

UWI2016-07-01 - COMPLIANCE (DATASET 1): DATA DICTIONARY

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Document Summary

Property	Value
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UWI2016-07-01 - Compliance (Dataset 1): 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		"ACTOplus XR/Placebo"="ACTOplus XR/Placebo"
CYCLE	Cycle		Char
DAY_1	Day		Numeric
FORM	Form		"CP_DCP_Compliance V2"="CP_DCP_Compliance V2"
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		Char
PHASE	Phase		"Treatment"="Treatment"
SEGMENT	Segment		"Day 15-22 (max day 26)"="Day 15-22 (max day 26)"
VISIT_DATE	Visit Date		SAS Date

Section 3: Compliance (Dataset 1)

Variable	Label	Description	Format Text
Amountofagentmissing	Amount Of Agent Missing/Not Accounted For This Period (Tabs)	The amount that describes how much of the agent was missing or not accounted for.	Numeric
Amountofagentprovided	Amount Of Agent Provided At Last Visit (Tabs)	The amount of agent that was provided at the last visit.	Numeric
Amountofagentreturned	Amount Of Agent Returned This Visit (Tabs)	The amount that describes how much of the agent was returned by the participant.	Numeric
Amountofagenttaken	Amount Of Agent Taken During This Period (Tabs)	The amount that describes how much of the agent was actually taken.	Numeric
DATEFirstDosetakenthisperiod	First Dose Taken This Period DATE	The date the participant started taking the agent for the specified visit period.	SAS Date
DATELastdosetakenthisperiod	Last Dose Taken This Period DATE	The date the participant finished taking the agent for the specified visit period.	SAS Date
Dateofdispenseofagent	Date Of Dispense Of Agent	The date the agent was given to the participant.	SAS Date
IfNospecifyreasonfornonc	If No, Specify Reason For Noncompliance	The text that describes the reason the participant was noncompliant.	Char
IfYesindicatenumbe rinterr	If Yes, Indicate Number Of Interruptions This Period	The number that specifies the additional agent interruptions.	Numeric
IfYesindicatenumbe rofmod	If Yes, Indicate Number Of Modifications This Period	The number that specifies the modification to the study agent	Char
Istheparticipantcompliant	Is The Participant Compliant With Protocol Intervention?	The indicator that represents whether the participant was compliant with the protocol intervention.	"Yes"="Yes"
TIMEFirstDosetakenthisperiod	First Dose Taken This Period Time	The time the participant started taking the agent for the specified visit period.	Numeric
TIMELastdosetakenthisperiod	Last Dose Taken This Period Time	The time the participant finished taking the agent for the specified visit period.	Numeric
Wasagentinterrupted	Was Agent Interrupted During This Period?	The indicator representing if the agent was interrupted during the period.	"No"="No" "Yes"="Yes"
Wasagentregimenmodified	Was Agent Regimen Modified During This Period?	The indicator representing if the agent was modified.	"No"="No"