

UWI2016-07-01 - BLOOD CHEMISTRY: DATA DICTIONARY

TABLE OF CONTENTS

Document Summary.....	2
UWI2016-07-01 - Blood Chemistry: Data Dictionary.....	3
Section 1: Identifiers	3
Section 2: Study-wide	4
Section 3: Blood Chemistry	5

Document Summary

Property	Value
Document Title	UWI2016-07-01 - Blood Chemistry: Data Dictionary
Date Created	07/10/2020
Sections	3
Entries	24
Document Filename	dictionary_bldchem.rtf

UWI2016-07-01 - Blood Chemistry: 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_Clinical_Lab/Chem V2"="CP_DCP_Clinical_Lab/Chem 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		"Missed"="Missed" "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	"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

Variable	Label	Description	Format Text
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"
ClinicallySignificant	Clinically Significant?	The indicator that represents the physician_s assessment of clinical significance.	"No"="No"
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"
DateSpecimenCollected	Date Specimen Collected	The date when the sample (specimen) was collected.	SAS Date
Fasting	Fasting?	Indicates whether the participant was fasting when the specimen was obtained.	"No"="No" "Unknown"="Unknown" "Yes"="Yes"
NotObtained	Mark If NOT Obtained	The indicator that represents whether the Lab test was not obtained	"Not Obtained"="Not Obtained"
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"
Result	Result	Character result of a laboratory analysis expressed as text.	Char

Variable	Label	Description	Format Text
Timespecimencollected	Time Specimen Collected	The time when the sample (specimen) was collected.	Numeric