NWU2017-09-01 - Adverse Events Data Dictionary

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NWU2017-09-01 - Adverse Events: Data Dictionary

Section 1: Identifiers

Class	Variable	Label	Description	Format Text
01. Principal	**build_dt**	Build Date		SAS Date
01. Principal	**ptid**	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**ae_action**	Change (If Any) In Agent Dose Due To Adverse Event		.M="Missing" .N="No Adverse Events Reported" 1="Agent Withdrawn" 2="Agent Dose Reduced" 3="Agent Dose Increased" 4="Agent Dose Not Changed" 5="Unknown" 6="Not Applicable" 7="Agent Interrupted"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_attribution**	Likelihood Adverse Event Was Caused By Study Agent		.M="Missing" 1="Unrelated" 2="Unlikely" 3="Possible" 4="Probable" 5="Definite"
01. Principal	**ae_comments**	Comments		Char
01. Principal	**ae_ctcae_term**	CTCAE Term v4.0		"Breast pain"="Breast pain" "Fatigue"="Fatigue" "General disorders and administration site conditions - Other, specify"="General disorders and administration site conditions - Other, specify" "Headache"="Headache" "Hot flashes"="Hot flashes" "Hyperhidrosis"="Hyperhidrosis" "Insomnia"="Insomnia" "Nausea"="Nausea" "Vaginal infection"="Vaginal infection"
01. Principal	**ae_ctcae_term_other**	CTCAE Term - Other (Specify)		Char
01. Principal	**ae_dropped**	Dropped Due To This Adverse Event?		.M="Missing" .N="N/A" 0="No" 1="Yes"
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		.M="Missing" 1="Mild" 2="Moderate" 3="Severe" 4="Life-Threatening" 5="Lethal"
01. Principal	**ae_meddra_v12**	MedDRA v12.0 Code		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_dt**	Onset Date Of Adverse Event		SAS Date
01. Principal	**ae_outcome**	Outcome Of Adverse Event		.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_sae**	Serious Adverse Event?		.M="Missing" .N="N/A" 0="No" 1="Yes"
01. Principal	**ae_system_organ**	MedDRA System Organ Class (SOC)		.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"