

Supplementary Table S2. Serious adverse events (SAEs) regardless of attribution in the safety population

SAE, <i>n</i> (%)	All patients (<i>N</i> = 60)
Total number of patients with at least one SAE	19 (31.7)
Total number of SAEs	35
Colitis	6 (10.0)
Pneumonia	3 (5.0)
Anemia	1 (1.7)
Back pain	1 (1.7)
<i>Clostridium difficile</i> colitis	1 (1.7)
Device related infection	1 (1.7)
Diarrhea	1 (1.7)
Enterocolitis	1 (1.7)
Fall	1 (1.7)
Gastrointestinal necrosis	1 (1.7)
Gastrointestinal vascular malformation	1 (1.7)
Hyperglycemia	1 (1.7)
Hypertension	1 (1.7)
Hyponatremia	1 (1.7)
Neutropenia	1 (1.7)
Peptic ulcer perforation	1 (1.7)
Pericardial effusion	1 (1.7)
Pleural effusion	1 (1.7)
Pulmonary embolism	1 (1.7)
Rash	1 (1.7)
Sepsis	1 (1.7)
Supraventricular tachycardia	1 (1.7)
Tooth abscess	1 (1.7)
Ureteral stent insertion	1 (1.7)

All SAE categories are preferred terms, encoded using MedDRA version 20.0. For frequency counts by preferred term, multiple occurrences of the same AE in an individual are counted once. For the total number of events, multiple occurrences of the same AE in an individual were counted separately.

MedDRA, Medical Dictionary for Regulatory Activities.