

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 |
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UWI2016-07-01 - Baseline Symptoms: 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 | | Char |
| CYCLE | Cycle | | Char |
| DAY_1 | Day | | Numeric |
| FORM | Form | | "CP_DCP_Baseline_Symptoms V2"="CP_DCP_Baseline_Symptoms 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 | | "Not Applicable"="Not Applicable" |
| PHASE | Phase | | "Treatment"="Treatment" |
| SEGMENT | Segment | | "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" |

Section 3: Baseline Symptoms

| Variable | Label | Description | Format Text |
|-----------------------------------|---|---|--|
| baselinesymptoms | Did Participant Have Any Baseline Symptoms? | The indicator representing that the participant has no baseline symptoms. | "Yes"="Yes" |
| CommentsBaselineSymptoms | Comments | The free text field for general notes. | Char |
| CTCAEGrade | Symptom Grade | Grade of severity of symptoms | "1-Mild"="1-Mild" "2-Moderate"="2-Moderate" |
| 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" |
| 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" |
| Ongoing | Ongoing? | The indicator used to represent continuation of a medical event or symptom experienced by a person. | "No"="No" "Yes"="Yes" |
| OnsetDate | Onset Date | The date the symptom was first observed or experienced. | SAS Date |
| OnsetDate_EXT | Onset Date Ext | | "Day"="Day" "Month"="Month" "Unknown"="Unknown" "Year"="Year" |
| StopDate | Stop Date | The date the symptom was no longer observed or experienced. | SAS Date |
| StopDate_EXT | Stop Date Ext | | "Day"="Day" |
| SymptomDescriptionVerbatim | Symptom Description (Verbatim Term) | The text that succinctly describes the symptom/adverse event. | Char |