

# UWI2016-07-01 - COMPLIANCE (DATASET 2): DATA DICTIONARY

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## Document Summary

Property	Value
Document Title	UWI2016-07-01 - Compliance (Dataset 2): Data Dictionary
Date Created	07/10/2020
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Entries	33
Document Filename	dictionary_compliance2.rtf

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# UWI2016-07-01 - Compliance (Dataset 2): Data Dictionary

## Section 1: Identifiers

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Variable	Label	Description	Format Text
<b>SEQUENCE_NO_</b>	Patient ID		Numeric

## Section 2: Study-wide

Variable	Label	Description	Format Text
<b>ARM</b>	Arm		"ACTOplus XR/Placebo"="ACTOplus XR/Placebo"
<b>CYCLE</b>	Cycle		Char
<b>DAY_1</b>	Day		Numeric
<b>FORM</b>	Form		"CP_DCP_Compliance V3"="CP_DCP_Compliance V3"
<b>FORM_DESC_</b>	Form Description		"Built for UW16110"="Built for UW16110"
<b>FORM_STATUS</b>	Form Status		"Completed"="Completed"
<b>LEVEL</b>	Level		Char
<b>MDS_DCPPProtocolNumber</b>	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"
<b>MDS_RegisteringInstitution</b>	Registering Institution	Code that uniquely identifies the institution where the research participant was registered in the clinical trial	"WI020"="WI020"
<b>NOT_APPLICABLE_OR_MISSING</b>	Not Applicable Or Missing		Char
<b>PHASE</b>	Phase		"Treatment"="Treatment"
<b>SEGMENT</b>	Segment		"Final Dosing Reminder Call"="Final Dosing Reminder Call"
<b>VISIT_DATE</b>	Visit Date		SAS Date

## Section 3: Compliance (Dataset 2)

Variable	Label	Description	Format Text
<b>Amountofagentmissing</b>	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
<b>Amountofagentprovided</b>	Amount Of Agent Provided At Last Visit (Tabs)	The amount of agent that was provided at the last visit.	Numeric
<b>Amountofagentreturned</b>	Amount Of Agent Returned This Visit (Tabs)	The amount that describes how much of the agent was returned by the participant.	Numeric
<b>Amountofagenttaken</b>	Amount Of Agent Taken During This Period (Tabs)	The amount that describes how much of the agent was actually taken.	Char
<b>DATEFirstDosetakenthisperiod</b>	First Dose Taken This Period DATE	The date the participant started taking the agent for the specified visit period.	Char
<b>DATEFirstDosetakenthisperiod_EXT</b>	First Dose Taken This Period DATE Ext		"Unknown"="Unknown"
<b>DATELastdosetakenthisperiod</b>	Last Dose Taken This Period DATE	The date the participant finished taking the agent for the specified visit period.	Char
<b>DATELastdosetakenthisperiod_EXT</b>	Last Dose Taken This Period DATE Ext		"Unknown"="Unknown"
<b>Dateofdispenseofagent</b>	Date Of Dispense Of Agent	The date the agent was given to the participant.	SAS Date
<b>IfNospecifyreasonfornonc</b>	If No, Specify Reason For Noncompliance	The text that describes the reason the participant was noncompliant.	Char
<b>IfYesindicatenumbe rinterr</b>	If Yes, Indicate Number Of Interruptions This Period	The number that specifies the additional agent interruptions.	Char
<b>IfYesindicatenumbe rofmod</b>	If Yes, Indicate Number Of Modifications This Period	The number that specifies the additional agent modifications.	Char
<b>Istheparticipantcompliant</b>	Is The Participant Compliant With Protocol Intervention?	The indicator that represents whether the participant was compliant with the protocol intervention.	"No"="No"
<b>TIMEFirstDosetakenthisperiod</b>	First Dose Taken This Period Time	The time the participant started taking the agent for the specified visit period.	Char
<b>TIMELastdosetakenthisperiod</b>	Last Dose Taken This Period Time	The time the participant finished taking the agent for the specified visit period.	Char
<b>Unknownamountofagenttaken</b>	Unknown Amount Of Agent Taken During This Period (Tabs)	The indicator representing that the amount of agent taken is unknown	"Unknown"="Unknown"

Variable	Label	Description	Format Text
<b>Unknownnumberofinterruptions</b>	Unknown Number Of Interruptions	The indicator representing that the number of interruptions is unknown	"Unknown"="Unknown"
<b>Wasagentinterrupted</b>	Was Agent Interrupted During This Period?	The indicator representing if the agent was interrupted during the period.	"Yes"="Yes"
<b>Wasagentregimenmodified</b>	Was Agent Regimen Modified During This Period?	The indicator representing if the agent was modified.	"No"="No"