Supplemental Digital Content 6. Treatment-emergent serious adverse events by system organ class and preferred term based on safety populations

Category	Infants n (m)			Children* n (m)	
	Core study		Extension study	Core study	Extension study‡
	SoC (n = 5)	Teduglutide† (n = 7)	(N = 2)	(N = 8)	(N = 7)
Any TESAE	**3 (6)**	**6 (14)**	**2 (4)**	**6 (15)**	**6 (18)**
Gastrointestinal disorders	**-**	**-**	**1 (1)**	**3 (3)**	**3 (4)**
Abdominal pain	-	-	-	1 (1)	-
Colonic hematoma	-	-	-	-	1 (1)
Enteritis	-	-	-	-	1 (1)
Enterocolitis	-	-	-	2 (2)	1 (2)
Pancreatitis acute	-	-	1 (1)	-	-
General disorders and administration site conditions	**-**	**3 (6)**	**-**	**2 (4)**	**1 (1)**

Pyrexia	-	3 (6)	-	2 (4)	1 (1)
Immune system disorder	**-**	**1 (1)**	**-**	**1 (1)**	**-**
Anaphylactic reaction	-	-	-	1 (1)	-
Immunization reaction	-	1 (1)	-	-	-
Infections and infestations	**2 (2)**	**2 (4)**	**1 (2)**	**5 (10)**	**4 (6)**
Adenovirus infection	-	-	-	1 (1)	-
Beta hemolytic streptococcal infection	-	-	-	-	1 (1)
Device-related infection	2 (2)	1 (2)	-	3 (4)	2 (3)
Gastroenteritis	-	-	-	1 (1)	-
Gastroenteritis adenovirus	-	-	-	-	1 (1)
Hand-foot-and-mouth disease	-	-	-	1 (1)	-
Medical device site infection	-	-	-	2 (3)	1 (1)
Upper respiratory tract infection	-	1 (2)	1 (1)	-	-
Viral pharyngitis	-	-	-	-	1 (1)
Investigations	**1 (1)**	**-**	**-**	**-**	**-**
Transaminases increased	1 (1)	-	-	-	-

Metabolism and nutrition disorder	**1 (1)**	**-**	**-**	**-**	**-**
Metabolic acidosis	1 (1)	-	1 (1)	-	-
Nervous system disorders	**1 (1)**	**-**	**-**	**-**	**-**
Ataxia	1 (1)	-	-	-	-
Seizure	-	-	1 (1)	-	-
Product issues	**1 (1)**	**2 (2)**	**-**	**1 (1)**	**4 (6)**
Device breakage	-	1 (1)	-	-	3 (5)
Device leakage	-	1 (1)	-	-	-
Device damage	-	-	-	1 (1)	-
Device occlusion	1 (1)	-	-	-	-
Respiratory, thoracic, and mediastinal disorders	**-**	**1 (1)**	**-**	**-**	**-**
Upper respiratory tract inflammation	-	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; TESAE = treatment-emergent serious adverse event.