

UWI2016-07-01 - Off Study Data Dictionary

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Document Summary

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

UWI2016-07-01 - Off Study: 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_Off_Study V3"="CP_DCP_Off_Study V3"
01. Principal	FORM_DESC_	Form Description		"Built for UW16110"="Built for UW16110"
01. Principal	FORM_STATUS	Form Status		"Amended"="Amended" "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_Registering Institution	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	NOT_APPLICABLE_OR_MISSING	Not Applicable Or Missing		Char
01. Principal	PHASE	Phase		"Treatment"="Treatment"
01. Principal	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"
01. Principal	VISIT_DATE	Visit Date		SAS Date

Section 3: Off Study

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