

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

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Document Summary

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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Any) in Agent Dose Due to Adverse Event | Change (if any) in Agent Dose due to Adverse Event | .M="Missing" 1="Agent Withdrawn" 4="Agent Dose Not Changed" 5="Unknown" 7="Agent Interrupted" |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" |