

UWI2016-07-01 - OFF STUDY: DATA DICTIONARY

TABLE OF CONTENTS

Document Summary.....	2
UWI2016-07-01 - Off Study: Data Dictionary.....	3
Section 1: Identifiers	3
Section 2: Study-wide	4
Section 3: Off Study	5

Document Summary

Property	Value
Document Title	UWI2016-07-01 - Off Study: Data Dictionary
Date Created	07/10/2020
Sections	3
Entries	26
Document Filename	dictionary_offstudy.rtf

UWI2016-07-01 - Off Study: 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_Off_Study V3"="CP_DCP_Off_Study V3"
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)" "Final Dosing Reminder Call"="Final Dosing Reminder Call" "Screening/Baseline"="Screening/Baseline"
VISIT_DATE	Visit Date		SAS Date

Section 3: Off Study

Variable	Label	Description	Format Text
AgentEndDate	Agent End Date	The last date the participant took study agent.	SAS Date
AgentEndDate_EXT	Agent End Date Ext		"Day"="Day" "Unknown"="Unknown"
DateOffFollowup	Date Off Follow-Up	The date the participant completed follow up.	Char
DateOffFollowupNot Applic	Date Off Follow-Up Not Applicable		"Not Applicable"="Not Applicable"
DateofLastContact	Date Of Last Contact	The date the participant was last seen or spoken to.	SAS Date
DateonFollowup	Date On Follow-Up		Char
DateonFollowupNot Applic	Date On Follow-Up Not Applicable	Indicator represents the date the participant began follow up is not applicable.	"Not Applicable"="Not Applicable"
MDS_AgentEndDate NotApplicable	Agent End Date Not Applicable	Indicator represents the last date the participant took study agent is not applicable.	"Not Applicable"="Not Applicable"
MDS_OffStudyDate	Off Study Date	The date when the participant is removed from the protocol.	SAS Date
MDS_ReasonOffStudy	Reason Off Study	Choice of reasons for removing a participant from a clinical trial.	"Ineligible"="Ineligible" "Participant Withdrawal"="Participant Withdrawal" "Study Complete"="Study Complete"
MDS_ReasonOffStudyOtherspecif	Reason Off Study Other, Specify	Text to describe the reason the participant is off study.	Char
OffStudyFormDate	Form Date	The date the form was started on.	SAS Date