

UWI2016-07-01 - Baseline Symptoms Data Dictionary

TABLE OF CONTENTS

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

Document Summary

Property	Value
Document Title	UWI2016-07-01 - Baseline Symptoms: Data Dictionary
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UWI2016-07-01 - Baseline Symptoms: 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		Char
01. Principal	CYCLE	Cycle		Char
01. Principal	DAY_1	Day		Numeric
01. Principal	FORM	Form		"CP_DCP_Baseline_Symptoms V2"="CP_DCP_Baseline_Symptoms 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.	"UW12016-07-01"="UW12016-07-01"
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		"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"

Section 3: Baseline Symptoms

Class	Variable	Label	Description	Format Text
01. Principal	baselinesymptoms	Did Participant Have Any Baseline Symptoms?	The indicator representing that the participant has no baseline symptoms.	"Yes"="Yes"
01. Principal	CommentsBaselineSymptoms	Comments	The free text field for general notes.	Char
01. Principal	CTCAEGrade	Symptom Grade	Grade of severity of symptoms	"1-Mild"="1-Mild" "2-Moderate"="2-Moderate"
01. Principal	MDS_CTCAETerm	CTCAE Term	Text that represents the Common Terminology Criteria for Adverse Events low level term name for an adverse event.	"Cough"="Cough" "Gastroesophageal reflux disease"="Gastroesophageal reflux disease" "Hypertension"="Hypertension" "Oral pain"="Oral pain" "Postnasal drip"="Postnasal drip" "Sore throat"="Sore throat"
01. Principal	MDS_MedDRASystemOrganClass	MedDRA System Organ Class (SOC)	Text term to represent the highest level of a terminology distinguished by anatomical or physiological system, etiology, or purpose, and referencing an international medical terminology (Medical Dictionary for Regulatory Activities) version 12.0, designed to support the classification, retrieval, presentation, and communication of medical information throughout the medical product regulatory cycle.	"Gastrointestinal disorders"="Gastrointestinal disorders" "Respiratory, thoracic and mediastinal disorders"="Respiratory, thoracic and mediastinal disorders" "Vascular disorders"="Vascular disorders"
01. Principal	Ongoing	Ongoing?	The indicator used to represent continuation of a medical event or symptom experienced by a person.	"No"="No" "Yes"="Yes"
01. Principal	OnsetDate	Onset Date	The date the symptom was first observed or experienced.	SAS Date
01. Principal	OnsetDate_EXT	Onset Date Ext		"Day"="Day" "Month"="Month" "Unknown"="Unknown" "Year"="Year"
01. Principal	StopDate	Stop Date	The date the symptom was no longer observed or experienced.	SAS Date
01. Principal	StopDate_EXT	Stop Date Ext		"Day"="Day"

Class	Variable	Label	Description	Format Text
01. Principal	SymptomDescriptionVerbatim	Symptom Description (Verbatim Term)	The text that succinctly describes the symptom/adverse event.	Char