UWI2016-07-01 - Adverse Events Data Dictionary

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UWI2016-07-01 - Adverse Events: Data Dictionary

Section 1: Identifiers

Class	Variable	Label	Description	Format Text
01. Principal	**SEQUENCE_NO_**	Patient ID		Numeric

Section 2: Study-wide

Class	Variable	Label	Description	Format Text
01. Principal	**ARM**	Arm		Char
01. Principal	**CYCLE**	Cycle		Char
01. Principal	**DAY_1**	Day		Numeric
01. Principal	**FORM**	Form		"CP_DCP_Adverse_Event_Log V4"="CP_DCP_Adverse_Event_Log V4"
01. Principal	**FORM_DESC_**	Form Description		"Built for UW16110"="Built for UW16110"
01. Principal	**FORM_STATUS**	Form Status		"Amended"="Amended" "Completed"="Completed"
01. Principal	**LEVEL**	Level		Char
01. Principal	**MDS_DCPProtocolNumber**	DCP Protocol Number	Unique alphanumeric identifier assigned to a protocol by the National Cancer Institute for reporting of data.	"UWI-2016-07-01"="UWI-2016-07-01"
01. Principal	**MDS_Registering Institution**	Registering Institution	Code that uniquely identifies the institution where the research participant was registered in the clinical trial	"MD017"="MD017" "MN022"="MN022" "WI020"="WI020"
01. Principal	**NOT_APPLICABLE_OR_MISSING**	Not Applicable Or Missing		"Not Applicable"="Not Applicable"
01. Principal	**PHASE**	Phase		"Treatment"="Treatment"
01. Principal	**SEGMENT**	Segment		"Screening/Baseline"="Screening/Baseline"
01. Principal	**VISIT_DATE**	Visit Date		SAS Date

Section 3: Adverse Events

Class	Variable	Label	Description	Format Text
01. Principal	**Action**	Action	The code representing the action taken as the result of the adverse event.	"4 = Agent Dose Not Changed"="4 = Agent Dose Not Changed" "6 = Not Applicable"="6 = Not Applicable"
01. Principal	**AEReportedDate**	Adverse Event Reported Date	The date the adverse event was first reported.	SAS Date
01. Principal	**AEReportedDate_EXT**	Adverse Event Reported Date Ext		"Day"="Day"
01. Principal	**CommentsAELog**	Comments	Comments regarding the adverse event.	Char
01. Principal	**endofstudynoae**	At The End Of The Study Only: Check This Box If Participant Experienced No Adverse Events.	The indicator representing that the participant experienced no adverse events.	Char
01. Principal	**MDS_AdverseEventAEVerbatim**	Adverse Event (AE) Verbatim Term	The text that describes the adverse event term word for word as described by the participant.	Char
01. Principal	**MDS_AEAttribution**	AE Attribution	Relation of the causality between the treatment modality and the specific adverse event.	"Possible"="Possible" "Probable"="Probable" "Unrelated"="Unrelated"
01. Principal	**MDS_CTCAETerm**	CTCAE Term	Text that represents the Common Terminology Criteria for Adverse Events low level term name for an adverse event.	"Abdominal pain"="Abdominal pain" "Allergic rhinitis"="Allergic rhinitis" "Diarrhea"="Diarrhea" "Dizziness"="Dizziness" "Fatigue"="Fatigue" "Hypertension"="Hypertension" "Nausea"="Nausea" "Sore throat"="Sore throat"
01. Principal	**MDS_DroppedduetoAE**	Dropped Due To AE?	The response to a question coded as 1 (Yes) or 2 (No) that asks if the participant was withdrawn or dropped out from a protocol related to this adverse event.	Numeric
01. Principal	**MDS_EventEndDate**	Event End Date	The last or final date of an event, described using a date.	SAS Date
01. Principal	**MDS_EventEndDate_EXT**	Event End Date Ext		"Day"="Day" "Month"="Month"
01. Principal	**MDS_EventOnsetDate**	Event Onset Date	The date on which the adverse event was first evident.	SAS Date

Class	Variable	Label	Description	Format Text
01. Principal	**MDS_EventOnsetDate_EXT**	Event Onset Date Ext		"Day"="Day" "Month"="Month"
01. Principal	**MDS_MedDRASystemOrganClassSOC**	MedDRA System Organ Class (SOC)	Text term to represent the highest level of a terminology distinguished by anatomical or physiological system, etiology, or purpose, and referencing an international medical terminology (Medical Dictionary for Regulatory Activities) version 12.0, designed to support the classification, retrieval, presentation, and communication of medical information throughout the medical product regulatory cycle.	"Gastrointestinal disorders"="Gastrointestinal disorders" "General disorders and administration site conditions"="General disorders and administration site conditions" "Nervous system disorders"="Nervous system disorders" "Respiratory, thoracic and mediastinal disorders"="Respiratory, thoracic and mediastinal disorders" "Vascular disorders"="Vascular disorders"
01. Principal	**MDS_Outcome**	Outcome	The final status of the participant related to the adverse event.	"Recovered/Resolved"="Recovered/Resolved" "Unknown"="Unknown"
01. Principal	**MDS_ReportedasSAE**	Reported As SAE?	The code representing whether the event was reported as a Severe Adverse Event. Response of 1 is yes and 2 is no.	Numeric
01. Principal	**MDSGrade**	AE Grade	Numeric representation of the intensity/severity of an unfavorable and unintended sign (including an abnormal laboratory finding), symptom, syndrome, or disease, temporally associated with the use of a medical product or procedure, regardless of whether or not it is considered related to the product or procedure (attribution of unrelated, unlikely, possible, probable, or definite).	Numeric
01. Principal	**TreatmentAssignmentCodeTAC**	Treatment Assignment Code (TAC)	A coded value representing a treatment assigned to be uniformly administered to a group of study subjects for separate statistical analysis.	"TAC1"="TAC1"