

MDA10-16-01 - ADVERSE EVENTS - 3.1: DATA DICTIONARY

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Document Summary

Property	Value
Document Title	MDA10-16-01 - Adverse Events - 3.1: Data Dictionary
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MDA10-16-01 - Adverse Events - 3.1: Data Dictionary

Section 1: Identifiers

Variable	Label	Description	Format Text
build_dt	Build Date	Build Date	SAS Date
MRNO	Participant ID (MRNO)	Participant ID (MRNO)	Char

Section 2: Event Details

Variable	Label	Description	Format Text
ae_action	Change (If Any) in Agent Dose Due to Adverse Event	Change (if any) in Agent Dose due to Adverse Event	.M="Missing" 1="Agent Withdrawn" 4="Agent Dose Not Changed" 5="Unknown" 7="Agent Interrupted"
ae_attribution	Likelihood Adverse Event Was Caused by Study Agent	Likelihood Adverse Event was Caused by Study Agent	1="Unrelated" 2="Unlikely" 3="Possible" 4="Probable" 5="Definite"
ae_ctcae_term	CTCAE Term v4.0	CTCAE Term v4.0	Char
ae_dropped	Dropped Due to This Adverse Event?	Dropped due to this Adverse Event?	0="No" 1="Yes"
ae_end_dt	End Date of Adverse Event	End Date of Adverse Event	SAS Date .M="Missing"
ae_event	Adverse Event as Described Verbatim	Adverse Event as Described Verbatim	Char
ae_grade	Severity of Adverse Event	Severity of Adverse Event	1="Mild" 2="Moderate" 3="Severe"
ae_meddra_v12	MedDRA v12.0 Code	MedDRA v12.0 Code	Numeric
ae_onset_dt	Onset Date of Adverse Event	Onset Date of Adverse Event	SAS Date .M="Missing"
ae_outcome	Outcome of Adverse Event	Outcome of Adverse Event	1="Recovered/Resolved" 2="Recovering/Resolving" 3="Not Recovered/Not Resolved" 4="Recovered/Resolved with Sequelae" 6="Unknown"
ae_sae	Serious Adverse Event?	Serious Adverse Event?	0="No"
ae_tox_group	Toxicity Group	Toxicity Group	1="Blood and Lymphatic System Disorders" 2="Cardiac Disorders" 4="Ear and Labyrinth Disorders" 7="Gastrointestinal Disorders" 8="General Disorders and Administration Site Conditions" 11="Infections and Infestations" 12="Injury, Poisoning and Procedural Complications" 13="Investigations" 14="Metabolism and Nutrition Disorders" 15="Musculoskeletal and Connective Tissue Disorders" 17="Nervous System Disorders" 21="Reproductive System and Breast Disorders" 22="Respiratory, Thoracic and Mediastinal Disorders" 23="Skin and Subcutaneous Tissue Disorders" 26="Vascular Disorders"