UWI2016-07-01 - Physical Examination (Dataset 1) Data Dictionary

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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_Physical_Exam V3"="CP_DCP_Physical_Exam V3"
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		"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	"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)

Class	Variable	Label	Description	Format Text
01. Principal	**BloodPressureDiastolic**	Blood Pressure Diastolic	The pressure of the blood against the artery walls during diastole (the relaxation phase).	Numeric
01. Principal	**BloodPressureDiastolic_UNITS**	Blood Pressure Diastolic Units		"mmHg"="mmHg"
01. Principal	**BloodPressureSystolic**	Blood Pressure Systolic	The pressure of the blood against the artery walls during systole (the contraction phase).	Numeric
01. Principal	**BloodPressureSystolic_UNITS**	Blood Pressure Systolic Units		"mmHg"="mmHg"
01. Principal	**bodysystemsexamined**	Were Body Systems Examined?	The yes/no indicator whether a physical examination has been performed.	"No"="No" "Yes"="Yes"
01. Principal	**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"
01. Principal	**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"
01. Principal	**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"
01. Principal	**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"

Class	Variable	Label	Description	Format Text
01. Principal	**ExaminationDate**	Examination Date	The date of the evaluation, procedure or visit that yielded data.	SAS Date
01. Principal	**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"
01. Principal	**Height**	Height	The number that describes the vertical distance of an individual.	Numeric
01. Principal	**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"
01. Principal	**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"
01. Principal	**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"
01. Principal	**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
01. Principal	**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

Class	Variable	Label	Description	Format Text
01. Principal	**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"
01. Principal	**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"
01. Principal	**Temperature**	Temperature	The numeric value of a person's body temperature.	Numeric
01. Principal	**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"
01. Principal	**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"
01. Principal	**Weight**	Weight	The number that describes the vertical force exerted by the mass of an individual as a result of gravity.	Numeric
01. Principal	**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"

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Class	Variable	Label	Description	Format Text
01. Principal	**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"