

ESM Table 3 Treatment emergent serious adverse events by system organ class, ITT cohort

	Detemir		Glargine	
	<i>n</i>	(%) E	<i>n</i>	(%) E
ITT analysis set	291		291	
Adverse event	42 (14.4)	47	53 (18.2)	73
Myo- endo- pericardial and valve disorders	6 (2.1)	6	7 (2.4)	7
Angina pectoris aggravated	1 (0.3)	1	1 (0.3)	1
Coronary artery disorder	2 (0.7)	2	6 (2.1)	6
Myocardial infarction	3 (1.0)	3	0 (0.0)	0
Body as a whole – general disorders	5 (1.7)	5	8 (2.7)	10
Allergic reaction	0 (0.0)	0	1 (0.3)	1
Back pain	0 (0.0)	0	2 (0.7)	2
Chest pain	2 (0.7)	2	4 (1.4)	6
Malaise	1 (0.3)	1	0 (0.0)	0
Nasal polyp	1 (0.3)	1	0 (0.0)	0
Syncope	1 (0.3)	1	1 (0.3)	1
Neoplasm	5 (1.7)	5	5 (1.7)	5
Adenocarcinoma nos	0 (0.0)	0	1 (0.3)	1
Bladder carcinoma	1 (0.3)	1	0 (0.0)	0
Breast neoplasm malignant female	1 (0.3)	1	1 (0.3)	1
Carcinoma	3 (1.0)	3	0 (0.0)	0
Colon carcinoma	0 (0.0)	0	1 (0.3)	1
Neoplasm nos	0 (0.0)	0	1 (0.3)	1
Ovarian cyst	0 (0.0)	0	1 (0.3)	1
Gastrointestinal system disorders	4 (1.4)	4	2 (0.7)	2
Abdominal pain	1 (0.3)	1	0 (0.0)	0
Duodenal ulcer	1 (0.3)	1	0 (0.0)	0
Gastritis	1 (0.3)	1	0 (0.0)	0
Gastrointestinal haemorrhage	0 (0.0)	0	1 (0.3)	1
Haemorrhage rectum	0 (0.0)	0	1 (0.3)	1
Pancreatitis	1 (0.3)	1	0 (0.0)	0
Central and peripheral nervous system disorders	3 (1.0)	3	0 (0.0)	0
Dizziness	1 (0.3)	1	0 (0.0)	0
Headache	1 (0.3)	1	0 (0.0)	0
Vertigo	1 (0.3)	1	0 (0.0)	0
Respiratory system disorders	3 (1.0)	3	4 (1.4)	4
Bronchitis	1 (0.3)	1	0 (0.0)	0
Dyspnoea	0 (0.0)	0	1 (0.3)	1
Pneumonia	2 (0.7)	2	1 (0.3)	1
Pulmonary fibrosis	0 (0.0)	0	1 (0.3)	1
Pulmonary infiltration	0 (0.0)	0	1 (0.3)	1
Secondary terms	3 (1.0)	3	3 (1.0)	3
Injury accidental	2 (0.7)	2	3 (1.0)	3
Other events	1 (0.3)	1	0 (0.0)	0
Vascular (extracardiac) disorders	3 (1.0)	3	7 (2.4)	7
Cerebrovascular disorder	1 (0.3)	1	5 (1.7)	5
Peripheral ischaemia	1 (0.3)	1	2 (0.7)	2
Vein varicose	1 (0.3)	1	0 (0.0)	0

Metabolic and nutritional disorders	2 (0.7)	2	4 (1.4)	4
Hyperglycaemia	0 (0.0)	0	1 (0.3)	1
Hypoglycaemia	2 (0.7)	2	3 (1.0)	3
Musculo-skeletal system disorders	2 (0.7)	2	10 (3.4)	10
Arthropathy	0 (0.0)	0	1 (0.3)	1
Arthrosis	1 (0.3)	1	2 (0.7)	2
Bone disorder	0 (0.0)	0	1 (0.3)	1
Dupuytren's contracture	0 (0.0)	0	1 (0.3)	1
Fracture bone	1 (0.3)	1	1 (0.3)	1
Fracture pathological	0 (0.0)	0	2 (0.7)	2
Polymyalgia rheumatica	0 (0.0)	0	1 (0.3)	1
Rhabdomyolysis	0 (0.0)	0	1 (0.3)	1
Urinary system disorders	2 (0.7)	2	2 (0.7)	3
Cystitis	0 (0.0)	0	1 (0.3)	1
Haematuria	0 (0.0)	0	1 (0.3)	1
Renal cyst	1 (0.3)	1	0 (0.0)	0
Renal pain	0 (0.0)	0	1 (0.3)	1
Urinary tract infection	1 (0.3)	1	0 (0.0)	0
Vision disorders	2 (0.7)	2	1 (0.3)	1
Cataract	0 (0.0)	0	1 (0.3)	1
Macula luteal degeneration	1 (0.3)	1	0 (0.0)	0
Retinitis	1 (0.3)	1	0 (0.0)	0
Application site disorders	1 (0.3)	1	1 (0.3)	2
Cellulitis	0 (0.0)	0	1 (0.3)	1
Injection site reaction	1 (0.3)	1	0 (0.0)	0
Skin necrosis	0 (0.0)	0	1 (0.3)	1
Cardiovascular disorders, general	1 (0.3)	1	5 (1.7)	5
Aneurysm	0 (0.0)	0	1 (0.3)	1
Cardiac failure	0 (0.0)	0	2 (0.7)	2
Hypertension	1 (0.3)	1	0 (0.0)	0
Hypertension aggravated	0 (0.0)	0	1 (0.3)	1
Hypotension	0 (0.0)	0	1 (0.3)	1
Endocrine disorders	1 (0.3)	1	0 (0.0)	0
Hyperthyroidism	1 (0.3)	1	0 (0.0)	0
Platelet, bleeding and clotting disorders	1 (0.3)	2	1 (0.3)	1
Embolism pulmonary	0 (0.0)	0	1 (0.3)	1
Thrombosis	1 (0.3)	2	0 (0.0)	0
Resistance mechanism disorders	1 (0.3)	1	2 (0.7)	2
Abscess	0 (0.0)	0	1 (0.3)	1
Infection bacterial	1 (0.3)	1	0 (0.0)	0
Infection wound	0 (0.0)	0	1 (0.3)	1
Skin and appendages disorders	1 (0.3)	1	0 (0.0)	0
Hyperkeratosis	1 (0.3)	1	0 (0.0)	0
Liver and biliary system disorders	0 (0.0)	0	3 (1.0)	3
Cholelithiasis	0 (0.0)	0	3 (1.0)	3
Psychiatric disorders	0 (0.0)	0	1 (0.3)	1
Depression	0 (0.0)	0	1 (0.3)	1
Erythrocyte disorders	0 (0.0)	0	2 (0.7)	2
Anaemia	0 (0.0)	0	2 (0.7)	2
Reproductive disorders, male	0 (0.0)	0	1 (0.3)	1

Hernia inguinal

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; nos, not otherwise specified; %, proportion of subjects in analysis set who experienced adverse event