

UWI2016-07-01 - SPECIMEN INFORMATION (TISSUE): DATA DICTIONARY

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Document Summary

Property	Value
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UWI2016-07-01 - Specimen Information (Tissue): 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_Specimen_Acquisition_Tissue V4"="CP_DCP_Specimen_Acquisition_Tissue V4"
FORM_DESC_	Form Description		"Built for UW16110"="Built for UW16110"
FORM_STATUS	Form Status		"Amended"="Amended" "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		"Not Applicable"="Not Applicable"
PHASE	Phase		"Treatment"="Treatment"
SEGMENT	Segment		"Day 15-22 (max day 26)"="Day 15-22 (max day 26)" "Final Dosing Reminder Call"="Final Dosing Reminder Call" "Screening/Baseline"="Screening/Baseline"
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.)	"Baseline"="Baseline" "Day 11-22 or Early Termination"="Day 11-22 or Early Termination" "Day 15-22 or Early Termination"="Day 15-22 or Early Termination"

Section 3: Specimen Information (Tissue)

Variable	Label	Description	Format Text
CommentsTissue	Comments	The free text field for general notes.	Char
DateLastStudyAgentTaken	Date Last Study Agent Taken	The last date the participant took study agent.	SAS Date
DateSpecimenCollected	Date Specimen Collected	The date when the sample (specimen) was collected.	SAS Date
SpecimenShippingDate	Specimen Shipping Date	The act or business of transporting goods or samples (blood, urine, tissue, etc.) to a laboratory for pharmacokinetic or other correlative study embedded within the primary protocol. _the date on which an observation was made or an event occurred.	Char
StorageTemperature	Storage Temperature	The temperature at which the specimen was stored expressed in degrees Celsius.	Numeric
StorageTemperature_UNITS	Storage Temperature Units		"C"="C"
TimeLastStudyAgentTaken	Time Last Study Agent Taken	The time the participant finished taking the agent for the specified visit period.	Numeric
TimeSpecimenCollected	Time Specimen Collected	The time at which a specimen was collected.	Numeric
Tissueobtained	Tissue Obtained?	The indicator that represents whether a specific test, exam, or specimen was obtained	"No"="No" "Yes"="Yes"
TissueType	Tissue Type	A subdivision of a particular kind of liquid or semi liquid substances produced by living organisms used to determine the character of the whole for use in testing, examination, or study.	"Normal"="Normal" "Tumor"="Tumor"