MDA-2013-01-01 ADVERSE EVENTS

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Document Summary

Property	Value
Document Title	MDA-2013-01-01 Adverse Events
Date Created	09/18/2019
For Dataset	adverse_events
Sections	2
Entries	16
Document Filename	dictionary_MDA-2013-01-01AdverseEvents.08192019.rtf

MDA-2013-01-01 Adverse Events

Section 1: Identifiers

Variable	Label	Description	Format Text
mrno	Subject ID	Subject ID	Num

Section 2: Adverse Events

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Change (If Any) In Agent Dose Due To Adverse Event	Change (if any) in agent dose due to Adverse Event	1="Agent Withdrawn" 2="Agent Dose Reduced" 4="Agent Dose Not Changed" 6="Not Applicable" 7="Agent Interrupted"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"
ae_comments	Adverse Events Comments	Adverse Events comments	Char
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	0="No Event" 1="Mild Adverse Event" 2="Moderate Adverse Event" 3="Severe Adverse Event" 4="Life threatening Adverse Event" 5="Death Related to Adverse Event"
ae_grade_desc	Adverse Events Grade Description	Adverse Events grade description	Char
ae_meddra_v12	MedDRA v12.0 Code	MedDRA v12.0 code	Num
ae_onset_dt	Onset Date Of Adverse Event	Onset date of Adverse Event	SAS Date
ae_outcome	Outcome Of Adverse Event	Outcome of Adverse Event	.M="Missing" 1="Recovered/Resolved" 3="Not Recovered/Not Resolved" 4="Recovered/Resolved with Sequelae" 6="Unknown"
ae_report_dt	Reported Date Of Adverse Event	Reported date of Adverse Event	SAS Date .M="Missing"
ae_sae	Serious Adverse Event?	Serious Adverse Event?	0="No" 1="Yes"

Variable	Label	Description	Format Text
ae_tox_group	Toxicity Group	Toxicity group	1="Blood and Lymphatic System Disorders" 2="Cardiac Disorders" 4="Ear and Labryinth Disorders" 6="Eye 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" 16="Neoplasms Benign, Malignant, and Unspecified (Including Cysts and Polyps)" 17="Nervous System Disorders" 19="Psychiatric Disorders" 20="Renal and Urinary Disorders" 21="Reproductive System and Breast Disorders" 22="Respiratory, Thoracic and Mediastinal Disorders" 23="Skin and Subcutaneous Tissue Disorders" 25="Surgical and Medical Procedures" 26="Vascular Disorders"

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