

MDA2014-04-02 - Adverse Events Data Dictionary

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Document Summary

Property	Value
Document Title	MDA2014-04-02 - Adverse Events: Data Dictionary
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Entries	15
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MDA2014-04-02 - Adverse Events: Data Dictionary

Section 1: Identifiers

Class	Variable	Label	Description	Format Text
01. Principal	build_dt	Build Date		SAS Date
01. Principal	MRNO	Participant ID		Char

Section 2: Adverse Events

Class	Variable	Label	Description	Format Text
01. Principal	ae_action	Change (If Any) In Agent Dose Due To Adverse Event		4="Agent Dose Not Changed" 6="Not Applicable"
01. Principal	ae_attribution	Likelihood Adverse Event Was Caused By Study Agent		1="Unrelated" 2="Unlikely" 3="Possible" 4="Probable" 5="Definite"
01. Principal	ae_ctcae_term	CTCAE Term v4.0		Char
01. Principal	ae_dropped	Dropped Due To This Adverse Event?		0="No"
01. Principal	ae_end_dt	End Date Of Adverse Event		SAS Date .M="Missing"
01. Principal	ae_event	Adverse Event As Described Verbatim		Char
01. Principal	ae_grade	Severity Of Adverse Event		1="Mild" 2="Moderate" 3="Severe"
01. Principal	ae_meddra_v12	MedDRA v12.0 Code		Numeric
01. Principal	ae_onset_dt	Onset Date Of Adverse Event		SAS Date
01. Principal	ae_outcome	Outcome Of Adverse Event		1="Recovered/Resolved" 2="Recovering/Resolving" 3="Not recovering/Not Resolved" 4="Recovered/Resolved with sequelae" 6="Unknown"
01. Principal	ae_report_dt	Report Date Of Adverse Event		SAS Date
01. Principal	ae_sae	Serious Adverse Event?		0="No" 1="Yes"

Class	Variable	Label	Description	Format Text
01. Principal	ae_tox_group	Toxicity Group		2="Cardiac Disorders" 7="Gastrointestinal Disorders" 8="General Disorders and Administration Site Conditions" 10="Immune System Disorders" 11="Infections and Infestations" 12="Injury, Poisoning and Procedural Complications" 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" 25="Surgical and Medical Procedures" 26="Vascular Disorders"