

# 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

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Class	Variable	Label	Description	Format Text
01. Principal	<b>SEQUENCE_NO_</b>	Patient ID		Numeric

## Section 2: Study-wide

Class	Variable	Label	Description	Format Text
01. Principal	<b>ARM</b>	Arm		Char
01. Principal	<b>CYCLE</b>	Cycle		Char
01. Principal	<b>DAY_1</b>	Day		Numeric
01. Principal	<b>FORM</b>	Form		"CP_DCP_Con_Meds_Log V4"="CP_DCP_Con_Meds_Log V4"
01. Principal	<b>FORM_DESC_</b>	Form Description		"Built for UW16110"="Built for UW16110"
01. Principal	<b>FORM_STATUS</b>	Form Status		"Amended"="Amended" "Completed"="Completed"
01. Principal	<b>LEVEL</b>	Level		Char
01. Principal	<b>MDS_DCPProtocolNumber</b>	DCP Protocol Number	Unique alphanumeric identifier assigned to a protocol by the National Cancer Institute for reporting of data.	"UW12016-07-01"="UW12016-07-01"
01. Principal	<b>MDS_Registering Institution</b>	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	<b>NOT_APPLICABLE_OR_MISSING</b>	Not Applicable Or Missing		"Not Applicable"="Not Applicable"
01. Principal	<b>PHASE</b>	Phase		"Treatment"="Treatment"
01. Principal	<b>SEGMENT</b>	Segment		"Screening/Baseline"="Screening/Baseline"
01. Principal	<b>VISIT_DATE</b>	Visit Date		SAS Date

## Section 3: Concomitant Medications

Class	Variable	Label	Description	Format Text
01. Principal	<b>Atendofstudynonmed</b>	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	<b>Continuing</b>	Continuing?	The indicator that describes if concomitant medication was continued.	"Yes"="Yes"
01. Principal	<b>Dose</b>	Dose	The amount that represents the dose of the agent.	Numeric
01. Principal	<b>DoseUnknown</b>	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	<b>Frequency</b>	Frequency	The frequency schedule used for administration of agents.	Char
01. Principal	<b>MDS_EndDate</b>	End Date	The end date for the administration of the intervention.	SAS Date
01. Principal	<b>MDS_EndDate_EXT</b>	End Date Ext		"Day"="Day" "Month"="Month"
01. Principal	<b>MDS_StartDate</b>	Start Date	The start date for the administration of the intervention.	SAS Date
01. Principal	<b>MDS_StartDate_EXT</b>	Start Date Ext		"Day"="Day" "Month"="Month" "Unknown"="Unknown" "Year"="Year"
01. Principal	<b>Medication</b>	Medication	The name that describes the concomitant medication.	Char
01. Principal	<b>Medreporteddate</b>	Medication Reported Date	The date the concomitant medication was reported	SAS Date
01. Principal	<b>Medreporteddate_EXT</b>	Medication Reported Date Ext		"Day"="Day"

Class	Variable	Label	Description	Format Text
01. Principal	<b>Reason</b>	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	<b>Units</b>	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