UWI2016-08-01 - Baseline Symptoms Data Dictionary

TABLE OF CONTENTS

Document Summary

Property	Value
Document Title	UWI2016-08-01 - Baseline Symptoms: Data Dictionary
Date Created	01/06/2025
Sections	3
Entries	14
Document Filename	dictionary_bsymptoms.rtf

UWI2016-08-01 - Baseline Symptoms: Data Dictionary

Section 1: Identifiers

Class	Variable	Label	Description	Format Text
01. Principal	**Sequence_No_**	Participant ID		Char

Section 2: Study-wide

Class	Variable	Label	Description	Format Text
01. Principal	**DCP_Protocol_Number**	DCP Protocol Number		"UWI2016-08-01"="UWI2016-08-01"
01. Principal	**Registering_Institution**	Registering Institution		"AL002"="AL002" "MN022"="MN022" "WI020"="WI020"

Section 3: Baseline Symptoms

Class	Variable	Label	Description	Format Text
01. Principal	**Comments**	Comments		Char
01. Principal	**CTCAE_Term**	CTCAE Term (v4.0)		"Abdominal distension"="Abdominal distension" "Abdominal pain"="Abdominal pain" "Arthralgia"="Arthralgia" "Arthritis"="Arthritis" "Back pain"="Back pain" "Constipation"="Constipation" "Cough"="Cough" "Depression"="Depression" "Dry skin"="Dry skin" "Dysmenorrhea"="Dysmenorrhea" "Dyspepsia"="Dyspepsia" "Edema limbs"="Edema limbs" "Fatigue"="Fatigue" "Gastroesophageal reflux disease"="Gastroesophageal reflux disease" "Headache"="Headache" "Hemorrhoidal hemorrhage"="Hemorrhoidal hemorrhage" "Hot flashes"="Hot flashes" "Hypertension"="Hypertension" "Insomnia"="Insomnia" "Investigations - Other, specify"="Investigations - Other, specify" "Joint effusion"="Joint effusion" "Myalgia"="Myalgia" "Nausea"="Nausea" "Neck pain"="Neck pain" "Pain in extremity"="Pain in extremity" "Pain"="Pain" "Pelvic pain"="Pelvic pain" "Reproductive system and breast disorders - Other, specify"="Reproductive system and breast disorders - Other, specify" "Urinary frequency"="Urinary frequency" "Urinary incontinence"="Urinary incontinence" "Urinary urgency"="Urinary urgency" "Uterine hemorrhage"="Uterine hemorrhage" "Vaginal discharge"="Vaginal discharge" [continued...]

Class	Variable	Label	Description	Format Text
01. Principal	**[...continued]** **CTCAE_Term**			[...continued] "Vaginal hemorrhage"="Vaginal hemorrhage"
01. Principal	**Did_participant_ have_any_Baseli n**	Did Participant Have Any Baseline Symptoms?		"No"="No" "Yes"="Yes"
01. Principal	**MedDRA_System _Organ_Class__ SOC_**	MedDRA System Organ Class (SOC) (V12.0)		"Gastrointestinal disorders"="Gastrointestinal disorders" "General disorders and administration site conditions"="General disorders and administration site conditions" "Investigations"="Investigations" "Musculoskeletal and connective tissue disorders"="Musculoskeletal and connective tissue disorders" "Nervous system disorders"="Nervous system disorders" "Psychiatric disorders"="Psychiatric disorders" "Renal and urinary disorders"="Renal and urinary disorders" "Reproductive system and breast disorders"="Reproductive system and breast disorders" "Respiratory, thoracic and mediastinal disorders"="Respiratory, thoracic and mediastinal disorders" "Skin and subcutaneous tissue disorders"="Skin and subcutaneous tissue disorders" "Vascular disorders"="Vascular disorders"
01. Principal	**Ongoing_**	Ongoing		"No"="No" "Yes"="Yes"
01. Principal	**Onset_Date**	Onset Date		SAS Date
01. Principal	**Onset_Date_Ext**	Onset Date (Accuracy)		"Day"="Day" "Month"="Month" "Unknown"="Unknown" "Year"="Year"
01. Principal	**Stop_Date**	Stop Date		SAS Date
01. Principal	**Symptom_Descri ption__Verbatim_ Te**	Symptom Description (Verbatim Term)		Char
01. Principal	**Symptom_Grade**	Symptom Grade		"1"="Mild Adverse Event" "2"="Moderate Adverse Event" "3"="Severe Adverse Event" "No Symptom"="No Symptom" "Ungradeable"="Ungradeable"

UWI2016-08-01 - Baseline Symptoms: Data Dictionary
01/06/2025

Class	Variable	Label	Description	Format Text
01. Principal	**Visit_Type**	Visit Type		"1 Day prior to Surgery"="1 Day prior to Surgery" "Baseline"="Baseline" "Day 1"="Day 1" "Day 15 telephone contact"="Day 15 telephone contact" "Day 15"="Day 15" "Day of Surgery"="Day of Surgery" "Surgery Visit"="Surgery Visit"