TABLE 2.1: AE Overview Table

ANALYSIS SET: Safety

	TOTAL Extract: 12JAN2023 (N=104) n (%)	m
Overall	74	-
>=1 TEAE	0	0
>=1 Serious TEAE	0	0
>=1 TEAE of CTCAE severity grade 3 or higher	0	0
>=1 TEAE of special interest	0	0
>=1 IRR event	0	0
>=1 Malignancy	0	0
>=1 Fatal TEAE	0	0
>=1 Treatment-related TEAE according to PI	0	0
>=1 Procedure-related TEAE	0	0
>=1 Serious treatment-related TEAE	0	0
>=1 TEAE for which the study drug was discontinued	0	0

DEFINITIONS:
Relation to Study Procedure: Causality of ITEM01, derived from SUPPAE.QVAL(where=(QNAM= 'AERELPRC')
Number of Days from Treatment Dose to AE start: if AESTDTC contains a full date then AERELDY = ASTDT-DOSEDT+1
Analysis relative time: if AESTDTC contains a full date time then AERELTM is the time between AESTDTC and DOSEDTM
Analysis Start Date: AE.AESTDTC converted to SAS date and imputed when incomplete = first day of the incomplete date except when: - a same treatment taken during the 'uncertainty period' then = date of first treatment - else if switch of treatments during the 'uncertainty period' then = first day of switched treatment
Analysis Start Datetime: AE.AESTDTC converted to SAS datetime and imputed when incomplete
Name of Treatment at AE start: EXTRT = EXTRT before AESTDTC
Treatment Emergent Analysis Flag: AEs starting on or after first administration of any study drug.
n = number of patients with event, m = number of events, TEAE = treatment-emergent adverse event
IRR: Preferred Term in Meddra SMQ (Version: any, broad scope): 'Hypersensitivity (SMQ)', 'Anaphylactic reaction (SMQ)', 'Extravasation events (injections, infusions and implants) (SMQ)', excluding implants, with onset within 48h (or 2 days if time not available) of an infusion or injection.
Malignancy: Preferred Term in Meddra SMQ (Version: any, narrow scope): 'Malignancies (SMQ)'.

Source: AE domain, Study(ies) (last updated): ARGX-113-1902 (2023-01-09). Program: taeov.sas, Version: -