

MAY2016-07-01 - Adverse Events Data Dictionary

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Document Summary

Property	Value
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MAY2016-07-01 - Adverse Events: Data Dictionary

Section 1: Identifiers

Class	Variable	Label	Description	Format Text
01. Principal	subject	Participant Identifier		Char

Section 2: Study-wide

Class	Variable	Label	Description	Format Text
01. Principal	ae_arm	Treatment Arm		Numeric

Section 3: Adverse Events

Class	Variable	Label	Description	Format Text
01. Principal	ae_attribute	AE Attribution		1="Unrelated" 2="Unlikely" 3="Possible" 4="Probable" 5="Definite"
01. Principal	ae_course	Course		Numeric
01. Principal	ae_ctcae	CTCAE Term		Char
01. Principal	ae_ctcae_v4_0	CTCAE V4.0		Numeric
01. Principal	ae_grade	Grade		Numeric
01. Principal	ae_meddra_v12	MedDRA Adverse Event Code (CTCAE V4.0)		Numeric
01. Principal	ae_off_study_dt	Off Study Date		SAS Date
01. Principal	ae_reported	Reported As SAE		0="No" 1="Yes"
01. Principal	ae_reported_dt	Adverse Event Reported Date		SAS Date
01. Principal	ae_system_organ	MedDRA System Organ Class (SOC)		1="Blood And Lymphatic System Disorders" 2="Cardiac Disorders" 4="Ear And Labyrinth Disorders" 6="Eye 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" 13="Investigations" 14="Metabolism And Nutrition Disorders" 15="Musculoskeletal And Connective Tissue Disorders" 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" 26="Vascular Disorders"