

UWI2016-07-01 - Blood Chemistry Data Dictionary

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Document Summary

Property	Value
Document Title	UWI2016-07-01 - Blood Chemistry: Data Dictionary
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UWI2016-07-01 - Blood Chemistry: 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_Clinical_Lab/Chem V2"="CP_DCP_Clinical_Lab/Chem V2"
01. Principal	FORM_DESC_	Form Description		"Built for UW16110"="Built for UW16110"
01. Principal	FORM_STATUS	Form Status		"Amended"="Amended" "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		"Missed"="Missed" "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)" "Final Dosing Reminder Call"="Final Dosing Reminder Call" "Screening/Baseline"="Screening/Baseline"
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	"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: Blood Chemistry

Class	Variable	Label	Description	Format Text
01. Principal	Chem	Chem	Identifier name given to a test performed on body fluid(s) and tissues; test names are typically comprised of the analyte name, properties (% , Ratio, etc.), the type of body fluid tested, and any special instructions.	"ALT/SGPT"="ALT/SGPT" "AST/SGOT"="AST/SGOT" "Albumin g/dL"="Albumin g/dL" "Alkaline Phosphatase U/ or IU/L"="Alkaline Phosphatase U/ or IU/L" "Anion Gap mmol/L or mEq/L"="Anion Gap mmol/L or mEq/L" "BUN mg/dL*"="BUN mg/dL*" "Bicarbonate mEq/ or mmol/L"="Bicarbonate mEq/ or mmol/L" "Bilirubin, Total mg/dL*"="Bilirubin, Total mg/dL*" "Calcium mg/dL"="Calcium mg/dL" "Chloride mEq/ or mmol/L"="Chloride mEq/ or mmol/L" "Creatinine mg/dL*"="Creatinine mg/dL*" "Estradiol (pg/mL)"="Estradiol (pg/mL)" "FSH (mIU/mL)"="FSH (mIU/mL)" "Glucose mg/dL"="Glucose mg/dL" "Potassium mEq/ or mmol/L"="Potassium mEq/ or mmol/L" "Progesterone (ng/mL)"="Progesterone (ng/mL)" "Protein total g/dL"="Protein total g/dL" "SGOT/AST U/ or IU/L"="SGOT/AST U/ or IU/L" "SGPT/ALT U/ or IU/L"="SGPT/ALT U/ or IU/L" "Sodium mEq/ or mmol/L"="Sodium mEq/ or mmol/L" "T3 Free ng/dL"="T3 Free ng/dL" "eGFR mL/min/1.73 sqm"="eGFR mL/min/1.73 sqm"
01. Principal	ClinicallySignificant	Clinically Significant?	The indicator that represents the physician's assessment of clinical significance.	"No"="No"
01. Principal	Comments	Comments	The free text field for general notes.	"eGFR value used for eligibility was performed on 03/14/2019 at 12:35pm"="eGFR value used for eligibility was performed on 03/14/2019 at 12:35pm"
01. Principal	DateSpecimenCollected	Date Specimen Collected	The date when the sample (specimen) was collected.	SAS Date
01. Principal	Fasting	Fasting?	Indicates whether the participant was fasting when the specimen was obtained.	"No"="No" "Unknown"="Unknown" "Yes"="Yes"
01. Principal	NotObtained	Mark If NOT Obtained	The indicator that represents whether the Lab test was not obtained	"Not Obtained"="Not Obtained"

Class	Variable	Label	Description	Format Text
01. Principal	OutofRange	Out Of Range?	The indicator that represents whether the test was outside of the normal range as specified by the laboratory.	"No"="No" "Yes"="Yes"
01. Principal	Result	Result	Character result of a laboratory analysis expressed as text.	Char
01. Principal	Timespecimencollected	Time Specimen Collected	The time when the sample (specimen) was collected.	Numeric