NWU2014-04-01 - Adverse Events Data Dictionary

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NWU2014-04-01 - Adverse Events: Data Dictionary
Section 1: Identifiers

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

Section 2: Adverse Events

Class	Variable	Label	Description	Format Text
01. Principal	**Action**	Action		4="Agent Dose Not Changed" 6="Not Applicable" 7="Agent Interrupted"
01. Principal	**Adverse_Event_ Verbatim_Term**	Adverse Event Verbatim Term		Char
01. Principal	**AE_Attribution**	AE Attribution		"Possible"="Possible" "Unlikely"="Unlikely" "Unrelated"="Unrelated"
01. Principal	**AE_Grade**	AE Grade		1="Mild Adverse Event" 2="Moderate Adverse Event" 3="Severe Adverse Event"
01. Principal	**Comments**	Comments		Char
01. Principal	**CTCAE_Term**	CTCAE Term		Char
01. Principal	**Dropped_due_to _AE_**	Dropped Due To AE?		2="No"
01. Principal	**End_Date**	End Date		Char

Class	Variable	Label	Description	Format Text
01. Principal	**MedDRA_System _Organ_Class__ SOC_**	MedDRA System Organ Class (SOC)		"Blood and lymphatic system disorders"="Blood and lymphatic system disorders" "Gastrointestinal disorders"="Gastrointestinal disorders" "General disorders and administration site conditions"="General disorders and administration site conditions" "Immune system disorders"="Immune system disorders" "Infections and infestations"="Infections and infestations" "Injury, poisoning and procedural complications"="Injury, poisoning and procedural complications" "Investigations"="Investigations" "Metabolism and nutrition disorders"="Metabolism and nutrition disorders" "Musculoskeletal and connective tissue disorders"="Musculoskeletal and connective tissue disorders" "Neoplasms benign, malignant and unspecified (incl cysts and polyps)"="Neoplasms benign, malignant and unspecified (incl cysts and polyps)" "Nervous system disorders"="Nervous system disorders" "Psychiatric disorders"="Psychiatric disorders" "Reproductive system and breast disorders"="Reproductive system and breast disorders" "Respiratory, thoracic and mediastinal disorders"="Respiratory, thoracic and mediastinal disorders" "Skin and subcutaneous tissue disorders"="Skin and subcutaneous tissue disorders" "Vascular disorders"="Vascular disorders"
01. Principal	**Other__Specify**	Other, Specify		Char
01. Principal	**Outcome**	Outcome		"Not Recovered/Not Resolved"="Not Recovered/Not Resolved" "Recovered/Resolved with Sequelae"="Recovered/Resolved with Sequelae" "Recovered/Resolved"="Recovered/Resolved" "Unknown"="Unknown"
01. Principal	**Reported_as_SA E_**	Reported As SAE?		1="Yes" 2="No"
01. Principal	**Start_Date**	Start Date		Char
01. Principal	**Treatment_Assig nment_Code__T AC_**	Treatment Assignment Code (TAC)		"TAC-0"="TAC-0" "TAC1"="TAC1"