

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

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Document Summary

Property	Value
Document Title	UWI2016-07-01 - Specimen Information (Blood): Data Dictionary
Date Created	07/10/2020
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Entries	24
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UWI2016-07-01 - Specimen Information (Blood): 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_Acquistion_Blood V2"="CP_DCP_Specimen_Acquistion_Blood V2"
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 (Blood)

Variable	Label	Description	Format Text
CommentsSpecAcqBlood	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
NotObtained	Not Obtained	The indicator that represents that a specific test, exam, or specimen was not obtained, not examined, not applicable, unknown or not required, etc.	"Not Obtained"="Not Obtained"
SpecimenShippingDate	Specimen Shipping Date	The date on which the specimen for pharmacokinetic or other correlative study was transported from one location to another.	SAS Date
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