

MDA2013-02-02 - Adverse Events Data Dictionary

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Document Summary

Property	Value
Document Title	MDA2013-02-02 - Adverse Events: Data Dictionary
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MDA2013-02-02 - Adverse Events: Data Dictionary

Section 1: Identifiers

Class	Variable	Label	Description	Format Text
01. Principal	mrno	Participant ID		Numeric

Section 2: Adverse Events

Class	Variable	Label	Description	Format Text
01. Principal	ae_action	Action		.M="Missing" .N="No Adverse Events Reported" 1="Agent Withdrawn" 2="Agent Dose Reduced" 3="Agent Dose Increased" 4="Agent Dose Not Changed" 5="Unknown" 6="Not Applicable" 7="Agent Interrupted"
01. Principal	ae_attribute	AE Attribution		.M="Missing" 1="Unrelated" 2="Unlikely" 3="Possible" 4="Probable" 5="Definite"
01. Principal	ae_comments	Comments		Char
01. Principal	ae_ctcae	CTCAE Term		Char
01. Principal	ae_ctcae_v4_0	CTCAE V4.0		Char
01. Principal	ae_dropped	Dropped Due To This AE		.M="Missing" .N="N/A" 0="No" 1="Yes"
01. Principal	ae_event_end_date	Event End Date		SAS Date .M="Missing" .U="Unknown"
01. Principal	ae_event_end_date_imputed	Event End Date Imputed		0="No" 1="Yes"
01. Principal	ae_grade	Grade		.M="Missing" 1="Mild" 2="Moderate" 3="Severe" 4="Life-Threatening" 5="Lethal"
01. Principal	ae_grade_description	Grade Description		Char
01. Principal	ae_interval	Interval		1="Event Interval Not Available" 2="Baseline 1" 3="Month 1" 4="Month 3"
01. Principal	ae_interval_date	Interval Date		SAS Date .M="Missing"
01. Principal	ae_meddra_v12	MedDRA Adverse Event Code (CTCAE V4.0)		Numeric .M="Missing" .N="No Adverse Events Reported" 99999999="No MedDRA Code Associated with CTCAE Term"

Class	Variable	Label	Description	Format Text
01. Principal	ae_onset_date	Event Onset Date		SAS Date .M="Missing" .U="Unknown"
01. Principal	ae_onset_date_imputed	Event Onset Date Imputed		0="No" 1="Yes"
01. Principal	ae_outcome	Outcome		.M="Missing" 1="Recovered/Resolved" 2="Recovering/Resolving" 3="Not recovering/Not Resolved" 4="Recovered/Resolved with sequelae" 5="Fatal" 6="Unknown"
01. Principal	ae_reported	Reported As Serious Adverse Events (SAE)		.M="Missing" .N="N/A" 0="No" 1="Yes"
01. Principal	ae_reported_date	Adverse Event Reported Date		SAS Date .M="Missing" .U="Unknown"
01. Principal	ae_system_organ	MedDRA System Organ Class (SOC) v12		.M="Missing" .N="No Adverse Events Reported" 1="Blood and Lymphatic System Disorders" 2="Cardiac Disorders" 3="Congenital, Familial and Genetic Disorders" 4="Ear and Labyrinth Disorders" 5="Endocrine Disorders" 6="Eye Disorders" 7="Gastrointestinal Disorders" 8="General Disorders and Administration Site Conditions" 9="Hepatobiliary Disorders" 10="Immune System Disorders" 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" 18="Pregnancy, Puerperium and Perinatal Conditions" 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" 24="Social Circumstances" 25="Surgical and Medical Procedures" 26="Vascular Disorders" 99="No Toxicity Group Associated With CTCAE Term"

Class	Variable	Label	Description	Format Text
01. Principal	ae_verbatim	Adverse Event Verbatim Term		Char