

UWI2016-07-01 - PHYSICAL EXAMINATION (DATASET 1): DATA DICTIONARY

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Document Summary

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UWI2016-07-01 - Physical Examination (Dataset 1): 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_Physical_Exam V3"="CP_DCP_Physical_Exam V3"
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	"Day 11-22 or Early Termination"="Day 11-22 or Early Termination" "Day 15-22 or Early Termination"="Day 15-22 or Early Termination" "Screening/Baseline"="Screening/Baseline"

Section 3: Physical Examination (Dataset 1)

Variable	Label	Description	Format Text
BloodPressureDiastolic	Blood Pressure Diastolic	The pressure of the blood against the artery walls during diastole (the relaxation phase).	Numeric
BloodPressureDiastolic_UNITS	Blood Pressure Diastolic Units		"mmHg"="mmHg"
BloodPressureSystolic	Blood Pressure Systolic	The pressure of the blood against the artery walls during systole (the contraction phase).	Numeric
BloodPressureSystolic_UNITS	Blood Pressure Systolic Units		"mmHg"="mmHg"
bodysystemsexamined	Were Body Systems Examined?	The yes/no indicator whether a physical examination has been performed.	"No"="No" "Yes"="Yes"
CHF	Does The Participant Demonstrate Signs Or Symptoms Of Congestive Heart Failure?	The yes/no/unknown indicator whether there is symptomatic congestive heart failure, signs of a complication of heart disease, defective cardiac filling and/or impaired contraction and emptying, resulting in the heart's inability to pump a sufficient amount of blood to meet the needs of the body tissues or to be able to do so only with an elevated filling pressure present.	"No"="No"
DiastolicNotObtained	Blood Pressure Diastolic 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"
ECOGPerformanceStatus	ECOG Performance Status	The ECOG functional performance status of the patient/participant.	"0 - Fully active"="0 - Fully active" "N/A at this visit"="N/A at this visit"
edema	Does The Participant Demonstrate Signs Of Edema?	The response to a question that asks whether there is swelling of soft tissues as a result of excess water accumulation for the body system examined.	"No"="No" "Yes"="Yes"
ExaminationDate	Examination Date	The date of the evaluation, procedure or visit that yielded data.	SAS Date

Variable	Label	Description	Format Text
ExaminationNotDone	Examination Not Done	The indicator that represents that a specific test, exam, or specimen was not obtained, not examined, not applicable, unknown or not required, etc.	"Not Done"="Not Done"
Height	Height	The number that describes the vertical distance of an individual.	Numeric
HeightNotObtained	Height 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"
HeightUnits	Height Units	The Unified Code for Units of Measure symbols that represent a determinate amount or quantity used as the standard of measurement for the vertical size of an individual person.	"cm"="cm" "in"="in"
PulseNotObtained	Pulse 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"
PulseRate	Pulse Rate	Numeric value to represent the measurement of the heart rate, which is the number of contractions (heart beats) expressed in "beats per minute" (bpm).	Numeric
RespirationRate	Respiration Rate	The numeric value of a person's respiratory rate (the rate of breathing (inhalation and exhalation) measured within in a unit time, usually expressed as breaths per minute).	Numeric
RespirationRateNotObtained	Respiration Rate 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"
SystolicNotObtained	Blood Pressure Systolic 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"
Temperature	Temperature	The numeric value of a person's body temperature.	Numeric

Variable	Label	Description	Format Text
TemperatureNotObtained	Temperature 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"
TemperatureUnits	Temperature Units	The Unified Code for Units of Measure symbols that represent a determinate amount or quantity used as the standard of measurement for the property of a body or region of space that determines whether or not there will be a net flow of heat into it or out of it from a neighboring body or region and in which direction (if any) the heat will flow, perceptible by living organism as a somatic sensation of cold or heat an individual person.	"C"="C" "F"="F"
Weight	Weight	The number that describes the vertical force exerted by the mass of an individual as a result of gravity.	Numeric
WeightNotObtained	Weight 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"
WeightUnits	Weight Units	The Unified Code for Units of Measure symbols that represent a determinate amount or quantity used as the standard of measurement for the vertical force exerted by the mass of an individual as a result of gravity.	"kg"="kg" "lb"="lb"