

UWI2016-07-01 - Concomitant Medications Data Dictionary

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Document Summary

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

Class	Variable	Label	Description	Format Text
01. Principal	Atendofstudynoc onmed	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
01. Principal	Continuing	Continuing?	The indicator that describes if concomitant medication was continued.	"Yes"="Yes"
01. Principal	Dose	Dose	The amount that represents the dose of the agent.	Numeric
01. Principal	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"
01. Principal	Frequency	Frequency	The frequency schedule used for administration of agents.	Char
01. Principal	MDS_EndDate	End Date	The end date for the administration of the intervention.	SAS Date
01. Principal	MDS_EndDate_E XT	End Date Ext		"Day"="Day" "Month"="Month"
01. Principal	MDS_StartDate	Start Date	The start date for the administration of the intervention.	SAS Date
01. Principal	MDS_StartDate_ EXT	Start Date Ext		"Day"="Day" "Month"="Month" "Unknown"="Unknown" "Year"="Year"
01. Principal	Medication	Medication	The name that describes the concomitant medication.	Char
01. Principal	Medreporteddate	Medication Reported Date	The date the concomitant medication was reported	SAS Date
01. Principal	Medreporteddate _EXT	Medication Reported Date Ext		"Day"="Day"

Class	Variable	Label	Description	Format Text
01. Principal	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
01. Principal	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