

UWI2016-07-01 - INTERVENTION ADMINISTRATION: DATA DICTIONARY

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Document Summary

Property	Value
Document Title	UWI2016-07-01 - Intervention Administration: Data Dictionary
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UWI2016-07-01 - Intervention Administration: 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_Intervention_Administration V2"="CP_DCP_Intervention_Administration 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" "WI020"="WI020"
NOT_APPLICABLE_OR_MISSING	Not Applicable Or Missing		Char
PHASE	Phase		"Treatment"="Treatment"
SEGMENT	Segment		"Randomization"="Randomization"
VISIT_DATE	Visit Date		SAS Date
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

Variable	Label	Description	Format Text
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"
DateAgentProvided	Date Agent Provided (To Participant)	The date the agent was given to the participant.	SAS Date
Dose	Dose	The amount that represents the dose of the agent.	Numeric
DoseUnits	Dose Units	The units that the dose is given in	"Tab"="Tab"
Frequency	Frequency	The frequency schedule used for administration of agents.	"Daily"="Daily"
MDS_DateAgentStar ted	Date Agent Started	The start date for the administration of the intervention.	SAS Date
MDS_DateAgentStar ted_EXT	Date Agent Started Ext		"Day"="Day" "Unknown"="Unknown"