

NWU2016-08-02 - Adverse Events Data Dictionary

TABLE OF CONTENTS

Document Summary.....	2
NWU2016-08-02 - Adverse Events: Data Dictionary	3
Section 1: Identifiers	3
Section 2: Adverse Events	4

Document Summary

Property	Value
Document Title	NWU2016-08-02 - Adverse Events: Data Dictionary
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NWU2016-08-02 - 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ae_action	Change (If Any) In Agent Dose Due To Adverse Event		.M="Missing" .N="No Adverse Events Reported" 1="Agent Withdrawn" 2="Agent Dose Reduced" 3="Agent Dose Increased" 4="Agent Dose Not Changed" 5="Unknown" 6="Not Applicable" 7="Agent Interrupted"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	CTCAE Term		3="Abdominal pain" 16="Alanine aminotransferase increased" 62="Back pain" 88="Bronchial infection" 113="Chest pain - cardiac" 134="Constipation" 138="Cough" 141="Creatinine increased" 157="Diarrhea" 172="Dysgeusia" 175="Dyspepsia" 190="Encephalopathy" 232="Fatigue" 239="Fever" 246="Flu like symptoms" 273="Generalized muscle weakness" 288="Headache" 314="Hyperglycemia" 321="Hypertension" 357="Injury = poisoning and procedural complications - Other = Specify" 476="Nausea" 478="Neck pain" 506="Pain" 616="Respiratory, thoracic and mediastinal disorders - Other, specify" 638="Seroma" 736="Urine output decreased" 755="Vaginal infection" 779="Vomiting" 784="Wheezing"
01. Principal	ae_ctcae_other	Other (Specify)		.M="Missing" 1="Postoperative hemorrhage"
01. Principal	ae_dropped	Dropped Due To This Adverse Event?		.M="Missing" .N="N/A" 0="No" 1="Yes"

Class	Variable	Label	Description	Format Text
01. Principal	ae_end_dt	End Date		SAS Date .M="Missing"
01. Principal	ae_grade	Severity Of Adverse Event		.M="Missing" 1="Mild" 2="Moderate" 3="Severe" 4="Life-Threatening" 5="Lethal"
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" 99="Unknown"
01. Principal	ae_sae	Serious Adverse Event?		.M="Missing" .N="N/A" 0="No" 1="Yes"
01. Principal	ae_soc	MedDRA System Organ Class (SOC)		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 (incl 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"
01. Principal	ae_start_dt	Start Date		SAS Date

Class	Variable	Label	Description	Format Text
01. Principal	ae_tac	Treatment Assignment Code (TAC)		0="TAC-0" 1="TAC1" 2="TAC2" 3="TAC3" 4="TAC4" 5="TAC5"
01. Principal	ae_toxcode	MedDRA Adverse Event Code (CTCAE V4.0)		10000081="Abdominal pain" 10001551="Alanine aminotransferase increased" 10003988="Back pain" 10008481="Chest pain - cardiac" 10010774="Constipation" 10011224="Cough" 10011368="Creatinine increased" 10012727="Diarrhea" 10013911="Dysgeusia" 10013946="Dyspepsia" 10014625="Encephalopathy" 10016256="Fatigue" 10016558="Fever" 10016791="Flu like symptoms" 10019211="Headache" 10020639="Hyperglycemia" 10020772="Hypertension" 10022117="Injury = poisoning and procedural complications - Other = Specify" 10028813="Nausea" 10028836="Neck pain" 10033371="Pain" 10038738="Respiratory, thoracic and mediastinal disorders - Other, specify" 10040102="Seroma" 10046914="Vaginal infection" 10047700="Vomiting" 10047924="Wheezing" 10055078="Bronchial infection" 10059895="Urine output decreased" 10062572="Generalized muscle weakness"
01. Principal	ae_verbatim	Adverse Event Verbatim Term		Char