

UWI2016-07-01 - AGENT MODIFICATIONS: DATA DICTIONARY

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Document Summary

Property	Value
Document Title	UWI2016-07-01 - Agent Modifications: Data Dictionary
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UWI2016-07-01 - Agent Modifications: 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_Modification V1"="CP_DCP_Agent_Modification V1"
FORM_DESC_	Form Description		"Built for UW16110"="Built for UW16110"
FORM_STATUS	Form Status		"Completed"="Completed"
LEVEL	Level		Char
MDS_DCPPProtocolNumber	DCP Protocol Number	Unique alphanumeric identifier assigned to a protocol by the National Cancer Institute for reporting of data.	Char
MDS_RegisteringInstitution	Registering Institution	Code that uniquely identifies the institution where the research participant was registered in a clinical trial.	Char
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	Char

Section 3: Agent Modifications

Variable	Label	Description	Format Text
DateModified	Specify Date Modified	The date the agent was modified.	Char
Dose	Dose	The text that describes the new dose of the agent.	Char
Frequency	Frequency	The new frequency of the agent.	Char
ModNumber	Modification Number	The free text field used to enter the numeric value of the agent interruption.	Char
ReasonModified	Reason Modified	The response regarding the reason an agent was modified.	Char
SpecifyReasonModified	Specify Reason Modified	Text explanation of the reason for a dose modification.	Char
Units	Units	The units describing the agent dose	Char