MDA2014-04-01 - Adverse Events Data Dictionary

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MDA2014-04-01 - Adverse Events: Data Dictionary

Section 1: Study-wide

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

Section 2: Adverse Events

Class	Variable	Label	Description	Format Text
01. Principal	**ae_action**	Action - [Adverse Events]		1="Agent Withdrawn" 4="Agent Dose Not Changed" 6="Not Applicable" 7="Agent Interrupted"
01. Principal	**ae_attribute**	AE Attribution - [Adverse Events]		1="Unrelated" 2="Unlikely" 3="Possible" 4="Probable" 5="Definite"
01. Principal	**ae_comments**	Comments - [Adverse Events]		Char
01. Principal	**ae_ctcae**	CTCAE Term - [Adverse Events]		Char
01. Principal	**ae_ctcae_v4_0**	CTCAE V4.0 - [Adverse Events]		1="4.0"
01. Principal	**ae_dropped**	Dropped Due To This AE - [Adverse Events]		0="No" 1="Yes"
01. Principal	**ae_event_end_date**	Event End Date - [Adverse Events]		SAS Date .M="Missing" 7="N/A" 8="Unknown"
01. Principal	**ae_event_end_date_imputed**	Event End Date Imputed - [Adverse Events]		0="No" 1="Yes"
01. Principal	**ae_grade**	Grade - [Adverse Events]		1="Mild Adverse Event" 2="Moderate Adverse Event" 3="Severe Adverse Event"
01. Principal	**ae_grade_description**	Grade Description - [Adverse Events]		Char
01. Principal	**ae_interval**	Interval - [Adverse Events]		1="Event Interval not available" 2="Baseline" 3="Month" 4="Month 1" 6="Follow-up 1"
01. Principal	**ae_interval_date**	Interval Date - [Adverse Events]		SAS Date .M="Missing"
01. Principal	**ae_meddra_v12**	MedDRA Adverse Event Code (CTCAE V4.0) - [Adverse Events]		Numeric
01. Principal	**ae_onset_date**	Event Onset Date - [Adverse Events]		SAS Date 8="Unknown"
01. Principal	**ae_onset_date_imputed**	Event Onset Date Imputed - [Adverse Events]		0="No" 1="Yes"

Class	Variable	Label	Description	Format Text
01. Principal	**ae_outcome**	Outcome - [Adverse Events]		1="Recovered/Resolved" 2="Recovering/Resolving" 3="Not Recovered/Not Resolved" 4="Recovered/Resolved with sequelae" 6="Unknown"
01. Principal	**ae_reported**	Reported As Serious Adverse Events (SAE) - [Adverse Events]		0="No" 1="Yes"
01. Principal	**ae_reported_date**	Adverse Event Reported Date - [Adverse Events]		SAS Date
01. Principal	**ae_reported_time**	Adverse Event Reported Time - [Adverse Events]		SAS Time
01. Principal	**ae_system_organ**	MedDRA System Organ Class (SOC) v12 - [Adverse Events]		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 (incl 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" 24="Social circumstances" 26="Vascular disorders"
01. Principal	**ae_verbatim**	Adverse Event Verbatim Term - [Adverse Events]		Char