UWI2016-07-01 - ADVERSE EVENTS: DATA DICTIONARY

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UWI2016-07-01 - Adverse Events: Data Dictionary

Section 1: Identifiers

Variable	Label	Description	Format Text
SEQUENCE_NO_	Patient ID		Numeric

Section 2: Study-wide

Variable	Label	Description	Format Text
ARM	Arm		Char
CYCLE	Cycle		Char
DAY_1	Day		Numeric
FORM	Form		"CP_DCP_Adverse_Event_Log V4"="CP_DCP_Adverse_Event_Log V4"
FORM_DESC_	Form Description		"Built for UW16110"="Built for UW16110"
FORM_STATUS	Form Status		"Amended"="Amended" "Completed"="Completed"
LEVEL	Level		Char
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"
MDS_RegisteringInstitution	Registering Institution	Code that uniquely identifies the institution where the research participant was registered in the clinical trial	"MD017"="MD017" "MN022"="MN022" "WI020"="WI020"
NOT_APPLICABLE_OR_MISSING	Not Applicable Or Missing		"Not Applicable"="Not Applicable"
PHASE	Phase		"Treatment"="Treatment"
SEGMENT	Segment		"Screening/Baseline"="Screening/Baseline"
VISIT_DATE	Visit Date		SAS Date

Section 3: Adverse Events

Variable	Label	Description	Format Text
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"
AEReportedDate	Adverse Event Reported Date	The date the adverse event was first reported.	SAS Date
AEReportedDate_EXT	Adverse Event Reported Date Ext		"Day"="Day"
CommentsAELog	Comments	Comments regarding the adverse event.	Char
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
MDS_AdverseEvent AEVerbatim	Adverse Event (AE) Verbatim Term	The text that describes the adverse event term word for word as described by the participant.	Char
MDS_AEAttribution	AE Attribution	Relation of the causality between the treatment modality and the specific adverse event.	"Possible"="Possible" "Probable"="Probable" "Unrelated"="Unrelated"
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"
MDS_Droppeddueto AE	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
MDS_EventEndDate	Event End Date	The last or final date of an event, described using a date.	SAS Date
MDS_EventEndDate_EXT	Event End Date Ext		"Day"="Day" "Month"="Month"
MDS_EventOnsetDate	Event Onset Date	The date on which the adverse event was first evident.	SAS Date
MDS_EventOnsetDate_EXT	Event Onset Date Ext		"Day"="Day" "Month"="Month"

Variable	Label	Description	Format Text
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"
MDS_Outcome	Outcome	The final status of the participant related to the adverse event.	"Recovered/Resolved"="Recovered/Resolved" "Unknown"="Unknown"
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
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
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"