

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

TABLE OF CONTENTS

Document Summary.....	2
UWI2016-07-01 - Compliance (Dataset 2): Data Dictionary.....	3
Section 1: Identifiers	3
Section 2: Study-wide	4
Section 3: Compliance (Dataset 2)	5

Document Summary

Property	Value
Document Title	UWI2016-07-01 - Compliance (Dataset 2): Data Dictionary
Date Created	01/02/2026
Sections	3
Entries	33
Document Filename	dictionary_compliance2.rtf

UWI2016-07-01 - Compliance (Dataset 2): 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		"ACTOplus XR/Placebo"="ACTOplus XR/Placebo"
01. Principal	CYCLE	Cycle		Char
01. Principal	DAY_1	Day		Numeric
01. Principal	FORM	Form		"CP_DCP_Compliance V3"="CP_DCP_Compliance V3"
01. Principal	FORM_DESC_	Form Description		"Built for UW16110"="Built for UW16110"
01. Principal	FORM_STATUS	Form Status		"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	"WI020"="WI020"
01. Principal	NOT_APPLICABLE_OR_MISSING	Not Applicable Or Missing		Char
01. Principal	PHASE	Phase		"Treatment"="Treatment"
01. Principal	SEGMENT	Segment		"Final Dosing Reminder Call"="Final Dosing Reminder Call"
01. Principal	VISIT_DATE	Visit Date		SAS Date

Section 3: Compliance (Dataset 2)

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

Class	Variable	Label	Description	Format Text
01. Principal	TIMEFirstDosetakeninthisperiod	First Dose Taken This Period Time	The time the participant started taking the agent for the specified visit period.	Char
01. Principal	TIMELastdosetakeninthisperiod	Last Dose Taken This Period Time	The time the participant finished taking the agent for the specified visit period.	Char
01. Principal	Unknownamountofagenttaken	Unknown Amount Of Agent Taken During This Period (Tabs)	The indicator representing that the amount of agent taken is unknown	"Unknown"="Unknown"
01. Principal	Unknownnumberofinterruptions	Unknown Number Of Interruptions	The indicator representing that the number of interruptions is unknown	"Unknown"="Unknown"
01. Principal	Wasagentinterrupted	Was Agent Interrupted During This Period?	The indicator representing if the agent was interrupted during the period.	"Yes"="Yes"
01. Principal	Wasagentregimenmodified	Was Agent Regimen Modified During This Period?	The indicator representing if the agent was modified.	"No"="No"