

Supplementary Table 2: Line listing of severe adverse events

System Order Class (SOC)	Preferred Term (PT)	Number
Cardiac disorders	Acute coronary syndrome	1
	Cardiac arrest	1
Gastrointestinal disorders	Abdominal pain	1
	Duodenal ulcer	1
	Gastrointestinal haemorrhage	1
	Intestinal perforation	1
Immune system disorders	Vasculitis	3
Infections and infestations	Gastroenteritis Escherichia coli	1
	Pneumonia/respiratory tract infection	9
	Urinary tract infection	3
Injury, poisoning, procedural complications / investigations	Wound dehiscence	1
Complications / investigations	Medical observation	1
Malignancy	B-cell lymphoma	1
Nervous system disorders	Cerebrovascular accident	1
Renal and urinary disorders	Enterovesical fistula	1
	Renal impairment	1
Respiratory, thoracic and mediastinal disorders	Laryngeal stenosis	3
Surgical and medical procedures	Small intestinal resection	1
Vascular disorders	Aortic dissection	1
	Deep vein thrombosis	5
	Pulmonary embolism	3