

付録 1 因果関係を問わないすべての有害事象および因果関係が否定できない有害事象の各集計結果

Table 27.1.1 Frequency [N (%)] of patients with adverse events by treatment, primary system organ class and preferred term - treated set

Treatment group	25 mg+fast		25 mg+fed		10 mg+fast	
	N	(%)	N	(%)	N	(%)
Number of subjects	18	(100.0)	18	(100.0)	18	(100.0)
Total with adverse events	2	(11.1)	2	(11.1)	4	(22.2)
Infections and infestations (感染症および寄生虫症)	0	0.0	0	0.0	1	(5.6)
Rhinitis (鼻炎)	0	0.0	0	0.0	1	(5.6)
Nervous system disorders (神経系障害)	0	0.0	2	(11.1)	3	(16.7)
Headache (頭痛)	0	0.0	1	(5.6)	2	(11.1)
Migraine (片頭痛)	0	0.0	0	0.0	1	(5.6)
Presyncope (失神寸前の状態)	0	0.0	1	(5.6)	0	0.0
Ear and labyrinth disorders (耳および迷路障害)	0	0.0	1	(5.6)	0	0.0
Vertigo (回転性めまい)	0	0.0	1	(5.6)	0	0.0
Gastrointestinal disorders (胃腸障害)	1	(5.6)	1	(5.6)	0	0.0
Vomiting (嘔吐)	1	(5.6)	1	(5.6)	0	0.0
Abdominal pain (腹痛)	0	0.0	1	(5.6)	0	0.0
Nausea (悪心)	0	0.0	1	(5.6)	0	0.0
Skin and subcutaneous tissue disorders (皮膚および皮下組織障害)	1	(5.6)	0	0.0	0	0.0
Neurodermatitis (神経皮膚炎)	1	(5.6)	0	0.0	0	0.0
Musculoskeletal and connective tissue disorders (筋骨格系および結合組織障害)	0	0.0	0	0.0	1	(5.6)
Myosclerosis (筋硬化症)	0	0.0	0	0.0	1	(5.6)

Containing data from study 1245_0079

MedDRA version used for reporting : XXXXXXXXXX

Table 24.1.1 Frequency [N (%)] of patients with adverse events by treatment, primary system organ class and preferred term - treated set

Treatment group	BI10773 FF		BI10774 TF2	
	N	(%)	N	(%)
Number of subjects	22	(100.0)	23	(100.0)
Total with adverse events	1	(4.5)	7	(30.4)
Infections and infestations (感染症および寄生虫症)	0	0.0	2	(8.7)
Nasopharyngitis (鼻咽頭炎)	0	0.0	1	(4.3)
Tonsillitis (扁桃炎)	0	0.0	1	(4.3)
Nervous system disorders (神経系障害)	1	(4.5)	5	(21.7)
Headache (頭痛)	1	(4.5)	4	(17.4)
Migraine with aura (前兆を伴う片頭痛)	0	0.0	1	(4.3)
Respiratory, thoracic and mediastinal disorders (呼吸器、胸郭および縦隔障害)	0	0.0	1	(4.3)
Oropharyngeal pain (口腔咽頭痛)	0	0.0	1	(4.3)
Gastrointestinal disorders (胃腸障害)	0	0.0	1	(4.3)
Diarrhoea (下痢)	0	0.0	1	(4.3)
Nausea (悪心)	0	0.0	1	(4.3)
Vomiting (嘔吐)	0	0.0	1	(4.3)
Skin and subcutaneous tissue disorders (皮膚および皮下組織障害)	0	0.0	1	(4.3)
Dermatitis allergic (アレルギー性皮膚炎)	0	0.0	1	(4.3)
Musculoskeletal and connective tissue disorders (筋骨格系および結合組織障害)	0	0.0	1	(4.3)
Pain in extremity (四肢痛)	0	0.0	1	(4.3)

Containing data from study 1245_0051

MedDRA version used for reporting : XXXXXXXXXX

Table 7.1.1 Frequency [N (%)] of patients with adverse events by treatment, primary system organ class and preferred term - treated set

Treatment group	Placebo		BI 10773 0.5 mg		BI 10773 2.5 mg		BI 10773 10 mg		BI 10773 25 mg		BI 10773 50 mg		BI 10773 100 mg		BI 10773 200 mg		BI 10773 400 mg		BI 10773 800 mg		oGTT		50 mg+oGTT		placebo+oGTT	
	N	(%)	N	(%)	N	(%)	N	(%)	N	(%)	N	(%)	N	(%)	N	(%)	N	(%)	N	(%)	N	(%)	N	(%)	N	(%)
Number of subjects	18	(100.0)	6	(100.0)	6	(100.0)	6	(100.0)	6	(100.0)	5	(100.0)	5	(100.0)	6	(100.0)	6	(100.0)	6	(100.0)	7	(100.0)	5	(100.0)	2	(100.0)
Total with adverse events	4	(22.2)	1	(16.7)	0	0.0	1	(16.7)	1	(16.7)	3	(60.0)	0	0.0	2	(33.3)	4	(66.7)	1	(16.7)	1	(14.3)	1	(20.0)	1	(50.0)
Infections and infestations (感染症および寄生虫症)	1	(5.6)	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	(16.7)	0	0.0	0	0.0	0	0.0	0	0.0
Nasopharyngitis (鼻咽 頭炎)	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	(16.7)	0	0.0	0	0.0	0	0.0	0	0.0
Otitis externa (外耳炎)	1	(5.6)	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Blood and lymphatic system disorders (血液お よびリンパ系障害)	0	0.0	1	(16.7)	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Lymphadenopathy (リン パ節症)	0	0.0	1	(16.7)	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Metabolism and nutrition disorders (代謝および栄 養障害)	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	(20.0)	0	0.0
Hypoglycaemia (低血 糖)	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	(20.0)	0	0.0
Nervous system disorders (神経系障害)	2	(11.1)	0	0.0	0	0.0	1	(16.7)	1	(16.7)	1	(20.0)	0	0.0	1	(16.7)	3	(50.0)	1	(16.7)	1	(14.3)	1	20.0	0	0.0
Dizziness (浮動性めま い)	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	(20.0)	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	20.0	0	0.0
Headache (頭痛)	2	(11.1)	0	0.0	0	0.0	1	(16.7)	1	(16.7)	0	0.0	0	0.0	1	(16.7)	3	(50.0)	1	(16.7)	1	(14.3)	0	0.0	0	0.0
Respiratory, thoracic and mediastinal disorders (呼 吸器、胸郭および縦隔障 害)	1	(5.6)	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	(20.0)	0	0.0

Treatment group	Placebo		BI 10773		BI 10773		BI 10773		BI 10773		BI 10773		BI 10773		BI 10773		BI 10773		oGTT		50 mg+oGTT		placebo+oGTT	
	0.5 mg		2.5 mg		10 mg		25 mg		50 mg		100 mg		200 mg		400 mg		800 mg							
	N	(%)	N	(%)	N	(%)	N	(%)	N	(%)	N	(%)	N	(%)	N	(%)	N	(%)	N	(%)	N	(%)	N	(%)
Epistaxis (鼻出血)	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	(20.0)	0	0.0
Pharyngeal erythema (咽頭紅斑)	1	(5.6)	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Gastrointestinal disorders (胃腸障害)	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	(40.0)	0	0.0	1	(16.7)	2	(33.3)	0	0.0	0	0.0	1	(50.0)
Diarrhoea (下痢)	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	(20.0)	0	0.0	0	0.0	1	(16.7)	0	0.0	0	0.0	0	0.0
Dry mouth (口内乾燥)	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	(16.7)	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Nausea (悪心)	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	(20.0)	0	0.0	0	0.0	1	(16.7)	0	0.0	0	0.0	0	0.0
Stomach discomfort (胃不快感)	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	(50.0)
Musculoskeletal and connective tissue disorders (筋骨格系および結合組織障害)	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	(20.0)	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Neck pain (頸部痛)	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	(20.0)	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
General disorders and administration site conditions (一般・全身障害および投与部位の状態)	1	(5.6)	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	(16.7)	0	0.0	0	0.0	1	(20.0)	0	0.0
Asthenia (無力症)	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	(20.0)	0	0.0
Feeling hot (熱感)	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	(16.7)	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Injection site erythema (注射部位紅斑)	1	(5.6)	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

Containing data from study 1245_0001

MedDRA version used for reporting : XXXXXXXXXX

Table 7.1.2 Frequency [N (%)] of patients with related adverse events by treatment, primary system organ class and preferred term - treated set

Treatment group	Placebo		BI 10773 0.5 mg		BI 10773 2.5 mg		BI 10773 10 mg		BI 10773 25 mg		BI 10773 50 mg		BI 10773 100 mg		BI 10773 200 mg		BI 10773 400 mg		BI 10773 800 mg		oGTT		50 mg+oGTT		placebo+oGTT	
	N	(%)	N	(%)	N	(%)	N	(%)	N	(%)	N	(%)	N	(%)	N	(%)	N	(%)	N	(%)	N	(%)	N	(%)	N	(%)
Number of subjects	18	(100.0)	6	(100.0)	6	(100.0)	6	(100.0)	6	(100.0)	5	(100.0)	5	(100.0)	6	(100.0)	6	(100.0)	6	(100.0)	7	(100.0)	5	(100.0)	2	(100.0)
Total with related adverse events	2	(11.1)	0	0.0	0	0.0	1	(16.7)	1	(16.7)	1	(20.0)	0	0.0	2	(33.3)	4	(66.7)	1	(16.7)	0	0.0	0	0.0	1	(50.0)
Nervous system disorders (神経系障害)	2	(11.1)	0	0.0	0	0.0	1	(16.7)	1	(16.7)	0	0.0	0	0.0	1	(16.7)	3	(50.0)	1	(16.7)	0	0.0	0	0.0	0	0.0
Dizziness (浮動性めまい)	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Headache (頭痛)	2	(11.1)	0	0.0	0	0.0	1	(16.7)	1	(16.7)	0	0.0	0	0.0	1	(16.7)	3	(50.0)	1	(16.7)	0	0.0	0	0.0	0	0.0
Gastrointestinal disorders (胃腸障害)	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	(20.0)	0	0.0	1	(16.7)	2	(33.3)	0	0.0	0	0.0	0	0.0	1	(50.0)
Diarrhoea (下痢)	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	(20.0)	0	0.0	0	0.0	1	(16.7)	0	0.0	0	0.0	0	0.0	0	0.0
Dry mouth (口内乾燥)	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	(16.7)	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Nausea (悪心)	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	(16.7)	0	0.0	0	0.0	0	0.0	0	0.0
Stomach discomfort (胃不快感)	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	(50.0)
General disorders and administration site conditions (一般・全身障 害および投与部位の状 態)	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	(16.7)	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Feeling hot (熱感)	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	(16.7)	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

Containing data from study 1245_0001

MedDRA version used for reporting : XXXXXXXXXX

Table 10.1.1 Frequency [N (%)] of patients with adverse events by treatment, primary system organ class and preferred term - treated set

Treatment group	BI 10773		BI 10773+Glim		Glimepiride	
	N	(%)	N	(%)	N	(%)
Number of subjects	16	(100.0)	16	(100.0)	16	(100.0)
Total with adverse events	3	(18.8)	1	(6.3)	4	(25.0)
General disorders and administration site conditions (一般・全身障害および投与部位の状態)	1	(6.3)	0	0.0	0	0.0
Fatigue (疲労)	1	(6.3)	0	0.0	0	0.0
Infections and infestations (感染症および寄生虫症)	1	(6.3)	1	(6.3)	0	0.0
Hordeolum (麦粒腫)	1	(6.3)	0	0.0	0	0.0
Nasopharyngitis (鼻咽頭炎)	0	0.0	1	(6.3)	0	0.0
Injury, poisoning and procedural complications (傷害, 中毒および処置合併症)	0	0.0	0	0.0	1	(6.3)
Contusion (挫傷)	0	0.0	0	0.0	1	(6.3)
Musculoskeletal and connective tissue disorders (筋骨格系および結合組織障害)	0	0.0	0	0.0	1	(6.3)
Pain in extremity (四肢痛)	0	0.0	0	0.0	1	(6.3)
Nervous system disorders (神経系障害)	1	(6.3)	0	0.0	2	(12.5)
Headache (頭痛)	1	(6.3)	0	0.0	2	(12.5)

Containing data from study 1245_0007

MedDRA version used for reporting : XXXXXXXXXX

Table 15.1.1 Frequency [N (%)] of patients with adverse events by treatment, primary system organ class and preferred term - treated set

Treatment group	BI10773		BI+Pio		Pioglitazone	
	N	(%)	N	(%)	N	(%)
Number of subjects	19	(100.0)	18	(100.0)	20	(100.0)
Total with adverse events	1	(5.3)	5	(27.8)	4	(20.0)
Eye disorders (眼障害)	0	0.0	2	(11.1)	0	0.0
Conjunctivitis (結膜炎)	0	0.0	1	(5.6)	0	0.0
Eyelid oedema (眼瞼浮腫)	0	0.0	1	(5.6)	0	0.0
Infections and infestations (感染症および寄生虫症)	0	0.0	2	(11.1)	0	0.0
Gastroenteritis (胃腸炎)	0	0.0	1	(5.6)	0	0.0
Nasopharyngitis (鼻咽頭炎)	0	0.0	1	(5.6)	0	0.0
Investigations (臨床検査)	0	0.0	0	0.0	1	(5.0)
Blood creatine phosphokinase increased (血中クレアチンホスホキナーゼ増加)	0	0.0	0	0.0	1	(5.0)
Metabolism and nutrition disorders (代謝および栄養障害)	1	(5.3)	0	0.0	1	(5.0)
Anorexia (食欲不振)	1	(5.3)	0	0.0	0	0.0
Increased appetite (食欲亢進)	0	0.0	0	0.0	1	(5.0)
Nervous system disorders (神経系障害)	0	0.0	0	0.0	2	(10.0)
Headache (頭痛)	0	0.0	0	0.0	2	(10.0)
Skin and subcutaneous tissue disorders (皮膚および皮下組織障害)	0	0.0	1	(5.6)	0	0.0
Rash (発疹)	0	0.0	1	(5.6)	0	0.0

Containing data from study 1245_0017

MedDRA version used for reporting : XXXXXXXXXX

Table 16.1.1 Frequency [N (%)] of patients with adverse events by treatment, primary system organ class and preferred term - treated set

Treatment group	BI10773		BI+Warf		Warfarin	
	N	(%)	N	(%)	N	(%)
Number of subjects	18	(100.0)	18	(100.0)	18	(100.0)
Total with adverse events	4	(22.2)	2	(11.1)	5	(27.8)
Gastrointestinal disorders (胃腸障害)	0	0.0	0	0.0	1	(5.6)
Vomiting(嘔吐)	0	0.0	0	0.0	1	(5.6)
General disorders and administration site conditions (一般・全身障害および投与部位の状態)	0	0.0	1	(5.6)	0	0.0
Induration (硬結)	0	0.0	1	(5.6)	0	0.0
Injury, poisoning and procedural complications (傷害, 中毒および処置合併症)	0	0.0	1	(5.6)	0	0.0
Arthropod sting (節足動物刺傷)	0	0.0	1	(5.6)	0	0.0
Musculoskeletal and connective tissue disorders (筋骨格系および結合組織障害)	0	0.0	0	0.0	1	(5.6)
Muscle spasms (筋痙攣)	0	0.0	0	0.0	1	(5.6)
Nervous system disorders (神経系障害)	3	(16.7)	0	0.0	2	(11.1)
Headache (頭痛)	3	(16.7)	0	0.0	2	(11.1)
Respiratory, thoracic and mediastinal disorders (呼吸器、胸郭および縦隔障害)	1	(5.6)	0	0.0	0	0.0
Oropharyngeal pain (口腔咽頭痛)	1	(5.6)	0	0.0	0	0.0
Skin and subcutaneous tissue disorders (皮膚および皮下組織障害)	0	0.0	0	0.0	1	(5.6)
Petechiae (点状出血)	0	0.0	0	0.0	1	(5.6)

Containing data from study 1245_0018

MedDRA version used for reporting : XXXXXXXXXX

Table 17.1.1 Frequency [N (%)] of patients with adverse events by treatment, primary system organ class and preferred term - treated set

Treatment group	BI10773		BI+Sita		Sita	
	N	(%)	N	(%)	N	(%)
Number of subjects	16	(100.0)	16	(100.0)	16	(100.0)
Total with adverse events	3	(18.8)	0	0.0	3	(18.8)
Gastrointestinal disorders (胃腸障害)	3	(18.8)	0	0.0	1	(6.3)
Diarrhoea (下痢)	3	(18.8)	0	0.0	0	0.0
Glossodynia (舌痛)	1	(6.3)	0	0.0	0	0.0
Nausea (悪心)	0	0.0	0	0.0	1	(6.3)
Vomiting (嘔吐)	0	0.0	0	0.0	1	(6.3)
Nervous system disorders (神経系障害)	0	0.0	0	0.0	2	(12.5)
Headache (頭痛)	0	0.0	0	0.0	2	(12.5)
Skin and subcutaneous tissue disorders (皮膚および皮下組織障害)	0	0.0	0	0.0	1	(6.3)
Rash (発疹)	0	0.0	0	0.0	1	(6.3)

Containing data from study 1245_0027

MedDRA version used for reporting : XXXXXXXXXX

Table 18.1.1 Frequency [N (%)] of patients with adverse events by treatment, primary system organ class and preferred term - treated set

Treatment group	BI10773		BI+Lina		Lina	
	N	(%)	N	(%)	N	(%)
Number of subjects	16	(100.0)	16	(100.0)	16	(100.0)
Total with adverse events	1	(6.3)	0	0.0	5	(31.3)
Blood and lymphatic system disorders (血液およびリンパ系障害)	0	0.0	0	0.0	1	(6.3)
Lymphadenopathy (リンパ節症)	0	0.0	0	0.0	1	(6.3)
Gastrointestinal disorders (胃腸障害)	1	(6.3)	0	0.0	0	0.0
Vomiting (嘔吐)	1	(6.3)	0	0.0	0	0.0
Infections and infestations (感染症および寄生虫症)	0	0.0	0	0.0	2	(12.5)
Nasopharyngitis (鼻咽頭炎)	0	0.0	0	0.0	2	(12.5)
Musculoskeletal and connective tissue disorders (筋骨格系および結合組織障害)	0	0.0	0	0.0	1	(6.3)
Back pain (背部痛)	0	0.0	0	0.0	1	(6.3)
Nervous system disorders (神経系障害)	0	0.0	0	0.0	2	(12.5)
Headache (頭痛)	0	0.0	0	0.0	2	(12.5)

Containing data from study 1245_0030

MedDRA version used for reporting : XXXXXXXXXX

Table 19.1.1 Frequency [N (%)] of patients with adverse events by treatment, primary system organ class and preferred term - treated set

Treatment group	Micro		BI+Micro	
	N	(%)	N	(%)
Number of subjects	18	(100.0)	18	(100.0)
Total with adverse events	10	(55.6)	10	(55.6)
Gastrointestinal disorders (胃腸障害)	1	(5.6)	2	(11.1)
Abdominal discomfort (腹部不快感)	0	0.0	1	(5.6)
Diarrhoea (下痢)	0	0.0	1	(5.6)
Nausea (悪心)	1	(5.6)	1	(5.6)
General disorders and administration site conditions (一般・全身障害および投与部位の状態)	0	0.0	2	(11.1)
Fatigue (疲労)	0	0.0	1	(5.6)
Thirst (口渇)	0	0.0	1	(5.6)
Infections and infestations (感染症および寄生虫症)	0	0.0	2	(11.1)
Oral herpes (口腔ヘルペス)	0	0.0	2	(11.1)
Rhinitis (鼻炎)	0	0.0	1	(5.6)
Injury, poisoning and procedural complications (傷害, 中毒および処置合併症)	1	(5.6)	2	(11.1)
Arthropod bite (節足動物咬傷)	0	0.0	1	(5.6)
Contusion (挫傷)	0	0.0	1	(5.6)
Sunburn (サンバーン)	1	(5.6)	0	0.0
Musculoskeletal and connective tissue disorders (筋骨格系および結合組織障害)	2	(11.1)	1	(5.6)
Musculoskeletal pain (筋骨格痛)	0	0.0	1	(5.6)
Myalgia (筋肉痛)	2	(11.1)	0	0.0
Neoplasms benign, malignant and unspecified (incl cysts and polyps) 良性、悪性および詳細不明の新生物 (嚢胞およびポリープを含む)	1	(5.6)	0	0.0
Melanocytic naevus (メラノサイト性母斑)	1	(5.6)	0	0.0
Nervous system disorders (神経系障害)	5	(27.8)	1	(5.6)
Dizziness (浮動性めまい)	2	(11.1)	1	(5.6)
Headache (頭痛)	3	(16.7)	1	(5.6)
Respiratory, thoracic and mediastinal disorders (呼吸器、胸郭および縦隔障害)	0	0.0	2	(11.1)
Oropharyngeal pain (口腔咽頭痛)	0	0.0	2	(11.1)
Vascular disorders (血管障害)	0	0.0	1	(5.6)
Haematoma (血腫)	0	0.0	1	(5.6)

Containing data from study 1245_0041

MedDRA version used for reporting : XXXXXXXXXX

Table 20.1.1 Frequency [N (%)] of patients with adverse events by treatment, primary system organ class and preferred term - treated set

Treatment group	Empa		HCT		Empa+HCT		TOR		Empa+TOR	
	N	(%)	N	(%)	N	(%)	N	(%)	N	(%)
Number of subjects	21	(100.0)	11	(100.0)	10	(100.0)	10	(100.0)	10	(100.0)
Total with adverse events	3	(14.3)	1	(9.1)	4	(40.0)	0	0.0	6	(60.0)
Cardiac disorders (心臓障害)	0	0.0	1	(9.1)	0	0.0	0	0.0	0	0.0
Atrial tachycardia (心房頻脈)	0	0.0	1	(9.1)	0	0.0	0	0.0	0	0.0
General disorders and administration site conditions (一般・全身障害および投与部位の状態)	0	0.0	0	0.0	2	(20.0)	0	0.0	6	(60.0)
Thirst (口渇)	0	0.0	0	0.0	2	(20.0)	0	0.0	6	(60.0)
Investigations (臨床検査)	1	(4.8)	0	0.0	0	0.0	0	0.0	0	0.0
Alanine aminotransferase normal (アラニンアミノトランスフェラーゼ正常)	1	(4.8)	0	0.0	0	0.0	0	0.0	0	0.0
Musculoskeletal and connective tissue disorders (筋骨格系および結合組織障害)	1	(4.8)	0	0.0	1	(10.0)	0	0.0	0	0.0
Arthralgia (関節痛)	1	(4.8)	0	0.0	0	0.0	0	0.0	0	0.0
Muscle spasms (筋痙攣)	0	0.0	0	0.0	1	(10.0)	0	0.0	0	0.0
Nervous system disorders (神経系障害)	1	(4.8)	0	0.0	1	(10.0)	0	0.0	0	0.0
Headache (頭痛)	1	(4.8)	0	0.0	1	(10.0)	0	0.0	0	0.0

Containing data from study 1245_0042

MedDRA version used for reporting : XXXXXXXXXX

Table 20.1.2 Frequency [N (%)] of patients with related adverse events by treatment, primary system organ class and preferred term - treated set

Treatment group	Empa		HCT		Empa+HCT		TOR		Empa+TOR	
	N	(%)	N	(%)	N	(%)	N	(%)	N	(%)
Number of subjects	21	(100.0)	11	(100.0)	10	(100.0)	10	(100.0)	10	(100.0)
Total with related adverse events	0	0.0	1	(9.1)	2	(20.0)	0	0.0	6	(60.0)
Cardiac disorders (心臓障害)	0	0.0	1	(9.1)	0	0.0	0	0.0	0	0.0
Atrial tachycardia (心房頻脈)	0	0.0	1	(9.1)	0	0.0	0	0.0	0	0.0
General disorders and administration site conditions (一般・全身障害および投与部位の状態)	0	0.0	0	0.0	2	(20.0)	0	0.0	6	(60.0)
Thirst (口渇)	0	0.0	0	0.0	2	(20.0)	0	0.0	6	(60.0)

Containing data from study 1245_0042

MedDRA version used for reporting : ■■■

Table 21.1.1 Frequency [N (%)] of patients with adverse events by treatment, primary system organ class and preferred term - treated set

Treatment group	BI10773		Verapamil		BI10773+Vera	
	N	(%)	N	(%)	N	(%)
Number of subjects	16	(100.0)	16	(100.0)	16	(100.0)
Total with adverse events	8	(50.0)	0	0.0	9	(56.3)
Infections and infestations (感染症および寄生虫症)	1	(6.3)	0	0.0	2	(12.5)
Oral herpes (口腔ヘルペス)	1	(6.3)	0	0.0	2	(12.5)
Nervous system disorders (神経系障害)	3	(18.8)	0	0.0	4	(25.0)
Headache (頭痛)	3	(18.8)	0	0.0	4	(25.0)
Dizziness (浮動性めまい)	0	0.0	0	0.0	1	(6.3)
Respiratory, thoracic and mediastinal disorders (呼吸器、胸郭および縦隔障害)	1	(6.3)	0	0.0	0	0.0
Oropharyngeal pain (口腔咽頭痛)	1	(6.3)	0	0.0	0	0.0
Gastrointestinal disorders (胃腸障害)	0	0.0	0	0.0	3	(18.8)
Constipation (便秘)	0	0.0	0	0.0	1	(6.3)
Diarrhoea (下痢)	0	0.0	0	0.0	1	(6.3)
Nausea (悪心)	0	0.0	0	0.0	1	(6.3)
Skin and subcutaneous tissue disorders (皮膚および皮下組織障害)	1	(6.3)	0	0.0	0	0.0
Rash (発疹)	1	(6.3)	0	0.0	0	0.0
Musculoskeletal and connective tissue disorders (筋骨格系および結合組織障害)	2	(12.5)	0	0.0	1	(6.3)
Back pain (背部痛)	1	(6.3)	0	0.0	0	0.0
Pain in extremity (四肢痛)	1	(6.3)	0	0.0	1	(6.3)
General disorders and administration site conditions (一般・全身障害および投与部位の状態)	1	(6.3)	0	0.0	0	0.0
Induration (硬結)	1	(6.3)	0	0.0	0	0.0
Injury, poisoning and procedural complications (傷害、中毒および処置合併症)	1	(6.3)	0	0.0	1	(6.3)
Arthropod bite (節足動物咬傷)	0	0.0	0	0.0	1	(6.3)
Skeletal injury (骨格損傷)	1	(6.3)	0	0.0	0	0.0

Containing data from study 1245_0043

MedDRA version used for reporting ■■■

Table 22.1.1 Frequency [N (%)] of patients with adverse events by treatment, primary system organ class and preferred term - treated set

Treatment group	BI10773		Ramipril		BI10773+Ram	
	N	(%)	N	(%)	N	(%)
Number of subjects	22	(100.0)	22	(100.0)	23	(100.0)
Total with adverse events	3	(13.6)	6	(27.3)	5	(21.7)
Gastrointestinal disorders (胃腸障害)	1	(4.5)	1	(4.5)	2	(8.7)
Abdominal pain upper (上腹部痛)	1	(4.5)	0	0.0	0	0.0
Dry mouth (口内乾燥)	0	0.0	1	(4.5)	0	0.0
Nausea (悪心)	0	0.0	0	0.0	2	(8.7)
General disorders and administration site conditions (一般・全身障害および投与部位の状態)	1	(4.5)	1	(4.5)	0	0.0
Fatigue (疲労)	1	(4.5)	0	0.0	0	0.0
Puncture site pain (穿刺部位疼痛)	0	0.0	1	(4.5)	0	0.0
Infections and infestations (感染症および寄生虫症)	1	(4.5)	0	0.0	2	(8.7)
Gastroenteritis (胃腸炎)	1	(4.5)	0	0.0	0	0.0
Hordeolum (麦粒腫)	0	0.0	0	0.0	1	(4.3)
Nasopharyngitis (鼻咽頭炎)	0	0.0	0	0.0	1	(4.3)
Musculoskeletal and connective tissue disorders (筋骨格系および結合組織障害)	0	0.0	0	0.0	1	(4.3)
Back pain (背部痛)	0	0.0	0	0.0	1	(4.3)
Nervous system disorders (神経系障害)	1	(4.5)	4	(18.2)	0	0.0
Dizziness (浮動性めまい)	0	0.0	1	(4.5)	0	0.0
Headache (頭痛)	1	(4.5)	3	(13.6)	0	0.0
Tongue biting (咬舌)	1	(4.5)	0	0.0	0	0.0
Reproductive system and breast disorders (生殖系および乳房障害)	1	(4.5)	0	0.0	0	0.0
Dysmenorrhoea (月経困難症)	1	(4.5)	0	0.0	0	0.0
Respiratory, thoracic and mediastinal disorders (呼吸器、胸郭および縦隔障害)	0	0.0	2	(9.1)	0	0.0
Hyperventilation (過換気)	0	0.0	1	(4.5)	0	0.0
Oropharyngeal pain (口腔咽頭痛)	0	0.0	1	(4.5)	0	0.0
Vascular disorders (血管障害)	0	0.0	2	(9.1)	0	0.0
Hot flush (ほてり)	0	0.0	1	(4.5)	0	0.0
Venous thrombosis (静脈血栓症)	0	0.0	1	(4.5)	0	0.0

Containing data from study 1245_0045

MedDRA version used for reporting : XXXXXXXXXX

Table 11.1.1 Frequency [N (%)] of patients with adverse events by treatment, primary system organ class and preferred term - treated set

Treatment group	BI 10773	
	N	(%)
Number of subjects	8	(100.0)
Total with adverse events	5	(62.5)
Gastrointestinal disorders (胃腸障害)	3	(37.5)
Abdominal distension (腹部膨満)	2	(25.0)
Flatulence (鼓腸)	2	(25.0)
Skin and subcutaneous tissue disorders (皮膚および皮下組織障害)	2	(25.0)
Erythema (紅斑)	2	(25.0)
Ecchymosis (斑状出血)	1	(12.5)
Musculoskeletal and connective tissue disorders (筋骨格系および結合組織障害)	1	(12.5)
Pain in extremity (四肢痛)	1	(12.5)
Injury, poisoning and procedural complications (傷害, 中毒および処置合併症)	1	(12.5)
Scratch (引っかき傷)	1	(12.5)

Containing data from study 1245_0008

MedDRA version used for reporting : XXXXXXXXXX

Table 23.1.1 Frequency [N (%)] of patients with adverse events by treatment, primary system organ class and preferred term - treated set

Treatment group	Pio		Pio+10BI		Pio+25BI		Pio+50BI	
	N	(%)	N	(%)	N	(%)	N	(%)
Number of subjects	20	(100.0)	18	(100.0)	17	(100.0)	16	(100.0)
Total with adverse events	8	(40.0)	10	(55.6)	5	(29.4)	6	(37.5)
Eye disorders (眼障害)	0	0.0	1	(5.6)	1	(5.9)	0	0.0
Conjunctivitis (結膜炎)	0	0.0	1	(5.6)	1	(5.9)	0	0.0
Gastrointestinal disorders (胃腸障害)	2	(10.0)	1	(5.6)	1	(5.9)	3	(18.8)
Abdominal pain upper (上腹部痛)	0	0.0	1	(5.6)	0	0.0	0	0.0
Diarrhoea (下痢)	0	0.0	0	0.0	1	(5.9)	1	(6.3)
Flatulence (鼓腸)	0	0.0	0	0.0	0	0.0	1	(6.3)
Nausea (悪心)	1	(5.0)	0	0.0	0	0.0	1	(6.3)
Toothache (歯痛)	1	(5.0)	0	0.0	0	0.0	0	0.0
Vomiting (嘔吐)	1	(5.0)	0	0.0	0	0.0	0	0.0
General disorders and administration site conditions (一般・全身障害および投与部位の状態)	0	0.0	3	(16.7)	0	0.0	2	(12.5)
Fatigue (疲労)	0	0.0	3	(16.7)	0	0.0	2	(12.5)
Infections and infestations 感染症および寄生虫症)	2	(10.0)	1	(5.6)	1	(5.9)	1	(6.3)
Hordeolum (麦粒腫)	1	(5.0)	0	0.0	0	0.0	0	0.0
Nasopharyngitis (鼻咽頭炎)	1	(5.0)	1	(5.6)	1	(5.9)	1	(6.3)
Musculoskeletal and connective tissue disorders (筋骨格系および結合組織障害)	0	0.0	1	(5.6)	0	0.0	0	0.0
Arthralgia (関節痛)	0	0.0	1	(5.6)	0	0.0	0	0.0
Nervous system disorders (神経系障害)	5	(25.0)	3	(16.7)	2	(11.8)	4	(25.0)
Dizziness (浮動性めまい)	1	(5.0)	1	(5.6)	0	0.0	0	0.0
Headache (頭痛)	5	(25.0)	3	(16.7)	1	(5.9)	3	(18.8)
Hyperaesthesia (知覚過敏)	0	0.0	0	0.0	1	(5.9)	1	(6.3)
Respiratory, thoracic and mediastinal disorders (呼吸器、胸郭および縦隔障害)	1	(5.0)	0	0.0	0	0.0	0	0.0
Nasal polyps (鼻茸)	1	(5.0)	0	0.0	0	0.0	0	0.0
Oropharyngeal pain (口腔咽頭痛)	1	(5.0)	0	0.0	0	0.0	0	0.0
Vascular disorders (血管障害)	0	0.0	1	(5.6)	0	0.0	0	0.0
Phlebitis (静脈炎)	0	0.0	1	(5.6)	0	0.0	0	0.0

Containing data from study 1245_0050

MedDRA version used for reporting ■■■

Table 23.1.2 Frequency [N (%)] of patients with related adverse events by treatment, primary system organ class and preferred term - treated set

Treatment group	Pio		Pio+10BI		Pio+25BI		Pio+50BI	
	N	(%)	N	(%)	N	(%)	N	(%)
Number of subjects	20	(100.0)	18	(100.0)	17	(100.0)	16	(100.0)
Total with related adverse events	3	(15.0)	8	(44.4)	3	(17.6)	6	(37.5)
Gastrointestinal disorders (胃腸障害)	0	0.0	1	(5.6)	1	(5.9)	3	(18.8)
Abdominal pain upper (上腹部痛)	0	0.0	1	(5.6)	0	0.0	0	0.0
Diarrhoea (下痢)	0	0.0	0	0.0	1	(5.9)	1	(6.3)
Flatulence (鼓腸)	0	0.0	0	0.0	0	0.0	1	(6.3)
Nausea (悪心)	0	0.0	0	0.0	0	0.0	1	(6.3)
General disorders and administration site conditions (一般・全身障害および投与部位の状態)	0	0.0	3	(16.7)	0	0.0	2	(12.5)
Fatigue (疲労)	0	0.0	3	(16.7)	0	0.0	2	(12.5)
Musculoskeletal and connective tissue disorders (筋骨格系および結合組織障害)	0	0.0	1	(5.6)	0	0.0	0	0.0
Arthralgia (関節痛)	0	0.0	1	(5.6)	0	0.0	0	0.0
Nervous system disorders (神経系障害)	3	(15.0)	3	(16.7)	2	(11.8)	4	(25.0)
Dizziness (浮動性めまい)	0	(5.0)	1	(5.6)	0	0.0	0	0.0
Headache (頭痛)	3	(15.0)	3	(16.7)	1	(5.9)	3	(18.8)
Hyperaesthesia (知覚過敏)	0	0.0	0	0.0	1	(5.9)	1	(6.3)

Containing data from study 1245_0050

MedDRA version used for reporting : XXXXXXXXXX

Table 25.1.1 Frequency [N (%)] of patients with adverse events by treatment, primary system organ class and preferred term - treated set

Treatment group	Gemfibrozil		BI+Gemfi		BI10773	
	N	(%)	N	(%)	N	(%)
Number of subjects	18	(100.0)	18	(100.0)	18	(100.0)
Total with adverse events	6	(33.3)	3	(16.7)	8	(44.4)
Gastrointestinal disorders (胃腸障害)	2	(11.1)	0	0.0	0	0.0
Diarrhoea (下痢)	1	(5.6)	0	0.0	0	0.0
Dyspepsia (消化不良)	1	(5.6)	0	0.0	0	0.0
Infections and infestations (感染症および寄生虫症)	1	(5.6)	0	0.0	1	(5.6)
Oral herpes (口腔ヘルペス)	0	0.0	0	0.0	1	(5.6)
Rhinitis (鼻炎)	1	(5.6)	0	0.0	0	0.0
Musculoskeletal and connective tissue disorders (筋骨格系および結合組織障害)	0	0.0	1	(5.6)	1	(5.6)
Muscle disorder (筋障害)	0	0.0	0	0.0	1	(5.6)
Muscle tightness (筋緊張)	0	0.0	0	0.0	1	(5.6)
Pain in extremity (四肢痛)	0	0.0	1	(5.6)	0	0.0
Nervous system disorders (神経系障害)	1	(5.6)	2	(11.1)	5	(27.8)
Dizziness (浮動性めまい)	0	0.0	1	(5.6)	1	(5.6)
Headache (頭痛)	1	(5.6)	1	(5.6)	4	(22.2)
Renal and urinary disorders (腎および尿路障害)	2	(11.1)	0	0.0	0	0.0
Nocturia (夜間頻尿)	1	(5.6)	0	0.0	0	0.0
Pollakiuria (頻尿)	1	(5.6)	0	0.0	0	0.0
Respiratory, thoracic and mediastinal disorders (呼吸器、胸郭および縦隔障害)	1	(5.6)	0	0.0	0	0.0
Dysphonia (発声障害)	1	(5.6)	0	0.0	0	0.0
Skin and subcutaneous tissue disorders (皮膚および皮下組織障害)	0	0.0	1	(5.6)	0	0.0
Erythema (紅斑)	0	0.0	1	(5.6)	0	0.0
Vascular disorders (血管障害)	0	0.0	0	0.0	2	(11.1)
Haematoma (血腫)	0	0.0	0	0.0	2	(11.1)

Containing data from study 1245_0058

MedDRA version used for reporting : XXXXXXXXXX

Table 26.1.1 Frequency [N (%)] of patients with adverse events by treatment, primary system organ class and preferred term - treated set

Treatment group	BI10773		Simvastatin		BI10773+Sim	
	N	(%)	N	(%)	N	(%)
Number of subjects	18	(100.0)	17	(100.0)	18	(100.0)
Total with adverse events	6	(33.3)	4	(23.5)	5	(27.8)
Gastrointestinal disorders (胃腸障害)	0	0.0	1	(5.9)	1	(5.6)
Abdominal pain (腹痛)	0	0.0	1	(5.9)	0	0.0
Nausea (悪心)	0	0.0	0	0.0	1	(5.6)
Infections and infestations (感染症および寄生虫症)	3	(16.7)	0	0.0	2	(11.1)
Nasopharyngitis (鼻咽頭炎)	2	(11.1)	0	0.0	1	(5.6)
Oral herpes (口腔ヘルペス)	1	(5.6)	0	0.0	0	0.0
Purulence (化膿)	0	0.0	0	0.0	1	(5.6)
Injury, poisoning and procedural complications (傷害、中毒および処置合併症)	0	0.0	1	(5.9)	0	0.0
Laceration (裂傷)	0	0.0	1	(5.9)	0	0.0
Nervous system disorders (神経系障害)	4	(22.2)	2	(11.8)	2	(11.1)
Headache (頭痛)	4	(22.2)	2	(11.8)	2	(11.1)
Respiratory, thoracic and mediastinal disorders (呼吸器、胸郭および縦隔障害)	0	0.0	0	0.0	1	(5.6)
Cough (咳嗽)	0	0.0	0	0.0	1	(5.6)

Containing data from study 1245_0063

MedDRA version used for reporting : XXXXXXXXXX

Table 28.1.1 Frequency [N (%)] of patients with adverse events by treatment, primary system organ class and preferred term - treated set

Treatment group	Empa		Empa+Rifam		Probe		Empa+Probe	
	N	(%)	N	(%)	N	(%)	N	(%)
Number of subjects	18	(100.0)	18	(100.0)	16	(100.0)	16	(100.0)
Total with adverse events	7	(38.9)	9	(50.0)	2	(12.5)	6	(37.5)
Nervous system disorders (神経系障害)	4	(22.2)	7	(38.9)	1	(6.3)	3	(18.8)
Headache (頭痛)	3	(16.7)	5	(27.8)	1	(6.3)	3	(18.8)
Dizziness (浮動性めまい)	0	0.0	2	(11.1)	0	0.0	0	0.0
Presyncope (失神寸前の状態)	1	(5.6)	0	0.0	0	0.0	0	0.0
Sciatica (坐骨神経痛)	0	0.0	1	(5.6)	0	0.0	0	0.0
Vascular disorders (血管障害)	1	(5.6)	0	0.0	0	0.0	0	0.0
Haematoma (血腫)	1	(5.6)	0	0.0	0	0.0	0	0.0
Gastrointestinal disorders (胃腸障害)	4	(22.2)	5	(27.8)	0	0.0	3	(18.8)
Nausea (悪心)	2	(11.1)	3	(16.7)	0	0.0	2	(12.5)
Vomiting (嘔吐)	2	(11.1)	3	(16.7)	0	0.0	1	(6.3)
Diarrhoea (下痢)	1	(5.6)	0	0.0	0	0.0	0	0.0
General disorders and administration site conditions (一般・全身障害および投与部位の状態)	0	0.0	0	0.0	1	(6.3)	0	0.0
Malaise (倦怠感)	0	0.0	0	0.0	1	(6.3)	0	0.0
Injury, poisoning and procedural complications (傷害, 中毒および処置合併症)	0	0.0	0	0.0	0	0.0	1	(6.3)
Muscle strain (肉離れ)	0	0.0	0	0.0	0	0.0	1	(6.3)

Containing data from study 1245_0083

MedDRA version used for reporting : XXXXXXXXXX

Table 28.1.2 Frequency [N (%)] of patients with related adverse events by treatment, primary system organ class and preferred term - treated set

Treatment group	Empa		Empa+Rifam		Probe		Empa+Probe	
	N	(%)	N	(%)	N	(%)	N	(%)
Number of subjects	18	(100.0)	18	(100.0)	16	(100.0)	16	(100.0)
Total with related adverse events	5	(27.8)	6	(33.3)	2	(12.5)	4	(25.0)
Nervous system disorders (神経系障害)	3	(16.7)	5	(27.8)	1	(6.3)	2	(12.5)
Headache (頭痛)	3	(16.7)	3	(16.7)	1	(6.3)	2	(12.5)
Dizziness (浮動性めまい)	0	0.0	2	(11.1)	0	0.0	0	0.0
Gastrointestinal disorders (胃腸障害)	3	(16.7)	4	(22.2)	0	0.0	3	(18.8)
Nausea (悪心)	2	(11.1)	3	(16.7)	0	0.0	2	(12.5)
Vomiting (嘔吐)	2	(11.1)	2	(11.1)	0	0.0	1	(6.3)
General disorders and administration site conditions (一般・全身障害および投与部位の状態)	0	0.0	0	0.0	1	(6.3)	0	0.0
Malaise (倦怠感)	0	0.0	0	0.0	1	(6.3)	0	0.0

Containing data from study 1245_0083

MedDRA version used for reporting XXXXXXXXXX

Table 12.1.1 Frequency [N (%)] of patients with adverse events by treatment, primary system organ class and preferred term - treated set

Treatment group	Normal		Mild		Moderate		Severe		Kidney fail	
	N	(%)	N	(%)	N	(%)	N	(%)	N	(%)
Number of subjects	8	(100.0)	9	(100.0)	7	(100.0)	8	(100.0)	8	(100.0)
Total with adverse events	1	(12.5)	0	0.0	1	(14.3)	0	0.0	2	(25.0)
Gastrointestinal disorders (胃腸障害)	1	(12.5)	0	0.0	0	0.0	0	0.0	1	(12.5)
Diarrhoea (下痢)	0	0.0	0	0.0	0	0.0	0	0.0	1	(12.5)
Nausea (悪心)	1	(12.5)	0	0.0	0	0.0	0	0.0	0	0.0
Nervous system disorders (神経系障害)	1	(12.5)	0	0.0	0	0.0	0	0.0	0	0.0
Headache (頭痛)	1	(12.5)	0	0.0	0	0.0	0	0.0	0	0.0
Skin and subcutaneous tissue disorders (皮膚および皮下組織障害)	0	0.0	0	0.0	1	(14.3)	0	0.0	1	(12.5)
Erythema (紅斑)	0	0.0	0	0.0	1	(14.3)	0	0.0	0	0.0
Pruritus (そう痒症)	0	0.0	0	0.0	1	(14.3)	0	0.0	1	(12.5)

Containing data from study 1245_0012

MedDRA version used for reporting : XXXXXXXXXX

Table 13.1.1 Frequency [N (%)] of patients with adverse events by treatment, primary system organ class and preferred term - treated set

Treatment group	Healthy		Mild		Moderate		Severe		Impaired	
	N	(%)	N	(%)	N	(%)	N	(%)	N	(%)
Number of subjects	12	(100.0)	8	(100.0)	8	(100.0)	8	(100.0)	24	(100.0)
Total with adverse events	6	(50.0)	0	0.0	3	(37.5)	2	(25.0)	5	(20.8)
Infections and infestations (感染症および寄生虫症)	0	0.0	0	0.0	0	0.0	1	(12.5)	1	(4.2)
Asymptomatic bacteriuria (無症候性細菌尿)	0	0.0	0	0.0	0	0.0	1	(12.5)	1	(4.2)
Nervous system disorders (神経系障害)	3	(25.0)	0	0.0	1	(12.5)	0	0.0	1	(4.2)
Headache (頭痛)	3	(25.0)	0	0.0	1	(12.5)	0	0.0	1	(4.2)
Cardiac disorders (心臓障害)	0	0.0	0	0.0	2	(25.0)	0	0.0	2	(8.3)
Myocardial ischaemia (心筋虚血)	0	0.0	0	0.0	2	(25.0)	0	0.0	2	(8.3)
Gastrointestinal disorders (胃腸障害)	4	(33.3)	0	0.0	0	0.0	1	(12.5)	1	(4.2)
Constipation (便秘)	4	(33.3)	0	0.0	0	0.0	1	(12.5)	1	(4.2)
Toothache (歯痛)	1	(8.3)	0	0.0	0	0.0	0	0.0	0	0.0
Musculoskeletal and connective tissue disorders (筋骨格系および結合組織障害)	1	(8.3)	0	0.0	0	0.0	0	0.0	0	0.0
Back pain (背部痛)	1	(8.3)	0	0.0	0	0.0	0	0.0	0	0.0
Renal and urinary disorders (腎および尿路障害)	0	0.0	0	0.0	0	0.0	1	(12.5)	1	(4.2)
Leukocyturia (白血球尿)	0	0.0	0	0.0	0	0.0	1	(12.5)	1	(4.2)
General disorders and administration site conditions (一般・全身障害および投与部位の状態)	0	0.0	0	0.0	0	0.0	1	(12.5)	1	(4.2)
Pyrexia (発熱)	0	0.0	0	0.0	0	0.0	1	(12.5)	1	(4.2)
Investigations (臨床検査)	2	(16.7)	0	0.0	0	0.0	1	(12.5)	1	(4.2)
Electrocardiogram abnormal (心電図異常)	2	(16.7)	0	0.0	0	0.0	0	0.0	0	0.0
Nitrite urine present (尿中亜硝酸塩陽性)	0	0.0	0	0.0	0	0.0	1	(12.5)	1	(4.2)

Containing data from study 1245_0013

MedDRA version used for reporting : XXXXXXXXXX

Table 9.1.1 Frequency [N (%)] of patients with adverse events by treatment, primary system organ class and preferred term - treated set

Treatment group	BI 10773		BI 10773+Metformin		Metformin	
	N	(%)	N	(%)	N	(%)
Number of subjects	16	(100.0)	16	(100.0)	16	(100.0)
Total with adverse events	5	(31.3)	7	(43.8)	11	(68.8)
Gastrointestinal disorders (胃腸障害)	1	(6.3)	4	(25.0)	10	(62.5)
Abdominal pain upper (上腹部痛)	0	0.0	0	0.0	3	(18.8)
Diarrhoea (下痢)	1	(6.3)	2	(12.5)	6	(37.5)
Dyspepsia (消化不良)	0	0.0	1	(6.3)	0	0.0
Flatulence (鼓腸)	0	0.0	0	0.0	1	(6.3)
Gastric disorder (胃障害)	1	(6.3)	0	0.0	0	0.0
Nausea (悪心)	0	0.0	1	(6.3)	4	(25.0)
Vomiting (嘔吐)	0	0.0	0	0.0	1	(6.3)
General disorders and administration site conditions (一般・全身障害および投与部位の状態)	1	(6.3)	0	0.0	1	(6.3)
Fatigue (疲労)	1	(6.3)	0	0.0	1	(6.3)
Infections and infestations (感染症および寄生虫症)	1	(6.3)	2	(12.5)	0	0.0
Nasopharyngitis (鼻咽頭炎)	1	(6.3)	2	(12.5)	0	0.0
Metabolism and nutrition disorders (代謝および栄養障害)	1	(6.3)	0	0.0	0	0.0
Anorexia (食欲不振)	1	(6.3)	0	0.0	0	0.0
Nervous system disorders (神経系障害)	3	(18.8)	0	0.0	3	(18.8)
Dizziness (浮動性めまい)	1	(6.3)	0	0.0	0	0.0
Headache (頭痛)	3	(18.8)	0	0.0	3	(18.8)
Respiratory, thoracic and mediastinal disorders (呼吸器、胸郭および縦隔障害)	0	0.0	1	(6.3)	0	0.0
Oropharyngeal pain (口腔咽頭痛)	0	0.0	1	(6.3)	0	0.0
Vascular disorders (血管障害)	0	0.0	1	(6.3)	0	0.0
Haematoma (血腫)	0	0.0	1	(6.3)	0	0.0

Containing data from study 1245_0006

MedDRA version used for reporting XXXXXXXXXX

Table 9.1.2 Frequency [N (%)] of patients with related adverse events by treatment, primary system organ class and preferred term - treated set

Treatment group	BI 10773		BI 10773+Metformin		Metformin	
	N	(%)	N	(%)	N	(%)
Number of subjects	16	(100.0)	16	(100.0)	16	(100.0)
Total with related adverse events	4	(25.0)	4	(25.0)	11	(68.8)
Gastrointestinal disorders (胃腸障害)	1	(6.3)	4	(25.0)	10	(62.5)
Abdominal pain upper (上腹部痛)	0	0.0	0	0.0	3	(18.8)
Diarrhoea (下痢)	1	(6.3)	2	(12.5)	6	(37.5)
Dyspepsia (消化不良)	0	0.0	1	(6.3)	0	0.0
Flatulence (鼓腸)	0	0.0	0	0.0	1	(6.3)
Gastric disorder (胃障害)	1	(6.3)	0	0.0	0	0.0
Nausea (悪心)	0	0.0	1	(6.3)	4	(25.0)
Vomiting (嘔吐)	0	0.0	0	0.0	1	(6.3)
General disorders and administration site conditions (一般・全身障害および投与部位の状態)	1	(6.3)	0	0.0	1	(6.3)
Fatigue (疲労)	1	(6.3)	0	0.0	1	(6.3)
Infections and infestations (感染症および寄生虫症)	0	0.0	1	(6.3)	0	0.0
Nasopharyngitis (鼻咽頭炎)	0	0.0	1	(6.3)	0	0.0
Metabolism and nutrition disorders (代謝および栄養障害)	1	(6.3)	0	0.0	0	0.0
Anorexia (食欲不振)	1	(6.3)	0	0.0	0	0.0
Nervous system disorders (神経系障害)	3	(18.8)	0	0.0	3	(18.8)
Dizziness (浮動性めまい)	1	(6.3)	0	0.0	0	0.0
Headache (頭痛)	3	(18.8)	0	0.0	3	(18.8)

Containing data from study 1245_0006

MedDRA version used for reporting : XXXXXXXXXX

Table 14.1.1 Frequency [N (%)] of patients with adverse events by treatment, primary system organ class and preferred term - treated set

Treatment group	Placebo		BI 25 mg		BI 200 mg		MOX 400 mg	
	N	(%)	N	(%)	N	(%)	N	(%)
Number of subjects	29	(100.0)	28	(100.0)	30	(100.0)	29	(100.0)
Total with adverse events	8	(27.6)	3	(10.7)	5	(16.7)	1	(3.4)
Infections and infestations (感染症および寄生虫症)	5	(17.2)	2	(7.1)	2	(6.7)	0	0.0
Nasopharyngitis (鼻咽頭炎)	5	(17.2)	2	(7.1)	2	(6.7)	0	0.0
Cystitis (膀胱炎)	0	0.0	0	0.0	1	(3.3)	0	0.0
Nervous system disorders (神経系障害)	2	(6.9)	1	(3.6)	0	0.0	0	0.0
Headache (頭痛)	2	(6.9)	1	(3.6)	0	0.0	0	0.0
Respiratory, thoracic and mediastinal disorders (呼吸器、胸郭および縦隔障害)	1	(3.4)	0	0.0	1	(3.3)	0	0.0
Oropharyngeal pain (口腔咽頭痛)	1	(3.4)	0	0.0	1	(3.3)	0	0.0
Gastrointestinal disorders (胃腸障害)	0	0.0	0	0.0	1	(3.3)	0	0.0
Nausea (悪心)	0	0.0	0	0.0	1	(3.3)	0	0.0
Vomiting (嘔吐)	0	0.0	0	0.0	1	(3.3)	0	0.0
Skin and subcutaneous tissue disorders (皮膚および皮下組織障害)	0	0.0	0	0.0	1	(3.3)	0	0.0
Rash (発疹)	0	0.0	0	0.0	1	(3.3)	0	0.0
Injury, poisoning and procedural complications (傷害、中毒および処置合併症)	1	(3.4)	0	0.0	0	0.0	1	(3.4)
Arthropod bite (節足動物咬傷)	1	(3.4)	0	0.0	0	0.0	0	0.0
Road traffic accident (交通事故)	0	0.0	0	0.0	0	0.0	1	(3.4)

Containing data from study 1245_0016

MedDRA version used for reporting : ■■■

Table 8.1.1 Frequency [N (%)] of patients with adverse events by treatment, primary system organ class and preferred term - treated set

Treatment group	Placebo		BI 10773 10 mg		BI 10773 25 mg		BI 10773 100 mg	
	N	(%)	N	(%)	N	(%)	N	(%)
Number of subjects	16	(100.0)	16	(100.0)	16	(100.0)	30	(100.0)
Total with adverse events	10	(62.5)	8	(50.0)	9	(56.3)	20	(66.7)
Infections and infestations (感染症および寄生虫症)	2	(12.5)	4	(25.0)	1	(6.3)	2	(6.7)
Nasopharyngitis (鼻咽頭炎)	1	(6.3)	4	(25.0)	0	0.0	2	(6.7)
Bronchitis (気管支炎)	0	0.0	0	0.0	1	(6.3)	0	0.0
Influenza (インフルエンザ)	1	(6.3)	0	0.0	0	0.0	0	0.0
Sinusitis (副鼻腔炎)	0	0.0	1	(6.3)	0	0.0	0	0.0
Urinary tract infection (尿路感染)	0	0.0	0	0.0	0	0.0	0	0.0
Metabolism and nutrition disorders (代謝および栄養障害)	1	(6.3)	0	0.0	0	0.0	3	(10.0)
Hypoglycaemia (低血糖)	1	(6.3)	0	0.0	0	0.0	2	(6.7)
Polydipsia (多飲症)	0	0.0	0	0.0	0	0.0	1	(3.3)
Nervous system disorders (神経系障害)	1	(6.3)	1	(6.3)	3	(18.8)	2	(6.7)
Headache (頭痛)	1	(6.3)	1	(6.3)	3	(18.8)	1	(3.3)
Dizziness (浮動性めまい)	0	0.0	0	0.0	0	0.0	1	(3.3)
Ear and labyrinth disorders (耳および迷路障害)	1	(6.3)	0	0.0	0	0.0	1	(3.3)
Vertigo (回転性めまい)	1	(6.3)	0	0.0	0	0.0	1	(3.3)
Cardiac disorders (心臓障害)	0	0.0	1	(6.3)	0	0.0	0	0.0
Ventricular extrasystoles (心室性期外収縮)	0	0.0	1	(6.3)	0	0.0	0	0.0
Vascular disorders (血管障害)	0	0.0	1	(6.3)	1	(6.3)	5	(16.7)
Thrombophlebitis (血栓性静脈炎)	0	0.0	0	0.0	0	0.0	5	(16.7)
Phlebitis (静脈炎)	0	0.0	1	(6.3)	1	(6.3)	0	0.0
Respiratory, thoracic and mediastinal disorders (呼吸器、胸郭および縦隔障害)	2	(12.5)	0	0.0	1	(6.3)	0	0.0
Cough (咳嗽)	1	(6.3)	0	0.0	1	(6.3)	0	0.0
Hiccups (しゃっくり)	1	(6.3)	0	0.0	0	0.0	0	0.0
Gastrointestinal disorders (胃腸障害)	2	(12.5)	1	(6.3)	4	(25.0)	8	(26.7)
Constipation (便秘)	2	(12.5)	0	0.0	1	(6.3)	4	(13.3)
Toothache(歯痛)	0	0.0	0	0.0	1	(6.3)	2	(6.7)
Abdominal pain upper(上腹部痛)	0	0.0	1	(6.3)	0	0.0	0	0.0
Diarrhoea (下痢)	0	0.0	0	0.0	1	(6.3)	1	(3.3)
Flatulence (鼓腸)	1	(6.3)	0	0.0	0	0.0	1	(3.3)
Gastroesophageal reflux disease (胃食道逆流性疾患)	0	0.0	0	0.0	1	(6.3)	0	0.0
Vomiting (嘔吐)	0	0.0	0	0.0	0	0.0	1	(3.3)
Skin and subcutaneous tissue disorders (皮膚および皮下組織障害)	0	0.0	0	0.0	1	(6.3)	2	(6.7)
Pruritus (そう痒症)	0	0.0	0	0.0	1	(6.3)	1	(3.3)
Eczema (湿疹)	0	0.0	0	0.0	0	0.0	1	(3.3)
Musculoskeletal and connective tissue disorders (筋骨格系および結合組織障害)	2	(12.5)	2	(12.5)	0	0.0	1	(3.3)
Back pain (背部痛)	2	(12.5)	1	(6.3)	0	0.0	0	0.0
Arthritis (関節痛)	0	0.0	1	(6.3)	0	0.0	0	0.0
Myalgia (筋肉痛)	0	0.0	0	0.0	0	0.0	1	(3.3)
Renal and urinary disorders (腎および尿路障害)	1	(6.3)	3	(18.8)	2	(12.5)	4	(13.3)
Pollakiuria (頻尿)	1	(6.3)	2	(12.5)	2	(12.5)	3	(10.0)

Treatment group	Placebo		BI 10773 10 mg		BI 10773 25 mg		BI 10773 100 mg	
	N	(%)	N	(%)	N	(%)	N	(%)
Polyuria (多尿)	0	0.0	1	(6.3)	0	0.0	0	0.0
Dysuria (排尿困難)	0	0.0	0	0.0	0	0.0	1	(3.3)
Reproductive system and breast disorders (生殖系および乳房障害)	0	0.0	0	0.0	2	(12.5)	0	0.0
Balanitis (亀頭炎)	0	0.0	0	0.0	1	(6.3)	0	0.0
Pruritus genital (陰部そう痒症)	0	0.0	0	0.0	1	(6.3)	0	0.0
General disorders and administration site conditions (一般・全身障害および投与部位の状態)	2	(12.5)	2	(12.5)	0	0.0	2	(6.7)
Fatigue (疲労)	1	(6.3)	1	(6.3)	0	0.0	0	0.0
Pain (疼痛)	1	(6.3)	0	0.0	0	0.0	0	0.0
Pyrexia (発熱)	0	0.0	1	(6.3)	0	0.0	0	0.0
Application site irritation (適用部位刺激感)	0	0.0	0	0.0	0	0.0	1	(3.3)
Chest pain (胸痛)	0	0.0	0	0.0	0	0.0	1	(3.3)
Investigations (臨床検査)	0	0.0	1	(6.3)	1	(6.3)	2	(6.7)
Lipase increased (リパーゼ増加)	0	0.0	0	0.0	1	(6.3)	2	(6.7)
Blood triglycerides increased (血中トリグリセリド増加)	0	0.0	1	(6.3)	0	0.0	0	0.0
Blood creatine phosphokinase increased (血中クレアチンホスホキナーゼ増加)	0	0.0	0	0.0	0	0.0	1	(3.3)
Injury, poisoning and procedural complications (傷害, 中毒および処置合併症)	0	0.0	0	0.0	0	0.0	1	(3.3)
Contusion (挫傷)	0	0.0	0	0.0	0	0.0	1	(3.3)

Containing data from study 1245_0004

MedDRA version used for reporting : XXXXXXXXXX

Table 8.1.2 Frequency [N (%)] of patients with related adverse events by treatment, primary system organ class and preferred term - treated set

Treatment group	Placebo		BI 10773 10 mg		BI 10773 25 mg		BI 10773 100 mg	
	N	(%)	N	(%)	N	(%)	N	(%)
Number of subjects	16	(100.0)	16	(100.0)	16	(100.0)	30	(100.0)
Total with treated adverse events	7	(43.8)	3	(18.8)	4	(25.0)	14	(46.7)
Metabolism and nutrition disorders (代謝および栄養障害)	1	(6.3)	0	0.0	0	0.0	3	(10.0)
Hypoglycaemia (低血糖)	1	(6.3)	0	0.0	0	0.0	2	(6.7)
Polydipsia (多飲症)	0	0.0	0	0.0	0	0.0	1	(3.3)
Nervous system disorders (神経系障害)	0	0.0	0	0.0	1	(6.3)	1	(3.3)
Headache (頭痛)	0	0.0	0	0.0	1	(6.3)	0	0.0
Dizziness (浮動性めまい)	0	0.0	0	0.0	0	0.0	1	(3.3)
Ear and labyrinth disorders (耳および迷路障害)	1	(6.3)	0	0.0	0	0.0	1	(3.3)
Vertigo (回転性めまい)	1	(6.3)	0	0.0	0	0.0	1	(3.3)
Cardiac disorders (心臓障害)	0	0.0	1	(6.3)	0	0.0	0	0.0
Ventricular extrasystoles (心室性期外収縮)	0	0.0	1	(6.3)	0	0.0	0	0.0
Respiratory, thoracic and mediastinal disorders (呼吸器、胸郭および縦隔障害)	2	(12.5)	0	0.0	1	(6.3)	0	0.0
Cough (咳嗽)	1	(6.3)	0	0.0	1	(6.3)	0	0.0
Hiccups (しゃっくり)	1	(6.3)	0	0.0	0	0.0	0	0.0
Gastrointestinal disorders (胃腸障害)	2	(12.5)	0	0.0	2	(12.5)	7	(23.3)
Constipation (便秘)	2	(12.5)	0	0.0	1	(6.3)	4	(13.3)
Toothache(歯痛)	0	0.0	0	0.0	0	0.0	1	(3.3)
Diarrhoea (下痢)	0	0.0	0	0.0	1	(6.3)	1	(3.3)
Flatulence (鼓腸)	1	(6.3)	0	0.0	0	0.0	1	(3.3)
Gastroesophageal reflux disease (胃食道逆流性疾患)	0	0.0	0	0.0	0	0.0	0	0.0
Vomiting (嘔吐)	0	0.0	0	0.0	0	0.0	1	(3.3)
Skin and subcutaneous tissue disorders (皮膚および皮下組織障害)	0	0.0	0	0.0	1	(6.3)	2	(6.7)
Pruritus (そう痒症)	0	0.0	0	0.0	1	(6.3)	1	(3.3)
Eczema (湿疹)	0	0.0	0	0.0	0	0.0	1	(3.3)
Renal and urinary disorders (腎および尿路障害)	1	(6.3)	2	(12.5)	1	(6.3)	4	(13.3)
Pollakiuria (頻尿)	1	(6.3)	2	(12.5)	1	(6.3)	3	(10.0)
Dysuria (排尿困難)	0	0.0	0	0.0	0	0.0	1	(3.3)
Reproductive system and breast disorders (生殖系および乳房障害)	0	0.0	0	0.0	2	(12.5)	0	0.0
Balanitis (亀頭炎)	0	0.0	0	0.0	1	(6.3)	0	0.0
Pruritus genital (陰部そう痒症)	0	0.0	0	0.0	1	(6.3)	0	0.0
General disorders and administration site conditions (一般・全身障害および投与部位の状態)	2	(12.5)	1	(6.3)	0	0.0	0	0.0
Fatigue (疲労)	1	(6.3)	1	(6.3)	0	0.0	0	0.0
Pain (疼痛)	1	(6.3)	0	0.0	0	0.0	0	0.0
Application site irritation (適用部位刺激感)	0	0.0	0	0.0	0	0.0	0	0.0
Investigations (臨床検査)	0	0.0	1	(6.3)	0	0.0	2	(6.7)
Lipase increased (リパーゼ増加)	0	0.0	0	0.0	0	0.0	2	(6.7)
Blood triglycerides increased (血中トリグリセリド増加)	0	0.0	1	(6.3)	0	0.0	0	0.0

Containing data from study 1245_0004

MedDRA version used for reporting : XXXXXXXXXX

Table 1.1.1 Frequency [N (%)] of patients with adverse events by treatment, primary system organ class and preferred term - treated set

	Placebo		Empa 1mg		Empa 5mg		Empa 10mg		Empa 25mg	
System organ class/ Preferred term	N	(%)	N	(%)	N	(%)	N	(%)	N	(%)
Number of patients	21	(100.0)	19	(100.0)	21	(100.0)	20	(100.0)	19	(100.0)
Total with adverse event:	2	(9.5)	6	(31.6)	4	(19.0)	6	(30.0)	7	(36.8)
Infections and infestations (感染症および寄生虫症)	0	(0.0)	2	(10.5)	1	(4.8)	0	(0.0)	2	(10.5)
Nasopharyngitis (鼻咽頭炎)	0	(0.0)	2	(10.5)	1	(4.8)	0	(0.0)	1	(5.3)
Cystitis (膀胱炎)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(5.3)
Metabolism and nutrition disorders (代謝および栄養障害)	1	(4.8)	1	(5.3)	0	(0.0)	1	(5.0)	0	(0.0)
Hypoglycaemia (低血糖症)	0	(0.0)	1	(5.3)	0	(0.0)	1	(5.0)	0	(0.0)
Hyperglycaemia (高血糖)	1	(4.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Nervous system disorders (神経系障害)	0	(0.0)	1	(5.3)	0	(0.0)	0	(0.0)	0	(0.0)
Transient ischaemic attack (一過性脳虚血発作)	0	(0.0)	1	(5.3)	0	(0.0)	0	(0.0)	0	(0.0)
Eye disorders (眼障害)	0	(0.0)	1	(5.3)	0	(0.0)	0	(0.0)	0	(0.0)
Dry eye (眼乾燥)	0	(0.0)	1	(5.3)	0	(0.0)	0	(0.0)	0	(0.0)
Cardiac disorders (心臓障害)	0	(0.0)	0	(0.0)	0	(0.0)	1	(5.0)	0	(0.0)
Ventricular extrasystoles (心室性期外収縮)	0	(0.0)	0	(0.0)	0	(0.0)	1	(5.0)	0	(0.0)
Gastrointestinal disorders (胃腸障害)	1	(4.8)	1	(5.3)	1	(4.8)	3	(15.0)	3	(15.8)
Abdominal pain upper (上腹部痛)	0	(0.0)	0	(0.0)	0	(0.0)	2	(10.0)	0	(0.0)
Constipation (便秘)	1	(4.8)	0	(0.0)	1	(4.8)	2	(10.0)	1	(5.3)
Diarrhoea (下痢)	0	(0.0)	1	(5.3)	0	(0.0)	0	(0.0)	1	(5.3)
Toothache (歯痛)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(5.3)
Skin and subcutaneous tissue disorders (皮膚および皮下組織障害)	0	(0.0)	0	(0.0)	1	(4.8)	1	(5.0)	1	(5.3)
Eczema (湿疹)	0	(0.0)	0	(0.0)	0	(0.0)	1	(5.0)	1	(5.3)
Haemorrhage subcutaneous (皮下出血)	0	(0.0)	0	(0.0)	1	(4.8)	0	(0.0)	0	(0.0)
Musculoskeletal and connective tissue disorders (筋骨格系および結合組織障害)	0	(0.0)	0	(0.0)	1	(4.8)	1	(5.0)	0	(0.0)
Back pain (背部痛)	0	(0.0)	0	(0.0)	0	(0.0)	1	(5.0)	0	(0.0)
Arthralgia (関節痛)	0	(0.0)	0	(0.0)	1	(4.8)	0	(0.0)	0	(0.0)
Renal and urinary disorders (腎および尿路障害)	0	(0.0)	0	(0.0)	0	(0.0)	1	(5.0)	1	(5.3)
Pollakiuria (頻尿)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(5.3)
Nocturia (夜間頻尿)	0	(0.0)	0	(0.0)	0	(0.0)	1	(5.0)	0	(0.0)
General disorders and administration site conditions (全身障害および投与局所様態)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(5.3)
Oedema peripheral (末梢性浮腫)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(5.3)
Investigations (臨床検査)	0	(0.0)	1	(5.3)	0	(0.0)	0	(0.0)	0	(0.0)
Alpha 1 microglobulin urine increased (尿中α 1 ミクログロブリン増加)	0	(0.0)	1	(5.3)	0	(0.0)	0	(0.0)	0	(0.0)
Beta 2 microglobulin urine increased (尿中β 2 ミクログロブリン増加)	0	(0.0)	1	(5.3)	0	(0.0)	0	(0.0)	0	(0.0)
Injury, poisoning and procedural complications (傷害、中毒および処置合併症)	0	(0.0)	2	(10.5)	0	(0.0)	0	(0.0)	0	(0.0)
Contusion (挫傷)	0	(0.0)	1	(5.3)	0	(0.0)	0	(0.0)	0	(0.0)
Fall (転倒・転落)	0	(0.0)	1	(5.3)	0	(0.0)	0	(0.0)	0	(0.0)
Heat illness (熱中症)	0	(0.0)	1	(5.3)	0	(0.0)	0	(0.0)	0	(0.0)

Percentages are calculated using total number of patients per treatment as the denominator.

Containing data from study 1245_0015

MedDRA version used for reporting: [REDACTED]

m276laetxae2014.sas 04JUL2014

Table 1.1.2 Frequency [N (%)] of patients with related adverse events by treatment, primary system organ class and preferred term - treated set

	Placebo		Empa 1mg		Empa 5mg		Empa 10mg		Empa 25mg	
System organ class/ Preferred term	N	(%)	N	(%)	N	(%)	N	(%)	N	(%)
Number of patients	21	(100.0)	19	(100.0)	21	(100.0)	20	(100.0)	19	(100.0)
Total with related adverse event	1	(4.8)	2	(10.5)	0	(0.0)	4	(20.0)	3	(15.8)
Infections and infestations (感染症および寄生虫症)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(5.3)
Cystitis (膀胱炎)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(5.3)
Metabolism and nutrition disorders (代謝および栄養障害)	0	(0.0)	1	(5.3)	0	(0.0)	1	(5.0)	0	(0.0)
Hypoglycaemia (低血糖症)	0	(0.0)	1	(5.3)	0	(0.0)	1	(5.0)	0	(0.0)
Cardiac disorders (心臓障害)	0	(0.0)	0	(0.0)	0	(0.0)	1	(5.0)	0	(0.0)
Ventricular extrasystoles (心室性期外収縮)	0	(0.0)	0	(0.0)	0	(0.0)	1	(5.0)	0	(0.0)
Gastrointestinal disorders (胃腸障害)	1	(4.8)	0	(0.0)	0	(0.0)	2	(10.0)	1	(5.3)
Constipation (便秘)	1	(4.8)	0	(0.0)	0	(0.0)	2	(10.0)	1	(5.3)
Renal and urinary disorders (腎および尿路障害)	0	(0.0)	0	(0.0)	0	(0.0)	1	(5.0)	1	(5.3)
Pollakiuria (頻尿)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(5.3)
Nocturia (夜間頻尿)	0	(0.0)	0	(0.0)	0	(0.0)	1	(5.0)	0	(0.0)
Investigations (臨床検査)	0	(0.0)	1	(5.3)	0	(0.0)	0	(0.0)	0	(0.0)
Alpha 1 microglobulin urine increased (尿中α 1 ミクログロブリン増加)	0	(0.0)	1	(5.3)	0	(0.0)	0	(0.0)	0	(0.0)
Beta 2 microglobulin urine increased (尿中β 2 ミクログロブリン増加)	0	(0.0)	1	(5.3)	0	(0.0)	0	(0.0)	0	(0.0)

Percentages are calculated using total number of patients per treatment as the denominator.

Containing data from study 1245_0015

MedDRA version used for reporting: [REDACTED]

m276laetxae14011.sas 04JUL2014

Table 5.1.1.1 Frequency [N (%)] of patients with adverse events by treatment, primary system organ class and preferred term - treated set - 12 weeks

System organ class/ Preferred term	Placebo		Empa 5mg		Empa		Empa		Empa	
	N	(%)	N	(%)	N	(%)	N	(%)	N	(%)
Number of patients	109	(100.0)	110	(100.0)	109	(100.0)	109	(100.0)	110	(100.0)
Total with adverse events	46	(42.2)	36	(32.7)	41	(37.6)	40	(36.7)	42	(38.2)
Infections and infestations (感染症および寄生虫症)	16	(14.7)	9	(8.2)	19	(17.4)	17	(15.6)	20	(18.2)
Nasopharyngitis (鼻咽頭炎)	10	(9.2)	8	(7.3)	9	(8.3)	11	(10.1)	11	(10.0)
Pharyngitis (咽頭炎)	1	(0.9)	0	(0.0)	4	(3.7)	3	(2.8)	2	(1.8)
Acute sinusitis (急性副鼻腔炎)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.8)
Acute tonsillitis (急性扁桃炎)	1	(0.9)	0	(0.0)	1	(0.9)	0	(0.0)	1	(0.9)
Bronchitis (気管支炎)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.9)	1	(0.9)
Cystitis (膀胱炎)	0	(0.0)	0	(0.0)	1	(0.9)	0	(0.0)	0	(0.0)
Diverticulitis (憩室炎)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.9)	0	(0.0)
Folliculitis (毛包炎)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.9)
Gastroenteritis (胃腸炎)	1	(0.9)	0	(0.0)	1	(0.9)	1	(0.9)	1	(0.9)
Herpes zoster (帯状疱疹)	1	(0.9)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.9)
Influenza (インフルエンザ)	0	(0.0)	0	(0.0)	1	(0.9)	0	(0.0)	0	(0.0)
Oral herpes (口腔ヘルペス)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.9)
Otitis media (中耳炎)	0	(0.0)	0	(0.0)	1	(0.9)	0	(0.0)	0	(0.0)
Pneumonia (肺炎)	1	(0.9)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.9)
Pulpitis dental (歯髄炎)	1	(0.9)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.9)
Skin infection (皮膚感染)	0	(0.0)	0	(0.0)	1	(0.9)	0	(0.0)	0	(0.0)
Subcutaneous abscess (皮下組織膿瘍)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.9)	0	(0.0)
Tinea pedis (足部白癬)	0	(0.0)	1	(0.9)	0	(0.0)	0	(0.0)	0	(0.0)
Upper respiratory tract infection (上気道感染)	0	(0.0)	0	(0.0)	1	(0.9)	1	(0.9)	0	(0.0)
Urinary tract infection (尿路感染)	1	(0.9)	0	(0.0)	0	(0.0)	1	(0.9)	1	(0.9)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (良性、悪性および詳細不明の新生物 (嚢胞およびポリープを含む))	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.9)	0	(0.0)
Gastric cancer (胃癌)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.9)	0	(0.0)
Blood and lymphatic system disorders (血液およびリンパ系障害)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.9)
Anaemia (貧血)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.9)
Metabolism and nutrition disorders (代謝および栄養障害)	8	(7.3)	2	(1.8)	4	(3.7)	2	(1.8)	2	(1.8)
Diabetes mellitus (糖尿病)	2	(1.8)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.9)
Dyslipidaemia (脂質異常症)	2	(1.8)	1	(0.9)	1	(0.9)	0	(0.0)	0	(0.0)
Hyperglycaemia (高血糖)	2	(1.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Hypoglycaemia (低血糖症)	1	(0.9)	1	(0.9)	2	(1.8)	2	(1.8)	1	(0.9)
Dehydration (脱水)	1	(0.9)	0	(0.0)	1	(0.9)	0	(0.0)	0	(0.0)
Nervous system disorders (神経系障害)	1	(0.9)	3	(2.7)	3	(2.8)	3	(2.8)	1	(0.9)
Headache (頭痛)	0	(0.0)	2	(1.8)	1	(0.9)	1	(0.9)	0	(0.0)
Cerebral infarction (脳梗塞)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.9)	0	(0.0)
Cervicobrachial syndrome (頸腕症候群)	1	(0.9)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Cubital tunnel syndrome (肘部管症候群)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.9)
Dizziness (浮動性めまい)	0	(0.0)	1	(0.9)	0	(0.0)	0	(0.0)	0	(0.0)
Hypoaesthesia (感覚鈍麻)	0	(0.0)	0	(0.0)	1	(0.9)	0	(0.0)	0	(0.0)
Parosmia (嗅覚錯誤)	0	(0.0)	0	(0.0)	1	(0.9)	0	(0.0)	0	(0.0)
Sciatica (坐骨神経痛)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.9)	0	(0.0)
Eye disorders (眼障害)	4	(3.7)	1	(0.9)	1	(0.9)	2	(1.8)	3	(2.7)
Dry eye (眼乾燥)	2	(1.8)	1	(0.9)	0	(0.0)	0	(0.0)	0	(0.0)
Blepharitis (眼瞼炎)	0	(0.0)	0	(0.0)	1	(0.9)	0	(0.0)	0	(0.0)
Conjunctival haemorrhage (結膜出血)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.9)	0	(0.0)
Conjunctivitis (結膜炎)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.9)
Conjunctivitis allergic (アレルギー性結膜炎)	1	(0.9)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Diabetic retinopathy (糖尿病網膜症)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.9)
Glaucoma (緑内障)	1	(0.9)	0	(0.0)	0	(0.0)	1	(0.9)	0	(0.0)
Iris exfoliation (虹彩脱落)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.9)
Ear and labyrinth disorders (耳および迷路障害)	1	(0.9)	2	(1.8)	0	(0.0)	0	(0.0)	0	(0.0)

	Placebo		Empa 5mg		Empa		Empa		Empa	
System organ class/ Preferred term	N	(%)	N	(%)	N	(%)	N	(%)	N	(%)
Sudden hearing loss (突発難聴)	0	(0.0)	2	(1.8)	0	(0.0)	0	(0.0)	0	(0.0)
Vertigo positional (頭位性回転性めまい)	1	(0.9)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Cardiac disorders (心臓障害)	3	(2.8)	0	(0.0)	1	(0.9)	0	(0.0)	3	(2.7)
Acute myocardial infarction (急性心筋梗塞)	1	(0.9)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Atrial fibrillation (心房細動)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.9)
Cardiomyopathy (心筋症)	0	(0.0)	0	(0.0)	1	(0.9)	0	(0.0)	0	(0.0)
Hypertrophic cardiomyopathy (肥大型心筋症)	1	(0.9)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Left ventricular hypertrophy (左室肥大)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.9)
Myocardial infarction (心筋梗塞)	1	(0.9)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Myocardial ischaemia (心筋虚血)	1	(0.9)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Palpitations (動悸)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.9)
Vascular disorders (血管障害)	0	(0.0)	0	(0.0)	1	(0.9)	1	(0.9)	0	(0.0)
Hypertension (高血圧)	0	(0.0)	0	(0.0)	1	(0.9)	0	(0.0)	0	(0.0)
Orthostatic hypotension (起立性低血圧)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.9)	0	(0.0)
Respiratory, thoracic and mediastinal disorders (呼吸器、胸郭および縦隔障害)	4	(3.7)	0	(0.0)	1	(0.9)	3	(2.8)	0	(0.0)
Upper respiratory tract inflammation (上気道の炎症)	2	(1.8)	0	(0.0)	1	(0.9)	1	(0.9)	0	(0.0)
Asthma (喘息)	1	(0.9)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Epistaxis (鼻出血)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.9)	0	(0.0)
Rhinitis allergic (アレルギー性鼻炎)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.9)	0	(0.0)
Rhinitis seasonal (季節性鼻炎)	1	(0.9)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Gastrointestinal disorders (胃腸障害)	8	(7.3)	8	(7.3)	4	(3.7)	9	(8.3)	9	(8.2)
Constipation (便秘)	3	(2.8)	2	(1.8)	0	(0.0)	4	(3.7)	2	(1.8)
Gastritis (胃炎)	0	(0.0)	1	(0.9)	0	(0.0)	3	(2.8)	1	(0.9)
Periodontal disease (歯周病)	0	(0.0)	1	(0.9)	0	(0.0)	0	(0.0)	2	(1.8)
Abdominal discomfort (腹部不快感)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.9)	0	(0.0)
Abdominal distension (腹部膨満)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.9)	0	(0.0)
Abdominal pain upper (上腹部痛)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.9)
Anal pruritus (肛門そう痒症)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.9)
Colonic polyp (結腸ポリープ)	0	(0.0)	1	(0.9)	0	(0.0)	0	(0.0)	0	(0.0)
Dental caries (齲歯)	0	(0.0)	1	(0.9)	1	(0.9)	1	(0.9)	0	(0.0)
Diarrhoea (下痢)	1	(0.9)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.9)
Enterocolitis (腸炎)	1	(0.9)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Faeces hard (硬便)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.9)
Gastritis atrophic (萎縮性胃炎)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.9)
Gingivitis (歯肉炎)	1	(0.9)	0	(0.0)	1	(0.9)	0	(0.0)	0	(0.0)
Haemorrhoids (痔核)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.9)	0	(0.0)
Nausea (悪心)	0	(0.0)	1	(0.9)	0	(0.0)	0	(0.0)	0	(0.0)
Periodontitis (歯周炎)	1	(0.9)	1	(0.9)	0	(0.0)	0	(0.0)	1	(0.9)
Stomatitis (口内炎)	0	(0.0)	0	(0.0)	1	(0.9)	0	(0.0)	0	(0.0)
Toothache (歯痛)	1	(0.9)	0	(0.0)	1	(0.9)	0	(0.0)	0	(0.0)
Skin and subcutaneous tissue disorders (皮膚および皮下組織障害)	1	(0.9)	4	(3.6)	3	(2.8)	4	(3.7)	5	(4.5)
Dermatitis (皮膚炎)	0	(0.0)	2	(1.8)	0	(0.0)	0	(0.0)	0	(0.0)
Dermatitis contact (接触性皮膚炎)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.9)	2	(1.8)
Eczema (湿疹)	0	(0.0)	1	(0.9)	0	(0.0)	0	(0.0)	1	(0.9)
Eczema asteatotic (皮脂欠乏性湿疹)	1	(0.9)	0	(0.0)	1	(0.9)	1	(0.9)	0	(0.0)
Hyperkeratosis (過角化)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.9)	0	(0.0)
Photosensitivity reaction (光線過敏性反応)	0	(0.0)	0	(0.0)	1	(0.9)	0	(0.0)	0	(0.0)
Pruritus (そう痒症)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.9)
Rash (発疹)	0	(0.0)	1	(0.9)	1	(0.9)	0	(0.0)	0	(0.0)
Seborrhoeic dermatitis (脂漏性皮膚炎)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.9)
Urticaria (蕁麻疹)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.9)	0	(0.0)
Musculoskeletal and connective tissue disorders (筋骨格系および結合組織障害)	4	(3.7)	8	(7.3)	5	(4.6)	2	(1.8)	3	(2.7)
Back pain (背部痛)	0	(0.0)	4	(3.6)	1	(0.9)	0	(0.0)	0	(0.0)
Arthralgia (関節痛)	1	(0.9)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.9)
Chondrosis (軟骨症)	0	(0.0)	0	(0.0)	1	(0.9)	0	(0.0)	0	(0.0)

	Placebo		Empa 5mg		Empa		Empa		Empa	
System organ class/ Preferred term	N	(%)	N	(%)	N	(%)	N	(%)	N	(%)
Intervertebral disc protrusion (椎間板突出)	1	(0.9)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Muscle spasms (筋痙攣)	0	(0.0)	1	(0.9)	0	(0.0)	0	(0.0)	0	(0.0)
Musculoskeletal pain (筋骨格痛)	0	(0.0)	0	(0.0)	1	(0.9)	0	(0.0)	0	(0.0)
Musculoskeletal stiffness (筋骨格硬直)	0	(0.0)	1	(0.9)	0	(0.0)	0	(0.0)	0	(0.0)
Myalgia (筋肉痛)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.9)
Osteoarthritis (変形性関節症)	0	(0.0)	1	(0.9)	0	(0.0)	0	(0.0)	0	(0.0)
Pain in extremity (四肢痛)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.9)	0	(0.0)
Periarthritis (関節周囲炎)	1	(0.9)	1	(0.9)	1	(0.9)	0	(0.0)	0	(0.0)
Spondylolisthesis (脊椎すべり症)	0	(0.0)	0	(0.0)	1	(0.9)	0	(0.0)	0	(0.0)
Tendonitis (腱炎)	0	(0.0)	0	(0.0)	1	(0.9)	0	(0.0)	0	(0.0)
Tenosynovitis (腱鞘炎)	0	(0.0)	1	(0.9)	0	(0.0)	0	(0.0)	0	(0.0)
Trigger finger (弾発指)	1	(0.9)	0	(0.0)	1	(0.9)	1	(0.9)	1	(0.9)
Renal and urinary disorders (腎および尿路障害)	1	(0.9)	5	(4.5)	4	(3.7)	8	(7.3)	7	(6.4)
Pollakiuria (頻尿)	1	(0.9)	4	(3.6)	1	(0.9)	7	(6.4)	6	(5.5)
Polyuria (多尿)	0	(0.0)	2	(1.8)	1	(0.9)	1	(0.9)	1	(0.9)
Haematuria (血尿)	0	(0.0)	0	(0.0)	1	(0.9)	0	(0.0)	0	(0.0)
Nephrolithiasis (腎結石症)	0	(0.0)	0	(0.0)	1	(0.9)	0	(0.0)	0	(0.0)
Reproductive system and breast disorders (生殖系および乳房障害)	0	(0.0)	1	(0.9)	1	(0.9)	0	(0.0)	3	(2.7)
Balanitis (亀頭炎)	0	(0.0)	0	(0.0)	1	(0.9)	0	(0.0)	1	(0.9)
Epididymitis (精巣上体炎)	0	(0.0)	1	(0.9)	0	(0.0)	0	(0.0)	0	(0.0)
Pruritus genital (陰部そう痒症)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.9)
Vulvovaginal pruritus (外陰陰部そう痒症)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.9)
General disorders and administration site conditions (一般・全身障害および投与部位の状態)	3	(2.8)	3	(2.7)	2	(1.8)	4	(3.7)	5	(4.5)
Thirst (口渇)	1	(0.9)	2	(1.8)	0	(0.0)	3	(2.8)	3	(2.7)
Hunger (空腹)	0	(0.0)	2	(1.8)	0	(0.0)	0	(0.0)	0	(0.0)
Chest pain (胸痛)	0	(0.0)	0	(0.0)	1	(0.9)	0	(0.0)	0	(0.0)
Device dislocation (医療機器位置異常)	1	(0.9)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Fatigue (疲労)	1	(0.9)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Feeling abnormal (異常感)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.9)	0	(0.0)
Hangover (宿酔)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.9)
Inflammation (炎症)	0	(0.0)	0	(0.0)	1	(0.9)	0	(0.0)	0	(0.0)
Pyrexia (発熱)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.9)
Investigations (臨床検査)	1	(0.9)	0	(0.0)	1	(0.9)	2	(1.8)	2	(1.8)
Weight decreased (体重減少)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.8)	0	(0.0)
Glycosylated haemoglobin increased (グリコヘモグロビン増加)	1	(0.9)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Lipase increased (リパーゼ増加)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.9)
Urine ketone body present (尿中ケトン体陽性)	0	(0.0)	0	(0.0)	1	(0.9)	0	(0.0)	0	(0.0)
Urine output increased (尿量増加)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.9)
Injury, poisoning and procedural complications (傷害、中毒および処置合併症)	0	(0.0)	2	(1.8)	1	(0.9)	1	(0.9)	3	(2.7)
Fall (転倒)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.8)
Ligament sprain (靱帯捻挫)	0	(0.0)	2	(1.8)	0	(0.0)	0	(0.0)	1	(0.9)
Arthropod bite (節足動物咬傷)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.9)
Contusion (挫傷)	0	(0.0)	1	(0.9)	1	(0.9)	0	(0.0)	0	(0.0)
Excoriation (擦過傷)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.9)
Laceration (裂傷)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.9)
Ligament injury (靱帯損傷)	0	(0.0)	1	(0.9)	0	(0.0)	0	(0.0)	0	(0.0)
Road traffic accident (交通事故)	0	(0.0)	1	(0.9)	0	(0.0)	0	(0.0)	0	(0.0)
Tooth fracture (歯牙破折)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.9)	0	(0.0)

Percentages are calculated using total number of patients per treatment as the denominator.

Containing data from study 1245_a038

MedDRA version used for reporting: [REDACTED]

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Table 5.1.1.2 Frequency [N (%)] of patients with related adverse events by treatment, primary system organ class and preferred term - treated set - 12weeks

	Placebo		Empa 5mg		Empa 10mg		Empa 25mg		Empa 50mg	
System organ class/ Preferred term	N	(%)	N	(%)	N	(%)	N	(%)	N	(%)
Number of patients	109	(100.0)	110	(100.0)	109	(100.0)	109	(100.0)	110	(100.0)
Total with related adverse events	8	(7.3)	10	(9.1)	8	(7.3)	12	(11.0)	13	(11.8)
Infections and infestations (感染症および寄生虫症)	1	(0.9)	0	(0.0)	1	(0.9)	1	(0.9)	1	(0.9)
Cystitis (膀胱炎)	0	(0.0)	0	(0.0)	1	(0.9)	0	(0.0)	0	(0.0)
Diverticuli is (憩室炎)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.9)	0	(0.0)
Urinary tract infection (尿路感染)	1	(0.9)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.9)
Metabolism and nutrition disorders (代謝および栄養障害)	2	(1.8)	1	(0.9)	3	(2.8)	2	(1.8)	1	(0.9)
Hypoglycaemia (低血糖症)	1	(0.9)	1	(0.9)	2	(1.8)	2	(1.8)	1	(0.9)
Dehydration (脱水)	0	(0.0)	0	(0.0)	1	(0.9)	0	(0.0)	0	(0.0)
Diabetes mellitus (糖尿病)	1	(0.9)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Cardiac disorders (心臓障害)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.9)
Atrial fibrillation (心房細動)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.9)
Gastrointestinal disorders (胃腸障害)	3	(2.8)	2	(1.8)	0	(0.0)	3	(2.8)	3	(2.7)
Constipation (便秘)	2	(1.8)	2	(1.8)	0	(0.0)	2	(1.8)	2	(1.8)
Abdominal distension (腹部膨満)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.9)	0	(0.0)
Diarrhoea (下痢)	1	(0.9)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Faeces hard (硬便)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.9)
Haemorrhoids (痔核)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.9)	0	(0.0)
Skin and subcutaneous tissue disorders (皮膚および皮下組織障害)	0	(0.0)	1	(0.9)	0	(0.0)	0	(0.0)	1	(0.9)
Eczema (湿疹)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.9)
Rash (発疹)	0	(0.0)	1	(0.9)	0	(0.0)	0	(0.0)	0	(0.0)
Renal and urinary disorders (腎および尿路障害)	1	(0.9)	5	(4.5)	3	(2.8)	7	(6.4)	7	(6.4)
Pollakiuria (頻尿)	1	(0.9)	4	(3.6)	1	(0.9)	6	(5.5)	6	(5.5)
Polyuria (多尿)	0	(0.0)	2	(1.8)	1	(0.9)	1	(0.9)	1	(0.9)
Nephrolithiasis (腎結石症)	0	(0.0)	0	(0.0)	1	(0.9)	0	(0.0)	0	(0.0)
Reproductive system and breast disorders (生殖系および乳房障害)	0	(0.0)	1	(0.9)	1	(0.9)	0	(0.0)	1	(0.9)
Balanitis (亀頭炎)	0	(0.0)	0	(0.0)	1	(0.9)	0	(0.0)	1	(0.9)
Epididymitis (精巣上体炎)	0	(0.0)	1	(0.9)	0	(0.0)	0	(0.0)	0	(0.0)
General disorders and administration site conditions (一般・全身障害および投与部位の状態)	2	(1.8)	3	(2.7)	0	(0.0)	3	(2.8)	3	(2.7)
Thirst (口渇)	1	(0.9)	2	(1.8)	0	(0.0)	3	(2.8)	3	(2.7)
Hunger (空腹)	0	(0.0)	2	(1.8)	0	(0.0)	0	(0.0)	0	(0.0)
Fatigue (疲労)	1	(0.9)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Investigations (臨床検査)	0	(0.0)	0	(0.0)	1	(0.9)	2	(1.8)	1	(0.9)
Weight decreased (体重減少)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.8)	0	(0.0)
Urine ketone body present (尿中ケトン体陽性)	0	(0.0)	0	(0.0)	1	(0.9)	0	(0.0)	0	(0.0)
Urine output increased (尿量増加)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.9)

Percentages are calculated using total number of patients per treatment as the denominator.

Containing data from study 1245_a038

MedDRA version used for reporting: [REDACTED]

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Table 5.1.2.1 Frequency [N (%)] of patients with adverse events by treatment, primary system organ class and preferred term - treated set - randomized to empagliflozin 10mg or 25 mg for 52 weeks

	Empa 10mg		Empa 25mg	
System organ class/ Preferred term	N	(%)	N	(%)
Number of patients	109	(100.0)	109	(100.0)
Total with adverse events	78	(71.6)	82	(75.2)
Infections and infestations (感染症および寄生虫症)	47	(43.1)	44	(40.4)
Nasopharyngitis (鼻咽頭炎)	30	(27.5)	33	(30.3)
Pharyngitis (咽頭炎)	6	(5.5)	6	(5.5)
Urinary tract infection (尿路感染)	4	(3.7)	3	(2.8)
Gastroenteritis (胃腸炎)	3	(2.8)	2	(1.8)
Bronchitis (気管支炎)	1	(0.9)	2	(1.8)
Gastroenteritis viral (ウイルス性胃腸炎)	0	(0.0)	2	(1.8)
Tinea pedis (足部白癬)	2	(1.8)	2	(1.8)
Upper respiratory tract infection (上気道感染)	2	(1.8)	1	(0.9)
Vulvovaginal candidiasis (外陰部腔カンジダ症)	2	(1.8)	0	(0.0)
Acute tonsillitis (急性扁桃炎)	1	(0.9)	0	(0.0)
Cystitis (膀胱炎)	1	(0.9)	0	(0.0)
Diverticulitis (憩室炎)	0	(0.0)	1	(0.9)
Eczema impetiginous (膿痂疹性湿疹)	0	(0.0)	1	(0.9)
Gastritis viral (ウイルス性胃炎)	0	(0.0)	1	(0.9)
Helicobacter gastritis (ヘリコバクター性胃炎)	1	(0.9)	0	(0.0)
Herpes simplex (単純ヘルペス)	1	(0.9)	0	(0.0)
Influenza (インフルエンザ)	1	(0.9)	1	(0.9)
Oral herpes (口腔ヘルペス)	0	(0.0)	1	(0.9)
Otitis media (中耳炎)	1	(0.9)	0	(0.0)
Paronychia (爪囲炎)	1	(0.9)	0	(0.0)
Parotitis (耳下腺炎)	0	(0.0)	1	(0.9)
Pericoronitis (歯冠周囲炎)	0	(0.0)	1	(0.9)
Pneumonia (肺炎)	0	(0.0)	1	(0.9)
Rhinitis (鼻炎)	0	(0.0)	1	(0.9)
Sinusitis (副鼻腔炎)	1	(0.9)	1	(0.9)
Skin infection (皮膚感染)	1	(0.9)	0	(0.0)
Subcutaneous abscess (皮下組織膿瘍)	0	(0.0)	1	(0.9)
Vaginal infection (腔感染)	1	(0.9)	0	(0.0)
Viral infection (ウイルス感染)	1	(0.9)	0	(0.0)
Vulvovaginitis (外陰部腔炎)	1	(0.9)	0	(0.0)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (良性、悪性および詳細不明の新生物 (嚢胞およびポリープを含む))	2	(1.8)	4	(3.7)
Benign ovarian tumour (卵巣良性腫瘍)	1	(0.9)	0	(0.0)

	Empa 10mg		Empa 25mg	
System organ class/ Preferred term	N	(%)	N	(%)
Colon cancer (結腸癌)	0	(0.0)	1	(0.9)
Diffuse large B-cell lymphoma (びまん性大細胞型B細胞性リンパ腫)	0	(0.0)	1	(0.9)
Gastric cancer (胃癌)	0	(0.0)	1	(0.9)
Haemangioma of liver (肝臓血管腫)	1	(0.9)	0	(0.0)
Oesophageal carcinoma (食道癌)	0	(0.0)	1	(0.9)
Blood and lymphatic system disorders (血液およびリンパ系障害)	1	(0.9)	3	(2.8)
Anaemia (貧血)	0	(0.0)	2	(1.8)
Haemoconcentration (血液濃縮)	0	(0.0)	1	(0.9)
Iron deficiency anaemia (鉄欠乏性貧血)	1	(0.9)	0	(0.0)
Immune system disorders (免疫系障害)	0	(0.0)	1	(0.9)
Seasonal allergy (季節性アレルギー)	0	(0.0)	1	(0.9)
Metabolism and nutrition disorders (代謝および栄養障害)	8	(7.3)	6	(5.5)
Hypoglycaemia (低血糖症)	2	(1.8)	3	(2.8)
Dehydration (脱水)	2	(1.8)	0	(0.0)
Diabetes mellitus (糖尿病)	1	(0.9)	0	(0.0)
Dyslipidaemia (脂質異常症)	1	(0.9)	1	(0.9)
Hyperglycaemia (高血糖)	1	(0.9)	1	(0.9)
Hyperlipidaemia (高脂血症)	0	(0.0)	1	(0.9)
Type 2 diabetes mellitus (2型糖尿病)	1	(0.9)	0	(0.0)
Psychiatric disorders (精神障害)	1	(0.9)	0	(0.0)
Insomnia (不眠症)	1	(0.9)	0	(0.0)
Nervous system disorders (神経系障害)	5	(4.6)	12	(11.0)
Headache (頭痛)	1	(0.9)	3	(2.8)
Hypoaesthesia (感覚鈍麻)	3	(2.8)	1	(0.9)
Neuropathy peripheral (末梢性ニューロパチー)	0	(0.0)	2	(1.8)
Sciatica (坐骨神経痛)	0	(0.0)	2	(1.8)
Cerebral infarction (脳梗塞)	0	(0.0)	1	(0.9)
Cervicobrachial syndrome (頸腕症候群)	0	(0.0)	1	(0.9)
Dizziness (浮動性めまい)	0	(0.0)	1	(0.9)
Paraesthesia (錯感覚)	0	(0.0)	1	(0.9)
Parosmia (嗅覚錯誤)	1	(0.9)	0	(0.0)
Eye disorders (眼障害)	3	(2.8)	9	(8.3)
Diabetic retinopathy (糖尿病網膜症)	1	(0.9)	3	(2.8)
Abnormal sensation in eye (眼の異常感)	1	(0.9)	0	(0.0)
Blepharitis (眼瞼炎)	1	(0.9)	0	(0.0)
Cataract (白内障)	0	(0.0)	1	(0.9)
Conjunctival haemorrhage (結膜出血)	0	(0.0)	1	(0.9)
Dry eye (眼乾燥)	0	(0.0)	1	(0.9)
Eyelid ptosis (眼瞼下垂)	0	(0.0)	1	(0.9)
Glaucoma (緑内障)	0	(0.0)	1	(0.9)

	Empa 10mg		Empa 25mg	
System organ class/ Preferred term	N	(%)	N	(%)
Vitreous floaters (硝子体浮遊物)	0	(0.0)	1	(0.9)
Ear and labyrinth disorders (耳および迷路障害)	1	(0.9)	0	(0.0)
Vertigo (回転性めまい)	1	(0.9)	0	(0.0)
Cardiac disorders (心臓障害)	1	(0.9)	0	(0.0)
Cardiomyopathy (心筋症)	1	(0.9)	0	(0.0)
Vascular disorders (血管障害)	3	(2.8)	3	(2.8)
Hypertension (高血圧)	3	(2.8)	1	(0.9)
Hypotension (低血圧)	0	(0.0)	1	(0.9)
Orthostatic hypotension (起立性低血圧)	0	(0.0)	1	(0.9)
Respiratory, thoracic and mediastinal disorders (呼吸器、 胸郭および縦隔障害)	3	(2.8)	7	(6.4)
Upper respiratory tract inflammation (上気道の炎症)	2	(1.8)	4	(3.7)
Epistaxis (鼻出血)	1	(0.9)	2	(1.8)
Rhinitis allergic (アレルギー性鼻炎)	0	(0.0)	1	(0.9)
Gastrointestinal disorders (胃腸障害)	18	(16.5)	28	(25.7)
Dental caries (齲蝕)	1	(0.9)	7	(6.4)
Constipation (便秘)	1	(0.9)	6	(5.5)
Gastritis (胃炎)	0	(0.0)	5	(4.6)
Gingivitis (歯肉炎)	3	(2.8)	3	(2.8)
Diarrhoea (下痢)	0	(0.0)	2	(1.8)
Enterocolitis (腸炎)	0	(0.0)	2	(1.8)
Haemorrhoids (痔核)	1	(0.9)	2	(1.8)
Nausea (悪心)	1	(0.9)	2	(1.8)
Stomatitis (口内炎)	1	(0.9)	2	(1.8)
Abdominal discomfort (腹部不快感)	0	(0.0)	1	(0.9)
Abdominal distension (腹部膨満)	1	(0.9)	1	(0.9)
Abdominal pain (腹痛)	0	(0.0)	1	(0.9)
Abdominal pain upper (上腹部痛)	1	(0.9)	0	(0.0)
Anal fissure (裂肛)	1	(0.9)	0	(0.0)
Cheilitis (口唇炎)	1	(0.9)	0	(0.0)
Colitis ischaemic (虚血性大腸炎)	1	(0.9)	0	(0.0)
Colonic polyp (結腸ポリープ)	1	(0.9)	1	(0.9)
Dyspepsia (消化不良)	1	(0.9)	0	(0.0)
Epigastric discomfort (心窩部不快感)	1	(0.9)	0	(0.0)
Gastritis erosive (びらん性胃炎)	1	(0.9)	1	(0.9)
Gastroesophageal reflux disease (胃食道逆流性疾患)	1	(0.9)	1	(0.9)
Glossodynia (舌痛)	0	(0.0)	1	(0.9)
Periodontal disease (歯周病)	0	(0.0)	1	(0.9)
Periodontitis (歯周炎)	0	(0.0)	1	(0.9)
Toothache (歯痛)	1	(0.9)	0	(0.0)
Vomiting (嘔吐)	0	(0.0)	1	(0.9)

	Empa 10mg		Empa 25mg	
System organ class/ Preferred term	N	(%)	N	(%)
Hepatobiliary disorders (肝胆道系障害)	1	(0.9)	2	(1.8)
Hepatic function abnormal (肝機能異常)	0	(0.0)	1	(0.9)
Hyperbilirubinaemia (高ビリルビン血症)	0	(0.0)	1	(0.9)
Liver disorder (肝障害)	1	(0.9)	0	(0.0)
Skin and subcutaneous tissue disorders (皮膚および皮下組織障害)	17	(15.6)	14	(12.8)
Eczema (湿疹)	3	(2.8)	3	(2.8)
Rash (発疹)	3	(2.8)	2	(1.8)
Dermatitis contact (接触性皮膚炎)	1	(0.9)	2	(1.8)
Heat rash (紅色汗疹)	0	(0.0)	2	(1.8)
Urticaria (蕁麻疹)	2	(1.8)	1	(0.9)
Alopecia areata (円形脱毛症)	1	(0.9)	0	(0.0)
Dermatitis (皮膚炎)	0	(0.0)	1	(0.9)
Dry skin (皮膚乾燥)	1	(0.9)	1	(0.9)
Eczema asteatotic (皮脂欠乏性湿疹)	1	(0.9)	1	(0.9)
Hyperkeratosis (過角化)	1	(0.9)	1	(0.9)
Ingrowing nail (嵌入爪)	1	(0.9)	0	(0.0)
Nail bed bleeding (爪床出血)	0	(0.0)	1	(0.9)
Photosensitivity reaction (光線過敏性反応)	1	(0.9)	0	(0.0)
Rash pruritic (そう痒性皮疹)	1	(0.9)	0	(0.0)
Skin exfoliation (皮膚剥脱)	0	(0.0)	1	(0.9)
Solar dermatitis (日光皮膚炎)	1	(0.9)	0	(0.0)
Musculoskeletal and connective tissue disorders (筋骨格系および結合組織障害)	18	(16.5)	15	(13.8)
Back pain (背部痛)	4	(3.7)	4	(3.7)
Arthralgia (関節痛)	3	(2.8)	0	(0.0)
Osteoarthritis (変形性関節症)	2	(1.8)	2	(1.8)
Pain in extremity (四肢痛)	1	(0.9)	2	(1.8)
Periarthritis (関節周囲炎)	2	(1.8)	0	(0.0)
Spinal osteoarthritis (変形性脊椎症)	2	(1.8)	0	(0.0)
Spondylolisthesis (脊椎すべり症)	2	(1.8)	0	(0.0)
Chondrosis (軟骨症)	1	(0.9)	0	(0.0)
Intervertebral disc protrusion (椎間板突出)	1	(0.9)	0	(0.0)
Monarthritis (単関節炎)	0	(0.0)	1	(0.9)
Muscle spasms (筋痙攣)	0	(0.0)	1	(0.9)
Muscular weakness (筋力低下)	0	(0.0)	1	(0.9)
Musculoskeletal pain (筋骨格痛)	1	(0.9)	0	(0.0)
Musculoskeletal stiffness (筋骨格硬直)	1	(0.9)	1	(0.9)
Myalgia (筋肉痛)	1	(0.9)	0	(0.0)
Spondylolysis (脊椎分離)	0	(0.0)	1	(0.9)
Tendon calcification (腱石灰化)	0	(0.0)	1	(0.9)
Tendonitis (腱炎)	1	(0.9)	1	(0.9)

	Empa 10mg		Empa 25mg	
System organ class/ Preferred term	N	(%)	N	(%)
Trigger finger (弾発指)	1	(0.9)	1	(0.9)
Renal and urinary disorders (腎および尿路障害)	7	(6.4)	11	(10.1)
Pollakiuria (頻尿)	1	(0.9)	8	(7.3)
Diabetic nephropathy (糖尿病性腎症)	1	(0.9)	0	(0.0)
Haematuria (血尿)	1	(0.9)	0	(0.0)
Hypertonic bladder (緊張性膀胱)	1	(0.9)	0	(0.0)
Nephrolithiasis (腎結石症)	1	(0.9)	1	(0.9)
Nocturia (夜間頻尿)	0	(0.0)	1	(0.9)
Polyuria (多尿)	1	(0.9)	1	(0.9)
Urethral caruncle (尿道カルンクル)	1	(0.9)	0	(0.0)
Reproductive system and breast disorders (生殖系および乳房障害)	5	(4.6)	1	(0.9)
Balanitis (亀頭炎)	3	(2.8)	0	(0.0)
Breast disorder (乳房障害)	1	(0.9)	0	(0.0)
Cervical polyp (子宮頸管ポリープ)	1	(0.9)	0	(0.0)
Vulvovaginal discomfort (外陰腔不快感)	0	(0.0)	1	(0.9)
Vulvovaginal pruritus (外陰腔そう痒症)	1	(0.9)	0	(0.0)
General disorders and administration site conditions (一般・全身障害および投与部位の状態)	3	(2.8)	7	(6.4)
Thirst (口渇)	1	(0.9)	4	(3.7)
Chest pain (胸痛)	1	(0.9)	0	(0.0)
Feeling abnormal (異常感)	0	(0.0)	1	(0.9)
Hunger (空腹)	0	(0.0)	1	(0.9)
Inflammation (炎症)	1	(0.9)	0	(0.0)
Pyrexia (発熱)	0	(0.0)	1	(0.9)
Investigations (臨床検査)	8	(7.3)	8	(7.3)
Weight decreased (体重減少)	3	(2.8)	4	(3.7)
Glycosylated haemoglobin increased (グリコヘモグロビン増加)	2	(1.8)	1	(0.9)
Alanine aminotransferase increased (アラニンアミノトランスフェラーゼ増加)	1	(0.9)	0	(0.0)
Aspartate aminotransferase increased (アスパラギン酸アミノトランスフェラーゼ増加)	1	(0.9)	0	(0.0)
Carbohydrate antigen 19-9 increased (糖鎖抗原 19-9 増加)	0	(0.0)	1	(0.9)
Electrocardiogram QT prolonged (心電図QT延長)	0	(0.0)	1	(0.9)
Lipase increased (リパーゼ増加)	0	(0.0)	1	(0.9)
Prostatic specific antigen increased (前立腺特異性抗原増加)	1	(0.9)	0	(0.0)
Urine ketone body present (尿中ケトン体陽性)	1	(0.9)	1	(0.9)
Injury, poisoning and procedural complications (傷害、中毒および処置合併症)	7	(6.4)	5	(4.6)
Fall (転倒)	4	(3.7)	2	(1.8)
Contusion (挫傷)	2	(1.8)	3	(2.8)

	Empa 10mg		Empa 25mg	
System organ class/ Preferred term	N	(%)	N	(%)
Tooth fracture (齒牙破折)	2	(1.8)	1	(0.9)
Avulsion fracture (剝離骨折)	1	(0.9)	0	(0.0)
Corneal abrasion (角膜擦過傷)	0	(0.0)	1	(0.9)
Excoriation (擦過傷)	1	(0.9)	0	(0.0)
Laceration (裂傷)	1	(0.9)	0	(0.0)
Ligament sprain (韌帶捻挫)	0	(0.0)	1	(0.9)
Road traffic accident (交通事故)	0	(0.0)	1	(0.9)
Tibia fracture (脛骨骨折)	1	(0.9)	0	(0.0)

Percentages are calculated using total number of patients per treatment as the denominator.

Containing data from study 1245_p038

MedDRA version used for reporting: [REDACTED]

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Table 5.1.2.2 Frequency [N (%)] of patients with related adverse events by treatment, primary system organ class and preferred term - treated set -
randomized to empagliflozin 10mg or 25 mg for 52 weeks

	Empa 10mg		Empa 25mg	
System organ class/ Preferred term	N	(%)	N	(%)
Number of patients	109	(100.0)	109	(100.0)
Total with related adverse events	21	(19.3)	20	(18.3)
Infections and infestations (感染症および寄生虫症)	6	(5.5)	3	(2.8)
Urinary tract infection (尿路感染)	4	(3.7)	2	(1.8)
Cystitis (膀胱炎)	1	(0.9)	0	(0.0)
Diverticulitis (憩室炎)	0	(0.0)	1	(0.9)
Vulvovaginitis (外陰部炎症)	1	(0.9)	0	(0.0)
Blood and lymphatic system disorders (血液およびリンパ系障害)	0	(0.0)	2	(1.8)
Anaemia (貧血)	0	(0.0)	1	(0.9)
Haemoconcentration (血液濃縮)	0	(0.0)	1	(0.9)
Metabolism and nutrition disorders (代謝および栄養障害)	3	(2.8)	3	(2.8)
Hypoglycaemia (低血糖症)	2	(1.8)	3	(2.8)
Dehydration (脱水)	1	(0.9)	0	(0.0)
Gastrointestinal disorders (胃腸障害)	2	(1.8)	5	(4.6)
Constipation (便秘)	0	(0.0)	4	(3.7)
Abdominal distension (腹部膨満)	1	(0.9)	1	(0.9)
Colonic polyp (結腸ポリープ)	1	(0.9)	0	(0.0)
Haemorrhoids (痔核)	0	(0.0)	1	(0.9)
Hepatobiliary disorders (肝胆道系障害)	0	(0.0)	1	(0.9)
Hepatic function abnormal (肝機能異常)	0	(0.0)	1	(0.9)
Renal and urinary disorders (腎および尿路障害)	4	(3.7)	8	(7.3)
Pollakiuria (頻尿)	1	(0.9)	7	(6.4)
Nephrolithiasis (腎結石症)	1	(0.9)	0	(0.0)
Polyuria (多尿)	1	(0.9)	1	(0.9)
Urethral caruncle (尿道カルンクル)	1	(0.9)	0	(0.0)
Reproductive system and breast disorders (生殖系および乳房障害)	4	(3.7)	1	(0.9)
Balanitis (亀頭炎)	3	(2.8)	0	(0.0)
Vulvovaginal discomfort (外陰部不快感)	0	(0.0)	1	(0.9)
Vulvovaginal pruritus (外陰部掻痒症)	1	(0.9)	0	(0.0)

	Empa 10mg		Empa 25mg	
System organ class/ Preferred term	N	(%)	N	(%)
General disorders and administration site conditions (一般・全身障害および投与部位の状態)	1	(0.9)	5	(4.6)
Thirst (口渴)	1	(0.9)	4	(3.7)
Hunger (空腹)	0	(0.0)	1	(0.9)
Investigations (臨床検査)	4	(3.7)	5	(4.6)
Weight decreased (体重減少)	3	(2.8)	4	(3.7)
Electrocardiogram QT prolonged (心電図QT延長)	0	(0.0)	1	(0.9)
Urine ketone body present (尿中ケトン体陽性)	1	(0.9)	1	(0.9)

Percentages are calculated using total number of patients per treatment as the denominator.

Containing data from study 1245_p038

MedDRA version used for reporting: [REDACTED]

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Table 5.1.3.1 Frequency [N (%)] of patients with adverse events by treatment, primary system organ class and preferred term - treated set - all BI 10mg and all BI 25 mg for 52 weeks

	Empa 10mg		Empa 25mg	
System organ class/ Preferred term	N	(%)	N	(%)
Number of patients	267	(100.0)	265	(100.0)
Total with adverse events	189	(70.8)	177	(66.8)
Infections and infestations (感染症および寄生虫症)	98	(36.7)	91	(34.3)
Nasopharyngitis (鼻咽頭炎)	62	(23.2)	63	(23.8)
Pharyngitis (咽頭炎)	11	(4.1)	9	(3.4)
Bronchitis (気管支炎)	6	(2.2)	6	(2.3)
Gastroenteritis (胃腸炎)	3	(1.1)	6	(2.3)
Herpes zoster (帯状疱疹)	4	(1.5)	0	(0.0)
Influenza (インフルエンザ)	2	(0.7)	4	(1.5)
Tinea pedis (足部白癬)	3	(1.1)	4	(1.5)
Urinary tract infection (尿路感染)	4	(1.5)	3	(1.1)
Cystitis (膀胱炎)	3	(1.1)	0	(0.0)
Upper respiratory tract infection (上気道感染)	3	(1.1)	1	(0.4)
Vulvovaginal candidiasis (外陰部膾カンジダ症)	3	(1.1)	0	(0.0)
Gastroenteritis viral (ウイルス性胃腸炎)	0	(0.0)	2	(0.8)
Hordeolum (麦粒腫)	2	(0.7)	2	(0.8)
Herpes simplex (単純ヘルペス)	2	(0.7)	0	(0.0)
Acute sinusitis (急性副鼻腔炎)	0	(0.0)	1	(0.4)
Acute tonsillitis (急性扁桃炎)	1	(0.4)	1	(0.4)
Cellulitis (蜂巣炎)	1	(0.4)	0	(0.0)
Diverticulitis (憩室炎)	0	(0.0)	1	(0.4)
Eczema impetiginous (膿痂疹性湿疹)	0	(0.0)	1	(0.4)
Empyema (蓄膿)	1	(0.4)	0	(0.0)
Folliculitis (毛包炎)	1	(0.4)	1	(0.4)
Gastritis viral (ウイルス性胃炎)	0	(0.0)	1	(0.4)
Helicobacter gastritis (ヘリコバクター性胃炎)	1	(0.4)	1	(0.4)
Impetigo (膿痂疹)	0	(0.0)	1	(0.4)
Infected dermal cyst (感染性皮膚嚢腫)	1	(0.4)	0	(0.0)
Onychomycosis (爪真菌症)	1	(0.4)	0	(0.0)
Oral herpes (口腔ヘルペス)	1	(0.4)	1	(0.4)
Otitis media (中耳炎)	1	(0.4)	0	(0.0)
Paronychia (爪囲炎)	1	(0.4)	0	(0.0)

	Empa 10mg		Empa 25mg	
System organ class/ Preferred term	N	(%)	N	(%)
Parotitis (耳下腺炎)	0	(0.0)	1	(0.4)
Pericoronitis (歯冠周囲炎)	0	(0.0)	1	(0.4)
Perirectal abscess (直腸周囲膿瘍)	1	(0.4)	0	(0.0)
Pneumonia (肺炎)	0	(0.0)	1	(0.4)
Rhinitis (鼻炎)	0	(0.0)	1	(0.4)
Sinusitis (副鼻腔炎)	1	(0.4)	1	(0.4)
Skin infection (皮膚感染)	1	(0.4)	0	(0.0)
Subcutaneous abscess (皮下組織膿瘍)	0	(0.0)	1	(0.4)
Tinea cruris (股部白癬)	1	(0.4)	0	(0.0)
Tonsillitis (扁桃炎)	0	(0.0)	1	(0.4)
Vaginal infection (膣感染)	1	(0.4)	0	(0.0)
Vaginitis bacterial (細菌性膣炎)	1	(0.4)	0	(0.0)
Viral infection (ウイルス感染)	1	(0.4)	0	(0.0)
Vulvovaginal mycotic infection (外陰膣真菌感染)	0	(0.0)	1	(0.4)
Vulvovaginitis (外陰部膣炎)	1	(0.4)	0	(0.0)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (良性、悪性および詳細不明の新生物 (嚢胞およびポリープを含む))	6	(2.2)	4	(1.5)
Lipoma (脂肪腫)	2	(0.7)	0	(0.0)
Benign ovarian tumour (卵巣良性腫瘍)	1	(0.4)	0	(0.0)
Bladder cancer (膀胱癌)	1	(0.4)	0	(0.0)
Colon cancer (結腸癌)	1	(0.4)	1	(0.4)
Diffuse large B-cell lymphoma (びまん性大細胞型B細胞性リンパ腫)	0	(0.0)	1	(0.4)
Gastric cancer (胃癌)	0	(0.0)	1	(0.4)
Haemangioma of liver (肝臓血管腫)	1	(0.4)	0	(0.0)
Lung cancer metastatic (転移性肺癌)	1	(0.4)	0	(0.0)
Metastases to bone marrow (骨髄転移)	1	(0.4)	0	(0.0)
Oesophageal carcinoma (食道癌)	0	(0.0)	1	(0.4)
Blood and lymphatic system disorders (血液およびリンパ系障害)	1	(0.4)	5	(1.9)
Anaemia (貧血)	0	(0.0)	3	(1.1)
Haemoconcentration (血液濃縮)	0	(0.0)	2	(0.8)
Iron deficiency anaemia (鉄欠乏性貧血)	1	(0.4)	0	(0.0)
Immune system disorders (免疫系障害)	1	(0.4)	1	(0.4)
Seasonal allergy (季節性アレルギー)	1	(0.4)	1	(0.4)
Metabolism and nutrition disorders (代謝および栄養障害)	19	(7.1)	12	(4.5)

	Empa 10mg		Empa 25mg	
System organ class/ Preferred term	N	(%)	N	(%)
Hypoglycaemia (低血糖症)	6	(2.2)	3	(1.1)
Hyperglycaemia (高血糖)	4	(1.5)	5	(1.9)
Dehydration (脱水)	3	(1.1)	0	(0.0)
Dyslipidaemia (脂質異常症)	1	(0.4)	2	(0.8)
Diabetes mellitus (糖尿病)	2	(0.7)	1	(0.4)
Gout (痛風)	0	(0.0)	1	(0.4)
Hyperkalaemia (高カリウム血症)	1	(0.4)	0	(0.0)
Hyperlipidaemia (高脂血症)	1	(0.4)	1	(0.4)
Type 2 diabetes mellitus (2型糖尿病)	1	(0.4)	0	(0.0)
Psychiatric disorders (精神障害)	3	(1.1)	3	(1.1)
Insomnia (不眠症)	3	(1.1)	1	(0.4)
Anxiety disorder (不安障害)	0	(0.0)	1	(0.4)
Initial insomnia (初期不眠症)	0	(0.0)	1	(0.4)
Nervous system disorders (神経系障害)	11	(4.1)	20	(7.5)
Headache (頭痛)	2	(0.7)	6	(2.3)
Sciatica (坐骨神経痛)	0	(0.0)	4	(1.5)
Dizziness (浮動性めまい)	2	(0.7)	3	(1.1)
Hypoaesthesia (感覚鈍麻)	3	(1.1)	3	(1.1)
Neuropathy peripheral (末梢性ニューロパチー)	1	(0.4)	2	(0.8)
Cerebral infarction (脳梗塞)	0	(0.0)	1	(0.4)
Cervicobrachial syndrome (頸腕症候群)	1	(0.4)	1	(0.4)
Dysaesthesia (異常感覚)	0	(0.0)	1	(0.4)
3rd nerve paralysis (第3脳神経麻痺)	1	(0.4)	0	(0.0)
Paraesthesia (錯感覚)	0	(0.0)	1	(0.4)
Parosmia (嗅覚錯誤)	1	(0.4)	0	(0.0)
Presyncope (失神寸前の状態)	1	(0.4)	0	(0.0)
Eye disorders (眼障害)	7	(2.6)	19	(7.2)
Diabetic retinopathy (糖尿病網膜症)	1	(0.4)	4	(1.5)
Conjunctival haemorrhage (結膜出血)	0	(0.0)	2	(0.8)
Conjunctivitis (結膜炎)	1	(0.4)	2	(0.8)
Abnormal sensation in eye (目の異常感)	1	(0.4)	0	(0.0)
Age-related macular degeneration (加齢黄斑変性)	0	(0.0)	1	(0.4)
Asthenopia (眼精疲労)	0	(0.0)	1	(0.4)
Blepharitis (眼瞼炎)	1	(0.4)	0	(0.0)
Cataract (白内障)	0	(0.0)	1	(0.4)
Conjunctivitis allergic (アレルギー性結膜炎)	1	(0.4)	0	(0.0)
Conjunctivochalasis (結膜弛緩症)	0	(0.0)	1	(0.4)

	Empa 10mg		Empa 25mg	
System organ class/ Preferred term	N	(%)	N	(%)
Corneal erosion (角膜びらん)	0	(0.0)	1	(0.4)
Dry eye (眼乾燥)	0	(0.0)	1	(0.4)
Eye pruritus (眼そう痒症)	1	(0.4)	0	(0.0)
Eyelid ptosis (眼瞼下垂)	0	(0.0)	1	(0.4)
Eyelids pruritus (眼瞼そう痒症)	0	(0.0)	1	(0.4)
Glaucoma (緑内障)	0	(0.0)	1	(0.4)
Iris adhesions (虹彩癒着)	1	(0.4)	0	(0.0)
Macular degeneration (黄斑変性)	0	(0.0)	1	(0.4)
Macular hole (黄斑円孔)	1	(0.4)	0	(0.0)
Ocular hyperaemia (眼充血)	0	(0.0)	1	(0.4)
Punctate keratitis (点状角膜炎)	0	(0.0)	1	(0.4)
Vitreous floaters (硝子体浮遊物)	0	(0.0)	1	(0.4)
Ear and labyrinth disorders (耳および迷路障害)	3	(1.1)	1	(0.4)
Ear pain (耳痛)	1	(0.4)	0	(0.0)
Sudden hearing loss (突発難聴)	1	(0.4)	1	(0.4)
Vertigo (回転性めまい)	1	(0.4)	0	(0.0)
Cardiac disorders (心臓障害)	3	(1.1)	3	(1.1)
Palpitations (動悸)	0	(0.0)	2	(0.8)
Acute myocardial infarction (急性心筋梗塞)	1	(0.4)	0	(0.0)
Angina pectoris (狭心症)	0	(0.0)	1	(0.4)
Atrial fibrillation (心房細動)	1	(0.4)	0	(0.0)
Cardiomyopathy (心筋症)	1	(0.4)	0	(0.0)
Vascular disorders (血管障害)	5	(1.9)	5	(1.9)
Hypertension (高血圧)	5	(1.9)	2	(0.8)
Orthostatic hypotension (起立性低血圧)	0	(0.0)	2	(0.8)
Hypotension (低血圧)	0	(0.0)	1	(0.4)
Respiratory, thoracic and mediastinal disorders (呼吸器、胸郭および縦隔障害)	6	(2.2)	12	(4.5)
Upper respiratory tract inflammation (上気道の炎症)	4	(1.5)	6	(2.3)
Epistaxis (鼻出血)	1	(0.4)	2	(0.8)
Rhinitis allergic (アレルギー性鼻炎)	1	(0.4)	2	(0.8)
Asthma (喘息)	0	(0.0)	1	(0.4)
Cough (咳嗽)	1	(0.4)	0	(0.0)
Sleep apnoea syndrome (睡眠時無呼吸症候群)	0	(0.0)	1	(0.4)
Gastrointestinal disorders (胃腸障害)	40	(15.0)	46	(17.4)
Constipation (便秘)	3	(1.1)	10	(3.8)
Dental caries (齲歯)	2	(0.7)	9	(3.4)

	Empa 10mg		Empa 25mg	
System organ class/ Preferred term	N	(%)	N	(%)
Gastritis (胃炎)	1	(0.4)	7	(2.6)
Gingivitis (歯肉炎)	5	(1.9)	4	(1.5)
Diarrhoea (下痢)	0	(0.0)	4	(1.5)
Abdominal pain upper (上腹部痛)	3	(1.1)	1	(0.4)
Enterocolitis (腸炎)	0	(0.0)	3	(1.1)
Periodontal disease (歯周病)	3	(1.1)	3	(1.1)
Toothache (歯痛)	3	(1.1)	0	(0.0)
Haemorrhoids (痔核)	2	(0.7)	2	(0.8)
Nausea (悪心)	1	(0.4)	2	(0.8)
Periodontitis (歯周炎)	0	(0.0)	2	(0.8)
Stomatitis (口内炎)	1	(0.4)	2	(0.8)
Cheilitis (口唇炎)	2	(0.7)	0	(0.0)
Colonic polyp (結腸ポリープ)	2	(0.7)	1	(0.4)
Epigastric discomfort (心窩部不快感)	2	(0.7)	0	(0.0)
Gastritis erosive (びらん性胃炎)	2	(0.7)	1	(0.4)
Abdominal discomfort (腹部不快感)	1	(0.4)	1	(0.4)
Abdominal distension (腹部膨満)	1	(0.4)	1	(0.4)
Abdominal pain (腹痛)	0	(0.0)	1	(0.4)
Anal fissure (裂肛)	1	(0.4)	0	(0.0)
Colitis ischaemic (虚血性大腸炎)	1	(0.4)	0	(0.0)
Duodenal ulcer (十二指腸潰瘍)	0	(0.0)	1	(0.4)
Dyspepsia (消化不良)	1	(0.4)	0	(0.0)
Gastric ulcer (胃潰瘍)	1	(0.4)	1	(0.4)
Gastroesophageal reflux disease (胃食道逆流性疾患)	1	(0.4)	1	(0.4)
Glossodynia (舌痛)	0	(0.0)	1	(0.4)
Intestinal polyp (腸管ポリープ)	1	(0.4)	0	(0.0)
Irritable bowel syndrome (過敏性腸症候群)	1	(0.4)	0	(0.0)
Parotid gland enlargement (耳下腺腫大)	1	(0.4)	0	(0.0)
Tooth loss (歯の脱落)	0	(0.0)	1	(0.4)
Vomiting (嘔吐)	0	(0.0)	1	(0.4)
Hepatobiliary disorders (肝胆道系障害)	2	(0.7)	3	(1.1)
Hepatic function abnormal (肝機能異常)	0	(0.0)	2	(0.8)
Cholecystitis (胆嚢炎)	1	(0.4)	0	(0.0)
Hyperbilirubinaemia (高ビリルビン血症)	0	(0.0)	1	(0.4)
Liver disorder (肝障害)	1	(0.4)	0	(0.0)

	Empa 10mg		Empa 25mg	
System organ class/ Preferred term	N	(%)	N	(%)
Skin and subcutaneous tissue disorders (皮膚および皮下組織障害)	29	(10.9)	28	(10.6)
Eczema (湿疹)	4	(1.5)	6	(2.3)
Eczema asteatotic (皮脂欠乏性湿疹)	4	(1.5)	2	(0.8)
Rash (発疹)	4	(1.5)	3	(1.1)
Urticaria (蕁麻疹)	3	(1.1)	4	(1.5)
Dermatitis contact (接触性皮膚炎)	2	(0.7)	3	(1.1)
Dry skin (皮膚乾燥)	1	(0.4)	3	(1.1)
Dermatitis atopic (アトピー性皮膚炎)	0	(0.0)	2	(0.8)
Heat rash (紅色汗疹)	0	(0.0)	2	(0.8)
Hyperkeratosis (過角化)	2	(0.7)	1	(0.4)
Alopecia (脱毛症)	1	(0.4)	0	(0.0)
Alopecia areata (円形脱毛症)	1	(0.4)	0	(0.0)
Dermatitis (皮膚炎)	0	(0.0)	1	(0.4)
Drug eruption (薬疹)	1	(0.4)	0	(0.0)
Erythema (紅斑)	0	(0.0)	1	(0.4)
Hyperhidrosis (多汗症)	0	(0.0)	1	(0.4)
Ingrowing nail (嵌入爪)	1	(0.4)	0	(0.0)
Nail bed bleeding (爪床出血)	0	(0.0)	1	(0.4)
Nail discolouration (爪変色)	0	(0.0)	1	(0.4)
Photosensitivity reaction (光線過敏性反応)	1	(0.4)	0	(0.0)
Pruritus generalised (全身性そう痒症)	1	(0.4)	0	(0.0)
Rash pruritic (そう痒性皮疹)	1	(0.4)	0	(0.0)
Seborrhoeic dermatitis (脂漏性皮膚炎)	0	(0.0)	1	(0.4)
Skin exfoliation (皮膚剥脱)	0	(0.0)	1	(0.4)
Solar dermatitis (日光皮膚炎)	1	(0.4)	0	(0.0)
Xeroderma (乾皮症)	1	(0.4)	0	(0.0)
Musculoskeletal and connective tissue disorders (筋骨格系および結合組織障害)	38	(14.2)	35	(13.2)
Back pain (背部痛)	14	(5.2)	10	(3.8)
Arthralgia (関節痛)	7	(2.6)	1	(0.4)
Periarthritis (関節周囲炎)	6	(2.2)	1	(0.4)
Musculoskeletal stiffness (筋骨格硬直)	2	(0.7)	5	(1.9)
Myalgia (筋肉痛)	2	(0.7)	3	(1.1)
Osteoarthritis (変形性関節症)	2	(0.7)	3	(1.1)
Pain in extremity (四肢痛)	2	(0.7)	3	(1.1)
Spinal osteoarthritis (変形性脊椎症)	2	(0.7)	0	(0.0)

	Empa 10mg		Empa 25mg	
System organ class/ Preferred term	N	(%)	N	(%)
Spondylolisthesis (脊椎すべり症)	2	(0.7)	0	(0.0)
Cervical spinal stenosis (頸部脊柱管狭窄症)	0	(0.0)	1	(0.4)
Chondrosis (軟骨症)	1	(0.4)	0	(0.0)
Exostosis (外骨腫)	1	(0.4)	0	(0.0)
Intervertebral disc protrusion (椎間板突出)	1	(0.4)	0	(0.0)
Monarthritis (単関節炎)	0	(0.0)	1	(0.4)
Muscle fatigue (筋肉疲労)	0	(0.0)	1	(0.4)
Muscle spasms (筋痙縮)	0	(0.0)	1	(0.4)
Muscular weakness (筋力低下)	0	(0.0)	1	(0.4)
Musculoskeletal pain (筋骨格痛)	1	(0.4)	0	(0.0)
Spondylolysis (脊椎分離)	0	(0.0)	1	(0.4)
Tendon calcification (腱石灰化)	0	(0.0)	1	(0.4)
Tendonitis (腱炎)	1	(0.4)	1	(0.4)
Tenosynovitis (腱鞘炎)	0	(0.0)	1	(0.4)
Trigger finger (弾発指)	1	(0.4)	1	(0.4)
Renal and urinary disorders (腎および尿路障害)	13	(4.9)	13	(4.9)
Pollakiuria (頻尿)	4	(1.5)	10	(3.8)
Nephrolithiasis (腎結石症)	2	(0.7)	1	(0.4)
Diabetic nephropathy (糖尿病性腎症)	1	(0.4)	0	(0.0)
Haematuria (血尿)	1	(0.4)	0	(0.0)
Hypertonic bladder (緊張性膀胱)	1	(0.4)	0	(0.0)
Micturition urgency (尿意切迫)	1	(0.4)	0	(0.0)
Nocturia (夜間頻尿)	1	(0.4)	1	(0.4)
Polyuria (多尿)	1	(0.4)	1	(0.4)
Urethral caruncle (尿道カルンクル)	1	(0.4)	0	(0.0)
Reproductive system and breast disorders (生殖系および乳房障害)	6	(2.2)	5	(1.9)
Balanitis (亀頭炎)	3	(1.1)	0	(0.0)
Benign prostatic hyperplasia (良性前立腺肥大症)	0	(0.0)	3	(1.1)
Breast disorder (乳房障害)	1	(0.4)	0	(0.0)
Cervical polyp (子宮頸管ポリープ)	1	(0.4)	0	(0.0)
Genital haemorrhage (性器出血)	0	(0.0)	1	(0.4)
Prostatitis (前立腺炎)	1	(0.4)	1	(0.4)
Vulvovaginal discomfort (外陰膣不快感)	0	(0.0)	1	(0.4)
Vulvovaginal pruritus (外陰膣そう痒症)	1	(0.4)	0	(0.0)
Congenital, familial and genetic disorders (先天性、家族性および遺伝性障害)	0	(0.0)	2	(0.8)

	Empa 10mg		Empa 25mg	
System organ class/ Preferred term	N	(%)	N	(%)
Congenital hip deformity (先天性股関節変形)	0	(0.0)	1	(0.4)
Hip dysplasia (股関節形成不全)	0	(0.0)	1	(0.4)
General disorders and administration site conditions (一般・全身障害および投与部位の状態)	12	(4.5)	13	(4.9)
Thirst (口渇)	3	(1.1)	8	(3.0)
Chest pain (胸痛)	2	(0.7)	1	(0.4)
Asthenia (無力症)	1	(0.4)	0	(0.0)
Device dislocation (医療機器位置異常)	0	(0.0)	1	(0.4)
Device expulsion (医療機器圧出)	1	(0.4)	0	(0.0)
Fatigue (疲労)	1	(0.4)	0	(0.0)
Feeling abnormal (異常感)	1	(0.4)	1	(0.4)
Hunger (空腹)	0	(0.0)	1	(0.4)
Hyperthermia (高熱)	1	(0.4)	0	(0.0)
Inflammation (炎症)	1	(0.4)	0	(0.0)
Malaise (倦怠感)	1	(0.4)	1	(0.4)
Pyrexia (発熱)	0	(0.0)	1	(0.4)
Investigations (臨床検査)	19	(7.1)	12	(4.5)
Glycosylated haemoglobin increased (グリコヘモグロビン増加)	7	(2.6)	2	(0.8)
Weight decreased (体重減少)	6	(2.2)	6	(2.3)
Electrocardiogram ST segment depression (心電図 S T 部分下降)	2	(0.7)	0	(0.0)
Alanine aminotransferase increased (アラニンアミノトランスフェラーゼ増加)	1	(0.4)	0	(0.0)
Albumin urine present (尿中アルブミン陽性)	1	(0.4)	0	(0.0)
Aspartate aminotransferase increased (アスパラギン酸アミノトランスフェラーゼ増加)	1	(0.4)	0	(0.0)
Blood ketone body present (血中ケトン体陽性)	0	(0.0)	1	(0.4)
Carbohydrate antigen 19-9 increased (糖鎖抗原 19 - 9 増加)	0	(0.0)	1	(0.4)
Electrocardiogram QT prolonged (心電図 Q T 延長)	0	(0.0)	1	(0.4)
Heart rate irregular (心拍数不整)	0	(0.0)	1	(0.4)
Lipase increased (リパーゼ増加)	1	(0.4)	1	(0.4)
Prostatic specific antigen increased (前立腺特異性抗原増加)	1	(0.4)	1	(0.4)
Urine ketone body present (尿中ケトン体陽性)	1	(0.4)	1	(0.4)
Injury, poisoning and procedural complications (傷害、中毒および処置合併症)	16	(6.0)	14	(5.3)
Fall (転倒)	9	(3.4)	4	(1.5)

	Empa 10mg		Empa 25mg	
System organ class/ Preferred term	N	(%)	N	(%)
Contusion (挫傷)	6	(2.2)	4	(1.5)
Tooth fracture (齒牙破折)	3	(1.1)	1	(0.4)
Arthropod sting (節足動物刺傷)	0	(0.0)	2	(0.8)
Road traffic accident (交通事故)	0	(0.0)	2	(0.8)
Excoriation (擦過傷)	2	(0.7)	0	(0.0)
Laceration (裂傷)	2	(0.7)	1	(0.4)
Ankle fracture (足關節部骨折)	0	(0.0)	1	(0.4)
Avulsion fracture (剝離骨折)	1	(0.4)	0	(0.0)
Corneal abrasion (角膜擦過傷)	0	(0.0)	1	(0.4)
Heat stroke (熱射病)	0	(0.0)	1	(0.4)
Joint dislocation (關節脫臼)	0	(0.0)	1	(0.4)
Ligament injury (韌帶損傷)	0	(0.0)	1	(0.4)
Ligament sprain (韌帶捻挫)	1	(0.4)	1	(0.4)
Post-traumatic neck syndrome (外傷後頸部症候群)	0	(0.0)	1	(0.4)
Rib fracture (肋骨骨折)	0	(0.0)	1	(0.4)
Thermal burn (熱傷)	0	(0.0)	1	(0.4)
Tibia fracture (脛骨骨折)	1	(0.4)	0	(0.0)
Tooth injury (齒牙損傷)	0	(0.0)	1	(0.4)
Ulna fracture (尺骨骨折)	1	(0.4)	0	(0.0)

Percentages are calculated using total number of patients per treatment as the denominator.

Containing data from study 1245_p038

MedDRA version used for reporting: [REDACTED]

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Table 5.1.3.2 Frequency [N (%)] of patients with related adverse events by treatment, primary system organ class and preferred term - treated set - all

BI 10mg and all BI 25 mg for 52 weeks

System organ class/ Preferred term	Empa 10mg		Empa 25mg	
	N	(%)	N	(%)
Number of patients	267	(100.0)	265	(100.0)
Total with related adverse events	37	(13.9)	38	(14.3)
Infections and infestations (感染症および寄生虫症)	8	(3.0)	3	(1.1)
Urinary tract infection (尿路感染)	4	(1.5)	2	(0.8)
Cystitis (膀胱炎)	3	(1.1)	0	(0.0)
Diverticulitis (憩室炎)	0	(0.0)	1	(0.4)
Vaginitis bacterial (細菌性膣炎)	1	(0.4)	0	(0.0)
Vulvovaginal candidiasis (外陰部膣カンジダ症)	1	(0.4)	0	(0.0)
Vulvovaginitis (外陰部膣炎)	1	(0.4)	0	(0.0)
Blood and lymphatic system disorders (血液およびリンパ系障害)	0	(0.0)	3	(1.1)
Haemoconcentration (血液濃縮)	0	(0.0)	2	(0.8)
Anaemia (貧血)	0	(0.0)	1	(0.4)
Metabolism and nutrition disorders (代謝および栄養障害)	7	(2.6)	4	(1.5)
Hypoglycaemia (低血糖症)	4	(1.5)	3	(1.1)
Dehydration (脱水)	2	(0.7)	0	(0.0)
Hyperglycaemia (高血糖)	0	(0.0)	1	(0.4)
Hyperlipidaemia (高脂血症)	1	(0.4)	0	(0.0)
Nervous system disorders (神経系障害)	0	(0.0)	1	(0.4)
Dizziness (浮動性めまい)	0	(0.0)	1	(0.4)
Ear and labyrinth disorders (耳および迷路障害)	0	(0.0)	1	(0.4)
Sudden hearing loss (突発難聴)	0	(0.0)	1	(0.4)
Gastrointestinal disorders (胃腸障害)	2	(0.7)	9	(3.4)
Constipation (便秘)	0	(0.0)	7	(2.6)
Abdominal distension (腹部膨満)	1	(0.4)	1	(0.4)
Colonic polyp (結腸ポリープ)	1	(0.4)	0	(0.0)
Diarrhoea (下痢)	0	(0.0)	1	(0.4)
Haemorrhoids (痔核)	0	(0.0)	1	(0.4)
Hepatobiliary disorders (肝胆道系障害)	0	(0.0)	1	(0.4)
Hepatic function abnormal (肝機能異常)	0	(0.0)	1	(0.4)
Skin and subcutaneous tissue disorders (皮膚および皮下組織障害)	2	(0.7)	3	(1.1)
Alopecia (脱毛症)	1	(0.4)	0	(0.0)
Dry skin (皮膚乾燥)	0	(0.0)	1	(0.4)

	Empa 10mg		Empa 25mg	
System organ class/ Preferred term	N	(%)	N	(%)
Eczema (湿疹)	1	(0.4)	0	(0.0)
Hyperhidrosis (多汗症)	0	(0.0)	1	(0.4)
Urticaria (蕁麻疹)	0	(0.0)	1	(0.4)
Musculoskeletal and connective tissue disorders (筋骨格系および結合組織障害)	0	(0.0)	1	(0.4)
Muscle fatigue (筋肉疲労)	0	(0.0)	1	(0.4)
Renal and urinary disorders (腎および尿路障害)	9	(3.4)	10	(3.8)
Pollakiuria (頻尿)	4	(1.5)	9	(3.4)
Micturition urgency (尿意切迫)	1	(0.4)	0	(0.0)
Nephrolithiasis (腎結石症)	1	(0.4)	0	(0.0)
Nocturia (夜間頻尿)	1	(0.4)	0	(0.0)
Polyuria (多尿)	1	(0.4)	1	(0.4)
Urethral caruncle (尿道カルンクル)	1	(0.4)	0	(0.0)
Reproductive system and breast disorders (生殖系および乳房障害)	4	(1.5)	1	(0.4)
Balanitis (亀頭炎)	3	(1.1)	0	(0.0)
Vulvovaginal discomfort (外陰腔不快感)	0	(0.0)	1	(0.4)
Vulvovaginal pruritus (外陰腔そう痒症)	1	(0.4)	0	(0.0)
General disorders and administration site conditions (一般・全身障害および投与部位の状態)	3	(1.1)	10	(3.8)
Thirst (口渇)	3	(1.1)	8	(3.0)
Hunger (空腹)	0	(0.0)	1	(0.4)
Malaise (倦怠感)	0	(0.0)	1	(0.4)
Investigations (臨床検査)	8	(3.0)	7	(2.6)
Weight decreased (体重減少)	6	(2.2)	6	(2.3)
Blood ketone body present (血中ケトン体陽性)	0	(0.0)	1	(0.4)
Electrocardiogram QT prolonged (心電図QT延長)	0	(0.0)	1	(0.4)
Electrocardiogram ST segment depression (心電図ST部分下降)	1	(0.4)	0	(0.0)
Urine ketone body present (尿中ケトン体陽性)	1	(0.4)	1	(0.4)

Percentages are calculated using total number of patients per treatment as the denominator.

Containing data from study 1245_p038

MedDRA version used for reporting: [REDACTED]

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Table 6.1.1 Frequency [N (%)] of patients with adverse events by background medication at screening, treatment, primary system organ class and preferred term - treated set

Background medication at screening=Sulfonylurea

	Empa 10mg		Empa 25mg		Metformin		Total	
System organ class/ Preferred term	N	(%)	N	(%)	N	(%)	N	(%)
Number of patients	136	(100.0)	137	(100.0)	63	(100.0)	336	(100.0)
Total with adverse events	105	(77.2)	106	(77.4)	54	(85.7)	265	(78.9)
Infections and infestations (感染症および寄生虫症)	60	(44.1)	61	(44.5)	36	(57.1)	157	(46.7)
Nasopharyngitis (鼻咽頭炎)	41	(30.1)	38	(27.7)	26	(41.3)	105	(31.3)
Influenza (インフルエンザ)	1	(0.7)	2	(1.5)	5	(7.9)	8	(2.4)
Bronchitis (気管支炎)	7	(5.1)	0	(0.0)	0	(0.0)	7	(2.1)
Pharyngitis (咽頭炎)	3	(2.2)	7	(5.1)	2	(3.2)	12	(3.6)
Gastroenteritis (胃腸炎)	1	(0.7)	4	(2.9)	2	(3.2)	7	(2.1)
Cystitis (膀胱炎)	3	(2.2)	4	(2.9)	1	(1.6)	8	(2.4)
Cellulitis (蜂巣炎)	3	(2.2)	2	(1.5)	0	(0.0)	5	(1.5)
Upper respiratory tract infection (上気道感染)	2	(1.5)	3	(2.2)	1	(1.6)	6	(1.8)
Acute sinusitis (急性副鼻腔炎)	0	(0.0)	0	(0.0)	1	(1.6)	1	(0.3)
Gingivitis (歯肉炎)	2	(1.5)	2	(1.5)	1	(1.6)	5	(1.5)
Herpes zoster (帯状疱疹)	1	(0.7)	0	(0.0)	1	(1.6)	2	(0.6)
Infected dermal cyst (感染性皮膚嚢腫)	1	1245_0	0	(0.0)	1	(1.6)	2	(0.6)
Oral candidiasis (口腔カンジダ症)	0	(0.0)	0	(0.0)	1	(1.6)	1	(0.3)
Periodontitis (歯周炎)	0	(0.0)	1	(0.7)	1	(1.6)	2	(0.6)
Tooth infection (歯感染)	0	(0.0)	0	(0.0)	1	(1.6)	1	(0.3)
Urinary tract infection (尿路感染)	2	(1.5)	2	(1.5)	1	(1.6)	5	(1.5)
Anal abscess (肛門膿瘍)	0	(0.0)	1	(0.7)	0	(0.0)	1	(0.3)
Asymptomatic bacteriuria (無症候性細菌尿)	0	(0.0)	1	(0.7)	0	(0.0)	1	(0.3)
Bacterial diarrhoea (細菌性下痢)	0	(0.0)	1	(0.7)	0	(0.0)	1	(0.3)
Enterocolitis viral (ウイルス性腸炎)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.3)
Gastroenteritis bacterial (細菌性胃腸炎)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.3)
Gastroenteritis viral (ウイルス性胃腸炎)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.3)
Gingival abscess (歯肉膿瘍)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.3)
Helicobacter infection (ヘリコバクター感染)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.3)
Hordeolum (麦粒腫)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.3)
Laryngitis (喉頭炎)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.3)
Otitis externa (外耳炎)	0	(0.0)	1	(0.7)	0	(0.0)	1	(0.3)
Otitis media (中耳炎)	0	(0.0)	1	(0.7)	0	(0.0)	1	(0.3)
Paronychia (爪囲炎)	1	(0.7)	1	(0.7)	0	(0.0)	2	(0.6)
Pulmonary tuberculosis (肺結核)	0	(0.0)	1	(0.7)	0	(0.0)	1	(0.3)
Purulence (化膿)	0	(0.0)	1	(0.7)	0	(0.0)	1	(0.3)
Pyelonephritis (腎盂腎炎)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.3)
Rhinitis (鼻炎)	0	(0.0)	1	(0.7)	0	(0.0)	1	(0.3)
Sinusitis (副鼻腔炎)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.3)
Skin candida (皮膚カンジダ)	0	(0.0)	1	(0.7)	0	(0.0)	1	(0.3)
Tinea infection (白癬感染)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.3)
Tinea pedis (足部白癬)	1	(0.7)	1	(0.7)	0	(0.0)	2	(0.6)
Trichophytosis (トリコフィトン感染症)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.3)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (良性、悪性および詳細不明の新生物 (嚢胞およびポリープを含む))	2	(1.5)	2	(1.5)	3	(4.8)	7	(2.1)
Colon cancer (結腸癌)	0	(0.0)	0	(0.0)	1	(1.6)	1	(0.3)
Gastric cancer (胃癌)	0	(0.0)	1	(0.7)	1	(1.6)	2	(0.6)

	Empa 10mg		Empa 25mg		Metformin		Total	
System organ class/ Preferred term	N	(%)	N	(%)	N	(%)	N	(%)
Lung neoplasm malignant (肺の悪性新生物)	0	(0.0)	0	(0.0)	1	(1.6)	1	(0.3)
Gastric adenoma (胃腺腫)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.3)
Prostate cancer (前立腺癌)	1	(0.7)	1	(0.7)	0	(0.0)	2	(0.6)
Immune system disorders (免疫系障害)	0	(0.0)	1	(0.7)	0	(0.0)	1	(0.3)
Seasonal allergy (季節性アレルギー)	0	(0.0)	1	(0.7)	0	(0.0)	1	(0.3)
Metabolism and nutrition disorders (代謝および栄養障害)	13	(9.6)	13	(9.5)	7	(11.1)	33	(9.8)
Hypoglycaemia (低血糖症)	11	(8.1)	12	(8.8)	6	(9.5)	29	(8.6)
Hyperglycaemia (高血糖)	0	(0.0)	1	(0.7)	1	(1.6)	2	(0.6)
Dyslipidaemia (脂質異常症)	2	(1.5)	0	(0.0)	0	(0.0)	2	(0.6)
Psychiatric disorders (精神障害)	3	(2.2)	5	(3.6)	1	(1.6)	9	(2.7)
Insomnia (不眠症)	2	(1.5)	5	(3.6)	1	(1.6)	8	(2.4)
Restlessness (落ち着きのなさ)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.3)
Nervous system disorders (神経系障害)	11	(8.1)	11	(8.0)	4	(6.3)	26	(7.7)
Headache (頭痛)	5	(3.7)	2	(1.5)	0	(0.0)	7	(2.1)
Dizziness (浮動性めまい)	2	(1.5)	2	(1.5)	2	(3.2)	6	(1.8)
Cervicobrachial syndrome (頸腕症候群)	0	(0.0)	1	(0.7)	1	(1.6)	2	(0.6)
Tremor (振戦)	1	(0.7)	1	(0.7)	1	(1.6)	3	(0.9)
Carotid arteriosclerosis (頸動脈硬化症)	2	(1.5)	0	(0.0)	0	(0.0)	2	(0.6)
Dysgeusia (味覚異常)	0	(0.0)	1	(0.7)	0	(0.0)	1	(0.3)
Hypoaesthesia (感覚鈍麻)	1	(0.7)	1	(0.7)	0	(0.0)	2	(0.6)
Intracranial aneurysm (頭蓋内動脈瘤)	0	(0.0)	1	(0.7)	0	(0.0)	1	(0.3)
Lacunar infarction (ラクナ梗塞)	0	(0.0)	1	(0.7)	0	(0.0)	1	(0.3)
Neuralgia (神経痛)	0	(0.0)	1	(0.7)	0	(0.0)	1	(0.3)
Tension headache (緊張性頭痛)	0	(0.0)	1	(0.7)	0	(0.0)	1	(0.3)
Eye disorders (眼障害)	6	(4.4)	10	(7.3)	4	(6.3)	20	(6.0)
Cataract (白内障)	1	(0.7)	4	(2.9)	0	(0.0)	5	(1.5)
Glaucoma (緑内障)	0	(0.0)	3	(2.2)	0	(0.0)	3	(0.9)
Asthenopia (眼精疲労)	1	(0.7)	0	(0.0)	1	(1.6)	2	(0.6)
Chalazion (霰粒腫)	0	(0.0)	0	(0.0)	1	(1.6)	1	(0.3)
Diabetic retinopathy (糖尿病網膜症)	0	(0.0)	1	(0.7)	1	(1.6)	2	(0.6)
Eye discharge (眼脂)	0	(0.0)	0	(0.0)	1	(1.6)	1	(0.3)
Retinal oedema (網膜浮腫)	0	(0.0)	0	(0.0)	1	(1.6)	1	(0.3)
Conjunctival haemorrhage (結膜出血)	0	(0.0)	2	(1.5)	0	(0.0)	2	(0.6)
Arteriosclerotic retinopathy (動脈硬化性網膜症)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.3)
Conjunctivitis allergic (アレルギー性結膜炎)	0	(0.0)	1	(0.7)	0	(0.0)	1	(0.3)
Conjunctivochalasis (結膜弛緩症)	0	(0.0)	1	(0.7)	0	(0.0)	1	(0.3)
Dry eye (眼乾燥)	0	(0.0)	1	(0.7)	0	(0.0)	1	(0.3)
Keratitis (角膜炎)	0	(0.0)	1	(0.7)	0	(0.0)	1	(0.3)
Macular oedema (黄斑浮腫)	0	(0.0)	1	(0.7)	0	(0.0)	1	(0.3)
Normal tension glaucoma (正常眼圧緑内障)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.3)
Retinal detachment (網膜剥離)	0	(0.0)	1	(0.7)	0	(0.0)	1	(0.3)
Vision blurred (霧視)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.3)
Vitreous detachment (硝子体剥離)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.3)
Ear and labyrinth disorders (耳および迷路障害)	5	(3.7)	8	(5.8)	0	(0.0)	13	(3.9)
Tinnitus (耳鳴)	2	(1.5)	3	(2.2)	0	(0.0)	5	(1.5)
Vertigo (回転性めまい)	1	(0.7)	2	(1.5)	0	(0.0)	3	(0.9)
Deafness (難聴)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.3)
Meniere's disease (メニエール病)	0	(0.0)	1	(0.7)	0	(0.0)	1	(0.3)
Motion sickness (乗物酔い)	0	(0.0)	1	(0.7)	0	(0.0)	1	(0.3)

	Empa 10mg		Empa 25mg		Metformin		Total	
System organ class/ Preferred term	N	(%)	N	(%)	N	(%)	N	(%)
Sudden hearing loss (突発難聴)	0	(0.0)	1	(0.7)	0	(0.0)	1	(0.3)
Vertigo positional (頭位性回転性めまい)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.3)
Cardiac disorders (心臓障害)	5	(3.7)	5	(3.6)	1	(1.6)	11	(3.3)
Supraventricular extrasystoles (上室性期外収縮)	0	(0.0)	0	(0.0)	1	(1.6)	1	(0.3)
Ventricular extrasystoles (心室性期外収縮)	0	(0.0)	1	(0.7)	1	(1.6)	2	(0.6)
Atrial fibrillation (心房細動)	0	(0.0)	2	(1.5)	0	(0.0)	2	(0.6)
Acute myocardial infarction (急性心筋梗塞)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.3)
Angina pectoris (狭心症)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.3)
Arteriosclerosis coronary artery (冠動脈硬化症)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.3)
Cardiac failure congestive (うっ血性心不全)	0	(0.0)	1	(0.7)	0	(0.0)	1	(0.3)
Myocardial ischaemia (心筋虚血)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.3)
Palpitations (動悸)	1	(0.7)	1	(0.7)	0	(0.0)	2	(0.6)
Sinus arrest (洞停止)	0	(0.0)	1	(0.7)	0	(0.0)	1	(0.3)
Sinus bradycardia (洞性徐脈)	0	(0.0)	1	(0.7)	0	(0.0)	1	(0.3)
Vascular disorders (血管障害)	5	(3.7)	6	(4.4)	1	(1.6)	12	(3.6)
Hypertension (高血圧)	1	(0.7)	4	(2.9)	1	(1.6)	6	(1.8)
Arteriosclerosis (動脈硬化症)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.3)
Artery dissection (動脈解離)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.3)
Hypotension (低血圧)	1	(0.7)	1	(0.7)	0	(0.0)	2	(0.6)
Orthostatic hypotension (起立性低血圧)	1	(0.7)	1	(0.7)	0	(0.0)	2	(0.6)
Peripheral arterial occlusive disease (末梢動脈閉塞性疾患)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.3)
Respiratory, thoracic and mediastinal disorders (呼吸器、 胸郭および縦隔障害)	13	(9.6)	14	(10.2)	7	(11.1)	34	(10.1)
Upper respiratory tract inflammation (上気道の炎症)	7	(5.1)	6	(4.4)	4	(6.3)	17	(5.1)
Rhinitis allergic (アレルギー性鼻炎)	1	(0.7)	3	(2.2)	0	(0.0)	4	(1.2)
Asthma (喘息)	2	(1.5)	1	(0.7)	1	(1.6)	4	(1.2)
Epistaxis (鼻出血)	0	(0.0)	1	(0.7)	1	(1.6)	2	(0.6)
Productive cough (湿性咳嗽)	0	(0.0)	0	(0.0)	1	(1.6)	1	(0.3)
Oropharyngeal pain (口腔咽頭痛)	2	(1.5)	2	(1.5)	0	(0.0)	4	(1.2)
Bronchitis chronic (慢性気管支炎)	0	(0.0)	1	(0.7)	0	(0.0)	1	(0.3)
Haemoptysis (喀血)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.3)
Sleep apnoea syndrome (睡眠時無呼吸症候群)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.3)
Gastrointestinal disorders (胃腸障害)	36	(26.5)	23	(16.8)	18	(28.6)	77	(22.9)
Diarrhoea (下痢)	2	(1.5)	2	(1.5)	5	(7.9)	9	(2.7)
Gastrooesophageal reflux disease (胃食道逆流性疾患)	3	(2.2)	0	(0.0)	3	(4.8)	6	(1.8)
Dental caries (齲歯)	6	(4.4)	2	(1.5)	1	(1.6)	9	(2.7)
Constipation (便秘)	5	(3.7)	5	(3.6)	2	(3.2)	12	(3.6)
Abdominal pain upper (上腹部痛)	1	(0.7)	1	(0.7)	2	(3.2)	4	(1.2)
Gastritis (胃炎)	3	(2.2)	2	(1.5)	2	(3.2)	7	(2.1)
Abdominal discomfort (腹部不快感)	3	(2.2)	0	(0.0)	0	(0.0)	3	(0.9)
Stomatitis (口内炎)	3	(2.2)	2	(1.5)	0	(0.0)	5	(1.5)
Cheilitis (口唇炎)	1	(0.7)	0	(0.0)	1	(1.6)	2	(0.6)
Dyspepsia (消化不良)	0	(0.0)	1	(0.7)	1	(1.6)	2	(0.6)
Enterocolitis (腸炎)	0	(0.0)	0	(0.0)	1	(1.6)	1	(0.3)
Flatulence (鼓腸)	0	(0.0)	0	(0.0)	1	(1.6)	1	(0.3)
Gastritis atrophic (萎縮性胃炎)	1	(0.7)	1	(0.7)	1	(1.6)	3	(0.9)
Gastritis erosive (びらん性胃炎)	1	(0.7)	0	(0.0)	1	(1.6)	2	(0.6)
Hiatus hernia (裂孔ヘルニア)	0	(0.0)	1	(0.7)	1	(1.6)	2	(0.6)

	Empa 10mg		Empa 25mg		Metformin		Total	
System organ class/ Preferred term	N	(%)	N	(%)	N	(%)	N	(%)
Infrequent bowel movements (排便回数減少)	0	(0.0)	0	(0.0)	1	(1.6)	1	(0.3)
Nausea (悪心)	0	(0.0)	0	(0.0)	1	(1.6)	1	(0.3)
Toothache (歯痛)	1	(0.7)	0	(0.0)	1	(1.6)	2	(0.6)
Abdominal pain (腹痛)	2	(1.5)	0	(0.0)	0	(0.0)	2	(0.6)
Colitis (大腸炎)	2	(1.5)	0	(0.0)	0	(0.0)	2	(0.6)
Haemorrhoids (痔核)	2	(1.5)	2	(1.5)	0	(0.0)	4	(1.2)
Abdominal distension (腹部膨満)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.3)
Colitis ulcerative (潰瘍性大腸炎)	0	(0.0)	1	(0.7)	0	(0.0)	1	(0.3)
Dental discomfort (歯不快感)	0	(0.0)	1	(0.7)	0	(0.0)	1	(0.3)
Duodenal polyp (十二指腸ポリープ)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.3)
Eructation (おくび)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.3)
Gastric ulcer (胃潰瘍)	0	(0.0)	1	(0.7)	0	(0.0)	1	(0.3)
Gastrointestinal disorder (胃腸障害)	0	(0.0)	1	(0.7)	0	(0.0)	1	(0.3)
Leukoplakia oral (口腔内白斑症)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.3)
Lumbar hernia (腰ヘルニア)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.3)
Megacolon (巨大結腸)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.3)
Periodontal disease (歯周病)	1	(0.7)	1	(0.7)	0	(0.0)	2	(0.6)
Proctalgia (肛門周囲痛)	0	(0.0)	1	(0.7)	0	(0.0)	1	(0.3)
Vomiting (嘔吐)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.3)
Hepatobiliary disorders (肝胆道系障害)	4	(2.9)	0	(0.0)	1	(1.6)	5	(1.5)
Hepatic function abnormal (肝機能異常)	0	(0.0)	0	(0.0)	1	(1.6)	1	(0.3)
Hepatic steatosis (脂肪肝)	2	(1.5)	0	(0.0)	0	(0.0)	2	(0.6)
Drug-induced liver injury (薬物性肝障害)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.3)
Hyperplastic cholecystopathy (過形成性胆嚢症)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.3)
Skin and subcutaneous tissue disorders (皮膚および皮下組織障害)	14	(10.3)	12	(8.8)	5	(7.9)	31	(9.2)
Eczema (湿疹)	6	(4.4)	3	(2.2)	1	(1.6)	10	(3.0)
Dermatitis contact (接触性皮膚炎)	1	(0.7)	2	(1.5)	2	(3.2)	5	(1.5)
Heat rash (紅色汗疹)	0	(0.0)	3	(2.2)	0	(0.0)	3	(0.9)
Hyperkeratosis (過角化)	0	(0.0)	3	(2.2)	0	(0.0)	3	(0.9)
Cold sweat (冷汗)	0	(0.0)	0	(0.0)	1	(1.6)	1	(0.3)
Rash (発疹)	2	(1.5)	1	(0.7)	1	(1.6)	4	(1.2)
Urticaria (蕁麻疹)	2	(1.5)	1	(0.7)	0	(0.0)	3	(0.9)
Dermatitis allergic (アレルギー性皮膚炎)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.3)
Dyshidrosis (発汗障害)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.3)
Erythema (紅斑)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.3)
Pruritus (そう痒症)	1	(0.7)	1	(0.7)	0	(0.0)	2	(0.6)
Musculoskeletal and connective tissue disorders (筋骨格系および結合組織障害)	22	(16.2)	20	(14.6)	10	(15.9)	52	(15.5)
Back pain (背部痛)	3	(2.2)	7	(5.1)	1	(1.6)	11	(3.3)
Arthralgia (関節痛)	6	(4.4)	2	(1.5)	3	(4.8)	11	(3.3)
Periarthritis (関節周囲炎)	1	(0.7)	0	(0.0)	2	(3.2)	3	(0.9)
Trigger finger (弾発指)	0	(0.0)	0	(0.0)	2	(3.2)	2	(0.6)
Pain in extremity (四肢痛)	3	(2.2)	2	(1.5)	1	(1.6)	6	(1.8)
Fasciitis (筋膜炎)	0	(0.0)	0	(0.0)	1	(1.6)	1	(0.3)
Myalgia (筋肉痛)	0	(0.0)	0	(0.0)	1	(1.6)	1	(0.3)
Spinal osteoarthritis (変形性脊椎症)	0	(0.0)	2	(1.5)	1	(1.6)	3	(0.9)
Intervertebral disc protrusion (椎間板突出)	2	(1.5)	1	(0.7)	0	(0.0)	3	(0.9)
Lumbar spinal stenosis (腰部脊柱管狭窄症)	2	(1.5)	1	(0.7)	0	(0.0)	3	(0.9)
Musculoskeletal stiffness (筋骨格硬直)	2	(1.5)	0	(0.0)	0	(0.0)	2	(0.6)

	Empa 10mg		Empa 25mg		Metformin		Total	
System organ class/ Preferred term	N	(%)	N	(%)	N	(%)	N	(%)
Osteoarthritis (変形性関節症)	0	(0.0)	2	(1.5)	0	(0.0)	2	(0.6)
Arthritis (関節炎)	0	(0.0)	1	(0.7)	0	(0.0)	1	(0.3)
Dupuytren's contracture (デュブイトラン拘縮)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.3)
Gouty arthritis (痛風性関節炎)	0	(0.0)	1	(0.7)	0	(0.0)	1	(0.3)
Muscle spasms (筋痙縮)	0	(0.0)	1	(0.7)	0	(0.0)	1	(0.3)
Musculoskeletal chest pain (筋骨格系胸痛)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.3)
Musculoskeletal discomfort (筋骨格不快感)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.3)
Musculoskeletal pain (筋骨格痛)	1	(0.7)	1	(0.7)	0	(0.0)	2	(0.6)
Spinal column stenosis (脊柱管狭窄症)	0	(0.0)	1	(0.7)	0	(0.0)	1	(0.3)
Synovial cyst (滑液嚢腫)	0	(0.0)	1	(0.7)	0	(0.0)	1	(0.3)
Tendonitis (腱炎)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.3)
Tenosynovitis (腱鞘炎)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.3)
Renal and urinary disorders (腎および尿路障害)	10	(7.4)	7	(5.1)	3	(4.8)	20	(6.0)
Pollakiuria (頻尿)	3	(2.2)	6	(4.4)	0	(0.0)	9	(2.7)
Diabetic nephropathy (糖尿病性腎症)	1	(0.7)	0	(0.0)	2	(3.2)	3	(0.9)
Nephrocalcinosis (腎石灰沈着症)	0	(0.0)	0	(0.0)	1	(1.6)	1	(0.3)
Haematuria (血尿)	2	(1.5)	0	(0.0)	0	(0.0)	2	(0.6)
Nocturia (夜間頻尿)	2	(1.5)	0	(0.0)	0	(0.0)	2	(0.6)
Hydronephrosis (水腎症)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.3)
Hypertonic bladder (緊張性膀胱)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.3)
Nephrolithiasis (腎結石症)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.3)
Terminal dribbling (終末尿滴下)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.3)
Urinary incontinence (尿失禁)	0	(0.0)	1	(0.7)	0	(0.0)	1	(0.3)
Reproductive system and breast disorders (生殖系および乳房障害)	4	(2.9)	2	(1.5)	1	(1.6)	7	(2.1)
Epididymitis (精巣上体炎)	1	(0.7)	0	(0.0)	1	(1.6)	2	(0.6)
Benign prostatic hyperplasia (良性前立腺肥大症)	2	(1.5)	2	(1.5)	0	(0.0)	4	(1.2)
Balanoposthitis (亀頭包皮炎)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.3)
Pruritus genital (陰部そう痒症)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.3)
Congenital, familial and genetic disorders (先天性、家族性および遺伝性障害)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.3)
Congenital cystic kidney disease (先天性嚢胞性腎疾患)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.3)
General disorders and administration site conditions (一般・全身障害および投与部位の状態)	7	(5.1)	9	(6.6)	2	(3.2)	18	(5.4)
Malaise (倦怠感)	2	(1.5)	3	(2.2)	1	(1.6)	6	(1.8)
Oedema peripheral (末梢性浮腫)	0	(0.0)	0	(0.0)	1	(1.6)	1	(0.3)
Feeling abnormal (異常感)	0	(0.0)	2	(1.5)	0	(0.0)	2	(0.6)
Hunger (空腹)	0	(0.0)	2	(1.5)	0	(0.0)	2	(0.6)
Thirst (口渇)	2	(1.5)	0	(0.0)	0	(0.0)	2	(0.6)
Asthenia (無力症)	0	(0.0)	1	(0.7)	0	(0.0)	1	(0.3)
Chest discomfort (胸部不快感)	0	(0.0)	1	(0.7)	0	(0.0)	1	(0.3)
Chest pain (胸痛)	1	(0.7)	1	(0.7)	0	(0.0)	2	(0.6)
Device failure (医療機器不具合)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.3)
Feeling cold (冷感)	0	(0.0)	1	(0.7)	0	(0.0)	1	(0.3)
Feeling hot (熱感)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.3)
Investigations (臨床検査)	6	(4.4)	2	(1.5)	1	(1.6)	9	(2.7)
Occult blood positive (便潜血陽性)	0	(0.0)	0	(0.0)	1	(1.6)	1	(0.3)
Blood pressure decreased (血圧低下)	2	(1.5)	0	(0.0)	0	(0.0)	2	(0.6)
Blood potassium increased (血中カリウム増加)	0	(0.0)	1	(0.7)	0	(0.0)	1	(0.3)
Blood pressure increased (血圧上昇)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.3)

	Empa 10mg		Empa 25mg		Metformin		Total	
System organ class/ Preferred term	N	(%)	N	(%)	N	(%)	N	(%)
Electrocardiogram QT prolonged (心電図QT延長)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.3)
Urine output increased (尿量増加)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.3)
Weight decreased (体重減少)	1	(0.7)	1	(0.7)	0	(0.0)	2	(0.6)
Injury, poisoning and procedural complications (傷害、中毒および処置合併症)	13	(9.6)	12	(8.8)	9	(14.3)	34	(10.1)
Fall (転倒)	4	(2.9)	6	(4.4)	5	(7.9)	15	(4.5)
Contusion (挫傷)	2	(1.5)	3	(2.2)	4	(6.3)	9	(2.7)
Epicondylitis (上顆炎)	0	(0.0)	0	(0.0)	1	(1.6)	1	(0.3)
Foot fracture (足骨折)	1	(0.7)	0	(0.0)	1	(1.6)	2	(0.6)
Heat stroke (熱射病)	0	(0.0)	0	(0.0)	1	(1.6)	1	(0.3)
Ligament sprain (靱帯捻挫)	0	(0.0)	2	(1.5)	1	(1.6)	3	(0.9)
Radius fracture (橈骨骨折)	0	(0.0)	0	(0.0)	1	(1.6)	1	(0.3)
Arthropod sting (節足動物刺傷)	0	(0.0)	2	(1.5)	0	(0.0)	2	(0.6)
Excoriation (擦過傷)	1	(0.7)	2	(1.5)	0	(0.0)	3	(0.9)
Laceration (裂傷)	2	(1.5)	2	(1.5)	0	(0.0)	4	(1.2)
Road traffic accident (交通事故)	2	(1.5)	0	(0.0)	0	(0.0)	2	(0.6)
Ankle fracture (足関節部骨折)	0	(0.0)	1	(0.7)	0	(0.0)	1	(0.3)
Arthropod bite (節足動物咬傷)	1	(0.7)	1	(0.7)	0	(0.0)	2	(0.6)
Chest crushing (胸部の圧挫傷)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.3)
Clavicle fracture (鎖骨骨折)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.3)
Head injury (頭部損傷)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.3)
Limb injury (四肢損傷)	0	(0.0)	1	(0.7)	0	(0.0)	1	(0.3)
Muscle strain (肉離れ)	0	(0.0)	1	(0.7)	0	(0.0)	1	(0.3)
Nail avulsion (爪裂離)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.3)
Pelvic fracture (骨盤骨折)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.3)
Skeletal injury (骨格損傷)	0	(0.0)	1	(0.7)	0	(0.0)	1	(0.3)
Thermal burn (熱傷)	1	(0.7)	1	(0.7)	0	(0.0)	2	(0.6)
Tooth fracture (歯牙破折)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.3)

Percentages are calculated using total number of patients in the background medication at screening/treatment class as the denominator.

Containing data from study 1245_0052

MedDRA version used for reporting: [REDACTED]

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Table 6.1.1 Frequency [N (%)] of patients with adverse events by background medication at screening, treatment, primary system organ class and preferred term - treated set

Background medication at screening=Biguanide

	Empa 10mg		Empa 25mg		Metformin		Total	
System organ class/ Preferred term	N	(%)	N	(%)	N	(%)	N	(%)
Number of patients	68	(100.0)	65	(100.0)	0	(0.0)	133	(100.0)
Total with adverse events	46	(67.6)	55	(84.6)	0	(0.0)	101	(75.9)
Infections and infestations (感染症および寄生虫症)	23	(33.8)	32	(49.2)	0	(0.0)	55	(41.4)
Nasopharyngitis (鼻咽頭炎)	12	(17.6)	23	(35.4)	0	(0.0)	35	(26.3)
Vulvovaginal candidiasis (外陰部腔カンジダ症)	4	(5.9)	1	(1.5)	0	(0.0)	5	(3.8)
Bronchitis (気管支炎)	3	(4.4)	3	(4.6)	0	(0.0)	6	(4.5)
Influenza (インフルエンザ)	3	(4.4)	2	(3.1)	0	(0.0)	5	(3.8)
Asymptomatic bacteriuria (無症候性細菌尿)	1	(1.5)	2	(3.1)	0	(0.0)	3	(2.3)
Gastroenteritis (胃腸炎)	0	(0.0)	2	(3.1)	0	(0.0)	2	(1.5)
Gingivitis (歯肉炎)	2	(2.9)	2	(3.1)	0	(0.0)	4	(3.0)
Upper respiratory tract infection (上気道感染)	2	(2.9)	1	(1.5)	0	(0.0)	3	(2.3)
Urinary tract infection (尿路感染)	2	(2.9)	1	(1.5)	0	(0.0)	3	(2.3)
Acute haemorrhagic conjunctivitis (急性出血性結膜炎)	0	(0.0)	1	(1.5)	0	(0.0)	1	(0.8)
Acute sinusitis (急性副鼻腔炎)	0	(0.0)	1	(1.5)	0	(0.0)	1	(0.8)
Candidiasis (カンジダ症)	0	(0.0)	1	(1.5)	0	(0.0)	1	(0.8)
Cystitis (膀胱炎)	1	(1.5)	1	(1.5)	0	(0.0)	2	(1.5)
Enteritis infectious (感染性腸炎)	0	(0.0)	1	(1.5)	0	(0.0)	1	(0.8)
Folliculitis (毛包炎)	0	(0.0)	1	(1.5)	0	(0.0)	1	(0.8)
Helicobacter infection (ヘリコバクター感染)	0	(0.0)	1	(1.5)	0	(0.0)	1	(0.8)
Herpes virus infection (ヘルペスウイルス感染)	0	(0.0)	1	(1.5)	0	(0.0)	1	(0.8)
Hordeolum (麦粒腫)	1	(1.5)	1	(1.5)	0	(0.0)	2	(1.5)
Onychomycosis (爪真菌症)	0	(0.0)	1	(1.5)	0	(0.0)	1	(0.8)
Oral herpes (口腔ヘルペス)	1	(1.5)	0	(0.0)	0	(0.0)	1	(0.8)
Otitis externa (外耳炎)	1	(1.5)	0	(0.0)	0	(0.0)	1	(0.8)
Otitis media chronic (慢性中耳炎)	1	(1.5)	0	(0.0)	0	(0.0)	1	(0.8)
Paronychia (爪囲炎)	0	(0.0)	1	(1.5)	0	(0.0)	1	(0.8)
Periodontitis (歯周炎)	0	(0.0)	1	(1.5)	0	(0.0)	1	(0.8)
Pharyngitis (咽頭炎)	1	(1.5)	1	(1.5)	0	(0.0)	2	(1.5)
Rhinitis (鼻炎)	1	(1.5)	1	(1.5)	0	(0.0)	2	(1.5)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (良性、悪性および詳細不明の新生物(嚢胞およびポリープを含む))	1	(1.5)	2	(3.1)	0	(0.0)	3	(2.3)
Benign ovarian tumour (卵巣良性腫瘍)	1	(1.5)	0	(0.0)	0	(0.0)	1	(0.8)
Laryngeal papilloma (喉頭乳頭腫)	0	(0.0)	1	(1.5)	0	(0.0)	1	(0.8)
Prostate cancer (前立腺癌)	0	(0.0)	1	(1.5)	0	(0.0)	1	(0.8)
Blood and lymphatic system disorders (血液およびリンパ系障害)	1	(1.5)	0	(0.0)	0	(0.0)	1	(0.8)
Lymphadenopathy (リンパ節症)	1	(1.5)	0	(0.0)	0	(0.0)	1	(0.8)
Immune system disorders (免疫系障害)	0	(0.0)	1	(1.5)	0	(0.0)	1	(0.8)
Seasonal allergy (季節性アレルギー)	0	(0.0)	1	(1.5)	0	(0.0)	1	(0.8)
Metabolism and nutrition disorders (代謝および栄養障害)	4	(5.9)	6	(9.2)	0	(0.0)	10	(7.5)
Hyperlipidaemia (高脂血症)	1	(1.5)	3	(4.6)	0	(0.0)	4	(3.0)
Hypoglycaemia (低血糖症)	2	(2.9)	3	(4.6)	0	(0.0)	5	(3.8)
Hyperglycaemia (高血糖)	1	(1.5)	0	(0.0)	0	(0.0)	1	(0.8)
Psychiatric disorders (精神障害)	0	(0.0)	3	(4.6)	0	(0.0)	3	(2.3)

	Empa 10mg		Empa 25mg		Metformin		Total	
System organ class/ Preferred term	N	(%)	N	(%)	N	(%)	N	(%)
Anxiety (不安)	0	(0.0)	1	(1.5)	0	(0.0)	1	(0.8)
Insomnia (不眠症)	0	(0.0)	1	(1.5)	0	(0.0)	1	(0.8)
Neurosis (神経症)	0	(0.0)	1	(1.5)	0	(0.0)	1	(0.8)
Nervous system disorders (神経系障害)	6	(8.8)	7	(10.8)	0	(0.0)	13	(9.8)
Dizziness (浮動性めまい)	4	(5.9)	0	(0.0)	0	(0.0)	4	(3.0)
Dysgeusia (味覚異常)	0	(0.0)	2	(3.1)	0	(0.0)	2	(1.5)
Headache (頭痛)	1	(1.5)	2	(3.1)	0	(0.0)	3	(2.3)
Diabetic neuropathy (糖尿病性ニューロパシー)	0	(0.0)	1	(1.5)	0	(0.0)	1	(0.8)
Dizziness postural (体位性めまい)	0	(0.0)	1	(1.5)	0	(0.0)	1	(0.8)
Neuralgia (神経痛)	0	(0.0)	1	(1.5)	0	(0.0)	1	(0.8)
Presyncope (失神寸前の状態)	1	(1.5)	0	(0.0)	0	(0.0)	1	(0.8)
Sciatica (坐骨神経痛)	1	(1.5)	0	(0.0)	0	(0.0)	1	(0.8)
Eye disorders (眼障害)	3	(4.4)	6	(9.2)	0	(0.0)	9	(6.8)
Conjunctivitis allergic (アレルギー性結膜炎)	0	(0.0)	2	(3.1)	0	(0.0)	2	(1.5)
Cataract (白内障)	1	(1.5)	0	(0.0)	0	(0.0)	1	(0.8)
Conjunctivitis (結膜炎)	1	(1.5)	0	(0.0)	0	(0.0)	1	(0.8)
Diabetic retinal oedema (糖尿病性網膜浮腫)	0	(0.0)	1	(1.5)	0	(0.0)	1	(0.8)
Eyelid bleeding (眼瞼出血)	0	(0.0)	1	(1.5)	0	(0.0)	1	(0.8)
Glaucoma (緑内障)	0	(0.0)	1	(1.5)	0	(0.0)	1	(0.8)
Retinal tear (網膜裂孔)	0	(0.0)	1	(1.5)	0	(0.0)	1	(0.8)
Retinopathy proliferative (増殖性網膜症)	0	(0.0)	1	(1.5)	0	(0.0)	1	(0.8)
Vitreous haemorrhage (硝子体出血)	1	(1.5)	0	(0.0)	0	(0.0)	1	(0.8)
Ear and labyrinth disorders (耳および迷路障害)	2	(2.9)	1	(1.5)	0	(0.0)	3	(2.3)
Vertigo (回転性めまい)	1	(1.5)	0	(0.0)	0	(0.0)	1	(0.8)
Vertigo positional (頭位性回転性めまい)	1	(1.5)	1	(1.5)	0	(0.0)	2	(1.5)
Cardiac disorders (心臓障害)	2	(2.9)	2	(3.1)	0	(0.0)	4	(3.0)
Congestive cardiomyopathy (うっ血性心筋症)	1	(1.5)	0	(0.0)	0	(0.0)	1	(0.8)
Coronary artery stenosis (冠動脈狭窄)	1	(1.5)	1	(1.5)	0	(0.0)	2	(1.5)
Palpitations (動悸)	0	(0.0)	1	(1.5)	0	(0.0)	1	(0.8)
Prinzmetal angina (プリンツメタル狭心症)	1	(1.5)	0	(0.0)	0	(0.0)	1	(0.8)
Vascular disorders (血管障害)	2	(2.9)	2	(3.1)	0	(0.0)	4	(3.0)
Hypotension (低血圧)	2	(2.9)	0	(0.0)	0	(0.0)	2	(1.5)
Haemorrhage (出血)	0	(0.0)	1	(1.5)	0	(0.0)	1	(0.8)
Peripheral arterial occlusive disease (末梢動脈閉塞性疾病)	0	(0.0)	1	(1.5)	0	(0.0)	1	(0.8)
Respiratory, thoracic and mediastinal disorders (呼吸器、胸郭および縦隔障害)	5	(7.4)	5	(7.7)	0	(0.0)	10	(7.5)
Upper respiratory tract inflammation (上気道の炎症)	0	(0.0)	3	(4.6)	0	(0.0)	3	(2.3)
Cough (咳嗽)	1	(1.5)	0	(0.0)	0	(0.0)	1	(0.8)
Nasal disorder (鼻部障害)	1	(1.5)	0	(0.0)	0	(0.0)	1	(0.8)
Oropharyngeal discomfort (口腔咽頭不快感)	1	(1.5)	0	(0.0)	0	(0.0)	1	(0.8)
Oropharyngeal pain (口腔咽頭痛)	0	(0.0)	1	(1.5)	0	(0.0)	1	(0.8)
Productive cough (湿性咳嗽)	1	(1.5)	0	(0.0)	0	(0.0)	1	(0.8)
Rhinitis allergic (アレルギー性鼻炎)	1	(1.5)	0	(0.0)	0	(0.0)	1	(0.8)
Sputum increased (喀痰増加)	1	(1.5)	0	(0.0)	0	(0.0)	1	(0.8)
Sputum retention (痰貯留)	0	(0.0)	1	(1.5)	0	(0.0)	1	(0.8)
Gastrointestinal disorders (胃腸障害)	17	(25.0)	13	(20.0)	0	(0.0)	30	(22.6)
Diarrhoea (下痢)	6	(8.8)	4	(6.2)	0	(0.0)	10	(7.5)
Constipation (便秘)	4	(5.9)	3	(4.6)	0	(0.0)	7	(5.3)
Abdominal pain upper (上腹部痛)	1	(1.5)	2	(3.1)	0	(0.0)	3	(2.3)

	Empa 10mg		Empa 25mg		Metformin		Total	
System organ class/ Preferred term	N	(%)	N	(%)	N	(%)	N	(%)
Periodontal disease (歯周病)	2	(2.9)	0	(0.0)	0	(0.0)	2	(1.5)
Abdominal discomfort (腹部不快感)	1	(1.5)	0	(0.0)	0	(0.0)	1	(0.8)
Anal pruritus (肛門そう痒症)	0	(0.0)	1	(1.5)	0	(0.0)	1	(0.8)
Dental caries (齲歯)	1	(1.5)	1	(1.5)	0	(0.0)	2	(1.5)
Dyspepsia (消化不良)	1	(1.5)	0	(0.0)	0	(0.0)	1	(0.8)
Enterocolitis (腸炎)	0	(0.0)	1	(1.5)	0	(0.0)	1	(0.8)
Epigastric discomfort (心窩部不快感)	0	(0.0)	1	(1.5)	0	(0.0)	1	(0.8)
Gastritis (胃炎)	1	(1.5)	1	(1.5)	0	(0.0)	2	(1.5)
Gastritis atrophic (萎縮性胃炎)	1	(1.5)	0	(0.0)	0	(0.0)	1	(0.8)
Gastritis erosive (びらん性胃炎)	1	(1.5)	0	(0.0)	0	(0.0)	1	(0.8)
Gastroesophageal reflux disease (胃食道逆流性疾患)	1	(1.5)	0	(0.0)	0	(0.0)	1	(0.8)
Haemorrhoids (痔核)	1	(1.5)	0	(0.0)	0	(0.0)	1	(0.8)
Hiatus hernia (裂孔ヘルニア)	1	(1.5)	0	(0.0)	0	(0.0)	1	(0.8)
Nausea (悪心)	1	(1.5)	0	(0.0)	0	(0.0)	1	(0.8)
Oesophagitis (食道炎)	0	(0.0)	1	(1.5)	0	(0.0)	1	(0.8)
Reflux gastritis (逆流性胃炎)	1	(1.5)	0	(0.0)	0	(0.0)	1	(0.8)
Tongue disorder (舌障害)	0	(0.0)	1	(1.5)	0	(0.0)	1	(0.8)
Vomiting (嘔吐)	1	(1.5)	1	(1.5)	0	(0.0)	2	(1.5)
Hepatobiliary disorders (肝胆道系障害)	1	(1.5)	0	(0.0)	0	(0.0)	1	(0.8)
Hepatic function abnormal (肝機能異常)	1	(1.5)	0	(0.0)	0	(0.0)	1	(0.8)
Skin and subcutaneous tissue disorders (皮膚および皮下組織障害)	11	(16.2)	9	(13.8)	0	(0.0)	20	(15.0)
Eczema (湿疹)	3	(4.4)	2	(3.1)	0	(0.0)	5	(3.8)
Hyperkeratosis (過角化)	0	(0.0)	2	(3.1)	0	(0.0)	2	(1.5)
Urticaria (蕁麻疹)	0	(0.0)	2	(3.1)	0	(0.0)	2	(1.5)
Rash (発疹)	2	(2.9)	1	(1.5)	0	(0.0)	3	(2.3)
Alopecia (脱毛症)	0	(0.0)	1	(1.5)	0	(0.0)	1	(0.8)
Blister (水疱)	1	(1.5)	0	(0.0)	0	(0.0)	1	(0.8)
Dermatitis (皮膚炎)	1	(1.5)	0	(0.0)	0	(0.0)	1	(0.8)
Dermatitis allergic (アレルギー性皮膚炎)	1	(1.5)	0	(0.0)	0	(0.0)	1	(0.8)
Dermatitis contact (接触性皮膚炎)	1	(1.5)	0	(0.0)	0	(0.0)	1	(0.8)
Drug eruption (薬疹)	1	(1.5)	0	(0.0)	0	(0.0)	1	(0.8)
Dyshidrosis (発汗障害)	0	(0.0)	1	(1.5)	0	(0.0)	1	(0.8)
Idiopathic urticaria (特発性蕁麻疹)	1	(1.5)	0	(0.0)	0	(0.0)	1	(0.8)
Ingrowing nail (嵌入爪)	0	(0.0)	1	(1.5)	0	(0.0)	1	(0.8)
Nail bed bleeding (爪床出血)	1	(1.5)	0	(0.0)	0	(0.0)	1	(0.8)
Papule (丘疹)	1	(1.5)	0	(0.0)	0	(0.0)	1	(0.8)
Pruritus (そう痒症)	1	(1.5)	1	(1.5)	0	(0.0)	2	(1.5)
Musculoskeletal and connective tissue disorders (筋骨格系および結合組織障害)	7	(10.3)	12	(18.5)	0	(0.0)	19	(14.3)
Back pain (背部痛)	0	(0.0)	5	(7.7)	0	(0.0)	5	(3.8)
Pain in extremity (四肢痛)	1	(1.5)	2	(3.1)	0	(0.0)	3	(2.3)
Periarthritis (関節周囲炎)	1	(1.5)	2	(3.1)	0	(0.0)	3	(2.3)
Arthralgia (関節痛)	0	(0.0)	1	(1.5)	0	(0.0)	1	(0.8)
Intervertebral disc protrusion (椎間板突出)	1	(1.5)	0	(0.0)	0	(0.0)	1	(0.8)
Lumbar spinal stenosis (腰部脊柱管狭窄症)	1	(1.5)	1	(1.5)	0	(0.0)	2	(1.5)
Muscle spasms (筋痙攣)	1	(1.5)	0	(0.0)	0	(0.0)	1	(0.8)
Musculoskeletal pain (筋骨格痛)	1	(1.5)	0	(0.0)	0	(0.0)	1	(0.8)
Neck pain (頸部痛)	0	(0.0)	1	(1.5)	0	(0.0)	1	(0.8)
Osteoarthritis (変形性関節症)	0	(0.0)	1	(1.5)	0	(0.0)	1	(0.8)

System organ class/ Preferred term	Empa 10mg		Empa 25mg		Metformin		Total	
	N	(%)	N	(%)	N	(%)	N	(%)
Spondylolisthesis (脊椎すべり症)	0	(0.0)	1	(1.5)	0	(0.0)	1	(0.8)
Trigger finger (弾発指)	1	(1.5)	1	(1.5)	0	(0.0)	2	(1.5)
Renal and urinary disorders (腎および尿路障害)	6	(8.8)	3	(4.6)	0	(0.0)	9	(6.8)
Nocturia (夜間頻尿)	3	(4.4)	1	(1.5)	0	(0.0)	4	(3.0)
Pollakiuria (頻尿)	2	(2.9)	0	(0.0)	0	(0.0)	2	(1.5)
Calculus urethral (尿道結石)	1	(1.5)	0	(0.0)	0	(0.0)	1	(0.8)
Dysuria (排尿困難)	0	(0.0)	1	(1.5)	0	(0.0)	1	(0.8)
Polyuria (多尿)	1	(1.5)	0	(0.0)	0	(0.0)	1	(0.8)
Urinary incontinence (尿失禁)	0	(0.0)	1	(1.5)	0	(0.0)	1	(0.8)
Reproductive system and breast disorders (生殖系および乳房障害)	1	(1.5)	4	(6.2)	0	(0.0)	5	(3.8)
Balanoposthitis (亀頭包皮炎)	0	(0.0)	1	(1.5)	0	(0.0)	1	(0.8)
Benign prostatic hyperplasia (良性前立腺肥大症)	0	(0.0)	1	(1.5)	0	(0.0)	1	(0.8)
Breast tenderness (乳房圧痛)	0	(0.0)	1	(1.5)	0	(0.0)	1	(0.8)
Pruritus genital (陰部そう痒症)	0	(0.0)	1	(1.5)	0	(0.0)	1	(0.8)
Vulvovaginal pruritus (外陰腔そう痒症)	1	(1.5)	0	(0.0)	0	(0.0)	1	(0.8)
General disorders and administration site conditions (一般・全身障害および投与部位の状態)	7	(10.3)	3	(4.6)	0	(0.0)	10	(7.5)
Thirst (口渇)	4	(5.9)	0	(0.0)	0	(0.0)	4	(3.0)
Malaise (倦怠感)	2	(2.9)	0	(0.0)	0	(0.0)	2	(1.5)
Chest discomfort (胸部不快感)	1	(1.5)	0	(0.0)	0	(0.0)	1	(0.8)
Chest pain (胸痛)	1	(1.5)	1	(1.5)	0	(0.0)	2	(1.5)
Fatigue (疲労)	0	(0.0)	1	(1.5)	0	(0.0)	1	(0.8)
Injection site haematoma (注射部位血腫)	1	(1.5)	0	(0.0)	0	(0.0)	1	(0.8)
Oedema peripheral (末梢性浮腫)	0	(0.0)	1	(1.5)	0	(0.0)	1	(0.8)
Vaccination site pain (ワクチン接種部位疼痛)	0	(0.0)	1	(1.5)	0	(0.0)	1	(0.8)
Investigations (臨床検査)	2	(2.9)	0	(0.0)	0	(0.0)	2	(1.5)
Blood pressure decreased (血圧低下)	1	(1.5)	0	(0.0)	0	(0.0)	1	(0.8)
Occult blood (便潜血)	1	(1.5)	0	(0.0)	0	(0.0)	1	(0.8)
Injury, poisoning and procedural complications (傷害、中毒および処置合併症)	6	(8.8)	6	(9.2)	0	(0.0)	12	(9.0)
Rib fracture (肋骨骨折)	3	(4.4)	0	(0.0)	0	(0.0)	3	(2.3)
Fall (転倒)	2	(2.9)	1	(1.5)	0	(0.0)	3	(2.3)
Aqueous humour leakage (房水漏出)	0	(0.0)	1	(1.5)	0	(0.0)	1	(0.8)
Chil blains (凍瘡)	0	(0.0)	1	(1.5)	0	(0.0)	1	(0.8)
Contusion (挫傷)	0	(0.0)	1	(1.5)	0	(0.0)	1	(0.8)
Excoriation (擦過傷)	1	(1.5)	0	(0.0)	0	(0.0)	1	(0.8)
Femur fracture (大腿骨骨折)	1	(1.5)	0	(0.0)	0	(0.0)	1	(0.8)
Foot fracture (足骨折)	1	(1.5)	0	(0.0)	0	(0.0)	1	(0.8)
Heat illness (熱中症)	1	(1.5)	0	(0.0)	0	(0.0)	1	(0.8)
Laceration (裂傷)	0	(0.0)	1	(1.5)	0	(0.0)	1	(0.8)
Ligament sprain (靱帯捻挫)	0	(0.0)	1	(1.5)	0	(0.0)	1	(0.8)
Thermal burn (熱傷)	1	(1.5)	1	(1.5)	0	(0.0)	2	(1.5)
Wrist fracture (手首関節骨折)	0	(0.0)	1	(1.5)	0	(0.0)	1	(0.8)

Percentages are calculated using total number of patients in the background medication at screening/treatment class as the denominator.

Containing data from study 1245_0052

MedDRA version used for reporting: [REDACTED]

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Table 6.1.1 Frequency [N (%)] of patients with adverse events by background medication at screening, treatment, primary system organ class and preferred term - treated set

Background medication at screening=Thiazolidinedione

	Empa 10mg		Empa 25mg		Metformin		Total	
System organ class/ Preferred term	N	(%)	N	(%)	N	(%)	N	(%)
Number of patients	137	(100.0)	136	(100.0)	0	(0.0)	273	(100.0)
Total with adverse events	106	(77.4)	101	(74.3)	0	(0.0)	207	(75.8)
Infections and infestations (感染症および寄生虫症)	64	(46.7)	61	(44.9)	0	(0.0)	125	(45.8)
Nasopharyngitis (鼻咽頭炎)	44	(32.1)	37	(27.2)	0	(0.0)	81	(29.7)
Pharyngitis (咽頭炎)	6	(4.4)	6	(4.4)	0	(0.0)	12	(4.4)
Bronchitis (気管支炎)	2	(1.5)	5	(3.7)	0	(0.0)	7	(2.6)
Cellulitis (蜂巣炎)	4	(2.9)	1	(0.7)	0	(0.0)	5	(1.8)
Cystitis (膀胱炎)	4	(2.9)	3	(2.2)	0	(0.0)	7	(2.6)
Gastroenteritis (胃腸炎)	4	(2.9)	1	(0.7)	0	(0.0)	5	(1.8)
Gastroenteritis viral (ウイルス性胃腸炎)	2	(1.5)	3	(2.2)	0	(0.0)	5	(1.8)
Influenza (インフルエンザ)	1	(0.7)	3	(2.2)	0	(0.0)	4	(1.5)
Periodontitis (歯周炎)	2	(1.5)	3	(2.2)	0	(0.0)	5	(1.8)
Sinusitis (副鼻腔炎)	3	(2.2)	0	(0.0)	0	(0.0)	3	(1.1)
Tinea pedis (足部白癬)	3	(2.2)	1	(0.7)	0	(0.0)	4	(1.5)
Tonsillitis (扁桃炎)	1	(0.7)	3	(2.2)	0	(0.0)	4	(1.5)
Gingivitis (歯肉炎)	2	(1.5)	0	(0.0)	0	(0.0)	2	(0.7)
Onychomycosis (爪真菌症)	2	(1.5)	0	(0.0)	0	(0.0)	2	(0.7)
Oral herpes (口腔ヘルペス)	1	(0.7)	2	(1.5)	0	(0.0)	3	(1.1)
Upper respiratory tract infection (上気道感染)	2	(1.5)	1	(0.7)	0	(0.0)	3	(1.1)
Urinary tract infection (尿路感染)	2	(1.5)	2	(1.5)	0	(0.0)	4	(1.5)
Vulvovaginal candidiasis (外陰部腔カンジダ症)	2	(1.5)	1	(0.7)	0	(0.0)	3	(1.1)
Acute tonsillitis (急性扁桃炎)	0	(0.0)	1	(0.7)	0	(0.0)	1	(0.4)
Adenoiditis (アデノイド咽頭炎)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.4)
Asymptomatic bacteriuria (無症候性細菌尿)	0	(0.0)	1	(0.7)	0	(0.0)	1	(0.4)
Candidiasis (カンジダ症)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.4)
Conjunctivitis infective (感染性結膜炎)	0	(0.0)	1	(0.7)	0	(0.0)	1	(0.4)
Diarrhoea infectious (感染性下痢)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.4)
Enterocolitis viral (ウイルス性腸炎)	0	(0.0)	1	(0.7)	0	(0.0)	1	(0.4)
Furuncle (せつ)	0	(0.0)	1	(0.7)	0	(0.0)	1	(0.4)
Gastrointestinal infection (消化管感染)	1	(0.7)	1	(0.7)	0	(0.0)	2	(0.7)
Helicobacter infection (ヘリコバクター感染)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.4)
Herpes virus infection (ヘルペスウイルス感染)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.4)
Herpes zoster (帯状疱疹)	1	(0.7)	1	(0.7)	0	(0.0)	2	(0.7)
Hordeolum (麦粒腫)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.4)
Infected dermal cyst (感染性皮膚嚢腫)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.4)
Orf (ヒツジ驚口瘡)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.4)
Otitis externa (外耳炎)	1	(0.7)	1	(0.7)	0	(0.0)	2	(0.7)
Otitis media (中耳炎)	0	(0.0)	1	(0.7)	0	(0.0)	1	(0.4)
Pneumonia (肺炎)	1	(0.7)	1	(0.7)	0	(0.0)	2	(0.7)
Pulpitis dental (歯髄炎)	1	(0.7)	1	(0.7)	0	(0.0)	2	(0.7)
Pyelonephritis (腎盂腎炎)	0	(0.0)	1	(0.7)	0	(0.0)	1	(0.4)
Rhinitis (鼻炎)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.4)
Tinea cruris (股部白癬)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.4)
Urinary tract infection fungal (真菌性尿路感染)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.4)

	Empa 10mg		Empa 25mg		Metformin		Total	
System organ class/ Preferred term	N	(%)	N	(%)	N	(%)	N	(%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (良性、悪性および詳細不明の新生物 (嚢胞およびポリープを含む))	3	(2.2)	2	(1.5)	0	(0.0)	5	(1.8)
Lipoma (脂肪腫)	2	(1.5)	0	(0.0)	0	(0.0)	2	(0.7)
Lung neoplasm malignant (肺の悪性新生物)	1	(0.7)	1	(0.7)	0	(0.0)	2	(0.7)
Rectal cancer (直腸癌)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.4)
Small cell lung cancer stage unspecified (小細胞肺癌、病期不明)	0	(0.0)	1	(0.7)	0	(0.0)	1	(0.4)
Blood and lymphatic system disorders (血液およびリンパ系障害)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.4)
Anaemia (貧血)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.4)
Immune system disorders (免疫系障害)	0	(0.0)	1	(0.7)	0	(0.0)	1	(0.4)
Seasonal allergy (季節性アレルギー)	0	(0.0)	1	(0.7)	0	(0.0)	1	(0.4)
Endocrine disorders (内分泌障害)	0	(0.0)	2	(1.5)	0	(0.0)	2	(0.7)
Goitre (甲状腺腫)	0	(0.0)	1	(0.7)	0	(0.0)	1	(0.4)
Thyroiditis chronic (慢性甲状腺炎)	0	(0.0)	1	(0.7)	0	(0.0)	1	(0.4)
Metabolism and nutrition disorders (代謝および栄養障害)	9	(6.6)	6	(4.4)	0	(0.0)	15	(5.5)
Hypoglycaemia (低血糖症)	4	(2.9)	2	(1.5)	0	(0.0)	6	(2.2)
Hyperlipidaemia (高脂血症)	1	(0.7)	3	(2.2)	0	(0.0)	4	(1.5)
Hypercholesterolaemia (高コレステロール血症)	2	(1.5)	0	(0.0)	0	(0.0)	2	(0.7)
Cachexia (悪液質)	0	(0.0)	1	(0.7)	0	(0.0)	1	(0.4)
Decreased appetite (食欲減退)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.4)
Diabetes mellitus (糖尿病)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.4)
Gout (痛風)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.4)
Hyperuricaemia (高尿酸血症)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.4)
Psychiatric disorders (精神障害)	3	(2.2)	1	(0.7)	0	(0.0)	4	(1.5)
Insomnia (不眠症)	3	(2.2)	1	(0.7)	0	(0.0)	4	(1.5)
Nervous system disorders (神経系障害)	13	(9.5)	14	(10.3)	0	(0.0)	27	(9.9)
Dizziness (浮動性めまい)	4	(2.9)	4	(2.9)	0	(0.0)	8	(2.9)
Dizziness postural (体位性めまい)	1	(0.7)	2	(1.5)	0	(0.0)	3	(1.1)
Headache (頭痛)	1	(0.7)	2	(1.5)	0	(0.0)	3	(1.1)
Neuralgia (神経痛)	2	(1.5)	0	(0.0)	0	(0.0)	2	(0.7)
Sciatica (坐骨神経痛)	2	(1.5)	0	(0.0)	0	(0.0)	2	(0.7)
Carotid arteriosclerosis (頸動脈硬化症)	0	(0.0)	1	(0.7)	0	(0.0)	1	(0.4)
Carotid artery stenosis (頸動脈狭窄)	1	(0.7)	1	(0.7)	0	(0.0)	2	(0.7)
Cerebral arteriosclerosis (脳動脈硬化症)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.4)
Cerebral infarction (脳梗塞)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.4)
Cervicobrachial syndrome (頸腕症候群)	0	(0.0)	1	(0.7)	0	(0.0)	1	(0.4)
Dysgeusia (味覚異常)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.4)
Hypoaesthesia (感覚鈍麻)	1	(0.7)	1	(0.7)	0	(0.0)	2	(0.7)
Lacunar infarction (ラクナ梗塞)	0	(0.0)	1	(0.7)	0	(0.0)	1	(0.4)
Restless legs syndrome (下肢静止不能症候群)	0	(0.0)	1	(0.7)	0	(0.0)	1	(0.4)
Tension headache (緊張性頭痛)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.4)
Thoracic outlet syndrome (胸郭出口症候群)	0	(0.0)	1	(0.7)	0	(0.0)	1	(0.4)
Transient ischaemic attack (一過性脳虚血発作)	0	(0.0)	1	(0.7)	0	(0.0)	1	(0.4)
VIIth nerve paralysis (第7脳神経麻痺)	0	(0.0)	1	(0.7)	0	(0.0)	1	(0.4)
Eye disorders (眼障害)	7	(5.1)	7	(5.1)	0	(0.0)	14	(5.1)
Abnormal sensation in eye (眼の異常感)	2	(1.5)	0	(0.0)	0	(0.0)	2	(0.7)
Cataract (白内障)	1	(0.7)	2	(1.5)	0	(0.0)	3	(1.1)
Conjunctivitis (結膜炎)	0	(0.0)	2	(1.5)	0	(0.0)	2	(0.7)

	Empa 10mg		Empa 25mg		Metformin		Total	
System organ class/ Preferred term	N	(%)	N	(%)	N	(%)	N	(%)
Age-related macular degeneration (加齢黄斑変性)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.4)
Asthenopia (眼精疲労)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.4)
Blepharitis (眼瞼炎)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.4)
Conjunctivitis allergic (アレルギー性結膜炎)	0	(0.0)	1	(0.7)	0	(0.0)	1	(0.4)
Dry eye (眼乾燥)	0	(0.0)	1	(0.7)	0	(0.0)	1	(0.4)
Entropion (眼瞼内反)	0	(0.0)	1	(0.7)	0	(0.0)	1	(0.4)
Episcleritis (上強膜炎)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.4)
Eye inflammation (眼の炎症)	0	(0.0)	1	(0.7)	0	(0.0)	1	(0.4)
Lacrimation increased (流涙増加)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.4)
Ocular hypertension (高眼圧症)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.4)
Vision blurred (霧視)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.4)
Ear and labyrinth disorders (耳および迷路障害)	2	(1.5)	4	(2.9)	0	(0.0)	6	(2.2)
Vertigo positional (頭位性回転性めまい)	0	(0.0)	2	(1.5)	0	(0.0)	2	(0.7)
Ear discomfort (耳不快感)	0	(0.0)	1	(0.7)	0	(0.0)	1	(0.4)
Meniere's disease (メニエール病)	0	(0.0)	1	(0.7)	0	(0.0)	1	(0.4)
Tinnitus (耳鳴)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.4)
Vertigo (回転性めまい)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.4)
Cardiac disorders (心臓障害)	3	(2.2)	3	(2.2)	0	(0.0)	6	(2.2)
Ventricular extrasystoles (心室性期外収縮)	0	(0.0)	2	(1.5)	0	(0.0)	2	(0.7)
Angina pectoris (狭心症)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.4)
Conduction disorder (伝導障害)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.4)
Mitral valve incompetence (僧帽弁閉鎖不全症)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.4)
Tricuspid valve incompetence (三尖弁閉鎖不全症)	1	(0.7)	1	(0.7)	0	(0.0)	2	(0.7)
Vascular disorders (血管障害)	5	(3.6)	2	(1.5)	0	(0.0)	7	(2.6)
Hypertension (高血圧)	2	(1.5)	0	(0.0)	0	(0.0)	2	(0.7)
Arteriosclerosis (動脈硬化症)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.4)
Hypotension (低血圧)	0	(0.0)	1	(0.7)	0	(0.0)	1	(0.4)
Orthostatic hypotension (起立性低血圧)	1	(0.7)	1	(0.7)	0	(0.0)	2	(0.7)
Peripheral arterial occlusive disease (末梢動脈閉塞性疾患)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.4)
Peripheral vascular disorder (末梢血管障害)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.4)
Respiratory, thoracic and mediastinal disorders (呼吸器、胸郭および縦隔障害)	10	(7.3)	7	(5.1)	0	(0.0)	17	(6.2)
Oropharyngeal pain (口腔咽頭痛)	1	(0.7)	3	(2.2)	0	(0.0)	4	(1.5)
Upper respiratory tract inflammation (上気道の炎症)	3	(2.2)	1	(0.7)	0	(0.0)	4	(1.5)
Rhinitis allergic (アレルギー性鼻炎)	2	(1.5)	1	(0.7)	0	(0.0)	3	(1.1)
Asthma (喘息)	1	(0.7)	1	(0.7)	0	(0.0)	2	(0.7)
Dysphonia (発声障害)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.4)
Epistaxis (鼻出血)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.4)
Haemoptysis (咯血)	0	(0.0)	1	(0.7)	0	(0.0)	1	(0.4)
Hyperventilation (過換気)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.4)
Productive cough (湿性咳嗽)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.4)
Gastrointestinal disorders (胃腸障害)	34	(24.8)	24	(17.6)	0	(0.0)	58	(21.2)
Constipation (便秘)	9	(6.6)	1	(0.7)	0	(0.0)	10	(3.7)
Diarrhoea (下痢)	5	(3.6)	2	(1.5)	0	(0.0)	7	(2.6)
Gastritis (胃炎)	4	(2.9)	2	(1.5)	0	(0.0)	6	(2.2)
Dental caries (齲歯)	3	(2.2)	2	(1.5)	0	(0.0)	5	(1.8)
Haemorrhoids (痔核)	0	(0.0)	3	(2.2)	0	(0.0)	3	(1.1)
Nausea (悪心)	3	(2.2)	0	(0.0)	0	(0.0)	3	(1.1)

	Empa 10mg		Empa 25mg		Metformin		Total	
System organ class/ Preferred term	N	(%)	N	(%)	N	(%)	N	(%)
Colonic polyp (結腸ポリープ)	2	(1.5)	2	(1.5)	0	(0.0)	4	(1.5)
Dyspepsia (消化不良)	1	(0.7)	2	(1.5)	0	(0.0)	3	(1.1)
Gastroesophageal reflux disease (胃食道逆流性疾患)	2	(1.5)	2	(1.5)	0	(0.0)	4	(1.5)
Abdominal distension (腹部膨満)	0	(0.0)	1	(0.7)	0	(0.0)	1	(0.4)
Abdominal pain (腹痛)	1	(0.7)	1	(0.7)	0	(0.0)	2	(0.7)
Anal fissure (裂肛)	0	(0.0)	1	(0.7)	0	(0.0)	1	(0.4)
Aphthous stomatitis (アフタ性口内炎)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.4)
Colitis (大腸炎)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.4)
Colitis ischaemic (虚血性大腸炎)	0	(0.0)	1	(0.7)	0	(0.0)	1	(0.4)
Diverticulum intestinal (腸憩室)	0	(0.0)	1	(0.7)	0	(0.0)	1	(0.4)
Duodenitis (十二指腸炎)	0	(0.0)	1	(0.7)	0	(0.0)	1	(0.4)
Enterocolitis (腸炎)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.4)
Eructation (おくび)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.4)
Faeces discoloured (変色便)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.4)
Flatulence (鼓腸)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.4)
Gastritis atrophic (萎縮性胃炎)	1	(0.7)	1	(0.7)	0	(0.0)	2	(0.7)
Inguinal hernia (鼠径ヘルニア)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.4)
Irritable bowel syndrome (過敏性腸症候群)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.4)
Melaena (メレナ)	1	(0.7)	1	(0.7)	0	(0.0)	2	(0.7)
Stomatitis (口内炎)	1	(0.7)	1	(0.7)	0	(0.0)	2	(0.7)
Toothache (歯痛)	1	(0.7)	1	(0.7)	0	(0.0)	2	(0.7)
Vomiting (嘔吐)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.4)
Hepatobiliary disorders (肝胆道系障害)	2	(1.5)	2	(1.5)	0	(0.0)	4	(1.5)
Drug-induced liver injury (薬物性肝障害)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.4)
Hepatic function abnormal (肝機能異常)	1	(0.7)	1	(0.7)	0	(0.0)	2	(0.7)
Hepatic steatosis (脂肪肝)	0	(0.0)	1	(0.7)	0	(0.0)	1	(0.4)
Skin and subcutaneous tissue disorders (皮膚および皮下組織障害)	8	(5.8)	13	(9.6)	0	(0.0)	21	(7.7)
Eczema (湿疹)	3	(2.2)	4	(2.9)	0	(0.0)	7	(2.6)
Dermatitis (皮膚炎)	0	(0.0)	2	(1.5)	0	(0.0)	2	(0.7)
Rash (発疹)	0	(0.0)	2	(1.5)	0	(0.0)	2	(0.7)
Urticaria (蕁麻疹)	0	(0.0)	2	(1.5)	0	(0.0)	2	(0.7)
Asteatosis (皮脂欠乏症)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.4)
Dermal cyst (皮膚嚢腫)	0	(0.0)	1	(0.7)	0	(0.0)	1	(0.4)
Dermatitis contact (接触性皮膚炎)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.4)
Dry skin (皮膚乾燥)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.4)
Eczema asteatotic (皮脂欠乏性湿疹)	0	(0.0)	1	(0.7)	0	(0.0)	1	(0.4)
Hangnail (逆むけ)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.4)
Heat rash (紅色汗疹)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.4)
Pruritus (そう痒症)	0	(0.0)	1	(0.7)	0	(0.0)	1	(0.4)
Rash erythematous (紅斑性皮疹)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.4)
Seborrhoeic dermatitis (脂漏性皮膚炎)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.4)
Senile pruritus (老人性そう痒症)	0	(0.0)	1	(0.7)	0	(0.0)	1	(0.4)
Urticaria chronic (慢性蕁麻疹)	0	(0.0)	1	(0.7)	0	(0.0)	1	(0.4)
Musculoskeletal and connective tissue disorders (筋骨格系および結合組織障害)	23	(16.8)	25	(18.4)	0	(0.0)	48	(17.6)
Back pain (背部痛)	8	(5.8)	8	(5.9)	0	(0.0)	16	(5.9)
Arthralgia (関節痛)	3	(2.2)	3	(2.2)	0	(0.0)	6	(2.2)
Musculoskeletal pain (筋骨格痛)	1	(0.7)	3	(2.2)	0	(0.0)	4	(1.5)

	Empa 10mg		Empa 25mg		Metformin		Total	
System organ class/ Preferred term	N	(%)	N	(%)	N	(%)	N	(%)
Muscle spasms (筋痙縮)	1	(0.7)	2	(1.5)	0	(0.0)	3	(1.1)
Myalgia (筋肉痛)	0	(0.0)	2	(1.5)	0	(0.0)	2	(0.7)
Osteoarthritis (変形性関節症)	2	(1.5)	0	(0.0)	0	(0.0)	2	(0.7)
Rotator cuff syndrome (肩回旋筋腱板症候群)	2	(1.5)	0	(0.0)	0	(0.0)	2	(0.7)
Spinal osteoarthritis (変形性脊椎症)	2	(1.5)	2	(1.5)	0	(0.0)	4	(1.5)
Tenosynovitis (腱鞘炎)	2	(1.5)	0	(0.0)	0	(0.0)	2	(0.7)
Arthritis (関節炎)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.4)
Flank pain (側腹部痛)	0	(0.0)	1	(0.7)	0	(0.0)	1	(0.4)
Intervertebral disc disorder (椎間板障害)	0	(0.0)	1	(0.7)	0	(0.0)	1	(0.4)
Intervertebral disc protrusion (椎間板突出)	0	(0.0)	1	(0.7)	0	(0.0)	1	(0.4)
Musculoskeletal chest pain (筋骨格系胸痛)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.4)
Musculoskeletal stiffness (筋骨格硬直)	1	(0.7)	1	(0.7)	0	(0.0)	2	(0.7)
Myofascial pain syndrome (筋膜疼痛症候群)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.4)
Neck pain (頸部痛)	0	(0.0)	1	(0.7)	0	(0.0)	1	(0.4)
Osteoporosis (骨粗鬆症)	1	(0.7)	1	(0.7)	0	(0.0)	2	(0.7)
Periarthritis (関節周囲炎)	1	(0.7)	1	(0.7)	0	(0.0)	2	(0.7)
Spinal column stenosis (脊柱管狭窄症)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.4)
Spondylolisthesis (脊椎すべり症)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.4)
Trigger finger (弾発指)	0	(0.0)	1	(0.7)	0	(0.0)	1	(0.4)
Renal and urinary disorders (腎および尿路障害)	15	(10.9)	9	(6.6)	0	(0.0)	24	(8.8)
Pollakiuria (頻尿)	11	(8.0)	3	(2.2)	0	(0.0)	14	(5.1)
Nocturia (夜間頻尿)	2	(1.5)	2	(1.5)	0	(0.0)	4	(1.5)
Polyuria (多尿)	1	(0.7)	2	(1.5)	0	(0.0)	3	(1.1)
Calculus ureteric (尿管結石)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.4)
Dysuria (排尿困難)	0	(0.0)	1	(0.7)	0	(0.0)	1	(0.4)
Hydronephrosis (水腎症)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.4)
Nephrolithiasis (腎結石症)	0	(0.0)	1	(0.7)	0	(0.0)	1	(0.4)
Renal cyst (腎嚢胞)	0	(0.0)	1	(0.7)	0	(0.0)	1	(0.4)
Ureteric stenosis (尿管狭窄)	0	(0.0)	1	(0.7)	0	(0.0)	1	(0.4)
Reproductive system and breast disorders (生殖系および乳房障害)	1	(0.7)	2	(1.5)	0	(0.0)	3	(1.1)
Benign prostatic hyperplasia (良性前立腺肥大症)	0	(0.0)	1	(0.7)	0	(0.0)	1	(0.4)
Menopausal symptoms (閉経期症状)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.4)
Pruritus genital (陰部そう痒症)	0	(0.0)	1	(0.7)	0	(0.0)	1	(0.4)
General disorders and administration site conditions (一般・全身障害および投与部位の状態)	2	(1.5)	5	(3.7)	0	(0.0)	7	(2.6)
Oedema peripheral (末梢性浮腫)	0	(0.0)	2	(1.5)	0	(0.0)	2	(0.7)
Thirst (口渇)	0	(0.0)	2	(1.5)	0	(0.0)	2	(0.7)
Asthenia (無力症)	0	(0.0)	1	(0.7)	0	(0.0)	1	(0.4)
Chest pain (胸痛)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.4)
Cyst (嚢胞)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.4)
Investigations (臨床検査)	1	(0.7)	3	(2.2)	0	(0.0)	4	(1.5)
Weight decreased (体重減少)	0	(0.0)	2	(1.5)	0	(0.0)	2	(0.7)
Blood pressure decreased (血圧低下)	0	(0.0)	1	(0.7)	0	(0.0)	1	(0.4)
Occult blood positive (便潜血陽性)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.4)
Injury, poisoning and procedural complications (傷害、中毒および処置合併症)	19	(13.9)	18	(13.2)	0	(0.0)	37	(13.6)
Fall (転倒)	9	(6.6)	8	(5.9)	0	(0.0)	17	(6.2)
Contusion (挫傷)	2	(1.5)	5	(3.7)	0	(0.0)	7	(2.6)

	Empa 10mg		Empa 25mg		Metformin		Total	
System organ class/ Preferred term	N	(%)	N	(%)	N	(%)	N	(%)
Hand fracture (手骨折)	3	(2.2)	1	(0.7)	0	(0.0)	4	(1.5)
Ankle fracture (足関節部骨折)	0	(0.0)	2	(1.5)	0	(0.0)	2	(0.7)
Arthropod bite (節足動物咬傷)	2	(1.5)	1	(0.7)	0	(0.0)	3	(1.1)
Excoriation (擦過傷)	2	(1.5)	1	(0.7)	0	(0.0)	3	(1.1)
Ligament sprain (靱帯捻挫)	2	(1.5)	1	(0.7)	0	(0.0)	3	(1.1)
Thermal burn (熱傷)	1	(0.7)	2	(1.5)	0	(0.0)	3	(1.1)
Alcohol poisoning (アルコール中毒)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.4)
Avulsion fracture (剥離骨折)	0	(0.0)	1	(0.7)	0	(0.0)	1	(0.4)
Chil blains (凍瘡)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.4)
Fibula fracture (腓骨骨折)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.4)
Foot fracture (足骨折)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.4)
Heat illness (熱中症)	0	(0.0)	1	(0.7)	0	(0.0)	1	(0.4)
Heat stroke (熱射病)	0	(0.0)	1	(0.7)	0	(0.0)	1	(0.4)
Joint dislocation (関節脱臼)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.4)
Laceration (裂傷)	0	(0.0)	1	(0.7)	0	(0.0)	1	(0.4)
Pelvic fracture (骨盤骨折)	0	(0.0)	1	(0.7)	0	(0.0)	1	(0.4)
Post-traumatic neck syndrome (外傷後頸部症候群)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.4)
Radial nerve injury (橈骨神経損傷)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.4)
Rib fracture (肋骨骨折)	0	(0.0)	1	(0.7)	0	(0.0)	1	(0.4)
Scratch (引っかき傷)	0	(0.0)	1	(0.7)	0	(0.0)	1	(0.4)
Subdural haematoma (硬膜下血腫)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.4)
Traumatic fracture (外傷性骨折)	1	(0.7)	1	(0.7)	0	(0.0)	2	(0.7)

Percentages are calculated using total number of patients in the background medication at screening/treatment class as the denominator.

Containing data from study 1245_0052

MedDRA version used for reporting: XXXXXXXXXX

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Table 6.1.1 Frequency [N (%)] of patients with adverse events by background medication at screening, treatment, primary system organ class and preferred term - treated set

Background medication at screening=Alpha glucosidase inhibitor

	Empa 10mg		Empa 25mg		Metformin		Total	
System organ class/ Preferred term	N	(%)	N	(%)	N	(%)	N	(%)
Number of patients	69	(100.0)	70	(100.0)	0	(0.0)	139	(100.0)
Total with adverse events	52	(75.4)	49	(70.0)	0	(0.0)	101	(72.7)
Infections and infestations (感染症および寄生虫症)	35	(50.7)	26	(37.1)	0	(0.0)	61	(43.9)
Nasopharyngitis (鼻咽頭炎)	26	(37.7)	21	(30.0)	0	(0.0)	47	(33.8)
Gastroenteritis (胃腸炎)	1	(1.4)	4	(5.7)	0	(0.0)	5	(3.6)
Vulvovaginal candidiasis (外陰部腔カンジダ症)	2	(2.9)	3	(4.3)	0	(0.0)	5	(3.6)
Cystitis (膀胱炎)	2	(2.9)	2	(2.9)	0	(0.0)	4	(2.9)
Gingivitis (歯肉炎)	1	(1.4)	2	(2.9)	0	(0.0)	3	(2.2)
Influenza (インフルエンザ)	2	(2.9)	2	(2.9)	0	(0.0)	4	(2.9)
Pharyngitis (咽頭炎)	0	(0.0)	2	(2.9)	0	(0.0)	2	(1.4)
Acute tonsillitis (急性扁桃炎)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)
Appendicitis (虫垂炎)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)
Asymptomatic bacteriuria (無症候性細菌尿)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)
Bronchitis (気管支炎)	1	(1.4)	0	(0.0)	0	(0.0)	1	(0.7)
Enteritis infectious (感染性腸炎)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)
Folliculitis (毛包炎)	1	(1.4)	0	(0.0)	0	(0.0)	1	(0.7)
Fungal infection (真菌感染)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)
Herpes simplex (単純ヘルペス)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)
Herpes zoster (帯状疱疹)	1	(1.4)	0	(0.0)	0	(0.0)	1	(0.7)
Hordeolum (麦粒腫)	1	(1.4)	1	(1.4)	0	(0.0)	2	(1.4)
Skin infection (皮膚感染)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)
Tinea infection (白癬感染)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)
Tinea pedis (足部白癬)	1	(1.4)	1	(1.4)	0	(0.0)	2	(1.4)
Upper respiratory tract infection (上気道感染)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)
Urinary tract infection (尿路感染)	1	(1.4)	0	(0.0)	0	(0.0)	1	(0.7)
Vaginal infection (腔感染)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (良性、悪性および詳細不明の新生物(嚢胞およびポリープを含む))	0	(0.0)	2	(2.9)	0	(0.0)	2	(1.4)
Prostate cancer (前立腺癌)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)
Uterine cancer (子宮癌)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)
Blood and lymphatic system disorders (血液およびリンパ系障害)	1	(1.4)	2	(2.9)	0	(0.0)	3	(2.2)
Anaemia (貧血)	1	(1.4)	1	(1.4)	0	(0.0)	2	(1.4)
Iron deficiency anaemia (鉄欠乏性貧血)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)
Immune system disorders (免疫系障害)	2	(2.9)	1	(1.4)	0	(0.0)	3	(2.2)
Allergy to arthropod sting (節足動物刺傷アレルギー)	1	(1.4)	0	(0.0)	0	(0.0)	1	(0.7)
Anaphylactic reaction (アナフィラキシー反応)	1	(1.4)	0	(0.0)	0	(0.0)	1	(0.7)
Contrast media allergy (造影剤アレルギー)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)
Endocrine disorders (内分泌障害)	1	(1.4)	0	(0.0)	0	(0.0)	1	(0.7)
Thyroid cyst (甲状腺嚢腫)	1	(1.4)	0	(0.0)	0	(0.0)	1	(0.7)
Metabolism and nutrition disorders (代謝および栄養障害)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)
Dehydration (脱水)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)
Psychiatric disorders (精神障害)	0	(0.0)	4	(5.7)	0	(0.0)	4	(2.9)

	Empa 10mg		Empa 25mg		Metformin		Total	
System organ class/ Preferred term	N	(%)	N	(%)	N	(%)	N	(%)
Insomnia (不眠症)	0	(0.0)	2	(2.9)	0	(0.0)	2	(1.4)
Anxiety (不安)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)
Schizophrenia (統合失調症)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)
Nervous system disorders (神経系障害)	9	(13.0)	6	(8.6)	0	(0.0)	15	(10.8)
Dizziness (浮動性めまい)	3	(4.3)	1	(1.4)	0	(0.0)	4	(2.9)
Headache (頭痛)	1	(1.4)	2	(2.9)	0	(0.0)	3	(2.2)
Cervicobrachial syndrome (頸腕症候群)	1	(1.4)	1	(1.4)	0	(0.0)	2	(1.4)
Diabetic neuropathy (糖尿病性ニューロパチー)	1	(1.4)	0	(0.0)	0	(0.0)	1	(0.7)
Hypoaesthesia (感覚鈍麻)	1	(1.4)	1	(1.4)	0	(0.0)	2	(1.4)
Lacunar infarction (ラクナ梗塞)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)
Paraesthesia (錯感覚)	1	(1.4)	0	(0.0)	0	(0.0)	1	(0.7)
Post herpetic neuralgia (ヘルペス後神経痛)	1	(1.4)	0	(0.0)	0	(0.0)	1	(0.7)
Syncope (失神)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)
Eye disorders (眼障害)	5	(7.2)	2	(2.9)	0	(0.0)	7	(5.0)
Cataract (白内障)	1	(1.4)	0	(0.0)	0	(0.0)	1	(0.7)
Chalazion (霰粒腫)	1	(1.4)	0	(0.0)	0	(0.0)	1	(0.7)
Conjunctivitis (結膜炎)	1	(1.4)	1	(1.4)	0	(0.0)	2	(1.4)
Dry eye (眼乾燥)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)
Eye inflammation (眼の炎症)	1	(1.4)	0	(0.0)	0	(0.0)	1	(0.7)
Glaucoma (緑内障)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)
Iritis (虹彩炎)	1	(1.4)	0	(0.0)	0	(0.0)	1	(0.7)
Macular hole (黄斑円孔)	1	(1.4)	0	(0.0)	0	(0.0)	1	(0.7)
Retinal haemorrhage (網膜出血)	1	(1.4)	0	(0.0)	0	(0.0)	1	(0.7)
Scleritis (強膜炎)	1	(1.4)	0	(0.0)	0	(0.0)	1	(0.7)
Ear and labyrinth disorders (耳および迷路障害)	3	(4.3)	4	(5.7)	0	(0.0)	7	(5.0)
Vertigo (回転性めまい)	1	(1.4)	2	(2.9)	0	(0.0)	3	(2.2)
Deafness neurosensory (感音性難聴)	1	(1.4)	0	(0.0)	0	(0.0)	1	(0.7)
Sudden hearing loss (突発難聴)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)
Tinnitus (耳鳴)	1	(1.4)	1	(1.4)	0	(0.0)	2	(1.4)
Cardiac disorders (心臓障害)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)
Tachycardia (頻脈)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)
Vascular disorders (血管障害)	3	(4.3)	2	(2.9)	0	(0.0)	5	(3.6)
Hypertension (高血圧)	2	(2.9)	1	(1.4)	0	(0.0)	3	(2.2)
Embolism arterial (動脈塞栓症)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)
Hypotension (低血圧)	1	(1.4)	0	(0.0)	0	(0.0)	1	(0.7)
Respiratory, thoracic and mediastinal disorders (呼吸器、 胸郭および縦隔障害)	5	(7.2)	4	(5.7)	0	(0.0)	9	(6.5)
Oropharyngeal pain (口腔咽頭痛)	3	(4.3)	0	(0.0)	0	(0.0)	3	(2.2)
Asthma (喘息)	0	(0.0)	2	(2.9)	0	(0.0)	2	(1.4)
Upper respiratory tract inflammation (上気道の炎症)	1	(1.4)	2	(2.9)	0	(0.0)	3	(2.2)
Emphysema (肺気腫)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)
Vocal cord atrophy (声帯萎縮)	1	(1.4)	0	(0.0)	0	(0.0)	1	(0.7)
Gastrointestinal disorders (胃腸障害)	17	(24.6)	20	(28.6)	0	(0.0)	37	(26.6)
Constipation (便秘)	1	(1.4)	8	(11.4)	0	(0.0)	9	(6.5)
Diarrhoea (下痢)	2	(2.9)	4	(5.7)	0	(0.0)	6	(4.3)
Gastritis (胃炎)	2	(2.9)	4	(5.7)	0	(0.0)	6	(4.3)
Abdominal distension (腹部膨満)	3	(4.3)	0	(0.0)	0	(0.0)	3	(2.2)
Abdominal pain upper (上腹部痛)	0	(0.0)	2	(2.9)	0	(0.0)	2	(1.4)
Colonic polyp (結腸ポリープ)	2	(2.9)	0	(0.0)	0	(0.0)	2	(1.4)

	Empa 10mg		Empa 25mg		Metformin		Total	
System organ class/ Preferred term	N	(%)	N	(%)	N	(%)	N	(%)
Enteritis (小腸炎)	2	(2.9)	0	(0.0)	0	(0.0)	2	(1.4)
Hiatus hernia (裂孔ヘルニア)	2	(2.9)	0	(0.0)	0	(0.0)	2	(1.4)
Periodontal disease (歯周病)	0	(0.0)	2	(2.9)	0	(0.0)	2	(1.4)
Anal fissure (裂肛)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)
Dental caries (齲歯)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)
Diverticulum intestinal (腸憩室)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)
Duodenal ulcer (十二指腸潰瘍)	1	(1.4)	0	(0.0)	0	(0.0)	1	(0.7)
Duodenitis (十二指腸炎)	1	(1.4)	0	(0.0)	0	(0.0)	1	(0.7)
Food poisoning (食中毒)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)
Gastric polyps (胃ポリープ)	1	(1.4)	0	(0.0)	0	(0.0)	1	(0.7)
Gastritis atrophic (萎縮性胃炎)	1	(1.4)	0	(0.0)	0	(0.0)	1	(0.7)
Gastritis erosive (びらん性胃炎)	1	(1.4)	0	(0.0)	0	(0.0)	1	(0.7)
Gastrointestinal haemorrhage (胃腸出血)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)
Gastroesophageal reflux disease (胃食道逆流性疾患)	1	(1.4)	0	(0.0)	0	(0.0)	1	(0.7)
Gingival swelling (歯肉腫脹)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)
Mouth cyst (口腔嚢胞)	1	(1.4)	0	(0.0)	0	(0.0)	1	(0.7)
Nausea (悪心)	1	(1.4)	0	(0.0)	0	(0.0)	1	(0.7)
Oral discomfort (口腔内不快感)	1	(1.4)	0	(0.0)	0	(0.0)	1	(0.7)
Stomatitis (口内炎)	1	(1.4)	1	(1.4)	0	(0.0)	2	(1.4)
Toothache (歯痛)	1	(1.4)	1	(1.4)	0	(0.0)	2	(1.4)
Hepatobiliary disorders (肝胆道系障害)	2	(2.9)	1	(1.4)	0	(0.0)	3	(2.2)
Hepatic function abnormal (肝機能異常)	2	(2.9)	0	(0.0)	0	(0.0)	2	(1.4)
Gallbladder polyp (胆嚢ポリープ)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)
Hepatic steatosis (脂肪肝)	1	(1.4)	0	(0.0)	0	(0.0)	1	(0.7)
Skin and subcutaneous tissue disorders (皮膚および皮下組織障害)	5	(7.2)	7	(10.0)	0	(0.0)	12	(8.6)
Dermatitis contact (接触性皮膚炎)	0	(0.0)	3	(4.3)	0	(0.0)	3	(2.2)
Dermatitis (皮膚炎)	0	(0.0)	2	(2.9)	0	(0.0)	2	(1.4)
Eczema (湿疹)	0	(0.0)	2	(2.9)	0	(0.0)	2	(1.4)
Pruritus (そう痒症)	2	(2.9)	1	(1.4)	0	(0.0)	3	(2.2)
Dry skin (皮膚乾燥)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)
Eczema asteatotic (皮脂欠乏性湿疹)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)
Pustular psoriasis (膿疱性乾癬)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)
Seborrhoeic dermatitis (脂漏性皮膚炎)	1	(1.4)	0	(0.0)	0	(0.0)	1	(0.7)
Skin irritation (皮膚刺激)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)
Skin ulcer (皮膚潰瘍)	1	(1.4)	0	(0.0)	0	(0.0)	1	(0.7)
Solar dermatitis (日光皮膚炎)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)
Stasis dermatitis (うっ滞性皮膚炎)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)
Urticaria (蕁麻疹)	1	(1.4)	0	(0.0)	0	(0.0)	1	(0.7)
Xeroderma (乾皮症)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)
Musculoskeletal and connective tissue disorders (筋骨格系および結合組織障害)	9	(13.0)	8	(11.4)	0	(0.0)	17	(12.2)
Arthralgia (関節痛)	2	(2.9)	0	(0.0)	0	(0.0)	2	(1.4)
Back pain (背部痛)	2	(2.9)	1	(1.4)	0	(0.0)	3	(2.2)
Intervertebral disc protrusion (椎間板突出)	0	(0.0)	2	(2.9)	0	(0.0)	2	(1.4)
Muscle spasms (筋痙攣)	2	(2.9)	0	(0.0)	0	(0.0)	2	(1.4)
Osteoarthritis (変形性関節症)	2	(2.9)	1	(1.4)	0	(0.0)	3	(2.2)
Bone pain (骨痛)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)
Groin pain (鼠径部痛)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)
Lumbar spinal stenosis (腰部脊柱管狭窄症)	1	(1.4)	0	(0.0)	0	(0.0)	1	(0.7)

	Empa 10mg		Empa 25mg		Metformin		Total	
System organ class/ Preferred term	N	(%)	N	(%)	N	(%)	N	(%)
Musculoskeletal pain (筋骨格痛)	1	(1.4)	1	(1.4)	0	(0.0)	2	(1.4)
Pain in extremity (四肢痛)	1	(1.4)	0	(0.0)	0	(0.0)	1	(0.7)
Periarthritis (関節周囲炎)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)
Polyarthritis (多発性関節炎)	1	(1.4)	0	(0.0)	0	(0.0)	1	(0.7)
Scleroderma (強皮症)	1	(1.4)	0	(0.0)	0	(0.0)	1	(0.7)
Synovial cyst (滑液嚢腫)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)
Trigger finger (弾発指)	1	(1.4)	0	(0.0)	0	(0.0)	1	(0.7)
Renal and urinary disorders (腎および尿路障害)	3	(4.3)	3	(4.3)	0	(0.0)	6	(4.3)
Pollakiuria (頻尿)	2	(2.9)	3	(4.3)	0	(0.0)	5	(3.6)
Calculus ureteric (尿管結石)	1	(1.4)	0	(0.0)	0	(0.0)	1	(0.7)
Reproductive system and breast disorders (生殖系および乳房障害)	1	(1.4)	3	(4.3)	0	(0.0)	4	(2.9)
Benign prostatic hyperplasia (良性前立腺肥大症)	1	(1.4)	1	(1.4)	0	(0.0)	2	(1.4)
Gynaecomastia (女性化乳房)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)
Metrorrhagia (不正子宮出血)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)
General disorders and administration site conditions (一般・全身障害および投与部位の状態)	3	(4.3)	4	(5.7)	0	(0.0)	7	(5.0)
Oedema (浮腫)	0	(0.0)	2	(2.9)	0	(0.0)	2	(1.4)
Oedema peripheral (末梢性浮腫)	0	(0.0)	2	(2.9)	0	(0.0)	2	(1.4)
Chest pain (胸痛)	1	(1.4)	0	(0.0)	0	(0.0)	1	(0.7)
Feeling drunk (酩酊感)	1	(1.4)	0	(0.0)	0	(0.0)	1	(0.7)
Pyrexia (発熱)	1	(1.4)	0	(0.0)	0	(0.0)	1	(0.7)
Investigations (臨床検査)	2	(2.9)	2	(2.9)	0	(0.0)	4	(2.9)
Blood pressure decreased (血圧低下)	1	(1.4)	0	(0.0)	0	(0.0)	1	(0.7)
Prostatic specific antigen increased (前立腺特異性抗原増加)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)
Urine output increased (尿量増加)	1	(1.4)	1	(1.4)	0	(0.0)	2	(1.4)
Injury, poisoning and procedural complications (傷害、中毒および処置合併症)	11	(15.9)	8	(11.4)	0	(0.0)	19	(13.7)
Contusion (挫傷)	2	(2.9)	4	(5.7)	0	(0.0)	6	(4.3)
Fall (転倒)	3	(4.3)	2	(2.9)	0	(0.0)	5	(3.6)
Ligament sprain (靱帯捻挫)	3	(4.3)	0	(0.0)	0	(0.0)	3	(2.2)
Procedural pain (処置による疼痛)	2	(2.9)	0	(0.0)	0	(0.0)	2	(1.4)
Spinal compression fracture (脊椎圧迫骨折)	1	(1.4)	2	(2.9)	0	(0.0)	3	(2.2)
Arthropod sting (節足動物刺傷)	1	(1.4)	0	(0.0)	0	(0.0)	1	(0.7)
Chil blains (凍瘡)	1	(1.4)	0	(0.0)	0	(0.0)	1	(0.7)
Foot fracture (足骨折)	1	(1.4)	1	(1.4)	0	(0.0)	2	(1.4)
Heat stroke (熱射病)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)
Remnant gastritis (残胃炎)	1	(1.4)	0	(0.0)	0	(0.0)	1	(0.7)
Road traffic accident (交通事故)	1	(1.4)	0	(0.0)	0	(0.0)	1	(0.7)

Percentages are calculated using total number of patients in the background medication at screening/treatment class as the denominator.

Containing data from study 1245_0052

MedDRA version used for reporting: [REDACTED]

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Table 6.1.1 Frequency [N (%)] of patients with adverse events by background medication at screening, treatment, primary system organ class and preferred term - treated set

Background medication at screening=DPP-IV inhibitor

	Empa 10mg		Empa 25mg		Metformin		Total	
System organ class/ Preferred term	N	(%)	N	(%)	N	(%)	N	(%)
Number of patients	68	(100.0)	71	(100.0)	0	(0.0)	139	(100.0)
Total with adverse events	56	(82.4)	57	(80.3)	0	(0.0)	113	(81.3)
Infections and infestations (感染症および寄生虫症)	34	(50.0)	26	(36.6)	0	(0.0)	60	(43.2)
Nasopharyngitis (鼻咽頭炎)	23	(33.8)	15	(21.1)	0	(0.0)	38	(27.3)
Pharyngitis (咽頭炎)	2	(2.9)	5	(7.0)	0	(0.0)	7	(5.0)
Bronchitis (気管支炎)	2	(2.9)	3	(4.2)	0	(0.0)	5	(3.6)
Asymptomatic bacteriuria (無症候性細菌尿)	2	(2.9)	0	(0.0)	0	(0.0)	2	(1.4)
Cystitis (膀胱炎)	2	(2.9)	1	(1.4)	0	(0.0)	3	(2.2)
Influenza (インフルエンザ)	2	(2.9)	0	(0.0)	0	(0.0)	2	(1.4)
Rhinitis (鼻炎)	2	(2.9)	0	(0.0)	0	(0.0)	2	(1.4)
Folliculitis (毛包炎)	0	(0.0)	2	(2.8)	0	(0.0)	2	(1.4)
Gastroenteritis (胃腸炎)	1	(1.5)	1	(1.4)	0	(0.0)	2	(1.4)
Herpes zoster (帯状疱疹)	1	(1.5)	1	(1.4)	0	(0.0)	2	(1.4)
Oral herpes (口腔ヘルペス)	1	(1.5)	0	(0.0)	0	(0.0)	1	(0.7)
Otitis externa (外耳炎)	1	(1.5)	0	(0.0)	0	(0.0)	1	(0.7)
Trichomoniasis (トリコモナス症)	1	(1.5)	0	(0.0)	0	(0.0)	1	(0.7)
Urinary tract infection (尿路感染)	1	(1.5)	0	(0.0)	0	(0.0)	1	(0.7)
Febrile infection (熱性感染症)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)
Tinea pedis (足部白癬)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)
Upper respiratory tract infection (上気道感染)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)
Vulvovaginal candidiasis (外陰部膣カンジダ症)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (良性、悪性および詳細不明の新生物 (嚢胞およびポリープを含む))	2	(2.9)	4	(5.6)	0	(0.0)	6	(4.3)
Benign breast neoplasm (乳房の良性新生物)	1	(1.5)	0	(0.0)	0	(0.0)	1	(0.7)
Seborrhoeic keratosis (脂漏性角化症)	1	(1.5)	0	(0.0)	0	(0.0)	1	(0.7)
Gastric cancer (胃癌)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)
Haemangioma of liver (肝臓血管腫)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)
Meningioma (髄膜腫)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)
Prostate cancer (前立腺癌)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)
Immune system disorders (免疫系障害)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)
Seasonal allergy (季節性アレルギー)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)
Metabolism and nutrition disorders (代謝および栄養障害)	2	(2.9)	3	(4.2)	0	(0.0)	5	(3.6)
Hypoglycaemia (低血糖症)	0	(0.0)	3	(4.2)	0	(0.0)	3	(2.2)
Decreased appetite (食欲減退)	1	(1.5)	0	(0.0)	0	(0.0)	1	(0.7)
Gout (痛風)	1	(1.5)	0	(0.0)	0	(0.0)	1	(0.7)
Psychiatric disorders (精神障害)	2	(2.9)	1	(1.4)	0	(0.0)	3	(2.2)
Anxiety disorder (不安障害)	1	(1.5)	0	(0.0)	0	(0.0)	1	(0.7)
Depression (うつ病)	1	(1.5)	0	(0.0)	0	(0.0)	1	(0.7)
Insomnia (不眠症)	1	(1.5)	1	(1.4)	0	(0.0)	2	(1.4)
Nervous system disorders (神経系障害)	8	(11.8)	8	(11.3)	0	(0.0)	16	(11.5)
Dizziness (浮動性めまい)	3	(4.4)	2	(2.8)	0	(0.0)	5	(3.6)
Headache (頭痛)	2	(2.9)	3	(4.2)	0	(0.0)	5	(3.6)
Dizziness postural (体位性めまい)	0	(0.0)	2	(2.8)	0	(0.0)	2	(1.4)
Cerebrovascular disorder (脳血管障害)	1	(1.5)	0	(0.0)	0	(0.0)	1	(0.7)

	Empa 10mg		Empa 25mg		Metformin		Total	
System organ class/ Preferred term	N	(%)	N	(%)	N	(%)	N	(%)
Cervicobrachial syndrome (頰腕症候群)	1	(1.5)	0	(0.0)	0	(0.0)	1	(0.7)
Lacunar infarction (ラクナ梗塞)	1	(1.5)	0	(0.0)	0	(0.0)	1	(0.7)
Restless legs syndrome (下肢静止不能症候群)	1	(1.5)	0	(0.0)	0	(0.0)	1	(0.7)
Sciatica (坐骨神経痛)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)
Eye disorders (眼障害)	6	(8.8)	5	(7.0)	0	(0.0)	11	(7.9)
Cataract (白内障)	2	(2.9)	1	(1.4)	0	(0.0)	3	(2.2)
Asthenopia (眼精疲労)	1	(1.5)	0	(0.0)	0	(0.0)	1	(0.7)
Keratitis (角膜炎)	1	(1.5)	0	(0.0)	0	(0.0)	1	(0.7)
Ocular hyperaemia (眼充血)	1	(1.5)	0	(0.0)	0	(0.0)	1	(0.7)
Open angle glaucoma (開放隅角緑内障)	1	(1.5)	0	(0.0)	0	(0.0)	1	(0.7)
Visual impairment (視力障害)	1	(1.5)	1	(1.4)	0	(0.0)	2	(1.4)
Conjunctival haemorrhage (結膜出血)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)
Conjunctival oedema (結膜浮腫)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)
Diabetic retinopathy (糖尿病網膜症)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)
Eye allergy (眼のアレルギー)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)
Ear and labyrinth disorders (耳および迷路障害)	1	(1.5)	2	(2.8)	0	(0.0)	3	(2.2)
Ear pain (耳痛)	1	(1.5)	0	(0.0)	0	(0.0)	1	(0.7)
Ear discomfort (耳不快感)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)
Vertigo (回転性めまい)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)
Cardiac disorders (心臓障害)	2	(2.9)	1	(1.4)	0	(0.0)	3	(2.2)
Acute myocardial infarction (急性心筋梗塞)	1	(1.5)	0	(0.0)	0	(0.0)	1	(0.7)
Myocardial infarction (心筋梗塞)	1	(1.5)	0	(0.0)	0	(0.0)	1	(0.7)
Angina pectoris (狭心症)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)
Vascular disorders (血管障害)	2	(2.9)	4	(5.6)	0	(0.0)	6	(4.3)
Hypertension (高血圧)	0	(0.0)	3	(4.2)	0	(0.0)	3	(2.2)
Orthostatic hypotension (起立性低血圧)	1	(1.5)	0	(0.0)	0	(0.0)	1	(0.7)
Varicose vein (静脈瘤)	1	(1.5)	0	(0.0)	0	(0.0)	1	(0.7)
Haematoma (血腫)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)
Respiratory, thoracic and mediastinal disorders (呼吸器、 胸郭および縦隔障害)	3	(4.4)	5	(7.0)	0	(0.0)	8	(5.8)
Asthma (喘息)	2	(2.9)	1	(1.4)	0	(0.0)	3	(2.2)
Cough (咳嗽)	1	(1.5)	0	(0.0)	0	(0.0)	1	(0.7)
Oropharyngeal discomfort (口腔咽頭不快感)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)
Oropharyngeal pain (口腔咽頭痛)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)
Pharyngeal cyst (咽頭嚢腫)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)
Rhinitis allergic (アレルギー性鼻炎)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)
Gastrointestinal disorders (胃腸障害)	14	(20.6)	19	(26.8)	0	(0.0)	33	(23.7)
Constipation (便秘)	5	(7.4)	7	(9.9)	0	(0.0)	12	(8.6)
Stomatitis (口内炎)	2	(2.9)	2	(2.8)	0	(0.0)	4	(2.9)
Haemorrhoids (痔核)	0	(0.0)	2	(2.8)	0	(0.0)	2	(1.4)
Abdominal pain upper (上腹部痛)	1	(1.5)	0	(0.0)	0	(0.0)	1	(0.7)
Dental caries (齲蝕)	1	(1.5)	0	(0.0)	0	(0.0)	1	(0.7)
Gastric ulcer (胃潰瘍)	1	(1.5)	0	(0.0)	0	(0.0)	1	(0.7)
Gastrointestinal disorder (胃腸障害)	1	(1.5)	0	(0.0)	0	(0.0)	1	(0.7)
Gastroesophageal reflux disease (胃食道逆流性疾患)	1	(1.5)	0	(0.0)	0	(0.0)	1	(0.7)
Nausea (悪心)	1	(1.5)	0	(0.0)	0	(0.0)	1	(0.7)
Toothache (歯痛)	1	(1.5)	0	(0.0)	0	(0.0)	1	(0.7)
Abdominal discomfort (腹部不快感)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)
Abdominal distension (腹部膨満)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)

	Empa 10mg		Empa 25mg		Metformin		Total	
System organ class/ Preferred term	N	(%)	N	(%)	N	(%)	N	(%)
Diarrhoea (下痢)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)
Duodenal ulcer (十二指腸潰瘍)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)
Enteritis (小腸炎)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)
Faecaloma (糞塊)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)
Gingival swelling (歯肉腫脹)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)
Inguinal hernia (鼠径ヘルニア)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)
Pancreatitis (膵炎)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)
Vomiting (嘔吐)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)
Hepatobiliary disorders (肝胆道系障害)	1	(1.5)	4	(5.6)	0	(0.0)	5	(3.6)
Gallbladder polyp (胆嚢ポリープ)	1	(1.5)	2	(2.8)	0	(0.0)	3	(2.2)
Cholelithiasis (胆石症)	1	(1.5)	1	(1.4)	0	(0.0)	2	(1.4)
Jaundice (黄疸)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)
Skin and subcutaneous tissue disorders (皮膚および皮下組織障害)	8	(11.8)	5	(7.0)	0	(0.0)	13	(9.4)
Eczema (湿疹)	1	(1.5)	3	(4.2)	0	(0.0)	4	(2.9)
Dermatitis contact (接触性皮膚炎)	2	(2.9)	0	(0.0)	0	(0.0)	2	(1.4)
Heat rash (紅色汗疹)	2	(2.9)	0	(0.0)	0	(0.0)	2	(1.4)
Eczema asteatotic (皮脂欠乏性湿疹)	1	(1.5)	0	(0.0)	0	(0.0)	1	(0.7)
Hyperkeratosis (過角化)	1	(1.5)	1	(1.4)	0	(0.0)	2	(1.4)
Urticaria (蕁麻疹)	1	(1.5)	0	(0.0)	0	(0.0)	1	(0.7)
Dermatitis (皮膚炎)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)
Pruritus (そう痒症)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)
Musculoskeletal and connective tissue disorders (筋骨格系および結合組織障害)	11	(16.2)	11	(15.5)	0	(0.0)	22	(15.8)
Back pain (背部痛)	1	(1.5)	5	(7.0)	0	(0.0)	6	(4.3)
Myalgia (筋肉痛)	0	(0.0)	3	(4.2)	0	(0.0)	3	(2.2)
Arthralgia (関節痛)	2	(2.9)	1	(1.4)	0	(0.0)	3	(2.2)
Musculoskeletal pain (筋骨格痛)	1	(1.5)	2	(2.8)	0	(0.0)	3	(2.2)
Osteoarthritis (変形性関節症)	0	(0.0)	2	(2.8)	0	(0.0)	2	(1.4)
Pain in extremity (四肢痛)	1	(1.5)	2	(2.8)	0	(0.0)	3	(2.2)
Bone pain (骨痛)	1	(1.5)	0	(0.0)	0	(0.0)	1	(0.7)
Intervertebral disc protrusion (椎間板突出)	1	(1.5)	0	(0.0)	0	(0.0)	1	(0.7)
Muscle spasms (筋痙攣)	1	(1.5)	0	(0.0)	0	(0.0)	1	(0.7)
Musculoskeletal stiffness (筋骨格硬直)	1	(1.5)	0	(0.0)	0	(0.0)	1	(0.7)
Osteoporosis (骨粗鬆症)	1	(1.5)	0	(0.0)	0	(0.0)	1	(0.7)
Periarthritis (関節周囲炎)	1	(1.5)	1	(1.4)	0	(0.0)	2	(1.4)
Spinal osteoarthritis (変形性脊椎症)	1	(1.5)	0	(0.0)	0	(0.0)	1	(0.7)
Tenosynovitis (腱鞘炎)	1	(1.5)	0	(0.0)	0	(0.0)	1	(0.7)
Neck pain (頸部痛)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)
Tenosynovitis stenosans (狭窄性腱鞘炎)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)
Renal and urinary disorders (腎および尿路障害)	8	(11.8)	13	(18.3)	0	(0.0)	21	(15.1)
Pollakiuria (頻尿)	4	(5.9)	7	(9.9)	0	(0.0)	11	(7.9)
Nocturia (夜間頻尿)	1	(1.5)	3	(4.2)	0	(0.0)	4	(2.9)
Renal cyst (腎嚢胞)	0	(0.0)	3	(4.2)	0	(0.0)	3	(2.2)
Bladder prolapse (膀胱脱)	1	(1.5)	0	(0.0)	0	(0.0)	1	(0.7)
Hydronephrosis (水腎症)	1	(1.5)	0	(0.0)	0	(0.0)	1	(0.7)
Nephrolithiasis (腎結石症)	1	(1.5)	0	(0.0)	0	(0.0)	1	(0.7)
Urinary retention (尿閉)	1	(1.5)	0	(0.0)	0	(0.0)	1	(0.7)
Reproductive system and breast disorders (生殖系および乳房障害)	4	(5.9)	1	(1.4)	0	(0.0)	5	(3.6)

	Empa 10mg		Empa 25mg		Metformin		Total	
System organ class/ Preferred term	N	(%)	N	(%)	N	(%)	N	(%)
Benign prostatic hyperplasia (良性前立腺肥大症)	2	(2.9)	1	(1.4)	0	(0.0)	3	(2.2)
Prostatitis (前立腺炎)	1	(1.5)	0	(0.0)	0	(0.0)	1	(0.7)
Pruritus genital (陰部そう痒症)	1	(1.5)	0	(0.0)	0	(0.0)	1	(0.7)
General disorders and administration site conditions (一般・全身障害および投与部位の状態)	3	(4.4)	3	(4.2)	0	(0.0)	6	(4.3)
Chest discomfort (胸部不快感)	1	(1.5)	0	(0.0)	0	(0.0)	1	(0.7)
Chest pain (胸痛)	1	(1.5)	0	(0.0)	0	(0.0)	1	(0.7)
Hunger (空腹)	1	(1.5)	1	(1.4)	0	(0.0)	2	(1.4)
Thirst (口渇)	1	(1.5)	0	(0.0)	0	(0.0)	1	(0.7)
Hangover (宿酔)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)
Pyrexia (発熱)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)
Investigations (臨床検査)	2	(2.9)	1	(1.4)	0	(0.0)	3	(2.2)
Blood pressure increased (血圧上昇)	1	(1.5)	0	(0.0)	0	(0.0)	1	(0.7)
Electrocardiogram ST segment elevation (心電図ST部分上昇)	1	(1.5)	0	(0.0)	0	(0.0)	1	(0.7)
Urine output increased (尿量増加)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)
Injury, poisoning and procedural complications (傷害、中毒および処置合併症)	7	(10.3)	7	(9.9)	0	(0.0)	14	(10.1)
Fall (転倒)	4	(5.9)	4	(5.6)	0	(0.0)	8	(5.8)
Contusion (挫傷)	2	(2.9)	4	(5.6)	0	(0.0)	6	(4.3)
Arthropod sting (節足動物刺傷)	1	(1.5)	0	(0.0)	0	(0.0)	1	(0.7)
Excoriation (擦過傷)	1	(1.5)	1	(1.4)	0	(0.0)	2	(1.4)
Femur fracture (大腿骨骨折)	1	(1.5)	0	(0.0)	0	(0.0)	1	(0.7)
Laceration (裂傷)	1	(1.5)	0	(0.0)	0	(0.0)	1	(0.7)
Foot fracture (足骨折)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)
Rib fracture (肋骨骨折)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)

Percentages are calculated using total number of patients in the background medication at screening/treatment class as the denominator.

Containing data from study 1245_0052

MedDRA version used for reporting: [REDACTED]

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Table 6.1.1 Frequency [N (%)] of patients with adverse events by background medication at screening, treatment, primary system organ class and preferred term - treated set

Background medication at screening=Glinide

	Empa 10mg		Empa 25mg		Metformin		Total	
System organ class/ Preferred term	N	(%)	N	(%)	N	(%)	N	(%)
Number of patients	70	(100.0)	70	(100.0)	0	(0.0)	140	(100.0)
Total with adverse events	49	(70.0)	50	(71.4)	0	(0.0)	99	(70.7)
Infections and infestations (感染症および寄生虫症)	24	(34.3)	32	(45.7)	0	(0.0)	56	(40.0)
Nasopharyngitis (鼻咽頭炎)	16	(22.9)	17	(24.3)	0	(0.0)	33	(23.6)
Pharyngitis (咽頭炎)	2	(2.9)	5	(7.1)	0	(0.0)	7	(5.0)
Bronchitis (気管支炎)	1	(1.4)	3	(4.3)	0	(0.0)	4	(2.9)
Influenza (インフルエンザ)	0	(0.0)	3	(4.3)	0	(0.0)	3	(2.1)
Upper respiratory tract infection (上気道感染)	3	(4.3)	0	(0.0)	0	(0.0)	3	(2.1)
Cellulitis (蜂巣炎)	0	(0.0)	2	(2.9)	0	(0.0)	2	(1.4)
Cystitis (膀胱炎)	1	(1.4)	2	(2.9)	0	(0.0)	3	(2.1)
Gastroenteritis (胃腸炎)	1	(1.4)	2	(2.9)	0	(0.0)	3	(2.1)
Gingivitis (歯肉炎)	2	(2.9)	0	(0.0)	0	(0.0)	2	(1.4)
Acute sinusitis (急性副鼻腔炎)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)
Asymptomatic bacteriuria (無症候性細菌尿)	1	(1.4)	0	(0.0)	0	(0.0)	1	(0.7)
Empyema (蓄膿)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)
Gangrene (壊疽)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)
Gastroenteritis viral (ウイルス性胃腸炎)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)
Helicobacter infection (ヘリコバクター感染)	1	(1.4)	0	(0.0)	0	(0.0)	1	(0.7)
Osteomyelitis (骨髄炎)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)
Otitis externa (外耳炎)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)
Pericoronitis (歯冠周囲炎)	1	(1.4)	0	(0.0)	0	(0.0)	1	(0.7)
Periodontitis (歯周炎)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)
Rhinitis (鼻炎)	1	(1.4)	1	(1.4)	0	(0.0)	2	(1.4)
Urinary tract infection (尿路感染)	1	(1.4)	0	(0.0)	0	(0.0)	1	(0.7)
Viral infection (ウイルス感染)	1	(1.4)	0	(0.0)	0	(0.0)	1	(0.7)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (良性、悪性および詳細不明の新生物(嚢胞およびポリープを含む))	0	(0.0)	3	(4.3)	0	(0.0)	3	(2.1)
Colon cancer (結腸癌)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)
Intraductal papillary mucinous neoplasm (膵管内乳頭粘液性腫瘍)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)
Oropharyngeal cancer stage unspecified (中咽頭癌、病期不明)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)
Blood and lymphatic system disorders (血液およびリンパ系障害)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)
Iron deficiency anaemia (鉄欠乏性貧血)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)
Metabolism and nutrition disorders (代謝および栄養障害)	0	(0.0)	5	(7.1)	0	(0.0)	5	(3.6)
Hypoglycaemia (低血糖症)	0	(0.0)	3	(4.3)	0	(0.0)	3	(2.1)
Gout (痛風)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)
Hyperglycaemia (高血糖)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)
Nervous system disorders (神経系障害)	9	(12.9)	3	(4.3)	0	(0.0)	12	(8.6)
Dizziness (浮動性めまい)	6	(8.6)	2	(2.9)	0	(0.0)	8	(5.7)
Altered state of consciousness (意識変容状態)	1	(1.4)	0	(0.0)	0	(0.0)	1	(0.7)
Diabetic neuropathy (糖尿病性ニューロパチー)	1	(1.4)	0	(0.0)	0	(0.0)	1	(0.7)
Headache (頭痛)	1	(1.4)	0	(0.0)	0	(0.0)	1	(0.7)
Lacunar infarction (ラクナ梗塞)	1	(1.4)	0	(0.0)	0	(0.0)	1	(0.7)

	Empa 10mg		Empa 25mg		Metformin		Total	
System organ class/ Preferred term	N	(%)	N	(%)	N	(%)	N	(%)
Presyncope (失神寸前の状態)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)
Tremor (振戦)	1	(1.4)	0	(0.0)	0	(0.0)	1	(0.7)
Eye disorders (眼障害)	6	(8.6)	6	(8.6)	0	(0.0)	12	(8.6)
Conjunctivitis (結膜炎)	0	(0.0)	2	(2.9)	0	(0.0)	2	(1.4)
Glaucoma (緑内障)	1	(1.4)	2	(2.9)	0	(0.0)	3	(2.1)
Blepharitis (眼瞼炎)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)
Cataract (白内障)	1	(1.4)	0	(0.0)	0	(0.0)	1	(0.7)
Corneal disorder (角膜障害)	1	(1.4)	0	(0.0)	0	(0.0)	1	(0.7)
Eczema eyelids (眼瞼湿疹)	1	(1.4)	0	(0.0)	0	(0.0)	1	(0.7)
Macular degeneration (黄斑変性)	1	(1.4)	0	(0.0)	0	(0.0)	1	(0.7)
Ocular hyperaemia (眼充血)	1	(1.4)	0	(0.0)	0	(0.0)	1	(0.7)
Retinal vein occlusion (網膜静脈閉塞)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)
Ear and labyrinth disorders (耳および迷路障害)	4	(5.7)	1	(1.4)	0	(0.0)	5	(3.6)
Vertigo (回転性めまい)	2	(2.9)	0	(0.0)	0	(0.0)	2	(1.4)
Ear discomfort (耳不快感)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)
Ear pain (耳痛)	1	(1.4)	0	(0.0)	0	(0.0)	1	(0.7)
Ear pruritus (耳そう痒症)	1	(1.4)	0	(0.0)	0	(0.0)	1	(0.7)
Vascular disorders (血管障害)	2	(2.9)	1	(1.4)	0	(0.0)	3	(2.1)
Arteriosclerosis (動脈硬化症)	1	(1.4)	0	(0.0)	0	(0.0)	1	(0.7)
Hypertension (高血圧)	1	(1.4)	1	(1.4)	0	(0.0)	2	(1.4)
Peripheral arterial occlusive disease (末梢動脈閉塞性疾患)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)
Respiratory, thoracic and mediastinal disorders (呼吸器、胸郭および縦隔障害)	5	(7.1)	1	(1.4)	0	(0.0)	6	(4.3)
Cough (咳嗽)	1	(1.4)	0	(0.0)	0	(0.0)	1	(0.7)
Emphysema (肺気腫)	1	(1.4)	0	(0.0)	0	(0.0)	1	(0.7)
Oropharyngeal pain (口腔咽頭痛)	1	(1.4)	0	(0.0)	0	(0.0)	1	(0.7)
Rhinorrhoea (鼻漏)	1	(1.4)	0	(0.0)	0	(0.0)	1	(0.7)
Upper respiratory tract inflammation (上気道の炎症)	1	(1.4)	1	(1.4)	0	(0.0)	2	(1.4)
Gastrointestinal disorders (胃腸障害)	12	(17.1)	13	(18.6)	0	(0.0)	25	(17.9)
Constipation (便秘)	3	(4.3)	0	(0.0)	0	(0.0)	3	(2.1)
Gastroesophageal reflux disease (胃食道逆流性疾患)	0	(0.0)	3	(4.3)	0	(0.0)	3	(2.1)
Gastritis (胃炎)	1	(1.4)	2	(2.9)	0	(0.0)	3	(2.1)
Abdominal discomfort (腹部不快感)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)
Abdominal pain (腹痛)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)
Abdominal pain upper (上腹部痛)	1	(1.4)	1	(1.4)	0	(0.0)	2	(1.4)
Anal fissure (裂肛)	1	(1.4)	0	(0.0)	0	(0.0)	1	(0.7)
Anal fistula (痔瘻)	1	(1.4)	0	(0.0)	0	(0.0)	1	(0.7)
Bowel movement irregularity (便通不規則)	1	(1.4)	0	(0.0)	0	(0.0)	1	(0.7)
Dental caries (齲歯)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)
Diarrhoea (下痢)	1	(1.4)	1	(1.4)	0	(0.0)	2	(1.4)
Dyspepsia (消化不良)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)
Enteritis (小腸炎)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)
Enterocolitis (腸炎)	1	(1.4)	0	(0.0)	0	(0.0)	1	(0.7)
Gastric polyps (胃ポリープ)	1	(1.4)	0	(0.0)	0	(0.0)	1	(0.7)
Gastritis atrophic (萎縮性胃炎)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)
Glossitis (舌炎)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)
Nausea (悪心)	1	(1.4)	0	(0.0)	0	(0.0)	1	(0.7)
Toothache (歯痛)	1	(1.4)	1	(1.4)	0	(0.0)	2	(1.4)

	Empa 10mg		Empa 25mg		Metformin		Total	
System organ class/ Preferred term	N	(%)	N	(%)	N	(%)	N	(%)
Hepatobiliary disorders (肝胆道系障害)	0	(0.0)	2	(2.9)	0	(0.0)	2	(1.4)
Gallbladder cholesterosis (胆嚢コレステリン沈着症)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)
Hepatic steatosis (脂肪肝)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)
Skin and subcutaneous tissue disorders (皮膚および皮下組織障害)	4	(5.7)	5	(7.1)	0	(0.0)	9	(6.4)
Eczema (湿疹)	2	(2.9)	2	(2.9)	0	(0.0)	4	(2.9)
Acne (ざ瘡)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)
Alopecia (脱毛症)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)
Hyperkeratosis (過角化)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)
Pruritus (そう痒症)	1	(1.4)	0	(0.0)	0	(0.0)	1	(0.7)
Rash (発疹)	1	(1.4)	0	(0.0)	0	(0.0)	1	(0.7)
Xeroderma (乾皮症)	1	(1.4)	0	(0.0)	0	(0.0)	1	(0.7)
Musculoskeletal and connective tissue disorders (筋骨格系および結合組織障害)	10	(14.3)	10	(14.3)	0	(0.0)	20	(14.3)
Back pain (背部痛)	4	(5.7)	3	(4.3)	0	(0.0)	7	(5.0)
Myalgia (筋肉痛)	2	(2.9)	0	(0.0)	0	(0.0)	2	(1.4)
Arthralgia (関節痛)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)
Arthritis (関節炎)	1	(1.4)	0	(0.0)	0	(0.0)	1	(0.7)
Intervertebral disc protrusion (椎間板突出)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)
Joint swelling (関節腫脹)	1	(1.4)	0	(0.0)	0	(0.0)	1	(0.7)
Musculoskeletal pain (筋骨格痛)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)
Musculoskeletal stiffness (筋骨格硬直)	1	(1.4)	0	(0.0)	0	(0.0)	1	(0.7)
Osteoarthritis (変形性関節症)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)
Osteoporosis (骨粗鬆症)	1	(1.4)	0	(0.0)	0	(0.0)	1	(0.7)
Sensation of heaviness (重感)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)
Synovial cyst (滑液嚢腫)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)
Tendonitis (腱炎)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)
Tenosynovitis (腱鞘炎)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)
Renal and urinary disorders (腎および尿路障害)	3	(4.3)	5	(7.1)	0	(0.0)	8	(5.7)
Pollakiuria (頻尿)	3	(4.3)	5	(7.1)	0	(0.0)	8	(5.7)
Calculus ureteric (尿管結石)	1	(1.4)	0	(0.0)	0	(0.0)	1	(0.7)
Renal cyst (腎嚢胞)	1	(1.4)	0	(0.0)	0	(0.0)	1	(0.7)
Reproductive system and breast disorders (生殖系および乳房障害)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)
Vulvovaginal pruritus (外陰腔そう痒症)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)
General disorders and administration site conditions (一般・全身障害および投与部位の状態)	6	(8.6)	0	(0.0)	0	(0.0)	6	(4.3)
Hunger (空腹)	3	(4.3)	0	(0.0)	0	(0.0)	3	(2.1)
Thirst (口渇)	2	(2.9)	0	(0.0)	0	(0.0)	2	(1.4)
Oedema peripheral (末梢性浮腫)	1	(1.4)	0	(0.0)	0	(0.0)	1	(0.7)
Investigations (臨床検査)	3	(4.3)	0	(0.0)	0	(0.0)	3	(2.1)
Blood pressure increased (血圧上昇)	1	(1.4)	0	(0.0)	0	(0.0)	1	(0.7)
Electrocardiogram ST-T segment abnormal (心電図S T - T部分異常)	1	(1.4)	0	(0.0)	0	(0.0)	1	(0.7)
Urine output increased (尿量増加)	1	(1.4)	0	(0.0)	0	(0.0)	1	(0.7)
Injury, poisoning and procedural complications (傷害、中毒および処置合併症)	5	(7.1)	5	(7.1)	0	(0.0)	10	(7.1)
Fall (転倒)	3	(4.3)	2	(2.9)	0	(0.0)	5	(3.6)
Animal bite (動物咬傷)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)
Arthropod bite (節足動物咬傷)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)
Contusion (挫傷)	1	(1.4)	1	(1.4)	0	(0.0)	2	(1.4)

	Empa 10mg		Empa 25mg		Metformin		Total	
System organ class/ Preferred term	N	(%)	N	(%)	N	(%)	N	(%)
Excoriation (擦過傷)	1	(1.4)	0	(0.0)	0	(0.0)	1	(0.7)
Heat stroke (熱射病)	1	(1.4)	0	(0.0)	0	(0.0)	1	(0.7)
Laceration (裂傷)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)
Ligament sprain (韌帶捻挫)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)
Spinal compression fracture (脊椎圧迫骨折)	1	(1.4)	0	(0.0)	0	(0.0)	1	(0.7)
Wrist fracture (手首関節骨折)	1	(1.4)	0	(0.0)	0	(0.0)	1	(0.7)

Percentages are calculated using total number of patients in the background medication at screening/treatment class as the denominator.

Containing data from study 1245_0052

MedDRA version used for reporting: [REDACTED]

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Table 6.1.2 Frequency [N (%)] of patients with related adverse events by background medication at screening, treatment, primary system organ class and preferred term - treated set

Background medication at screening=Sulfonylurea

System organ class/ Preferred term	Empa 10mg		Empa 25mg		Metformin		Total	
	N	(%)	N	(%)	N	(%)	N	(%)
Number of patients	136	(100.0)	137	(100.0)	63	(100.0)	336	(100.0)
Total with related adverse events	19	(14.0)	25	(18.2)	13	(20.6)	57	(17.0)
Infections and infestations (感染症および寄生虫症)	3	(2.2)	3	(2.2)	0	(0.0)	6	(1.8)
Cystitis (膀胱炎)	2	(1.5)	2	(1.5)	0	(0.0)	4	(1.2)
Asymptomatic bacteriuria (無症候性細菌尿)	0	(0.0)	1	(0.7)	0	(0.0)	1	(0.3)
Urinary tract infection (尿路感染)	1	(0.7)	1	(0.7)	0	(0.0)	2	(0.6)
Metabolism and nutrition disorders (代謝および栄養障害)	9	(6.6)	10	(7.3)	6	(9.5)	25	(7.4)
Hypoglycaemia (低血糖症)	9	(6.6)	10	(7.3)	6	(9.5)	25	(7.4)
Nervous system disorders (神経系障害)	1	(0.7)	1	(0.7)	1	(1.6)	3	(0.9)
Tremor (振戦)	1	(0.7)	1	(0.7)	1	(1.6)	3	(0.9)
Ear and labyrinth disorders (耳および迷路障害)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.3)
Tinnitus (耳鳴)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.3)
Cardiac disorders (心臓障害)	0	(0.0)	1	(0.7)	0	(0.0)	1	(0.3)
Sinus arrest (洞停止)	0	(0.0)	1	(0.7)	0	(0.0)	1	(0.3)
Vascular disorders (血管障害)	1	(0.7)	1	(0.7)	0	(0.0)	2	(0.6)
Hypotension (低血圧)	1	(0.7)	1	(0.7)	0	(0.0)	2	(0.6)
Gastrointestinal disorders (胃腸障害)	2	(1.5)	3	(2.2)	3	(4.8)	8	(2.4)
Diarrhoea (下痢)	0	(0.0)	0	(0.0)	3	(4.8)	3	(0.9)
Constipation (便秘)	1	(0.7)	3	(2.2)	0	(0.0)	4	(1.2)
Abdominal discomfort (腹部不快感)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.3)
Hepatobiliary disorders (肝胆道系障害)	0	(0.0)	0	(0.0)	1	(1.6)	1	(0.3)
Hepatic function abnormal (肝機能異常)	0	(0.0)	0	(0.0)	1	(1.6)	1	(0.3)
Skin and subcutaneous tissue disorders (皮膚および皮下組織障害)	0	(0.0)	0	(0.0)	1	(1.6)	1	(0.3)
Cold sweat (冷汗)	0	(0.0)	0	(0.0)	1	(1.6)	1	(0.3)
Renal and urinary disorders (腎および尿路障害)	4	(2.9)	6	(4.4)	1	(1.6)	11	(3.3)
Pollakiuria (頻尿)	3	(2.2)	5	(3.6)	0	(0.0)	8	(2.4)
Diabetic nephropathy (糖尿病性腎症)	0	(0.0)	0	(0.0)	1	(1.6)	1	(0.3)
Nocturia (夜間頻尿)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.3)
Urinary incontinence (尿失禁)	0	(0.0)	1	(0.7)	0	(0.0)	1	(0.3)
Reproductive system and breast disorders (生殖系および乳房障害)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.3)
Pruritus genital (陰部そう痒症)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.3)
General disorders and administration site conditions (一般・全身障害および投与部位の状態)	2	(1.5)	2	(1.5)	1	(1.6)	5	(1.5)
Oedema peripheral (末梢性浮腫)	0	(0.0)	0	(0.0)	1	(1.6)	1	(0.3)
Hunger (空腹)	0	(0.0)	2	(1.5)	0	(0.0)	2	(0.6)
Thirst (口渇)	2	(1.5)	0	(0.0)	0	(0.0)	2	(0.6)
Asthenia (無力症)	0	(0.0)	1	(0.7)	0	(0.0)	1	(0.3)
Investigations (臨床検査)	1	(0.7)	2	(1.5)	0	(0.0)	3	(0.9)
Blood potassium increased (血中カリウム増加)	0	(0.0)	1	(0.7)	0	(0.0)	1	(0.3)
Urine output increased (尿量増加)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.3)
Weight decreased (体重減少)	0	(0.0)	1	(0.7)	0	(0.0)	1	(0.3)
Injury, poisoning and procedural complications (傷害、中毒および処置合併症)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.3)

	Empa 10mg		Empa 25mg		Metformin		Total	
System organ class/ Preferred term	N	(%)	N	(%)	N	(%)	N	(%)
Fall (転倒)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.3)
Head injury (頭部損傷)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.3)

Percentages are calculated using total number of patients in the background medication at screening/treatment class as the denominator.

Containing data from study 1245_0052

MedDRA version used for reporting: [REDACTED]

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Table 6.1.2 Frequency [N (%)] of patients with related adverse events by background medication at screening, treatment, primary system organ class and preferred term - treated set

Background medication at screening=Biguanide

	Empa 10mg		Empa 25mg		Metformin		Total	
System organ class/ Preferred term	N	(%)	N	(%)	N	(%)	N	(%)
Number of patients	68	(100.0)	65	(100.0)	0	(0.0)	133	(100.0)
Total with related adverse events	13	(19.1)	9	(13.8)	0	(0.0)	22	(16.5)
Infections and infestations (感染症および寄生虫症)	2	(2.9)	1	(1.5)	0	(0.0)	3	(2.3)
Cystitis (膀胱炎)	1	(1.5)	0	(0.0)	0	(0.0)	1	(0.8)
Urinary tract infection (尿路感染)	1	(1.5)	0	(0.0)	0	(0.0)	1	(0.8)
Vulvovaginal candidiasis (外陰部腔カンジダ症)	1	(1.5)	1	(1.5)	0	(0.0)	2	(1.5)
Metabolism and nutrition disorders (代謝および栄養障害)	2	(2.9)	4	(6.2)	0	(0.0)	6	(4.5)
Hypoglycaemia (低血糖症)	1	(1.5)	3	(4.6)	0	(0.0)	4	(3.0)
Hyperlipidaemia (高脂血症)	1	(1.5)	1	(1.5)	0	(0.0)	2	(1.5)
Nervous system disorders (神経系障害)	0	(0.0)	1	(1.5)	0	(0.0)	1	(0.8)
Dysgeusia (味覚異常)	0	(0.0)	1	(1.5)	0	(0.0)	1	(0.8)
Vascular disorders (血管障害)	2	(2.9)	0	(0.0)	0	(0.0)	2	(1.5)
Hypotension (低血圧)	2	(2.9)	0	(0.0)	0	(0.0)	2	(1.5)
Gastrointestinal disorders (胃腸障害)	1	(1.5)	0	(0.0)	0	(0.0)	1	(0.8)
Constipation (便秘)	1	(1.5)	0	(0.0)	0	(0.0)	1	(0.8)
Skin and subcutaneous tissue disorders (皮膚および皮下組織障害)	1	(1.5)	1	(1.5)	0	(0.0)	2	(1.5)
Alopecia (脱毛症)	0	(0.0)	1	(1.5)	0	(0.0)	1	(0.8)
Dermatitis contact (接触性皮膚炎)	1	(1.5)	0	(0.0)	0	(0.0)	1	(0.8)
Renal and urinary disorders (腎および尿路障害)	4	(5.9)	2	(3.1)	0	(0.0)	6	(4.5)
Nocturia (夜間頻尿)	2	(2.9)	1	(1.5)	0	(0.0)	3	(2.3)
Pollakiuria (頻尿)	2	(2.9)	0	(0.0)	0	(0.0)	2	(1.5)
Dysuria (排尿困難)	0	(0.0)	1	(1.5)	0	(0.0)	1	(0.8)
Polyuria (多尿)	1	(1.5)	0	(0.0)	0	(0.0)	1	(0.8)
Reproductive system and breast disorders (生殖系および乳房障害)	0	(0.0)	1	(1.5)	0	(0.0)	1	(0.8)
Balanoposthitis (亀頭包皮炎)	0	(0.0)	1	(1.5)	0	(0.0)	1	(0.8)
General disorders and administration site conditions (一般・全身障害および投与部位の状態)	2	(2.9)	0	(0.0)	0	(0.0)	2	(1.5)
Thirst (口渇)	2	(2.9)	0	(0.0)	0	(0.0)	2	(1.5)
Investigations (臨床検査)	1	(1.5)	0	(0.0)	0	(0.0)	1	(0.8)
Blood pressure decreased (血圧低下)	1	(1.5)	0	(0.0)	0	(0.0)	1	(0.8)

Percentages are calculated using total number of patients in the background medication at screening/treatment class as the denominator.

Containing data from study 1245_0052

MedDRA version used for reporting: XXXXXXXXXX

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Table 6.1.2 Frequency [N (%)] of patients with related adverse events by background medication at screening, treatment, primary system organ class and preferred term - treated set

Background medication at screening=Thiazolidinedione

	Empa 10mg		Empa 25mg		Metformin		Total	
System organ class/ Preferred term	N	(%)	N	(%)	N	(%)	N	(%)
Number of patients	137	(100.0)	136	(100.0)	0	(0.0)	273	(100.0)
Total with related adverse events	20	(14.6)	19	(14.0)	0	(0.0)	39	(14.3)
Infections and infestations (感染症および寄生虫症)	1	(0.7)	2	(1.5)	0	(0.0)	3	(1.1)
Urinary tract infection (尿路感染)	0	(0.0)	2	(1.5)	0	(0.0)	2	(0.7)
Vulvovaginal candidiasis (外陰部腔カンジダ症)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.4)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (良性、悪性および詳細不明の新生物 (嚢胞およびポリープを含む))	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.4)
Rectal cancer (直腸癌)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.4)
Metabolism and nutrition disorders (代謝および栄養障害)	2	(1.5)	4	(2.9)	0	(0.0)	6	(2.2)
Hyperlipidaemia (高脂血症)	1	(0.7)	3	(2.2)	0	(0.0)	4	(1.5)
Decreased appetite (食欲減退)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.4)
Hypoglycaemia (低血糖症)	1	(0.7)	1	(0.7)	0	(0.0)	2	(0.7)
Nervous system disorders (神経系障害)	3	(2.2)	2	(1.5)	0	(0.0)	5	(1.8)
Dizziness postural (体位性めまい)	1	(0.7)	1	(0.7)	0	(0.0)	2	(0.7)
Dysgeusia (味覚異常)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.4)
Headache (頭痛)	0	(0.0)	1	(0.7)	0	(0.0)	1	(0.4)
Neuralgia (神経痛)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.4)
Sciatica (坐骨神経痛)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.4)
Eye disorders (眼障害)	1	(0.7)	1	(0.7)	0	(0.0)	2	(0.7)
Cataract (白内障)	0	(0.0)	1	(0.7)	0	(0.0)	1	(0.4)
Episcleritis (上強膜炎)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.4)
Vascular disorders (血管障害)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.4)
Peripheral arterial occlusive disease (末梢動脈閉塞性疾患)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.4)
Gastrointestinal disorders (胃腸障害)	2	(1.5)	0	(0.0)	0	(0.0)	2	(0.7)
Abdominal pain (腹痛)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.4)
Colonic polyp (結腸ポリープ)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.4)
Constipation (便秘)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.4)
Faeces discoloured (変色便)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.4)
Melaena (メレナ)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.4)
Hepatobiliary disorders (肝胆道系障害)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.4)
Drug-induced liver injury (薬物性肝障害)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.4)
Musculoskeletal and connective tissue disorders (筋骨格系および結合組織障害)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.4)
Myofascial pain syndrome (筋膜疼痛症候群)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.4)
Spinal column stenosis (脊柱管狭窄症)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.4)
Spinal osteoarthritis (変形性脊椎症)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.4)
Spondylolisthesis (脊椎すべり症)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.4)
Renal and urinary disorders (腎および尿路障害)	14	(10.2)	6	(4.4)	0	(0.0)	20	(7.3)
Pollakiuria (頻尿)	10	(7.3)	2	(1.5)	0	(0.0)	12	(4.4)
Nocturia (夜間頻尿)	2	(1.5)	2	(1.5)	0	(0.0)	4	(1.5)
Polyuria (多尿)	1	(0.7)	2	(1.5)	0	(0.0)	3	(1.1)
Hydronephrosis (水腎症)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.4)

	Empa 10mg		Empa 25mg		Metformin		Total	
System organ class/ Preferred term	N	(%)	N	(%)	N	(%)	N	(%)
Reproductive system and breast disorders (生殖系および乳房障害)	0	(0.0)	1	(0.7)	0	(0.0)	1	(0.4)
Pruritus genital (陰部そう痒症)	0	(0.0)	1	(0.7)	0	(0.0)	1	(0.4)
General disorders and administration site conditions (一般・全身障害および投与部位の状態)	0	(0.0)	2	(1.5)	0	(0.0)	2	(0.7)
Asthenia (無力症)	0	(0.0)	1	(0.7)	0	(0.0)	1	(0.4)
Thirst (口渇)	0	(0.0)	1	(0.7)	0	(0.0)	1	(0.4)
Investigations (臨床検査)	1	(0.7)	2	(1.5)	0	(0.0)	3	(1.1)
Weight decreased (体重減少)	0	(0.0)	2	(1.5)	0	(0.0)	2	(0.7)
Occult blood positive (便潜血陽性)	1	(0.7)	0	(0.0)	0	(0.0)	1	(0.4)

Percentages are calculated using total number of patients in the background medication at screening/treatment class as the denominator.

Containing data from study 1245_0052

MedDRA version used for reporting: XXXXXXXXXX

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Table 6.1.2 Frequency [N (%)] of patients with related adverse events by background medication at screening, treatment, primary system organ class and preferred term - treated set

Background medication at screening=Alpha glucosidase inhibitor

System organ class/ Preferred term	Empa 10mg		Empa 25mg		Metformin		Total	
	N	(%)	N	(%)	N	(%)	N	(%)
Number of patients	69	(100.0)	70	(100.0)	0	(0.0)	139	(100.0)
Total with related adverse events	7	(10.1)	5	(7.1)	0	(0.0)	12	(8.6)
Infections and infestations (感染症および寄生虫症)	2	(2.9)	1	(1.4)	0	(0.0)	3	(2.2)
Cystitis (膀胱炎)	1	(1.4)	0	(0.0)	0	(0.0)	1	(0.7)
Vulvovaginal candidiasis (外陰部腔カンジダ症)	1	(1.4)	1	(1.4)	0	(0.0)	2	(1.4)
Ear and labyrinth disorders (耳および迷路障害)	1	(1.4)	0	(0.0)	0	(0.0)	1	(0.7)
Deafness neurosensory (感音性難聴)	1	(1.4)	0	(0.0)	0	(0.0)	1	(0.7)
Gastrointestinal disorders (胃腸障害)	0	(0.0)	2	(2.9)	0	(0.0)	2	(1.4)
Constipation (便秘)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)
Diarrhoea (下痢)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)
Musculoskeletal and connective tissue disorders (筋骨格系および結合組織障害)	1	(1.4)	0	(0.0)	0	(0.0)	1	(0.7)
Pain in extremity (四肢痛)	1	(1.4)	0	(0.0)	0	(0.0)	1	(0.7)
Renal and urinary disorders (腎および尿路障害)	2	(2.9)	2	(2.9)	0	(0.0)	4	(2.9)
Pollakiuria (頻尿)	2	(2.9)	2	(2.9)	0	(0.0)	4	(2.9)
Investigations (臨床検査)	1	(1.4)	1	(1.4)	0	(0.0)	2	(1.4)
Urine output increased (尿量増加)	1	(1.4)	1	(1.4)	0	(0.0)	2	(1.4)

Percentages are calculated using total number of patients in the background medication at screening/treatment class as the denominator.

Containing data from study 1245_0052

MedDRA version used for reporting: [REDACTED]

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Table 6.1.2 Frequency [N (%)] of patients with related adverse events by background medication at screening, treatment, primary system organ class and preferred term - treated set

Background medication at screening=DPP-IV inhibitor

System organ class/ Preferred term	Empa 10mg		Empa 25mg		Metformin		Total	
	N	(%)	N	(%)	N	(%)	N	(%)
Number of patients	68	(100.0)	71	(100.0)	0	(0.0)	139	(100.0)
Total with related adverse events	9	(13.2)	18	(25.4)	0	(0.0)	27	(19.4)
Infections and infestations (感染症および寄生虫症)	2	(2.9)	1	(1.4)	0	(0.0)	3	(2.2)
Cystitis (膀胱炎)	1	(1.5)	1	(1.4)	0	(0.0)	2	(1.4)
Trichomoniasis (トリコモナス症)	1	(1.5)	0	(0.0)	0	(0.0)	1	(0.7)
Metabolism and nutrition disorders (代謝および栄養障害)	0	(0.0)	3	(4.2)	0	(0.0)	3	(2.2)
Hypoglycaemia (低血糖症)	0	(0.0)	3	(4.2)	0	(0.0)	3	(2.2)
Nervous system disorders (神経系障害)	0	(0.0)	2	(2.8)	0	(0.0)	2	(1.4)
Dizziness (浮動性めまい)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)
Dizziness postural (体位性めまい)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)
Cardiac disorders (心臓障害)	1	(1.5)	0	(0.0)	0	(0.0)	1	(0.7)
Acute myocardial infarction (急性心筋梗塞)	1	(1.5)	0	(0.0)	0	(0.0)	1	(0.7)
Gastrointestinal disorders (胃腸障害)	2	(2.9)	3	(4.2)	0	(0.0)	5	(3.6)
Constipation (便秘)	2	(2.9)	1	(1.4)	0	(0.0)	3	(2.2)
Abdominal distension (腹部膨満)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)
Pancreatitis (膵炎)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)
Renal and urinary disorders (腎および尿路障害)	4	(5.9)	10	(14.1)	0	(0.0)	14	(10.1)
Pollakiuria (頻尿)	3	(4.4)	7	(9.9)	0	(0.0)	10	(7.2)
Nocturia (夜間頻尿)	1	(1.5)	3	(4.2)	0	(0.0)	4	(2.9)
Reproductive system and breast disorders (生殖系および乳房障害)	1	(1.5)	0	(0.0)	0	(0.0)	1	(0.7)
Pruritus genital (陰部そう痒症)	1	(1.5)	0	(0.0)	0	(0.0)	1	(0.7)
General disorders and administration site conditions (一般・全身障害および投与部位の状態)	2	(2.9)	0	(0.0)	0	(0.0)	2	(1.4)
Hunger (空腹)	1	(1.5)	0	(0.0)	0	(0.0)	1	(0.7)
Thirst (口渇)	1	(1.5)	0	(0.0)	0	(0.0)	1	(0.7)
Investigations (臨床検査)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)
Urine output increased (尿量増加)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)

Percentages are calculated using total number of patients in the background medication at screening/treatment class as the denominator.

Containing data from study 1245_0052

MedDRA version used for reporting: [REDACTED]

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Table 6.1.2 Frequency [N (%)] of patients with related adverse events by background medication at screening, treatment, primary system organ class and preferred term - treated set

Background medication at screening=Glinide

System organ class/ Preferred term	Empa 10mg		Empa 25mg		Metformin		Total	
	N	(%)	N	(%)	N	(%)	N	(%)
Number of patients	70	(100.0)	70	(100.0)	0	(0.0)	140	(100.0)
Total with related adverse events	9	(12.9)	9	(12.9)	0	(0.0)	18	(12.9)
Infections and infestations (感染症および寄生虫症)	2	(2.9)	0	(0.0)	0	(0.0)	2	(1.4)
Asymptomatic bacteriuria (無症候性細菌尿)	1	(1.4)	0	(0.0)	0	(0.0)	1	(0.7)
Urinary tract infection (尿路感染)	1	(1.4)	0	(0.0)	0	(0.0)	1	(0.7)
Metabolism and nutrition disorders (代謝および栄養障害)	0	(0.0)	3	(4.3)	0	(0.0)	3	(2.1)
Hypoglycaemia (低血糖症)	0	(0.0)	3	(4.3)	0	(0.0)	3	(2.1)
Nervous system disorders (神経系障害)	2	(2.9)	0	(0.0)	0	(0.0)	2	(1.4)
Dizziness (浮動性めまい)	1	(1.4)	0	(0.0)	0	(0.0)	1	(0.7)
Tremor (振戦)	1	(1.4)	0	(0.0)	0	(0.0)	1	(0.7)
Gastrointestinal disorders (胃腸障害)	1	(1.4)	1	(1.4)	0	(0.0)	2	(1.4)
Abdominal discomfort (腹部不快感)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)
Constipation (便秘)	1	(1.4)	0	(0.0)	0	(0.0)	1	(0.7)
Skin and subcutaneous tissue disorders (皮膚および皮下組織障害)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)
Alopecia (脱毛症)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.7)
Musculoskeletal and connective tissue disorders (筋骨格系および結合組織障害)	1	(1.4)	0	(0.0)	0	(0.0)	1	(0.7)
Osteoporosis (骨粗鬆症)	1	(1.4)	0	(0.0)	0	(0.0)	1	(0.7)
Renal and urinary disorders (腎および尿路障害)	3	(4.3)	5	(7.1)	0	(0.0)	8	(5.7)
Pollakiuria (頻尿)	3	(4.3)	5	(7.1)	0	(0.0)	8	(5.7)
Calculus ureteric (尿管結石)	1	(1.4)	0	(0.0)	0	(0.0)	1	(0.7)
Renal cyst (腎嚢胞)	1	(1.4)	0	(0.0)	0	(0.0)	1	(0.7)
General disorders and administration site conditions (一般・全身障害および投与部位の状態)	5	(7.1)	0	(0.0)	0	(0.0)	5	(3.6)
Hunger (空腹)	3	(4.3)	0	(0.0)	0	(0.0)	3	(2.1)
Thirst (口渇)	2	(2.9)	0	(0.0)	0	(0.0)	2	(1.4)
Investigations (臨床検査)	1	(1.4)	0	(0.0)	0	(0.0)	1	(0.7)
Urine output increased (尿量増加)	1	(1.4)	0	(0.0)	0	(0.0)	1	(0.7)

Percentages are calculated using total number of patients in the background medication at screening/treatment class as the denominator.

Containing data from study 1245_0052

MedDRA version used for reporting: [REDACTED]

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Table 2.1.1 Frequency [N (%)] of patients with adverse events by treatment, primary system organ class and preferred term - treated set and open-label

set

	Placebo		Empa 10mg		Empa 25mg		Sitagliptin		Empa 25mg OL	
System organ class/ Preferred term	N	(%)	N	(%)	N	(%)	N	(%)	N	(%)
Number of patients	220	(100.0)	216	(100.0)	215	(100.0)	215	(100.0)	81	(100.0)
Total with adverse events	131	(59.5)	115	(53.2)	128	(59.5)	111	(51.6)	50	(61.7)
Infections and infestations (感染症および寄生虫症)	51	(23.2)	57	(26.4)	51	(23.7)	45	(20.9)	12	(14.8)
Nasopharyngitis (鼻咽頭炎)	17	(7.7)	16	(7.4)	11	(5.1)	15	(7.0)	1	(1.2)
Urinary tract infection (尿路感染)	9	(4.1)	12	(5.6)	8	(3.7)	11	(5.1)	3	(3.7)
Upper respiratory tract infection (上気道感染)	8	(3.6)	10	(4.6)	8	(3.7)	10	(4.7)	3	(3.7)
Bronchitis (気管支炎)	2	(0.9)	3	(1.4)	0	(0.0)	3	(1.4)	2	(2.5)
Gastroenteritis (胃腸炎)	1	(0.5)	2	(0.9)	4	(1.9)	2	(0.9)	0	(0.0)
Sinusitis (副鼻腔炎)	1	(0.5)	3	(1.4)	1	(0.5)	4	(1.9)	1	(1.2)
Asymptomatic bacteriuria (無症候性細菌尿)	2	(0.9)	1	(0.5)	3	(1.4)	1	(0.5)	0	(0.0)
Influenza (インフルエンザ)	3	(1.4)	1	(0.5)	3	(1.4)	2	(0.9)	0	(0.0)
Vulvovaginal candidiasis (外陰部腔カンジダ症)	0	(0.0)	1	(0.5)	3	(1.4)	0	(0.0)	0	(0.0)
Body tinea (体部白癬)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)
Furuncle (せつ)	1	(0.5)	2	(0.9)	0	(0.0)	0	(0.0)	1	(1.2)
Subcutaneous abscess (皮下組織膿瘍)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	1	(1.2)
Genital infection fungal (真菌性性器感染)	0	(0.0)	1	(0.5)	2	(0.9)	0	(0.0)	0	(0.0)
Herpes zoster (帯状疱疹)	0	(0.0)	2	(0.9)	1	(0.5)	0	(0.0)	0	(0.0)
Pharyngitis (咽頭炎)	0	(0.0)	2	(0.9)	1	(0.5)	1	(0.5)	0	(0.0)
Pneumonia (肺炎)	1	(0.5)	2	(0.9)	0	(0.0)	0	(0.0)	0	(0.0)
Tooth abscess (歯膿瘍)	0	(0.0)	1	(0.5)	2	(0.9)	0	(0.0)	0	(0.0)
Abscess limb (四肢膿瘍)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Amoebiasis (アメーバ症)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Bacteriuria (細菌尿)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Carbuncle (癰)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Cellulitis (蜂巣炎)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Cystitis (膀胱炎)	1	(0.5)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Diarrhoea infectious (感染性下痢)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Diverticulitis (憩室炎)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Febrile infection (熱性感染症)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Fungal skin infection (皮膚真菌感染)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Gastroenteritis norovirus (ノロウイルス性胃腸炎)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Genital candidiasis (性器カンジダ症)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Genital infection (性器感染)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Hepatitis infectious (感染性肝炎)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Herpes virus infection (ヘルペスウイルス感染)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Infected cyst (感染性嚢腫)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Infected dermal cyst (感染性皮膚嚢腫)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Infection (感染)	0	(0.0)	1	(0.5)	0	(0.0)	1	(0.5)	0	(0.0)
Localised infection (限局性感染)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Lower respiratory tract infection (下気道感染)	0	(0.0)	1	(0.5)	1	(0.5)	0	(0.0)	0	(0.0)
Oral candidiasis (口腔カンジダ症)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Oral herpes (口腔ヘルペス)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Otitis media (中耳炎)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Paronychia (爪囲炎)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Pneumonia primary atypical (原発性異型肺炎)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Purulence (化膿)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Rhinitis (鼻炎)	1	(0.5)	1	(0.5)	1	(0.5)	1	(0.5)	0	(0.0)
Spirochaetal infection (スピロヘータ感染)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Tinea pedis (足部白癬)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Tinea versicolour (癬風)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Tonsillitis (扁桃炎)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Tracheitis (気管炎)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Vaginal infection (腔感染)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Vaginitis bacterial (細菌性陰炎)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Vestibular neuronitis (前庭神経炎)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Viral infection (ウイルス感染)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)

	Placebo		Empa 10mg		Empa 25mg		Sitagliptin		Empa 25mg OL	
System organ class/ Preferred term	N	(%)	N	(%)	N	(%)	N	(%)	N	(%)
Vulvovaginal mycotic infection (外陰腔真菌感染)	0	(0.0)	1	(0.5)	1	(0.5)	0	(0.0)	0	(0.0)
Vulvovaginitis (外陰部腔炎)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Wound infection (創傷感染)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (良性、悪性および詳細不明の 新生物 (嚢胞およびポリープを含む))	2	(0.9)	2	(0.9)	1	(0.5)	1	(0.5)	0	(0.0)
Benign neoplasm of thyroid gland (甲状腺の良 性新生物)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Breast cancer female (女性乳癌)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Colon cancer (結腸癌)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Lung neoplasm malignant (肺の悪性新生物)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Metastases to central nervous system (中枢神経 系転移)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Seborrhoeic keratosis (脂漏性角化症)	0	(0.0)	1	(0.5)	0	(0.0)	1	(0.5)	0	(0.0)
Blood and lymphatic system disorders (血液およ びリンパ系障害)	7	(3.2)	1	(0.5)	2	(0.9)	3	(1.4)	0	(0.0)
Anaemia (貧血)	6	(2.7)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Eosinophilia (好酸球増加症)	1	(0.5)	0	(0.0)	0	(0.0)	2	(0.9)	0	(0.0)
Leukopenia (白血球減少症)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Lymphadenopathy (リンパ節症)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Monocytosis (単球増加症)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Thrombocytopenia (血小板減少症)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Immune system disorders (免疫系障害)	0	(0.0)	2	(0.9)	0	(0.0)	1	(0.5)	0	(0.0)
Anaphylactic reaction (アナフィラキシー反 応)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Seasonal allergy (季節性アレルギー)	0	(0.0)	1	(0.5)	0	(0.0)	1	(0.5)	0	(0.0)
Endocrine disorders (内分泌障害)	1	(0.5)	3	(1.4)	3	(1.4)	2	(0.9)	0	(0.0)
Basedow's disease (バセドウ病)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Goitre (甲状腺腫)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Hyperaldosteronism (高アルドステロン症)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Hyperparathyroidism (副甲状腺機能亢進症)	1	(0.5)	1	(0.5)	0	(0.0)	1	(0.5)	0	(0.0)
Hyperparathyroidism primary (原発性副甲状腺 機能亢進症)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Hyperparathyroidism secondary (続発性副甲状 腺機能亢進症)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Hyperthyroidism (甲状腺機能亢進症)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Hypothyroidism (甲状腺機能低下症)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Metabolism and nutrition disorders (代謝および栄 養障害)	52	(23.6)	23	(10.6)	23	(10.7)	27	(12.6)	21	(25.9)
Hyperglycaemia (高血糖)	35	(15.9)	5	(2.3)	4	(1.9)	13	(6.0)	14	(17.3)
Dyslipidaemia (脂質異常症)	10	(4.5)	11	(5.1)	7	(3.3)	4	(1.9)	4	(4.9)
Hyperlipidaemia (高脂血症)	3	(1.4)	1	(0.5)	3	(1.4)	3	(1.4)	2	(2.5)
Hypertriglyceridaemia (高トリグリセリド血 症)	3	(1.4)	1	(0.5)	5	(2.3)	1	(0.5)	1	(1.2)
Hypercholesterolaemia (高コレステロール血 症)	0	(0.0)	0	(0.0)	0	(0.0)	4	(1.9)	1	(1.2)
Vitamin D deficiency (ビタミンD欠乏)	3	(1.4)	4	(1.9)	0	(0.0)	2	(0.9)	1	(1.2)
Hypoglycaemia (低血糖症)	2	(0.9)	1	(0.5)	1	(0.5)	1	(0.5)	1	(1.2)
Increased appetite (食欲亢進)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	1	(1.2)
Hyperkalaemia (高カリウム血症)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Hyperuricaemia (高尿酸血症)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Hypervitaminosis (ビタミン過剰症)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Hypocalcaemia (低カルシウム血症)	1	(0.5)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Hypokalaemia (低カリウム血症)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Lipid metabolism disorder (脂質代謝障害)	0	(0.0)	1	(0.5)	1	(0.5)	0	(0.0)	0	(0.0)
Polydipsia (多飲症)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Psychiatric disorders (精神障害)	2	(0.9)	3	(1.4)	1	(0.5)	6	(2.8)	1	(1.2)
Depression (うつ病)	1	(0.5)	0	(0.0)	1	(0.5)	1	(0.5)	1	(1.2)
Insomnia (不眠症)	2	(0.9)	1	(0.5)	0	(0.0)	2	(0.9)	0	(0.0)
Sleep disorder (睡眠障害)	0	(0.0)	1	(0.5)	0	(0.0)	2	(0.9)	0	(0.0)
Libido decreased (リビドー減退)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Major depression (大うつ病)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Nervous system disorders (神経系障害)	14	(6.4)	10	(4.6)	15	(7.0)	10	(4.7)	9	(11.1)
Headache (頭痛)	6	(2.7)	2	(0.9)	4	(1.9)	1	(0.5)	1	(1.2)
Dizziness (浮動性めまい)	3	(1.4)	2	(0.9)	5	(2.3)	4	(1.9)	2	(2.5)

	Placebo		Empa 10mg		Empa 25mg		Sitagliptin		Empa 25mg OL	
System organ class/ Preferred term	N	(%)	N	(%)	N	(%)	N	(%)	N	(%)
Neuropathy peripheral (末梢性ニューロパチー)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(2.5)
Hypoaesthesia (感覚鈍麻)	3	(1.4)	0	(0.0)	0	(0.0)	1	(0.5)	1	(1.2)
Diabetic neuropathy (糖尿病性ニューロパチー)	1	(0.5)	0	(0.0)	1	(0.5)	0	(0.0)	1	(1.2)
Dysgeusia (味覚異常)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)
Restless legs syndrome (下肢静止不能症候群)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)
Migraine (片頭痛)	0	(0.0)	2	(0.9)	0	(0.0)	0	(0.0)	0	(0.0)
Paraesthesia (錯感覚)	0	(0.0)	1	(0.5)	2	(0.9)	1	(0.5)	0	(0.0)
Transient ischaemic attack (一過性脳虚血発作)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.9)	0	(0.0)
Tremor (振戦)	0	(0.0)	0	(0.0)	2	(0.9)	1	(0.5)	0	(0.0)
Cerebellar infarction (小脳梗塞)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Cerebrovascular accident (脳血管発作)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Dizziness exertional (労作性めまい)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Hypotonia (筋緊張低下)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Peroneal nerve palsy (腓骨神経麻痺)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Polyneuropathy (多発ニューロパチー)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Sciatica (坐骨神経痛)	0	(0.0)	1	(0.5)	0	(0.0)	1	(0.5)	0	(0.0)
Sensory disturbance (感覚障害)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
VIIth nerve paralysis (第7脳神経麻痺)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
VIth nerve paralysis (第6脳神経麻痺)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Vertebrobasilar insufficiency (椎骨脳底動脈不全)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Eye disorders (眼障害)	3	(1.4)	6	(2.8)	0	(0.0)	2	(0.9)	0	(0.0)
Cataract (白内障)	0	(0.0)	2	(0.9)	0	(0.0)	0	(0.0)	0	(0.0)
Conjunctivitis (結膜炎)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Conjunctivitis allergic (アレルギー性結膜炎)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Eyelid oedema (眼瞼浮腫)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Glaucoma (緑内障)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Iridocyclitis (虹彩毛様体炎)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Vision blurred (霧視)	1	(0.5)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Visual impairment (視力障害)	1	(0.5)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Ear and labyrinth disorders (耳および迷路障害)	1	(0.5)	3	(1.4)	2	(0.9)	5	(2.3)	3	(3.7)
Vertigo (回転性めまい)	0	(0.0)	1	(0.5)	0	(0.0)	3	(1.4)	1	(1.2)
Presbycusis (老人性難聴)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)
Tinnitus (耳鳴)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	1	(1.2)
Cerumen impaction (耳垢栓塞)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Ear pain (耳痛)	1	(0.5)	1	(0.5)	1	(0.5)	0	(0.0)	0	(0.0)
Sudden hearing loss (突発難聴)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Vertigo positional (頭位性回転性めまい)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Cardiac disorders (心臓障害)	4	(1.8)	0	(0.0)	3	(1.4)	7	(3.3)	1	(1.2)
Palpitations (動悸)	1	(0.5)	0	(0.0)	1	(0.5)	3	(1.4)	0	(0.0)
Angina unstable (不安定狭心症)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)
Acute myocardial infarction (急性心筋梗塞)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Angina pectoris (狭心症)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Aortic valve incompetence (大動脈弁閉鎖不全症)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Atrial fibrillation (心房細動)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Atrioventricular block first degree (第一度房室ブロック)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Bundle branch block left (左脚ブロック)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Mitral valve incompetence (僧帽弁閉鎖不全症)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Myocardial infarction (心筋梗塞)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Myocardial ischaemia (心筋虚血)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Sinus bradycardia (洞性徐脈)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Supraventricular extrasystoles (上室性期外収縮)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Vascular disorders (血管障害)	9	(4.1)	7	(3.2)	4	(1.9)	12	(5.6)	2	(2.5)
Hypertension (高血圧)	6	(2.7)	4	(1.9)	2	(0.9)	7	(3.3)	1	(1.2)
Hypotension (低血圧)	1	(0.5)	1	(0.5)	0	(0.0)	1	(0.5)	1	(1.2)
Arteriosclerosis (動脈硬化症)	1	(0.5)	1	(0.5)	1	(0.5)	1	(0.5)	0	(0.0)
Hot flush (ほてり)	0	(0.0)	1	(0.5)	0	(0.0)	1	(0.5)	0	(0.0)

	Placebo		Empa 10mg		Empa 25mg		Sitagliptin		Empa 25mg OL	
System organ class/ Preferred term	N	(%)	N	(%)	N	(%)	N	(%)	N	(%)
Peripheral coldness (末梢冷感)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Peripheral vascular disorder (末梢血管障害)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Phlebitis (静脈炎)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Thrombophlebitis (血栓性静脈炎)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Respiratory, thoracic and mediastinal disorders (呼吸器、胸郭および縦隔障害)	7	(3.2)	6	(2.8)	8	(3.7)	11	(5.1)	1	(1.2)
Cough (咳嗽)	3	(1.4)	2	(0.9)	3	(1.4)	0	(0.0)	1	(1.2)
Asthma (喘息)	1	(0.5)	0	(0.0)	0	(0.0)	2	(0.9)	0	(0.0)
Oropharyngeal pain (口腔咽頭痛)	1	(0.5)	1	(0.5)	0	(0.0)	2	(0.9)	0	(0.0)
Sinus congestion (副鼻腔うっ血)	1	(0.5)	0	(0.0)	0	(0.0)	2	(0.9)	0	(0.0)
Allergic bronchitis (アレルギー性気管支炎)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Allergic cough (アレルギー性咳嗽)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Chronic obstructive pulmonary disease (慢性閉塞性肺疾患)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Dyspnoea (呼吸困難)	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.5)	0	(0.0)
Epistaxis (鼻出血)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Hypercapnia (高炭酸ガス血症)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Interstitial lung disease (間質性肺疾患)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Nasal congestion (鼻閉)	1	(0.5)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Respiratory failure (呼吸不全)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Rhinitis seasonal (季節性鼻炎)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Rhinorrhoea (鼻漏)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Sleep apnoea syndrome (睡眠時無呼吸症候群)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Upper respiratory tract congestion (上気道うっ血)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Upper respiratory tract inflammation (上気道の炎症)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Upper-airway cough syndrome (上気道咳症候群)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Vocal cord inflammation (声帯の炎症)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Gastrointestinal disorders (胃腸障害)	17	(7.7)	24	(11.1)	22	(10.2)	17	(7.9)	7	(8.6)
Diarrhoea (下痢)	3	(1.4)	4	(1.9)	3	(1.4)	1	(0.5)	4	(4.9)
Constipation (便秘)	4	(1.8)	2	(0.9)	3	(1.4)	7	(3.3)	1	(1.2)
Dry mouth (口内乾燥)	1	(0.5)	1	(0.5)	4	(1.9)	0	(0.0)	0	(0.0)
Nausea (悪心)	2	(0.9)	4	(1.9)	2	(0.9)	0	(0.0)	0	(0.0)
Abdominal pain upper (上腹部痛)	4	(1.8)	2	(0.9)	0	(0.0)	1	(0.5)	0	(0.0)
Gastroesophageal reflux disease (胃食道逆流性疾患)	0	(0.0)	2	(0.9)	1	(0.5)	3	(1.4)	0	(0.0)
Toothache (歯痛)	0	(0.0)	3	(1.4)	1	(0.5)	0	(0.0)	1	(1.2)
Gastritis (胃炎)	1	(0.5)	1	(0.5)	1	(0.5)	1	(0.5)	1	(1.2)
Dyspepsia (消化不良)	1	(0.5)	1	(0.5)	0	(0.0)	2	(0.9)	0	(0.0)
Haemorrhoids (痔核)	0	(0.0)	2	(0.9)	1	(0.5)	0	(0.0)	0	(0.0)
Abdominal distension (腹部膨満)	1	(0.5)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Abdominal pain (腹痛)	1	(0.5)	1	(0.5)	1	(0.5)	0	(0.0)	0	(0.0)
Abdominal pain lower (下腹部痛)	0	(0.0)	1	(0.5)	1	(0.5)	1	(0.5)	0	(0.0)
Anal fissure (裂肛)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Anal pruritus (肛門そう痒症)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Barrett's oesophagus (バレット食道)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Colonic polyp (結腸ポリープ)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Dental caries (齲歯)	1	(0.5)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Diverticulum intestinal (腸憩室)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Dysphagia (嚥下障害)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Enteritis (小腸炎)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Flatulence (鼓腸)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Gastric polyps (胃ポリープ)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Gastric ulcer (胃潰瘍)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Gastrointestinal pain (消化器痛)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Gingivitis (歯肉炎)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Haematemesis (吐血)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Hyperchlorhydria (胃酸過多)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Irritable bowel syndrome (過敏性腸症候群)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Mouth ulceration (口腔内潰瘍形成)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Proctitis (直腸炎)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Rectal haemorrhage (直腸出血)	0	(0.0)	1	(0.5)	0	(0.0)	1	(0.5)	0	(0.0)
Vomiting (嘔吐)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Hepatobiliary disorders (肝胆道系障害)	2	(0.9)	1	(0.5)	5	(2.3)	2	(0.9)	1	(1.2)

	Placebo		Empa 10mg		Empa 25mg		Sitagliptin		Empa 25mg OL	
System organ class/ Preferred term	N	(%)	N	(%)	N	(%)	N	(%)	N	(%)
Hyperbilirubinaemia (高ビリルビン血症)	0	(0.0)	0	(0.0)	3	(1.4)	0	(0.0)	0	(0.0)
Chronic hepatitis (慢性肝炎)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)
Cholelithiasis (胆石症)	1	(0.5)	0	(0.0)	0	(0.0)	2	(0.9)	0	(0.0)
Hepatic steatosis (脂肪肝)	0	(0.0)	0	(0.0)	2	(0.9)	0	(0.0)	0	(0.0)
Cholecystitis (胆嚢炎)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Cholecystitis acute (急性胆嚢炎)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Liver disorder (肝障害)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Skin and subcutaneous tissue disorders (皮膚および皮下組織障害)	11	(5.0)	7	(3.2)	10	(4.7)	12	(5.6)	5	(6.2)
Dermatitis contact (接触性皮膚炎)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	3	(3.7)
Eczema (湿疹)	4	(1.8)	0	(0.0)	1	(0.5)	5	(2.3)	0	(0.0)
Pruritus (そう痒症)	0	(0.0)	3	(1.4)	2	(0.9)	1	(0.5)	1	(1.2)
Erythema (紅斑)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)
Pruritus generalised (全身性そう痒症)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)
Rash (発疹)	2	(0.9)	2	(0.9)	1	(0.5)	2	(0.9)	1	(1.2)
Hyperkeratosis (過角化)	2	(0.9)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Alopecia areata (円形脱毛症)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Capillaritis (毛細血管炎)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Cold sweat (冷汗)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Dermatitis (皮膚炎)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Dermatitis allergic (アレルギー性皮膚炎)	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.5)	0	(0.0)
Dry skin (皮膚乾燥)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Hair texture abnormal (毛質異常)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Hyperhidrosis (多汗症)	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.5)	0	(0.0)
Onychalgia (爪痛)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Onychoclasia (爪破損)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Photosensitivity allergic reaction (アレルギー性光線過敏性反応)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Photosensitivity reaction (光線過敏性反応)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Psoriasis (乾癬)	1	(0.5)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Rash erythematous (紅斑性皮疹)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Skin fissures (皮膚亀裂)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Musculoskeletal and connective tissue disorders (筋骨格系および結合組織障害)	18	(8.2)	18	(8.3)	20	(9.3)	28	(13.0)	10	(12.3)
Back pain (背部痛)	3	(1.4)	1	(0.5)	2	(0.9)	6	(2.8)	3	(3.7)
Osteoarthritis (変形性関節症)	1	(0.5)	1	(0.5)	2	(0.9)	2	(0.9)	2	(2.5)
Arthralgia (関節痛)	4	(1.8)	5	(2.3)	4	(1.9)	4	(1.9)	1	(1.2)
Pain in extremity (四肢痛)	2	(0.9)	2	(0.9)	1	(0.5)	4	(1.9)	1	(1.2)
Musculoskeletal pain (筋骨格痛)	1	(0.5)	2	(0.9)	1	(0.5)	3	(1.4)	0	(0.0)
Spinal osteoarthritis (変形性脊椎症)	1	(0.5)	2	(0.9)	0	(0.0)	3	(1.4)	0	(0.0)
Tendonitis (腱炎)	0	(0.0)	0	(0.0)	0	(0.0)	3	(1.4)	1	(1.2)
Muscle spasms (筋痙攣)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	1	(1.2)
Myalgia (筋肉痛)	1	(0.5)	2	(0.9)	2	(0.9)	0	(0.0)	1	(1.2)
Neck pain (頸部痛)	0	(0.0)	0	(0.0)	2	(0.9)	0	(0.0)	1	(1.2)
Periarthritis (関節周囲炎)	1	(0.5)	1	(0.5)	1	(0.5)	2	(0.9)	0	(0.0)
Bone pain (骨痛)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Bursitis (滑液包炎)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Chondrocalcinosis pyrophosphate (ピロリン酸カルシウム結晶性軟骨石灰化症)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Costochondritis (肋軟骨炎)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Dupuytren's contracture (デュブイトラン拘縮)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Fasciitis (筋膜炎)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Flank pain (側腹部痛)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Foot deformity (足変形)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Gouty arthritis (痛風性関節炎)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Haemarthrosis (出血性関節症)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Intervertebral disc protrusion (椎間板突出)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Joint swelling (関節腫脹)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Limb discomfort (四肢不快感)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Muscular weakness (筋力低下)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Musculoskeletal chest pain (筋骨格系胸痛)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Musculoskeletal discomfort (筋骨格不快感)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Osteoporosis (骨粗鬆症)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Plantar fasciitis (足底筋膜炎)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Spinal disorder (脊椎障害)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Spondylitis (脊椎炎)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)

	Placebo		Empa 10mg		Empa 25mg		Sitagliptin		Empa 25mg OL	
System organ class/ Preferred term	N	(%)	N	(%)	N	(%)	N	(%)	N	(%)
Temporomandibular joint syndrome (顎関節症候群)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Tendon calcification (腱石灰化)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Tendon disorder (腱障害)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Torticollis (斜頸)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Trigger finger (弾発指)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Renal and urinary disorders (腎および尿路障害)	2	(0.9)	9	(4.2)	10	(4.7)	6	(2.8)	1	(1.2)
Polyuria (多尿)	0	(0.0)	3	(1.4)	5	(2.3)	1	(0.5)	1	(1.2)
Pollakiuria (頻尿)	0	(0.0)	4	(1.9)	4	(1.9)	1	(0.5)	0	(0.0)
Dysuria (排尿困難)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Haematuria (血尿)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Nephrolithiasis (腎結石症)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Nocturia (夜間頻尿)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Proteinuria (蛋白尿)	0	(0.0)	1	(0.5)	0	(0.0)	1	(0.5)	0	(0.0)
Renal cyst (腎嚢胞)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Renal failure acute (急性腎不全)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Renal tubular disorder (腎尿細管障害)	1	(0.5)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Urine odour abnormal (尿臭異常)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Reproductive system and breast disorders (生殖系および乳房障害)	2	(0.9)	6	(2.8)	10	(4.7)	4	(1.9)	5	(6.2)
Benign prostatic hyperplasia (良性前立腺肥大症)	0	(0.0)	1	(0.5)	1	(0.5)	3	(1.4)	2	(2.5)
Balanoposthitis (亀頭包皮炎)	0	(0.0)	3	(1.4)	0	(0.0)	0	(0.0)	1	(1.2)
Breast pain (乳房痛)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	1	(1.2)
Genital rash (性器発疹)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)
Pruritus genital (陰部そう痒症)	0	(0.0)	0	(0.0)	2	(0.9)	0	(0.0)	0	(0.0)
Vulvovaginal pruritus (外陰陰そう痒症)	2	(0.9)	1	(0.5)	1	(0.5)	0	(0.0)	0	(0.0)
Balanitis (亀頭炎)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Breast mass (乳房腫瘍)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Cervical polyp (子宮頸管ポリープ)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Erectile dysfunction (勃起不全)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Genital haemorrhage (性器出血)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Haematospermia (血精液症)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Prostatitis (前立腺炎)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Vaginal haemorrhage (陰道出血)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Vulvovaginal discomfort (外陰陰不快感)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Congenital, familial and genetic disorders (先天性、家族性および遺伝性障害)	1	(0.5)	2	(0.9)	1	(0.5)	0	(0.0)	0	(0.0)
Phimosis (包茎)	0	(0.0)	2	(0.9)	0	(0.0)	0	(0.0)	0	(0.0)
Gilbert's syndrome (ジルベール症候群)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Hydrocele (陰嚢水腫)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
General disorders and administration site conditions (一般・全身障害および投与部位の状態)	11	(5.0)	11	(5.1)	15	(7.0)	12	(5.6)	6	(7.4)
Thirst (口渇)	0	(0.0)	3	(1.4)	7	(3.3)	0	(0.0)	1	(1.2)
Asthenia (無力症)	2	(0.9)	1	(0.5)	2	(0.9)	3	(1.4)	1	(1.2)
Fatigue (疲労)	1	(0.5)	1	(0.5)	3	(1.4)	2	(0.9)	1	(1.2)
Oedema peripheral (末梢性浮腫)	1	(0.5)	1	(0.5)	1	(0.5)	3	(1.4)	0	(0.0)
Pain (疼痛)	2	(0.9)	1	(0.5)	0	(0.0)	0	(0.0)	1	(1.2)
Pyrexia (発熱)	2	(0.9)	1	(0.5)	1	(0.5)	2	(0.9)	1	(1.2)
Xerosis (乾燥症)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)
Chest discomfort (胸部不快感)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Chest pain (胸痛)	0	(0.0)	1	(0.5)	0	(0.0)	1	(0.5)	0	(0.0)
Cyst (嚢胞)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Feeling hot (熱感)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Hernia (ヘルニア)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Hunger (空腹)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Implant site effusion (埋込み部位滲出液)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Malaise (倦怠感)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Nodule (小結節)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Non-cardiac chest pain (非心臓性胸痛)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Investigations (臨床検査)	19	(8.6)	7	(3.2)	14	(6.5)	12	(5.6)	3	(3.7)
Beta-N-acetyl-D-glucosaminidase increased (β-NアセチルDグルコサミニダーゼ増加)	2	(0.9)	2	(0.9)	7	(3.3)	2	(0.9)	0	(0.0)
Blood creatine phosphokinase increased (血中クレアチンホスホキナーゼ増加)	3	(1.4)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)

	Placebo		Empa 10mg		Empa 25mg		Sitagliptin		Empa 25mg OL	
System organ class/ Preferred term	N	(%)	N	(%)	N	(%)	N	(%)	N	(%)
Blood glucose increased (血中ブドウ糖増加)	3	(1.4)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Blood parathyroid hormone increased (血中副甲状腺ホルモン増加)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	1	(1.2)
Blood triglycerides increased (血中トリグリセリド増加)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)
Urine leukocyte esterase positive (尿中白血球エステラーゼ陽性)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)
Aspartate aminotransferase increased (アスパラギン酸アミノトランスフェラーゼ増加)	1	(0.5)	1	(0.5)	0	(0.0)	2	(0.9)	0	(0.0)
Blood creatinine increased (血中クレアチニン増加)	2	(0.9)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Glycosylated haemoglobin increased (グリコヘモグロビン増加)	2	(0.9)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Alanine aminotransferase increased (アラニン・アミノトランスフェラーゼ増加)	0	(0.0)	1	(0.5)	0	(0.0)	1	(0.5)	0	(0.0)
Alpha 1 microglobulin increased (α1 ミクログロブリン増加)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Bacterial test positive (細菌検査陽性)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Blood bilirubin increased (血中ビリルビン増加)	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.5)	0	(0.0)
Blood creatine phosphokinase MB increased (血中クレアチンホスホキナーゼMB増加)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Blood lactate dehydrogenase increased (血中乳酸脱水素酵素増加)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Blood pressure increased (血圧上昇)	1	(0.5)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Creatinine renal clearance decreased (腎クレアチニン・クリアランス減少)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Culture urine positive (尿培養陽性)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Electrocardiogram abnormal (心電図異常)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Electrocardiogram change (心電図変化)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Eosinophil count increased (好酸球数増加)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Gamma-glutamyltransferase increased (γ-グルタミルトランスフェラーゼ増加)	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.5)	0	(0.0)
General physical condition normal (全身健康状態正常)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Glomerular filtration rate decreased (糸球体濾過率減少)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Haemoglobin decreased (ヘモグロビン減少)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Lipase increased (リパーゼ増加)	1	(0.5)	1	(0.5)	0	(0.0)	1	(0.5)	0	(0.0)
Neutrophil count increased (好中球数増加)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Platelet count increased (血小板数増加)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Urine albumin/creatinine ratio increased (尿中アルブミン/クレアチニン比増加)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Vitamin D decreased (ビタミンD減少)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Weight decreased (体重減少)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
White blood cell count increased (白血球数増加)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
White blood cells urine positive (尿中白血球陽性)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Injury, poisoning and procedural complications (傷害、中毒および処置合併症)	3	(1.4)	15	(6.9)	8	(3.7)	8	(3.7)	3	(3.7)
Muscle strain (肉離れ)	0	(0.0)	1	(0.5)	1	(0.5)	3	(1.4)	0	(0.0)
Excoriation (擦過傷)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	1	(1.2)
Soft tissue injury (軟部組織損傷)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)
Wrist fracture (手首関節骨折)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)
Animal bite (動物咬傷)	0	(0.0)	2	(0.9)	0	(0.0)	0	(0.0)	0	(0.0)
Contusion (挫傷)	0	(0.0)	2	(0.9)	1	(0.5)	1	(0.5)	0	(0.0)
Arthropod bite (節足動物咬傷)	0	(0.0)	1	(0.5)	1	(0.5)	0	(0.0)	0	(0.0)
Back injury (背部損傷)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Burns first degree (第1度熱傷)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Epicondylitis (上顆炎)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Eye injury (眼外傷)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Foreign body (体内異物)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Hand fracture (手骨折)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Injury (損傷)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)

	Placebo		Empa 10mg		Empa 25mg		Sitagliptin		Empa 25mg OL	
System organ class/ Preferred term	N	(%)	N	(%)	N	(%)	N	(%)	N	(%)
Laceration (裂傷)	1	(0.5)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Limb injury (四肢損傷)	0	(0.0)	1	(0.5)	1	(0.5)	1	(0.5)	0	(0.0)
Meniscus lesion (半月板障害)	0	(0.0)	1	(0.5)	0	(0.0)	1	(0.5)	0	(0.0)
Rib fracture (肋骨骨折)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Road traffic accident (交通事故)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Scratch (引っかき傷)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Spinal column injury (脊柱損傷)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Tendon rupture (腱断裂)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Thermal burn (熱傷)	1	(0.5)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Tibia fracture (脛骨骨折)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Surgical and medical procedures (外科および内科 処置)	2	(0.9)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Artificial crown procedure (人工歯冠処置)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Dental care (デンタルケア)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Endodontic procedure (歯内療法)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)

Percentages are calculated using total number of patients per treatment as the denominator.

Containing data from study 1245_0020

MedDRA version used for reporting: XXXXXXXXXX

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Table 2.1.2 Frequency [N (%)] of patients with related adverse events by treatment, primary system organ class and preferred term - treated set actual and open-label set

	Placebo		Empa 10mg		Empa 25mg		Sitagliptin		Empa 25mg OL	
System organ class/ Preferred term	N	(%)	N	(%)	N	(%)	N	(%)	N	(%)
Number of patients	221	(100.0)	217	(100.0)	216	(100.0)	215	(100.0)	81	(100.0)
Total with related adverse events	15	(6.8)	22	(10.1)	38	(17.6)	17	(7.9)	11	(13.6)
Infections and infestations (感染症および寄生虫症)	0	(0.0)	6	(2.8)	10	(4.6)	3	(1.4)	2	(2.5)
Urinary tract infection (尿路感染)	0	(0.0)	2	(0.9)	3	(1.4)	3	(1.4)	2	(2.5)
Asymptomatic bacteriuria (無症候性細菌尿)	0	(0.0)	1	(0.5)	2	(0.9)	0	(0.0)	0	(0.0)
Genital infection fungal (真菌性性器感染)	0	(0.0)	1	(0.5)	2	(0.9)	0	(0.0)	0	(0.0)
Amoebiasis (アメーバ症)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Cystitis (膀胱炎)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Fungal skin infection (皮膚真菌感染)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Genital candidiasis (性器カンジダ症)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Upper respiratory tract infection (上気道感染)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Vaginal infection (陰感染)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Vulvovaginal candidiasis (外陰部陰カンジダ症)	0	(0.0)	1	(0.5)	1	(0.5)	0	(0.0)	0	(0.0)
Vulvovaginal mycotic infection (外陰陰真菌感染)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Blood and lymphatic system disorders (血液およびリンパ系障害)	0	(0.0)	1	(0.5)	1	(0.5)	0	(0.0)	0	(0.0)
Anaemia (貧血)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Thrombocytopenia (血小板減少症)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Metabolism and nutrition disorders (代謝および栄養障害)	6	(2.7)	4	(1.8)	4	(1.9)	7	(3.3)	4	(4.9)
Hyperglycaemia (高血糖)	5	(2.3)	2	(0.9)	0	(0.0)	4	(1.9)	2	(2.5)
Hypoglycaemia (低血糖症)	1	(0.5)	1	(0.5)	1	(0.5)	1	(0.5)	1	(1.2)
Increased appetite (食欲亢進)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	1	(1.2)
Dyslipidaemia (脂質異常症)	0	(0.0)	0	(0.0)	2	(0.9)	1	(0.5)	0	(0.0)
Hypertriglyceridaemia (高トリグリセリド血症)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Lipid metabolism disorder (脂質代謝障害)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Psychiatric disorders (精神障害)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.9)	0	(0.0)
Libido decreased (リビドー減退)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Sleep disorder (睡眠障害)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Nervous system disorders (神経系障害)	1	(0.5)	2	(0.9)	3	(1.4)	3	(1.4)	2	(2.5)
Diabetic neuropathy (糖尿病性ニューロパチー)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)
Dysgeusia (味覚異常)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)
Dizziness (浮動性めまい)	0	(0.0)	1	(0.5)	1	(0.5)	2	(0.9)	0	(0.0)
Cerebrovascular accident (脳血管発作)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Headache (頭痛)	1	(0.5)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Hypotonia (筋緊張低下)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Paraesthesia (錯感覚)	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.5)	0	(0.0)
Cardiac disorders (心臓障害)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Palpitations (動悸)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Gastrointestinal disorders (胃腸障害)	3	(1.4)	4	(1.8)	6	(2.8)	0	(0.0)	0	(0.0)
Constipation (便秘)	2	(0.9)	0	(0.0)	2	(0.9)	0	(0.0)	0	(0.0)
Diarrhoea (下痢)	1	(0.5)	2	(0.9)	1	(0.5)	0	(0.0)	0	(0.0)
Dry mouth (口内乾燥)	0	(0.0)	0	(0.0)	2	(0.9)	0	(0.0)	0	(0.0)
Abdominal distension (腹部膨満)	1	(0.5)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Flatulence (鼓腸)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Gastritis (胃炎)	0	(0.0)	1	(0.5)	1	(0.5)	0	(0.0)	0	(0.0)
Gastrointestinal pain (消化器痛)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Gastroesophageal reflux disease (胃食道逆流性疾患)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Hepatobiliary disorders (肝胆道系障害)	0	(0.0)	0	(0.0)	2	(0.9)	0	(0.0)	0	(0.0)
Hyperbilirubinaemia (高ビリルビン血症)	0	(0.0)	0	(0.0)	2	(0.9)	0	(0.0)	0	(0.0)

	Placebo		Empa 10mg		Empa 25mg		Sitagliptin		Empa 25mg OL	
System organ class/ Preferred term	N	(%)	N	(%)	N	(%)	N	(%)	N	(%)
Skin and subcutaneous tissue disorders (皮膚および皮下組織障害)	1	(0.5)	2	(0.9)	3	(1.4)	1	(0.5)	0	(0.0)
Pruritus (そう痒症)	0	(0.0)	1	(0.5)	2	(0.9)	0	(0.0)	0	(0.0)
Rash (発疹)	0	(0.0)	2	(0.9)	0	(0.0)	0	(0.0)	0	(0.0)
Dry skin (皮膚乾燥)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Eczema (湿疹)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Photosensitivity reaction (光線過敏性反応)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Musculoskeletal and connective tissue disorders (筋骨格系および結合組織障害)	2	(0.9)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Arthralgia (関節痛)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Muscular weakness (筋力低下)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Myalgia (筋肉痛)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Renal and urinary disorders (腎および尿路障害)	0	(0.0)	7	(3.2)	7	(3.2)	1	(0.5)	1	(1.2)
Pollakiuria (頻尿)	0	(0.0)	3	(1.4)	4	(1.9)	0	(0.0)	0	(0.0)
Polyuria (多尿)	0	(0.0)	3	(1.4)	3	(1.4)	1	(0.5)	1	(1.2)
Renal failure acute (急性腎不全)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Renal tubular disorder (腎尿細管障害)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Reproductive system and breast disorders (生殖系および乳房障害)	1	(0.5)	1	(0.5)	3	(1.4)	0	(0.0)	2	(2.5)
Balanoposthitis (亀頭包皮炎)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	1	(1.2)
Genital rash (性器発疹)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)
Pruritus genital (陰部そう痒症)	0	(0.0)	0	(0.0)	2	(0.9)	0	(0.0)	0	(0.0)
Balanitis (亀頭炎)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Vulvovaginal pruritus (外陰陰部そう痒症)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
General disorders and administration site conditions (一般・全身障害および投与部位の状態)	1	(0.5)	5	(2.3)	10	(4.6)	2	(0.9)	0	(0.0)
Thirst (口渇)	0	(0.0)	3	(1.4)	6	(2.8)	0	(0.0)	0	(0.0)
Fatigue (疲労)	0	(0.0)	1	(0.5)	2	(0.9)	1	(0.5)	0	(0.0)
Asthenia (無力症)	0	(0.0)	1	(0.5)	1	(0.5)	1	(0.5)	0	(0.0)
Hunger (空腹)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Pain (疼痛)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Pyrexia (発熱)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Investigations (臨床検査)	1	(0.5)	2	(0.9)	4	(1.9)	3	(1.4)	0	(0.0)
Beta-N-acetyl-D-glucosaminidase increased (β-NアセチルDグルコサミニダーゼ増加)	0	(0.0)	1	(0.5)	2	(0.9)	0	(0.0)	0	(0.0)
Aspartate aminotransferase increased (アスパラギン酸アミノトランスフェラーゼ増加)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Blood bilirubin increased (血中ビリルビン増加)	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.5)	0	(0.0)
Blood creatine phosphokinase increased (血中クレアチンホスホキナーゼ増加)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Creatinine renal clearance decreased (腎クレアチニン・クリアランス減少)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Lipase increased (リパーゼ増加)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Weight decreased (体重減少)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)

Percentages are calculated using total number of patients per treatment as the denominator.

Containing data from study 1245_0020

MedDRA version used for reporting: [REDACTED]

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Table 3.1.1.1 Frequency [N (%)] of patients with adverse events by treatment, primary system organ class and preferred term - treated set (naive)

System organ class/ Preferred term	Placebo		Empa 10mg		Empa 25mg		Sitagliptin	
	N	(%)	N	(%)	N	(%)	N	(%)
Number of patients	220	(100.0)	216	(100.0)	215	(100.0)	215	(100.0)
Total with adverse events	153	(69.5)	142	(65.7)	149	(69.3)	137	(63.7)
Infections and infestations (感染症および寄生虫症)	70	(31.8)	76	(35.2)	70	(32.6)	64	(29.8)
Nasopharyngitis (鼻咽頭炎)	22	(10.0)	25	(11.6)	21	(9.8)	21	(9.8)
Urinary tract infection (尿路感染)	15	(6.8)	17	(7.9)	11	(5.1)	14	(6.5)
Upper respiratory tract infection (上気道感染)	11	(5.0)	12	(5.6)	11	(5.1)	12	(5.6)
Bronchitis (気管支炎)	7	(3.2)	8	(3.7)	4	(1.9)	6	(2.8)
Influenza (インフルエンザ)	8	(3.6)	5	(2.3)	4	(1.9)	3	(1.4)
Sinusitis (副鼻腔炎)	2	(0.9)	6	(2.8)	2	(0.9)	6	(2.8)
Asymptomatic bacteriuria (無症候性細菌尿)	2	(0.9)	1	(0.5)	4	(1.9)	1	(0.5)
Gastroenteritis (胃腸炎)	1	(0.5)	2	(0.9)	4	(1.9)	3	(1.4)
Pharyngitis (咽頭炎)	1	(0.5)	3	(1.4)	1	(0.5)	1	(0.5)
Vulvovaginal candidiasis (外陰部腔カンジダ症)	0	(0.0)	2	(0.9)	3	(1.4)	0	(0.0)
Acute sinusitis (急性副鼻腔炎)	2	(0.9)	0	(0.0)	0	(0.0)	0	(0.0)
Cystitis (膀胱炎)	2	(0.9)	0	(0.0)	1	(0.5)	2	(0.9)
Ear infection (耳感染)	0	(0.0)	2	(0.9)	0	(0.0)	0	(0.0)
Furuncle (せつ)	1	(0.5)	2	(0.9)	0	(0.0)	0	(0.0)
Genital infection fungal (真菌性性器感染)	0	(0.0)	1	(0.5)	2	(0.9)	0	(0.0)
Herpes zoster (帯状疱疹)	0	(0.0)	2	(0.9)	1	(0.5)	1	(0.5)
Pneumonia (肺炎)	2	(0.9)	2	(0.9)	0	(0.0)	0	(0.0)
Rhinitis (鼻炎)	1	(0.5)	1	(0.5)	2	(0.9)	1	(0.5)
Tooth abscess (歯膿瘍)	0	(0.0)	1	(0.5)	2	(0.9)	0	(0.0)
Vulvovaginal mycotic infection (外陰腔真菌感染)	0	(0.0)	2	(0.9)	1	(0.5)	0	(0.0)
Abscess limb (四肢膿瘍)	1	(0.5)	0	(0.0)	1	(0.5)	0	(0.0)
Acute tonsillitis (急性扁桃炎)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Amoebiasis (アメーバ症)	0	(0.0)	1	(0.5)	0	(0.0)	1	(0.5)
Bacteriuria (細菌尿)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Balanitis candida (カンジダ性亀頭炎)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Carbuncle (癰)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Cellulitis (蜂巣炎)	0	(0.0)	1	(0.5)	1	(0.5)	0	(0.0)
Diarrhoea infectious (感染性下痢)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Diverticulitis (憩室炎)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Febrile infection (熱性感染症)	1	(0.5)	0	(0.0)	0	(0.0)	1	(0.5)
Folliculitis (毛包炎)	0	(0.0)	1	(0.5)	1	(0.5)	0	(0.0)
Fungal infection (真菌感染)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Fungal skin infection (皮膚真菌感染)	1	(0.5)	0	(0.0)	1	(0.5)	0	(0.0)
Gastroenteritis norovirus (ノロウイルス性胃腸炎)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Gastroenteritis viral (ウイルス性胃腸炎)	0	(0.0)	1	(0.5)	1	(0.5)	0	(0.0)
Genital candidiasis (性器カンジダ症)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Genital infection (性器感染)	0	(0.0)	1	(0.5)	1	(0.5)	0	(0.0)
Genitourinary tract infection (泌尿生殖器感染)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Gingival infection (歯肉感染)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Helicobacter infection (ヘリコバクター感染)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Hepatitis infectious (感染性肝炎)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Herpes simplex (単純ヘルペス)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)

System organ class/ Preferred term	Placebo		Empa 10mg		Empa 25mg		Sitagliptin	
	N	(%)	N	(%)	N	(%)	N	(%)
Herpes virus infection (ヘルペスウイルス感染)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Infected bites (咬傷感染)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Infected cyst (感染性嚢腫)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Infected dermal cyst (感染性皮膚嚢腫)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Infected skin ulcer (感染性皮膚潰瘍)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Infection (感染)	0	(0.0)	1	(0.5)	0	(0.0)	1	(0.5)
Laryngitis (喉頭炎)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Localised infection (限局性感染)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Lower respiratory tract infection (下気道感染)	0	(0.0)	1	(0.5)	1	(0.5)	0	(0.0)
Muscle abscess (筋膿瘍)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Nasal abscess (鼻膿瘍)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Oral candidiasis (口腔カンジダ症)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Oral herpes (口腔ヘルペス)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Otitis externa (外耳炎)	1	(0.5)	1	(0.5)	0	(0.0)	0	(0.0)
Otitis media (中耳炎)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Paronychia (爪囲炎)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Peritonitis (腹膜炎)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Pharyngitis streptococcal (レンサ球菌性咽頭炎)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Pilonidal cyst (毛嚢嚢胞)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Pneumonia primary atypical (原発性異型肺炎)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Purulence (化膿)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Rash pustular (膿疱性皮疹)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Sexually transmitted disease (性行為感染症)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Spirochaetal infection (スピロヘータ感染)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Subcutaneous abscess (皮下組織膿瘍)	0	(0.0)	1	(0.5)	0	(0.0)	1	(0.5)
Tinea pedis (足部白癬)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Tinea versicolour (癬風)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Tonsillitis (扁桃炎)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Tracheitis (気管炎)	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.5)
Vaginal infection (陰感染)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Vaginitis bacterial (細菌性陰炎)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Vestibular neuronitis (前庭神経炎)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Viral infection (ウイルス感染)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Viral myositis (ウイルス性筋炎)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Vulvovaginitis (外陰部陰炎)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Wound infection (創傷感染)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (良性、悪性および詳細不明の新生物 (嚢胞およびポリープを含む))	2	(0.9)	2	(0.9)	4	(1.9)	2	(0.9)
Benign neoplasm of thyroid gland (甲状腺の良性新生物)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Bile duct cancer (胆管癌)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Breast cancer female (女性乳癌)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Bronchial carcinoma (気管支癌)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Colon cancer (結腸癌)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Gastroesophageal cancer (胃食道癌)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Lung neoplasm malignant (肺の悪性新生物)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Metastases to central nervous system (中枢神経系転移)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Seborrhoeic keratosis (脂漏性角化症)	0	(0.0)	1	(0.5)	0	(0.0)	1	(0.5)
Uterine leiomyoma (子宮平滑筋腫)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)

System organ class/ Preferred term	Placebo		Empa 10mg		Empa 25mg		Sitagliptin	
	N	(%)	N	(%)	N	(%)	N	(%)
Blood and lymphatic system disorders (血液およびリンパ系障害)	9	(4.1)	5	(2.3)	3	(1.4)	4	(1.9)
Anaemia (貧血)	6	(2.7)	2	(0.9)	1	(0.5)	0	(0.0)
Eosinophilia (好酸球増加症)	2	(0.9)	2	(0.9)	1	(0.5)	2	(0.9)
Leukopenia (白血球減少症)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Lymphadenopathy (リンパ節症)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Monocytosis (単球増加症)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Splenic cyst (脾嚢胞)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Thrombocytopenia (血小板減少症)	0	(0.0)	1	(0.5)	0	(0.0)	1	(0.5)
Immune system disorders (免疫系障害)	0	(0.0)	3	(1.4)	2	(0.9)	3	(1.4)
Seasonal allergy (季節性アレルギー)	0	(0.0)	2	(0.9)	1	(0.5)	2	(0.9)
Anaphylactic reaction (アナフィラキシー反応)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Drug hypersensitivity (薬物過敏症)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Hypersensitivity (過敏症)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Endocrine disorders (内分泌障害)	1	(0.5)	3	(1.4)	4	(1.9)	3	(1.4)
Autoimmune thyroiditis (自己免疫性甲状腺炎)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Basedow's disease (バセドウ病)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Goitre (甲状腺腫)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Hyperaldosteronism (高アルドステロン症)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Hyperparathyroidism (副甲状腺機能亢進症)	1	(0.5)	1	(0.5)	1	(0.5)	1	(0.5)
Hyperparathyroidism primary (原発性副甲状腺機能亢進症)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Hyperparathyroidism secondary (続発性副甲状腺機能亢進症)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Hyperthyroidism (甲状腺機能亢進症)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Hypothyroidism (甲状腺機能低下症)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Metabolism and nutrition disorders (代謝および栄養障害)	68	(30.9)	31	(14.4)	30	(14.0)	40	(18.6)
Hyperglycaemia (高血糖)	53	(24.1)	11	(5.1)	6	(2.8)	24	(11.2)
Dyslipidaemia (脂質異常症)	11	(5.0)	11	(5.1)	8	(3.7)	4	(1.9)
Hypertriglyceridaemia (高トリグリセリド血症)	3	(1.4)	2	(0.9)	5	(2.3)	1	(0.5)
Hypercholesterolaemia (高コレステロール血症)	0	(0.0)	0	(0.0)	0	(0.0)	4	(1.9)
Hyperlipidaemia (高脂血症)	4	(1.8)	2	(0.9)	4	(1.9)	3	(1.4)
Vitamin D deficiency (ビタミンD欠乏)	4	(1.8)	4	(1.9)	0	(0.0)	3	(1.4)
Hyperuricaemia (高尿酸血症)	3	(1.4)	1	(0.5)	0	(0.0)	2	(0.9)
Hypoglycaemia (低血糖症)	3	(1.4)	1	(0.5)	1	(0.5)	1	(0.5)
Decreased appetite (食欲減退)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Dehydration (脱水)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Hyperkalaemia (高カリウム血症)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Hypervitaminosis (ビタミン過剰症)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Hypocalcaemia (低カルシウム血症)	1	(0.5)	0	(0.0)	0	(0.0)	1	(0.5)
Hypokalaemia (低カリウム血症)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Hyponatraemia (低ナトリウム血症)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Increased appetite (食欲亢進)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Iron deficiency (鉄欠乏)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Ketosis (ケトosis)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Lipid metabolism disorder (脂質代謝障害)	0	(0.0)	1	(0.5)	1	(0.5)	0	(0.0)
Polydipsia (多飲症)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Psychiatric disorders (精神障害)	2	(0.9)	5	(2.3)	4	(1.9)	9	(4.2)
Insomnia (不眠症)	2	(0.9)	1	(0.5)	0	(0.0)	4	(1.9)
Sleep disorder (睡眠障害)	0	(0.0)	1	(0.5)	0	(0.0)	3	(1.4)
Anxiety (不安)	0	(0.0)	2	(0.9)	0	(0.0)	0	(0.0)
Depression (うつ病)	1	(0.5)	0	(0.0)	2	(0.9)	2	(0.9)
Alcohol abuse (アルコール乱用)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)

System organ class/ Preferred term	Placebo		Empa 10mg		Empa 25mg		Sitagliptin	
	N	(%)	N	(%)	N	(%)	N	(%)
Libido decreased (リビドー減退)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Major depression (大うつ病)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Panic attack (パニック発作)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Restlessness (落ち着きのなさ)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Nervous system disorders (神経系障害)	19	(8.6)	18	(8.3)	20	(9.3)	13	(6.0)
Headache (頭痛)	7	(3.2)	5	(2.3)	6	(2.8)	2	(0.9)
Dizziness (浮動性めまい)	5	(2.3)	2	(0.9)	6	(2.8)	6	(2.8)
Paraesthesia (錯感覚)	0	(0.0)	2	(0.9)	4	(1.9)	1	(0.5)
Hypoaesthesia (感覚鈍麻)	3	(1.4)	1	(0.5)	0	(0.0)	1	(0.5)
Cerebrovascular accident (脳血管発作)	0	(0.0)	2	(0.9)	0	(0.0)	0	(0.0)
Migraine (片頭痛)	1	(0.5)	2	(0.9)	0	(0.0)	0	(0.0)
Sciatica (坐骨神経痛)	0	(0.0)	2	(0.9)	0	(0.0)	1	(0.5)
Syncope (失神)	0	(0.0)	2	(0.9)	0	(0.0)	0	(0.0)
Transient ischaemic attack (一過性脳虚血発作)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.9)
Tremor (振戦)	0	(0.0)	0	(0.0)	2	(0.9)	1	(0.5)
Aphonia (失声症)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Carpal tunnel syndrome (手根管症候群)	1	(0.5)	1	(0.5)	0	(0.0)	0	(0.0)
Cerebellar infarction (小脳梗塞)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Cerebral infarction (脳梗塞)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Diabetic neuropathy (糖尿病性ニューロパチー)	1	(0.5)	0	(0.0)	1	(0.5)	0	(0.0)
Dizziness exertional (労作性めまい)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Dysgeusia (味覚異常)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Hypotonia (筋緊張低下)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Nerve compression (神経圧迫)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Nerve root compression (神経根圧迫)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Neuralgia (神経痛)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Peroneal nerve palsy (腓骨神経麻痺)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Polyneuropathy (多発ニューロパチー)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Presyncope (失神寸前の状態)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Sensory disturbance (感覚障害)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Sinus headache (副鼻腔炎に伴う頭痛)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Somnolence (傾眠)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Subarachnoid haemorrhage (くも膜下出血)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
VIIth nerve paralysis (第7脳神経麻痺)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
VIIIth nerve paralysis (第8脳神経麻痺)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Vertebrobasilar insufficiency (椎骨脳底動脈不全)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Eye disorders (眼障害)	5	(2.3)	14	(6.5)	1	(0.5)	6	(2.8)
Cataract (白内障)	0	(0.0)	4	(1.9)	0	(0.0)	0	(0.0)
Conjunctivitis (結膜炎)	0	(0.0)	3	(1.4)	0	(0.0)	2	(0.9)
Vision blurred (霧視)	1	(0.5)	3	(1.4)	0	(0.0)	0	(0.0)
Glaucoma (緑内障)	2	(0.9)	0	(0.0)	0	(0.0)	1	(0.5)
Visual impairment (視力障害)	2	(0.9)	1	(0.5)	0	(0.0)	0	(0.0)
Abnormal sensation in eye (眼の異常感)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Asthenopia (眼精疲労)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Blepharitis (眼瞼炎)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Conjunctivitis allergic (アレルギー性結膜炎)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Diabetic retinopathy (糖尿病網膜症)	1	(0.5)	1	(0.5)	0	(0.0)	1	(0.5)
Eye pain (眼痛)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Eyelid oedema (眼瞼浮腫)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Iridocyclitis (虹彩毛様体炎)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Ear and labyrinth disorders (耳および迷路障害)	4	(1.8)	3	(1.4)	4	(1.9)	7	(3.3)
Ear pain (耳痛)	3	(1.4)	1	(0.5)	1	(0.5)	0	(0.0)

System organ class/ Preferred term	Placebo		Empa 10mg		Empa 25mg		Sitagliptin	
	N	(%)	N	(%)	N	(%)	N	(%)
Vertigo (回転性めまい)	0	(0.0)	1	(0.5)	0	(0.0)	3	(1.4)
Tinnitus (耳鳴)	0	(0.0)	0	(0.0)	2	(0.9)	1	(0.5)
Vertigo positional (頭位性回転性めまい)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.9)
Cerumen impaction (耳垢栓塞)	1	(0.5)	1	(0.5)	0	(0.0)	1	(0.5)
Sudden hearing loss (突発難聴)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Cardiac disorders (心臓障害)	6	(2.7)	3	(1.4)	4	(1.9)	8	(3.7)
Palpitations (動悸)	1	(0.5)	0	(0.0)	2	(0.9)	4	(1.9)
Acute myocardial infarction (急性心筋梗塞)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Angina pectoris (狭心症)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Aortic valve incompetence (大動脈弁閉鎖不全症)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Atrial fibrillation (心房細動)	0	(0.0)	1	(0.5)	0	(0.0)	1	(0.5)
Atrioventricular block first degree (第一度房室ブロック)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Bradycardia (徐脈)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Bundle branch block left (左脚ブロック)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Cardiovascular disorder (心血管障害)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Mitral valve incompetence (僧帽弁閉鎖不全症)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Myocardial infarction (心筋梗塞)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Myocardial ischaemia (心筋虚血)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Sinus bradycardia (洞性徐脈)	1	(0.5)	0	(0.0)	1	(0.5)	0	(0.0)
Supraventricular extrasystoles (上室性期外収縮)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Supraventricular tachycardia (上室性頻脈)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Ventricular tachycardia (心室性頻脈)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Vascular disorders (血管障害)	13	(5.9)	11	(5.1)	6	(2.8)	15	(7.0)
Hypertension (高血圧)	9	(4.1)	7	(3.2)	3	(1.4)	10	(4.7)
Arteriosclerosis (動脈硬化症)	1	(0.5)	1	(0.5)	1	(0.5)	1	(0.5)
Flushing (潮紅)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Hot flush (ほてり)	0	(0.0)	1	(0.5)	0	(0.0)	1	(0.5)
Hypotension (低血圧)	1	(0.5)	1	(0.5)	1	(0.5)	1	(0.5)
Orthostatic hypotension (起立性低血圧)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Peripheral coldness (末梢冷感)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Peripheral vascular disorder (末梢血管障害)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Phlebitis (静脈炎)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Thrombophlebitis (血栓性静脈炎)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Respiratory, thoracic and mediastinal disorders (呼吸器、胸郭および縦隔障害)	11	(5.0)	14	(6.5)	15	(7.0)	17	(7.9)
Cough (咳嗽)	4	(1.8)	4	(1.9)	3	(1.4)	4	(1.9)
Oropharyngeal pain (口腔咽頭痛)	3	(1.4)	1	(0.5)	0	(0.0)	2	(0.9)
Upper respiratory tract inflammation (上気道の炎症)	1	(0.5)	2	(0.9)	3	(1.4)	1	(0.5)
Asthma (喘息)	1	(0.5)	0	(0.0)	1	(0.5)	2	(0.9)
Epistaxis (鼻出血)	0	(0.0)	1	(0.5)	2	(0.9)	0	(0.0)
Sinus congestion (副鼻腔うっ血)	2	(0.9)	1	(0.5)	1	(0.5)	2	(0.9)
Upper-airway cough syndrome (上気道咳症候群)	2	(0.9)	0	(0.0)	0	(0.0)	0	(0.0)
Allergic bronchitis (アレルギー性気管支炎)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Allergic cough (アレルギー性咳嗽)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Bronchitis chronic (慢性気管支炎)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Chronic obstructive pulmonary disease (慢性閉塞性肺疾患)	0	(0.0)	1	(0.5)	0	(0.0)	1	(0.5)
Dysphonia (発声障害)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)

System organ class/ Preferred term	Placebo		Empa 10mg		Empa 25mg		Sitagliptin	
	N	(%)	N	(%)	N	(%)	N	(%)
Dyspnoea (呼吸困難)	0	(0.0)	1	(0.5)	1	(0.5)	1	(0.5)
Hypercapnia (高炭酸ガス血症)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Interstitial lung disease (間質性肺疾患)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Nasal congestion (鼻閉)	1	(0.5)	0	(0.0)	0	(0.0)	1	(0.5)
Pharyngeal erythema (咽頭紅斑)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Respiratory failure (呼吸不全)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Rhinitis allergic (アレルギー性鼻炎)	0	(0.0)	1	(0.5)	0	(0.0)	1	(0.5)
Rhinitis seasonal (季節性鼻炎)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Rhinorrhoea (鼻漏)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Sleep apnoea syndrome (睡眠時無呼吸症候群)	1	(0.5)	0	(0.0)	1	(0.5)	1	(0.5)
Upper respiratory tract congestion (上気道うっ血)	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.5)
Vocal cord inflammation (声帯の炎症)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Gastrointestinal disorders (胃腸障害)	28	(12.7)	36	(16.7)	34	(15.8)	31	(14.4)
Constipation (便秘)	6	(2.7)	3	(1.4)	3	(1.4)	7	(3.3)
Abdominal pain upper (上腹部痛)	6	(2.7)	4	(1.9)	0	(0.0)	1	(0.5)
Diarrhoea (下痢)	5	(2.3)	5	(2.3)	5	(2.3)	3	(1.4)
Gastroesophageal reflux disease (胃食道逆流性疾患)	0	(0.0)	4	(1.9)	5	(2.3)	5	(2.3)
Nausea (悪心)	4	(1.8)	5	(2.3)	3	(1.4)	1	(0.5)
Dry mouth (口内乾燥)	1	(0.5)	1	(0.5)	4	(1.9)	0	(0.0)
Toothache (歯痛)	0	(0.0)	4	(1.9)	1	(0.5)	0	(0.0)
Dental caries (齲歯)	1	(0.5)	1	(0.5)	2	(0.9)	3	(1.4)
Gastritis (胃炎)	1	(0.5)	1	(0.5)	1	(0.5)	3	(1.4)
Vomiting (嘔吐)	0	(0.0)	3	(1.4)	2	(0.9)	1	(0.5)
Abdominal distension (腹部膨満)	2	(0.9)	1	(0.5)	0	(0.0)	1	(0.5)
Abdominal pain (腹痛)	2	(0.9)	1	(0.5)	1	(0.5)	0	(0.0)
Abdominal pain lower (下腹部痛)	0	(0.0)	2	(0.9)	1	(0.5)	1	(0.5)
Colonic polyp (結腸ポリープ)	1	(0.5)	0	(0.0)	2	(0.9)	1	(0.5)
Dyspepsia (消化不良)	2	(0.9)	1	(0.5)	1	(0.5)	2	(0.9)
Gastric ulcer (胃潰瘍)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.9)
Gastrointestinal pain (消化器痛)	0	(0.0)	2	(0.9)	0	(0.0)	0	(0.0)
Haemorrhoids (痔核)	0	(0.0)	2	(0.9)	1	(0.5)	2	(0.9)
Periodontitis (歯周炎)	0	(0.0)	0	(0.0)	2	(0.9)	0	(0.0)
Abdominal discomfort (腹部不快感)	1	(0.5)	0	(0.0)	1	(0.5)	0	(0.0)
Anal fissure (裂肛)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Anal pruritus (肛門そう痒症)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Aphthous stomatitis (アフタ性口内炎)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Barrett's oesophagus (バレット食道)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Colitis ulcerative (潰瘍性大腸炎)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Diverticulum intestinal (腸憩室)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Duodenal ulcer (十二指腸潰瘍)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Dysphagia (嚥下障害)	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.5)
Enteritis (小腸炎)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Flatulence (鼓腸)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Gastric polyps (胃ポリープ)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Gastritis atrophic (萎縮性胃炎)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Gingivitis (歯肉炎)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Glossitis (舌炎)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Haematemesis (吐血)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Hyperchlorhydria (胃酸過多)	0	(0.0)	1	(0.5)	0	(0.0)	1	(0.5)
Intestinal polyp (腸管ポリープ)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Irritable bowel syndrome (過敏性腸症候群)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Mouth ulceration (口腔内潰瘍形成)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Periodontal disease (歯周病)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Proctitis (直腸炎)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)

System organ class/ Preferred term	Placebo		Empa 10mg		Empa 25mg		Sitagliptin	
	N	(%)	N	(%)	N	(%)	N	(%)
Radicular cyst (歯根嚢胞)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Rectal haemorrhage (直腸出血)	1	(0.5)	1	(0.5)	0	(0.0)	1	(0.5)
Hepatobiliary disorders (肝胆道系障害)	4	(1.8)	3	(1.4)	8	(3.7)	3	(1.4)
Cholelithiasis (胆石症)	3	(1.4)	1	(0.5)	1	(0.5)	2	(0.9)
Hepatic steatosis (脂肪肝)	0	(0.0)	2	(0.9)	3	(1.4)	1	(0.5)
Hyperbilirubinaemia (高ビリルビン血症)	0	(0.0)	0	(0.0)	3	(1.4)	0	(0.0)
Cholecystitis (胆嚢炎)	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.5)
Cholecystitis acute (急性胆嚢炎)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Cirrhosis alcoholic (アルコール性肝硬変)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Gallbladder polyp (胆嚢ポリープ)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Hepatic function abnormal (肝機能異常)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Liver disorder (肝障害)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Skin and subcutaneous tissue disorders (皮膚および皮下組織障害)	15	(6.8)	12	(5.6)	19	(8.8)	14	(6.5)
Eczema (湿疹)	5	(2.3)	0	(0.0)	4	(1.9)	5	(2.3)
Pruritus (そう痒症)	1	(0.5)	4	(1.9)	3	(1.4)	1	(0.5)
Hyperkeratosis (過角化)	3	(1.4)	0	(0.0)	0	(0.0)	0	(0.0)
Rash (発疹)	2	(0.9)	3	(1.4)	1	(0.5)	2	(0.9)
Hyperhidrosis (多汗症)	1	(0.5)	0	(0.0)	2	(0.9)	1	(0.5)
Night sweats (寝汗)	0	(0.0)	2	(0.9)	0	(0.0)	0	(0.0)
Alopecia (脱毛症)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Alopecia areata (円形脱毛症)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Capillaritis (毛細血管炎)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Cold sweat (冷汗)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Dermatitis (皮膚炎)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Dermatitis allergic (アレルギー性皮膚炎)	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.5)
Dry skin (皮膚乾燥)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Hair texture abnormal (毛質異常)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Ingrowing nail (嵌入爪)	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.5)
Onychalgia (爪痛)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Onychoclasia (爪破損)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Papule (丘疹)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Photosensitivity allergic reaction (アレルギー性光線過敏性反応)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Photosensitivity reaction (光線過敏性反応)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Pigmentation disorder (色素沈着障害)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Psoriasis (乾癬)	1	(0.5)	0	(0.0)	1	(0.5)	0	(0.0)
Rash erythematous (紅斑性皮疹)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Rash pruritic (そう痒性皮疹)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Skin fissures (皮膚亀裂)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Skin lesion (皮膚病変)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Skin ulcer (皮膚潰瘍)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Urticaria (蕁麻疹)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Musculoskeletal and connective tissue disorders (筋骨格系および結合組織障害)	27	(12.3)	25	(11.6)	29	(13.5)	40	(18.6)
Back pain (背部痛)	6	(2.7)	2	(0.9)	5	(2.3)	12	(5.6)
Arthralgia (関節痛)	6	(2.7)	7	(3.2)	6	(2.8)	6	(2.8)
Pain in extremity (四肢痛)	3	(1.4)	5	(2.3)	1	(0.5)	6	(2.8)
Myalgia (筋肉痛)	1	(0.5)	4	(1.9)	4	(1.9)	3	(1.4)
Osteoarthritis (変形性関節症)	4	(1.8)	2	(0.9)	2	(0.9)	3	(1.4)
Musculoskeletal pain (筋骨格痛)	1	(0.5)	2	(0.9)	2	(0.9)	3	(1.4)
Spinal osteoarthritis (変形性脊椎症)	1	(0.5)	2	(0.9)	0	(0.0)	3	(1.4)
Tendonitis (腱炎)	1	(0.5)	0	(0.0)	1	(0.5)	3	(1.4)
Arthritis (関節炎)	0	(0.0)	2	(0.9)	0	(0.0)	0	(0.0)
Muscle spasms (筋痙攣)	1	(0.5)	2	(0.9)	1	(0.5)	1	(0.5)

System organ class/ Preferred term	Placebo		Empa 10mg		Empa 25mg		Sitagliptin	
	N	(%)	N	(%)	N	(%)	N	(%)
Musculoskeletal discomfort (筋骨格不快感)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.9)
Neck pain (頸部痛)	0	(0.0)	0	(0.0)	2	(0.9)	1	(0.5)
Periarthritis (関節周囲炎)	1	(0.5)	2	(0.9)	1	(0.5)	2	(0.9)
Bone pain (骨痛)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Bursitis (滑液包炎)	1	(0.5)	0	(0.0)	1	(0.5)	0	(0.0)
Chondrocalcinosis pyrophosphate (ピロリン酸カルシウム結晶性軟骨石灰化症)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Costochondritis (肋軟骨炎)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Dupuytren's contracture (デュプイトラン拘縮)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Facet joint syndrome (椎間関節症候群)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Fasciitis (筋膜炎)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Flank pain (側腹部痛)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Foot deformity (足変形)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Gouty arthritis (痛風性関節炎)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Haemarthrosis (出血性関節症)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Intervertebral disc protrusion (椎間板突出)	1	(0.5)	0	(0.0)	1	(0.5)	0	(0.0)
Joint swelling (関節腫脹)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Limb discomfort (四肢不快感)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Muscular weakness (筋力低下)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Musculoskeletal chest pain (筋骨格系胸痛)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Musculoskeletal stiffness (筋骨格硬直)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Osteoporosis (骨粗鬆症)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Plantar fasciitis (足底筋膜炎)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Plica syndrome (たな症候群)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Spinal disorder (脊椎障害)	1	(0.5)	1	(0.5)	0	(0.0)	0	(0.0)
Spondylitis (脊椎炎)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Temporomandibular joint syndrome (顎関節症候群)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Tendon calcification (腱石灰化)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Tendon disorder (腱障害)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Torticollis (斜頸)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Trigger finger (弾発指)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Renal and urinary disorders (腎および尿路障害)	3	(1.4)	15	(6.9)	15	(7.0)	7	(3.3)
Pollakiuria (頻尿)	0	(0.0)	5	(2.3)	5	(2.3)	1	(0.5)
Polyuria (多尿)	0	(0.0)	3	(1.4)	5	(2.3)	1	(0.5)
Nocturia (夜間頻尿)	0	(0.0)	0	(0.0)	2	(0.9)	1	(0.5)
Proteinuria (蛋白尿)	0	(0.0)	2	(0.9)	0	(0.0)	1	(0.5)
Calculus ureteric (尿管結石)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Diabetic nephropathy (糖尿病性腎症)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Dysuria (排尿困難)	0	(0.0)	1	(0.5)	1	(0.5)	1	(0.5)
Haematuria (血尿)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Hypertonic bladder (緊張性膀胱)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Micturition urgency (尿意切迫)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Nephrolithiasis (腎結石症)	0	(0.0)	1	(0.5)	0	(0.0)	1	(0.5)
Renal cyst (腎嚢胞)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Renal failure acute (急性腎不全)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Renal impairment (腎機能障害)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Renal tubular disorder (腎尿細管障害)	1	(0.5)	1	(0.5)	0	(0.0)	0	(0.0)
Urine odour abnormal (尿臭異常)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Reproductive system and breast disorders (生殖系および乳房障害)	4	(1.8)	6	(2.8)	12	(5.6)	4	(1.9)
Balanoposthitis (亀頭包皮炎)	0	(0.0)	3	(1.4)	1	(0.5)	0	(0.0)
Benign prostatic hyperplasia (良性前立腺肥大症)	0	(0.0)	1	(0.5)	1	(0.5)	3	(1.4)
Pruritus genital (陰部そう痒症)	0	(0.0)	0	(0.0)	2	(0.9)	0	(0.0)

System organ class/ Preferred term	Placebo		Empa 10mg		Empa 25mg		Sitagliptin	
	N	(%)	N	(%)	N	(%)	N	(%)
Vulvovaginal pruritus (外陰掻痒症)	2	(0.9)	1	(0.5)	1	(0.5)	0	(0.0)
Balanitis (亀頭炎)	1	(0.5)	0	(0.0)	1	(0.5)	0	(0.0)
Breast mass (乳房腫瘍)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Breast pain (乳房痛)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Cervical polyp (子宮頸管ポリープ)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Epididymitis (精巣上体炎)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Erectile dysfunction (勃起不全)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Genital haemorrhage (性器出血)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Haemospermia (血精液症)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Menorrhagia (月経過多)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Prostatitis (前立腺炎)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Vaginal haemorrhage (膣出血)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Vulvovaginal discomfort (外陰腔不快感)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Congenital, familial and genetic disorders (先天性、家族性および遺伝性障害)	1	(0.5)	3	(1.4)	1	(0.5)	0	(0.0)
Phimosis (包茎)	0	(0.0)	3	(1.4)	0	(0.0)	0	(0.0)
Gilbert's syndrome (ジルベール症候群)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Hydrocele (陰嚢水腫)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
General disorders and administration site conditions (一般・全身障害および投与部位の状態)	16	(7.3)	18	(8.3)	17	(7.9)	13	(6.0)
Thirst (口渇)	0	(0.0)	3	(1.4)	7	(3.3)	0	(0.0)
Asthenia (無力症)	2	(0.9)	1	(0.5)	2	(0.9)	3	(1.4)
Fatigue (疲労)	2	(0.9)	3	(1.4)	3	(1.4)	2	(0.9)
Oedema peripheral (末梢性浮腫)	2	(0.9)	1	(0.5)	2	(0.9)	3	(1.4)
Pyrexia (発熱)	3	(1.4)	3	(1.4)	1	(0.5)	3	(1.4)
Non-cardiac chest pain (非心臓性胸痛)	0	(0.0)	1	(0.5)	2	(0.9)	1	(0.5)
Pain (疼痛)	2	(0.9)	1	(0.5)	0	(0.0)	0	(0.0)
Adverse drug reaction (医薬品副作用)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Chest discomfort (胸部不快感)	1	(0.5)	1	(0.5)	0	(0.0)	0	(0.0)
Chest pain (胸痛)	0	(0.0)	1	(0.5)	0	(0.0)	1	(0.5)
Cyst (嚢胞)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Feeling hot (熱感)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Hernia (ヘルニア)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Hunger (空腹)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Implant site effusion (埋込み部位滲出液)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Malaise (倦怠感)	1	(0.5)	1	(0.5)	0	(0.0)	0	(0.0)
Nodule (小結節)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Unevaluable event (評価不能の事象)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Investigations (臨床検査)	26	(11.8)	15	(6.9)	16	(7.4)	15	(7.0)
Beta-N-acetyl-D-glucosaminidase increased (β- ーNアセチルDグルコサミニダーゼ増加)	2	(0.9)	2	(0.9)	7	(3.3)	2	(0.9)
Glycosylated haemoglobin increased (グリコヘ モグロビン増加)	7	(3.2)	3	(1.4)	0	(0.0)	3	(1.4)
Blood creatinine increased (血中クレアチニン 増加)	3	(1.4)	2	(0.9)	4	(1.9)	3	(1.4)
Blood creatine phosphokinase increased (血中 クレアチンホスホキナーゼ増加)	4	(1.8)	2	(0.9)	0	(0.0)	0	(0.0)
Blood glucose increased (血中ブドウ糖増加)	3	(1.4)	0	(0.0)	1	(0.5)	0	(0.0)
Blood pressure increased (血圧上昇)	3	(1.4)	0	(0.0)	0	(0.0)	1	(0.5)
Alanine aminotransferase increased (アラニン アミノトランスフェラーゼ増加)	2	(0.9)	1	(0.5)	0	(0.0)	1	(0.5)
Aspartate aminotransferase increased (アスパ ラギン酸アミノトランスフェラーゼ増加)	1	(0.5)	1	(0.5)	0	(0.0)	2	(0.9)

System organ class/ Preferred term	Placebo		Empa 10mg		Empa 25mg		Sitagliptin	
	N	(%)	N	(%)	N	(%)	N	(%)
Creatinine renal clearance decreased (腎クレアチニン・クリアランス減少)	1	(0.5)	1	(0.5)	1	(0.5)	2	(0.9)
Lipase increased (リパーゼ増加)	2	(0.9)	1	(0.5)	0	(0.0)	1	(0.5)
Alpha 1 microglobulin increased (α1ミクログロブリン増加)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Bacterial test positive (細菌検査陽性)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Blood bilirubin increased (血中ビリルビン増加)	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.5)
Blood calcium increased (血中カルシウム増加)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Blood creatine phosphokinase MB increased (血中クレアチンホスホキナーゼMB増加)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Blood lactate dehydrogenase increased (血中乳酸脱水素酵素増加)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Blood parathyroid hormone increased (血中副甲状腺ホルモン増加)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Blood potassium decreased (血中カリウム減少)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Blood triglycerides increased (血中トリグリセリド増加)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Culture urine positive (尿培養陽性)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Electrocardiogram abnormal (心電図異常)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Electrocardiogram change (心電図変化)	1	(0.5)	1	(0.5)	0	(0.0)	0	(0.0)
Eosinophil count increased (好酸球数増加)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Gamma-glutamyltransferase increased (γ-グルタミルトランスフェラーゼ増加)	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.5)
General physical condition normal (全身健康状態正常)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Glomerular filtration rate decreased (糸球体濾過率減少)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Haemoglobin decreased (ヘモグロビン減少)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Neutrophil count increased (好中球数増加)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Platelet count increased (血小板数増加)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Tuberculin test positive (ツベルクリン反応陽性)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Urine albumin/creatinine ratio increased (尿中アルブミン/クレアチニン比増加)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Urine leukocyte esterase positive (尿中白血球エステラーゼ陽性)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Vitamin D decreased (ビタミンD減少)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Weight decreased (体重減少)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
White blood cell count increased (白血球数増加)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
White blood cells urine positive (尿中白血球陽性)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Injury, poisoning and procedural complications (傷害、中毒および処置合併症)	9	(4.1)	21	(9.7)	10	(4.7)	10	(4.7)
Contusion (挫傷)	1	(0.5)	3	(1.4)	1	(0.5)	1	(0.5)
Muscle strain (肉離れ)	0	(0.0)	2	(0.9)	2	(0.9)	3	(1.4)
Animal bite (動物咬傷)	0	(0.0)	2	(0.9)	0	(0.0)	0	(0.0)
Excoriation (擦過傷)	1	(0.5)	2	(0.9)	0	(0.0)	0	(0.0)
Fall (転倒)	0	(0.0)	2	(0.9)	0	(0.0)	1	(0.5)
Thermal burn (熱傷)	2	(0.9)	0	(0.0)	1	(0.5)	0	(0.0)
Ankle fracture (足関節部骨折)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Arthropod bite (節足動物咬傷)	0	(0.0)	1	(0.5)	1	(0.5)	0	(0.0)

System organ class/ Preferred term	Placebo		Empa 10mg		Empa 25mg		Sitagliptin	
	N	(%)	N	(%)	N	(%)	N	(%)
Back injury (背部損傷)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Burns first degree (第1度熱傷)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Epicondylitis (上顎炎)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Eye injury (眼外傷)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Facial bones fracture (顔面骨骨折)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Foot fracture (足骨折)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Foreign body (体内異物)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Foreign body in eye (眼内異物)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Hand fracture (手骨折)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Injury (損傷)	1	(0.5)	1	(0.5)	0	(0.0)	0	(0.0)
Laceration (裂傷)	1	(0.5)	1	(0.5)	1	(0.5)	0	(0.0)
Limb injury (四肢損傷)	0	(0.0)	1	(0.5)	1	(0.5)	1	(0.5)
Meniscus lesion (半月板障害)	0	(0.0)	1	(0.5)	0	(0.0)	1	(0.5)
Muscle rupture (筋断裂)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Periorbital haematoma (眼窩周囲血腫)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Post procedural complication (処置後合併症)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Rib fracture (肋骨骨折)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Road traffic accident (交通事故)	1	(0.5)	1	(0.5)	0	(0.0)	0	(0.0)
Sciatic nerve injury (坐骨神経損傷)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Scratch (引っかき傷)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Spinal column injury (脊柱損傷)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Subdural haematoma (硬膜下血腫)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Tendon rupture (腱断裂)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Tibia fracture (脛骨骨折)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Traumatic fracture (外傷性骨折)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Upper limb fracture (上肢骨折)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Surgical and medical procedures (外科および内科処置)	2	(0.9)	1	(0.5)	0	(0.0)	0	(0.0)
Artificial crown procedure (人工歯冠処置)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Dental care (デンタルケア)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Endodontic procedure (歯内療法)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Hip arthroplasty (股関節形成)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)

Percentages are calculated using total number of patients per treatment as the denominator.

Containing data from study 1245_p031

MedDRA version used for reporting: XXXXXXXXXX

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Table 3.1.1.2 Frequency [N (%)] of patients with related adverse events by treatment, primary system organ class and preferred term - treated set actual (naive)

	Placebo		Empa 10mg		Empa 25mg		Sitagliptin	
System organ class/ Preferred term	N	(%)	N	(%)	N	(%)	N	(%)
Number of patients	221	(100.0)	217	(100.0)	216	(100.0)	215	(100.0)
Total with related adverse events	22	(10.0)	31	(14.3)	40	(18.5)	21	(9.8)
Infections and infestations (感染症および寄生虫症)	2	(0.9)	9	(4.1)	10	(4.6)	7	(3.3)
Urinary tract infection (尿路感染)	0	(0.0)	4	(1.8)	3	(1.4)	5	(2.3)
Asymptomatic bacteriuria (無症候性細菌尿)	0	(0.0)	1	(0.5)	2	(0.9)	0	(0.0)
Genital infection fungal (真菌性性器感染)	0	(0.0)	1	(0.5)	2	(0.9)	0	(0.0)
Sinusitis (副鼻腔炎)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.9)
Vulvovaginal candidiasis (外陰部腔カンジダ症)	0	(0.0)	2	(0.9)	1	(0.5)	0	(0.0)
Amoebiasis (アメーバ症)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Cystitis (膀胱炎)	1	(0.5)	0	(0.0)	1	(0.5)	1	(0.5)
Fungal skin infection (皮膚真菌感染)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Genital candidiasis (性器カンジダ症)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Genital infection (性器感染)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Genitourinary tract infection (泌尿生殖器感染)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Gingival infection (歯肉感染)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Upper respiratory tract infection (上気道感染)	1	(0.5)	1	(0.5)	0	(0.0)	1	(0.5)
Vaginal infection (腔感染)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Vulvovaginal mycotic infection (外陰腔真菌感染)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Blood and lymphatic system disorders (血液およびリンパ系障害)	0	(0.0)	3	(1.4)	1	(0.5)	0	(0.0)
Anaemia (貧血)	0	(0.0)	1	(0.5)	1	(0.5)	0	(0.0)
Eosinophilia (好酸球増加症)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Thrombocytopenia (血小板減少症)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Metabolism and nutrition disorders (代謝および栄養障害)	9	(4.1)	4	(1.8)	4	(1.9)	7	(3.3)
Hyperglycaemia (高血糖)	8	(3.6)	2	(0.9)	0	(0.0)	4	(1.9)
Dyslipidaemia (脂質異常症)	0	(0.0)	0	(0.0)	2	(0.9)	1	(0.5)
Hypertriglyceridaemia (高トリグリセリド血症)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Hypoglycaemia (低血糖症)	1	(0.5)	1	(0.5)	1	(0.5)	1	(0.5)
Increased appetite (食欲亢進)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Lipid metabolism disorder (脂質代謝障害)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Psychiatric disorders (精神障害)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.9)
Libido decreased (リビドー減退)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Sleep disorder (睡眠障害)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Nervous system disorders (神経系障害)	1	(0.5)	2	(0.9)	3	(1.4)	3	(1.4)
Dizziness (浮動性めまい)	0	(0.0)	1	(0.5)	1	(0.5)	2	(0.9)
Cerebrovascular accident (脳血管発作)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Headache (頭痛)	1	(0.5)	0	(0.0)	1	(0.5)	0	(0.0)
Hypotonia (筋緊張低下)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Paraesthesia (錯感覚)	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.5)
Cardiac disorders (心臓障害)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Palpitations (動悸)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Vascular disorders (血管障害)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)

	Placebo		Empa 10mg		Empa 25mg		Sitagliptin	
System organ class/ Preferred term	N	(%)	N	(%)	N	(%)	N	(%)
Orthostatic hypotension (起立性低血圧)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Gastrointestinal disorders (胃腸障害)	4	(1.8)	5	(2.3)	6	(2.8)	1	(0.5)
Constipation (便秘)	2	(0.9)	0	(0.0)	2	(0.9)	0	(0.0)
Diarrhoea (下痢)	2	(0.9)	2	(0.9)	1	(0.5)	0	(0.0)
Dry mouth (口内乾燥)	0	(0.0)	0	(0.0)	2	(0.9)	0	(0.0)
Abdominal distension (腹部膨満)	1	(0.5)	1	(0.5)	0	(0.0)	0	(0.0)
Colitis ulcerative (潰瘍性大腸炎)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Flatulence (鼓腸)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Gastric ulcer (胃潰瘍)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Gastritis (胃炎)	0	(0.0)	1	(0.5)	1	(0.5)	0	(0.0)
Gastrointestinal pain (消化器痛)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Gastroesophageal reflux disease (胃食道逆流性疾患)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Nausea (悪心)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Hepatobiliary disorders (肝胆道系障害)	0	(0.0)	0	(0.0)	2	(0.9)	0	(0.0)
Hyperbilirubinaemia (高ビリルビン血症)	0	(0.0)	0	(0.0)	2	(0.9)	0	(0.0)
Skin and subcutaneous tissue disorders (皮膚および皮下組織障害)	1	(0.5)	2	(0.9)	3	(1.4)	1	(0.5)
Pruritus (そう痒症)	0	(0.0)	1	(0.5)	2	(0.9)	0	(0.0)
Rash (発疹)	0	(0.0)	2	(0.9)	0	(0.0)	0	(0.0)
Dry skin (皮膚乾燥)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Eczema (湿疹)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Photosensitivity reaction (光線過敏性反応)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Musculoskeletal and connective tissue disorders (筋骨格系および結合組織障害)	2	(0.9)	0	(0.0)	1	(0.5)	1	(0.5)
Arthralgia (関節痛)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Back pain (背部痛)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Muscular weakness (筋力低下)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Myalgia (筋肉痛)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Renal and urinary disorders (腎および尿路障害)	0	(0.0)	9	(4.1)	10	(4.6)	1	(0.5)
Pollakiuria (頻尿)	0	(0.0)	4	(1.8)	5	(2.3)	0	(0.0)
Polyuria (多尿)	0	(0.0)	3	(1.4)	4	(1.9)	1	(0.5)
Dysuria (排尿困難)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Nocturia (夜間頻尿)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Renal failure acute (急性腎不全)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Renal tubular disorder (腎尿細管障害)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Reproductive system and breast disorders (生殖系および乳房障害)	2	(0.9)	1	(0.5)	4	(1.9)	0	(0.0)
Pruritus genital (陰部そう痒症)	0	(0.0)	0	(0.0)	2	(0.9)	0	(0.0)
Balanitis (亀頭炎)	1	(0.5)	0	(0.0)	1	(0.5)	0	(0.0)
Balanoposthitis (亀頭包皮炎)	0	(0.0)	1	(0.5)	1	(0.5)	0	(0.0)
Vulvovaginal pruritus (外陰腔そう痒症)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Congenital, familial and genetic disorders (先天性、家族性および遺伝性障害)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Phimosis (包茎)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
General disorders and administration site conditions (一般・全身障害および投与部位の状態)	1	(0.5)	6	(2.8)	10	(4.6)	2	(0.9)
Thirst (口渇)	0	(0.0)	3	(1.4)	6	(2.8)	0	(0.0)
Fatigue (疲労)	0	(0.0)	2	(0.9)	2	(0.9)	1	(0.5)
Asthenia (無力症)	0	(0.0)	1	(0.5)	1	(0.5)	1	(0.5)

	Placebo		Empa 10mg		Empa 25mg		Sitagliptin	
System organ class/ Preferred term	N	(%)	N	(%)	N	(%)	N	(%)
Hunger (空腹)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Pain (疼痛)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Pyrexia (発熱)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Investigations (臨床検査)	5	(2.3)	4	(1.8)	6	(2.8)	3	(1.4)
Alanine aminotransferase increased (アラニンアミノトランスフェラーゼ増加)	2	(0.9)	0	(0.0)	0	(0.0)	0	(0.0)
Beta-N-acetyl-D-glucosaminidase increased (β-NアセチルDグルコサミニダーゼ増加)	0	(0.0)	1	(0.5)	2	(0.9)	0	(0.0)
Creatinine renal clearance decreased (腎クレアチニン・クリアランス減少)	1	(0.5)	1	(0.5)	1	(0.5)	2	(0.9)
Aspartate aminotransferase increased (アスパラギン酸アミノトランスフェラーゼ増加)	1	(0.5)	0	(0.0)	0	(0.0)	1	(0.5)
Blood bilirubin increased (血中ビリルビン増加)	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.5)
Blood creatine phosphokinase increased (血中クレアチンホスホキナーゼ増加)	1	(0.5)	1	(0.5)	0	(0.0)	0	(0.0)
Blood creatinine increased (血中クレアチニン増加)	1	(0.5)	1	(0.5)	1	(0.5)	0	(0.0)
Blood pressure increased (血圧上昇)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Lipase increased (リパーゼ増加)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)
Tuberculin test positive (ツベルクリン反応陽性)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Weight decreased (体重減少)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)
Injury, poisoning and procedural complications (傷害、中毒および処置合併症)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)
Sciatic nerve injury (坐骨神経損傷)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)

Percentages are calculated using total number of patients per treatment as the denominator.

Containing data from study 1245_p031

MedDRA version used for reporting: [REDACTED]

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Table 4.1.1 Frequency [N (%)] of patients with adverse events by treatment, primary system organ class and preferred term - treated set

	Placebo		Empa 10mg		Empa 25mg	
System organ class/ Preferred term	N	(%)	N	(%)	N	(%)
Number of patients	319	(100.0)	98	(100.0)	321	(100.0)
Total with adverse events	270	(84.6)	86	(87.8)	268	(83.5)
Infections and infestations (感染症および寄生虫症)	136	(42.6)	49	(50.0)	144	(44.9)
Upper respiratory tract infection (上気道感染)	25	(7.8)	14	(14.3)	35	(10.9)
Urinary tract infection (尿路感染)	41	(12.9)	14	(14.3)	41	(12.8)
Nasopharyngitis (鼻咽頭炎)	29	(9.1)	6	(6.1)	27	(8.4)
Influenza (インフルエンザ)	8	(2.5)	6	(6.1)	8	(2.5)
Balanitis candida (カンジダ性亀頭炎)	0	(0.0)	5	(5.1)	0	(0.0)
Cellulitis (蜂巣炎)	4	(1.3)	3	(3.1)	5	(1.6)
Lower respiratory tract infection (下気道感染)	9	(2.8)	0	(0.0)	3	(0.9)
Bronchitis (気管支炎)	7	(2.2)	1	(1.0)	5	(1.6)
Gastroenteritis (胃腸炎)	6	(1.9)	2	(2.0)	6	(1.9)
Sinusitis (副鼻腔炎)	3	(0.9)	2	(2.0)	2	(0.6)
Fungal infection (真菌感染)	1	(0.3)	0	(0.0)	5	(1.6)
Vulvovaginal mycotic infection (外陰腔真菌感染)	0	(0.0)	1	(1.0)	5	(1.6)
Pneumonia (肺炎)	4	(1.3)	0	(0.0)	1	(0.3)
Tooth infection (歯感染)	4	(1.3)	0	(0.0)	3	(0.9)
Viral infection (ウイルス感染)	4	(1.3)	1	(1.0)	4	(1.2)
Cystitis (膀胱炎)	1	(0.3)	0	(0.0)	4	(1.2)
Herpes zoster (帯状疱疹)	1	(0.3)	0	(0.0)	4	(1.2)
Abscess (膿瘍)	0	(0.0)	1	(1.0)	0	(0.0)
Diverticulitis (憩室炎)	0	(0.0)	1	(1.0)	0	(0.0)
Eye infection (眼感染)	0	(0.0)	1	(1.0)	0	(0.0)
Furuncle (せつ)	3	(0.9)	1	(1.0)	1	(0.3)
Gingival infection (歯肉感染)	0	(0.0)	1	(1.0)	0	(0.0)
Hordeolum (麦粒腫)	0	(0.0)	1	(1.0)	0	(0.0)
Infected skin ulcer (感染性皮膚潰瘍)	0	(0.0)	1	(1.0)	0	(0.0)
Localised infection (限局性感染)	1	(0.3)	1	(1.0)	2	(0.6)
Prostate infection (前立腺感染)	0	(0.0)	1	(1.0)	0	(0.0)
Respiratory tract infection (気道感染)	0	(0.0)	1	(1.0)	3	(0.9)
Tinea pedis (足部白癬)	0	(0.0)	1	(1.0)	3	(0.9)
Tropical eosinophilia (熱帯性好酸球増加症)	1	(0.3)	1	(1.0)	1	(0.3)
Vaginitis bacterial (細菌性膇炎)	0	(0.0)	1	(1.0)	0	(0.0)
Viral upper respiratory tract infection (ウイルス性上気道感染)	1	(0.3)	1	(1.0)	0	(0.0)
Pyelonephritis chronic (慢性腎盂腎炎)	3	(0.9)	0	(0.0)	0	(0.0)
Vaginal infection (膇感染)	2	(0.6)	0	(0.0)	3	(0.9)
Ear infection (耳感染)	2	(0.6)	0	(0.0)	1	(0.3)
Gastroenteritis viral (ウイルス性胃腸炎)	2	(0.6)	0	(0.0)	2	(0.6)

	Placebo		Empa 10mg		Empa 25mg	
System organ class/ Preferred term	N	(%)	N	(%)	N	(%)
Otitis externa (外耳炎)	2	(0.6)	0	(0.0)	1	(0.3)
Skin infection (皮膚感染)	1	(0.3)	0	(0.0)	2	(0.6)
Subcutaneous abscess (皮下組織膿瘍)	0	(0.0)	0	(0.0)	2	(0.6)
Vulvovaginal candidiasis (外陰部腔カンジダ症)	2	(0.6)	0	(0.0)	1	(0.3)
Abdominal wall abscess (腹壁膿瘍)	1	(0.3)	0	(0.0)	0	(0.0)
Abscess limb (四肢膿瘍)	1	(0.3)	0	(0.0)	0	(0.0)
Asymptomatic bacteriuria (無症候性細菌尿)	1	(0.3)	0	(0.0)	1	(0.3)
Bacteriuria (細菌尿)	0	(0.0)	0	(0.0)	1	(0.3)
Blister infected (感染性水疱)	1	(0.3)	0	(0.0)	0	(0.0)
Bronchopneumonia (気管支肺炎)	1	(0.3)	0	(0.0)	0	(0.0)
Campylobacter gastroenteritis (カンピロバクター胃腸炎)	1	(0.3)	0	(0.0)	0	(0.0)
Cervicitis (子宮頸管炎)	1	(0.3)	0	(0.0)	0	(0.0)
Dengue fever (デング熱)	0	(0.0)	0	(0.0)	1	(0.3)
Erysipelas (丹毒)	1	(0.3)	0	(0.0)	0	(0.0)
Escherichia urinary tract infection (大腸菌性尿路感染)	1	(0.3)	0	(0.0)	0	(0.0)
Febrile infection (熱性感染症)	1	(0.3)	0	(0.0)	0	(0.0)
Fungal skin infection (皮膚真菌感染)	1	(0.3)	0	(0.0)	0	(0.0)
Gangrene (壊疽)	0	(0.0)	0	(0.0)	1	(0.3)
Genital infection (性器感染)	0	(0.0)	0	(0.0)	1	(0.3)
Gingival abscess (歯肉膿瘍)	0	(0.0)	0	(0.0)	1	(0.3)
Infection (感染)	1	(0.3)	0	(0.0)	0	(0.0)
Infection parasitic (寄生虫感染)	0	(0.0)	0	(0.0)	1	(0.3)
Malaria (マラリア)	1	(0.3)	0	(0.0)	1	(0.3)
Nail infection (爪感染)	1	(0.3)	0	(0.0)	0	(0.0)
Onychomycosis (爪真菌症)	0	(0.0)	0	(0.0)	1	(0.3)
Oral fungal infection (口腔真菌感染)	1	(0.3)	0	(0.0)	0	(0.0)
Oral herpes (口腔ヘルペス)	1	(0.3)	0	(0.0)	1	(0.3)
Otitis media (中耳炎)	0	(0.0)	0	(0.0)	1	(0.3)
Otitis media acute (急性中耳炎)	1	(0.3)	0	(0.0)	0	(0.0)
Paronychia (爪囲炎)	1	(0.3)	0	(0.0)	1	(0.3)
Pharyngitis (咽頭炎)	0	(0.0)	0	(0.0)	1	(0.3)
Pneumonia primary atypical (原発性異型肺炎)	1	(0.3)	0	(0.0)	0	(0.0)
Post procedural infection (処置後感染)	1	(0.3)	0	(0.0)	0	(0.0)
Pulmonary tuberculosis (肺結核)	0	(0.0)	0	(0.0)	1	(0.3)
Purulent discharge (化膿性分泌物)	1	(0.3)	0	(0.0)	0	(0.0)
Sepsis (敗血症)	0	(0.0)	0	(0.0)	1	(0.3)
Tinea versicolour (癬風)	0	(0.0)	0	(0.0)	1	(0.3)
Tooth abscess (歯膿瘍)	1	(0.3)	0	(0.0)	1	(0.3)
Typhoid fever (腸チフス熱)	1	(0.3)	0	(0.0)	0	(0.0)
Urinary tract infection enterococcal (腸球菌性尿路感染)	0	(0.0)	0	(0.0)	1	(0.3)
Vulvitis (外陰部炎)	0	(0.0)	0	(0.0)	1	(0.3)

	Placebo		Empa 10mg		Empa 25mg	
System organ class/ Preferred term	N	(%)	N	(%)	N	(%)
Wound infection (創傷感染)	1	(0.3)	0	(0.0)	1	(0.3)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (良性、悪性および詳細不明の新生物 (嚢胞およびポリープを含む))	13	(4.1)	0	(0.0)	5	(1.6)
Lipoma (脂肪腫)	2	(0.6)	0	(0.0)	0	(0.0)
Acrochordon (アクロコルドン)	1	(0.3)	0	(0.0)	0	(0.0)
Angiomyolipoma (血管筋脂肪腫)	0	(0.0)	0	(0.0)	1	(0.3)
Benign breast neoplasm (乳房の良性新生物)	1	(0.3)	0	(0.0)	0	(0.0)
Benign neoplasm of thyroid gland (甲状腺の良性新生物)	1	(0.3)	0	(0.0)	0	(0.0)
Haemangioma (血管腫)	1	(0.3)	0	(0.0)	0	(0.0)
Malignant melanoma (悪性黒色腫)	0	(0.0)	0	(0.0)	1	(0.3)
Oesophageal carcinoma (食道癌)	0	(0.0)	0	(0.0)	1	(0.3)
Oropharyngeal cancer stage unspecified (中咽頭癌、病期不明)	0	(0.0)	0	(0.0)	1	(0.3)
Pancreatic carcinoma (膵癌)	1	(0.3)	0	(0.0)	0	(0.0)
Papilloma (乳頭腫)	0	(0.0)	0	(0.0)	1	(0.3)
Prostate cancer metastatic (転移性前立腺癌)	1	(0.3)	0	(0.0)	0	(0.0)
Seborrheic keratosis (脂漏性角化症)	1	(0.3)	0	(0.0)	0	(0.0)
Skin cancer (皮膚癌)	1	(0.3)	0	(0.0)	0	(0.0)
Skin papilloma (皮膚乳頭腫)	1	(0.3)	0	(0.0)	0	(0.0)
Squamous cell carcinoma (扁平上皮癌)	1	(0.3)	0	(0.0)	0	(0.0)
Squamous cell carcinoma of skin (皮膚有棘細胞癌)	1	(0.3)	0	(0.0)	0	(0.0)
Thyroid neoplasm (甲状腺新生物)	1	(0.3)	0	(0.0)	0	(0.0)
Blood and lymphatic system disorders (血液およびリンパ系障害)	16	(5.0)	2	(2.0)	13	(4.0)
Anaemia (貧血)	9	(2.8)	0	(0.0)	5	(1.6)
Iron deficiency anaemia (鉄欠乏性貧血)	0	(0.0)	1	(1.0)	1	(0.3)
Lymphocytosis (リンパ球増加症)	0	(0.0)	1	(1.0)	0	(0.0)
Monocytosis (単球増加症)	0	(0.0)	1	(1.0)	0	(0.0)
Eosinophilia (好酸球増加症)	2	(0.6)	0	(0.0)	1	(0.3)
Nephrogenic anaemia (腎性貧血)	2	(0.6)	0	(0.0)	0	(0.0)
Thrombocytopenia (血小板減少症)	0	(0.0)	0	(0.0)	2	(0.6)
Haemorrhagic anaemia (出血性貧血)	1	(0.3)	0	(0.0)	1	(0.3)
Hypochromic anaemia (低色素性貧血)	1	(0.3)	0	(0.0)	0	(0.0)
Leukocytosis (白血球増加症)	0	(0.0)	0	(0.0)	1	(0.3)
Lymphadenopathy (リンパ節症)	1	(0.3)	0	(0.0)	1	(0.3)
Neutrophilia (好中球増加症)	0	(0.0)	0	(0.0)	1	(0.3)
Pernicious anaemia (悪性貧血)	1	(0.3)	0	(0.0)	0	(0.0)
Splenomegaly (脾腫)	0	(0.0)	0	(0.0)	1	(0.3)
Immune system disorders (免疫系障害)	5	(1.6)	0	(0.0)	2	(0.6)
Hypersensitivity (過敏症)	2	(0.6)	0	(0.0)	0	(0.0)
Seasonal allergy (季節性アレルギー)	2	(0.6)	0	(0.0)	1	(0.3)
Drug hypersensitivity (薬物過敏症)	1	(0.3)	0	(0.0)	1	(0.3)

	Placebo		Empa 10mg		Empa 25mg	
System organ class/ Preferred term	N	(%)	N	(%)	N	(%)
Endocrine disorders (内分泌障害)	3	(0.9)	1	(1.0)	2	(0.6)
Hyperparathyroidism (副甲状腺機能亢進症)	0	(0.0)	1	(1.0)	0	(0.0)
Goitre (甲状腺腫)	1	(0.3)	0	(0.0)	1	(0.3)
Hyperparathyroidism primary (原発性副甲状腺機能亢進症)	1	(0.3)	0	(0.0)	0	(0.0)
Hyperparathyroidism secondary (続発性副甲状腺機能亢進症)	0	(0.0)	0	(0.0)	1	(0.3)
Hyperthyroidism (甲状腺機能亢進症)	1	(0.3)	0	(0.0)	0	(0.0)
Metabolism and nutrition disorders (代謝および栄養障害)	142	(44.5)	34	(34.7)	128	(39.9)
Hypoglycaemia (低血糖症)	92	(28.8)	27	(27.6)	92	(28.7)
Hyperglycaemia (高血糖)	41	(12.9)	4	(4.1)	25	(7.8)
Dyslipidaemia (脂質異常症)	8	(2.5)	3	(3.1)	6	(1.9)
Decreased appetite (食欲減退)	7	(2.2)	0	(0.0)	1	(0.3)
Gout (痛風)	6	(1.9)	0	(0.0)	7	(2.2)
Hyperkalaemia (高カリウム血症)	6	(1.9)	0	(0.0)	5	(1.6)
Hyperuricaemia (高尿酸血症)	1	(0.3)	1	(1.0)	4	(1.2)
Hypercholesterolaemia (高コレステロール血症)	0	(0.0)	1	(1.0)	0	(0.0)
Hypokalaemia (低カリウム血症)	0	(0.0)	1	(1.0)	1	(0.3)
Vitamin D deficiency (ビタミンD欠乏)	1	(0.3)	1	(1.0)	1	(0.3)
Dehydration (脱水)	1	(0.3)	0	(0.0)	2	(0.6)
Diabetes mellitus inadequate control (コントロール不良の糖尿病)	2	(0.6)	0	(0.0)	1	(0.3)
Fluid retention (体液貯留)	2	(0.6)	0	(0.0)	0	(0.0)
Food craving (食物渴望)	0	(0.0)	0	(0.0)	2	(0.6)
Hypercalcaemia (高カルシウム血症)	1	(0.3)	0	(0.0)	2	(0.6)
Hypovolaemia (血液量減少症)	2	(0.6)	0	(0.0)	0	(0.0)
Diabetes mellitus (糖尿病)	1	(0.3)	0	(0.0)	1	(0.3)
Diabetic ketoacidosis (糖尿病性ケトアシドーシス)	1	(0.3)	0	(0.0)	1	(0.3)
Fluid overload (水分過負荷)	1	(0.3)	0	(0.0)	0	(0.0)
Hyperlipasaemia (高リパーゼ血症)	1	(0.3)	0	(0.0)	0	(0.0)
Hypertriglyceridaemia (高トリグリセリド血症)	1	(0.3)	0	(0.0)	0	(0.0)
Hypomagnesaemia (低マグネシウム血症)	1	(0.3)	0	(0.0)	0	(0.0)
Hyponatraemia (低ナトリウム血症)	1	(0.3)	0	(0.0)	0	(0.0)
Hypovitaminosis (ビタミン欠乏症)	1	(0.3)	0	(0.0)	0	(0.0)
Metabolic acidosis (代謝性アシドーシス)	1	(0.3)	0	(0.0)	0	(0.0)
Metabolic disorder (代謝障害)	1	(0.3)	0	(0.0)	0	(0.0)
Polydipsia (多飲症)	0	(0.0)	0	(0.0)	1	(0.3)
Vitamin B12 deficiency (ビタミンB12欠乏)	1	(0.3)	0	(0.0)	0	(0.0)
Psychiatric disorders (精神障害)	14	(4.4)	5	(5.1)	17	(5.3)
Depression (うつ病)	2	(0.6)	1	(1.0)	6	(1.9)
Insomnia (不眠症)	3	(0.9)	1	(1.0)	6	(1.9)
Anxiety (不安)	3	(0.9)	1	(1.0)	4	(1.2)

	Placebo		Empa 10mg		Empa 25mg	
System organ class/ Preferred term	N	(%)	N	(%)	N	(%)
Sleep disorder (睡眠障害)	0	(0.0)	1	(1.0)	0	(0.0)
Stress (ストレス)	0	(0.0)	1	(1.0)	1	(0.3)
Abnormal behaviour (異常行動)	1	(0.3)	0	(0.0)	0	(0.0)
Alcoholism (アルコール症)	1	(0.3)	0	(0.0)	0	(0.0)
Confusional state (錯乱状態)	1	(0.3)	0	(0.0)	0	(0.0)
Depressed mood (抑うつ気分)	1	(0.3)	0	(0.0)	0	(0.0)
Depressive symptom (抑うつ症状)	1	(0.3)	0	(0.0)	0	(0.0)
Emotional distress (感情的苦悩)	1	(0.3)	0	(0.0)	0	(0.0)
Initial insomnia (初期不眠症)	0	(0.0)	0	(0.0)	1	(0.3)
Mental disorder due to a general medical condition (身体疾患による精神障害)	1	(0.3)	0	(0.0)	0	(0.0)
Restlessness (落ち着きのなさ)	0	(0.0)	0	(0.0)	1	(0.3)
Nervous system disorders (神経系障害)	56	(17.6)	15	(15.3)	50	(15.6)
Headache (頭痛)	13	(4.1)	5	(5.1)	16	(5.0)
Dizziness (浮動性めまい)	16	(5.0)	3	(3.1)	9	(2.8)
Tremor (振戦)	2	(0.6)	2	(2.0)	3	(0.9)
Neuropathy peripheral (末梢性ニューロパチー)	6	(1.9)	1	(1.0)	3	(0.9)
Hypoaesthesia (感覚鈍麻)	4	(1.3)	1	(1.0)	3	(0.9)
Lethargy (嗜眠)	4	(1.3)	0	(0.0)	3	(0.9)
Balance disorder (平衡障害)	0	(0.0)	1	(1.0)	1	(0.3)
Diabetic neuropathy (糖尿病性ニューロパチー)	1	(0.3)	1	(1.0)	2	(0.6)
Memory impairment (記憶障害)	1	(0.3)	1	(1.0)	1	(0.3)
Meralgia paraesthetica (感覚異常性大腿神経痛)	0	(0.0)	1	(1.0)	0	(0.0)
Paraesthesia (錯感覚)	3	(0.9)	1	(1.0)	2	(0.6)
Radicular pain (神経根痛)	0	(0.0)	1	(1.0)	0	(0.0)
Syncope (失神)	1	(0.3)	0	(0.0)	3	(0.9)
Cerebrovascular accident (脳血管発作)	1	(0.3)	0	(0.0)	2	(0.6)
Dysarthria (構語障害)	2	(0.6)	0	(0.0)	0	(0.0)
Loss of consciousness (意識消失)	2	(0.6)	0	(0.0)	0	(0.0)
Sciatica (坐骨神経痛)	2	(0.6)	0	(0.0)	0	(0.0)
Amnesia (健忘)	1	(0.3)	0	(0.0)	0	(0.0)
Aphasia (失語症)	1	(0.3)	0	(0.0)	0	(0.0)
Carpal tunnel syndrome (手根管症候群)	1	(0.3)	0	(0.0)	0	(0.0)
Cerebral infarction (脳梗塞)	0	(0.0)	0	(0.0)	1	(0.3)
Cubital tunnel syndrome (肘部管症候群)	1	(0.3)	0	(0.0)	0	(0.0)
Dizziness postural (体位性めまい)	0	(0.0)	0	(0.0)	1	(0.3)
Embolic cerebral infarction (塞栓性脳梗塞)	1	(0.3)	0	(0.0)	0	(0.0)
Hypoxic-ischaemic encephalopathy (低酸素性虚血性脳症)	1	(0.3)	0	(0.0)	0	(0.0)
Lacunar infarction (ラクナ梗塞)	0	(0.0)	0	(0.0)	1	(0.3)
Migraine (片頭痛)	1	(0.3)	0	(0.0)	0	(0.0)
Mononeuritis (単神経炎)	1	(0.3)	0	(0.0)	0	(0.0)
Nerve compression (神経圧迫)	1	(0.3)	0	(0.0)	0	(0.0)

	Placebo		Empa 10mg		Empa 25mg	
System organ class/ Preferred term	N	(%)	N	(%)	N	(%)
Neuralgia (神経痛)	0	(0.0)	0	(0.0)	1	(0.3)
Optic neuritis (視神経炎)	0	(0.0)	0	(0.0)	1	(0.3)
Peripheral sensory neuropathy (末梢性感覚ニューロパチー)	1	(0.3)	0	(0.0)	0	(0.0)
Sensorimotor disorder (感覚運動障害)	1	(0.3)	0	(0.0)	0	(0.0)
Tongue biting (咬舌)	1	(0.3)	0	(0.0)	0	(0.0)
Transient ischaemic attack (一過性脳虚血発作)	1	(0.3)	0	(0.0)	1	(0.3)
Vertebrobasilar insufficiency (椎骨脳底動脈不全)	0	(0.0)	0	(0.0)	1	(0.3)
Eye disorders (眼障害)	22	(6.9)	10	(10.2)	25	(7.8)
Cataract (白内障)	3	(0.9)	0	(0.0)	10	(3.1)
Diabetic retinopathy (糖尿病網膜症)	2	(0.6)	2	(2.0)	2	(0.6)
Retinopathy (網膜症)	0	(0.0)	2	(2.0)	0	(0.0)
Blepharospasm (眼瞼痙攣)	0	(0.0)	1	(1.0)	0	(0.0)
Dry eye (眼乾燥)	2	(0.6)	1	(1.0)	1	(0.3)
Keratitis (角膜炎)	0	(0.0)	1	(1.0)	0	(0.0)
Macular oedema (黄斑浮腫)	1	(0.3)	1	(1.0)	0	(0.0)
Ocular hyperaemia (眼充血)	0	(0.0)	1	(1.0)	0	(0.0)
Visual acuity reduced (視力低下)	1	(0.3)	1	(1.0)	0	(0.0)
Visual impairment (視力障害)	0	(0.0)	1	(1.0)	0	(0.0)
Glaucoma (緑内障)	2	(0.6)	0	(0.0)	3	(0.9)
Eye pain (眼痛)	2	(0.6)	0	(0.0)	0	(0.0)
Vision blurred (霧視)	2	(0.6)	0	(0.0)	1	(0.3)
Age-related macular degeneration (加齢黄斑変性)	1	(0.3)	0	(0.0)	0	(0.0)
Blepharitis (眼瞼炎)	1	(0.3)	0	(0.0)	1	(0.3)
Conjunctival haemorrhage (結膜出血)	1	(0.3)	0	(0.0)	1	(0.3)
Conjunctivitis allergic (アレルギー性結膜炎)	1	(0.3)	0	(0.0)	0	(0.0)
Cystoid macular oedema (嚢胞様黄斑浮腫)	0	(0.0)	0	(0.0)	1	(0.3)
Diplopia (複視)	0	(0.0)	0	(0.0)	1	(0.3)
Eye swelling (眼部腫脹)	0	(0.0)	0	(0.0)	1	(0.3)
Eyelid cyst (眼瞼嚢胞)	1	(0.3)	0	(0.0)	0	(0.0)
Eyelid oedema (眼瞼浮腫)	0	(0.0)	0	(0.0)	1	(0.3)
Lacrimation increased (流涙増加)	1	(0.3)	0	(0.0)	1	(0.3)
Macular degeneration (黄斑変性)	1	(0.3)	0	(0.0)	0	(0.0)
Normal tension glaucoma (正常眼圧緑内障)	0	(0.0)	0	(0.0)	1	(0.3)
Photopsia (光視症)	1	(0.3)	0	(0.0)	0	(0.0)
Retinal artery occlusion (網膜動脈閉塞)	0	(0.0)	0	(0.0)	1	(0.3)
Retinal disorder (網膜障害)	1	(0.3)	0	(0.0)	0	(0.0)
Retinal haemorrhage (網膜出血)	0	(0.0)	0	(0.0)	1	(0.3)
Retinopathy hypertensive (高血圧性網膜症)	0	(0.0)	0	(0.0)	1	(0.3)
Ear and labyrinth disorders (耳および迷路障害)	5	(1.6)	1	(1.0)	11	(3.4)
Vertigo (回転性めまい)	2	(0.6)	0	(0.0)	5	(1.6)
Vertigo positional (頭位性回転性めまい)	0	(0.0)	1	(1.0)	0	(0.0)

	Placebo		Empa 10mg		Empa 25mg	
System organ class/ Preferred term	N	(%)	N	(%)	N	(%)
Cerumen impaction (耳垢栓塞)	0	(0.0)	0	(0.0)	1	(0.3)
Deafness (難聴)	1	(0.3)	0	(0.0)	1	(0.3)
Ear discomfort (耳不快感)	0	(0.0)	0	(0.0)	1	(0.3)
Ear pain (耳痛)	0	(0.0)	0	(0.0)	1	(0.3)
External ear pain (外耳痛)	0	(0.0)	0	(0.0)	1	(0.3)
Tinnitus (耳鳴)	1	(0.3)	0	(0.0)	1	(0.3)
Tympanic membrane perforation (鼓膜穿孔)	1	(0.3)	0	(0.0)	0	(0.0)
Cardiac disorders (心臓障害)	25	(7.8)	3	(3.1)	15	(4.7)
Atrial fibrillation (心房細動)	5	(1.6)	0	(0.0)	3	(0.9)
Arrhythmia (不整脈)	4	(1.3)	0	(0.0)	0	(0.0)
Acute coronary syndrome (急性冠動脈症候群)	0	(0.0)	1	(1.0)	0	(0.0)
Extrasystoles (期外収縮)	0	(0.0)	1	(1.0)	0	(0.0)
Palpitations (動悸)	1	(0.3)	1	(1.0)	0	(0.0)
Cardiac failure (心不全)	3	(0.9)	0	(0.0)	0	(0.0)
Tachycardia (頻脈)	1	(0.3)	0	(0.0)	3	(0.9)
Acute myocardial infarction (急性心筋梗塞)	2	(0.6)	0	(0.0)	0	(0.0)
Angina unstable (不安定狭心症)	2	(0.6)	0	(0.0)	0	(0.0)
Atrioventricular block first degree (第一度房室ブロック)	2	(0.6)	0	(0.0)	1	(0.3)
Bradycardia (徐脈)	2	(0.6)	0	(0.0)	0	(0.0)
Mitral valve incompetence (僧帽弁閉鎖不全症)	2	(0.6)	0	(0.0)	0	(0.0)
Ventricular extrasystoles (心室性期外収縮)	0	(0.0)	0	(0.0)	2	(0.6)
Angina pectoris (狭心症)	1	(0.3)	0	(0.0)	0	(0.0)
Aortic valve sclerosis (大動脈弁硬化症)	1	(0.3)	0	(0.0)	0	(0.0)
Atrial flutter (心房粗動)	1	(0.3)	0	(0.0)	0	(0.0)
Atrioventricular block (房室ブロック)	0	(0.0)	0	(0.0)	1	(0.3)
Atrioventricular block second degree (第二度房室ブロック)	1	(0.3)	0	(0.0)	0	(0.0)
Bundle branch block left (左脚ブロック)	0	(0.0)	0	(0.0)	1	(0.3)
Cardiac arrest (心停止)	1	(0.3)	0	(0.0)	1	(0.3)
Cardiac failure congestive (うっ血性心不全)	1	(0.3)	0	(0.0)	0	(0.0)
Cardiogenic shock (心原性ショック)	1	(0.3)	0	(0.0)	0	(0.0)
Coronary artery occlusion (冠動脈閉塞)	0	(0.0)	0	(0.0)	1	(0.3)
Long QT syndrome (QT延長症候群)	0	(0.0)	0	(0.0)	1	(0.3)
Myocardial ischaemia (心筋虚血)	1	(0.3)	0	(0.0)	0	(0.0)
Sick sinus syndrome (洞不全症候群)	0	(0.0)	0	(0.0)	1	(0.3)
Sinus bradycardia (洞性徐脈)	0	(0.0)	0	(0.0)	1	(0.3)
Sinus tachycardia (洞性頻脈)	0	(0.0)	0	(0.0)	1	(0.3)
Vascular disorders (血管障害)	37	(11.6)	3	(3.1)	25	(7.8)
Hypertension (高血圧)	22	(6.9)	1	(1.0)	14	(4.4)
Hypotension (低血圧)	4	(1.3)	0	(0.0)	3	(0.9)
Aortic stenosis (大動脈狭窄)	0	(0.0)	1	(1.0)	0	(0.0)
Orthostatic hypotension (起立性低血圧)	0	(0.0)	1	(1.0)	1	(0.3)

	Placebo		Empa 10mg		Empa 25mg	
System organ class/ Preferred term	N	(%)	N	(%)	N	(%)
Circulatory collapse (循環虚脱)	2	(0.6)	0	(0.0)	0	(0.0)
Hot flush (ほてり)	0	(0.0)	0	(0.0)	2	(0.6)
Peripheral vascular disorder (末梢血管障害)	2	(0.6)	0	(0.0)	0	(0.0)
Blood pressure inadequately controlled (コントロール不良の血圧)	1	(0.3)	0	(0.0)	0	(0.0)
Deep vein thrombosis (深部静脈血栓症)	0	(0.0)	0	(0.0)	1	(0.3)
Essential hypertension (本態性高血圧症)	1	(0.3)	0	(0.0)	0	(0.0)
Extremity necrosis (四肢壊死)	0	(0.0)	0	(0.0)	1	(0.3)
Iliac artery stenosis (腸骨動脈狭窄)	1	(0.3)	0	(0.0)	0	(0.0)
Intra-abdominal haematoma (腹腔内血腫)	1	(0.3)	0	(0.0)	0	(0.0)
Lymphocele (リンパ嚢腫)	1	(0.3)	0	(0.0)	0	(0.0)
Macroangiopathy (大血管障害)	1	(0.3)	0	(0.0)	0	(0.0)
Peripheral coldness (末梢冷感)	1	(0.3)	0	(0.0)	1	(0.3)
Peripheral ischaemia (末梢性虚血)	0	(0.0)	0	(0.0)	1	(0.3)
Phlebitis (静脈炎)	1	(0.3)	0	(0.0)	1	(0.3)
Phlebitis superficial (表在性静脈炎)	0	(0.0)	0	(0.0)	1	(0.3)
Subclavian artery stenosis (鎖骨下動脈狭窄)	1	(0.3)	0	(0.0)	0	(0.0)
Thrombophlebitis (血栓性静脈炎)	1	(0.3)	0	(0.0)	1	(0.3)
Thrombosis (血栓症)	1	(0.3)	0	(0.0)	0	(0.0)
Varicose vein (静脈瘤)	1	(0.3)	0	(0.0)	1	(0.3)
Respiratory, thoracic and mediastinal disorders (呼吸器、胸郭および縦隔障害)	46	(14.4)	9	(9.2)	22	(6.9)
Cough (咳嗽)	25	(7.8)	2	(2.0)	11	(3.4)
Oropharyngeal pain (口腔咽頭痛)	7	(2.2)	3	(3.1)	4	(1.2)
Dyspnoea (呼吸困難)	7	(2.2)	0	(0.0)	1	(0.3)
Chronic obstructive pulmonary disease (慢性閉塞性肺疾患)	0	(0.0)	1	(1.0)	0	(0.0)
Productive cough (湿性咳嗽)	2	(0.6)	1	(1.0)	1	(0.3)
Rhinitis allergic (アレルギー性鼻炎)	1	(0.3)	1	(1.0)	2	(0.6)
Wheezing (喘鳴)	2	(0.6)	1	(1.0)	0	(0.0)
Dyspnoea exertional (労作性呼吸困難)	1	(0.3)	0	(0.0)	2	(0.6)
Epistaxis (鼻出血)	2	(0.6)	0	(0.0)	1	(0.3)
Pulmonary oedema (肺水腫)	2	(0.6)	0	(0.0)	0	(0.0)
Throat irritation (咽喉刺激感)	2	(0.6)	0	(0.0)	0	(0.0)
Upper respiratory tract congestion (上気道うっ血)	0	(0.0)	0	(0.0)	2	(0.6)
Asthma (喘息)	1	(0.3)	0	(0.0)	0	(0.0)
Bronchial hyperreactivity (気管支反応性亢進)	0	(0.0)	0	(0.0)	1	(0.3)
Haemoptysis (咯血)	1	(0.3)	0	(0.0)	0	(0.0)
Hypoxia (低酸素症)	1	(0.3)	0	(0.0)	1	(0.3)
Nasal dryness (鼻乾燥)	1	(0.3)	0	(0.0)	0	(0.0)
Pharyngeal oedema (咽頭浮腫)	1	(0.3)	0	(0.0)	0	(0.0)
Pulmonary embolism (肺塞栓症)	1	(0.3)	0	(0.0)	0	(0.0)
Respiratory disorder (呼吸障害)	0	(0.0)	0	(0.0)	1	(0.3)

	Placebo		Empa 10mg		Empa 25mg	
System organ class/ Preferred term	N	(%)	N	(%)	N	(%)
Respiratory tract congestion (気道うっ血)	1	(0.3)	0	(0.0)	0	(0.0)
Rhinorrhoea (鼻漏)	1	(0.3)	0	(0.0)	1	(0.3)
Sleep apnoea syndrome (睡眠時無呼吸症候群)	1	(0.3)	0	(0.0)	0	(0.0)
Sputum discoloured (変色痰)	1	(0.3)	0	(0.0)	0	(0.0)
Upper-airway cough syndrome (上気道咳症候群)	1	(0.3)	0	(0.0)	0	(0.0)
Gastrointestinal disorders (胃腸障害)	64	(20.1)	17	(17.3)	75	(23.4)
Nausea (悪心)	6	(1.9)	2	(2.0)	16	(5.0)
Diarrhoea (下痢)	13	(4.1)	4	(4.1)	14	(4.4)
Rectal haemorrhage (直腸出血)	4	(1.3)	4	(4.1)	0	(0.0)
Vomiting (嘔吐)	5	(1.6)	4	(4.1)	11	(3.4)
Constipation (便秘)	10	(3.1)	3	(3.1)	11	(3.4)
Dyspepsia (消化不良)	5	(1.6)	1	(1.0)	8	(2.5)
Abdominal discomfort (腹部不快感)	1	(0.3)	2	(2.0)	2	(0.6)
Abdominal pain upper (上腹部痛)	3	(0.9)	2	(2.0)	5	(1.6)
Gastritis (胃炎)	5	(1.6)	2	(2.0)	5	(1.6)
Abdominal pain (腹痛)	6	(1.9)	1	(1.0)	3	(0.9)
Abdominal pain lower (下腹部痛)	4	(1.3)	0	(0.0)	3	(0.9)
Abdominal distension (腹部膨満)	2	(0.6)	1	(1.0)	2	(0.6)
Food poisoning (食中毒)	1	(0.3)	1	(1.0)	0	(0.0)
Gingival pain (歯肉痛)	0	(0.0)	1	(1.0)	0	(0.0)
Gingivitis (歯肉炎)	0	(0.0)	1	(1.0)	0	(0.0)
Mouth ulceration (口腔内潰瘍形成)	0	(0.0)	1	(1.0)	1	(0.3)
Oesophageal varices haemorrhage (食道静脈瘤出血)	0	(0.0)	1	(1.0)	0	(0.0)
Toothache (歯痛)	1	(0.3)	1	(1.0)	1	(0.3)
Colonic polyp (結腸ポリープ)	3	(0.9)	0	(0.0)	3	(0.9)
Dental caries (齲歯)	0	(0.0)	0	(0.0)	3	(0.9)
Gastroesophageal reflux disease (胃食道逆流性疾患)	2	(0.6)	0	(0.0)	3	(0.9)
Dry mouth (口内乾燥)	1	(0.3)	0	(0.0)	2	(0.6)
Haemorrhoids (痔核)	2	(0.6)	0	(0.0)	2	(0.6)
Oral pain (口腔内痛)	1	(0.3)	0	(0.0)	2	(0.6)
Pancreatitis (膵炎)	2	(0.6)	0	(0.0)	0	(0.0)
Abdominal hernia (腹部ヘルニア)	1	(0.3)	0	(0.0)	0	(0.0)
Abdominal tenderness (腹部圧痛)	0	(0.0)	0	(0.0)	1	(0.3)
Aphthous stomatitis (アフタ性口内炎)	1	(0.3)	0	(0.0)	1	(0.3)
Change of bowel habit (便習慣変化)	1	(0.3)	0	(0.0)	0	(0.0)
Colitis (大腸炎)	0	(0.0)	0	(0.0)	1	(0.3)
Defaecation urgency (便意切迫)	1	(0.3)	0	(0.0)	0	(0.0)
Diverticulum intestinal (腸憩室)	0	(0.0)	0	(0.0)	1	(0.3)
Dysphagia (嚥下障害)	0	(0.0)	0	(0.0)	1	(0.3)
Epigastric discomfort (心窩部不快感)	0	(0.0)	0	(0.0)	1	(0.3)
Eructation (おくび)	1	(0.3)	0	(0.0)	0	(0.0)

	Placebo		Empa 10mg		Empa 25mg	
System organ class/ Preferred term	N	(%)	N	(%)	N	(%)
Flatulence (鼓腸)	1	(0.3)	0	(0.0)	1	(0.3)
Frequent bowel movements (排便回数増加)	0	(0.0)	0	(0.0)	1	(0.3)
Gastritis erosive (びらん性胃炎)	1	(0.3)	0	(0.0)	1	(0.3)
Gastrointestinal disorder (胃腸障害)	0	(0.0)	0	(0.0)	1	(0.3)
Gingival bleeding (歯肉出血)	1	(0.3)	0	(0.0)	1	(0.3)
Haemorrhoidal haemorrhage (痔出血)	0	(0.0)	0	(0.0)	1	(0.3)
Hyperchlorhydria (胃酸過多)	1	(0.3)	0	(0.0)	0	(0.0)
Impaired gastric emptying (胃排出不全)	1	(0.3)	0	(0.0)	0	(0.0)
Intestinal obstruction (腸閉塞)	0	(0.0)	0	(0.0)	1	(0.3)
Irritable bowel syndrome (過敏性腸症候群)	1	(0.3)	0	(0.0)	0	(0.0)
Mouth haemorrhage (口腔内出血)	1	(0.3)	0	(0.0)	0	(0.0)
Oesophageal stenosis (食道狭窄)	1	(0.3)	0	(0.0)	0	(0.0)
Pancreatitis acute (急性膵炎)	0	(0.0)	0	(0.0)	1	(0.3)
Subileus (亜イレウス)	1	(0.3)	0	(0.0)	0	(0.0)
Umbilical hernia (臍ヘルニア)	1	(0.3)	0	(0.0)	0	(0.0)
Hepatobiliary disorders (肝胆道系障害)	6	(1.9)	1	(1.0)	12	(3.7)
Hepatic steatosis (脂肪肝)	2	(0.6)	0	(0.0)	6	(1.9)
Cholelithiasis (胆石症)	3	(0.9)	0	(0.0)	5	(1.6)
Cholecystitis acute (急性胆嚢炎)	0	(0.0)	1	(1.0)	0	(0.0)
Cholecystitis (胆嚢炎)	2	(0.6)	0	(0.0)	2	(0.6)
Gallbladder polyp (胆嚢ポリープ)	0	(0.0)	0	(0.0)	1	(0.3)
Hepatic fibrosis (肝線維症)	0	(0.0)	0	(0.0)	1	(0.3)
Hepatitis (肝炎)	0	(0.0)	0	(0.0)	1	(0.3)
Skin and subcutaneous tissue disorders (皮膚および皮下組織障害)	29	(9.1)	11	(11.2)	27	(8.4)
Pruritus (そう痒症)	3	(0.9)	4	(4.1)	7	(2.2)
Rash (発疹)	0	(0.0)	1	(1.0)	6	(1.9)
Dermatitis (皮膚炎)	4	(1.3)	0	(0.0)	2	(0.6)
Alopecia (脱毛症)	2	(0.6)	1	(1.0)	0	(0.0)
Erythema (紅斑)	0	(0.0)	1	(1.0)	0	(0.0)
Granuloma annulare (環状肉芽腫)	0	(0.0)	1	(1.0)	0	(0.0)
Hyperhidrosis (多汗症)	3	(0.9)	1	(1.0)	1	(0.3)
Ingrowing nail (嵌入爪)	0	(0.0)	1	(1.0)	1	(0.3)
Rash pruritic (そう痒性皮膚疹)	1	(0.3)	1	(1.0)	0	(0.0)
Rosacea (酒さ)	0	(0.0)	1	(1.0)	0	(0.0)
Skin chapped (ひび・あかぎれ)	0	(0.0)	1	(1.0)	0	(0.0)
Skin ulcer (皮膚潰瘍)	2	(0.6)	1	(1.0)	2	(0.6)
Dry skin (皮膚乾燥)	2	(0.6)	0	(0.0)	0	(0.0)
Ecchymosis (斑状出血)	2	(0.6)	0	(0.0)	0	(0.0)
Eczema (湿疹)	2	(0.6)	0	(0.0)	2	(0.6)
Skin lesion (皮膚病変)	2	(0.6)	0	(0.0)	1	(0.3)
Actinic keratosis (日光性角化症)	1	(0.3)	0	(0.0)	0	(0.0)

	Placebo		Empa 10mg		Empa 25mg	
System organ class/ Preferred term	N	(%)	N	(%)	N	(%)
Cold sweat (冷汗)	1	(0.3)	0	(0.0)	1	(0.3)
Dermal cyst (皮膚嚢腫)	1	(0.3)	0	(0.0)	0	(0.0)
Diabetic foot (糖尿病性足病変)	0	(0.0)	0	(0.0)	1	(0.3)
Hyperkeratosis (過角化)	1	(0.3)	0	(0.0)	1	(0.3)
Intertrigo (間擦疹)	1	(0.3)	0	(0.0)	0	(0.0)
Lipodystrophy acquired (後天性リポジストロフィー)	0	(0.0)	0	(0.0)	1	(0.3)
Night sweats (寝汗)	0	(0.0)	0	(0.0)	1	(0.3)
Papule (丘疹)	1	(0.3)	0	(0.0)	0	(0.0)
Pruritus generalised (全身性そう痒症)	0	(0.0)	0	(0.0)	1	(0.3)
Psoriasis (乾癬)	1	(0.3)	0	(0.0)	0	(0.0)
Rash papular (丘疹性皮膚疹)	0	(0.0)	0	(0.0)	1	(0.3)
Seborrhoeic dermatitis (脂漏性皮膚炎)	1	(0.3)	0	(0.0)	0	(0.0)
Skin exfoliation (皮膚剥脱)	0	(0.0)	0	(0.0)	1	(0.3)
Skin hyperpigmentation (皮膚色素過剰)	1	(0.3)	0	(0.0)	0	(0.0)
Skin mass (皮膚腫瘍)	0	(0.0)	0	(0.0)	1	(0.3)
Stasis dermatitis (うっ滞性皮膚炎)	1	(0.3)	0	(0.0)	0	(0.0)
Urticaria (蕁麻疹)	0	(0.0)	0	(0.0)	1	(0.3)
Musculoskeletal and connective tissue disorders (筋骨格系および結合組織障害)	78	(24.5)	31	(31.6)	66	(20.6)
Back pain (背部痛)	20	(6.3)	8	(8.2)	19	(5.9)
Pain in extremity (四肢痛)	10	(3.1)	8	(8.2)	7	(2.2)
Arthralgia (関節痛)	21	(6.6)	7	(7.1)	13	(4.0)
Muscle spasms (筋痙攣)	11	(3.4)	4	(4.1)	2	(0.6)
Musculoskeletal pain (筋骨格痛)	10	(3.1)	2	(2.0)	9	(2.8)
Osteoarthritis (変形性関節症)	6	(1.9)	1	(1.0)	8	(2.5)
Musculoskeletal chest pain (筋骨格系胸痛)	0	(0.0)	2	(2.0)	2	(0.6)
Tendonitis (腱炎)	0	(0.0)	2	(2.0)	0	(0.0)
Myalgia (筋肉痛)	5	(1.6)	1	(1.0)	3	(0.9)
Bunion (バニオン)	0	(0.0)	1	(1.0)	0	(0.0)
Dupuytren's contracture (デュプイトラン拘縮)	0	(0.0)	1	(1.0)	0	(0.0)
Intervertebral disc protrusion (椎間板突出)	0	(0.0)	1	(1.0)	1	(0.3)
Jaw disorder (顎障害)	0	(0.0)	1	(1.0)	0	(0.0)
Muscle twitching (筋攣縮)	0	(0.0)	1	(1.0)	0	(0.0)
Neck pain (頸部痛)	2	(0.6)	1	(1.0)	1	(0.3)
Periarthritis (関節周囲炎)	0	(0.0)	1	(1.0)	1	(0.3)
Plantar fasciitis (足底筋膜炎)	2	(0.6)	1	(1.0)	2	(0.6)
Rotator cuff syndrome (肩回旋筋腱板症候群)	0	(0.0)	1	(1.0)	1	(0.3)
Spinal osteoarthritis (変形性脊椎症)	0	(0.0)	1	(1.0)	0	(0.0)
Trigger finger (弾発指)	3	(0.9)	1	(1.0)	1	(0.3)
Joint stiffness (関節硬直)	0	(0.0)	0	(0.0)	3	(0.9)
Arthritis (関節炎)	1	(0.3)	0	(0.0)	2	(0.6)
Bursitis (滑液包炎)	2	(0.6)	0	(0.0)	0	(0.0)

	Placebo		Empa 10mg		Empa 25mg	
System organ class/ Preferred term	N	(%)	N	(%)	N	(%)
Exostosis (外骨腫)	2	(0.6)	0	(0.0)	2	(0.6)
Fibromyalgia (線維筋痛)	0	(0.0)	0	(0.0)	2	(0.6)
Gouty arthritis (痛風性関節炎)	2	(0.6)	0	(0.0)	0	(0.0)
Groin pain (鼠径部痛)	2	(0.6)	0	(0.0)	0	(0.0)
Joint swelling (関節腫脹)	2	(0.6)	0	(0.0)	0	(0.0)
Ankylosing spondylitis (強直性脊椎炎)	0	(0.0)	0	(0.0)	1	(0.3)
Costochondritis (肋軟骨炎)	0	(0.0)	0	(0.0)	1	(0.3)
Lumbar spinal stenosis (腰部脊柱管狭窄症)	1	(0.3)	0	(0.0)	0	(0.0)
Muscle haemorrhage (筋肉内出血)	1	(0.3)	0	(0.0)	0	(0.0)
Musculoskeletal stiffness (筋骨格硬直)	0	(0.0)	0	(0.0)	1	(0.3)
Neuropathic arthropathy (神経障害性関節症)	1	(0.3)	0	(0.0)	0	(0.0)
Osteopenia (骨減少症)	1	(0.3)	0	(0.0)	1	(0.3)
Osteoporosis (骨粗鬆症)	1	(0.3)	0	(0.0)	0	(0.0)
Pain in jaw (顎痛)	0	(0.0)	0	(0.0)	1	(0.3)
Polyarthritis (多発性関節炎)	0	(0.0)	0	(0.0)	1	(0.3)
Synovial cyst (滑液嚢腫)	0	(0.0)	0	(0.0)	1	(0.3)
Tendon disorder (腱障害)	1	(0.3)	0	(0.0)	0	(0.0)
Renal and urinary disorders (腎および尿路障害)	39	(12.2)	16	(16.3)	43	(13.4)
Glycosuria (糖尿)	2	(0.6)	4	(4.1)	1	(0.3)
Polyuria (多尿)	0	(0.0)	4	(4.1)	3	(0.9)
Haematuria (血尿)	5	(1.6)	3	(3.1)	1	(0.3)
Pollakiuria (頻尿)	4	(1.3)	3	(3.1)	6	(1.9)
Dysuria (排尿困難)	4	(1.3)	0	(0.0)	7	(2.2)
Nephrolithiasis (腎結石症)	7	(2.2)	0	(0.0)	3	(0.9)
Nocturia (夜間頻尿)	2	(0.6)	1	(1.0)	5	(1.6)
Renal impairment (腎機能障害)	4	(1.3)	0	(0.0)	5	(1.6)
Proteinuria (蛋白尿)	0	(0.0)	1	(1.0)	0	(0.0)
Renal colic (腎仙痛)	1	(0.3)	1	(1.0)	0	(0.0)
Urinary incontinence (尿失禁)	0	(0.0)	1	(1.0)	0	(0.0)
Urinary retention (尿閉)	1	(0.3)	1	(1.0)	1	(0.3)
Renal cyst (腎嚢胞)	3	(0.9)	0	(0.0)	0	(0.0)
Renal failure (腎不全)	2	(0.6)	0	(0.0)	3	(0.9)
Renal failure acute (急性腎不全)	3	(0.9)	0	(0.0)	3	(0.9)
Azotaemia (高窒素血症)	0	(0.0)	0	(0.0)	2	(0.6)
Ketonuria (ケトン尿)	2	(0.6)	0	(0.0)	0	(0.0)
Micturition urgency (尿意切迫)	1	(0.3)	0	(0.0)	2	(0.6)
Bladder dilatation (膀胱拡大)	0	(0.0)	0	(0.0)	1	(0.3)
Bladder discomfort (膀胱不快感)	0	(0.0)	0	(0.0)	1	(0.3)
Bladder diverticulum (膀胱憩室)	0	(0.0)	0	(0.0)	1	(0.3)
Diabetic nephropathy (糖尿病性腎症)	1	(0.3)	0	(0.0)	0	(0.0)
Focal segmental glomerulosclerosis (巣状分節性糸球体硬化症)	0	(0.0)	0	(0.0)	1	(0.3)

	Placebo		Empa 10mg		Empa 25mg	
System organ class/ Preferred term	N	(%)	N	(%)	N	(%)
Hyperuricosuria (高尿酸尿症)	1	(0.3)	0	(0.0)	1	(0.3)
Kidney fibrosis (腎線維症)	1	(0.3)	0	(0.0)	0	(0.0)
Renal failure chronic (慢性腎不全)	1	(0.3)	0	(0.0)	1	(0.3)
Renal pain (腎臓痛)	0	(0.0)	0	(0.0)	1	(0.3)
Urinary hesitation (排尿躊躇)	1	(0.3)	0	(0.0)	0	(0.0)
Urinary tract disorder (尿路障害)	0	(0.0)	0	(0.0)	1	(0.3)
Reproductive system and breast disorders (生殖系および乳房障害)	13	(4.1)	7	(7.1)	15	(4.7)
Vulvovaginal pruritus (外陰陰そう痒症)	1	(0.3)	3	(3.1)	8	(2.5)
Benign prostatic hyperplasia (良性前立腺肥大症)	3	(0.9)	1	(1.0)	4	(1.2)
Balanitis (亀頭炎)	1	(0.3)	1	(1.0)	1	(0.3)
Menopausal symptoms (閉経期症状)	0	(0.0)	1	(1.0)	0	(0.0)
Postmenopausal haemorrhage (閉経後出血)	0	(0.0)	1	(1.0)	0	(0.0)
Vulvovaginal burning sensation (外陰陰灼熱感)	0	(0.0)	1	(1.0)	0	(0.0)
Prostatitis (前立腺炎)	2	(0.6)	0	(0.0)	0	(0.0)
Pruritus genital (陰部そう痒症)	2	(0.6)	0	(0.0)	1	(0.3)
Dysmenorrhoea (月経困難症)	1	(0.3)	0	(0.0)	0	(0.0)
Erectile dysfunction (勃起不全)	1	(0.3)	0	(0.0)	1	(0.3)
Genital ulceration (性器潰瘍形成)	1	(0.3)	0	(0.0)	0	(0.0)
Ovarian cyst (卵巣嚢胞)	1	(0.3)	0	(0.0)	0	(0.0)
Uterine mass (子宮腫瘍)	1	(0.3)	0	(0.0)	0	(0.0)
Congenital, familial and genetic disorders (先天性、家族性および遺伝性障害)	1	(0.3)	1	(1.0)	0	(0.0)
Phimosis (包茎)	0	(0.0)	1	(1.0)	0	(0.0)
Dermoid cyst (皮様嚢腫)	1	(0.3)	0	(0.0)	0	(0.0)
General disorders and administration site conditions (一般・全身障害および投与部位の状態)	48	(15.0)	15	(15.3)	34	(10.6)
Oedema peripheral (末梢性浮腫)	15	(4.7)	1	(1.0)	3	(0.9)
Thirst (口渇)	0	(0.0)	4	(4.1)	1	(0.3)
Pyrexia (発熱)	8	(2.5)	1	(1.0)	3	(0.9)
Asthenia (無力症)	2	(0.6)	2	(2.0)	5	(1.6)
Chest pain (胸痛)	5	(1.6)	2	(2.0)	4	(1.2)
Malaise (倦怠感)	1	(0.3)	2	(2.0)	1	(0.3)
Pain (疼痛)	3	(0.9)	1	(1.0)	4	(1.2)
Cyst (嚢胞)	0	(0.0)	1	(1.0)	0	(0.0)
Fatigue (疲労)	3	(0.9)	1	(1.0)	2	(0.6)
Feeling abnormal (異常感)	0	(0.0)	1	(1.0)	0	(0.0)
Feeling hot (熱感)	1	(0.3)	1	(1.0)	0	(0.0)
Inflammation (炎症)	2	(0.6)	1	(1.0)	2	(0.6)
Influenza like illness (インフルエンザ様疾患)	3	(0.9)	1	(1.0)	0	(0.0)
Mass (腫瘍)	0	(0.0)	1	(1.0)	0	(0.0)
Chest discomfort (胸部不快感)	2	(0.6)	0	(0.0)	3	(0.9)
Hunger (空腹)	0	(0.0)	0	(0.0)	3	(0.9)

	Placebo		Empa 10mg		Empa 25mg	
System organ class/ Preferred term	N	(%)	N	(%)	N	(%)
Oedema (浮腫)	3	(0.9)	0	(0.0)	3	(0.9)
Adverse drug reaction (医薬品副作用)	0	(0.0)	0	(0.0)	1	(0.3)
Chills (悪寒)	1	(0.3)	0	(0.0)	0	(0.0)
Device malfunction (医療機器機能不良)	1	(0.3)	0	(0.0)	0	(0.0)
Discomfort (不快感)	0	(0.0)	0	(0.0)	1	(0.3)
Facial pain (顔面痛)	0	(0.0)	0	(0.0)	1	(0.3)
Feeling cold (冷感)	0	(0.0)	0	(0.0)	1	(0.3)
Hernia (ヘルニア)	1	(0.3)	0	(0.0)	0	(0.0)
Injection site irritation (注射部位刺激感)	1	(0.3)	0	(0.0)	0	(0.0)
Local swelling (局所腫脹)	0	(0.0)	0	(0.0)	1	(0.3)
Sensation of pressure (圧迫感)	1	(0.3)	0	(0.0)	0	(0.0)
Sluggishness (不活発)	1	(0.3)	0	(0.0)	0	(0.0)
Sudden cardiac death (心突然死)	1	(0.3)	0	(0.0)	0	(0.0)
Swelling (腫脹)	1	(0.3)	0	(0.0)	1	(0.3)
Investigations (臨床検査)	42	(13.2)	14	(14.3)	28	(8.7)
Blood glucose decreased (血中ブドウ糖減少)	0	(0.0)	3	(3.1)	0	(0.0)
Blood pressure increased (血圧上昇)	4	(1.3)	2	(2.0)	7	(2.2)
Lipase increased (リパーゼ増加)	4	(1.3)	2	(2.0)	2	(0.6)
Blood creatinine increased (血中クレアチニン増加)	3	(0.9)	1	(1.0)	6	(1.9)
Blood creatine phosphokinase increased (血中クレアチンホスホキナーゼ増加)	5	(1.6)	0	(0.0)	2	(0.6)
Blood glucose increased (血中ブドウ糖増加)	5	(1.6)	0	(0.0)	0	(0.0)
Blood uric acid increased (血中尿酸増加)	2	(0.6)	1	(1.0)	0	(0.0)
Cardiac murmur (心雑音)	2	(0.6)	1	(1.0)	0	(0.0)
Colonoscopy (結腸内視鏡検査)	1	(0.3)	1	(1.0)	0	(0.0)
Heart rate increased (心拍数増加)	0	(0.0)	1	(1.0)	0	(0.0)
Lipids increased (脂質増加)	0	(0.0)	1	(1.0)	1	(0.3)
Thyroid function test abnormal (甲状腺機能検査異常)	0	(0.0)	1	(1.0)	0	(0.0)
Weight decreased (体重減少)	1	(0.3)	1	(1.0)	2	(0.6)
Blood alkaline phosphatase increased (血中アルカリホスファターゼ増加)	2	(0.6)	0	(0.0)	0	(0.0)
Blood calcium increased (血中カルシウム増加)	1	(0.3)	0	(0.0)	2	(0.6)
Blood triglycerides increased (血中トリグリセリド増加)	2	(0.6)	0	(0.0)	0	(0.0)
Blood urea increased (血中尿素増加)	1	(0.3)	0	(0.0)	2	(0.6)
Glycosylated haemoglobin increased (グリコヘモグロビン増加)	2	(0.6)	0	(0.0)	1	(0.3)
Liver function test abnormal (肝機能検査異常)	2	(0.6)	0	(0.0)	0	(0.0)
Vitamin D decreased (ビタミンD減少)	2	(0.6)	0	(0.0)	0	(0.0)
Aortic bruit (大動脈雑音)	1	(0.3)	0	(0.0)	0	(0.0)
Bacterial test positive (細菌検査陽性)	1	(0.3)	0	(0.0)	0	(0.0)
Blood insulin decreased (血中インスリン減少)	1	(0.3)	0	(0.0)	0	(0.0)
Blood potassium increased (血中カリウム増加)	1	(0.3)	0	(0.0)	0	(0.0)

	Placebo		Empa 10mg		Empa 25mg	
System organ class/ Preferred term	N	(%)	N	(%)	N	(%)
Blood pressure abnormal (血圧異常)	1	(0.3)	0	(0.0)	0	(0.0)
Blood pressure diastolic increased (拡張期血圧上昇)	1	(0.3)	0	(0.0)	0	(0.0)
Blood pressure systolic increased (収縮期血圧上昇)	1	(0.3)	0	(0.0)	1	(0.3)
Culture urine positive (尿培養陽性)	1	(0.3)	0	(0.0)	0	(0.0)
Electrocardiogram ST segment depression (心電図ST部分下降)	0	(0.0)	0	(0.0)	1	(0.3)
Electrocardiogram T wave inversion (心電図T波逆転)	0	(0.0)	0	(0.0)	1	(0.3)
Electrocardiogram abnormal (心電図異常)	0	(0.0)	0	(0.0)	1	(0.3)
Epidermal growth factor receptor decreased (上皮増殖因子受容体減少)	1	(0.3)	0	(0.0)	0	(0.0)
Glomerular filtration rate increased (糸球体濾過率増加)	0	(0.0)	0	(0.0)	1	(0.3)
Glucose urine (尿中ブドウ糖)	1	(0.3)	0	(0.0)	0	(0.0)
Haemoglobin decreased (ヘモグロビン減少)	0	(0.0)	0	(0.0)	1	(0.3)
Lipids abnormal (脂質異常)	0	(0.0)	0	(0.0)	1	(0.3)
Prostatic specific antigen increased (前立腺特異性抗原増加)	1	(0.3)	0	(0.0)	0	(0.0)
Right ventricular systolic pressure increased (右室収縮期圧上昇)	1	(0.3)	0	(0.0)	0	(0.0)
Urine cytology abnormal (尿細胞診異常)	0	(0.0)	0	(0.0)	1	(0.3)
Urine output increased (尿量増加)	1	(0.3)	0	(0.0)	0	(0.0)
Weight increased (体重増加)	1	(0.3)	0	(0.0)	1	(0.3)
White blood cell count increased (白血球数増加)	1	(0.3)	0	(0.0)	0	(0.0)
Injury, poisoning and procedural complications (傷害、中毒および処置合併症)	31	(9.7)	15	(15.3)	29	(9.0)
Fall (転倒)	6	(1.9)	3	(3.1)	5	(1.6)
Contusion (挫傷)	3	(0.9)	2	(2.0)	3	(0.9)
Epicondylitis (上顎炎)	1	(0.3)	2	(2.0)	0	(0.0)
Skeletal injury (骨格損傷)	0	(0.0)	2	(2.0)	1	(0.3)
Ligament sprain (靱帯捻挫)	4	(1.3)	0	(0.0)	2	(0.6)
Arthropod sting (節足動物刺傷)	0	(0.0)	1	(1.0)	0	(0.0)
Excoriation (擦過傷)	1	(0.3)	1	(1.0)	2	(0.6)
Face injury (顔面損傷)	0	(0.0)	1	(1.0)	0	(0.0)
Laceration (裂傷)	1	(0.3)	1	(1.0)	2	(0.6)
Limb injury (四肢損傷)	2	(0.6)	1	(1.0)	0	(0.0)
Lower limb fracture (下肢骨折)	0	(0.0)	1	(1.0)	0	(0.0)
Muscle strain (肉離れ)	0	(0.0)	1	(1.0)	0	(0.0)
Rib fracture (肋骨骨折)	3	(0.9)	1	(1.0)	1	(0.3)
Tendon injury (腱損傷)	1	(0.3)	1	(1.0)	0	(0.0)
Wound (創傷)	0	(0.0)	1	(1.0)	2	(0.6)
Joint injury (関節損傷)	2	(0.6)	0	(0.0)	3	(0.9)
Muscle injury (筋損傷)	0	(0.0)	0	(0.0)	3	(0.9)
Procedural pain (処置による疼痛)	2	(0.6)	0	(0.0)	1	(0.3)
Radius fracture (橈骨骨折)	2	(0.6)	0	(0.0)	0	(0.0)

	Placebo		Empa 10mg		Empa 25mg	
System organ class/ Preferred term	N	(%)	N	(%)	N	(%)
Soft tissue injury (軟部組織損傷)	0	(0.0)	0	(0.0)	2	(0.6)
Wrist fracture (手首関節骨折)	2	(0.6)	0	(0.0)	0	(0.0)
Accident (事故)	0	(0.0)	0	(0.0)	1	(0.3)
Ankle fracture (足関節部骨折)	1	(0.3)	0	(0.0)	0	(0.0)
Clavicle fracture (鎖骨骨折)	1	(0.3)	0	(0.0)	0	(0.0)
Eye injury (眼外傷)	0	(0.0)	0	(0.0)	1	(0.3)
Foot fracture (足骨折)	1	(0.3)	0	(0.0)	0	(0.0)
Head injury (頭部損傷)	1	(0.3)	0	(0.0)	1	(0.3)
Humerus fracture (上腕骨骨折)	1	(0.3)	0	(0.0)	0	(0.0)
Neck injury (頸部損傷)	0	(0.0)	0	(0.0)	1	(0.3)
Pelvic fracture (骨盤骨折)	0	(0.0)	0	(0.0)	1	(0.3)
Pneumothorax traumatic (外傷性気胸)	1	(0.3)	0	(0.0)	0	(0.0)
Post procedural haematoma (処置後血腫)	1	(0.3)	0	(0.0)	0	(0.0)
Post-traumatic neck syndrome (外傷後頸部症候群)	1	(0.3)	0	(0.0)	1	(0.3)
Scratch (引っかき傷)	1	(0.3)	0	(0.0)	0	(0.0)
Spinal compression fracture (脊椎圧迫骨折)	1	(0.3)	0	(0.0)	0	(0.0)
Spinal fracture (脊椎骨折)	1	(0.3)	0	(0.0)	0	(0.0)
Subdural haematoma (硬膜下血腫)	1	(0.3)	0	(0.0)	0	(0.0)
Thermal burn (熱傷)	1	(0.3)	0	(0.0)	0	(0.0)
Tibia fracture (脛骨骨折)	0	(0.0)	0	(0.0)	1	(0.3)
Tooth fracture (歯牙破折)	1	(0.3)	0	(0.0)	0	(0.0)
Traumatic lung injury (外傷性肺損傷)	1	(0.3)	0	(0.0)	0	(0.0)
Surgical and medical procedures (外科および内科処置)	6	(1.9)	1	(1.0)	7	(2.2)
Exploratory operation (試験的手術)	0	(0.0)	1	(1.0)	0	(0.0)
Tooth extraction (抜歯)	3	(0.9)	0	(0.0)	3	(0.9)
Cardiac pacemaker replacement (心臓ペースメーカー置換)	0	(0.0)	0	(0.0)	1	(0.3)
Cystopexy (膀胱固定)	0	(0.0)	0	(0.0)	1	(0.3)
Ear tube insertion (耳チューブ挿入)	1	(0.3)	0	(0.0)	0	(0.0)
Intraocular lens implant (眼内レンズ挿入)	1	(0.3)	0	(0.0)	1	(0.3)
Joint manipulation (関節徒手整復)	1	(0.3)	0	(0.0)	0	(0.0)
Phlebectomy (静脈切除術)	0	(0.0)	0	(0.0)	1	(0.3)

Percentages are calculated using total number of patients per treatment as the denominator.

Containing data from study 1245_0036

MedDRA version used for reporting: [REDACTED]

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Table 4.1.2 Frequency [N (%)] of patients with related adverse events by treatment, primary system organ class and preferred term - treated set actual

	Placebo		Empa 10mg		Empa 25mg	
System organ class/ Preferred term	N	(%)	N	(%)	N	(%)
Number of patients	319	(100.0)	100	(100.0)	321	(100.0)
Total with related adverse events	87	(27.3)	37	(37.0)	101	(31.5)
Infections and infestations (感染症および寄生虫症)	22	(6.9)	13	(13.0)	23	(7.2)
Urinary tract infection (尿路感染)	18	(5.6)	5	(5.0)	15	(4.7)
Balanitis candida (カンジダ性亀頭炎)	0	(0.0)	4	(4.0)	0	(0.0)
Furuncle (せつ)	0	(0.0)	1	(1.0)	0	(0.0)
Localised infection (限局性感染)	0	(0.0)	1	(1.0)	0	(0.0)
Prostate infection (前立腺感染)	0	(0.0)	1	(1.0)	0	(0.0)
Vaginitis bacterial (細菌性膣炎)	0	(0.0)	1	(1.0)	0	(0.0)
Vulvovaginal mycotic infection (外陰膣真菌感染)	0	(0.0)	1	(1.0)	2	(0.6)
Cystitis (膀胱炎)	1	(0.3)	0	(0.0)	2	(0.6)
Asymptomatic bacteriuria (無症候性細菌尿)	1	(0.3)	0	(0.0)	0	(0.0)
Cervicitis (子宮頸管炎)	1	(0.3)	0	(0.0)	0	(0.0)
Fungal infection (真菌感染)	0	(0.0)	0	(0.0)	1	(0.3)
Fungal skin infection (皮膚真菌感染)	1	(0.3)	0	(0.0)	0	(0.0)
Genital infection (性器感染)	0	(0.0)	0	(0.0)	1	(0.3)
Pyelonephritis chronic (慢性腎盂腎炎)	1	(0.3)	0	(0.0)	0	(0.0)
Urinary tract infection enterococcal (腸球菌性尿路感染)	0	(0.0)	0	(0.0)	1	(0.3)
Vaginal infection (膣感染)	0	(0.0)	0	(0.0)	1	(0.3)
Vulvitis (外陰部炎)	0	(0.0)	0	(0.0)	1	(0.3)
Vulvovaginal candidiasis (外陰部膣カンジダ症)	0	(0.0)	0	(0.0)	1	(0.3)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (良性、悪性および詳細不明の新生物 (嚢胞およびポリープを含む))	1	(0.3)	0	(0.0)	0	(0.0)
Haemangioma (血管腫)	1	(0.3)	0	(0.0)	0	(0.0)
Blood and lymphatic system disorders (血液およびリンパ系障害)	1	(0.3)	0	(0.0)	1	(0.3)
Eosinophilia (好酸球増加症)	1	(0.3)	0	(0.0)	1	(0.3)
Metabolism and nutrition disorders (代謝および栄養障害)	51	(16.0)	16	(16.0)	55	(17.1)
Hypoglycaemia (低血糖症)	46	(14.4)	16	(16.0)	51	(15.9)
Hyperglycaemia (高血糖)	5	(1.6)	0	(0.0)	1	(0.3)
Food craving (食物渴望)	0	(0.0)	0	(0.0)	2	(0.6)
Dehydration (脱水)	0	(0.0)	0	(0.0)	1	(0.3)
Diabetes mellitus inadequate control (コントロール不良の糖尿病)	1	(0.3)	0	(0.0)	0	(0.0)
Gout (痛風)	0	(0.0)	0	(0.0)	1	(0.3)
Hyperkalaemia (高カリウム血症)	1	(0.3)	0	(0.0)	0	(0.0)
Hyperlipasaemia (高リパーゼ血症)	1	(0.3)	0	(0.0)	0	(0.0)
Hypovolaemia (血液量減少症)	1	(0.3)	0	(0.0)	0	(0.0)

	Placebo		Empa 10mg		Empa 25mg	
System organ class/ Preferred term	N	(%)	N	(%)	N	(%)
Polydipsia (多飲症)	0	(0.0)	0	(0.0)	1	(0.3)
Psychiatric disorders (精神障害)	1	(0.3)	0	(0.0)	1	(0.3)
Depression (うつ病)	1	(0.3)	0	(0.0)	0	(0.0)
Restlessness (落ち着きのなさ)	0	(0.0)	0	(0.0)	1	(0.3)
Nervous system disorders (神経系障害)	3	(0.9)	5	(5.0)	5	(1.6)
Tremor (振戦)	0	(0.0)	2	(2.0)	0	(0.0)
Balance disorder (平衡障害)	0	(0.0)	1	(1.0)	0	(0.0)
Dizziness (浮動性めまい)	0	(0.0)	1	(1.0)	1	(0.3)
Hypoaesthesia (感覚鈍麻)	1	(0.3)	1	(1.0)	0	(0.0)
Paraesthesia (錯感覚)	1	(0.3)	1	(1.0)	0	(0.0)
Headache (頭痛)	1	(0.3)	0	(0.0)	2	(0.6)
Lethargy (嗜眠)	0	(0.0)	0	(0.0)	2	(0.6)
Eye disorders (眼障害)	1	(0.3)	1	(1.0)	0	(0.0)
Dry eye (眼乾燥)	0	(0.0)	1	(1.0)	0	(0.0)
Lacrimation increased (流涙増加)	1	(0.3)	0	(0.0)	0	(0.0)
Cardiac disorders (心臓障害)	0	(0.0)	0	(0.0)	2	(0.6)
Long QT syndrome (QT延長症候群)	0	(0.0)	0	(0.0)	1	(0.3)
Sinus bradycardia (洞性徐脈)	0	(0.0)	0	(0.0)	1	(0.3)
Vascular disorders (血管障害)	2	(0.6)	0	(0.0)	1	(0.3)
Hypertension (高血圧)	1	(0.3)	0	(0.0)	0	(0.0)
Hypotension (低血圧)	1	(0.3)	0	(0.0)	1	(0.3)
Respiratory, thoracic and mediastinal disorders (呼吸器、胸郭および縦隔障害)	2	(0.6)	0	(0.0)	0	(0.0)
Cough (咳嗽)	1	(0.3)	0	(0.0)	0	(0.0)
Pulmonary oedema (肺水腫)	1	(0.3)	0	(0.0)	0	(0.0)
Gastrointestinal disorders (胃腸障害)	5	(1.6)	3	(3.0)	11	(3.4)
Nausea (悪心)	0	(0.0)	0	(0.0)	4	(1.2)
Abdominal distension (腹部膨満)	0	(0.0)	1	(1.0)	2	(0.6)
Abdominal pain upper (上腹部痛)	0	(0.0)	1	(1.0)	1	(0.3)
Diarrhoea (下痢)	0	(0.0)	1	(1.0)	1	(0.3)
Dyspepsia (消化不良)	0	(0.0)	1	(1.0)	0	(0.0)
Constipation (便秘)	2	(0.6)	0	(0.0)	2	(0.6)
Dry mouth (口内乾燥)	0	(0.0)	0	(0.0)	2	(0.6)
Vomiting (嘔吐)	1	(0.3)	0	(0.0)	2	(0.6)
Frequent bowel movements (排便回数増加)	0	(0.0)	0	(0.0)	1	(0.3)
Gastrointestinal disorder (胃腸障害)	0	(0.0)	0	(0.0)	1	(0.3)
Gastroesophageal reflux disease (胃食道逆流性疾病)	1	(0.3)	0	(0.0)	1	(0.3)
Oral pain (口腔内痛)	1	(0.3)	0	(0.0)	0	(0.0)
Hepatobiliary disorders (肝胆道系障害)	1	(0.3)	0	(0.0)	0	(0.0)
Cholelithiasis (胆石症)	1	(0.3)	0	(0.0)	0	(0.0)

	Placebo		Empa 10mg		Empa 25mg	
System organ class/ Preferred term	N	(%)	N	(%)	N	(%)
Hepatic steatosis (脂肪肝)	1	(0.3)	0	(0.0)	0	(0.0)
Skin and subcutaneous tissue disorders (皮膚および皮下組織障害)	1	(0.3)	2	(2.0)	4	(1.2)
Rash (発疹)	0	(0.0)	1	(1.0)	2	(0.6)
Skin chapped (ひび・あかぎれ)	0	(0.0)	1	(1.0)	0	(0.0)
Cold sweat (冷汗)	0	(0.0)	0	(0.0)	1	(0.3)
Pruritus (そう痒症)	1	(0.3)	0	(0.0)	1	(0.3)
Musculoskeletal and connective tissue disorders (筋骨格系および結合組織障害)	2	(0.6)	0	(0.0)	4	(1.2)
Back pain (背部痛)	1	(0.3)	0	(0.0)	2	(0.6)
Arthralgia (関節痛)	0	(0.0)	0	(0.0)	1	(0.3)
Myalgia (筋肉痛)	0	(0.0)	0	(0.0)	1	(0.3)
Pain in extremity (四肢痛)	1	(0.3)	0	(0.0)	0	(0.0)
Renal and urinary disorders (腎および尿路障害)	9	(2.8)	8	(8.0)	21	(6.5)
Glycosuria (糖尿)	1	(0.3)	4	(4.0)	1	(0.3)
Pollakiuria (頻尿)	2	(0.6)	2	(2.0)	6	(1.9)
Polyuria (多尿)	0	(0.0)	2	(2.0)	3	(0.9)
Nocturia (夜間頻尿)	0	(0.0)	1	(1.0)	4	(1.2)
Dysuria (排尿困難)	1	(0.3)	0	(0.0)	2	(0.6)
Renal failure (腎不全)	0	(0.0)	0	(0.0)	2	(0.6)
Renal failure acute (急性腎不全)	2	(0.6)	0	(0.0)	1	(0.3)
Renal impairment (腎機能障害)	1	(0.3)	0	(0.0)	2	(0.6)
Haematuria (血尿)	1	(0.3)	0	(0.0)	0	(0.0)
Micturition urgency (尿意切迫)	1	(0.3)	0	(0.0)	1	(0.3)
Reproductive system and breast disorders (生殖系および乳房障害)	5	(1.6)	3	(3.0)	6	(1.9)
Vulvovaginal pruritus (外陰膺そう痒症)	1	(0.3)	2	(2.0)	5	(1.6)
Balanitis (亀頭炎)	1	(0.3)	1	(1.0)	0	(0.0)
Ovarian cyst (卵巣嚢胞)	1	(0.3)	0	(0.0)	0	(0.0)
Prostatitis (前立腺炎)	1	(0.3)	0	(0.0)	0	(0.0)
Pruritus genital (陰部そう痒症)	1	(0.3)	0	(0.0)	1	(0.3)
Uterine mass (子宮腫瘍)	1	(0.3)	0	(0.0)	0	(0.0)
General disorders and administration site conditions (一般・全身障害および投与部位の状態)	0	(0.0)	3	(3.0)	2	(0.6)
Asthenia (無力症)	0	(0.0)	1	(1.0)	0	(0.0)
Feeling abnormal (異常感)	0	(0.0)	1	(1.0)	0	(0.0)
Malaise (倦怠感)	0	(0.0)	1	(1.0)	0	(0.0)
Thirst (口渇)	0	(0.0)	1	(1.0)	0	(0.0)
Hunger (空腹)	0	(0.0)	0	(0.0)	2	(0.6)
Discomfort (不快感)	0	(0.0)	0	(0.0)	1	(0.3)
Investigations (臨床検査)	4	(1.3)	2	(2.0)	3	(0.9)
Lipase increased (リパーゼ増加)	1	(0.3)	1	(1.0)	0	(0.0)

	Placebo		Empa 10mg		Empa 25mg	
System organ class/ Preferred term	N	(%)	N	(%)	N	(%)
Weight decreased (体重減少)	0	(0.0)	1	(1.0)	1	(0.3)
Blood creatinine increased (血中クレアチニン増加)	0	(0.0)	0	(0.0)	2	(0.6)
Blood creatine phosphokinase increased (血中クレアチンホスホキナーゼ増加)	1	(0.3)	0	(0.0)	0	(0.0)
Blood triglycerides increased (血中トリグリセリド増加)	1	(0.3)	0	(0.0)	0	(0.0)
Blood urea increased (血中尿素増加)	0	(0.0)	0	(0.0)	1	(0.3)
Liver function test abnormal (肝機能検査異常)	1	(0.3)	0	(0.0)	0	(0.0)
Urine output increased (尿量増加)	1	(0.3)	0	(0.0)	0	(0.0)

Percentages are calculated using total number of patients per treatment as the denominator.

Containing data from study 1245_0036

MedDRA version used for reporting: XXXXXXXXXX

m276\aelxae14012.sas 13AUG2013

付録 2 死亡および重篤な有害事象の一覧表

Listing 1.8.1 Adverse event episodes by treatment and subject – serious event only – treated set

treatment : BI 10773 TF2

Patient	Race	Age/ gender	Actual TRT at onset of AE	system organ class	prefered term	start hour	stop hour	Duration	Intensity	Drug rel.	Action taken	Therapy required	Outcome	other significant	serious
1245_0051_20	White	48/M	BI 10773 TF2	Nervous system disorders (神経系障害)	Migraine with aura (前兆を伴う片頭痛)	121	249	128	sev	No	None	Yes	Rcver	No	Req hsp

Containing data from study 1245_0051
MedDRA version used for reporting: XXXXXXXXXX

Listing 1.8.2 Adverse event episodes by treatment and subject – serious event only – treated set

treatment : Mox 400 mg

Patient	Race	Age/ gender	Actual TRT at onset of AE	system organ class	preferred term	start hour	stop hour	Duration	Intensity	Drug rel.	Action taken	Therapy required	Outcome	other significant	serious
1245_0016_16	White	22/F	Mox 400 mg	Injury, poisoning and procedural complications (傷害, 中毒および処置合併 症)	Road traffic accident (交通事故)	111	111	0 sev	No	No	Disc	No	Fatal	No	Fatal

Containing data from study 1245_0016

MedDRA version used for reporting: [REDACTED]

Listing 1.2.1 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Empa 1mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_001 5_010538	Asian	66/F	Post trt	Nervous system disorders (	Transient ischaemic attack (	61	61	1	Mod	No	None	Yes	Rcver	No	Req hsp
				神経系障害)	一過性脳虚血発作										

Comment: THE EVENT SEEMS TO HAVE BEEN CAUSED BY CEREBROVASCULAR ARTERIOSCLEROTIC CHANGES,

@ Related to start of treatment, 7 = censored, # = Lost to follow up, & = Follow up sufficient
Episodes with a negative start day are not assigned to the analysing treatment.

MedDRA version used for reporting: ■■■■

Listing 7.1.1 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Empa 5mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_000 9_008912	White	77/F	Empa 5mg	Cardiac disorders (	Myocardial infarction (	5	23	19	Mild	No	Disc	Yes	Rcver	No	Req hsp
				心臟障害)	心筋梗塞)										
1245_000 9_009883	Asian	68/M	Post trt	Cardiac disorders (	Acute myocardial infarction (	43	56	14	Sev	No	Disc	Yes	Rcver	No	Req hsp
				心臟障害)	急性心筋梗塞)										

@ Related to start of treatment, 7 = censored, # = Lost to follow up, & = Follow up sufficient
 Episodes with a negative start day are not assigned to the analysing treatment.

MedDRA version used for reporting: [REDACTED]

Listing 7.1.1 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Empa 25mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_000 9_009648	Asian	61/M	Empa 25mg	Gastrointestinal disorders (胃腸障害)	Intestinal functional disorder (腸管機能障害)	8	15	8	Mod	No	Cont	Yes	Rcver	No	Req hsp

@ Related to start of treatment, 7 = censored, # = Lost to follow up, & = Follow up sufficient
Episodes with a negative start day are not assigned to the analysing treatment.

MedDRA version used for reporting: [REDACTED]

Listing 7.1.1 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Metformin

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_000 9_008336	White	48/M	Metformin	Injury, poisoning and procedural complications (	Hand fracture (	56	947	397	Sev	No	Disc	Yes	Nrec&	No	Req hsp
				傷害、中毒および 処置合併症)	手骨折)										
Comment: TELEPHONE CALL WITH PATIENT															
	White		Metformin	Injury, poisoning and procedural complications (	Ligament rupture	56	947	397	Sev	No	Disc	Yes	Nrec&	No	Req hsp
				傷害、中毒および 処置合併症)	(靱帯断裂)										
Comment: TELEPHONE CALL WITH PATIENT															
	White		Metformin	Injury, poisoning and procedural complications (	Road traffic accident (	56	56	1	Sev	No	Disc	Yes	Rcver	No	Req hsp
				傷害、中毒および 処置合併症)	交通事故)										
Comment: TELEPHONE CALL WITH PATIENT															
	White		Metformin	Injury, poisoning and procedural complications (	Pelvic fracture	56	947	397	Sev	No	Disc	Yes	Nrec&	No	Req hsp
				傷害、中毒および 処置合併症)	(骨盤骨折)										
Comment: TELEPHONE CALL WITH PATIENT															
1245_000 9_009464	Asian	43/M	Metformin	Cardiac disorders (	Prinzmetal angina (	27	30	4	Sev	No	Disc	Yes	Rcver	No	Req hsp
				心臓障害) 心症)	プリンツメタル狭										

@ Related to start of treatment, 7 = censored, # = Lost to follow up, & = Follow up sufficient
 Episodes with a negative start day are not assigned to the analysing treatment.
 MedDRA version used for reporting: [REDACTED]

Listing 7.1.1 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Metformin

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_000 9_009488	Asian	65/F	Metformin	Injury, poisoning and procedural complications (傷害、中毒および 処置合併症)	Meniscus lesion (半月板障害)	50	817	327	Mod	No	Cont	Yes	Nrec&	No	Req hsp

@ Related to start of treatment, 7 = censored, # = Lost to follow up, & = Follow up sufficient
 Episodes with a negative start day are not assigned to the analysing treatment.
 MedDRA version used for reporting: [REDACTED]

Listing 7.1.2 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Placebo

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_001 0_002367	White	77/F	Placebo	Infections and infestations (感染症および寄生 虫症)	Pneumonia (肺炎)	12	25	14	Mod	No	Rein	Yes	Rcver	No	Req hsp
1245_001 0_003861	White	56/M	Placebo	Cardiac disorders (心臓障害)	Myocardial infarction (心筋梗塞)	73	86	14	Mod	No	Cont	Yes	Rcver	No	Req hsp
	White		Placebo	Cardiac disorders (心臓障害)	Myocardial ischaemia (心筋虚血)	73	86	14	Mod	No	Cont	Yes	Rcver	No	Req hsp

@ Related to start of treatment, 7 = censored, # = Lost to follow up, & = Follow up sufficient

Episodes with a negative start day are not assigned to the analysing treatment.

MedDRA version used for reporting: [REDACTED]

Listing 7.1.2 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Empa 5mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_001 0_006063	White	68/M	Empa 5mg	Cardiac disorders (	Myocardial infarction (	81	85	5	Sev	No	Cont	Yes	Rcver	No	Imm thrt/Req hsp
1245_001 0_006122	White	62/F	Empa 5mg	Endocrine disorders (	Thyroid cyst (	62	917	307	Mod	No	Cont	Yes	Nrec&	No	Req hsp
Comment: EXTIRPATION OF THE CYST OF THYROID GLAND WITH RETROSTERNAL LOCATION															
1245_001 0_007494	White	62/F	Empa 5mg	Neoplasms benign, malignant and unspecified (incl cysts and polyps) (	Chronic lymphocytic leukaemia (	35	1047	707	Mod	No	Cont	Yes	Nrec&	No	Other
Comment: INCREASED LEVEL OF WBC(17.44 GI/L),LYMPHOCITE COUNT(12.44 GI/L)WAS DETECTED DURING SCREENING ON 19MAR. AS A RESULT OF FRUTHER INVESTIGATION DIAGNOSIS OF CHRONIC LYMPHOLEUKOSIS CONFIRMED ON 09JUN.															

@ Related to start of treatment, 7 = censored, # = Lost to follow up, & = Follow up sufficient
 Episodes with a negative start day are not assigned to the analysing treatment.
 MedDRA version used for reporting:

Listing 7.1.2 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Empa 10mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_001 0_004705	White	64/M	Empa 10mg	Cardiac disorders (	Atrial fibrillation (	31	35	5	Mod	No	Disc	Yes	Rcver	No	Req hsp
Comment: DISCONTINUED STUDY DRUG DUE TO MIC															
	White		Empa 10mg	General disorders and administration site conditions (	Chest discomfort (胸部不快感)	31	35	5	Mod	No	Disc	Yes	Rcver	No	Prol hsp
Comment: PATIENT DISCONTINUED STUDY MEDICATION AT THE HOSPITAL. BUT NOT DUE TO CHEST DISCOMFORT.															

@ Related to start of treatment, 7 = censored, # = Lost to follow up, & = Follow up sufficient
 Episodes with a negative start day are not assigned to the analysing treatment.
 MedDRA version used for reporting: [REDACTED]

Listing 7.1.2 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Empa 25mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_001 0_005651	White	48/F	Empa 25mg	Hepatobiliary disorders (	Cholecystitis acute (	29	37	9	Mod	No	Rein	Yes	Rcver	No	Other/Req hsp
Comment: ON 04 BECAMES SERIOUS BECAUSE INVESTIGATOR CRITERIA															
1245_001 0_005811	White	70/M	Empa 25mg	Cardiac disorders (	Coronary artery disease (	9	53	45	Mod	No	Cont	Yes	Rcver	No	Req hsp

@ Related to start of treatment, 7 = censored, # = Lost to follow up, & = Follow up sufficient

Episodes with a negative start day are not assigned to the analysing treatment.

MedDRA version used for reporting: [REDACTED]

Listing 7.1.2 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Empa 50mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_001 0_001186	White	57/M	Empa 50mg	Injury, poisoning and procedural complications (傷害、中毒および 処置合併症)	Arthropod bite (節足動物咬傷)	3	4	2	Mod	No	Cont	Yes	Rcver	No	Req hsp
	White		Empa 50mg	General disorders and administration site conditions (全身障害および投 与局所様態)	Chest pain (胸痛)	3	4	2	Mod	No	Cont	No	Rcver	No	Req hsp
	White		Empa 50mg	Skin and subcutaneous tissue disorders (皮膚および皮下組 織障害)	Urticaria (蕁麻疹)	3	4	2	Mod	No	Cont	Yes	Rcver	No	Req hsp
1245_001 0_003215	White	56/F	Empa 50mg	Infections and infestations (感染症および寄生 虫症)	Pyelonephritis (腎盂腎炎)	29	35	7	Mod	No	Disc	Yes	Rcver	No	Req hsp
1245_001 0_007483	White	50/M	Empa 50mg	Infections and infestations (感染症および寄生 虫症)	Pneumonia (肺炎)	28	46	19	Mod	No	Disc	Yes	Rcver	No	Req hsp

Comment: STUDY DRUG WAS DISCONTINUED ON 22-MAY-2011.

@ Related to start of treatment, 7 = censored, # = Lost to follow up, & = Follow up sufficient
Episodes with a negative start day are not assigned to the analysing treatment.
MedDRA version used for reporting: 20.0

Listing 6.2.1 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Empa 25mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_005 2_219007	Asian	68/M	Empa 25mg	Neoplasms benign, malignant and unspecified (incl cysts and polyps) (	Colon cancer (	220	220	1	Mild	No	None	Yes	Rcver	No	Other
				良性、悪性および 詳細不明の新生物 (嚢胞およびポリ ーブを含む))	結腸癌)										
Comment: THE EVENT WAS ASSESSED AS UNRELATED TO THE STUDY DRUG CONSIDERING ITS MECHANISM OF ACTION.															
1245_005 2_220017	Asian	54/M	Empa 25mg	Neoplasms benign, malignant and unspecified (incl cysts and polyps) (	Gastric cancer (	184	397	214	Mod	No	Disc	Yes	Rcver	No	Req hsp/Other
				良性、悪性および 詳細不明の新生物 (嚢胞およびポリ ーブを含む))	胃癌)										
Comment: THE EVENT WAS ASSESSED AS UNRELATED TO THE STUDY DRUG CONSIDERING ITS MECHANISM OF ACTION.															
	Asian		Post trt	Infections and infestations (	Pulmonary tuberculosis (	330	475	146	Sev	No	None	Yes	Nrec&	No	Req hsp
				感染症および寄生 虫症)	肺結核)										
Comment: THE EVENT WAS ASSESSED AS BEING UNRELATED TO THE STUDY DRUG CONSIDERING ITS MECHANISM OF ACTION AND THE EVENT WAS CAUSED BY INFECTION WITH THE TUBERCLE BACILLUS.															
1245_005 2_222002	Asian	78/F	Empa 25mg	Cardiac disorders (	Atrial fibrillation (	305	372	68	Mod	No	None	Yes	Nrec&	No	Req hsp
				心臓障害)	心房細動)										
Comment: IMPROVEMENT IN THE EVENT DESPITE CONTINUED ADMINISTRATION OF BI10773.															

@ Related to start of treatment, 7 = censored, # = Lost to follow up, & = Follow up sufficient
Episodes with a negative start day are not assigned to the analysing treatment.
MedDRA version used for reporting: [REDACTED]

Listing 6.2.1 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Empa 25mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_005 2_222002	Asian	78/F	Empa 25mg	Cardiac disorders (	Cardiac failure congestive (	305	372	7	Mod	No	None	Yes	Nrec&	No	Req hsp
Comment: IMPROVEMENT IN THE EVENT DESPITE CONTINUED ADMINISTRATION OF BI10773.															
1245_005 2_223001	Asian	53/M	Empa 25mg	Infections and infestations (	Febrile infection (	347	355	9	Mod	No	None	Yes	Rcver	No	Req hsp
Comment: PYREXIA WAS CAUSED BY INFECTION AND IS NOT RELATED TO THE STUDY DRUG OR THE CONCOMITANT DRUGS.ON 12 JUNE, THE PATIENT EXPERIENCE MALAISE WHICH APPEARS TO BE DUE TO PYREXIA.															
1245_005 2_226020	Asian	65/F	Empa 25mg	Eye disorders (	Cataract (	116	329	214	Mod	Yes	None	Yes	Rcver	No	Req hsp
Comment: THE PATIENT HAS HAD CATARACT SINCE BEFORE HER PARTICIPATION IN THE CLINICAL STUDY AND THE PREEXISTING CONDITION MAY HAVE WORSENED DURING THE COURSE OF DIABETES MELLITUS.															
1245_005 2_231016	Asian	77/F	Empa 25mg	Blood and lymphatic system disorders (	Anaemia (貧血)	68	183	116	Sev	No	Disc	Yes	Rcver	No	Req hsp
Comment: TO TAKE PRAZAXA															
	Asian		Empa 25mg	Gastrointestinal disorders (	Gastrointestinal haemorrhage (	68	127	60	Sev	No	Disc	Yes	Rcver	No	Req hsp
Comment: TO TAKE PRAZAXA															
	Asian		Post trt	Vascular disorders (	Embolism arterial (	79	80	2	Sev	No	None	Yes	Rcver	No	Req hsp
Comment: TO DISCONTINUE PRAZAXA															

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 Episodes with a negative start day are not assigned to the analysing treatment.
 MedDRA version used for reporting: [REDACTED]

Listing 6.2.1 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Empa 25mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_005 2_234001	Asian	71/M	Empa 25mg	Gastrointestinal disorders (胃腸障害)	Inguinal hernia (鼠径ヘルニア)	57	136	80	Mild	No	None	Yes	Rcver	No	Req hsp
Comment: A CAUSAL RELATIONSHIP CAN BE EXCLUDED CONSIDERING THE ACTION MECHANISM OF THE STUDY DRUG.															
1245_005 2_234006	Asian	75/M	Empa 25mg	Neoplasms benign, malignant and unspecified (incl cysts and polyps) (良性、悪性および詳細不明の新生物 (嚢胞およびポリープを含む))	Gastric cancer (胃癌)	15	997	857	Sev	No	Disc	Yes	Nrec&	No	Other
Comment: GASTRIC CANCER WAS FOUND ONLY A MONTH AFTER INITIATION OF THE STUDY DRUG. CONSIDERING LONG LATENCY PERIOD OF CANCER DEVELOPMENT, A CAUSAL RELATIONSHIP BETWEEN THE EVENT AND THE STUDY DRUG CAN BE RULED															
1245_005 2_235009	Asian	67/M	Empa 25mg	Gastrointestinal disorders (胃腸障害)	Haemorrhoids (痔核)	110	137	28	Mod	No	None	Yes	Rcver	No	Req hsp
Comment: ADVANCE OF COMPLICATION. THE HEMORROIDAL RADICAL SURGERY WAS EXECUTED.															
	Asian		Empa 25mg	Neoplasms benign, malignant and unspecified (incl cysts and polyps) (良性、悪性および詳細不明の新生物 (嚢胞およびポリープを含む))	Prostate cancer (前立腺癌)	177	2707	947	Sev	No	Disc	Yes	Nrec&	No	Other
Comment: THE PRODUCTION OF CANCER IS THOUGHT TO BE SEVERAL YEARS AGO IF IT THINKS FROM THE STATE OF A PRESENT PROSTATE.															

@ Related to start of treatment, 7 = censored, # = Lost to follow up, & = Follow up sufficient
Episodes with a negative start day are not assigned to the analysing treatment.

MedDRA version used for reporting: [REDACTED]

Listing 6.2.1 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Empa 25mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_005 2_236002	Asian	70/M	Empa 25mg	Infections and infestations (	Cellulitis (	44	85	42	Sev	No	None	Yes	Rcver	No	Req hsp
				感染症および寄生 虫症)	蜂巣炎)										
Comment: ON RECONSIDERING THE MATTER,I THOUGHT THAT THE EVENT WAS DUE TO BACTERIAL INFECTION FROM PYORRHOEA THAT HAD BEEN LEFT UNTREATED AND HAS NO CAUSAL RELATIONSHIP WITH THE STUDY DRUG.															
	Asian		Post trt	Neoplasms benign, malignant and unspecified (incl cysts and 明) polyps) (	Oropharyngeal cancer stage unspecified (	65	3167	2527	Mild	No	None	Yes	Nrec&	No	Other
				良性、悪性および 詳細不明の新生物 (嚢胞およびポリ ーブを含む))	中咽頭癌、病期不 明)										
Comment: OROPHARYNDEAL CANCER WAS CONSIDERED TO BE CAUSED BY SMOKING AND DRINKING OF MENY YEARS.SINCE OROPHARYNGEAL CANCER CANNNOT DEVELOP WITHIN A SHORT PERIOD,IT PROBABLY PREEXISTED THE STUDY.															
1245_005 2_241008	Asian	66/M	Empa 25mg	Infections and infestations (	Gangrene (壊疽)	132	1657	347	Sev	No	None	Yes	Seq	No	Disabl/Req hsp
				感染症および寄生 虫症)											
Comment: IT SEEMS THAT THERE IS NO CAUSAL RELATIONSHIP BETWEEN THIS EVENT AND INVESTIGATIONAL PRODUCT,															
	Asian		Empa 25mg	Infections and infestations (	Osteomyelitis (	132	1657	347	Sev	No	None	Yes	Seq	No	Disabl/Req hsp
				感染症および寄生 虫症)	骨髓炎)										
Comment: IT SEEMS THAT THERE IS NO CAUSAL RELATIONSHIP BETWEEN THIS EVENT AND INVESTIGATIONAL PRODUCT,															

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Episodes with a negative start day are not assigned to the analysing treatment.
MedDRA version used for reporting: [REDACTED]

Listing 6.2.1 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Empa 25mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_005 2_242002	Asian	67/F	Empa 25mg	Neoplasms benign, malignant and unspecified (incl cysts and polyps) (	Uterine cancer (	331	495	165	Mod	No	Disc	Yes	Rcver	No	Other
				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))	子宮癌)										
Comment: UTERINE CANCER.THE EVENT IS UNRELATED TO THE STUDY DRUG BECAUSE THE RATIONAL ASSOCIATION IS NOT ACCEPTED															
1245_005 2_244008	Asian	72/M	Post trt	Neoplasms benign, malignant and unspecified (incl cysts and polyps) (	Lung neoplasm malignant (	374	403	30	Sev	No	None	Yes	Fatal	No	Fatal/Req hsp
				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))	肺の悪性新生物)										
Comment: GIVEN THAT THE PATIENT HAD BEEN SMOKING UNTIL MORE THAN TEN YEARS AGO AND HAS CURRENTLY BEEN WORKING IN AN ENVIRONMENT EXPOSED TO MUCH SECOND-HAND SMOKE, AN ASSOCIATION BETWEEN SMOKING AND THE EVENT															
1245_005 2_247001	Asian	67/M	Empa 25mg	Neoplasms benign, malignant and unspecified (incl cysts and polyps) (	Meningioma (	281	325	45	Mild	No	Disc	Yes	Rcver	No	Req hsp
				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))	髄膜腫)										
Comment: THE TUMOR DETECTED IS CONSIDERED TO HAVE DEVELOPED BEFORE THE INITIATION OF THE CLINICAL STUDY GIVEN ITS SIZE															

@ Related to start of treatment, 7 = censored, # = Lost to follow up, & = Follow up sufficient

Episodes with a negative start day are not assigned to the analysing treatment.

MedDRA version used for reporting: ■■■■

Listing 6.2.1 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Empa 25mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_005 2_250010	Asian	67/M	Empa 25mg	Eye disorders (眼障害)	Cataract (白内障)	131	283	153	Mod	No	None	Yes	Rcver	No	Req hsp
Comment: THE EVENT IS CAUSED BY A PREEXISTING COMPLICATION.DUE TO AGING.															
1245_005 2_251003	Asian	66/M	Empa 25mg	Injury, poisoning and procedural complications (傷害、中毒および処置合併症)	Pelvic fracture (骨盤骨折)	317	366	50	Sev	No	Disc	Yes	Rcver	No	Req hsp
Comment: IT IS A SUDDEN EVENT, AND IN VIEW OF ITS ONSET AFTER LUNCH, OCCURRENCE OF HYPOGLYCAEMIA IS UNLIKELY.THE EVENT THEREFORE WAS ASSESSED AS UNRELATED TO THE STUDY DRUG.IT WAS TRAUMATIC FRACTURE.															
1245_005 2_252020	Asian	49/M	Empa 25mg	Nervous system disorders (神経系障害)	VIIth nerve paralysis (第7脳神経麻痺)	176	231	56	Mod	No	Disc	Yes	Rcver	No	Req hsp
Comment: BECAUSE THERE IS NO A REASONABLE CAUSAL RELATIONSHIP BETWEEN TRIAL DRUG AND SAE,CAUSAL RELATIONSHIP IS DENIED.															
1245_005 2_255014	Asian	73/M	Empa 25mg	Injury, poisoning and procedural complications (傷害、中毒および処置合併症)	Ankle fracture (足関節部骨折)	358	381	24	Mod	No	Disc	Yes	Rcver	No	Req hsp
Comment: PHYSICAL CAUSE DEVELOPED THIS EVENT.NO RELATIONSHIP IT WAS TRAUMATIC.															
1245_005 2_255033	Asian	64/M	Empa 25mg	Infections and infestations (感染症および寄生虫)	Pneumonia (肺炎)	110	119	10	Sev	No	Disc	Yes	Rcver	No	Req hsp
Comment: SEASONAL IN FECTION NO RELATIONSHIP.															

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 Episodes with a negative start day are not assigned to the analysing treatment.
 MedDRA version used for reporting: █

Listing 6.2.1 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Empa 25mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_005 2_255033	Asian	64/M	Empa 25mg	Neoplasms benign, malignant and unspecified (incl cysts and polyps) (不明) 良性、悪性および 詳細不明の新生物 (嚢胞およびポリ ーブを含む))	Small cell lung cancer stage unspecified (小細胞肺癌、病期	111	3707	2607	Sev	No	Disc	Yes	Nrec&	No	Other
Comment: LONG TERM CIGARRETLE SMOKING SHOULD BE CONSIDERED TO THE CAUSE OF THIS EVENT. NO RELATIONSHIP.															
1245_005 2_256007	Asian	65/M	Empa 25mg	Neoplasms benign, malignant and unspecified (incl cysts and polyps) (不明) 良性、悪性および 詳細不明の新生物 (嚢胞およびポリ ーブを含む))	Prostate cancer (前立腺癌)	352	484	133	Mod	No	None	Yes	Rcver	No	Req hsp
Comment: PROSTATE BIOPSY RESULTS, THEPATIENT WAS DIAGONOSED WITH MODERATELY DIFFERENTIATED ADENOCARCINOMA.DEGREE OF DIFFERETIATION THAN IT IS OF THE TYPE AND MODERATELY DIFFERENTIATED,															
1245_005 2_257003	Asian	81/F	Run-in	Hepatobiliary disorders (肝胆道系障害)	Cholecystitis acute (急性胆嚢炎)	-1	53	54	Sev	No	Disc	Yes	Rcver	No	Req hsp
Comment: SINCE THE ADVERSE EVENT IS REVEALED AT THE PLACEBO TERM OF AN INVESTIGATIONAL NEW DRUG, IT IS JUDGED THAT THERE IS NO CAUSAL RELATIONSHIP WITH AN INVESTIGATIONAL NEW DRUG.															
	Asian		Run-in	Gastrointestinal disorders (胃腸障害)	Gastritis haemorrhagic (出血性胃炎)	-1	53	54	Sev	No	Disc	Yes	Rcver	No	Req hsp
Comment: SINCE THE ADVERSE EVENT IS REVEALED AT THE PLACEBO TERM OF AN INVESTIGATIONAL NEW DRUG, IT IS JUDGED THAT THERE IS NO CAUSAL RELATIONSHIP WITH AN INVESTIGATIONAL NEW DRUG.															

@ Related to start of treatment, 7 = censored, # = Lost to follow up, & = Follow up sufficient

Episodes with a negative start day are not assigned to the analysing treatment.

MedDRA version used for reporting: [REDACTED]

Listing 6.2.1 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Empa 25mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_005 2_257006	Asian	80/M	Empa 25mg	Neoplasms benign, malignant and unspecified (incl cysts and polyps) (	Prostate cancer (前立腺癌)	99	4137	3157	Sev	No	None	Yes	Nrec&	No	Other
良性、悪性および 詳細不明の新生物 (嚢胞およびポリ ーブを含む)) Comment: BECAUSE THIS PATIENT IS AN OLD MAN AND SERUM PSA LEVEL HAVE BEEN HIGH BEFORE THE CLINICAL-TRIAL BEGAN , I THINK THERE IS NO CAUSAL RELATIONSHIP BETWEEN THE MACROHEMATURIA AND BI-10773.															
1245_005 2_264002	Asian	73/M	Empa 25mg	Cardiac disorders (	Coronary artery stenosis (	18	5657	5487	Mod	No	None	Yes	Nrec&	No	Req hsp
心臓障害) 冠動脈狭窄) Comment: THE EVENT IS CONSIDERED TO HAVE BEEN CAUSED BY RISK FACTORS SUCH AS A TEN YEAR HISTORY OF DIABETES AND OBESITY.THE EVENT THUS IS NOT RELATED TO THE STUDY DRUG.															
1245_005 2_268010	Asian	34/M	Empa 25mg	Psychiatric disorders (	Schizophrenia (	158	3727	2157	Mild	No	None	Yes	Nrec&	No	Req hsp
精神障害) Comment: DUE TO DEATH OF FATHER															
1245_005 2_270004	Asian	77/F	Empa 25mg	Infections and infestations (	Cellulitis (	234	294	61	Mod	No	None	Yes	Rcver	No	Req hsp
感染症および寄生 虫症) Comment: DUE TO ACCIDENTAL EVENT															
1245_005 2_272002	Asian	66/F	Empa 25mg	Gastrointestinal disorders (	Melaena (	285	313	29	Mod	No	None	Yes	Rcver	No	Req hsp
胃腸障害) メレナ) Comment: INTESTINAL IRRITATION DUE TO INTESTINAL EXTENSION SEEMS TO HAVE RESULTED IN DIVERTICULAR VASCULAR DAMAGE AND CAUSED HAEMORRHAGE FROM COLONIC DIVERTICULUM, WHICH WAS ASSESSED AS THE CAUSE FOR MELAENA.															

@ Related to start of treatment, 7 = censored, # = Lost to follow up, & = Follow up sufficient
 Episodes with a negative start day are not assigned to the analysing treatment.
 MedDRA version used for reporting: [REDACTED]

Listing 6.2.1 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Empa 25mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_005 2_281001	Asian	78/M	Empa 25mg	Gastrointestinal disorders (胃腸障害)	Duodenitis (十二指腸炎)	6	14	9	Mod	No	None	Yes	Rcver	No	Req hsp
Comment: DUE TO VIRUS INFECTION.															
1245_005 2_289002	Asian	71/F	Empa 25mg	Injury, poisoning and procedural complications (傷害、中毒および処置合併症)	Heat illness (熱中症)	131	133	3	Mod	No	None	Yes	Rcver	No	Req hsp
Comment: THE EVENT WAS CAUSED BY LONG HOURS OF FARM WORK UNDER THE BLAZING SUN.THE PATIENT RECOVERED IMMEDIATELY AFTER RECEIVING TREATMENT AT THIS HOSPITAL.OCCURRENCE OF HYPOGLYCAEMIA IS UNLIKELY BECAUSE OF															

@ Related to start of treatment, 7 = censored, # = Lost to follow up, & = Follow up sufficient
 Episodes with a negative start day are not assigned to the analysing treatment.
 MedDRA version used for reporting: [REDACTED]

Listing 6.2.1 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Metformin

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_005 2_217006	Asian	51/M	Metformin	Neoplasms benign, malignant and unspecified (incl cysts and polyps) (	Colon cancer (	290	300	11	Mild	No	None	Yes	Rcver	No	Req hsp
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)) Comment: ALTHOUGH THERE IS NO REASONABLE CAUSAL RELATIONSHIP BETWEEN THE EVENT AND THE STUDY DRUG, THEIR RELATIONSHIP CANNOT BE COMPLETELY RULED OUT BECAUSE OF UNDETERMINED ONSET TIME OF THE EVENT AND BECAUSE															
1245_005 2_266005	Asian	77/M	Metformin	Neoplasms benign, malignant and unspecified (incl cysts and polyps) (	Gastric cancer (	142	180	39	Sev	No	Disc	Yes	Rcver	No	Other
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)) Comment: THE EVENT WAS SERIOUS BECAUSE IT WAS CANCER. IT IS PLANED HOSPITAL ADMISSION FOR TREATMENT. IT IS IMPOSSIBLE FOR PATIENT TO GO TO A CLINICAL TRIAL SITE. (DISCONTINUED)															
1245_005 2_270003	Asian	73/M	Metformin	Neoplasms benign, malignant and unspecified (incl cysts and polyps) (	Lung neoplasm malignant (	337	467	131	Mild	No	None	No	Nrec&	No	Req hsp/Other
肺の悪性新生物 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)) Comment: THIS PATIENT HAS A LONG HISTORY OF SMOKING AND SPUTUM SYMPTOMS WAS SEEN OCCASIONALLY BEFORE THE START OF THE TRIAL. DETERMINE A CAUSAL RELATIONSHIP WITH THE STUDY DRUG IS NOT FOR THE EVENT.															

@ Related to start of treatment, 7 = censored, # = Lost to follow up, & = Follow up sufficient
 Episodes with a negative start day are not assigned to the analysing treatment.
 MedDRA version used for reporting:

Listing 7.1.3 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Placebo

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_001 9_010206	White	62/F	Placebo	Injury, poisoning and procedural complications (傷害、中毒および 処置合併症)	Traumatic fracture (外傷性骨折)	81	1657	857	Sev	No	Disc	Yes	Nrec&	No	Req hsp
Comment: PATIENT SLIPPED ON A SOAPY WET FLOOR IN A RESTAURANT. DISCLOCATED AND FRACTURED ANKLE - SURGICAL REPAIR NEEDED. TRAUMATIC INJURY. FOLLOW UP WITH PATIENT NOV 21, 2011.															
1245_001 9_010677	White	70/F	Placebo	Infections and infestations (感染症および寄生 虫症)	Pyelonephritis acute (急性腎盂腎炎)	118	130	13	Sev	Yes	Disc	Yes	Rcver	No	Req hsp
Comment: PERSISTING UTI (PROBABLY DUE TO PARTIAL TREATMENT) RESULTED TO SEVERE AC. PYEL. PATIENT WAS HOSPITALIZED AND RECEIVED IV ANTIBIOTICS. FULLY RECOVERED FROM A.P. DURING HOSPITALISATION AND WAS RELEASED.															
1245_001 9_010833	Asian	34/F	Placebo	Gastrointestinal disorders (胃腸障害)	Anal fissure (裂肛)	121	174	54	Mild	No	None	Yes	Rcver	No	Req hsp
1245_001 9_011031	Asian	45/M	Placebo	Injury, poisoning and procedural complications (傷害、中毒および 処置合併症)	Humerus fracture (上腕骨骨折)	8	259	252	Sev	No	None	Yes	Rcver	No	Other
Comment: ALLEGED HISTORY OF RTA ON 10-3-11 FOLLOWING WHICH HE HAD PAIN AND SWELLING IN L SHOULDER JOINT , DIAGNOSIS WAS GIVEN AS TRAUMATIC FRACTURE OF GREATER TUBEROSITY OF LEFT HUMERUS AND PROXIMAL PHALANX.															
	Asian		Placebo	Injury, poisoning and procedural complications (傷害、中毒および 処置合併症)	Hand fracture (手骨折)	8	259	252	Sev	No	None	Yes	Rcver	No	Other
Comment: ALLEGED HISTORY OF RTA ON 10-3-11 FOLLOWING WHICH HE HAD PAIN AND SWELLING IN L SHOULDER JOINT , DIAGNOSIS WAS GIVEN AS TRAUMATIC FRACTURE OF GREATER TUBEROSITY OF LEFT HUMERUS AND PROXIMAL PHALANX.															

@ Related to start of treatment, 7 = censored, * = partial date or missing date/time imputed, # = Lost to follow up, & = Follow up sufficient
Episodes with a negative start day are not assigned to the analysing treatment.

MedDRA version used for reporting: 20.0

Listing 7.1.3 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Placebo

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_001 9_011031	Asian	45/M	Placebo	Injury, poisoning and procedural complications (	Road traffic accident (	8	259	252	Sev	No	None	Yes	Rcver	No	Other
傷害、中毒および 処置合併症) Comment: ALLEGED HISTORY OF RTA ON 09-3- FOLLOWING WHICH HE HAD PAIN AND SWELLING IN LEFT SHOULDER JOINT , HIS DIAGNOSIS WAS GIVEN AS FRACTURE OF GREATER TUBEROSITY OF LEFT HUMERUS AND PROXIMAL PHALANX.															
1245_001 9_011081	Asian	55/F	Placebo	Skin and subcutaneous tissue disorders (	Skin ulcer (	161	183	23	Mod	No	Disc	Yes	Fatal	No	Fatal
皮膚および皮下組 織障害) Comment: SUBJECT IS DEAD															
	Asian		Placebo	Cardiac disorders (	Myocardial ischaemia (	170	183	14	Sev	Yes	None	Yes	Fatal	No	Fatal
心臓障害) Comment: SUBJECT IS DEAD															
	Asian		Placebo	Investigations (	Haemoglobin decreased (	170	183	14	Mild	No	None	No	Fatal	No	Fatal
臨床検査) ヘモグロビン減少) Comment: SUBJECT IS DEAD															
1245_001 9_011255	Asian	51/F	Placebo	Hepatobiliary disorders (	Cholecystitis acute (	47	51	5	Sev	No	None	Yes	Rcver	No	Req hsp
肝胆道系障害) 急性胆嚢炎)															
1245_001 9_011296	Asian	55/F	Placebo	Gastrointestinal disorders (	Constipation (	3	195	193	Sev	Yes	None	Yes	Rcver	No	Req hsp
胃腸障害) 便秘) Comment: SUBJECT WAS READMITTED AT A HIGHER CENTER ON 07FEB20 FOR DIAGNOSTIC WORK-UP ONLY (COLONOSCOPY)															

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 Episodes with a negative start day are not assigned to the analysing treatment.

MedDRA version used for reporting:

Listing 7.1.3 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Empa 10mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_001 9_010070	White	64/M	Empa 10mg	Infections and infestations (	Urosepsis (	153	160	8	Sev	Yes	Disc	Yes	Rcver	No	Req hsp
感染症および寄生 虫症) Comment: SYMPTOMATIC UROSEPSIS WITH HIGH FEVERS ELEVATED LACTATE AND HAEMODYNAMIC LIABILITY, CULTURES WERE NEGATIVE. GIVEN IV FLUIDS AND ANTIBIOTICS AT ADMISSION.IP WAS DISCONTINUED.															
1245_001 9_010079	White	60/M	Empa 10mg	Musculoskeletal and connective tissue disorders (	Arthralgia (	117	121	5	Mild	No	None	Yes	Rcver	No	Req hsp
筋骨格系および結 合組織障害) White Empa 10mg Musculoskeletal and connective tissue disorders (筋骨格系および結 合組織障害) Joint swelling (関節腫脹) 117 121 5 Mild No None Yes Rcver No Req hsp															
1245_001 9_010139	Asian	65/F	Empa 10mg	Eye disorders (	Diabetic retinopathy (	68	68	1	Sev	No	None	Yes	Rcver	No	Req hsp
眼障害) Comment: THERAPY FOR EVENT WAS LEFT VITRECTOMY 糖尿病網膜症) 1245_001 Asian 45/F Empa 10mg Infections and infestations (Amoebic colitis 感染症および寄生 アメーバ性大腸炎 虫症) 1245_001 Asian 50/M Empa 10mg Hepatobiliary disorders (Cholecystitis (胆嚢炎) 肝胆道系障害)															

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 Episodes with a negative start day are not assigned to the analysing treatment.

MedDRA version used for reporting: [REDACTED]

Listing 7.1.3 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Empa 10mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_001 9_011539	White	56/M	Empa 10mg	Infections and infestations (	Cellulitis (	147	2067	607	Sev	No	None	Yes	Nrec&	No	Req hsp
				感染症および寄生 虫症)	蜂巣炎)										
1245_001 9_011851	White	72/M	Empa 10mg	Musculoskeletal and connective tissue disorders	Musculoskeletal chest pain (	161	162	2	Mod	No	None	No	Rcver	No	Req hsp
				(	筋骨格系胸痛)										
				筋骨格系および結 合組織障害)											

Comment: SUBJECT EXPERIENCE CHEST PAIN AND WENT TO THE EMERGENCY ROOM. SUBJECT WAS HELD OVER NIGHT FOR OBSERVATION AND RELEASED THE NEXT DAY.PER HOSPITAL RECORD DISCHARGE DIAGNOSIS IS MUSCULOSKETAL CHEST PAIN

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Episodes with a negative start day are not assigned to the analysing treatment.

MedDRA version used for reporting: [REDACTED]

Listing 7.1.3 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Empa 25mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_001 9_010813	Asian	40/M	Empa 25mg	Infections and infestations (	Dengue fever (	35			Sev	No	Disc	Yes	Unk	No	Req hsp
				感染症および寄生 虫症)	デング熱)										
	Asian		Empa 25mg	Infections and infestations (	Septic shock (	35			Sev	No	Disc	Yes	Unk	No	Req hsp
				感染症および寄生 虫症)	敗血症性ショック										
	Asian		Post trt	Cardiac disorders (	Atrial fibrillation (	39			Sev	No	None	Yes	Unk	No	Prol hsp
				心臓障害)	心房細動)										
	Asian		Post trt	Cardiac disorders (	Atrial flutter (	39			Sev	No	None	Yes	Unk	No	Prol hsp
				心臓障害)	心房粗動)										
	Asian		Post trt	Cardiac disorders (	Cardio- respiratory arrest (	40	40	1	Sev	No	None	Yes	Fatal	No	Fatal
				心臓障害)	心肺停止)										
1245_001 9_010820	Asian	48/F	Empa 25mg	Cardiac disorders (	Myocardial ischaemia (	3	12	10	Mild	No	Disc	Yes	Rcver	No	Req hsp
				心臓障害)	心筋虚血)										
	Asian		Empa 25mg	Vascular disorders (	Haematoma (	12	20	9	Mild	No	None	Yes	Seq	No	Prol hsp
				血管障害)	血腫)										
	Asian		Empa 25mg	Vascular disorders (	Haematoma (	27	99	73	Mild	No	None	Yes	Rcver	No	Req hsp
				血管障害)	血腫)										

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Episodes with a negative start day are not assigned to the analysing treatment.

MedDRA version used for reporting: [REDACTED]

Listing 7.1.3 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Empa 25mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_001 9_010820	Asian	48/F	Empa 25mg	Infections and infestations (感染症および寄生 虫症)	Pseudomonas infection (シュードモナス感 染)	27	99	73	Mild	No	None	Yes	Rcver	No	Req hsp
	Asian		Post trt	Infections and infestations (感染症および寄生 虫症)	Cellulitis (蜂巣炎)	38	53	16	Mod	No	None	Yes	Rcver	No	Req hsp
1245_001 9_010941	Asian	58/F	Empa 25mg	Nervous system disorders (神経系障害)	Brain stem infarction (脳幹梗塞)	27	99	73	Sev	No	None	Yes	Rcver	No	Req hsp
Comment: THE SAE EVENT ACUTE RIGHT HEMIPARESIS AND INFARCT IN THE LFT HALF OF PONS IS ONE AND THE SAME.THEY ARE NOT 2 SEPARATE EVENTS AND HENCE WE CANNOT GIVE 2 SEPARATE STOP DATES.															
1245_001 9_011116	Asian	64/F	Empa 25mg	Neoplasms benign, malignant and unspecified (incl cysts and polyps) (良性、悪性および 詳細不明の新生物 (嚢胞およびポリープを含む))	Breast cancer (乳癌)	59	207†	149†	Sev	No	None	No	Nrec&	No	Other
Comment: FOR THIS AE PATIENT WOULD REQUIRE HOSPITALISATION FOR SURGERY FOLLOWED BY CHEMOTHEROPY.THE PATIENT WILL BE FOLLOWED UP IN THE EXTENSION TRIAL (1245.31).															
1245_001 9_012054	White	74/M	Empa 25mg	Gastrointestinal disorders (胃腸障害)	Oesophageal rupture (食道破裂)	66*	208	143*	Sev	No	Disc	Yes	Fatal	No	Fatal/Imm thrt/Req hsp/Prol hsp

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Episodes with a negative start day are not assigned to the analysing treatment.

MedDRA version used for reporting: █

Listing 7.1.3 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Empa 25mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_001 9_012357	White	77/M	Empa 25mg	Investigations (臨床検査)	Haemoglobin decreased (ヘモグロビン減少)	163	165	3	Mod	No	None	Yes	Rcver	No	Req hsp

Comment: SUBJECT WAS HOSPITALIZED FOR LOW HAEMOGLOBIN.

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Episodes with a negative start day are not assigned to the analysing treatment.

MedDRA version used for reporting: [REDACTED]

Listing 2.2.1 Adverse event episodes by treatment and patient - serious event only- treated set or open label set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Placebo

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_002 0_020021	White	71/M	Placebo	Congenital, familial and genetic disorders () 先天性、家族性お よび遺伝性障害)	Gilbert's syndrome () ジルベール症候群	169	1697	17	Mod	No	None	No	Nrec#	No	Req hsp
1245_002 0_020401	White	63/F	Placebo	Hepatobiliary disorders () 肝胆道系障害)	Cholecystitis acute () 急性胆嚢炎)	21	48	28	Sev	No	Disc	Yes	Rcver	No	Req hsp
1245_002 0_020721	White	60/M	Placebo	Neoplasms benign, malignant and unspecified (incl cysts and polyps) () 良性、悪性および 詳細不明の新生物 (嚢胞およびポリ ーブを含む))	Colon cancer () 結腸癌)	16	49	34	Mod	No	None	Yes	Rcver	No	Req hsp
Comment: HISTOPATHOLOGY SHOWED CA BOWEL AT SPLENIC FLEXURE FOLLOWING A COLONOSCOPY															
1245_002 0_022143	White	80/F	Placebo	Cardiac disorders () 心臓障害)	Myocardial infarction () 心筋梗塞)	93	93	1	Sev	No	Disc	No	Fatal	No	Fatal
1245_002 0_023425	White	61/F	Placebo	Metabolism and nutrition disorders () 代謝および栄養障 害)	Hyperglycaemia () 高血糖)	45	48	4	Mild	No	None	Yes	Rcver	No	Req hsp

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Episodes with a negative start day are not assigned to the analysing treatment.
MedDRA version used for reporting: [REDACTED]

Listing 2.2.1 Adverse event episodes by treatment and patient - serious event only- treated set or open label set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Empa 10mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_002 0_020009	White	58/F	Empa 10mg	Injury, poisoning and procedural complications (傷害、中毒および 処置合併症)	Animal bite (動物咬傷)	123	128	6	Mod	No	None	Yes	Rcver	No	Req hsp
1245_002 0_020064	White	61/M	Empa 10mg	Nervous system disorders (神経系障害)	Cerebrovascular accident (脳血管発作)	165	171	7	Sev	Yes	None	No	Seq	No	Req hsp
1245_002 0_020263	White	66/F	Empa 10mg	Injury, poisoning and procedural complications (傷害、中毒および 処置合併症)	Tendon rupture (腱断裂)	50	59	10	Sev	No	None	Yes	Seq	No	Req hsp
Comment: PAIN IN THE SHOULDER, DIAGNOSIS WITH MRI															
1245_002 0_021081	Asian	45/F	Empa 10mg	Neoplasms benign, malignant and unspecified (incl cysts and polyps) (良性、悪性および 詳細不明の新生物 (嚢胞およびポリ ーブを含む))	Breast cancer female (女性乳癌)	121	1827	627	Mod	No	None	Yes	Nrec&	No	Req hsp/Other
Comment: FOLLOW-UP SUFFICIENT IN 08/AUG/2014. THERE IS HIGH POSSIBILITY THAT BREAST CANCER HAVE DEVELOPED BEFORE THE INVESTIGATIONAL PRODUCT ADMINISTERED, CONSIDERING THE TIME COURSE. BECAUSE THE MAIN TUMOR WAS															

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Episodes with a negative start day are not assigned to the analysing treatment.

MedDRA version used for reporting: 20.0

Listing 2.2.1 Adverse event episodes by treatment and patient - serious event only- treated set or open label set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Empa 10mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_002 0_021376	Asian	74/M	Empa 10mg	Injury, poisoning and procedural complications (傷害、中毒および 処置合併症)	Injury (損傷)	14	93	80	Mod	No	None	Yes	Rcver	No	Req hsp
Comment: THE SUBJECT WAS ADMITTED TO THE SEIAI HOSPITAL BY AMBULANCE DUE TO TRAFFIC ACCIDENT ON HIS WAY HOME ON 22/NOV/2014. THERE ARE NO DETAILED INFORMATION ABOUT THE SITE AND SEVERITY OF TRAUMA,															
	Asian		Empa 10mg	Eye disorders (眼障害)	Cataract (白内障)	79	82	4	Mild	No	None	Yes	Rcver	No	Req hsp
Comment: THE SUBJECT WAS HOSPITALISED FOR CATARACT OPERATION ON 26-JAN-2015. HE NEEDS TO HAVE NEW GLASSES AS THEY WERE BROKEN. IT WAS DECIDED TO HAVE AN OPERATION FOR CATARACT UPON RENEWING HIS GLASSES.															
1245_002 0_023685	Asian	58/F	Empa 10mg	Infections and infestations (感染症および寄生 虫症)	Herpes virus infection (ヘルペスウイルス 感染)	65	80	16	Sev	No	None	Yes	Rcver	No	Req hsp
1245_002 0_023731	Asian	66/M	Empa 10mg	Hepatobiliary disorders (肝胆道系障害)	Liver disorder (肝障害)	93	113	21	Mild	No	Disc	Yes	Unk	No	Req hsp
Comment: ACCORDING TO THE SAE NARRATIVE, THE PATIENT RECOVERED FROM THE LIVER OCCUPATION BUT IT IS UNKNOWN IF THE LIVER DISEASE HAS IMPROVED OR WORSENER, DUE TO INABILITY TO CONNECT WITH THE PATIENT.															
1245_002 0_024184	Asian	48/M	Empa 10mg	Gastrointestinal disorders (胃腸障害)	Haemorrhoids (痔核)	42	56	15	Mild	No	None	Yes	Rcver	No	Req hsp

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Episodes with a negative start day are not assigned to the analysing treatment.
MedDRA version used for reporting: 20.1

Listing 2.2.1 Adverse event episodes by treatment and patient - serious event only- treated set or open label set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Empa 25mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_002 0_020107	White	57/M	Empa 25mg	Endocrine disorders (	Goitre (	54	141	88	Mild	No	None	Yes	Rcver	No	Req hsp
Comment: HOSPITALISATION WAS FROM 07-OCT-20 UNTIL 10-OCT-20															
1245_002 0_020832	Black/ Africa Amer.	51/F	Empa 25mg	Cardiac disorders (	Acute myocardial infarction (	141	142	2	Sev	No	None	Yes	Rcver	No	Req hsp
1245_002 0_022271	White	52/M	Empa 25mg	Injury, poisoning and procedural complications (	Tibia fracture (	123	1687	467	Sev	No	None	Yes	Nrec&	No	Req hsp
Comment: IT WAS A TRAUMATIC FRACTURE DUE TO A FALL															
1245_002 0_022303	White	77/M	Empa 25mg	Neoplasms benign, malignant and unspecified (incl cysts and polyps) (	Metastases to central nervous system (	146	1667	217	Sev	No	None	Yes	Nrec&	No	Other
Comment: ORIGIN OF BRAIN METASTASIS IS LUNG CANCER															

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 Episodes with a negative start day are not assigned to the analysing treatment.
 MedDRA version used for reporting:

Listing 2.2.1 Adverse event episodes by treatment and patient - serious event only- treated set or open label set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Empa 25mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_002 0_022303	White	77/M	Empa 25mg	Neoplasms benign, malignant and unspecified (incl cysts and polyps) (	Lung neoplasm malignant (	146	1667	217	Sev	No	None	Yes	Nrec&	No	Other
				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))	肺の悪性新生物)										
Comment: DISEASE WILL RESULT IN DEATH															
1245_002 0_024681	White	68/F	Empa 25mg	Reproductive system and breast disorders (	Breast mass (	36	437	87	Sev	No	None	No	Unk	No	Other
				生殖系および乳房 障害)	乳房腫瘍)										
Comment: NEW FINDING ON ROUTINE MAMMOGRAM SCREENING. UNSURE IF PATIENT FOLLOWED UP WITH FURTHER TREATMENT															

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Episodes with a negative start day are not assigned to the analysing treatment.
MedDRA version used for reporting: [REDACTED]

Listing 2.2.1 Adverse event episodes by treatment and patient - serious event only- treated set or open label set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Sitagliptin

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_002 0_022061	White	70/M	Sitagliptin	Cardiac disorders (	Atrial fibrillation (	1	1797	1797	Mild	No	None	Yes	Nrec&	No	Other
Comment: DUE TO THE RISK OF CARDIAL EMBOLISM															
1245_002 0_022244	White	67/M	Post trt	Respiratory, thoracic and mediastinal disorders (	Chronic obstructive pulmonary disease (	41	58	18	Sev	No	None	Yes	Rcver	No	Req hsp
				呼吸器、胸郭およ び縦隔障害)	慢性閉塞性肺疾患										
	White		Post trt	Respiratory, thoracic and mediastinal disorders (	Hypercapnia (	41	58	18	Sev	No	None	Yes	Rcver	No	Req hsp
				呼吸器、胸郭およ び縦隔障害)	高炭酸ガス血症)										
1245_002 0_023048	Asian	56/M	Sitagliptin	Nervous system disorders (	Transient ischaemic attack	29	29	1	Mild	No	None	Yes	Rcver	No	Req hsp
				神経系障害)	(										
					一過性脳虚血発作										
	Asian		Sitagliptin	Nervous system disorders (	Vertebrobasilar insufficiency (	29	1727	1447	Mild	No	None	Yes	Nrec&	No	Req hsp
				神経系障害)	椎骨脳底動脈不全										
1245_002 0_023659	Asian	63/M	Post trt	General disorders and administration site conditions	Hernia (	43	54	12	Mod	No	Disc	Yes	Rcver	No	Req hsp
				(	ヘルニア)										
				一般・全身障害お よび投与部位の状 態)											

@ Related to start of treatment, 7 = censored, # = Lost to follow up, & = Follow up sufficient
Episodes with a negative start day are not assigned to the analysing treatment.
MedDRA version used for reporting: [REDACTED]

Listing 2.2.1 Adverse event episodes by treatment and patient - serious event only- treated set or open label set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Sitagliptin

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_002 0_023659	Asian	63/M	Post trt (障害)	Reproductive system and breast disorders (生殖系および乳房 障害)	Benign prostatic hyperplasia (良性前立腺肥大症)	43	54	12	Mod	No	Disc	Yes	Rcver	No	Req hsp
1245_002 0_024110	Asian	51/F	Sitagliptin	Gastrointestinal disorders (胃腸障害)	Colonic polyp (結腸ポリープ)	117	132	16	Mild	No	None	Yes	Rcver	No	Req hsp

Comment: THE PATIENT WAS HOSPITALIZED ON 27 DEC 2014, BECAUSE COLONIC POLYPS.

@ Related to start of treatment, 7 = censored, # = Lost to follow up, & = Follow up sufficient
 Episodes with a negative start day are not assigned to the analysing treatment.
 MedDRA version used for reporting: 20.0

Listing 2.2.1 Adverse event episodes by treatment and patient - serious event only- treated set or open label set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Empa 25mg OL

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_002 0_023504	Asian	61/M	Empa 25mg OL	Cardiac disorders (	Angina unstable (不安定狭心症)	107	120	14	Mild	No	Disc	Yes	Seq	No	Req hsp
Comment: SUBJECT IS DIAGNOSED OF DIABETIC CARDIOMYOPATHY AND WILL GO TO CLINIC FREQUENTLY															
1245_002 0_023531	Asian	44/M	Empa 25mg OL	Injury, poisoning and procedural complications (	Soft tissue injury (	79	104	26	Mod	No	None	Yes	Rcver	No	Req hsp
Comment: THE PATIENT CAN NOT PROVIDE THE CASE REPORT OF HIS HOSPITALIZATION															
1245_002 0_023539	Asian	64/M	Empa 25mg OL	Nervous system disorders (	Diabetic neuropathy (	10	98	89	Mod	Yes	Disc	Yes	Rcver	No	Req hsp

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Episodes with a negative start day are not assigned to the analysing treatment.

MedDRA version used for reporting: [REDACTED]

Listing 7.1.4 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Placebo

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_002 3_030031	White	71/F	Placebo	Musculoskeletal and connective tissue disorders (筋骨格系および結 合組織障害)	Foot deformity (足 変形)	134	141	8	Sev	No	None	Yes	Rcver	No	Req hsp
1245_002 3_030096	White	76/M	Placebo	Cardiac disorders (心臓 障害)	Aortic valve stenosis (大動脈 弁狭窄)	54	193	140	Mod	No	None	Yes	Rcver	No	Req hsp
1245_002 3_030181	White	64/M	Post trt	Hepatobiliary disorders (肝胆 道系障害)	Hepatitis toxic (中 毒性肝炎)	128	223	96	Sev	No	Disc	Yes	Rcver	No	Req hsp
1245_002 3_030563	White	76/F	Placebo	Infections and infestations (感 染症および寄生 虫症)	Listeria sepsis (リ ステリア性敗血 症)	160	181	22	Sev	No	None	Yes	Rcver	No	Req hsp
1245_002 3_030638	White	66/M	Placebo	General disorders and administration site conditions (一般・全身障害お よび投与部位の状 態)	Non-cardiac chest pain (非心 臓性胸痛)	112	115	4	Sev	No	None	Yes	Rcver	No	Req hsp
1245_002 3_031429	White	74/F	Placebo	Cardiac disorders (心臓 障害)	Cardiac failure congestive (うっ 血性心不全)	37	40	4	Sev	No	Disc	No	Rcver	No	Req hsp
1245_002 3_031451	White	61/F	Placebo	Cardiac disorders (心臓 障害)	Myocardial infarction (心筋 梗塞)	78	84	7	Sev	No	Disc	Yes	Rcver	No	Req hsp

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Episodes with a negative start day are not assigned to the analysing treatment.
MedDRA version used for reporting: █

Listing 7.1.4 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Placebo

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_002 3_031544	White	57/M	Placebo	Nervous system disorders (	Intercostal neuralgia (	42	45	4	Mod	No	None	Yes	Rcver	No	Req hsp
				神経系障害)	肋間神経痛)										
1245_002 3_032249	Asian	75/F	Placebo	Immune system disorders (	Hypersensitivity (過敏症)	6	16	11	Mod	Yes	Disc	Yes	Rcver	No	Req hsp
				免疫系障害)											
1245_002 3_032546	Asian	58/F	Placebo	Infections and infestations (	Herpes zoster (	36	58	23	Mod	No	None	Yes	Rcver	No	Req hsp
				感染症および寄生 虫症)	帯状疱疹)										
1245_002 3_032696	Asian	59/F	Placebo	Musculoskeletal and connective tissue disorders (	Osteoarthritis (	111	120	10	Sev	No	None	Yes	Rcver	No	Req hsp
				筋骨格系および結 合組織障害)	変形性関節症)										
Comment: THE PATIENT HAS A PRIOR HISTORY OF DEGENERATIVE OSTEOARTHRITS FOR TEN YEARS, THE PATIENT INCREASED 5 DAYS HOSPITAL.															
1245_002 3_032716	Asian	61/M	Placebo	Endocrine disorders (	Goitre (	22	33	12	Sev	No	None	Yes	Rcver	No	Req hsp
				内分泌障害)	甲状腺腫)										
Comment: THE PATIENT DURING A PHYSICAL EXAMINATION, THE GOITER IS LARGER ON MAY 20, BUT HE DECIDE HOSPITAL ON JUN 20															
1245_002 3_033062	White	68/M	Placebo	General disorders and administration site conditions (	Chest pain (	162	162	1	Mild	No	None	Yes	Rcver	No	Req hsp
				一般・全身障害お よび投与部位の状 態)	胸痛)										

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Episodes with a negative start day are not assigned to the analysing treatment.

MedDRA version used for reporting:

Listing 7.1.4 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Placebo

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_002 3_033131	White	60/F	Run-in	Respiratory, thoracic and mediastinal disorders (呼吸器、胸郭および縦隔障害)	Respiratory failure (呼吸不全)	-11	1817	1927	Mod	No	None	Yes	Nrec#	No	Req hsp
1245_002 3_034006	Asian	67/M	Post trt	Neoplasms benign, malignant and unspecified (incl cysts and polyps) (良性、悪性および 詳細不明の新生物 (嚢胞およびポリープを含む))	Colon cancer (結腸癌)	36	657	307	Sev	No	None	Yes	Nrec&	No	Req hsp
Comment: LAPAROSCOPIC LEFT COLECTOMY AND ANASTOMOSIS ON APRIL 22															
1245_002 3_034227	Asian	61/M	Placebo	Infections and infestations (感染症および寄生 虫症)	Pneumonia primary atypical (原発性異型肺炎)	73	78	6	Mod	No	None	Yes	Rcver	No	Req hsp
1245_002 3_036040	Asian	43/F	Placebo	Infections and infestations (感染症および寄生 虫症)	Cellulitis (蜂巣炎)	69	102	34	Mod	No	None	Yes	Rcver	No	Req hsp
Comment: PATIENT CAME TO OPD WITH COMPLAINT OF PAIN IN PERIANAL REGION AND DIFFICULTY IN WALKING.ON LOCAL EXAMINATION SWELLING+, REDNESS+,TENDERNESS															
	Asian		Placebo	Infections and infestations (感染症および寄生 虫症)	Anal abscess (肛門膿瘍)	69	102	34	Mod	No	None	Yes	Rcver	No	Req hsp
Comment: PATIENT CAME TO OPD WITH COMPLAINT OF PAIN IN PERIANAL REGION AND DIFFICULTY IN WALKING.ON LOCAL EXAMINATION SWELLING+, REDNESS+,TENDERNESS															

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Episodes with a negative start day are not assigned to the analysing treatment.

MedDRA version used for reporting: [REDACTED]

Listing 7.1.4 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Placebo

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_002 3_036040	Asian	43/F	Placebo	Infections and infestations (	Sepsis (敗血症)	69	102	34	Mod	No	None	Yes	Rcver	No	Req hsp
虫症) Comment: PATIENT CAME TO OPD WITH COMPLAINT OF PAIN IN PERIANAL REGION AND DIFFICULTY IN WALKING.ON LOCAL EXAMINATION SWELLING+, REDNESS+,TENDERNESS															
1245_002 3_036602	White	51/M	Placebo	Congenital, familial and genetic disorders (	Hydrocele (陰嚢水瘤)	135	138	4	Sev	No	None	Yes	Rcver	No	Req hsp
先天性、家族性お よび遺伝性障害)															
1245_002 3_037001	Black/ Africa n Amer.	50/F	Placebo	Investigations (臨床検査)	Blood creatinine increased (血中クレアチニン 増加)	85	116	32	Mod	Yes	Disc	No	Rcver	No	Other
Comment: ELEVATED CREATININE, DECREASED GFR AND BUN AS REPORTED IN SAE FORM IS SIGNIFICANT MEDICAL EVENT															
1245_002 3_037022	White	57/M	Placebo	Renal and urinary disorders (	Cystitis haemorrhagic (出血性膀胱炎)	31	47	17	Sev	No	None	Yes	Rcver	No	Req hsp
腎および尿路障害) Comment: SUBJECT EXPERIENCED BLOOD IN URINE AND EVENTUALLY STOPPED URINATING SO HE WENT TO THE ER. HE WAS ADMITTED FROM 27FEB20 TO 01MAR20.															
1245_002 3_037269	White	68/M	Placebo	Infections and infestations (	Pneumonia (肺炎)	163	3087	1467	Sev	No	None		Nrec#	No	Req hsp
虫症) Comment: NO INFORMATION AVAILABLE FROM HOSPITAL ON TREATMENT REQUIRED TO TREAT															
1245_002 3_037496	Asian	60/F	Post trt	Cardiac disorders (	Myocardial infarction (心筋梗塞)	117	149	33	Sev	Yes	Disc	Yes	Rcver	No	Req hsp
心臓障害)															

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 Episodes with a negative start day are not assigned to the analysing treatment.
 MedDRA version used for reporting:

Listing 7.1.4 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Empa 10mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_002 3_030191	White	70/M	Empa 10mg	Congenital, familial and genetic disorders (	Phimosis (包茎)	40	62	23	Mod	No	None	Yes	Rcver	No	Req hsp
				先天性、家族性お よび遺伝性障害)											
1245_002 3_030240	White	61/F	Empa 10mg	Gastrointestinal disorders (	Faecaloma (糞塊)	57	59	3	Sev	No	None	Yes	Rcver	No	Req hsp
				胃腸障害)											
Comment: DURING THE NIGHT OF 21-FEB-2019, PATIENT DEVELOPPED SEVERE ABDOMINAL PAIN AND REQUESTED HOSPITALISATION ON MORNING 21-FEB-2019. AFTER LAXATION SYMPTOMS IMPROOVED. FURHTER DIAGNOSTICS WITHOUT FINDINGS.															
1245_002 3_030336	White	63/M	Empa 10mg	Reproductive system and breast disorders (	Benign prostatic hyperplasia (良性前立腺肥大症)	111*	151	41*	Mod	No	None	Yes	Rcver	No	Req hsp
				生殖系および乳房 障害)											
Comment: HOSPITALIZATION 05-JUN-2019 - 10-JUN-2019. ON 07-JUN-2019 TRANSURETHAL PROSTATECTOMY (TUR)															
1245_002 3_030565	White	56/M	Empa 10mg	Vascular disorders (	Peripheral arterial occlusive disease (末梢動脈閉塞性疾 患)	68	71	4	Mod	No	None	Yes	Rcver	No	Req hsp
	White		Empa 10mg	Vascular disorders (	Peripheral arterial occlusive disease (末梢動脈閉塞性疾 患)	153	202	50	Mod	No	None	Yes	Rcver	No	Req hsp

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MedDRA version used for reporting: 20.1

Listing 7.1.4 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Empa 10mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_002 3_032151	Asian	39/M	Empa 10mg	Injury, poisoning and procedural complications (	Comminuted fracture (	117	1287	127	Sev	No	Disc	Yes	Nrec&	No	Req hsp
				傷害、中毒および 処置合併症)	粉碎骨折)										
Comment: THE FRACTURE IS TRAUMATIC.															
1245_002 3_032200	Asian	52/F	Empa 10mg	Nervous system disorders (	Lacunar infarction (	50	65	16	Sev	No	None	Yes	Rcver	No	Req hsp
				神経系障害)	ラクナ梗塞)										
Comment: SYMPTOMS:DIZZY,BLURRED VISION,NAUSEA															
1245_002 3_032421	Asian	45/M	Run-in	Cardiac disorders (	Myocardial ischaemia (	-2	12	14	Sev	No	None	Yes	Rcver	No	Req hsp
				心臓障害)	心筋虚血)										
1245_002 3_032584	Asian	61/F	Empa 10mg	Cardiac disorders (	Angina unstable (不安定狭心症)	63	74	12	Sev	No	None	Yes	Rcver	No	Req hsp
				心臓障害)											
Comment: SHE WAS HOSPITALIZED ON 13-JUL-20 FOR THE FURTHER EXAMINATION AND TREATMENT.STOPPED TAKING THE TRIAL DRUG ON 14-JUL-20.RECEIVED SELECTIVE CORONARY ANGIOGRPHY+PTCA+STENT ON 19-JUL-20 SUCCESSFULLY															
1245_002 3_032592	Asian	56/M	Empa 10mg	Gastrointestinal disorders (	Gastritis (	77	85	9	Mod	No	Disc	Yes	Rcver	No	Req hsp
				胃腸障害)	胃炎)										
1245_002 3_032694	Asian	62/F	Empa 10mg	Gastrointestinal disorders (	Gastritis (	133	140	8	Mild	No	None	Yes	Rcver	No	Req hsp
				胃腸障害)	胃炎)										
Comment: THE PATIENT IS THE RULE-PATIENT EXAMINATION, ABOUT EVERY SIX MONTHES, DO ENDSOPY IN MARCH, WITHOUT ANY PROBLEM,ON 15 AUG 20 SHOW INTESTINAL ENDOSCOPY IN THE EXPANSION,THEN ADMITTED TO HOSPITAL															
	Asian		Empa 10mg	Gastrointestinal disorders (	Duodenal ulcer (	133	140	8	Mild	No	None	Yes	Rcver	No	Req hsp
				胃腸障害)	十二指腸潰瘍)										
Comment: THE PATIENT IS THE RULE-PATIENT EXAMINATION, ABOUT EVERY SIX MONTHES, DO ENDSOPY IN MARCH, WITHOUT ANY PROBLEM,ON 15 AUG 20 SHOW INTESTINAL ENDOSCOPY IN THE EXPANSION,THEN ADMITTED TO HOSPITAL.															

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Episodes with a negative start day are not assigned to the analysing treatment.
MedDRA version used for reporting:

Listing 7.1.4 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Empa 10mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_002 3_032719	Asian	61/M	Empa 10mg	Nervous system disorders (	Dizziness (	37	1747	1387	Mild	No	None	Yes	Nrec#	No	Req hsp
Comment: THE PATIENT WAS CHECKED ELECTROENCEPHALOGRAM AND REHEOENCEPHALOGRAM, HE DIDN'T FIND HYPOGLYCEMIA WITH DIZZINESS FINALLY															
1245_002 3_033592	White	56/F	Empa 10mg	Cardiac disorders (	Acute myocardial infarction (	65	65	1	Sev	No	Disc	No	Fatal	No	Fatal
Comment: PATIENT STARTED ON 13APR20 AT 00:30 WITH SEVERE PRECORDIAL PAIN AND DYSPNEA, WITHOUT ANY ADDITIONAL TREATMENT, REQUESTING AN AMBULANCE, BUT PATIENT DIED AT 01:15 PREVIOUS TO AMBULANCE ARRIVAL															
1245_002 3_034123	Asian	48/F	Empa 10mg	Nervous system disorders (	Syringomyelia (	133	141	9	Sev	No	None	Yes	Rcver	No	Req hsp
	Asian		Empa 10mg	Injury, poisoning and procedural complications (	Neck injury (	133	141	9	Sev	No	None	Yes	Rcver	No	Req hsp
	Asian		Empa 10mg	Injury, poisoning and procedural complications ()	Post-traumatic neck syndrome (	133	141	9	Sev	No	None	No	Rcver	No	Req hsp
1245_002 3_034136	Asian	53/M	Empa 10mg	Nervous system disorders (	Trigeminal neuralgia (	156	169	14	Mod	No	None	Yes	Rcver	No	Req hsp

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Episodes with a negative start day are not assigned to the analysing treatment.

MedDRA version used for reporting:

Listing 7.1.4 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Empa 10mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_002 3_034764	Asian	49/F	Empa 10mg	Injury, poisoning and procedural complications (	Fall (転倒)	123	123	1	Mild	No	None	No	Rcver	No	Req hsp
				傷害、中毒および 処置合併症)											
	Asian		Empa 10mg	Injury, poisoning and procedural complications (	Facial bones fracture (	123	134	12	Mild	No	None	Yes	Rcver	No	Req hsp
				傷害、中毒および 処置合併症)	顔面骨折)										
Comment: THIS EVENT WAS TRAUMATIC EVENT.															
1245_002 3_034836	Asian	50/F	Empa 10mg	Psychiatric disorders (	Stress (	144	188	45	Mild	No	None	Yes	Rcver	No	Req hsp
				精神障害)	ストレス)										
1245_002 3_035031	White	62/F	Empa 10mg	Injury, poisoning and procedural complications (	Fall (転倒)	46	46	1	Mod	No	None	No	Rcver	No	Req hsp
				傷害、中毒および 処置合併症)											
Comment: FALL WAS DUE TO BAD WEATHER CONDITIONS,THE ROUT WAS ICE GLAZED,PATIENT NOT SUFFERED FROM DIZZINES BEFORE FALL															
	White		Empa 10mg	Injury, poisoning and procedural complications (	Femoral neck fracture (	46	181	136	Mod	No	None	Yes	Rcver	No	Req hsp
				傷害、中毒および 処置合併症)	大腿骨頸部骨折)										
Comment: FRACTURE WAS TRAUMATIC-DUE TO FALL /BAD WEATHER CONDITIONS-THE GROUND WAS ICE GLAZED/PATIENT NOT SUFFERED FROM DIZZINES BEFORE FALL.PATIENT WAS DISCHARGED FROM HOSPITAL ON 22.12.20															

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Episodes with a negative start day are not assigned to the analysing treatment.

MedDRA version used for reporting:

Listing 7.1.4 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Empa 10mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_002 3_036600	White	51/F	Empa 10mg	Gastrointestinal disorders (	Abdominal hernia (腹部ヘルニア)	56	67	12	Sev	No	None	Yes	Rcver	No	Req hsp
1245_002 3_037617	Asian	59/M	Empa 10mg	Cardiac disorders (	Arteriosclerosis coronary artery (冠動脈硬化症)	122	138	17	Sev	No	None	Yes	Rcver	No	Req hsp

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Episodes with a negative start day are not assigned to the analysing treatment.

MedDRA version used for reporting: [REDACTED]

Listing 7.1.4 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Empa 25mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_002 3_030002	White	56/M	Empa 25mg	Vascular disorders (血管障害)	Peripheral arterial occlusive disease (末梢動脈閉塞性疾患)	168	169	2	Mild	No	None	No	Rcver	No	Req hsp
1245_002 3_030033	White	58/F	Empa 25mg	Injury, poisoning and procedural complications (傷害、中毒および処置合併症)	Ligament rupture (靱帯断裂)	176	185	10	Sev	No	None	Yes	Rcver	No	Req hsp
	White		Empa 25mg	Injury, poisoning and procedural complications (傷害、中毒および処置合併症)	Tendon rupture (腱断裂)	176	185	10	Sev	No	None	Yes	Rcver	No	Req hsp
1245_002 3_030062	White	78/F	Empa 25mg	Nervous system disorders (神経系障害)	Cerebrovascular accident (脳血管発作)	19	45	27	Sev	No	None	Yes	Seq	No	Req hsp
Comment: THE BRAIN STEM INSULT RESULTED IN A HEMIPARESIS(LEFT)WHICH IS ONGOING.THE FOLLOW-UP IS CONSIDERED SUFFICIENT FOR THIS TRIAL. THE PATIENT IS ENTERED IN THE EXTENSION TRAIL 1245.31															
1245_002 3_030346	White	66/F	Run-in	Musculoskeletal and connective tissue disorders (筋骨格系および結合組織障害)	Intervertebral disc disorder (椎間板障害)	-6	2977	3037	Sev	No	None	Yes	Nrec&	No	Req hsp
Comment: SHOULDER PAIN RIGHT KNOWN SINCE 16/FEB/2011 DID NOR RESPOND TO MELOXICAM AND GOT MORE SEVERE REQUIRING HOSPITALISATION.DISCHARGE 20-MAR-2011															

@ Related to start of treatment, 7 = censored, * = partial date or missing date/time imputed, # = Lost to follow up, & = Follow up sufficient
Episodes with a negative start day are not assigned to the analysing treatment.

MedDRA version used for reporting: 20.1

Listing 7.1.4 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Empa 25mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_002 3_030346	White	66/F	Run-in	Nervous system disorders (	Cervicobrachial syndrome (	-6	2337	2397	Sev	No	None	Yes	Nrec&	No	Req hsp
Comment: SHOULDER PAIN RIGHT KNOWN SINCE 16/FEB/2016 DID NOT RESPOND TO MELOXICAM AND GOT MORE SEVERE REQUIRING HOSPITALISATION.DISCHARGE 20-MAR-2016															
1245_002 3_030871	White	61/F	Empa 25mg	Neoplasms benign, malignant and unspecified (incl cysts and polyps) (	Breast cancer (	162	2837	1227	Sev	No	None	Yes	Nrec&	No	Other
Comment: SUBJECT WILL BE HAVING RADIATION THERAPY-															
1245_002 3_032124	Asian	33/M	Placebo	Renal and urinary disorders (	Diabetic nephropathy (	51	73	23	Mild	No	None	Yes	Rcver	No	Req hsp
)															
1245_002 3_033221	White	52/M	Empa 25mg	Neoplasms benign, malignant and unspecified (incl cysts and polyps) (	Prostatic adenoma (	143	176	34	Mild	No	None	Yes	Rcver	No	Req hsp
)															

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Episodes with a negative start day are not assigned to the analysing treatment.

MedDRA version used for reporting: 20.1

Listing 3.2.1 Adverse event episodes by treatment and patient - serious event only (naive)- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Placebo

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_002 0_020016	White	57/M	Placebo	Musculoskeletal and connective tissue disorders (筋骨格系および結 合組織障害)	Osteoarthritis (変形性関節症)	197			Mod	No	None	No	Nrec	No	Req hsp
1245_002 0_020021	White	71/M	Placebo	Congenital, familial and genetic disorders (先天性、家族性お よび遺伝性障害)	Gilbert's syndrome (ジルベール症候群)	169	1697	17	Mod	No	None	No	Nrec#	No	Req hsp
	White		Placebo	Congenital, familial and genetic disorders (先天性、家族性お よび遺伝性障害)	Gilbert's syndrome (ジルベール症候群)	169			Mod	No	Disc	No	Nrec	No	Req hsp
	White		Placebo	Congenital, familial and genetic disorders (先天性、家族性お よび遺伝性障害)	Gilbert's syndrome (ジルベール症候群)	169			Mod	No	None	No	Nrec	No	Req hsp
1245_002 0_020401	White	63/F	Placebo	Hepatobiliary disorders (肝胆道系障害)	Cholecystitis acute (急性胆嚢炎)	21	48	28	Sev	No	Disc	Yes	Rcver	No	Req hsp

@ Related to start of treatment, 7 = censored, # = Lost to follow up, & = Follow up sufficient

Episodes with a negative start day are not assigned to the analysing treatment.

MedDRA version used for reporting: [REDACTED]

Listing 3.2.1 Adverse event episodes by treatment and patient - serious event only (naive)- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Placebo

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_002 0_020721	White	60/M	Placebo	Neoplasms benign, malignant and unspecified (incl cysts and polyps) (	Colon cancer (	16	49	34	Mod	No	None	Yes	Rcver	No	Req hsp
				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))	結腸癌)										
Comment: HISTOPATHOLOGY SHOWED CA BOWEL AT SPLENIC FLEXURE FOLLOWING A COLONOSCOPY															
1245_002 0_021365	Asian	63/M	Placebo	Nervous system disorders (	Subarachnoid haemorrhage (	323	328	6	Mod	No	None	Yes	Rcver	No	Req hsp
				神経系障害)	くも膜下出血)										
Comment: THE PATIENT FELL WITH THE MOTORCYCLE WHILE TRYING TO AVOID AN OBSTACLE AND SUSTAINED A TRAUMA.THUS THE EVENT WAS ASSESSED AS "UNRELATED" TO THE STUDY DRUG.															
	Asian		Placebo	Injury, poisoning and procedural complications (	Injury (損傷)	323	328	6	Mod	No	None	Yes	Rcver	No	Req hsp
				傷害、中毒および 処置合併症)											
Comment: THE PATIENT FELL WITH THE MOTORCYCLE WHILE TRYING TO AVOID AN OBSTACLE AND SUSTAINED A TRAUMA.THUS THE EVENT WAS ASSESSED AS "UNRELATED" TO THE STUDY DRUG.															
1245_002 0_022143	White	80/F	Placebo	Cardiac disorders (	Myocardial infarction (	93	93	1	Sev	No	Disc	No	Fatal	No	Fatal
				心臓障害)	心筋梗塞)										

@ Related to start of treatment, 7 = censored, # = Lost to follow up, & = Follow up sufficient

Episodes with a negative start day are not assigned to the analysing treatment.

MedDRA version used for reporting: [REDACTED]

Listing 3.2.1 Adverse event episodes by treatment and patient - serious event only (naive)- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Placebo

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_002 0_023038	Asian	51/F	Placebo	Investigations (臨床検査)	Blood creatine phosphokinase increased (血中クレアチンホスホキナーゼ増加)	294	315	22	Mod	Yes	None	No	Rcver	No	Other
Comment: PATIENT WAS ON STUDY DRUG, ATORVASTATIN & FENOLIP, THE CONTRIBUTION OF THE SAME FOR THIS EVENT CAN'T BE RULED OUT. HENCE IT IS CONSIDERED TO BE POSSIBLY RELATED TO THE STUDY DRUG & AS IMP EVENT.															
1245_002 0_023425	White	61/F	Placebo	Metabolism and nutrition disorders (代謝および栄養障害)	Hyperglycaemia (高血糖)	45	48	4	Mild	No	None	Yes	Rcver	No	Req hsp
1245_002 0_023802	Asian	62/F	Placebo	Vascular disorders (血管障害)	Hypertension (高血圧)	363	390	28	Sev	No	None	No	Rcver	No	Req hsp
1245_002 0_024993	White	68/M	Placebo	Nervous system disorders (神経系障害)	Presyncope (失神寸前の状態)	260	310	51	Mod	No	None	Yes	Rcver	No	Req hsp
Comment: AUTOMATED IMPLANTABLE CARDIOVERTER-DEFIBRILLATOR PLACED 19JAN2014															
	White		Placebo	Cardiac disorders (心臓障害)	Ventricular tachycardia (心室性頻脈)	260	310	51	Mod	No	None	Yes	Rcver	No	Req hsp

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 Episodes with a negative start day are not assigned to the analysing treatment.
 MedDRA version used for reporting: 25.1

Listing 3.2.1 Adverse event episodes by treatment and patient - serious event only (naive)- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Empa 10mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_002 0_020009	White	58/F	Empa 10mg	Injury, poisoning and procedural complications (傷害、中毒および 処置合併症)	Animal bite (動物咬傷)	123	128	6	Mod	No	None	Yes	Rcver	No	Req hsp
1245_002 0_020064	White	61/M	Empa 10mg	Nervous system disorders (神経系障害)	Cerebrovascular accident (脳血管発作)	165	171	7	Sev	Yes	None	No	Seq	No	Req hsp
1245_002 0_020071	White	70/M	Empa 10mg	Nervous system disorders (神経系障害)	Syncope (失神)	247	255	9	Mod	No	None	No	Rcver	No	Req hsp
1245_002 0_020145	White	68/F	Empa 10mg	Surgical and medical procedures (外科および内科処 置)	Hip arthroplasty (股関節形成)	229	264	36	Sev	No	None	Yes	Rcver	No	Req hsp
	White		Empa 10mg	Injury, poisoning and procedural complications (傷害、中毒および 処置合併症)	Muscle strain (肉離れ)	264	266	3	Sev	No	None	Yes	Rcver	No	Req hsp
1245_002 0_020263	White	66/F	Empa 10mg	Injury, poisoning and procedural complications (傷害、中毒および 処置合併症)	Tendon rupture (腱断裂)	50	59	10	Sev	No	None	Yes	Seq	No	Req hsp

Comment: PAIN IN THE SHOULDER, DIAGNOSIS WITH MRI

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Episodes with a negative start day are not assigned to the analysing treatment.
MedDRA version used for reporting: █

Listing 3.2.1 Adverse event episodes by treatment and patient - serious event only (naive)- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Empa 10mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_002 0_020741	White	64/F	Empa 10mg	Nervous system disorders (	Cerebrovascular accident (	314	4497	1367	Mod	No	Disc	Yes	Nrec&	No	Req hsp
				神経系障害)	脳血管発作)										
1245_002 0_021081	Asian	45/F	Empa 10mg	Neoplasms benign, malignant and unspecified (incl cysts and polyps) (	Breast cancer female (	121	1827	627	Mod	No	None	Yes	Nrec&	No	Req hsp/Other
				良性、悪性および 詳細不明の新生物 (嚢胞およびポリ ーブを含む))	女性乳癌)										
Comment: FOLLOW-UP SUFFICIENT IN 08/AUG/2014. THERE IS HIGH POSSIBILITY THAT BREAST CANCER HAVE DEVELOPED BEFORE THE INVESTIGATIONAL PRODUCT ADMINISTERED, CONSIDERING THE TIME COURSE. BECAUSE THE MAIN TUMOR WAS															
1245_002 0_021186	Asian	68/M	Empa 10mg	Injury, poisoning and procedural complications (	Subdural haematoma (	343	448	106	Mod	No	Disc	Yes	Rcver	No	Req hsp
				傷害、中毒および 処置合併症)	硬膜下血腫)										
Comment: THE PATIENT HAD FACE FRACTURE FOLLOWING LOSS OF CONSCIOUSNESS AND FALL, WHICH SUGGESTED THAT HE BUMPED HIS HEAD VERY HARD.															
1245_002 0_021195	Asian	51/M	Empa 10mg	Gastrointestinal disorders (	Colitis ulcerative (	427			Mod	Yes	Disc	Yes	Nrec	No	Req hsp
				胃腸障害)	潰瘍性大腸炎)										
Comment: ULCERATIVE COLITIS IS A NON-SPECIFIC INFLAMMATORY DISEASE OF UNSPECIFIED ETIOLOGY. THERE HAS BEEN NO REPORTS ON THE OCCURRENCE OF THE DISEASE AS A RESULT OF CERTAIN DRUG USE, AND EPIDEMIOLOGICALLY,															

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Episodes with a negative start day are not assigned to the analysing treatment.
MedDRA version used for reporting: 20.0

Listing 3.2.1 Adverse event episodes by treatment and patient - serious event only (naive)- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Empa 10mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_002 0_021376	Asian	74/M	Empa 10mg	Injury, poisoning and procedural complications (	Injury (損傷)	14	93	80	Mod	No	None	Yes	Rcver	No	Req hsp
傷害、中毒および 処置合併症) Comment: THE SUBJECT WAS ADMITTED TO THE SEIAI HOSPITAL BY AMBULANCE DUE TO TRAFFIC ACCIDENT ON HIS WAY HOME ON 22/NOV/2013. THERE ARE NO DETAILED INFORMATION ABOUT THE SITE AND SEVERITY OF TRAUMA,															
	Asian		Empa 10mg	Eye disorders (	Cataract (白内障)	79	82	4	Mild	No	None	Yes	Rcver	No	Req hsp
眼障害) Comment: THE SUBJECT WAS HOSPITALISED FOR CATARACT OPERATION ON 26-JAN-2014. HE NEEDS TO HAVE NEW GLASSES AS THEY WERE BROKEN. IT WAS DECIDED TO HAVE AN OPERATION FOR CATARACT UPON RENEWING HIS GLASSES.															
1245_002 0_023036	Asian	47/M	Empa 10mg	Investigations (	Blood creatine phosphokinase increased (	294	315	22	Mild	No	None	No	Rcver	No	Other
臨床検査) 血中クレアチンホ スホキナーゼ増加 Comment: AS PER PI DISCRETION , INCREASED CPK IS BEEN CAPTURED AS IMPORTANT MEDICAL EVENT.															
1245_002 0_023043	Asian	62/F	Post trt	Infections and infestations (	Genital infection (	260	264	5	Mod	Yes	None	Yes	Rcver	No	Req hsp
感染症および寄生 性器感染) 虫症) Comment: SYMPTOMATIC; DURING HOSPITALIZATION, URIN R/M WAS DONE WHICH REVEALED BACTERIURIA & URINE CULTURE WAS NORMAL WITHOUT ANY GROWTH.															
1245_002 0_023685	Asian	58/F	Empa 10mg	Infections and infestations (	Herpes virus infection (	65	80	16	Sev	No	None	Yes	Rcver	No	Req hsp
感染症および寄生 ヘルペスウイルス 虫症) 感染)															

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 Episodes with a negative start day are not assigned to the analysing treatment.
 MedDRA version used for reporting: 20.1

Listing 3.2.1 Adverse event episodes by treatment and patient - serious event only (naive)- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Empa 10mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_002 0_023731	Asian	66/M	Empa 10mg	Hepatobiliary disorders (肝 胆道系障害)	Liver disorder (肝障害)	93	113	21	Mild	No	Disc	Yes	Unk	No	Req hsp
Comment: ACCORDING TO THE SAE NARRATIVE, THE PATIENT RECOVERED FROM THE LIVER OCCUPATION BUT IT IS UNKNOWN IF THE LIVER DISEASE HAS IMPROVED OR WORSENER, DUE TO INABILITY TO CONNECT WITH THE PATIENT.															
1245_002 0_024184	Asian	48/M	Empa 10mg	Gastrointestinal disorders (胃腸障害)	Haemorrhoids (痔核)	42	56	15	Mild	No	None	Yes	Rcver	No	Req hsp
1245_002 0_024864	White	61/F	Empa 10mg	Injury, poisoning and procedural complications (傷害、中毒および 処置合併症)	Meniscus lesion (半月板障害)	116	247	132	Mod	No	None	Yes	Rcver	No	Req hsp

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 Episodes with a negative start day are not assigned to the analysing treatment.
 MedDRA version used for reporting: [REDACTED]

Listing 3.2.1 Adverse event episodes by treatment and patient - serious event only (naive)- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Empa 25mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_002 0_020022	White	58/M	Empa 25mg	Hepatobiliary disorders (肝 胆道系障害)	Cirrhosis alcoholic (ア ルコール性肝 硬変)	418			Sev	No	Disc	Yes	Nrec	No	Req hsp
	White		Empa 25mg	Infections and infestations (感 染症および寄 生虫症)	Peritonitis (腹 膜炎)	470	493	24	Mod	No	None	Yes	Rcver	No	Prol hsp
1245_002 0_020101	White	47/M	Empa 25mg	Infections and infestations (感 染症および寄 生虫症)	Infected skin ulcer (感染性 皮膚潰瘍)	171	289	119	Mild	No	None	Yes	Rcver	No	Req hsp
Comment: ULCUS CRURIS WITH WOUND INFECTION															
1245_002 0_020107	White	57/M	Empa 25mg	Endocrine disorders (内 分泌障害)	Goitre (甲状腺 腫)	54	141	88	Mild	No	None	Yes	Rcver	No	Req hsp
Comment: HOSPITALISATION WAS FROM 07-OCT-20 UNTIL 10-OCT-20															
1245_002 0_020623	White	37/F	Empa 25mg	Reproductive system and breast disorders (生殖系および乳 房障害)	Menorrhagia (月 経過多)	211	354	144	Mod	No	None	Yes	Rcver	No	Req hsp

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 Episodes with a negative start day are not assigned to the analysing treatment.
 MedDRA version used for reporting:

Listing 3.2.1 Adverse event episodes by treatment and patient - serious event only (naive)- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Empa 25mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_002 0_020704	White	69/M	Empa 25mg	Neoplasms benign, malignant and unspecified (incl cysts and polyps) (	Bronchial carcinoma (	472			Sev	No	None	No	Nrec	No	Other
(良性、悪性および 詳細不明の新生物 (嚢胞およびポリ ーブを含む)) Comment: DIAGNOSED 22-MAR-20 BY CAT SCAN NO OTHER DETAILS PRESENTLY AVAILABLE															
1245_002 0_020832	Black/ Africa n Amer.	51/F	Empa 25mg	Cardiac disorders (	Acute myocardial infarction (	141	142	2	Sev	No	None	Yes	Rcver	No	Req hsp
	Black/ Africa n Amer.		Empa 25mg	General disorders and administration site conditions (	Non-cardiac chest pain (	168	168	1	Sev	No	None	Yes	Rcver	No	Req hsp
(一般・全身障害お よび投与部位の状 態) 1245_002 Asian 55/M Empa 25mg Neoplasms Bile duct cancer 403 0_021141 benign, malignant and unspecified (胆管癌) (incl cysts and polyps) (															
(良性、悪性および 詳細不明の新生物 (嚢胞およびポリ ーブを含む)) Comment: SERIOUS BECAUSE OF SUSPECTED CANCER.THERE IS NOT EVIDENCE OF EVENT															

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 Episodes with a negative start day are not assigned to the analysing treatment.
 MedDRA version used for reporting:

Listing 3.2.1 Adverse event episodes by treatment and patient - serious event only (naive)- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Empa 25mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_002 0_021431	Asian	63/F	Empa 25mg	Endocrine disorders (内分泌障害) 症)	Hyperparathyroid ism (副甲状腺機能亢進 症)	228	235	8	Mod	No	None	Yes	Rcver	No	Req hsp
Comment: THE EVENT IS CONSIDERED BE UNRELATED TO THE STUDY DRUG BECAUSE THE EVENT WAS IDENTIFIED ON EXAMINATIONS PERFORMED BEFORE INITIATION OF STUDY DRUG ADMINISTRATION.															
1245_002 0_021493	Asian	51/F	Empa 25mg	Respiratory, thoracic and mediastinal disorders (呼吸器、胸郭および縦隔障害) 群)	Sleep apnoea syndrome (睡眠時無呼吸症候 群)	351			Mild	No	None	Yes	Nrec	No	Req hsp
Comment: THE PATIENT HAD HAD THE SYMPTOMS SINCE BEFORE INITIATION OF THE STUDY DRUG.															
1245_002 0_022271	White	52/M	Empa 25mg	Injury, poisoning and procedural complications (傷害、中毒および処置合併症)	Tibia fracture (脛骨骨折)	123	231	109	Sev	No	None	Yes	Rcver	No	Req hsp
Comment: IT WAS A TRAUMATIC FRACTURE DUE TO A FALL/TRAUMATIC FRACTURE DUE TO A FALL															
1245_002 0_022303	White	77/M	Empa 25mg	Neoplasms benign, malignant and unspecified (incl cysts and polyps) (良性、悪性および詳細不明の新生物 (嚢胞およびポリ ーブを含む))	Metastases to central nervous system (中枢神経系転移)	146	1667	217	Sev	No	None	Yes	Nrec&	No	Other
Comment: ORIGIN OF BRAIN METASTASIS IS LUNG CANCER															

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Episodes with a negative start day are not assigned to the analysing treatment.
MedDRA version used for reporting: █

Listing 3.2.1 Adverse event episodes by treatment and patient - serious event only (naive)- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Empa 25mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_002 0_022303	White	77/M	Empa 25mg	Neoplasms benign, malignant and unspecified (incl cysts and polyps) (	Lung neoplasm malignant (	146	1667	217	Sev	No	None	Yes	Nrec&	No	Other
				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))	肺の悪性新生物)										
Comment: DISEASE WILL RESULT IN DEATH															
1245_002 0_024681	White	68/F	Empa 25mg	Reproductive system and breast disorders (	Breast mass (	36	437	87	Sev	No	None	No	Unk	No	Other
				生殖系および乳房 障害)	乳房腫瘍)										

Comment: NEW FINDING ON ROUTINE MAMMOGRAM SCREENING. UNSURE IF PATIENT FOLLOWED UP WITH FURTHER TREATMENT

@ Related to start of treatment, 7 = censored, # = Lost to follow up, & = Follow up sufficient
 Episodes with a negative start day are not assigned to the analysing treatment.
 MedDRA version used for reporting: [REDACTED]

Listing 3.2.1 Adverse event episodes by treatment and patient - serious event only (naive)- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Sitagliptin

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_002 0_020023	White	78/F	Sitagliptin	Metabolism and nutrition disorders () 代謝および栄養障 害)	Hyponatraemia () 低ナトリウム血症	302	317	16	Mod	No	None	No	Rcver	No	Req hsp
1245_002 0_020106	White	43/F	Sitagliptin	Musculoskeletal and connective tissue disorders () 筋骨格系および結 合組織障害)	Osteoarthritis () 変形性関節症)	215			Mild	No	None	Yes	Nrec	No	Req hsp
	White		Sitagliptin	Musculoskeletal and connective tissue disorders () 筋骨格系および結 合組織障害)	Plica syndrome () たな症候群)	219			Mild	No	None	Yes	Nrec	No	Req hsp
1245_002 0_022061	White	70/M	Sitagliptin	Cardiac disorders () 心臓障害)	Atrial fibrillation () 心房細動)	1	2207	2207	Mild	No	None	Yes	Nrec&	No	Other
Comment: DUE TO THE RISK OF CARDIAL EMBOLISM/DUE TO THE RISK OF CARDIAL EMBOLISM															
1245_002 0_022244	White	67/M	Post trt	Respiratory, thoracic and mediastinal disorders () 呼吸器、胸郭およ び縦隔障害)	Chronic obstructive pulmonary disease () 慢性閉塞性肺疾患	41	58	18	Sev	No	None	Yes	Rcver	No	Req hsp
	White		Post trt	Respiratory, thoracic and mediastinal disorders () 呼吸器、胸郭およ び縦隔障害)	Hypercapnia () 高炭酸ガス血症)	41	58	18	Sev	No	None	Yes	Rcver	No	Req hsp

@ Related to start of treatment, 7 = censored, # = Lost to follow up, & = Follow up sufficient
Episodes with a negative start day are not assigned to the analysing treatment.
MedDRA version used for reporting: [REDACTED]

Listing 3.2.1 Adverse event episodes by treatment and patient - serious event only (naive)- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Sitagliptin

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_002 0_023048	Asian	56/M	Sitagliptin	Nervous system disorders (神経系障害)	Transient ischaemic attack (一過性脳虚血発作)	29	29	1	Mild	No	None	Yes	Rcver	No	Req hsp
	Asian		Sitagliptin	Nervous system disorders (神経系障害)	Vertebrobasilar insufficiency (椎骨脳底動脈不全)	29	1727	1447	Mild	No	None	Yes	Nrec&	No	Req hsp
	Asian		Sitagliptin	Nervous system disorders (神経系障害)	Vertebrobasilar insufficiency (椎骨脳底動脈不全)	29			Mild	No	None	Yes	Nrec	No	Req hsp
1245_002 0_023066	Asian	53/M	Sitagliptin	Neoplasms benign, malignant and unspecified (incl cysts and polyps) (良性、悪性および詳細不明の新生物 (嚢胞およびポリープを含む))	Gastroesophageal cancer (胃食道癌)	257	3097	537	Sev	No	None	Yes	Nrec&	No	Other
Comment: SUBJECT WAS SUFFERING FROM LOSS OF APPETITE, NAUSEA, VOMITING AND DIFFICULTY IN SWALLOWING. ENDOSCOPY SHOWED A GROWTH IN OESOPHAGUS GASTRIC JUNCTION. HISTOPATHOLOGIC REPORTS CONFIRMED NEOPLASTIC CHANGES															
1245_002 0_023659	Asian	63/M	Post trt	General disorders and administration site conditions (一般・全身障害および投与部位の状態)	Hernia (ヘルニア)	43	54	12	Mod	No	Disc	Yes	Rcver	No	Req hsp

@ Related to start of treatment, 7 = censored, # = Lost to follow up, & = Follow up sufficient
Episodes with a negative start day are not assigned to the analysing treatment.

MedDRA version used for reporting: [REDACTED]

Listing 3.2.1 Adverse event episodes by treatment and patient - serious event only (naive)- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Sitagliptin

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_002 0_023659	Asian	63/M	Post trt (障害)	Reproductive system and breast disorders (生殖系および乳房 障害)	Benign prostatic hyperplasia (良性前立腺肥大症)	43	54	12	Mod	No	Disc	Yes	Rcver	No	Req hsp
1245_002 0_024110	Asian	51/F	Sitagliptin	Gastrointestinal disorders (胃腸障害)	Colonic polyp (結腸ポリープ)	117	132	16	Mild	No	None	Yes	Rcver	No	Req hsp

Comment: THE PATIENT WAS HOSPITALIZED ON 27 DEC 2014, BECAUSE COLONIC POLYPS.

@ Related to start of treatment, 7 = censored, # = Lost to follow up, & = Follow up sufficient

Episodes with a negative start day are not assigned to the analysing treatment.

MedDRA version used for reporting: 20.0

Listing 3.2.2 Adverse event episodes by treatment and patient - serious event only (pioglitazon)- treated set

Treatment analysis: 1st rec., 7 day WO, active only

Treatment: Placebo

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_001 9_010206	White	62/F	Placebo	Injury, poisoning and procedural complications (	Traumatic fracture (	81	165	7	Sev	No	Disc	Yes	Nrec&	No	Req hsp
傷害、中毒および 処置合併症) Comment: PATIENT SLIPPED ON A SOAPY WET FLOOR IN A RESTAURANT. DISCLOCATED AND FRACTURED ANKLE - SURGICAL REPAIR NEEDED. TRAUMATIC INJURY. FOLLOW UP WITH PATIENT NOV 21, 2010.															
1245_001 9_010677	White	70/F	Placebo	Infections and infestations (	Pyелonephritis acute (	118	130	13	Sev	Yes	Disc	Yes	Rcver	No	Req hsp
感染症および寄生 急性腎盂腎炎) 虫症) Comment: PERSISTING UTI (PROBABLY DUE TO PARTIAL TREATMENT) RESULTED TO SEVERE AC. PYEL. PATIENT WAS HOSPITALIZED AND RECEIVED IV ANTIBIOTICS. FULLY RECOVERED FROM A.P. DURING HOSPITALISATION AND WAS RELEASED.															
1245_001 9_010831	Asian	51/F	Placebo	Infections and infestations (	Urinary tract infection (	210	224	15	Mod	No	None	Yes	Rcver	No	Req hsp
感染症および寄生 尿路感染) 虫症) Comment: BURNING MICTURITION, INCREASED FREQUENCY OF URINATION 7-8 TIMES FROM 3 DAYS															
	Asian		Placebo	Gastrointestinal disorders (	Gastritis (	216	224	9	Sev	Yes	None	Yes	Rcver	No	Req hsp
胃腸障害) 胃炎)															
1245_001 9_010833	Asian	34/F	Placebo	Gastrointestinal disorders (	Anal fissure (	121	174	54	Mild	No	None	Yes	Rcver	No	Req hsp
胃腸障害) 裂肛)															
1245_001 9_011031	Asian	45/M	Placebo	Injury, poisoning and procedural complications (	Humerus fracture (上腕骨骨折)	8	259	252	Sev	No	None	Yes	Rcver	No	Other
傷害、中毒および 処置合併症) Comment: ALLEGED HISTORY OF RTA ON 10-3-2010 FOLLOWING WHICH HE HAD PAIN AND SWELLING IN L SHOULDER JOINT , DIAGNOSIS WAS GIVEN AS TRAUMATIC FRACTURE OF GREATER TUBEROSITY OF LEFT HUMERUS AND PROXIMAL PHALANX.															

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 Episodes with a negative start day are not assigned to the analysing treatment.

MedDRA version used for reporting: 20.0

Listing 3.2.2 Adverse event episodes by treatment and patient - serious event only (pioglitazon)- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Placebo

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_001 9_011031	Asian	45/M	Placebo	Injury, poisoning and procedural complications (	Hand fracture (	8	259	252	Sev	No	None	Yes	Rcver	No	Other
傷害、中毒および 処置合併症) Comment: ALLEGED HISTORY OF RTA ON 10-3- FOLLOWING WHICH HE HAD PAIN AND SWELLING IN L SHOULDER JOINT , DIAGNOSIS WAS GIVEN AS TRAUMATIC FRACTURE OF GREATER TUBEROSITY OF LEFT HUMERUS AND PROXIMAL PHALANX.															
	Asian		Placebo	Injury, poisoning and procedural complications (	Road traffic accident (	8	259	252	Sev	No	None	Yes	Rcver	No	Other
交通事故) 傷害、中毒および 処置合併症) Comment: ALLEGED HISTORY OF RTA ON 09-3- FOLLOWING WHICH HE HAD PAIN AND SWELLING IN LEFT SHOULDER JOINT , HIS DIAGNOSIS WAS GIVEN AS FRACTURE OF GREATER TUBEROSITY OF LEFT HUMERUS AND PROXIMAL PHALANX.															
1245_001 9_011081	Asian	55/F	Placebo	Skin and subcutaneous tissue disorders (	Skin ulcer (	161	183	23	Mod	No	Disc	Yes	Fatal	No	Fatal
皮膚および皮下組 織障害) Comment: SUBJECT IS DEAD															
	Asian		Placebo	Cardiac disorders (	Myocardial ischaemia (	170	183	14	Sev	Yes	None	Yes	Fatal	No	Fatal
心臓障害) 心筋虚血) Comment: SUBJECT IS DEAD															
	Asian		Placebo	Investigations (	Haemoglobin decreased (	170	183	14	Mild	No	None	No	Fatal	No	Fatal
臨床検査) ヘモグロビン減少) Comment: SUBJECT IS DEAD															

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 Episodes with a negative start day are not assigned to the analysing treatment.
 MedDRA version used for reporting:

Listing 3.2.2 Adverse event episodes by treatment and patient - serious event only (pioglitazon)- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Placebo

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_001 9_011255	Asian	51/F	Placebo	Hepatobiliary disorders (肝 胆道系障害)	Cholecystitis acute (急性胆 囊炎)	47	51	5	Sev	No	None	Yes	Rcver	No	Req hsp
1245_001 9_011296	Asian	55/F	Placebo	Gastrointestinal disorders (胃 腸障害)	Constipation (便秘)	3	195	193	Sev	Yes	None	Yes	Rcver	No	Req hsp
Comment: SUBJECT WAS READMITTED AT A HIGHER CENTER ON 07FEB20 FOR DIAGNOSTIC WORK-UP ONLY (COLONOSCOPY)/STARTED AFTER VISIT 3; CONFIRMED BY COLONOSCOPY DATED 07FEB20															
1245_001 9_011308	Asian	58/F	Placebo	Cardiac disorders (心 臓障害)	Acute myocardial infarction (急性 心筋梗塞)	241	247	7	Sev	No	None	Yes	Rcver	No	Req hsp
1245_001 9_011455	White	61/F	Placebo	Infections and infestations (感 染症および寄生 虫症)	Pneumonia (肺炎)	359	372	14	Sev	No	None	Yes	Rcver	No	Req hsp

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Episodes with a negative start day are not assigned to the analysing treatment.
MedDRA version used for reporting:

Listing 3.2.2 Adverse event episodes by treatment and patient - serious event only (pioglitazon)- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Empa 10mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_001 9_010070	White	64/M	Empa 10mg	Infections and infestations (	Urosepsis (	153	160	8	Sev	Yes	Disc	Yes	Rcver	No	Req hsp
虫症) Comment: SYMPTOMATIC UROSEPSIS WITH HIGH FEVERS ELEVATED LACTATE AND HAEMODYNAMIC LIABILITY, CULTURES WERE NEGATIVE. GIVEN IV FLUIDS AND ANTIBIOTICS AT ADMISSION.IP WAS DISCONTINUED.															
1245_001 9_010079	White	60/M	Empa 10mg	Musculoskeletal and connective tissue disorders (	Arthralgia (	117	121	5	Mild	No	None	Yes	Rcver	No	Req hsp
筋骨格系および結 合組織障害)															
	White		Empa 10mg	Musculoskeletal and connective tissue disorders (	Joint swelling (	117	121	5	Mild	No	None	Yes	Rcver	No	Req hsp
筋骨格系および結 合組織障害)															
1245_001 9_010139	Asian	65/F	Empa 10mg	Eye disorders (	Diabetic retinopathy (	68	68	1	Sev	No	None	Yes	Rcver	No	Req hsp
眼障害) Comment: THERAPY FOR EVENT WAS LEFT VITRECTOMY															
1245_001 9_010814	Asian	45/F	Empa 10mg	Infections and infestations (	Amoebic colitis (	96	112	17	Mod	Yes	None	Yes	Rcver	No	Req hsp
感染症および寄生 虫症) アメーバ性大腸炎)															
	Asian		Empa 10mg	Infections and infestations (	Cervicitis (	324	350	27	Mild	No	None	Yes	Rcver	No	Req hsp
感染症および寄生 虫症) Comment: GTI. SUBJECT UNDERWENT HYSTERECTOMY ON 19 FEB 20██.															

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Episodes with a negative start day are not assigned to the analysing treatment.

MedDRA version used for reporting: ████

Listing 3.2.2 Adverse event episodes by treatment and patient - serious event only (pioglitazon)- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Empa 10mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_001 9_010814	Asian	45/F	Empa 10mg	Reproductive system and breast disorders (生殖系および乳房 障害)	Endometrial hyperplasia (子宮内膜増殖症)	324	350	27	Mod	No	None	Yes	Rcver	No	Req hsp
1245_001 9_010821	Asian	50/M	Empa 10mg	Hepatobiliary disorders (肝胆道系障害)	Cholecystitis (胆嚢炎)	72	99	28	Mild	No	None	Yes	Rcver	No	Req hsp
1245_001 9_011276	Asian	64/F	Empa 10mg	Hepatobiliary disorders (肝胆道系障害)	Liver injury (肝損傷)	220	260	41	Mild	No	None	No	Rcver	No	Other
Comment: THERE WAS A THREEFOLD INCREASE OF SGPT AND SGOT COMPARED TO BASELINE ON THE PATIENT'S SERUM COLLECTED ON 14-OCT-2011. THIS IS A PROTOCOL DEFINED SIGNIFICANT AE															
1245_001 9_011333	Asian	65/F	Empa 10mg	Cardiac disorders (心臓障害)	Coronary artery disease (冠動脈疾患)	212			Mild	No	None	Yes	Nrec	No	Req hsp
1245_001 9_011539	White	56/M	Empa 10mg	Infections and infestations (感染症および寄生 虫症)	Cellulitis (蜂巣炎)	147	277	131	Sev	No	None	Yes	Rcver	No	Req hsp
Comment: AE STARTED 03-OCT-2011. THE PATIENT WAS ABROAD. ON 10-OCT-2011 CAME TO THE HOSPITAL. PATIENT HAS BEEN HOSPITALIZED IN SURGICAL DEPARTMENT															
1245_001 9_011851	White	72/M	Empa 10mg	Musculoskeletal and connective tissue disorders (筋骨格系および結 合組織障害)	Musculoskeletal chest pain (筋骨格系胸痛)	161	162	2	Mod	No	None	No	Rcver	No	Req hsp
Comment: SUBJECT EXPERIENCE CHEST PAIN AND WENT TO THE EMERGENCY ROOM. SUBJECT WAS HELD OVER NIGHT FOR OBSERVATION AND RELEASED THE NEXT DAY.PER HOSPITAL RECORD DISCHARGE DIAGNOSIS IS MUSCULOSKETAL CHEST PAIN															

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Episodes with a negative start day are not assigned to the analysing treatment.

MedDRA version used for reporting: 20.1

Listing 3.2.2 Adverse event episodes by treatment and patient - serious event only (pioglitazon)- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Empa 25mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_001 9_010813	Asian	40/M	Empa 25mg	Infections and infestations (	Dengue fever (	35			Sev	No	Disc	Yes	Unk	No	Req hsp
				感染症および寄生 虫症)	デング熱)										
	Asian		Empa 25mg	Infections and infestations (	Septic shock (	35			Sev	No	Disc	Yes	Unk	No	Req hsp
				感染症および寄生 虫症)	敗血症性ショック										
	Asian		Post trt	Cardiac disorders (	Atrial fibrillation (	39			Sev	No	None	Yes	Unk	No	Prol hsp
				心臓障害)	心房細動)										
	Asian		Post trt	Cardiac disorders (	Atrial flutter (	39			Sev	No	None	Yes	Unk	No	Prol hsp
				心臓障害)	心房粗動)										
	Asian		Post trt	Cardiac disorders (	Cardio- respiratory arrest (	40	40	1	Sev	No	None	Yes	Fatal	No	Fatal
				心臓障害)	心肺停止)										
1245_001 9_010819	Asian	59/F	Empa 25mg	Cardiac disorders (	Angina unstable (不安定狭心症)	234	239	6	Mild	No	None	Yes	Rcver	No	Req hsp
				心臓障害)											
1245_001 9_010820	Asian	48/F	Empa 25mg	Cardiac disorders (	Myocardial ischaemia (	3	12	10	Mild	No	Disc	Yes	Rcver	No	Req hsp
				心臓障害)	心筋虚血)										
	Asian		Empa 25mg	Vascular disorders (	Haematoma (	12	20	9	Mild	No	None	Yes	Seq	No	Prol hsp
				血管障害)	血腫)										
	Asian		Empa 25mg	Vascular disorders (	Haematoma (	27	99	73	Mild	No	None	Yes	Rcver	No	Req hsp
				血管障害)	血腫)										

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Episodes with a negative start day are not assigned to the analysing treatment.

MedDRA version used for reporting: [REDACTED]

Listing 3.2.2 Adverse event episodes by treatment and patient - serious event only (pioglitazon)- treated set

Treatment analysis: 1st rec., 7 day WO, active only

Treatment: Empa 25mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_001 9_010820	Asian	48/F	Empa 25mg	Infections and infestations (	Pseudomonas infection (	27	99	73	Mild	No	None	Yes	Rcver	No	Req hsp
			虫症)	感染症および寄生 虫症)	シュードモナス感 染)										
	Asian		Post trt	Infections and infestations (	Cellulitis (	38	53	16	Mod	No	None	Yes	Rcver	No	Req hsp
			虫症)	感染症および寄生 虫症)	蜂巣炎)										
1245_001 9_010941	Asian	58/F	Empa 25mg	Nervous system disorders (	Brain stem infarction (	27	99	73	Sev	No	None	Yes	Rcver	No	Req hsp
				神経系障害)	脳幹梗塞)										
Comment: THE SAE EVENT ACUTE RIGHT HEMIPARESIS AND INFARCT IN THE LFT HALF OF PONS IS ONE AND THE SAME.THEY ARE NOT 2 SEPARATE EVENTS AND HENCE WE CANNOT GIVE 2 SEPARATE STOP DATES.															
1245_001 9_011007	Asian	54/F	Empa 25mg	Ear and labyrinth disorders (	Vertigo positional (	247	251	5	Mod	No	None	Yes	Rcver	No	Req hsp
				耳および迷路障害 い)	頭位性回転性めま										
	Asian		Empa 25mg	Ear and labyrinth disorders (	Vertigo positional (	247	251	5	Sev	No	None	Yes	Rcver	No	Req hsp
				耳および迷路障害 い)	頭位性回転性めま										

@ Related to start of treatment, 7 = censored, * = partial date or missing date/time imputed, # = Lost to follow up, & = Follow up sufficient
Episodes with a negative start day are not assigned to the analysing treatment.

MedDRA version used for reporting: [REDACTED]

Listing 3.2.2 Adverse event episodes by treatment and patient - serious event only (pioglitazon)- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Empa 25mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_001 9_011116	Asian	64/F	Empa 25mg	Neoplasms benign, malignant and unspecified (incl cysts and polyps) (	Breast cancer (	59	207	149	Sev	No	None	No	Nrec	No	Other
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)) Comment: FOR THIS AE PATIENT WOULD REQUIRE HOSPITALISATION FOR SURGERY FOLLOWED BY CHEMOTHEROPY.THE PATIENT WILL BE FOLLOWED UP IN THE EXTENSION TRIAL (1245.31).															
	Asian		Empa 25mg	Neoplasms benign, malignant and unspecified (incl cysts and polyps) (	Breast cancer (	59			Sev	No	None	No	Nrec	No	Other
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)) Comment: FOR THIS AE PATIENT WOULD REQUIRE HOSPITALISATION FOR SURGERY FOLLOWED BY CHEMOTHEROPY															
1245_001 9_011542	White	62/M	Empa 25mg	Skin and subcutaneous tissue disorders (	Diabetic foot (	290			Mod	No	None	Yes	Nrec	No	Req hsp
皮膚および皮下組 織障害)															
1245_001 9_012054	White	74/M	Empa 25mg	Gastrointestinal disorders (	Oesophageal rupture (	66*	208	143*	Sev	No	Disc	Yes	Fatal	No	Fatal/Imm thrt/Req hsp/Prol hsp
胃腸障害) 食道破裂)															

@ Related to start of treatment, 7 = censored, * = partial date or missing date/time imputed, # = Lost to follow up, & = Follow up sufficient
 Episodes with a negative start day are not assigned to the analysing treatment.
 MedDRA version used for reporting: ■■■■

Listing 3.2.2 Adverse event episodes by treatment and patient - serious event only (pioglitazon)- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Empa 25mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_001 9_012190	White	46/M	Empa 25mg	General disorders and administration site conditions (一般・全身障害お よび投与部位の状 態)	Chest pain (胸痛)	342	345	4	Mod	No	None	Yes	Rcver	No	Req hsp
1245_001 9_012357	White	77/M	Empa 25mg	Investigations (臨床検査)	Haemoglobin decreased (ヘモグロビン減少)	163	165	3	Mod	No	None	Yes	Rcver	No	Req hsp

Comment: SUBJECT WAS HOSPITALIZED FOR LOW HAEMOGLOBIN.

@ Related to start of treatment, 7 = censored, * = partial date or missing date/time imputed, # = Lost to follow up, & = Follow up sufficient
Episodes with a negative start day are not assigned to the analysing treatment.
MedDRA version used for reporting: [REDACTED]

Listing 3.2.3 Adverse event episodes by treatment and patient - serious event only (Metformin only)- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Placebo

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_002 3_030031	White	71/F	Placebo	Musculoskeletal and connective tissue disorders (筋骨格系および結 合組織障害)	Foot deformity (足変形)	134	141	8	Sev	No	None	Yes	Rcver	No	Req hsp
1245_002 3_030075	White	64/M	Placebo	Injury, poisoning and procedural complications (傷害、中毒および 処置合併症)	Fall (転倒)	193	193	1	Mod	No	None	No	Rcver	No	Req hsp
	White		Placebo	Injury, poisoning and procedural complications (傷害、中毒および 処置合併症)	Tibia fracture (脛骨骨折)	193	326	134	Mod	No	Disc	Yes	Rcver	No	Req hsp
Comment: FALL FROM A LADDER IS THE REASON FOR THIS FRACTURE, TRAUMATIC FRACTURE															
1245_002 3_030076	White	76/M	Placebo	Cardiac disorders (心臓障害)	Acute myocardial infarction (急性心筋梗塞)	341	352	12	Sev	No	None	No	Rcver	No	Req hsp
1245_002 3_030181	White	64/M	Post trt	Hepatobiliary disorders (肝胆道系障害)	Hepatitis toxic (中毒性肝炎)	128	223	96	Sev	No	Disc	Yes	Rcver	No	Req hsp
1245_002 3_030305	White	57/M	Placebo	Ear and labyrinth disorders (耳および迷路障害)	Vertigo (回転性めまい)	237	244	8	Mod	No	None	Yes	Rcver	No	Req hsp

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Episodes with a negative start day are not assigned to the analysing treatment.

MedDRA version used for reporting: [REDACTED]

Listing 3.2.3 Adverse event episodes by treatment and patient - serious event only (Metformin only)- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Placebo

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_002 3_030350	White	70/M	Placebo	Renal and urinary disorders (	Nephrolithiasis (腎結石症)	277	312	36	Sev	No	None	Yes	Rcver	No	Req hsp
) Comment: HOSPITALIZATION 27-DEC-2010 - 04-JAN-2011;															
	White		Placebo	Nervous system disorders (	Transient ischaemic attack (一過性脳虚血発作)	281	281	1	Mod	No	None	Yes	Rcver	No	Prol hsp
) Comment: POSTOPERATIVE HYPOVOLEMNIA AND TRANSIENT CEREBRAL BLOOD FLOW DECREASE CAUSED TIA MANIFESTED BY DESORIENTATION AND SPEECH PROBLEMS															
1245_002 3_030638	White	66/M	Placebo	General disorders and administration site conditions (	Non-cardiac chest pain (	112	115	4	Sev	No	None	Yes	Rcver	No	Req hsp
一般・全身障害および投与部位の状態)															
1245_002 3_031247	White	69/F	Placebo	Cardiac disorders (	Coronary artery disease (	402	402	1	Mod	No	None	Yes	Rcver	No	Req hsp
心臓障害) 冠動脈疾患) Comment: 2 STENTS WERE DONE ON 2-FEB-2011.															
1245_002 3_031429	White	74/F	Placebo	Cardiac disorders (	Cardiac failure congestive (	37	40	4	Sev	No	Disc	No	Rcver	No	Req hsp
心臓障害) うっ血性心不全)															
1245_002 3_032249	Asian	75/F	Placebo	Immune system disorders (	Hypersensitivity (過敏症)	6	16	11	Mod	Yes	Disc	Yes	Rcver	No	Req hsp
免疫系障害)															

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Episodes with a negative start day are not assigned to the analysing treatment.

MedDRA version used for reporting: 20.0

Listing 3.2.3 Adverse event episodes by treatment and patient - serious event only (Metformin only)- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Placebo

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_002 3_032429	Asian	49/F	Placebo	Endocrine disorders (	Empty sella syndrome (	276	321	46	Mild	No	None	Yes	Rcver	No	Req hsp
				内分泌障害)	エンブティセラ症候群)										
	Asian		Placebo	Nervous system disorders (	Cerebral ischaemia (	307			Mild	No	None	Yes	Nrec	No	Req hsp
				神経系障害)	脳虚血)										
1245_002 3_033061	White	61/M	Placebo	Cardiac disorders (	Myocardial ischaemia (	189			Mod	No	None	Yes	Nrec	No	Req hsp
				心臓障害)	心筋虚血)										
	White		Placebo	Cardiac disorders (	Prinzmetal angina (	189			Mod	No	None	Yes	Nrec	No	Req hsp
				心臓障害)	プリンツメタル狭心症)										
1245_002 3_035003	White	51/F	Placebo	Reproductive system and breast disorders (	Postmenopausal haemorrhage (	404	423	20	Mild	No	None	No	Rcver	No	Req hsp
				生殖系および乳房障害)	閉経後出血)										
1245_002 3_036040	Asian	43/F	Placebo	Infections and infestations (	Cellulitis (	69	102	34	Mod	No	None	Yes	Rcver	No	Req hsp
				感染症および寄生虫症)	蜂巣炎)										
Comment: PATIENT CAME TO OPD WITH COMPLAINT OF PAIN IN PERIANAL REGION AND DIFFICULTY IN WALKING.ON LOCAL EXAMINATION SWELLING+, REDNESS+,TENDERNESS															
	Asian		Placebo	Infections and infestations (	Anal abscess (	69	102	34	Mod	No	None	Yes	Rcver	No	Req hsp
				感染症および寄生虫症)	肛門膿瘍)										
Comment: PATIENT CAME TO OPD WITH COMPLAINT OF PAIN IN PERIANAL REGION AND DIFFICULTY IN WALKING.ON LOCAL EXAMINATION SWELLING+, REDNESS+,TENDERNESS															

@ Related to start of treatment, 7 = censored, * = partial date or missing date/time imputed, # = Lost to follow up, & = Follow up sufficient
Episodes with a negative start day are not assigned to the analysing treatment.
MedDRA version used for reporting: █

Listing 3.2.3 Adverse event episodes by treatment and patient - serious event only (Metformin only)- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Placebo

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_002 3_036040	Asian	43/F	Placebo	Infections and infestations (	Sepsis (敗血症)	69	102	34	Mod	No	None	Yes	Rcver	No	Req hsp
虫症) Comment: PATIENT CAME TO OPD WITH COMPLAINT OF PAIN IN PERIANAL REGION AND DIFFICULTY IN WALKING.ON LOCAL EXAMINATION SWELLING+, REDNESS+,TENDERNESS															
1245_002 3_037496	Asian	60/F	Post trt	Cardiac disorders (	Myocardial infarction (	117	149	33	Sev	Yes	Disc	Yes	Rcver	No	Req hsp
				心臓障害)	心筋梗塞)										
1245_002 3_037680	Asian	51/F	Placebo	Nervous system disorders (	Carotid artery disease (	179	215	37	Mod	No	None	Yes	Rcver	No	Req hsp
				神経系障害)	頸動脈疾患)										

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 Episodes with a negative start day are not assigned to the analysing treatment.

MedDRA version used for reporting: [REDACTED]

Listing 3.2.3 Adverse event episodes by treatment and patient - serious event only (Metformin only)- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Empa 10mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_002 3_030233	White	60/M	Empa 10mg	Endocrine disorders (	Goitre (	224	228	5	Sev	No	None	Yes	Rcver	No	Req hsp
Comment: ON 27-JUL-2012 THYROIDECTOMY; HOSPITALIZATION FROM 27-JUL-2012 - 29-JUL-2012															
	White		Empa 10mg	Musculoskeletal and connective tissue disorders (	Osteoarthritis (	262	318	57	Mod	No	None	Yes	Rcver	No	Req hsp
Comment: HOSPITALIZATION 04-OCT-2012 - 27-OCT-2012 FOR TEP SURGERY															
	White		Empa 10mg	Musculoskeletal and connective tissue disorders (	Osteoarthritis (	372	416	45	Mod	No	None	Yes	Rcver	No	Req hsp
Comment: HOSPITALIZATION 18-JAN-2013 - 02-FEB-2013; 19-JAN-2013 TEP LEFT															
1245_002 3_030272	White	46/M	Empa 10mg	Vascular disorders (	Hypertension (	514	515	2	Mod	No	None	No	Rcver	No	Req hsp
	White		Empa 10mg	Musculoskeletal and connective tissue disorders (	Spinal osteoarthritis (	514	518	5	Mod	No	None	No	Rcver	No	Req hsp
1245_002 3_030332	White	62/F	Empa 10mg	Infections and infestations (	Urosepsis (	260	267	8	Mild	Yes	None	Yes	Rcver	No	Req hsp
Comment: HOSPITALIZATION 06-SEP-2012 - 13-SEP-2012. UTI CONFIRMED BY URINE CULTURE															

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Episodes with a negative start day are not assigned to the analysing treatment.
MedDRA version used for reporting: 20.1

Listing 3.2.3 Adverse event episodes by treatment and patient - serious event only (Metformin only)- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Empa 10mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_002 3_030336	White	63/M	Empa 10mg	Reproductive system and breast disorders (生殖系および乳房 障害)	Benign prostatic hyperplasia (良性前立腺肥大症)	111*	151	41*	Mod	No	None	Yes	Rcver	No	Req hsp
Comment: HOSPITALIZATION 05-JUN-2011 - 10-JUN-2011. ON 07-JUN-2011 TRANSURETHAL PROSTATECTOMY (TUR)															
1245_002 3_030983	White	67/M	Post trt	Cardiac disorders (心臓障害)	Coronary artery disease (冠動脈疾患)	211			Sev	Yes	Disc	Yes	Nrec	No	Req hsp
Comment: SUBJECT WAS TREATED WITH A CABG.															
1245_002 3_031612	White	55/M	Empa 10mg	Neoplasms benign, malignant and unspecified (incl cysts and polyps) (良性、悪性および 詳細不明の新生物 (嚢胞およびポリ ーブを含む))	Colon cancer (結腸癌)	363			Sev	No	None	Yes	Nrec	No	Other
Comment: DIAGNOSIS OF CANCER IS SAE															
1245_002 3_032151	Asian	39/M	Empa 10mg	Injury, poisoning and procedural complications (傷害、中毒および 処置合併症)	Comminuted fracture (粉碎骨折)	117	1287	127	Sev	No	Disc	Yes	Nrec&	No	Req hsp
Comment: THE FRACTURE IS TRAUMATIC.															
1245_002 3_032200	Asian	52/F	Empa 10mg	Nervous system disorders (神経系障害)	Lacunar infarction (ラクナ梗塞)	50	65	16	Sev	No	None	Yes	Rcver	No	Req hsp
Comment: SYMPTOMS:DIZZY,BLURRED VISION,NAUSEA															

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Episodes with a negative start day are not assigned to the analysing treatment.

MedDRA version used for reporting: 20.0

Listing 3.2.3 Adverse event episodes by treatment and patient - serious event only (Metformin only)- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Empa 10mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_002 3_032584	Asian	61/F	Empa 10mg	Cardiac disorders (	Angina unstable (不安定狭心症)	63	74	12	Sev	No	None	Yes	Rcver	No	Req hsp
Comment: SHE WAS HOSPITALIZED ON 13-JUL-2014 FOR THE FURTHER EXAMINATION AND TREATMENT.STOPPED TAKING THE TRIAL DRUG ON 14-JUL-2014.RECEIVED SELECTIVE CORONARY ANGIOGRPHY+PTCA+STENT ON 19-JUL-2014 SUCCESSFULLY															
1245_002 3_032815	Asian	53/M	Empa 10mg	Infections and infestations (	Herpes zoster (	337	372	36	Mild	No	None	Yes	Rcver	No	Req hsp
				感染症および寄生 虫症)	带状疱疹)										
1245_002 3_034136	Asian	53/M	Empa 10mg	Nervous system disorders (	Trigeminal neuralgia (	156	169	14	Mod	No	None	Yes	Rcver	No	Req hsp
				神経系障害)	三叉神経痛)										
1245_002 3_034764	Asian	49/F	Empa 10mg	Injury, poisoning and procedural complications (	Fall (転倒)	123	123	1	Mild	No	None	No	Rcver	No	Req hsp
				傷害、中毒および 処置合併症)											
		Asian	Empa 10mg	Injury, poisoning and procedural complications (	Facial bones fracture (	123	134	12	Mild	No	None	Yes	Rcver	No	Req hsp
				傷害、中毒および 処置合併症)	顔面骨折)										
Comment: THIS EVENT WAS TRAUMATIC EVENT.															
1245_002 3_035531	White	71/M	Empa 10mg	Cardiac disorders (	Cardiac failure (心不全)	228	230	3	Mild	No	None	Yes	Rcver	No	Req hsp
				心臓障害)											
		White	Empa 10mg	Cardiac disorders (	Congestive cardiomyopathy (	228			Mild	No	None	No	Nrec	No	Req hsp
				心臓障害)	うつ血性心筋症)										

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Episodes with a negative start day are not assigned to the analysing treatment.

MedDRA version used for reporting: 20.0

Listing 3.2.3 Adverse event episodes by treatment and patient - serious event only (Metformin only)- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Empa 10mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_002 3_037272	White	56/F	Empa 10mg	Gastrointestinal disorders (胃腸障害)	Gastrooesophagea l reflux disease (胃食道逆流性疾患)	177			Mod	No	None	Yes	Nrec	No	Req hsp
1245_002 3_037617	Asian	59/M	Empa 10mg	Cardiac disorders (心臓障害)	Arteriosclerosis coronary artery (冠動脈硬化症)	122	138	17	Sev	No	None	Yes	Rcver	No	Req hsp

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 Episodes with a negative start day are not assigned to the analysing treatment.
 MedDRA version used for reporting: [REDACTED]

Listing 3.2.3 Adverse event episodes by treatment and patient - serious event only (Metformin only)- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Empa 25mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_002 3_030002	White	56/M	Empa 25mg	Vascular disorders (血管障害)	Peripheral arterial occlusive disease (末梢動脈閉塞性疾患)	168	169	2	Mild	No	None	No	Rcver	No	Req hsp
1245_002 3_030033	White	58/F	Empa 25mg	Injury, poisoning and procedural complications (傷害、中毒および処置合併症)	Ligament rupture (靱帯断裂)	176	185	10	Sev	No	None	Yes	Rcver	No	Req hsp
	White		Empa 25mg	Injury, poisoning and procedural complications (傷害、中毒および処置合併症)	Tendon rupture (腱断裂)	176	185	10	Sev	No	None	Yes	Rcver	No	Req hsp
1245_002 3_030054	White	61/M	Empa 25mg	Musculoskeletal and connective tissue disorders (筋骨格系および結合組織障害)	Osteoarthritis (変形性関節症)	243	248	6	Mod	No	None	Yes	Rcver	No	Req hsp

@ Related to start of treatment, 7 = censored, * = partial date or missing date/time imputed, # = Lost to follow up, & = Follow up sufficient
Episodes with a negative start day are not assigned to the analysing treatment.

MedDRA version used for reporting: [REDACTED]

Listing 3.2.3 Adverse event episodes by treatment and patient - serious event only (Metformin only)- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Empa 25mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_002 3_030871	White	61/F	Empa 25mg	Neoplasms benign, malignant and unspecified (incl cysts and polyps) (	Breast cancer (	162	2837	1227	Sev	No	None	Yes	Nrec&	No	Other
				良性、悪性および 詳細不明の新生物 (嚢胞およびポリ ーブを含む))	乳癌)										
Comment: SUBJECT WILL BE HAVING RADIATION THERAPY-															
1245_002 3_031254	Asian	68/M	Empa 25mg	Cardiac disorders (	Angina pectoris (狭心症)	141	219	79	Mild	No	None	Yes	Rcver	No	Req hsp
				心臓障害)											
Comment: WORSENING OF PREEXISTING HEART CONDITION ANGINA -ASYMPTOMATIC BUT IN CORONAROGRAPHY FROM 27-09-2013 MULTIPLE VESSELS DISEASE.															
1245_002 3_031423	White	65/F	Empa 25mg	Renal and urinary disorders (	Renal failure acute (	545	552	8	Sev	No	None	Yes	Rcver	No	Req hsp
				腎および尿路障害	急性腎不全)										
	White		Empa 25mg	Metabolism and nutrition disorders (	Dehydration (	545	552	8	Sev	No	None	Yes	Rcver	No	Req hsp
				代謝および栄養障	脱水)										
	White		Empa 25mg	Infections and infestations (	Gastroenteritis (胃腸炎)	545	552	8	Sev	No	None	Yes	Rcver	No	Req hsp
				感染症および寄生											
				虫症)											
	White		Empa 25mg	Nervous system disorders (	Syncope (失神)	545	552	8	Sev	No	None	Yes	Rcver	No	Req hsp
				神経系障害)											

@ Related to start of treatment, 7 = censored, * = partial date or missing date/time imputed, # = Lost to follow up, & = Follow up sufficient
Episodes with a negative start day are not assigned to the analysing treatment.

MedDRA version used for reporting: 20.0

Listing 3.2.3 Adverse event episodes by treatment and patient - serious event only (Metformin only)- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Empa 25mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_002 3_031432	White	65/F	Empa 25mg	Renal and urinary disorders (	Renal failure acute (	176	186	11	Sev	Yes	Disc	Yes	Rcver	No	Req hsp
			)	腎および尿路障害	急性腎不全)										
	White		Post trt	Metabolism and nutrition disorders (	Lactic acidosis (	179	186	8	Sev	Yes	None	No	Rcver	No	Req hsp
				代謝および栄養障	乳酸アシドーシス										
				害)											
	White		Post trt	Skin and subcutaneous tissue disorders (	Skin ulcer (	179	186	8	Sev	No	None	No	Rcver	No	Req hsp
				皮膚および皮下組	皮膚潰瘍)										
				織障害)											
	White		Post trt	Renal and urinary disorders (	Renal tubular necrosis (	179	186	8	Sev	Yes	None	Yes	Rcver	No	Req hsp
				腎および尿路障害	腎尿細管壊死)										
				)											
1245_002 3_032124	Asian	33/M	Placebo	Renal and urinary disorders (	Diabetic nephropathy (	51	73	23	Mild	No	None	Yes	Rcver	No	Req hsp
				腎および尿路障害	糖尿病性腎症)										
				)											
1245_002 3_032310	Asian	60/F	Empa 25mg	Infections and infestations (	Gastroenteritis (	252	259	8	Sev	No	None	Yes	Rcver	No	Req hsp
				感染症および寄生	胃腸炎)										
				虫症)											

@ Related to start of treatment, 7 = censored, * = partial date or missing date/time imputed, # = Lost to follow up, & = Follow up sufficient
Episodes with a negative start day are not assigned to the analysing treatment.

MedDRA version used for reporting: [REDACTED]

Listing 3.2.3 Adverse event episodes by treatment and patient - serious event only (Metformin only)- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Empa 25mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_002 3_033221	White	52/M	Empa 25mg	Neoplasms benign, malignant and unspecified (incl cysts and polyps) (良性、悪性および 詳細不明の新生物 (嚢胞およびポリ ーブを含む))	Prostatic adenoma (前立腺腺腫)	143	176	34	Mild	No	None	Yes	Rcver	No	Req hsp

@ Related to start of treatment, 7 = censored, * = partial date or missing date/time imputed, # = Lost to follow up, & = Follow up sufficient
 Episodes with a negative start day are not assigned to the analysing treatment.
 MedDRA version used for reporting: ■■■■

Listing 3.2.4 Adverse event episodes by treatment and patient - serious event only (Met+SU)- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Placebo

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_002 3_030096	White	76/M	Placebo	Cardiac disorders (	Aortic valve stenosis (	54	193	140	Mod	No	None	Yes	Rcver	No	Req hsp
				心臓障害)	大動脈弁狭窄)										
1245_002 3_030128	White	63/F	Placebo	Nervous system disorders (	Convulsion (	211	211	1	Sev	No	None	Yes	Rcver	No	Req hsp
				神経系障害)	痙攣)										
Comment: SEIZURE INDUCED BY STRONG EFFORT															
	White		Post trt	Cardiac disorders (	Stress cardiomyopathy (	212	233	22	Sev	No	None	Yes	Rcver	No	Req hsp
				心臓障害)	ストレス心筋症)										
Comment: STRESS INDUCED CARDIOMYOPATHY															
1245_002 3_030563	White	76/F	Placebo	Infections and infestations (	Listeria sepsis (	160	181	22	Sev	No	None	Yes	Rcver	No	Req hsp
				感染症および寄生 虫症)	リステリア性敗血 症)										
1245_002 3_031248	Asian	74/M	Placebo	Neoplasms benign, malignant and unspecified (incl cysts and polyps) (	Prostate cancer (前立腺癌)	336			Mod	No	None	Yes	Nrec	No	Req hsp
				良性、悪性および 詳細不明の新生物 (嚢胞およびポリ ーブを含む)											
Comment: IN PRIOR RECORD THE SUBJECT DID HAVE PROSTATE ENLARGMENT WITH SLIGHTLY ELEVATED PSA															
1245_002 3_031451	White	61/F	Placebo	Cardiac disorders (	Myocardial infarction (	78	84	7	Sev	No	Disc	Yes	Rcver	No	Req hsp
				心臓障害)	心筋梗塞)										

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Episodes with a negative start day are not assigned to the analysing treatment.

MedDRA version used for reporting: [REDACTED]

Listing 3.2.4 Adverse event episodes by treatment and patient - serious event only (Met+SU)- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Placebo

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_002 3_031544	White	57/M	Placebo	Nervous system disorders (	Intercostal neuralgia (	42	45	4	Mod	No	None	Yes	Rcver	No	Req hsp
	White		Placebo	Nervous system disorders (	Carpal tunnel syndrome (	169			Mild	No	None	No	Nrec	No	Req hsp
Comment: PATIENT WAS ADMITTED AS AN OUTPATIENT FOR CARPAL TUNNEL REPAIR ON HIS LEFT WRIST ON 15-MAR-2011															
1245_002 3_032303	Asian	55/M	Placebo	Eye disorders (	Lens dislocation (水晶体脱臼)	250	260	11	Sev	No	None	Yes	Rcver	No	Req hsp
1245_002 3_032546	Asian	58/F	Placebo	Infections and infestations (	Herpes zoster (	36	58	23	Mod	No	None	Yes	Rcver	No	Req hsp
				感染症および寄生 虫症)	带状疱疹)										
1245_002 3_032696	Asian	59/F	Placebo	Musculoskeletal and connective tissue disorders (	Osteoarthritis (	111	120	10	Sev	No	None	Yes	Rcver	No	Req hsp
				筋骨格系および結 合組織障害)	変形性関節症)										
Comment: THE PATIENT HAS A PRIOR HISTORY OF DEGENERATIVE OSTEOARTHRITS FOR TEN YEARS, THE PATIENT INCREASED 5 DAYS HOSPITAL.															
1245_002 3_032716	Asian	61/M	Placebo	Endocrine disorders (	Goitre (	22	33	12	Sev	No	None	Yes	Rcver	No	Req hsp
				内分泌障害)	甲状腺腫)										
Comment: THE PATIENT DURING A PHYSICAL EXAMINATION, THE GOITER IS LARGER ON MAY 2011,BUT HE DECIDE HOSPITAL ON JUN 2011															

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Episodes with a negative start day are not assigned to the analysing treatment.
MedDRA version used for reporting: 20.0

Listing 3.2.4 Adverse event episodes by treatment and patient - serious event only (Met+SU)- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Placebo

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_002 3_033062	White	68/M	Placebo	General disorders and administration site conditions (一般・全身障害お よび投与部位の状 態)	Chest pain (胸痛)	162	162	1	Mild	No	None	Yes	Rcver	No	Req hsp
1245_002 3_033131	White	60/F	Run-in	Respiratory, thoracic and mediastinal disorders (呼吸器、 胸郭および縦隔障 害)	Respiratory failure (呼吸不全)	-11	1817	1927	Mod	No	None	Yes	Nrec#	No	Req hsp
1245_002 3_034006	Asian	67/M	Post trt	Neoplasms benign, malignant and unspecified (incl cysts and polyps) (良性、悪 性および詳細不明 の新生物 (嚢胞お よびポリープを含 む))	Colon cancer (結腸 癌)	36	657	307	Sev	No	None	Yes	Nrec&	No	Req hsp
Comment: LAPAROSCOPIC LEFT COLECTOMY AND ANASTOMOSIS ON APRIL 22															
1245_002 3_034072	Asian	73/F	Placebo	Musculoskeletal and connective tissue disorders (筋骨格系および結合組織障 害)	Intervertebral disc protrusion (椎間板突出)	265	267	3	Mod	No	None	Yes	Rcver	No	Req hsp
Comment: OPERATION FOR C3-4-5 DISECTOMY AND INTERBODY FUSION WITH CAGE-PLATE ON 02JAN20															

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Episodes with a negative start day are not assigned to the analysing treatment.

MedDRA version used for reporting:

Listing 3.2.4 Adverse event episodes by treatment and patient - serious event only (Met+SU)- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Placebo

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_002 3_034227	Asian	61/M	Placebo	Infections and infestations (	Pneumonia primary atypical	73	78	6	Mod	No	None	Yes	Rcver	No	Req hsp
	Asian		Placebo	Renal and urinary disorders (	Nephrolithiasis (腎結石症)	270	278	9	Mild	No	None	Yes	Rcver	No	Req hsp
	Asian		Placebo	Infections and infestations (	Urosepsis (	270	278	9	Sev	Yes	None	Yes	Rcver	No	Req hsp
Comment: UTI WAS DIAGNOSED BASED ON THE POSITIVE URINALYSIS RESULT															
1245_002 3_034277	Asian	49/M	Placebo	Infections and infestations (	Urinary tract infection (	209	214	6	Sev	Yes	Disc	Yes	Rcver	No	Req hsp
Comment: 20AUG20 U/A SHOWED RBC 1358/HPF,WBC 3552/HPF.															
1245_002 3_034285	Asian	58/F	Placebo	Musculoskeletal and connective tissue disorders (	Spondylolisthesi s (	183	364	182	Sev	No	None	Yes	Rcver	No	Req hsp
	Asian		Placebo	Cardiac disorders (	Angina pectoris (狭心症)	508	510	3	Mod	No	None	Yes	Rcver	No	Req hsp
	Asian		Placebo	Cardiac disorders (	Prinzmetal angina (	509			Mild	No	None	Yes	Nrec	No	Req hsp

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Episodes with a negative start day are not assigned to the analysing treatment.
MedDRA version used for reporting:

Listing 3.2.4 Adverse event episodes by treatment and patient - serious event only (Met+SU)- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Placebo

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_002 3_034746	Asian	60/F	Placebo	Investigations (臨床検査)	(Smear cervix abnormal (子宮頸部スミア異常)	378	388	11	Mild	No	None	Yes	Rcver	No	Req hsp
1245_002 3_036602	White	51/M	Placebo	Congenital, familial and genetic disorders (先天性、家族性および遺伝性障害)	Hydrocele (陰嚢水瘤)	135	138	4	Sev	No	None	Yes	Rcver	No	Req hsp
1245_002 3_036636	White	55/M	Placebo	Musculoskeletal and connective tissue disorders (筋骨格系および結合組織障害)	Tenosynovitis stenosaurs (狭窄性腱鞘炎)	377	379	3	Mod	No	None	Yes	Rcver	No	Req hsp
1245_002 3_037001	Black/ Africa n Amer.	50/F	Placebo	Investigations (臨床検査)	(Blood creatinine increased (血中クレアチニン増加)	85	116	32	Mod	Yes	Disc	No	Rcver	No	Other
Comment: ELEVATED CREATININE, DECREASED GFR AND BUN AS REPORTED IN SAE FORM IS SIGNIFICANT MEDICAL EVENT															
1245_002 3_037022	White	57/M	Placebo	Renal and urinary disorders (腎および尿路障害)	Cystitis haemorrhagic (出血性膀胱炎)	31	47	17	Sev	No	None	Yes	Rcver	No	Req hsp
Comment: SUBJECT EXPERIENCED BLOOD IN URINE AND EVENTUALLY STOPPED URINATING SO HE WENT TO THE ER. HE WAS ADMITTED FROM 27FEB2011 TO 01MAR2011.															
1245_002 3_037269	White	68/M	Placebo	Infections and infestations (感染症および寄生虫症)	Pneumonia (肺炎)	163	3087	1467	Sev	No	None		Nrec#	No	Req hsp
Comment: NO INFORMATION AVAILABLE FROM HOSPITAL ON TREATMENT REQUIRED TO TREAT															

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 Episodes with a negative start day are not assigned to the analysing treatment.
 MedDRA version used for reporting: 15.0

Listing 3.2.4 Adverse event episodes by treatment and patient - serious event only (Met+SU)- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Empa 10mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_002 3_030061	White	69/M	Empa 10mg	Infections and infestations (感染症および寄生 虫症)	Pneumonia (肺炎)	470	479	10	Mod	No	None	No	Rcver	No	Req hsp
	White		Empa 10mg	Cardiac disorders (心臓障害)	Cardiac failure (心不全)	514	522	9	Mod	No	None	No	Rcver	No	Req hsp
	White		Empa 10mg	Renal and urinary disorders (腎および尿路障害)	Renal failure (腎不全)	514	564	51	Mod	No	Disc	No	Rcver	No	Prol hsp
1245_002 3_030191	White	70/M	Empa 10mg	Congenital, familial and genetic disorders (先天性、家族性および遺伝性障害)	Phimosis (包茎)	40	62	23	Mod	No	None	Yes	Rcver	No	Req hsp
1245_002 3_030240	White	61/F	Empa 10mg	Gastrointestinal disorders (胃腸障害)	Faecaloma (糞塊)	57	59	3	Sev	No	None	Yes	Rcver	No	Req hsp
Comment: DURING THE NIGHT OF 21-FEB-2012, PATIENT DEVELOPPED SEVERE ABDOMINAL PAIN AND REQUESTED HOSPITALISATION ON MORNING 21-FEB-2012. AFTER LAXATION SYMPTOMS IMPROOVED. FURHTER DIAGNOSTICS WITHOUT FINDINGS.															
1245_002 3_030282	White	81/M	Empa 10mg	Vascular disorders (血管障害)	Peripheral arterial occlusive disease (末梢動脈閉塞性疾患)	321*	371	51*	Mod	No	None	Yes	Rcver	No	Req hsp
Comment: HOSPITALISATION FROM 12.03.12 UNTIL 22.03.12															

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Episodes with a negative start day are not assigned to the analysing treatment.

MedDRA version used for reporting: 20.0

Listing 3.2.4 Adverse event episodes by treatment and patient - serious event only (Met+SU)- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Empa 10mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_002 3_030340	White	60/M	Empa 10mg	Respiratory, thoracic and mediastinal disorders (	Upper airway resistance syndrome (	297*	388	92*	Mod	No	None	Yes	Rcver	No	Req hsp
				呼吸器、胸郭および縦隔障害)	上気道抵抗症候群										
Comment: HOSPITALIZATION 09-JAN-20				- 13-JAN-20											
1245_002 3_030565	White	56/M	Empa 10mg	Vascular disorders (	Peripheral arterial occlusive disease (	68	71	4	Mod	No	None	Yes	Rcver	No	Req hsp
				血管障害)	末梢動脈閉塞性疾患)										
White			Empa 10mg	Vascular disorders (	Peripheral arterial occlusive disease (	153	202	50	Mod	No	None	Yes	Rcver	No	Req hsp
				血管障害)	末梢動脈閉塞性疾患)										
1245_002 3_031241	Asian	65/F	Empa 10mg	Musculoskeletal and connective tissue disorders	Back pain (	449	471	23	Sev	No	None	Yes	Rcver	No	Req hsp
				(	背部痛)										
				筋骨格系および結合組織障害)											
Comment: HOSPITALIZATION FROM 09 -JAN-20				TO 28- JAN -20											
1245_002 3_032421	Asian	45/M	Run-in	Cardiac disorders (	Myocardial ischaemia (	-2	12	14	Sev	No	None	Yes	Rcver	No	Req hsp
				心臓障害)	心筋虚血)										
1245_002 3_032592	Asian	56/M	Empa 10mg	Gastrointestinal disorders (	Gastritis (	77	85	9	Mod	No	Disc	Yes	Rcver	No	Req hsp
				胃腸障害)	胃炎)										

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Episodes with a negative start day are not assigned to the analysing treatment.

MedDRA version used for reporting:

Listing 3.2.4 Adverse event episodes by treatment and patient - serious event only (Met+SU)- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Empa 10mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_002 3_032694	Asian	62/F	Empa 10mg	Gastrointestinal disorders (胃腸障害)	Gastritis (胃炎)	133	140	8	Mild	No	None	Yes	Rcver	No	Req hsp
Comment: THE PATIENT IS THE RULE-PATIENT EXAMINATION, ABOUT EVERY SIX MONTHES, DO ENDSOPY IN MARCH, WITHOUT ANY PROBLEM,ON 15 AUG 2013 SHOW INTESTINAL ENDOSCOPY IN THE EXPANSION,THEN ADMITTED TO HOSPITAL															
	Asian		Empa 10mg	Gastrointestinal disorders (胃腸障害)	Duodenal ulcer (十二指腸潰瘍)	133	140	8	Mild	No	None	Yes	Rcver	No	Req hsp
Comment: THE PATIENT IS THE RULE-PATIENT EXAMINATION, ABOUT EVERY SIX MONTHES, DO ENDSOPY IN MARCH, WITHOUT ANY PROBLEM,ON 15 AUG 2013 SHOW INTESTINAL ENDOSCOPY IN THE EXPANSION,THEN ADMITTED TO HOSPITAL.															
1245_002 3_032719	Asian	61/M	Empa 10mg	Nervous system disorders (神経系障害)	Dizziness (浮動性めまい)	37	174?	138?	Mild	No	None	Yes	Nrec#	No	Req hsp
Comment: THE PATIENT WAS CHECKED ELECTROENCEPHALOGRAM AND REHEOENCEPHALOGRAM,HE DIDN'T FIND HYPOGLYCEMIA WITH DIZZINESS FINALLY															
1245_002 3_033592	White	56/F	Empa 10mg	Cardiac disorders (心臓障害)	Acute myocardial infarction (急性心筋梗塞)	65	65	1	Sev	No	Disc	No	Fatal	No	Fatal
Comment: PATIENT STARTED ON 13APR2013 AT 00:30 WITH SEVERE PRECORDIAL PAIN AND DYSPNEA, WITHOUT ANY ADDITIONAL TREATMENT, REQUESTING AN AMBULANCE, BUT PATIENT DIED AT 01:15 PREVIOUS TO AMBULANCE ARRIVAL															
1245_002 3_034011	Asian	60/F	Empa 10mg	Infections and infestations (感染症および寄生虫)	Cellulitis (蜂巣炎)	213	226	14	Mild	No	None	Yes	Rcver	No	Req hsp
1245_002 3_034123	Asian	48/F	Empa 10mg	Nervous system disorders (神経系障害)	Syringomyelia (脊髓空洞症)	133	141	9	Sev	No	None	Yes	Rcver	No	Req hsp

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Episodes with a negative start day are not assigned to the analysing treatment.

MedDRA version used for reporting: 20.1

Listing 3.2.4 Adverse event episodes by treatment and patient - serious event only (Met+SU)- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Empa 10mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_002 3_034123	Asian	48/F	Empa 10mg	Injury, poisoning and procedural complications (	Neck injury (	133	141	9	Sev	No	None	Yes	Rcver	No	Req hsp
				傷害、中毒および 処置合併症)	頸部損傷)										
	Asian		Empa 10mg	Injury, poisoning and procedural complications ()	Post-traumatic neck syndrome (	133	141	9	Sev	No	None	No	Rcver	No	Req hsp
				傷害、中毒および 処置合併症)	外傷後頸部症候群										
	Asian		Empa 10mg	Nervous system disorders (	Syringomyelia (	261	271	11	Sev	No	None	Yes	Rcver	No	Req hsp
				神経系障害)	脊髄空洞症)										
1245_002 3_034124	Asian	52/M	Empa 10mg	Neoplasms benign, malignant and unspecified (incl cysts and polyps) (	Anaplastic large cell lymphoma T- and null-cell types (	184	210	27	Sev	No	None	No	Seq	No	Req hsp
				ンバ腫、T細胞お 良性、悪性および よびヌル細胞型) 詳細不明の新生物 (嚢胞およびボリ ープを含む))	未分化大細胞型リ ンパ腫、T細胞お よびヌル細胞型)										
1245_002 3_034754	Asian	48/F	Empa 10mg	Musculoskeletal and connective tissue disorders (	Lumbar spinal stenosis (	429	474	46	Mod	No	None	Yes	Rcver	No	Req hsp
				筋骨格系および結 合組織障害)	腰部脊柱管狭窄症										

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Episodes with a negative start day are not assigned to the analysing treatment.

MedDRA version used for reporting: ■■■■

Listing 3.2.4 Adverse event episodes by treatment and patient - serious event only (Met+SU)- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Empa 10mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_002 3_034836	Asian	50/F	Empa 10mg	Psychiatric disorders (	Stress (	144	188	45	Mild	No	None	Yes	Rcver	No	Req hsp
				精神障害)	ストレス)										
1245_002 3_035031	White	62/F	Empa 10mg	Injury, poisoning and procedural complications (	Femoral neck fracture (	46	181	136	Mod	No	None	Yes	Rcver	No	Req hsp
				傷害、中毒および 処置合併症)	大腿骨頸部骨折)										
Comment: FRACTURE WAS TRAUMATIC-DUE TO FALL /BAD WEATHER CONDITIONS-THE GROUND WAS ICE GLAZED/PATIENT NOT SUFFERED FROM DIZZINES BEFORE FALL.PATIENT WAS DISCHARGED FROM HOSPITAL ON 22.12.2016/FRACTURE WAS TRAUMATIC-DUE TO FALL /BAD WEATHER CONDITIONS-THE GROUND WAS ICE GLAZED/PATIENT NOT SUFFERED FROM DIZZINES BEFORE FALL															
	White		Empa 10mg	Injury, poisoning and procedural complications (	Fall (転倒)	46	46	1	Mod	No	None	No	Rcver	No	Req hsp
				傷害、中毒および 処置合併症)											
Comment: FALL WAS DUE TO BAD WEATHER CONDITIONS,THE ROUT WAS ICE GLAZED,PATIENT NOT SUFFERED FROM DIZZINES BEFORE FALL															
1245_002 3_036600	White	51/F	Empa 10mg	Gastrointestinal disorders (	Abdominal hernia (腹部ヘルニア)	56	67	12	Sev	No	None	Yes	Rcver	No	Req hsp
				胃腸障害)											
1245_002 3_036627	White	74/M	Empa 10mg	Gastrointestinal disorders (	Inguinal hernia (鼠径ヘルニア)	192	195	4	Mod	No	None	Yes	Rcver	No	Req hsp
				胃腸障害)											

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Episodes with a negative start day are not assigned to the analysing treatment.

MedDRA version used for reporting: 20.0

Listing 3.2.4 Adverse event episodes by treatment and patient - serious event only (Met+SU)- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Empa 25mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_002 3_030062	White	78/F	Empa 25mg	Nervous system disorders (	Cerebrovascular accident (	19	45	27	Sev	No	None	Yes	Seq	No	Req hsp
Comment: THE BRAIN STEM INSULT RESULTED IN A HEMIPARESIS(LEFT)WHICH IS ONGOING.THE FOLLOW-UP IS CONSIDERED SUFFICIENT FOR THIS TRIAL. THE PATIENT IS ENTERED IN THE EXTENSION TRAIL 1245.31															
1245_002 3_030066	White	72/M	Empa 25mg	Skin and subcutaneous tissue disorders (	Skin ulcer (	311	324	14	Mod	No	None	Yes	Rcver	No	Req hsp
(皮膚および皮下組織障害)															
	White		Empa 25mg	Musculoskeletal and connective tissue disorders (	Osteoarthritis (	501			Mod	No	None	No	Nrec	No	Req hsp
(筋骨格系および結合組織障害)															
1245_002 3_030227	White	64/M	Empa 25mg	Cardiac disorders (	Angina pectoris (狭心症)	487	500	14	Mod	No	None	Yes	Rcver	No	Req hsp
Comment: HOSPITALIZATION 26.03. - 28.03., STENT IMPLANTATION 26.03.															
1245_002 3_030254	White	80/M	Empa 25mg	Gastrointestinal disorders (	Inguinal hernia (鼠径ヘルニア)	214	258	45	Mod	No	None	Yes	Rcver	No	Req hsp
(胃腸障害)															
1245_002 3_030346	White	66/F	Run-in	Musculoskeletal and connective tissue disorders (	Intervertebral disc disorder (	-6	2977	3037	Sev	No	None	Yes	Rcver	No	Req hsp
(筋骨格系および結合組織障害)															
Comment: SHOULDER PAIN RIGHT KNOWN SINCE 16/FEB/20 DID NOR RESPOND TO MELOXICAM AND GOT MORE SEVERE REQUIRING HOSPITALISATION.DISCHARGE 20-MAR-20 /SHOULDER PAIN RIGHT KNOWN SINCE 16/FEB/20 DID NOR RESPOND TO MELOXICAM AND GOT MORE SEVERE REQUIRING HOSPITALISATION.DISCHARGE 20-MAR-20															

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Episodes with a negative start day are not assigned to the analysing treatment.

MedDRA version used for reporting:

Listing 3.2.4 Adverse event episodes by treatment and patient - serious event only (Met+SU)- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Empa 25mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_002 3_030346	White	66/F	Run-in	Nervous system disorders (	Cervicobrachial syndrome (	-6	2337	2397	Sev	No	None	Yes	Nrec&	No	Req hsp
Comment: SHOULDER PAIN RIGHT KNOWN SINCE 16/FEB/20 DID NOR RESPOND TO MELOXICAM AND GOT MORE SEVERE REQUIRING HOSPITALISATION.DISCARGE 20-MAR-20															
1245_002 3_031152	White	62/M	Empa 25mg	Musculoskeletal and connective tissue disorders (筋骨格系および結 合組織障害)	Osteoarthritis (	225	435	211	Sev	No	None	Yes	Rcver	No	Req hsp
Comment: RELATED TO THE OSTEOARTHRITIS OF THE HIP, HAD HIP REPLACEMENT															
1245_002 3_031214	Black/ Africa n Amer.	67/F	Empa 25mg	Nervous system disorders (	Radiculitis brachial (	441			Sev	No	Disc	Yes	Nrec	No	Req hsp
Comment: AE CHANGE BASED ON DISCHARGE SUMMARY OBTAIN FROM JEWISH HOSPITAL															
1245_002 3_032031	Asian	65/M	Empa 25mg	Nervous system disorders (	Dizziness (	200	200	1	Mod	No	None	Yes	Rcver	No	Req hsp
	Asian		Empa 25mg	Gastrointestinal disorders (	Nausea (悪心)	200	200	1	Mod	No	None	Yes	Rcver	No	Req hsp
	Asian		Empa 25mg	Ear and labyrinth disorders (	Sudden hearing loss (突発難聴)	200	248	49	Mod	No	None	Yes	Rcver	No	Req hsp
				耳および迷路障害)											

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Episodes with a negative start day are not assigned to the analysing treatment.

MedDRA version used for reporting:

Listing 3.2.4 Adverse event episodes by treatment and patient - serious event only (Met+SU)- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Empa 25mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_002 3_032031	Asian	65/M	Empa 25mg	Ear and labyrinth disorders (	Tinnitus (耳鳴)	200	214	15	Mod	No	None	Yes	Rcver	No	Req hsp
			)	耳および迷路障害											
	Asian		Empa 25mg	Gastrointestinal disorders (	Vomiting (嘔吐)	200	200	1	Mod	No	None	Yes	Rcver	No	Req hsp
				胃腸障害)											
1245_002 3_034286	Asian	51/M	Empa 25mg	Neoplasms benign, malignant and unspecified (incl cysts and polyps) (	Rectosigmoid cancer (	247			Sev	No	Disc	Yes	Nrec	No	Req hsp
				良性、悪性および 詳細不明の新生物 (嚢胞およびポリ ーブを含む))	直腸S状結腸癌)										
1245_002 3_034563	Asian	59/M	Empa 25mg	Gastrointestinal disorders (	Gastric ulcer (	449			Mod	No	None	Yes	Nrec	No	Req hsp
				胃腸障害)	胃潰瘍)										
1245_002 3_034564	Asian	61/M	Empa 25mg	Neoplasms benign, malignant and unspecified (incl cysts and polyps) (	Lung squamous cell carcinoma stage unspecified (	371	4617	917	Sev	No	Disc	Yes	Nrec&	No	Req hsp
				肺扁平上皮癌、病 期不明)	stage unspecified (										
				良性、悪性および 詳細不明の新生物 (嚢胞およびポリ ーブを含む))											

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Episodes with a negative start day are not assigned to the analysing treatment.

MedDRA version used for reporting: [REDACTED]

Listing 3.2.4 Adverse event episodes by treatment and patient - serious event only (Met+SU)- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Empa 25mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_002 3_034622	Asian	60/F	Empa 25mg	Injury, poisoning and procedural complications (傷害、中毒および 処置合併症)	Ankle fracture (足関節部骨折)	377	433	57	Mod	No	None	Yes	Rcver	No	Req hsp
Comment: TRAUMATIC															
1245_002 3_034625	Asian	49/F	Empa 25mg	Injury, poisoning and procedural complications (傷害、中毒および 処置合併症)	Ligament rupture (靱帯断裂)	192	256	65	Mod	No	None	Yes	Rcver	No	Req hsp
1245_002 3_034753	Asian	61/M	Empa 25mg	Neoplasms benign, malignant and unspecified (incl cysts and polyps) (良性、悪性および 詳細不明の新生物 (嚢胞およびポリ ーブを含む))	Gastric cancer (胃癌)	292	327	36	Mod	No	Disc	Yes	Rcver	No	Req hsp
1245_002 3_034820	Asian	57/M	Empa 25mg	General disorders and administration site conditions (一般・全身障害お よび投与部位の状 態)	Chest discomfort (胸部不快感)	284	317	34	Mild	No	None	No	Rcver	No	Req hsp

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Episodes with a negative start day are not assigned to the analysing treatment.

MedDRA version used for reporting: █

Listing 3.2.4 Adverse event episodes by treatment and patient - serious event only (Met+SU)- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Empa 25mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_002 3_036506	White	54/F	Empa 25mg	Infections and infestations (感染症および寄生 虫症)	Appendicitis (虫垂炎)	227	242	16	Sev	No	Disc	Yes	Rcver	No	Req hsp
1245_002 3_037533	Asian	67/M	Empa 25mg	Skin and subcutaneous tissue disorders (皮膚および皮下組 織障害)	Dermal cyst (皮膚囊腫)	281			Mild	No	None	Yes	Nrec	No	Req hsp

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 Episodes with a negative start day are not assigned to the analysing treatment.
 MedDRA version used for reporting: ■■■■

Listing 7.1.7 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Placebo

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_003 3_004061	White	65/F	Placebo	Musculoskeletal and connective tissue disorders (筋骨格系および結 合組織障害)	Arthralgia (関節痛)	219	559	341	Sev	No	None	Yes	Rcver	No	Req hsp
1245_003 3_004066	White	69/M	Placebo	Respiratory, thoracic and mediastinal disorders (呼吸器、胸郭およ び縦隔障害)	Chronic obstructive pulmonary disease (慢性閉塞性肺疾患)	79	134	56	Mod	No	None	Yes	Rcver	No	Req hsp
1245_003 3_004134	White	63/M	Placebo	Neoplasms benign, malignant and unspecified (incl cysts and polyps) (良性、悪性および 詳細不明の新生物 (嚢胞およびポリ ーブを含む))	Prostate cancer (前立腺癌)	122	493	372	Mild	No	None	No	Rcver	No	Other
Comment: TRANSRECTAL ULTRASOUND OF THE PROSTATE. BIOPSIES FROM PROSTATE WAS TAKEN 23SEP. CANCER WAS FOUND IN ONE BIOPSY. NEW BLOOD SAMPLE IN JANUARY 20. WILL BE TAKEN.															
1245_003 3_004141	White	63/M	Placebo	Cardiac disorders (心臓障害)	Angina pectoris (狭心症)	393	394	2	Sev	No	None	Yes	Rcver	No	Req hsp

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Episodes with a negative start day are not assigned to the analysing treatment.

MedDRA version used for reporting:

Listing 7.1.7 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Placebo

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_003 3_004184	White	61/F	Placebo	Neoplasms benign, malignant and unspecified (incl cysts and polyps) (	Colon cancer (	416	451	36	Sev	No	None	Yes	Rcver	No	Req hsp
				良性、悪性および 詳細不明の新生物 (嚢胞およびポリ ーブを含む))	結腸癌)										
1245_003 3_004550	White	63/F	Placebo	Vascular disorders (	Peripheral vascular disorder (	49	5797	5317	Mod	No	None	Yes	Nrec&	No	Req hsp
				血管障害)	末梢血管障害)										
1245_003 3_004571	White	79/F	Placebo	Nervous system disorders (	Haemorrhagic stroke (	232	236	5	Sev	No	Disc	No	Fatal	No	Fatal/Req hsp
				神経系障害)	出血性卒中)										
1245_003 3_004722	White	58/M	Placebo	Surgical and medical procedures (	Carotid endarterectomy (	475	477	3	Mod	No	None	No	Rcver	No	Req hsp
				置) 外科および内科処	頸動脈内膜摘除)										
Comment: RIGHT SIDED CAROTID ENDARTERECTOMY															
	White		Post trt	Cardiac disorders (	Coronary artery disease (	538	545	8	Mod	No	Disc	Yes	Rcver	No	Req hsp
				心臓障害)	冠動脈疾患)										
Comment: CABG NOT RESULTING FROM EMERGENCY ADMISSION WAS ELECTIVE SURGERY. ANGIOGRAM NOV 2010 SHOWED 3 VESSEL DISEASE SO BOOKED FOR CABG. CONDITION DID NOT CHANGE OR ALTER AFTER STARTING TRIAL MEDICATION.															

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Episodes with a negative start day are not assigned to the analysing treatment.
MedDRA version used for reporting: 20.1

Listing 7.1.7 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Placebo

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_003 3_004963	Asian	65/F	Placebo	Injury, poisoning and procedural complications (	Radius fracture (桡骨骨折)	280	566	287	Mild	No	None	Yes	Rcver	No	Req hsp
				傷害、中毒および 処置合併症)											
Comment: NON TRAUMATIC INJURY															
1245_003 3_005056	Asian	46/M	Placebo	Musculoskeletal and connective tissue disorders (	Joint instability (	422*	573	152*	Mod	No	None	Yes	Rcver	No	Req hsp
				筋骨格系および結 合組織障害)											
Comment: PATIENT DO NOT KNOW EXACT START DATE OF THE EVENT															
1245_003 3_005064	Asian	72/F	Placebo	Neoplasms benign, malignant and unspecified (incl cysts and polyps) (	Breast cancer (	399*	5697	1717	Sev	No	None	Yes	Nrec&	No	Req hsp
				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))											
1245_003 3_005071	Asian	70/F	Placebo	Musculoskeletal and connective tissue disorders (	Rotator cuff syndrome (	408	494	87	Mod	No	None	Yes	Rcver	No	Req hsp
				筋骨格系および結 合組織障害)	肩回旋筋腱板症候 群)										
1245_003 3_005144	Asian	71/F	Placebo	Eye disorders (	Vitreous haemorrhage (	290	329	40	Mod	No	None	Yes	Rcver	No	Req hsp
				眼障害)	硝子体出血)										

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Episodes with a negative start day are not assigned to the analysing treatment.

MedDRA version used for reporting: [REDACTED]

Listing 7.1.7 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Placebo

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_003 3_005321	Black/ African Amer.	56/M	Placebo	Vascular disorders (	Orthostatic hypotension (	369	372	4	Mod	No	None	Yes	Rcver	No	Req hsp
	Black/ African Amer.		Placebo	Metabolism and nutrition disorders (	Dehydration (	371	372	2	Mod	No	None	Yes	Rcver	No	Req hsp
				代謝および栄養障 害)	脱水)										
1245_003 3_005323	Black/ African Amer.	61/M	Placebo	Renal and urinary disorders (	Nephrotic syndrome (	21	25	5	Sev	No	None	Yes	Rcver	No	Req hsp
	Black/ African Amer.		Placebo	Skin and subcutaneous tissue disorders	Skin ulcer (	208	232	25	Sev	No	None	Yes	Rcver	No	Req hsp
				(	皮膚潰瘍)										
				皮膚および皮下組 織障害)											
	Black/ African Amer.		Placebo	Infections and infestations (	Osteomyelitis (	208	232	25	Sev	No	None	Yes	Rcver	No	Req hsp
				感染症および寄生 虫症)	骨髓炎)										
1245_003 3_005597	Black/ African Amer.	42/M	Placebo	Cardiac disorders (	Angina unstable	28	29	2	Sev	No	None	Yes	Rcver	No	Req hsp
				心臓障害)	(不安定狭心症)										
1245_003 3_005627	Black/ African Amer.	55/M	Placebo	Gastrointestinal disorders (	Pancreatitis acute (	246	262	17	Sev	No	None	Yes	Rcver	No	Req hsp
				胃腸障害)	急性膵炎)										

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Episodes with a negative start day are not assigned to the analysing treatment.
MedDRA version used for reporting: [REDACTED]

Listing 7.1.7 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Placebo

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_003 3_005627	Black/ Africa n Amer.	55/M	Placebo	Musculoskeletal and connective tissue disorders (筋骨格系および結 合組織障害)	Costochondritis (肋軟骨炎)	297	306	10	Mod	No	None	Yes	Rcver	No	Req hsp
1245_003 3_005684	White	61/M	Post trt	Infections and infestations (	Cystitis (	466	471	6	Sev	No	None	Yes	Seq	No	Req hsp
Comment: THIS AE IS RELATED TO KIDNEY STONES PER PI															
	White		Post trt	Renal and urinary disorders (	Nephrolithiasis (腎結石症)	466	471	6	Sev	No	None	Yes	Seq	No	Req hsp
Comment: THIS AE IS RELATED TO KIDNEY STONES PER PI															
	White		Post trt	Renal and urinary disorders (	Neurogenic bladder (	466	5847	1197	Sev	No	None	Yes	Seq	No	Disabl
	White		Post trt	Infections and infestations (	Sepsis (敗血症)	466	471	6	Sev	No	None	Yes	Seq	No	Req hsp
Comment: THIS AE IS RELATED TO KIDNEY STONES PER PI															
1245_003 3_005695	White	41/M	Placebo	Renal and urinary disorders (	Nephrolithiasis (腎結石症)	466	467	2	Sev	No	None	Yes	Rcver	No	Req hsp

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Episodes with a negative start day are not assigned to the analysing treatment.

MedDRA version used for reporting: [REDACTED]

Listing 7.1.7 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Placebo

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_003 3_005783	Black/ Africa n Amer.	55/M	Placebo	Nervous system disorders (	Convulsion (	169	225	57	Mild	No	None	No	Rcver	No	Req hsp
				神経系障害)	痙攣)										
1245_003 3_005784	Black/ Africa n Amer.	49/M	Placebo	Psychiatric disorders (	Depression (	492	581	90	Mod	No	None	Yes	Rcver	No	Req hsp
				精神障害)	うつ病)										
1245_003 3_005928	White	62/M	Placebo	Infections and infestations (	Enterocolitis infectious (	210	217	8	Sev	No	None	Yes	Rcver	No	Req hsp
				感染症および寄生 虫症)	感染性小腸結腸炎)										
1245_003 3_006281	White	71/M	Placebo	Nervous system disorders (	Carotid artery stenosis (	43	43	1	Mod	No	None	Yes	Rcver	No	Req hsp
				神経系障害)	頸動脈狭窄)										
1245_003 3_006431	White	56/M	Placebo	Gastrointestinal disorders (	Oesophageal ulcer (	7	9	3	Sev	No	None	Yes	Rcver	No	Req hsp
				胃腸障害)	食道潰瘍)										
1245_003 3_006524	White	66/M	Placebo	Neoplasms benign, malignant and unspecified (incl cysts and polyps) (	Prostate cancer (前立腺癌)	168	267*	100*	Mod	No	None	Yes	Rcver	No	Other
				良性、悪性および 詳細不明の新生物 (嚢胞およびポリ ーブを含む))											
Comment: THE PT WILL HAVE PROSTATE SURGURY TO REMOVE PROSTATE.															
1245_003 3_006853	White	73/F	Post trt	Gastrointestinal disorders (	Haematochezia (	549	553	5	Sev	No	None	No	Rcver	No	Req hsp
				胃腸障害)	血便排泄)										

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Episodes with a negative start day are not assigned to the analysing treatment.
MedDRA version used for reporting:

Listing 7.1.7 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Placebo

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_003 3_006853	White	73/F	Post trt	Gastrointestinal disorders (胃腸障害)	Rectal haemorrhage (直腸出血)	549	553	5	Sev	No	None	No	Rcver	No	Req hsp
1245_003 3_006857	White	55/M	Placebo	Cardiac disorders (心臓障害)	Coronary artery disease (冠動脈疾患)	393	551	159	Mod	No	None	Yes	Rcver	No	Other
Comment: ON 19 SEP 2011 PATIENT WAS SUBMITTED TO CORONARY ANGIOPLASTY THAT SHOULDED RIGHT CORONARY ARTERY AND DESCENDING CORONARY ARTERY OCLUDED. THERE IS A CLEAR DETERIORATION FROM BASELINE															
1245_003 3_006941	White	62/M	Placebo	Injury, poisoning and procedural complications (傷害、中毒および処置合併症)	Overdose (過量投与)	1	36	36	Mild	No	None	No	Rcver	No	Other

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Episodes with a negative start day are not assigned to the analysing treatment.
MedDRA version used for reporting: 20.0

Listing 7.1.7 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Empa 10mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_003 3_004100	White	52/M	Empa 10mg	Eye disorders (眼障害)	Retinal detachment (網膜剥離)	530	532	3	Mod	No	None	Yes	Rcver	No	Req hsp
1245_003 3_004101	White	82/M	Empa 10mg	Injury, poisoning and procedural complications (傷害、中毒および処置合併症)	Accident at home (家庭内事故)	171	171	1	Mod	No	None	No	Rcver	No	Req hsp
	White		Empa 10mg	Injury, poisoning and procedural complications (傷害、中毒および処置合併症)	Contusion (挫傷)	171	308	138	Mod	No	None	No	Rcver	No	Req hsp
	White		Empa 10mg	Injury, poisoning and procedural complications (傷害、中毒および処置合併症)	Contusion (挫傷)	171	5797	4097	Mod	No	None	No	Nrec&	No	Req hsp
	White		Empa 10mg	Injury, poisoning and procedural complications (傷害、中毒および処置合併症)	Fall (転倒)	171	171	1	Mod	No	None	No	Rcver	No	Req hsp
1245_003 3_004121	White	70/M	Empa 10mg	Injury, poisoning and procedural complications (傷害、中毒および処置合併症)	Skeletal injury (骨格損傷)	228	239	12	Sev	No	None	Yes	Rcver	No	Req hsp

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Episodes with a negative start day are not assigned to the analysing treatment.

MedDRA version used for reporting: [REDACTED]

Listing 7.1.7 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Empa 10mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_003 3_004121	White	70/M	Empa 10mg	Nervous system disorders (	Cerebral haemorrhage (	228	239	12	Sev	No	None	Yes	Rcver	No	Req hsp
	White		Empa 10mg	Injury, poisoning and procedural complications (	Road traffic accident (	228	228	1	Mod	No	None	Yes	Rcver	No	Req hsp
傷害、中毒および 処置合併症) Comment: WAS FOUND UNCONSCIOUS, GLUCOSE 7.6 MMOL/L. BROKEN LEFT COLLAR BONE, LEFT SHOULDER BLADE AND SOM RIBS. SMALL CONTUSION ON RIGHT FRONTAL SIDE OF CRANIUM.															
	White		Empa 10mg	Nervous system disorders (	Syncope (失神)	421	423	3	Mod	No	None	No	Rcver	No	Req hsp
1245_003 3_004137	White	57/M	Empa 10mg	Neoplasms benign, malignant and unspecified (incl cysts and polyps) (	Bladder cancer (	511	536	26	Mod	No	None	Yes	Rcver	No	Other
良性、悪性および 詳細不明の新生物 (嚢胞およびポリ ーブを含む)) Comment: RESECTION OF THE TUMORS WERE PERFORMED 29NOV20															
1245_003 3_004331	White	69/M	Empa 10mg	Renal and urinary disorders (	Renal failure (	167	172	6	Sev	No	Disc	No	Rcver	No	Req hsp
腎および尿路障害)															

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 Episodes with a negative start day are not assigned to the analysing treatment.

MedDRA version used for reporting:

Listing 7.1.7 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Empa 10mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_003 3_004397	White	65/M	Empa 10mg	Infections and infestations (	Diverticulitis (	297	300	4	Mod	No	None	Yes	Rcver	No	Req hsp
感染症および寄生 虫症) Comment: HOSPITALIZATION ON THE 27/JUL/20 TO 30/JUL/20 FOR ABDOMINAL PAIN AND CONSTIPATION. ABDOMINAL CT SCAN SHOWED DIVITICULITIS WITH SIGMOIDITIS.ONLY MEDICAL TREATMENT AND DIET															
	White		Empa 10mg	Eye disorders (	Macular fibrosis	365	367	3	Mod	No	None	Yes	Rcver	No	Req hsp
眼障害) Comment: VITRECTOMY OF LEFT EYE ON 4TH OCTOBER 20 AT 9:41AM.DIAGNOSTICS: EPIMACULAR MEMBRANE															
1245_003 3_004611	White	68/F	Empa 10mg	Cardiac disorders (	Right ventricular failure (	474	483	10	Mod	No	None	Yes	Rcver	No	Req hsp
心臓障害) Comment: BREATHLESSNESS AND LEG OEDEMA 右室不全)															
1245_003 3_004632	White	79/F	Empa 10mg	Gastrointestinal disorders (	Oesophagitis (	252	256	5	Mod	No	None	Yes	Rcver	No	Req hsp
胃腸障害) 食道炎)															
	White		Empa 10mg	Gastrointestinal disorders (	Abdominal distension (	381	383	3	Mild	No	None	No	Rcver	No	Req hsp
胃腸障害) 腹部膨満)															
	White		Empa 10mg	Renal and urinary disorders (	Renal failure acute (	381	7657	3857	Mild	Yes	None	No	Nrec&	No	Req hsp/Prol hsp
腎および尿路障害) Comment: FOLLOW UP SUFFICIENT 23/11/															
	White		Empa 10mg	Gastrointestinal disorders (	Constipation (	381	383	3	Mild	No	None	No	Rcver	No	Req hsp
胃腸障害) 便秘)															

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MedDRA version used for reporting:

Listing 7.1.7 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Empa 10mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_003 3_004661	White	73/M	Empa 10mg	Nervous system disorders (	Cerebrovascular accident (	174	174	1	Mod	No	None	Yes	Seq	No	Disabl
				神経系障害)	脳血管発作)										
1245_003 3_004842	White	64/M	Run-in	Musculoskeletal and connective tissue disorders (	Neck pain (	-17	5527	5697	Sev	No	None	Yes	Nrec&	No	Req hsp
				筋骨格系および結 合組織障害)	頸部痛)										
Comment: NERVE ROOT COMPRESSION OF C3/C4															
1245_003 3_005024	Asian	74/F	Empa 10mg	Cardiac disorders (	Angina pectoris (狭心症)	326	408	83	Mod	No	Disc	Yes	Rcver	No	Req hsp
				心臓障害)											
1245_003 3_005060	Asian	41/F	Empa 10mg	Musculoskeletal and connective tissue disorders (	Rotator cuff syndrome (	53*	481	429*	Mod	No	None	Yes	Rcver	No	Req hsp
				群) 筋骨格系および結 合組織障害)	肩回旋筋腱板症候 群)										
Comment: THE PATIENT DID NOT REMEMBER THE EXACT START DATE.															
	Asian		Empa 10mg	Musculoskeletal and connective tissue disorders (	Musculoskeletal stiffness (	53*	481	429*	Mod	No	None	Yes	Rcver	No	Req hsp
				筋骨格系および結 合組織障害)	筋骨格硬直)										
Comment: THE PATIENT DID NOT REMEMBER THE EXACT START DATE.															
1245_003 3_005077	Asian	60/F	Empa 10mg	Injury, poisoning and procedural complications (	Concussion (	345	547*	203*	Mod	No	None	Yes	Rcver	No	Req hsp
				傷害、中毒および 処置合併症)	脳振盪)										

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MedDRA version used for reporting: [REDACTED]

Listing 7.1.7 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Empa 10mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_003 3_005142	Asian	61/M	Empa 10mg	Respiratory, thoracic and mediastinal disorders (	Vocal cord polyp (声帯ポリープ)	162	178	17	Mod	No	None	Yes	Rcver	No	Req hsp
				呼吸器、胸郭およ び縦隔障害)											
1245_003 3_005182	Asian	63/F	Empa 10mg	General disorders and administration site conditions (	Chest discomfort (胸部不快感)	246	247	2	Mild	No	None	Yes	Rcver	No	Req hsp
				一般・全身障害お よび投与部位の状 態)											
1245_003 3_005184	Asian	46/F	Empa 10mg	Injury, poisoning and procedural complications (	Ligament sprain (靱帯捻挫)	175	573	399	Mild	No	None	Yes	Rcver	No	Req hsp
				傷害、中毒および 処置合併症)											
	Asian		Empa 10mg	Injury, poisoning and procedural complications (	Road traffic accident (	175	175	1	Mild	No	None	Yes	Rcver	No	Req hsp
				傷害、中毒および 処置合併症)	交通事故)										
1245_003 3_005473	White	56/F	Empa 10mg	Cardiac disorders (	Coronary artery disease (	455	462	8	Mod	No	None	Yes	Seq	No	Req hsp
				心臓障害)	冠動脈疾患)										
Comment: END DATE CONFIRMED 06JUL20															
	White		Empa 10mg	Cardiac disorders (	Coronary artery occlusion (	455	462	8	Mod	No	None	Yes	Rcver	No	Req hsp
				心臓障害)	冠動脈閉塞)										

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MedDRA version used for reporting:

Listing 7.1.7 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Empa 10mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_003 3_005746	White	51/M	Empa 10mg	Infections and infestations (	Scrotal abscess (陰囊膿瘍)	112	175	64	Mod	No	Disc	Yes	Rcver	No	Req hsp
虫症)															
Comment: STUDY SUBJECT WAS ADMITTED TO THE HOSPITAL FOR ABSCESS TO THE SCROTUM NO ADDITIONAL INFORMATION SINCE NO MEDICAL RECORDS WERE RELEASED															
1245_003 3_005894	White	61/M	Empa 10mg	Cardiac disorders (	Atrial fibrillation (	2	5	4	Mod	No	None	Yes	Rcver	No	Req hsp
	White		Empa 10mg	Cardiac disorders (	Atrial flutter (	92	101	10	Sev	No	None	Yes	Rcver	No	Req hsp
	White		Empa 10mg	Cardiac disorders (	Atrial fibrillation (	206	207	2	Mild	No	None	Yes	Rcver	No	Req hsp
	White		Empa 10mg	Cardiac disorders (	Bradycardia (	541	544	4	Sev	No	None	Yes	Rcver	No	Req hsp
				心臓障害)	徐脈)										
1245_003 3_005984	White	71/F	Empa 10mg	Neoplasms benign, malignant and unspecified (incl cysts and polyps) (	Breast cancer (	60*	156*	97*	Sev	No	Disc	Yes	Rcver	No	Other
				良性、悪性および 詳細不明の新生物 (嚢胞およびポリ ーブを含む)	乳癌)										
Comment: SUBJECT HAD LEFT LUMPECTOMY ON 05AUG2013, STARTED CHEMOTHERAPY ON 04OCT2013, SUBJECT CLEARED UNK/JUN/2014 BY DOCTOR.															

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MedDRA version used for reporting: 20.1

Listing 7.1.7 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Empa 10mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_003 3_006073	White	55/M	Empa 10mg	Cardiac disorders (	Myocardial infarction (	68	72	5	Mild	Yes	Disc	Yes	Rcver	No	Req hsp
				心臓障害)	心筋梗塞)										
1245_003 3_006165	White	60/F	Empa 10mg	Cardiac disorders (	Coronary artery disease (	413	423	11	Mod	No	Disc	Yes	Rcver	No	Req hsp
				心臓障害)	冠動脈疾患)										
1245_003 3_006373	White	68/F	Post trt	Psychiatric disorders (	Depression (	190	194	5	Mod	No	Disc	Yes	Rcver	No	Req hsp
				精神障害)	うつ病)										
1245_003 3_006641	White	58/F	Post trt	Metabolism and nutrition disorders (	Dehydration (	553	554	2	Sev	No	None	Yes	Rcver	No	Req hsp
				代謝および栄養障 害)	脱水)										
Comment: SEE DESCRIPTION WITH ASSOCIATED UTI ON PREVIOUS ECRF PAGE															
	White		Post trt	Infections and infestations (	Urinary tract infection (	553	561	9	Mod	No	None	Yes	Rcver	No	Req hsp
				感染症および寄生 虫症)	尿路感染)										
Comment: SUBJECT HAD SYMPTOMS OF FAINTNESS, WEAKNESS, ELEVATED POTASSIUM AND BLOOD SUGAR AND DECREASED BP AND O2. HOSPITALIZED OVERNGHT FOR HYDRATION/OBSERVATION. UTI DIAGNOSED IN AT ER VISIT															
1245_003 3_006677	White	65/M	Empa 10mg	Cardiac disorders (	Bradycardia (	440	443	4	Sev	No	None	Yes	Rcver	No	Req hsp
				心臓障害)	徐脈)										
Comment: RELATED TO SAE - SYNCOPAL EVENT PREVIOUSLY REPORTED.															
	White		Empa 10mg	Nervous system disorders (	Syncope (失神)	440	443	4	Sev	No	None	Yes	Rcver	No	Req hsp
				神経系障害)											

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MedDRA version used for reporting: [REDACTED]

Listing 7.1.7 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Empa 10mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_003 3_006680	White	75/M	Empa 10mg	Musculoskeletal and connective tissue disorders (筋骨格系および結 合組織障害)	Osteoarthritis (変形性関節症)	523	526	4	Sev	No	None	Yes	Rcver	No	Req hsp
1245_003 3_006859	White	69/M	Empa 10mg	Neoplasms benign, malignant and unspecified (incl cysts and polyps) (良性、悪性および 詳細不明の新生物 (嚢胞およびポリ ーブを含む))	Lung neoplasm malignant (肺の悪性新生物)	461	5737	1137	Sev	No	Disc	Yes	Nrec&	No	Disabl
Comment: PATIENT STARTED WITH HAEMOPTYSIS IN NOVEMBER 2011. A CTSCAN AND A BRONCHOSCOPY WERE PERFORMED AND CONFIRMED SQUAMOUS CELL CANCER OF THE LUNG.FINAL DIAGNOSTIC:SQUAMOUS CELL CANCER OF THE LUNG:MALIGNANT															
1245_003 3_007214	White	59/M	Empa 10mg	Congenital, familial and genetic disorders (先天性、家族性お よび遺伝性障害)	Arnold-Chiari malformation (アーノルド・キア リ奇形)	177	233	57	Mod	No	None	Yes	Rcver	No	Req hsp
Comment: PRIMARY DIAGNOSIS FOR "LEFT-SIDED HEAD PAIN AND LOSS OF CONSCIOUSNESS".															
1245_003 3_007222	Black/ Africa n Amer.	60/M	Empa 10mg	Musculoskeletal and connective tissue disorders (筋骨格系および結 合組織障害)	Osteoarthritis (変形性関節症)	401	525	125	Mod	No	None	Yes	Rcver	No	Req hsp
Comment: WORSENING OSTEOARTHRITIS RESULTING IN RIGHT TOTAL KNEE REPLACEMENT 25-JAN-2012															

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MedDRA version used for reporting: [REDACTED]

Listing 7.1.7 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Empa 25mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_003 3_004003	White	87/M	Empa 25mg	Investigations (臨床検査)	Hepatic enzyme increased (肝酵素上昇)	379	464	86	Mod	Yes	Disc	No	Rcver	No	Other
Comment: PROTOCOL-SPECIFIED SIGNIFICANT ADVERSE EVENT (AST AND ALT > 3*ULN)															
1245_003 3_004004	White	70/M	Empa 25mg	Injury, poisoning and procedural complications (傷害、中毒および処置合併症)	Contusion (挫傷)	127	5887	4627	Mild	No	None	No	Nrec&	No	Req hsp
Comment: AS A BUS PASSENGER, PT 4004, INVOLVED IN ACCIDENT UNDER WHICH THE BUS ROLLED OVER ON ITS SIDE. PT 4004 SUSTAINED CONTUSIONS TO THE CERVICAL COLUMNA. SIMPLE BACK CONTUSION, NO OBJECTIVE SIGNS OF INJURY															
1245_003 3_004035	White	46/F	Empa 25mg	Gastrointestinal disorders (胃腸障害)	Enterocutaneous fistula (腸管皮膚瘻)	245	269	25	Sev	No	None	Yes	Rcver	No	Req hsp
1245_003 3_004065	White	65/M	Empa 25mg	General disorders and administration site conditions (一般・全身障害および投与部位の状態)	Chest pain (胸痛)	445	462	18	Sev	No	None	Yes	Rcver	No	Req hsp
	White		Empa 25mg	Respiratory, thoracic and mediastinal disorders (呼吸器、胸郭および縦隔障害)	Dyspnoea (呼吸困難)	462	561	100	Mod	No	None	Yes	Rcver	No	Req hsp
1245_003 3_004091	White	74/M	Empa 25mg	Infections and infestations (感染症および寄生虫症)	Pneumonia (肺炎)	38	47	10	Mod	No	None	Yes	Rcver	No	Req hsp

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MedDRA version used for reporting: [REDACTED]

Listing 7.1.7 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Empa 25mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_003 3_004094	White	75/M	Empa 25mg	Neoplasms benign, malignant and unspecified (incl cysts and polyps) (	Gastric cancer (	13	1957	1837	Sev	No	Disc	Yes	Nrec#	No	Imm thrt/Disab l/Req hsp
				良性、悪性および 詳細不明の新生物 (嚢胞およびポリ ーブを含む))	胃癌)										
Comment: GASSTROSCOPI				17/5-20	. NO SIGNS OF METASTASIS.										
	White		Empa 25mg	Cardiac disorders (	Acute myocardial infarction (	49	49	1	Sev	No	Disc	Yes	Seq	No	Imm thrt/Req hsp
				心臓障害)	急性心筋梗塞)										
	White		Empa 25mg	Cardiac disorders (	Cardiac arrest (	49	49	1	Sev	No	Disc	Yes	Rcver	No	Imm thrt/Req hsp
				心臓障害)	心停止)										
1245_003 3_004097	White	58/M	Empa 25mg	General disorders and administration site conditions (	Device failure (	477	478	2	Mod	No	None	Yes	Rcver	No	Req hsp
				一般・全身障害お よび投与部位の状 態)	医療機器不具合)										

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MedDRA version used for reporting:

Listing 7.1.7 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Empa 25mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_003 3_004367	White	73/M	Empa 25mg	Neoplasms benign, malignant and unspecified (incl cysts and polyps) (	Prostatic adenoma (	104	123	20	Mild	No	Disc	Yes	Rcver	No	Req hsp
				良性、悪性および 詳細不明の新生物 (嚢胞およびポリ ーブを含む))	前立腺腺腫)										
1245_003 3_004371	White	49/F	Empa 25mg	Neoplasms benign, malignant and unspecified (incl cysts and polyps) (	Thyroid cancer (	298	411	114	Mild	No	None	Yes	Rcver	No	Req hsp
				良性、悪性および 詳細不明の新生物 (嚢胞およびポリ ーブを含む))	甲状腺癌)										
Comment: THERAPY FOR EVENT : TOTAL THYROIDECTOMY ON 20/04/20															
1245_003 3_004394	White	74/M	Empa 25mg	Neoplasms benign, malignant and unspecified (incl cysts and polyps) (	Pancreatic carcinoma (	470	524	7	Sev	Yes	Disc	No	Nrec&	No	Req hsp
				良性、悪性および 詳細不明の新生物 (嚢胞およびポリ ーブを含む))	膵癌)										
Comment: CAUSAL RELATIONSHIP: THE RIGHT ANSWER IS "POSSIBLE"															

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MedDRA version used for reporting:

Listing 7.1.7 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Empa 25mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_003 3_004515	White	54/F	Empa 25mg	Infections and infestations (	Sinusitis (	3	50	48	Mod	Yes	Disc	Yes	Rcver	No	Req hsp
感染症および寄生 虫症) Comment: HEADACH , VERTIGO ,AND VOMITING , RISING TWO DAYS AFTER RANDOMISATION															
1245_003 3_004543	White	61/F	Empa 25mg	Nervous system disorders (	Transient ischaemic attack (	287	288	2	Sev	No	None	Yes	Rcver	No	Req hsp
神経系障害) 一過性脳虚血発作)															
1245_003 3_004605	White	61/M	Empa 25mg	Injury, poisoning and procedural complications (	Wrist fracture (	272	307	36	Sev	No	None	Yes	Rcver	No	Req hsp
傷害、中毒および 処置合併症) Comment: PATIENT SLIPPED OFF LADDER SUBSTAINING FRACTURE OF LEFT WRIST. HAD INSERTION OF K WIRES AND PLASTER OF PARIS. WAS A TRAUMATIC EVENT.															
1245_003 3_004961	Asian	53/M	Empa 25mg	Musculoskeletal and connective tissue disorders (	Joint contracture (	207*	274	68*	Sev	No	None	Yes	Rcver	No	Req hsp
筋骨格系および結 合組織障害) Asian Empa 25mg Gastrointestinal disorders (															
Gastric ulcer haemorrhage (															
胃腸障害) 出血性胃潰瘍)															

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 Episodes with a negative start day are not assigned to the analysing treatment.

MedDRA version used for reporting: [REDACTED]

Listing 7.1.7 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Empa 25mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_003 3_004993	Asian	47/F	Empa 25mg	Neoplasms benign, malignant and unspecified (incl cysts and polyps) (癌) 良性、悪性および 詳細不明の新生物 (嚢胞およびポリ ーブを含む)	Squamous cell carcinoma of the cervix (子宮頸部扁平上皮	226	6587	4337	Sev	No	None	Yes	Nrec&	No	Req hsp
1245_003 3_005066	Asian	70/F	Empa 25mg	Nervous system disorders (神経系障害)	Cerebral infarction (脳梗塞)	192	205	14	Sev	Yes	None	Yes	Seq	No	Req hsp
	Asian		Empa 25mg	Metabolism and nutrition disorders (代謝および栄養障 害)	Hypoglycaemia (低血糖症)	210	210	1	Sev	Yes	Disc	Yes	Rcver	No	Req hsp
Comment: THIS PATIENT HAD SAE WHEN HYPOGLYCEMIA OCCURS, SO ASSISTANT IS REQUIRED															
	Asian		Empa 25mg	Nervous system disorders (神経系障害)	Cerebral infarction (脳梗塞)	210	232	23	Sev	Yes	Disc	Yes	Seq	No	Req hsp
1245_003 3_005072	Asian	69/M	Empa 25mg	Cardiac disorders (心臓障害)	Myocardial ischaemia (心筋虚血)	97*	158	62*	Mod	No	None	Yes	Rcver	No	Req hsp

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MedDRA version used for reporting: [REDACTED]

Listing 7.1.7 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Empa 25mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_003 3_005072	Asian	69/M	Empa 25mg	Neoplasms benign, malignant and unspecified (incl cysts and 腫) polyps) (腫) 良性、悪性および 詳細不明の新生物 (嚢胞およびポリ ーブを含む)	Malignant fibrous histiocytoma (腫) 悪性線維性組織球	257	279	23	Mild	No	None	Yes	Rcver	No	Req hsp
1245_003 3_005111	Asian	54/F	Empa 25mg	Nervous system disorders (腫) 神経系障害)	Sciatica (腫) 坐骨神経痛)	334*	4067	737	Sev	No	None	Yes	Nrec&	No	Req hsp
1245_003 3_005175	Asian	32/M	Empa 25mg	Injury, poisoning and procedural complications (腫) 傷害、中毒および 処置合併症)	Accident at work (腫) 労働災害)	75	75	1	Sev	No	None	Yes	Rcver	No	Req hsp
	Asian		Empa 25mg	Injury, poisoning and procedural complications (腫) 傷害、中毒および 処置合併症)	Limb crushing injury (腫) 四肢圧挫損傷)	75	133	59	Sev	No	None	Yes	Rcver	No	Req hsp
1245_003 3_005658	White	66/F	Empa 25mg	Infections and infestations (腫) 感染症および寄生 虫症)	Pyelonephritis (腫) 腎盂腎炎)	36	39	4	Sev	No	None	Yes	Rcver	No	Req hsp
Comment: HOSPITAL DISCHARGE SUMMARY DOCUMENTS DIAGNOSIS AS PYELONEPHITIS WHICH WAS CAUSED BY AN E COLI INFECTION															

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Episodes with a negative start day are not assigned to the analysing treatment.

MedDRA version used for reporting: [REDACTED]

Listing 7.1.7 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Empa 25mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_003 3_005715	White	58/M	Empa 25mg	Ear and labyrinth disorders (	Vertigo (回 転性めまい)	135	137	3	Sev	No	None	Yes	Rcver	No	Req hsp
)															
Comment: PATIENT STATES HE WAS ADMITTED TO HOSPITAL AFTER SOME DIZZINESS AND NAUSEA, STROKE AND CARDIOVASCULAR EVENTS WERE RULED OUT. PATIENT WAS DIAGNOSED WITH PERIPHERAL VERTIGO AND DISCHARGED.															
1245_003 3_005869	White	67/M	Empa 25mg	Cardiac disorders (	Myocardial infarction (	501	501	1	Sev	No	Disc	Yes	Rcver	No	Prol hsp
)															
Comment: THE PATIENT BEGAN FEELING NAUSEOUS, PERSPIRING HEAVILY AND VOMINTING. THE PARAMEDICS WERE CALLED TO THE SCENE. THE PATIENT WAS TAKEN TO THE HOSPITAL FOR OBSERVATION.															
1245_003 3_005871	Black/ Africa n Amer.	50/F	Empa 25mg	Neoplasms benign, malignant and unspecified (incl cysts and polyps) (	Thyroid cancer (	200	230	31	Mod	No	None	Yes	Rcver	No	Req hsp
)															
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Comment: SUBJECT WENT IN FOR REMOVAL OF THYROID NODULE ON DEC-20-2016. PATHOLOGY REPORT REVEALED CARCINOMA.															
1245_003 3_006222	White	76/F	Empa 25mg	Renal and urinary disorders (	Renal failure acute (	1	32	32	Sev	No	Disc	Yes	Rcver	No	Req hsp
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Listing 7.1.7 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Empa 25mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_003 3_006461	White	63/F	Empa 25mg	Nervous system disorders (	Carotid artery occlusion (	279	280	2	Sev	No	None	Yes	Rcver	No	Req hsp
	White		Empa 25mg	Nervous system disorders (	Carotid artery occlusion (	412	413	2	Sev	No	None	Yes	Rcver	No	Req hsp
	White		Empa 25mg	Vascular disorders (	Femoral arterial stenosis (	544	546	3	Sev	No	None	Yes	Seq	No	Req hsp
1245_003 3_006884	White	77/M	Empa 25mg	Neoplasms benign, malignant and unspecified (incl cysts and polyps) (	Mycosis fungoides (	231	7027	4727	Mod	No	None	Yes	Nrec&	No	Other
良性、悪性および 詳細不明の新生物 (嚢胞およびボリ ープを含む)) Comment: STARTED AS A EXANTEMA IN THE LEGS, WICH PROGRESSED DISPITE TREATMENT. BIOPSY WAS PERFORMED ON APR20 AND A T- CELL LIMPOMA WAS FOUND (MUCOSIS FUNGOIDIS). LESIONS DISAPPEARED WITH TOPIC CORTICOIDES.															
	White		Empa 25mg	Nervous system disorders (	Cerebrovascular accident (	293	301	9	Mild	No	Disc	Yes	Rcver	No	Req hsp
1245_003 3_006988	White	71/F	Empa 25mg	General disorders and administration site conditions (	Non-cardiac chest pain (	117	118	2	Mild	No	None	Yes	Rcver	No	Req hsp
一般・全身障害お よび投与部位の状 態)															

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 Episodes with a negative start day are not assigned to the analysing treatment.

MedDRA version used for reporting:

Listing 7.1.7 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Empa 25mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_003 3_007224	White	60/F	Empa 25mg	Musculoskeletal and connective tissue disorders (筋骨格系および結 合組織障害)	Osteoarthritis (変形性関節症)	214	243	30	Mod	No	None	Yes	Rcver	No	Req hsp

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MedDRA version used for reporting: [REDACTED]

Listing 4.2.1 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day WO, active only

Treatment: Placebo

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_003 6_001085	White	78/M	Placebo	Infections and infestations (	Campylobacter gastroenteritis	296	361	66	Mod	No	Disc	Yes	Rcver	No	Req hsp
	White		Placebo	感染症および寄生 (	カンピロバクター										
				胃腸炎)											
				Metabolism and nutrition disorders (	Hypovolaemia (	296	314	19	Mod	No	None	No	Rcver	No	Prol hsp
				代謝および栄養障	血流量減少症)										
				害)											
Comment: PATIENT RECIEVED INTRAVENOUS NORMAL SALINE BOLUS FOR EVENT															
	White		Post trt	Renal and urinary disorders (	Renal failure acute (	304	314	11	Mod	No	None	No	Rcver	No	Prol hsp
				腎および尿路障害	急性腎不全)										
				)											
1245_003 6_001146	White	60/M	Post trt	Cardiac disorders (	Acute myocardial infarction (	229	232	4	Sev	No	None	Yes	Rcver	No	Imm thrt/Req hsp
				心臓障害)	急性心筋梗塞)										
Comment: REPORT HAS BEEN SENT TO DRUG SAFETY - TREATED WITH ANGIOPLASTY AND STENTING															
1245_003 6_001152	White	78/M	Placebo	Infections and infestations (	Pneumonia primary atypical	65	86	22	Sev	No	None	Yes	Rcver	No	Req hsp
				感染症および寄生 (	原発性異型肺炎)										
				虫症)											
Comment: HAS BEEN REPORTED TO DRUG SAFETY															
1245_003 6_001189	White	68/F	Placebo	Hepatobiliary disorders (	Cholelithiasis (	218	218	1	Sev	No	None	Yes	Rcver	No	Req hsp
				肝胆道系障害)	胆石症)										
Comment: PATIENT WAS ADMITTED TO HOSPITAL FOR LAPAROSCOPIC CHOLECYSTECTOMY															

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MedDRA version used for reporting: [REDACTED]

Listing 4.2.1 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Placebo

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_003 6_001189	White	68/F	Placebo	Infections and infestations (	Post procedural infection (	222	229	8	Sev	No	None	Yes	Rcver	No	Req hsp
				感染症および寄生 虫症)	処置後感染)										
1245_003 6_001197	White	59/F	Placebo	General disorders and administration site conditions (一般・全身障害お よび投与部位の状 態)	Chest pain (	95	242	148	Mild	No	None	No	Rcver	No	Req hsp
					胸痛)										
Comment: PT WAS ADMITTED TO HOSPITAL ON 06 JUN 20 BY CARDIOLOGIST SO PATIENT DID NOT NEED TO WAIT LONG FOR TESTS, NOT BECAUSE OF THE SEVERITY OF THE CHEST PAINS. PT WAS DISCHARGED ON 07 JUN 20															
1245_003 6_001246	White	60/F	Placebo	General disorders and administration site conditions (一般・全身障害お よび投与部位の状 態)	Chest pain (	121	121	1	Mod	No	None	Yes	Rcver	No	Req hsp
					胸痛)										
1245_003 6_001263	White	77/M	Placebo	Cardiac disorders (	Arrhythmia (	104	105	2	Mod	No	None	No	Rcver	No	Req hsp
				心臓障害)	不整脈)										
Comment: COLLAPS UNKNOWN CAUSE															
	White		Placebo	Vascular disorders (	Circulatory collapse (	104	105	2	Mod	No	None	No	Rcver	No	Req hsp
				血管障害)	循環虚脱)										
Comment: COLLAPS UNKNOWN CAUSE															

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MedDRA version used for reporting:

Listing 4.2.1 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Placebo

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_003 6_001263	White	77/M	Placebo	Renal and urinary disorders (	Renal impairment (腎機能障害)	105	111	7	Mod	No	None	No	Rcver	No	Prol hsp
Comment: PASSAGERE DECREASED RENAL FUNCTION AFTER COLLAPS															
	White		Placebo	Injury, poisoning and procedural complications (	Subdural haematoma (	253	274	22	Mod	No	None	No	Rcver	No	Req hsp
Comment: SURGICAL RESECTION															
	White		Placebo	Neoplasms benign, malignant and unspecified (incl cysts and polyps) (	Squamous cell carcinoma of skin (	270	270	1	Mild	No	None	Yes	Rcver	No	Other
	White		Post trt	Nervous system disorders (	Transient ischaemic attack (	378	380	3	Mild	No	None	No	Rcver	No	Other
1245_003 6_001283	White	76/F	Placebo	Cardiac disorders (	Myocardial ischaemia (	165	267	103	Sev	No	None	Yes	Rcver	No	Req hsp
Comment: PATIENT WAS HOSPITALIZED FROM FEBRUARY 21TH TILL 23TH FOR CAG AND FROM MARCH 15TH TILL 16TH FOR 2 STENTS (PCI), MONOCEDOCARD 25MG, PLAVIX 75MG															

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Episodes with a negative start day are not assigned to the analysing treatment.
MedDRA version used for reporting: [REDACTED]

Listing 4.2.1 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Placebo

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_003 6_001402	White	70/F	Placebo	Cardiac disorders (心臓障害)	Cardiac failure (心不全)	142	4367	2957	Mild	No	None	Yes	Nrec&	No	Req hsp
Comment: INCREASED WEIGHT AND DYSPNEA															
1245_003 6_001441	White	74/F	Placebo	Eye disorders (眼障害)	Cataract (白内障)	333	334	2	Sev	No	None	Yes	Rcver	No	Req hsp
	White		Placebo	Metabolism and nutrition disorders (代謝および栄養障害)	Diabetes mellitus inadequate control (糖尿病のコントロール不良)	334	337	4	Mod	Yes	None	Yes	Rcver	No	Prol hsp
Comment: HYPERGLYCEMIA															
1245_003 6_001462	White	74/M	Run-in	Neoplasms benign, malignant and unspecified (incl cysts and polyps) (良性、悪性および詳細不明の新生物 (嚢胞およびポリープを含む))	Prostate cancer (前立腺癌)	-11	92	103	Sev	No	Disc	Yes	Unk	No	Other
Comment: FROM 24TH/MARCH TO 14TH/JUNE, DOSE DOESN'T CHANGED.THEN SUBJECT TEMPORARY DISCONTINUED FROM 15TH/JUNE TO 16TH/JUNE. AFTER HE STARTS AGAIN ON THE 17TH/JUNE. HE PERMANENTLY DISCONTINUED ON 19TH OF JUNE															
	White		Placebo	Nervous system disorders (神経系障害)	Aphasia (失語症)	72	75	4	Mod	No	None	No	Rcver	No	Prol hsp
	White		Placebo	Psychiatric disorders (精神障害)	Abnormal behaviour (異常行動)	72	75	4	Mod	No	None	No	Rcver	No	Prol hsp

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Episodes with a negative start day are not assigned to the analysing treatment.

MedDRA version used for reporting: █

Listing 4.2.1 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Placebo

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_003 6_001462	White	74/M	Placebo	Nervous system disorders (	Dysarthria (	72	75	4	Mod	No	None	No	Rcver	No	Prol hsp
	White		Placebo	Vascular disorders (	Hypotension (	72	75	4	Sev	No	None	Yes	Rcver	No	Prol hsp
Comment: SPEECH DISORDERS, APHASIA AND UPPER FUNCTIONS TROUBLES DURING PROSTATECTOMY ON THE 14TH OF JUNE (FOLLOW UP SUFFICIENT ON THE 20TH OF JUNE)															
	White		Placebo	Vascular disorders (	Intra-abdominal haematoma (	75	92	18	Sev	No	None	No	Unk	No	Req hsp
	White		Placebo	Vascular disorders (	Lymphocele (	75	92	18	Sev	No	None	No	Unk	No	Req hsp
	White		Post study	Respiratory, thoracic and mediastinal disorders (	Dyspnoea (	82	86	5	Mod	No	None	Yes	Rcver	No	Imm thrt/Disab l/Req hsp/Prol
	White		Post study	Respiratory, thoracic and mediastinal disorders (	Hypoxia (	82	86	5	Mod	No	None	Yes	Rcver	No	Prol hsp
	White		Post study	Respiratory, thoracic and mediastinal disorders (	Pharyngeal oedema (	82	92	11	Sev	No	None	Yes	Unk	No	Prol hsp

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Episodes with a negative start day are not assigned to the analysing treatment.

MedDRA version used for reporting: [REDACTED]

Listing 4.2.1 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Placebo

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_003 6_001462	White	74/M	Post study	Renal and urinary disorders (腎および尿路障害)	Renal failure (腎不全)	82	92	11	Sev	No	None	No	Unk	No	Req hsp
Comment: PATIENT HAS BEEN ADMITTED AT EMERGENCY ON THE 24TH OF JUNE; WE ARE WAITING FOR THE REPORT.															
	White		Post study	Respiratory, thoracic and mediastinal disorders (呼吸器、胸郭および縦隔障害)	Pulmonary embolism (肺塞栓症)	83	92	10	Sev	No	None	Yes	Unk	No	Prol hsp
1245_003 6_001463	White	73/F	Placebo	General disorders and administration site conditions (一般・全身障害および投与部位の状態)	Chest pain (胸痛)	54	54	1	Sev	No	None	Yes	Rcver	No	Disabl/Req hsp
	White		Placebo	Respiratory, thoracic and mediastinal disorders (呼吸器、胸郭および縦隔障害)	Dyspnoea (呼吸困難)	54	54	1	Sev	No	None	Yes	Rcver	No	Imm thrt/Disab l/Req hsp

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Episodes with a negative start day are not assigned to the analysing treatment.

MedDRA version used for reporting: [REDACTED]

Listing 4.2.1 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Placebo

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_003 6_001544	White	77/M	Post trt	Neoplasms benign, malignant and unspecified (incl cysts and polyps) (	Prostate cancer metastatic (	250	5267	2777	Sev	No	Disc	Yes	Nrec&	No	Imm thrt
				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))	転移性前立腺癌)										
Comment: AE 1,3 AND 4 WERE RELATED TO THIS SAE															
1245_003 6_001628	White	66/F	Placebo	Gastrointestinal disorders (	Colonic polyp (	31	32	2	Sev	No	None	Yes	Rcver	No	Req hsp
				胃腸障害)	結腸ポリープ)										
Comment: POLIPECTOMY															
	White		Placebo	Metabolism and nutrition disorders (	Metabolic disorder (	95	199	105	Sev	No	Disc	No	Rcver	No	Req hsp
				害)	代謝および栄養障 害)										
Comment: HYPERGLUCEMY															
1245_003 6_001636	White	76/M	Placebo	General disorders and administration site conditions (	Oedema peripheral (	366	371	6	Sev	No	None	No	Rcver	No	Req hsp
				一般・全身障害お よび投与部位の状 態)	末梢性浮腫)										
1245_003 6_001661	White	61/F	Placebo	Psychiatric disorders (	Depressive symptom (	71	2787	2087	Sev	No	Disc	Yes	Nrec&	No	Req hsp
				精神障害)	抑うつ症状)										
Comment: ELECTROCONVULSIVE THERAPY GIVEN TO THE PATIENT															

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MedDRA version used for reporting: [REDACTED]

Listing 4.2.1 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Placebo

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_003 6_001729	White	72/F	Placebo	Injury, poisoning and procedural complications (	Spinal fracture (脊椎骨折)	46	3867	3417	Sev	No	None	Yes	Nrec&	No	Req hsp
傷害、中毒および 処置合併症) Comment: THE PATIENT WAS FALLEN AT HOME [TRAUMATIC FRACTURE]															
1245_003 6_002026	White	68/M	Placebo	Musculoskeletal and connective tissue disorders (	Arthritis (	22	28	7	Sev	No	None	Yes	Rcver	No	Req hsp
筋骨格系および結 合組織障害)															
1245_003 6_002141	White	73/F	Placebo	Vascular disorders (	Circulatory collapse (	214	230	17	Mod	No	None	Yes	Rcver	No	Req hsp
血管障害)															
	White		Placebo	Nervous system disorders (	Cerebrovascular accident (	284	303	20	Mod	No	None	Yes	Rcver	No	Req hsp
神経系障害)															
1245_003 6_002265	White	70/M	Placebo	Cardiac disorders (	Angina unstable (不安定狭心症)	69	78	10	Sev	No	None	Yes	Rcver	No	Req hsp
心臓障害)															
	White		Placebo	Vascular disorders (	Subclavian artery stenosis (	88	91	4	Mod	No	None	Yes	Rcver	No	Req hsp
血管障害)															
	White		Placebo	Vascular disorders (	Subclavian artery stenosis (	237	249	13	Sev	No	None	Yes	Rcver	No	Req hsp
血管障害)															
鎖骨下動脈狭窄)															

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MedDRA version used for reporting: [REDACTED]

Listing 4.2.1 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Placebo

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_003 6_002265	White	70/M	Placebo	Hepatobiliary disorders (肝胆道系障害)	Cholecystitis (胆囊炎)	252	263	12	Sev	No	None	Yes	Rcver	No	Req hsp
1245_003 6_002326	Asian	53/M	Post trt	Infections and infestations (感染症および寄生 虫症)	Bronchopneumonia (気管支肺炎)	374	378	5	Mod	No	None	Yes	Rcver	No	Req hsp
Comment: PATIENT DEVELOPED BREATHLESSNESS ON 16/02/2016 AND ADMITTED TO HOSPITAL FROM 16/2/2016-20/2/2016. COMMENCED ON IV ANTIBIOTICS AND DISCHARGED WELL ON 20/02/2016.															
1245_003 6_002344	Asian	55/F	Placebo	Renal and urinary disorders (腎および尿路障害)	Diabetic nephropathy (糖尿病性腎症)	140	163	24	Mild	No	None	Yes	Rcver	No	Req hsp
	Asian		Placebo	Metabolism and nutrition disorders (代謝および栄養障 害)	Fluid overload (水分過負荷)	140	163	24	Mild	No	None	Yes	Rcver	No	Req hsp
	Asian		Placebo	Cardiac disorders (心臓障害)	Cardiac failure (心不全)	160	163	4	Mild	No	None	Yes	Rcver	No	Req hsp
	Asian		Placebo	Cardiac disorders (心臓障害)	Cardiac failure congestive (うっ血性心不全)	192	199	8	Mild	No	None	Yes	Rcver	No	Req hsp
	Asian		Placebo	Metabolism and nutrition disorders (代謝および栄養障 害)	Fluid overload (水分過負荷)	192	199	8	Mild	No	None	Yes	Rcver	No	Req hsp

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MedDRA version used for reporting: 20.0

Listing 4.2.1 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Placebo

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_003 6_002345	Asian	48/M	Placebo	Metabolism and nutrition disorders (代謝および栄養障 害)	Diabetic ketoacidosis (糖尿病性ケトアシ ドーシス)	353	359	7	Sev	No	None	Yes	Rcver	No	Req hsp
Comment: SYMPTOMATIC OF HYPERGLYCEMIA, SUGAR HIGH INDEX, SEVERE METAOBOLIC ACIDOSIS, URINE KETONE 3+															
	Asian		Placebo	Gastrointestinal disorders (胃腸障害)	Pancreatitis (膵炎)	353	359	7	Sev	No	None	Yes	Rcver	No	Req hsp
Comment: SEVERE VOMITING, SERUM AMYLASE 2325,SERUM CALCIUM 2.03, PHOSPHATE 0.5, ULTRASOUND PROBABLE PANCRAETITIS															
1245_003 6_002371	Asian	57/M	Placebo	Injury, poisoning and procedural complications (傷害、中毒および 処置合併症)	Limb injury (四肢損傷)	88	127	40	Mod	No	None	Yes	Rcver	No	Req hsp
1245_003 6_002557	Asian	57/M	Placebo	Cardiac disorders (心臓障害)	Atrial fibrillation (心房細動)	166	258	93	Mod	No	None	Yes	Rcver	No	Other
Comment: PATIENT NOTICED THAT ON MODERATE EXCERTION, HE EXPERIENCED SHORTNESS OF BREATH AND PALPITATION. PATIENT ATTRIBUTED IT INITIALLY TO HIS PULMONARY PROBLEM.															
	Asian		Placebo	Nervous system disorders (神経系障害)	Embolic cerebral infarction (塞栓性脳梗塞)	239	551	313	Sev	No	None	Yes	Seq	No	Disabl
Comment: CONTINUING WITH SEQUELAE AS OF 22 NOV 2016															
1245_003 6_002561	Asian	37/M	Post trt	General disorders and administration site conditions (一般・全身障害お よび投与部位の状 態)	Sudden cardiac death (心突然死)	29	29	1	Sev	No	Disc	No	Fatal	No	Fatal

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Listing 4.2.1 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Placebo

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_003 6_002664	White	49/F	Placebo	Vascular disorders (	Hypertension (	230	241	12	Mod	No	None	Yes	Rcver	No	Req hsp
Comment: ON 06FEB 2016 PATIENT HAD VISITED HER PHYSICIAN WITH COMPLAINTS OF WEAKNESS AND DYSPNEA. BLOOD PRESSURE WAS FOUND AS 240/100 MM HG AND PATIENT WAS HOSPITALIZED															
1245_003 6_002786	White	73/M	Placebo	Cardiac disorders (	Cardiac failure	18	24	7	Mod	No	None	Yes	Rcver	No	Req hsp
Comment: PATIENT WAS HOSPITALIZED ON 14 MAY 2016, STUDY DRUG WAS DISCONTINUED ON 15 MAY 2016 AND REINTRODUCED ON 21 MAY 2016.															
	White		Placebo	Cardiac disorders (	Acute myocardial infarction (	305	325	21	Mod	No	None	Yes	Rcver	No	Req hsp
	White		Placebo	Cardiac disorders (	Cardiac arrest (	305	305	1	Sev	No	None	Yes	Rcver	No	Imm thrt/Req hsp
Comment: ON 25. FEB.2016 PATIENT EXPERIENCED DYSPNOEA, COLLAPSE, MOBILE EMERGENCY CARE UNIT WAS CALLED, PATIENT WAS GIVEN CARDIOPULMONARY RESUSCITATION AND AFTER HOSPITALIZED															
	White		Placebo	Nervous system disorders (	Hypoxic- ischaemic encephalopathy (	305	305	1	Sev	No	None	Yes	Rcver	No	Imm thrt/Req hsp
Comment: PATIENT EXPERIENCED OD CARDIAC ARREST WITH SUCCESSFUL RESUSCITATION, PATIENT WAS HOSPITALIZED AND HYPOXIC ENCEPHALOPATHIA WAS DIAGNOSED															
	White		Placebo	Infections and infestations (	Pneumonia (	305	343	39	Mod	No	None	Yes	Rcver	No	Req hsp
虫症)															

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Listing 4.2.1 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Placebo

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_003 6_002786	White	73/M	Placebo	Cardiac disorders (	Acute myocardial infarction (	339	351	13	Mod	No	None	Yes	Rcver	No	Req hsp
	White		Placebo	Respiratory, thoracic and mediastinal disorders (	Pulmonary oedema (肺水腫)	339	343	5	Mod	No	None	Yes	Rcver	No	Req hsp
				呼吸器、胸郭およ び縦隔障害)											
1245_003 6_002901	White	65/F	Placebo	Hepatobiliary disorders (	Cholecystitis (	78	83	6	Mod	No	None	Yes	Rcver	No	Req hsp
				肝胆道系障害)	胆嚢炎)										
1245_003 6_002966	Asian	58/F	Placebo	Nervous system disorders (	Dizziness (	29	30	2	Mod	No	None	Yes	Rcver	No	Req hsp
	Asian		Placebo	Nervous system disorders (	Hypoaesthesia (	29	30	2	Mod	No	None	Yes	Rcver	No	Req hsp
				神経系障害)	感覚鈍麻)										
1245_003 6_003042	Asian	73/M	Placebo	Injury, poisoning and procedural complications (	Clavicle fracture (	205	4147	2107	Mod	No	None	Yes	Nrec&	No	Req hsp
				傷害、中毒および 処置合併症)	鎖骨骨折)										
Comment: SLIP AND FELL ON BUS. FRACTURE RIBS AND CLAVICLE (TRAUMATIC FRACTURE)															
	Asian		Placebo	Injury, poisoning and procedural complications (	Fall (転倒)	205	212	8	Mod	No	None	Yes	Rcver	No	Req hsp
				傷害、中毒および 処置合併症)											
Comment: SLIP AND FELL ON BUS. FRACTURE RIBS & CLAVICLE. RIGHT LUNG CONTUSION, PNEUMOTHROX															

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 Episodes with a negative start day are not assigned to the analysing treatment.
 MedDRA version used for reporting: ■■■■

Listing 4.2.1 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Placebo

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_003 6_003042	Asian	73/M	Placebo	Injury, poisoning and procedural complications (	Rib fracture (	205	4147	2107	Mod	No	None	Yes	Nrec&	No	Req hsp
				傷害、中毒および 処置合併症)	肋骨骨折)										
Comment: SLIP AND FELL ON BUS. FRACTURE RIBS AND CLAVICLE (TRAUMATIC FRACTURE)															
	Asian		Placebo	Injury, poisoning and procedural complications (	Traumatic lung injury (	205	254	50	Mod	No	None	Yes	Rcver	No	Req hsp
				傷害、中毒および 処置合併症)	外傷性肺損傷)										
	Asian		Placebo	Injury, poisoning and procedural complications (	Pneumothorax traumatic (	205	254	50	Mod	No	None	Yes	Rcver	No	Req hsp
				傷害、中毒および 処置合併症)	外傷性気胸)										
1245_003 6_003047	Asian	67/F	Placebo	Vascular disorders (	Hypertension (	288	289	2	Mild	No	None	No	Rcver	No	Req hsp
				血管障害)	高血圧)										
1245_003 6_003126	Asian	26/F	Placebo	Respiratory, thoracic and mediastinal disorders (	Pulmonary oedema (肺水腫)	75	141	67	Sev	Yes	Disc	Yes	Fatal	No	Fatal
				呼吸器、胸郭およ び縦隔障害)											
Comment: THE SUBJECT HAS DEVELOPED,ORTHOPNOEA,SOB ON MINIMAL EXERCISE(GRIII),ANASARCA AND TIGHTNESS IN BOTH LOWER LIMBS.CLINICAL THE SUBJECT HAS WORSENING OF THE ONGOING CLINICAL CONDITION AND THERE IS FLUID															

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Listing 4.2.1 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Placebo

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_003 6_003133	Asian	58/F	Placebo	Musculoskeletal and connective tissue disorders (筋骨格系および結 合組織障害)	Back pain (背部痛)	266	289	24	Mod	No	None	Yes	Rcver	No	Req hsp
	Asian		Placebo	Renal and urinary disorders (腎および尿路障害)	Renal colic (腎仙痛)	289	292	4	Sev	No	None	Yes	Rcver	No	Req hsp
Comment: SUBJECT PRESENTED WITH C/O PAIN IN THE LEFT LOIN EXTENDING TO GROIN. THE PAIN STARTED AT 3 AM. LATER SINCE MORNING SHE IS EXPERIENCING BURNING MICTURATION,ALONG WITH FEVER AND VOMITINGS.															
1245_003 6_003229	Asian	58/F	Post trt	Renal and urinary disorders (腎および尿路障害)	Renal failure acute (急性腎不全)	229	238	10	Mod	Yes	None	Yes	Rcver	No	Req hsp
	Asian		Post trt	Blood and lymphatic system disorders (血液およびリンパ系障害)	Anaemia (貧血)	229	238	10	Mod	No	None	Yes	Rcver	No	Req hsp
	Asian		Post trt	Infections and infestations (感染症および寄生虫症)	Urinary tract infection (尿路感染)	229	238	10	Mod	Yes	None	Yes	Rcver	No	Req hsp
Comment: SYMPTOMATIC AND ALSO CONFIRMED WITH URINE CULTURE AND SENSITIVITY TEST															

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Listing 4.2.1 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Placebo

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_003 6_003552	White	71/M	Placebo	Neoplasms benign, malignant and unspecified (incl cysts and polyps) (	Squamous cell carcinoma (	79	88	10	Mild	No	None	Yes	Rcver	No	Other
				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))	扁平上皮癌)										
Comment: AGENCY REPORTING REQUIRMENT PER SPONSOR. PATIENT NOTICED SPOT ON LIP, WENT TO HIS PHYSICIAN. PATIENT HAS A HISTORY OF ACTUNIC KERATOSIS. SPOT REMOVED SUCCESSFULLY.															
1245_003 6_003641	White	60/F	Placebo	Renal and urinary disorders (	Renal failure acute (	338	341	4	Mod	Yes	None	Yes	Rcver	No	Req hsp
				腎および尿路障害)	急性腎不全)										
	White		Placebo	Infections and infestations (	Urinary tract infection (	338	343	6	Mild	Yes	None	Yes	Rcver	No	Req hsp
				感染症および寄生 虫症)	尿路感染)										
Comment: ASYMPTOMATIC UTI WITH MODERATED LEUKOCYTES ON URINALYSIS															
	White		Placebo	Metabolism and nutrition disorders (	Hypovolaemia (	338	341	4	Mod	Yes	None	Yes	Rcver	No	Req hsp
				代謝および栄養障 害)	血液量減少症)										
	White		Placebo	Cardiac disorders (	Angina unstable (不安定狭心症)	354	359	6	Mod	No	None	Yes	Rcver	No	Req hsp
				心臓障害)											
1245_003 6_003702	White	76/M	Placebo	Gastrointestinal disorders (	Pancreatitis (	272	303	32	Mild	No	None	No	Rcver	No	Req hsp
				胃腸障害)	膵炎)										

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Listing 4.2.1 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Placebo

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_003 6_003721	White	64/F	Placebo	Neoplasms benign, malignant and unspecified (incl cysts and polyps) (	Pancreatic carcinoma (	362	3867	257	Sev	No	None	Yes	Nrec&	No	Imm thrt
				良性、悪性および 詳細不明の新生物 (嚢胞およびポリ ーブを含む))	膵癌)										
1245_003 6_003761	Amer.I nd./Al aska Nat	68/M	Placebo	Cardiac disorders (	Cardiogenic shock (	348	349	2	Sev	No	Disc	Yes	Fatal	No	Fatal/Imm thrt/Req hsp
				心臓障害)	心原性ショック)										
Comment: SUBJECT DIED 01/APR/2016.															
1245_003 6_003865	White	78/M	Placebo	Neoplasms benign, malignant and unspecified (incl cysts and polyps) (	Skin cancer (	19	20	2	Mod	No	None	Yes	Seq	No	Req hsp
				良性、悪性および 詳細不明の新生物 (嚢胞およびポリ ーブを含む))	皮膚癌)										
Comment: SKIN CANCER WOUND TREATMENT ONLY STOPPED 1 AUGUST 2016. WOUNDS HEALED ON 1 AUG 2016.															
1245_003 6_003877	White	58/F	Placebo	Injury, poisoning and procedural complications (	Fall (転倒)	98	112	15	Mod	No	None	Yes	Rcver	No	Req hsp
				傷害、中毒および 処置合併症)											
Comment: DUE TO PT FALLING AND TRIPPING, TRAUMATIC FRACTURE															

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Listing 4.2.1 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Placebo

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_003 6_003877	White	58/F	Placebo	Injury, poisoning and procedural complications (	Humerus fracture (上腕骨折)	98	112	15	Mod	No	None	Yes	Rcver	No	Req hsp
傷害、中毒および 処置合併症) Comment: DUE TO PT FALLING AND TRIPPING, TRAUMATIC FRACTURE															
1245_003 6_003918	Asian	65/M	Placebo	Cardiac disorders (	Atrial fibrillation (	66	77	12	Mod	No	Disc	No	Rcver	No	Req hsp
心臓障害) 心房細動) Comment: PATIENT HAD EPISODE OF SYNCOPE ON 15/07/20 AT 0800HRS WHILE WALKING IN THE PARK. ADMITTED TO HOSPITAL AND TELEMETRY SHOWED RUNS OF PAROXYSMAL ATRIAL FIBRILLATION WHICH IS THE MOST LIKELY CAUSE.															
1245_003 6_003919	Asian	62/M	Placebo	Gastrointestinal disorders (	Abdominal pain upper (	41	42	2	Sev	No	None	Yes	Rcver	No	Req hsp
胃腸障害) 上腹部痛) Comment: PATIENT HAD MODERATELY SEVERE PAINS, COLICLY IN NATURE, AFTER DINNER. WENT TO EMENCENCY AND GIVEN ANTISPAMODIC INJECTION BUSCOPEAN. ADMITTED FOR OVERNIGHT OBSERVATION. RECOVERED FULLY. DIAGNOSIS: GALL															

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 Episodes with a negative start day are not assigned to the analysing treatment.

MedDRA version used for reporting:

Listing 4.2.1 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Empa 10mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_003 6_001132	White	80/M	Empa 10mg	Cardiac disorders (	Acute coronary syndrome (	87	95	9	Sev	No	None	Yes	Rcver	No	Req hsp
Comment: ACUTE CORONARY SYNDROME (心臓障害) 急性冠動脈症候群)															
1245_003 6_001187	White	67/M	Empa 10mg	Musculoskeletal and connective tissue disorders (	Osteoarthritis (	254	254	1	Sev	No	None	Yes	Rcver	No	Req hsp
Comment: PT WAS ADMITTED TO HOSPITAL FOR LEFT HIP REPLACEMENT SURGERY TO TREAT THIS EVENT (筋骨格系および結 合組織障害) 変形性関節症)															
1245_003 6_001906	White	65/M	Empa 10mg	Hepatobiliary disorders (	Cholecystitis acute (	323	413	91	Sev	No	None	Yes	Rcver	No	Req hsp
Comment: INTERMITTENT ABDO PAIN & VOMITING SINCE 3.1.11, WORSENING OVERNIGHT 11.1.11, ADMITTED TO HOSPITAL. LAPAROSCOPIC 肝胆道系障害) 急性胆嚢炎) CHOLECYSTECTOMY PERFORMED 23 MARCH 2011.															
1245_003 6_001967	White	71/M	Empa 10mg	General disorders and administration site conditions (	Chest pain (	86	92	7	Mod	No	None	Yes	Rcver	No	Req hsp
Comment: ADMITTED TO HOSPITAL 9/5/11 (一般・全身障害お よび投与部位の状 態)															
	White		Empa 10mg	Vascular disorders (	Aortic stenosis (大動脈狭窄)	220	228	9	Sev	No	None	Yes	Rcver	No	Req hsp
Comment: PLANNED SURGERY AORTIC VALVE REPLACEMENT PROCEDURE UNDERTAKEN 23/9/11 (血管障害)															

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Episodes with a negative start day are not assigned to the analysing treatment.
MedDRA version used for reporting: 11.0

Listing 4.2.1 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Empa 10mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_003 6_002362	Asian	55/M	Empa 10mg	Gastrointestinal disorders (	Oesophageal varices haemorrhage (	316	323	8	Sev	No	None	Yes	Rcver	No	Imm thrt
Comment: UPPER GASTROINTESTINAL BLEED DUE TO BLEEDING FUNDAL VARICES															
1245_003 6_002377	Asian	78/M	Empa 10mg	Reproductive system and breast disorders (	Benign prostatic hyperplasia (	249	260	12	Mod	No	None	Yes	Rcver	No	Req hsp
				生殖系および乳房 障害)	良性前立腺肥大症										
	Asian		Empa 10mg	Reproductive system and breast disorders (	Benign prostatic hyperplasia (	249	260	12	Sev	No	None	Yes	Rcver	No	Req hsp
				生殖系および乳房 障害)	良性前立腺肥大症										

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 Episodes with a negative start day are not assigned to the analysing treatment.
 MedDRA version used for reporting: ■■■■

Listing 4.2.1 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Empa 25mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_003 6_001035	White	72/F	Empa 25mg	Nervous system disorders (	Transient ischaemic attack (一過性脳虚血発作)	71	71	1	Mod	No	None	Yes	Rcver	No	Other
Comment: UPDATED BI PROCESS, TIA'S ALWAYS A SAE															
1245_003 6_001110	Black/ Africa n Amer.	60/F	Empa 25mg	Infections and infestations (	Cellulitis (	120	4357	3167	Sev	No	Disc	Yes	Nrec& hsp	No	Req hsp/Prol
Comment: ADMISSION TO HOSPITAL FOR PERIOD AUG 29/ TO SEP 26/ . TO BE FOLLOWED IN MDCC-CLINIC ON ROUTINE BASIS.															
	Black/ Africa n Amer.		Empa 25mg	Injury, poisoning and procedural complications (	Wound (創傷)	120	4007	2817	Sev	No	Disc	Yes	Nrec&	No	Req hsp/Prol hsp
Comment: ADMISSION TO HOSPITAL FOR PERIOD AUG 29/ TO SEP 26/ . TO BE FOLLOWED IN MDCC-CLINIC ON ROUTINE BASIS.															
1245_003 6_001128	Asian	56/M	Empa 25mg	Nervous system disorders (	Lacunar infarction (	111	116	6	Sev	No	None	Yes	Rcver	No	Req hsp
1245_003 6_001200	White	75/F	Empa 25mg	Gastrointestinal disorders (	Constipation (	177	184	8	Mod	No	None	Yes	Rcver	No	Req hsp
	White		Empa 25mg	Gastrointestinal disorders (	Abdominal pain (	180	181	2	Sev	No	None	No	Rcver	No	Req hsp
Comment: PT STOPPED TAKING THE STUDY MEDICATION ON HER OWN ACCORD.															

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Episodes with a negative start day are not assigned to the analysing treatment.

MedDRA version used for reporting:

Listing 4.2.1 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Empa 25mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_003 6_001200	White	75/F	Empa 25mg	Renal and urinary disorders (腎および尿路障害)	Renal failure acute (急性腎不全)	180	184	5	Sev	No	None	No	Rcver	No	Req hsp
Comment: PT STOPPED STUDY MEDICATION ON HER OWN ACCORD															
	White		Empa 25mg	Gastrointestinal disorders (胃腸障害)	Diarrhoea (下痢)	180	180	1	Sev	No	None	No	Rcver	No	Req hsp
Comment: PT STOPPED TAKING STUDY MEDICATION ON HER OWN ACCORD.															
	White		Empa 25mg	Nervous system disorders (神経系障害)	Syncope (失神)	180	182	3	Sev	No	Disc	No	Rcver	No	Req hsp
Comment: PT STOPPED STUDY MEDICATION ON HER OWN ACCORD															
1245_003 6_001213	Asian	61/M	Post trt	Infections and infestations (感染症および寄生 虫症)	Sepsis (敗血症)	86	957	107	Sev	No	None	Yes	Nrec&	No	Req hsp
Comment: PATIENT WAS ADMITTED TO HOSPITAL ON 22 SEP 2016. COMPLAINING OF GENERALISED ANSARCA AND BREATHLESSNESS. HE EXPIRED IN THE HOSPITAL ON 24 SEP 2016.															
1245_003 6_001215	Asian	52/F	Empa 25mg	Infections and infestations (感染症および寄生 虫症)	Urinary tract infection (尿路感染)	339	382	44	Mod	Yes	None	Yes	Rcver	No	Req hsp
Comment: PATIENT HAD FEVER AND NOTICED BURNING MICTURITION AND WAS ADVISED TO GET HER URINE ROUTINE,CBC TEST AND PS FOR MP.T.NORFLOX,T.CALPOL AND SYP.CITAL WAS PRESCRIBED.															

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MedDRA version used for reporting: 20.1

Listing 4.2.1 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Empa 25mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_003 6_001281	White	75/M	Empa 25mg	Neoplasms benign, malignant and unspecified (incl cysts and polyps) (明) 良性、悪性および 詳細不明の新生物 (嚢胞およびポリ ーブを含む)	Oropharyngeal cancer stage unspecified (中咽頭癌、病期不	113	198	86	Sev	No	Disc	Yes	Rcver	No	Req hsp
Comment: STUDY MEDICATION WAS STOPPED AT 13TH OCTOBER 2016. PATIENT WAS HOSPITALISED FROM 28 TILL 29 SEPTEMBER 2016 FOR PANENDOSCOPY.															
	White		Empa 25mg	Respiratory, thoracic and mediastinal disorders (呼吸器、胸郭および縦隔障害)	Epistaxis (鼻出血)	120	126	7	Sev	No	None	Yes	Rcver	No	Req hsp
Comment: EPISTAXIS FOLLOWING PANENDOSCOPY OROPHARYNGEAL REGION, PATIENT WAS SEEN AT THE EMERGENCY ROOM.															
1245_003 6_001425	Black/ Africa n Amer.	42/M	Empa 25mg	Renal and urinary disorders (腎および尿路障害)	Renal failure (腎不全)	171	2627	927	Sev	Yes	Disc	No	Nrec&	No	Other
Comment: WORSENING OF PRE-EXISTING RENAL FAILURE LEADING TO PREPARATION OF THE PATIENT FOR HAEMODIALYSIS IN ERMERGENCY															
1245_003 6_001561	White	74/F	Empa 25mg	Metabolism and nutrition disorders (代謝および栄養障害)	Hyperglycaemia (高血糖)	132	273	142	Mod	No	None	No	Rcver	No	Req hsp
Comment: HOSPITALISATION FROM 05/03/2016 TO 09/03/2016															

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MedDRA version used for reporting: 20.1

Listing 4.2.1 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Empa 25mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_003 6_001638	White	76/M	Empa 25mg	Respiratory, thoracic and mediastinal disorders (	Hypoxia (	212	217	6	Sev	No	None	No	Rcver	No	Req hsp
				呼吸器、胸郭およ び縦隔障害)	低酸素症)										
	White		Empa 25mg	Infections and infestations (	Respiratory tract infection	212	217	6	Sev	No	None	Yes	Rcver	No	Req hsp
				感染症および寄生 虫症)	(気道感染)										
1245_003 6_001815	White	62/M	Empa 25mg	Neoplasms benign, malignant and unspecified (incl cysts and polyps) (	Malignant melanoma (	233	3717	1397	Sev	No	None	Yes	Nrec&	No	Other
				良性、悪性および 詳細不明の新生物 (嚢胞およびポリ ーブを含む))	悪性黒色腫)										
Comment: RECESSION OF CUTANEOUS MELANOMA															
1245_003 6_001816	White	65/M	Empa 25mg	Gastrointestinal disorders (	Pancreatitis acute (	309	312	4	Sev	No	None	Yes	Rcver	No	Req hsp
				胃腸障害)	急性膵炎)										
1245_003 6_001922	White	73/M	Empa 25mg	Eye disorders (	Retinal artery occlusion (	47	5507	5047	Mod	No	None	Yes	Nrec&	No	Other
				眼障害)	網膜動脈閉塞)										
Comment: RESULTING IN MINOR BUT PERMANENT VISUAL IMPAIRMENT															

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 MedDRA version used for reporting: ■■■■

Listing 4.2.1 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Empa 25mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_003 6_001973	White	79/F	Empa 25mg	Injury, poisoning and procedural complications (	Pelvic fracture (骨盤骨折)	102	185*	84*	Sev	No	None	Yes	Seq	No	Disabl/Req hsp
Comment: PATIENT FELL , CAUSE OF FALL UNKNOWN. RESULTING IN FRACTURE, TRAUMATIC INJURY. HEALED BY UNK/AUG/20															
1245_003 6_002060	White	52/M	Empa 25mg	Musculoskeletal and connective tissue disorders (	Pain in extremity (	264	313	50	Sev	No	None	Yes	Rcver	No	Req hsp
Comment: SUDDEN PAIN IN L CALF WHICH LATER LED TO HOSPITALISATION FOR TORN MUSCLE IN L LEG															
1245_003 6_002142	White	63/F	Empa 25mg	Hepatobiliary disorders (	Cholelithiasis (	82	85	4	Mild	No	None	Yes	Rcver	No	Req hsp
1245_003 6_002244	White	68/F	Empa 25mg	Cardiac disorders (	Coronary artery occlusion (	366	366	1	Mild	No	None	Yes	Rcver	No	Req hsp
Comment: CRITICAL OCCLUSION OF CIRCUMFLEX CORONARY ARTERY FOUND DURING PLANNED CORONAROGRAPHY, DES IMPLANTED WITH GOOD HAEMODYNAMIC EFFECT.															
1245_003 6_002268	White	52/M	Empa 25mg	Skin and subcutaneous tissue disorders (	Diabetic foot (	306	338	33	Sev	No	Disc	Yes	Rcver	No	Req hsp
	White		Empa 25mg	Vascular disorders (	Extremity necrosis (	306	338	33	Sev	No	Disc	Yes	Rcver	No	Req hsp

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MedDRA version used for reporting:

Listing 4.2.1 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Empa 25mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_003 6_002343	Asian	63/M	Empa 25mg	Infections and infestations (感染症および寄生 虫症)	Dengue fever (デング熱)	193	204	12	Mild	No	None	Yes	Rcver	No	Req hsp
Comment: 16 JULY 2016: DENGUE RAPIT TEST POSITIVE. 17 JULY 2016: PLT 151,000. DIAGNOSIS: DENGUE FEVER															
	Asian		Empa 25mg	Blood and lymphatic system disorders (血液およびリンパ 系障害)	Thrombocytopenia (血小板減少症)	195	203	9	Mild	No	None	Yes	Rcver	No	Prol hsp
Comment: 18 JULY 2016: PLT READING - NO BLEEDING TENDENCY, GIVEN FLUID THERAPY. 26 JULY 2016: PLT RECOVERED.															
	Asian		Empa 25mg	Hepatobiliary disorders (肝胆道系障害)	Hepatitis (肝炎)	196	2597	647	Mild	No	None	No	Nrec&	No	Prol hsp
Comment: DURING HOSPITALIZATION, PATIENT HAD SERIAL LIVER FUNCTION TEST DONE; INDICATION IS HEPATITIS PICTURE SECONDARY TO VIRAL INFECTION															
	Asian		Empa 25mg	Vascular disorders (血管障害)	Thrombophlebitis (血栓性静脈炎)	197	203	7	Mild	No	None	Yes	Rcver	No	Prol hsp
Comment: PATINET WAS NOTED TO HAVE SPIKING OF TEMPERATURE ON 20 JULY 2016 AND THERE WAS SIGNS OF INFLAMATION ON (R) DOWN OF THE HAND AT THE BRANULA SITE.SO THE BRANULA WAS OFF AND IV CLOXA 500MGQID WAS STARTED															
1245_003 6_002449	Asian	57/F	Empa 25mg	Eye disorders (眼障害)	Glaucoma (緑内障)	12	50	39	Mild	No	None	No	Rcver	No	Req hsp
Comment: GLUCOMA SUSPECT ADMITTED TO EYE WARD FOR PHASING TO DAY (2-JUN-2016)DISCHARGED 3-JUN-2016. NO GLUCOMA															
1245_003 6_002847	White	68/M	Empa 25mg	Vascular disorders (血管障害)	Peripheral ischaemia (末梢性虚血)	97	3997	3037	Mod	No	None	Yes	Nrec&	No	Req hsp

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MedDRA version used for reporting: 20.1

Listing 4.2.1 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Empa 25mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_003 6_002873	White	69/M	Empa 25mg	Renal and urinary disorders (	Renal failure chronic (	279	310	32	Mod	No	None	Yes	Rcver	No	Req hsp
			)	腎および尿路障害	慢性腎不全)										
	White		Empa 25mg	Infections and infestations (	Urinary tract infection (	296	310	15	Mod	No	None	Yes	Rcver	No	Prol hsp
				感染症および寄生 虫症)	尿路感染)										
Comment: ASYMPTOMATIC ACUTE URINARY TRACT INFECTION WITH POSITIVE CULTIVATION OF URINE - E.COLI, CANDIDA ALBICANS															
1245_003 6_002909	White	66/M	Empa 25mg	Infections and infestations (	Pharyngitis (	15	22	8	Mild	No	None	Yes	Rcver	No	Req hsp
				感染症および寄生 虫症)	咽頭炎)										
1245_003 6_002916	White	60/M	Empa 25mg	Infections and infestations (	Gangrene (	56	127	72	Sev	No	None	Yes	Seq	No	Req hsp
				感染症および寄生 虫症)	壊疽)										
Comment: FOOT AMPUTATED															
1245_003 6_002967	Asian	63/F	Empa 25mg	Injury, poisoning and procedural complications (	Joint injury (	353	367	15	Mild	No	None	Yes	Rcver	No	Req hsp
				傷害、中毒および 処置合併症)	関節損傷)										
	Asian		Empa 25mg	Injury, poisoning and procedural complications (	Neck injury (	353	367	15	Mild	No	None	Yes	Rcver	No	Req hsp
				傷害、中毒および 処置合併症)	頸部損傷)										

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MedDRA version used for reporting: [REDACTED]

Listing 4.2.1 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Empa 25mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_003 6_003024	Asian	68/M	Empa 25mg	Metabolism and nutrition disorders (代謝および栄養障害)	Hypoglycaemia (低血糖症)	26	31	6	Sev	Yes	Disc	Yes	Rcver	No	Req hsp
Comment: ADMITTED TO HOSPITAL BECAUSE FELT WEAK AND BLURRED VISION AT ABOUT 18:00 WHILST EATING DINNER AT RESTAURANT . NO LOSS OF CONSCIOUSNESS. NO METER TO CHECK GLUCOSE.															
1245_003 6_003041	Asian	39/F	Empa 25mg	Renal and urinary disorders (腎および尿路障害)	Renal failure acute (急性腎不全)	85	4297	3457	Mod	No	None	No	Nrec&	No	Req hsp
Comment: TO STOP NSAIDS (OFFENDING DRUGS - DICLOFENAC). PATIENT WAS HOSPITALIZED DURING 7SEP - 9SEP20 TO PERFORM RENAL BIOPSY.															
1245_003 6_003048	Asian	67/M	Empa 25mg	Metabolism and nutrition disorders (代謝および栄養障害)	Hypoglycaemia (低血糖症)	25	26	2	Mild	No	None	Yes	Rcver	No	Req hsp
Comment: HYPOGLYCAEMIA ATTACK AS DIZZINESS, ANOREXIA, DIZZINESS, H'STIX2.3, RESUME DIAMICRON AT LOWER DOSE 80MG ON 1/8/20															
	Asian		Empa 25mg	Nervous system disorders (神経系障害)	Cerebrovascular accident (脳血管発作)	27	1187	927	Mod	No	Disc	Yes	Nrec&	No	Req hsp
Comment: ADMITTED FOR DIZZINESS ON 28JUL20. CT BRAIN SHOWED BILATERAL LACUNAR INFARCTS. ALSO DEVELOPED GOUTY ATTACK.															
1245_003 6_003113	Asian	58/M	Empa 25mg	Infections and infestations (感染症および寄生虫症)	Urinary tract infection (尿路感染)	265	346	82	Sev	Yes	Disc	Yes	Rcver	No	Req hsp
Comment: (SYMPTOMATIC)BURNING MICTURATION AND URINE REPORTS SHOWED 20-25 PUS CELLS AND CULTURE IS POSITIVE FOR KLEBSIELLA.															

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MedDRA version used for reporting:

Listing 4.2.1 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Empa 25mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_003 6_003129	Asian	50/M	Empa 25mg	Nervous system disorders (	Cerebral infarction (	37	4087	3727	Mod	No	None	Yes	Nrec&	No	Other
Comment: VERTIGO, IRREVELANT BEHAVIOUR, LOSS OF MEMORY, LACUNAR INFACITS 神経系障害) 脳梗塞)															
	Asian		Empa 25mg	Nervous system disorders (	Cerebrovascular accident (	37	3637	3277	Mod	No	None	Yes	Nrec&	No	Other
Comment: VERTIGO, IRREVELANT BEHAVIOUR, LOSS OF MEMORY, LACUNAR INFACITS 神経系障害) 脳血管発作)															
1245_003 6_003264	Asian	54/M	Empa 25mg	Cardiac disorders (	Cardiac arrest (	59	59	1	Sev	No	Disc	No	Fatal	No	Fatal
Comment: PATIENT APPARENTLY HAD A CARDIAC ARREST AT HOME ON 23 JUN 20 AND THE EVENT WAS INFORMED TELEPHONICALLY TO THE PI BY THE FAMILY MEMBER ON 29 JUN 20 AT 09:30 AM 心臓障害)															
1245_003 6_003304	Asian	64/F	Empa 25mg	Blood and lymphatic system disorders (	Anaemia (貧血)	291	293	3	Sev	No	None	Yes	Rcver	No	Req hsp
Comment: SAE FINISHED BUT GRADE CHANGED TO MILD ANEMIA 血液およびリンパ系障害)															
	Asian		Empa 25mg	Gastrointestinal disorders (	Gastritis erosive (	291	293	3	Mod	No	None	Yes	Rcver	No	Req hsp
Comment: UPPER GI ENDO DONE -EROSIVE GASTRITIS 胃腸障害) びらん性胃炎)															

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Episodes with a negative start day are not assigned to the analysing treatment.
MedDRA version used for reporting:

Listing 4.2.1 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Empa 25mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_003 6_003481	Asian	67/M	Empa 25mg	Neoplasms benign, malignant and unspecified (incl cysts and polyps) (	Oesophageal carcinoma (	11	2997	2897	Sev	No	Disc	Yes	Seq	No	Disabl/Req hsp
				良性、悪性および 詳細不明の新生物 (嚢胞およびポリ ーブを含む))	食道癌)										
1245_003 6_003515	White	52/M	Empa 25mg	Vascular disorders (	Deep vein thrombosis (	155	156	2	Sev	No	None	Yes	Rcver	No	Req hsp
				血管障害)	深部静脈血栓症)										
Comment: PHELIBITIS.PT.SITTING CONTINUOUSLY ON A 5HR DRIVE,SAT THRO MEETING AND DROVE BACK SAME DAY ANOTHER 5 HRS															
1245_003 6_003542	White	75/F	Empa 25mg	Cardiac disorders (	Atrioventricular block (	178	180	3	Sev	No	None	Yes	Rcver	No	Req hsp
				心臓障害)	房室ブロック)										
	White		Empa 25mg	Cardiac disorders (	Sick sinus syndrome (	178	180	3	Sev	No	None	Yes	Rcver	No	Req hsp
				心臓障害)	洞不全症候群)										
	White		Empa 25mg	Cardiac disorders (	Atrial fibrillation (	232	232	1	Mod	No	None	No	Rcver	No	Req hsp
				心臓障害)	心房細動)										
1245_003 6_003571	White	70/F	Empa 25mg	Infections and infestations (	Cellulitis (	127	145	19	Sev	No	Disc	Yes	Rcver	No	Req hsp
				感染症および寄生 虫症)	蜂巣炎)										

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Episodes with a negative start day are not assigned to the analysing treatment.

MedDRA version used for reporting: █

Listing 4.2.1 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Empa 25mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_003 6_003705	White	76/M	Empa 25mg	Renal and urinary disorders (腎および尿路障害)	Renal failure acute (急性腎不全)	91	106	16	Mild	Yes	None	No	Rcver	No	Other
Comment: SERIOUS PER B.I. CRITERIA; VISIT 5 LAB WORK REVEALED HIGH CREATININE, BUN, AND LOW GFR.															
	White		Empa 25mg	Musculoskeletal and connective tissue disorders (筋骨格系および結合組織障害)	Osteoarthritis (変形性関節症)	314	318	5	Mod	No	None	No	Rcver	No	Req hsp
Comment: SURGICAL REVISION OF RIGHT KNEE															
1245_003 6_003727	White	72/F	Empa 25mg	Gastrointestinal disorders (胃腸障害)	Intestinal obstruction (腸閉塞)	246	260	15	Sev	No	None	Yes	Rcver	No	Req hsp
Comment: PATIENT LEFT A VOICEMAIL STATING SHE WAS HOSPITALIZED FOR A BOWEL OBSTRUCTION. WILL ADD MORE INFO AS WE RECEIVE IT. LATER ENTRY-SPOKE WITH PATIENT AND OBTAINED FURTHER INFORMATION. AWAITING RECORDS															
1245_003 6_003779	White	71/F	Empa 25mg	Metabolism and nutrition disorders (代謝および栄養障害)	Hyperglycaemia (高血糖)	47	49	3	Sev	No	None	Yes	Rcver	No	Req hsp
	White		Empa 25mg	Metabolism and nutrition disorders (代謝および栄養障害)	Hypoglycaemia (低血糖症)	121	122	2	Mod	No	None	Yes	Rcver	No	Req hsp
Comment: INTIAL GLUCOSE WAS 61, SUBJECT GIVEN D50. SUBJECT DID NOT ACTIVELY NEEDED ASSISTANCE . SUBJECT RECIEVED IV D50 FROM HOSPITAL NURSE															

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Episodes with a negative start day are not assigned to the analysing treatment.

MedDRA version used for reporting: █

Listing 4.2.1 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Empa 25mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_003 6_003969	Asian	67/M	Empa 25mg	Gastrointestinal disorders (胃腸障害)	Colonic polyp (結腸ポリープ)	203	205	3	Mild	No	None	No	Rcver	No	Req hsp
Comment: PATIENT WAS ADMITTED TO HOSPITAL ON 03-01-2012 FOR ELECTIVE COLONOSCOPY AND 1 SESSILE POLYP AT HEPATIC FLEXURE FOUND. POLYP WAS REMOVED DURING COLONOSCOPY AND PATIENT DISCHARGED ON 05-01-2012.															

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 Episodes with a negative start day are not assigned to the analysing treatment.
 MedDRA version used for reporting: 20.0

Listing 5.2.1 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: Rand. trt. regimen, active only

Treatment: Empa 10mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_003 8_820015	Asian	49/F	Empa 10mg	Infections and infestations (	Viral infection (ウイルス感染)	183	223	41	Mod	No	None	Yes	Rcver	No	Req hsp
虫症)															
Comment: IT IS ASSUMED THAT THE EVENT WAS FORTUITOUS CONSIDERING THE ACTION MECHANISM OF THE STUDY DRUG.															
1245_003 8_820016	Asian	58/M	Empa 10mg	Investigations (	Prostatic specific antigen increased (	253	373	121	Mild	No	None	No	Nrec&	No	Req hsp
				臨床検査)	前立腺特異性抗原 増加)										
Comment: A CAUSAL RELATIONSHIP BETWEEN THE EVENT AND THE STUDY DRUG CAN BE RULED OUT BECAUSE THE EVENT IS AN AGE-RELATED SYMPTOM.															
1245_003 8_830012	Asian	42/M	Empa 10mg	Gastrointestinal disorders (	Colonic polyp (	239	362	124	Mod	Yes	None	Yes	Rcver	No	Req hsp
				胃腸障害)	結腸ポリープ)										
Comment: INFORMATION FOR MAKING DIAGNOSIS MIGHT HAVE BEEN PROVIDED IF A LARGE INTESTINAL EXAMINATION HAD BEEN PERFORMED IMMEDIATELY AFTER DETECTION OF OCCULT BLOOD IN FAECES AT A MEDICAL CHECKUP AS OF 28 JULY,															

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 Episodes with a negative start day are not assigned to the analysing treatment.
 MedDRA version used for reporting: ■■■■

Listing 5.2.1 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: Rand. trt. regimen, active only

Treatment: Empa 25mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_003 8_801013	Asian	69/M	Empa 25mg	Nervous system disorders (	Cerebral infarction (	71	86	16	Mod	No	Disc	Yes	Seq	No	Req hsp
Comment: CAUSED BY A HISTORY BY HYPERTENSION. 神経系障害) 脳梗塞)															
1245_003 8_801043	Asian	56/M	Empa 25mg	Neoplasms benign, malignant and unspecified (incl cysts and polyps) (	Diffuse large B- cell lymphoma (	325	384	7	Sev	No	None	Yes	Nrec&	No	Req hsp/Other
Comment: OTHER COMPARABLE MEDICAL CRITERIA IS MALIGNANCY. THE DIAGNOSIS OF MALIGNANT LYMPHOMA BECAME DEFINITE ACCORDING TO THE BLOOD SAMPLE RESULT. びまん性大細胞型 B細胞性リンパ腫 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)															
1245_003 8_809009	Asian	70/M	Empa 25mg	Hepatobiliary disorders (	Hyperbilirubinae mia (	169	388	7	Mild	No	None	No	Nrec&	No	Req hsp
Comment: IT IS BECAUSE THE SYMPTOMS ARE CONSIDERED TO BE ATTRIBUTED TO THE CONCOMITANT DISEASE, CONSTIPATION. 肝胆道系障害) 高ビリルビン血症)															
	Asian		Empa 25mg	Investigations (	Carbohydrate antigen 19-9 increased (	179	388	7	Mild	No	None	No	Nrec&	No	Req hsp
Comment: EXAMINATION RULED OUT THE POSSIBILITY OF CANCER AND SHOWED NO OTHER ABNORMALITY.A TUMOR MARKER BLOOD TEST IS KNOWN TO OFTEN SHOW A FALSE POSITIVE FOR CA19-9, AND CONSIDERING THE DEGREE OF CA19-9 臨床検査) 糖鎖抗原19-9 増加)															

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Episodes with a negative start day are not assigned to the analysing treatment.
MedDRA version used for reporting: [REDACTED]

Listing 5.2.1 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: Rand. trt. regimen, active only

Treatment: Empa 25mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_003 8_809010	Asian	63/M	Empa 25mg	Neoplasms benign, malignant and unspecified (incl cysts and polyps) (良性、悪性および 詳細不明の新生物 (嚢胞およびポリ ーブを含む))	Oesophageal carcinoma (食道癌)	259	5057	2477	Sev	No	Disc	No	Nrec&	No	Req hsp
Comment: DUE TO INSUFFICIENT INFORMATION TO EXPLAIN THE RELATIONSHIP BETWEEN THE STUDY DRUG AND THE SAE RATIONALLY, THE CAUSALITY SHOULD BE CONCLUDED TO "NO" CURRENTLY(24OCT2018).THE EVENT IS CONSIDERED TO															
1245_003 8_810018	Asian	69/M	Empa 25mg	Neoplasms benign, malignant and unspecified (incl cysts and polyps) (良性、悪性および 詳細不明の新生物 (嚢胞およびポリ ーブを含む))	Colon cancer (結腸癌)	179*	339	161*	Mild	No	None	Yes	Rcver	No	Req hsp
Comment: THE PATIENT WAS INITIALLY CONSIDERED TO HAVE LARGE INTESTINE POLYP;HOWEVER,WAS HISTOLOGICALLY FOUND TO HAVE LARGE INTESTINE CARCINOMA.THE TUMOR OBSERVED IN THIS CASE IS LARGE,VISUALLY A TUMOR GROWS															
1245_003 8_821010	Asian	57/M	Empa 25mg	General disorders and administration site conditions (一般・全身障害お よび投与部位の状 態)	Pyrexia (発熱)	97	108	12	Sev	No	None	Yes	Rcver	No	Req hsp
Comment: FEVER OF UNKNOWN ORIGIN IS CAUSED BY A BACTERIAL INFECTION DUE TO RECOVER BY THE ANTIBIOTICS,THOUGH DETAILED INFORMATION FROM THE DOCTOR IN CHARGE OF THE KYOTO CITY HOSPITAL ARE STILL UNKNOWN.															

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Episodes with a negative start day are not assigned to the analysing treatment.

MedDRA version used for reporting: 25.1

Listing 5.2.1 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: Rand. trt. regimen, active only

Treatment: Empa 25mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_003 8_823006	Asian	32/M	Empa 25mg	Infections and infestations (感染症および寄生 虫症)	Pharyngitis (咽頭炎)	51	65	15	Mild	No	None	Yes	Rcver	No	Req hsp
Comment: DUE TO SEASONALITY															
1245_003 8_825007	Asian	59/M	Empa 25mg	Neoplasms benign, malignant and unspecified (incl cysts and polyps) (良性、悪性および 詳細不明の新生物 (嚢胞およびポリ ーブを含む))	Gastric cancer (胃癌)	40	707	317	Mod	No	Disc	No	Nrec&	No	Other
Comment: THIS AE IS CANCER,SO IS SERIOUS.BECAUSE POLYPS BEFORE STUDY DRUG TAKEN,NO CASUAL RELATION TO THE STUDY DRUG.AGREEMENT DAY OF THE FOLLOW-UP SUFFICIENT:01/MAR/2013.															

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Episodes with a negative start day are not assigned to the analysing treatment.
MedDRA version used for reporting: 20.0

Listing 5.2.1 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: Rand. trt. regimen, active only

Treatment: Plac, Empa10

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug Action rel. taken	Therapy required	Outcome	Other signi- ficant	Serious	
1245_003 8_809015	Asian	64/M	Empa 10mg	Eye disorders (眼障害)	Macular hole (黄斑円孔)	310	472	163	Mod	No	None	Yes	Nrec&	No	Req hsp
Comment: THE ETIOLOGY OF RIGHT MACULAR HOLE REMAINS UNKNOWN, BUT DUE TO THE FACT THAT THE PATIENT HAS PREVIOUSLY HAD THE SAME EVENT BEFORE HIS PARTICIPATION IN THE CLINICAL STUDY, THE EVENT IS CONSIDERED TO															
1245_003 8_815107	Asian	71/M	Placebo	Cardiac disorders (心臓障害)	Myocardial infarction (心筋梗塞)	2	2	1	Mod	No	Disc	Yes	Rcver	No	Req hsp
Comment: PATHOLOGICAL CHANGE OF THE ORGANS SHOULD HAVE OCCURRED BEFORE ADMINISTRATION OF THE TRIAL DRUG BECAUSE, THE PATIENT IS ELDERLY MAN WHO HAD SOME HISTORY OF SMOKING,															
1245_003 8_822126	Asian	57/M	Empa 10mg	Cardiac disorders (心臓障害)	Acute myocardial infarction (急性心筋梗塞)	216	419	204	Mod	No	Disc	Yes	Seq	No	Req hsp
Comment: ALTHOUGH THE EVENT OCCURRED AFTER INITIATION OF THE STUDY DRUG, THE EVENT IS LIKELY DUE TO UNDERLYING RISK FACTORS INCLUDING DIABETES MELLITUS AND CONCOMITANT DYSLIPIDAEMIA.															

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Episodes with a negative start day are not assigned to the analysing treatment.

MedDRA version used for reporting: [REDACTED]

Listing 5.2.1 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: Rand. trt. regimen, active only

Treatment: Plac, Empa25

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_003 8_816007	Asian	49/M	Empa 25mg	General disorders and administration site conditions (一般・全身障害および投与部位の状態)	Device dislocation (医療機器位置異常)	203	229	27	Mild	No	None	Yes	Rcver	No	Req hsp
Comment: ACCIDENTAL PHENOMENON.BECAUSE THE FIXATION OF THE INTRAOCULAR LENS WAS NOT ENOUGH, I THINK THAT IT IS A CAUSED PHENOMENON.															
1245_003 8_820007	Asian	49/M	Empa 25mg	Infections and infestations (感染症および寄生虫)	Tonsillitis (扁桃炎)	205	214	10	Mod	No	None	Yes	Rcver	No	Req hsp
Comment: SYMPTOMATIC RECOVERY WITH ANTIBIOTIC INDICATES THAT THE EVENT WAS CAUSED BY INFECTION.															
1245_003 8_824013	Asian	58/M	Placebo	Eye disorders (眼障害)	Glaucoma (緑内障)	11	12	2	Mod	No	None	Yes	Rcver	No	Req hsp
Comment: THIS ADVERSE EVENT IS NOT RELATED TO BI10773.BECAUSE THE PATIENT HAS BEEN AFFECTED WITH GLAUCOMA SINCE 12/NOV/2012, AND ALSO IT'S BEEN GETTING WORSE FROM YEAR TO YEAR.															

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MedDRA version used for reporting: 25.1

Listing 5.2.1 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: Rand. trt. regimen, active only

Treatment: Empa 5,10mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_003 8_809006	Asian	53/M	Empa 10mg	Neoplasms benign, malignant and unspecified (incl cysts and polyps) (	Colon cancer (	194	4057	2127	Sev	No	Disc	No	Nrec&	No	Req hsp/Other
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))															
Comment: THERE IS NO CAUSAL RELATIONSHIP WITH BI10773.THIS IS BECAUSE THE NATURE OF THE CANCER,THE TIME ELAPSED WAS DETERMINED THAT THE PARTICIPANT HAD DEVELOPED BEFORE THE TRIAL.															
	Asian		Empa 10mg	Neoplasms benign, malignant and unspecified (incl cysts and polyps) (	Lung cancer metastatic (	194	4057	2127	Sev	No	Disc	No	Nrec&	No	Req hsp/Other
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))															
Comment: THERE IS NO CAUSAL RELATIONSHIP WITH BI10773.THIS IS BECAUSE THE NATURE OF THE CANCER,THE TIME ELAPSED WAS DETERMINED THAT THE PARTICIPANT HAD DEVELOPED BEFORE THE TRIAL.															
	Asian		Empa 10mg	Neoplasms benign, malignant and unspecified (incl cysts and polyps) (	Metastases to bone marrow (	194	4357	2427	Sev	No	Disc	No	Nrec&	No	Req hsp/Other
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))															
Comment: THERE IS NO CAUSAL RELATIONSHIP WITH BI10773.THIS IS BECAUSE THE NATURE OF THE CANCER,THE TIME ELAPSED WAS DETERMINED THAT THE PARTICIPANT HAD DEVELOPED BEFORE THE TRIAL.															

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 Episodes with a negative start day are not assigned to the analysing treatment.

MedDRA version used for reporting: [REDACTED]

Listing 5.2.1 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: Rand. trt. regimen, active only

Treatment: Empa 5,25mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_003 8_815134	Asian	64/M	Empa 25mg	Gastrointestinal disorders (胃腸障害)	Duodenal ulcer (十二指腸潰瘍)	186	369	184	Mod	No	None	Yes	Rcver	No	Req hsp
Comment: ALTHOUGH THE EVENT OCCURRED DURING ADMINISTRATION OF THE STUDY DRUG, THERE WAS NO REASONABLE CAUSE-AND-EFFECT RELATIONSHIP BETWEEN THE EVENT AND THE STUDY DRUG BECAUSE OF THE PATIENT'S PAST HISTORY															
	Asian		Empa 25mg	Injury, poisoning and procedural complications (傷害、中毒および処置合併症)	Joint dislocation (関節脱臼)	300	3867	877	Mod	No	None	Yes	Nrec&	No	Req hsp
Comment: TRAUMATIC.ACCIDENTAL EVENT[ALTHOUGH THE EVENT OCCURRED DURING ADMINISTRATION OF THE STUDY DRUG, THERE WAS NO REASONABLE CAUSE-AND-EFFECT RELATIONSHIP BETWEEN THE EVENT AND															
	Asian		Empa 25mg	Injury, poisoning and procedural complications (傷害、中毒および処置合併症)	Ankle fracture (足関節部骨折)	300	3917	927	Mod	No	None	Yes	Nrec&	No	Req hsp
Comment: TRAUMATIC.ACCIDENTAL EVENT[ALTHOUGH THE EVENT OCCURRED DURING ADMINISTRATION OF THE STUDY DRUG, THERE WAS NO REASONABLE CAUSE-AND-EFFECT RELATIONSHIP BETWEEN THE EVENT AND															
1245_003 8_817006	Asian	58/F	Empa 25mg	Hepatobiliary disorders (肝胆道系障害)	Hepatic function abnormal (肝機能異常)	252	281	30	Sev	No	Disc	No	Rcver	No	Req hsp
Comment: THE PATIENT WAS TAKING BOTH STUDY DRUG AND CONCOMITANT MEDICINES. AFTER QUITTING ALL OF THEM THE DATA RECOVERED DAY BY DAY, SO DRUG-INDUCED LIVER INJURY WAS SUSPECTED.															

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Episodes with a negative start day are not assigned to the analysing treatment.

MedDRA version used for reporting: [REDACTED]

Listing 5.2.1 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: Rand. trt. regimen, active only

Treatment: Empa 50,10mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_003 8_806006	Asian	60/M	Empa 10mg	Neoplasms benign, malignant and unspecified (incl cysts and polyps) (良性、悪性および 詳細不明の新生物 (嚢胞およびポリ ーブを含む))	Bladder cancer (膀胱癌)	252	4467	1957	Mod	No	Disc	Yes	Nrec&	No	Other
Comment: CANCER. IT IS REASONABLE TO THINK THAT THE TUMORS DEVELOPED BEFORE INITIATION OF STUDY DRUG ADMINISTRATION.															
1245_003 8_830002	Asian	52/M	Empa 10mg	Neoplasms benign, malignant and unspecified (incl cysts and polyps) (良性、悪性および 詳細不明の新生物 (嚢胞およびポリ ーブを含む))	Lipoma (脂肪腫)	134	221	88	Mod	No	None	Yes	Rcver	No	Req hsp
Comment: THE EVENT IS CONSIDERED TO HAVE OCCURRED BEFORE INITIATION OF THE STUDY DRUG ADMINISTRATION AND THEREFORE IS UNRELATED TO THE STUDY DRUG.															

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 Episodes with a negative start day are not assigned to the analysing treatment.
 MedDRA version used for reporting: ■■■■

Listing 5.2.1 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: Rand. trt. regimen, active only

Treatment: Empa 50,25mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_003 8_812016	Asian	60/M	Empa 25mg	Investigations (臨床検査)	Prostatic specific antigen increased (前立腺特異性抗原増加)	148	4107	2637	Mild	No	None	No	Nrec&	No	Req hsp
Comment: THE PATIENT HAS HAD HIGH PSA VALUE BEFORE PARTICIPATION OF THE TRIAL.															
1245_003 8_822097	Asian	69/M	Empa 25mg	Ear and labyrinth disorders (耳および迷路障害)	Sudden hearing loss (突発難聴)	165	2947	1307	Mod	Yes	Disc	Yes	Nrec&	No	Req hsp
Comment: ALTHOUGH THE PATIENT HAD PREEXISTING DIABETES MELLITUS AND HYPERTENSION WHICH ARE BELIEVED TO BE RISK FACTORS FOR SUDDEN HEARING LOSS, A CAUSAL RELATIONSHIP BETWEEN THE EVENT															
1245_003 8_824015	Asian	66/F	Empa 50mg	Cardiac disorders (心臓障害)	Left ventricular hypertrophy (左室肥大)	56	3647	3097	Mod	No	None	Yes	Nrec&	No	Req hsp
Comment: THIS ADVERSE EVENT IS NOT RELATED TO BI 10773.THIS EVENT COULD HAPPENED DUE TO DIABETIC ANGIOPATHY.THIS PATIENT HAS BEEN AFFECTED WITH DIABETIC MELLITUS AND HYPERTENSION SINCE 19■■■.															

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Episodes with a negative start day are not assigned to the analysing treatment.

MedDRA version used for reporting: ■■■

Listing 7.1.8 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Placebo

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_004 8_010570	White	81/M	Placebo	Ear and labyrinth disorders (	Acute vestibular syndrome (	19	23	5	Mod	No	None	Yes	Rcver	No	Req hsp
				耳および迷路障害	急性前庭症候群)										
1245_004 8_011194	White	58/F	Placebo	Injury, poisoning and procedural complications (	Traumatic fracture (	2	7	6	Sev	No	None	Yes	Rcver	No	Req hsp
				傷害、中毒および	外傷性骨折)										
				処置合併症)											
1245_004 8_011222	White	59/F	Placebo	Gastrointestinal disorders (	Constipation (	43	56	14	Mod	No	Disc	Yes	Rcver	No	Req hsp
				胃腸障害)	便秘)										
1245_004 8_012030	White	69/M	Placebo	Renal and urinary disorders (	Urethral stenosis (	63	65	3	Sev	No	None	Yes	Rcver	No	Req hsp
				腎および尿路障害	尿道狭窄)										
				)											
Comment: AFTER TURP THE PATIENT HAD STRICTURAE URETHRAE AND ON 18APR20 WAS THE PROCEDURE - URETHROTOMY. THE PATIENT WAS HOSPITALIZED 17APR-19APR20															
1245_004 8_012586	White	64/F	Placebo	Cardiac disorders (	Angina pectoris (狭心症)	12	43	32	Mod	No	Disc	Yes	Rcver	No	Req hsp
				心臓障害)											
1245_004 8_016484	White	46/F	Placebo	Metabolism and nutrition disorders (	Diabetic ketoacidosis (	84	85	2	Sev	No	None	Yes	Rcver	No	Req hsp
				代謝および栄養障	糖尿病性ケトアシ										
				害)	ドーシス)										

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Episodes with a negative start day are not assigned to the analysing treatment.
MedDRA version used for reporting:

Listing 7.1.8 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Placebo

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_004 8_016614	Hawaii an/Pac	55/F	Placebo	Hepatobiliary disorders (	Cholecystitis acute (	8	11	4	Sev	No	None	Yes	Rcver	No	Req hsp
	if. Isle			肝胆道系障害)	急性胆囊炎)										

Comment: PATIENT HAS SEVERE BACK PAIN, NAUSEA, BLOATING, AND ELEVATED LIPASE LAB VALUES.

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 Episodes with a negative start day are not assigned to the analysing treatment.
 MedDRA version used for reporting: [REDACTED]

Listing 7.1.8 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Empa 10mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_004 8_014122	White	58/F	Empa 10mg	General disorders and administration site conditions (一般・全身障害および投与部位の状態)	Sudden death (突然死)	90	90	1	Sev	Yes	None	No	Fatal	No	Fatal
Comment: POSSIBLE															
1245_004 8_015231	White	78/F	Post trt	Nervous system disorders (神経系障害)	Dizziness (浮動性めまい)	88	89	2	Mod	No	None	No	Rcver	No	Req hsp
1245_004 8_016619	White	51/M	Empa 10mg	Infections and infestations (感染症および寄生虫症)	Osteomyelitis (骨髓炎)	37	40	4	Sev	No	None	Yes	Rcver	No	Req hsp
Comment: HOSPITALIZATION OCCURRED FROM 28-APR-20 TO 1-MAY-20. AMPUTATION DUE TO OSTEOMYELITIS OF 5TH DIGIT OF RIGHT FOOT PERFORMED.															

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 Episodes with a negative start day are not assigned to the analysing treatment.
 MedDRA version used for reporting:

Listing 7.1.8 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Empa 25mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_004 8_014562	White	60/M	Post trt	Nervous system disorders (	Carotid artery thrombosis (	27	54	28	Sev	No	None	Yes	Rcver	No	Imm thrt/Req hsp
Comment: 12-OCT-20 THE PATIENT FOR THE FIRST TIME SINCE THE EARLY 90S HAD WHAT WAS INTERPRETED AS RETINAL MIGRAINE.ON 30-OCT-20 THE PATIENT CALLED ME AND TOLD THAT HE ON THE PREVIOUS DAY FOR TEN MINUTES C															
1245_004 8_015150	White	73/M	Empa 25mg	Infections and infestations (	Pneumonia (	82	103	22	Mod	No	None	Yes	Rcver	No	Req hsp
				感染症および寄生 虫症)											
1245_004 8_016389	White	54/F	Empa 25mg	General disorders and administration site conditions (	Chest pain (	72	87	16	Mod	No	None	Yes	Rcver	No	Req hsp
				一般・全身障害お よび投与部位の状 態)											
			White	Post trt	Investigations (	86	87	2	Mild	No	None	Yes	Rcver	No	Req hsp
					臨床検査)	Electrocardiogra m T wave inversion (									
					心電図T波逆転)										
1245_004 8_016394	Black/ Africa n Amer.	63/F	Empa 25mg	Hepatobiliary disorders (	Cholecystitis (	17	17	1	Sev	No	None	Yes	Rcver	No	Req hsp
				肝胆道系障害)											

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 Episodes with a negative start day are not assigned to the analysing treatment.
 MedDRA version used for reporting:

Listing 7.1.6 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Empa 25mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_002 8_080040	White	68/F	Empa 25mg	Neoplasms benign, malignant and unspecified (incl cysts and polyps) (良性、悪性および 詳細不明の新生物 (嚢胞およびポリ ーブを含む))	Malignant melanoma in situ (表皮内悪性黒色腫	351	406	56	Mod	No	None	Yes	Rcver	No	Other
Comment: CARCINOMA															
1245_002 8_080049	White	62/M	Empa 25mg	Nervous system disorders (神経系障害)	Headache (頭痛)	184	186	3	Sev	No	None	Yes	Rcver	No	Req hsp
1245_002 8_080148	Black/ Africa n Amer.	41/F	Empa 25mg	Nervous system disorders (神経系障害)	Dizziness (浮動性めまい)	401	402	2	Mod	No	None	No	Rcver	No	Req hsp
	Black/ Africa n Amer.		Empa 25mg	Cardiac disorders (心臓障害)	Palpitations (動悸)	401	402	2	Mild	No	None	No	Rcver	No	Req hsp
1245_002 8_080210	White	65/M	Empa 25mg	Reproductive system and breast disorders (生殖系および乳房 障害)	Benign prostatic hyperplasia (良性前立腺肥大症	145	146	2	Mod	No	None	Yes	Rcver	No	Req hsp
1245_002 8_080218	White	45/M	Empa 25mg	Infections and infestations (感染症および寄生 虫症)	Cystitis escherichia (大腸菌性膀胱炎)	190	216	27	Sev	No	None	Yes	Rcver	No	Req hsp
Comment: PATIENT ADMITTED TO HOSPITAL 12/30/20 AND DISCHARGED 1/4/															

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Episodes with a negative start day are not assigned to the analysing treatment.
MedDRA version used for reporting:

Listing 7.1.6 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Empa 25mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_002 8_080218	White	45/M	Empa 25mg	Infections and infestations (	Escherichia bacteraemia (	190	216	27	Sev	No	None	Yes	Rcver	No	Req hsp
	White		Empa 25mg	Infections and infestations (	Kidney infection (腎感染)	190	216	27	Sev	No	None	Yes	Rcver	No	Req hsp
Comment: PATIENT ADMITTED TO HOSPITAL 12/30/20 AND DISCHARGED 1/4/															
1245_002 8_080251	Black/ Africa n Amer.	43/F	Empa 25mg	Hepatobiliary disorders (	Cholelithiasis (	117	126	10	Sev	No	None	Yes	Rcver	No	Req hsp
1245_002 8_080302	White	49/M	Empa 25mg	Gastrointestinal disorders (	Pancreatitis (	10	13	4	Sev	No	None	Yes	Rcver	No	Req hsp
1245_002 8_080402	White	63/M	Empa 25mg	Cardiac disorders (	Coronary artery disease (	257	414	158	Mod	No	Disc	Yes	Rcver	No	Req hsp
Comment: QUADRUPLE BYPASS SURGERY DONE 05 JAN 20															
1245_002 8_080405	White	59/M	Empa 25mg	Neoplasms benign, malignant and unspecified (incl cysts and polyps) (	Basal cell carcinoma (	365	365	1	Mod	No	None	Yes	Rcver	No	Other
Comment: LESION REMOVED FROM R FOREARM - PATHOLOGY DIAGNOSED AS BASAL CELL CARCINOMA															

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MedDRA version used for reporting:

Listing 7.1.6 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Empa 25mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_002 8_080417	White	49/M	Empa 25mg	Infections and infestations (	Infectious mononucleosis (	362	Cont		Sev	No	None	Yes	Nrec	No	Req hsp
				感染症および寄生 虫症)	伝染性単核症)										
1245_002 8_080425	White	64/M	Run-in	Reproductive system and breast disorders (	Calculus prostatic (	-12	254	266	Sev	No	None	Yes	Rcver	No	Req hsp
				生殖系および乳房 障害)	前立腺結石)										
Comment: PATIENT HAD INTERMITTENT HEMATURIA SINCE 18 FEB 26 AND HE HAD DIAGNOSIS OF PROSTATIC LITHIASIS ON 29 SEP 26 AND THE TWO EVENTS ARE CONNECTED															
1245_002 8_080468	White	52/M	Empa 25mg	Injury, poisoning and procedural complications (	Fall (転倒)	371	421	51	Sev	No	Disc	Yes	Seq	No	Req hsp
				傷害、中毒および 処置合併症)											
	White		Empa 25mg	Injury, poisoning and procedural complications (	Traumatic fracture (	371	421	51	Sev	No	Disc	Yes	Seq	No	Req hsp
				傷害、中毒および 処置合併症)	外傷性骨折)										

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MedDRA version used for reporting:

Listing 7.1.6 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Empa 25mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_002 8_080527	White	63/M	Empa 25mg	Neoplasms benign, malignant and unspecified (incl cysts and polyps) (	Pancreatic carcinoma (	116	2467	1317	Sev	No	Disc	Yes	Nrec&	No	Req hsp/Other
良性、悪性および 詳細不明の新生物 (嚢胞およびポリ ーブを含む)) Comment: FURTHER EXPLORATION OF ABDOMINAL PAIN RESULTED IN PANCREATIC TAIL LESION WITH REASON FOR CONCERN FOR PANCREATIC NEOPLASM FURTHER EXPLORATION PENDING ABDOMINAL PAIN WAS A SYMPTOM OF PANCREATIC CANCER															
	White		Empa 25mg	Injury, poisoning and procedural complications (	Post procedural constipation (	155	156	2	Sev	No	None	Yes	Rcver	No	Req hsp/Other
傷害、中毒および 処置合併症) Comment: INCREASING ABDOMINAL PAIN POST OP DAY 7 OF PANCREATIC RESECTION FOR PANCREATIC CANCER ADMITTED TO HOSPITAL															
1245_002 8_080579	White	67/M	Empa 25mg	Gastrointestinal disorders (	Volvulus (	165	165	1	Sev	No	None	Yes	Rcver	No	Req hsp
	White		Empa 25mg	Gastrointestinal disorders (	Gastrointestinal haemorrhage (	172	175	4	Sev	No	None	Yes	Rcver	No	Req hsp
				胃腸障害)	胃腸出血)										
1245_002 8_080654	White	46/M	Empa 25mg	General disorders and administration site conditions (	Non-cardiac chest pain (	457	461	5	Mod	No	None	Yes	Rcver	No	Req hsp
				一般・全身障害お よび投与部位の状 態)	非心臓性胸痛)										

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 Episodes with a negative start day are not assigned to the analysing treatment.

MedDRA version used for reporting: [REDACTED]

Listing 7.1.6 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Empa 25mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_002 8_080827	White	69/F	Empa 25mg	Gastrointestinal disorders (胃腸障害)	Abdominal hernia (腹部ヘルニア)	89	222	134	Mod	No	None	Yes	Rcver	No	Req hsp
Comment: SURGICAL MADE TO 13/JUL/2013															
	White		Empa 25mg	Gastrointestinal disorders (胃腸障害)	Hiatus hernia (裂孔ヘルニア)	217	222	6	Mod	No	None	Yes	Rcver	No	Req hsp
Comment: SURGERY OF HIATAL HERNIA															
1245_002 8_080829	White	52/M	Empa 25mg	Respiratory, thoracic and mediastinal disorders (呼吸器、胸郭および縦隔障害)	Dyspnoea (呼吸困難)	573	Cont		Mod	No	None	Yes	Nrec	No	Req hsp
1245_002 8_080834	White	78/F	Empa 25mg	Neoplasms benign, malignant and unspecified (incl cysts and polyps) (良性、悪性および詳細不明の新生物 (嚢胞およびポリプを含む))	Breast cancer (乳癌)	15	3017	2877	Mild	No	None	Yes	Nrec&	No	Req hsp/Other
Comment: THE SURGICAL INTERVENTION IS DONE															
1245_002 8_080848	White	68/M	Empa 25mg	Gastrointestinal disorders (胃腸障害)	Abdominal pain (腹痛)	7	263	257	Sev	No	Disc	Yes	Rcver	No	Req hsp
	White		Empa 25mg	Gastrointestinal disorders (胃腸障害)	Vomiting (嘔吐)	7	8	2	Sev	No	Disc	Yes	Rcver	No	Req hsp

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Episodes with a negative start day are not assigned to the analysing treatment.

MedDRA version used for reporting: 20.0

Listing 7.1.6 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Empa 25mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_002 8_080912	White	59/M	Empa 25mg	Neoplasms benign, malignant and unspecified (incl cysts and polyps) (	Adenocarcinoma pancreas (	29	3597	3317	Sev	No	Disc	Yes	Nrec&	No	Req hsp
				良性、悪性および 詳細不明の新生物 (嚢胞およびポリ ーブを含む))	膵腺癌)										
1245_002 8_080913	White	52/F	Empa 25mg	Gastrointestinal disorders (	Abdominal pain upper (	185	186	2	Mod	No	None	Yes	Rcver	No	Req hsp
				胃腸障害)	上腹部痛)										
	White		Empa 25mg	Metabolism and nutrition disorders (	Hypokalaemia (	185	192	8	Mild	No	None	Yes	Rcver	No	Req hsp
				代謝および栄養障 害)	低カリウム血症)										
1245_002 8_081618	White	67/F	Empa 25mg	Injury, poisoning and procedural complications (	Fall (転倒)	176	176	1	Mod	No	None	Yes	Seq	No	Req hsp
				傷害、中毒および 処置合併症)											
Comment: THE PATIENT TRIPPED AND FELL IN HER KITCHEN ON THE 26/07/2016 SUSTAINING A LEFT HIP FRACTURE REQUIRING SURGERY AND HOSPITALIZATION. THE FALL WAS NOT CAUSED BY DIZZINESS, CHEST PAIN OR HYPOTENSION.															
	White		Empa 25mg	Injury, poisoning and procedural complications (	Femur fracture (	176	178	3	Mod	No	None	Yes	Rcver	No	Req hsp
				傷害、中毒および 処置合併症)	大腿骨骨折)										
Comment: THE PATIENT FELL AT HOME ON THE 26 JUL 2016. SHE SUFFERED A LEFT INTER-TROCHONTERIC FRACTURE (GRADE IV). SHE UNDERWENT SURGERY THE SAME DAY. SHE WENT HOME 28JUL2016. SHE HAS RECOVERED, TRAUMATIC EVENT															

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Episodes with a negative start day are not assigned to the analysing treatment.
MedDRA version used for reporting: 20.1

Listing 7.1.6 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Empa 25mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_002 8_081767	White	35/M	Empa 25mg	Injury, poisoning and procedural complications (	Radius fracture (桡骨骨折)	228	279	52	Mod	No	None	Yes	Rcver	No	Disabl/Req hsp
				傷害、中毒および 処置合併症)											
Comment: FRACTURE WAS TRAUMATIC															
1245_002 8_081806	White	59/F	Empa 25mg	Infections and infestations (	Diarrhoea infectious (	259	2817	237	Sev	No	None	Yes	Unk	No	Req hsp
				感染症および寄生 感染性下痢) 虫症)											
	White		Empa 25mg	Metabolism and nutrition disorders (	Electrolyte imbalance (	262	2817	207	Sev	No	None	Yes	Unk	No	Req hsp
				代謝および栄養障 害)											
Comment: PATIENT HAS HIDROELECTROLYTE DISORDER DUE TO INFECTIOUS DIARRHEA AND VOMITING															
	White		Empa 25mg	Respiratory, thoracic and mediastinal disorders (	Lung consolidation (	266	2817	167	Sev	No	None		Nrec&	No	Req hsp
				呼吸器、胸郭およ び縦隔障害)											
	White		Empa 25mg	General disorders and administration site conditions (	Multi-organ failure (	281	281	1	Sev	No	Disc		Fatal	No	Fatal
				一般・全身障害お よび投与部位の状 態)											
Comment: A MEDICAL REPORT HAS BEEN ASKED TO THE HOSPITAL, ONCE THE INFO IS GOTTEN, IT WILL BE UPDATED															

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Episodes with a negative start day are not assigned to the analysing treatment.

MedDRA version used for reporting: ■■■■

Listing 7.1.6 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Empa 25mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_002 8_081806	White	59/F	Empa 25mg	Infections and infestations (感染症および寄生 虫症)	Septic shock (敗血症性ショック)	281	2817	17	Sev	No	None	No	Unk	No	Imm thrt
1245_002 8_082010	White	41/F	Empa 25mg	Surgical and medical procedures (外科および内科処 置)	Hysterectomy (子宮摘出)	281	283	3	Mod	No	None	Yes	Rcver	No	Req hsp
1245_002 8_082157	White	59/F	Empa 25mg	Nervous system disorders (神経系障害)	Cerebrovascular accident (脳血管発作)	16	Cont		Sev	No	None	Yes	Seq	No	Disabl
	White		Empa 25mg	Cardiac disorders (心臓障害)	Cardiac failure (心不全)	39	Cont		Mod	No	None	Yes	Nrec	No	Req hsp
1245_002 8_082413	White	52/F	Empa 25mg	Nervous system disorders (神経系障害)	Ischaemic stroke (虚血性脳卒中)	211	Cont		Mod	No	None	Yes	Nrec	No	Other
Comment: RELEVANT MEDICAL EVENT															
1245_002 8_082486	White	71/F	Empa 25mg	General disorders and administration site conditions (一般・全身障害お よび投与部位の状 態)	Sudden death (突然死)	14	14	1	Sev	No	Disc	No	Fatal	No	Fatal

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Episodes with a negative start day are not assigned to the analysing treatment.
MedDRA version used for reporting: [REDACTED]

Listing 7.1.6 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Empa 25mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_002 8_082570	White	80/F	Empa 25mg	Injury, poisoning and procedural complications (	Fibula fracture (腓骨骨折)	305	Cont		Mod	No	None	Yes	Nrec	No	Req hsp
				傷害、中毒および 処置合併症)											
Comment: TRAUMATIC															
	White		Empa 25mg	Injury, poisoning and procedural complications (	Tibia fracture (脛骨骨折)	305	Cont		Mod	No	None	Yes	Nrec	No	Req hsp
				傷害、中毒および 処置合併症)											
Comment: TRAUMATIC															
1245_002 8_082582	White	55/M	Empa 25mg	Skin and subcutaneous tissue disorders (	Diabetic foot (糖尿病性足病変)	383	413	31	Sev	No	None	Yes	Rcver	No	Req hsp
				皮膚および皮下組 織障害)											
1245_002 8_082611	White	41/F	Empa 25mg	Hepatobiliary disorders (	Cholecystitis acute (急性胆嚢炎)	350	356	7	Sev	No	None	Yes	Rcver	No	Req hsp
				肝胆道系障害)											
1245_002 8_082883	White	75/F	Empa 25mg	Neoplasms benign, malignant and unspecified (incl cysts and polyps) (	Lung adenocarcinoma stage IV (肺腺癌第4期)	33	55*	23*	Sev	No	Disc	Yes	Fatal	No	Fatal/Other
				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))											
Comment: ADENOCARCINOMA OF THE LUNG															

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 MedDRA version used for reporting: █

Listing 7.1.6 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Empa 25mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_002 8_082883	White	75/F	Empa 25mg	Neoplasms benign, malignant and unspecified (incl cysts and polyps) (	Metastases to bone (骨転移)	33	55*	23*	Sev	No	Disc	Yes	Fatal	No	Fatal/Othe r
				詳細不明の新生物 (嚢胞およびポリ ーブを含む)											
Comment: ADENOCARCINOMA OF THE LUNG															
	White		Empa 25mg	Neoplasms benign, malignant and unspecified (incl cysts and polyps) (	Metastases to liver (肝転移)	33	55*	23*	Sev	No	Disc	Yes	Fatal	No	Fatal/Othe r
				詳細不明の新生物 (嚢胞およびポリ ーブを含む)											
Comment: ADENOCARCINOMA OF THE LUNG															
1245_002 8_082889	White	60/M	Empa 25mg	Cardiac disorders (	Angina unstable (不安定狭心症)	277	284	8	Sev	No	None	Yes	Rcver	No	Req hsp
				心臓障害)											
1245_002 8_082898	Asian	45/M	Empa 25mg	Gastrointestinal disorders (	Colitis (	163	210	48	Sev	No	None	Yes	Rcver	No	Req hsp
				胃腸障害)											

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Episodes with a negative start day are not assigned to the analysing treatment.

MedDRA version used for reporting: [REDACTED]

Listing 7.1.6 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Empa 25mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_002 8_083221	White	51/F	Empa 25mg	General disorders and administration site conditions (一般・全身障害お よび投与部位の状 態)	Chest pain (胸痛)	70	71	2	Mod	No	None	No	Rcver	No	Req hsp
Comment: NON CARDIAC CHEST PAIN															
1245_002 8_083274	White	68/M	Empa 25mg	Reproductive system and breast disorders (生殖系および乳房 障害)	Prostatism (前立腺症)	259	324	66	Mod	No	None	Yes	Rcver	No	Req hsp
Comment: SYMPTOMS OF PROSTATISM IS HESITATION AND POLLAKISURIA. NO URINARY TRACT INFECTION OR FUNGAL INFECTION IN THIS PERIOD															
1245_002 8_084021	Asian	72/F	Empa 25mg	Gastrointestinal disorders (胃腸障害)	Enterocolitis haemorrhagic (出血性腸炎)	270	274	5	Sev	No	None	Yes	Rcver	No	Req hsp
	Asian		Empa 25mg	Gastrointestinal disorders (胃腸障害)	Proctitis haemorrhagic (出血性直腸炎)	270	274	5	Sev	No	None	Yes	Rcver	No	Req hsp
1245_002 8_084054	Asian	62/M	Empa 25mg	Infections and infestations (感染症および寄生 虫症)	Cellulitis (蜂巣炎)	434	441	8	Mild	No	None	Yes	Rcver	No	Req hsp

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MedDRA version used for reporting: [REDACTED]

Listing 7.1.6 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Empa 25mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_002 8_084426	White	64/M	Empa 25mg	Neoplasms benign, malignant and unspecified (incl cysts and polyps) (	Rectal cancer (	53	90	38	Sev	No	Disc	Yes	Rcver	No	Req hsp/Other
				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))	直腸癌)										
Comment: FIRST COLONOSCOPY ON 10-FEB-2010 FOUND SUSPECTED POLYP,IN HISTOLOGICAL REPORT MALIGNANCY FOUND, THEREFORE NEW DIAGNOSIS IS RECTUM CANCER															
1245_002 8_084427	White	68/M	Empa 25mg	Injury, poisoning and procedural complications (	Fall (転倒)	241	241	1	Sev	No	None	No	Rcver	No	Req hsp
				傷害、中毒および 処置合併症)											
	White		Empa 25mg	Respiratory, thoracic and mediastinal disorders (	Pneumothorax (	241	248	8	Sev	No	None	Yes	Rcver	No	Req hsp
				呼吸器、胸郭およ び縦隔障害)	気胸)										
Comment: EVENT ON 20-AUG, ADMISSION TO HOSPITAL ON 22-AUG, TRAUMA AT GARDEN WORKING															
	White		Empa 25mg	Injury, poisoning and procedural complications (	Traumatic fracture (	241	248	8	Sev	No	None	No	Rcver	No	Req hsp
				傷害、中毒および 処置合併症)	外傷性骨折)										

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MedDRA version used for reporting: 20.1

Listing 7.1.6 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Empa 25mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_002 8_084427	White	68/M	Empa 25mg	Musculoskeletal and connective tissue disorders (筋骨格系および結 合組織障害)	Back pain (背部痛)	395	404	10	Mod	No	None	Yes	Rcver	No	Req hsp
Comment: ADMITTED FOR PAIN THERAPY, LUMBAGO AS CONCOMITANT DISEASE KNOWN SINCE 26.10.10. [REDACTED]															
1245_002 8_084446	White	54/M	Empa 25mg	Nervous system disorders (神経系障害)	Carpal tunnel syndrome (手根管症候群)	262	263	2	Mild	No	None	Yes	Rcver	No	Req hsp
Comment: PATIENT HAD A PLANNED MICROSURGICAL TREATMENT OF CARPAL TUNNEL SYNDROM (RIGHT HAND). SURGERY ON 6.10.10. [REDACTED], HOSPITALISATION FROM 06-07.10.10. [REDACTED] AS REPORTED AT VISIT 9.															
1245_002 8_084467	White	63/F	Empa 25mg	Nervous system disorders (神経系障害)	Carotid artery stenosis (頸動脈狭窄)	104	119	16	Sev	No	None	Yes	Rcver	No	Req hsp
	White		Empa 25mg	Cardiac disorders (心臓障害)	Coronary artery disease (冠動脈疾患)	104	119	16	Sev	No	None	Yes	Rcver	No	Req hsp
1245_002 8_084480	White	38/F	Empa 25mg	Injury, poisoning and procedural complications (傷害、中毒および 処置合併症)	Procedural headache (処置による頭痛)	233	234	2	Sev	No	None	Yes	Rcver	No	Req hsp
Comment: PATIENT REPROTED SUDDEN OCCURENCE OF FRONTAL AND PARIETAL HEADACHE AND WAS HOSPITALISED FOR SUSPECTED SUBARACHNOID HEMORRHAGE WITH NO SIGNS FOR IT AFTER CLINICAL INVESTIGATION															

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Episodes with a negative start day are not assigned to the analysing treatment.
MedDRA version used for reporting: [REDACTED]

Listing 7.1.6 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Empa 25mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_002 8_084480	White	38/F	Empa 25mg	Injury, poisoning and procedural complications (	Procedural headache (	258	261	4	Sev	No	None	Yes	Rcver	No	Req hsp
				傷害、中毒および 処置合併症)	処置による頭痛)	Comment: PATIENT WAS HPSITALISED WITH DIAGNOSIS POST-DURAL-PUNCTURE HEADACHE. ON 21.03 ■ TREATMENT WITH EPIDURAL BLOOD POUCH, WITH SIGNIFICANT PAIN RELIEF IN PATIENT.									
	White		Empa 25mg	Reproductive system and breast disorders (	Menorrhagia (	349	351	3	Mild	No	None	Yes	Rcver	No	Req hsp
				生殖系および乳房 障害)	月経過多)	Comment: PATIEN WENT TO GYN DEPARTMENT FOR PLANNED CURRETAGE WITH HOSPITALISATION BETWEEN 18.06-20.06.20 ■ FOR REASON PERMANENT VAGINAL BLEEDING									
1245_002 8_084833	White	48/M	Empa 25mg	Hepatobiliary disorders (	Hepatic failure (肝不全)	270	276	7	Sev	No	Disc	Yes	Fatal	No	Fatal
				肝胆道系障害)											
	White		Empa 25mg	Renal and urinary disorders (	Renal failure (	270	276	7	Sev	No	Disc	Yes	Seq	No	Req hsp
				腎および尿路障害)	腎不全)										
	White		Empa 25mg	Gastrointestinal disorders (	Gastrointestinal haemorrhage (	273	273	1	Sev	No	Disc	Yes	Rcver	No	Imm thrt
				胃腸障害)	胃腸出血)										
	White		Post study	Hepatobiliary disorders (	Hepatic cirrhosis (	280*	280*	1*	Mild	No	None	No	Nrec	No	Fatal
				肝胆道系障害)	肝硬変)										

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MedDRA version used for reporting: ■

Listing 7.1.6 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Empa 25mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_002 8_084870	White	50/F	Empa 25mg	Musculoskeletal and connective tissue disorders (筋骨格系および結 合組織障害)	Synovitis (滑膜炎)	447	451	5	Mild	No	None	Yes	Rcver	No	Req hsp
Comment: ARTHROSCOPY AND SHAVING OF LEFT SHOULDER/THE PATIENT FELL DOWN AND HURT LEFT ARM/.															
1245_002 8_084873	White	60/M	Empa 25mg	Musculoskeletal and connective tissue disorders (筋骨格系および結 合組織障害)	Musculoskeletal pain (筋骨格痛)	6	23	18	Mod	No	None	Yes	Rcver	No	Req hsp
1245_002 8_084885	White	40/F	Empa 25mg	Injury, poisoning and procedural complications (傷害、中毒および 処置合併症)	Meniscus lesion (半月板障害)	512	514	3	Mild	No	None	Yes	Rcver	No	Req hsp
1245_002 8_084894	White	54/M	Empa 25mg	Congenital, familial and genetic disorders (先天性、家族性および 遺伝性障害)	Phimosis (包茎)	195	197	3	Mild	No	None	Yes	Rcver	No	Req hsp
Comment: BECAUSE OF THE PHIMOSIS WAS PROVIDED CIRCUMCISIO BY OPERATION.															
1245_002 8_085616	Asian	62/M	Empa 25mg	Gastrointestinal disorders (胃腸障害)	Colonic polyp (結腸ポリープ)	308	308	1	Mild	No	None	No	Rcver	No	Req hsp
1245_002 8_086076	Asian	45/F	Empa 25mg	Infections and infestations (感染症および寄生 虫症)	Viral infection (ウイルス感染)	307	320	14	Mod	No	None	Yes	Rcver	No	Req hsp

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 MedDRA version used for reporting: [REDACTED]

Listing 7.1.6 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Empa 25mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_002 8_086158	Asian	44/F	Empa 25mg	Infections and infestations (感染症および寄生 虫症)	Gastroenteritis (胃腸炎)	53	60	8	Sev	No	None	Yes	Rcver	No	Req hsp
1245_002 8_086326	Asian	51/M	Empa 25mg	General disorders and administration site conditions (一般・全身障害お よび投与部位の状 態)	Pyrexia (発熱)	444	454	11	Sev	No	None	Yes	Rcver	No	Req hsp
	Asian		Empa 25mg	Infections and infestations (感染症および寄生 虫症)	Viral infection (ウイルス感染)	444	454	11	Sev	No	None	Yes	Rcver	No	Req hsp
1245_002 8_086429	Asian	59/M	Empa 25mg	Blood and lymphatic system disorders (血液およびリンパ 系障害)	Iron deficiency anaemia (鉄欠乏性貧血)	200	281	82	Mod	No	None	Yes	Rcver	No	Req hsp
1245_002 8_086440	Asian	38/M	Empa 25mg	General disorders and administration site conditions (一般・全身障害お よび投与部位の状 態)	Pyrexia (発熱)	53	60	8	Mod	No	None	Yes	Rcver	No	Req hsp

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MedDRA version used for reporting: [REDACTED]

Listing 7.1.6 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Empa 25mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_002 8_086440	Asian	38/M	Empa 25mg	Infections and infestations (	Viral infection (ウイルス感染)	53	60	8	Mod	No	None	Yes	Rcver	No	Req hsp
				感染症および寄生 虫症)											
1245_002 8_086444	Asian	51/F	Empa 25mg	Infections and infestations (	Sialoadenitis (	522	541	20	Mild	No	None	Yes	Rcver	No	Req hsp
				感染症および寄生 虫症)	唾液腺炎)										
1245_002 8_086462	Asian	59/M	Empa 25mg	Nervous system disorders (	Hemiparesis (	175	180	6	Mod	No	Disc	No	Seq	No	Req hsp
				神経系障害)	不全片麻痺)										
Comment: PATIENT HAD RIGHT SIDED HEMIPARETIC DUE TO CEREBROVASCULAR ACCIDENT. PATIENT WAS ADMITTED ON 13 SEP 20 AND DISCHARGED ON 18 SEP 20 WITH RIGHT SIDED HEMIPARETIC STILL PRESENT.															
1245_002 8_086529	Asian	49/F	Empa 25mg	Infections and infestations (	Cellulitis (	305	322	18	Mod	No	None	Yes	Rcver	No	Req hsp
				感染症および寄生 虫症)	蜂巣炎)										
Comment: THE EVENT WAS DUE TO THE MOTOR VEHICLE ACCIDENT															
1245_002 8_086852	Asian	43/F	Empa 25mg	Reproductive system and breast disorders (	Dysfunctional uterine bleeding (	13	15	3	Mild	No	None	Yes	Rcver	No	Req hsp
				生殖系および乳房 血) 障害)	機能障害性子宮出 血)										
	Asian		Empa 25mg	Infections and infestations (	Abscess limb (	140	142	3	Mild	No	None	Yes	Rcver	No	Req hsp
				感染症および寄生 虫症)	四肢膿瘍)										

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MedDRA version used for reporting:

Listing 7.1.6 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Empa 25mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_002 8_086857	Asian	45/F	Empa 25mg	Infections and infestations (	Pyelonephritis acute (	95	99	5	Mild	No	None	Yes	Rcver	No	Req hsp
Comment: CLINICALLY SYMPTOMATIC															
	Asian		Empa 25mg	Hepatobiliary disorders (	Cholecystitis chronic (	95	99	5	Mild	No	None	Yes	Rcver	No	Req hsp
1245_002 8_086859	Asian	59/F	Empa 25mg	Nervous system disorders (	Ischaemic stroke (虚血性脳卒中)	127	141	15	Mod	No	None	Yes	Rcver	No	Imm thrt
1245_002 8_086930	Asian	46/M	Empa 25mg	Nervous system disorders (	Cerebrovascular disorder (	221	Cont		Mod	No	None	Yes	Seq	No	Req hsp
Comment: HOURS PRIOR TO ADMISSION, PCEREBROVASCULAR DISEASE, FRONTOPIRIETAL PERIVENTRICULAR INFARCTS, HCVD; PATIENT FELL ON HIS RIGHT SIDE OF THE BODY WITH A NOTE OF SLURRED SPEECH.															
1245_002 8_086943	Asian	62/M	Empa 25mg	Musculoskeletal and connective tissue disorders (	Cervical spinal stenosis (	130	133	4	Mild	No	None	Yes	Rcver	No	Req hsp
Comment: TEMPORARY; THE CT SCAN RESULT WAS UNREMARKABLE.															
	Asian		Empa 25mg	Musculoskeletal and connective tissue disorders (	Spinal osteoarthritis (	130	133	4	Mild	No	None	Yes	Rcver	No	Req hsp
Comment: TEMPORARY; THE CT SCAN RESULT WAS UNREMARKABLE.															

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Episodes with a negative start day are not assigned to the analysing treatment.
MedDRA version used for reporting: [REDACTED]

Listing 7.1.6 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Empa 25mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_002 8_088028	White	58/M	Empa 25mg	Gastrointestinal disorders (胃腸障害)	Abdominal pain upper (上腹部痛)	114	116	3	Sev	No	None	No	Rcver	No	Req hsp
	White		Empa 25mg	Gastrointestinal disorders (胃腸障害)	Vomiting (嘔吐)	114	116	3	Sev	No	None	No	Rcver	No	Req hsp
1245_002 8_088133	White	79/M	Empa 25mg	Infections and infestations (感染症および寄生虫症)	Erysipelas (丹毒)	13	19	7	Sev	No	None	Yes	Rcver	No	Req hsp
1245_002 8_088431	White	59/M	Empa 25mg	Nervous system disorders (神経系障害)	Cerebrovascular accident (脳血管発作)	165	165	1	Mod	No	None	Yes	Rcver	No	Other
Comment: CONSIDERED SAE BY PI AS IMPORTANT MEDICAL EVENT (EXTENSION OF PREVIOUS CVA)															
1245_002 8_088449	Asian	61/M	Empa 25mg	Nervous system disorders (神経系障害)	Cerebrovascular accident (脳血管発作)	295	295	1	Mod	No	None	No	Rcver	No	Other
Comment: THIS IS NOT A CURRENT STROKE BUT THE CT SCAN SHOWED THE OLD INFARCT															
1245_002 8_088494	White	75/F	Empa 25mg	Gastrointestinal disorders (胃腸障害)	Gastrointestinal haemorrhage (胃腸出血)	365	372	8	Sev	No	None	No	Rcver	No	Req hsp
Comment: DAUGHTER CALLED ON 28-02-2012 MOTHER HAD EVIDENCE OF GI BLEEDING FROM 24-02-2012, ADVISED TO ATTEND LOCAL A&E, PATIENT ADMITTED TO WARD NO FURTHER DETAILS (MALENA STOOL & HAEMATEMESIS - ON WARFARIN)															
	White		Post study	Nervous system disorders (神経系障害)	Cerebrovascular accident (脳血管発作)	377	433	7	Sev	No	Disc	Yes	Seq	No	Imm thrt/Req hsp/Disabl /Prol hsp
Comment: SLURRING SPEECH, LATER UNABLE TO TALK/WHILST IN HOSPITAL AFTER FIRST CVA, EXPERIENCED A FURTHER CVA															

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Episodes with a negative start day are not assigned to the analysing treatment.

MedDRA version used for reporting: 20.0

Listing 7.1.6 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Empa 25mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_002 8_088563	White	63/M	Empa 25mg	Cardiac disorders (心臓障害)	Atrial fibrillation (心房細動)	324	325	2	Sev	No	None	Yes	Rcver	No	Prol hsp
Comment: WENT INTO FAST AF ON INDUCTION OF ANAESTHESIA, ENOUGH TO CANCEL OPERATION															
	White		Empa 25mg	Cardiac disorders (心臓障害)	Atrial fibrillation (心房細動)	349	349	1	Sev	No	None	No	Rcver	No	Other
Comment: WENT INTO FAST AF UNDER ANAESTHESIA															
	White		Empa 25mg	Neoplasms benign, malignant and unspecified (incl cysts and polyps) (良性、悪性および詳細不明の新生物 (嚢胞およびポリープを含む))	Laryngeal cancer (喉頭癌)	362	5247	1637	Sev	No	None	Yes	Nrec&	No	Other
Comment: HAD RADIO THERAPY FOR VOCAL CORD CANCER															
1245_002 8_088575	Asian	55/F	Empa 25mg	Infections and infestations (感染症および寄生虫症)	Lung infection (肺炎)	40	50	11	Sev	No	None	Yes	Rcver	No	Req hsp
	Asian		Empa 25mg	Respiratory, thoracic and mediastinal disorders (呼吸器、胸郭および縦隔障害)	Pleural effusion (胸水)	73	4137	3417	Sev	No	None	Yes	Nrec&	No	Req hsp
1245_002 8_088577	Asian	42/M	Empa 25mg	Cardiac disorders (心臓障害)	Angina unstable (不安定狭心症)	10	19	10	Mod	No	None	No	Rcver	No	Req hsp
Comment: CHEST PAIN RESULTING IN HOSPITAL ADMISSION ON 15TH JULY 2016															

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 MedDRA version used for reporting: 20.0

Listing 7.1.6 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Empa 25mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_002 8_088857	White	69/F	Empa 25mg	Gastrointestinal disorders (胃腸障害)	Abdominal pain (腹痛)	233	238	6	Mod	No	None	Yes	Rcver	No	Req hsp
Comment: ABDONINAL PAIN, REFERRED TO SPECIALIST, PT ADMITTED TO HOSPITAL															
	White		Empa 25mg	Surgical and medical procedures (外科および内科処置)	Oophorectomy bilateral (両側卵巣摘出術)	315	318	4	Mod	No	None	No	Rcver	No	Req hsp
Comment: AE IS CONTINUATION OF SAE NO 1															
	White		Empa 25mg	Surgical and medical procedures (外科および内科処置)	Omentectomy (大網切除)	315	318	4	Mod	No	None	No	Rcver	No	Req hsp
Comment: AE IS CONTINUATION OF SAE NO 1															
1245_002 8_088926	Asian	60/M	Empa 25mg	Eye disorders (眼障害)	Retinal detachment (網膜剥離)	466	Cont		Sev	No	None	Yes	Nrec	No	Req hsp
Comment: HAD LASER TREATMENT FOR DIABETIC RETINOPATHY															
1245_002 8_088945	White	56/F	Empa 25mg	Renal and urinary disorders (腎および尿路障害)	Nephrolithiasis (腎結石症)	480	486	7	Sev	No	None	Yes	Rcver	No	Req hsp
1245_002 8_088955	White	83/F	Empa 25mg	Injury, poisoning and procedural complications (傷害、中毒および処置合併症)	Fall (転倒)	331	348	18	Sev	No	None	Yes	Rcver	No	Req hsp
Comment: PATIENT HAD FALL ON 08MAR20 AND WAS ADMITTED INTO HOSPITAL. DIAGNOSIS WAS SOFT TISSUE INJURY TO LOWER LUMBAR SPINE AND RIGHT HIP. PT READMITTED 17MAR FOR SEVERE PAIN FROM SAME INJURY. RESOLVED 25/03/															

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 MedDRA version used for reporting:

Listing 7.1.6 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Empa 25mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_002 8_088955	White	83/F	Empa 25mg	General disorders and administration site conditions (一般・全身障害お よび投与部位の状 態)	Pain (疼痛)	331	348	18	Sev	No	None	Yes	Rcver	No	Req hsp
Comment: PT READMITTED FOF SEVERE PAIN AND DISCHARGED AFTER 1 DAY															
	White		Empa 25mg	Injury, poisoning and procedural complications (傷害、中毒および 処置合併症)	Soft tissue injury (軟部組織損傷)	331	348	18	Sev	No	None	Yes	Rcver	No	Req hsp
Comment: PATIENT HAD FALL ON 08MAR20 AND WAS ADMITTED INTO HOSPITAL.DIAGNOSIS WAS SOFT TISSUE INJURY TO LOWER LUMBAR SPINE AND RIGHT HIP.PT READMITTED17MAR FOR SEVERE PAIN FROM SAME INJURY.RESOLVED25/03/															
	White		Empa 25mg	Infections and infestations (感染症および寄生 虫症)	Pyelonephritis (腎盂腎炎)	461	463	3	Sev	No	None	Yes	Rcver	No	Req hsp
Comment: PATIENT WAS ADMITTED TO HOSPITAL FOR SEVERE GASTROENTERITIS AND RECEIVED SALINE IV, AND MEDS FROM THE 16JUL UNTIL DISCHARGE ON 18JUL20.															

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MedDRA version used for reporting:

Listing 7.1.6 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Glimepiride

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_002 8_080060	Black/ Africa n Amer.	56/M	Glimepiride	Musculoskeletal and connective tissue disorders (筋骨格系および結 合組織障害)	Arthralgia (関節痛)	237	Cont		Sev	No	None	Yes	Nrec	No	Req hsp
1245_002 8_080290	White	49/M	Glimepiride	General disorders and administration site conditions (一般・全身障害お よび投与部位の状 態)	Chest pain (胸痛)	44	47	4	Sev	No	None	Yes	Rcver	No	Req hsp
1245_002 8_080307	White	52/F	Glimepiride	Gastrointestinal disorders (胃腸障害)	Abdominal hernia (腹部ヘルニア)	265	267	3	Sev	No	None	Yes	Rcver	No	Req hsp
Comment: HISTORY OF VENTRAL HERNIA, DECIDED TO HAVE IT REPAIRED AFTER BEING ELBOWED IN IT AT WORK, WORSENING THE CONDITIONJ															
1245_002 8_080461	White	51/M	Glimepiride	Neoplasms benign, malignant and unspecified (incl cysts and polyps) (良性、悪性および 詳細不明の新生物 (嚢胞およびポリ ーブを含む))	Basal cell carcinoma (基底細胞癌)	71	258	188	Mild	No	None	Yes	Rcver	No	Other
Comment: NO BIOPSY. TREATED TOPICALLY ONLY															

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MedDRA version used for reporting: [REDACTED]

Listing 7.1.6 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Glimepiride

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_002 8_080522	White	67/M	Glimepiride	Neoplasms benign, malignant and unspecified (incl cysts and polyps) (	Squamous cell carcinoma (	618	Cont		Mod	No	None	No	Nrec	No	Other
				良性、悪性および 詳細不明の新生物 (嚢胞およびポリ ーブを含む)	扁平上皮癌)										
Comment: SQUAMOUS CELL CARCINOMA FOUND															
1245_002 8_080536	White	55/F	Glimepiride	Injury, poisoning and procedural complications (	Overdose (	411	413	3	Sev	No	None	Yes	Rcver	No	Req hsp
				傷害、中毒および 処置合併症)	過量投与)										
Comment: SUBJECT TOOK AN OVERDOSE OF ACETAMINOPHEN AND A SLEEP AID CONTAINING DIPHENHYDRAMINE															
1245_002 8_080600	White	47/F	Glimepiride	Nervous system disorders (	Cerebrovascular accident (	96	163	68	Mod	No	None	No	Rcver	No	Req hsp
				神経系障害)	脳血管発作)										
1245_002 8_080624	White	47/M	Glimepiride	Musculoskeletal and connective tissue disorders (	Back pain (	412	416	5	Sev	No	None	Yes	Rcver	No	Req hsp
				筋骨格系および結 合組織障害)	背部痛)										
Comment: SURGICAL INTERVENTION FOR PREVIOUS MEDICAL HISTORY. SURGERY WAS NOT SCHEDULED PRIOR TO SIGNING CONSENT															
1245_002 8_080854	White	73/M	Glimepiride	Infections and infestations (	Pneumonia (	386	391	6	Sev	No	None	Yes	Rcver	No	Req hsp
				感染症および寄生 虫症)	肺炎)										
Comment: RIGHT BASAL LOBE PNEUMONIA															

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MedDRA version used for reporting: [REDACTED]

Listing 7.1.6 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Glimepiride

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_002 8_081260	White	67/F	Glimepiride	Cardiac disorders (	Myocardial ischaemia (	228	229	2	Sev	No	Disc	Yes	Rcver	No	Req hsp
				心臓障害)	心筋虚血)										
1245_002 8_081646	White	44/M	Glimepiride	Gastrointestinal disorders (	Pancreatitis acute (	536	540	5	Sev	No	None	Yes	Rcver	No	Req hsp
				胃腸障害)	急性膵炎)										
1245_002 8_081757	White	59/F	Glimepiride	Injury, poisoning and procedural complications (	Fibula fracture (腓骨骨折)	243	246	4	Sev	No	None	Yes	Rcver	No	Req hsp
				傷害、中毒および 処置合併症)											
Comment: PATIENT RECEIVED GUN SHOT ON RIGHT LEG, DUE TO BLOOD LOSS PATIENT HAS A HEMOTRANSFUSION AT HOSPITAL. WOUND WAS CLEANED, BULLET WAS NOT HOSTED, PATIENT WAS DISCHARGED ON 27DEC ■ DUE TO GOOD EVOLUTION															
1245_002 8_081813	White	45/F	Glimepiride	Gastrointestinal disorders (	Gastritis (	11	12	2	Mod	No	None	Yes	Rcver	No	Req hsp
				胃腸障害)	胃炎)										
1245_002 8_082259	White	71/M	Glimepiride	Cardiac disorders (	Acute myocardial infarction (	322	326	5	Sev	No	None	Yes	Rcver	No	Req hsp
				心臓障害)	急性心筋梗塞)										
	White		Glimepiride	Cardiac disorders (	Coronary artery disease (	392	Cont		Sev	No	None	Yes	Nrec	No	Req hsp
				心臓障害)	冠動脈疾患)										
Comment: PATIENT WHO UNDERWENT CORONARY ARTERY BYPASS GRAFTING SURGERY AND IS CURRENTLY HOSPITALIZED ON THE INTENSIVE CARE UNIT.															

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Listing 7.1.6 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Glimepiride

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_002 8_082489	White	47/F	Glimepiride	Neoplasms benign, malignant and unspecified (incl cysts and polyps) (	Uterine leiomyoma (	319	321	3	Mod	No	None	Yes	Rcver	No	Req hsp
				良性、悪性および 詳細不明の新生物 (嚢胞およびポリ ーブを含む))	子宮平滑筋腫)										
Comment: NON-DRUG TREATMENT (HYSTERECTOMY) WAS RECEIVED.															
1245_002 8_082495	White	44/F	Glimepiride	Reproductive system and breast disorders (	Metrorrhagia (	370	380	11	Mod	No	None	Yes	Rcver	No	Req hsp
				生殖系および乳房 障害)	不正子宮出血)										
Comment: NON-DRUG TREATMENT (CURETTAGE) WAS RECEIVED.															
1245_002 8_082617	White	41/F	Glimepiride	Metabolism and nutrition disorders (	Obesity (肥満)	279	282	4	Mod	No	None	Yes	Rcver	No	Req hsp
				代謝および栄養障 害)											
1245_002 8_082838	White	58/M	Post study	Cardiac disorders (	Coronary artery disease (	525	Cont		Sev	No	Disc	Yes	Nrec	No	Req hsp
				心臓障害)	冠動脈疾患)										
Comment: AE CORONARY ARTERIAL DISEASE WAS UPGRADED TO SAE ON THE 13TH OF AUGUST 20															
1245_002 8_083213	White	66/M	Screening	Infections and infestations (	Pneumonia (	-28	83	111	Sev	No	None	Yes	Rcver	No	Req hsp
				感染症および寄生 虫症)	肺炎)										

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Listing 7.1.6 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Glimepiride

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_002 8_083215	White	68/M	Glimepiride	Cardiac disorders (	Acute myocardial infarction (	384	385	2	Mod	No	None	Yes	Rcver	No	Req hsp
Comment: SAE FORM SENT															
	White		Glimepiride	Cardiac disorders (	Acute myocardial infarction (	391	394	4	Mod	No	None	Yes	Rcver	No	Prol hsp
Comment: SAE FORM SENT															
1245_002 8_083220	White	64/M	Glimepiride	Musculoskeletal and connective tissue disorders (筋骨格系および結 合組織障害)	Tendonitis (	9	Cont		Mod	No	None	Yes	Nrec	No	Req hsp
	White		Glimepiride	General disorders and administration site conditions (一般・全身障害お よび投与部位の状 態)	Non-cardiac chest pain (	50	120	71	Mild	No	None	No	Rcver	No	Req hsp
Comment: CATEGORIZED AS "NON-CARDIAC CHEST PAIN"															
1245_002 8_083226	White	62/F	Glimepiride	General disorders and administration site conditions (一般・全身障害お よび投与部位の状 態)	Chest pain (	298	301	4	Mod	No	None	No	Rcver	No	Req hsp

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 MedDRA version used for reporting: [REDACTED]

Listing 7.1.6 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Glimepiride

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_002 8_083239	White	61/M	Glimepiride	Neoplasms benign, malignant and unspecified (incl cysts and polyps) (	Prostate cancer (前立腺癌)	314	383	70	Sev	No	None	Yes	Rcver	No	Other
				良性、悪性および 詳細不明の新生物 (嚢胞およびポリ ーブを含む))											
Comment: PROSTATECTOMY 19 DEC 20															
1245_002 8_083263	White	53/M	Glimepiride	Musculoskeletal and connective tissue disorders (	Intervertebral disc protrusion (椎間板突出)	99	Cont		Mod	No	None	Yes	Nrec	No	Req hsp
				(筋骨格系および結 合組織障害)											
1245_002 8_084047	Asian	30/F	Glimepiride	Eye disorders (	Open angle glaucoma (	238	Cont		Sev	No	None	Yes	Nrec	No	Req hsp
				眼障害)	開放隅角緑内障)										
Asian			Glimepiride	Eye disorders (	Retinal neovascularisati on (	238	Cont		Sev	No	None	Yes	Nrec	No	Req hsp
				眼障害)	網膜血管新生)										
Asian			Glimepiride	Nervous system disorders (	Optic neuritis (	238	Cont		Sev	No	None	Yes	Nrec	No	Req hsp
				神経系障害)	視神経炎)										
1245_002 8_084414	Asian	40/F	Glimepiride	Infections and infestations (	Appendicitis (	531	534	4	Mod	No	None	Yes	Rcver	No	Req hsp
				感染症および寄生 虫症)	虫垂炎)										

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Listing 7.1.6 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Glimepiride

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_002 8_084425	White	55/M	Glimepiride	Infections and infestations (	Pneumonia (	54	59	6	Sev	No	None	Yes	Rcver	No	Req hsp
				感染症および寄生 虫症)											
	White		Glimepiride	Cardiac disorders (	Coronary artery disease (	200	213	14	Mod	No	None	Yes	Rcver	No	Req hsp
				心臓障害)	冠動脈疾患)										
	White		Glimepiride	Infections and infestations (	Gastroenteritis	200	213	14	Mod	No	None	Yes	Rcver	No	Req hsp
				感染症および寄生 虫症)	salmonella (										
					サルモネラ菌性胃 腸炎)										
	White		Glimepiride	Gastrointestinal disorders (	Impaired gastric emptying (	400	403	4	Mod	No	None	Yes	Rcver	No	Req hsp
				胃腸障害)	胃排出不全)										
	White		Glimepiride	Respiratory, thoracic and mediastinal disorders (	Dyspnoea (	432	441	10	Sev	No	None	Yes	Rcver	No	Req hsp
				呼吸器、胸郭およ び縦隔障害)	呼吸困難)										
	White		Glimepiride	Cardiac disorders (	Cardiac disorder	432	441	10	Sev	No	None	Yes	Rcver	No	Req hsp
				心臓障害)	(心障害)										
Comment: ADMISSION TO HOSPITAL															
1245_002 8_084430	White	55/M	Glimepiride	Musculoskeletal and connective tissue disorders (	Intervertebral disc protrusion	17	24	8	Mod	No	None	Yes	Seq	No	Req hsp
				(筋骨格系および結 合組織障害)	椎間板突出)										

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Episodes with a negative start day are not assigned to the analysing treatment.

MedDRA version used for reporting: [REDACTED]

Listing 7.1.6 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Glimepiride

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_002 8_084430	White	55/M	Glimepiride	Musculoskeletal and connective tissue disorders (	Intervertebral disc protrusion (椎間板突出) (筋骨格系および結 合組織障害)	30	31	2	Mod	No	None	Yes	Rcver	No	Req hsp
Comment: COMPUTERTOMOGRAPHY ADVISED INFILTRATION DONE IN HOSPITAL STAY															
1245_002 8_084457	White	68/M	Screening	Infections and infestations (	Herpes zoster ophthalmic (	-23	1	24	Mild	No	None	Yes	Rcver	No	Req hsp
Comment: HERPES ZOSTER LEFT EYE															
1245_002 8_084463	White	69/F	Glimepiride	General disorders and administration site conditions (	Cyst (嚢胞)	59	96	38	Mod	No	None	Yes	Rcver	No	Req hsp
Comment: PATIENT WAS HOSPITALIZED FROM 03-06-2016 TILL 06-06-2016 AND A MENISCECTOMY WAS PERFORMED															
1245_002 8_084466	White	53/M	Glimepiride	Injury, poisoning and procedural complications (	Road traffic accident (	60	60	1	Sev	No	None	No	Rcver	No	Req hsp
Comment: PATIENT WAS HOSPITALIZED FROM 03-06-2016 TILL 06-06-2016 AND A MENISCECTOMY WAS PERFORMED															
	White		Glimepiride	Nervous system disorders (	Subarachnoid haemorrhage (	60	63	4	Sev	No	None	No	Rcver	No	Req hsp

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MedDRA version used for reporting: 20.1

Listing 7.1.6 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Glimepiride

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_002 8_084466	White	53/M	Glimepiride	Vascular disorders (血管障害)	Peripheral arterial occlusive disease (末梢動脈閉塞性疾患)	149	309	161	Mod	No	None	Yes	Rcver	No	Req hsp
Comment: DUE TO PREEXISTING PAVK (LEFT LEG) PATIENT WAS HOSPITALIZED TO PERFORM A PERCUTANEOUS TRANSLUMINAL ANGIOPLATY = PTA (ELECTIVE PROCEDURE) + STENT.															
1245_002 8_084865	White	59/F	Glimepiride	Gastrointestinal disorders (胃腸障害)	Inguinal hernia, obstructive (閉塞性鼠径ヘルニア)	450	456	7	Mod	No	None	Yes	Rcver	No	Req hsp
1245_002 8_084869	White	62/F	Glimepiride	Endocrine disorders (内分泌障害)	Goitre (甲状腺腫)	162	168	7	Mod	No	None	Yes	Rcver	No	Req hsp
Comment: THYREOIDECTOMY TOTALIS 05. SEPT. 2010															
1245_002 8_084877	White	64/F	Glimepiride	Musculoskeletal and connective tissue disorders (筋骨格系および結合組織障害)	Intervertebral disc disorder (椎間板障害)	233	240	8	Mod	No	None	Yes	Rcver	No	Req hsp
	White		Glimepiride	Musculoskeletal and connective tissue disorders (筋骨格系および結合組織障害)	Spinal osteoarthritis (変形性脊椎症)	233	240	8	Mod	No	None	Yes	Rcver	No	Req hsp

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 MedDRA version used for reporting: [REDACTED]

Listing 7.1.6 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Glimepiride

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_002 8_084896	White	47/M	Glimepiride	Injury, poisoning and procedural complications (	Incisional hernia (	309	317	9	Mod	No	None	Yes	Rcver	No	Req hsp
				傷害、中毒および 処置合併症)	癒痕ヘルニア)										
Comment: BECAUSE OF HERNIA IN CICATRIXPATIENT UNDERGO HERNIOTOMY. DURING THE HOSPITALISATION PATIENT WAS RECOVERED															
1245_002 8_084906	White	66/M	Post study	Cardiac disorders (	Acute myocardial infarction (	441	441	1	Sev	No	None	No	Unk	No	Imm thrt
				心臓障害)	急性心筋梗塞)										
Comment: ACUTE CORONARY SYNDROM WITH RUPTURE OF LEFT VENTRICLE RESULTED CARDIAC TAMPONADE AND DEATH															
	White		Post study	Cardiac disorders (	Cardiac tamponade (	441	441	1	Sev	No	Disc	No	Fatal	No	Fatal
				心臓障害)	心タンポナーデ)										
	White		Post study	Cardiac disorders (	Ventricle rupture (	441	441	1	Sev	No	None	No	Unk	No	Imm thrt
				心臓障害)	心室破裂)										
1245_002 8_085642	Asian	34/F	Glimepiride	Immune system disorders (	Drug hypersensitivity	210	211	2	Mild	No	None	Yes	Rcver	No	Req hsp
				免疫系障害)	(薬物過敏症)										
1245_002 8_086424	Asian	72/F	Glimepiride	Nervous system disorders (	Cerebral haemorrhage (	57	67	11	Sev	No	None	Yes	Rcver	No	Req hsp
				神経系障害)	脳出血)										
1245_002 8_086437	Asian	52/F	Glimepiride	Blood and lymphatic system disorders (	Anaemia (貧血)	273	282	10	Mild	No	None	Yes	Rcver	No	Req hsp
				血液およびリンパ 系障害)											

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MedDRA version used for reporting: [REDACTED]

Listing 7.1.6 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Glimepiride

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_002 8_086437	Asian	52/F	Glimepiride	Gastrointestinal disorders (胃腸障害)	Oesophageal varices haemorrhage (食道静脈瘤出血)	273	282	10	Mild	No	None	Yes	Rcver	No	Req hsp
	Asian		Glimepiride	Gastrointestinal disorders (胃腸障害)	Oesophageal varices haemorrhage (食道静脈瘤出血)	347	350	4	Mild	No	None	Yes	Rcver	No	Req hsp
Comment: OGDS ON 2 DEC 2016 ■ SHOWED OESOPHAGEAL VARICES GRADE 2(2-3 COLUMNS), NO BLEED SEEN															
	Asian		Glimepiride	Blood and lymphatic system disorders (血液およびリンパ系障害)	Anaemia (貧血)	353	356	4	Mild	No	None	Yes	Rcver	No	Req hsp
Comment: PATIENT HAD PROGRESIVE LETHARGY SINCE 28 NOV 2016 ■ BUT WORSEN ON 1 DEC 2016 ■, WHICH WAS ASSOCIATED WITH PALPITATION AND SHORTNESS OF BREATH OF EXERTION. TRANSFUSION OF PACK CELL AND DIAGNOSTICS OGDS															
	Asian		Glimepiride	Gastrointestinal disorders (胃腸障害)	Oesophageal varices haemorrhage (食道静脈瘤出血)	399	401	3	Mod	No	None	Yes	Rcver	No	Req hsp
	Asian		Glimepiride	Blood and lymphatic system disorders (血液およびリンパ系障害)	Anaemia (貧血)	400	402	3	Mod	No	None	Yes	Rcver	No	Req hsp
	Asian		Glimepiride	Blood and lymphatic system disorders (血液およびリンパ系障害)	Anaemia (貧血)	461	464	4	Mod	No	None	Yes	Rcver	No	Req hsp

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Listing 7.1.6 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Glimepiride

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_002 8_086437	Asian	52/F	Glimepiride	Gastrointestinal disorders (胃腸障害)	Oesophageal varices haemorrhage (食道静脈瘤出血)	461	462	2	Mod	No	None	Yes	Rcver	No	Req hsp
	Asian		Glimepiride	Blood and lymphatic system disorders (血液およびリンパ系障害)	Anaemia (貧血)	496	497	2	Mod	No	None	Yes	Rcver	No	Req hsp
	Asian		Glimepiride	Metabolism and nutrition disorders (代謝および栄養障害)	Diabetes mellitus inadequate control (糖尿病のコントロール不良)	496	500	5	Mild	No	None	Yes	Rcver	No	Req hsp
	Asian		Glimepiride	Gastrointestinal disorders (胃腸障害)	Oesophageal varices haemorrhage (食道静脈瘤出血)	496	497	2	Mod	No	None	Yes	Rcver	No	Req hsp
	Asian		Glimepiride	Vascular disorders (血管障害)	Thrombophlebitis (血栓性静脈炎)	497	499	3	Mild	No	None	Yes	Rcver	No	Req hsp
	Asian		Glimepiride	Blood and lymphatic system disorders (血液およびリンパ系障害)	Anaemia (貧血)	555	557	3	Mod	No	None	Yes	Rcver	No	Req hsp

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MedDRA version used for reporting: [REDACTED]

Listing 7.1.6 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Glimepiride

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_002 8_086437	Asian	52/F	Glimepiride	Gastrointestinal disorders (胃腸障害)	Oesophageal varices haemorrhage (食道静脈瘤出血)	555	559	5	Mod	No	None	Yes	Rcver	No	Req hsp
	Asian		Glimepiride	General disorders and administration site conditions (一般・全身障害および投与部位の状態)	Pyrexia (発熱)	557	559	3	Mild	No	None	Yes	Rcver	No	Req hsp
	Asian		Glimepiride	Gastrointestinal disorders (胃腸障害)	Diverticulum intestinal (腸憩室)	560	5957	367	Mild	No	None	No	Nrec&	No	Req hsp
	Asian		Glimepiride	Gastrointestinal disorders (胃腸障害)	Haemorrhoids (痔核)	560	5957	367	Mild	No	None	No	Nrec&	No	Req hsp
	Asian		Glimepiride	Gastrointestinal disorders (胃腸障害)	Rectal polyp (直腸ポリープ)	560	5957	367	Mild	No	None	No	Nrec&	No	Req hsp
	Asian		Glimepiride	Metabolism and nutrition disorders (代謝および栄養障害)	Fluid overload (水分過負荷)	561	571	11	Mild	No	None	Yes	Rcver	No	Req hsp
	Asian		Glimepiride	Infections and infestations (感染症および寄生虫症)	Peritonitis bacterial (細菌性腹膜炎)	567	571	5	Mild	No	None	Yes	Rcver	No	Req hsp

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Listing 7.1.6 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Glimepiride

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_002 8_086451	Asian	67/M	Glimepiride	Cardiac disorders (	Coronary artery disease (	78	106	29	Mild	No	None	No	Rcver	No	Req hsp
	Asian		Glimepiride	Cardiac disorders (	Angina pectoris (狭心症)	305	5557	2517	Sev	No	None	Yes	Nrec&	No	Req hsp
1245_002 8_086828	Asian	49/F	Glimepiride	Cardiac disorders (	Myocardial ischaemia (	352	5447	1937	Mod	Yes	None	Yes	Nrec&	No	Other
Comment: 13 JAN 2011, PATIENT EXPERIENCED EASY FATIGABILITY AND DIFFICULTY OF BREATHING. THE TEAM WAS INFORMED AND ADVISED TO SEE US THE FOLLOWING DAY. ECG DONE WHICH REVEALED ISCHEMIA.															
	Asian		Post trt	Gastrointestinal disorders (	Abdominal pain (	356	356	1	Mod	No	None	Yes	Rcver	No	Req hsp
Comment: PATIENT EXPERIENCED ON AND OFF EPIGASTRIC PAIN ESPECIALLY AFTER EATING WHICH STARTED SECOND WEEK OF DECEMBER. NO CONSULT DONE FEW HOURS PRIOR TO ADMISSION. SHE EXPERIENCED SEVERE ABDOMINAL PAIN.															
1245_002 8_086850	Asian	76/M	Glimepiride	Hepatobiliary disorders (	Drug-induced liver injury (	250	259	10	Mod	No	None	Yes	Rcver	No	Req hsp
Comment: FEVER NOTED ABOUT A WEEK PRIOR TO ADMISSION ASSOCIATED WITH BODY MALAISE. UPON ADMISSION NOTED TO BE JAUNDICED, HENCE WORKED-UP. STARTED ON ANTIBIOTIC TREATMENT.															
	Asian		Glimepiride	Cardiac disorders (	Acute myocardial infarction (	516	522	7	Sev	No	None	Yes	Rcver	No	Req hsp
1245_002 8_087223	Asian	36/M	Glimepiride	Injury, poisoning and procedural complications (	Foreign body (	172	173	2	Mod	No	None	Yes	Rcver	No	Req hsp
傷害、中毒および 処置合併症)															

Listing 7.1.6 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Glimepiride

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_002 8_087249	Asian	61/F	Glimepiride	Nervous system disorders (神経系障害)	Brain stem infarction (脳幹梗塞)	565	572	8	Sev	No	None	Yes	Seq	No	Disabl/Req hsp
1245_002 8_087309	Asian	61/F	Glimepiride	Neoplasms benign, malignant and unspecified (incl cysts and polyps) (良性、悪性および詳細不明の新生物 (嚢胞およびポリープを含む))	Malignant pleural effusion (悪性胸水)	338	386	49	Sev	No	Disc	Yes	Fatal	No	Fatal/Req hsp
Comment: SUBJECT WAS ADMITTEDV SINCE 09-05-2016 DUE TO DYSPNEA AND CHEST DISCOMFORT. SHE HAD BILATERAL PLEURAL AND PERICARDIAL EFFUSION. CYTOLOGY REPORT ATYPICAL CELLS, SUSPECTED CARCINOMA. F/U DATA WAS REPORT															
	Asian		Glimepiride	Neoplasms benign, malignant and unspecified (incl cysts and polyps) (良性、悪性および詳細不明の新生物 (嚢胞およびポリープを含む))	Pericardial effusion malignant (悪性心嚢液貯留)	338	386	49	Sev	No	Disc	Yes	Fatal	No	Fatal/Req hsp
Comment: SUBJECT WAS ADMITTEDV SINCE 09-05-2016 DUE TO DYSPNEA AND CHEST DISCOMFORT. SHE HAD BILATERAL PLEURAL AND PERICARDIAL EFFUSION. CYTOLOGY REPORT ATYPICAL CELLS, SUSPECTED CARCINOMA															
1245_002 8_087311	Asian	58/M	Glimepiride	Infections and infestations (感染症および寄生虫症)	Diarrhoea infectious (感染性下痢)	166	170	5	Sev	No	None	Yes	Rcver	No	Req hsp

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Listing 7.1.6 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Glimepiride

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_002 8_088033	White	64/F	Glimepiride	Blood and lymphatic system disorders (血液およびリンパ系障害)	Anaemia (貧血)	371	373	3	Sev	No	None	Yes	Rcver	No	Req hsp
Comment: ANEMIA WORSENING WITH LOW BLOOD COUNT, ADMITTED TO HOSPITAL, BLOOD TRANSFUSION															
	White		Glimepiride	Neoplasms benign, malignant and unspecified (incl cysts and polyps) (良性、悪性および 詳細不明の新生物 (嚢胞およびポリ ーブを含む))	Colon cancer (結腸癌)	642	Cont		Sev	No	None	No	Nrec	No	Other
Comment: COLOSCOPY SHOWED AN COLON TUMOR BUT FURTHER EXAMINATION WILL BE DONE															
1245_002 8_088036	White	48/M	Glimepiride	Psychiatric disorders (精神障害)	Suicide attempt (自殺企図)	499	504	6	Sev	No	None	Yes	Rcver	No	Imm thrt/Req hsp
Comment: TRIED TO COMMIT SUICED															
	White		Glimepiride	Infections and infestations (感染症および寄生 虫症)	Sepsis (敗血症)	511	517	7	Sev	No	None	Yes	Rcver	No	Req hsp
	White		Glimepiride	Infections and infestations (感染症および寄生 虫症)	Febrile infection (熱性感染症)	576	588	13	Sev	No	None	Yes	Rcver	No	Req hsp

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MedDRA version used for reporting: [REDACTED]

Listing 7.1.6 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Glimepiride

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_002 8_088073	White	67/M	Glimepiride	Injury, poisoning and procedural complications (	Head injury (	46	46	1	Sev	No	None	No	Rcver	No	Req hsp
				傷害、中毒および 処置合併症)	頭部損傷)										
	White		Glimepiride	Injury, poisoning and procedural complications (	Subdural haematoma (	57	133	77	Sev	No	None	Yes	Rcver	No	Req hsp
				傷害、中毒および 処置合併症)	硬膜下血腫)										
1245_002 8_088145	White	57/M	Glimepiride	Eye disorders (	Retinal detachment (	109	111	3	Mod	No	None	Yes	Seq	No	Req hsp
				眼障害)	網膜剥離)										
1245_002 8_088445	Asian	69/F	Glimepiride	Surgical and medical procedures (	Knee arthroplasty (	549	553	5	Mod	No	None	Yes	Rcver	No	Req hsp
				外科および内科処 置)	膝関節形成)										
Comment: PATIENT HAD PREBOOKED APPOINTMENT FOR THE KNEE REPLACEMENT															
1245_002 8_088510	White	70/M	Glimepiride	Reproductive system and breast disorders	Benign prostatic hyperplasia (	259	260	2	Mod	No	None	Yes	Rcver	No	Req hsp
				(	良性前立腺肥大症										
				生殖系および乳房 障害)											
Comment: ADMITTED TO THE BATH CLINIC 8 FEB 20 FOR TUR(P) AND BILATERAL RETROGRADE PYELOGRAMS. RETROGRADE PYELOGRAMS DEMONSTRATED NORMAL FLOW OF BOTH URETERS WITH NO EVIDENCE OF STONES.															

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Listing 7.1.6 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Glimepiride

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_002 8_088510	White	70/M	Glimepiride	Musculoskeletal and connective tissue disorders (筋骨格系および結 合組織障害)	Osteoarthritis (変形性関節症)	341	348	8	Mod	No	None	Yes	Rcver	No	Req hsp
Comment: RIGHT KNEE REPLACEMENT PLANNED AFTER DATE OF CONSENT															
	White		Glimepiride	Renal and urinary disorders (腎および尿路障害)	Renal failure acute (急性腎不全)	380	383	4	Mod	No	None	Yes	Rcver	No	Req hsp
Comment: SECONDARY RENAL FAILURE DETECTED ON BLOOD RESULTS REQUIRING HOSPITALISATION															
	White		Glimepiride	Metabolism and nutrition disorders (代謝および栄養障 害)	Dehydration (脱水)	380	383	4	Mod	No	None	Yes	Rcver	No	Req hsp
Comment: SECONDARY RENAL FAILURE DETECTED ON BLOOD RESULTS REQUIRING HOSPITALISATION															
1245_002 8_088573	Asian	61/F	Glimepiride	Gastrointestinal disorders (胃腸障害)	Dyspepsia (消化不良)	438	441	4	Sev	No	None	Yes	Rcver	No	Req hsp
Comment: PATIENT COMPLAINED OF CHEST PAIN 3 DAYS AGO. ECG SHOWED ISCHAEMIC CHANGES, SIMILAR TO LAST ECG. AMBULENCE CALLED TO RULE OUT MYOCARDIAL INFARCTION															
1245_002 8_088842	White	62/F	Glimepiride	Nervous system disorders (神経系障害)	Carpal tunnel syndrome (手根管症候群)	175	178	4	Mod	No	None	No	Rcver	No	Req hsp
1245_002 8_088883	White	78/F	Glimepiride	Eye disorders (眼障害)	Cataract (白内障)	296	538	243	Mild	No	None	Yes	Rcver	No	Other
Comment: PATIENT HAD CATARACT OPERATION ON LEFT EYE															

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Episodes with a negative start day are not assigned to the analysing treatment.

MedDRA version used for reporting: [REDACTED]

Listing 7.1.6 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Glimepiride

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_002 8_088883	White	78/F	Glimepiride	Eye disorders (眼障害)	Cataract (白内障)	296	421	126	Mild	No	None	Yes	Rcver	No	Other
Comment: PATIENT HAD CATARACT OPERATION TO RIGHT EYE															
1245_002 8_088890	White	47/F	Glimepiride	Nervous system disorders (神経系障害)	Carpal tunnel syndrome (手根管症候群)	65	Cont		Mod	No	None	Yes	Nrec	No	Other
Comment: OPERATION LEFT WRIST															
	White		Glimepiride	Nervous system disorders (神経系障害)	Carpal tunnel syndrome (手根管症候群)	75	Cont		Mod	No	None	Yes	Nrec	No	Other
Comment: SYMPTOMS STARTED ON LEFT HAND INITIALLY ON 5TH MAY 2016 AND PROGRESSED TO RIGHT HAND BY 15 MAY 2016.															
1245_002 8_088893	White	53/F	Glimepiride	Nervous system disorders (神経系障害)	Convulsion (痙攣)	74	75	2	Sev	No	Disc	Yes	Rcver	No	Req hsp
1245_002 8_088907	White	56/F	Glimepiride	Hepatobiliary disorders (肝胆道系障害)	Portal hypertension (門脈圧亢進症)	300	Cont		Sev	No	None	Yes	Nrec	No	Req hsp
Comment: PATIENT HOSPITALISED ON THE 2 MAY 2016 FOR FURTHER INVESTIGATION OF ABDOMINAL PAIN AND THE DIAGNOSIS OF PORTAL HYPERTENSION WAS MADE , SHE WAS DISCHARGE ON THE 4 MAY 2016 FROM HOSPITAL															
1245_002 8_088950	White	50/M	Glimepiride	Gastrointestinal disorders (胃腸障害)	Umbilical hernia (臍ヘルニア)	347	362	16	Sev	No	None	Yes	Rcver	No	Req hsp
1245_002 8_088951	White	60/F	Glimepiride	Injury, poisoning and procedural complications (傷害、中毒および処置合併症)	Incisional hernia (瘢痕ヘルニア)	344	346	3	Sev	No	None	Yes	Rcver	No	Req hsp

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Episodes with a negative start day are not assigned to the analysing treatment.

MedDRA version used for reporting: 20.1

Listing 7.1.6 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Glimepiride

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_002 8_089031	Asian	50/F	Glimepiride	Cardiac disorders (心臟障害)	Acute myocardial infarction (急性心筋梗塞)	300	300	1	Sev	No	Disc	Yes	Fatal	No	Fatal
Comment: PATIENT DIED OF MYOCARDIAL INFARCTION AT THE P I PRACTICE															

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Episodes with a negative start day are not assigned to the analysing treatment.

MedDRA version used for reporting: [REDACTED]

Listing 7.1.5 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Placebo

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_000 9_008616	White	71/M	Empa 25mg	Reproductive system and breast disorders (生殖系および乳房 障害)	Benign prostatic hyperplasia (良性前立腺肥大症)	204	213	10	Mod	No	None	Yes	Rcver	No	Req hsp
	White		Empa 25mg	Injury, poisoning and procedural complications (傷害、中毒および 処置合併症)	Post procedural haematuria (処置後血尿)	208	218	11	Mod	No	None	Yes	Rcver	No	Req hsp
	White		Empa 25mg	Renal and urinary disorders (腎および尿路障害)	Urinary retention (尿閉)	208	218	11	Mod	No	None	Yes	Rcver	No	Req hsp
1245_000 9_008963	White	56/F	Empa 10mg	Hepatobiliary disorders (肝胆道系障害)	Bile duct obstruction (胆管閉塞)	400	431	32	Sev	No	None	Yes	Rcver	No	Req hsp
	White		Empa 10mg	Hepatobiliary disorders (肝胆道系障害)	Cholelithiasis (胆石症)	400	431	32	Sev	No	None	Yes	Rcver	No	Req hsp
	White		Empa 10mg	Neoplasms benign, malignant and unspecified (incl cysts and polyps) (良性、悪性および 詳細不明の新生物 (嚢胞およびポリ ーブを含む))	Bile duct cancer (胆管癌)	410	4627	537	Sev	No	Disc	Yes	Nrec#	No	Prol hsp/Disabl

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Episodes with a negative start day are not assigned to the analysing treatment.

MedDRA version used for reporting: [REDACTED]

Listing 7.1.5 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Placebo

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_000 9_009670	White	72/M	Empa 25mg	Ear and labyrinth disorders (	Vertigo (	614	615	2	Mod	No	None	No	Rcver	No	Req hsp
				)	回転性めまい)										
1245_000 9_009764	White	64/F	Empa 25mg	Cardiac disorders (	Palpitations (	410	411	2	Mod	No	None	No	Rcver	No	Req hsp
				心臓障害)	動悸)										
1245_001 0_002367	White	77/F	Placebo	Infections and infestations (	Pneumonia (	12	25	14	Mod	No	None	Yes	Rcver	No	Req hsp
				感染症および寄生 虫症)	肺炎)										
1245_001 0_003431	White	61/M	Empa 25mg	Hepatobiliary disorders (	Cholecystitis acute (	228	230	3	Sev	No	None	Yes	Rcver	No	Req hsp
				肝胆道系障害)	急性胆嚢炎)										
1245_001 0_003632	White	60/F	Empa 25mg	General disorders and administration site conditions (	Non-cardiac chest pain (	434	435	2	Mild	No	None	Yes	Rcver	No	Req hsp
				一般・全身障害お よび投与部位の状 態)	非心臓性胸痛)										
1245_001 0_003861	White	56/M	Placebo	Cardiac disorders (	Myocardial infarction (	73	86	14	Mod	No	None	Yes	Rcver	No	Req hsp
				心臓障害)	心筋梗塞)										
	White		Placebo	Cardiac disorders (	Myocardial ischaemia (	73	86	14	Mod	No	None	Yes	Rcver	No	Req hsp
				心臓障害)	心筋虚血)										

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Episodes with a negative start day are not assigned to the analysing treatment.

MedDRA version used for reporting: [REDACTED]

Listing 7.1.5 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Placebo

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_001 0_006209	White	67/F	Empa 10mg	Surgical and medical procedures (	Hysterectomy (	585	585	1	Mod	No	None	Yes	Rcver	No	Req hsp
				置) 外科および内科処	子宮摘出)										

Comment: PATIENT DID NOT TAKE STUSY DRUG ON 17. AND 18.FEB. 2017.

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Episodes with a negative start day are not assigned to the analysing treatment.

MedDRA version used for reporting: 20.0

Listing 7.1.5 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Empa 1mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_001 0_001035	White	50/M	Empa 10mg	Cardiac disorders (	Angina unstable (不安定狭心症)	371	374	4	Sev	No	None	Yes	Rcver	No	Req hsp
1245_001 0_002395	White	69/M	Empa 25mg	General disorders and administration site conditions (一般・全身障害お よび投与部位の状 態)	Pyrexia (発熱)	223	230	8	Mod	No	None	Yes	Rcver	No	Req hsp
1245_001 0_003865	White	58/F	Empa 10mg	Hepatobiliary disorders (	Cholecystitis (	392	399	8	Mod	No	None	Yes	Rcver	No	Req hsp
Comment: LAPAROSCOPIC CHOLECYSTECTOMIA AT 06 JULY 2013															
	White		Empa 10mg	Hepatobiliary disorders (	Cholelithiasis (	392	399	8	Mod	No	None	Yes	Rcver	No	Req hsp
Comment: LAPAROSCOPIC CHOLECYSTECTOMIA AT 06 JULY 2013															
1245_001 0_004304	White	59/F	Empa 25mg	Musculoskeletal and connective tissue disorders (筋骨格系および結 合組織障害)	Rotator cuff syndrome (	363	659†	297†	Mod	No	None	Yes	Nrec&	No	Req hsp
Comment: HOSPITALISATION:29.-30.AUG.2013															
1245_001 0_004967	White	60/M	Empa 25mg	Infections and infestations (	Post procedural infection (	279*	401	123*	Sev	No	None	Yes	Rcver	No	Req hsp
Comment: STARTDATE UNKNOWN, COMPLICATION OF AE 1, HOSPITALISATION ON 21MAR2013, RE-SURGERY ON 22MAR2013															

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Episodes with a negative start day are not assigned to the analysing treatment.

MedDRA version used for reporting: 20.0

Listing 7.1.5 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Empa 1mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_001 0_004967	White	60/M	Empa 25mg	Nervous system disorders (神経系障害)	Transient ischaemic attack (一過性脳虚血発作)	376	378	3	Mod	No	None	Yes	Rcver	No	Req hsp

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 Episodes with a negative start day are not assigned to the analysing treatment.
 MedDRA version used for reporting: [REDACTED]

Listing 7.1.5 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Empa 5mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_000 9_008210	White	76/M	Empa 10mg	Reproductive system and breast disorders (障害)	Benign prostatic hyperplasia (良性前立腺肥大症 生殖系および乳房)	79	85	7	Sev	No	None	Yes	Rcver	No	Req hsp
	White		Empa 10mg	Nervous system disorders (神経系障害)	Cerebrovascular accident (脳血管発作)	501	535	35	Mod	No	None	Yes	Rcver	No	Req hsp
1245_000 9_008214	White	52/M	Empa 10mg	Gastrointestinal disorders (胃腸障害)	Inguinal hernia (鼠径ヘルニア)	628	631	4	Mod	No	None	Yes	Rcver	No	Req hsp
1245_000 9_008567	White	62/M	Empa 10mg	Injury, poisoning and procedural complications (傷害、中毒および 処置合併症)	Wrist fracture (手首関節骨折)	473	474	2	Sev	No	None	Yes	Seq	No	Req hsp
	White		Empa 10mg	Injury, poisoning and procedural complications (傷害、中毒および 処置合併症)	Ligament rupture (靱帯断裂)	473	474	2	Sev	No	None	Yes	Seq	No	Req hsp
1245_000 9_008570	White	53/F	Empa 10mg	Gastrointestinal disorders (胃腸障害)	Abdominal hernia (腹部ヘルニア)	214	357	144	Mod	No	None	Yes	Rcver	No	Req hsp
Comment: THE PATIENT DISCONTINUED THE STUDY DRUG BY HER INITIATIVE AND WITHDREW CONSENT															
1245_000 9_008912	White	77/F	Empa 5mg	Cardiac disorders (心臓障害)	Myocardial infarction (心筋梗塞)	5	23	19	Mild	No	Disc	Yes	Rcver	No	Req hsp

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Episodes with a negative start day are not assigned to the analysing treatment.

MedDRA version used for reporting: [REDACTED]

Listing 7.1.5 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Empa 5mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_000 9_009883	Asian	68/M	Post trt	Cardiac disorders (	Acute myocardial infarction (	43	56	14	Sev	No	Disc	Yes	Rcver	No	Req hsp
				心臓障害)	急性心筋梗塞)										
1245_001 0_002215	White	65/F	Empa 10mg	Musculoskeletal and connective tissue disorders (	Osteoarthritis (	280	287	8	Mild	No	None	Yes	Rcver	No	Req hsp
				筋骨格系および結 合組織障害)	変形性関節症)										
Comment: SURGERY FOR COXARTHROSIS PLANNED SINCE NOVEMBER 20															
1245_001 0_005730	White	60/M	Empa 25mg	Nervous system disorders (	Transient ischaemic attack (	173	173	1	Mod	No	None	Yes	Rcver	No	Req hsp
				神経系障害)	一過性脳虚血発作)										
1245_001 0_005812	White	62/M	Empa 25mg	Musculoskeletal and connective tissue disorders (	Osteoarthritis (	384	607	224	Mod	No	Disc	Yes	Rcver	No	Req hsp
				筋骨格系および結 合組織障害)	変形性関節症)										
1245_001 0_006063	White	68/M	Empa 5mg	Cardiac disorders (	Myocardial infarction (	81	85	5	Sev	No	None	Yes	Rcver	No	Imm thrt/Req hsp
				心臓障害)	心筋梗塞)										
1245_001 0_006122	White	62/F	Empa 5mg	Endocrine disorders (	Thyroid cyst (	62	917	307	Mod	No	None	Yes	Rcver	No	Req hsp
				内分泌障害)	甲状腺嚢腫)										
Comment: EXTIRPATION OF THE CYST OF THYROID GLAND WITH RETROSTERNAL LOCATION															

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Episodes with a negative start day are not assigned to the analysing treatment.

MedDRA version used for reporting:

Listing 7.1.5 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Empa 5mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_001 0_007494	White	62/F	Empa 5mg	Neoplasms benign, malignant and unspecified (incl cysts and polyps) (病) 良性、悪性および 詳細不明の新生物 (嚢胞およびポリ ーブを含む)	Chronic lymphocytic leukaemia (慢性リンパ性白血	35	1047	707	Mod	No	None	Yes	Nrec&	No	Other
Comment: INCREASED LEVEL OF WBC(17.44 GI/L),LYMPHOCITE COUNT(12.44 GI/L)WAS DETECTED DURING SCREENING ON 19MAR. AS A RESULT OF FRUTHER INVESTIGATION DIAGNOSIS OF CHRONIC LYMPHOLEUKOSIS CONFIRMED ON 09JUN.															
1245_001 0_007510	White	62/F	Empa 10mg	Nervous system disorders (神経系障害)	Carotid artery stenosis (頸動脈狭窄)	306	463	158	Mod	No	None	Yes	Rcver	No	Req hsp
Comment: PERFORMED THERAPY FOR EVENT IS ENDARTERECTOMIA OF LEFT CAROTIDE ARTERY															

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 Episodes with a negative start day are not assigned to the analysing treatment.
 MedDRA version used for reporting:

Listing 7.1.5 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Empa 10mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_000 9_008230	White	42/M	Empa 10mg	Gastrointestinal disorders (胃腸障害)	Gingival cyst (歯肉嚢胞)	181	182	2	Sev	No	None	Yes	Rcver	No	Req hsp
1245_000 9_008271	White	58/F	Empa 10mg	Eye disorders (眼障害)	Visual acuity reduced (視力低下)	108	108	1	Mild	No	None	No	Rcver	No	Req hsp
1245_000 9_008325	White	69/M	Empa 10mg	Reproductive system and breast disorders (生殖系および乳房 障害)	Benign prostatic hyperplasia (良性前立腺肥大症)	531*	579	49*	Mild	No	None	Yes	Rcver	No	Req hsp
1245_000 9_008582	White	74/M	Post study	Vascular disorders (血管障害)	Hypertension (高血圧)	555	555	1	Sev	No	Disc	No	Fatal	No	Fatal
Comment: THE PATIENT DIED															
1245_000 9_008618	White	53/M	Empa 10mg	Gastrointestinal disorders (胃腸障害)	Anal fistula (痔瘻)	275	448	174	Mod	No	None	Yes	Rcver	No	Req hsp
1245_001 0_001353	White	65/F	Empa 10mg	Infections and infestations (感染症および寄生 虫症)	Gastroenteritis (胃腸炎)	394	394	1	Mod	No	None	Yes	Rcver	No	Other
Comment: PER PI IMPORTANT MEDICAL EVENT DUE TO SEVERITY															
1245_001 0_003633	White	58/F	Empa 10mg	Gastrointestinal disorders (胃腸障害)	Lumbar hernia (腰ヘルニア)	143	151	9	Sev	No	None	Yes	Rcver	No	Req hsp
1245_001 0_004705	White	64/M	Empa 10mg	Cardiac disorders (心臓障害)	Atrial fibrillation (心房細動)	31	35	5	Mod	No	Disc	Yes	Rcver	No	Req hsp
Comment: DISCONTINUED STUDY DRUG DUE TO MIC															

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Episodes with a negative start day are not assigned to the analysing treatment.

MedDRA version used for reporting: [REDACTED]

Listing 7.1.5 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Empa 10mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_001 0_004705	White	64/M	Empa 10mg	General disorders and administration site conditions (一般・全身障害お よび投与部位の状 態)	Chest discomfort (胸部不快感)	31	35	5	Mod	No	Disc	Yes	Rcver	No	Prol hsp
Comment: PATIENT DISCONTINUED STUDY MEDICATION AT THE HOSPITAL. BUT NOT DUE TO CHEST DISCOMFORT.															
1245_001 0_004792	White	69/M	Empa 10mg	Cardiac disorders (	Myocardial infarction (	384	388	5	Sev	No	Disc	Yes	Rcver	No	Req hsp
				心臓障害)	心筋梗塞)										
1245_001 0_007497	White	54/F	Empa 10mg	Nervous system disorders (	Ischaemic stroke (虚血性脳卒中)	441	449	9	Mod	No	None	Yes	Rcver	No	Req hsp
				神経系障害)											

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Episodes with a negative start day are not assigned to the analysing treatment.
MedDRA version used for reporting: [REDACTED]

Listing 7.1.5 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Empa 25mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_000 9_008307	White	58/M	Empa 25mg	Infections and infestations (	Cellulitis (	214	214	1	Sev	No	None	Yes	Rcver	No	Req hsp
感染症および寄生 虫症) Comment: AMPUTATION BIG TOE RIGHT FOOT															
	White		Empa 25mg	Injury, poisoning and procedural complications (	Vascular graft occlusion (	301	319	19	Sev	No	None	Yes	Rcver	No	Req hsp
傷害、中毒および 処置合併症) Comment: REMOTE THROMBENARTERIECTOMY ARTERIA FEMORALIS AND STENT SEGMENT I ARTERIAL POPLITEA, DILATATION ARTERIA FEMORALIS RIGHT															
1245_000 9_008329	White	50/M	Empa 25mg	Cardiac disorders (	Myocardial infarction (	177	182	6	Mod	No	None	Yes	Rcver	No	Req hsp
心臓障害) 心筋梗塞)															
1245_000 9_008581	White	79/F	Empa 25mg	Cardiac disorders (	Atrial fibrillation (	292	468	177	Sev	No	None	Yes	Rcver	No	Req hsp
心臓障害) 心房細動)															
1245_000 9_009270	Asian	64/F	Empa 25mg	Injury, poisoning and procedural complications (	Fall (転倒)	514	514	1	Mild	No	None	Yes	Rcver	No	Req hsp
傷害、中毒および 処置合併症)															
	Asian		Empa 25mg	Injury, poisoning and procedural complications (	Fibula fracture (腓骨骨折)	514	555	42	Mild	No	None	Yes	Rcver	No	Req hsp
傷害、中毒および 処置合併症)															

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 Episodes with a negative start day are not assigned to the analysing treatment.

MedDRA version used for reporting: [REDACTED]

Listing 7.1.5 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Empa 25mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_000 9_009648	Asian	61/M	Empa 25mg	Gastrointestinal disorders (胃腸障害)	Intestinal functional disorder (腸管機能障害)	8	15	8	Mod	No	None	Yes	Rcver	No	Req hsp
1245_001 0_002242	White	60/M	Empa 25mg	Infections and infestations (感染症および寄生虫症)	Anal abscess (肛門膿瘍)	396	397	2	Mod	No	None	Yes	Rcver	No	Req hsp
1245_001 0_004808	White	66/M	Empa 25mg	Injury, poisoning and procedural complications (傷害、中毒および処置合併症)	Concussion (脳振盪)	454	455	2	Sev	No	None	No	Rcver	No	Req hsp
	White		Empa 25mg	Injury, poisoning and procedural complications (傷害、中毒および処置合併症)	Fall (転倒)	454	455	2	Sev	No	None	No	Rcver	No	Req hsp
1245_001 0_005651	White	48/F	Empa 25mg	Hepatobiliary disorders (肝胆道系障害)	Cholecystitis acute (急性胆嚢炎)	29	37	9	Mod	No	None	Yes	Rcver	No	Other/Req hsp
Comment: ON 04 BECAMES SERIUS BECAUSE INVESTIGATOR CRITERIA															
1245_001 0_005811	White	70/M	Empa 25mg	Cardiac disorders (心臓障害)	Coronary artery disease (冠動脈疾患)	9	53	45	Mod	No	None	Yes	Rcver	No	Req hsp
	White		Empa 25mg	Cardiac disorders (心臓障害)	Coronary artery disease (冠動脈疾患)	96	248	153	Mod	No	None	Yes	Rcver	No	Req hsp

@ Related to start of treatment, 7 = censored, * = partial date or missing date/time imputed, # = Lost to follow up, & = Follow up sufficient
 Episodes with a negative start day are not assigned to the analysing treatment.

MedDRA version used for reporting: [REDACTED]

Listing 7.1.5 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Empa 50mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_001 0_001037	White	68/F	Empa 25mg	Nervous system disorders (	Carotid artery stenosis (	597	598	2	Mild	No	None	Yes	Rcver	No	Req hsp
				神経系障害)	頸動脈狭窄)										
1245_001 0_001186	White	57/M	Empa 50mg	Injury, poisoning and procedural complications (	Arthropod bite (	3	4	2	Mod	No	None	Yes	Rcver	No	Req hsp
				傷害、中毒および 処置合併症)	節足動物咬傷)										
	White		Empa 50mg	General disorders and administration site conditions (	Chest pain (	3	4	2	Mod	No	None	No	Rcver	No	Req hsp
				一般・全身障害お よび投与部位の状 態)	胸痛)										
	White		Empa 50mg	Skin and subcutaneous tissue disorders (	Urticaria (	3	4	2	Mod	No	None	Yes	Rcver	No	Req hsp
				皮膚および皮下組 織障害)	蕁麻疹)										
1245_001 0_003215	White	56/F	Empa 50mg	Infections and infestations (	Pyelonephritis (	29	35	7	Mod	No	Disc	Yes	Rcver	No	Req hsp
				感染症および寄生 虫症)	腎盂腎炎)										
1245_001 0_004335	White	66/F	Empa 25mg	Cardiac disorders (	Angina unstable (不安定狭心症)	397	453	57	Sev	No	Disc	Yes	Rcver	No	Req hsp
				心臓障害)											

Comment: REHABILITATION FROM 31-AUG-20 TILL 28-SEP-20

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Episodes with a negative start day are not assigned to the analysing treatment.

MedDRA version used for reporting:

Listing 7.1.5 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Empa 50mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_001 0_004770	White	66/F	Empa 25mg	Endocrine disorders (	Goitre (	500	505	6	Mod	No	None	Yes	Rcver	No	Req hsp
1245_001 0_007339	White	69/M	Empa 10mg	Neoplasms benign, malignant and unspecified (incl cysts and polyps) (	Prostate cancer (前立腺癌)	301	308	8	Mod	No	None	Yes	Rcver	No	Req hsp
				良性、悪性および 詳細不明の新生物 (嚢胞およびポリ ーブを含む))											
1245_001 0_007483	White	50/M	Empa 50mg	Infections and infestations (	Pneumonia (	28	46	19	Mod	No	Disc	Yes	Rcver	No	Req hsp
				感染症および寄生 虫症)	肺炎)										

Comment: STUDY DRUG WAS DISCONTINUED ON 22-MAY-2013.

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 Episodes with a negative start day are not assigned to the analysing treatment.
 MedDRA version used for reporting: 20.0

Listing 7.1.5 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Metformin

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_000 9_008336	White	48/M	Metformin	Injury, poisoning and procedural complications (	Hand fracture (	56	947	397	Sev	No	Disc	Yes	Nrec&	No	Req hsp
傷害、中毒および 処置合併症) Comment: TELEPHONE CALL WITH PATIENT															
	White		Metformin	Injury, poisoning and procedural complications (	Ligament rupture	56	947	397	Sev	No	Disc	Yes	Nrec&	No	Req hsp
傷害、中毒および 処置合併症) Comment: TELEPHONE CALL WITH PATIENT															
	White		Metformin	Injury, poisoning and procedural complications (	Road traffic accident (	56	56	1	Sev	No	Disc	Yes	Rcver	No	Req hsp
傷害、中毒および 処置合併症) Comment: TELEPHONE CALL WITH PATIENT															
	White		Metformin	Injury, poisoning and procedural complications (	Pelvic fracture	56	947	397	Sev	No	Disc	Yes	Nrec&	No	Req hsp
傷害、中毒および 処置合併症) Comment: TELEPHONE CALL WITH PATIENT															
1245_000 9_008977	White	61/F	Metformin	Injury, poisoning and procedural complications (	Traumatic fracture (	204	263	60	Sev	No	None	Yes	Rcver	No	Req hsp
傷害、中毒および 処置合併症)															

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 Episodes with a negative start day are not assigned to the analysing treatment.
 MedDRA version used for reporting: [REDACTED]

Listing 7.1.5 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Metformin

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_000 9_009464	Asian	43/M	Metformin	Cardiac disorders (心臓障害)	Prinzmetal angina (プリンツメタル狭心症)	27	30	4	Sev	No	Disc	Yes	Rcver	No	Req hsp
1245_000 9_009488	Asian	65/F	Metformin	Injury, poisoning and procedural complications (傷害、中毒および処置合併症)	Meniscus lesion (半月板障害)	50	361	312	Mod	No	None	Yes	Rcver	No	Req hsp
Comment: THIS SUBJECT WAS ROLLED OVER FROM 1245.9 TRIAL AND HAS BEEN OBSERVED OF THE AE. RELATED CTS STOPPED IN PREVIOUS TRIAL.															
1245_000 9_009602	Asian	50/F	Metformin	Neoplasms benign, malignant and unspecified (incl cysts and polyps) (良性、悪性および詳細不明の新生物 (嚢胞およびポリープを含む))	Breast cancer (乳癌)	269	3547	867	Sev	No	None	Yes	Nrec&	No	Req hsp/Other
Comment: THIS SUBJECT WAS ROLLED OVER FROM 1245.9 TRIAL AND ENROLLED INTO 1245.24 TRIAL ON 29 JUL 2011. SHE IS EXPECTED TO REQUIRE MEDICAL OR SUGICAL INTERVANTION.SO IT'S CONSIDERED AS AN IMPORTANT MEDICAL EVENT															
1245_000 9_009953	Asian	48/M	Metformin	General disorders and administration site conditions (一般・全身障害および投与部位の状態)	Death (死亡)	422	422	1	Sev	No	Disc	No	Fatal	No	Fatal

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Episodes with a negative start day are not assigned to the analysing treatment.

MedDRA version used for reporting: █

Listing 7.1.5 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Sitagliptin

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_001 0_002362	White	74/M	Sitagliptin	Respiratory, thoracic and mediastinal disorders (	Acute respiratory failure (	243	257	15	Mod	No	None	Yes	Rcver	No	Req hsp
				呼吸器、胸郭およ び縦隔障害)	急性呼吸不全)										
	White		Sitagliptin	Gastrointestinal disorders (	Colonic polyp (	243	257	15	Mild	No	None	Yes	Rcver	No	Other
				胃腸障害)	結腸ポリープ)										
Comment: A COLONOSCOPIC STUDY WAS PERFORMED AND SOME POLYPS WERE DISCOVERED AND REMOVED															
	White		Sitagliptin	Metabolism and nutrition disorders (	Hyperglycaemia (	243	379	137	Mod	No	None	Yes	Rcver	No	Other
				代謝および栄養障 害)	高血糖)										
Comment: WHEN PATIENT WAS ADMITTED TO HOSPITAL, GLUCOSE LEVELS WERE 401 MG/DL. HIS DOCTORS DECIDED TO STOP STUDY GROUP AND TO INITIATE INSULIN															
	White		Sitagliptin	Neoplasms benign, malignant and unspecified (incl cysts and polyps) (	Refractory cytopenia with multilineage dysplasia (	256	6537	3987	Sev	No	None	Yes	Nrec&	No	Req hsp
				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)	多血球系異形成を 伴う不応性血球減 少症)										

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Episodes with a negative start day are not assigned to the analysing treatment.

MedDRA version used for reporting: [REDACTED]

Listing 7.1.5 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Sitagliptin

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_001 0_002362	White	74/M	Sitagliptin	Neoplasms benign, malignant and unspecified (incl cysts and polyps) (	Transitional cell carcinoma (	576	580	5	Mod	No	None	Yes	Rcver	No	Req hsp
				良性、悪性および 詳細不明の新生物 (嚢胞およびポリ ーブを含む))	移行上皮癌)										
1245_001 0_003035	White	56/M	Sitagliptin	Metabolism and nutrition disorders (	Hyperglycaemia (	409	412	4	Mod	Yes	None	No	Rcver	No	Req hsp
				代謝および栄養障 害)	高血糖)										
1245_001 0_003813	White	57/F	Sitagliptin	Neoplasms benign, malignant and unspecified (incl cysts and polyps) (	Cervix carcinoma recurrent (	539	6667	1287	Sev	No	None	Yes	Nrec#	No	Disabl/Req hsp
				良性、悪性および 詳細不明の新生物 (嚢胞およびポリ ーブを含む))	再発子宮頸部癌)										
Comment: SPECIFY THE EXACT START DATE															
1245_001 0_004121	White	67/M	Sitagliptin	Hepatobiliary disorders (	Cholecystitis acute (	220	227	8	Sev	No	None	Yes	Rcver	No	Req hsp
				肝胆道系障害)	急性胆嚢炎)										
	White		Sitagliptin	Hepatobiliary disorders (	Cholelithiasis (	220	227	8	Sev	No	None	Yes	Rcver	No	Req hsp
				肝胆道系障害)	胆石症)										

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Episodes with a negative start day are not assigned to the analysing treatment.

MedDRA version used for reporting: █

Listing 7.1.5 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Sitagliptin

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_001 0_004135	White	68/M	Sitagliptin	Nervous system disorders (	Aphasia (	177	6937	5177	Sev	No	None	Yes	Seq	No	Disabl/Req hsp
	White		Sitagliptin	Nervous system disorders (	Ischaemic stroke (虚血性脳卒中)	177	6937	5177	Sev	No	Disc	Yes	Seq	No	Disabl/Req hsp
	White		Sitagliptin	Nervous system disorders (	Hemiplegia (	177	6937	5177	Sev	No	None	Yes	Seq	No	Disabl/Req hsp
1245_001 0_004153	White	50/F	Sitagliptin	Musculoskeletal and connective tissue disorders (筋骨格系および結 合組織障害)	Spinal osteoarthritis (	87	108	22	Mod	No	None	Yes	Rcver	No	Req hsp
1245_001 0_007482	White	71/F	Sitagliptin	Nervous system disorders (	Cerebral infarction (	150	157	8	Mild	No	None	Yes	Rcver	No	Req hsp
Comment: LOCALISATION OF CEREBRAL INFARCTION IS A.CEREBRI MEDIA REGION															
	White		Sitagliptin	Cardiac disorders (	Angina unstable (不安定狭心症)	484	492	9	Mod	No	None	Yes	Rcver	No	Req hsp
1245_001 0_007489	White	53/F	Sitagliptin	Hepatobiliary disorders (	Cholecystitis acute (	144	150	7	Sev	No	None	Yes	Rcver	No	Req hsp
Comment: THERAPY OF EVENT- CHOLECYSTECTOMY															
1245_001 0_007501	White	65/M	Sitagliptin	Nervous system disorders (	Cerebral infarction (	269	296	28	Mod	No	None	Yes	Rcver	No	Req hsp

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Episodes with a negative start day are not assigned to the analysing treatment.

MedDRA version used for reporting: [REDACTED]

Listing 7.1.5 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Sitagliptin

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_001 0_007501	White	65/M	Sitagliptin	Cardiac disorders (	Angina pectoris (狭心症)	374	429	56	Mod	No	None	Yes	Rcver	No	Req hsp
Comment: SYMPTOMS STARTED ON 13-MAY-2011, PATIENT IS NOT RECOVERED YET.SAE REPORT WAS SENT DUE TO HOSPITALISATION FOR THERAPY ADJUSTMENT ON 02-JUL-2011 TILL 07-JUL-2011															

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 Episodes with a negative start day are not assigned to the analysing treatment.
 MedDRA version used for reporting: 11.0

Listing 6.2.1 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Empa 10mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_005 2_205006	Asian	66/M	Run-in	Cardiac disorders (	Angina unstable (不安定狭心症)	-15	5977	6127	Mild	No	None	Yes	Nrec&	No	Req hsp
Comment: IT IS[MEDICAL TREATMENT]UNDER CONTINUATION,AND RECOVERY CANNOT BE JUDGED BUT IS AN OUTCOME OF EVENT "LIGHTNESS"STILL NOW.AGREEMENT:25/JUL/2016 IT IS CONSIDERED TO BE NO CAUSAL RELATIONSHIP BETWEEN THE															
1245_005 2_206020	Asian	70/M	Screening	Neoplasms benign, malignant and unspecified (incl cysts and polyps) (	Squamous cell carcinoma (	-15	84	99	Mod	No	None	Yes	Rcver	No	Other
Comment: THE EVENT WAS ASSESSED AS "UNRELATED" TO THE STUDY DRUG BECAUSE THE SUBJECTIVE SYMPTOM (20/JUN/2016)OCCURRED BEFORE INITATION OF THE STUDY DRUG.															
1245_005 2_206064	Asian	70/M	Empa 10mg	Gastrointestinal disorders (	Megacolon (	127	131	5	Mod	No	None	Yes	Rcver	No	Req hsp
Comment: THE EVENT WAS CONSIDERED TO BE DUE TO ACCIDENTAL WORSENING OF MEGACOLON.THUS,IT WAS ASSESSED AS "UNRELATED" TO THE STUDY DRUG.															
	Asian		Empa 10mg	Gastrointestinal disorders (	Megacolon (	173	191	19	Mod	No	Disc	Yes	Rcver	No	Req hsp
Comment: THE EVENT WAS CONSIDERED TO BE DUE TO ACCIDENTAL WORSENING OF MEGACOLON.THUS,IT WAS ASSESSED AS "UNRELATED" TO THE STUDY DRUG.															
1245_005 2_209001	Asian	69/M	Empa 10mg	Gastrointestinal disorders (	Colonic polyp (	347	6317	2857	Mod	Yes	None	Yes	Nrec&	No	Req hsp
Comment: COLONIC POLYP IS ALSO ASSUMED TO HAVE CAUSALITY WITH STUDY DRUG DUE TO LACK OF DENIABLE EVIDENCE AND DIFFICULTY IN SPECIFYING THE TIME OF OCCURRENCE.BECAUSE PATIENT HAS BEEN TAKING STUDY DRUG FOR ONE															

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Episodes with a negative start day are not assigned to the analysing treatment.
MedDRA version used for reporting: 20.1

Listing 6.2.1 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Empa 10mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_005 2_209001	Asian	69/M	Post trt	Neoplasms benign, malignant and unspecified (incl cysts and polyps) (	Rectal cancer (	364	364	1	Mod	Yes	None	Yes	Rcver	No	Req hsp
				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))	直腸癌)										
Comment: EXISTENCE OF CAUSALITY WITH STUDY DRUG IS ASSUMED BECAUSE PATIENT HAS BEEN TAKING STUDY DRUG FOR ONE YEAR AND ADENOCARCINOMA WAS FOUND WITH EARLY STAGE.															
1245_005 2_209010	Asian	58/M	Empa 10mg	Renal and urinary disorders (	Calculus ureteric (	8	4667	4597	Mod	No	None	Yes	Nrec&	No	Req hsp
				腎および尿路障害)	尿管結石)										
Comment: RENAL CALCULUS(COMPLICATION) WAS MOVED DOWN TO AN URETER.A CONTINUOUS FOLLOW-UP OF THE EVENT IS CONSIDERED UNNECESSARY BECAUSE IT WOULD SEEM THAT THE EVENT NEITHER INTERFERES WITH THE PATIENT`S USUAL															
1245_005 2_209017	Asian	64/M	Empa 10mg	Musculoskeletal and connective tissue disorders (	Spinal column stenosis (	251	373	123	Mild	Yes	None	Yes	Rcver	No	Req hsp
				(筋骨格系および結 合組織障害)	脊柱管狭窄症)										
Comment: THE SYMPTOMS APPEARED ABOUT SEVEN MONTHS AFTER INITIATION OF THE STUDY DRUG.THE ABSENCE OF RELATIVE COMPLICATIONS AND CHANGES IN LIFE HABITS.THEREFORE I AM UNABLE TO COMPLETELY RULE OUT															
1245_005 2_212008	Asian	74/M	Empa 10mg	Injury, poisoning and procedural complications (	Subdural haematoma (	53	78	26	Sev	No	None	Yes	Rcver	No	Req hsp
				傷害、中毒および 処置合併症)	硬膜下血腫)										
Comment: IN JULY 2011,THE PATIENT HAD BUMPED HIS HEAD AND SINCE THEN HE HAD PERSISTENT DULL HEADACHE.THE EVENT APPEARS TO HAVE BEEN CAUSED BY BUMPING HIS HEAD AND WAS ASSESSED AS UNRELATED TO THE STUDY DRUG.															

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Episodes with a negative start day are not assigned to the analysing treatment.
MedDRA version used for reporting: 20.1

Listing 6.2.1 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Empa 10mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_005 2_214009	Asian	62/M	Empa 10mg	Gastrointestinal disorders (胃腸障害)	Leukoplakia oral (口腔内白斑症)	347	426	80	Mild	No	None	Yes	Rcver	No	Req hsp
Comment: IT IS A FORTUITOUS EVENT AND CONSIDERED TO BE UNRELATED TO THE STUDY DRUG.															
1245_005 2_216019	Asian	61/M	Post trt	Cardiac disorders (心臓障害)	Myocardial infarction (心筋梗塞)	35	49	15	Sev	No	Disc	Yes	Rcver	No	Req hsp
Comment: THE CAUSAL RELATION IS NONE BECAUSE THE CARDIOVASCULAR SYSTEM RISK WAS HIGH DUE TO DIABETIC.															
1245_005 2_216028	Asian	59/M	Empa 10mg	Injury, poisoning and procedural complications (傷害、中毒および処置合併症)	Femur fracture (大腿骨骨折)	116	204	89	Sev	No	None	Yes	Rcver	No	Req hsp
Comment: DUE TO STRONG IMPACT BY ACCIDENTAL FALL-DOWN.(IT IS TRAUMATIC FRACTURE.)															
1245_005 2_218001	Asian	67/M	Empa 10mg	Cardiac disorders (心臓障害)	Acute myocardial infarction (急性心筋梗塞)	167	198	32	Sev	No	Disc	Yes	Rcver	No	Req hsp
Comment: A CAUSAL RELATIONSHIP BETWEEN THE EVENT AND THE STUDY DRUG CAN BE RULED OUT CONSIDERING ITS PHARMACODYNAMIC ACTION AND THE STATUS OF BLOOD GLUCOSE CONTROL.															
1245_005 2_225011	Asian	63/F	Empa 10mg	Respiratory, thoracic and mediastinal disorders (呼吸器、胸郭および縦隔障害)	Hyperventilation (過換気)	274	281	8	Mod	No	Disc	Yes	Rcver	No	Req hsp
Comment: THE INVESTIGATOR ASSESSED THE EVENT AS UNRELATED TO THE STUDY DRUG BECAUSE THE PATIENT HAD EXPERIENCED HYPERVENTILATION SYNDROME FIVE YEARS AGO AND THE CURRENT SYMPTOMS ARE SIMILAR TO THOSE SHE HAD EX															
1245_005 2_226019	Asian	66/M	Empa 10mg	Nervous system disorders (神経系障害)	Carotid artery stenosis (頸動脈狭窄)	46	99	54	Sev	No	None	Yes	Rcver	No	Req hsp
Comment: THIS EVENT IS A COMPLICATION(LEFT INTERNAL CAROTID ARTERY STRICTURE)AND CHANGE OVER TIME DUE TO DETERIORATION,DO NOT THINK CAUSATION.															

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Episodes with a negative start day are not assigned to the analysing treatment.
MedDRA version used for reporting: █

Listing 6.2.1 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Empa 10mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_005 2_230009	Asian	60/M	Empa 10mg	Infections and infestations (	Cellulitis (	76	120	45	Mod	No	None	Yes	Rcver	No	Req hsp
感染症および寄生 虫症)															
Comment: DO TO ACCIDENTAL INFECTION															
1245_005 2_237012	Asian	61/M	Empa 10mg	Musculoskeletal and connective tissue disorders (	Polyarthritits (	311	4357	1257	Mod	No	None	Yes	Nrec&	No	Req hsp
多発性関節炎) (筋骨格系および結 合組織障害)															
Comment: IT IS CONSIDERED TO BE A FORTUITOUS EVENT.															
1245_005 2_239016	Asian	59/M	Empa 10mg	Nervous system disorders (	Cerebral arteriosclerosis (脳動脈硬化症)	22	36	15	Mod	No	Disc	Yes	Seq	No	Req hsp
Comment: AGREEMENT:31/OCT/2016 SINC SINCE THERE ARE DIABETES MELLITUS AND A HYPERTENSION DISEASE HISTRY, IT IS CONSIDERED ATHEROMA CEREBRAL INFECTION. THEREFORE, IT WAS JUDGED THAT THERE WAS NO CAUSAL															
	Asian		Empa 10mg	Nervous system disorders (	Cerebral infarction (	22	36	15	Mod	No	Disc	Yes	Seq	No	Req hsp
神経系障害) 脳梗塞) Comment: AGREEMENT:31/OCT/2016 SINC SINCE THERE ARE DIABETES MELLITUS AND A HYPERTENTION DISEASE HISTRY, IT IS CONSIDERED ATHEROMA CEREBRAL INFECTION. THEREFORE, IT WAS JUDGED THAT THERE WAS NO CAUSAL															
1245_005 2_240008	Asian	76/M	Empa 10mg	Vascular disorders (	Peripheral arterial occlusive disease (	218	238	21	Mod	No	None	Yes	Rcver	No	Req hsp
血管障害) 末梢動脈閉塞性疾 患)															
Comment: THE PATIENT RECEIVED A DIAGNOSIS OF PERIPHERAL ARTERIAL DISEASE IN 2016. I THINK I CAN DENY ANY LINK WITH THE STUDY DRUG BECAUSE THIS WORSENING RESULTED BY HAVING JUST LEFT IT.															

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Episodes with a negative start day are not assigned to the analysing treatment.

MedDRA version used for reporting: 20.1

Listing 6.2.1 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Empa 10mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_005 2_240008	Asian	76/M	Empa 10mg	Cardiac disorders (	Angina pectoris (狭心症)	237	260	24	Mod	No	None	Yes	Rcver	No	Req hsp
Comment: GIVEN THAT THE PATIENT WAS DIAGNOSED AS HAVING PERIPHERAL ARTERIAL DISEASE IN 2010 AND HAS BEEN SUFFERING FROM TYPE II DIABETES MELLITUS FOR MORE THAN 10 YEARS,															
1245_005 2_242006	Asian	73/M	Empa 10mg	Immune system disorders (	Anaphylactic reaction (	94	98	5	Mod	No	None	Yes	Rcver	No	Other
Comment: IT IS CONSIDERED THAT NO RELATIONSHIP WITH BI 10773, BECAUSE THE ANAPHYLACTIC REACTION WAS OBSERVED JUST AFTER ADMINISTRATION OF THE CONTRAST DYE, "FLUORESCITE ". NBI IMPLIED SERIOUS PTS.															
1245_005 2_243002	Asian	62/M	Empa 10mg	Injury, poisoning and procedural complications (	Pelvic fracture (骨盤骨折)	14	58	45	Mod	No	None	Yes	Rcver	No	Req hsp
Comment: TRAFFIC ACCIDENT (TRAUMATIC)															
1245_005 2_243007	Asian	61/M	Post trt	Cardiac disorders (	Acute myocardial infarction (	8	197	190	Sev	Yes	Disc	Yes	Rcver	No	Req hsp
Comment: ACUTE MYOCARDIAL INFARCTION MAY HAVE BEEN CAUSED BY DEHYDRATION DUE TO THE EFFECTS OF THE STUDY DRUG. THE EVENT THUS IS CONSIDERED TO BE RELATED TO THE STUDY DRUG.															
1245_005 2_244010	Asian	72/F	Empa 10mg	Injury, poisoning and procedural complications (	Femur fracture (	21	1957	1757	Sev	No	Disc	Yes	Nrec&	No	Req hsp
Comment: IT WAS CONSIDERED THAT THE EVENT WAS ACCIDENTALLY OCCURRED AND NO RELATIONSHIP WITH THE TRIAL PRODUCT.SO I DECIDED NO FURTHER TRACE IS NEED.THIS FRACTURE IS NON-TRAUMATIC.															

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Episodes with a negative start day are not assigned to the analysing treatment.
MedDRA version used for reporting: [REDACTED]

Listing 6.2.1 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Empa 10mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_005 2_246002	Asian	67/M	Empa 10mg	Nervous system disorders (	Lacunar infarction (	297	341	45	Mod	No	Disc	Yes	Rcver	No	Req hsp
Comment: BECAUSE THIS PATIENT HAD MULTIPLE RISK FACTORS FOR CEREBRAL INFARCTION INCLUDING BEING ELDERLY AND A SMOKER AS WELL AS BEING UNDER TREATMENT OF DIABETES MELLITUS AND HYPERTENSION, THE EVENT MAY HAVE															
1245_005 2_250005	Asian	77/M	Empa 10mg	General disorders and administration site conditions (一般・全身障害お よび投与部位の状 態)	Chest pain (	233	242	10	Mild	No	None	Yes	Rcver	No	Req hsp
Comment: THE CAUSE FOR CHEST PAIN IS UNCLEAR AND THERE WERE NO FINDINGS TO SUPPORT A CAUSAL RELATIONSHIP BETWEEN THE EVENT AND THE STUDY DRUG.															
1245_005 2_250006	Asian	48/M	Empa 10mg	Cardiac disorders (	Coronary artery stenosis (	152	153	2	Mild	No	None	Yes	Rcver	No	Req hsp
Comment: IT IS BECAUSE STENOSIS PREEXISTED THE PATIENT'S PARTICIPATION IN THE CLINICAL STUDY.															
1245_005 2_255018	Asian	62/M	Empa 10mg	Eye disorders (	Cataract (	311	365	55	Mild	No	None	Yes	Rcver	No	Req hsp
Comment: THIS EVENT HAS BEEN CONSIDERED TO BE NATURAL COURSE OF AGING. NO RELATIONSHIP.															
1245_005 2_259005	Asian	49/M	Empa 10mg	Vascular disorders (	Artery dissection (	265	278	14	Sev	No	Disc	Yes	Rcver	No	Req hsp
Comment: IT IS CONSIDERED THAT THE EVENT IS BASED ON A PATIENT BACKGROUND, SO THERE IS NO CAUSAL RELATIONSHIP BETWEEN THE EVENT AND THE STUDY MEDICATION.															
1245_005 2_259014	Asian	60/F	Post trt	Renal and urinary disorders (	Diabetic nephropathy (	281	4047	1247	Sev	No	Disc	Yes	Nrec&	No	Req hsp
Comment: IT DEPENDS ON AGGRAVATION OF NATURAL, PASSING.															

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Episodes with a negative start day are not assigned to the analysing treatment.
MedDRA version used for reporting: [REDACTED]

Listing 6.2.1 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Empa 10mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_005 2_261003	Asian	40/M	Empa 10mg	Infections and infestations (	Urinary tract infection (	6	18	13	Sev	Yes	Disc	Yes	Rcver	No	Req hsp
Comment: SGLT-2 INHIBITOR IS EXCRETIONING GLUCOSE TO URINE.SO THE SUBJECT GOT INFECTION EASILY OF URINARY.4/SEP/2013 URINE CULTURE WAS POSITIVE															
1245_005 2_261007	Asian	80/M	Empa 10mg	Cardiac disorders (	Arteriosclerosis coronary artery (冠動脈硬化症)	232	252	21	Mild	No	None	No	Rcver	No	Req hsp
Comment: I CONFIRMED THAT HE DID NOT HAVE ANGINA. HIGH CALCIFICATION SCORE OF CORONARY IS NOT CLINICALLY SIGNIFICANT. THEREFORE,THE EVENT WAS NOT RELATED TO THE STUDY DRUG.															
	Asian		Empa 10mg	Neoplasms benign, malignant and unspecified (incl cysts and polyps) (	Prostate cancer (前立腺癌)	309	567	259	Mild	No	None	No	Nrec&	No	Other
Comment: ON THE BASIS OF REPORTS RULING OUT GENOTOXICITY OF THE STUDY DRUG AND EXCLUDING OF CARCINOGENICITY RESULTS IN RATS AND MICE TO HUMANS,TAKEN TOGETHER THAT THE SUBJECTS ARE OLDER AGE.															
1245_005 2_262009	Asian	55/F	Empa 10mg	Renal and urinary disorders (	Bladder prolapse (膀胱脱)	187	270	84	Mod	No	None	Yes	Rcver	No	Req hsp
Comment: NATURAL COUSE															

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 Episodes with a negative start day are not assigned to the analysing treatment.
 MedDRA version used for reporting: 25.1

Listing 6.2.1 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Empa 10mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_005 2_263013	Asian	55/F	Empa 10mg	Neoplasms benign, malignant and unspecified (incl cysts and polyps) (	Benign ovarian tumour (	135	176	42	Mod	No	None	Yes	Rcver	No	Req hsp
				良性、悪性および 詳細不明の新生物 (嚢胞およびポリ ーブを含む))	卵巣良性腫瘍)										
Comment: I THINK THIS PATIENT HAS HAVE THE OVARIAN CYSTOMA BEFORE STARTING THIS STUDY.															
1245_005 2_263020	Asian	82/M	Empa 10mg	Infections and infestations (	Pneumonia (	100	113	14	Mod	No	None	Yes	Rcver	No	Req hsp
				感染症および寄生 虫症)	肺炎)										
Comment: THE TEST FOR INFLUENZA A VIRUS WAS POSITIVE. THIS EVENT IS THE SEASONAL INFECTION.															
	Asian		Empa 10mg	Infections and infestations (	Pneumonia (	300	358	59	Mod	No	None	Yes	Rcver	No	Req hsp
				感染症および寄生 虫症)	肺炎)										
Comment: I CONCLUDED THAT THIS EVENT WAS THE SEASONAL INFECTION.															
	Asian		Empa 10mg	Neoplasms benign, malignant and unspecified (incl cysts and polyps) (	Lung neoplasm malignant (	304	3657	627	Mild	No	None	No	Nrec&	No	Other
				良性、悪性および 詳細不明の新生物 (嚢胞およびポリ ーブを含む))	肺の悪性新生物)										
Comment: LUNG CANCER.HE WAS A HEAVY SMOKER. SMOKING IS RESPONSIBLE FOR THE CASE OF LUNG CANCER AND THE LUNG CANCER IS NOT RELATED TO TEMPORAL RELATIONSHIP															

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Episodes with a negative start day are not assigned to the analysing treatment.

MedDRA version used for reporting: ■■■■

Listing 6.2.1 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Empa 10mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_005 2_264001	Asian	72/M	Empa 10mg	Reproductive system and breast disorders (生殖系および乳房 障害)	Benign prostatic hyperplasia (良性前立腺肥大症)	114	3787	2657	Mild	No	None	Yes	Nrec&	No	Req hsp
Comment: AT PRESENT THERE IS NO BASIS TO JUDGE THAT PROSTATIC HYPERTROPHY IS RELATED TO THE STUDY DRUG.															
1245_005 2_266004	Asian	58/F	Empa 10mg	Cardiac disorders (心臓障害)	Prinzmetal angina (ブリンツメタル狭 心症)	237	5617	3257	Mod	No	None	Yes	Nrec&	No	Req hsp
Comment: UPON REVIEWING THE TREATMENT COURSE SO FAR AND INFORMATION FROM ANOTHER HOSPITAL, I DETERMINE THAT A CAUSAL RELATIONSHIP BETWEEN THE EVENT AND THE STUDY DRUG COULD BE RULED OUT BECAUSE THERE ARE NO															
	Asian		Empa 10mg	Cardiac disorders (心臓障害)	Congestive cardiomyopathy (うっ血性心筋症)	237	5617	3257	Mod	No	None	Yes	Nrec&	No	Req hsp
Comment: FROM NORMAL CORONARY ARTERIAL FINDINGS, I THINK SUSPECTED DILATED CARDIOMYOPATHY IS UNLIKELY TO BE DUE TO ISCHAEMIA. DIABETES MELLITUS AND VIRAL INFECTION ARE POSSIBLE ETIOLOGIES, ALTHOUGH ARE NOT COMMON															
1245_005 2_266008	Asian	75/F	Empa 10mg	Respiratory, thoracic and mediastinal disorders (呼吸器、胸郭およ び縦隔障害)	Sleep apnoea syndrome (睡眠時無呼吸症候 群)	181	3917	2117	Mod	No	None	Yes	Nrec&	No	Req hsp
Comment: THE EVENT WAS ASSESSED AS UNRELATED TO THE STUDY DRUG BECAUSE THERE WAS NO EVIDENCE TO INDICATE THEIR CAUSAL RELATIONSHIP. THE PATIENT'S CONDITION IS STABLE AT PRESENT AND THERE IS NO PROBLEM WITH															

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Episodes with a negative start day are not assigned to the analysing treatment.

MedDRA version used for reporting: [REDACTED]

Listing 6.2.1 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Empa 10mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_005 2_266009	Asian	65/F	Empa 10mg	Musculoskeletal and connective tissue disorders	Lumbar spinal stenosis (腰部脊柱管狭窄症 (筋骨格系および結 合組織障害)	84	2327	1497	Sev	No	None	Yes	Nrec&	No	Req hsp
Comment: ALTHOUGH THE EVENT OCCURRED FOLLOWING EXERCISE DURING THE COURSE OF THE TRIAL, THERE WAS NO EVIDENCE TO INDICATE A CAUSAL RELATIONSHIP BETWEEN THE EVENT AND THE STUDY DRUG.															
1245_005 2_268002	Asian	59/M	Empa 10mg	Musculoskeletal and connective tissue disorders	Rotator cuff syndrome (肩回旋筋腱板症候 群) (筋骨格系および結 合組織障害)	58	3727	3157	Mild	No	None	Yes	Nrec&	No	Req hsp
Comment: DUE TO FALLING															
1245_005 2_268006	Asian	63/M	Empa 10mg	Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion (椎間板突出) (筋骨格系および結 合組織障害)	171	4057	2357	Mod	No	None	Yes	Nrec&	No	Req hsp
Comment: DUE TO AGING															
1245_005 2_271002	Asian	71/F	Empa 10mg	Musculoskeletal and connective tissue disorders	Lumbar spinal stenosis (腰部脊柱管狭窄症 (筋骨格系および結 合組織障害)	238	4227	1857	Mod	No	None	Yes	Nrec&	No	Req hsp
Comment: DUE TO FATIGUE WITH THE MOVING.															
1245_005 2_281002	Asian	72/M	Empa 10mg	Hepatobiliary disorders (肝胆道系障害)	Drug-induced liver injury (薬物性肝障害)	253	3267	747	Mod	Yes	Disc	No	Nrec&	No	Other
Comment: LABORATORY TEST LEVELS INCLUDING LIVER FUNCTION TESTS AND BILIARY SYSTEMS ENZYMES DECREASED AFTER DISCONTINUATION OF THE STUDY DRUG AND THEN AGAIN INCREASED. BACKGROUND,															

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MedDRA version used for reporting: [REDACTED]

Listing 6.2.1 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Empa 10mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_005 2_281004	Asian	70/M	Empa 10mg	Cardiac disorders (	Angina pectoris (狭心症)	328	4007	737	Mod	No	None	Yes	Nrec&	No	Req hsp/Other
Comment: THE CAUSES OF CORONARY ARTERY STENOSIS WERE DIABETES, HYPERLIPIDEMIA, HYPERTENSION, HYPERURICEMIA AND AGE. THERE IS NO RELATION BETWEEN CORONARY STENOSIS AND THIS REGIMAN.															

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 Episodes with a negative start day are not assigned to the analysing treatment.
 MedDRA version used for reporting: [REDACTED]

Listing 6.2.1 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Empa 25mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_005 2_201003	Asian	64/M	Empa 25mg	Gastrointestinal disorders (胃腸障害)	Anal fissure (裂肛)	282	392	111	Mod	No	None	Yes	Rcver	No	Req hsp
Comment: ON THE BASIS OF THE PATIENT'S STATEMENT THAT HE HAD REPEATED EPISODES OF ANAL PAIN EVEN BEFORE HIS PARTICIPATION IN THE CLINICAL STUDY, THE EVENT WAS ASSESSED AS UNRELATED TO THE STUDY DRUG.															
1245_005 2_201010	Asian	64/M	Empa 25mg	Eye disorders (眼障害)	Retinal detachment (網膜剥離)	83	336	254	Mod	No	None	Yes	Rcver	No	Req hsp
Comment: IT IS CONSIDERED TO BE AN AGE-RELATED FORTUITOUS EVENT AND HAVE NO CAUSAL RELATIONSHIP WITH THE STUDY DRUG.															
	Asian		Empa 25mg	Eye disorders (眼障害)	Cataract (白内障)	98	336	239	Mild	No	None	Yes	Rcver	No	Req hsp
Comment: IT IS CONSIDERED TO BE AN AGE-RELATED FORTUITOUS EVENT AND HAVE NO CAUSAL RELATIONSHIP WITH THE STUDY DRUG.															
1245_005 2_203008	Asian	42/F	Empa 25mg	Infections and infestations (感染症および寄生虫)	Pyelonephritis (腎盂腎炎)	284	340	57	Mod	No	None	Yes	Rcver	No	Req hsp
Comment: ON THE BASIS OF THE PATIENT'S PAST HISTORY OF UROLITHIASIS, THE EVENT (PYELONEPHRITIS) IS CONSIDERED TO BE FORTUITOUS AND A CAUSAL RELATIONSHIP BETWEEN THE EVENT AND THE STUDY DRUG CAN BE RULED OUT.															
	Asian		Empa 25mg	Renal and urinary disorders (腎および尿路障害)	Nephrolithiasis (腎結石症)	284	340	57	Mod	No	None	Yes	Rcver	No	Req hsp
Comment: ON THE BASIS OF THE PATIENT'S PAST HISTORY OF UROLITHIASIS, THE EVENT (PYELONEPHRITIS) IS CONSIDERED TO BE FORTUITOUS AND A CAUSAL RELATIONSHIP BETWEEN THE EVENT AND THE STUDY DRUG CAN BE RULED OUT.															
1245_005 2_206040	Asian	65/M	Empa 25mg	Gastrointestinal disorders (胃腸障害)	Colitis ischaemic (虚血性大腸炎)	65	73	9	Mod	No	None	Yes	Rcver	No	Req hsp
Comment: ALTHOUGH THE EVENT OCCURRED DURING STUDY DRUG ADMINISTRATION, THE EVENT WAS ASSESSED AS UNRELATED TO THE STUDY DRUG BECAUSE REAPPEARANCE IS NOT SEEN EVEN AFTER THE STUDY DRUG RESUMPTION AND ISCHAEMIC															

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Episodes with a negative start day are not assigned to the analysing treatment.

MedDRA version used for reporting: [REDACTED]

Listing 6.2.1 Adverse event episodes by treatment and patient - serious event only- treated set

Treatment analysis: 1st rec., 7 day W0, active only

Treatment: Empa 25mg

Patient	Race	Age/ Gender	Actual TRT at onset of AE	System organ clas	Preferred term	Start day@	Stop day@	Dura- tion	Inten- sity	Drug rel.	Action taken	Therapy required	Outcome	Other signi- ficant	Serious
1245_005 2_210032	Asian	63/F	Empa 25mg	Injury, poisoning and procedural complications (	Ankle fracture (	148	203	56	Sev	No	None	Yes	Rcver	No	Req hsp
足関節部骨折) 傷害、中毒および 処置合併症) Comment: FOR THE LEG RODE ON THE STONE,SHE FELL AND SUFFERED A FRACTURE BY CARELESSNESS.TRAUMATIC.THERE IS NO CAUSAL RELATIONSHIP.															
1245_005 2_213006	Asian	65/M	Empa 25mg	Nervous system disorders (	Transient ischaemic attack	293	317	25	Mild	No	None	No	Rcver	No	Other
神経系障害) (一過性脳虚血発作) Comment: ACCOMPANYING SYMPTOM:DIIZZINESS,THE RIGHT-SIDED SLIGHT PARALYSIS. IT WAS STUDY DRUG CONTINUATION,BUT THE SYMPTOM DISAPPEARED. IT IS THOUGHT THAT IT ORIGINATED IN THESE AND THIS EVENT FROM HYPERTENSION,															
1245_005 2_214020	Asian	70/M	Empa 25mg	Neoplasms benign, malignant and unspecified (incl cysts and polyps) (	Prostate cancer (前立腺癌)	141	3667	2267	Mild	No	None	Yes	Nrec&	No	Other
良性、悪性および 詳細不明の新生物 (嚢胞およびポリ ーブを含む)) Comment: IT SEEMS NO RELATION BETWEEN THE EVENT AND THE STUDY MEDICATION, BECAUSE OF AGING AND ANY ACCIDENTAL OCCURE.															
1245_005 2_216035	Asian	62/F	Empa 25mg	Eye disorders (	Glaucoma (	251	314	64	Mod	No	None	Yes	Rcver	No	Req hsp
眼障害) 緑内障) Comment: DUE TO LONG AFFECTION PERIOD OF DIABETES															

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 Episodes with a negative start day are not assigned to the analysing treatment.
 MedDRA version used for reporting: █