Electronic supplementary material

ESM Table 1 Treatment emergent adverse events probably or possibly related to trial product by system organ class, ITT cohort

	Detemir			Glargine		
	n	(%)	E	*n*	(%)	E
ITT analysis set	291			291		
Adverse event	40	(13.7)	56	32	(11.0)	53
Application site disorders	13	(4.5)	13	4	(1.4)	5
Injection site haematoma	1	(0.3)	1	2	(0.7)	2
Injection site inflammation	3	(1.0)	3	0	(0.0)	0
Injection site pain	0	(0.0)	0	2	(0.7)	2
Injection site reaction	9	(3.1)	9	1	(0.3)	1
Body as a whole – general disorders	8	(2.7)	9	7	(2.4)	9
Abdomen enlarged	0	(0.0)	0	1	(0.3)	1
Allergic reaction	0	(0.0)	0	1	(0.3)	1
Allergy	3	(1.0)	3	0	(0.0)	0
Asthenia	1	(0.3)	1	1	(0.3)	2
Fatigue	3	(1.0)	3	2	(0.7)	2
Oedema peripheral	2	(0.7)	2	3	(1.0)	3
Central and peripheral nervous system disorders	7	(2.4)	10	11	(3.8)	22
Convulsions	1	(0.3)	1	0	(0.0)	0
Dizziness	1	(0.3)	1	3	(1.0)	4
Gait abnormal	0	(0.0)	0	1	(0.3)	1
Headache	5	(1.7)	7	5	(1.7)	13
Hypoaesthesia	1	(0.3)	1	0	(0.0)	0
Neuralgia	0	(0.0)	0	1	(0.3)	1
Tremor	0	(0.0)	0	1	(0.3)	2
Visual field defect	0	(0.0)	0	1	(0.3)	1
Metabolic and nutritional disorders	6	(2.1)	7	6	(2.1)	6
Hyperglycaemia	0	(0.0)	0	1	(0.3)	1
Hypoglycaemia	2	(0.7)	2	3	(1.0)	3
Hypokalaemia	1	(0.3)	1	0	(0.0)	0
Lipodystrophy	2	(0.7)	2	1	(0.3)	1
Obesity	1	(0.3)	1	0	(0.0)	0
Weight increase	1	(0.3)	1	1	(0.3)	1
Skin and appendages disorders	6	(2.1)	6	1	(0.3)	1
Pruritus	3	(1.0)	3	1	(0.3)	1
Rash	1	(0.3)	1	0	(0.0)	0
Rash erythematous	1	(0.3)	1	0	(0.0)	0
Sweating increased	1	(0.3)	1	0	(0.0)	0
Vision disorders	4	(1.4)	5	2	(0.7)	2
Diplopia	0	(0.0)	0	1	(0.3)	1
Retinal disorder	2	(0.7)	2	0	(0.0)	0
Retinal oedema	1	(0.3)	1	0	(0.0)	0
Vision abnormal	2	(0.7)	2	1	(0.3)	1
Psychiatric disorders	2	(0.7)	2	1	(0.3)	1
Anorexia	1	(0.3)	1	0	(0.0)	0

Appetite increased	1 (0.3) 1	0 (0.0) 0
Somnolence	0 (0.0) 0	1 (0.3) 1
Cardiovascular disorders, general	1 (0.3) 1	0 (0.0) 0
Circulatory failure	1 (0.3) 1	0 (0.0) 0
Endocrine disorders	1 (0.3) 1	0 (0.0) 0
Hyperthyroidism	1 (0.3) 1	0 (0.0) 0
Musculo-skeletal system disorders	1 (0.3) 1	2 (0.7) 2
Arthralgia	1 (0.3) 1	0 (0.0) 0
Arthritis	0 (0.0) 0	1 (0.3) 1
Myalgia	0 (0.0) 0	1 (0.3) 1
Secondary terms	1 (0.3) 1	0 (0.0) 0
Injury accidental	1 (0.3) 1	0 (0.0) 0
Gastrointestinal system disorders	0 (0.0) 0	2 (0.7) 2
Abdominal pain	0 (0.0) 0	1 (0.3) 1
Nausea	0 (0.0) 0	1 (0.3) 1
Myo- endo- pericardial and valve disorders	0 (0.0) 0	1 (0.3) 1
Angina pectoris	0 (0.0) 0	1 (0.3) 1
Respiratory system disorders	0 (0.0) 0	1 (0.3) 1
Coughing	0 (0.0) 0	1 (0.3) 1
Vascular (extracardiac) disorders	0 (0.0) 0	1 (0.3) 1
Vein disorder	0 (0.0) 0	1 (0.3) 1

ITT analysis set consists of all subjects exposed to trial product
E, number of adverse events; *n*, number of subjects with adverse event; %, proportion of subjects in analysis set who experienced adverse event