

UWI2016-07-01 - Agent Interruptions Data Dictionary

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Document Summary

Property	Value
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UWI2016-07-01 - Agent Interruptions: 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_Agent_Interruption V2"="CP_DCP_Agent_Interruption V2"
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_Registering Institution	Registering Institution	Code that uniquely identifies the institution where the research participant was registered in the clinical trial	"MD017"="MD017" "MN022"="MN022"
01. Principal	NOT_APPLICABLE_OR_MISSING	Not Applicable Or Missing		"Not Applicable"="Not Applicable"
01. Principal	PHASE	Phase		"Treatment"="Treatment"
01. Principal	SEGMENT	Segment		"Day 15-22 (max day 26)"="Day 15-22 (max day 26)"
01. Principal	VISIT_DATE	Visit Date		SAS Date
01. Principal	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

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