

UWI2016-07-01 - Intervention Administration Data Dictionary

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Document Summary

Property	Value
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UWI2016-07-01 - Intervention Administration: 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_Intervention_Administration V2"="CP_DCP_Intervention_Administration 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" "WI020"="WI020"
01. Principal	NOT_APPLICABLE_OR_MISSING	Not Applicable Or Missing		Char
01. Principal	PHASE	Phase		"Treatment"="Treatment"
01. Principal	SEGMENT	Segment		"Randomization"="Randomization"
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 (i.e., baseline, Month 1, etc.)	"Randomization"="Randomization"

Section 3: Intervention Administration

Class	Variable	Label	Description	Format Text
01. Principal	AgentPlacebo	Agent/Placebo	A text name for an Agent. An agent is a distinct substance or ingredient or compound/product/mixture thereof, contained in drugs, biologics, foods, and devices that act to produce a specific effect (commonly health related). This can include radiopharmaceutical, nutritional, complimentary and alternative medicine (CAM), molecular components of devices (i.e. silicon in implants) and nano-technologic agents but does not include whole devices (implants), or procedures (i.e. surgeries). Individual agents included in a treatment regimen or therapy is included in this definition, however, whole regimen names or other broad classification of therapies (i.e. "CHOP", "chemotherapy", etc), are not.	"ACTOplus met® XR/placebo"="ACTOplus met® XR/placebo"
01. Principal	DateAgentProvided	Date Agent Provided (To Participant)	The date the agent was given to the participant.	SAS Date
01. Principal	Dose	Dose	The amount that represents the dose of the agent.	Numeric
01. Principal	DoseUnits	Dose Units	The units that the dose is given in	"Tab"="Tab"
01. Principal	Frequency	Frequency	The frequency schedule used for administration of agents.	"Daily"="Daily"
01. Principal	MDS_DateAgentStarted	Date Agent Started	The start date for the administration of the intervention.	SAS Date
01. Principal	MDS_DateAgentStarted_EXT	Date Agent Started Ext		"Day"="Day" "Unknown"="Unknown"

