4-1 改編〕

表 2.7.4.7-73. 臨床検査値の各項目のシフトテーブル（定量試験）：613/1022 試験

Paramaters (Unit)	Timepoint	Baseline[a]	Placebo N=89								SI-613 30 mg N=87							
			Low		Normal		High		Total		Low		Normal		High		Total	
			n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]
Leukocytes (/uL)	Week 2	Low	0		2	(2.4)	0		2	(2.4)	1	(1.1)	1	(1.1)	0		2	(2.3)
		Normal	0		81	(95.3)	0		81	(95.3)	0		79	(90.8)	1	(1.1)	80	(92.0)
		High	0		1	(1.2)	1	(1.2)	2	(2.4)	0		2	(2.3)	3	(3.4)	5	(5.7)
		Total	0		84	(98.8)	1	(1.2)	85	(100.0)	1	(1.1)	82	(94.3)	4	(4.6)	87	(100.0)
	Week 4	Low	0		1	(1.2)	0		1	(1.2)	1	(1.2)	2	(2.3)	0		3	(3.5)
		Normal	0		80	(96.4)	0		80	(96.4)	0		78	(90.7)	3	(3.5)	81	(94.2)
		High	0		1	(1.2)	1	(1.2)	2	(2.4)	0		1	(1.2)	1	(1.2)	2	(2.3)
		Total	0		82	(98.8)	1	(1.2)	83	(100.0)	1	(1.2)	81	(94.2)	4	(4.7)	86	(100.0)
	Week 8	Low	0		2	(2.4)	0		2	(2.4)	1	(1.2)	0		0		1	(1.2)
		Normal	0		79	(95.2)	0		79	(95.2)	0		78	(91.8)	1	(1.2)	79	(92.9)
		High	0		1	(1.2)	1	(1.2)	2	(2.4)	0		2	(2.4)	3	(3.5)	5	(5.9)
		Total	0		82	(98.8)	1	(1.2)	83	(100.0)	1	(1.2)	80	(94.1)	4	(4.7)	85	(100.0)
	Week 12	Low	0		1	(1.2)	0		1	(1.2)	1	(1.2)	1	(1.2)	0		2	(2.4)
		Normal	0		78	(96.3)	0		78	(96.3)	0		77	(91.7)	4	(4.8)	81	(96.4)
		High	0		1	(1.2)	1	(1.2)	2	(2.5)	0		1	(1.2)	0		1	(1.2)
		Total	0		80	(98.8)	1	(1.2)	81	(100.0)	1	(1.2)	79	(94.0)	4	(4.8)	84	(100.0)
	Week 24	Low	0		0		0		0		1	(1.2)	0		0		1	(1.2)
		Normal	0		79	(97.5)	1	(1.2)	80	(98.8)	0		75	(91.5)	1	(1.2)	76	(92.7)
		High	0		1	(1.2)	0		1	(1.2)	0		2	(2.4)	3	(3.7)	5	(6.1)
		Total	0		80	(98.8)	1	(1.2)	81	(100.0)	1	(1.2)	77	(93.9)	4	(4.9)	82	(100.0)
Neutrophils/Leukocytes (%)	Week 2	Low	1	(1.2)	1	(1.2)	0		2	(2.4)	0		3	(3.4)	0		3	(3.4)
		Normal	1	(1.2)	82	(96.5)	0		83	(97.6)	3	(3.4)	77	(88.5)	3	(3.4)	83	(95.4)
		High	0		0		0		0		0		1	(1.1)	0		1	(1.1)
		Total	2	(2.4)	83	(97.6)	0		85	(100.0)	3	(3.4)	81	(93.1)	3	(3.4)	87	(100.0)
	Week 4	Low	0		2	(2.4)	0		2	(2.4)	0		1	(1.2)	0		1	(1.2)
		Normal	2	(2.4)	79	(95.2)	0		81	(97.6)	3	(3.5)	78	(90.7)	3	(3.5)	84	(97.7)
		High	0		0		0		0		0		1	(1.2)	0		1	(1.2)
		Total	2	(2.4)	81	(97.6)	0		83	(100.0)	3	(3.5)	80	(93.0)	3	(3.5)	86	(100.0)
	Week 8	Low	1	(1.2)	1	(1.2)	0		2	(2.4)	2	(2.4)	2	(2.4)	0		4	(4.7)
		Normal	1	(1.2)	79	(95.2)	0		80	(96.4)	1	(1.2)	77	(90.6)	3	(3.5)	81	(95.3)
		High	0		1	(1.2)	0		1	(1.2)	0		0		0		0	
		Total	2	(2.4)	81	(97.6)	0		83	(100.0)	3	(3.5)	79	(92.9)	3	(3.5)	85	(100.0)
	Week 12	Low	1	(1.2)	1	(1.2)	0		2	(2.5)	1	(1.2)	1	(1.2)	0		2	(2.4)
		Normal	1	(1.2)	78	(96.3)	0		79	(97.5)	2	(2.4)	77	(91.7)	3	(3.6)	82	(97.6)
		High	0		0		0		0		0		0		0		0	
		Total	2	(2.5)	79	(97.5)	0		81	(100.0)	3	(3.6)	78	(92.9)	3	(3.6)	84	(100.0)
	Week 24	Low	1	(1.2)	2	(2.5)	0		3	(3.7)	1	(1.2)	3	(3.7)	0		4	(4.9)
		Normal	1	(1.2)	77	(95.1)	0		78	(96.3)	2	(2.4)	72	(87.8)	3	(3.7)	77	(93.9)
		High	0		0		0		0		0		1	(1.2)	0		1	(1.2)
		Total	2	(2.5)	79	(97.5)	0		81	(100.0)	3	(3.7)	76	(92.7)	3	(3.7)	82	(100.0)
Lymphocytes/Leukocytes (%)	Week 2	Low	0		0		0		0		0		2	(2.3)	0		2	(2.3)
		Normal	1	(1.2)	83	(97.6)	0		84	(98.8)	2	(2.3)	76	(87.4)	4	(4.6)	82	(94.3)
		High	0		0		1	(1.2)	1	(1.2)	0		2	(2.3)	1	(1.1)	3	(3.4)
		Total	1	(1.2)	83	(97.6)	1	(1.2)	85	(100.0)	2	(2.3)	80	(92.0)	5	(5.7)	87	(100.0)
	Week 4	Low	0		0		0		0		0		2	(2.3)	0		2	(2.3)
		Normal	1	(1.2)	80	(96.4)	1	(1.2)	82	(98.8)	2	(2.3)	75	(87.2)	5	(5.8)	82	(95.3)
		High	0		1	(1.2)	0		1	(1.2)	0		2	(2.3)	0		2	(2.3)
		Total	1	(1.2)	81	(97.6)	1	(1.2)	83	(100.0)	2	(2.3)	79	(91.9)	5	(5.8)	86	(100.0)
	Week 8	Low	0		1	(1.2)	0		1	(1.2)	0		1	(1.2)	0		1	(1.2)
		Normal	1	(1.2)	80	(96.4)	0		81	(97.6)	2	(2.4)	75	(88.2)	3	(3.5)	80	(94.1)
		High	0		0		1	(1.2)	1	(1.2)	0		2	(2.4)	2	(2.4)	4	(4.7)

Paramaters (Unit)	Timepoint	Baseline[a]	Placebo N=89								SI-613 30 mg N=87							
			Low		Normal		High		Total		Low		Normal		High		Total	
			n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]
		Total	1	(1.2)	81	(97.6)	1	(1.2)	83	(100.0)	2	(2.4)	78	(91.8)	5	(5.9)	85	(100.0)
	Week 12	Low	0		0		0		0		0		0		0		0	
		Normal	1	(1.2)	79	(97.5)	0		80	(98.8)	2	(2.4)	76	(90.5)	4	(4.8)	82	(97.6)
		High	0		0		1	(1.2)	1	(1.2)	0		1	(1.2)	1	(1.2)	2	(2.4)
		Total	1	(1.2)	79	(97.5)	1	(1.2)	81	(100.0)	2	(2.4)	77	(91.7)	5	(6.0)	84	(100.0)
	Week 24	Low	0		0		0		0		0		1	(1.2)	0		1	(1.2)
		Normal	1	(1.2)	78	(96.3)	0		79	(97.5)	2	(2.4)	71	(86.6)	4	(4.9)	77	(93.9)
		High	0		1	(1.2)	1	(1.2)	2	(2.5)	0		3	(3.7)	1	(1.2)	4	(4.9)
		Total	1	(1.2)	79	(97.5)	1	(1.2)	81	(100.0)	2	(2.4)	75	(91.5)	5	(6.1)	82	(100.0)
Monocytes/Leukocytes (%)	Week 2	Low	0		0		0		0		0		0		0		0	
		Normal	0		72	(84.7)	1	(1.2)	73	(85.9)	0		79	(90.8)	2	(2.3)	81	(93.1)
		High	0		7	(8.2)	5	(5.9)	12	(14.1)	0		3	(3.4)	3	(3.4)	6	(6.9)
		Total	0		79	(92.9)	6	(7.1)	85	(100.0)	0		82	(94.3)	5	(5.7)	87	(100.0)
	Week 4	Low	0		0		0		0		0		0		0		0	
		Normal	0		74	(89.2)	1	(1.2)	75	(90.4)	0		78	(90.7)	3	(3.5)	81	(94.2)
		High	0		3	(3.6)	5	(6.0)	8	(9.6)	0		4	(4.7)	1	(1.2)	5	(5.8)
		Total	0		77	(92.8)	6	(7.2)	83	(100.0)	0		82	(95.3)	4	(4.7)	86	(100.0)
	Week 8	Low	0		0		0		0		0		0		0		0	
		Normal	0		75	(90.4)	2	(2.4)	77	(92.8)	0		74	(87.1)	2	(2.4)	76	(89.4)
		High	0		2	(2.4)	4	(4.8)	6	(7.2)	0		7	(8.2)	2	(2.4)	9	(10.6)
		Total	0		77	(92.8)	6	(7.2)	83	(100.0)	0		81	(95.3)	4	(4.7)	85	(100.0)
	Week 12	Low	0		0		0		0		0		0		0		0	
		Normal	0		69	(85.2)	3	(3.7)	72	(88.9)	0		75	(89.3)	3	(3.6)	78	(92.9)
		High	0		6	(7.4)	3	(3.7)	9	(11.1)	0		5	(6.0)	1	(1.2)	6	(7.1)
		Total	0		75	(92.6)	6	(7.4)	81	(100.0)	0		80	(95.2)	4	(4.8)	84	(100.0)
	Week 24	Low	0		0		0		0		0		0		0		0	
		Normal	0		71	(87.7)	2	(2.5)	73	(90.1)	0		73	(89.0)	3	(3.7)	76	(92.7)
		High	0		4	(4.9)	4	(4.9)	8	(9.9)	0		5	(6.1)	1	(1.2)	6	(7.3)
		Total	0		75	(92.6)	6	(7.4)	81	(100.0)	0		78	(95.1)	4	(4.9)	82	(100.0)
Eosinophils/Leukocytes (%)	Week 2	Low	0		0		0		0		0		0		0		0	
		Normal	0		79	(92.9)	1	(1.2)	80	(94.1)	0		79	(90.8)	0		79	(90.8)
		High	0		3	(3.5)	2	(2.4)	5	(5.9)	0		4	(4.6)	4	(4.6)	8	(9.2)
		Total	0		82	(96.5)	3	(3.5)	85	(100.0)	0		83	(95.4)	4	(4.6)	87	(100.0)
	Week 4	Low	0		0		0		0		0		0		0		0	
		Normal	0		78	(94.0)	2	(2.4)	80	(96.4)	0		80	(93.0)	2	(2.3)	82	(95.3)
		High	0		2	(2.4)	1	(1.2)	3	(3.6)	0		2	(2.3)	2	(2.3)	4	(4.7)
		Total	0		80	(96.4)	3	(3.6)	83	(100.0)	0		82	(95.3)	4	(4.7)	86	(100.0)
	Week 8	Low	0		0		0		0		0		0		0		0	
		Normal	0		78	(94.0)	2	(2.4)	80	(96.4)	0		80	(94.1)	2	(2.4)	82	(96.5)
		High	0		2	(2.4)	1	(1.2)	3	(3.6)	0		1	(1.2)	2	(2.4)	3	(3.5)
		Total	0		80	(96.4)	3	(3.6)	83	(100.0)	0		81	(95.3)	4	(4.7)	85	(100.0)
	Week 12	Low	0		0		0		0		0		0		0		0	
		Normal	0		76	(93.8)	2	(2.5)	78	(96.3)	0		79	(94.0)	2	(2.4)	81	(96.4)
		High	0		2	(2.5)	1	(1.2)	3	(3.7)	0		1	(1.2)	2	(2.4)	3	(3.6)
		Total	0		78	(96.3)	3	(3.7)	81	(100.0)	0		80	(95.2)	4	(4.8)	84	(100.0)
	Week 24	Low	0		0		0		0		0		0		0		0	
		Normal	0		77	(95.1)	2	(2.5)	79	(97.5)	0		75	(91.5)	3	(3.7)	78	(95.1)
		High	0		1	(1.2)	1	(1.2)	2	(2.5)	0		3	(3.7)	1	(1.2)	4	(4.9)
		Total	0		78	(96.3)	3	(3.7)	81	(100.0)	0		78	(95.1)	4	(4.9)	82	(100.0)
Basophils/Leukocytes (%)	Week 2	Low	0		0		0		0		0		0		0		0	
		Normal	0		85	(100.0)	0		85	(100.0)	0		86	(98.9)	0		86	(98.9)
		High	0		0		0		0		0		1	(1.1)	0		1	(1.1)
		Total	0		85	(100.0)	0		85	(100.0)	0		87	(100.0)	0		87	(100.0)

Paramaters (Unit)	Timepoint	Baseline[a]	Placebo N=89								SI-613 30 mg N=87							
			Low		Normal		High		Total		Low		Normal		High		Total	
			n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]
	Week 4	Low	0		0		0		0		0		0		0		0	
		Normal	0		83	(100.0)	0		83	(100.0)	0		86	(100.0)	0		86	(100.0)
		High	0		0		0		0		0		0		0		0	
		Total	0		83	(100.0)	0		83	(100.0)	0		86	(100.0)	0		86	(100.0)
	Week 8	Low	0		0		0		0		0		0		0		0	
		Normal	0		83	(100.0)	0		83	(100.0)	0		85	(100.0)	0		85	(100.0)
		High	0		0		0		0		0		0		0		0	
		Total	0		83	(100.0)	0		83	(100.0)	0		85	(100.0)	0		85	(100.0)
	Week 12	Low	0		0		0		0		0		0		0		0	
		Normal	0		80	(98.8)	0		80	(98.8)	0		84	(100.0)	0		84	(100.0)
		High	0		1	(1.2)	0		1	(1.2)	0		0		0		0	
		Total	0		81	(100.0)	0		81	(100.0)	0		84	(100.0)	0		84	(100.0)
	Week 24	Low	0		0		0		0		0		0		0		0	
		Normal	0		81	(100.0)	0		81	(100.0)	0		82	(100.0)	0		82	(100.0)
		High	0		0		0		0		0		0		0		0	
		Total	0		81	(100.0)	0		81	(100.0)	0		82	(100.0)	0		82	(100.0)
Erythrocytes (10^4/uL)	Week 2	Low	7	(8.2)	5	(5.9)	0		12	(14.1)	6	(6.9)	2	(2.3)	0		8	(9.2)
		Normal	1	(1.2)	72	(84.7)	0		73	(85.9)	3	(3.4)	75	(86.2)	1	(1.1)	79	(90.8)
		High	0		0		0		0		0		0		0		0	
		Total	8	(9.4)	77	(90.6)	0		85	(100.0)	9	(10.3)	77	(88.5)	1	(1.1)	87	(100.0)
	Week 4	Low	6	(7.2)	4	(4.8)	0		10	(12.0)	6	(7.0)	2	(2.3)	0		8	(9.3)
		Normal	2	(2.4)	71	(85.5)	0		73	(88.0)	3	(3.5)	74	(86.0)	1	(1.2)	78	(90.7)
		High	0		0		0		0		0		0		0		0	
		Total	8	(9.6)	75	(90.4)	0		83	(100.0)	9	(10.5)	76	(88.4)	1	(1.2)	86	(100.0)
	Week 8	Low	6	(7.2)	4	(4.8)	0		10	(12.0)	8	(9.4)	3	(3.5)	0		11	(12.9)
		Normal	2	(2.4)	71	(85.5)	0		73	(88.0)	1	(1.2)	72	(84.7)	1	(1.2)	74	(87.1)
		High	0		0		0		0		0		0		0		0	
		Total	8	(9.6)	75	(90.4)	0		83	(100.0)	9	(10.6)	75	(88.2)	1	(1.2)	85	(100.0)
	Week 12	Low	6	(7.4)	7	(8.6)	0		13	(16.0)	6	(7.1)	3	(3.6)	0		9	(10.7)
		Normal	2	(2.5)	66	(81.5)	0		68	(84.0)	3	(3.6)	70	(83.3)	1	(1.2)	74	(88.1)
		High	0		0		0		0		0		1	(1.2)	0		1	(1.2)
		Total	8	(9.9)	73	(90.1)	0		81	(100.0)	9	(10.7)	74	(88.1)	1	(1.2)	84	(100.0)
	Week 24	Low	6	(7.4)	10	(12.3)	0		16	(19.8)	6	(7.3)	3	(3.7)	0		9	(11.0)
		Normal	2	(2.5)	63	(77.8)	0		65	(80.2)	2	(2.4)	69	(84.1)	1	(1.2)	72	(87.8)
		High	0		0		0		0		0		1	(1.2)	0		1	(1.2)
		Total	8	(9.9)	73	(90.1)	0		81	(100.0)	8	(9.8)	73	(89.0)	1	(1.2)	82	(100.0)
Hemoglobin (g/dL)	Week 2	Low	2	(2.4)	3	(3.5)	0		5	(5.9)	6	(6.9)	1	(1.1)	0		7	(8.0)
		Normal	3	(3.5)	77	(90.6)	0		80	(94.1)	3	(3.4)	76	(87.4)	1	(1.1)	80	(92.0)
		High	0		0		0		0		0		0		0		0	
		Total	5	(5.9)	80	(94.1)	0		85	(100.0)	9	(10.3)	77	(88.5)	1	(1.1)	87	(100.0)
	Week 4	Low	3	(3.6)	4	(4.8)	0		7	(8.4)	7	(8.1)	2	(2.3)	0		9	(10.5)
		Normal	2	(2.4)	74	(89.2)	0		76	(91.6)	1	(1.2)	75	(87.2)	1	(1.2)	77	(89.5)
		High	0		0		0		0		0		0		0		0	
		Total	5	(6.0)	78	(94.0)	0		83	(100.0)	8	(9.3)	77	(89.5)	1	(1.2)	86	(100.0)
	Week 8	Low	2	(2.4)	3	(3.6)	0		5	(6.0)	8	(9.4)	1	(1.2)	0		9	(10.6)
		Normal	3	(3.6)	75	(90.4)	0		78	(94.0)	0		75	(88.2)	1	(1.2)	76	(89.4)
		High	0		0		0		0		0		0		0		0	
		Total	5	(6.0)	78	(94.0)	0		83	(100.0)	8	(9.4)	76	(89.4)	1	(1.2)	85	(100.0)
	Week 12	Low	3	(3.7)	6	(7.4)	0		9	(11.1)	8	(9.5)	5	(6.0)	0		13	(15.5)
		Normal	2	(2.5)	70	(86.4)	0		72	(88.9)	0		70	(83.3)	1	(1.2)	71	(84.5)
		High	0		0		0		0		0		0		0		0	
		Total	5	(6.2)	76	(93.8)	0		81	(100.0)	8	(9.5)	75	(89.3)	1	(1.2)	84	(100.0)
	Week 24	Low	1	(1.2)	5	(6.2)	0		6	(7.4)	7	(8.5)	2	(2.4)	0		9	(11.0)

Paramaters (Unit)	Timepoint	Baseline[a]	Placebo N=89								SI-613 30 mg N=87							
			Low		Normal		High		Total		Low		Normal		High		Total	
			n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]
		Normal	4	(4.9)	71	(87.7)	0		75	(92.6)	1	(1.2)	71	(86.6)	1	(1.2)	73	(89.0)
		High	0		0		0		0		0		0		0		0	
		Total	5	(6.2)	76	(93.8)	0		81	(100.0)	8	(9.8)	73	(89.0)	1	(1.2)	82	(100.0)
Hematocrit (%)	Week 2	Low	5	(5.9)	2	(2.4)	0		7	(8.2)	6	(6.9)	0		0		6	(6.9)
		Normal	4	(4.7)	74	(87.1)	0		78	(91.8)	3	(3.4)	77	(88.5)	1	(1.1)	81	(93.1)
		High	0		0		0		0		0		0		0		0	
		Total	9	(10.6)	76	(89.4)	0		85	(100.0)	9	(10.3)	77	(88.5)	1	(1.1)	87	(100.0)
	Week 4	Low	5	(6.0)	1	(1.2)	0		6	(7.2)	7	(8.1)	2	(2.3)	0		9	(10.5)
		Normal	4	(4.8)	73	(88.0)	0		77	(92.8)	1	(1.2)	75	(87.2)	1	(1.2)	77	(89.5)
		High	0		0		0		0		0		0		0		0	
		Total	9	(10.8)	74	(89.2)	0		83	(100.0)	8	(9.3)	77	(89.5)	1	(1.2)	86	(100.0)
	Week 8	Low	4	(4.8)	3	(3.6)	0		7	(8.4)	6	(7.1)	3	(3.5)	0		9	(10.6)
		Normal	5	(6.0)	71	(85.5)	0		76	(91.6)	2	(2.4)	73	(85.9)	1	(1.2)	76	(89.4)
		High	0		0		0		0		0		0		0		0	
		Total	9	(10.8)	74	(89.2)	0		83	(100.0)	8	(9.4)	76	(89.4)	1	(1.2)	85	(100.0)
	Week 12	Low	4	(4.9)	4	(4.9)	0		8	(9.9)	8	(9.5)	4	(4.8)	0		12	(14.3)
		Normal	5	(6.2)	68	(84.0)	0		73	(90.1)	0		70	(83.3)	1	(1.2)	71	(84.5)
		High	0		0		0		0		0		1	(1.2)	0		1	(1.2)
		Total	9	(11.1)	72	(88.9)	0		81	(100.0)	8	(9.5)	75	(89.3)	1	(1.2)	84	(100.0)
	Week 24	Low	2	(2.5)	4	(4.9)	0		6	(7.4)	6	(7.3)	2	(2.4)	0		8	(9.8)
		Normal	7	(8.6)	68	(84.0)	0		75	(92.6)	2	(2.4)	71	(86.6)	1	(1.2)	74	(90.2)
		High	0		0		0		0		0		0		0		0	
		Total	9	(11.1)	72	(88.9)	0		81	(100.0)	8	(9.8)	73	(89.0)	1	(1.2)	82	(100.0)
Platelets (10^4/uL)	Week 2	Low	0		0		0		0		1	(1.1)	1	(1.1)	0		2	(2.3)
		Normal	0		83	(98.8)	0		83	(98.8)	0		79	(90.8)	1	(1.1)	80	(92.0)
		High	0		1	(1.2)	0		1	(1.2)	0		3	(3.4)	2	(2.3)	5	(5.7)
		Total	0		84	(100.0)	0		84	(100.0)	1	(1.1)	83	(95.4)	3	(3.4)	87	(100.0)
	Week 4	Low	0		2	(2.4)	0		2	(2.4)	1	(1.2)	0		0		1	(1.2)
		Normal	0		79	(96.3)	0		79	(96.3)	0		81	(94.2)	2	(2.3)	83	(96.5)
		High	0		1	(1.2)	0		1	(1.2)	0		1	(1.2)	1	(1.2)	2	(2.3)
		Total	0		82	(100.0)	0		82	(100.0)	1	(1.2)	82	(95.3)	3	(3.5)	86	(100.0)
	Week 8	Low	0		1	(1.2)	0		1	(1.2)	1	(1.2)	1	(1.2)	0		2	(2.4)
		Normal	0		80	(97.6)	0		80	(97.6)	0		80	(94.1)	1	(1.2)	81	(95.3)
		High	0		1	(1.2)	0		1	(1.2)	0		0		2	(2.4)	2	(2.4)
		Total	0		82	(100.0)	0		82	(100.0)	1	(1.2)	81	(95.3)	3	(3.5)	85	(100.0)
	Week 12	Low	0		1	(1.3)	0		1	(1.3)	1	(1.2)	0		0		1	(1.2)
		Normal	0		79	(98.8)	0		79	(98.8)	0		79	(94.0)	2	(2.4)	81	(96.4)
		High	0		0		0		0		0		1	(1.2)	1	(1.2)	2	(2.4)
		Total	0		80	(100.0)	0		80	(100.0)	1	(1.2)	80	(95.2)	3	(3.6)	84	(100.0)
	Week 24	Low	0		1	(1.3)	0		1	(1.3)	1	(1.2)	0		0		1	(1.2)
		Normal	0		78	(97.5)	0		78	(97.5)	0		78	(95.1)	1	(1.2)	79	(96.3)
		High	0		1	(1.3)	0		1	(1.3)	0		0		2	(2.4)	2	(2.4)
		Total	0		80	(100.0)	0		80	(100.0)	1	(1.2)	78	(95.1)	3	(3.7)	82	(100.0)
Protein (g/dL)	Week 2	Low	4	(4.7)	1	(1.2)	0		5	(5.9)	3	(3.4)	5	(5.7)	0		8	(9.2)
		Normal	3	(3.5)	77	(90.6)	0		80	(94.1)	6	(6.9)	73	(83.9)	0		79	(90.8)
		High	0		0		0		0		0		0		0		0	
		Total	7	(8.2)	78	(91.8)	0		85	(100.0)	9	(10.3)	78	(89.7)	0		87	(100.0)
	Week 4	Low	6	(7.2)	3	(3.6)	0		9	(10.8)	6	(7.0)	9	(10.5)	0		15	(17.4)
		Normal	1	(1.2)	73	(88.0)	0		74	(89.2)	2	(2.3)	69	(80.2)	0		71	(82.6)
		High	0		0		0		0		0		0		0		0	
		Total	7	(8.4)	76	(91.6)	0		83	(100.0)	8	(9.3)	78	(90.7)	0		86	(100.0)
	Week 8	Low	3	(3.6)	3	(3.6)	0		6	(7.2)	4	(4.7)	12	(14.1)	0		16	(18.8)
		Normal	4	(4.8)	73	(88.0)	0		77	(92.8)	4	(4.7)	65	(76.5)	0		69	(81.2)

Paramaters (Unit)	Timepoint	Baseline[a]	Placebo N=89								SI-613 30 mg N=87							
			Low		Normal		High		Total		Low		Normal		High		Total	
			n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]
		High	0		0		0		0		0		0		0		0	
		Total	7	(8.4)	76	(91.6)	0		83	(100.0)	8	(9.4)	77	(90.6)	0		85	(100.0)
	Week 12	Low	6	(7.4)	4	(4.9)	0		10	(12.3)	3	(3.6)	6	(7.1)	0		9	(10.7)
		Normal	1	(1.2)	70	(86.4)	0		71	(87.7)	5	(6.0)	70	(83.3)	0		75	(89.3)
		High	0		0		0		0		0		0		0		0	
		Total	7	(8.6)	74	(91.4)	0		81	(100.0)	8	(9.5)	76	(90.5)	0		84	(100.0)
	Week 24	Low	5	(6.2)	6	(7.4)	0		11	(13.6)	2	(2.4)	9	(11.0)	0		11	(13.4)
		Normal	2	(2.5)	68	(84.0)	0		70	(86.4)	5	(6.1)	66	(80.5)	0		71	(86.6)
		High	0		0		0		0		0		0		0		0	
		Total	7	(8.6)	74	(91.4)	0		81	(100.0)	7	(8.5)	75	(91.5)	0		82	(100.0)
Albumin (g/dL)	Week 2	Low	0		0		0		0		0		0		0		0	
		Normal	1	(1.2)	84	(98.8)	0		85	(100.0)	0		87	(100.0)	0		87	(100.0)
		High	0		0		0		0		0		0		0		0	
		Total	1	(1.2)	84	(98.8)	0		85	(100.0)	0		87	(100.0)	0		87	(100.0)
	Week 4	Low	0		0		0		0		0		0		0		0	
		Normal	1	(1.2)	82	(98.8)	0		83	(100.0)	0		86	(100.0)	0		86	(100.0)
		High	0		0		0		0		0		0		0		0	
		Total	1	(1.2)	82	(98.8)	0		83	(100.0)	0		86	(100.0)	0		86	(100.0)
	Week 8	Low	0		1	(1.2)	0		1	(1.2)	0		0		0		0	
		Normal	1	(1.2)	81	(97.6)	0		82	(98.8)	0		85	(100.0)	0		85	(100.0)
		High	0		0		0		0		0		0		0		0	
		Total	1	(1.2)	82	(98.8)	0		83	(100.0)	0		85	(100.0)	0		85	(100.0)
	Week 12	Low	0		0		0		0		0		1	(1.2)	0		1	(1.2)
		Normal	1	(1.2)	80	(98.8)	0		81	(100.0)	0		83	(98.8)	0		83	(98.8)
		High	0		0		0		0		0		0		0		0	
		Total	1	(1.2)	80	(98.8)	0		81	(100.0)	0		84	(100.0)	0		84	(100.0)
	Week 24	Low	0		0		0		0		0		0		0		0	
		Normal	1	(1.2)	80	(98.8)	0		81	(100.0)	0		82	(100.0)	0		82	(100.0)
		High	0		0		0		0		0		0		0		0	
		Total	1	(1.2)	80	(98.8)	0		81	(100.0)	0		82	(100.0)	0		82	(100.0)
Bilirubin (mg/dL)	Week 2	Low	0		0		0		0		0		0		0		0	
		Normal	0		84	(98.8)	0		84	(98.8)	0		83	(95.4)	1	(1.1)	84	(96.6)
		High	0		1	(1.2)	0		1	(1.2)	0		1	(1.1)	2	(2.3)	3	(3.4)
		Total	0		85	(100.0)	0		85	(100.0)	0		84	(96.6)	3	(3.4)	87	(100.0)
	Week 4	Low	0		0		0		0		0		0		0		0	
		Normal	0		81	(97.6)	0		81	(97.6)	0		82	(95.3)	0		82	(95.3)
		High	0		2	(2.4)	0		2	(2.4)	0		1	(1.2)	3	(3.5)	4	(4.7)
		Total	0		83	(100.0)	0		83	(100.0)	0		83	(96.5)	3	(3.5)	86	(100.0)
	Week 8	Low	0		0		0		0		0		0		0		0	
		Normal	0		81	(97.6)	0		81	(97.6)	0		81	(95.3)	0		81	(95.3)
		High	0		2	(2.4)	0		2	(2.4)	0		1	(1.2)	3	(3.5)	4	(4.7)
		Total	0		83	(100.0)	0		83	(100.0)	0		82	(96.5)	3	(3.5)	85	(100.0)
	Week 12	Low	0		0		0		0		0		0		0		0	
		Normal	0		79	(97.5)	0		79	(97.5)	0		78	(92.9)	0		78	(92.9)
		High	0		2	(2.5)	0		2	(2.5)	0		3	(3.6)	3	(3.6)	6	(7.1)
		Total	0		81	(100.0)	0		81	(100.0)	0		81	(96.4)	3	(3.6)	84	(100.0)
	Week 24	Low	0		0		0		0		0		0		0		0	
		Normal	0		80	(98.8)	0		80	(98.8)	0		76	(92.7)	2	(2.4)	78	(95.1)
		High	0		1	(1.2)	0		1	(1.2)	0		3	(3.7)	1	(1.2)	4	(4.9)
		Total	0		81	(100.0)	0		81	(100.0)	0		79	(96.3)	3	(3.7)	82	(100.0)
Direct Bilirubin (mg/dL)	Week 2	Low	0		0		0		0		0		0		0		0	
		Normal	0		85	(100.0)	0		85	(100.0)	0		86	(98.9)	1	(1.1)	87	(100.0)
		High	0		0		0		0		0		0		0		0	

Paramaters (Unit)	Timepoint	Baseline[a]	Placebo N=89								SI-613 30 mg N=87							
			Low		Normal		High		Total		Low		Normal		High		Total	
			n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]
		Total	0		85	(100.0)	0		85	(100.0)	0		86	(98.9)	1	(1.1)	87	(100.0)
	Week 4	Low	0		0		0		0		0		0		0		0	
		Normal	0		83	(100.0)	0		83	(100.0)	0		84	(97.7)	0		84	(97.7)
		High	0		0		0		0		0		1	(1.2)	1	(1.2)	2	(2.3)
		Total	0		83	(100.0)	0		83	(100.0)	0		85	(98.8)	1	(1.2)	86	(100.0)
	Week 8	Low	0		0		0		0		0		0		0		0	
		Normal	0		83	(100.0)	0		83	(100.0)	0		84	(98.8)	0		84	(98.8)
		High	0		0		0		0		0		0		1	(1.2)	1	(1.2)
		Total	0		83	(100.0)	0		83	(100.0)	0		84	(98.8)	1	(1.2)	85	(100.0)
	Week 12	Low	0		0		0		0		0		0		0		0	
		Normal	0		81	(100.0)	0		81	(100.0)	0		83	(98.8)	0		83	(98.8)
		High	0		0		0		0		0		0		1	(1.2)	1	(1.2)
		Total	0		81	(100.0)	0		81	(100.0)	0		83	(98.8)	1	(1.2)	84	(100.0)
	Week 24	Low	0		0		0		0		0		0		0		0	
		Normal	0		81	(100.0)	0		81	(100.0)	0		81	(98.8)	0		81	(98.8)
		High	0		0		0		0		0		0		1	(1.2)	1	(1.2)
		Total	0		81	(100.0)	0		81	(100.0)	0		81	(98.8)	1	(1.2)	82	(100.0)
Aspartate Aminotransferase (U/L)	Week 2	Low	0		0		0		0		0		0		0		0	
		Normal	0		82	(96.5)	0		82	(96.5)	0		82	(94.3)	1	(1.1)	83	(95.4)
		High	0		1	(1.2)	2	(2.4)	3	(3.5)	0		1	(1.1)	3	(3.4)	4	(4.6)
		Total	0		83	(97.6)	2	(2.4)	85	(100.0)	0		83	(95.4)	4	(4.6)	87	(100.0)
	Week 4	Low	0		0		0		0		0		0		0		0	
		Normal	0		81	(97.6)	0		81	(97.6)	0		82	(95.3)	1	(1.2)	83	(96.5)
		High	0		0		2	(2.4)	2	(2.4)	0		0		3	(3.5)	3	(3.5)
		Total	0		81	(97.6)	2	(2.4)	83	(100.0)	0		82	(95.3)	4	(4.7)	86	(100.0)
	Week 8	Low	0		0		0		0		0		0		0		0	
		Normal	0		81	(97.6)	1	(1.2)	82	(98.8)	0		81	(95.3)	3	(3.5)	84	(98.8)
		High	0		0		1	(1.2)	1	(1.2)	0		0		1	(1.2)	1	(1.2)
		Total	0		81	(97.6)	2	(2.4)	83	(100.0)	0		81	(95.3)	4	(4.7)	85	(100.0)
	Week 12	Low	0		0		0		0		0		0		0		0	
		Normal	0		78	(96.3)	2	(2.5)	80	(98.8)	0		79	(94.0)	3	(3.6)	82	(97.6)
		High	0		1	(1.2)	0		1	(1.2)	0		1	(1.2)	1	(1.2)	2	(2.4)
		Total	0		79	(97.5)	2	(2.5)	81	(100.0)	0		80	(95.2)	4	(4.8)	84	(100.0)
	Week 24	Low	0		0		0		0		0		0		0		0	
		Normal	0		77	(95.1)	2	(2.5)	79	(97.5)	0		78	(95.1)	2	(2.4)	80	(97.6)
		High	0		2	(2.5)	0		2	(2.5)	0		0		2	(2.4)	2	(2.4)
		Total	0		79	(97.5)	2	(2.5)	81	(100.0)	0		78	(95.1)	4	(4.9)	82	(100.0)
Alanine Aminotransferase (U/L)	Week 2	Low	1	(1.2)	0		0		1	(1.2)	0		0		0		0	
		Normal	0		81	(95.3)	0		81	(95.3)	0		82	(94.3)	1	(1.1)	83	(95.4)
		High	0		0		3	(3.5)	3	(3.5)	0		1	(1.1)	3	(3.4)	4	(4.6)
		Total	1	(1.2)	81	(95.3)	3	(3.5)	85	(100.0)	0		83	(95.4)	4	(4.6)	87	(100.0)
	Week 4	Low	0		0		0		0		0		0		0		0	
		Normal	1	(1.2)	79	(95.2)	1	(1.2)	81	(97.6)	0		82	(95.3)	1	(1.2)	83	(96.5)
		High	0		0		2	(2.4)	2	(2.4)	0		0		3	(3.5)	3	(3.5)
		Total	1	(1.2)	79	(95.2)	3	(3.6)	83	(100.0)	0		82	(95.3)	4	(4.7)	86	(100.0)
	Week 8	Low	1	(1.2)	0		0		1	(1.2)	0		0		0		0	
		Normal	0		78	(94.0)	1	(1.2)	79	(95.2)	0		81	(95.3)	2	(2.4)	83	(97.6)
		High	0		1	(1.2)	2	(2.4)	3	(3.6)	0		0		2	(2.4)	2	(2.4)
		Total	1	(1.2)	79	(95.2)	3	(3.6)	83	(100.0)	0		81	(95.3)	4	(4.7)	85	(100.0)
	Week 12	Low	1	(1.2)	0		0		1	(1.2)	0		0		0		0	
		Normal	0		76	(93.8)	2	(2.5)	78	(96.3)	0		80	(95.2)	3	(3.6)	83	(98.8)
		High	0		1	(1.2)	1	(1.2)	2	(2.5)	0		0		1	(1.2)	1	(1.2)
		Total	1	(1.2)	77	(95.1)	3	(3.7)	81	(100.0)	0		80	(95.2)	4	(4.8)	84	(100.0)

Paramaters (Unit)	Timepoint	Baseline[a]	Placebo N=89								SI-613 30 mg N=87							
			Low		Normal		High		Total		Low		Normal		High		Total	
			n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]
	Week 24	Low	0		0		0		0		0		0		0		0	
		Normal	1	(1.2)	77	(95.1)	2	(2.5)	80	(98.8)	0		77	(93.9)	2	(2.4)	79	(96.3)
		High	0		0		1	(1.2)	1	(1.2)	0		1	(1.2)	2	(2.4)	3	(3.7)
		Total	1	(1.2)	77	(95.1)	3	(3.7)	81	(100.0)	0		78	(95.1)	4	(4.9)	82	(100.0)
Lactate Dehydrogenase (U/L)	Week 2	Low	0		0		0		0		1	(1.1)	0		0		1	(1.1)
		Normal	0		78	(91.8)	4	(4.7)	82	(96.5)	0		82	(94.3)	1	(1.1)	83	(95.4)
		High	0		1	(1.2)	2	(2.4)	3	(3.5)	0		0		3	(3.4)	3	(3.4)
		Total	0		79	(92.9)	6	(7.1)	85	(100.0)	1	(1.1)	82	(94.3)	4	(4.6)	87	(100.0)
	Week 4	Low	0		0		0		0		1	(1.2)	0		0		1	(1.2)
		Normal	0		77	(92.8)	4	(4.8)	81	(97.6)	0		78	(90.7)	3	(3.5)	81	(94.2)
		High	0		0		2	(2.4)	2	(2.4)	0		3	(3.5)	1	(1.2)	4	(4.7)
		Total	0		77	(92.8)	6	(7.2)	83	(100.0)	1	(1.2)	81	(94.2)	4	(4.7)	86	(100.0)
	Week 8	Low	0		0		0		0		1	(1.2)	0		0		1	(1.2)
		Normal	0		77	(92.8)	1	(1.2)	78	(94.0)	0		79	(92.9)	3	(3.5)	82	(96.5)
		High	0		0		5	(6.0)	5	(6.0)	0		1	(1.2)	1	(1.2)	2	(2.4)
		Total	0		77	(92.8)	6	(7.2)	83	(100.0)	1	(1.2)	80	(94.1)	4	(4.7)	85	(100.0)
	Week 12	Low	0		0		0		0		1	(1.2)	0		0		1	(1.2)
		Normal	0		74	(91.4)	3	(3.7)	77	(95.1)	0		77	(91.7)	2	(2.4)	79	(94.0)
		High	0		1	(1.2)	3	(3.7)	4	(4.9)	0		3	(3.6)	1	(1.2)	4	(4.8)
		Total	0		75	(92.6)	6	(7.4)	81	(100.0)	1	(1.2)	80	(95.2)	3	(3.6)	84	(100.0)
	Week 24	Low	0		0		0		0		1	(1.2)	0		0		1	(1.2)
		Normal	0		75	(92.6)	2	(2.5)	77	(95.1)	0		78	(95.1)	1	(1.2)	79	(96.3)
		High	0		0		4	(4.9)	4	(4.9)	0		0		2	(2.4)	2	(2.4)
		Total	0		75	(92.6)	6	(7.4)	81	(100.0)	1	(1.2)	78	(95.1)	3	(3.7)	82	(100.0)
Alkaline Phosphatase (U/L)	Week 2	Low	0		0		0		0		0		0		0		0	
		Normal	0		71	(83.5)	3	(3.5)	74	(87.1)	0		78	(89.7)	1	(1.1)	79	(90.8)
		High	0		3	(3.5)	8	(9.4)	11	(12.9)	0		2	(2.3)	6	(6.9)	8	(9.2)
		Total	0		74	(87.1)	11	(12.9)	85	(100.0)	0		80	(92.0)	7	(8.0)	87	(100.0)
	Week 4	Low	0		0		0		0		0		1	(1.2)	0		1	(1.2)
		Normal	0		69	(83.1)	4	(4.8)	73	(88.0)	0		76	(88.4)	1	(1.2)	77	(89.5)
		High	0		3	(3.6)	7	(8.4)	10	(12.0)	0		3	(3.5)	5	(5.8)	8	(9.3)
		Total	0		72	(86.7)	11	(13.3)	83	(100.0)	0		80	(93.0)	6	(7.0)	86	(100.0)
	Week 8	Low	0		0		0		0		0		0		0		0	
		Normal	0		68	(81.9)	4	(4.8)	72	(86.7)	0		78	(91.8)	0		78	(91.8)
		High	0		4	(4.8)	7	(8.4)	11	(13.3)	0		1	(1.2)	6	(7.1)	7	(8.2)
		Total	0		72	(86.7)	11	(13.3)	83	(100.0)	0		79	(92.9)	6	(7.1)	85	(100.0)
	Week 12	Low	0		0		0		0		0		0		0		0	
		Normal	0		69	(85.2)	3	(3.7)	72	(88.9)	0		74	(88.1)	2	(2.4)	76	(90.5)
		High	0		1	(1.2)	8	(9.9)	9	(11.1)	0		4	(4.8)	4	(4.8)	8	(9.5)
		Total	0		70	(86.4)	11	(13.6)	81	(100.0)	0		78	(92.9)	6	(7.1)	84	(100.0)
	Week 24	Low	0		0		0		0		0		0		0		0	
		Normal	0		68	(84.0)	5	(6.2)	73	(90.1)	0		72	(87.8)	3	(3.7)	75	(91.5)
		High	0		2	(2.5)	6	(7.4)	8	(9.9)	0		4	(4.9)	3	(3.7)	7	(8.5)
		Total	0		70	(86.4)	11	(13.6)	81	(100.0)	0		76	(92.7)	6	(7.3)	82	(100.0)
Gamma Glutamyl Transferase (U/L)	Week 2	Low	-		-		-		-		-		-		-		-	
		Normal	-		69	(81.2)	5	(5.9)	74	(87.1)	-		64	(73.6)	3	(3.4)	67	(77.0)
		High	-		2	(2.4)	9	(10.6)	11	(12.9)	-		7	(8.0)	13	(14.9)	20	(23.0)
		Total	-		71	(83.5)	14	(16.5)	85	(100.0)	-		71	(81.6)	16	(18.4)	87	(100.0)
	Week 4	Low	-		-		-		-		-		-		-		-	
		Normal	-		68	(81.9)	4	(4.8)	72	(86.7)	-		64	(74.4)	2	(2.3)	66	(76.7)
		High	-		2	(2.4)	9	(10.8)	11	(13.3)	-		6	(7.0)	14	(16.3)	20	(23.3)
		Total	-		70	(84.3)	13	(15.7)	83	(100.0)	-		70	(81.4)	16	(18.6)	86	(100.0)
	Week 8	Low	-		-		-		-		-		-		-		-	

Paramaters (Unit)	Timepoint	Baseline[a]	Placebo N=89								SI-613 30 mg N=87							
			Low		Normal		High		Total		Low		Normal		High		Total	
			n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]
		Normal	-		65	(78.3)	4	(4.8)	69	(83.1)	-		62	(72.9)	5	(5.9)	67	(78.8)
		High	-		5	(6.0)	9	(10.8)	14	(16.9)	-		7	(8.2)	11	(12.9)	18	(21.2)
		Total	-		70	(84.3)	13	(15.7)	83	(100.0)	-		69	(81.2)	16	(18.8)	85	(100.0)
	Week 12	Low	-		-		-		-		-		-		-		-	
		Normal	-		65	(80.2)	2	(2.5)	67	(82.7)	-		64	(76.2)	3	(3.6)	67	(79.8)
		High	-		3	(3.7)	11	(13.6)	14	(17.3)	-		4	(4.8)	13	(15.5)	17	(20.2)
		Total	-		68	(84.0)	13	(16.0)	81	(100.0)	-		68	(81.0)	16	(19.0)	84	(100.0)
	Week 24	Low	-		-		-		-		-		-		-		-	
		Normal	-		64	(79.0)	3	(3.7)	67	(82.7)	-		59	(72.0)	6	(7.3)	65	(79.3)
		High	-		4	(4.9)	10	(12.3)	14	(17.3)	-		7	(8.5)	10	(12.2)	17	(20.7)
		Total	-		68	(84.0)	13	(16.0)	81	(100.0)	-		66	(80.5)	16	(19.5)	82	(100.0)
Urate (mg/dL)	Week 2	Low	0		0		0		0		2	(2.3)	0		0		2	(2.3)
		Normal	0		75	(88.2)	1	(1.2)	76	(89.4)	1	(1.1)	75	(86.2)	0		76	(87.4)
		High	0		4	(4.7)	5	(5.9)	9	(10.6)	0		3	(3.4)	6	(6.9)	9	(10.3)
		Total	0		79	(92.9)	6	(7.1)	85	(100.0)	3	(3.4)	78	(89.7)	6	(6.9)	87	(100.0)
	Week 4	Low	0		0		0		0		1	(1.2)	1	(1.2)	0		2	(2.3)
		Normal	0		74	(89.2)	0		74	(89.2)	1	(1.2)	74	(86.0)	1	(1.2)	76	(88.4)
		High	0		3	(3.6)	6	(7.2)	9	(10.8)	0		3	(3.5)	5	(5.8)	8	(9.3)
		Total	0		77	(92.8)	6	(7.2)	83	(100.0)	2	(2.3)	78	(90.7)	6	(7.0)	86	(100.0)
	Week 8	Low	0		0		0		0		1	(1.2)	0		0		1	(1.2)
		Normal	0		72	(86.7)	4	(4.8)	76	(91.6)	1	(1.2)	77	(90.6)	3	(3.5)	81	(95.3)
		High	0		5	(6.0)	2	(2.4)	7	(8.4)	0		0		3	(3.5)	3	(3.5)
		Total	0		77	(92.8)	6	(7.2)	83	(100.0)	2	(2.4)	77	(90.6)	6	(7.1)	85	(100.0)
	Week 12	Low	0		0		0		0		1	(1.2)	0		0		1	(1.2)
		Normal	0		68	(84.0)	3	(3.7)	71	(87.7)	1	(1.2)	74	(88.1)	3	(3.6)	78	(92.9)
		High	0		7	(8.6)	3	(3.7)	10	(12.3)	0		2	(2.4)	3	(3.6)	5	(6.0)
		Total	0		75	(92.6)	6	(7.4)	81	(100.0)	2	(2.4)	76	(90.5)	6	(7.1)	84	(100.0)
	Week 24	Low	0		0		0		0		1	(1.2)	0		0		1	(1.2)
		Normal	0		72	(88.9)	3	(3.7)	75	(92.6)	1	(1.2)	68	(82.9)	1	(1.2)	70	(85.4)
		High	0		3	(3.7)	3	(3.7)	6	(7.4)	0		6	(7.3)	5	(6.1)	11	(13.4)
		Total	0		75	(92.6)	6	(7.4)	81	(100.0)	2	(2.4)	74	(90.2)	6	(7.3)	82	(100.0)
Blood Urea Nitrogen (mg/dL)	Week 2	Low	0		1	(1.2)	0		1	(1.2)	0		0		0		0	
		Normal	1	(1.2)	81	(95.3)	1	(1.2)	83	(97.6)	1	(1.1)	82	(94.3)	1	(1.1)	84	(96.6)
		High	0		1	(1.2)	0		1	(1.2)	0		1	(1.1)	2	(2.3)	3	(3.4)
		Total	1	(1.2)	83	(97.6)	1	(1.2)	85	(100.0)	1	(1.1)	83	(95.4)	3	(3.4)	87	(100.0)
	Week 4	Low	0		0		0		0		0		0		0		0	
		Normal	1	(1.2)	79	(95.2)	1	(1.2)	81	(97.6)	1	(1.2)	80	(93.0)	1	(1.2)	82	(95.3)
		High	0		2	(2.4)	0		2	(2.4)	0		2	(2.3)	2	(2.3)	4	(4.7)
		Total	1	(1.2)	81	(97.6)	1	(1.2)	83	(100.0)	1	(1.2)	82	(95.3)	3	(3.5)	86	(100.0)
	Week 8	Low	1	(1.2)	0		0		1	(1.2)	0		1	(1.2)	0		1	(1.2)
		Normal	0		80	(96.4)	1	(1.2)	81	(97.6)	1	(1.2)	80	(94.1)	2	(2.4)	83	(97.6)
		High	0		1	(1.2)	0		1	(1.2)	0		0		1	(1.2)	1	(1.2)
		Total	1	(1.2)	81	(97.6)	1	(1.2)	83	(100.0)	1	(1.2)	81	(95.3)	3	(3.5)	85	(100.0)
	Week 12	Low	0		0		0		0		0		0		0		0	
		Normal	1	(1.2)	79	(97.5)	1	(1.2)	81	(100.0)	1	(1.2)	79	(94.0)	2	(2.4)	82	(97.6)
		High	0		0		0		0		0		1	(1.2)	1	(1.2)	2	(2.4)
		Total	1	(1.2)	79	(97.5)	1	(1.2)	81	(100.0)	1	(1.2)	80	(95.2)	3	(3.6)	84	(100.0)
	Week 24	Low	0		0		0		0		0		0		0		0	
		Normal	1	(1.2)	79	(97.5)	0		80	(98.8)	1	(1.2)	77	(93.9)	1	(1.2)	79	(96.3)
		High	0		0		1	(1.2)	1	(1.2)	0		1	(1.2)	2	(2.4)	3	(3.7)
		Total	1	(1.2)	79	(97.5)	1	(1.2)	81	(100.0)	1	(1.2)	78	(95.1)	3	(3.7)	82	(100.0)
Creatinine (mg/dL)	Week 2	Low	4	(4.7)	1	(1.2)	0		5	(5.9)	4	(4.6)	0		0		4	(4.6)
		Normal	2	(2.4)	72	(84.7)	2	(2.4)	76	(89.4)	1	(1.1)	74	(85.1)	2	(2.3)	77	(88.5)

Paramaters (Unit)	Timepoint	Baseline[a]	Placebo N=89								SI-613 30 mg N=87							
			Low		Normal		High		Total		Low		Normal		High		Total	
			n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]
		High	0		2	(2.4)	2	(2.4)	4	(4.7)	0		1	(1.1)	5	(5.7)	6	(6.9)
		Total	6	(7.1)	75	(88.2)	4	(4.7)	85	(100.0)	5	(5.7)	75	(86.2)	7	(8.0)	87	(100.0)
	Week 4	Low	4	(4.8)	0		0		4	(4.8)	4	(4.7)	0		0		4	(4.7)
		Normal	2	(2.4)	70	(84.3)	2	(2.4)	74	(89.2)	0		72	(83.7)	3	(3.5)	75	(87.2)
		High	0		3	(3.6)	2	(2.4)	5	(6.0)	0		3	(3.5)	4	(4.7)	7	(8.1)
		Total	6	(7.2)	73	(88.0)	4	(4.8)	83	(100.0)	4	(4.7)	75	(87.2)	7	(8.1)	86	(100.0)
	Week 8	Low	3	(3.6)	1	(1.2)	0		4	(4.8)	2	(2.4)	0		0		2	(2.4)
		Normal	3	(3.6)	69	(83.1)	2	(2.4)	74	(89.2)	2	(2.4)	72	(84.7)	2	(2.4)	76	(89.4)
		High	0		3	(3.6)	2	(2.4)	5	(6.0)	0		2	(2.4)	5	(5.9)	7	(8.2)
		Total	6	(7.2)	73	(88.0)	4	(4.8)	83	(100.0)	4	(4.7)	74	(87.1)	7	(8.2)	85	(100.0)
	Week 12	Low	3	(3.7)	0		0		3	(3.7)	2	(2.4)	2	(2.4)	0		4	(4.8)
		Normal	3	(3.7)	67	(82.7)	2	(2.5)	72	(88.9)	2	(2.4)	69	(82.1)	3	(3.6)	74	(88.1)
		High	0		4	(4.9)	2	(2.5)	6	(7.4)	0		2	(2.4)	4	(4.8)	6	(7.1)
		Total	6	(7.4)	71	(87.7)	4	(4.9)	81	(100.0)	4	(4.8)	73	(86.9)	7	(8.3)	84	(100.0)
	Week 24	Low	2	(2.5)	1	(1.2)	0		3	(3.7)	0		1	(1.2)	0		1	(1.2)
		Normal	4	(4.9)	66	(81.5)	1	(1.2)	71	(87.7)	4	(4.9)	68	(82.9)	1	(1.2)	73	(89.0)
		High	0		4	(4.9)	3	(3.7)	7	(8.6)	0		2	(2.4)	6	(7.3)	8	(9.8)
		Total	6	(7.4)	71	(87.7)	4	(4.9)	81	(100.0)	4	(4.9)	71	(86.6)	7	(8.5)	82	(100.0)
Cholesterol (mg/dL)	Week 2	Low	0		0		0		0		0		0		0		0	
		Normal	0		50	(58.8)	4	(4.7)	54	(63.5)	1	(1.1)	50	(57.5)	10	(11.5)	61	(70.1)
		High	0		7	(8.2)	24	(28.2)	31	(36.5)	0		5	(5.7)	21	(24.1)	26	(29.9)
		Total	0		57	(67.1)	28	(32.9)	85	(100.0)	1	(1.1)	55	(63.2)	31	(35.6)	87	(100.0)
	Week 4	Low	0		0		0		0		0		0		0		0	
		Normal	0		44	(53.0)	2	(2.4)	46	(55.4)	1	(1.2)	50	(58.1)	9	(10.5)	60	(69.8)
		High	0		11	(13.3)	26	(31.3)	37	(44.6)	0		4	(4.7)	22	(25.6)	26	(30.2)
		Total	0		55	(66.3)	28	(33.7)	83	(100.0)	1	(1.2)	54	(62.8)	31	(36.0)	86	(100.0)
	Week 8	Low	0		0		0		0		0		0		0		0	
		Normal	0		45	(54.2)	4	(4.8)	49	(59.0)	1	(1.2)	49	(57.6)	7	(8.2)	57	(67.1)
		High	0		10	(12.0)	24	(28.9)	34	(41.0)	0		4	(4.7)	24	(28.2)	28	(32.9)
		Total	0		55	(66.3)	28	(33.7)	83	(100.0)	1	(1.2)	53	(62.4)	31	(36.5)	85	(100.0)
	Week 12	Low	0		0		0		0		0		0		0		0	
		Normal	0		43	(53.1)	4	(4.9)	47	(58.0)	1	(1.2)	43	(51.2)	9	(10.7)	53	(63.1)
		High	0		10	(12.3)	24	(29.6)	34	(42.0)	0		9	(10.7)	22	(26.2)	31	(36.9)
		Total	0		53	(65.4)	28	(34.6)	81	(100.0)	1	(1.2)	52	(61.9)	31	(36.9)	84	(100.0)
	Week 24	Low	0		0		0		0		0		0		0		0	
		Normal	0		48	(59.3)	8	(9.9)	56	(69.1)	1	(1.2)	43	(52.4)	8	(9.8)	52	(63.4)
		High	0		5	(6.2)	20	(24.7)	25	(30.9)	0		8	(9.8)	22	(26.8)	30	(36.6)
		Total	0		53	(65.4)	28	(34.6)	81	(100.0)	1	(1.2)	51	(62.2)	30	(36.6)	82	(100.0)
Triglycerides (mg/dL)	Week 2	Low	0		0		0		0		0		0		0		0	
		Normal	0		43	(50.6)	7	(8.2)	50	(58.8)	0		44	(50.6)	7	(8.0)	51	(58.6)
		High	0		7	(8.2)	28	(32.9)	35	(41.2)	0		10	(11.5)	26	(29.9)	36	(41.4)
		Total	0		50	(58.8)	35	(41.2)	85	(100.0)	0		54	(62.1)	33	(37.9)	87	(100.0)
	Week 4	Low	0		0		0		0		0		0		0		0	
		Normal	0		43	(51.8)	9	(10.8)	52	(62.7)	0		41	(47.7)	9	(10.5)	50	(58.1)
		High	0		5	(6.0)	26	(31.3)	31	(37.3)	0		12	(14.0)	24	(27.9)	36	(41.9)
		Total	0		48	(57.8)	35	(42.2)	83	(100.0)	0		53	(61.6)	33	(38.4)	86	(100.0)
	Week 8	Low	0		0		0		0		0		0		0		0	
		Normal	0		40	(48.2)	14	(16.9)	54	(65.1)	0		46	(54.1)	15	(17.6)	61	(71.8)
		High	0		8	(9.6)	21	(25.3)	29	(34.9)	0		7	(8.2)	17	(20.0)	24	(28.2)
		Total	0		48	(57.8)	35	(42.2)	83	(100.0)	0		53	(62.4)	32	(37.6)	85	(100.0)
	Week 12	Low	0		0		0		0		0		0		0		0	
		Normal	0		40	(49.4)	9	(11.1)	49	(60.5)	0		39	(46.4)	10	(11.9)	49	(58.3)
		High	0		8	(9.9)	24	(29.6)	32	(39.5)	0		13	(15.5)	22	(26.2)	35	(41.7)

Paramaters (Unit)	Timepoint	Baseline[a]	Placebo N=89								SI-613 30 mg N=87							
			Low		Normal		High		Total		Low		Normal		High		Total	
			n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]
		Total	0		48	(59.3)	33	(40.7)	81	(100.0)	0		52	(61.9)	32	(38.1)	84	(100.0)
	Week 24	Low	0		0		0		0		0		0		0		0	
		Normal	0		40	(49.4)	8	(9.9)	48	(59.3)	0		36	(43.9)	12	(14.6)	48	(58.5)
		High	0		8	(9.9)	25	(30.9)	33	(40.7)	0		15	(18.3)	19	(23.2)	34	(41.5)
		Total	0		48	(59.3)	33	(40.7)	81	(100.0)	0		51	(62.2)	31	(37.8)	82	(100.0)
C Reactive Protein (mg/dL)	Week 2	Low	-		-		-		-		-		-		-		-	
		Normal	-		78	(91.8)	6	(7.1)	84	(98.8)	-		84	(96.6)	2	(2.3)	86	(98.9)
		High	-		1	(1.2)	0		1	(1.2)	-		1	(1.1)	0		1	(1.1)
		Total	-		79	(92.9)	6	(7.1)	85	(100.0)	-		85	(97.7)	2	(2.3)	87	(100.0)
	Week 4	Low	-		-		-		-		-		-		-		-	
		Normal	-		75	(90.4)	5	(6.0)	80	(96.4)	-		84	(97.7)	2	(2.3)	86	(100.0)
		High	-		2	(2.4)	1	(1.2)	3	(3.6)	-		0		0		0	
		Total	-		77	(92.8)	6	(7.2)	83	(100.0)	-		84	(97.7)	2	(2.3)	86	(100.0)
	Week 8	Low	-		-		-		-		-		-		-		-	
		Normal	-		74	(89.2)	4	(4.8)	78	(94.0)	-		78	(91.8)	2	(2.4)	80	(94.1)
		High	-		3	(3.6)	2	(2.4)	5	(6.0)	-		5	(5.9)	0		5	(5.9)
		Total	-		77	(92.8)	6	(7.2)	83	(100.0)	-		83	(97.6)	2	(2.4)	85	(100.0)
	Week 12	Low	-		-		-		-		-		-		-		-	
		Normal	-		75	(92.6)	5	(6.2)	80	(98.8)	-		79	(94.0)	2	(2.4)	81	(96.4)
		High	-		0		1	(1.2)	1	(1.2)	-		3	(3.6)	0		3	(3.6)
		Total	-		75	(92.6)	6	(7.4)	81	(100.0)	-		82	(97.6)	2	(2.4)	84	(100.0)
	Week 24	Low	-		-		-		-		-		-		-		-	
		Normal	-		74	(91.4)	5	(6.2)	79	(97.5)	-		77	(93.9)	2	(2.4)	79	(96.3)
		High	-		1	(1.2)	1	(1.2)	2	(2.5)	-		3	(3.7)	0		3	(3.7)
		Total	-		75	(92.6)	6	(7.4)	81	(100.0)	-		80	(97.6)	2	(2.4)	82	(100.0)
Sodium (mEq/L)	Week 2	Low	0		0		0		0		0		1	(1.1)	0		1	(1.1)
		Normal	0		83	(97.6)	2	(2.4)	85	(100.0)	0		85	(97.7)	1	(1.1)	86	(98.9)
		High	0		0		0		0		0		0		0		0	
		Total	0		83	(97.6)	2	(2.4)	85	(100.0)	0		86	(98.9)	1	(1.1)	87	(100.0)
	Week 4	Low	0		0		0		0		0		0		0		0	
		Normal	0		81	(97.6)	2	(2.4)	83	(100.0)	0		85	(98.8)	1	(1.2)	86	(100.0)
		High	0		0		0		0		0		0		0		0	
		Total	0		81	(97.6)	2	(2.4)	83	(100.0)	0		85	(98.8)	1	(1.2)	86	(100.0)
	Week 8	Low	0		0		0		0		0		0		0		0	
		Normal	0		81	(97.6)	2	(2.4)	83	(100.0)	0		84	(98.8)	1	(1.2)	85	(100.0)
		High	0		0		0		0		0		0		0		0	
		Total	0		81	(97.6)	2	(2.4)	83	(100.0)	0		84	(98.8)	1	(1.2)	85	(100.0)
	Week 12	Low	0		0		0		0		0		0		0		0	
		Normal	0		79	(97.5)	2	(2.5)	81	(100.0)	0		83	(98.8)	1	(1.2)	84	(100.0)
		High	0		0		0		0		0		0		0		0	
		Total	0		79	(97.5)	2	(2.5)	81	(100.0)	0		83	(98.8)	1	(1.2)	84	(100.0)
	Week 24	Low	0		1	(1.2)	0		1	(1.2)	0		0		0		0	
		Normal	0		78	(96.3)	2	(2.5)	80	(98.8)	0		82	(100.0)	0		82	(100.0)
		High	0		0		0		0		0		0		0		0	
		Total	0		79	(97.5)	2	(2.5)	81	(100.0)	0		82	(100.0)	0		82	(100.0)
Potassium (mEq/L)	Week 2	Low	0		1	(1.2)	0		1	(1.2)	1	(1.1)	3	(3.4)	0		4	(4.6)
		Normal	1	(1.2)	80	(94.1)	2	(2.4)	83	(97.6)	1	(1.1)	81	(93.1)	1	(1.1)	83	(95.4)
		High	0		1	(1.2)	0		1	(1.2)	0		0		0		0	
		Total	1	(1.2)	82	(96.5)	2	(2.4)	85	(100.0)	2	(2.3)	84	(96.6)	1	(1.1)	87	(100.0)
	Week 4	Low	0		1	(1.2)	0		1	(1.2)	1	(1.2)	0		0		1	(1.2)
		Normal	1	(1.2)	79	(95.2)	1	(1.2)	81	(97.6)	1	(1.2)	83	(96.5)	1	(1.2)	85	(98.8)
		High	0		0		1	(1.2)	1	(1.2)	0		0		0		0	
		Total	1	(1.2)	80	(96.4)	2	(2.4)	83	(100.0)	2	(2.3)	83	(96.5)	1	(1.2)	86	(100.0)

Paramaters (Unit)	Timepoint	Baseline[a]	Placebo N=89								SI-613 30 mg N=87							
			Low		Normal		High		Total		Low		Normal		High		Total	
			n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]
	Week 8	Low	0		0		0		0		1	(1.2)	0		0		1	(1.2)
		Normal	1	(1.2)	77	(92.8)	2	(2.4)	80	(96.4)	1	(1.2)	81	(95.3)	1	(1.2)	83	(97.6)
		High	0		3	(3.6)	0		3	(3.6)	0		1	(1.2)	0		1	(1.2)
		Total	1	(1.2)	80	(96.4)	2	(2.4)	83	(100.0)	2	(2.4)	82	(96.5)	1	(1.2)	85	(100.0)
	Week 12	Low	0		1	(1.2)	0		1	(1.2)	1	(1.2)	1	(1.2)	0		2	(2.4)
		Normal	1	(1.2)	76	(93.8)	1	(1.2)	78	(96.3)	1	(1.2)	79	(94.0)	1	(1.2)	81	(96.4)
		High	0		1	(1.2)	1	(1.2)	2	(2.5)	0		1	(1.2)	0		1	(1.2)
		Total	1	(1.2)	78	(96.3)	2	(2.5)	81	(100.0)	2	(2.4)	81	(96.4)	1	(1.2)	84	(100.0)
	Week 24	Low	0		3	(3.7)	0		3	(3.7)	1	(1.2)	2	(2.4)	0		3	(3.7)
		Normal	1	(1.2)	74	(91.4)	2	(2.5)	77	(95.1)	1	(1.2)	77	(93.9)	1	(1.2)	79	(96.3)
		High	0		1	(1.2)	0		1	(1.2)	0		0		0		0	
		Total	1	(1.2)	78	(96.3)	2	(2.5)	81	(100.0)	2	(2.4)	79	(96.3)	1	(1.2)	82	(100.0)
Chloride (mEq/L)	Week 2	Low	0		0		0		0		0		0		0		0	
		Normal	0		85	(100.0)	0		85	(100.0)	0		84	(96.6)	3	(3.4)	87	(100.0)
		High	0		0		0		0		0		0		0		0	
		Total	0		85	(100.0)	0		85	(100.0)	0		84	(96.6)	3	(3.4)	87	(100.0)
	Week 4	Low	0		0		0		0		0		0		0		0	
		Normal	0		82	(98.8)	0		82	(98.8)	0		83	(96.5)	2	(2.3)	85	(98.8)
		High	0		1	(1.2)	0		1	(1.2)	0		0		1	(1.2)	1	(1.2)
		Total	0		83	(100.0)	0		83	(100.0)	0		83	(96.5)	3	(3.5)	86	(100.0)
	Week 8	Low	0		0		0		0		0		0		0		0	
		Normal	0		83	(100.0)	0		83	(100.0)	0		82	(96.5)	3	(3.5)	85	(100.0)
		High	0		0		0		0		0		0		0		0	
		Total	0		83	(100.0)	0		83	(100.0)	0		82	(96.5)	3	(3.5)	85	(100.0)
	Week 12	Low	0		0		0		0		0		0		0		0	
		Normal	0		81	(100.0)	0		81	(100.0)	0		81	(96.4)	2	(2.4)	83	(98.8)
		High	0		0		0		0		0		0		1	(1.2)	1	(1.2)
		Total	0		81	(100.0)	0		81	(100.0)	0		81	(96.4)	3	(3.6)	84	(100.0)
	Week 24	Low	0		0		0		0		0		0		0		0	
		Normal	0		81	(100.0)	0		81	(100.0)	0		80	(97.6)	2	(2.4)	82	(100.0)
		High	0		0		0		0		0		0		0		0	
		Total	0		81	(100.0)	0		81	(100.0)	0		80	(97.6)	2	(2.4)	82	(100.0)
Calcium (mg/dL)	Week 2	Low	0		0		0		0		0		0		0		0	
		Normal	0		85	(100.0)	0		85	(100.0)	0		85	(97.7)	0		85	(97.7)
		High	0		0		0		0		0		2	(2.3)	0		2	(2.3)
		Total	0		85	(100.0)	0		85	(100.0)	0		87	(100.0)	0		87	(100.0)
	Week 4	Low	0		0		0		0		0		0		0		0	
		Normal	0		83	(100.0)	0		83	(100.0)	0		86	(100.0)	0		86	(100.0)
		High	0		0		0		0		0		0		0		0	
		Total	0		83	(100.0)	0		83	(100.0)	0		86	(100.0)	0		86	(100.0)
	Week 8	Low	0		0		0		0		0		0		0		0	
		Normal	0		83	(100.0)	0		83	(100.0)	0		85	(100.0)	0		85	(100.0)
		High	0		0		0		0		0		0		0		0	
		Total	0		83	(100.0)	0		83	(100.0)	0		85	(100.0)	0		85	(100.0)
	Week 12	Low	0		0		0		0		0		0		0		0	
		Normal	0		80	(98.8)	0		80	(98.8)	0		84	(100.0)	0		84	(100.0)
		High	0		1	(1.2)	0		1	(1.2)	0		0		0		0	
		Total	0		81	(100.0)	0		81	(100.0)	0		84	(100.0)	0		84	(100.0)
	Week 24	Low	0		0		0		0		0		0		0		0	
		Normal	0		81	(100.0)	0		81	(100.0)	0		81	(98.8)	0		81	(98.8)
		High	0		0		0		0		0		1	(1.2)	0		1	(1.2)
		Total	0		81	(100.0)	0		81	(100.0)	0		82	(100.0)	0		82	(100.0)
Creatine Kinase (U/L)	Week 2	Low	2	(2.4)	2	(2.4)	0		4	(4.7)	0		0		0		0	

Paramaters (Unit)	Timepoint	Baseline[a]	Placebo N=89								SI-613 30 mg N=87							
			Low		Normal		High		Total		Low		Normal		High		Total	
			n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]
		Normal	1	(1.2)	70	(82.4)	3	(3.5)	74	(87.1)	1	(1.1)	71	(81.6)	1	(1.1)	73	(83.9)
		High	0		2	(2.4)	5	(5.9)	7	(8.2)	0		4	(4.6)	10	(11.5)	14	(16.1)
		Total	3	(3.5)	74	(87.1)	8	(9.4)	85	(100.0)	1	(1.1)	75	(86.2)	11	(12.6)	87	(100.0)
	Week 4	Low	3	(3.6)	1	(1.2)	0		4	(4.8)	0		0		0		0	
		Normal	0		66	(79.5)	2	(2.4)	68	(81.9)	1	(1.2)	70	(81.4)	4	(4.7)	75	(87.2)
		High	0		5	(6.0)	6	(7.2)	11	(13.3)	0		4	(4.7)	7	(8.1)	11	(12.8)
		Total	3	(3.6)	72	(86.7)	8	(9.6)	83	(100.0)	1	(1.2)	74	(86.0)	11	(12.8)	86	(100.0)
	Week 8	Low	2	(2.4)	1	(1.2)	0		3	(3.6)	1	(1.2)	0		0		1	(1.2)
		Normal	0		67	(80.7)	3	(3.6)	70	(84.3)	0		64	(75.3)	6	(7.1)	70	(82.4)
		High	1	(1.2)	4	(4.8)	5	(6.0)	10	(12.0)	0		9	(10.6)	5	(5.9)	14	(16.5)
		Total	3	(3.6)	72	(86.7)	8	(9.6)	83	(100.0)	1	(1.2)	73	(85.9)	11	(12.9)	85	(100.0)
	Week 12	Low	2	(2.5)	1	(1.2)	0		3	(3.7)	0		0		0		0	
		Normal	1	(1.2)	64	(79.0)	5	(6.2)	70	(86.4)	1	(1.2)	65	(77.4)	5	(6.0)	71	(84.5)
		High	0		5	(6.2)	3	(3.7)	8	(9.9)	0		8	(9.5)	5	(6.0)	13	(15.5)
		Total	3	(3.7)	70	(86.4)	8	(9.9)	81	(100.0)	1	(1.2)	73	(86.9)	10	(11.9)	84	(100.0)
	Week 24	Low	2	(2.5)	1	(1.2)	0		3	(3.7)	1	(1.2)	1	(1.2)	0		2	(2.4)
		Normal	1	(1.2)	66	(81.5)	3	(3.7)	70	(86.4)	0		67	(81.7)	4	(4.9)	71	(86.6)
		High	0		3	(3.7)	5	(6.2)	8	(9.9)	0		3	(3.7)	6	(7.3)	9	(11.0)
		Total	3	(3.7)	70	(86.4)	8	(9.9)	81	(100.0)	1	(1.2)	71	(86.6)	10	(12.2)	82	(100.0)
Hemoglobin A1C /Hemoglobin (%)	Week 2	Low	1	(1.2)	0		0		1	(1.2)	0		1	(1.1)	0		1	(1.1)
		Normal	0		68	(80.0)	1	(1.2)	69	(81.2)	0		74	(85.1)	0		74	(85.1)
		High	0		1	(1.2)	14	(16.5)	15	(17.6)	0		1	(1.1)	11	(12.6)	12	(13.8)
		Total	1	(1.2)	69	(81.2)	15	(17.6)	85	(100.0)	0		76	(87.4)	11	(12.6)	87	(100.0)
	Week 4	Low	1	(1.2)	0		0		1	(1.2)	0		0		0		0	
		Normal	0		68	(81.9)	1	(1.2)	69	(83.1)	0		75	(87.2)	0		75	(87.2)
		High	0		0		13	(15.7)	13	(15.7)	0		0		11	(12.8)	11	(12.8)
		Total	1	(1.2)	68	(81.9)	14	(16.9)	83	(100.0)	0		75	(87.2)	11	(12.8)	86	(100.0)
	Week 8	Low	1	(1.2)	0		0		1	(1.2)	0		0		0		0	
		Normal	0		65	(78.3)	1	(1.2)	66	(79.5)	0		74	(87.1)	0		74	(87.1)
		High	0		3	(3.6)	13	(15.7)	16	(19.3)	0		0		11	(12.9)	11	(12.9)
		Total	1	(1.2)	68	(81.9)	14	(16.9)	83	(100.0)	0		74	(87.1)	11	(12.9)	85	(100.0)
	Week 12	Low	0		0		0		0		0		0		0		0	
		Normal	1	(1.2)	64	(79.0)	1	(1.2)	66	(81.5)	0		72	(85.7)	1	(1.2)	73	(86.9)
		High	0		3	(3.7)	12	(14.8)	15	(18.5)	0		1	(1.2)	10	(11.9)	11	(13.1)
		Total	1	(1.2)	67	(82.7)	13	(16.0)	81	(100.0)	0		73	(86.9)	11	(13.1)	84	(100.0)
	Week 24	Low	1	(1.2)	0		0		1	(1.2)	0		0		0		0	
		Normal	0		66	(81.5)	2	(2.5)	68	(84.0)	0		70	(85.4)	3	(3.7)	73	(89.0)
		High	0		1	(1.2)	11	(13.6)	12	(14.8)	0		1	(1.2)	8	(9.8)	9	(11.0)
		Total	1	(1.2)	67	(82.7)	13	(16.0)	81	(100.0)	0		71	(86.6)	11	(13.4)	82	(100.0)

a:Baseline is value of screening.
b: Percentages are based on the number of subjects with non-missing values at both baseline and each timepoint.
-:Not applicable.
〔5.3.5.1-2 Table 14.3.4-2 改編〕

表 2.7.4.7-74. 臨床検査値の各項目のシフトテーブル（定性試験）：613/1022 試験

Paramaters	Treatment group	Timepoint	Baseline[a]	-		±		+		2+		3+		4+		5+		Total	
				n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]
Protein	Placebo	Week 2	-	81	(95.3)	0		0		0		0		0		0		81	(95.3)
			±	3	(3.5)	1	(1.2)	0		0		0		0		0		4	(4.7)
			+	0		0		0		0		0		0		0		0	
			2+	0		0		0		0		0		0		0		0	
			3+	0		0		0		0		0		0		0		0	
			4+	0		0		0		0		0		0		0		0	
			5+	0		0		0		0		0		0		0		0	
			Total	84	(98.8)	1	(1.2)	0		0		0		0		0		85	(100.0)
	SI-613 30 mg	Week 2	-	78	(90.7)	0		1	(1.2)	0		0		0		0		79	(91.9)
			±	1	(1.2)	1	(1.2)	0		0		0		0		0		2	(2.3)
			+	1	(1.2)	1	(1.2)	1	(1.2)	0		0		0		0		3	(3.5)
			2+	0		0		1	(1.2)	0		1	(1.2)	0		0		2	(2.3)
			3+	0		0		0		0		0		0		0		0	
			4+	0		0		0		0		0		0		0		0	
			5+	0		0		0		0		0		0		0		0	
			Total	80	(93.0)	2	(2.3)	3	(3.5)	0		1	(1.2)	0		0		86	(100.0)
	Placebo	Week 4	-	78	(94.0)	0		0		0		0		0		0		78	(94.0)
			±	3	(3.6)	1	(1.2)	0		0		0		0		0		4	(4.8)
			+	1	(1.2)	0		0		0		0		0		0		1	(1.2)
			2+	0		0		0		0		0		0		0		0	
			3+	0		0		0		0		0		0		0		0	
			4+	0		0		0		0		0		0		0		0	
			5+	0		0		0		0		0		0		0		0	
			Total	82	(98.8)	1	(1.2)	0		0		0		0		0		83	(100.0)
	SI-613 30 mg	Week 4	-	77	(89.5)	1	(1.2)	1	(1.2)	0		0		0		0		79	(91.9)
			±	3	(3.5)	0		0		0		0		0		0		3	(3.5)
			+	0		1	(1.2)	2	(2.3)	0		0		0		0		3	(3.5)
			2+	0		0		0		0		1	(1.2)	0		0		1	(1.2)
			3+	0		0		0		0		0		0		0		0	
			4+	0		0		0		0		0		0		0		0	
			5+	0		0		0		0		0		0		0		0	
			Total	80	(93.0)	2	(2.3)	3	(3.5)	0		1	(1.2)	0		0		86	(100.0)
	Placebo	Week 8	-	78	(94.0)	1	(1.2)	0		0		0		0		0		79	(95.2)
			±	4	(4.8)	0		0		0		0		0		0		4	(4.8)
			+	0		0		0		0		0		0		0		0	
			2+	0		0		0		0		0		0		0		0	
			3+	0		0		0		0		0		0		0		0	
			4+	0		0		0		0		0		0		0		0	
			5+	0		0		0		0		0		0		0		0	
			Total	82	(98.8)	1	(1.2)	0		0		0		0		0		83	(100.0)
	SI-613 30 mg	Week 8	-	73	(85.9)	1	(1.2)	1	(1.2)	0		0		0		0		75	(88.2)
			±	6	(7.1)	0		1	(1.2)	0		0		0		0		7	(8.2)
			+	0		1	(1.2)	1	(1.2)	0		0		0		0		2	(2.4)
			2+	0		0		0		0		1	(1.2)	0		0		1	(1.2)
			3+	0		0		0		0		0		0		0		0	
			4+	0		0		0		0		0		0		0		0	
			5+	0		0		0		0		0		0		0		0	
			Total	79	(92.9)	2	(2.4)	3	(3.5)	0		1	(1.2)	0		0		85	(100.0)
	Placebo	Week 12	-	77	(95.1)	1	(1.2)	0		0		0		0		0		78	(96.3)
			±	1	(1.2)	0		0		0		0		0		0		1	(1.2)
			+	1	(1.2)	0		0		0		0		0		0		1	(1.2)
			2+	1	(1.2)	0		0		0		0		0		0		1	(1.2)
			3+	0		0		0		0		0		0		0		0	
			4+	0		0		0		0		0		0		0		0	

Paramaters	Treatment group	Timepoint	Baseline[a]	-		±		+		2+		3+		4+		5+		Total	
				n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]
			5+	0		0		0		0		0		0		0		0	
			Total	80	(98.8)	1	(1.2)	0		0		0		0		0		81	(100.0)
	SI-613 30 mg	Week 12	-	73	(86.9)	1	(1.2)	1	(1.2)	0		0		0		0		75	(89.3)
			±	3	(3.6)	0		1	(1.2)	0		0		0		0		4	(4.8)
			+	0		1	(1.2)	0		0		0		0		0		1	(1.2)
			2+	2	(2.4)	0		1	(1.2)	0		1	(1.2)	0		0		4	(4.8)
			3+	0		0		0		0		0		0		0		0	
			4+	0		0		0		0		0		0		0		0	
			5+	0		0		0		0		0		0		0		0	
			Total	78	(92.9)	2	(2.4)	3	(3.6)	0		1	(1.2)	0		0		84	(100.0)
	Placebo	Week 24	-	77	(95.1)	0		0		0		0		0		0		77	(95.1)
			±	1	(1.2)	1	(1.2)	0		0		0		0		0		2	(2.5)
			+	2	(2.5)	0		0		0		0		0		0		2	(2.5)
			2+	0		0		0		0		0		0		0		0	
			3+	0		0		0		0		0		0		0		0	
			4+	0		0		0		0		0		0		0		0	
			5+	0		0		0		0		0		0		0		0	
			Total	80	(98.8)	1	(1.2)	0		0		0		0		0		81	(100.0)
	SI-613 30 mg	Week 24	-	71	(86.6)	1	(1.2)	1	(1.2)	0		0		0		0		73	(89.0)
			±	3	(3.7)	0		0		0		0		0		0		3	(3.7)
			+	2	(2.4)	1	(1.2)	1	(1.2)	0		0		0		0		4	(4.9)
			2+	0		0		1	(1.2)	0		1	(1.2)	0		0		2	(2.4)
			3+	0		0		0		0		0		0		0		0	
			4+	0		0		0		0		0		0		0		0	
			5+	0		0		0		0		0		0		0		0	
			Total	76	(92.7)	2	(2.4)	3	(3.7)	0		1	(1.2)	0		0		82	(100.0)
Glucose	Placebo	Week 2	-	74	(87.1)	0		1	(1.2)	0		0		0		0		75	(88.2)
			±	0		0		0		0		0		0		0		0	
			+	1	(1.2)	0		1	(1.2)	0		0		0		0		2	(2.4)
			2+	1	(1.2)	0		1	(1.2)	0		0		0		1	(1.2)	3	(3.5)
			3+	1	(1.2)	0		0		0		1	(1.2)	0		0		2	(2.4)
			4+	0		0		0		0		0		0		1	(1.2)	1	(1.2)
			5+	0		0		0		0		0		1	(1.2)	1	(1.2)	2	(2.4)
			Total	77	(90.6)	0		3	(3.5)	0		1	(1.2)	1	(1.2)	3	(3.5)	85	(100.0)
	SI-613 30 mg	Week 2	-	80	(93.0)	0		0		0		0		0		0		80	(93.0)
			±	0		0		0		0		0		0		0		0	
			+	0		0		0		0		0		0		0		0	
			2+	2	(2.3)	0		0		0		0		0		0		2	(2.3)
			3+	0		0		0		0		0		0		0		0	
			4+	1	(1.2)	0		0		0		0		1	(1.2)	0		2	(2.3)
			5+	0		0		0		0		0		0		2	(2.3)	2	(2.3)
			Total	83	(96.5)	0		0		0		0		1	(1.2)	2	(2.3)	86	(100.0)
	Placebo	Week 4	-	75	(90.4)	0		1	(1.2)	0		1	(1.2)	0		0		77	(92.8)
			±	0		0		0		0		0		0		0		0	
			+	0		0		1	(1.2)	0		0		0		1	(1.2)	2	(2.4)
			2+	0		0		0		0		0		0		1	(1.2)	1	(1.2)
			3+	0		0		1	(1.2)	0		0		1	(1.2)	0		2	(2.4)
			4+	0		0		0		0		0		0		1	(1.2)	1	(1.2)
			5+	0		0		0		0		0		0		0		0	
			Total	75	(90.4)	0		3	(3.6)	0		1	(1.2)	1	(1.2)	3	(3.6)	83	(100.0)
	SI-613 30 mg	Week 4	-	77	(89.5)	0		0		0		0		0		0		77	(89.5)
			±	0		0		0		0		0		0		0		0	
			+	1	(1.2)	0		0		0		0		0		0		1	(1.2)
			2+	4	(4.7)	0		0		0		0		0		0		4	(4.7)
			3+	1	(1.2)	0		0		0		0		1	(1.2)	0		2	(2.3)

Paramaters	Treatment group	Timepoint	Baseline[a]	-		±		+		2+		3+		4+		5+		Total	
				n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]
			4+	0		0		0		0		0		0		1	(1.2)	1	(1.2)
			5+	0		0		0		0		0		0		1	(1.2)	1	(1.2)
			Total	83	(96.5)	0		0		0		0		1	(1.2)	2	(2.3)	86	(100.0)
	Placebo	Week 8	-	74	(89.2)	0		2	(2.4)	0		1	(1.2)	0		1	(1.2)	78	(94.0)
			±	0		0		0		0		0		0		0		0	
			+	0		0		0		0		0		0		0		0	
			2+	1	(1.2)	0		1	(1.2)	0		0		0		1	(1.2)	3	(3.6)
			3+	0		0		0		0		0		0		0		0	
			4+	0		0		0		0		0		0		0		0	
			5+	0		0		0		0		0		1	(1.2)	1	(1.2)	2	(2.4)
			Total	75	(90.4)	0		3	(3.6)	0		1	(1.2)	1	(1.2)	3	(3.6)	83	(100.0)
	SI-613 30 mg	Week 8	-	80	(94.1)	0		0		0		0		0		0		80	(94.1)
			±	0		0		0		0		0		0		0		0	
			+	0		0		0		0		0		0		0		0	
			2+	2	(2.4)	0		0		0		0		0		1	(1.2)	3	(3.5)
			3+	0		0		0		0		0		0		0		0	
			4+	0		0		0		0		0		1	(1.2)	0		1	(1.2)
			5+	0		0		0		0		0		0		1	(1.2)	1	(1.2)
			Total	82	(96.5)	0		0		0		0		1	(1.2)	2	(2.4)	85	(100.0)
	Placebo	Week 12	-	72	(88.9)	0		2	(2.5)	0		1	(1.2)	0		1	(1.2)	76	(93.8)
			±	0		0		0		0		0		0		0		0	
			+	0		0		0		0		0		0		1	(1.2)	1	(1.2)
			2+	0		0		0		0		0		0		1	(1.2)	1	(1.2)
			3+	0		0		0		0		0		1	(1.2)	0		1	(1.2)
			4+	1	(1.2)	0		1	(1.2)	0		0		0		0		2	(2.5)
			5+	0		0		0		0		0		0		0		0	
			Total	73	(90.1)	0		3	(3.7)	0		1	(1.2)	1	(1.2)	3	(3.7)	81	(100.0)
	SI-613 30 mg	Week 12	-	78	(92.9)	0		0		0		0		0		0		78	(92.9)
			±	0		0		0		0		0		0		0		0	
			+	2	(2.4)	0		0		0		0		0		1	(1.2)	3	(3.6)
			2+	1	(1.2)	0		0		0		0		0		0		1	(1.2)
			3+	0		0		0		0		0		0		0		0	
			4+	0		0		0		0		0		1	(1.2)	0		1	(1.2)
			5+	0		0		0		0		0		0		1	(1.2)	1	(1.2)
			Total	81	(96.4)	0		0		0		0		1	(1.2)	2	(2.4)	84	(100.0)
	Placebo	Week 24	-	72	(88.9)	0		3	(3.7)	0		1	(1.2)	0		0		76	(93.8)
			±	0		0		0		0		0		0		0		0	
			+	0		0		0		0		0		0		0		0	
			2+	0		0		0		0		0		0		2	(2.5)	2	(2.5)
			3+	0		0		0		0		0		1	(1.2)	0		1	(1.2)
			4+	0		0		0		0		0		0		0		0	
			5+	1	(1.2)	0		0		0		0		0		1	(1.2)	2	(2.5)
			Total	73	(90.1)	0		3	(3.7)	0		1	(1.2)	1	(1.2)	3	(3.7)	81	(100.0)
	SI-613 30 mg	Week 24	-	75	(91.5)	0		0		0		0		0		1	(1.2)	76	(92.7)
			±	0		0		0		0		0		0		0		0	
			+	2	(2.4)	0		0		0		0		0		0		2	(2.4)
			2+	1	(1.2)	0		0		0		0		0		0		1	(1.2)
			3+	1	(1.2)	0		0		0		0		0		0		1	(1.2)
			4+	0		0		0		0		0		0		0		0	
			5+	0		0		0		0		0		1	(1.2)	1	(1.2)	2	(2.4)
			Total	79	(96.3)	0		0		0		0		1	(1.2)	2	(2.4)	82	(100.0)
Urobilinogen	Placebo	Week 2	-	0		0		0		0		0		0		0		0	
			±	0		85	(100.0)	0		0		0		0		0		85	(100.0)
			+	0		0		0		0		0		0		0		0	
			2+	0		0		0		0		0		0		0		0	

Paramaters	Treatment group	Timepoint	Baseline[a]	-		±		+		2+		3+		4+		5+		Total	
				n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]
			3+	0		0		0		0		0		0		0		0	
			4+	0		0		0		0		0		0		0		0	
			5+	0		0		0		0		0		0		0		0	
			Total	0		85	(100.0)	0		0		0		0		0		85	(100.0)
	SI-613 30 mg	Week 2	-	0		0		0		0		0		0		0		0	
			±	0		86	(100.0)	0		0		0		0		0		86	(100.0)
			+	0		0		0		0		0		0		0		0	
			2+	0		0		0		0		0		0		0		0	
			3+	0		0		0		0		0		0		0		0	
			4+	0		0		0		0		0		0		0		0	
			5+	0		0		0		0		0		0		0		0	
			Total	0		86	(100.0)	0		0		0		0		0		86	(100.0)
	Placebo	Week 4	-	0		0		0		0		0		0		0		0	
			±	0		83	(100.0)	0		0		0		0		0		83	(100.0)
			+	0		0		0		0		0		0		0		0	
			2+	0		0		0		0		0		0		0		0	
			3+	0		0		0		0		0		0		0		0	
			4+	0		0		0		0		0		0		0		0	
			5+	0		0		0		0		0		0		0		0	
			Total	0		83	(100.0)	0		0		0		0		0		83	(100.0)
	SI-613 30 mg	Week 4	-	0		0		0		0		0		0		0		0	
			±	0		86	(100.0)	0		0		0		0		0		86	(100.0)
			+	0		0		0		0		0		0		0		0	
			2+	0		0		0		0		0		0		0		0	
			3+	0		0		0		0		0		0		0		0	
			4+	0		0		0		0		0		0		0		0	
			5+	0		0		0		0		0		0		0		0	
			Total	0		86	(100.0)	0		0		0		0		0		86	(100.0)
	Placebo	Week 8	-	0		0		0		0		0		0		0		0	
			±	0		83	(100.0)	0		0		0		0		0		83	(100.0)
			+	0		0		0		0		0		0		0		0	
			2+	0		0		0		0		0		0		0		0	
			3+	0		0		0		0		0		0		0		0	
			4+	0		0		0		0		0		0		0		0	
			5+	0		0		0		0		0		0		0		0	
			Total	0		83	(100.0)	0		0		0		0		0		83	(100.0)
	SI-613 30 mg	Week 8	-	0		0		0		0		0		0		0		0	
			±	0		85	(100.0)	0		0		0		0		0		85	(100.0)
			+	0		0		0		0		0		0		0		0	
			2+	0		0		0		0		0		0		0		0	
			3+	0		0		0		0		0		0		0		0	
			4+	0		0		0		0		0		0		0		0	
			5+	0		0		0		0		0		0		0		0	
			Total	0		85	(100.0)	0		0		0		0		0		85	(100.0)
	Placebo	Week 12	-	0		0		0		0		0		0		0		0	
			±	0		81	(100.0)	0		0		0		0		0		81	(100.0)
			+	0		0		0		0		0		0		0		0	
			2+	0		0		0		0		0		0		0		0	
			3+	0		0		0		0		0		0		0		0	
			4+	0		0		0		0		0		0		0		0	
			5+	0		0		0		0		0		0		0		0	
			Total	0		81	(100.0)	0		0		0		0		0		81	(100.0)
	SI-613 30 mg	Week 12	-	0		0		0		0		0		0		0		0	
			±	0		84	(100.0)	0		0		0		0		0		84	(100.0)
			+	0		0		0		0		0		0		0		0	

Paramaters	Treatment group	Timepoint	Baseline[a]	-		±		+		2+		3+		4+		5+		Total	
				n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]
			2+	0		0		0		0		0		0		0		0	
			3+	0		0		0		0		0		0		0		0	
			4+	0		0		0		0		0		0		0		0	
			5+	0		0		0		0		0		0		0		0	
			Total	0		84	(100.0)	0		0		0		0		0		84	(100.0)
	Placebo	Week 24	-	0		0		0		0		0		0		0		0	
			±	0		81	(100.0)	0		0		0		0		0		81	(100.0)
			+	0		0		0		0		0		0		0		0	
			2+	0		0		0		0		0		0		0		0	
			3+	0		0		0		0		0		0		0		0	
			4+	0		0		0		0		0		0		0		0	
			5+	0		0		0		0		0		0		0		0	
			Total	0		81	(100.0)	0		0		0		0		0		81	(100.0)
	SI-613 30 mg	Week 24	-	0		0		0		0		0		0		0		0	
			±	0		82	(100.0)	0		0		0		0		0		82	(100.0)
			+	0		0		0		0		0		0		0		0	
			2+	0		0		0		0		0		0		0		0	
			3+	0		0		0		0		0		0		0		0	
			4+	0		0		0		0		0		0		0		0	
			5+	0		0		0		0		0		0		0		0	
			Total	0		82	(100.0)	0		0		0		0		0		82	(100.0)

a:Baseline is value of screening.
b:Percentages are based on the number of subjects with non-missing values at both baseline and each timepoint.
〔5.3.5.1-2 Table 14.3.4-3 改編〕

表 2.7.4.7-75. 臨床検査値の各項目のシフトテーブル（定量試験）：613/1031 試験

			Placebo N=220								SI-613 30 mg N=220							
Paramaters	Timepoint	Baseline[a]	Low		Normal		High		Total		Low		Normal		High		Total	
			n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]
Leukocytes	Week 2	Low	1	(0.5)	2	(0.9)	0		3	(1.4)	1	(0.5)	3	(1.4)	0		4	(1.8)
		Normal	2	(0.9)	199	(92.6)	7	(3.3)	208	(96.7)	2	(0.9)	193	(88.5)	9	(4.1)	204	(93.6)
		High	0		3	(1.4)	1	(0.5)	4	(1.9)	0		6	(2.8)	4	(1.8)	10	(4.6)
		Total	3	(1.4)	204	(94.9)	8	(3.7)	215	(100.0)	3	(1.4)	202	(92.7)	13	(6.0)	218	(100.0)
	Week 12	Low	1	(0.5)	0		0		1	(0.5)	1	(0.5)	1	(0.5)	0		2	(0.9)
		Normal	2	(0.9)	195	(91.5)	6	(2.8)	203	(95.3)	2	(0.9)	190	(90.0)	9	(4.3)	201	(95.3)
		High	0		7	(3.3)	2	(0.9)	9	(4.2)	0		4	(1.9)	4	(1.9)	8	(3.8)
		Total	3	(1.4)	202	(94.8)	8	(3.8)	213	(100.0)	3	(1.4)	195	(92.4)	13	(6.2)	211	(100.0)
	Week 24	Low	2	(1.0)	1	(0.5)	0		3	(1.4)	1	(0.5)	4	(1.9)	0		5	(2.4)
		Normal	1	(0.5)	197	(94.3)	6	(2.9)	204	(97.6)	2	(1.0)	178	(86.4)	9	(4.4)	189	(91.7)
		High	0		0		2	(1.0)	2	(1.0)	0		8	(3.9)	4	(1.9)	12	(5.8)
		Total	3	(1.4)	198	(94.7)	8	(3.8)	209	(100.0)	3	(1.5)	190	(92.2)	13	(6.3)	206	(100.0)
Neutrophils /Leukocytes	Week 2	Low	4	(1.9)	4	(1.9)	0		8	(3.7)	1	(0.5)	4	(1.8)	0		5	(2.3)
		Normal	2	(0.9)	202	(94.0)	2	(0.9)	206	(95.8)	0		208	(95.4)	3	(1.4)	211	(96.8)
		High	0		1	(0.5)	0		1	(0.5)	0		2	(0.9)	0		2	(0.9)
		Total	6	(2.8)	207	(96.3)	2	(0.9)	215	(100.0)	1	(0.5)	214	(98.2)	3	(1.4)	218	(100.0)
	Week 12	Low	4	(1.9)	3	(1.4)	0		7	(3.3)	1	(0.5)	0		0		1	(0.5)
		Normal	2	(0.9)	200	(93.9)	2	(0.9)	204	(95.8)	0		205	(97.2)	3	(1.4)	208	(98.6)
		High	0		2	(0.9)	0		2	(0.9)	0		2	(0.9)	0		2	(0.9)
		Total	6	(2.8)	205	(96.2)	2	(0.9)	213	(100.0)	1	(0.5)	207	(98.1)	3	(1.4)	211	(100.0)
	Week 24	Low	3	(1.4)	1	(0.5)	0		4	(1.9)	1	(0.5)	3	(1.5)	1	(0.5)	5	(2.4)
		Normal	3	(1.4)	197	(94.3)	2	(1.0)	202	(96.7)	0		194	(94.2)	2	(1.0)	196	(95.1)
		High	0		3	(1.4)	0		3	(1.4)	0		5	(2.4)	0		5	(2.4)
		Total	6	(2.9)	201	(96.2)	2	(1.0)	209	(100.0)	1	(0.5)	202	(98.1)	3	(1.5)	206	(100.0)

Paramaters	Timepoint	Baseline[a]	Placebo N=220								SI-613 30 mg N=220							
			Low		Normal		High		Total		Low		Normal		High		Total	
			n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]
Lymphocytes /Leukocytes	Week 2	Low	1	(0.5)	5	(2.3)	0		6	(2.8)	2	(0.9)	3	(1.4)	0		5	(2.3)
		Normal	3	(1.4)	200	(93.0)	3	(1.4)	206	(95.8)	6	(2.8)	203	(93.1)	0		209	(95.9)
		High	0		1	(0.5)	2	(0.9)	3	(1.4)	0		3	(1.4)	1	(0.5)	4	(1.8)
		Total	4	(1.9)	206	(95.8)	5	(2.3)	215	(100.0)	8	(3.7)	209	(95.9)	1	(0.5)	218	(100.0)
	Week 12	Low	1	(0.5)	5	(2.3)	0		6	(2.8)	3	(1.4)	2	(0.9)	0		5	(2.4)
		Normal	3	(1.4)	197	(92.5)	2	(0.9)	202	(94.8)	5	(2.4)	200	(94.8)	0		205	(97.2)
		High	0		2	(0.9)	3	(1.4)	5	(2.3)	0		0		1	(0.5)	1	(0.5)
		Total	4	(1.9)	204	(95.8)	5	(2.3)	213	(100.0)	8	(3.8)	202	(95.7)	1	(0.5)	211	(100.0)
	Week 24	Low	1	(0.5)	4	(1.9)	0		5	(2.4)	3	(1.5)	3	(1.5)	0		6	(2.9)
		Normal	3	(1.4)	194	(92.8)	4	(1.9)	201	(96.2)	5	(2.4)	193	(93.7)	0		198	(96.1)
		High	0		2	(1.0)	1	(0.5)	3	(1.4)	0		1	(0.5)	1	(0.5)	2	(1.0)
		Total	4	(1.9)	200	(95.7)	5	(2.4)	209	(100.0)	8	(3.9)	197	(95.6)	1	(0.5)	206	(100.0)
Monocytes /Leukocytes	Week 2	Low	0		1	(0.5)	0		1	(0.5)	0		0		0		0	
		Normal	0		198	(92.1)	6	(2.8)	204	(94.9)	0		204	(93.6)	11	(5.0)	215	(98.6)
		High	0		5	(2.3)	5	(2.3)	10	(4.7)	0		2	(0.9)	1	(0.5)	3	(1.4)
		Total	0		204	94.9	11	(5.1)	215	(100.0)	0		206	(94.5)	12	(5.5)	218	(100.0)
	Week 12	Low	0		0		0		0		0		0		0		0	
		Normal	0		197	(92.5)	5	(2.3)	202	(94.8)	0		196	(92.9)	7	(3.3)	203	(96.2)
		High	0		5	(2.3)	6	(2.8)	11	(5.2)	0		3	(1.4)	5	(2.4)	8	(3.8)
		Total	0		202	94.8	11	(5.2)	213	(100.0)	0		199	(94.3)	12	(5.7)	211	(100.0)
	Week 24	Low	0		0		0		0		0		0		0		0	
		Normal	0		190	(90.9)	6	(2.9)	196	(93.8)	0		189	(91.7)	7	(3.4)	196	(95.1)
		High	0		8	(3.8)	5	(2.4)	13	(6.2)	0		6	(2.9)	4	(1.9)	10	(4.9)
		Total	0		198	(94.7)	11	(5.3)	209	(100.0)	0		195	(94.7)	11	(5.3)	206	(100.0)
Eosinophils /Leukocytes	Week 2	Low	0		0		0		0		0		0		0		0	
		Normal	0		208	(96.7)	1	(0.5)	209	(97.2)	0		209	(95.9)	4	(1.8)	213	(97.7)
		High	0		3	(1.4)	3	(1.4)	6	(2.8)	0		3	(1.4)	2	(0.9)	5	(2.3)
		Total	0		211	(98.1)	4	(1.9)	215	(100.0)	0		212	(97.2)	6	(2.8)	218	(100.0)
	Week 12	Low	0		0		0		0		0		0		0		0	
		Normal	0		205	(96.2)	1	(0.5)	206	(96.7)	0		199	(94.3)	4	(1.9)	203	(96.2)
		High	0		4	(1.9)	3	(1.4)	7	(3.3)	0		6	(2.8)	2	(0.9)	8	(3.8)
		Total	0		209	(98.1)	4	(1.9)	213	(100.0)	0		205	(97.2)	6	(2.8)	211	(100.0)
	Week 24	Low	0		0		0		0		0		0		0		0	
		Normal	0		203	(97.1)	3	(1.4)	206	(98.6)	0		198	(96.1)	2	(1.0)	200	(97.1)
		High	0		2	(1.0)	1	(0.5)	3	(1.4)	0		2	(1.0)	4	(1.9)	6	(2.9)
		Total	0		205	(98.1)	4	(1.9)	209	(100.0)	0		200	(97.1)	6	(2.9)	206	(100.0)
Basophils /Leukocytes	Week 2	Low	0		0		0		0		0		0		0		0	
		Normal	0		215	(100.0)	0		215	(100.0)	0		218	(100.0)	0		218	(100.0)
		High	0		0		0		0		0		0		0		0	
		Total	0		215	(100.0)	0		215	(100.0)	0		218	(100.0)	0		218	(100.0)
	Week 12	Low	0		0		0		0		0		0		0		0	
		Normal	0		213	(100.0)	0		213	(100.0)	0		211	(100.0)	0		211	(100.0)
		High	0		0		0		0		0		0		0		0	
		Total	0		213	(100.0)	0		213	(100.0)	0		211	(100.0)	0		211	(100.0)
	Week 24	Low	0		0		0		0		0		0		0		0	
		Normal	0		208	(99.5)	0		208	(99.5)	0		205	(99.5)	0		205	(99.5)
		High	0		1	(0.5)	0		1	(0.5)	0		1	(0.5)	0		1	(0.5)
		Total	0		209	(100.0)	0		209	(100.0)	0		206	(100.0)	0		206	(100.0)
Erythrocytes	Week 2	Low	14	(6.5)	6	(2.8)	0		20	(9.3)	21	(9.6)	7	(3.2)	0		28	(12.8)
		Normal	5	(2.3)	185	(86.0)	2	(0.9)	192	(89.3)	4	(1.8)	179	(82.1)	2	(0.9)	185	(84.9)
		High	0		0		3	(1.4)	3	(1.4)	0		1	(0.5)	4	(1.8)	5	(2.3)
		Total	19	(8.8)	191	(88.8)	5	(2.3)	215	(100.0)	25	(11.5)	187	(85.8)	6	(2.8)	218	(100.0)
	Week 12	Low	13	(6.1)	14	(6.6)	0		27	(12.7)	18	(8.5)	14	(6.6)	0		32	(15.2)

Paramaters	Timepoint	Baseline[a]	Placebo N=220								SI-613 30 mg N=220							
			Low		Normal		High		Total		Low		Normal		High		Total	
			n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]
		Normal	6	(2.8)	171	(80.3)	3	(1.4)	180	(84.5)	5	(2.4)	166	(78.7)	5	(2.4)	176	(83.4)
		High	0		4	(1.9)	2	(0.9)	6	(2.8)	0		2	(0.9)	1	(0.5)	3	(1.4)
		Total	19	(8.9)	189	(88.7)	5	(2.3)	213	(100.0)	23	(10.9)	182	(86.3)	6	(2.8)	211	(100.0)
	Week 24	Low	17	(8.1)	6	(2.9)	0		23	(11.0)	14	(6.8)	7	(3.4)	0		21	(10.2)
		Normal	2	(1.0)	178	(85.2)	3	(1.4)	183	(87.6)	7	(3.4)	169	(82.0)	4	(1.9)	180	(87.4)
		High	0		1	(0.5)	2	(1.0)	3	(1.4)	0		3	(1.5)	2	(1.0)	5	(2.4)
		Total	19	(9.1)	185	(88.5)	5	(2.4)	209	(100.0)	21	(10.2)	179	(86.9)	6	(2.9)	206	(100.0)
Hemoglobin	Week 2	Low	12	(5.6)	6	(2.8)	0		18	(8.4)	18	(8.3)	7	(3.2)	0		25	(11.5)
		Normal	5	(2.3)	185	(86.0)	3	(1.4)	193	(89.8)	1	(0.5)	188	(86.2)	2	(0.9)	191	(87.6)
		High	0		3	(1.4)	1	(0.5)	4	(1.9)	0		0		2	(0.9)	2	(0.9)
		Total	17	(7.9)	194	(90.2)	4	(1.9)	215	(100.0)	19	(8.7)	195	(89.4)	4	(1.8)	218	(100.0)
	Week 12	Low	10	(4.7)	5	(2.3)	0		15	(7.0)	11	(5.2)	8	(3.8)	0		19	(9.0)
		Normal	7	(3.3)	185	(86.9)	3	(1.4)	195	(91.5)	7	(3.3)	181	(85.8)	2	(0.9)	190	(90.0)
		High	0		2	(0.9)	1	(0.5)	3	(1.4)	0		0		2	(0.9)	2	(0.9)
		Total	17	(8.0)	192	(90.1)	4	(1.9)	213	(100.0)	18	(8.5)	189	(89.6)	4	(1.9)	211	(100.0)
	Week 24	Low	11	(5.3)	5	(2.4)	0		16	(7.7)	9	(4.4)	3	(1.5)	0		12	(5.8)
		Normal	6	(2.9)	180	(86.1)	3	(1.4)	189	(90.4)	8	(3.9)	181	(87.9)	2	(1.0)	191	(92.7)
		High	0		3	(1.4)	1	(0.5)	4	(1.9)	0		1	(0.5)	2	(1.0)	3	(1.5)
		Total	17	(8.1)	188	(90.0)	4	(1.9)	209	(100.0)	17	(8.3)	185	(89.8)	4	(1.9)	206	(100.0)
Hematocrit	Week 2	Low	12	(5.6)	7	(3.3)	0		19	(8.8)	21	(9.6)	5	(2.3)	0		26	(11.9)
		Normal	4	(1.9)	188	(87.4)	0		192	(89.3)	4	(1.8)	184	(84.4)	2	(0.9)	190	(87.2)
		High	0		2	(0.9)	2	(0.9)	4	(1.9)	0		0		2	(0.9)	2	(0.9)
		Total	16	(7.4)	197	(91.6)	2	(0.9)	215	(100.0)	25	(11.5)	189	(86.7)	4	(1.8)	218	(100.0)
	Week 12	Low	8	(3.8)	13	(6.1)	0		21	(9.9)	13	(6.2)	11	(5.2)	0		24	(11.4)
		Normal	8	(3.8)	180	(84.5)	1	(0.5)	189	(88.7)	11	(5.2)	172	(81.5)	3	(1.4)	186	(88.2)
		High	0		2	(0.9)	1	(0.5)	3	(1.4)	0		0		1	(0.5)	1	(0.5)
		Total	16	(7.5)	195	(91.5)	2	(0.9)	213	(100.0)	24	(11.4)	183	(86.7)	4	(1.9)	211	(100.0)
	Week 24	Low	12	(5.7)	6	(2.9)	0		18	(8.6)	10	(4.9)	2	(1.0)	0		12	(5.8)
		Normal	4	(1.9)	183	(87.6)	1	(0.5)	188	(90.0)	12	(5.8)	178	(86.4)	3	(1.5)	193	(93.7)
		High	0		2	(1.0)	1	(0.5)	3	(1.4)	0		0		1	(0.5)	1	(0.5)
		Total	16	(7.7)	191	(91.4)	2	(1.0)	209	(100.0)	22	(10.7)	180	(87.4)	4	(1.9)	206	(100.0)
Platelets	Week 2	Low	1	(0.5)	0		0		1	(0.5)	0		1	(0.5)	0		1	(0.5)
		Normal	1	(0.5)	204	(94.9)	1	(0.5)	206	(95.8)	1	(0.5)	204	(93.6)	2	(0.9)	207	(95.0)
		High	0		3	(1.4)	5	(2.3)	8	(3.7)	0		3	(1.4)	7	(3.2)	10	(4.6)
		Total	2	(0.9)	207	(96.3)	6	(2.8)	215	(100.0)	1	(0.5)	208	(95.4)	9	(4.1)	218	(100.0)
	Week 12	Low	1	(0.5)	3	(1.4)	0		4	(1.9)	1	(0.5)	1	(0.5)	0		2	(0.9)
		Normal	1	(0.5)	197	(92.5)	3	(1.4)	201	(94.4)	0		196	(92.9)	1	(0.5)	197	(93.4)
		High	0		5	(2.3)	3	(1.4)	8	(3.8)	0		4	(1.9)	8	(3.8)	12	(5.7)
		Total	2	(0.9)	205	(96.2)	6	(2.8)	213	(100.0)	1	(0.5)	201	(95.3)	9	(4.3)	211	(100.0)
	Week 24	Low	1	(0.5)	0		0		1	(0.5)	0		0		0		0	
		Normal	1	(0.5)	196	(94.2)	2	(1.0)	199	(95.7)	1	(0.5)	194	(94.2)	3	(1.5)	198	(96.1)
		High	0		4	(1.9)	4	(1.9)	8	(3.8)	0		2	(1.0)	6	(2.9)	8	(3.9)
		Total	2	(1.0)	200	(96.2)	6	(2.9)	208	(100.0)	1	(0.5)	196	(95.1)	9	(4.4)	206	(100.0)
Protein	Week 2	Low	18	(8.4)	15	(7.0)	0		33	(15.3)	9	(4.1)	20	(9.2)	0		29	(13.3)
		Normal	8	(3.7)	174	(80.9)	0		182	(84.7)	8	(3.7)	180	(82.6)	1	(0.5)	189	(86.7)
		High	0		0		0		0		0		0		0		0	
		Total	26	(12.1)	189	(87.9)	0		215	(100.0)	17	(7.8)	200	(91.7)	1	(0.5)	218	(100.0)
	Week 12	Low	14	(6.6)	14	(6.6)	0		28	(13.1)	7	(3.3)	12	(5.7)	0		19	(9.0)
		Normal	12	(5.6)	173	(81.2)	0		185	(86.9)	9	(4.3)	183	(86.7)	0		192	(91.0)
		High	0		0		0		0		0		0		0		0	
		Total	26	(12.2)	187	(87.8)	0		213	(100.0)	16	(7.6)	195	(92.4)	0		211	(100.0)
	Week 24	Low	15	(7.2)	13	(6.2)	0		28	(13.4)	5	(2.4)	16	(7.8)	0		21	(10.2)
		Normal	11	(5.3)	170	(81.3)	0		181	(86.6)	9	(4.4)	175	(85.0)	0		184	(89.3)

Paramaters	Timepoint	Baseline[a]	Placebo N=220								SI-613 30 mg N=220							
			Low		Normal		High		Total		Low		Normal		High		Total	
			n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]
		High	0		0		0		0		0		1	(0.5)	0		1	(0.5)
		Total	26	(12.4)	183	(87.6)	0		209	(100.0)	14	(6.8)	192	(93.2)	0		206	(100.0)
Albumin	Week 2	Low	0		0		0		0		0		1	(0.5)	0		1	(0.5)
		Normal	0		215	(100.0)	0		215	(100.0)	0		217	(99.5)	0		217	(99.5)
		High	0		0		0		0		0		0		0		0	
		Total	0		215	(100.0)	0		215	(100.0)	0		218	(100.0)	0		218	(100.0)
	Week 12	Low	0		2	(0.9)	0		2	(0.9)	0		0		0		0	
		Normal	0		211	(99.1)	0		211	(99.1)	0		211	(100.0)	0		211	(100.0)
		High	0		0		0		0		0		0		0		0	
		Total	0		213	(100.0)	0		213	(100.0)	0		211	(100.0)	0		211	(100.0)
	Week 24	Low	0		0		0		0		0		0		0		0	
		Normal	0		209	(100.0)	0		209	(100.0)	0		206	(100.0)	0		206	(100.0)
		High	0		0		0		0		0		0		0		0	
		Total	0		209	(100.0)	0		209	(100.0)	0		206	(100.0)	0		206	(100.0)
Bilirubin	Week 2	Low	0		0		0		0		0		0		0		0	
		Normal	0		207	(96.3)	1	(0.5)	208	(96.7)	0		205	(94.0)	5	(2.3)	210	(96.3)
		High	0		4	(1.9)	3	(1.4)	7	(3.3)	0		6	(2.8)	2	(0.9)	8	(3.7)
		Total	0		211	(98.1)	4	(1.9)	215	(100.0)	0		211	(96.8)	7	(3.2)	218	(100.0)
	Week 12	Low	0		0		0		0		0		0		0		0	
		Normal	0		206	(96.7)	2	(0.9)	208	(97.7)	0		199	(94.3)	4	(1.9)	203	(96.2)
		High	0		3	(1.4)	2	(0.9)	5	(2.3)	0		5	(2.4)	3	(1.4)	8	(3.8)
		Total	0		209	(98.1)	4	(1.9)	213	(100.0)	0		204	(96.7)	7	(3.3)	211	(100.0)
	Week 24	Low	0		0		0		0		0		0		0		0	
		Normal	0		201	(96.2)	3	(1.4)	204	(97.6)	0		190	(92.2)	7	(3.4)	197	(95.6)
		High	0		4	(1.9)	1	(0.5)	5	(2.4)	0		9	(4.4)	0		9	(4.4)
		Total	0		205	(98.1)	4	(1.9)	209	(100.0)	0		199	(96.6)	7	(3.4)	206	(100.0)
Direct Bilirubin	Week 2	Low	0		0		0		0		0		0		0		0	
		Normal	0		212	(98.6)	0		212	(98.6)	0		211	(96.8)	4	(1.8)	215	(98.6)
		High	0		1	(0.5)	2	(0.9)	3	(1.4)	0		3	(1.4)	0		3	(1.4)
		Total	0		213	(99.1)	2	(0.9)	215	(100.0)	0		214	(98.2)	4	(1.8)	218	(100.0)
	Week 12	Low	0		0		0		0		0		0		0		0	
		Normal	0		211	(99.1)	0		211	(99.1)	0		205	(97.2)	4	(1.9)	209	(99.1)
		High	0		0		2	(0.9)	2	(0.9)	0		2	(0.9)	0		2	(0.9)
		Total	0		211	(99.1)	2	(0.9)	213	(100.0)	0		207	(98.1)	4	(1.9)	211	(100.0)
	Week 24	Low	0		0		0		0		0		0		0		0	
		Normal	0		207	(99.0)	1	(0.5)	208	(99.5)	0		200	(97.1)	4	(1.9)	204	(99.0)
		High	0		0		1	(0.5)	1	(0.5)	0		2	(1.0)	0		2	(1.0)
		Total	0		207	(99.0)	2	(1.0)	209	(100.0)	0		202	(98.1)	4	(1.9)	206	(100.0)
Aspartate Aminotransferase	Week 2	Low	0		0		0		0		0		0		0		0	
		Normal	0		199	(92.6)	3	(1.4)	202	(94.0)	0		207	(95.0)	4	(1.8)	211	(96.8)
		High	0		4	(1.9)	9	(4.2)	13	(6.0)	0		4	(1.8)	3	(1.4)	7	(3.2)
		Total	0		203	(94.4)	12	(5.6)	215	(100.0)	0		211	(96.8)	7	(3.2)	218	(100.0)
	Week 12	Low	0		0		0		0		0		0		0		0	
		Normal	0		197	(92.5)	5	(2.3)	202	(94.8)	0		195	(92.4)	5	(2.4)	200	(94.8)
		High	0		4	(1.9)	7	(3.3)	11	(5.2)	0		9	(4.3)	2	(0.9)	11	(5.2)
		Total	0		201	(94.4)	12	(5.6)	213	(100.0)	0		204	(96.7)	7	(3.3)	211	(100.0)
	Week 24	Low	0		0		0		0		0		0		0		0	
		Normal	0		194	(92.8)	5	(2.4)	199	(95.2)	0		187	(90.8)	3	(1.5)	190	(92.2)
		High	0		4	(1.9)	6	(2.9)	10	(4.8)	0		12	(5.8)	4	(1.9)	16	(7.8)
		Total	0		198	(94.7)	11	(5.3)	209	(100.0)	0		199	(96.6)	7	(3.4)	206	(100.0)
Alanine Aminotransferase	Week 2	Low	0		0		0		0		2	(0.9)	0		0		2	(0.9)
		Normal	0		204	(94.9)	0		204	(94.9)	0		205	(94.0)	3	(1.4)	208	(95.4)
		High	0		5	(2.3)	6	(2.8)	11	(5.1)	0		2	(0.9)	6	(2.8)	8	(3.7)

Paramaters	Timepoint	Baseline[a]	Placebo N=220								SI-613 30 mg N=220							
			Low		Normal		High		Total		Low		Normal		High		Total	
			n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]
		Total	0		209	(97.2)	6	(2.8)	215	(100.0)	2	(0.9)	207	(95.0)	9	(4.1)	218	(100.0)
	Week 12	Low	0		0		0		0		2	(0.9)	0		0		2	(0.9)
		Normal	0		199	(93.4)	3	(1.4)	202	(94.8)	0		196	(92.9)	4	(1.9)	200	(94.8)
		High	0		8	(3.8)	3	(1.4)	11	(5.2)	0		4	(1.9)	5	(2.4)	9	(4.3)
		Total	0		207	(97.2)	6	(2.8)	213	(100.0)	2	(0.9)	200	(94.8)	9	(4.3)	211	(100.0)
	Week 24	Low	0		0		0		0		2	(1.0)	0		0		2	(1.0)
		Normal	0		196	(93.8)	3	(1.4)	199	(95.2)	0		186	(90.3)	4	(1.9)	190	(92.2)
		High	0		7	(3.3)	3	(1.4)	10	(4.8)	0		9	(4.4)	5	(2.4)	14	(6.8)
		Total	0		203	(97.1)	6	(2.9)	209	(100.0)	2	(1.0)	195	(94.7)	9	(4.4)	206	(100.0)
Lactate	Week 2	Low	0		0		0		0		1	(0.5)	1	(0.5)	0		2	(0.9)
Dehydrogenase		Normal	0		190	(88.4)	6	(2.8)	196	(91.2)	0		202	(92.7)	5	(2.3)	207	(95.0)
		High	0		7	(3.3)	12	(5.6)	19	(8.8)	0		6	(2.8)	3	(1.4)	9	(4.1)
		Total	0		197	(91.6)	18	(8.4)	215	(100.0)	1	(0.5)	209	(95.9)	8	(3.7)	218	(100.0)
	Week 12	Low	0		1	(0.5)	0		1	(0.5)	1	(0.5)	1	(0.5)	0		2	(0.9)
		Normal	0		191	(89.7)	9	(4.2)	200	(93.9)	0		196	(92.9)	3	(1.4)	199	(94.3)
		High	0		3	(1.4)	9	(4.2)	12	(5.6)	0		5	(2.4)	5	(2.4)	10	(4.7)
		Total	0		195	(91.5)	18	(8.5)	213	(100.0)	1	(0.5)	202	(95.7)	8	(3.8)	211	(100.0)
	Week 24	Low	0		1	(0.5)	0		1	(0.5)	1	(0.5)	1	(0.5)	0		2	(1.0)
		Normal	0		182	(87.1)	6	(2.9)	188	(90.0)	0		192	(93.2)	2	(1.0)	194	(94.2)
		High	0		8	(3.8)	12	(5.7)	20	(9.6)	0		4	(1.9)	6	(2.9)	10	(4.9)
		Total	0		191	(91.4)	18	(8.6)	209	(100.0)	1	(0.5)	197	(95.6)	8	(3.9)	206	(100.0)
	Week 2	Low	0		0		0		0		0		0		0		0	
Alkaline		Normal	0		177	(82.3)	9	(4.2)	186	(86.5)	0		189	(86.7)	4	(1.8)	193	(88.5)
Phosphatase		High	0		8	(3.7)	21	(9.8)	29	(13.5)	0		8	(3.7)	17	(7.8)	25	(11.5)
		Total	0		185	(86.0)	30	(14.0)	215	(100.0)	0		197	(90.4)	21	(9.6)	218	(100.0)
	Week 12	Low	0		0		0		0		0		0		0		0	
		Normal	0		176	(82.6)	8	(3.8)	184	(86.4)	0		181	(85.8)	9	(4.3)	190	(90.0)
		High	0		8	(3.8)	21	(9.9)	29	(13.6)	0		9	(4.3)	12	(5.7)	21	(10.0)
		Total	0		184	(86.4)	29	(13.6)	213	(100.0)	0		190	(90.0)	21	(10.0)	211	(100.0)
	Week 24	Low	0		0		0		0		0		0		0		0	
		Normal	0		172	(82.3)	6	(2.9)	178	(85.2)	0		175	(85.0)	8	(3.9)	183	(88.8)
		High	0		9	(4.3)	22	(10.5)	31	(14.8)	0		11	(5.3)	12	(5.8)	23	(11.2)
		Total	0		181	(86.6)	28	(13.4)	209	(100.0)	0		186	(90.3)	20	(9.7)	206	(100.0)
Gamma	Week 2	Low	-		-		-		-		-		-		-		-	
Glutamyl		Normal	-		162	(75.3)	6	(2.8)	168	(78.1)	-		163	(74.8)	8	(3.7)	171	(78.4)
Transferase		High	-		5	(2.3)	42	(19.5)	47	(21.9)	-		9	(4.1)	38	(17.4)	47	(21.6)
		Total	-		167	(77.7)	48	(22.3)	215	(100.0)	-		172	(78.9)	46	(21.1)	218	(100.0)
	Week 12	Low	-		-		-		-		-		-		-		-	
		Normal	-		155	(72.8)	8	(3.8)	163	(76.5)	-		153	(72.5)	6	(2.8)	159	(75.4)
		High	-		11	(5.2)	39	(18.3)	50	(23.5)	-		12	(5.7)	40	(19.0)	52	(24.6)
		Total	-		166	(77.9)	47	(22.1)	213	(100.0)	-		165	(78.2)	46	(21.8)	211	(100.0)
	Week 24	Low	-		-		-		-		-		-		-		-	
		Normal	-		152	(72.7)	8	(3.8)	160	(76.6)	-		145	(70.4)	6	(2.9)	151	(73.3)
		High	-		11	(5.3)	38	(18.2)	49	(23.4)	-		16	(7.8)	39	(18.9)	55	(26.7)
		Total	-		163	(78.0)	46	(22.0)	209	(100.0)	-		161	(78.2)	45	(21.8)	206	(100.0)
Urate	Week 2	Low	3	(1.4)	0		0		3	(1.4)	3	(1.4)	0		0		3	(1.4)
		Normal	2	(0.9)	187	(87.0)	6	(2.8)	195	(90.7)	1	(0.5)	183	(83.9)	7	(3.2)	191	(87.6)
		High	0		5	(2.3)	12	(5.6)	17	(7.9)	0		9	(4.1)	15	(6.9)	24	(11.0)
		Total	5	(2.3)	192	(89.3)	18	(8.4)	215	(100.0)	4	(1.8)	192	(88.1)	22	(10.1)	218	(100.0)
	Week 12	Low	1	(0.5)	0		0		1	(0.5)	2	(0.9)	0		0		2	(0.9)
		Normal	4	(1.9)	186	(87.3)	6	(2.8)	196	(92.0)	2	(0.9)	177	(83.9)	11	(5.2)	190	(90.0)
		High	0		4	(1.9)	12	(5.6)	16	(7.5)	0		8	(3.8)	11	(5.2)	19	(9.0)
		Total	5	(2.3)	190	(89.2)	18	(8.5)	213	(100.0)	4	(1.9)	185	(87.7)	22	(10.4)	211	(100.0)

Paramaters	Timepoint	Baseline[a]	Placebo N=220								SI-613 30 mg N=220							
			Low		Normal		High		Total		Low		Normal		High		Total	
			n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]
	Week 24	Low	2	(1.0)	0		0		2	(1.0)	3	(1.5)	0		0		3	(1.5)
		Normal	3	(1.4)	182	(87.1)	10	(4.8)	195	(93.3)	1	(0.5)	172	(83.5)	8	(3.9)	181	(87.9)
		High	0		4	(1.9)	8	(3.8)	12	(5.7)	0		9	(4.4)	13	(6.3)	22	(10.7)
		Total	5	(2.4)	186	(89.0)	18	(8.6)	209	(100.0)	4	(1.9)	181	(87.9)	21	(10.2)	206	(100.0)
Blood Urea Nitrogen	Week 2	Low	0		0		0		0		1	(0.5)	0		0		1	(0.5)
		Normal	1	(0.5)	205	(95.3)	4	(1.9)	210	(97.7)	0		204	(93.6)	3	(1.4)	207	(95.0)
		High	0		2	(0.9)	3	(1.4)	5	(2.3)	0		7	(3.2)	3	(1.4)	10	(4.6)
		Total	1	(0.5)	207	(96.3)	7	(3.3)	215	(100.0)	1	(0.5)	211	(96.8)	6	(2.8)	218	(100.0)
	Week 12	Low	1	(0.5)	0		0		1	(0.5)	0		1	(0.5)	0		1	(0.5)
		Normal	0		200	(93.9)	4	(1.9)	204	(95.8)	1	(0.5)	201	(95.3)	4	(1.9)	206	(97.6)
		High	0		5	(2.3)	3	(1.4)	8	(3.8)	0		2	(0.9)	2	(0.9)	4	(1.9)
		Total	1	(0.5)	205	(96.2)	7	(3.3)	213	(100.0)	1	(0.5)	204	(96.7)	6	(2.8)	211	(100.0)
	Week 24	Low	1	(0.5)	0		0		1	(0.5)	0		0		0		0	
		Normal	0		200	(95.7)	5	(2.4)	205	(98.1)	1	(0.5)	194	(94.2)	3	(1.5)	198	(96.1)
		High	0		1	(0.5)	2	(1.0)	3	(1.4)	0		5	(2.4)	3	(1.5)	8	(3.9)
		Total	1	(0.5)	201	(96.2)	7	(3.3)	209	(100.0)	1	(0.5)	199	(96.6)	6	(2.9)	206	(100.0)
Creatinine	Week 2	Low	12	(5.6)	4	(1.9)	0		16	(7.4)	5	(2.3)	5	(2.3)	0		10	(4.6)
		Normal	10	(4.7)	173	(80.5)	2	(0.9)	185	(86.0)	3	(1.4)	181	(83.0)	4	(1.8)	188	(86.2)
		High	0		6	(2.8)	8	(3.7)	14	(6.5)	0		6	(2.8)	14	(6.4)	20	(9.2)
		Total	22	(10.2)	183	(85.1)	10	(4.7)	215	(100.0)	8	(3.7)	192	(88.1)	18	(8.3)	218	(100.0)
	Week 12	Low	10	(4.7)	6	(2.8)	0		16	(7.5)	6	(2.8)	4	(1.9)	0		10	(4.7)
		Normal	12	(5.6)	169	(79.3)	5	(2.3)	186	(87.3)	2	(0.9)	178	(84.4)	5	(2.4)	185	(87.7)
		High	0		6	(2.8)	5	(2.3)	11	(5.2)	0		4	(1.9)	12	(5.7)	16	(7.6)
		Total	22	(10.3)	181	(85.0)	10	(4.7)	213	(100.0)	8	(3.8)	186	(88.2)	17	(8.1)	211	(100.0)
	Week 24	Low	12	(5.7)	8	(3.8)	0		20	(9.6)	2	(1.0)	4	(1.9)	0		6	(2.9)
		Normal	9	(4.3)	163	(78.0)	2	(1.0)	174	(83.3)	5	(2.4)	175	(85.0)	5	(2.4)	185	(89.8)
		High	0		8	(3.8)	7	(3.3)	15	(7.2)	0		3	(1.5)	12	(5.8)	15	(7.3)
		Total	21	(10.0)	179	(85.6)	9	(4.3)	209	(100.0)	7	(3.4)	182	(88.3)	17	(8.3)	206	(100.0)
Cholesterol	Week 2	Low	1	(0.5)	0		0		1	(0.5)	0		0		0		0	
		Normal	0		128	(59.5)	18	(8.4)	146	(67.9)	0		111	(50.9)	25	(11.5)	136	(62.4)
		High	0		12	(5.6)	56	(26.0)	68	(31.6)	0		9	(4.1)	73	(33.5)	82	(37.6)
		Total	1	(0.5)	140	(65.1)	74	(34.4)	215	(100.0)	0		120	(55.0)	98	(45.0)	218	(100.0)
	Week 12	Low	1	(0.5)	1	(0.5)	0		2	(0.9)	0		1	(0.5)	0		1	(0.5)
		Normal	0		122	(57.3)	18	(8.5)	140	(65.7)	0		94	(44.5)	29	(13.7)	123	(58.3)
		High	0		16	(7.5)	55	(25.8)	71	(33.3)	0		21	(10.0)	66	(31.3)	87	(41.2)
		Total	1	(0.5)	139	(65.3)	73	(34.3)	213	(100.0)	0		116	(55.0)	95	(45.0)	211	(100.0)
	Week 24	Low	1	(0.5)	1	(0.5)	0		2	(1.0)	0		1	(0.5)	0		1	(0.5)
		Normal	0		113	(54.1)	23	(11.0)	136	(65.1)	0		91	(44.2)	21	(10.2)	112	(54.4)
		High	0		22	(10.5)	49	(23.4)	71	(34.0)	0		20	(9.7)	73	(35.4)	93	(45.1)
		Total	1	(0.5)	136	(65.1)	72	(34.4)	209	(100.0)	0		112	(54.4)	94	(45.6)	206	(100.0)
Triglycerides	Week 2	Low	0		0		0		0		0		0		0		0	
		Normal	0		101	(47.0)	23	(10.7)	124	(57.7)	0		105	(48.2)	19	(8.7)	124	(56.9)
		High	0		32	(14.9)	59	(27.4)	91	(42.3)	0		31	(14.2)	63	(28.9)	94	(43.1)
		Total	0		133	(61.9)	82	(38.1)	215	(100.0)	0		136	(62.4)	82	(37.6)	218	(100.0)
	Week 12	Low	0		0		0		0		0		0		0		0	
		Normal	0		101	(47.4)	23	(10.8)	124	(58.2)	0		105	(49.8)	30	(14.2)	135	(64.0)
		High	0		32	(15.0)	57	(26.8)	89	(41.8)	0		26	(12.3)	50	(23.7)	76	(36.0)
		Total	0		133	(62.4)	80	(37.6)	213	(100.0)	0		131	(62.1)	80	(37.9)	211	(100.0)
	Week 24	Low	0		0		0		0		0		0		0		0	
		Normal	0		101	(48.3)	25	(12.0)	126	(60.3)	0		107	(51.9)	21	(10.2)	128	(62.1)
		High	0		30	(14.4)	53	(25.4)	83	(39.7)	0		19	(9.2)	59	(28.6)	78	(37.9)
		Total	0		131	(62.7)	78	(37.3)	209	(100.0)	0		126	(61.2)	80	(38.8)	206	(100.0)
	Week 2	Low	-		-		-		-		-		-		-		-	

Paramaters	Timepoint	Baseline[a]	Placebo N=220								SI-613 30 mg N=220							
			Low		Normal		High		Total		Low		Normal		High		Total	
			n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]
C Reactive Protein		Normal	-		199	(92.6)	7	(3.3)	206	(95.8)	-		199	(91.3)	9	(4.1)	208	(95.4)
		High	-		6	(2.8)	3	(1.4)	9	(4.2)	-		8	(3.7)	2	(0.9)	10	(4.6)
		Total	-		205	(95.3)	10	(4.7)	215	(100.0)	-		207	(95.0)	11	(5.0)	218	(100.0)
	Week 12	Low	-		-		-		-		-		-		-		-	
		Normal	-		199	(93.4)	8	(3.8)	207	(97.2)	-		196	(92.9)	8	(3.8)	204	(96.7)
		High	-		4	(1.9)	2	(0.9)	6	(2.8)	-		4	(1.9)	3	(1.4)	7	(3.3)
		Total	-		203	(95.3)	10	(4.7)	213	(100.0)	-		200	(94.8)	11	(5.2)	211	(100.0)
	Week 24	Low	-		-		-		-		-		-		-		-	
		Normal	-		193	(92.3)	9	(4.3)	202	(96.7)	-		188	(91.3)	7	(3.4)	195	(94.7)
		High	-		6	(2.9)	1	(0.5)	7	(3.3)	-		7	(3.4)	4	(1.9)	11	(5.3)
		Total	-		199	(95.2)	10	(4.8)	209	(100.0)	-		195	(94.7)	11	(5.3)	206	(100.0)
Sodium	Week 2	Low	0		1	(0.5)	0		1	(0.5)	0		0		0		0	
		Normal	1	(0.5)	213	(99.1)	0		214	(99.5)	2	(0.9)	214	(98.2)	1	(0.5)	217	(99.5)
		High	0		0		0		0		0		1	(0.5)	0		1	(0.5)
		Total	1	(0.5)	214	(99.5)	0		215	(100.0)	2	(0.9)	215	(98.6)	1	(0.5)	218	(100.0)
	Week 12	Low	1	(0.5)	1	(0.5)	0		2	(0.9)	0		0		0		0	
		Normal	0		210	(98.6)	0		210	(98.6)	2	(0.9)	208	(98.6)	1	(0.5)	211	(100.0)
		High	0		1	(0.5)	0		1	(0.5)	0		0		0		0	
		Total	1	(0.5)	212	(99.5)	0		213	(100.0)	2	(0.9)	208	(98.6)	1	(0.5)	211	(100.0)
	Week 24	Low	0		1	(0.5)	0		1	(0.5)	2	(1.0)	1	(0.5)	0		3	(1.5)
		Normal	1	(0.5)	207	(99.0)	0		208	(99.5)	0		201	(97.6)	1	(0.5)	202	(98.1)
		High	0		0		0		0		0		1	(0.5)	0		1	(0.5)
		Total	1	(0.5)	208	(99.5)	0		209	(100.0)	2	(1.0)	203	(98.5)	1	(0.5)	206	(100.0)
Potassium	Week 2	Low	0		6	(2.8)	0		6	(2.8)	2	(0.9)	0		0		2	(0.9)
		Normal	1	(0.5)	202	(94.0)	1	(0.5)	204	(94.9)	2	(0.9)	210	(96.3)	2	(0.9)	214	(98.2)
		High	0		5	(2.3)	0		5	(2.3)	0		1	(0.5)	1	(0.5)	2	(0.9)
		Total	1	(0.5)	213	(99.1)	1	(0.5)	215	(100.0)	4	(1.8)	211	(96.8)	3	(1.4)	218	(100.0)
	Week 12	Low	0		2	(0.9)	0		2	(0.9)	2	(0.9)	1	(0.5)	0		3	(1.4)
		Normal	1	(0.5)	205	(96.2)	1	(0.5)	207	(97.2)	2	(0.9)	202	(95.7)	2	(0.9)	206	(97.6)
		High	0		4	(1.9)	0		4	(1.9)	0		2	(0.9)	0		2	(0.9)
		Total	1	(0.5)	211	(99.1)	1	(0.5)	213	(100.0)	4	(1.9)	205	(97.2)	2	(0.9)	211	(100.0)
	Week 24	Low	0		3	(1.4)	0		3	(1.4)	1	(0.5)	0		0		1	(0.5)
		Normal	1	(0.5)	203	(97.1)	0		204	(97.6)	3	(1.5)	200	(97.1)	2	(1.0)	205	(99.5)
		High	0		1	(0.5)	1	(0.5)	2	(1.0)	0		0		0		0	
		Total	1	(0.5)	207	(99.0)	1	(0.5)	209	(100.0)	4	(1.9)	200	(97.1)	2	(1.0)	206	(100.0)
Chloride	Week 2	Low	0		0		0		0		0		1	(0.5)	0		1	(0.5)
		Normal	0		213	(99.1)	1	(0.5)	214	(99.5)	1	(0.5)	210	(96.3)	2	(0.9)	213	(97.7)
		High	0		0		1	(0.5)	1	(0.5)	0		4	(1.8)	0		4	(1.8)
		Total	0		213	(99.1)	2	(0.9)	215	(100.0)	1	(0.5)	215	(98.6)	2	(0.9)	218	(100.0)
	Week 12	Low	0		1	(0.5)	0		1	(0.5)	0		0		0		0	
		Normal	0		209	(98.1)	2	(0.9)	211	(99.1)	1	(0.5)	204	(96.7)	2	(0.9)	207	(98.1)
		High	0		1	(0.5)	0		1	(0.5)	0		4	(1.9)	0		4	(1.9)
		Total	0		211	(99.1)	2	(0.9)	213	(100.0)	1	(0.5)	208	(98.6)	2	(0.9)	211	(100.0)
	Week 24	Low	0		0		0		0		1	(0.5)	1	(0.5)	0		2	(1.0)
		Normal	0		207	(99.0)	2	(1.0)	209	(100.0)	0		203	(98.5)	1	(0.5)	204	(99.0)
		High	0		0		0		0		0		0		0		0	
		Total	0		207	(99.0)	2	(1.0)	209	(100.0)	1	(0.5)	204	(99.0)	1	(0.5)	206	(100.0)
Calcium	Week 2	Low	1	(0.5)	4	(1.9)	0		5	(2.3)	0		3	(1.4)	0		3	(1.4)
		Normal	2	(0.9)	208	(96.7)	0		210	(97.7)	0		214	(98.2)	1	(0.5)	215	(98.6)
		High	0		0		0		0		0		0		0		0	
		Total	3	(1.4)	212	(98.6)	0		215	(100.0)	0		217	(99.5)	1	(0.5)	218	(100.0)
	Week 12	Low	0		3	(1.4)	0		3	(1.4)	0		4	(1.9)	0		4	(1.9)

Paramaters	Timepoint	Baseline[a]	Placebo N=220								SI-613 30 mg N=220							
			Low		Normal		High		Total		Low		Normal		High		Total	
			n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]
		Normal	3	(1.4)	207	(97.2)	0		210	(98.6)	0		205	(97.2)	0		205	(97.2)
		High	0		0		0		0		0		1	(0.5)	1	(0.5)	2	(0.9)
		Total	3	(1.4)	210	(98.6)	0		213	(100.0)	0		210	(99.5)	1	(0.5)	211	(100.0)
	Week 24	Low	0		1	(0.5)	0		1	(0.5)	0		4	(1.9)	0		4	(1.9)
		Normal	3	(1.4)	205	(98.1)	0		208	(99.5)	0		200	(97.1)	0		200	(97.1)
		High	0		0		0		0		0		1	(0.5)	1	(0.5)	2	(1.0)
		Total	3	(1.4)	206	(98.6)	0		209	(100.0)	0		205	(99.5)	1	(0.5)	206	(100.0)
Creatine	Week 2	Low	2	(0.9)	0		0		2	(0.9)	1	(0.5)	4	(1.8)	0		5	(2.3)
Kinase		Normal	1	(0.5)	174	(80.9)	8	(3.7)	183	(85.1)	0		166	(76.1)	15	(6.9)	181	(83.0)
		High	0		14	(6.5)	16	(7.4)	30	(14.0)	0		15	(6.9)	17	(7.8)	32	(14.7)
		Total	3	(1.4)	188	(87.4)	24	(11.2)	215	(100.0)	1	(0.5)	185	(84.9)	32	(14.7)	218	(100.0)
	Week 12	Low	1	(0.5)	1	(0.5)	0		2	(0.9)	1	(0.5)	3	(1.4)	0		4	(1.9)
		Normal	2	(0.9)	170	(79.8)	9	(4.2)	181	(85.0)	0		162	(76.8)	15	(7.1)	177	(83.9)
		High	0		15	(7.0)	15	(7.0)	30	(14.1)	0		13	(6.2)	17	(8.1)	30	(14.2)
		Total	3	(1.4)	186	(87.3)	24	(11.3)	213	(100.0)	1	(0.5)	178	(84.4)	32	(15.2)	211	(100.0)
	Week 24	Low	2	(1.0)	1	(0.5)	0		3	(1.4)	1	(0.5)	2	(1.0)	0		3	(1.5)
		Normal	1	(0.5)	168	(80.4)	10	(4.8)	179	(85.6)	0		160	(77.7)	16	(7.8)	176	(85.4)
		High	0		13	(6.2)	14	(6.7)	27	(12.9)	0		11	(5.3)	16	(7.8)	27	(13.1)
		Total	3	(1.4)	182	(87.1)	24	(11.5)	209	(100.0)	1	(0.5)	173	(84.0)	32	(15.5)	206	(100.0)
Hemoglobin	Week 2	Low	0		0		0		0		1	(0.5)	0		0		1	(0.5)
A1C		Normal	0		180	(84.1)	4	(1.9)	184	(86.0)	0		185	(84.9)	5	(2.3)	190	(87.2)
/Hemoglobin		High	0		5	(2.3)	25	(11.7)	30	(14.0)	0		2	(0.9)	25	(11.5)	27	(12.4)
		Total	0		185	(86.4)	29	(13.6)	214	(100.0)	1	(0.5)	187	(85.8)	30	(13.8)	218	(100.0)
	Week 12	Low	0		0		0		0		1	(0.5)	1	(0.5)	0		2	(0.9)
		Normal	0		179	(84.4)	6	(2.8)	185	(87.3)	0		174	(82.5)	2	(0.9)	176	(83.4)
		High	0		5	(2.4)	22	(10.4)	27	(12.7)	0		7	(3.3)	26	(12.3)	33	(15.6)
		Total	0		184	(86.8)	28	(13.2)	212	(100.0)	1	(0.5)	182	(86.3)	28	(13.3)	211	(100.0)
	Week 24	Low	0		0		0		0		1	(0.5)	1	(0.5)	0		2	(1.0)
		Normal	0		166	(79.8)	3	(1.4)	169	(81.3)	0		170	(82.5)	5	(2.4)	175	(85.0)
		High	0		14	(6.7)	25	(12.0)	39	(18.8)	0		6	(2.9)	23	(11.2)	29	(14.1)
		Total	0		180	(86.5)	28	(13.5)	208	(100.0)	1	(0.5)	177	(85.9)	28	(13.6)	206	(100.0)

a: Baseline is value at screening.
b: Percentages are based on the number of subjects with non-missing values at both baseline and each timepoint.
-: Not applicable.
〔5.3.5.1-3 Table 14.3.4-2 改編〕

表 2.7.4.7-76. 臨床検査値の各項目のシフトテーブル（定性試験）①：613/1031 試験

Paramaters	Treatment group	Timepoint	Baseline[a]	-		±		1+		2+		3+		4+		Total	
				n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]
Protein	Placebo	Week 2	-	192	(89.3)	2	(0.9)	1	(0.5)	0		1	(0.5)	0		196	(91.2)
			±	6	(2.8)	3	(1.4)	2	(0.9)	0		0		0		11	(5.1)
			1+	3	(1.4)	0		1	(0.5)	1	(0.5)	0		0		5	(2.3)
			2+	0		0		0		2	(0.9)	0		0		2	(0.9)
			3+	0		0		0		0		1	(0.5)	0		1	(0.5)
			4+	0		0		0		0		0		0		0	
			Total	201	(93.5)	5	(2.3)	4	(1.9)	3	(1.4)	2	(0.9)	0		215	(100.0)
	SI-613 30 mg	Week 2	-	191	(87.6)	6	(2.8)	2	(0.9)	0		0		0		199	(91.3)
			±	9	(4.1)	3	(1.4)	2	(0.9)	0		0		0		14	(6.4)
			1+	1	(0.5)	0		3	(1.4)	1	(0.5)	0		0		5	(2.3)
			2+	0		0		0		0		0		0		0	
			3+	0		0		0		0		0		0		0	
			4+	0		0		0		0		0		0		0	
			Total	201	(92.2)	9	(4.1)	7	(3.2)	1	(0.5)	0		0		218	(100.0)
	Placebo	Week 12	-	187	(87.8)	2	(0.9)	1	(0.5)	0		1	(0.5)	0		191	(89.7)
			±	8	(3.8)	2	(0.9)	1	(0.5)	0		0		0		11	(5.2)
			1+	4	(1.9)	1	(0.5)	2	(0.9)	2	(0.9)	0		0		9	(4.2)
			2+	0		0		0		1	(0.5)	0		0		1	(0.5)
			3+	0		0		0		0		1	(0.5)	0		1	(0.5)
			4+	0		0		0		0		0		0		0	
			Total	199	(93.4)	5	(2.3)	4	(1.9)	3	(1.4)	2	(0.9)	0		213	(100.0)
	SI-613 30 mg	Week 12	-	187	(88.2)	5	(2.4)	3	(1.4)	0		0		0		195	(92.0)
			±	7	(3.3)	0		2	(0.9)	0		0		0		9	(4.2)
			1+	3	(1.4)	2	(0.9)	0		1	(0.5)	0		0		6	(2.8)
			2+	0		0		2	(0.9)	0		0		0		2	(0.9)
			3+	0		0		0		0		0		0		0	
			4+	0		0		0		0		0		0		0	
			Total	197	(92.9)	7	(3.3)	7	(3.3)	1	(0.5)	0		0		212	(100.0)
	Placebo	Week 24	-	186	(89.0)	3	(1.4)	2	(1.0)	0		1	(0.5)	0		192	(91.9)
			±	6	(2.9)	2	(1.0)	0		0		0		0		8	(3.8)
			1+	2	(1.0)	0		1	(0.5)	2	(1.0)	0		0		5	(2.4)
			2+	1	(0.5)	0		1	(0.5)	1	(0.5)	1	(0.5)	0		4	(1.9)
			3+	0		0		0		0		0		0		0	
			4+	0		0		0		0		0		0		0	
			Total	195	(93.3)	5	(2.4)	4	(1.9)	3	(1.4)	2	(1.0)	0		209	(100.0)
	SI-613 30 mg	Week 24	-	183	(88.8)	6	(2.9)	4	(1.9)	0		0		0		193	(93.7)
			±	5	(2.4)	1	(0.5)	2	(1.0)	0		0		0		8	(3.9)
			1+	3	(1.5)	0		1	(0.5)	1	(0.5)	0		0		5	(2.4)
			2+	0		0		0		0		0		0		0	
			3+	0		0		0		0		0		0		0	
			4+	0		0		0		0		0		0		0	
			Total	191	(92.7)	7	(3.4)	7	(3.4)	1	(0.5)	0		0		206	(100.0)

a: Baseline is value at screening.
b: Percentages are based on the number of subjects with non-missing values at both baseline and each timepoint.
〔5.3.5.1-3 Table 14.3.4-3 改編〕

表 2.7.4.7-77. 臨床検査値の各項目のシフトテーブル（定性試験）②：613/1031 試験

Paramaters	Treatment group	Timepoint	Baseline[a]	-		1+		2+		3+		4+		5+		Total	
				n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]
Glucose	Placebo	Week 2	-	199	(92.6)	2	(0.9)	0		0		0		0		201	(93.5)
			1+	1	(0.5)	1	(0.5)	0		0		0		0		2	(0.9)
			2+	1	(0.5)	1	(0.5)	2	(0.9)	1	(0.5)	0		0		5	(2.3)

Paramaters	Treatment group	Timepoint	Baseline[a]	-		1+		2+		3+		4+		5+		Total	
				n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]
			3+	0		0		0		0		0		0		0	
			4+	0		0		1	(0.5)	0		0		0		1	(0.5)
			5+	0		0		0		1	(0.5)	2	(0.9)	3	(1.4)	6	(2.8)
			Total	201	(93.5)	4	(1.9)	3	(1.4)	2	(0.9)	2	(0.9)	3	(1.4)	215	(100.0)
	SI-613 30 mg	Week 2	-	201	(92.2)	0		2	(0.9)	1	(0.5)	2	(0.9)	1	(0.5)	207	(95.0)
			1+	1	(0.5)	0		1	(0.5)	0		0		0		2	(0.9)
			2+	1	(0.5)	0		0		0		1	(0.5)	0		2	(0.9)
			3+	2	(0.9)	0		0		0		0		1	(0.5)	3	(1.4)
			4+	0		0		0		0		0		1	(0.5)	1	(0.5)
			5+	0		0		0		0		0		3	(1.4)	3	(1.4)
			Total	205	(94.0)	0		3	(1.4)	1	(0.5)	3	(1.4)	6	(2.8)	218	(100.0)
	Placebo	Week 12	-	194	(91.1)	3	(1.4)	0		1	(0.5)	0		0		198	(93.0)
			1+	2	(0.9)	0		1	(0.5)	0		0		0		3	(1.4)
			2+	0		1	(0.5)	0		0		0		1	(0.5)	2	(0.9)
			3+	2	(0.9)	0		0		0		0		1	(0.5)	3	(1.4)
			4+	1	(0.5)	0		0		1	(0.5)	0		1	(0.5)	3	(1.4)
			5+	0		0		2	(0.9)	0		2	(0.9)	0		4	(1.9)
			Total	199	(93.4)	4	(1.9)	3	(1.4)	2	(0.9)	2	(0.9)	3	(1.4)	213	(100.0)
	SI-613 30 mg	Week 12	-	194	(91.5)	0		3	(1.4)	0		2	(0.9)	1	(0.5)	200	(94.3)
			1+	0		0		0		0		0		0		0	
			2+	5	(2.4)	0		0		0		0		1	(0.5)	6	(2.8)
			3+	1	(0.5)	0		0		0		0		0		1	(0.5)
			4+	0		0		0		0		0		0		0	
			5+	0		0		0		1	(0.5)	0		4	(1.9)	5	(2.4)
			Total	200	(94.3)	0		3	(1.4)	1	(0.5)	2	(0.9)	6	(2.8)	212	(100.0)
	Placebo	Week 24	-	189	(90.4)	2	(1.0)	1	(0.5)	2	(1.0)	0		0		194	(92.8)
			1+	2	(1.0)	0		1	(0.5)	0		0		0		3	(1.4)
			2+	2	(1.0)	0		0		0		0		0		2	(1.0)
			3+	1	(0.5)	1	(0.5)	0		0		0		1	(0.5)	3	(1.4)
			4+	1	(0.5)	0		0		0		0		0		1	(0.5)
			5+	0		1	(0.5)	1	(0.5)	0		2	(1.0)	2	(1.0)	6	(2.9)
			Total	195	(93.3)	4	(1.9)	3	(1.4)	2	(1.0)	2	(1.0)	3	(1.4)	209	(100.0)
	SI-613 30 mg	Week 24	-	188	(91.3)	0		2	(1.0)	0		2	(1.0)	1	(0.5)	193	(93.7)
			1+	1	(0.5)	0		0		0		0		0		1	(0.5)
			2+	0		0		0		0		0		0		0	
			3+	1	(0.5)	0		0		0		0		0		1	(0.5)
			4+	2	(1.0)	0		1	(0.5)	1	(0.5)	0		0		4	(1.9)
			5+	2	(1.0)	0		0		0		0		5	(2.4)	7	(3.4)
			Total	194	(94.2)	0		3	(1.5)	1	(0.5)	2	(1.0)	6	(2.9)	206	(100.0)

a: Baseline is value at screening.
b: Percentages are based on the number of subjects with non-missing values at both baseline and each timepoint.
〔5.3.5.1-3 Table 14.3.4-3 改編〕

表 2.7.4.7-78. 臨床検査値の各項目のシフトテーブル（定性試験）③：613/1031 試験

Paramater	Treatment group	Timepoint	Baseline[a]	±		1+		2+		3+		Total	
				n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]
Urobilinogen	Placebo	Week 2	±	215	(100.0)	0		0		0		215	(100.0)
			1+	0		0		0		0		0	
			2+	0		0		0		0		0	
			3+	0		0		0		0		0	
			Total	215	(100.0)	0		0		0		215	(100.0)
	SI-613 30 mg	Week 2	±	218	(100.0)	0		0		0		218	(100.0)
			1+	0		0		0		0		0	
			2+	0		0		0		0		0	

Paramater	Treatment group	Timepoint	Baseline[a]	±		1+		2+		3+		Total	
				n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]
			3+	0		0		0		0		0	
			Total	218	(100.0)	0		0		0		218	(100.0)
	Placebo	Week 12	±	213	(100.0)	0		0		0		213	(100.0)
			1+	0		0		0		0		0	
			2+	0		0		0		0		0	
			3+	0		0		0		0		0	
			Total	213	(100.0)	0		0		0		213	(100.0)
	SI-613 30 mg	Week 12	±	212	(100.0)	0		0		0		212	(100.0)
			1+	0		0		0		0		0	
			2+	0		0		0		0		0	
			3+	0		0		0		0		0	
			Total	212	(100.0)	0		0		0		212	(100.0)
	Placebo	Week 24	±	209	(100.0)	0		0		0		209	(100.0)
			1+	0		0		0		0		0	
			2+	0		0		0		0		0	
			3+	0		0		0		0		0	
			Total	209	(100.0)	0		0		0		209	(100.0)
	SI-613 30 mg	Week 24	±	206	(100.0)	0		0		0		206	(100.0)
			1+	0		0		0		0		0	
			2+	0		0		0		0		0	
			3+	0		0		0		0		0	
			Total	206	(100.0)	0		0		0		206	(100.0)

a: Baseline is value at screening.
b: Percentages are based on the number of subjects with non-missing values at both baseline and each timepoint.
〔5.3.5.1-3 Table 14.3.4-3 改編〕

表 2.7.4.7-79. 臨床検査値の各項目のシフトテーブル（定量試験）：613/1033 試験

Paramaters	Timepoint	Baseline[a]	Placebo N=144								SI-613 30 mg N=146							
			Low		Normal		High		Total		Low		Normal		High		Total	
			n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]
Leukocytes	Week 2	Low	0		1	(0.7)	0		1	(0.7)	0		0		0		0	
		Normal	0		139	(97.2)	1	(0.7)	140	(97.9)	0		139	(95.2)	4	(2.7)	143	(97.9)
		High	0		1	(0.7)	1	(0.7)	2	(1.4)	0		1	(0.7)	2	(1.4)	3	(2.1)
		Total	0		141	(98.6)	2	(1.4)	143	(100.0)	0		140	(95.9)	6	(4.1)	146	(100.0)
	Week 12	Low	0		0		0		0		0		1	(0.7)	0		1	(0.7)
		Normal	0		135	(97.8)	1	(0.7)	136	(98.6)	0		135	(94.4)	5	(3.5)	140	(97.9)
		High	0		2	(1.4)	0		2	(1.4)	0		1	(0.7)	1	(0.7)	2	(1.4)
		Total	0		137	(99.3)	1	(0.7)	138	(100.0)	0		137	(95.8)	6	(4.2)	143	(100.0)
Neutrophils /Leukocytes	Week 2	Low	0		0		0		0		3	(2.1)	0		0		3	(2.1)
		Normal	0		134	(93.7)	3	(2.1)	137	(95.8)	0		135	(92.5)	4	(2.7)	139	(95.2)
		High	0		4	(2.8)	2	(1.4)	6	(4.2)	0		3	(2.1)	1	(0.7)	4	(2.7)
		Total	0		138	(96.5)	5	(3.5)	143	(100.0)	3	(2.1)	138	(94.5)	5	(3.4)	146	(100.0)
	Week 12	Low	0		3	(2.2)	0		3	(2.2)	1	(0.7)	1	(0.7)	0		2	(1.4)
		Normal	0		130	(94.2)	4	(2.9)	134	(97.1)	2	(1.4)	132	(92.3)	3	(2.1)	137	(95.8)
		High	0		0		1	(0.7)	1	(0.7)	0		2	(1.4)	2	(1.4)	4	(2.8)
		Total	0		133	(96.4)	5	(3.6)	138	(100.0)	3	(2.1)	135	(94.4)	5	(3.5)	143	(100.0)
Lymphocytes /Leukocytes	Week 2	Low	2	(1.4)	4	(2.8)	0		6	(4.2)	3	(2.1)	6	(4.1)	0		9	(6.2)
		Normal	2	(1.4)	134	(93.7)	0		136	(95.1)	4	(2.7)	129	(88.4)	0		133	(91.1)
		High	0		1	(0.7)	0		1	(0.7)	0		1	(0.7)	3	(2.1)	4	(2.7)
		Total	4	(2.8)	139	(97.2)	0		143	(100.0)	7	(4.8)	136	(93.2)	3	(2.1)	146	(100.0)
	Week 12	Low	2	(1.4)	2	(1.4)	0		4	(2.9)	4	(2.8)	4	(2.8)	0		8	(5.6)
		Normal	2	(1.4)	128	(92.8)	0		130	(94.2)	3	(2.1)	129	(90.2)	2	(1.4)	134	(93.7)
		High	0		4	(2.9)	0		4	(2.9)	0		0		1	(0.7)	1	(0.7)

Paramaters	Timepoint	Baseline[a]	Placebo N=144								SI-613 30 mg N=146							
			Low		Normal		High		Total		Low		Normal		High		Total	
			n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]
		Total	4	(2.9)	134	(97.1)	0		138	(100.0)	7	(4.9)	133	(93.0)	3	(2.1)	143	(100.0)
Monocytes	Week 2	Low	0		0		0		0		0		1	(0.7)	0		1	(0.7)
/Leukocytes		Normal	1	(0.7)	134	(93.7)	2	(1.4)	137	(95.8)	0		134	(91.8)	4	(2.7)	138	(94.5)
		High	0		5	(3.5)	1	(0.7)	6	(4.2)	0		4	(2.7)	3	(2.1)	7	(4.8)
		Total	1	(0.7)	139	(97.2)	3	(2.1)	143	(100.0)	0		139	(95.2)	7	(4.8)	146	(100.0)
	Week 12	Low	0		0		0		0		0		0		0		0	
		Normal	1	(0.7)	124	(89.9)	2	(1.4)	127	(92.0)	0		129	(90.2)	2	(1.4)	131	(91.6)
		High	0		11	(8.0)	0		11	(8.0)	0		8	(5.6)	4	(2.8)	12	(8.4)
		Total	1	(0.7)	135	(97.8)	2	(1.4)	138	(100.0)	0		137	(95.8)	6	(4.2)	143	(100.0)
Eosinophils	Week 2	Low	0		0		0		0		0		0		0		0	
/Leukocytes		Normal	0		138	(96.5)	3	(2.1)	141	(98.6)	0		139	(95.2)	1	(0.7)	140	(95.9)
		High	0		1	(0.7)	1	(0.7)	2	(1.4)	0		3	(2.1)	3	(2.1)	6	(4.1)
		Total	0		139	(97.2)	4	(2.8)	143	(100.0)	0		142	(97.3)	4	(2.7)	146	(100.0)
	Week 12	Low	0		0		0		0		0		0		0		0	
		Normal	0		127	(92.0)	4	(2.9)	131	(94.9)	0		136	(95.1)	1	(0.7)	137	(95.8)
		High	0		6	(4.3)	1	(0.7)	7	(5.1)	0		3	(2.1)	3	(2.1)	6	(4.2)
		Total	0		133	(96.4)	5	(3.6)	138	(100.0)	0		139	(97.2)	4	(2.8)	143	(100.0)
Basophils	Week 2	Low	0		0		0		0		0		0		0		0	
/Leukocytes		Normal	0		143	(100.0)	0		143	(100.0)	0		146	(100.0)	0		146	(100.0)
		High	0		0		0		0		0		0		0		0	
		Total	0		143	(100.0)	0		143	(100.0)	0		146	(100.0)	0		146	(100.0)
	Week 12	Low	0		0		0		0		0		0		0		0	
		Normal	0		138	(100.0)	0		138	(100.0)	0		143	(100.0)	0		143	(100.0)
		High	0		0		0		0		0		0		0		0	
		Total	0		138	(100.0)	0		138	(100.0)	0		143	(100.0)	0		143	(100.0)
Erythrocytes	Week 2	Low	15	(10.5)	6	(4.2)	0		21	(14.7)	15	(10.3)	6	(4.1)	0		21	(14.4)
		Normal	5	(3.5)	115	(80.4)	1	(0.7)	121	(84.6)	2	(1.4)	122	(83.6)	1	(0.7)	125	(85.6)
		High	0		1	(0.7)	0		1	(0.7)	0		0		0		0	
		Total	20	(14.0)	122	(85.3)	1	(0.7)	143	(100.0)	17	(11.6)	128	(87.7)	1	(0.7)	146	(100.0)
	Week 12	Low	16	(11.6)	8	(5.8)	0		24	(17.4)	13	(9.1)	11	(7.7)	0		24	(16.8)
		Normal	4	(2.9)	107	(77.5)	0		111	(80.4)	4	(2.8)	114	(79.7)	1	(0.7)	119	(83.2)
		High	0		2	(1.4)	1	(0.7)	3	(2.2)	0		0		0		0	
		Total	20	(14.5)	117	(84.8)	1	(0.7)	138	(100.0)	17	(11.9)	125	(87.4)	1	(0.7)	143	(100.0)
Hemoglobin	Week 2	Low	14	(9.7)	10	(6.9)	0		24	(16.7)	12	(8.2)	4	(2.7)	0		16	(11.0)
		Normal	4	(2.8)	112	(77.8)	2	(1.4)	118	(81.9)	2	(1.4)	126	(86.3)	2	(1.4)	130	(89.0)
		High	0		1	(0.7)	1	(0.7)	2	(1.4)	0		0		0		0	
		Total	18	(12.5)	123	(85.4)	3	(2.1)	144	(100.0)	14	(9.6)	130	(89.0)	2	(1.4)	146	(100.0)
	Week 12	Low	14	(10.1)	3	(2.2)	0		17	(12.3)	10	(7.0)	10	(7.0)	0		20	(14.0)
		Normal	4	(2.9)	113	(81.9)	2	(1.4)	119	(86.2)	3	(2.1)	117	(81.8)	0		120	(83.9)
		High	0		1	(0.7)	1	(0.7)	2	(1.4)	0		1	(0.7)	2	(1.4)	3	(2.1)
		Total	18	(13.0)	117	(84.8)	3	(2.2)	138	(100.0)	13	(9.1)	128	(89.5)	2	(1.4)	143	(100.0)
Hematocrit	Week 2	Low	14	(9.8)	10	(7.0)	0		24	(16.8)	11	(7.5)	7	(4.8)	0		18	(12.3)
		Normal	4	(2.8)	111	(77.6)	2	(1.4)	117	(81.8)	3	(2.1)	124	(84.9)	1	(0.7)	128	(87.7)
		High	0		1	(0.7)	1	(0.7)	2	(1.4)	0		0		0		0	
		Total	18	(12.6)	122	(85.3)	3	(2.1)	143	(100.0)	14	(9.6)	131	(89.7)	1	(0.7)	146	(100.0)
	Week 12	Low	13	(9.4)	5	(3.6)	0		18	(13.0)	10	(7.0)	10	(7.0)	0		20	(14.0)
		Normal	5	(3.6)	111	(80.4)	1	(0.7)	117	(84.8)	3	(2.1)	118	(82.5)	1	(0.7)	122	(85.3)
		High	0		1	(0.7)	2	(1.4)	3	(2.2)	0		1	(0.7)	0		1	(0.7)
		Total	18	(13.0)	117	(84.8)	3	(2.2)	138	(100.0)	13	(9.1)	129	(90.2)	1	(0.7)	143	(100.0)
Platelets	Week 2	Low	1	(0.7)	2	(1.4)	0		3	(2.1)	1	(0.7)	2	(1.4)	0		3	(2.1)
		Normal	1	(0.7)	131	(92.3)	1	(0.7)	133	(93.7)	0		133	(91.1)	3	(2.1)	136	(93.2)
		High	0		2	(1.4)	4	(2.8)	6	(4.2)	0		2	(1.4)	5	(3.4)	7	(4.8)
		Total	2	(1.4)	135	(95.1)	5	(3.5)	142	(100.0)	1	(0.7)	137	(93.8)	8	(5.5)	146	(100.0)

Paramaters	Timepoint	Baseline[a]	Placebo N=144								SI-613 30 mg N=146							
			Low		Normal		High		Total		Low		Normal		High		Total	
			n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]
	Week 12	Low	1	(0.7)	2	(1.4)	0		3	(2.2)	0		0		0		0	
		Normal	0		125	(90.6)	1	(0.7)	126	(91.3)	1	(0.7)	133	(93.0)	3	(2.1)	137	(95.8)
		High	0		5	(3.6)	4	(2.9)	9	(6.5)	0		1	(0.7)	5	(3.5)	6	(4.2)
		Total	1	(0.7)	132	(95.7)	5	(3.6)	138	(100.0)	1	(0.7)	134	(93.7)	8	(5.6)	143	(100.0)
Protein	Week 2	Low	13	(9.0)	17	(11.8)	0		30	(20.8)	8	(5.5)	5	(3.4)	0		13	(8.9)
		Normal	6	(4.2)	108	(75.0)	0		114	(79.2)	4	(2.7)	126	(86.3)	1	(0.7)	131	(89.7)
		High	0		0		0		0		0		0		2	(1.4)	2	(1.4)
		Total	19	(13.2)	125	(86.8)	0		144	(100.0)	12	(8.2)	131	(89.7)	3	(2.1)	146	(100.0)
	Week 12	Low	11	(8.0)	7	(5.1)	0		18	(13.0)	7	(4.9)	9	(6.3)	0		16	(11.2)
		Normal	8	(5.8)	110	(79.7)	0		118	(85.5)	5	(3.5)	119	(83.2)	1	(0.7)	125	(87.4)
		High	0		2	(1.4)	0		2	(1.4)	0		0		2	(1.4)	2	(1.4)
		Total	19	(13.8)	119	(86.2)	0		138	(100.0)	12	(8.4)	128	(89.5)	3	(2.1)	143	(100.0)
Albumin	Week 2	Low	3	(2.1)	3	(2.1)	0		6	(4.2)	1	(0.7)	4	(2.7)	0		5	(3.4)
		Normal	1	(0.7)	137	(95.1)	0		138	(95.8)	2	(1.4)	139	(95.2)	0		141	(96.6)
		High	0		0		0		0		0		0		0		0	
		Total	4	(2.8)	140	(97.2)	0		144	(100.0)	3	(2.1)	143	(97.9)	0		146	(100.0)
	Week 12	Low	1	(0.7)	3	(2.2)	0		4	(2.9)	1	(0.7)	5	(3.5)	0		6	(4.2)
		Normal	3	(2.2)	131	(94.9)	0		134	(97.1)	2	(1.4)	135	(94.4)	0		137	(95.8)
		High	0		0		0		0		0		0		0		0	
		Total	4	(2.9)	134	(97.1)	0		138	(100.0)	3	(2.1)	140	(97.9)	0		143	(100.0)
Bilirubin	Week 2	Low	0		0		0		0		0		0		0		0	
		Normal	0		138	(95.8)	1	(0.7)	139	(96.5)	0		136	(93.2)	4	(2.7)	140	(95.9)
		High	0		3	(2.1)	2	(1.4)	5	(3.5)	0		4	(2.7)	2	(1.4)	6	(4.1)
		Total	0		141	(97.9)	3	(2.1)	144	(100.0)	0		140	(95.9)	6	(4.1)	146	(100.0)
	Week 12	Low	0		0		0		0		0		0		0		0	
		Normal	0		134	(97.1)	2	(1.4)	136	(98.6)	0		135	(94.4)	5	(3.5)	140	(97.9)
		High	0		1	(0.7)	1	(0.7)	2	(1.4)	0		2	(1.4)	1	(0.7)	3	(2.1)
		Total	0		135	(97.8)	3	(2.2)	138	(100.0)	0		137	(95.8)	6	(4.2)	143	(100.0)
Direct Bilirubin	Week 2	Low	0		0		0		0		0		0		0		0	
		Normal	0		144	(100.0)	0		144	(100.0)	0		146	(100.0)	0		146	(100.0)
		High	0		0		0		0		0		0		0		0	
		Total	0		144	(100.0)	0		144	(100.0)	0		146	(100.0)	0		146	(100.0)
	Week 12	Low	0		0		0		0		0		0		0		0	
		Normal	0		138	(100.0)	0		138	(100.0)	0		143	(100.0)	0		143	(100.0)
		High	0		0		0		0		0		0		0		0	
		Total	0		138	(100.0)	0		138	(100.0)	0		143	(100.0)	0		143	(100.0)
Aspartate	Week 2	Low	0		0		0		0		0		0		0		0	
Aminotransferase		Normal	0		141	(97.9)	0		141	(97.9)	0		133	(91.1)	4	(2.7)	137	(93.8)
		High	0		2	(1.4)	1	(0.7)	3	(2.1)	0		5	(3.4)	4	(2.7)	9	(6.2)
		Total	0		143	(99.3)	1	(0.7)	144	(100.0)	0		138	(94.5)	8	(5.5)	146	(100.0)
	Week 12	Low	0		0		0		0		0		0		0		0	
		Normal	0		135	(97.8)	1	(0.7)	136	(98.6)	0		133	(93.0)	4	(2.8)	137	(95.8)
		High	0		2	(1.4)	0		2	(1.4)	0		2	(1.4)	4	(2.8)	6	(4.2)
		Total	0		137	(99.3)	1	(0.7)	138	(100.0)	0		135	(94.4)	8	(5.6)	143	(100.0)
Alanine	Week 2	Low	0		0		0		0		0		0		0		0	
Aminotransferase		Normal	0		138	(95.8)	2	(1.4)	140	(97.2)	0		134	(91.8)	1	(0.7)	135	(92.5)
		High	0		3	(2.1)	1	(0.7)	4	(2.8)	0		3	(2.1)	8	(5.5)	11	(7.5)
		Total	0		141	(97.9)	3	(2.1)	144	(100.0)	0		137	(93.8)	9	(6.2)	146	(100.0)
	Week 12	Low	0		0		0		0		0		0		0		0	
		Normal	0		134	(97.1)	1	(0.7)	135	(97.8)	0		129	(90.2)	1	(0.7)	130	(90.9)
		High	0		1	(0.7)	2	(1.4)	3	(2.2)	0		5	(3.5)	8	(5.6)	13	(9.1)
		Total	0		135	(97.8)	3	(2.2)	138	(100.0)	0		134	(93.7)	9	(6.3)	143	(100.0)
	Week 2	Low	0		0		0		0		2	(1.4)	0		0		2	(1.4)

Paramaters	Timepoint	Baseline[a]	Placebo N=144								SI-613 30 mg N=146							
			Low		Normal		High		Total		Low		Normal		High		Total	
			n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]
Lactate Dehydrogenase		Normal	0		125	(86.8)	4	(2.8)	129	(89.6)	0		130	(89.0)	5	(3.4)	135	(92.5)
		High	0		4	(2.8)	11	(7.6)	15	(10.4)	0		5	(3.4)	4	(2.7)	9	(6.2)
		Total	0		129	(89.6)	15	(10.4)	144	(100.0)	2	(1.4)	135	(92.5)	9	(6.2)	146	(100.0)
	Week 12	Low	0		0		0		0		2	(1.4)	0		0		2	(1.4)
		Normal	0		115	(83.3)	5	(3.6)	120	(87.0)	0		124	(86.7)	5	(3.5)	129	(90.2)
		High	0		8	(5.8)	10	(7.2)	18	(13.0)	0		8	(5.6)	4	(2.8)	12	(8.4)
		Total	0		123	(89.1)	15	(10.9)	138	(100.0)	2	(1.4)	132	(92.3)	9	(6.3)	143	(100.0)
Alkaline Phosphatase	Week 2	Low	1	(0.7)	3	(2.1)	0		4	(2.8)	1	(0.7)	0		0		1	(0.7)
		Normal	1	(0.7)	120	(83.3)	4	(2.8)	125	(86.8)	0		117	(80.1)	4	(2.7)	121	(82.9)
		High	0		6	(4.2)	9	(6.3)	15	(10.4)	0		4	(2.7)	20	(13.7)	24	(16.4)
		Total	2	(1.4)	129	(89.6)	13	(9.0)	144	(100.0)	1	(0.7)	121	(82.9)	24	(16.4)	146	(100.0)
	Week 12	Low	2	(1.4)	1	(0.7)	0		3	(2.2)	1	(0.7)	0		0		1	(0.7)
		Normal	0		116	(84.1)	4	(2.9)	120	(87.0)	0		109	(76.2)	4	(2.8)	113	(79.0)
		High	0		6	(4.3)	9	(6.5)	15	(10.9)	0		9	(6.3)	20	(14.0)	29	(20.3)
		Total	2	(1.4)	123	(89.1)	13	(9.4)	138	(100.0)	1	(0.7)	118	(82.5)	24	(16.8)	143	(100.0)
Gamma Glutamyl Transferase	Week 2	Low	-		-		-		-		-		-		-		-	
		Normal	-		111	(77.1)	2	(1.4)	113	(78.5)	-		109	(74.7)	8	(5.5)	117	(80.1)
		High	-		7	(4.9)	24	(16.7)	31	(21.5)	-		5	(3.4)	24	(16.4)	29	(19.9)
		Total	-		118	(81.9)	26	(18.1)	144	(100.0)	-		114	(78.1)	32	(21.9)	146	(100.0)
	Week 12	Low	-		-		-		-		-		-		-		-	
		Normal	-		106	(76.8)	3	(2.2)	109	(79.0)	-		106	(74.1)	12	(8.4)	118	(82.5)
		High	-		7	(5.1)	22	(15.9)	29	(21.0)	-		7	(4.9)	18	(12.6)	25	(17.5)
		Total	-		113	(81.9)	25	(18.1)	138	(100.0)	-		113	(79.0)	30	(21.0)	143	(100.0)
Urate	Week 2	Low	1	(0.7)	1	(0.7)	0		2	(1.4)	1	(0.7)	2	(1.4)	0		3	(2.1)
		Normal	2	(1.4)	119	(82.6)	8	(5.6)	129	(89.6)	0		127	(87.0)	3	(2.1)	130	(89.0)
		High	0		4	(2.8)	9	(6.3)	13	(9.0)	0		6	(4.1)	7	(4.8)	13	(8.9)
		Total	3	(2.1)	124	(86.1)	17	(11.8)	144	(100.0)	1	(0.7)	135	(92.5)	10	(6.8)	146	(100.0)
	Week 12	Low	0		3	(2.2)	0		3	(2.2)	1	(0.7)	1	(0.7)	0		2	(1.4)
		Normal	3	(2.2)	111	(80.4)	9	(6.5)	123	(89.1)	0		124	(86.7)	4	(2.8)	128	(89.5)
		High	0		4	(2.9)	8	(5.8)	12	(8.7)	0		7	(4.9)	6	(4.2)	13	(9.1)
		Total	3	(2.2)	118	(85.5)	17	(12.3)	138	(100.0)	1	(0.7)	132	(92.3)	10	(7.0)	143	(100.0)
Blood Urea Nitrogen	Week 2	Low	0		1	(0.7)	0		1	(0.7)	1	(0.7)	0		0		1	(0.7)
		Normal	0		107	(74.3)	16	(11.1)	123	(85.4)	1	(0.7)	111	(76.0)	18	(12.3)	130	(89.0)
		High	0		6	(4.2)	14	(9.7)	20	(13.9)	0		6	(4.1)	9	(6.2)	15	(10.3)
		Total	0		114	(79.2)	30	(20.8)	144	(100.0)	2	(1.4)	117	(80.1)	27	(18.5)	146	(100.0)
	Week 12	Low	0		0		0		0		1	(0.7)	0		0		1	(0.7)
		Normal	0		100	(72.5)	14	(10.1)	114	(82.6)	1	(0.7)	106	(74.1)	17	(11.9)	124	(86.7)
		High	0		9	(6.5)	15	(10.9)	24	(17.4)	0		9	(6.3)	9	(6.3)	18	(12.6)
		Total	0		109	(79.0)	29	(21.0)	138	(100.0)	2	(1.4)	115	(80.4)	26	(18.2)	143	(100.0)
Creatinine	Week 2	Low	4	(2.8)	2	(1.4)	0		6	(4.2)	2	(1.4)	7	(4.8)	0		9	(6.2)
		Normal	3	(2.1)	121	(84.0)	7	(4.9)	131	(91.0)	1	(0.7)	122	(83.6)	5	(3.4)	128	(87.7)
		High	0		1	(0.7)	6	(4.2)	7	(4.9)	0		2	(1.4)	7	(4.8)	9	(6.2)
		Total	7	(4.9)	124	(86.1)	13	(9.0)	144	(100.0)	3	(2.1)	131	(89.7)	12	(8.2)	146	(100.0)
	Week 12	Low	3	(2.2)	4	(2.9)	0		7	(5.1)	1	(0.7)	4	(2.8)	0		5	(3.5)
		Normal	3	(2.2)	113	(81.9)	5	(3.6)	121	(87.7)	2	(1.4)	118	(82.5)	5	(3.5)	125	(87.4)
		High	0		2	(1.4)	8	(5.8)	10	(7.2)	0		6	(4.2)	7	(4.9)	13	(9.1)
		Total	6	(4.3)	119	(86.2)	13	(9.4)	138	(100.0)	3	(2.1)	128	(89.5)	12	(8.4)	143	(100.0)
Cholesterol	Week 2	Low	0		0		0		0		0		0		0		0	
		Normal	1	(0.7)	71	(49.3)	16	(11.1)	88	(61.1)	0		85	(58.2)	10	(6.8)	95	(65.1)
		High	0		10	(6.9)	46	(31.9)	56	(38.9)	0		12	(8.2)	39	(26.7)	51	(34.9)
		Total	1	(0.7)	81	(56.3)	62	(43.1)	144	(100.0)	0		97	(66.4)	49	(33.6)	146	(100.0)
	Week 12	Low	0		0		0		0		0		1	(0.7)	0		1	(0.7)

Paramaters	Timepoint	Baseline[a]	Placebo N=144								SI-613 30 mg N=146							
			Low		Normal		High		Total		Low		Normal		High		Total	
			n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]
		Normal	1	(0.7)	64	(46.4)	9	(6.5)	74	(53.6)	0		80	(55.9)	9	(6.3)	89	(62.2)
		High	0		14	(10.1)	50	(36.2)	64	(46.4)	0		15	(10.5)	38	(26.6)	53	(37.1)
		Total	1	(0.7)	78	(56.5)	59	(42.8)	138	(100.0)	0		96	(67.1)	47	(32.9)	143	(100.0)
Triglycerides	Week 2	Low	0		1	(0.7)	0		1	(0.7)	0		0		0		0	
		Normal	0		77	(53.5)	16	(11.1)	93	(64.6)	0		65	(44.5)	16	(11.0)	81	(55.5)
		High	0		15	(10.4)	35	(24.3)	50	(34.7)	0		15	(10.3)	50	(34.2)	65	(44.5)
		Total	0		93	(64.6)	51	(35.4)	144	(100.0)	0		80	(54.8)	66	(45.2)	146	(100.0)
	Week 12	Low	0		2	(1.4)	0		2	(1.4)	0		0		0		0	
		Normal	0		70	(50.7)	13	(9.4)	83	(60.1)	0		59	(41.3)	20	(14.0)	79	(55.2)
		High	0		17	(12.3)	36	(26.1)	53	(38.4)	0		18	(12.6)	46	(32.2)	64	(44.8)
		Total	0		89	(64.5)	49	(35.5)	138	(100.0)	0		77	(53.8)	66	(46.2)	143	(100.0)
C Reactive Protein	Week 2	Low	-		-		-		-		-		-		-		-	
		Normal	-		130	(90.9)	5	(3.5)	135	(94.4)	-		119	(82.1)	11	(7.6)	130	(89.7)
		High	-		7	(4.9)	1	(0.7)	8	(5.6)	-		8	(5.5)	7	(4.8)	15	(10.3)
		Total	-		137	(95.8)	6	(4.2)	143	(100.0)	-		127	(87.6)	18	(12.4)	145	(100.0)
	Week 12	Low	-		-		-		-		-		-		-		-	
		Normal	-		125	(91.2)	5	(3.6)	130	(94.9)	-		116	(81.1)	11	(7.7)	127	(88.8)
		High	-		6	(4.4)	1	(0.7)	7	(5.1)	-		10	(7.0)	6	(4.2)	16	(11.2)
		Total	-		131	(95.6)	6	(4.4)	137	(100.0)	-		126	(88.1)	17	(11.9)	143	(100.0)
Sodium	Week 2	Low	0		0		0		0		0		2	(1.4)	0		2	(1.4)
		Normal	1	(0.7)	143	(99.3)	0		144	(100.0)	2	(1.4)	142	(97.3)	0		144	(98.6)
		High	0		0		0		0		0		0		0		0	
		Total	1	(0.7)	143	(99.3)	0		144	(100.0)	2	(1.4)	144	(98.6)	0		146	(100.0)
	Week 12	Low	0		0		0		0		2	(1.4)	3	(2.1)	0		5	(3.5)
		Normal	1	(0.7)	135	(97.8)	0		136	(98.6)	0		136	(95.1)	0		136	(95.1)
		High	0		2	(1.4)	0		2	(1.4)	0		2	(1.4)	0		2	(1.4)
		Total	1	(0.7)	137	(99.3)	0		138	(100.0)	2	(1.4)	141	(98.6)	0		143	(100.0)
Potassium	Week 2	Low	0		0		0		0		0		1	(0.7)	0		1	(0.7)
		Normal	0		137	(95.1)	2	(1.4)	139	(96.5)	2	(1.4)	137	(93.8)	3	(2.1)	142	(97.3)
		High	0		5	(3.5)	0		5	(3.5)	0		3	(2.1)	0		3	(2.1)
		Total	0		142	(98.6)	2	(1.4)	144	(100.0)	2	(1.4)	141	(96.6)	3	(2.1)	146	(100.0)
	Week 12	Low	0		0		0		0		0		0		0		0	
		Normal	0		134	(97.1)	2	(1.4)	136	(98.6)	2	(1.4)	134	(93.7)	3	(2.1)	139	(97.2)
		High	0		2	(1.4)	0		2	(1.4)	0		4	(2.8)	0		4	(2.8)
		Total	0		136	(98.6)	2	(1.4)	138	(100.0)	2	(1.4)	138	(96.5)	3	(2.1)	143	(100.0)
Chloride	Week 2	Low	0		0		0		0		0		0		0		0	
		Normal	1	(0.7)	134	(93.1)	5	(3.5)	140	(97.2)	0		143	(97.9)	1	(0.7)	144	(98.6)
		High	0		4	(2.8)	0		4	(2.8)	0		2	(1.4)	0		2	(1.4)
		Total	1	(0.7)	138	(95.8)	5	(3.5)	144	(100.0)	0		145	(99.3)	1	(0.7)	146	(100.0)
	Week 12	Low	0		1	(0.7)	0		1	(0.7)	0		3	(2.1)	0		3	(2.1)
		Normal	1	(0.7)	128	(92.8)	5	(3.6)	134	(97.1)	0		134	(93.7)	1	(0.7)	135	(94.4)
		High	0		3	(2.2)	0		3	(2.2)	0		5	(3.5)	0		5	(3.5)
		Total	1	(0.7)	132	(95.7)	5	(3.6)	138	(100.0)	0		142	(99.3)	1	(0.7)	143	(100.0)
Calcium	Week 2	Low	1	(0.7)	0		0		1	(0.7)	0		0		0		0	
		Normal	1	(0.7)	139	(96.5)	1	(0.7)	141	(97.9)	0		146	(100.0)	0		146	(100.0)
		High	0		2	(1.4)	0		2	(1.4)	0		0		0		0	
		Total	2	(1.4)	141	(97.9)	1	(0.7)	144	(100.0)	0		146	(100.0)	0		146	(100.0)
	Week 12	Low	0		0		0		0		0		0		0		0	
		Normal	2	(1.4)	131	(94.9)	1	(0.7)	134	(97.1)	0		142	(99.3)	0		142	(99.3)
		High	0		4	(2.9)	0		4	(2.9)	0		1	(0.7)	0		1	(0.7)
		Total	2	(1.4)	135	(97.8)	1	(0.7)	138	(100.0)	0		143	(100.0)	0		143	(100.0)
Creatine Kinase	Week 2	Low	1	(0.7)	0		0		1	(0.7)	8	(5.5)	1	(0.7)	0		9	(6.2)
		Normal	1	(0.7)	120	(83.3)	4	(2.8)	125	(86.8)	0		118	(80.8)	5	(3.4)	123	(84.2)

Paramaters	Timepoint	Baseline[a]	Placebo N=144								SI-613 30 mg N=146							
			Low		Normal		High		Total		Low		Normal		High		Total	
			n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]
		High	0		12	(8.3)	6	(4.2)	18	(12.5)	0		6	(4.1)	8	(5.5)	14	(9.6)
		Total	2	(1.4)	132	(91.7)	10	(6.9)	144	(100.0)	8	(5.5)	125	(85.6)	13	(8.9)	146	(100.0)
	Week 12	Low	1	(0.7)	1	(0.7)	0		2	(1.4)	6	(4.2)	0		0		6	(4.2)
		Normal	1	(0.7)	117	(84.8)	4	(2.9)	122	(88.4)	2	(1.4)	116	(81.1)	6	(4.2)	124	(86.7)
		High	0		9	(6.5)	5	(3.6)	14	(10.1)	0		6	(4.2)	7	(4.9)	13	(9.1)
		Total	2	(1.4)	127	(92.0)	9	(6.5)	138	(100.0)	8	(5.6)	122	(85.3)	13	(9.1)	143	(100.0)
Hemoglobin	Week 2	Low	0		0		0		0		0		0		0		0	
A1C/Hemoglobin		Normal	0		119	(82.6)	0		119	(82.6)	0		121	(82.9)	2	(1.4)	123	(84.2)
		High	0		6	(4.2)	19	(13.2)	25	(17.4)	0		2	(1.4)	21	(14.4)	23	(15.8)
		Total	0		125	(86.8)	19	(13.2)	144	(100.0)	0		123	(84.2)	23	(15.8)	146	(100.0)
	Week 12	Low	0		0		0		0		0		0		0		0	
		Normal	0		112	(81.2)	0		112	(81.2)	0		119	(83.2)	2	(1.4)	121	(84.6)
		High	0		7	(5.1)	19	(13.8)	26	(18.8)	0		1	(0.7)	21	(14.7)	22	(15.4)
		Total	0		119	(86.2)	19	(13.8)	138	(100.0)	0		120	(83.9)	23	(16.1)	143	(100.0)

a: Baseline is value at screening.
b: Percentages are based on the number of subjects with non-missing values at both baseline and each timepoint.
-: Not applicable.
〔5.3.5.1-4 Table 14.3.4-2 改編〕

表 2.7.4.7-80. 臨床検査値の各項目のシフトテーブル（定性試験）①：613/1033 試験

Paramaters	Treatment group	Timepoint	Baseline[a]	-		±		1+		2+		3+		4+		Total	
				n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]
Protein	Placebo	Week 2	-	126	(87.5)	2	(1.4)	2	(1.4)	0		0		0		130	(90.3)
			±	4	(2.8)	2	(1.4)	0		1	(0.7)	0		0		7	(4.9)
			1+	2	(1.4)	1	(0.7)	2	(1.4)	1	(0.7)	0		0		6	(4.2)
			2+	0		0		0		0		0		0		0	
			3+	0		0		0		0		1	(0.7)	0		1	(0.7)
			4+	0		0		0		0		0		0		0	
			Total	132	(91.7)	5	(3.5)	4	(2.8)	2	(1.4)	1	(0.7)	0		144	(100.0)
	SI-613 30 mg	Week 2	-	126	(86.3)	6	(4.1)	2	(1.4)	0		0		0		134	(91.8)
			±	3	(2.1)	0		3	(2.1)	0		0		0		6	(4.1)
			1+	0		2	(1.4)	3	(2.1)	1	(0.7)	0		0		6	(4.1)
			2+	0		0		0		0		0		0		0	
			3+	0		0		0		0		0		0		0	
			4+	0		0		0		0		0		0		0	
			Total	129	(88.4)	8	(5.5)	8	(5.5)	1	(0.7)	0		0		146	(100.0)
	Placebo	Week 12	-	123	(89.1)	1	(0.7)	2	(1.4)	0		0		0		126	(91.3)
			±	3	(2.2)	2	(1.4)	0		1	(0.7)	0		0		6	(4.3)
			1+	0		2	(1.4)	1	(0.7)	0		0		0		3	(2.2)
			2+	1	(0.7)	0		0		1	(0.7)	0		0		2	(1.4)
			3+	0		0		0		0		1	(0.7)	0		1	(0.7)
			4+	0		0		0		0		0		0		0	
			Total	127	(92.0)	5	(3.6)	3	(2.2)	2	(1.4)	1	(0.7)	0		138	(100.0)
	SI-613 30 mg	Week 12	-	122	(85.3)	7	(4.9)	7	(4.9)	1	(0.7)	0		0		137	(95.8)
			±	1	(0.7)	1	(0.7)	0		0		0		0		2	(1.4)
			1+	3	(2.1)	0		1	(0.7)	0		0		0		4	(2.8)
			2+	0		0		0		0		0		0		0	
			3+	0		0		0		0		0		0		0	
			4+	0		0		0		0		0		0		0	
			Total	126	(88.1)	8	(5.6)	8	(5.6)	1	(0.7)	0		0		143	(100.0)

a: Baseline is value at screening.
b: Percentages are based on the number of subjects with non-missing values at both baseline and each timepoint.
〔5.3.5.1-4 Table 14.3.4-3 改編〕

表 2.7.4.7-81. 臨床検査値の各項目のシフトテーブル（定性試験）②：613/1033 試験

Paramaters	Treatment group	Timepoint	Baseline[a]	-		1+		2+		3+		4+		5+		Total	
				n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]
Glucose	Placebo	Week 2	-	127	(88.2)	3	(2.1)	0		1	(0.7)	0		0		131	(91.0)
			1+	4	(2.8)	1	(0.7)	1	(0.7)	0		0		0		6	(4.2)
			2+	2	(1.4)	1	(0.7)	0		0		0		0		3	(2.1)
			3+	0		1	(0.7)	0		0		0		0		1	(0.7)
			4+	0		0		0		0		1	(0.7)	0		1	(0.7)
			5+	0		0		0		0		0		2	(1.4)	2	(1.4)
			Total	133	(92.4)	6	(4.2)	1	(0.7)	1	(0.7)	1	(0.7)	2	(1.4)	144	(100.0)
	SI-613 30 mg	Week 2	-	133	(91.1)	0		2	(1.4)	1	(0.7)	1	(0.7)	0		137	(93.8)
			1+	2	(1.4)	0		0		0		1	(0.7)	0		3	(2.1)
			2+	0		0		0		1	(0.7)	0		0		1	(0.7)
			3+	2	(1.4)	0		0		0		0		0		2	(1.4)
			4+	0		0		1	(0.7)	0		0		0		1	(0.7)
			5+	1	(0.7)	0		0		0		1	(0.7)	0		2	(1.4)
			Total	138	(94.5)	0		3	(2.1)	2	(1.4)	3	(2.1)	0		146	(100.0)
	Placebo	Week 12	-	123	(89.1)	2	(1.4)	0		1	(0.7)	0		0		126	(91.3)
			1+	3	(2.2)	1	(0.7)	1	(0.7)	0		0		0		5	(3.6)
			2+	1	(0.7)	1	(0.7)	0		0		0		0		2	(1.4)
			3+	0		1	(0.7)	0		0		0		0		1	(0.7)

Paramaters	Treatment group	Timepoint	Baseline[a]	-		1+		2+		3+		4+		5+		Total	
				n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]
			4+	0		1	(0.7)	0		0		1	(0.7)	0		2	(1.4)
			5+	0		0		0		0		0		2	(1.4)	2	(1.4)
			Total	127	(92.0)	6	(4.3)	1	(0.7)	1	(0.7)	1	(0.7)	2	(1.4)	138	(100.0)
	SI-613 30 mg	Week 12	-	131	(91.6)	0		3	(2.1)	1	(0.7)	1	(0.7)	0		136	(95.1)
			1+	1	(0.7)	0		0		0		0		0		1	(0.7)
			2+	1	(0.7)	0		0		1	(0.7)	0		0		2	(1.4)
			3+	1	(0.7)	0		0		0		0		0		1	(0.7)
			4+	0		0		0		0		0		0		0	
			5+	1	(0.7)	0		0		0		2	(1.4)	0		3	(2.1)
			Total	135	(94.4)	0		3	(2.1)	2	(1.4)	3	(2.1)	0		143	(100.0)

a: Baseline is value at screening.
b: Percentages are based on the number of subjects with non-missing values at both baseline and each timepoint.
〔5.3.5.1-4 Table 14.3.4-3 改編〕

表 2.7.4.7-82. 臨床検査値の各項目のシフトテーブル（定性試験）③：613/1033 試験

Paramater	Treatment group	Timepoint	Baseline[a]	±		1+		2+		3+		Total	
				n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]
Urobilinogen	Placebo	Week 2	±	144	(100.0)	0		0		0		144	(100.0)
			1+	0		0		0		0		0	
			2+	0		0		0		0		0	
			3+	0		0		0		0		0	
			Total	144	(100.0)	0		0		0		144	(100.0)
	SI-613 30 mg	Week 2	±	146	(100.0)	0		0		0		146	(100.0)
			1+	0		0		0		0		0	
			2+	0		0		0		0		0	
			3+	0		0		0		0		0	
			Total	146	(100.0)	0		0		0		146	(100.0)
	Placebo	Week 12	±	138	(100.0)	0		0		0		138	(100.0)
			1+	0		0		0		0		0	
			2+	0		0		0		0		0	
			3+	0		0		0		0		0	
			Total	138	(100.0)	0		0		0		138	(100.0)
	SI-613 30 mg	Week 12	±	143	(100.0)	0		0		0		143	(100.0)
			1+	0		0		0		0		0	
			2+	0		0		0		0		0	
			3+	0		0		0		0		0	
			Total	143	(100.0)	0		0		0		143	(100.0)

a: Baseline is value at screening.
b: Percentages are based on the number of subjects with non-missing values at both baseline and each timepoint.
〔5.3.5.1-4 Table 14.3.4-3 改編〕

表 2.7.4.7-83. 臨床検査値の各項目のシフトテーブル（定量試験）：613/1032 試験

Paramaters	Time point	Baseline[a]	Knee N=126								Execpt for knee N=40								Total N=166							
			Low		Normal		High		Total		Low		Normal		High		Total		Low		Normal		High		Total	
			n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]
Leukocytes	Week 2	Low	0		1	(0.8)	0		1	(0.8)	0		0		0		0		0		1	(0.6)	0		1	(0.6)
		Normal	0		114	(90.5)	3	(2.4)	117	(92.9)	0		32	(84.2)	3	(7.9)	35	(92.1)	0		146	(89.0)	6	(3.7)	152	(92.7)
		High	0		3	(2.4)	5	(4.0)	8	(6.3)	0		2	(5.3)	1	(2.6)	3	(7.9)	0		5	(3.0)	6	(3.7)	11	(6.7)
		Total	0		118	(93.7)	8	(6.3)	126	(100.0)	0		34	(89.5)	4	(10.5)	38	(100.0)	0		152	(92.7)	12	(7.3)	164	(100.0)
	Week 12	Low	0		1	(0.8)	0		1	(0.8)	0		0		0		0		0		1	(0.6)	0		1	(0.6)
		Normal	0		111	(91.0)	4	(3.3)	115	(94.3)	0		35	(87.5)	3	(7.5)	38	(95.0)	0		146	(90.1)	7	(4.3)	153	(94.4)
		High	0		3	(2.5)	3	(2.5)	6	(4.9)	0		1	(2.5)	1	(2.5)	2	(5.0)	0		4	(2.5)	4	(2.5)	8	(4.9)
		Total	0		115	(94.3)	7	(5.7)	122	(100.0)	0		36	(90.0)	4	(10.0)	40	(100.0)	0		151	(93.2)	11	(6.8)	162	(100.0)
	Week 24	Low	0		1	(0.8)	0		1	(0.8)	0		0		0		0		0		1	(0.6)	0		1	(0.6)
		Normal	0		110	(90.9)	5	(4.1)	115	(95.0)	0		33	(89.2)	2	(5.4)	35	(94.6)	0		143	(90.5)	7	(4.4)	150	(94.9)
		High	0		3	(2.5)	2	(1.7)	5	(4.1)	0		0		2	(5.4)	2	(5.4)	0		3	(1.9)	4	(2.5)	7	(4.4)
		Total	0		114	(94.2)	7	(5.8)	121	(100.0)	0		33	(89.2)	4	(10.8)	37	(100.0)	0		147	(93.0)	11	(7.0)	158	(100.0)
	Week 36	Low	0		1	(0.8)	0		1	(0.8)	0		1	(2.7)	0		1	(2.7)	0		2	(1.3)	0		2	(1.3)
		Normal	0		109	(90.8)	4	(3.3)	113	(94.2)	0		32	(86.5)	2	(5.4)	34	(91.9)	0		141	(89.8)	6	(3.8)	147	(93.6)
		High	0		3	(2.5)	3	(2.5)	6	(5.0)	0		0		2	(5.4)	2	(5.4)	0		3	(1.9)	5	(3.2)	8	(5.1)
		Total	0		113	(94.2)	7	(5.8)	120	(100.0)	0		33	(89.2)	4	(10.8)	37	(100.0)	0		146	(93.0)	11	(7.0)	157	(100.0)
	Week 52	Low	0		1	(0.8)	0		1	(0.8)	0		1	(2.7)	0		1	(2.7)	0		2	(1.3)	0		2	(1.3)
		Normal	0		111	(93.3)	5	(4.2)	116	(97.5)	0		31	(83.8)	3	(8.1)	34	(91.9)	0		142	(91.0)	8	(5.1)	150	(96.2)
		High	0		0		2	(1.7)	2	(1.7)	0		1	(2.7)	1	(2.7)	2	(5.4)	0		1	(0.6)	3	(1.9)	4	(2.6)
		Total	0		112	(94.1)	7	(5.9)	119	(100.0)	0		33	(89.2)	4	(10.8)	37	(100.0)	0		145	(92.9)	11	(7.1)	156	(100.0)
Neutrophils /Leukocytes	Week 2	Low	1	(0.8)	1	(0.8)	0		2	(1.6)	0		1	(2.6)	0		1	(2.6)	1	(0.6)	2	(1.2)	0		3	(1.8)
		Normal	0		119	(94.4)	3	(2.4)	122	(96.8)	0		35	(92.1)	1	(2.6)	36	(94.7)	0		154	(93.9)	4	(2.4)	158	(96.3)
		High	0		1	(0.8)	1	(0.8)	2	(1.6)	0		0		1	(2.6)	1	(2.6)	0		1	(0.6)	2	(1.2)	3	(1.8)
		Total	1	(0.8)	121	(96.0)	4	(3.2)	126	(100.0)	0		36	(94.7)	2	(5.3)	38	(100.0)	1	(0.6)	157	(95.7)	6	(3.7)	164	(100.0)
	Week 12	Low	1	(0.8)	0		0		1	(0.8)	0		0		0		0		1	(0.6)	0		0		1	(0.6)
		Normal	0		115	(94.3)	4	(3.3)	119	(97.5)	0		37	(92.5)	1	(2.5)	38	(95.0)	0		152	(93.8)	5	(3.1)	157	(96.9)
		High	0		2	(1.6)	0		2	(1.6)	0		1	(2.5)	1	(2.5)	2	(5.0)	0		3	(1.9)	1	(0.6)	4	(2.5)
		Total	1	(0.8)	117	(95.9)	4	(3.3)	122	(100.0)	0		38	(95.0)	2	(5.0)	40	(100.0)	1	(0.6)	155	(95.7)	6	(3.7)	162	(100.0)
	Week 24	Low	1	(0.8)	3	(2.5)	0		4	(3.3)	0		1	(2.7)	0		1	(2.7)	1	(0.6)	4	(2.5)	0		5	(3.2)
		Normal	0		112	(92.6)	4	(3.3)	116	(95.9)	0		34	(91.9)	2	(5.4)	36	(97.3)	0		146	(92.4)	6	(3.8)	152	(96.2)
		High	0		1	(0.8)	0		1	(0.8)	0		0		0		0		0		1	(0.6)	0		1	(0.6)
		Total	1	(0.8)	116	(95.9)	4	(3.3)	121	(100.0)	0		35	(94.6)	2	(5.4)	37	(100.0)	1	(0.6)	151	(95.6)	6	(3.8)	158	(100.0)

Paramaters	Time point	Baseline[a]	Knee N=126								Execpt for knee N=40								Total N=166							
			Low		Normal		High		Total		Low		Normal		High		Total		Low		Normal		High		Total	
			n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]
	Week 36	Low	1	(0.8)	0		0		1	(0.8)	0		2	(5.4)	0		2	(5.4)	1	(0.6)	2	(1.3)	0		3	(1.9)
		Normal	0		111	(92.5)	2	(1.7)	113	(94.2)	0		33	(89.2)	2	(5.4)	35	(94.6)	0		144	(91.7)	4	(2.5)	148	(94.3)
		High	0		4	(3.3)	2	(1.7)	6	(5.0)	0		0		0		0		0		4	(2.5)	2	(1.3)	6	(3.8)
		Total	1	(0.8)	115	(95.8)	4	(3.3)	120	(100.0)	0		35	(94.6)	2	(5.4)	37	(100.0)	1	(0.6)	150	(95.5)	6	(3.8)	157	(100.0)
	Week 52	Low	0		1	(0.8)	0		1	(0.8)	0		1	(2.7)	0		1	(2.7)	0		2	(1.3)	0		2	(1.3)
		Normal	1	(0.8)	113	(95.0)	4	(3.4)	118	(99.2)	0		34	(91.9)	2	(5.4)	36	(97.3)	1	(0.6)	147	(94.2)	6	(3.8)	154	(98.7)
		High	0		0		0		0		0		0		0		0		0		0		0		0	
		Total	1	(0.8)	114	(95.8)	4	(3.4)	119	(100.0)	0		35	(94.6)	2	(5.4)	37	(100.0)	1	(0.6)	149	(95.5)	6	(3.8)	156	(100.0)
Lymphocytes /Leukocytes	Week 2	Low	2	(1.6)	1	(0.8)	0		3	(2.4)	0		1	(2.6)	0		1	(2.6)	2	(1.2)	2	(1.2)	0		4	(2.4)
		Normal	4	(3.2)	116	(92.1)	0		120	(95.2)	2	(5.3)	35	(92.1)	0		37	(97.4)	6	(3.7)	151	(92.1)	0		157	(95.7)
		High	0		3	(2.4)	0		3	(2.4)	0		0		0		0		0		3	(1.8)	0		3	(1.8)
		Total	6	(4.8)	120	(95.2)	0		126	(100.0)	2	(5.3)	36	(94.7)	0		38	(100.0)	8	(4.9)	156	(95.1)	0		164	(100.0)
	Week 12	Low	1	(0.8)	2	(1.6)	0		3	(2.5)	1	(2.5)	1	(2.5)	0		2	(5.0)	2	(1.2)	3	(1.9)	0		5	(3.1)
		Normal	5	(4.1)	114	(93.4)	0		119	(97.5)	1	(2.5)	37	(92.5)	0		38	(95.0)	6	(3.7)	151	(93.2)	0		157	(96.9)
		High	0		0		0		0		0		0		0		0		0		0		0		0	
		Total	6	(4.9)	116	(95.1)	0		122	(100.0)	2	(5.0)	38	(95.0)	0		40	(100.0)	8	(4.9)	154	(95.1)	0		162	(100.0)
	Week 24	Low	0		1	(0.8)	0		1	(0.8)	1	(2.7)	0		0		1	(2.7)	1	(0.6)	1	(0.6)	0		2	(1.3)
		Normal	5	(4.1)	111	(91.7)	0		116	(95.9)	1	(2.7)	35	(94.6)	0		36	(97.3)	6	(3.8)	146	(92.4)	0		152	(96.2)
		High	1	(0.8)	3	(2.5)	0		4	(3.3)	0		0		0		0		1	(0.6)	3	(1.9)	0		4	(2.5)
		Total	6	(5.0)	115	(95.0)	0		121	(100.0)	2	(5.4)	35	(94.6)	0		37	(100.0)	8	(5.1)	150	(94.9)	0		158	(100.0)
	Week 36	Low	2	(1.7)	7	(5.8)	0		9	(7.5)	0		0		0		0		2	(1.3)	7	(4.5)	0		9	(5.7)
		Normal	4	(3.3)	107	(89.2)	0		111	(92.5)	2	(5.4)	33	(89.2)	0		35	(94.6)	6	(3.8)	140	(89.2)	0		146	(93.0)
		High	0		0		0		0		0		2	(5.4)	0		2	(5.4)	0		2	(1.3)	0		2	(1.3)
		Total	6	(5.0)	114	(95.0)	0		120	(100.0)	2	(5.4)	35	(94.6)	0		37	(100.0)	8	(5.1)	149	(94.9)	0		157	(100.0)
	Week 52	Low	0		2	(1.7)	0		2	(1.7)	0		0		0		0		0		2	(1.3)	0		2	(1.3)
		Normal	6	(5.0)	110	(92.4)	0		116	(97.5)	2	(5.4)	35	(94.6)	0		37	(100.0)	8	(5.1)	145	(92.9)	0		153	(98.1)
		High	0		1	(0.8)	0		1	(0.8)	0		0		0		0		0		1	(0.6)	0		1	(0.6)
		Total	6	(5.0)	113	(95.0)	0		119	(100.0)	2	(5.4)	35	(94.6)	0		37	(100.0)	8	(5.1)	148	(94.9)	0		156	(100.0)
Monocytes /Leukocytes	Week 2	Low	0		0		0		0		0		0		0		0		0		0		0		0	
		Normal	0		111	(88.1)	6	(4.8)	117	(92.9)	0		33	(86.8)	2	(5.3)	35	(92.1)	0		144	(87.8)	8	(4.9)	152	(92.7)
		High	0		6	(4.8)	3	(2.4)	9	(7.1)	0		1	(2.6)	2	(5.3)	3	(7.9)	0		7	(4.3)	5	(3.0)	12	(7.3)
		Total	0		117	(92.9)	9	(7.1)	126	(100.0)	0		34	(89.5)	4	(10.5)	38	(100.0)	0		151	(92.1)	13	(7.9)	164	(100.0)
	Week 12	Low	0		0		0		0		0		0		0		0		0		0		0		0	
		Normal	0		106	(86.9)	5	(4.1)	111	(91.0)	0		36	(90.0)	2	(5.0)	38	(95.0)	0		142	(87.7)	7	(4.3)	149	(92.0)

Paramaters	Time point	Baseline[a]	Knee N=126								Execpt for knee N=40								Total N=166							
			Low		Normal		High		Total		Low		Normal		High		Total		Low		Normal		High		Total	
			n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]
		High	0		7	(5.7)	4	(3.3)	11	(9.0)	0		0		2	(5.0)	2	(5.0)	0		7	(4.3)	6	(3.7)	13	(8.0)
		Total	0		113	(92.6)	9	(7.4)	122	(100.0)	0		36	(90.0)	4	(10.0)	40	(100.0)	0		149	(92.0)	13	(8.0)	162	(100.0)
	Week 24	Low	0		0		0		0		0		0		0		0		0		0		0		0	
		Normal	0		106	(87.6)	7	(5.8)	113	(93.4)	0		33	(89.2)	2	(5.4)	35	(94.6)	0		139	(88.0)	9	(5.7)	148	(93.7)
		High	0		6	(5.0)	2	(1.7)	8	(6.6)	0		0		2	(5.4)	2	(5.4)	0		6	(3.8)	4	(2.5)	10	(6.3)
		Total	0		112	(92.6)	9	(7.4)	121	(100.0)	0		33	(89.2)	4	(10.8)	37	(100.0)	0		145	(91.8)	13	(8.2)	158	(100.0)
	Week 36	Low	0		0		0		0		0		0		0		0		0		0		0		0	
		Normal	0		106	(88.3)	7	(5.8)	113	(94.2)	0		31	(83.8)	3	(8.1)	34	(91.9)	0		137	(87.3)	10	(6.4)	147	(93.6)
		High	0		5	(4.2)	2	(1.7)	7	(5.8)	0		2	(5.4)	1	(2.7)	3	(8.1)	0		7	(4.5)	3	(1.9)	10	(6.4)
		Total	0		111	(92.5)	9	(7.5)	120	(100.0)	0		33	(89.2)	4	(10.8)	37	(100.0)	0		144	(91.7)	13	(8.3)	157	(100.0)
	Week 52	Low	0		0		0		0		0		0		0		0		0		0		0		0	
		Normal	0		107	(89.9)	5	(4.2)	112	(94.1)	0		32	(86.5)	3	(8.1)	35	(94.6)	0		139	(89.1)	8	(5.1)	147	(94.2)
		High	0		3	(2.5)	4	(3.4)	7	(5.9)	0		1	(2.7)	1	(2.7)	2	(5.4)	0		4	(2.6)	5	(3.2)	9	(5.8)
		Total	0		110	(92.4)	9	(7.6)	119	(100.0)	0		33	(89.2)	4	(10.8)	37	(100.0)	0		143	(91.7)	13	(8.3)	156	(100.0)
Eosinophils /Leukocytes	Week 2	Low	0		0		0		0		0		0		0		0		0		0		0		0	
		Normal	0		121	(96.0)	1	(0.8)	122	(96.8)	0		36	(94.7)	0		36	(94.7)	0		157	(95.7)	1	(0.6)	158	(96.3)
		High	0		1	(0.8)	3	(2.4)	4	(3.2)	0		1	(2.6)	1	(2.6)	2	(5.3)	0		2	(1.2)	4	(2.4)	6	(3.7)
		Total	0		122	(96.8)	4	(3.2)	126	(100.0)	0		37	(97.4)	1	(2.6)	38	(100.0)	0		159	(97.0)	5	(3.0)	164	(100.0)
	Week 12	Low	0		0		0		0		0		0		0		0		0		0		0		0	
		Normal	0		119	(97.5)	2	(1.6)	121	(99.2)	0		38	(95.0)	0		38	(95.0)	0		157	(96.9)	2	(1.2)	159	(98.1)
		High	0		0		1	(0.8)	1	(0.8)	0		1	(2.5)	1	(2.5)	2	(5.0)	0		1	(0.6)	2	(1.2)	3	(1.9)
		Total	0		119	(97.5)	3	(2.5)	122	(100.0)	0		39	(97.5)	1	(2.5)	40	(100.0)	0		158	(97.5)	4	(2.5)	162	(100.0)
	Week 24	Low	0		0		0		0		0		0		0		0		0		0		0		0	
		Normal	0		117	(96.7)	3	(2.5)	120	(99.2)	0		35	(94.6)	0		35	(94.6)	0		152	(96.2)	3	(1.9)	155	(98.1)
		High	0		1	(0.8)	0		1	(0.8)	0		1	(2.7)	1	(2.7)	2	(5.4)	0		2	(1.3)	1	(0.6)	3	(1.9)
		Total	0		118	(97.5)	3	(2.5)	121	(100.0)	0		36	(97.3)	1	(2.7)	37	(100.0)	0		154	(97.5)	4	(2.5)	158	(100.0)
	Week 36	Low	0		0		0		0		0		0		0		0		0		0		0		0	
		Normal	0		115	(95.8)	3	(2.5)	118	(98.3)	0		35	(94.6)	0		35	(94.6)	0		150	(95.5)	3	(1.9)	153	(97.5)
		High	0		2	(1.7)	0		2	(1.7)	0		1	(2.7)	1	(2.7)	2	(5.4)	0		3	(1.9)	1	(0.6)	4	(2.5)
		Total	0		117	(97.5)	3	(2.5)	120	(100.0)	0		36	(97.3)	1	(2.7)	37	(100.0)	0		153	(97.5)	4	(2.5)	157	(100.0)
	Week 52	Low	0		0		0		0		0		0		0		0		0		0		0		0	
		Normal	0		115	(96.6)	2	(1.7)	117	(98.3)	0		36	(97.3)	0		36	(97.3)	0		151	(96.8)	2	(1.3)	153	(98.1)
		High	0		1	(0.8)	1	(0.8)	2	(1.7)	0		0		1	(2.7)	1	(2.7)	0		1	(0.6)	2	(1.3)	3	(1.9)
		Total	0		116	(97.5)	3	(2.5)	119	(100.0)	0		36	(97.3)	1	(2.7)	37	(100.0)	0		152	(97.4)	4	(2.6)	156	(100.0)

Paramaters	Time point	Baseline[a]	Knee N=126								Execpt for knee N=40								Total N=166							
			Low		Normal		High		Total		Low		Normal		High		Total		Low		Normal		High		Total	
			n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]
Basophils /Leukocytes	Week 2	Low	0		0		0		0		0		0		0		0		0		0		0		0	
		Normal	0		125	(99.2)	1	(0.8)	126	(100.0)	0		38	(100.0)	0		38	(100.0)	0		163	(99.4)	1	(0.6)	164	(100.0)
		High	0		0		0		0		0		0		0		0		0		0		0		0	
		Total	0		125	(99.2)	1	(0.8)	126	(100.0)	0		38	(100.0)	0		38	(100.0)	0		163	(99.4)	1	(0.6)	164	(100.0)
	Week 12	Low	0		0		0		0		0		0		0		0		0		0		0		0	
		Normal	0		121	(99.2)	1	(0.8)	122	(100.0)	0		40	(100.0)	0		40	(100.0)	0		161	(99.4)	1	(0.6)	162	(100.0)
		High	0		0		0		0		0		0		0		0		0		0		0		0	
		Total	0		121	(99.2)	1	(0.8)	122	(100.0)	0		40	(100.0)	0		40	(100.0)	0		161	(99.4)	1	(0.6)	162	(100.0)
	Week 24	Low	0		0		0		0		0		0		0		0		0		0		0		0	
		Normal	0		120	(99.2)	1	(0.8)	121	(100.0)	0		37	(100.0)	0		37	(100.0)	0		157	(99.4)	1	(0.6)	158	(100.0)
		High	0		0		0		0		0		0		0		0		0		0		0		0	
		Total	0		120	(99.2)	1	(0.8)	121	(100.0)	0		37	(100.0)	0		37	(100.0)	0		157	(99.4)	1	(0.6)	158	(100.0)
	Week 36	Low	0		0		0		0		0		0		0		0		0		0		0		0	
		Normal	0		118	(98.3)	1	(0.8)	119	(99.2)	0		37	(100.0)	0		37	(100.0)	0		155	(98.7)	1	(0.6)	156	(99.4)
		High	0		1	(0.8)	0		1	(0.8)	0		0		0		0		0		1	(0.6)	0		1	(0.6)
		Total	0		119	(99.2)	1	(0.8)	120	(100.0)	0		37	(100.0)	0		37	(100.0)	0		156	(99.4)	1	(0.6)	157	(100.0)
	Week 52	Low	0		0		0		0		0		0		0		0		0		0		0		0	
		Normal	0		118	(99.2)	1	(0.8)	119	(100.0)	0		37	(100.0)	0		37	(100.0)	0		155	(99.4)	1	(0.6)	156	(100.0)
		High	0		0		0		0		0		0		0		0		0		0		0		0	
		Total	0		118	(99.2)	1	(0.8)	119	(100.0)	0		37	(100.0)	0		37	(100.0)	0		155	(99.4)	1	(0.6)	156	(100.0)
Erythrocytes	Week 2	Low	21	(16.7)	12	(9.5)	0		33	(26.2)	3	(7.9)	1	(2.6)	0		4	(10.5)	24	(14.6)	13	(7.9)	0		37	(22.6)
		Normal	0		91	(72.2)	1	(0.8)	92	(73.0)	1	(2.6)	33	(86.8)	0		34	(89.5)	1	(0.6)	124	(75.6)	1	(0.6)	126	(76.8)
		High	0		1	(0.8)	0		1	(0.8)	0		0		0		0		0		1	(0.6)	0		1	(0.6)
		Total	21	(16.7)	104	(82.5)	1	(0.8)	126	(100.0)	4	(10.5)	34	(89.5)	0		38	(100.0)	25	(15.2)	138	(84.1)	1	(0.6)	164	(100.0)
	Week 12	Low	18	(14.8)	6	(4.9)	0		24	(19.7)	6	(15.0)	1	(2.5)	0		7	(17.5)	24	(14.8)	7	(4.3)	0		31	(19.1)
		Normal	3	(2.5)	94	(77.0)	1	(0.8)	98	(80.3)	0		33	(82.5)	0		33	(82.5)	3	(1.9)	127	(78.4)	1	(0.6)	131	(80.9)
		High	0		0		0		0		0		0		0		0		0		0		0		0	
		Total	21	(17.2)	100	(82.0)	1	(0.8)	122	(100.0)	6	(15.0)	34	(85.0)	0		40	(100.0)	27	(16.7)	134	(82.7)	1	(0.6)	162	(100.0)
	Week 24	Low	18	(14.9)	7	(5.8)	0		25	(20.7)	6	(16.2)	2	(5.4)	0		8	(21.6)	24	(15.2)	9	(5.7)	0		33	(20.9)
		Normal	3	(2.5)	91	(75.2)	0		94	(77.7)	0		29	(78.4)	0		29	(78.4)	3	(1.9)	120	(75.9)	0		123	(77.8)
		High	0		1	(0.8)	1	(0.8)	2	(1.7)	0		0		0		0		0		1	(0.6)	1	(0.6)	2	(1.3)
		Total	21	(17.4)	99	(81.8)	1	(0.8)	121	(100.0)	6	(16.2)	31	(83.8)	0		37	(100.0)	27	(17.1)	130	(82.3)	1	(0.6)	158	(100.0)
	Week 36	Low	17	(14.2)	6	(5.0)	0		23	(19.2)	4	(10.8)	2	(5.4)	0		6	(16.2)	21	(13.4)	8	(5.1)	0		29	(18.5)
		Normal	4	(3.3)	92	(76.7)	0		96	(80.0)	2	(5.4)	28	(75.7)	0		30	(81.1)	6	(3.8)	120	(76.4)	0		126	(80.3)

Paramaters	Time point	Baseline[a]	Knee N=126								Execpt for knee N=40								Total N=166							
			Low		Normal		High		Total		Low		Normal		High		Total		Low		Normal		High		Total	
			n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]
		High	0		0		1	(0.8)	1	(0.8)	0		1	(2.7)	0		1	(2.7)	0		1	(0.6)	1	(0.6)	2	(1.3)
		Total	21	(17.5)	98	(81.7)	1	(0.8)	120	(100.0)	6	(16.2)	31	(83.8)	0		37	(100.0)	27	(17.2)	129	(82.2)	1	(0.6)	157	(100.0)
	Week 52	Low	17	(14.3)	10	(8.4)	0		27	(22.7)	6	(16.2)	2	(5.4)	0		8	(21.6)	23	(14.7)	12	(7.7)	0		35	(22.4)
		Normal	4	(3.4)	87	(73.1)	1	(0.8)	92	(77.3)	0		29	(78.4)	0		29	(78.4)	4	(2.6)	116	(74.4)	1	(0.6)	121	(77.6)
		High	0		0		0		0		0		0		0		0		0		0		0		0	
		Total	21	(17.6)	97	(81.5)	1	(0.8)	119	(100.0)	6	(16.2)	31	(83.8)	0		37	(100.0)	27	(17.3)	128	(82.1)	1	(0.6)	156	(100.0)
Hemoglobin	Week 2	Low	10	(7.9)	5	(4.0)	0		15	(11.9)	5	(12.5)	4	(10.0)	0		9	(22.5)	15	(9.0)	9	(5.4)	0		24	(14.5)
		Normal	4	(3.2)	104	(82.5)	3	(2.4)	111	(88.1)	0		30	(75.0)	1	(2.5)	31	(77.5)	4	(2.4)	134	(80.7)	4	(2.4)	142	(85.5)
		High	0		0		0		0		0		0		0		0		0		0		0		0	
		Total	14	(11.1)	109	(86.5)	3	(2.4)	126	(100.0)	5	(12.5)	34	(85.0)	1	(2.5)	40	(100.0)	19	(11.4)	143	(86.1)	4	(2.4)	166	(100.0)
	Week 12	Low	8	(6.6)	6	(4.9)	0		14	(11.5)	5	(12.5)	3	(7.5)	0		8	(20.0)	13	(8.0)	9	(5.6)	0		22	(13.6)
		Normal	5	(4.1)	99	(81.1)	3	(2.5)	107	(87.7)	0		31	(77.5)	0		31	(77.5)	5	(3.1)	130	(80.2)	3	(1.9)	138	(85.2)
		High	0		1	(0.8)	0		1	(0.8)	0		0		1	(2.5)	1	(2.5)	0		1	(0.6)	1	(0.6)	2	(1.2)
		Total	13	(10.7)	106	(86.9)	3	(2.5)	122	(100.0)	5	(12.5)	34	(85.0)	1	(2.5)	40	(100.0)	18	(11.1)	140	(86.4)	4	(2.5)	162	(100.0)
	Week 24	Low	8	(6.6)	4	(3.3)	0		12	(9.9)	4	(10.8)	2	(5.4)	0		6	(16.2)	12	(7.6)	6	(3.8)	0		18	(11.4)
		Normal	5	(4.1)	99	(81.8)	2	(1.7)	106	(87.6)	1	(2.7)	29	(78.4)	0		30	(81.1)	6	(3.8)	128	(81.0)	2	(1.3)	136	(86.1)
		High	0		2	(1.7)	1	(0.8)	3	(2.5)	0		0		1	(2.7)	1	(2.7)	0		2	(1.3)	2	(1.3)	4	(2.5)
		Total	13	(10.7)	105	(86.8)	3	(2.5)	121	(100.0)	5	(13.5)	31	(83.8)	1	(2.7)	37	(100.0)	18	(11.4)	136	(86.1)	4	(2.5)	158	(100.0)
	Week 36	Low	6	(5.0)	4	(3.3)	0		10	(8.3)	4	(10.8)	3	(8.1)	0		7	(18.9)	10	(6.4)	7	(4.5)	0		17	(10.8)
		Normal	7	(5.8)	99	(82.5)	2	(1.7)	108	(90.0)	1	(2.7)	28	(75.7)	0		29	(78.4)	8	(5.1)	127	(80.9)	2	(1.3)	137	(87.3)
		High	0		1	(0.8)	1	(0.8)	2	(1.7)	0		0		1	(2.7)	1	(2.7)	0		1	(0.6)	2	(1.3)	3	(1.9)
		Total	13	(10.8)	104	(86.7)	3	(2.5)	120	(100.0)	5	(13.5)	31	(83.8)	1	(2.7)	37	(100.0)	18	(11.5)	135	(86.0)	4	(2.5)	157	(100.0)
	Week 52	Low	7	(5.9)	5	(4.2)	0		12	(10.1)	5	(13.5)	2	(5.4)	0		7	(18.9)	12	(7.7)	7	(4.5)	0		19	(12.2)
		Normal	6	(5.0)	96	(80.7)	3	(2.5)	105	(88.2)	0		29	(78.4)	1	(2.7)	30	(81.1)	6	(3.8)	125	(80.1)	4	(2.6)	135	(86.5)
		High	0		2	(1.7)	0		2	(1.7)	0		0		0		0		0		2	(1.3)	0		2	(1.3)
		Total	13	(10.9)	103	(86.6)	3	(2.5)	119	(100.0)	5	(13.5)	31	(83.8)	1	(2.7)	37	(100.0)	18	(11.5)	134	(85.9)	4	(2.6)	156	(100.0)
Hematocrit	Week 2	Low	9	(7.1)	7	(5.6)	0		16	(12.7)	3	(7.9)	4	(10.5)	0		7	(18.4)	12	(7.3)	11	(6.7)	0		23	(14.0)
		Normal	4	(3.2)	104	(82.5)	2	(1.6)	110	(87.3)	0		30	(78.9)	1	(2.6)	31	(81.6)	4	(2.4)	134	(81.7)	3	(1.8)	141	(86.0)
		High	0		0		0		0		0		0		0		0		0		0		0		0	
		Total	13	(10.3)	111	(88.1)	2	(1.6)	126	(100.0)	3	(7.9)	34	(89.5)	1	(2.6)	38	(100.0)	16	(9.8)	145	(88.4)	3	(1.8)	164	(100.0)
	Week 12	Low	9	(7.4)	7	(5.7)	0		16	(13.1)	4	(10.0)	4	(10.0)	0		8	(20.0)	13	(8.0)	11	(6.8)	0		24	(14.8)
		Normal	4	(3.3)	99	(81.1)	2	(1.6)	105	(86.1)	0		31	(77.5)	0		31	(77.5)	4	(2.5)	130	(80.2)	2	(1.2)	136	(84.0)
		High	0		1	(0.8)	0		1	(0.8)	0		0		1	(2.5)	1	(2.5)	0		1	(0.6)	1	(0.6)	2	(1.2)
		Total	13	(10.7)	107	(87.7)	2	(1.6)	122	(100.0)	4	(10.0)	35	(87.5)	1	(2.5)	40	(100.0)	17	(10.5)	142	(87.7)	3	(1.9)	162	(100.0)

Paramaters	Time point	Baseline[a]	Knee N=126								Execpt for knee N=40								Total N=166							
			Low		Normal		High		Total		Low		Normal		High		Total		Low		Normal		High		Total	
			n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]
	Week 24	Low	9	(7.4)	7	(5.8)	0		16	(13.2)	4	(10.8)	3	(8.1)	0		7	(18.9)	13	(8.2)	10	(6.3)	0		23	(14.6)
		Normal	4	(3.3)	98	(81.0)	1	(0.8)	103	(85.1)	0		29	(78.4)	0		29	(78.4)	4	(2.5)	127	(80.4)	1	(0.6)	132	(83.5)
		High	0		1	(0.8)	1	(0.8)	2	(1.7)	0		0		1	(2.7)	1	(2.7)	0		1	(0.6)	2	(1.3)	3	(1.9)
		Total	13	(10.7)	106	(87.6)	2	(1.7)	121	(100.0)	4	(10.8)	32	(86.5)	1	(2.7)	37	(100.0)	17	(10.8)	138	(87.3)	3	(1.9)	158	(100.0)
	Week 36	Low	8	(6.7)	3	(2.5)	0		11	(9.2)	4	(10.8)	2	(5.4)	0		6	(16.2)	12	(7.6)	5	(3.2)	0		17	(10.8)
		Normal	5	(4.2)	101	(84.2)	2	(1.7)	108	(90.0)	0		30	(81.1)	0		30	(81.1)	5	(3.2)	131	(83.4)	2	(1.3)	138	(87.9)
		High	0		1	(0.8)	0		1	(0.8)	0		0		1	(2.7)	1	(2.7)	0		1	(0.6)	1	(0.6)	2	(1.3)
		Total	13	(10.8)	105	(87.5)	2	(1.7)	120	(100.0)	4	(10.8)	32	(86.5)	1	(2.7)	37	(100.0)	17	(10.8)	137	(87.3)	3	(1.9)	157	(100.0)
	Week 52	Low	10	(8.4)	9	(7.6)	0		19	(16.0)	4	(10.8)	3	(8.1)	0		7	(18.9)	14	(9.0)	12	(7.7)	0		26	(16.7)
		Normal	3	(2.5)	94	(79.0)	2	(1.7)	99	(83.2)	0		29	(78.4)	1	(2.7)	30	(81.1)	3	(1.9)	123	(78.8)	3	(1.9)	129	(82.7)
		High	0		1	(0.8)	0		1	(0.8)	0		0		0		0		0		1	(0.6)	0		1	(0.6)
		Total	13	(10.9)	104	(87.4)	2	(1.7)	119	(100.0)	4	(10.8)	32	(86.5)	1	(2.7)	37	(100.0)	17	(10.9)	136	(87.2)	3	(1.9)	156	(100.0)
Platelets	Week 2	Low	4	(3.2)	1	(0.8)	0		5	(4.0)	0		0		0		0		4	(2.4)	1	(0.6)	0		5	(3.0)
		Normal	0		110	(87.3)	5	(4.0)	115	(91.3)	1	(2.6)	31	(81.6)	2	(5.3)	34	(89.5)	1	(0.6)	141	(86.0)	7	(4.3)	149	(90.9)
		High	0		1	(0.8)	5	(4.0)	6	(4.8)	0		1	(2.6)	3	(7.9)	4	(10.5)	0		2	(1.2)	8	(4.9)	10	(6.1)
		Total	4	(3.2)	112	(88.9)	10	(7.9)	126	(100.0)	1	(2.6)	32	(84.2)	5	(13.2)	38	(100.0)	5	(3.0)	144	(87.8)	15	(9.1)	164	(100.0)
	Week 12	Low	4	(3.3)	1	(0.8)	0		5	(4.1)	0		0		0		0		4	(2.5)	1	(0.6)	0		5	(3.1)
		Normal	0		107	(87.7)	2	(1.6)	109	(89.3)	1	(2.5)	33	(82.5)	1	(2.5)	35	(87.5)	1	(0.6)	140	(86.4)	3	(1.9)	144	(88.9)
		High	0		0		8	(6.6)	8	(6.6)	0		1	(2.5)	4	(10.0)	5	(12.5)	0		1	(0.6)	12	(7.4)	13	(8.0)
		Total	4	(3.3)	108	(88.5)	10	(8.2)	122	(100.0)	1	(2.5)	34	(85.0)	5	(12.5)	40	(100.0)	5	(3.1)	142	(87.7)	15	(9.3)	162	(100.0)
	Week 24	Low	2	(1.7)	1	(0.8)	0		3	(2.5)	0		0		0		0		2	(1.3)	1	(0.6)	0		3	(1.9)
		Normal	2	(1.7)	106	(87.6)	4	(3.3)	112	(92.6)	0		30	(85.7)	2	(5.7)	32	(91.4)	2	(1.3)	136	(87.2)	6	(3.8)	144	(92.3)
		High	0		0		6	(5.0)	6	(5.0)	0		1	(2.9)	2	(5.7)	3	(8.6)	0		1	(0.6)	8	(5.1)	9	(5.8)
		Total	4	(3.3)	107	(88.4)	10	(8.3)	121	(100.0)	0		31	(88.6)	4	(11.4)	35	(100.0)	4	(2.6)	138	(88.5)	14	(9.0)	156	(100.0)
	Week 36	Low	2	(1.7)	2	(1.7)	0		4	(3.3)	0		0		0		0		2	(1.3)	2	(1.3)	0		4	(2.5)
		Normal	1	(0.8)	104	(86.7)	3	(2.5)	108	(90.0)	1	(2.7)	31	(83.8)	2	(5.4)	34	(91.9)	2	(1.3)	135	(86.0)	5	(3.2)	142	(90.4)
		High	0		1	(0.8)	7	(5.8)	8	(6.7)	0		1	(2.7)	2	(5.4)	3	(8.1)	0		2	(1.3)	9	(5.7)	11	(7.0)
		Total	3	(2.5)	107	(89.2)	10	(8.3)	120	(100.0)	1	(2.7)	32	(86.5)	4	(10.8)	37	(100.0)	4	(2.5)	139	(88.5)	14	(8.9)	157	(100.0)
	Week 52	Low	2	(1.7)	1	(0.8)	0		3	(2.5)	0		0		0		0		2	(1.3)	1	(0.6)	0		3	(1.9)
		Normal	2	(1.7)	102	(85.7)	5	(4.2)	109	(91.6)	1	(2.7)	30	(81.1)	2	(5.4)	33	(89.2)	3	(1.9)	132	(84.6)	7	(4.5)	142	(91.0)
		High	0		3	(2.5)	4	(3.4)	7	(5.9)	0		2	(5.4)	2	(5.4)	4	(10.8)	0		5	(3.2)	6	(3.8)	11	(7.1)
		Total	4	(3.4)	106	(89.1)	9	(7.6)	119	(100.0)	1	(2.7)	32	(86.5)	4	(10.8)	37	(100.0)	5	(3.2)	138	(88.5)	13	(8.3)	156	(100.0)
Protein	Week 2	Low	10	(7.9)	18	(14.3)	0		28	(22.2)	3	(7.7)	6	(15.4)	0		9	(23.1)	13	(7.9)	24	(14.5)	0		37	(22.4)
		Normal	4	(3.2)	94	(74.6)	0		98	(77.8)	2	(5.1)	28	(71.8)	0		30	(76.9)	6	(3.6)	122	(73.9)	0		128	(77.6)

Paramaters	Time point	Baseline[a]	Knee N=126							Execpt for knee N=40							Total N=166							
			Low		Normal		High		Total		Low		Normal		High		Total		Low		Normal		High		Total	
			n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]
		High	0		0		0		0		0		0		0		0		0		0		0		0	
		Total	14	(11.1)	112	(88.9)	0		126	(100.0)	5	(12.8)	34	(87.2)	0		39	(100.0)	19	(11.5)	146	(88.5)	0		165	(100.0)
	Week 12	Low	8	(6.6)	11	(9.0)	0		19	(15.6)	0		1	(2.6)	0		1	(2.6)	8	(5.0)	12	(7.5)	0		20	(12.4)
		Normal	5	(4.1)	98	(80.3)	0		103	(84.4)	5	(12.8)	33	(84.6)	0		38	(97.4)	10	(6.2)	131	(81.4)	0		141	(87.6)
		High	0		0		0		0		0		0		0		0		0		0		0		0	
		Total	13	(10.7)	109	(89.3)	0		122	(100.0)	5	(12.8)	34	(87.2)	0		39	(100.0)	18	(11.2)	143	(88.8)	0		161	(100.0)
	Week 24	Low	8	(6.6)	13	(10.7)	0		21	(17.4)	0		3	(8.3)	0		3	(8.3)	8	(5.1)	16	(10.2)	0		24	(15.3)
		Normal	5	(4.1)	95	(78.5)	0		100	(82.6)	5	(13.9)	28	(77.8)	0		33	(91.7)	10	(6.4)	123	(78.3)	0		133	(84.7)
		High	0		0		0		0		0		0		0		0		0		0		0		0	
		Total	13	(10.7)	108	(89.3)	0		121	(100.0)	5	(13.9)	31	(86.1)	0		36	(100.0)	18	(11.5)	139	(88.5)	0		157	(100.0)
	Week 36	Low	6	(5.0)	12	(10.0)	0		18	(15.0)	0		2	(5.6)	0		2	(5.6)	6	(3.8)	14	(9.0)	0		20	(12.8)
		Normal	7	(5.8)	95	(79.2)	0		102	(85.0)	5	(13.9)	29	(80.6)	0		34	(94.4)	12	(7.7)	124	(79.5)	0		136	(87.2)
		High	0		0		0		0		0		0		0		0		0		0		0		0	
		Total	13	(10.8)	107	(89.2)	0		120	(100.0)	5	(13.9)	31	(86.1)	0		36	(100.0)	18	(11.5)	138	(88.5)	0		156	(100.0)
	Week 52	Low	7	(5.8)	14	(11.7)	0		21	(17.5)	3	(8.3)	2	(5.6)	0		5	(13.9)	10	(6.4)	16	(10.3)	0		26	(16.7)
		Normal	6	(5.0)	93	(77.5)	0		99	(82.5)	2	(5.6)	29	(80.6)	0		31	(86.1)	8	(5.1)	122	(78.2)	0		130	(83.3)
		High	0		0		0		0		0		0		0		0		0		0		0		0	
		Total	13	(10.8)	107	(89.2)	0		120	(100.0)	5	(13.9)	31	(86.1)	0		36	(100.0)	18	(11.5)	138	(88.5)	0		156	(100.0)
Albumin	Week 2	Low	2	(1.6)	5	(4.0)	0		7	(5.6)	3	(7.7)	2	(5.1)	0		5	(12.8)	5	(3.0)	7	(4.2)	0		12	(7.3)
		Normal	5	(4.0)	114	(90.5)	0		119	(94.4)	0		34	(87.2)	0		34	(87.2)	5	(3.0)	148	(89.7)	0		153	(92.7)
		High	0		0		0		0		0		0		0		0		0		0		0		0	
		Total	7	(5.6)	119	(94.4)	0		126	(100.0)	3	(7.7)	36	(92.3)	0		39	(100.0)	10	(6.1)	155	(93.9)	0		165	(100.0)
	Week 12	Low	4	(3.3)	3	(2.5)	0		7	(5.7)	1	(2.6)	2	(5.1)	0		3	(7.7)	5	(3.1)	5	(3.1)	0		10	(6.2)
		Normal	2	(1.6)	113	(92.6)	0		115	(94.3)	2	(5.1)	34	(87.2)	0		36	(92.3)	4	(2.5)	147	(91.3)	0		151	(93.8)
		High	0		0		0		0		0		0		0		0		0		0		0		0	
		Total	6	(4.9)	116	(95.1)	0		122	(100.0)	3	(7.7)	36	(92.3)	0		39	(100.0)	9	(5.6)	152	(94.4)	0		161	(100.0)
	Week 24	Low	2	(1.7)	3	(2.5)	0		5	(4.1)	2	(5.6)	1	(2.8)	0		3	(8.3)	4	(2.5)	4	(2.5)	0		8	(5.1)
		Normal	4	(3.3)	112	(92.6)	0		116	(95.9)	1	(2.8)	32	(88.9)	0		33	(91.7)	5	(3.2)	144	(91.7)	0		149	(94.9)
		High	0		0		0		0		0		0		0		0		0		0		0		0	
		Total	6	(5.0)	115	(95.0)	0		121	(100.0)	3	(8.3)	33	(91.7)	0		36	(100.0)	9	(5.7)	148	(94.3)	0		157	(100.0)
	Week 36	Low	3	(2.5)	4	(3.3)	0		7	(5.8)	2	(5.6)	1	(2.8)	0		3	(8.3)	5	(3.2)	5	(3.2)	0		10	(6.4)
		Normal	3	(2.5)	110	(91.7)	0		113	(94.2)	1	(2.8)	32	(88.9)	0		33	(91.7)	4	(2.6)	142	(91.0)	0		146	(93.6)
		High	0		0		0		0		0		0		0		0		0		0		0		0	
		Total	6	(5.0)	114	(95.0)	0		120	(100.0)	3	(8.3)	33	(91.7)	0		36	(100.0)	9	(5.8)	147	(94.2)	0		156	(100.0)

Paramaters	Time point	Baseline[a]	Knee N=126								Execpt for knee N=40								Total N=166							
			Low		Normal		High		Total		Low		Normal		High		Total		Low		Normal		High		Total	
			n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]
	Week 52	Low	2	(1.7)	5	(4.2)	0		7	(5.8)	2	(5.6)	2	(5.6)	0		4	(11.1)	4	(2.6)	7	(4.5)	0		11	(7.1)
		Normal	4	(3.3)	109	(90.8)	0		113	(94.2)	1	(2.8)	31	(86.1)	0		32	(88.9)	5	(3.2)	140	(89.7)	0		145	(92.9)
		High	0		0		0		0		0		0		0		0		0		0		0		0	
		Total	6	(5.0)	114	(95.0)	0		120	(100.0)	3	(8.3)	33	(91.7)	0		36	(100.0)	9	(5.8)	147	(94.2)	0		156	(100.0)
Bilirubin	Week 2	Low	0		0		0		0		0		0		0		0		0		0		0		0	
		Normal	0		117	(92.9)	3	(2.4)	120	(95.2)	0		38	(97.4)	0		38	(97.4)	0		155	(93.9)	3	(1.8)	158	(95.8)
		High	0		3	(2.4)	3	(2.4)	6	(4.8)	0		0		1	(2.6)	1	(2.6)	0		3	(1.8)	4	(2.4)	7	(4.2)
		Total	0		120	(95.2)	6	(4.8)	126	(100.0)	0		38	(97.4)	1	(2.6)	39	(100.0)	0		158	(95.8)	7	(4.2)	165	(100.0)
	Week 12	Low	0		0		0		0		0		0		0		0		0		0		0		0	
		Normal	0		114	(93.4)	3	(2.5)	117	(95.9)	0		37	(94.9)	1	(2.6)	38	(97.4)	0		151	(93.8)	4	(2.5)	155	(96.3)
		High	0		2	(1.6)	3	(2.5)	5	(4.1)	0		1	(2.6)	0		1	(2.6)	0		3	(1.9)	3	(1.9)	6	(3.7)
		Total	0		116	(95.1)	6	(4.9)	122	(100.0)	0		38	(97.4)	1	(2.6)	39	(100.0)	0		154	(95.7)	7	(4.3)	161	(100.0)
	Week 24	Low	0		0		0		0		0		0		0		0		0		0		0		0	
		Normal	0		112	(92.6)	3	(2.5)	115	(95.0)	0		35	(97.2)	1	(2.8)	36	(100.0)	0		147	(93.6)	4	(2.5)	151	(96.2)
		High	0		3	(2.5)	3	(2.5)	6	(5.0)	0		0		0		0		0		3	(1.9)	3	(1.9)	6	(3.8)
		Total	0		115	(95.0)	6	(5.0)	121	(100.0)	0		35	(97.2)	1	(2.8)	36	(100.0)	0		150	(95.5)	7	(4.5)	157	(100.0)
	Week 36	Low	0		0		0		0		0		0		0		0		0		0		0		0	
		Normal	0		113	(94.2)	5	(4.2)	118	(98.3)	0		35	(97.2)	1	(2.8)	36	(100.0)	0		148	(94.9)	6	(3.8)	154	(98.7)
		High	0		1	(0.8)	1	(0.8)	2	(1.7)	0		0		0		0		0		1	(0.6)	1	(0.6)	2	(1.3)
		Total	0		114	(95.0)	6	(5.0)	120	(100.0)	0		35	(97.2)	1	(2.8)	36	(100.0)	0		149	(95.5)	7	(4.5)	156	(100.0)
	Week 52	Low	0		0		0		0		0		0		0		0		0		0		0		0	
		Normal	0		113	(94.2)	4	(3.3)	117	(97.5)	0		34	(94.4)	1	(2.8)	35	(97.2)	0		147	(94.2)	5	(3.2)	152	(97.4)
		High	0		1	(0.8)	2	(1.7)	3	(2.5)	0		1	(2.8)	0		1	(2.8)	0		2	(1.3)	2	(1.3)	4	(2.6)
		Total	0		114	(95.0)	6	(5.0)	120	(100.0)	0		35	(97.2)	1	(2.8)	36	(100.0)	0		149	(95.5)	7	(4.5)	156	(100.0)
Direct Bilirubin	Week 2	Low	0		0		0		0		0		0		0		0		0		0		0		0	
		Normal	0		126	(100.0)	0		126	(100.0)	0		39	(100.0)	0		39	(100.0)	0		165	(100.0)	0		165	(100.0)
		High	0		0		0		0		0		0		0		0		0		0		0		0	
		Total	0		126	(100.0)	0		126	(100.0)	0		39	(100.0)	0		39	(100.0)	0		165	(100.0)	0		165	(100.0)
	Week 12	Low	0		0		0		0		0		0		0		0		0		0		0		0	
		Normal	0		121	(99.2)	0		121	(99.2)	0		39	(100.0)	0		39	(100.0)	0		160	(99.4)	0		160	(99.4)
		High	0		1	(0.8)	0		1	(0.8)	0		0		0		0		0		1	(0.6)	0		1	(0.6)
		Total	0		122	(100.0)	0		122	(100.0)	0		39	(100.0)	0		39	(100.0)	0		161	(100.0)	0		161	(100.0)
	Week 24	Low	0		0		0		0		0		0		0		0		0		0		0		0	
		Normal	0		121	(100.0)	0		121	(100.0)	0		36	(100.0)	0		36	(100.0)	0		157	(100.0)	0		157	(100.0)

Paramaters	Time point	Baseline[a]	Knee N=126								Execpt for knee N=40								Total N=166							
			Low		Normal		High		Total		Low		Normal		High		Total		Low		Normal		High		Total	
			n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]
		High	0		0		0		0		0		0		0		0		0		0		0		0	
		Total	0		121	(100.0)	0		121	(100.0)	0		36	(100.0)	0		36	(100.0)	0		157	(100.0)	0		157	(100.0)
	Week 36	Low	0		0		0		0		0		0		0		0		0		0		0		0	
		Normal	0		120	(100.0)	0		120	(100.0)	0		36	(100.0)	0		36	(100.0)	0		156	(100.0)	0		156	(100.0)
		High	0		0		0		0		0		0		0		0		0		0		0		0	
		Total	0		120	(100.0)	0		120	(100.0)	0		36	(100.0)	0		36	(100.0)	0		156	(100.0)	0		156	(100.0)
	Week 52	Low	0		0		0		0		0		0		0		0		0		0		0		0	
		Normal	0		120	(100.0)	0		120	(100.0)	0		36	(100.0)	0		36	(100.0)	0		156	(100.0)	0		156	(100.0)
		High	0		0		0		0		0		0		0		0		0		0		0		0	
		Total	0		120	(100.0)	0		120	(100.0)	0		36	(100.0)	0		36	(100.0)	0		156	(100.0)	0		156	(100.0)
Aspartate Aminotransferase	Week 2	Low	0		0		0		0		0		0		0		0		0		0		0		0	
		Normal	0		116	(92.1)	5	(4.0)	121	(96.0)	0		36	(92.3)	1	(2.6)	37	(94.9)	0		152	(92.1)	6	(3.6)	158	(95.8)
		High	0		2	(1.6)	3	(2.4)	5	(4.0)	0		1	(2.6)	1	(2.6)	2	(5.1)	0		3	(1.8)	4	(2.4)	7	(4.2)
		Total	0		118	(93.7)	8	(6.3)	126	(100.0)	0		37	(94.9)	2	(5.1)	39	(100.0)	0		155	(93.9)	10	(6.1)	165	(100.0)
	Week 12	Low	0		0		0		0		0		0		0		0		0		0		0		0	
		Normal	0		111	(91.0)	5	(4.1)	116	(95.1)	0		36	(92.3)	1	(2.6)	37	(94.9)	0		147	(91.3)	6	(3.7)	153	(95.0)
		High	0		3	(2.5)	3	(2.5)	6	(4.9)	0		1	(2.6)	1	(2.6)	2	(5.1)	0		4	(2.5)	4	(2.5)	8	(5.0)
		Total	0		114	(93.4)	8	(6.6)	122	(100.0)	0		37	(94.9)	2	(5.1)	39	(100.0)	0		151	(93.8)	10	(6.2)	161	(100.0)
	Week 24	Low	0		0		0		0		0		0		0		0		0		0		0		0	
		Normal	0		108	(89.3)	4	(3.3)	112	(92.6)	0		33	(91.7)	1	(2.8)	34	(94.4)	0		141	(89.8)	5	(3.2)	146	(93.0)
		High	0		5	(4.1)	4	(3.3)	9	(7.4)	0		1	(2.8)	1	(2.8)	2	(5.6)	0		6	(3.8)	5	(3.2)	11	(7.0)
		Total	0		113	(93.4)	8	(6.6)	121	(100.0)	0		34	(94.4)	2	(5.6)	36	(100.0)	0		147	(93.6)	10	(6.4)	157	(100.0)
	Week 36	Low	0		0		0		0		0		0		0		0		0		0		0		0	
		Normal	0		110	(91.7)	5	(4.2)	115	(95.8)	0		33	(91.7)	1	(2.8)	34	(94.4)	0		143	(91.7)	6	(3.8)	149	(95.5)
		High	0		3	(2.5)	2	(1.7)	5	(4.2)	0		1	(2.8)	1	(2.8)	2	(5.6)	0		4	(2.6)	3	(1.9)	7	(4.5)
		Total	0		113	(94.2)	7	(5.8)	120	(100.0)	0		34	(94.4)	2	(5.6)	36	(100.0)	0		147	(94.2)	9	(5.8)	156	(100.0)
	Week 52	Low	0		0		0		0		0		0		0		0		0		0		0		0	
		Normal	0		110	(91.7)	6	(5.0)	116	(96.7)	0		31	(86.1)	2	(5.6)	33	(91.7)	0		141	(90.4)	8	(5.1)	149	(95.5)
		High	0		2	(1.7)	2	(1.7)	4	(3.3)	0		3	(8.3)	0		3	(8.3)	0		5	(3.2)	2	(1.3)	7	(4.5)
		Total	0		112	(93.3)	8	(6.7)	120	(100.0)	0		34	(94.4)	2	(5.6)	36	(100.0)	0		146	(93.6)	10	(6.4)	156	(100.0)
Alanine Aminotransferase	Week 2	Low	0		0		0		0		0		0		0		0		0		0		0		0	
		Normal	0		112	(88.9)	3	(2.4)	115	(91.3)	0		37	(94.9)	0		37	(94.9)	0		149	(90.3)	3	(1.8)	152	(92.1)
		High	0		3	(2.4)	8	(6.3)	11	(8.7)	0		0		2	(5.1)	2	(5.1)	0		3	(1.8)	10	(6.1)	13	(7.9)
		Total	0		115	(91.3)	11	(8.7)	126	(100.0)	0		37	(94.9)	2	(5.1)	39	(100.0)	0		152	(92.1)	13	(7.9)	165	(100.0)

Paramaters	Time point	Baseline[a]	Knee N=126								Execpt for knee N=40								Total N=166							
			Low		Normal		High		Total		Low		Normal		High		Total		Low		Normal		High		Total	
			n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]
	Week 12	Low	0		0		0		0		0		0		0		0		0		0		0		0	
		Normal	0		107	(87.7)	5	(4.1)	112	(91.8)	0		37	(94.9)	0		37	(94.9)	0		144	(89.4)	5	(3.1)	149	(92.5)
		High	0		4	(3.3)	6	(4.9)	10	(8.2)	0		0		2	(5.1)	2	(5.1)	0		4	(2.5)	8	(5.0)	12	(7.5)
		Total	0		111	(91.0)	11	(9.0)	122	(100.0)	0		37	(94.9)	2	(5.1)	39	(100.0)	0		148	(91.9)	13	(8.1)	161	(100.0)
	Week 24	Low	0		0		0		0		0		0		0		0		0		0		0		0	
		Normal	0		104	(86.0)	3	(2.5)	107	(88.4)	0		34	(94.4)	0		34	(94.4)	0		138	(87.9)	3	(1.9)	141	(89.8)
		High	0		6	(5.0)	8	(6.6)	14	(11.6)	0		0		2	(5.6)	2	(5.6)	0		6	(3.8)	10	(6.4)	16	(10.2)
		Total	0		110	(90.9)	11	(9.1)	121	(100.0)	0		34	(94.4)	2	(5.6)	36	(100.0)	0		144	(91.7)	13	(8.3)	157	(100.0)
	Week 36	Low	0		0		0		0		0		0		0		0		0		0		0		0	
		Normal	0		106	(88.3)	8	(6.7)	114	(95.0)	0		34	(94.4)	0		34	(94.4)	0		140	(89.7)	8	(5.1)	148	(94.9)
		High	0		4	(3.3)	2	(1.7)	6	(5.0)	0		0		2	(5.6)	2	(5.6)	0		4	(2.6)	4	(2.6)	8	(5.1)
		Total	0		110	(91.7)	10	(8.3)	120	(100.0)	0		34	(94.4)	2	(5.6)	36	(100.0)	0		144	(92.3)	12	(7.7)	156	(100.0)
	Week 52	Low	0		0		0		0		0		0		0		0		0		0		0		0	
		Normal	0		106	(88.3)	7	(5.8)	113	(94.2)	0		32	(88.9)	1	(2.8)	33	(91.7)	0		138	(88.5)	8	(5.1)	146	(93.6)
		High	0		3	(2.5)	4	(3.3)	7	(5.8)	0		2	(5.6)	1	(2.8)	3	(8.3)	0		5	(3.2)	5	(3.2)	10	(6.4)
		Total	0		109	(90.8)	11	(9.2)	120	(100.0)	0		34	(94.4)	2	(5.6)	36	(100.0)	0		143	(91.7)	13	(8.3)	156	(100.0)
Lactate Dehydrogenase	Week 2	Low	1	(0.8)	0		0		1	(0.8)	0		1	(2.6)	0		1	(2.6)	1	(0.6)	1	(0.6)	0		2	(1.2)
		Normal	0		113	(89.7)	5	(4.0)	118	(93.7)	0		35	(89.7)	1	(2.6)	36	(92.3)	0		148	(89.7)	6	(3.6)	154	(93.3)
		High	0		1	(0.8)	6	(4.8)	7	(5.6)	0		0		2	(5.1)	2	(5.1)	0		1	(0.6)	8	(4.8)	9	(5.5)
		Total	1	(0.8)	114	(90.5)	11	(8.7)	126	(100.0)	0		36	(92.3)	3	(7.7)	39	(100.0)	1	(0.6)	150	(90.9)	14	(8.5)	165	(100.0)
	Week 12	Low	1	(0.8)	0		0		1	(0.8)	0		0		0		0		1	(0.6)	0		0		1	(0.6)
		Normal	0		103	(84.4)	6	(4.9)	109	(89.3)	0		36	(92.3)	2	(5.1)	38	(97.4)	0		139	(86.3)	8	(5.0)	147	(91.3)
		High	0		7	(5.7)	5	(4.1)	12	(9.8)	0		0		1	(2.6)	1	(2.6)	0		7	(4.3)	6	(3.7)	13	(8.1)
		Total	1	(0.8)	110	(90.2)	11	(9.0)	122	(100.0)	0		36	(92.3)	3	(7.7)	39	(100.0)	1	(0.6)	146	(90.7)	14	(8.7)	161	(100.0)
	Week 24	Low	1	(0.8)	0		0		1	(0.8)	0		0		0		0		1	(0.6)	0		0		1	(0.6)
		Normal	0		104	(86.0)	4	(3.3)	108	(89.3)	0		33	(91.7)	1	(2.8)	34	(94.4)	0		137	(87.3)	5	(3.2)	142	(90.4)
		High	0		5	(4.1)	7	(5.8)	12	(9.9)	0		0		2	(5.6)	2	(5.6)	0		5	(3.2)	9	(5.7)	14	(8.9)
		Total	1	(0.8)	109	(90.1)	11	(9.1)	121	(100.0)	0		33	(91.7)	3	(8.3)	36	(100.0)	1	(0.6)	142	(90.4)	14	(8.9)	157	(100.0)
	Week 36	Low	1	(0.8)	1	(0.8)	0		2	(1.7)	0		1	(2.8)	0		1	(2.8)	1	(0.6)	2	(1.3)	0		3	(1.9)
		Normal	0		103	(85.8)	5	(4.2)	108	(90.0)	0		32	(88.9)	1	(2.8)	33	(91.7)	0		135	(86.5)	6	(3.8)	141	(90.4)
		High	0		5	(4.2)	5	(4.2)	10	(8.3)	0		0		2	(5.6)	2	(5.6)	0		5	(3.2)	7	(4.5)	12	(7.7)
		Total	1	(0.8)	109	(90.8)	10	(8.3)	120	(100.0)	0		33	(91.7)	3	(8.3)	36	(100.0)	1	(0.6)	142	(91.0)	13	(8.3)	156	(100.0)
	Week 52	Low	1	(0.8)	0		0		1	(0.8)	0		0		0		0		1	(0.6)	0		0		1	(0.6)
		Normal	0		102	(85.0)	4	(3.3)	106	(88.3)	0		31	(86.1)	2	(5.6)	33	(91.7)	0		133	(85.3)	6	(3.8)	139	(89.1)

Paramaters	Time point	Baseline[a]	Knee N=126								Execpt for knee N=40								Total N=166							
			Low		Normal		High		Total		Low		Normal		High		Total		Low		Normal		High		Total	
			n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]
		High	0		6	(5.0)	7	(5.8)	13	(10.8)	0		2	(5.6)	1	(2.8)	3	(8.3)	0		8	(5.1)	8	(5.1)	16	(10.3)
		Total	1	(0.8)	108	(90.0)	11	(9.2)	120	(100.0)	0		33	(91.7)	3	(8.3)	36	(100.0)	1	(0.6)	141	(90.4)	14	(9.0)	156	(100.0)
Alkaline Phosphatase	Week 2	Low	1	(0.8)	0		0		1	(0.8)	0		0		0		0		1	(0.6)	0		0		1	(0.6)
		Normal	0		108	(85.7)	6	(4.8)	114	(90.5)	0		33	(84.6)	0		33	(84.6)	0		141	(85.5)	6	(3.6)	147	(89.1)
		High	0		3	(2.4)	8	(6.3)	11	(8.7)	0		4	(10.3)	2	(5.1)	6	(15.4)	0		7	(4.2)	10	(6.1)	17	(10.3)
		Total	1	(0.8)	111	(88.1)	14	(11.1)	126	(100.0)	0		37	(94.9)	2	(5.1)	39	(100.0)	1	(0.6)	148	(89.7)	16	(9.7)	165	(100.0)
	Week 12	Low	1	(0.8)	0		0		1	(0.8)	0		0		0		0		1	(0.6)	0		0		1	(0.6)
		Normal	0		102	(83.6)	6	(4.9)	108	(88.5)	0		36	(92.3)	1	(2.6)	37	(94.9)	0		138	(85.7)	7	(4.3)	145	(90.1)
		High	0		5	(4.1)	8	(6.6)	13	(10.7)	0		1	(2.6)	1	(2.6)	2	(5.1)	0		6	(3.7)	9	(5.6)	15	(9.3)
		Total	1	(0.8)	107	(87.7)	14	(11.5)	122	(100.0)	0		37	(94.9)	2	(5.1)	39	(100.0)	1	(0.6)	144	(89.4)	16	(9.9)	161	(100.0)
	Week 24	Low	1	(0.8)	0		0		1	(0.8)	0		0		0		0		1	(0.6)	0		0		1	(0.6)
		Normal	0		104	(86.0)	6	(5.0)	110	(90.9)	0		34	(94.4)	1	(2.8)	35	(97.2)	0		138	(87.9)	7	(4.5)	145	(92.4)
		High	0		2	(1.7)	8	(6.6)	10	(8.3)	0		1	(2.8)	0		1	(2.8)	0		3	(1.9)	8	(5.1)	11	(7.0)
		Total	1	(0.8)	106	(87.6)	14	(11.6)	121	(100.0)	0		35	(97.2)	1	(2.8)	36	(100.0)	1	(0.6)	141	(89.8)	15	(9.6)	157	(100.0)
	Week 36	Low	1	(0.8)	0		0		1	(0.8)	0		0		0		0		1	(0.6)	0		0		1	(0.6)
		Normal	0		96	(80.0)	5	(4.2)	101	(84.2)	0		31	(86.1)	1	(2.8)	32	(88.9)	0		127	(81.4)	6	(3.8)	133	(85.3)
		High	0		9	(7.5)	9	(7.5)	18	(15.0)	0		4	(11.1)	0		4	(11.1)	0		13	(8.3)	9	(5.8)	22	(14.1)
		Total	1	(0.8)	105	(87.5)	14	(11.7)	120	(100.0)	0		35	(97.2)	1	(2.8)	36	(100.0)	1	(0.6)	140	(89.7)	15	(9.6)	156	(100.0)
	Week 52	Low	1	(0.8)	0		0		1	(0.8)	0		0		0		0		1	(0.6)	0		0		1	(0.6)
		Normal	0		93	(77.5)	7	(5.8)	100	(83.3)	0		34	(94.4)	0		34	(94.4)	0		127	(81.4)	7	(4.5)	134	(85.9)
		High	0		12	(10.0)	7	(5.8)	19	(15.8)	0		1	(2.8)	1	(2.8)	2	(5.6)	0		13	(8.3)	8	(5.1)	21	(13.5)
		Total	1	(0.8)	105	(87.5)	14	(11.7)	120	(100.0)	0		35	(97.2)	1	(2.8)	36	(100.0)	1	(0.6)	140	(89.7)	15	(9.6)	156	(100.0)
Gamma Glutamyl Transferase	Week 2	Low	-		-		-		-		-		-		-		-		-		-		-		-	
		Normal	-		96	(76.2)	3	(2.4)	99	(78.6)	-		32	(82.1)	0		32	(82.1)	-		128	(77.6)	3	(1.8)	131	(79.4)
		High	-		4	(3.2)	23	(18.3)	27	(21.4)	-		2	(5.1)	5	(12.8)	7	(17.9)	-		6	(3.6)	28	(17.0)	34	(20.6)
		Total	-		100	(79.4)	26	(20.6)	126	(100.0)	-		34	(87.2)	5	(12.8)	39	(100.0)	-		134	(81.2)	31	(18.8)	165	(100.0)
	Week 12	Low	-		-		-		-		-		-		-		-		-		-		-		-	
		Normal	-		91	(74.6)	3	(2.5)	94	(77.0)	-		31	(79.5)	0		31	(79.5)	-		122	(75.8)	3	(1.9)	125	(77.6)
		High	-		5	(4.1)	23	(18.9)	28	(23.0)	-		3	(7.7)	5	(12.8)	8	(20.5)	-		8	(5.0)	28	(17.4)	36	(22.4)
		Total	-		96	(78.7)	26	(21.3)	122	(100.0)	-		34	(87.2)	5	(12.8)	39	(100.0)	-		130	(80.7)	31	(19.3)	161	(100.0)
	Week 24	Low	-		-		-		-		-		-		-		-		-		-		-		-	
		Normal	-		88	(72.7)	6	(5.0)	94	(77.7)	-		30	(83.3)	0		30	(83.3)	-		118	(75.2)	6	(3.8)	124	(79.0)
		High	-		7	(5.8)	20	(16.5)	27	(22.3)	-		2	(5.6)	4	(11.1)	6	(16.7)	-		9	(5.7)	24	(15.3)	33	(21.0)
		Total	-		95	(78.5)	26	(21.5)	121	(100.0)	-		32	(88.9)	4	(11.1)	36	(100.0)	-		127	(80.9)	30	(19.1)	157	(100.0)

Paramaters	Time point	Baseline[a]	Knee N=126								Execpt for knee N=40								Total N=166							
			Low		Normal		High		Total		Low		Normal		High		Total		Low		Normal		High		Total	
			n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]
	Week 36	Low	-		-		-		-		-		-		-		-		-		-		-		-	
		Normal	-		87	(72.5)	7	(5.8)	94	(78.3)	-		29	(80.6)	0		29	(80.6)	-		116	(74.4)	7	(4.5)	123	(78.8)
		High	-		8	(6.7)	18	(15.0)	26	(21.7)	-		3	(8.3)	4	(11.1)	7	(19.4)	-		11	(7.1)	22	(14.1)	33	(21.2)
		Total	-		95	(79.2)	25	(20.8)	120	(100.0)	-		32	(88.9)	4	(11.1)	36	(100.0)	-		127	(81.4)	29	(18.6)	156	(100.0)
	Week 52	Low	-		-		-		-		-		-		-		-		-		-		-		-	
		Normal	-		88	(73.3)	8	(6.7)	96	(80.0)	-		29	(80.6)	1	(2.8)	30	(83.3)	-		117	(75.0)	9	(5.8)	126	(80.8)
		High	-		6	(5.0)	18	(15.0)	24	(20.0)	-		3	(8.3)	3	(8.3)	6	(16.7)	-		9	(5.8)	21	(13.5)	30	(19.2)
		Total	-		94	(78.3)	26	(21.7)	120	(100.0)	-		32	(88.9)	4	(11.1)	36	(100.0)	-		126	(80.8)	30	(19.2)	156	(100.0)
Urate	Week 2	Low	2	(1.6)	1	(0.8)	0		3	(2.4)	0		1	(2.6)	0		1	(2.6)	2	(1.2)	2	(1.2)	0		4	(2.4)
		Normal	1	(0.8)	110	(87.3)	2	(1.6)	113	(89.7)	1	(2.6)	34	(87.2)	1	(2.6)	36	(92.3)	2	(1.2)	144	(87.3)	3	(1.8)	149	(90.3)
		High	0		4	(3.2)	6	(4.8)	10	(7.9)	0		0		2	(5.1)	2	(5.1)	0		4	(2.4)	8	(4.8)	12	(7.3)
		Total	3	(2.4)	115	(91.3)	8	(6.3)	126	(100.0)	1	(2.6)	35	(89.7)	3	(7.7)	39	(100.0)	4	(2.4)	150	(90.9)	11	(6.7)	165	(100.0)
	Week 12	Low	2	(1.6)	0		0		2	(1.6)	1	(2.6)	1	(2.6)	0		2	(5.1)	3	(1.9)	1	(0.6)	0		4	(2.5)
		Normal	1	(0.8)	104	(85.2)	3	(2.5)	108	(88.5)	0		34	(87.2)	1	(2.6)	35	(89.7)	1	(0.6)	138	(85.7)	4	(2.5)	143	(88.8)
		High	0		9	(7.4)	3	(2.5)	12	(9.8)	0		0		2	(5.1)	2	(5.1)	0		9	(5.6)	5	(3.1)	14	(8.7)
		Total	3	(2.5)	113	(92.6)	6	(4.9)	122	(100.0)	1	(2.6)	35	(89.7)	3	(7.7)	39	(100.0)	4	(2.5)	148	(91.9)	9	(5.6)	161	(100.0)
	Week 24	Low	3	(2.5)	1	(0.8)	0		4	(3.3)	1	(2.8)	1	(2.8)	0		2	(5.6)	4	(2.5)	2	(1.3)	0		6	(3.8)
		Normal	0		105	(86.8)	2	(1.7)	107	(88.4)	0		30	(83.3)	1	(2.8)	31	(86.1)	0		135	(86.0)	3	(1.9)	138	(87.9)
		High	0		6	(5.0)	4	(3.3)	10	(8.3)	0		1	(2.8)	2	(5.6)	3	(8.3)	0		7	(4.5)	6	(3.8)	13	(8.3)
		Total	3	(2.5)	112	(92.6)	6	(5.0)	121	(100.0)	1	(2.8)	32	(88.9)	3	(8.3)	36	(100.0)	4	(2.5)	144	(91.7)	9	(5.7)	157	(100.0)
	Week 36	Low	3	(2.5)	2	(1.7)	0		5	(4.2)	0		0		0		0		3	(1.9)	2	(1.3)	0		5	(3.2)
		Normal	0		105	(87.5)	6	(5.0)	111	(92.5)	1	(2.8)	31	(86.1)	1	(2.8)	33	(91.7)	1	(0.6)	136	(87.2)	7	(4.5)	144	(92.3)
		High	0		4	(3.3)	0		4	(3.3)	0		1	(2.8)	2	(5.6)	3	(8.3)	0		5	(3.2)	2	(1.3)	7	(4.5)
		Total	3	(2.5)	111	(92.5)	6	(5.0)	120	(100.0)	1	(2.8)	32	(88.9)	3	(8.3)	36	(100.0)	4	(2.6)	143	(91.7)	9	(5.8)	156	(100.0)
	Week 52	Low	3	(2.5)	1	(0.8)	0		4	(3.3)	0		0		0		0		3	(1.9)	1	(0.6)	0		4	(2.6)
		Normal	0		107	(89.2)	5	(4.2)	112	(93.3)	1	(2.8)	30	(83.3)	2	(5.6)	33	(91.7)	1	(0.6)	137	(87.8)	7	(4.5)	145	(92.9)
		High	0		3	(2.5)	1	(0.8)	4	(3.3)	0		2	(5.6)	1	(2.8)	3	(8.3)	0		5	(3.2)	2	(1.3)	7	(4.5)
		Total	3	(2.5)	111	(92.5)	6	(5.0)	120	(100.0)	1	(2.8)	32	(88.9)	3	(8.3)	36	(100.0)	4	(2.6)	143	(91.7)	9	(5.8)	156	(100.0)
Blood Urea Nitrogen	Week 2	Low	0		0		0		0		0		0		0		0		0		0		0		0	
		Normal	0		88	(69.8)	15	(11.9)	103	(81.7)	1	(2.6)	28	(71.8)	3	(7.7)	32	(82.1)	1	(0.6)	116	(70.3)	18	(10.9)	135	(81.8)
		High	0		10	(7.9)	13	(10.3)	23	(18.3)	0		3	(7.7)	4	(10.3)	7	(17.9)	0		13	(7.9)	17	(10.3)	30	(18.2)
		Total	0		98	(77.8)	28	(22.2)	126	(100.0)	1	(2.6)	31	(79.5)	7	(17.9)	39	(100.0)	1	(0.6)	129	(78.2)	35	(21.2)	165	(100.0)
	Week 12	Low	0		0		0		0		1	(2.6)	0		0		1	(2.6)	1	(0.6)	0		0		1	(0.6)
		Normal	0		81	(66.4)	7	(5.7)	88	(72.1)	0		29	(74.4)	2	(5.1)	31	(79.5)	0		110	(68.3)	9	(5.6)	119	(73.9)

Paramaters	Time point	Baseline[a]	Knee N=126								Execpt for knee N=40								Total N=166							
			Low		Normal		High		Total		Low		Normal		High		Total		Low		Normal		High		Total	
			n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]
		High	0		15	(12.3)	19	(15.6)	34	(27.9)	0		2	(5.1)	5	(12.8)	7	(17.9)	0		17	(10.6)	24	(14.9)	41	(25.5)
		Total	0		96	(78.7)	26	(21.3)	122	(100.0)	1	(2.6)	31	(79.5)	7	(17.9)	39	(100.0)	1	(0.6)	127	(78.9)	33	(20.5)	161	(100.0)
	Week 24	Low	0		0		0		0		1	(2.8)	0		0		1	(2.8)	1	(0.6)	0		0		1	(0.6)
		Normal	0		84	(69.4)	13	(10.7)	97	(80.2)	0		28	(77.8)	3	(8.3)	31	(86.1)	0		112	(71.3)	16	(10.2)	128	(81.5)
		High	0		11	(9.1)	13	(10.7)	24	(19.8)	0		1	(2.8)	3	(8.3)	4	(11.1)	0		12	(7.6)	16	(10.2)	28	(17.8)
		Total	0		95	(78.5)	26	(21.5)	121	(100.0)	1	(2.8)	29	(80.6)	6	(16.7)	36	(100.0)	1	(0.6)	124	(79.0)	32	(20.4)	157	(100.0)
	Week 36	Low	0		1	(0.8)	0		1	(0.8)	0		0		0		0		0		1	(0.6)	0		1	(0.6)
		Normal	0		87	(72.5)	8	(6.7)	95	(79.2)	1	(2.8)	27	(75.0)	2	(5.6)	30	(83.3)	1	(0.6)	114	(73.1)	10	(6.4)	125	(80.1)
		High	0		6	(5.0)	18	(15.0)	24	(20.0)	0		2	(5.6)	4	(11.1)	6	(16.7)	0		8	(5.1)	22	(14.1)	30	(19.2)
		Total	0		94	(78.3)	26	(21.7)	120	(100.0)	1	(2.8)	29	(80.6)	6	(16.7)	36	(100.0)	1	(0.6)	123	(78.8)	32	(20.5)	156	(100.0)
	Week 52	Low	0		0		0		0		1	(2.8)	0		0		1	(2.8)	1	(0.6)	0		0		1	(0.6)
		Normal	0		85	(70.8)	12	(10.0)	97	(80.8)	0		25	(69.4)	2	(5.6)	27	(75.0)	0		110	(70.5)	14	(9.0)	124	(79.5)
		High	0		9	(7.5)	14	(11.7)	23	(19.2)	0		4	(11.1)	4	(11.1)	8	(22.2)	0		13	(8.3)	18	(11.5)	31	(19.9)
		Total	0		94	(78.3)	26	(21.7)	120	(100.0)	1	(2.8)	29	(80.6)	6	(16.7)	36	(100.0)	1	(0.6)	123	(78.8)	32	(20.5)	156	(100.0)
Creatinine	Week 2	Low	1	(0.8)	3	(2.4)	0		4	(3.2)	2	(5.1)	0		0		2	(5.1)	3	(1.8)	3	(1.8)	0		6	(3.6)
		Normal	3	(2.4)	106	(84.1)	5	(4.0)	114	(90.5)	3	(7.7)	30	(76.9)	0		33	(84.6)	6	(3.6)	136	(82.4)	5	(3.0)	147	(89.1)
		High	0		3	(2.4)	5	(4.0)	8	(6.3)	0		2	(5.1)	2	(5.1)	4	(10.3)	0		5	(3.0)	7	(4.2)	12	(7.3)
		Total	4	(3.2)	112	(88.9)	10	(7.9)	126	(100.0)	5	(12.8)	32	(82.1)	2	(5.1)	39	(100.0)	9	(5.5)	144	(87.3)	12	(7.3)	165	(100.0)
	Week 12	Low	1	(0.8)	2	(1.6)	0		3	(2.5)	1	(2.6)	0		0		1	(2.6)	2	(1.2)	2	(1.2)	0		4	(2.5)
		Normal	2	(1.6)	98	(80.3)	5	(4.1)	105	(86.1)	4	(10.3)	31	(79.5)	0		35	(89.7)	6	(3.7)	129	(80.1)	5	(3.1)	140	(87.0)
		High	1	(0.8)	8	(6.6)	5	(4.1)	14	(11.5)	0		1	(2.6)	2	(5.1)	3	(7.7)	1	(0.6)	9	(5.6)	7	(4.3)	17	(10.6)
		Total	4	(3.3)	108	(88.5)	10	(8.2)	122	(100.0)	5	(12.8)	32	(82.1)	2	(5.1)	39	(100.0)	9	(5.6)	140	(87.0)	12	(7.5)	161	(100.0)
	Week 24	Low	1	(0.8)	3	(2.5)	0		4	(3.3)	3	(8.3)	0		0		3	(8.3)	4	(2.5)	3	(1.9)	0		7	(4.5)
		Normal	3	(2.5)	97	(80.2)	4	(3.3)	104	(86.0)	2	(5.6)	28	(77.8)	0		30	(83.3)	5	(3.2)	125	(79.6)	4	(2.5)	134	(85.4)
		High	0		7	(5.8)	6	(5.0)	13	(10.7)	0		1	(2.8)	2	(5.6)	3	(8.3)	0		8	(5.1)	8	(5.1)	16	(10.2)
		Total	4	(3.3)	107	(88.4)	10	(8.3)	121	(100.0)	5	(13.9)	29	(80.6)	2	(5.6)	36	(100.0)	9	(5.7)	136	(86.6)	12	(7.6)	157	(100.0)
	Week 36	Low	0		3	(2.5)	0		3	(2.5)	2	(5.6)	0		0		2	(5.6)	2	(1.3)	3	(1.9)	0		5	(3.2)
		Normal	4	(3.3)	97	(80.8)	4	(3.3)	105	(87.5)	3	(8.3)	28	(77.8)	0		31	(86.1)	7	(4.5)	125	(80.1)	4	(2.6)	136	(87.2)
		High	0		6	(5.0)	6	(5.0)	12	(10.0)	0		1	(2.8)	2	(5.6)	3	(8.3)	0		7	(4.5)	8	(5.1)	15	(9.6)
		Total	4	(3.3)	106	(88.3)	10	(8.3)	120	(100.0)	5	(13.9)	29	(80.6)	2	(5.6)	36	(100.0)	9	(5.8)	135	(86.5)	12	(7.7)	156	(100.0)
	Week 52	Low	2	(1.7)	1	(0.8)	0		3	(2.5)	1	(2.8)	0		0		1	(2.8)	3	(1.9)	1	(0.6)	0		4	(2.6)
		Normal	1	(0.8)	98	(81.7)	4	(3.3)	103	(85.8)	4	(11.1)	27	(75.0)	0		31	(86.1)	5	(3.2)	125	(80.1)	4	(2.6)	134	(85.9)
		High	0		8	(6.7)	6	(5.0)	14	(11.7)	0		2	(5.6)	2	(5.6)	4	(11.1)	0		10	(6.4)	8	(5.1)	18	(11.5)
		Total	3	(2.5)	107	(89.2)	10	(8.3)	120	(100.0)	5	(13.9)	29	(80.6)	2	(5.6)	36	(100.0)	8	(5.1)	136	(87.2)	12	(7.7)	156	(100.0)

Paramaters	Time point	Baseline[a]	Knee N=126								Execpt for knee N=40								Total N=166							
			Low		Normal		High		Total		Low		Normal		High		Total		Low		Normal		High		Total	
			n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]
Cholesterol	Week 2	Low	1	(0.8)	0		0		1	(0.8)	0		0		0		0		1	(0.6)	0		0		1	(0.6)
		Normal	0		68	(54.0)	15	(11.9)	83	(65.9)	0		22	(56.4)	4	(10.3)	26	(66.7)	0		90	(54.5)	19	(11.5)	109	(66.1)
		High	0		7	(5.6)	35	(27.8)	42	(33.3)	0		4	(10.3)	9	(23.1)	13	(33.3)	0		11	(6.7)	44	(26.7)	55	(33.3)
		Total	1	(0.8)	75	(59.5)	50	(39.7)	126	(100.0)	0		26	(66.7)	13	(33.3)	39	(100.0)	1	(0.6)	101	(61.2)	63	(38.2)	165	(100.0)
	Week 12	Low	1	(0.8)	0		0		1	(0.8)	0		0		0		0		1	(0.6)	0		0		1	(0.6)
		Normal	0		61	(50.0)	12	(9.8)	73	(59.8)	0		24	(61.5)	6	(15.4)	30	(76.9)	0		85	(52.8)	18	(11.2)	103	(64.0)
		High	0		10	(8.2)	38	(31.1)	48	(39.3)	0		2	(5.1)	7	(17.9)	9	(23.1)	0		12	(7.5)	45	(28.0)	57	(35.4)
		Total	1	(0.8)	71	(58.2)	50	(41.0)	122	(100.0)	0		26	(66.7)	13	(33.3)	39	(100.0)	1	(0.6)	97	(60.2)	63	(39.1)	161	(100.0)
	Week 24	Low	0		0		0		0		0		0		0		0		0		0		0		0	
		Normal	1	(0.8)	58	(47.9)	13	(10.7)	72	(59.5)	0		17	(47.2)	2	(5.6)	19	(52.8)	1	(0.6)	75	(47.8)	15	(9.6)	91	(58.0)
		High	0		12	(9.9)	37	(30.6)	49	(40.5)	0		7	(19.4)	10	(27.8)	17	(47.2)	0		19	(12.1)	47	(29.9)	66	(42.0)
		Total	1	(0.8)	70	(57.9)	50	(41.3)	121	(100.0)	0		24	(66.7)	12	(33.3)	36	(100.0)	1	(0.6)	94	(59.9)	62	(39.5)	157	(100.0)
	Week 36	Low	1	(0.8)	0		0		1	(0.8)	0		0		0		0		1	(0.6)	0		0		1	(0.6)
		Normal	0		53	(44.2)	12	(10.0)	65	(54.2)	0		17	(47.2)	3	(8.3)	20	(55.6)	0		70	(44.9)	15	(9.6)	85	(54.5)
		High	0		16	(13.3)	38	(31.7)	54	(45.0)	0		7	(19.4)	9	(25.0)	16	(44.4)	0		23	(14.7)	47	(30.1)	70	(44.9)
		Total	1	(0.8)	69	(57.5)	50	(41.7)	120	(100.0)	0		24	(66.7)	12	(33.3)	36	(100.0)	1	(0.6)	93	(59.6)	62	(39.7)	156	(100.0)
	Week 52	Low	0		0		0		0		0		0		0		0		0		0		0		0	
		Normal	1	(0.8)	59	(49.2)	14	(11.7)	74	(61.7)	0		18	(50.0)	4	(11.1)	22	(61.1)	1	(0.6)	77	(49.4)	18	(11.5)	96	(61.5)
		High	0		11	(9.2)	35	(29.2)	46	(38.3)	0		6	(16.7)	8	(22.2)	14	(38.9)	0		17	(10.9)	43	(27.6)	60	(38.5)
		Total	1	(0.8)	70	(58.3)	49	(40.8)	120	(100.0)	0		24	(66.7)	12	(33.3)	36	(100.0)	1	(0.6)	94	(60.3)	61	(39.1)	156	(100.0)
Triglycerides	Week 2	Low	0		0		0		0		0		0		0		0		0		0		0		0	
		Normal	0		54	(42.9)	16	(12.7)	70	(55.6)	0		13	(33.3)	6	(15.4)	19	(48.7)	0		67	(40.6)	22	(13.3)	89	(53.9)
		High	0		16	(12.7)	40	(31.7)	56	(44.4)	0		8	(20.5)	12	(30.8)	20	(51.3)	0		24	(14.5)	52	(31.5)	76	(46.1)
		Total	0		70	(55.6)	56	(44.4)	126	(100.0)	0		21	(53.8)	18	(46.2)	39	(100.0)	0		91	(55.2)	74	(44.8)	165	(100.0)
	Week 12	Low	0		0		0		0		0		0		0		0		0		0		0		0	
		Normal	0		51	(41.8)	19	(15.6)	70	(57.4)	0		15	(38.5)	4	(10.3)	19	(48.7)	0		66	(41.0)	23	(14.3)	89	(55.3)
		High	0		16	(13.1)	36	(29.5)	52	(42.6)	0		6	(15.4)	14	(35.9)	20	(51.3)	0		22	(13.7)	50	(31.1)	72	(44.7)
		Total	0		67	(54.9)	55	(45.1)	122	(100.0)	0		21	(53.8)	18	(46.2)	39	(100.0)	0		88	(54.7)	73	(45.3)	161	(100.0)
	Week 24	Low	0		0		0		0		0		0		0		0		0		0		0		0	
		Normal	0		46	(38.0)	24	(19.8)	70	(57.9)	0		16	(44.4)	7	(19.4)	23	(63.9)	0		62	(39.5)	31	(19.7)	93	(59.2)
		High	0		21	(17.4)	30	(24.8)	51	(42.1)	0		4	(11.1)	9	(25.0)	13	(36.1)	0		25	(15.9)	39	(24.8)	64	(40.8)
		Total	0		67	(55.4)	54	(44.6)	121	(100.0)	0		20	(55.6)	16	(44.4)	36	(100.0)	0		87	(55.4)	70	(44.6)	157	(100.0)
	Week 36	Low	0		0		0		0		0		0		0		0		0		0		0		0	
		Normal	0		50	(41.7)	22	(18.3)	72	(60.0)	0		16	(44.4)	5	(13.9)	21	(58.3)	0		66	(42.3)	27	(17.3)	93	(59.6)

Paramaters	Time point	Baseline[a]	Knee N=126								Execpt for knee N=40								Total N=166							
			Low		Normal		High		Total		Low		Normal		High		Total		Low		Normal		High		Total	
			n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]
		High	0		16	(13.3)	32	(26.7)	48	(40.0)	0		4	(11.1)	11	(30.6)	15	(41.7)	0		20	(12.8)	43	(27.6)	63	(40.4)
		Total	0		66	(55.0)	54	(45.0)	120	(100.0)	0		20	(55.6)	16	(44.4)	36	(100.0)	0		86	(55.1)	70	(44.9)	156	(100.0)
	Week 52	Low	0		0		0		0		0		0		0		0		0		0		0		0	
		Normal	0		47	(39.2)	22	(18.3)	69	(57.5)	0		15	(41.7)	6	(16.7)	21	(58.3)	0		62	(39.7)	28	(17.9)	90	(57.7)
		High	0		19	(15.8)	32	(26.7)	51	(42.5)	0		5	(13.9)	10	(27.8)	15	(41.7)	0		24	(15.4)	42	(26.9)	66	(42.3)
		Total	0		66	(55.0)	54	(45.0)	120	(100.0)	0		20	(55.6)	16	(44.4)	36	(100.0)	0		86	(55.1)	70	(44.9)	156	(100.0)
C Reactive Protein	Week 2	Low	-		-		-		-		-		-		-		-		-		-		-		-	
		Normal	-		105	(83.3)	9	(7.1)	114	(90.5)	-		31	(79.5)	2	(5.1)	33	(84.6)	-		136	(82.4)	11	(6.7)	147	(89.1)
		High	-		8	(6.3)	4	(3.2)	12	(9.5)	-		4	(10.3)	2	(5.1)	6	(15.4)	-		12	(7.3)	6	(3.6)	18	(10.9)
		Total	-		113	(89.7)	13	(10.3)	126	(100.0)	-		35	(89.7)	4	(10.3)	39	(100.0)	-		148	(89.7)	17	(10.3)	165	(100.0)
	Week 12	Low	-		-		-		-		-		-		-		-		-		-		-		-	
		Normal	-		103	(84.4)	10	(8.2)	113	(92.6)	-		32	(82.1)	1	(2.6)	33	(84.6)	-		135	(83.9)	11	(6.8)	146	(90.7)
		High	-		7	(5.7)	2	(1.6)	9	(7.4)	-		3	(7.7)	3	(7.7)	6	(15.4)	-		10	(6.2)	5	(3.1)	15	(9.3)
		Total	-		110	(90.2)	12	(9.8)	122	(100.0)	-		35	(89.7)	4	(10.3)	39	(100.0)	-		145	(90.1)	16	(9.9)	161	(100.0)
	Week 24	Low	-		-		-		-		-		-		-		-		-		-		-		-	
		Normal	-		99	(81.8)	9	(7.4)	108	(89.3)	-		32	(88.9)	1	(2.8)	33	(91.7)	-		131	(83.4)	10	(6.4)	141	(89.8)
		High	-		10	(8.3)	3	(2.5)	13	(10.7)	-		1	(2.8)	2	(5.6)	3	(8.3)	-		11	(7.0)	5	(3.2)	16	(10.2)
		Total	-		109	(90.1)	12	(9.9)	121	(100.0)	-		33	(91.7)	3	(8.3)	36	(100.0)	-		142	(90.4)	15	(9.6)	157	(100.0)
	Week 36	Low	-		-		-		-		-		-		-		-		-		-		-		-	
		Normal	-		98	(81.7)	10	(8.3)	108	(90.0)	-		31	(86.1)	2	(5.6)	33	(91.7)	-		129	(82.7)	12	(7.7)	141	(90.4)
		High	-		10	(8.3)	2	(1.7)	12	(10.0)	-		2	(5.6)	1	(2.8)	3	(8.3)	-		12	(7.7)	3	(1.9)	15	(9.6)
		Total	-		108	(90.0)	12	(10.0)	120	(100.0)	-		33	(91.7)	3	(8.3)	36	(100.0)	-		141	(90.4)	15	(9.6)	156	(100.0)
	Week 52	Low	-		-		-		-		-		-		-		-		-		-		-		-	
		Normal	-		103	(85.8)	9	(7.5)	112	(93.3)	-		30	(83.3)	1	(2.8)	31	(86.1)	-		133	(85.3)	10	(6.4)	143	(91.7)
		High	-		5	(4.2)	3	(2.5)	8	(6.7)	-		3	(8.3)	2	(5.6)	5	(13.9)	-		8	(5.1)	5	(3.2)	13	(8.3)
		Total	-		108	(90.0)	12	(10.0)	120	(100.0)	-		33	(91.7)	3	(8.3)	36	(100.0)	-		141	(90.4)	15	(9.6)	156	(100.0)
Sodium	Week 2	Low	0		0		0		0		0		0		0		0		0		0		0		0	
		Normal	3	(2.4)	121	(96.0)	2	(1.6)	126	(100.0)	0		39	(100.0)	0		39	(100.0)	3	(1.8)	160	(97.0)	2	(1.2)	165	(100.0)
		High	0		0		0		0		0		0		0		0		0		0		0		0	
		Total	3	(2.4)	121	(96.0)	2	(1.6)	126	(100.0)	0		39	(100.0)	0		39	(100.0)	3	(1.8)	160	(97.0)	2	(1.2)	165	(100.0)
	Week 12	Low	1	(0.8)	0		0		1	(0.8)	0		1	(2.6)	0		1	(2.6)	1	(0.6)	1	(0.6)	0		2	(1.2)
		Normal	2	(1.6)	117	(95.9)	2	(1.6)	121	(99.2)	0		38	(97.4)	0		38	(97.4)	2	(1.2)	155	(96.3)	2	(1.2)	159	(98.8)
		High	0		0		0		0		0		0		0		0		0		0		0		0	
		Total	3	(2.5)	117	(95.9)	2	(1.6)	122	(100.0)	0		39	(100.0)	0		39	(100.0)	3	(1.9)	156	(96.9)	2	(1.2)	161	(100.0)

Paramaters	Time point	Baseline[a]	Knee N=126								Execpt for knee N=40								Total N=166							
			Low		Normal		High		Total		Low		Normal		High		Total		Low		Normal		High		Total	
			n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]
	Week 24	Low	0		1	(0.8)	0		1	(0.8)	0		0		0		0		0		1	(0.6)	0		1	(0.6)
		Normal	3	(2.5)	114	(94.2)	2	(1.7)	119	(98.3)	0		36	(100.0)	0		36	(100.0)	3	(1.9)	150	(95.5)	2	(1.3)	155	(98.7)
		High	0		1	(0.8)	0		1	(0.8)	0		0		0		0		0		1	(0.6)	0		1	(0.6)
		Total	3	(2.5)	116	(95.9)	2	(1.7)	121	(100.0)	0		36	(100.0)	0		36	(100.0)	3	(1.9)	152	(96.8)	2	(1.3)	157	(100.0)
	Week 36	Low	1	(0.8)	1	(0.8)	0		2	(1.7)	0		0		0		0		1	(0.6)	1	(0.6)	0		2	(1.3)
		Normal	2	(1.7)	114	(95.0)	2	(1.7)	118	(98.3)	0		36	(100.0)	0		36	(100.0)	2	(1.3)	150	(96.2)	2	(1.3)	154	(98.7)
		High	0		0		0		0		0		0		0		0		0		0		0		0	
		Total	3	(2.5)	115	(95.8)	2	(1.7)	120	(100.0)	0		36	(100.0)	0		36	(100.0)	3	(1.9)	151	(96.8)	2	(1.3)	156	(100.0)
	Week 52	Low	2	(1.7)	0		0		2	(1.7)	0		1	(2.8)	0		1	(2.8)	2	(1.3)	1	(0.6)	0		3	(1.9)
		Normal	1	(0.8)	115	(95.8)	2	(1.7)	118	(98.3)	0		35	(97.2)	0		35	(97.2)	1	(0.6)	150	(96.2)	2	(1.3)	153	(98.1)
		High	0		0		0		0		0		0		0		0		0		0		0		0	
		Total	3	(2.5)	115	(95.8)	2	(1.7)	120	(100.0)	0		36	(100.0)	0		36	(100.0)	3	(1.9)	151	(96.8)	2	(1.3)	156	(100.0)
Potassium	Week 2	Low	1	(0.8)	0		0		1	(0.8)	1	(2.6)	0		0		1	(2.6)	2	(1.2)	0		0		2	(1.2)
		Normal	0		120	(95.2)	3	(2.4)	123	(97.6)	0		38	(97.4)	0		38	(97.4)	0		158	(95.8)	3	(1.8)	161	(97.6)
		High	0		2	(1.6)	0		2	(1.6)	0		0		0		0		0		2	(1.2)	0		2	(1.2)
		Total	1	(0.8)	122	(96.8)	3	(2.4)	126	(100.0)	1	(2.6)	38	(97.4)	0		39	(100.0)	2	(1.2)	160	(97.0)	3	(1.8)	165	(100.0)
	Week 12	Low	1	(0.8)	1	(0.8)	0		2	(1.6)	0		0		0		0		1	(0.6)	1	(0.6)	0		2	(1.2)
		Normal	0		115	(94.3)	3	(2.5)	118	(96.7)	1	(2.6)	38	(97.4)	0		39	(100.0)	1	(0.6)	153	(95.0)	3	(1.9)	157	(97.5)
		High	0		2	(1.6)	0		2	(1.6)	0		0		0		0		0		2	(1.2)	0		2	(1.2)
		Total	1	(0.8)	118	(96.7)	3	(2.5)	122	(100.0)	1	(2.6)	38	(97.4)	0		39	(100.0)	2	(1.2)	156	(96.9)	3	(1.9)	161	(100.0)
	Week 24	Low	1	(0.8)	0		0		1	(0.8)	0		0		0		0		1	(0.6)	0		0		1	(0.6)
		Normal	0		114	(94.2)	3	(2.5)	117	(96.7)	1	(2.8)	35	(97.2)	0		36	(100.0)	1	(0.6)	149	(94.9)	3	(1.9)	153	(97.5)
		High	0		3	(2.5)	0		3	(2.5)	0		0		0		0		0		3	(1.9)	0		3	(1.9)
		Total	1	(0.8)	117	(96.7)	3	(2.5)	121	(100.0)	1	(2.8)	35	(97.2)	0		36	(100.0)	2	(1.3)	152	(96.8)	3	(1.9)	157	(100.0)
	Week 36	Low	1	(0.8)	0		0		1	(0.8)	0		0		0		0		1	(0.6)	0		0		1	(0.6)
		Normal	0		114	(95.0)	3	(2.5)	117	(97.5)	1	(2.8)	34	(94.4)	0		35	(97.2)	1	(0.6)	148	(94.9)	3	(1.9)	152	(97.4)
		High	0		2	(1.7)	0		2	(1.7)	0		1	(2.8)	0		1	(2.8)	0		3	(1.9)	0		3	(1.9)
		Total	1	(0.8)	116	(96.7)	3	(2.5)	120	(100.0)	1	(2.8)	35	(97.2)	0		36	(100.0)	2	(1.3)	151	(96.8)	3	(1.9)	156	(100.0)
	Week 52	Low	1	(0.8)	2	(1.7)	0		3	(2.5)	0		0		0		0		1	(0.6)	2	(1.3)	0		3	(1.9)
		Normal	0		112	(93.3)	3	(2.5)	115	(95.8)	1	(2.8)	35	(97.2)	0		36	(100.0)	1	(0.6)	147	(94.2)	3	(1.9)	151	(96.8)
		High	0		2	(1.7)	0		2	(1.7)	0		0		0		0		0		2	(1.3)	0		2	(1.3)
		Total	1	(0.8)	116	(96.7)	3	(2.5)	120	(100.0)	1	(2.8)	35	(97.2)	0		36	(100.0)	2	(1.3)	151	(96.8)	3	(1.9)	156	(100.0)
Chloride	Week 2	Low	0		0		0		0		0		0		0		0		0		0		0		0	
		Normal	0		120	(95.2)	2	(1.6)	122	(96.8)	0		37	(94.9)	2	(5.1)	39	(100.0)	0		157	(95.2)	4	(2.4)	161	(97.6)

Paramaters	Time point	Baseline[a]	Knee N=126								Execpt for knee N=40								Total N=166							
			Low		Normal		High		Total		Low		Normal		High		Total		Low		Normal		High		Total	
			n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]
		High	0		3	(2.4)	1	(0.8)	4	(3.2)	0		0		0		0		0		3	(1.8)	1	(0.6)	4	(2.4)
		Total	0		123	(97.6)	3	(2.4)	126	(100.0)	0		37	(94.9)	2	(5.1)	39	(100.0)	0		160	(97.0)	5	(3.0)	165	(100.0)
	Week 12	Low	0		0		0		0		0		0		0		0		0		0		0		0	
		Normal	0		117	(95.9)	2	(1.6)	119	(97.5)	0		35	(89.7)	2	(5.1)	37	(94.9)	0		152	(94.4)	4	(2.5)	156	(96.9)
		High	0		2	(1.6)	1	(0.8)	3	(2.5)	0		2	(5.1)	0		2	(5.1)	0		4	(2.5)	1	(0.6)	5	(3.1)
		Total	0		119	(97.5)	3	(2.5)	122	(100.0)	0		37	(94.9)	2	(5.1)	39	(100.0)	0		156	(96.9)	5	(3.1)	161	(100.0)
	Week 24	Low	0		0		0		0		0		0		0		0		0		0		0		0	
		Normal	0		115	(95.0)	2	(1.7)	117	(96.7)	0		32	(88.9)	2	(5.6)	34	(94.4)	0		147	(93.6)	4	(2.5)	151	(96.2)
		High	0		3	(2.5)	1	(0.8)	4	(3.3)	0		2	(5.6)	0		2	(5.6)	0		5	(3.2)	1	(0.6)	6	(3.8)
		Total	0		118	(97.5)	3	(2.5)	121	(100.0)	0		34	(94.4)	2	(5.6)	36	(100.0)	0		152	(96.8)	5	(3.2)	157	(100.0)
	Week 36	Low	0		1	(0.8)	0		1	(0.8)	0		0		0		0		0		1	(0.6)	0		1	(0.6)
		Normal	0		111	(92.5)	1	(0.8)	112	(93.3)	0		33	(91.7)	2	(5.6)	35	(97.2)	0		144	(92.3)	3	(1.9)	147	(94.2)
		High	0		5	(4.2)	2	(1.7)	7	(5.8)	0		1	(2.8)	0		1	(2.8)	0		6	(3.8)	2	(1.3)	8	(5.1)
		Total	0		117	(97.5)	3	(2.5)	120	(100.0)	0		34	(94.4)	2	(5.6)	36	(100.0)	0		151	(96.8)	5	(3.2)	156	(100.0)
	Week 52	Low	0		0		0		0		0		0		0		0		0		0		0		0	
		Normal	0		112	(93.3)	2	(1.7)	114	(95.0)	0		33	(91.7)	2	(5.6)	35	(97.2)	0		145	(92.9)	4	(2.6)	149	(95.5)
		High	0		5	(4.2)	1	(0.8)	6	(5.0)	0		1	(2.8)	0		1	(2.8)	0		6	(3.8)	1	(0.6)	7	(4.5)
		Total	0		117	(97.5)	3	(2.5)	120	(100.0)	0		34	(94.4)	2	(5.6)	36	(100.0)	0		151	(96.8)	5	(3.2)	156	(100.0)
Calcium	Week 2	Low	0		2	(1.6)	0		2	(1.6)	0		0		0		0		0		2	(1.2)	0		2	(1.2)
		Normal	0		124	(98.4)	0		124	(98.4)	0		39	(100.0)	0		39	(100.0)	0		163	(98.8)	0		163	(98.8)
		High	0		0		0		0		0		0		0		0		0		0		0		0	
		Total	0		126	(100.0)	0		126	(100.0)	0		39	(100.0)	0		39	(100.0)	0		165	(100.0)	0		165	(100.0)
	Week 12	Low	0		2	(1.6)	0		2	(1.6)	0		0		0		0		0		2	(1.2)	0		2	(1.2)
		Normal	0		120	(98.4)	0		120	(98.4)	0		39	(100.0)	0		39	(100.0)	0		159	(98.8)	0		159	(98.8)
		High	0		0		0		0		0		0		0		0		0		0		0		0	
		Total	0		122	(100.0)	0		122	(100.0)	0		39	(100.0)	0		39	(100.0)	0		161	(100.0)	0		161	(100.0)
	Week 24	Low	0		0		0		0		0		0		0		0		0		0		0		0	
		Normal	0		120	(99.2)	0		120	(99.2)	0		36	(100.0)	0		36	(100.0)	0		156	(99.4)	0		156	(99.4)
		High	0		1	(0.8)	0		1	(0.8)	0		0		0		0		0		1	(0.6)	0		1	(0.6)
		Total	0		121	(100.0)	0		121	(100.0)	0		36	(100.0)	0		36	(100.0)	0		157	(100.0)	0		157	(100.0)
	Week 36	Low	0		0		0		0		0		0		0		0		0		0		0		0	
		Normal	0		118	(98.3)	0		118	(98.3)	0		36	(100.0)	0		36	(100.0)	0		154	(98.7)	0		154	(98.7)
		High	0		2	(1.7)	0		2	(1.7)	0		0		0		0		0		2	(1.3)	0		2	(1.3)
		Total	0		120	(100.0)	0		120	(100.0)	0		36	(100.0)	0		36	(100.0)	0		156	(100.0)	0		156	(100.0)

Paramaters	Time point	Baseline[a]	Knee N=126								Execpt for knee N=40								Total N=166							
			Low		Normal		High		Total		Low		Normal		High		Total		Low		Normal		High		Total	
			n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]
	Week 52	Low	0		1	(0.8)	0		1	(0.8)	0		0		0		0		0		1	(0.6)	0		1	(0.6)
		Normal	0		119	(99.2)	0		119	(99.2)	0		36	(100.0)	0		36	(100.0)	0		155	(99.4)	0		155	(99.4)
		High	0		0		0		0		0		0		0		0		0		0		0		0	
		Total	0		120	(100.0)	0		120	(100.0)	0		36	(100.0)	0		36	(100.0)	0		156	(100.0)	0		156	(100.0)
Creatine Kinase	Week 2	Low	0		3	(2.4)	0		3	(2.4)	3	(7.7)	1	(2.6)	0		4	(10.3)	3	(1.8)	4	(2.4)	0		7	(4.2)
		Normal	2	(1.6)	95	(75.4)	7	(5.6)	104	(82.5)	1	(2.6)	28	(71.8)	1	(2.6)	30	(76.9)	3	(1.8)	123	(74.5)	8	(4.8)	134	(81.2)
		High	0		6	(4.8)	13	(10.3)	19	(15.1)	0		1	(2.6)	4	(10.3)	5	(12.8)	0		7	(4.2)	17	(10.3)	24	(14.5)
		Total	2	(1.6)	104	(82.5)	20	(15.9)	126	(100.0)	4	(10.3)	30	(76.9)	5	(12.8)	39	(100.0)	6	(3.6)	134	(81.2)	25	(15.2)	165	(100.0)
	Week 12	Low	0		5	(4.1)	0		5	(4.1)	2	(5.1)	1	(2.6)	0		3	(7.7)	2	(1.2)	6	(3.7)	0		8	(5.0)
		Normal	2	(1.6)	89	(73.0)	10	(8.2)	101	(82.8)	2	(5.1)	27	(69.2)	2	(5.1)	31	(79.5)	4	(2.5)	116	(72.0)	12	(7.5)	132	(82.0)
		High	0		6	(4.9)	10	(8.2)	16	(13.1)	0		2	(5.1)	3	(7.7)	5	(12.8)	0		8	(5.0)	13	(8.1)	21	(13.0)
		Total	2	(1.6)	100	(82.0)	20	(16.4)	122	(100.0)	4	(10.3)	30	(76.9)	5	(12.8)	39	(100.0)	6	(3.7)	130	(80.7)	25	(15.5)	161	(100.0)
	Week 24	Low	0		0		0		0		4	(11.1)	1	(2.8)	0		5	(13.9)	4	(2.5)	1	(0.6)	0		5	(3.2)
		Normal	2	(1.7)	93	(76.9)	4	(3.3)	99	(81.8)	0		24	(66.7)	1	(2.8)	25	(69.4)	2	(1.3)	117	(74.5)	5	(3.2)	124	(79.0)
		High	0		6	(5.0)	16	(13.2)	22	(18.2)	0		3	(8.3)	3	(8.3)	6	(16.7)	0		9	(5.7)	19	(12.1)	28	(17.8)
		Total	2	(1.7)	99	(81.8)	20	(16.5)	121	(100.0)	4	(11.1)	28	(77.8)	4	(11.1)	36	(100.0)	6	(3.8)	127	(80.9)	24	(15.3)	157	(100.0)
	Week 36	Low	0		2	(1.7)	0		2	(1.7)	1	(2.8)	1	(2.8)	0		2	(5.6)	1	(0.6)	3	(1.9)	0		4	(2.6)
		Normal	2	(1.7)	91	(75.8)	8	(6.7)	101	(84.2)	3	(8.3)	26	(72.2)	2	(5.6)	31	(86.1)	5	(3.2)	117	(75.0)	10	(6.4)	132	(84.6)
		High	0		5	(4.2)	12	(10.0)	17	(14.2)	0		1	(2.8)	2	(5.6)	3	(8.3)	0		6	(3.8)	14	(9.0)	20	(12.8)
		Total	2	(1.7)	98	(81.7)	20	(16.7)	120	(100.0)	4	(11.1)	28	(77.8)	4	(11.1)	36	(100.0)	6	(3.8)	126	(80.8)	24	(15.4)	156	(100.0)
	Week 52	Low	1	(0.8)	2	(1.7)	0		3	(2.5)	1	(2.8)	0		0		1	(2.8)	2	(1.3)	2	(1.3)	0		4	(2.6)
		Normal	1	(0.8)	89	(74.2)	8	(6.7)	98	(81.7)	3	(8.3)	25	(69.4)	1	(2.8)	29	(80.6)	4	(2.6)	114	(73.1)	9	(5.8)	127	(81.4)
		High	0		7	(5.8)	12	(10.0)	19	(15.8)	0		3	(8.3)	3	(8.3)	6	(16.7)	0		10	(6.4)	15	(9.6)	25	(16.0)
		Total	2	(1.7)	98	(81.7)	20	(16.7)	120	(100.0)	4	(11.1)	28	(77.8)	4	(11.1)	36	(100.0)	6	(3.8)	126	(80.8)	24	(15.4)	156	(100.0)
Hemoglobin A1C/Hemoglobin	Week 2	Low	0		0		0		0		0		0		0		0		0		0		0		0	
		Normal	0		100	(79.4)	5	(4.0)	105	(83.3)	0		32	(82.1)	2	(5.1)	34	(87.2)	0		132	(80.0)	7	(4.2)	139	(84.2)
		High	0		0		21	(16.7)	21	(16.7)	0		1	(2.6)	4	(10.3)	5	(12.8)	0		1	(0.6)	25	(15.2)	26	(15.8)
		Total	0		100	(79.4)	26	(20.6)	126	(100.0)	0		33	(84.6)	6	(15.4)	39	(100.0)	0		133	(80.6)	32	(19.4)	165	(100.0)
	Week 12	Low	0		0		0		0		0		0		0		0		0		0		0		0	
		Normal	0		96	(78.7)	3	(2.5)	99	(81.1)	0		33	(84.6)	3	(7.7)	36	(92.3)	0		129	(80.1)	6	(3.7)	135	(83.9)
		High	0		1	(0.8)	22	(18.0)	23	(18.9)	0		0		3	(7.7)	3	(7.7)	0		1	(0.6)	25	(15.5)	26	(16.1)
		Total	0		97	(79.5)	25	(20.5)	122	(100.0)	0		33	(84.6)	6	(15.4)	39	(100.0)	0		130	(80.7)	31	(19.3)	161	(100.0)
	Week 24	Low	0		0		0		0		0		0		0		0		0		0		0		0	
		Normal	0		88	(72.7)	4	(3.3)	92	(76.0)	0		29	(80.6)	1	(2.8)	30	(83.3)	0		117	(74.5)	5	(3.2)	122	(77.7)

Paramaters	Time point	Baseline[a]	Knee N=126								Execpt for knee N=40								Total N=166							
			Low		Normal		High		Total		Low		Normal		High		Total		Low		Normal		High		Total	
			n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]
		High	0		8	(6.6)	21	(17.4)	29	(24.0)	0		1	(2.8)	5	(13.9)	6	(16.7)	0		9	(5.7)	26	(16.6)	35	(22.3)
		Total	0		96	(79.3)	25	(20.7)	121	(100.0)	0		30	(83.3)	6	(16.7)	36	(100.0)	0		126	(80.3)	31	(19.7)	157	(100.0)
	Week 36	Low	0		0		0		0		0		0		0		0		0		0		0		0	
		Normal	0		85	(70.8)	1	(0.8)	86	(71.7)	0		28	(77.8)	2	(5.6)	30	(83.3)	0		113	(72.4)	3	(1.9)	116	(74.4)
		High	0		11	(9.2)	23	(19.2)	34	(28.3)	0		2	(5.6)	4	(11.1)	6	(16.7)	0		13	(8.3)	27	(17.3)	40	(25.6)
		Total	0		96	(80.0)	24	(20.0)	120	(100.0)	0		30	(83.3)	6	(16.7)	36	(100.0)	0		126	(80.8)	30	(19.2)	156	(100.0)
	Week 52	Low	0		0		0		0		0		0		0		0		0		0		0		0	
		Normal	0		84	(70.0)	2	(1.7)	86	(71.7)	0		30	(83.3)	3	(8.3)	33	(91.7)	0		114	(73.1)	5	(3.2)	119	(76.3)
		High	0		12	(10.0)	22	(18.3)	34	(28.3)	0		0		3	(8.3)	3	(8.3)	0		12	(7.7)	25	(16.0)	37	(23.7)
		Total	0		96	(80.0)	24	(20.0)	120	(100.0)	0		30	(83.3)	6	(16.7)	36	(100.0)	0		126	(80.8)	30	(19.2)	156	(100.0)

a: Baseline is value at screening.
b: Percentages are based on the number of subjects with non-missing values at both baseline and each timepoint.
-: Not applicable.
〔5.3.5.2-1 Table 14.3.4-2 改編〕

表 2.7.4.7-84. 臨床検査値の各項目のシフトテーブル（定性試験）①：613/1032 試験

Parameters	Time point	Baseline[a]	Knee N=126										Except fot knee N=40										Total N=166									
			-		±		+		2+		3+	Total		-		±		+		2+		3+	Total		-		±		+		2+		3+	Total	
			n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]
Protein	Week 2	-	106	(84.1)	8	(6.3)	1	(0.8)	0		0	115	(91.3)	33	(82.5)	3	(7.5)	0		0		0	36	(90.0)	139	(83.7)	11	(6.6)	1	(0.6)	0		0	151	(91.0)
		±	4	(3.2)	3	(2.4)	0		0		0	7	(5.6)	0		1	(2.5)	1	(2.5)	0		0	2	(5.0)	4	(2.4)	4	(2.4)	1	(0.6)	0		0	9	(5.4)
		+	2	(1.6)	1	(0.8)	1	(0.8)	0		0	4	(3.2)	0		0		1	(2.5)	0		0	1	(2.5)	2	(1.2)	1	(0.6)	2	(1.2)	0		0	5	(3.0)
		2+	0		0		0		0		0	0		0		0		1	(2.5)	0		0	1	(2.5)	0		0		1	(0.6)	0		0	1	(0.6)
		3+	0		0		0		0		0	0		0		0		0		0		0	0		0		0		0		0		0		
		Total	112	(88.9)	12	(9.5)	2	(1.6)	0		0	126	(100.0)	33	(82.5)	4	(10.0)	3	(7.5)	0		0	40	(100.0)	145	(87.3)	16	(9.6)	5	(3.0)	0		0	166	(100.0)
	Week 12	-	100	(82.0)	7	(5.7)	1	(0.8)	0		0	108	(88.5)	29	(72.5)	2	(5.0)	1	(2.5)	0		0	32	(80.0)	129	(79.6)	9	(5.6)	2	(1.2)	0		0	140	(86.4)
		±	7	(5.7)	4	(3.3)	0		0		0	11	(9.0)	4	(10.0)	1	(2.5)	1	(2.5)	0		0	6	(15.0)	11	(6.8)	5	(3.1)	1	(0.6)	0		0	17	(10.5)
		+	1	(0.8)	1	(0.8)	0		0		0	2	(1.6)	0		1	(2.5)	1	(2.5)	0		0	2	(5.0)	1	(0.6)	2	(1.2)	1	(0.6)	0		0	4	(2.5)
		2+	0		0		1	(0.8)	0		0	1	(0.8)	0		0		0		0		0	0		0		0		1	(0.6)	0		0	1	(0.6)
		3+	0		0		0		0		0	0		0		0		0		0		0	0		0		0		0		0		0		
		Total	108	(88.5)	12	(9.8)	2	(1.6)	0		0	122	(100.0)	33	(82.5)	4	(10.0)	3	(7.5)	0		0	40	(100.0)	141	(87.0)	16	(9.9)	5	(3.1)	0		0	162	(100.0)
	Week 24	-	98	(81.0)	7	(5.8)	1	(0.8)	0		0	106	(87.6)	28	(75.7)	2	(5.4)	2	(5.4)	0		0	32	(86.5)	126	(79.7)	9	(5.7)	3	(1.9)	0		0	138	(87.3)

Parameters	Time point	Baseline[a]	Knee N=126										Except fot knee N=40										Total N=166									
			-		±		+		2+		3+		Total		-		±		+		2+		3+		Total		-		±		+		2+		3+		Total	
			n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]
		±	9	(7.4)	2	(1.7)	1	(0.8)	0		0		12	(9.9)	2	(5.4)	1	(2.7)	0		0		0		3	(8.1)	11	(7.0)	3	(1.9)	1	(0.6)	0		0		15	(9.5)
		+	0		3	(2.5)	0		0		0		3	(2.5)	0		1	(2.7)	0		0		0		1	(2.7)	0		4	(2.5)	0		0		0		4	(2.5)
		2+	0		0		0		0		0		0		0		0		1	(2.7)	0		0		1	(2.7)	0		0		1	(0.6)	0		0		1	(0.6)
		3+	0		0		0		0		0		0		0		0		0		0		0		0		0		0		0		0		0		0	
		Total	107	(88.4)	12	(9.9)	2	(1.7)	0		0		121	(100.0)	30	(81.1)	4	(10.8)	3	(8.1)	0		0		37	(100.0)	137	(86.7)	16	(10.1)	5	(3.2)	0		0		158	(100.0)
	Week 36	-	93	(77.5)	7	(5.8)	2	(1.7)	0		0		102	(85.0)	28	(75.7)	3	(8.1)	1	(2.7)	0		0		32	(86.5)	121	(77.1)	10	(6.4)	3	(1.9)	0		0		134	(85.4)
		±	8	(6.7)	3	(2.5)	0		0		0		11	(9.2)	1	(2.7)	0		1	(2.7)	0		0		2	(5.4)	9	(5.7)	3	(1.9)	1	(0.6)	0		0		13	(8.3)
		+	4	(3.3)	2	(1.7)	0		0		0		6	(5.0)	1	(2.7)	1	(2.7)	0		0		0		2	(5.4)	5	(3.2)	3	(1.9)	0		0		0		8	(5.1)
		2+	1	(0.8)	0		0		0		0		1	(0.8)	0		0		1	(2.7)	0		0		1	(2.7)	1	(0.6)	0		1	(0.6)	0		0		2	(1.3)
		3+	0		0		0		0		0		0		0		0		0		0		0		0		0		0		0		0		0		0	
		Total	106	(88.3)	12	(10.0)	2	(1.7)	0		0		120	(100.0)	30	(81.1)	4	(10.8)	3	(8.1)	0		0		37	(100.0)	136	(86.6)	16	(10.2)	5	(3.2)	0		0		157	(100.0)
	Week 52	-	90	(75.0)	7	(5.8)	0		0		0		97	(80.8)	26	(70.3)	2	(5.4)	1	(2.7)	0		0		29	(78.4)	116	(73.9)	9	(5.7)	1	(0.6)	0		0		126	(80.3)
		±	12	(10.0)	2	(1.7)	1	(0.8)	0		0		15	(12.5)	4	(10.8)	1	(2.7)	1	(2.7)	0		0		6	(16.2)	16	(10.2)	3	(1.9)	2	(1.3)	0		0		21	(13.4)
		+	4	(3.3)	2	(1.7)	1	(0.8)	0		0		7	(5.8)	0		1	(2.7)	0		0		0		1	(2.7)	4	(2.5)	3	(1.9)	1	(0.6)	0		0		8	(5.1)
		2+	0		1	(0.8)	0		0		0		1	(0.8)	0		0		1	(2.7)	0		0		1	(2.7)	0		1	(0.6)	1	(0.6)	0		0		2	(1.3)
		3+	0		0		0		0		0		0		0		0		0		0		0		0		0		0		0		0		0		0	
		Total	106	(88.3)	12	(10.0)	2	(1.7)	0		0		120	(100.0)	30	(81.1)	4	(10.8)	3	(8.1)	0		0		37	(100.0)	136	(86.6)	16	(10.2)	5	(3.2)	0		0		157	(100.0)
Glucose	Week 2	-	113	(89.7)	0		1	(0.8)	0		1	(0.8)	115	(91.3)	35	(87.5)	1	(2.5)	1	(2.5)	1	(2.5)	0		38	(95.0)	148	(89.2)	1	(0.6)	2	(1.2)	1	(0.6)	1	(0.6)	153	(92.2)
		±	3	(2.4)	0		0		0		0		3	(2.4)	0		0		0		0		0		0		3	(1.8)	0		0		0		0		3	(1.8)
		+	2	(1.6)	1	(0.8)	1	(0.8)	0		0		4	(3.2)	1	(2.5)	0		0		0		0		1	(2.5)	3	(1.8)	1	(0.6)	1	(0.6)	0		0		5	(3.0)
		2+	2	(1.6)	1	(0.8)	1	(0.8)	0		0		4	(3.2)	0		0		1	(2.5)	0		0		1	(2.5)	2	(1.2)	1	(0.6)	2	(1.2)	0		0		5	(3.0)
		3+	0		0		0		0		0		0		0		0		0		0		0		0		0		0		0		0		0		0	
		Total	120	(95.2)	2	(1.6)	3	(2.4)	0		1	(0.8)	126	(100.0)	36	(90.0)	1	(2.5)	2	(5.0)	1	(2.5)	0		40	(100.0)	156	(94.0)	3	(1.8)	5	(3.0)	1	(0.6)	1	(0.6)	166	(100.0)
	Week 12	-	112	(91.8)	1	(0.8)	2	(1.6)	0		0		115	(94.3)	35	(87.5)	0		1	(2.5)	1	(2.5)	0		37	(92.5)	147	(90.7)	1	(0.6)	3	(1.9)	1	(0.6)	0		152	(93.8)
		±	3	(2.5)	1	(0.8)	0		0		0		4	(3.3)	1	(2.5)	0		0		0		0		1	(2.5)	4	(2.5)	1	(0.6)	0		0		0		5	(3.1)
		+	1	(0.8)	0		1	(0.8)	0		0		2	(1.6)	0		0		1	(2.5)	0		0		1	(2.5)	1	(0.6)	0		2	(1.2)	0		0		3	(1.9)
		2+	0		0		0		0		0		0		0		0		0		0		0		0		0		0		0		0		0		0	
		3+	0		0		0		0		1	(0.8)	1	(0.8)	0		1	(2.5)	0		0		0		1	(2.5)	0		1	(0.6)	0		0		1	(0.6)	2	(1.2)
		Total	116	(95.1)	2	(1.6)	3	(2.5)	0		1	(0.8)	122	(100.0)	36	(90.0)	1	(2.5)	2	(5.0)	1	(2.5)	0		40	(100.0)	152	(93.8)	3	(1.9)	5	(3.1)	1	(0.6)	1	(0.6)	162	(100.0)
	Week 24	-	111	(91.7)	2	(1.7)	0		0		0		113	(93.4)	32	(86.5)	0		1	(2.7)	1	(2.7)	0		34	(91.9)	143	(90.5)	2	(1.3)	1	(0.6)	1	(0.6)	0		147	(93.0)
		±	2	(1.7)	0		1	(0.8)	0		0		3	(2.5)	0		0		1	(2.7)	0		0		1	(2.7)	2	(1.3)	0		2	(1.3)	0		0		4	(2.5)
		+	0		0		0		0		0		0		0		0		0		0		0		0		0		0		0		0		0		0	
		2+	0		0		1	(0.8)	0		0		1	(0.8)	1	(2.7)	1	(2.7)	0		0		0		2	(5.4)	1	(0.6)	1	(0.6)	1	(0.6)	0		0		3	(1.9)
		3+	2	(1.7)	0		1	(0.8)	0		1	(0.8)	4	(3.3)	0		0		0		0		0		0		2	(1.3)	0		1	(0.6)	0		1	(0.6)	4	(2.5)

Parameters	Time point	Baseline[a]	Knee N=126												Except fot knee N=40												Total N=166											
			-		±		+		2+		3+		Total		-		±		+		2+		3+		Total		-		±		+		2+		3+		Total	
			n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]
		Total	115	(95.0)	2	(1.7)	3	(2.5)	0		1	(0.8)	121	(100.0)	33	(89.2)	1	(2.7)	2	(5.4)	1	(2.7)	0		37	(100.0)	148	(93.7)	3	(1.9)	5	(3.2)	1	(0.6)	1	(0.6)	158	(100.0)
	Week 36	-	110	(91.7)	2	(1.7)	1	(0.8)	0		0		113	(94.2)	31	(83.8)	0		2	(5.4)	1	(2.7)	0		34	(91.9)	141	(89.8)	2	(1.3)	3	(1.9)	1	(0.6)	0		147	(93.6)
		±	1	(0.8)	0		0		0		0		1	(0.8)	0		0		0		0		0		0		1	(0.6)	0		0		0		0		1	(0.6)
		+	2	(1.7)	0		0		0		0		2	(1.7)	1	(2.7)	0		0		0		0		1	(2.7)	3	(1.9)	0		0		0		0		3	(1.9)
		2+	0		0		0		0		0		0		0		0		0		0		0		0		0		0		0		0		0		0	
		3+	1	(0.8)	0		2	(1.7)	0		1	(0.8)	4	(3.3)	1	(2.7)	1	(2.7)	0		0		0		2	(5.4)	2	(1.3)	1	(0.6)	2	(1.3)	0		1	(0.6)	6	(3.8)
		Total	114	(95.0)	2	(1.7)	3	(2.5)	0		1	(0.8)	120	(100.0)	33	(89.2)	1	(2.7)	2	(5.4)	1	(2.7)	0		37	(100.0)	147	(93.6)	3	(1.9)	5	(3.2)	1	(0.6)	1	(0.6)	157	(100.0)
	Week 52	-	113	(94.2)	0		0		0		1	(0.8)	114	(95.0)	32	(86.5)	0		1	(2.7)	0		0		33	(89.2)	145	(92.4)	0		1	(0.6)	0		1	(0.6)	147	(93.6)
		±	1	(0.8)	0		1	(0.8)	0		0		2	(1.7)	1	(2.7)	0		0		0		0		1	(2.7)	2	(1.3)	0		1	(0.6)	0		0		3	(1.9)
		+	1	(0.8)	1	(0.8)	0		0		0		2	(1.7)	0		0		0		0		0		0		1	(0.6)	1	(0.6)	0		0		0		2	(1.3)
		2+	0		0		1	(0.8)	0		0		1	(0.8)	0		0		0		0		0		0		0		0		1	(0.6)	0		0		1	(0.6)
		3+	0		0		1	(0.8)	0		0		1	(0.8)	0		1	(2.7)	1	(2.7)	1	(2.7)	0		3	(8.1)	0		1	(0.6)	2	(1.3)	1	(0.6)	0		4	(2.5)
		Total	115	(95.8)	1	(0.8)	3	(2.5)	0		1	(0.8)	120	(100.0)	33	(89.2)	1	(2.7)	2	(5.4)	1	(2.7)	0		37	(100.0)	148	(94.3)	2	(1.3)	5	(3.2)	1	(0.6)	1	(0.6)	157	(100.0)

a: Baseline is value at screening.
b: Percentages are based on the number of subjects with non-missing values at both baseline and each timepoint.
〔5.3.5.2-1 Table 14.3.4-3 改編〕

表 2.7.4.7-85. 臨床検査値の各項目のシフトテーブル（定性試験）②：613/1032 試験

Parameters	Time point	Baseline[a]	Knee N=126												Except fot knee N=40												SI-613 30 mg N=166											
			±		+		2+		3+		Total				±		+		2+		3+		Total				±		+		2+		3+		Total			
			n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]			n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]			n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]		
Urobilinogen	Week 2	±	123	(97.6)	1	(0.8)	0		0		124	(98.4)			39	(97.5)	0		0		0		39	(97.5)			162	(97.6)	1	(0.6)	0		0		163	(98.2)		
		+	2	(1.6)	0		0		0		2	(1.6)			1	(2.5)	0		0		0		1	(2.5)			3	(1.8)	0		0		0		3	(1.8)		
		2+	0		0		0		0		0				0		0		0		0		0				0		0		0		0		0			
		3+	0		0		0		0		0				0		0		0		0		0				0		0		0		0		0			
		Total	125	(99.2)	1	(0.8)	0		0		126	(100.0)			40	(100.0)	0		0		0		40	(100.0)			165	(99.4)	1	(0.6)	0		0		166	(100.0)		
	Week 12	±	120	(98.4)	1	(0.8)	0		0		121	(99.2)			40	(100.0)	0		0		0		40	(100.0)			160	(98.8)	1	(0.6)	0		0		161	(99.4)		
		+	1	(0.8)	0		0		0		1	(0.8)			0		0		0		0		0				1	(0.6)	0		0		0		1	(0.6)		
		2+	0		0		0		0		0				0		0		0		0		0				0		0		0		0		0			
		3+	0		0		0		0		0				0		0		0		0		0				0		0		0		0		0			
		Total	121	(99.2)	1	(0.8)	0		0		122	(100.0)			40	(100.0)	0		0		0		40	(100.0)			161	(99.4)	1	(0.6)	0		0		162	(100.0)		

Parameters	Time point	Baseline[a]	Knee N=126										Except fot knee N=40										SI-613 30 mg N=166									
			±		+		2+		3+		Total		±		+		2+		3+		Total		±		+		2+		3+		Total	
			n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]
	Week 24	±	118	(97.5)	1	(0.8)	0		0		119	(98.3)	37	(100.0)	0		0		0		37	(100.0)	155	(98.1)	1	(0.6)	0		0		156	(98.7)
		+	2	(1.7)	0		0		0		2	(1.7)	0		0		0		0		0		2	(1.3)	0		0		0		2	(1.3)
		2+	0		0		0		0		0		0		0		0		0		0		0		0		0		0		0	
		3+	0		0		0		0		0		0		0		0		0		0		0		0		0		0		0	
		Total	120	(99.2)	1	(0.8)	0		0		121	(100.0)	37	(100.0)	0		0		0		37	(100.0)	157	(99.4)	1	(0.6)	0		0		158	(100.0)
	Week 36	±	118	(98.3)	1	(0.8)	0		0		119	(99.2)	37	(100.0)	0		0		0		37	(100.0)	155	(98.7)	1	(0.6)	0		0		156	(99.4)
		+	1	(0.8)	0		0		0		1	(0.8)	0		0		0		0		0		1	(0.6)	0		0		0		1	(0.6)
		2+	0		0		0		0		0		0		0		0		0		0		0		0		0		0		0	
		3+	0		0		0		0		0		0		0		0		0		0		0		0		0		0		0	
		Total	119	(99.2)	1	(0.8)	0		0		120	(100.0)	37	(100.0)	0		0		0		37	(100.0)	156	(99.4)	1	(0.6)	0		0		157	(100.0)
	Week 52	±	117	(97.5)	1	(0.8)	0		0		118	(98.3)	37	(100.0)	0		0		0		37	(100.0)	154	(98.1)	1	(0.6)	0		0		155	(98.7)
		+	2	(1.7)	0		0		0		2	(1.7)	0		0		0		0		0		2	(1.3)	0		0		0		2	(1.3)
		2+	0		0		0		0		0		0		0		0		0		0		0		0		0		0		0	
		3+	0		0		0		0		0		0		0		0		0		0		0		0		0		0		0	
		Total	119	(99.2)	1	(0.8)	0		0		120	(100.0)	37	(100.0)	0		0		0		37	(100.0)	156	(99.4)	1	(0.6)	0		0		157	(100.0)

a: Baseline is value at screening.
b: Percentages are based on the number of subjects with non-missing values at both baseline and each timepoint.
〔5.3.5.2-1 Table 14.3.4-3 改編〕

表 2.7.4.7-86. バイタルサインの各項目の平均値と中央値：613/1021 試験

Parameters		Timepoint	Placebo N=40 n	Value at timepoint	Change from baseline	SI-613 15 mg N=40 n	Value at timepoint	Change from baseline	SI-613 30 mg N=40 n	Value at timepoint	Change from baseline
Diastolic Blood Pressure (mmHg)	Mean (SD)	Baseline	40	130.6 (16.6)	-	40	131.7 (15.7)	-	41	133.9 (14.5)	-
		Week 1	39	130.7 (18.8)	-	40	128.3 (16.2)	-	41	131.5 (15.2)	-
		Week 2	40	129.0 (15.1)	-	38	127.8 (17.5)	-	39	131.5 (13.2)	-
		Week 4	40	126.6 (17.7)	-	38	128.1 (19.3)	-	40	130.8 (17.2)	-
		Week 12	38	126.8 (19.1)	-	37	126.8 (17.9)	-	38	131.5 (14.8)	-
	Median (25%, 75%)	Baseline	40	130.5 (118.0, 142.5)	-	40	131.5 (120.5, 144.0)	-	41	135.0 (128.0, 143.0)	-
		Week 1	39	131.0 (119.0, 144.0)	-	40	128.5 (114.5, 139.0)	-	41	132.0 (121.0, 144.0)	-
		Week 2	40	126.5 (120.0, 141.5)	-	38	128.5 (114.0, 143.0)	-	39	130.0 (122.0, 140.0)	-
		Week 4	40	128.0 (112.5, 139.0)	-	38	129.0 (114.0, 145.0)	-	40	132.0 (118.5, 142.0)	-
		Week 12	38	125.0 (111.0, 142.0)	-	37	127.0 (114.0, 138.0)	-	38	133.5 (125. , 138.0)	-
Systolic Blood Pressure (mmHg)	Mean (SD)	Baseline	40	77.6 (10.6)	-	40	77.6 (10.1)	-	41	80.4 (9.2)	-
		Week 1	39	78.2 (12.3)	-	40	77.1 (10.6)	-	41	79.1 (10.6)	-
		Week 2	40	76.2 (10.2)	-	38	76.1 (12.4)	-	39	79.4 (8.9)	-
		Week 4	40	75.3 (11.5)	-	38	77.3 (10.6)	-	40	79.1 (11.6)	-
		Week 12	38	75.5 (11.6)	-	37	77.8 (12.0)	-	38	77.6 (8.5)	-
	Median (25%, 75%)	Baseline	40	76.5 (70.0, 86.5)	-	40	79.5 (69.0, 86.5)	-	41	83.0 (76.0, 85.0)	-
		Week 1	39	78.0 (69.0, 87.0)	-	40	78.5 (69.0, 84.5)	-	41	80.0 (70.0, 86.0)	-
		Week 2	40	77.0 (68.0, 86.5)	-	38	76.0 (67.0, 86.0)	-	39	80.0 (75.0, 84.0)	-
		Week 4	40	76.5 (65.0, 85.0)	-	38	78.0 (67.0, 87.0)	-	40	80.5 (72.5, 84.5)	-
		Week 12	38	77.0 (64.0, 85.0)	-	37	78.0 (69.0, 88.0)	-	38	79.0 (72.0, 83.0)	-
Pulse Rate (bpm)	Mean (SD)	Baseline	40	69.2 (8.8)	-	40	72.6 (8.5)	-	41	70.3 (10.7)	-
		Week 1	39	68.5 (7.4)	-	40	71.3 (10.2)	-	41	70.0 (10.3)	-
		Week 2	40	70.3 (7.0)	-	38	71.2 (9.5)	-	39	68.5 (10.1)	-
		Week 4	40	69.1 (6.8)	-	38	71.7 (10.1)	-	40	69.4 (11.9)	-
		Week 12	38	68.8 (7.1)	-	37	68.7 (7.9)	-	38	67.9 (9.5)	-
	Median (25%, 75%)	Baseline	40	66.5 (63.5, 72.0)	-	40	72.0 (66.5, 78.5)	-	41	67.0 (65.0, 76.0)	-
		Week 1	39	68.0 (63.0, 73.0)	-	40	70.0 (66.0, 76.0)	-	41	70.0 (63.0, 74.0)	-
		Week 2	40	69.0 (66.0, 74.5)	-	38	69.0 (66.0, 76.0)	-	39	67.0 (61.0, 72.0)	-
		Week 4	40	68.0 (65.5, 72.0)	-	38	71.5 (65.0, 77.0)	-	40	67.5 (61.5, 75.5)	-
		Week 12	38	67.5 (63.0, 73.0)	-	37	69.0 (65.0, 72.0)	-	38	68.5 (60.0, 75.0)	-
Temperature (C)	Mean (SD)	Baseline	40	36.08 (0.49)	-	40	36.17 (0.44)	-	41	36.12 (0.45)	-
		Week 1	39	36.23 (0.41)	-	40	36.25 (0.41)	-	41	36.06 (0.47)	-
		Week 2	40	36.21 (0.45)	-	38	36.16 (0.35)	-	39	36.02 (0.48)	-
		Week 4	40	36.23 (0.41)	-	38	36.24 (0.36)	-	40	36.05 (0.54)	-
		Week 12	38	36.22 (0.40)	-	37	36.23 (0.33)	-	38	36.05 (0.42)	-
	Median (25%, 75%)	Baseline	40	36.10 (35.80, 36.45)	-	40	36.25 (35.90, 36.50)	-	41	36.20 (36.00, 36.40)	-
		Week 1	39	36.30 (36.00, 36.50)	-	40	36.30 (36.00, 36.50)	-	41	36.00 (35.80, 36.50)	-
		Week 2	40	36.20 (36.00, 36.60)	-	38	36.20 (36.00, 36.30)	-	39	36.10 (35.60, 36.30)	-
		Week 4	40	36.20 (35.85, 36.65)	-	38	36.25 (36.10, 36.50)	-	40	36.15 (35.75, 36.40)	-
		Week 12	38	36.25 (36.00 , 36.50)	-	37	36.30 (36.00 , 36.40)	-	38	36.15 (35.80, 36.30)	-

〔5.3.5.1-1 表 14.3.4-3 改編〕

表 2.7.4.7-87. バイタルサインの各項目の平均値と中央値：613/1022 試験

Parameters		Timepoint	Placebo N=89 n	Value at timepoint	Change from baseline	SI-613 30 mg N=87 n	Value at timepoint	Change from baseline
Diastolic Blood Pressure (mmHg)	Mean (SD)	Baseline	89	78.1 (11.0)	-	87	77.8 (11.0)	-
		Week 4	83	77.9 (9.9)	-0.2 (8.0)	86	77.3 (10.2)	-0.4 (9.3)
		Week 8	83	76.7 (10.5)	-1.4 (9.5)	85	76.7 (9.8)	-1.0 (9.2)

Parameters		Timepoint	Placebo N=89 n	Placebo N=89 Value at timepoint	Placebo N=89 Change from baseline	SI-613 30 mg N=87 n	SI-613 30 mg N=87 Value at timepoint	SI-613 30 mg N=87 Change from baseline
		Week 12	81	77.2 (10.0)	-1.1 (10.5)	84	75.7 (9.0)	-2.2 (9.0)
		Week 24	81	76.9 (10.6)	-1.4 (9.3)	82	78.2 (9.1)	0.2 (9.1)
	Median	Baseline	89	78.0 (70.0, 86.0)	-	87	77.0 (71.0, 84.0)	-
	(25%, 75%)	Week 4	83	77.0 (72.0, 84.0)	0.0 (-5.0, 6.0)	86	76.0 (71.0, 85.0)	0.0 (-6.0, 5.0)
		Week 8	83	76.0 (69.0, 84.0)	-3.0 (-7.0, 4.0)	85	77.0 (70.0, 83.0)	-2.0 (-6.0, 5.0)
		Week 12	81	78.0 (70.0, 84.0)	-1.0 (-6.0, 5.0)	84	76.0 (69.0, 82.5)	-2.0 (-7.0, 3.5)
		Week 24	81	77.0 (68.0, 85.0)	-1.0 (-7.0, 5.0)	82	78.5 (73.0, 83.0)	0.0 (-5.0, 7.0)
Systolic Blood	Mean (SD)	Baseline	89	132.1 (16.2)	-	87	128.9 (13.8)	-
Pressure (mmHg)		Week 4	83	130.4 (15.4)	-2.1 (14.1)	86	126.8 (15.2)	-1.9 (12.2)
		Week 8	83	127.6 (14.6)	-4.9 (12.1)	85	126.1 (13.0)	-2.2 (12.2)
		Week 12	81	126.9 (13.1)	-5.5 (13.5)	84	126.2 (15.5)	-2.2 (13.2)
		Week 24	81	128.3 (13.3)	-4.2 (15.2)	82	126.7 (13.7)	-1.9 (12.0)
	Median	Baseline	89	134.0 (122.0, 141.0)	-	87	131.0 (121.0, 138.0)	-
	(25%, 75%)	Week 4	83	133.0 (123.0, 141.0)	1.0 (-12.0, 8.0)	86	128.0 (114.0, 136.0)	-2.5 (-9.0, 6.0)
		Week 8	83	130.0 (118.0, 137.0)	-5.0 (-11.0, 3.0)	85	126.0 (117.0, 136.0)	-2.0 (-10.0, 6.0)
		Week 12	81	128.0 (119.0, 134.0)	-6.0 (-14.0, 4.0)	84	125.0 (114.0, 135.5)	-3.0 (-12.0, 6.5)
		Week 24	81	130.0 (120.0, 138.0)	-3.0 (-12.0, 6.0)	82	126.0 (118.0, 138.0)	-4.0 (-10.0, 6.0)
Pulse Rate	Mean (SD)	Baseline	89	73.1 (10.3)	-	87	72.1 (10.4)	-
(beats/min)		Week 4	83	72.2 (9.9)	-0.6 (8.5)	86	71.3 (8.7)	-0.7 (7.2)
		Week 8	83	70.8 (9.6)	-2.1 (8.8)	85	71.7 (9.9)	-0.3 (7.8)
		Week 12	81	72.2 (10.6)	-0.9 (9.4)	84	70.4 (9.2)	-1.4 (7.7)
		Week 24	81	72.1 (10.6)	-1.0 (9.2)	82	71.1 (9.5)	-0.9 (8.0)
	Median	Baseline	89	73.0 (66.0, 80.0)	-	87	72.0 (65.0, 80.0)	-
	(25%, 75%)	Week 4	83	72.0 (65.0, 79.0)	-2.0 (-4.0, 2.0)	86	71.0 (65.0, 78.0)	0.5 (-5.0, 4.0)
		Week 8	83	70.0 (64.0, 76.0)	-2.0 (-6.0, 3.0)	85	73.0 (65.0, 77.0)	1.0 (-5.0, 4.0)
		Week 12	81	72.0 (63.0, 79.0)	0.0 (-5.0, 4.0)	84	70.0 (64.5, 74.5)	-1.0 (-6.0, 3.0)
		Week 24	81	71.0 (66.0, 79.0)	0.0 (-6.0, 5.0)	82	70.0 (65.0, 76.0)	0.0 (-5.0, 3.0)
Temperature (C)	Mean (SD)	Baseline	89	36.30 (0.47)	-	87	36.28 (0.39)	-
		Week 4	83	36.28 (0.43)	-0.01 (0.42)	86	36.26 (0.36)	-0.02 (0.40)
		Week 8	83	36.25 (0.48)	-0.05 (0.49)	85	36.27 (0.41)	-0.01 (0.34)
		Week 12	81	36.27 (0.48)	-0.02 (0.42)	84	36.25 (0.39)	-0.03 (0.38)
		Week 24	81	36.24 (0.43)	-0.05 (0.48)	82	36.24 (0.37)	-0.04 (0.41)
	Median	Baseline	89	36.40 (36.00, 36.60)	-	87	36.30 (36.00, 36.60)	-
	(25%, 75%)	Week 4	83	36.30 (36.00, 36.60)	0.00 (-0.30, 0.20)	86	36.30 (36.00, 36.50)	-0.10 (-0.30, 0.20)
		Week 8	83	36.40 (36.00, 36.60)	-0.10 (-0.40, 0.20)	85	36.30 (36.10, 36.50)	0.00 (-0.30, 0.20)
		Week 12	81	36.30 (36.00, 36.60)	0.00 (-0.30, 0.20)	84	36.30 (36.00, 36.50)	-0.10 (-0.20, 0.20)
		Week 24	81	36.30 (36.00, 36.60)	0.00 (-0.40, 0.20)	82	36.20 (36.00, 36.50)	-0.10 (-0.30, 0.20)

〔5.3.5.1-2 Table 14.3.4-4 改編〕

表 2.7.4.7-88. バイタルサインの各項目の平均値と中央値：613/1031 試験

Parameters		Timepoint	Placebo N=220 n	Placebo N=220 Value at timepoint	Placebo N=220 Change from baseline	SI-613 30 mg N=220 n	SI-613 30 mg N=220 Value at timepoint	SI-613 30 mg N=220 Change from baseline
Diastolic Blood	Mean (SD)	Baseline	220	79.4 (12.3)	-	220	78.7 (11.6)	-
Pressure (mmHg)		Week2	215	78.4 (11.1)	-1.1 (9.5)	218	77.7 (11.4)	-1.0 (8.9)
		Week 4	213	77.8 (10.8)	-1.9 (8.9)	218	77.9 (12.2)	-0.8 (9.8)
		Week 8	213	77.9 (11.0)	-1.7 (9.7)	214	76.7 (11.2)	-2.0 (8.8)
		Week 12	213	77.0 (11.0)	-2.7 (9.7)	212	78.2 (11.5)	-0.6 (9.2)
		Week 16	211	77.3 (11.2)	-2.4 (10.0)	206	78.0 (11.1)	-0.7 (8.9)
		Week 20	209	77.6 (10.6)	-2.1 (9.8)	205	77.8 (11.4)	-1.0 (8.5)
		Week 24	209	77.9 (10.6)	-1.8 (9.7)	206	78.1 (11.4)	-0.6 (9.0)

Parameters		Timepoint	Placebo N=220 n	Placebo N=220 Value at timepoint	Placebo N=220 Change from baseline	SI-613 30 mg N=220 n	SI-613 30 mg N=220 Value at timepoint	SI-613 30 mg N=220 Change from baseline
	Median	Baseline	220	79.0 (71.0, 87.0)	-	220	79.0 (70.0, 87.0)	-
	(25%, 75%)	Week2	215	78.0 (71.0, 87.0)	-1.0 (-7.0, 5.0)	218	78.0 (70.0, 85.0)	-1.0 (-6.0, 5.0)
		Week 4	213	77.0 (70.0, 86.0)	-2.0 (-8.0, 4.0)	218	78.0 (70.0, 86.0)	0.0 (-7.0, 6.0)
		Week 8	213	79.0 (71.0, 84.0)	-2.0 (-8.0, 3.0)	214	77.5 (68.0, 85.0)	-2.0 (-6.0, 4.0)
		Week 12	213	77.0 (70.0, 84.0)	-3.0 (-8.0, 3.0)	212	78.0 (71.5, 86.0)	0.0 (-6.0, 5.0)
		Week 16	211	78.0 (70.0, 85.0)	-2.0 (-8.0, 3.0)	206	78.5 (71.0, 85.0)	0.0 (-7.0, 6.0)
		Week 20	209	77.0 (70.0, 85.0)	-2.0 (-7.0, 4.0)	205	79.0 (70.0, 85.0)	-1.0 (-7.0, 4.0)
		Week 24	209	78.0 (71.0, 85.0)	-2.0 (-8.0, 3.0)	206	78.0 (71.0, 87.0)	0.0 (-6.0, 5.0)
Systolic Blood Pressure (mmHg)	Mean (SD)	Baseline	220	133.3 (18.2)	-	220	131.0 (16.5)	-
		Week2	215	130.3 (15.8)	-3.2 (13.4)	218	129.3 (15.4)	-1.6 (12.4)
		Week 4	213	129.8 (16.4)	-3.6 (12.8)	218	130.3 (17.3)	-0.6 (12.7)
		Week 8	213	129.2 (15.9)	-4.3 (13.4)	214	130.8 (17.3)	-0.2 (13.1)
		Week 12	213	128.1 (16.2)	-5.4 (12.7)	212	130.1 (16.5)	-0.9 (12.0)
		Week 16	211	128.4 (15.4)	-5.2 (13.6)	206	129.7 (16.5)	-1.3 (13.4)
		Week 20	209	129.9 (15.4)	-3.5 (13.9)	205	128.7 (16.0)	-2.2 (13.5)
		Week 24	209	130.9 (16.1)	-2.5 (14.1)	206	129.6 (15.3)	-1.3 (12.9)
	Median	Baseline	220	132.0 (122.0, 143.5)	-	220	130.0 (120.0, 142.0)	-
	(25%, 75%)	Week2	215	129.0 (120.0, 141.0)	-3.0 (-9.0, 4.0)	218	128.0 (121.0, 140.0)	-1.5 (-9.0, 5.0)
		Week 4	213	130.0 (120.0, 140.0)	-3.0 (-10.0, 4.0)	218	130.0 (118.0, 140.0)	-1.0 (-8.0, 7.0)
		Week 8	213	129.0 (119.0, 138.0)	-2.0 (-11.0, 4.0)	214	131.0 (118.0, 140.0)	0.0 (-8.0, 7.0)
		Week 12	213	128.0 (117.0, 139.0)	-4.0 (-12.0, 2.0)	212	130.0 (120.5, 139.0)	0.0 (-8.0, 7.0)
		Week 16	211	129.0 (117.0, 138.0)	-3.0 (-13.0, 3.0)	206	129.0 (119.0, 140.0)	-1.0 (-9.0, 6.0)
		Week 20	209	130.0 (121.0, 139.0)	-3.0 (-11.0, 6.0)	205	128.0 (118.0, 139.0)	-2.0 (-11.0, 6.0)
		Week 24	209	132.0 (119.0, 142.0)	-2.0 (-10.0, 6.0)	206	130.0 (120.0, 139.0)	-2.0 (-10.0, 7.0)
Pulse Rate (beats/min)	Mean (SD)	Baseline	220	72.8 (10.5)	-	220	72.9 (10.1)	-
		Week2	215	73.5 (9.8)	0.8 (7.8)	218	72.6 (10.0)	-0.4 (7.9)
		Week 4	213	72.9 (10.2)	0.2 (7.6)	218	72.7 (10.2)	-0.2 (8.8)
		Week 8	213	74.1 (9.7)	1.3 (7.4)	214	72.6 (10.5)	-0.3 (8.7)
		Week 12	213	73.5 (10.4)	0.6 (8.4)	212	71.9 (10.5)	-0.8 (8.9)
		Week 16	211	74.3 (9.9)	1.5 (8.0)	206	73.2 (10.0)	0.4 (8.4)
		Week 20	209	73.1 (9.8)	0.2 (8.5)	205	73.2 (10.3)	0.4 (8.3)
		Week 24	209	74.2 (9.5)	1.3 (8.6)	206	72.9 (9.8)	0.1 (8.9)
	Median	Baseline	220	72.0 (65.5, 78.0)	-	220	72.5 (65.0, 80.0)	-
	(25%, 75%)	Week2	215	73.0 (67.0, 80.0)	1.0 (-4.0, 5.0)	218	72.0 (66.0, 78.0)	0.0 (-4.0, 4.0)
		Week 4	213	71.0 (67.0, 79.0)	0.0 (-4.0, 5.0)	218	72.0 (65.0, 79.0)	0.0 (-6.0, 5.0)
		Week 8	213	74.0 (67.0, 80.0)	1.0 (-4.0, 5.0)	214	72.0 (65.0, 79.0)	-1.0 (-6.0, 5.0)
		Week 12	213	72.0 (66.0, 80.0)	1.0 (-5.0, 5.0)	212	70.0 (65.0, 79.0)	0.0 (-6.0, 4.5)
		Week 16	211	74.0 (67.0, 80.0)	2.0 (-4.0, 6.0)	206	72.5 (67.0, 80.0)	1.0 (-5.0, 5.0)
		Week 20	209	73.0 (66.0, 80.0)	0.0 (-5.0, 6.0)	205	73.0 (66.0, 80.0)	0.0 (-5.0, 5.0)
		Week 24	209	74.0 (68.0, 81.0)	2.0 (-4.0, 7.0)	206	72.0 (67.0, 79.0)	0.0 (-6.0, 6.0)
Temperature (C)	Mean (SD)	Baseline	220	36.36 (0.36)	-	220	36.35 (0.38)	-
		Week2	215	36.39 (0.35)	0.02 (0.36)	218	36.32 (0.37)	-0.03 (0.38)
		Week 4	213	36.38 (0.38)	0.01 (0.36)	218	36.34 (0.37)	-0.01 (0.38)
		Week 8	213	36.38 (0.34)	0.01 (0.40)	214	36.38 (0.37)	0.03 (0.38)
		Week 12	213	36.36 (0.37)	-0.01 (0.39)	212	36.35 (0.36)	0.00 (0.40)
		Week 16	211	36.36 (0.36)	0.00 (0.40)	206	36.37 (0.35)	0.01 (0.41)
		Week 20	209	36.37 (0.37)	0.01 (0.40)	205	36.36 (0.38)	0.00 (0.41)
		Week 24	209	36.36 (0.36)	0.00 (0.41)	206	36.35 (0.41)	0.00 (0.42)
	Median	Baseline	220	36.40 (36.20, 36.60)	-	220	36.40 (36.20, 36.60)	-
	(25%, 75%)	Week2	215	36.40 (36.20, 36.60)	0.00 (-0.20, 0.20)	218	36.40 (36.10, 36.60)	0.00 (-0.30, 0.20)
		Week 4	213	36.40 (36.20, 36.60)	0.00 (-0.20, 0.20)	218	36.40 (36.20, 36.60)	0.00 (-0.20, 0.20)
		Week 8	213	36.40 (36.10, 36.60)	0.00 (-0.20, 0.30)	214	36.40 (36.20, 36.70)	0.00 (-0.20, 0.30)
		Week 12	213	36.40 (36.20, 36.60)	0.00 (-0.20, 0.20)	212	36.40 (36.10, 36.60)	0.00 (-0.30, 0.20)
		Week 16	211	36.40 (36.20, 36.60)	0.00 (-0.20, 0.20)	206	36.40 (36.20, 36.60)	0.00 (-0.20, 0.20)

Parameters	Timepoint	Placebo N=220 n	Placebo N=220 Value at timepoint	Placebo N=220 Change from baseline	SI-613 30 mg N=220 n	SI-613 30 mg N=220 Value at timepoint	SI-613 30 mg N=220 Change from baseline
	Week 20	209	36.40 (36.10, 36.60)	0.00 (-0.20, 0.20)	205	36.40 (36.20, 36.60)	0.00 (-0.30, 0.30)
	Week 24	209	36.40 (36.20, 36.60)	0.00 (-0.20, 0.30)	206	36.40 (36.10, 36.60)	0.00 (-0.20, 0.20)

〔5.3.5.1-3 Table 14.3.4-4 改編〕

表 2.7.4.7-89. バイタルサインの各項目の平均値と中央値：613/1033 試験

Parameters		Timepoint	Placebo N=144 n	Placebo N=144 Value at timepoint	Placebo N=144 Change from baseline	SI-613 30 mg N=146 n	SI-613 30 mg N=146 Value at timepoint	SI-613 30 mg N=146 Change from baseline
Diastolic Blood Pressure (mmHg)	Mean (SD)	Baseline	144	78.1 (11.3)	-	146	79.5 (11.4)	-
		Week2	144	77.2 (11.1)	-1.0 (8.7)	146	76.3 (11.7)	-3.2 (9.3)
		Week 4	142	77.9 (11.2)	-0.4 (10.0)	146	77.4 (11.1)	-2.1 (8.6)
		Week 8	141	76.5 (10.4)	-1.7 (8.0)	143	77.7 (10.8)	-1.7 (9.4)
		Week 12	138	76.4 (10.2)	-1.8 (9.3)	143	77.2 (11.0)	-2.2 (9.5)
	Median (25%, 75%)	Baseline	144	78.5 (70.0, 85.0)	-	146	80.5 (70.0, 88.0)	-
		Week2	144	76.0 (70.0, 84.0)	-1.5 (-6.0, 4.0)	146	78.0 (68.0, 85.0)	-4.0 (-9.0, 4.0)
		Week 4	142	78.0 (71.0, 87.0)	0.0 (-6.0, 5.0)	146	78.0 (68.0, 85.0)	-2.0 (-7.0, 3.0)
		Week 8	141	76.0 (70.0, 83.0)	-1.0 (-8.0, 4.0)	143	78.0 (70.0, 84.0)	-2.0 (-8.0, 4.0)
		Week 12	138	76.0 (69.0, 84.0)	-2.0 (-8.0, 4.0)	143	78.0 (69.0, 85.0)	-2.0 (-7.0, 4.0)
Systolic Blood Pressure (mmHg)	Mean (SD)	Baseline	144	131.9 (18.5)	-	146	133.9 (14.6)	-
		Week2	144	130.6 (17.7)	-1.3 (13.4)	146	130.3 (14.2)	-3.5 (12.4)
		Week 4	142	130.9 (17.3)	-1.2 (12.9)	146	130.4 (14.4)	-3.5 (11.7)
		Week 8	141	130.1 (16.9)	-2.2 (11.9)	143	129.5 (14.5)	-4.3 (13.1)
		Week 12	138	129.8 (15.8)	-2.5 (13.7)	143	129.9 (15.2)	-3.9 (14.1)
	Median (25%, 75%)	Baseline	144	132.0 (116.0, 144.5)	-	146	134.0 (125.0, 143.0)	-
		Week2	144	131.0 (117.5, 142.0)	-2.0 (-9.5, 6.0)	146	131.0 (120.0, 140.0)	-2.0 (-13.0, 5.0)
		Week 4	142	131.0 (118.0, 141.0)	-2.0 (-7.0, 5.0)	146	130.0 (122.0, 140.0)	-4.0 (-11.0, 4.0)
		Week 8	141	132.0 (118.0, 141.0)	-2.0 (-10.0, 6.0)	143	131.0 (119.0, 139.0)	-3.0 (-13.0, 4.0)
		Week 12	138	130.0 (118.0, 140.0)	-3.0 (-11.0, 5.0)	143	131.0 (119.0, 141.0)	-3.0 (-13.0, 4.0)
Pulse Rate (beats/min)	Mean (SD)	Baseline	144	74.9 (10.4)	-	146	75.1 (10.8)	-
		Week2	144	73.7 (10.3)	-1.2 (8.9)	146	75.3 (11.1)	0.2 (8.6)
		Week 4	142	75.5 (10.5)	0.6 (8.5)	146	76.4 (10.4)	1.3 (8.7)
		Week 8	141	75.1 (10.4)	0.2 (8.6)	143	75.9 (10.6)	0.8 (7.9)
		Week 12	138	74.6 (11.8)	-0.4 (8.7)	143	75.8 (10.2)	0.6 (9.2)
	Median (25%, 75%)	Baseline	144	73.5 (68.0, 81.0)	-	146	73.0 (68.0, 82.0)	-
		Week2	144	73.0 (67.0, 80.5)	-1.0 (-6.0, 4.0)	146	73.0 (67.0, 82.0)	1.0 (-5.0, 5.0)
		Week 4	142	74.0 (68.0, 82.0)	0.0 (-4.0, 5.0)	146	74.0 (69.0, 81.0)	1.0 (-4.0, 6.0)
		Week 8	141	73.0 (68.0, 82.0)	0.0 (-5.0, 5.0)	143	75.0 (69.0, 83.0)	1.0 (-4.0, 8.0)
		Week 12	138	73.0 (66.0, 82.0)	-1.0 (-5.0, 4.0)	143	75.0 (69.0, 82.0)	0.0 (-5.0, 6.0)
Temperature (C)	Mean (SD)	Baseline	144	36.31 (0.42)	-	146	36.30 (0.42)	-
		Week2	144	36.37 (0.41)	0.06 (0.44)	146	36.30 (0.42)	-0.01 (0.48)
		Week 4	142	36.35 (0.41)	0.03 (0.39)	146	36.31 (0.43)	0.00 (0.41)
		Week 8	141	36.32 (0.40)	0.00 (0.41)	143	36.30 (0.42)	-0.01 (0.42)
		Week 12	138	36.31 (0.40)	-0.02 (0.49)	143	36.31 (0.40)	0.01 (0.43)
	Median (25%, 75%)	Baseline	144	36.40 (36.10, 36.60)	-	146	36.40 (36.00, 36.60)	-
		Week2	144	36.40 (36.10, 36.70)	0.00 (-0.20, 0.30)	146	36.40 (36.10, 36.60)	0.05 (-0.30, 0.20)
		Week 4	142	36.40 (36.20, 36.60)	0.00 (-0.20, 0.30)	146	36.40 (36.00, 36.60)	0.00 (-0.20, 0.20)
		Week 8	141	36.40 (36.10, 36.60)	0.00 (-0.30, 0.20)	143	36.30 (36.00, 36.60)	0.00 (-0.30, 0.20)
		Week 12	138	36.30 (36.00, 36.60)	0.00 (-0.40, 0.30)	143	36.40 (36.00, 36.60)	0.00 (-0.20, 0.20)

〔5.3.5.1-4 Table 14.3.4-4 改編〕

表 2.7.4.7-90. バイタルサインの各項目の平均値と中央値：613/1032 試験

Parameters		Timepoint	Knee N=126 n	Knee Value at timepoint	Knee Change from baseline	Except for knee N=40 n	Except for knee Value at timepoint	Except for knee Change from baseline	Total N=166 n	Total Value at timepoint	Total Change from baseline
Diastolic Blood Pressure (mmHg)	Mean (SD)	Baseline	126	78.2 (11.3)	-	40	82.1 (13.2)	-	166	79.2 (11.9)	-
		Week 2	126	77.0 (11.9)	-1.2 (10.3)	40	80.3 (13.4)	-1.7 (9.7)	166	77.8 (12.3)	-1.4 (10.1)
		Week 4	126	78.6 (12.2)	0.4 (10.1)	40	79.4 (12.0)	-2.6 (9.3)	166	78.8 (12.1)	-0.4 (10.0)
		Week 8	125	77.9 (11.1)	-0.5 (9.8)	40	77.5 (13.7)	-4.6 (9.6)	165	77.8 (11.7)	-1.5 (9.9)
		Week 12	122	77.3 (11.2)	-1.2 (10.5)	40	77.6 (12.8)	-4.5 (10.3)	162	77.3 (11.6)	-2.0 (10.5)
		Week 24	121	78.0 (10.9)	-0.4 (9.1)	37	81.6 (13.5)	-0.8 (9.9)	158	78.9 (11.6)	-0.5 (9.3)
		Week 36	120	78.0 (10.8)	-0.5 (9.8)	37	79.7 (11.7)	-2.7 (9.5)	157	78.4 (11.0)	-1.0 (9.7)
		Week 52	120	77.0 (10.6)	-1.3 (9.8)	37	78.1 (11.1)	-4.4 (6.7)	157	77.2 (10.7)	-2.1 (9.2)
	Median (25%, 75%)	Baseline	126	79.0 (70.0, 86.0)	-	40	81.0 (73.0, 88.0)	-	166	79.5 (71.0, 86.0)	-
		Week 2	126	77.0 (68.0, 86.0)	-2.0 (-7.0, 4.0)	40	80.5 (69.5, 90.5)	-1.5 (-9.0, 5.0)	166	78.0 (68.0, 86.0)	-2.0 (-7.0, 4.0)
		Week 4	126	78.0 (70.0, 87.0)	-0.5 (-5.0, 6.0)	40	78.0 (71.5, 86.5)	-2.5 (-8.0, 2.5)	166	78.0 (70.0, 87.0)	-1.0 (-6.0, 6.0)
		Week 8	125	78.0 (70.0, 86.0)	-1.0 (-6.0, 4.0)	40	77.0 (68.5, 83.5)	-5.5 (-10.5, 1.5)	165	77.0 (70.0, 85.0)	-3.0 (-7.0, 4.0)
		Week 12	122	78.0 (70.0, 85.0)	-2.0 (-8.0, 4.0)	40	76.0 (69.0, 86.0)	-2.0 (-11.0, 2.5)	162	77.5 (69.0, 85.0)	-2.0 (-8.0, 4.0)
		Week 24	121	78.0 (71.0, 86.0)	0.0 (-5.0, 5.0)	37	83.0 (73.0, 88.0)	-3.0 (-8.0, 6.0)	158	79.0 (71.0, 86.0)	-0.5 (-5.0, 6.0)
		Week 36	120	78.0 (70.0, 86.0)	0.0 (-7.0, 5.0)	37	80.0 (72.0, 87.0)	-3.0 (-9.0, 3.0)	157	79.0 (70.0, 86.0)	-1.0 (-8.0, 5.0)
		Week 52	120	78.0 (70.5, 85.5)	-1.0 (-6.0, 3.0)	37	79.0 (71.0, 86.0)	-4.0 (-7.0, 1.0)	157	78.0 (71.0, 86.0)	-3.0 (-7.0, 3.0)
Systolic Blood Pressure (mmHg)	Mean (SD)	Baseline	126	132.8 (16.8)	-	40	133.7 (17.1)	-	166	133.0 (16.8)	-
		Week 2	126	132.0 (18.8)	-0.8 (13.9)	40	132.0 (21.1)	-1.7 (13.6)	166	132.0 (19.3)	-1.0 (13.8)
		Week 4	126	133.0 (18.3)	0.2 (14.2)	40	131.9 (19.2)	-1.8 (13.0)	166	132.7 (18.5)	-0.3 (13.9)
		Week 8	125	130.1 (15.9)	-2.9 (13.9)	40	130.2 (20.4)	-3.5 (13.1)	165	130.1 (17.0)	-3.1 (13.7)
		Week 12	122	131.7 (17.7)	-1.6 (16.6)	40	130.2 (19.3)	-3.5 (13.5)	162	131.3 (18.0)	-2.1 (15.9)
		Week 24	121	133.8 (17.2)	0.7 (14.8)	37	137.9 (23.3)	4.2 (15.9)	158	134.7 (18.8)	1.5 (15.1)
		Week 36	120	132.1 (14.9)	-0.9 (15.0)	37	134.5 (17.2)	0.9 (12.3)	157	132.6 (15.5)	-0.5 (14.4)
		Week 52	120	130.2 (15.6)	-2.8 (14.8)	37	130.8 (15.3)	-2.9 (12.9)	157	130.4 (15.5)	-2.8 (14.4)
	Median (25%, 75%)	Baseline	126	133.0 (122.0, 144.0)	-	40	133.0 (122.5, 147.0)	-	166	133.0 (122.0, 145.0)	-
		Week 2	126	131.5 (120.0, 144.0)	0.0 (-10.0, 10.0)	40	128.0 (113.0, 152.5)	-1.0 (-8.0, 3.5)	166	130.0 (119.0, 145.0)	-0.5 (-10.0, 8.0)
		Week 4	126	133.0 (122.0, 144.0)	0.0 (-11.0, 9.0)	40	128.5 (119.0, 147.0)	-4.0 (-10.0, 5.0)	166	132.0 (121.0, 146.0)	0.0 (-11.0, 8.0)
		Week 8	125	131.0 (117.0, 140.0)	-5.0 (-13.0, 5.0)	40	124.0 (114.5, 146.0)	-4.5 (-14.5, 2.0)	165	130.0 (117.0, 140.0)	-5.0 (-13.0, 4.0)
		Week 12	122	130.5 (120.0, 145.0)	-2.0 (-12.0, 8.0)	40	124.5 (112.5, 142.5)	-3.5 (-12.5, 5.5)	162	130.0 (119.0, 144.0)	-2.5 (-12.0, 7.0)
		Week 24	121	134.0 (120.0, 146.0)	1.0 (-9.0, 10.0)	37	130.0 (122.0, 157.0)	3.0 (-5.0, 17.0)	158	134.0 (121.0, 147.0)	1.0 (-9.0, 11.0)
		Week 36	120	130.0 (124.0, 140.0)	-1.5 (-10.0, 10.0)	37	128.0 (123.0, 146.0)	1.0 (-6.0, 7.0)	157	130.0 (124.0, 141.0)	0.0 (-10.0, 9.0)
		Week 52	120	130.5 (119.0, 139.0)	-3.0 (-13.0, 7.5)	37	128.0 (124.0, 138.0)	1.0 (-11.0, 5.0)	157	130.0 (120.0, 139.0)	-2.0 (-12.0, 6.0)
	Mean (SD)	Baseline	126	73.0 (10.2)	-	40	72.6 (14.0)	-	166	72.9 (11.2)	-

Parameters		Timepoint	Knee N=126 n	Value at timepoint	Change from baseline	Except for knee N=40 n	Value at timepoint	Change from baseline	Total N=166 n	Value at timepoint	Change from baseline
Pulse Rate		Week 2	126	73.2 (11.0)	0.2 (9.3)	40	72.7 (13.4)	0.1 (8.5)	166	73.1 (11.6)	0.2 (9.1)
(beats/min)		Week 4	126	72.4 (10.0)	-0.6 (8.7)	40	72.7 (12.7)	0.1 (9.1)	166	72.5 (10.6)	-0.4 (8.7)
		Week 8	125	73.4 (10.1)	0.4 (8.4)	40	70.5 (12.0)	-2.1 (9.4)	165	72.7 (10.6)	-0.2 (8.7)
		Week 12	122	71.8 (11.1)	-1.2 (9.0)	40	69.4 (10.8)	-3.2 (8.7)	162	71.2 (11.0)	-1.7 (9.0)
		Week 24	121	72.1 (10.8)	-1.0 (8.7)	37	70.5 (13.0)	-2.2 (10.7)	158	71.7 (11.3)	-1.3 (9.2)
		Week 36	120	73.2 (10.4)	0.1 (9.0)	37	72.1 (13.7)	-0.6 (8.9)	157	72.9 (11.2)	-0.1 (8.9)
		Week 52	120	72.3 (11.3)	-0.7 (9.1)	37	72.0 (13.0)	-0.7 (11.9)	157	72.3 (11.7)	-0.7 (9.8)
	Median	Baseline	126	72.5 (66.0, 78.0)	-	40	69.0 (64.0, 82.0)	-	166	72.0 (65.0, 79.0)	-
	(25%, 75%)	Week 2	126	72.0 (65.0, 80.0)	-0.5 (-6.0, 6.0)	40	73.0 (62.5, 80.5)	2.0 (-2.5, 5.0)	166	73.0 (65.0, 80.0)	0.0 (-5.0, 5.0)
		Week 4	126	71.0 (65.0, 79.0)	0.0 (-6.0, 5.0)	40	71.5 (64.5, 82.0)	0.0 (-3.0, 5.5)	166	71.0 (65.0, 80.0)	0.0 (-5.0, 5.0)
		Week 8	125	72.0 (67.0, 79.0)	0.0 (-4.0, 5.0)	40	70.5 (63.5, 75.0)	-2.0 (-5.0, 3.0)	165	71.0 (66.0, 78.0)	0.0 (-4.0, 5.0)
		Week 12	122	70.5 (65.0, 78.0)	-1.0 (-6.0, 4.0)	40	68.0 (60.0, 78.0)	-2.0 (-6.5, 1.5)	162	70.0 (65.0, 78.0)	-1.0 (-6.0, 3.0)
		Week 24	121	72.0 (66.0, 78.0)	-1.0 (-7.0, 4.0)	37	70.0 (60.0, 78.0)	0.0 (-10.0, 5.0)	158	71.0 (65.0, 78.0)	-1.0 (-7.0, 5.0)
		Week 36	120	72.5 (66.5, 78.0)	0.0 (-7.0, 5.0)	37	68.0 (62.0, 81.0)	0.0 (-5.0, 5.0)	157	72.0 (65.0, 78.0)	0.0 (-6.0, 5.0)
		Week 52	120	71.0 (65.5, 80.0)	-1.0 (-7.0, 5.0)	37	70.0 (62.0, 81.0)	2.0 (-5.0, 5.0)	157	71.0 (65.0, 80.0)	0.0 (-7.0, 5.0)
Temperature (C)	Mean (SD)	Baseline	126	36.35 (0.37)	-	40	36.40 (0.39)	-	166	36.36 (0.38)	-
		Week 2	126	36.30 (0.40)	-0.04 (0.41)	40	36.39 (0.35)	-0.02 (0.32)	166	36.32 (0.39)	-0.04 (0.39)
		Week 4	126	36.34 (0.35)	-0.01 (0.39)	40	36.42 (0.42)	0.02 (0.42)	166	36.36 (0.37)	0.00 (0.39)
		Week 8	125	36.31 (0.36)	-0.04 (0.41)	40	36.43 (0.36)	0.03 (0.38)	165	36.34 (0.36)	-0.02 (0.40)
		Week 12	122	36.25 (0.39)	-0.09 (0.36)	40	36.32 (0.37)	-0.09 (0.37)	162	36.27 (0.38)	-0.09 (0.37)
		Week 24	121	36.32 (0.39)	-0.02 (0.42)	37	36.39 (0.34)	-0.01 (0.36)	158	36.34 (0.38)	-0.02 (0.41)
		Week 36	120	36.33 (0.40)	-0.02 (0.46)	37	36.35 (0.46)	-0.04 (0.42)	157	36.33 (0.41)	-0.02 (0.45)
		Week 52	120	36.29 (0.41)	-0.05 (0.45)	37	36.36 (0.49)	-0.03 (0.40)	157	36.31 (0.43)	-0.05 (0.44)
	Median	Baseline	126	36.40 (36.10, 36.60)	-	40	36.50 (36.25, 36.60)	-	166	36.40 (36.20, 36.60)	-
	(25%, 75%)	Week 2	126	36.30 (36.10, 36.60)	-0.05 (-0.30, 0.20)	40	36.40 (36.20, 36.60)	0.00 (-0.30, 0.25)	166	36.40 (36.10, 36.60)	0.00 (-0.30, 0.20)
		Week 4	126	36.40 (36.20, 36.60)	0.00 (-0.20, 0.20)	40	36.40 (36.20, 36.70)	0.05 (-0.20, 0.30)	166	36.40 (36.20, 36.60)	0.00 (-0.20, 0.20)
		Week 8	125	36.30 (36.10, 36.50)	0.00 (-0.30, 0.20)	40	36.50 (36.20, 36.70)	0.05 (-0.20, 0.15)	165	36.30 (36.10, 36.60)	0.00 (-0.30, 0.20)
		Week 12	122	36.30 (36.10, 36.50)	-0.10 (-0.30, 0.10)	40	36.30 (36.10, 36.60)	0.00 (-0.25, 0.10)	162	36.30 (36.10, 36.50)	-0.10 (-0.30, 0.10)
		Week 24	121	36.30 (36.10, 36.60)	0.00 (-0.30, 0.20)	37	36.40 (36.20, 36.60)	0.00 (-0.30, 0.10)	158	36.40 (36.10, 36.60)	0.00 (-0.30, 0.20)
		Week 36	120	36.40 (36.10, 36.60)	0.00 (-0.30, 0.20)	37	36.40 (36.10, 36.60)	0.00 (-0.20, 0.30)	157	36.40 (36.10, 36.60)	0.00 (-0.30, 0.20)
		Week 52	120	36.30 (36.10, 36.60)	0.00 (-0.30, 0.20)	37	36.50 (36.10, 36.70)	0.00 (-0.20, 0.20)	157	36.30 (36.10, 36.60)	0.00 (-0.30, 0.20)

〔5.3.5.2-1 Table 14.3.4-4 改編〕

表 2.7.4.7-91. 関節徒手検査結果のシフトテーブル：613/1022 試験

Target knee examination	Time point	Baseline[a]	Placebo N=89								SI-613 30 mg N=87							
			Negative		Borderline		Positive		Total		Negative		Borderline		Positive		Total	
			n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]
Joint effusion	Week 1	Negative	57	(64.0)	9	(10.1)	2	(2.2)	68	(76.4)	59	(67.8)	8	(9.2)	4	(4.6)	71	(81.6)
		Borderline	5	(5.6)	7	(7.9)	2	(2.2)	14	(15.7)	3	(3.4)	4	(4.6)	5	(5.7)	12	(13.8)
		Positive	1	(1.1)	1	(1.1)	5	(5.6)	7	(7.9)	1	(1.1)	2	(2.3)	1	(1.1)	4	(4.6)
		Total	63	(70.8)	17	(19.1)	9	(10.1)	89	(100.0)	63	(72.4)	14	(16.1)	10	(11.5)	87	(100.0)
	Week 2	Negative	55	(64.7)	9	(10.6)	3	(3.5)	67	(78.8)	61	(70.1)	9	(10.3)	2	(2.3)	72	(82.8)
		Borderline	4	(4.7)	7	(8.2)	1	(1.2)	12	(14.1)	1	(1.1)	3	(3.4)	6	(6.9)	10	(11.5)
		Positive	2	(2.4)	0		4	(4.7)	6	(7.1)	1	(1.1)	2	(2.3)	2	(2.3)	5	(5.7)
		Total	61	(71.8)	16	(18.8)	8	(9.4)	85	(100.0)	63	(72.4)	14	(16.1)	10	(11.5)	87	(100.0)
	Week 4	Negative	54	(65.1)	10	(12.0)	3	(3.6)	67	(80.7)	61	(70.9)	10	(11.6)	4	(4.7)	75	(87.2)
		Borderline	2	(2.4)	5	(6.0)	1	(1.2)	8	(9.6)	1	(1.2)	1	(1.2)	3	(3.5)	5	(5.8)
		Positive	3	(3.6)	1	(1.2)	4	(4.8)	8	(9.6)	1	(1.2)	3	(3.5)	2	(2.3)	6	(7.0)
		Total	59	(71.1)	16	(19.3)	8	(9.6)	83	(100.0)	63	(73.3)	14	(16.3)	9	(10.5)	86	(100.0)
	Week 6	Negative	54	(65.9)	9	(11.0)	2	(2.4)	65	(79.3)	61	(71.8)	10	(11.8)	4	(4.7)	75	(88.2)
		Borderline	3	(3.7)	7	(8.5)	4	(4.9)	14	(17.1)	1	(1.2)	4	(4.7)	2	(2.4)	7	(8.2)
		Positive	1	(1.2)	0		2	(2.4)	3	(3.7)	0		0		3	(3.5)	3	(3.5)
		Total	58	(70.7)	16	(19.5)	8	(9.8)	82	(100.0)	62	(72.9)	14	(16.5)	9	(10.6)	85	(100.0)
	Week 8	Negative	54	(65.1)	11	(13.3)	3	(3.6)	68	(81.9)	60	(70.6)	9	(10.6)	6	(7.1)	75	(88.2)
		Borderline	2	(2.4)	5	(6.0)	1	(1.2)	8	(9.6)	2	(2.4)	5	(5.9)	0		7	(8.2)
		Positive	3	(3.6)	0		4	(4.8)	7	(8.4)	0		0		3	(3.5)	3	(3.5)
		Total	59	(71.1)	16	(19.3)	8	(9.6)	83	(100.0)	62	(72.9)	14	(16.5)	9	(10.6)	85	(100.0)
	Week 10	Negative	56	(68.3)	12	(14.6)	3	(3.7)	71	(86.6)	61	(71.8)	10	(11.8)	6	(7.1)	77	(90.6)
		Borderline	2	(2.4)	3	(3.7)	2	(2.4)	7	(8.5)	0		3	(3.5)	2	(2.4)	5	(5.9)
		Positive	0		1	(1.2)	3	(3.7)	4	(4.9)	1	(1.2)	1	(1.2)	1	(1.2)	3	(3.5)
		Total	58	(70.7)	16	(19.5)	8	(9.8)	82	(100.0)	62	(72.9)	14	(16.5)	9	(10.6)	85	(100.0)
	Week 12	Negative	54	(66.7)	10	(12.3)	3	(3.7)	67	(82.7)	60	(71.4)	9	(10.7)	6	(7.1)	75	(89.3)
		Borderline	3	(3.7)	6	(7.4)	2	(2.5)	11	(13.6)	1	(1.2)	5	(6.0)	0		6	(7.1)
		Positive	0		0		3	(3.7)	3	(3.7)	0		0		3	(3.6)	3	(3.6)
		Total	57	(70.4)	16	(19.8)	8	(9.9)	81	(100.0)	61	(72.6)	14	(16.7)	9	(10.7)	84	(100.0)
	Week 16	Negative	56	(69.1)	13	(16.0)	4	(4.9)	73	(90.1)	58	(69.0)	11	(13.1)	6	(7.1)	75	(89.3)
		Borderline	1	(1.2)	2	(2.5)	2	(2.5)	5	(6.2)	1	(1.2)	3	(3.6)	2	(2.4)	6	(7.1)
		Positive	0		1	(1.2)	2	(2.5)	3	(3.7)	2	(2.4)	0		1	(1.2)	3	(3.6)
		Total	57	(70.4)	16	(19.8)	8	(9.9)	81	(100.0)	61	(72.6)	14	(16.7)	9	(10.7)	84	(100.0)
	Week 20	Negative	56	(69.1)	11	(13.6)	3	(3.7)	70	(86.4)	57	(69.5)	9	(11.0)	6	(7.3)	72	(87.8)
		Borderline	1	(1.2)	4	(4.9)	3	(3.7)	8	(9.9)	0		4	(4.9)	1	(1.2)	5	(6.1)
		Positive	0		1	(1.2)	2	(2.5)	3	(3.7)	2	(2.4)	1	(1.2)	2	(2.4)	5	(6.1)
		Total	57	(70.4)	16	(19.8)	8	(9.9)	81	(100.0)	59	(72.0)	14	(17.1)	9	(11.0)	82	(100.0)
	Week 24	Negative	57	(70.4)	13	(16.0)	5	(6.2)	75	(92.6)	57	(69.5)	11	(13.4)	6	(7.3)	74	(90.2)
		Borderline	0		3	(3.7)	0		3	(3.7)	2	(2.4)	3	(3.7)	1	(1.2)	6	(7.3)
		Positive	0		0		3	(3.7)	3	(3.7)	0		0		2	(2.4)	2	(2.4)
		Total	57	(70.4)	16	(19.8)	8	(9.9)	81	(100.0)	59	(72.0)	14	(17.1)	9	(11.0)	82	(100.0)
Swelling	Week 1	Negative	48	(53.9)	13	(14.6)	4	(4.5)	65	(73.0)	55	(63.2)	6	(6.9)	5	(5.7)	66	(75.9)
		Borderline	7	(7.9)	8	(9.0)	4	(4.5)	19	(21.3)	3	(3.4)	7	(8.0)	5	(5.7)	15	(17.2)
		Positive	1	(1.1)	1	(1.1)	3	(3.4)	5	(5.6)	0		1	(1.1)	5	(5.7)	6	(6.9)
		Total	56	(62.9)	22	(24.7)	11	(12.4)	89	(100.0)	58	(66.7)	14	(16.1)	15	(17.2)	87	(100.0)
	Week 2	Negative	48	(56.5)	9	(10.6)	5	(5.9)	62	(72.9)	58	(66.7)	7	(8.0)	5	(5.7)	70	(80.5)
		Borderline	5	(5.9)	10	(11.8)	3	(3.5)	18	(21.2)	0		7	(8.0)	8	(9.2)	15	(17.2)
		Positive	1	(1.2)	2	(2.4)	2	(2.4)	5	(5.9)	0		0		2	(2.3)	2	(2.3)
		Total	54	(63.5)	21	(24.7)	10	(11.8)	85	(100.0)	58	(66.7)	14	(16.1)	15	(17.2)	87	(100.0)
	Week 4	Negative	47	(56.6)	12	(14.5)	5	(6.0)	64	(77.1)	56	(65.1)	6	(7.0)	5	(5.8)	67	(77.9)
		Borderline	5	(6.0)	7	(8.4)	2	(2.4)	14	(16.9)	1	(1.2)	8	(9.3)	5	(5.8)	14	(16.3)
		Positive	1	(1.2)	1	(1.2)	3	(3.6)	5	(6.0)	0		0		5	(5.8)	5	(5.8)

Target knee examination	Time point	Baseline[a]	Placebo N=89								SI-613 30 mg N=87							
			Negative		Borderline		Positive		Total		Negative		Borderline		Positive		Total	
			n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]
		Total	53	(63.9)	20	(24.1)	10	(12.0)	83	(100.0)	57	(66.3)	14	(16.3)	15	(17.4)	86	(100.0)
	Week 6	Negative	48	(58.5)	10	(12.2)	4	(4.9)	62	(75.6)	56	(65.9)	9	(10.6)	7	(8.2)	72	(84.7)
		Borderline	4	(4.9)	7	(8.5)	5	(6.1)	16	(19.5)	0		4	(4.7)	4	(4.7)	8	(9.4)
		Positive	0		3	(3.7)	1	(1.2)	4	(4.9)	0		1	(1.2)	4	(4.7)	5	(5.9)
		Total	52	(63.4)	20	(24.4)	10	(12.2)	82	(100.0)	56	(65.9)	14	(16.5)	15	(17.6)	85	(100.0)
	Week 8	Negative	48	(57.8)	11	(13.3)	4	(4.8)	63	(75.9)	54	(63.5)	10	(11.8)	8	(9.4)	72	(84.7)
		Borderline	4	(4.8)	7	(8.4)	4	(4.8)	15	(18.1)	2	(2.4)	3	(3.5)	3	(3.5)	8	(9.4)
		Positive	1	(1.2)	2	(2.4)	2	(2.4)	5	(6.0)	0		1	(1.2)	4	(4.7)	5	(5.9)
		Total	53	(63.9)	20	(24.1)	10	(12.0)	83	(100.0)	56	(65.9)	14	(16.5)	15	(17.6)	85	(100.0)
	Week 10	Negative	49	(59.8)	12	(14.6)	6	(7.3)	67	(81.7)	54	(63.5)	10	(11.8)	10	(11.8)	74	(87.1)
		Borderline	3	(3.7)	6	(7.3)	3	(3.7)	12	(14.6)	2	(2.4)	4	(4.7)	2	(2.4)	8	(9.4)
		Positive	1	(1.2)	1	(1.2)	1	(1.2)	3	(3.7)	0		0		3	(3.5)	3	(3.5)
		Total	53	(64.6)	19	(23.2)	10	(12.2)	82	(100.0)	56	(65.9)	14	(16.5)	15	(17.6)	85	(100.0)
	Week 12	Negative	50	(61.7)	11	(13.6)	6	(7.4)	67	(82.7)	55	(65.5)	10	(11.9)	7	(8.3)	72	(85.7)
		Borderline	1	(1.2)	6	(7.4)	2	(2.5)	9	(11.1)	1	(1.2)	2	(2.4)	3	(3.6)	6	(7.1)
		Positive	0		3	(3.7)	2	(2.5)	5	(6.2)	0		2	(2.4)	4	(4.8)	6	(7.1)
		Total	51	(63.0)	20	(24.7)	10	(12.3)	81	(100.0)	56	(66.7)	14	(16.7)	14	(16.7)	84	(100.0)
	Week 16	Negative	46	(56.8)	15	(18.5)	8	(9.9)	69	(85.2)	51	(60.7)	10	(11.9)	8	(9.5)	69	(82.1)
		Borderline	4	(4.9)	4	(4.9)	2	(2.5)	10	(12.3)	5	(6.0)	2	(2.4)	3	(3.6)	10	(11.9)
		Positive	1	(1.2)	1	(1.2)	0		2	(2.5)	0		2	(2.4)	3	(3.6)	5	(6.0)
		Total	51	(63.0)	20	(24.7)	10	(12.3)	81	(100.0)	56	(66.7)	14	(16.7)	14	(16.7)	84	(100.0)
	Week 20	Negative	49	(60.5)	13	(16.0)	6	(7.4)	68	(84.0)	50	(61.0)	11	(13.4)	10	(12.2)	71	(86.6)
		Borderline	2	(2.5)	5	(6.2)	4	(4.9)	11	(13.6)	4	(4.9)	2	(2.4)	2	(2.4)	8	(9.8)
		Positive	0		2	(2.5)	0		2	(2.5)	0		1	(1.2)	2	(2.4)	3	(3.7)
		Total	51	(63.0)	20	(24.7)	10	(12.3)	81	(100.0)	54	(65.9)	14	(17.1)	14	(17.1)	82	(100.0)
	Week 24	Negative	51	(63.0)	14	(17.3)	8	(9.9)	73	(90.1)	50	(61.0)	8	(9.8)	11	(13.4)	69	(84.1)
		Borderline	0		3	(3.7)	1	(1.2)	4	(4.9)	4	(4.9)	5	(6.1)	2	(2.4)	11	(13.4)
		Positive	0		3	(3.7)	1	(1.2)	4	(4.9)	0		1	(1.2)	1	(1.2)	2	(2.4)
		Total	51	(63.0)	20	(24.7)	10	(12.3)	81	(100.0)	54	(65.9)	14	(17.1)	14	(17.1)	82	(100.0)
Redness	Week 1	Negative	87	(97.8)	1	(1.1)	0		88	(98.9)	84	(96.6)	1	(1.1)	0		85	(97.7)
		Borderline	1	(1.1)	0		0		1	(1.1)	2	(2.3)	0		0		2	(2.3)
		Positive	0		0		0		0		0		0		0		0	
		Total	88	(98.9)	1	(1.1)	0		89	(100.0)	86	(98.9)	1	(1.1)	0		87	(100.0)
	Week 2	Negative	83	(97.6)	1	(1.2)	0		84	(98.8)	86	(98.9)	1	(1.1)	0		87	(100.0)
		Borderline	1	(1.2)	0		0		1	(1.2)	0		0		0		0	
		Positive	0		0		0		0		0		0		0		0	
		Total	84	(98.8)	1	(1.2)	0		85	(100.0)	86	(98.9)	1	(1.1)	0		87	(100.0)
	Week 4	Negative	81	(97.6)	1	(1.2)	0		82	(98.8)	84	(97.7)	1	(1.2)	0		85	(98.8)
		Borderline	1	(1.2)	0		0		1	(1.2)	1	(1.2)	0		0		1	(1.2)
		Positive	0		0		0		0		0		0		0		0	
		Total	82	(98.8)	1	(1.2)	0		83	(100.0)	85	(98.8)	1	(1.2)	0		86	(100.0)
	Week 6	Negative	80	(97.6)	1	(1.2)	0		81	(98.8)	83	(97.6)	1	(1.2)	0		84	(98.8)
		Borderline	1	(1.2)	0		0		1	(1.2)	1	(1.2)	0		0		1	(1.2)
		Positive	0		0		0		0		0		0		0		0	
		Total	81	(98.8)	1	(1.2)	0		82	(100.0)	84	(98.8)	1	(1.2)	0		85	(100.0)
	Week 8	Negative	80	(96.4)	1	(1.2)	0		81	(97.6)	83	(97.6)	1	(1.2)	0		84	(98.8)
		Borderline	2	(2.4)	0		0		2	(2.4)	1	(1.2)	0		0		1	(1.2)
		Positive	0		0		0		0		0		0		0		0	
		Total	82	(98.8)	1	(1.2)	0		83	(100.0)	84	(98.8)	1	(1.2)	0		85	(100.0)
	Week 10	Negative	80	(97.6)	1	(1.2)	0		81	(98.8)	83	(97.6)	1	(1.2)	0		84	(98.8)
		Borderline	1	(1.2)	0		0		1	(1.2)	1	(1.2)	0		0		1	(1.2)
		Positive	0		0		0		0		0		0		0		0	
		Total	81	(98.8)	1	(1.2)	0		82	(100.0)	84	(98.8)	1	(1.2)	0		85	(100.0)

Target knee examination	Time point	Baseline[a]	Placebo N=89								SI-613 30 mg N=87							
			Negative		Borderline		Positive		Total		Negative		Borderline		Positive		Total	
			n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]
	Week 12	Negative	78	(96.3)	1	(1.2)	0		79	(97.5)	81	(96.4)	1	(1.2)	0		82	(97.6)
		Borderline	1	(1.2)	0		0		1	(1.2)	2	(2.4)	0		0		2	(2.4)
		Positive	1	(1.2)	0		0		1	(1.2)	0		0		0		0	
		Total	80	(98.8)	1	(1.2)	0		81	(100.0)	83	(98.8)	1	(1.2)	0		84	(100.0)
	Week 16	Negative	78	(96.3)	1	(1.2)	0		79	(97.5)	82	(97.6)	1	(1.2)	0		83	(98.8)
		Borderline	1	(1.2)	0		0		1	(1.2)	1	(1.2)	0		0		1	(1.2)
		Positive	1	(1.2)	0		0		1	(1.2)	0		0		0		0	
		Total	80	(98.8)	1	(1.2)	0		81	(100.0)	83	(98.8)	1	(1.2)	0		84	(100.0)
	Week 20	Negative	78	(96.3)	1	(1.2)	0		79	(97.5)	80	(97.6)	1	(1.2)	0		81	(98.8)
		Borderline	2	(2.5)	0		0		2	(2.5)	0		0		0		0	
		Positive	0		0		0		0		1	(1.2)	0		0		1	(1.2)
		Total	80	(98.8)	1	(1.2)	0		81	(100.0)	81	(98.8)	1	(1.2)	0		82	(100.0)
	Week 24	Negative	78	(96.3)	1	(1.2)	0		79	(97.5)	80	(97.6)	1	(1.2)	0		81	(98.8)
		Borderline	2	(2.5)	0		0		2	(2.5)	1	(1.2)	0		0		1	(1.2)
		Positive	0		0		0		0		0		0		0		0	
		Total	80	(98.8)	1	(1.2)	0		81	(100.0)	81	(98.8)	1	(1.2)	0		82	(100.0)

a:Baseline is value of screening.
b:Percentages are based on the number of subjects with non-missing values at both baseline and each timepoint.
〔5.3.5.1-2 Table14.3.4-6 改編〕

表 2.7.4.7-92. 関節徒手検査結果のシフトテーブル：613/1031 試験

Target knee examination	Time point	Baseline[a]	Placebo N=220								SI-613 30 mg N=220							
			Negative		Borderline		Positive		Total		Negative		Borderline		Positive		Total	
			n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]
Joint effusion	Week 1	Negative	139	(63.5)	21	(9.6)	1	(0.5)	161	(73.5)	142	(64.8)	26	(11.9)	4	(1.8)	172	(78.5)
		Borderline	9	(4.1)	22	(10.0)	6	(2.7)	37	(16.9)	7	(3.2)	17	(7.8)	11	(5.0)	35	(16.0)
		Positive	1	(0.5)	5	(2.3)	15	(6.8)	21	(9.6)	2	(0.9)	4	(1.8)	6	(2.7)	12	(5.5)
		Total	149	(68.0)	48	(21.9)	22	(10.0)	219	(100.0)	151	(68.9)	47	(21.5)	21	(9.6)	219	(100.0)
	Week 2	Negative	138	(64.2)	17	(7.9)	3	(1.4)	158	(73.5)	140	(64.2)	21	(9.6)	5	(2.3)	166	(76.1)
		Borderline	6	(2.8)	26	(12.1)	2	(0.9)	34	(15.8)	6	(2.8)	23	(10.6)	6	(2.8)	35	(16.1)
		Positive	2	(0.9)	5	(2.3)	16	(7.4)	23	(10.7)	4	(1.8)	3	(1.4)	10	(4.6)	17	(7.8)
		Total	146	(67.9)	48	(22.3)	21	(9.8)	215	(100.0)	150	(68.8)	47	(21.6)	21	(9.6)	218	(100.0)
	Week 4	Negative	136	(63.8)	22	(10.3)	2	(0.9)	160	(75.1)	136	(62.4)	29	(13.3)	4	(1.8)	169	(77.5)
		Borderline	7	(3.3)	23	(10.8)	6	(2.8)	36	(16.9)	13	(6.0)	17	(7.8)	7	(3.2)	37	(17.0)
		Positive	1	(0.5)	3	(1.4)	13	(6.1)	17	(8.0)	0		2	(0.9)	10	(4.6)	12	(5.5)
		Total	144	(67.6)	48	(22.5)	21	(9.9)	213	(100.0)	149	(68.3)	48	(22.0)	21	(9.6)	218	(100.0)
	Week 6	Negative	129	(61.1)	31	(14.7)	3	(1.4)	163	(77.3)	143	(66.5)	29	(13.5)	7	(3.3)	179	(83.3)
		Borderline	12	(5.7)	12	(5.7)	4	(1.9)	28	(13.3)	5	(2.3)	14	(6.5)	6	(2.8)	25	(11.6)
		Positive	1	(0.5)	5	(2.4)	14	(6.6)	20	(9.5)	0		3	(1.4)	8	(3.7)	11	(5.1)
		Total	142	(67.3)	48	(22.7)	21	(10.0)	211	(100.0)	148	(68.8)	46	(21.4)	21	(9.8)	215	(100.0)
	Week 8	Negative	138	(64.8)	27	(12.7)	4	(1.9)	169	(79.3)	139	(65.0)	26	(12.1)	4	(1.9)	169	(79.0)
		Borderline	4	(1.9)	17	(8.0)	4	(1.9)	25	(11.7)	8	(3.7)	17	(7.9)	6	(2.8)	31	(14.5)
		Positive	1	(0.5)	5	(2.3)	13	(6.1)	19	(8.9)	1	(0.5)	2	(0.9)	11	(5.1)	14	(6.5)
		Total	143	(67.1)	49	(23.0)	21	(9.9)	213	(100.0)	148	(69.2)	45	(21.0)	21	(9.8)	214	(100.0)
	Week 10	Negative	136	(63.8)	34	(16.0)	4	(1.9)	174	(81.7)	142	(66.7)	29	(13.6)	9	(4.2)	180	(84.5)
		Borderline	7	(3.3)	10	(4.7)	6	(2.8)	23	(10.8)	3	(1.4)	14	(6.6)	4	(1.9)	21	(9.9)
		Positive	0		5	(2.3)	11	(5.2)	16	(7.5)	2	(0.9)	2	(0.9)	8	(3.8)	12	(5.6)
		Total	143	(67.1)	49	(23.0)	21	(9.9)	213	(100.0)	147	(69.0)	45	(21.1)	21	(9.9)	213	(100.0)
	Week 12	Negative	135	(63.4)	37	(17.4)	5	(2.3)	177	(83.1)	145	(68.4)	30	(14.2)	6	(2.8)	181	(85.4)
		Borderline	6	(2.8)	10	(4.7)	6	(2.8)	22	(10.3)	1	(0.5)	14	(6.6)	4	(1.9)	19	(9.0)
		Positive	2	(0.9)	2	(0.9)	10	(4.7)	14	(6.6)	1	(0.5)	2	(0.9)	9	(4.2)	12	(5.7)

Target knee examination	Time point	Baseline[a]	Placebo N=220								SI-613 30 mg N=220							
			Negative		Borderline		Positive		Total		Negative		Borderline		Positive		Total	
			n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]
		Total	143	(67.1)	49	(23.0)	21	(9.9)	213	(100.0)	147	(69.3)	46	(21.7)	19	(9.0)	212	(100.0)
	Week 16	Negative	132	(62.6)	33	(15.6)	5	(2.4)	170	(80.6)	139	(67.5)	34	(16.5)	5	(2.4)	178	(86.4)
		Borderline	7	(3.3)	11	(5.2)	4	(1.9)	22	(10.4)	3	(1.5)	8	(3.9)	8	(3.9)	19	(9.2)
		Positive	2	(0.9)	5	(2.4)	12	(5.7)	19	(9.0)	2	(1.0)	1	(0.5)	6	(2.9)	9	(4.4)
		Total	141	(66.8)	49	(23.2)	21	(10.0)	211	(100.0)	144	(69.9)	43	(20.9)	19	(9.2)	206	(100.0)
	Week 20	Negative	133	(63.6)	32	(15.3)	4	(1.9)	169	(80.9)	138	(67.3)	33	(16.1)	7	(3.4)	178	(86.8)
		Borderline	4	(1.9)	15	(7.2)	6	(2.9)	25	(12.0)	6	(2.9)	7	(3.4)	8	(3.9)	21	(10.2)
		Positive	2	(1.0)	2	(1.0)	11	(5.3)	15	(7.2)	0		3	(1.5)	3	(1.5)	6	(2.9)
		Total	139	(66.5)	49	(23.4)	21	(10.0)	209	(100.0)	144	(70.2)	43	(21.0)	18	(8.8)	205	(100.0)
	Week 24	Negative	133	(63.6)	35	(16.7)	5	(2.4)	173	(82.8)	140	(68.0)	34	(16.5)	8	(3.9)	182	(88.3)
		Borderline	3	(1.4)	11	(5.3)	7	(3.3)	21	(10.0)	4	(1.9)	7	(3.4)	7	(3.4)	18	(8.7)
		Positive	3	(1.4)	3	(1.4)	9	(4.3)	15	(7.2)	0		2	(1.0)	4	(1.9)	6	(2.9)
		Total	139	(66.5)	49	(23.4)	21	(10.0)	209	(100.0)	144	(69.9)	43	(20.9)	19	(9.2)	206	(100.0)
Swelling	Week 1	Negative	128	(58.4)	19	(8.7)	5	(2.3)	152	(69.4)	139	(63.5)	25	(11.4)	6	(2.7)	170	(77.6)
		Borderline	14	(6.4)	26	(11.9)	7	(3.2)	47	(21.5)	7	(3.2)	20	(9.1)	6	(2.7)	33	(15.1)
		Positive	0		3	(1.4)	17	(7.8)	20	(9.1)	2	(0.9)	5	(2.3)	9	(4.1)	16	(7.3)
		Total	142	(64.8)	48	(21.9)	29	(13.2)	219	(100.0)	148	(67.6)	50	(22.8)	21	(9.6)	219	(100.0)
	Week 2	Negative	130	(60.5)	21	(9.8)	3	(1.4)	154	(71.6)	140	(64.2)	26	(11.9)	5	(2.3)	171	(78.4)
		Borderline	11	(5.1)	21	(9.8)	8	(3.7)	40	(18.6)	6	(2.8)	23	(10.6)	6	(2.8)	35	(16.1)
		Positive	0		6	(2.8)	15	(7.0)	21	(9.8)	1	(0.5)	1	(0.5)	10	(4.6)	12	(5.5)
		Total	141	(65.6)	48	(22.3)	26	(12.1)	215	(100.0)	147	(67.4)	50	(22.9)	21	(9.6)	218	(100.0)
	Week 4	Negative	131	(61.5)	21	(9.9)	4	(1.9)	156	(73.2)	136	(62.4)	31	(14.2)	4	(1.8)	171	(78.4)
		Borderline	6	(2.8)	23	(10.8)	10	(4.7)	39	(18.3)	10	(4.6)	20	(9.2)	7	(3.2)	37	(17.0)
		Positive	1	(0.5)	4	(1.9)	13	(6.1)	18	(8.5)	0		0		10	(4.6)	10	(4.6)
		Total	138	(64.8)	48	(22.5)	27	(12.7)	213	(100.0)	146	(67.0)	51	(23.4)	21	(9.6)	218	(100.0)
	Week 6	Negative	126	(59.7)	24	(11.4)	7	(3.3)	157	(74.4)	135	(62.8)	32	(14.9)	5	(2.3)	172	(80.0)
		Borderline	9	(4.3)	20	(9.5)	7	(3.3)	36	(17.1)	10	(4.7)	16	(7.4)	10	(4.7)	36	(16.7)
		Positive	2	(0.9)	4	(1.9)	12	(5.7)	18	(8.5)	0		1	(0.5)	6	(2.8)	7	(3.3)
		Total	137	(64.9)	48	(22.7)	26	(12.3)	211	(100.0)	145	(67.4)	49	(22.8)	21	(9.8)	215	(100.0)
	Week 8	Negative	131	(61.5)	31	(14.6)	5	(2.3)	167	(78.4)	137	(64.0)	35	(16.4)	3	(1.4)	175	(81.8)
		Borderline	6	(2.8)	14	(6.6)	8	(3.8)	28	(13.1)	8	(3.7)	13	(6.1)	7	(3.3)	28	(13.1)
		Positive	1	(0.5)	4	(1.9)	13	(6.1)	18	(8.5)	0		1	(0.5)	10	(4.7)	11	(5.1)
		Total	138	(64.8)	49	(23.0)	26	(12.2)	213	(100.0)	145	(67.8)	49	(22.9)	20	(9.3)	214	(100.0)
	Week 10	Negative	129	(60.6)	29	(13.6)	8	(3.8)	166	(77.9)	135	(63.4)	36	(16.9)	6	(2.8)	177	(83.1)
		Borderline	9	(4.2)	17	(8.0)	8	(3.8)	34	(16.0)	8	(3.8)	12	(5.6)	6	(2.8)	26	(12.2)
		Positive	0		3	(1.4)	10	(4.7)	13	(6.1)	1	(0.5)	1	(0.5)	8	(3.8)	10	(4.7)
		Total	138	(64.8)	49	(23.0)	26	(12.2)	213	(100.0)	144	(67.6)	49	(23.0)	20	(9.4)	213	(100.0)
	Week 12	Negative	130	(61.0)	30	(14.1)	7	(3.3)	167	(78.4)	138	(65.1)	34	(16.0)	6	(2.8)	178	(84.0)
		Borderline	6	(2.8)	16	(7.5)	6	(2.8)	28	(13.1)	6	(2.8)	14	(6.6)	4	(1.9)	24	(11.3)
		Positive	2	(0.9)	3	(1.4)	13	(6.1)	18	(8.5)	0		2	(0.9)	8	(3.8)	10	(4.7)
		Total	138	(64.8)	49	(23.0)	26	(12.2)	213	(100.0)	144	(67.9)	50	(23.6)	18	(8.5)	212	(100.0)
	Week 16	Negative	128	(60.7)	32	(15.2)	7	(3.3)	167	(79.1)	133	(64.6)	38	(18.4)	4	(1.9)	175	(85.0)
		Borderline	8	(3.8)	11	(5.2)	8	(3.8)	27	(12.8)	5	(2.4)	9	(4.4)	9	(4.4)	23	(11.2)
		Positive	0		6	(2.8)	11	(5.2)	17	(8.1)	2	(1.0)	1	(0.5)	5	(2.4)	8	(3.9)
		Total	136	(64.5)	49	(23.2)	26	(12.3)	211	(100.0)	140	(68.0)	48	(23.3)	18	(8.7)	206	(100.0)
	Week 20	Negative	128	(61.2)	29	(13.9)	10	(4.8)	167	(79.9)	130	(63.4)	38	(18.5)	7	(3.4)	175	(85.4)
		Borderline	3	(1.4)	17	(8.1)	8	(3.8)	28	(13.4)	10	(4.9)	7	(3.4)	6	(2.9)	23	(11.2)
		Positive	3	(1.4)	3	(1.4)	8	(3.8)	14	(6.7)	0		3	(1.5)	4	(2.0)	7	(3.4)
		Total	134	(64.1)	49	(23.4)	26	(12.4)	209	(100.0)	140	(68.3)	48	(23.4)	17	(8.3)	205	(100.0)
	Week 24	Negative	129	(61.7)	31	(14.8)	13	(6.2)	173	(82.8)	133	(64.6)	39	(18.9)	8	(3.9)	180	(87.4)
		Borderline	2	(1.0)	13	(6.2)	4	(1.9)	19	(9.1)	6	(2.9)	8	(3.9)	8	(3.9)	22	(10.7)
		Positive	3	(1.4)	5	(2.4)	9	(4.3)	17	(8.1)	1	(0.5)	1	(0.5)	2	(1.0)	4	(1.9)
		Total	134	(64.1)	49	(23.4)	26	(12.4)	209	(100.0)	140	(68.0)	48	(23.3)	18	(8.7)	206	(100.0)

Target knee examination	Time point	Baseline[a]	Placebo N=220								SI-613 30 mg N=220							
			Negative		Borderline		Positive		Total		Negative		Borderline		Positive		Total	
			n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]
Redness	Week 1	Negative	212	(96.8)	2	(0.9)	0		214	(97.7)	214	(97.7)	4	(1.8)	0		218	(99.5)
		Borderline	3	(1.4)	1	(0.5)	1	(0.5)	5	(2.3)	1	(0.5)	0		0		1	(0.5)
		Positive	0		0		0		0		0		0		0		0	
		Total	215	(98.2)	3	(1.4)	1	(0.5)	219	(100.0)	215	(98.2)	4	(1.8)	0		219	(100.0)
	Week 2	Negative	209	(97.2)	3	(1.4)	0		212	(98.6)	214	(98.2)	4	(1.8)	0		218	(100.0)
		Borderline	1	(0.5)	0		1	(0.5)	2	(0.9)	0		0		0		0	
		Positive	1	(0.5)	0		0		1	(0.5)	0		0		0		0	
		Total	211	(98.1)	3	(1.4)	1	(0.5)	215	(100.0)	214	(98.2)	4	(1.8)	0		218	(100.0)
	Week 4	Negative	208	(97.7)	3	(1.4)	1	(0.5)	212	(99.5)	213	(97.7)	4	(1.8)	0		217	(99.5)
		Borderline	1	(0.5)	0		0		1	(0.5)	1	(0.5)	0		0		1	(0.5)
		Positive	0		0		0		0		0		0		0		0	
		Total	209	(98.1)	3	(1.4)	1	(0.5)	213	(100.0)	214	(98.2)	4	(1.8)	0		218	(100.0)
	Week 6	Negative	206	(97.6)	3	(1.4)	0		209	(99.1)	209	(97.2)	4	(1.9)	0		213	(99.1)
		Borderline	1	(0.5)	0		1	(0.5)	2	(0.9)	2	(0.9)	0		0		2	(0.9)
		Positive	0		0		0		0		0		0		0		0	
		Total	207	(98.1)	3	(1.4)	1	(0.5)	211	(100.0)	211	(98.1)	4	(1.9)	0		215	(100.0)
	Week 8	Negative	207	(97.2)	2	(0.9)	0		209	(98.1)	207	(96.7)	4	(1.9)	0		211	(98.6)
		Borderline	2	(0.9)	1	(0.5)	1	(0.5)	4	(1.9)	2	(0.9)	0		0		2	(0.9)
		Positive	0		0		0		0		1	(0.5)	0		0		1	(0.5)
		Total	209	(98.1)	3	(1.4)	1	(0.5)	213	(100.0)	210	(98.1)	4	(1.9)	0		214	(100.0)
	Week 10	Negative	206	(96.7)	3	(1.4)	0		209	(98.1)	209	(98.1)	3	(1.4)	0		212	(99.5)
		Borderline	2	(0.9)	0		1	(0.5)	3	(1.4)	0		1	(0.5)	0		1	(0.5)
		Positive	1	(0.5)	0		0		1	(0.5)	0		0		0		0	
		Total	209	(98.1)	3	(1.4)	1	(0.5)	213	(100.0)	209	(98.1)	4	(1.9)	0		213	(100.0)
	Week 12	Negative	207	(97.2)	2	(0.9)	0		209	(98.1)	207	(97.6)	3	(1.4)	0		210	(99.1)
		Borderline	2	(0.9)	1	(0.5)	1	(0.5)	4	(1.9)	1	(0.5)	1	(0.5)	0		2	(0.9)
		Positive	0		0		0		0		0		0		0		0	
		Total	209	(98.1)	3	(1.4)	1	(0.5)	213	(100.0)	208	(98.1)	4	(1.9)	0		212	(100.0)
	Week 16	Negative	204	(96.7)	2	(0.9)	0		206	(97.6)	202	(98.1)	3	(1.5)	0		205	(99.5)
		Borderline	3	(1.4)	1	(0.5)	1	(0.5)	5	(2.4)	1	(0.5)	0		0		1	(0.5)
		Positive	0		0		0		0		0		0		0		0	
		Total	207	(98.1)	3	(1.4)	1	(0.5)	211	(100.0)	203	(98.5)	3	(1.5)	0		206	(100.0)
	Week 20	Negative	204	(97.6)	2	(1.0)	0		206	(98.6)	201	(98.0)	2	(1.0)	0		203	(99.0)
		Borderline	1	(0.5)	1	(0.5)	1	(0.5)	3	(1.4)	1	(0.5)	1	(0.5)	0		2	(1.0)
		Positive	0		0		0		0		0		0		0		0	
		Total	205	(98.1)	3	(1.4)	1	(0.5)	209	(100.0)	202	(98.5)	3	(1.5)	0		205	(100.0)
	Week 24	Negative	205	(98.1)	3	(1.4)	0		208	(99.5)	203	(98.5)	3	(1.5)	0		206	(100.0)
		Borderline	0		0		1	(0.5)	1	(0.5)	0		0		0		0	
		Positive	0		0		0		0		0		0		0		0	
		Total	205	(98.1)	3	(1.4)	1	(0.5)	209	(100.0)	203	(98.5)	3	(1.5)	0		206	(100.0)
Warmth	Week 1	Negative	197	(90.0)	6	(2.7)	0		203	(92.7)	201	(91.8)	4	(1.8)	1	(0.5)	206	(94.1)
		Borderline	1	(0.5)	7	(3.2)	2	(0.9)	10	(4.6)	1	(0.5)	7	(3.2)	2	(0.9)	10	(4.6)
		Positive	0		3	(1.4)	3	(1.4)	6	(2.7)	1	(0.5)	0		2	(0.9)	3	(1.4)
		Total	198	(90.4)	16	(7.3)	5	(2.3)	219	(100.0)	203	(92.7)	11	(5.0)	5	(2.3)	219	(100.0)
	Week 2	Negative	191	(88.8)	7	(3.3)	0		198	(92.1)	198	(90.8)	5	(2.3)	1	(0.5)	204	(93.6)
		Borderline	4	(1.9)	3	(1.4)	3	(1.4)	10	(4.7)	3	(1.4)	4	(1.8)	2	(0.9)	9	(4.1)
		Positive	0		5	(2.3)	2	(0.9)	7	(3.3)	1	(0.5)	2	(0.9)	2	(0.9)	5	(2.3)
		Total	195	(90.7)	15	(7.0)	5	(2.3)	215	(100.0)	202	(92.7)	11	(5.0)	5	(2.3)	218	(100.0)
	Week 4	Negative	191	(89.7)	5	(2.3)	0		196	(92.0)	197	(90.4)	7	(3.2)	2	(0.9)	206	(94.5)
		Borderline	1	(0.5)	8	(3.8)	1	(0.5)	10	(4.7)	4	(1.8)	4	(1.8)	1	(0.5)	9	(4.1)
		Positive	1	(0.5)	2	(0.9)	4	(1.9)	7	(3.3)	1	(0.5)	0		2	(0.9)	3	(1.4)
		Total	193	(90.6)	15	(7.0)	5	(2.3)	213	(100.0)	202	(92.7)	11	(5.0)	5	(2.3)	218	(100.0)
	Week 6	Negative	187	(88.6)	6	(2.8)	0		193	(91.5)	191	(88.8)	5	(2.3)	3	(1.4)	199	(92.6)

Target knee examination	Time point	Baseline[a]	Placebo N=220								SI-613 30 mg N=220							
			Negative		Borderline		Positive		Total		Negative		Borderline		Positive		Total	
			n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]
		Borderline	3	(1.4)	9	(4.3)	2	(0.9)	14	(6.6)	7	(3.3)	5	(2.3)	2	(0.9)	14	(6.5)
		Positive	1	(0.5)	0		3	(1.4)	4	(1.9)	1	(0.5)	1	(0.5)	0		2	(0.9)
		Total	191	(90.5)	15	(7.1)	5	(2.4)	211	(100.0)	199	(92.6)	11	(5.1)	5	(2.3)	215	(100.0)
	Week 8	Negative	188	(88.3)	7	(3.3)	0		195	(91.5)	193	(90.2)	6	(2.8)	1	(0.5)	200	(93.5)
		Borderline	5	(2.3)	6	(2.8)	2	(0.9)	13	(6.1)	3	(1.4)	5	(2.3)	2	(0.9)	10	(4.7)
		Positive	0		2	(0.9)	3	(1.4)	5	(2.3)	2	(0.9)	0		2	(0.9)	4	(1.9)
		Total	193	(90.6)	15	(7.0)	5	(2.3)	213	(100.0)	198	(92.5)	11	(5.1)	5	(2.3)	214	(100.0)
	Week 10	Negative	187	(87.8)	6	(2.8)	0		193	(90.6)	193	(90.6)	6	(2.8)	1	(0.5)	200	(93.9)
		Borderline	5	(2.3)	8	(3.8)	2	(0.9)	15	(7.0)	4	(1.9)	3	(1.4)	3	(1.4)	10	(4.7)
		Positive	1	(0.5)	1	(0.5)	3	(1.4)	5	(2.3)	0		2	(0.9)	1	(0.5)	3	(1.4)
		Total	193	(90.6)	15	(7.0)	5	(2.3)	213	(100.0)	197	(92.5)	11	(5.2)	5	(2.3)	213	(100.0)
	Week 12	Negative	192	(90.1)	10	(4.7)	1	(0.5)	203	(95.3)	189	(89.2)	10	(4.7)	2	(0.9)	201	(94.8)
		Borderline	1	(0.5)	5	(2.3)	3	(1.4)	9	(4.2)	7	(3.3)	0		3	(1.4)	10	(4.7)
		Positive	0		0		1	(0.5)	1	(0.5)	0		1	(0.5)	0		1	(0.5)
		Total	193	(90.6)	15	(7.0)	5	(2.3)	213	(100.0)	196	(92.5)	11	(5.2)	5	(2.4)	212	(100.0)
	Week 16	Negative	188	(89.1)	9	(4.3)	2	(0.9)	199	(94.3)	188	(91.3)	8	(3.9)	2	(1.0)	198	(96.1)
		Borderline	3	(1.4)	6	(2.8)	0		9	(4.3)	3	(1.5)	2	(1.0)	2	(1.0)	7	(3.4)
		Positive	0		0		3	(1.4)	3	(1.4)	0		0		1	(0.5)	1	(0.5)
		Total	191	(90.5)	15	(7.1)	5	(2.4)	211	(100.0)	191	(92.7)	10	(4.9)	5	(2.4)	206	(100.0)
	Week 20	Negative	185	(88.5)	8	(3.8)	0		193	(92.3)	187	(91.2)	5	(2.4)	1	(0.5)	193	(94.1)
		Borderline	4	(1.9)	5	(2.4)	3	(1.4)	12	(5.7)	4	(2.0)	4	(2.0)	0		8	(3.9)
		Positive	0		2	(1.0)	2	(1.0)	4	(1.9)	0		1	(0.5)	3	(1.5)	4	(2.0)
		Total	189	(90.4)	15	(7.2)	5	(2.4)	209	(100.0)	191	(93.2)	10	(4.9)	4	(2.0)	205	(100.0)
	Week 24	Negative	187	(89.5)	10	(4.8)	2	(1.0)	199	(95.2)	189	(91.7)	8	(3.9)	2	(1.0)	199	(96.6)
		Borderline	2	(1.0)	5	(2.4)	2	(1.0)	9	(4.3)	1	(0.5)	2	(1.0)	1	(0.5)	4	(1.9)
		Positive	0		0		1	(0.5)	1	(0.5)	1	(0.5)	0		2	(1.0)	3	(1.5)
		Total	189	(90.4)	15	(7.2)	5	(2.4)	209	(100.0)	191	(92.7)	10	(4.9)	5	(2.4)	206	(100.0)

a: Baseline is value at week 0.
b: Percentages are based on the number of subjects with non-missing values at both baseline and each timepoint.
〔5.3.5.1-3 Table 14.3.4-5 改編〕

表 2.7.4.7-93. 関節徒手検査結果のシフトテーブル：613/1033 試験

Target joint examination	Time point	Baseline[a]	Placebo N=144								SI-613 30 mg N=146							
			Negative		Borderline		Positive		Total		Negative		Borderline		Positive		Total	
			n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]
Joint effusion	Week 1	Negative	125	(86.8)	10	(6.9)	1	(0.7)	136	(94.4)	130	(89.0)	6	(4.1)	1	(0.7)	137	(93.8)
		Borderline	4	(2.8)	4	(2.8)	0		8	(5.6)	2	(1.4)	2	(1.4)	1	(0.7)	5	(3.4)
		Positive	0		0		0		0		0		1	(0.7)	3	(2.1)	4	(2.7)
		Total	129	(89.6)	14	(9.7)	1	(0.7)	144	(100.0)	132	(90.4)	9	(6.2)	5	(3.4)	146	(100.0)
	Week 2	Negative	126	(87.5)	10	(6.9)	1	(0.7)	137	(95.1)	132	(90.4)	4	(2.7)	1	(0.7)	137	(93.8)
		Borderline	3	(2.1)	4	(2.8)	0		7	(4.9)	0		5	(3.4)	3	(2.1)	8	(5.5)
		Positive	0		0		0		0		0		0		1	(0.7)	1	(0.7)
		Total	129	(89.6)	14	(9.7)	1	(0.7)	144	(100.0)	132	(90.4)	9	(6.2)	5	(3.4)	146	(100.0)
	Week 4	Negative	124	(87.3)	9	(6.3)	0		133	(93.7)	132	(90.4)	6	(4.1)	1	(0.7)	139	(95.2)
		Borderline	3	(2.1)	5	(3.5)	1	(0.7)	9	(6.3)	0		3	(2.1)	3	(2.1)	6	(4.1)
		Positive	0		0		0		0		0		0		1	(0.7)	1	(0.7)
		Total	127	(89.4)	14	(9.9)	1	(0.7)	142	(100.0)	132	(90.4)	9	(6.2)	5	(3.4)	146	(100.0)
	Week 6	Negative	124	(87.3)	11	(7.7)	0		135	(95.1)	132	(91.0)	5	(3.4)	3	(2.1)	140	(96.6)
		Borderline	3	(2.1)	2	(1.4)	1	(0.7)	6	(4.2)	0		3	(2.1)	1	(0.7)	4	(2.8)
		Positive	0		1	(0.7)	0		1	(0.7)	0		0		1	(0.7)	1	(0.7)
		Total	127	(89.4)	14	(9.9)	1	(0.7)	142	(100.0)	132	(91.0)	8	(5.5)	5	(3.4)	145	(100.0)

Target joint examination	Time point	Baseline[a]	Placebo N=144								SI-613 30 mg N=146							
			Negative		Borderline		Positive		Total		Negative		Borderline		Positive		Total	
			n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]
	Week 8	Negative	123	(87.2)	11	(7.8)	1	(0.7)	135	(95.7)	130	(90.9)	5	(3.5)	2	(1.4)	137	(95.8)
		Borderline	2	(1.4)	2	(1.4)	0		4	(2.8)	0		2	(1.4)	2	(1.4)	4	(2.8)
		Positive	1	(0.7)	1	(0.7)	0		2	(1.4)	0		1	(0.7)	1	(0.7)	2	(1.4)
		Total	126	(89.4)	14	(9.9)	1	(0.7)	141	(100.0)	130	(90.9)	8	(5.6)	5	(3.5)	143	(100.0)
	Week 10	Negative	122	(87.1)	11	(7.9)	0		133	(95.0)	130	(90.9)	6	(4.2)	3	(2.1)	139	(97.2)
		Borderline	3	(2.1)	3	(2.1)	0		6	(4.3)	0		1	(0.7)	1	(0.7)	2	(1.4)
		Positive	0		0		1	(0.7)	1	(0.7)	0		1	(0.7)	1	(0.7)	2	(1.4)
		Total	125	(89.3)	14	(10.0)	1	(0.7)	140	(100.0)	130	(90.9)	8	(5.6)	5	(3.5)	143	(100.0)
	Week 12	Negative	121	(87.7)	11	(8.0)	0		132	(95.7)	129	(90.2)	6	(4.2)	3	(2.1)	138	(96.5)
		Borderline	2	(1.4)	3	(2.2)	1	(0.7)	6	(4.3)	1	(0.7)	2	(1.4)	1	(0.7)	4	(2.8)
		Positive	0		0		0		0		0		0		1	(0.7)	1	(0.7)
		Total	123	(89.1)	14	(10.1)	1	(0.7)	138	(100.0)	130	(90.9)	8	(5.6)	5	(3.5)	143	(100.0)
Swelling	Week 1	Negative	108	(75.0)	12	(8.3)	1	(0.7)	121	(84.0)	107	(73.3)	9	(6.2)	1	(0.7)	117	(80.1)
		Borderline	4	(2.8)	6	(4.2)	2	(1.4)	12	(8.3)	5	(3.4)	12	(8.2)	3	(2.1)	20	(13.7)
		Positive	1	(0.7)	3	(2.1)	7	(4.9)	11	(7.6)	0		2	(1.4)	7	(4.8)	9	(6.2)
		Total	113	(78.5)	21	(14.6)	10	(6.9)	144	(100.0)	112	(76.7)	23	(15.8)	11	(7.5)	146	(100.0)
	Week 2	Negative	109	(75.7)	12	(8.3)	2	(1.4)	123	(85.4)	107	(73.3)	8	(5.5)	2	(1.4)	117	(80.1)
		Borderline	3	(2.1)	7	(4.9)	1	(0.7)	11	(7.6)	5	(3.4)	13	(8.9)	2	(1.4)	20	(13.7)
		Positive	1	(0.7)	2	(1.4)	7	(4.9)	10	(6.9)	0		2	(1.4)	7	(4.8)	9	(6.2)
		Total	113	(78.5)	21	(14.6)	10	(6.9)	144	(100.0)	112	(76.7)	23	(15.8)	11	(7.5)	146	(100.0)
	Week 4	Negative	106	(74.6)	12	(8.5)	2	(1.4)	120	(84.5)	108	(74.0)	9	(6.2)	2	(1.4)	119	(81.5)
		Borderline	3	(2.1)	8	(5.6)	2	(1.4)	13	(9.2)	4	(2.7)	13	(8.9)	4	(2.7)	21	(14.4)
		Positive	2	(1.4)	1	(0.7)	6	(4.2)	9	(6.3)	0		1	(0.7)	5	(3.4)	6	(4.1)
		Total	111	(78.2)	21	(14.8)	10	(7.0)	142	(100.0)	112	(76.7)	23	(15.8)	11	(7.5)	146	(100.0)
	Week 6	Negative	106	(74.6)	16	(11.3)	2	(1.4)	124	(87.3)	106	(73.1)	10	(6.9)	4	(2.8)	120	(82.8)
		Borderline	4	(2.8)	5	(3.5)	2	(1.4)	11	(7.7)	6	(4.1)	11	(7.6)	3	(2.1)	20	(13.8)
		Positive	1	(0.7)	0		6	(4.2)	7	(4.9)	0		1	(0.7)	4	(2.8)	5	(3.4)
		Total	111	(78.2)	21	(14.8)	10	(7.0)	142	(100.0)	112	(77.2)	22	(15.2)	11	(7.6)	145	(100.0)
	Week 8	Negative	104	(73.8)	14	(9.9)	2	(1.4)	120	(85.1)	106	(74.1)	10	(7.0)	3	(2.1)	119	(83.2)
		Borderline	5	(3.5)	6	(4.3)	2	(1.4)	13	(9.2)	4	(2.8)	11	(7.7)	3	(2.1)	18	(12.6)
		Positive	1	(0.7)	1	(0.7)	6	(4.3)	8	(5.7)	0		1	(0.7)	5	(3.5)	6	(4.2)
		Total	110	(78.0)	21	(14.9)	10	(7.1)	141	(100.0)	110	(76.9)	22	(15.4)	11	(7.7)	143	(100.0)
	Week 10	Negative	101	(72.1)	16	(11.4)	1	(0.7)	118	(84.3)	104	(72.7)	11	(7.7)	6	(4.2)	121	(84.6)
		Borderline	6	(4.3)	3	(2.1)	5	(3.6)	14	(10.0)	6	(4.2)	10	(7.0)	2	(1.4)	18	(12.6)
		Positive	2	(1.4)	2	(1.4)	4	(2.9)	8	(5.7)	0		1	(0.7)	3	(2.1)	4	(2.8)
		Total	109	(77.9)	21	(15.0)	10	(7.1)	140	(100.0)	110	(76.9)	22	(15.4)	11	(7.7)	143	(100.0)
	Week 12	Negative	103	(74.6)	13	(9.4)	2	(1.4)	118	(85.5)	106	(74.1)	13	(9.1)	6	(4.2)	125	(87.4)
		Borderline	3	(2.2)	8	(5.8)	4	(2.9)	15	(10.9)	4	(2.8)	8	(5.6)	1	(0.7)	13	(9.1)
		Positive	1	(0.7)	0		4	(2.9)	5	(3.6)	0		1	(0.7)	4	(2.8)	5	(3.5)
		Total	107	(77.5)	21	(15.2)	10	(7.2)	138	(100.0)	110	(76.9)	22	(15.4)	11	(7.7)	143	(100.0)
Redness	Week 1	Negative	144	(100.0)	0		0		144	(100.0)	146	(100.0)	0		0		146	(100.0)
		Borderline	0		0		0		0		0		0		0		0	
		Positive	0		0		0		0		0		0		0		0	
		Total	144	(100.0)	0		0		144	(100.0)	146	(100.0)	0		0		146	(100.0)
	Week 2	Negative	143	(99.3)	0		0		143	(99.3)	145	(99.3)	0		0		145	(99.3)
		Borderline	1	(0.7)	0		0		1	(0.7)	1	(0.7)	0		0		1	(0.7)
		Positive	0		0		0		0		0		0		0		0	
		Total	144	(100.0)	0		0		144	(100.0)	146	(100.0)	0		0		146	(100.0)
	Week 4	Negative	142	(100.0)	0		0		142	(100.0)	146	(100.0)	0		0		146	(100.0)
		Borderline	0		0		0		0		0		0		0		0	
		Positive	0		0		0		0		0		0		0		0	
		Total	142	(100.0)	0		0		142	(100.0)	146	(100.0)	0		0		146	(100.0)
	Week 6	Negative	142	(100.0)	0		0		142	(100.0)	144	(99.3)	0		0		144	(99.3)

Target joint examination	Time point	Baseline[a]	Placebo N=144								SI-613 30 mg N=146							
			Negative		Borderline		Positive		Total		Negative		Borderline		Positive		Total	
			n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]
		Borderline	0		0		0		0		1	(0.7)	0		0		1	(0.7)
		Positive	0		0		0		0		0		0		0		0	
		Total	142	(100.0)	0		0		142	(100.0)	145	(100.0)	0		0		145	(100.0)
	Week 8	Negative	140	(99.3)	0		0		140	(99.3)	142	(99.3)	0		0		142	(99.3)
		Borderline	1	(0.7)	0		0		1	(0.7)	1	(0.7)	0		0		1	(0.7)
		Positive	0		0		0		0		0		0		0		0	
		Total	141	(100.0)	0		0		141	(100.0)	143	(100.0)	0		0		143	(100.0)
	Week 10	Negative	139	(99.3)	0		0		139	(99.3)	142	(99.3)	0		0		142	(99.3)
		Borderline	1	(0.7)	0		0		1	(0.7)	1	(0.7)	0		0		1	(0.7)
		Positive	0		0		0		0		0		0		0		0	
		Total	140	(100.0)	0		0		140	(100.0)	143	(100.0)	0		0		143	(100.0)
	Week 12	Negative	137	(99.3)	0		0		137	(99.3)	143	(100.0)	0		0		143	(100.0)
		Borderline	1	(0.7)	0		0		1	(0.7)	0		0		0		0	
		Positive	0		0		0		0		0		0		0		0	
		Total	138	(100.0)	0		0		138	(100.0)	143	(100.0)	0		0		143	(100.0)
Warmth	Week 1	Negative	132	(91.7)	4	(2.8)	1	(0.7)	137	(95.1)	138	(94.5)	2	(1.4)	0		140	(95.9)
		Borderline	2	(1.4)	2	(1.4)	0		4	(2.8)	1	(0.7)	1	(0.7)	0		2	(1.4)
		Positive	1	(0.7)	1	(0.7)	1	(0.7)	3	(2.1)	0		1	(0.7)	3	(2.1)	4	(2.7)
		Total	135	(93.8)	7	(4.9)	2	(1.4)	144	(100.0)	139	(95.2)	4	(2.7)	3	(2.1)	146	(100.0)
	Week 2	Negative	131	(91.0)	6	(4.2)	1	(0.7)	138	(95.8)	139	(95.2)	2	(1.4)	1	(0.7)	142	(97.3)
		Borderline	4	(2.8)	1	(0.7)	0		5	(3.5)	0		1	(0.7)	1	(0.7)	2	(1.4)
		Positive	0		0		1	(0.7)	1	(0.7)	0		1	(0.7)	1	(0.7)	2	(1.4)
		Total	135	(93.8)	7	(4.9)	2	(1.4)	144	(100.0)	139	(95.2)	4	(2.7)	3	(2.1)	146	(100.0)
	Week 4	Negative	128	(90.1)	4	(2.8)	1	(0.7)	133	(93.7)	138	(94.5)	3	(2.1)	2	(1.4)	143	(97.9)
		Borderline	5	(3.5)	3	(2.1)	1	(0.7)	9	(6.3)	1	(0.7)	1	(0.7)	0		2	(1.4)
		Positive	0		0		0		0		0		0		1	(0.7)	1	(0.7)
		Total	133	(93.7)	7	(4.9)	2	(1.4)	142	(100.0)	139	(95.2)	4	(2.7)	3	(2.1)	146	(100.0)
	Week 6	Negative	128	(90.1)	5	(3.5)	1	(0.7)	134	(94.4)	137	(94.5)	3	(2.1)	3	(2.1)	143	(98.6)
		Borderline	5	(3.5)	2	(1.4)	1	(0.7)	8	(5.6)	1	(0.7)	1	(0.7)	0		2	(1.4)
		Positive	0		0		0		0		0		0		0		0	
		Total	133	(93.7)	7	(4.9)	2	(1.4)	142	(100.0)	138	(95.2)	4	(2.8)	3	(2.1)	145	(100.0)
	Week 8	Negative	126	(89.4)	6	(4.3)	2	(1.4)	134	(95.0)	135	(94.4)	3	(2.1)	1	(0.7)	139	(97.2)
		Borderline	6	(4.3)	1	(0.7)	0		7	(5.0)	1	(0.7)	1	(0.7)	2	(1.4)	4	(2.8)
		Positive	0		0		0		0		0		0		0		0	
		Total	132	(93.6)	7	(5.0)	2	(1.4)	141	(100.0)	136	(95.1)	4	(2.8)	3	(2.1)	143	(100.0)
	Week 10	Negative	128	(91.4)	6	(4.3)	1	(0.7)	135	(96.4)	135	(94.4)	4	(2.8)	3	(2.1)	142	(99.3)
		Borderline	3	(2.1)	1	(0.7)	1	(0.7)	5	(3.6)	1	(0.7)	0		0		1	(0.7)
		Positive	0		0		0		0		0		0		0		0	
		Total	131	(93.6)	7	(5.0)	2	(1.4)	140	(100.0)	136	(95.1)	4	(2.8)	3	(2.1)	143	(100.0)
	Week 12	Negative	125	(90.6)	4	(2.9)	1	(0.7)	130	(94.2)	135	(94.4)	4	(2.8)	3	(2.1)	142	(99.3)
		Borderline	4	(2.9)	3	(2.2)	1	(0.7)	8	(5.8)	1	(0.7)	0		0		1	(0.7)
		Positive	0		0		0		0		0		0		0		0	
		Total	129	(93.5)	7	(5.1)	2	(1.4)	138	(100.0)	136	(95.1)	4	(2.8)	3	(2.1)	143	(100.0)

a: Baseline is value at week 0.

b: Percentages are based on the number of subjects with non-missing values at both baseline and each timepoint.

〔5.3.5.1-4 Table 14.3.4-5 改編〕

表 2.7.4.7-94. 関節徒手検査結果のシフトテーブル：613/1032 試験

Target joint examination	Timepoint	Baseline[a]	Knee N=126								Except for knee N=40								Total N=166							
			Negative		Borderline		Positive		Total		Negative		Borderline		Positive		Total		Negative		Borderline		Positive		Total	
			n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]
Joint effusion	Week 2	Negative	80	(63.5)	13	(10.3)	9	(7.1)	102	(81.0)	36	(90.0)	0		0		36	(90.0)	116	(69.9)	13	(7.8)	9	(5.4)	138	(83.1)
		Borderline	2	(1.6)	9	(7.1)	8	(6.3)	19	(15.1)	1	(2.5)	3	(7.5)	0		4	(10.0)	3	(1.8)	12	(7.2)	8	(4.8)	23	(13.9)
		Positive	0		0		5	(4.0)	5	(4.0)	0		0		0		0		0		0		5	(3.0)	5	(3.0)
		Total	82	(65.1)	22	(17.5)	22	(17.5)	126	(100.0)	37	(92.5)	3	(7.5)	0		40	(100.0)	119	(71.7)	25	(15.1)	22	(13.3)	166	(100.0)
	Week 4	Negative	80	(63.5)	10	(7.9)	6	(4.8)	96	(76.2)	35	(87.5)	1	(2.5)	0		36	(90.0)	115	(69.3)	11	(6.6)	6	(3.6)	132	(79.5)
		Borderline	0		9	(7.1)	1	(0.8)	10	(7.9)	2	(5.0)	2	(5.0)	0		4	(10.0)	2	(1.2)	11	(6.6)	1	(0.6)	14	(8.4)
		Positive	2	(1.6)	3	(2.4)	15	(11.9)	20	(15.9)	0		0		0		0		2	(1.2)	3	(1.8)	15	(9.0)	20	(12.0)
		Total	82	(65.1)	22	(17.5)	22	(17.5)	126	(100.0)	37	(92.5)	3	(7.5)	0		40	(100.0)	119	(71.7)	25	(15.1)	22	(13.3)	166	(100.0)
	Week 8	Negative	79	(63.2)	14	(11.2)	9	(7.2)	102	(81.6)	37	(92.5)	2	(5.0)	0		39	(97.5)	116	(70.3)	16	(9.7)	9	(5.5)	141	(85.5)
		Borderline	1	(0.8)	5	(4.0)	2	(1.6)	8	(6.4)	0		1	(2.5)	0		1	(2.5)	1	(0.6)	6	(3.6)	2	(1.2)	9	(5.5)
		Positive	1	(0.8)	3	(2.4)	11	(8.8)	15	(12.0)	0		0		0		0		1	(0.6)	3	(1.8)	11	(6.7)	15	(9.1)
		Total	81	(64.8)	22	(17.6)	22	(17.6)	125	(100.0)	37	(92.5)	3	(7.5)	0		40	(100.0)	118	(71.5)	25	(15.2)	22	(13.3)	165	(100.0)
	Week 12	Negative	79	(64.8)	13	(10.7)	9	(7.4)	101	(82.8)	37	(92.5)	3	(7.5)	0		40	(100.0)	116	(71.6)	16	(9.9)	9	(5.6)	141	(87.0)
		Borderline	0		4	(3.3)	2	(1.6)	6	(4.9)	0		0		0		0		0		4	(2.5)	2	(1.2)	6	(3.7)
		Positive	1	(0.8)	4	(3.3)	10	(8.2)	15	(12.3)	0		0		0		0		1	(0.6)	4	(2.5)	10	(6.2)	15	(9.3)
		Total	80	(65.6)	21	(17.2)	21	(17.2)	122	(100.0)	37	(92.5)	3	(7.5)	0		40	(100.0)	117	(72.2)	24	(14.8)	21	(13.0)	162	(100.0)
	Week 16	Negative	78	(63.9)	14	(11.5)	10	(8.2)	102	(83.6)	34	(91.9)	3	(8.1)	0		37	(100.0)	112	(70.4)	17	(10.7)	10	(6.3)	139	(87.4)
		Borderline	0		4	(3.3)	2	(1.6)	6	(4.9)	0		0		0		0		0		4	(2.5)	2	(1.3)	6	(3.8)
		Positive	2	(1.6)	3	(2.5)	9	(7.4)	14	(11.5)	0		0		0		0		2	(1.3)	3	(1.9)	9	(5.7)	14	(8.8)
		Total	80	(65.6)	21	(17.2)	21	(17.2)	122	(100.0)	34	(91.9)	3	(8.1)	0		37	(100.0)	114	(71.7)	24	(15.1)	21	(13.2)	159	(100.0)
	Week 20	Negative	75	(61.5)	16	(13.1)	9	(7.4)	100	(82.0)	34	(91.9)	2	(5.4)	0		36	(97.3)	109	(68.6)	18	(11.3)	9	(5.7)	136	(85.5)
		Borderline	2	(1.6)	5	(4.1)	2	(1.6)	9	(7.4)	0		1	(2.7)	0		1	(2.7)	2	(1.3)	6	(3.8)	2	(1.3)	10	(6.3)
		Positive	2	(1.6)	1	(0.8)	10	(8.2)	13	(10.7)	0		0		0		0		2	(1.3)	1	(0.6)	10	(6.3)	13	(8.2)
		Total	79	(64.8)	22	(18.0)	21	(17.2)	122	(100.0)	34	(91.9)	3	(8.1)	0		37	(100.0)	113	(71.1)	25	(15.7)	21	(13.2)	159	(100.0)
	Week 24	Negative	77	(63.6)	17	(14.0)	12	(9.9)	106	(87.6)	34	(91.9)	3	(8.1)	0		37	(100.0)	111	(70.3)	20	(12.7)	12	(7.6)	143	(90.5)
		Borderline	1	(0.8)	1	(0.8)	1	(0.8)	3	(2.5)	0		0		0		0		1	(0.6)	1	(0.6)	1	(0.6)	3	(1.9)
		Positive	1	(0.8)	3	(2.5)	8	(6.6)	12	(9.9)	0		0		0		0		1	(0.6)	3	(1.9)	8	(5.1)	12	(7.6)
		Total	79	(65.3)	21	(17.4)	21	(17.4)	121	(100.0)	34	(91.9)	3	(8.1)	0		37	(100.0)	113	(71.5)	24	(15.2)	21	(13.3)	158	(100.0)
	Week 28	Negative	78	(64.5)	17	(14.0)	11	(9.1)	106	(87.6)	34	(91.9)	3	(8.1)	0		37	(100.0)	112	(70.9)	20	(12.7)	11	(7.0)	143	(90.5)
		Borderline	1	(0.8)	1	(0.8)	0		2	(1.7)	0		0		0		0		1	(0.6)	1	(0.6)	0		2	(1.3)
		Positive	0		3	(2.5)	10	(8.3)	13	(10.7)	0		0		0		0		0		3	(1.9)	10	(6.3)	13	(8.2)
		Total	79	(65.3)	21	(17.4)	21	(17.4)	121	(100.0)	34	(91.9)	3	(8.1)	0		37	(100.0)	113	(71.5)	24	(15.2)	21	(13.3)	158	(100.0)

Target joint examination	Timepoint	Baseline[a]	Knee N=126								Except for knee N=40								Total N=166							
			Negative		Borderline		Positive		Total		Negative		Borderline		Positive		Total		Negative		Borderline		Positive		Total	
			n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]
	Week 32	Negative	79	(65.3)	18	(14.9)	12	(9.9)	109	(90.1)	34	(91.9)	3	(8.1)	0		37	(100.0)	113	(71.5)	21	(13.3)	12	(7.6)	146	(92.4)
		Borderline	0		1	(0.8)	0		1	(0.8)	0		0		0		0		0		1	(0.6)	0		1	(0.6)
		Positive	0		2	(1.7)	9	(7.4)	11	(9.1)	0		0		0		0		0		2	(1.3)	9	(5.7)	11	(7.0)
		Total	79	(65.3)	21	(17.4)	21	(17.4)	121	(100.0)	34	(91.9)	3	(8.1)	0		37	(100.0)	113	(71.5)	24	(15.2)	21	(13.3)	158	(100.0)
	Week 36	Negative	78	(65.0)	18	(15.0)	13	(10.8)	109	(90.8)	34	(91.9)	3	(8.1)	0		37	(100.0)	112	(71.3)	21	(13.4)	13	(8.3)	146	(93.0)
		Borderline	0		1	(0.8)	0		1	(0.8)	0		0		0		0		0		1	(0.6)	0		1	(0.6)
		Positive	1	(0.8)	2	(1.7)	7	(5.8)	10	(8.3)	0		0		0		0		1	(0.6)	2	(1.3)	7	(4.5)	10	(6.4)
		Total	79	(65.8)	21	(17.5)	20	(16.7)	120	(100.0)	34	(91.9)	3	(8.1)	0		37	(100.0)	113	(72.0)	24	(15.3)	20	(12.7)	157	(100.0)
	Week 40	Negative	77	(64.2)	17	(14.2)	12	(10.0)	106	(88.3)	34	(91.9)	3	(8.1)	0		37	(100.0)	111	(70.7)	20	(12.7)	12	(7.6)	143	(91.1)
		Borderline	0		2	(1.7)	1	(0.8)	3	(2.5)	0		0		0		0		0		2	(1.3)	1	(0.6)	3	(1.9)
		Positive	2	(1.7)	1	(0.8)	8	(6.7)	11	(9.2)	0		0		0		0		2	(1.3)	1	(0.6)	8	(5.1)	11	(7.0)
		Total	79	(65.8)	20	(16.7)	21	(17.5)	120	(100.0)	34	(91.9)	3	(8.1)	0		37	(100.0)	113	(72.0)	23	(14.6)	21	(13.4)	157	(100.0)
	Week 44	Negative	77	(64.2)	18	(15.0)	14	(11.7)	109	(90.8)	33	(89.2)	3	(8.1)	0		36	(97.3)	110	(70.1)	21	(13.4)	14	(8.9)	145	(92.4)
		Borderline	0		1	(0.8)	1	(0.8)	2	(1.7)	1	(2.7)	0		0		1	(2.7)	1	(0.6)	1	(0.6)	1	(0.6)	3	(1.9)
		Positive	2	(1.7)	1	(0.8)	6	(5.0)	9	(7.5)	0		0		0		0		2	(1.3)	1	(0.6)	6	(3.8)	9	(5.7)
		Total	79	(65.8)	20	(16.7)	21	(17.5)	120	(100.0)	34	(91.9)	3	(8.1)	0		37	(100.0)	113	(72.0)	23	(14.6)	21	(13.4)	157	(100.0)
	Week 48	Negative	78	(65.0)	16	(13.3)	13	(10.8)	107	(89.2)	33	(89.2)	3	(8.1)	0		36	(97.3)	111	(70.7)	19	(12.1)	13	(8.3)	143	(91.1)
		Borderline	0		2	(1.7)	1	(0.8)	3	(2.5)	1	(2.7)	0		0		1	(2.7)	1	(0.6)	2	(1.3)	1	(0.6)	4	(2.5)
		Positive	1	(0.8)	2	(1.7)	7	(5.8)	10	(8.3)	0		0		0		0		1	(0.6)	2	(1.3)	7	(4.5)	10	(6.4)
		Total	79	(65.8)	20	(16.7)	21	(17.5)	120	(100.0)	34	(91.9)	3	(8.1)	0		37	(100.0)	113	(72.0)	23	(14.6)	21	(13.4)	157	(100.0)
	Week 52	Negative	78	(65.0)	18	(15.0)	15	(12.5)	111	(92.5)	34	(91.9)	3	(8.1)	0		37	(100.0)	112	(71.3)	21	(13.4)	15	(9.6)	148	(94.3)
		Borderline	1	(0.8)	1	(0.8)	2	(1.7)	4	(3.3)	0		0		0		0		1	(0.6)	1	(0.6)	2	(1.3)	4	(2.5)
		Positive	0		1	(0.8)	4	(3.3)	5	(4.2)	0		0		0		0		0		1	(0.6)	4	(2.5)	5	(3.2)
		Total	79	(65.8)	20	(16.7)	21	(17.5)	120	(100.0)	34	(91.9)	3	(8.1)	0		37	(100.0)	113	(72.0)	23	(14.6)	21	(13.4)	157	(100.0)
Swelling	Week 2	Negative	77	(61.1)	18	(14.3)	6	(4.8)	101	(80.2)	30	(75.0)	2	(5.0)	1	(2.5)	33	(82.5)	107	(64.5)	20	(12.0)	7	(4.2)	134	(80.7)
		Borderline	2	(1.6)	13	(10.3)	6	(4.8)	21	(16.7)	1	(2.5)	4	(10.0)	0		5	(12.5)	3	(1.8)	17	(10.2)	6	(3.6)	26	(15.7)
		Positive	0		1	(0.8)	3	(2.4)	4	(3.2)	0		0		2	(5.0)	2	(5.0)	0		1	(0.6)	5	(3.0)	6	(3.6)
		Total	79	(62.7)	32	(25.4)	15	(11.9)	126	(100.0)	31	(77.5)	6	(15.0)	3	(7.5)	40	(100.0)	110	(66.3)	38	(22.9)	18	(10.8)	166	(100.0)
	Week 4	Negative	76	(60.3)	16	(12.7)	5	(4.0)	97	(77.0)	30	(75.0)	4	(10.0)	1	(2.5)	35	(87.5)	106	(63.9)	20	(12.0)	6	(3.6)	132	(79.5)
		Borderline	2	(1.6)	15	(11.9)	4	(3.2)	21	(16.7)	1	(2.5)	2	(5.0)	0		3	(7.5)	3	(1.8)	17	(10.2)	4	(2.4)	24	(14.5)
		Positive	1	(0.8)	1	(0.8)	6	(4.8)	8	(6.3)	0		0		2	(5.0)	2	(5.0)	1	(0.6)	1	(0.6)	8	(4.8)	10	(6.0)
		Total	79	(62.7)	32	(25.4)	15	(11.9)	126	(100.0)	31	(77.5)	6	(15.0)	3	(7.5)	40	(100.0)	110	(66.3)	38	(22.9)	18	(10.8)	166	(100.0)
	Week 8	Negative	76	(60.8)	20	(16.0)	6	(4.8)	102	(81.6)	31	(77.5)	5	(12.5)	1	(2.5)	37	(92.5)	107	(64.8)	25	(15.2)	7	(4.2)	139	(84.2)
		Borderline	2	(1.6)	10	(8.0)	5	(4.0)	17	(13.6)	0		1	(2.5)	0		1	(2.5)	2	(1.2)	11	(6.7)	5	(3.0)	18	(10.9)

Target joint examination	Timepoint	Baseline[a]	Knee N=126								Except for knee N=40								Total N=166							
			Negative		Borderline		Positive		Total		Negative		Borderline		Positive		Total		Negative		Borderline		Positive		Total	
			n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]
		Positive	0		2	(1.6)	4	(3.2)	6	(4.8)	0		0		2	(5.0)	2	(5.0)	0		2	(1.2)	6	(3.6)	8	(4.8)
		Total	78	(62.4)	32	(25.6)	15	(12.0)	125	(100.0)	31	(77.5)	6	(15.0)	3	(7.5)	40	(100.0)	109	(66.1)	38	(23.0)	18	(10.9)	165	(100.0)
	Week 12	Negative	76	(62.3)	20	(16.4)	6	(4.9)	102	(83.6)	30	(75.0)	5	(12.5)	1	(2.5)	36	(90.0)	106	(65.4)	25	(15.4)	7	(4.3)	138	(85.2)
		Borderline	0		9	(7.4)	5	(4.1)	14	(11.5)	1	(2.5)	1	(2.5)	0		2	(5.0)	1	(0.6)	10	(6.2)	5	(3.1)	16	(9.9)
		Positive	1	(0.8)	2	(1.6)	3	(2.5)	6	(4.9)	0		0		2	(5.0)	2	(5.0)	1	(0.6)	2	(1.2)	5	(3.1)	8	(4.9)
		Total	77	(63.1)	31	(25.4)	14	(11.5)	122	(100.0)	31	(77.5)	6	(15.0)	3	(7.5)	40	(100.0)	108	(66.7)	37	(22.8)	17	(10.5)	162	(100.0)
	Week 16	Negative	73	(59.8)	23	(18.9)	3	(2.5)	99	(81.1)	27	(73.0)	5	(13.5)	1	(2.7)	33	(89.2)	100	(62.9)	28	(17.6)	4	(2.5)	132	(83.0)
		Borderline	3	(2.5)	7	(5.7)	4	(3.3)	14	(11.5)	1	(2.7)	1	(2.7)	0		2	(5.4)	4	(2.5)	8	(5.0)	4	(2.5)	16	(10.1)
		Positive	1	(0.8)	1	(0.8)	7	(5.7)	9	(7.4)	0		0		2	(5.4)	2	(5.4)	1	(0.6)	1	(0.6)	9	(5.7)	11	(6.9)
		Total	77	(63.1)	31	(25.4)	14	(11.5)	122	(100.0)	28	(75.7)	6	(16.2)	3	(8.1)	37	(100.0)	105	(66.0)	37	(23.3)	17	(10.7)	159	(100.0)
	Week 20	Negative	72	(59.0)	24	(19.7)	5	(4.1)	101	(82.8)	27	(73.0)	6	(16.2)	1	(2.7)	34	(91.9)	99	(62.3)	30	(18.9)	6	(3.8)	135	(84.9)
		Borderline	2	(1.6)	8	(6.6)	5	(4.1)	15	(12.3)	1	(2.7)	0		0		1	(2.7)	3	(1.9)	8	(5.0)	5	(3.1)	16	(10.1)
		Positive	2	(1.6)	0		4	(3.3)	6	(4.9)	0		0		2	(5.4)	2	(5.4)	2	(1.3)	0		6	(3.8)	8	(5.0)
		Total	76	(62.3)	32	(26.2)	14	(11.5)	122	(100.0)	28	(75.7)	6	(16.2)	3	(8.1)	37	(100.0)	104	(65.4)	38	(23.9)	17	(10.7)	159	(100.0)
	Week 24	Negative	73	(60.3)	26	(21.5)	8	(6.6)	107	(88.4)	27	(73.0)	6	(16.2)	1	(2.7)	34	(91.9)	100	(63.3)	32	(20.3)	9	(5.7)	141	(89.2)
		Borderline	2	(1.7)	3	(2.5)	2	(1.7)	7	(5.8)	1	(2.7)	0		2	(5.4)	3	(8.1)	3	(1.9)	3	(1.9)	4	(2.5)	10	(6.3)
		Positive	1	(0.8)	2	(1.7)	4	(3.3)	7	(5.8)	0		0		0		0		1	(0.6)	2	(1.3)	4	(2.5)	7	(4.4)
		Total	76	(62.8)	31	(25.6)	14	(11.6)	121	(100.0)	28	(75.7)	6	(16.2)	3	(8.1)	37	(100.0)	104	(65.8)	37	(23.4)	17	(10.8)	158	(100.0)
	Week 28	Negative	74	(61.2)	24	(19.8)	7	(5.8)	105	(86.8)	28	(75.7)	6	(16.2)	1	(2.7)	35	(94.6)	102	(64.6)	30	(19.0)	8	(5.1)	140	(88.6)
		Borderline	2	(1.7)	4	(3.3)	4	(3.3)	10	(8.3)	0		0		1	(2.7)	1	(2.7)	2	(1.3)	4	(2.5)	5	(3.2)	11	(7.0)
		Positive	0		3	(2.5)	3	(2.5)	6	(5.0)	0		0		1	(2.7)	1	(2.7)	0		3	(1.9)	4	(2.5)	7	(4.4)
		Total	76	(62.8)	31	(25.6)	14	(11.6)	121	(100.0)	28	(75.7)	6	(16.2)	3	(8.1)	37	(100.0)	104	(65.8)	37	(23.4)	17	(10.8)	158	(100.0)
	Week 32	Negative	75	(62.0)	26	(21.5)	7	(5.8)	108	(89.3)	27	(73.0)	6	(16.2)	3	(8.1)	36	(97.3)	102	(64.6)	32	(20.3)	10	(6.3)	144	(91.1)
		Borderline	1	(0.8)	4	(3.3)	4	(3.3)	9	(7.4)	1	(2.7)	0		0		1	(2.7)	2	(1.3)	4	(2.5)	4	(2.5)	10	(6.3)
		Positive	0		1	(0.8)	3	(2.5)	4	(3.3)	0		0		0		0		0		1	(0.6)	3	(1.9)	4	(2.5)
		Total	76	(62.8)	31	(25.6)	14	(11.6)	121	(100.0)	28	(75.7)	6	(16.2)	3	(8.1)	37	(100.0)	104	(65.8)	37	(23.4)	17	(10.8)	158	(100.0)
	Week 36	Negative	75	(62.5)	26	(21.7)	9	(7.5)	110	(91.7)	28	(75.7)	6	(16.2)	3	(8.1)	37	(100.0)	103	(65.6)	32	(20.4)	12	(7.6)	147	(93.6)
		Borderline	0		4	(3.3)	2	(1.7)	6	(5.0)	0		0		0		0		0		4	(2.5)	2	(1.3)	6	(3.8)
		Positive	1	(0.8)	1	(0.8)	2	(1.7)	4	(3.3)	0		0		0		0		1	(0.6)	1	(0.6)	2	(1.3)	4	(2.5)
		Total	76	(63.3)	31	(25.8)	13	(10.8)	120	(100.0)	28	(75.7)	6	(16.2)	3	(8.1)	37	(100.0)	104	(66.2)	37	(23.6)	16	(10.2)	157	(100.0)
	Week 40	Negative	74	(61.7)	26	(21.7)	7	(5.8)	107	(89.2)	28	(75.7)	6	(16.2)	3	(8.1)	37	(100.0)	102	(65.0)	32	(20.4)	10	(6.4)	144	(91.7)
		Borderline	0		4	(3.3)	3	(2.5)	7	(5.8)	0		0		0		0		0		4	(2.5)	3	(1.9)	7	(4.5)
		Positive	2	(1.7)	0		4	(3.3)	6	(5.0)	0		0		0		0		2	(1.3)	0		4	(2.5)	6	(3.8)
		Total	76	(63.3)	30	(25.0)	14	(11.7)	120	(100.0)	28	(75.7)	6	(16.2)	3	(8.1)	37	(100.0)	104	(66.2)	36	(22.9)	17	(10.8)	157	(100.0)

Target joint examination	Timepoint	Baseline[a]	Knee N=126								Except for knee N=40								Total N=166							
			Negative		Borderline		Positive		Total		Negative		Borderline		Positive		Total		Negative		Borderline		Positive		Total	
			n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]
	Week 44	Negative	74	(61.7)	26	(21.7)	10	(8.3)	110	(91.7)	28	(75.7)	6	(16.2)	3	(8.1)	37	(100.0)	102	(65.0)	32	(20.4)	13	(8.3)	147	(93.6)
		Borderline	1	(0.8)	4	(3.3)	2	(1.7)	7	(5.8)	0		0		0		0		1	(0.6)	4	(2.5)	2	(1.3)	7	(4.5)
		Positive	1	(0.8)	0		2	(1.7)	3	(2.5)	0		0		0		0		1	(0.6)	0		2	(1.3)	3	(1.9)
		Total	76	(63.3)	30	(25.0)	14	(11.7)	120	(100.0)	28	(75.7)	6	(16.2)	3	(8.1)	37	(100.0)	104	(66.2)	36	(22.9)	17	(10.8)	157	(100.0)
	Week 48	Negative	74	(61.7)	25	(20.8)	9	(7.5)	108	(90.0)	28	(75.7)	6	(16.2)	3	(8.1)	37	(100.0)	102	(65.0)	31	(19.7)	12	(7.6)	145	(92.4)
		Borderline	1	(0.8)	3	(2.5)	2	(1.7)	6	(5.0)	0		0		0		0		1	(0.6)	3	(1.9)	2	(1.3)	6	(3.8)
		Positive	1	(0.8)	2	(1.7)	3	(2.5)	6	(5.0)	0		0		0		0		1	(0.6)	2	(1.3)	3	(1.9)	6	(3.8)
		Total	76	(63.3)	30	(25.0)	14	(11.7)	120	(100.0)	28	(75.7)	6	(16.2)	3	(8.1)	37	(100.0)	104	(66.2)	36	(22.9)	17	(10.8)	157	(100.0)
	Week 52	Negative	74	(61.7)	26	(21.7)	11	(9.2)	111	(92.5)	28	(75.7)	6	(16.2)	3	(8.1)	37	(100.0)	102	(65.0)	32	(20.4)	14	(8.9)	148	(94.3)
		Borderline	2	(1.7)	3	(2.5)	1	(0.8)	6	(5.0)	0		0		0		0		2	(1.3)	3	(1.9)	1	(0.6)	6	(3.8)
		Positive	0		1	(0.8)	2	(1.7)	3	(2.5)	0		0		0		0		0		1	(0.6)	2	(1.3)	3	(1.9)
		Total	76	(63.3)	30	(25.0)	14	(11.7)	120	(100.0)	28	(75.7)	6	(16.2)	3	(8.1)	37	(100.0)	104	(66.2)	36	(22.9)	17	(10.8)	157	(100.0)
Redness	Week 2	Negative	122	(96.8)	4	(3.2)	0		126	(100.0)	38	(95.0)	2	(5.0)	0		40	(100.0)	160	(96.4)	6	(3.6)	0		166	(100.0)
		Borderline	0		0		0		0		0		0		0		0		0		0		0		0	
		Positive	0		0		0		0		0		0		0		0		0		0		0		0	
		Total	122	(96.8)	4	(3.2)	0		126	(100.0)	38	(95.0)	2	(5.0)	0		40	(100.0)	160	(96.4)	6	(3.6)	0		166	(100.0)
	Week 4	Negative	122	(96.8)	4	(3.2)	0		126	(100.0)	38	(95.0)	2	(5.0)	0		40	(100.0)	160	(96.4)	6	(3.6)	0		166	(100.0)
		Borderline	0		0		0		0		0		0		0		0		0		0		0		0	
		Positive	0		0		0		0		0		0		0		0		0		0		0		0	
		Total	122	(96.8)	4	(3.2)	0		126	(100.0)	38	(95.0)	2	(5.0)	0		40	(100.0)	160	(96.4)	6	(3.6)	0		166	(100.0)
	Week 8	Negative	121	(96.8)	4	(3.2)	0		125	(100.0)	38	(95.0)	2	(5.0)	0		40	(100.0)	159	(96.4)	6	(3.6)	0		165	(100.0)
		Borderline	0		0		0		0		0		0		0		0		0		0		0		0	
		Positive	0		0		0		0		0		0		0		0		0		0		0		0	
		Total	121	(96.8)	4	(3.2)	0		125	(100.0)	38	(95.0)	2	(5.0)	0		40	(100.0)	159	(96.4)	6	(3.6)	0		165	(100.0)
	Week 12	Negative	118	(96.7)	4	(3.3)	0		122	(100.0)	38	(95.0)	2	(5.0)	0		40	(100.0)	156	(96.3)	6	(3.7)	0		162	(100.0)
		Borderline	0		0		0		0		0		0		0		0		0		0		0		0	
		Positive	0		0		0		0		0		0		0		0		0		0		0		0	
		Total	118	(96.7)	4	(3.3)	0		122	(100.0)	38	(95.0)	2	(5.0)	0		40	(100.0)	156	(96.3)	6	(3.7)	0		162	(100.0)
	Week 16	Negative	118	(96.7)	4	(3.3)	0		122	(100.0)	35	(94.6)	2	(5.4)	0		37	(100.0)	153	(96.2)	6	(3.8)	0		159	(100.0)
		Borderline	0		0		0		0		0		0		0		0		0		0		0		0	
		Positive	0		0		0		0		0		0		0		0		0		0		0		0	
		Total	118	(96.7)	4	(3.3)	0		122	(100.0)	35	(94.6)	2	(5.4)	0		37	(100.0)	153	(96.2)	6	(3.8)	0		159	(100.0)
	Week 20	Negative	118	(96.7)	4	(3.3)	0		122	(100.0)	35	(94.6)	2	(5.4)	0		37	(100.0)	153	(96.2)	6	(3.8)	0		159	(100.0)
		Borderline	0		0		0		0		0		0		0		0		0		0		0		0	

Target joint examination	Timepoint	Baseline[a]	Knee N=126								Except for knee N=40								Total N=166							
			Negative		Borderline		Positive		Total		Negative		Borderline		Positive		Total		Negative		Borderline		Positive		Total	
			n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]
		Positive	0		0		0		0		0		0		0		0		0		0		0		0	
		Total	118	(96.7)	4	(3.3)	0		122	(100.0)	35	(94.6)	2	(5.4)	0		37	(100.0)	153	(96.2)	6	(3.8)	0		159	(100.0)
	Week 24	Negative	117	(96.7)	4	(3.3)	0		121	(100.0)	35	(94.6)	2	(5.4)	0		37	(100.0)	152	(96.2)	6	(3.8)	0		158	(100.0)
		Borderline	0		0		0		0		0		0		0		0		0		0		0		0	
		Positive	0		0		0		0		0		0		0		0		0		0		0		0	
		Total	117	(96.7)	4	(3.3)	0		121	(100.0)	35	(94.6)	2	(5.4)	0		37	(100.0)	152	(96.2)	6	(3.8)	0		158	(100.0)
	Week 28	Negative	117	(96.7)	4	(3.3)	0		121	(100.0)	35	(94.6)	2	(5.4)	0		37	(100.0)	152	(96.2)	6	(3.8)	0		158	(100.0)
		Borderline	0		0		0		0		0		0		0		0		0		0		0		0	
		Positive	0		0		0		0		0		0		0		0		0		0		0		0	
		Total	117	(96.7)	4	(3.3)	0		121	(100.0)	35	(94.6)	2	(5.4)	0		37	(100.0)	152	(96.2)	6	(3.8)	0		158	(100.0)
	Week 32	Negative	117	(96.7)	4	(3.3)	0		121	(100.0)	35	(94.6)	2	(5.4)	0		37	(100.0)	152	(96.2)	6	(3.8)	0		158	(100.0)
		Borderline	0		0		0		0		0		0		0		0		0		0		0		0	
		Positive	0		0		0		0		0		0		0		0		0		0		0		0	
		Total	117	(96.7)	4	(3.3)	0		121	(100.0)	35	(94.6)	2	(5.4)	0		37	(100.0)	152	(96.2)	6	(3.8)	0		158	(100.0)
	Week 36	Negative	116	(96.7)	4	(3.3)	0		120	(100.0)	35	(94.6)	2	(5.4)	0		37	(100.0)	151	(96.2)	6	(3.8)	0		157	(100.0)
		Borderline	0		0		0		0		0		0		0		0		0		0		0		0	
		Positive	0		0		0		0		0		0		0		0		0		0		0		0	
		Total	116	(96.7)	4	(3.3)	0		120	(100.0)	35	(94.6)	2	(5.4)	0		37	(100.0)	151	(96.2)	6	(3.8)	0		157	(100.0)
	Week 40	Negative	116	(96.7)	4	(3.3)	0		120	(100.0)	35	(94.6)	2	(5.4)	0		37	(100.0)	151	(96.2)	6	(3.8)	0		157	(100.0)
		Borderline	0		0		0		0		0		0		0		0		0		0		0		0	
		Positive	0		0		0		0		0		0		0		0		0		0		0		0	
		Total	116	(96.7)	4	(3.3)	0		120	(100.0)	35	(94.6)	2	(5.4)	0		37	(100.0)	151	(96.2)	6	(3.8)	0		157	(100.0)
	Week 44	Negative	116	(96.7)	4	(3.3)	0		120	(100.0)	35	(94.6)	2	(5.4)	0		37	(100.0)	151	(96.2)	6	(3.8)	0		157	(100.0)
		Borderline	0		0		0		0		0		0		0		0		0		0		0		0	
		Positive	0		0		0		0		0		0		0		0		0		0		0		0	
		Total	116	(96.7)	4	(3.3)	0		120	(100.0)	35	(94.6)	2	(5.4)	0		37	(100.0)	151	(96.2)	6	(3.8)	0		157	(100.0)
	Week 48	Negative	116	(96.7)	4	(3.3)	0		120	(100.0)	35	(94.6)	2	(5.4)	0		37	(100.0)	151	(96.2)	6	(3.8)	0		157	(100.0)
		Borderline	0		0		0		0		0		0		0		0		0		0		0		0	
		Positive	0		0		0		0		0		0		0		0		0		0		0		0	
		Total	116	(96.7)	4	(3.3)	0		120	(100.0)	35	(94.6)	2	(5.4)	0		37	(100.0)	151	(96.2)	6	(3.8)	0		157	(100.0)
	Week 52	Negative	116	(96.7)	4	(3.3)	0		120	(100.0)	35	(94.6)	2	(5.4)	0		37	(100.0)	151	(96.2)	6	(3.8)	0		157	(100.0)
		Borderline	0		0		0		0		0		0		0		0		0		0		0		0	
		Positive	0		0		0		0		0		0		0		0		0		0		0		0	
		Total	116	(96.7)	4	(3.3)	0		120	(100.0)	35	(94.6)	2	(5.4)	0		37	(100.0)	151	(96.2)	6	(3.8)	0		157	(100.0)

Target joint examination	Timepoint	Baseline[a]	Knee N=126								Except for knee N=40								Total N=166							
			Negative		Borderline		Positive		Total		Negative		Borderline		Positive		Total		Negative		Borderline		Positive		Total	
			n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]
Warmth	Week 2	Negative	118	(93.7)	8	(6.3)	0		126	(100.0)	37	(92.5)	3	(7.5)	0		40	(100.0)	155	(93.4)	11	(6.6)	0		166	(100.0)
		Borderline	0		0		0		0		0		0		0		0		0		0		0		0	
		Positive	0		0		0		0		0		0		0		0		0		0		0		0	
		Total	118	(93.7)	8	(6.3)	0		126	(100.0)	37	(92.5)	3	(7.5)	0		40	(100.0)	155	(93.4)	11	(6.6)	0		166	(100.0)
	Week 4	Negative	117	(92.9)	8	(6.3)	0		125	(99.2)	37	(92.5)	3	(7.5)	0		40	(100.0)	154	(92.8)	11	(6.6)	0		165	(99.4)
		Borderline	0		0		0		0		0		0		0		0		0		0		0		0	
		Positive	1	(0.8)	0		0		1	(0.8)	0		0		0		0		1	(0.6)	0		0		1	(0.6)
		Total	118	(93.7)	8	(6.3)	0		126	(100.0)	37	(92.5)	3	(7.5)	0		40	(100.0)	155	(93.4)	11	(6.6)	0		166	(100.0)
	Week 8	Negative	116	(92.8)	8	(6.4)	0		124	(99.2)	37	(92.5)	3	(7.5)	0		40	(100.0)	153	(92.7)	11	(6.7)	0		164	(99.4)
		Borderline	1	(0.8)	0		0		1	(0.8)	0		0		0		0		1	(0.6)	0		0		1	(0.6)
		Positive	0		0		0		0		0		0		0		0		0		0		0		0	
		Total	117	(93.6)	8	(6.4)	0		125	(100.0)	37	(92.5)	3	(7.5)	0		40	(100.0)	154	(93.3)	11	(6.7)	0		165	(100.0)
	Week 12	Negative	114	(93.4)	8	(6.6)	0		122	(100.0)	37	(92.5)	3	(7.5)	0		40	(100.0)	151	(93.2)	11	(6.8)	0		162	(100.0)
		Borderline	0		0		0		0		0		0		0		0		0		0		0		0	
		Positive	0		0		0		0		0		0		0		0		0		0		0		0	
		Total	114	(93.4)	8	(6.6)	0		122	(100.0)	37	(92.5)	3	(7.5)	0		40	(100.0)	151	(93.2)	11	(6.8)	0		162	(100.0)
	Week 16	Negative	114	(93.4)	8	(6.6)	0		122	(100.0)	34	(91.9)	3	(8.1)	0		37	(100.0)	148	(93.1)	11	(6.9)	0		159	(100.0)
		Borderline	0		0		0		0		0		0		0		0		0		0		0		0	
		Positive	0		0		0		0		0		0		0		0		0		0		0		0	
		Total	114	(93.4)	8	(6.6)	0		122	(100.0)	34	(91.9)	3	(8.1)	0		37	(100.0)	148	(93.1)	11	(6.9)	0		159	(100.0)
	Week 20	Negative	114	(93.4)	8	(6.6)	0		122	(100.0)	34	(91.9)	3	(8.1)	0		37	(100.0)	148	(93.1)	11	(6.9)	0		159	(100.0)
		Borderline	0		0		0		0		0		0		0		0		0		0		0		0	
		Positive	0		0		0		0		0		0		0		0		0		0		0		0	
		Total	114	(93.4)	8	(6.6)	0		122	(100.0)	34	(91.9)	3	(8.1)	0		37	(100.0)	148	(93.1)	11	(6.9)	0		159	(100.0)
	Week 24	Negative	113	(93.4)	8	(6.6)	0		121	(100.0)	34	(91.9)	3	(8.1)	0		37	(100.0)	147	(93.0)	11	(7.0)	0		158	(100.0)
		Borderline	0		0		0		0		0		0		0		0		0		0		0		0	
		Positive	0		0		0		0		0		0		0		0		0		0		0		0	
		Total	113	(93.4)	8	(6.6)	0		121	(100.0)	34	(91.9)	3	(8.1)	0		37	(100.0)	147	(93.0)	11	(7.0)	0		158	(100.0)
	Week 28	Negative	113	(93.4)	8	(6.6)	0		121	(100.0)	34	(91.9)	3	(8.1)	0		37	(100.0)	147	(93.0)	11	(7.0)	0		158	(100.0)
		Borderline	0		0		0		0		0		0		0		0		0		0		0		0	
		Positive	0		0		0		0		0		0		0		0		0		0		0		0	
		Total	113	(93.4)	8	(6.6)	0		121	(100.0)	34	(91.9)	3	(8.1)	0		37	(100.0)	147	(93.0)	11	(7.0)	0		158	(100.0)
	Week 32	Negative	113	(93.4)	8	(6.6)	0		121	(100.0)	34	(91.9)	3	(8.1)	0		37	(100.0)	147	(93.0)	11	(7.0)	0		158	(100.0)
		Borderline	0		0		0		0		0		0		0		0		0		0		0		0	

Target joint examination	Timepoint	Baseline[a]	Knee N=126								Except for knee N=40								Total N=166							
			Negative		Borderline		Positive		Total		Negative		Borderline		Positive		Total		Negative		Borderline		Positive		Total	
			n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]	n	(%)[b]
		Positive	0		0		0		0		0		0		0		0		0		0		0		0	
		Total	113	(93.4)	8	(6.6)	0		121	(100.0)	34	(91.9)	3	(8.1)	0		37	(100.0)	147	(93.0)	11	(7.0)	0		158	(100.0)
	Week 36	Negative	112	(93.3)	8	(6.7)	0		120	(100.0)	34	(91.9)	3	(8.1)	0		37	(100.0)	146	(93.0)	11	(7.0)	0		157	(100.0)
		Borderline	0		0		0		0		0		0		0		0		0		0		0		0	
		Positive	0		0		0		0		0		0		0		0		0		0		0		0	
		Total	112	(93.3)	8	(6.7)	0		120	(100.0)	34	(91.9)	3	(8.1)	0		37	(100.0)	146	(93.0)	11	(7.0)	0		157	(100.0)
	Week 40	Negative	113	(94.2)	7	(5.8)	0		120	(100.0)	34	(91.9)	3	(8.1)	0		37	(100.0)	147	(93.6)	10	(6.4)	0		157	(100.0)
		Borderline	0		0		0		0		0		0		0		0		0		0		0		0	
		Positive	0		0		0		0		0		0		0		0		0		0		0		0	
		Total	113	(94.2)	7	(5.8)	0		120	(100.0)	34	(91.9)	3	(8.1)	0		37	(100.0)	147	(93.6)	10	(6.4)	0		157	(100.0)
	Week 44	Negative	113	(94.2)	7	(5.8)	0		120	(100.0)	34	(91.9)	3	(8.1)	0		37	(100.0)	147	(93.6)	10	(6.4)	0		157	(100.0)
		Borderline	0		0		0		0		0		0		0		0		0		0		0		0	
		Positive	0		0		0		0		0		0		0		0		0		0		0		0	
		Total	113	(94.2)	7	(5.8)	0		120	(100.0)	34	(91.9)	3	(8.1)	0		37	(100.0)	147	(93.6)	10	(6.4)	0		157	(100.0)
	Week 48	Negative	113	(94.2)	7	(5.8)	0		120	(100.0)	34	(91.9)	3	(8.1)	0		37	(100.0)	147	(93.6)	10	(6.4)	0		157	(100.0)
		Borderline	0		0		0		0		0		0		0		0		0		0		0		0	
		Positive	0		0		0		0		0		0		0		0		0		0		0		0	
		Total	113	(94.2)	7	(5.8)	0		120	(100.0)	34	(91.9)	3	(8.1)	0		37	(100.0)	147	(93.6)	10	(6.4)	0		157	(100.0)
	Week 52	Negative	113	(94.2)	7	(5.8)	0		120	(100.0)	34	(91.9)	3	(8.1)	0		37	(100.0)	147	(93.6)	10	(6.4)	0		157	(100.0)
		Borderline	0		0		0		0		0		0		0		0		0		0		0		0	
		Positive	0		0		0		0		0		0		0		0		0		0		0		0	
		Total	113	(94.2)	7	(5.8)	0		120	(100.0)	34	(91.9)	3	(8.1)	0		37	(100.0)	147	(93.6)	10	(6.4)	0		157	(100.0)

a: Baseline is value at week 0.
b: Percentages are based on the number of subjects with non-missing values at both baseline and each timepoint.
〔5.3.5.2-1 Table 14.3.4-5 改編〕

参考文献

（1） Klepper MJ, Cobert B. Drug safety data: How to analyze, summarize, and interpret to determine risk. Massachusetts; Jones & Bartlett Learning; 2011: 187-189.