Supplemental Digital Content 5. Treatment-emergent adverse events related to teduglutide by system organ class and preferred term based on safety populations

Category	Infants n (m)		Children* n (m)	
	Core study† (n = 7)	Extension study (N = 2)	Core study (N = 8)	Extension study‡ (n = 7)
Any TEAE related to teduglutide	2 (9)	-	6 (20)	2 (2)
Gastrointestinal disorders	**1 (7)**	**-**	**3 (4)**	**1 (1)**
Abdominal distension	1 (1)	-	-	-
Abdominal pain	-	-	2 (2)	-
Constipation	-	-	1 (1)	-
Gastritis	-	-	1 (1)	-
Gastric disorder		-	-	1 (1)
Gastrointestinal sounds abnormal	1 (1)	-	-	-
Vomiting	1 (5)	-	-	-
Investigations	**2 (2)**	**-**	**-**	**-**
Alanine aminotransferase increased	1 (1)	-	-	-

Fecal volume increased	1 (1)	-	-	-
General disorders and administration site conditions	**-**	**-**	**4 (15)**	**1 (1)**
Injection site erythema	-	-	3 (9)	-
Injection site rash	-	-	1 (4)	-
Injection site reaction	-	-	1 (1)	-
Injection site pain	-	-	1 (1)	1 (1)

*For study NCT02980666 and its extension NCT03268811, six of eight children were enrolled and received teduglutide treatment after protocol amendment, which included improved training for parents to administer doses of teduglutide to patients.

†Data pooled from studies NCT03571516 (n = 5; patients randomized to receive teduglutide treatment compared with SoC group) and NCT02980666 (N = 2; patients only received teduglutide).

‡Of the children enrolled in the extension study, one child did not receive teduglutide owing to ongoing enteral autonomy from the core study.

m = number of events; n = number of patients experiencing the event; SoC = standard of care; TEAE = treatment-emergent adverse event.