

UWI2016-07-01 - AGENT INTERRUPTIONS: DATA DICTIONARY

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Document Summary

Property	Value
Document Title	UWI2016-07-01 - Agent Interruptions: Data Dictionary
Date Created	07/10/2020
Sections	3
Entries	24
Document Filename	dictionary_agint.rtf

UWI2016-07-01 - Agent Interruptions: 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_Agent_Interruption V2"="CP_DCP_Agent_Interruption V2"
FORM_DESC_	Form Description		"Built for UW16110"="Built for UW16110"
FORM_STATUS	Form Status		"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"
NOT_APPLICABLE_OR_MISSING	Not Applicable Or Missing		"Not Applicable"="Not Applicable"
PHASE	Phase		"Treatment"="Treatment"
SEGMENT	Segment		"Day 15-22 (max day 26)"="Day 15-22 (max day 26)"
VISIT_DATE	Visit Date		SAS Date
VisitType	Visit Type	The visit at which the data reported on the form was collected	"Day 15-22 or Early Termination"="Day 15-22 or Early Termination"

Section 3: Agent Interruptions

Variable	Label	Description	Format Text
DateStopped	Specify Date Stopped	The date the agent was stopped.	SAS Date
DateStopped_EXT	Specify Date Stopped Ext		"Day"="Day" "Unknown"="Unknown"
Ifyesspecifydate restarted	If Yes, Specify Date Restarted	The date the agent was restarted.	SAS Date
Ifyesspecifydate restarted_EXT	If Yes, Specify Date Restarted Ext		"Day"="Day" "Unknown"="Unknown"
InterruptNumber	Interruption Number	The free text field used to enter the numeric value of the agent interruption.	Numeric
ReasonStopped	Reason Stopped	The reason representing why the agent was stopped.	"Participant decision, specify"="Participant decision, specify"
Specifyreason restarted	Specify Reason Restarted	The reason for restarting the agent.	"Participant decision"="Participant decision"
SpecifyReasonStopped	Specify Reason Stopped	The reason representing why the agent was stopped.	Char
Wasagent restarted	Was Agent Restarted?	The indicator representing if the agent was restarted.	"Yes"="Yes"