

UWI2016-07-01 - CONCOMITANT MEDICATIONS: DATA DICTIONARY

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Document Summary

Property	Value
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UWI2016-07-01 - Concomitant Medications: 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_Con_Meds_Log V4"="CP_DCP_Con_Meds_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.	"UWI2016-07-01"="UWI2016-07-01"
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: Concomitant Medications

Variable	Label	Description	Format Text
Atendofstudynoconmed	At End Of Study Only: Check This Box If Participant Did Not Take Any Concomitant Medications.	The indicator representing that the participant did not take any concomitant medications throughout the study.	Char
Continuing	Continuing?	The indicator that describes if concomitant medication was continued.	"Yes"="Yes"
Dose	Dose	The amount that represents the dose of the agent.	Numeric
DoseUnknown	Dose Unknown?	The yes/no indicator related to information regarding the not known, not observed, not recorded, or refused quantity of an agent (such as substance or energy) administered or taken of a substance.	"No"="No"
Frequency	Frequency	The frequency schedule used for administration of agents.	Char
MDS_EndDate	End Date	The end date for the administration of the intervention.	SAS Date
MDS_EndDate_EXT	End Date Ext		"Day"="Day" "Month"="Month"
MDS_StartDate	Start Date	The start date for the administration of the intervention.	SAS Date
MDS_StartDate_EXT	Start Date Ext		"Day"="Day" "Month"="Month" "Unknown"="Unknown" "Year"="Year"
Medication	Medication	The name that describes the concomitant medication.	Char
Medreporteddate	Medication Reported Date	The date the concomitant medication was reported	SAS Date
Medreporteddate_EXT	Medication Reported Date Ext		"Day"="Day"
Reason	Reason	The reason for administration of a concomitant (nonstudy) agent or measure. This is not the pharmacologic classification of an agent (antibiotic, analgesic, etc.), but the reason for its administration to the patient.	Char

Variable	Label	Description	Format Text
Units	Units	A code system intended to include all units of measures being contemporarily used in interventions in international science, engineering, and business. Its purpose is to facilitate unambiguous electronic communication of quantities together with their units.	Char