

UWI2016-07-01 - Agent Modifications Data Dictionary

TABLE OF CONTENTS

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

Document Summary

Property	Value
Document Title	UWI2016-07-01 - Agent Modifications: Data Dictionary
Date Created	01/02/2026
Sections	3
Entries	22
Document Filename	dictionary_agmod.rtf

UWI2016-07-01 - Agent Modifications: 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_Modification V1"="CP_DCP_Agent_Modification V1"
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.	Char
01. Principal	MDS_Registering Institution	Registering Institution	Code that uniquely identifies the institution where the research participant was registered in a clinical trial.	Char
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	Char

Section 3: Agent Modifications

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