# UWI2016-07-01 - Randomization Data Dictionary

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# UWI2016-07-01 - Randomization: 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 | | "ACTOplus XR/Placebo"="ACTOplus XR/Placebo" |
| 01. Principal | **CYCLE** | Cycle | | Char |
| 01. Principal | **DAY_1** | Day | | Numeric |
| 01. Principal | **FORM** | Form | | "CP_DCP_Randomization V1"="CP_DCP_Randomization V1" |
| 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 | | Char |
| 01. Principal | **PHASE** | Phase | | "Treatment"="Treatment" |
| 01. Principal | **SEGMENT** | Segment | | "Randomization"="Randomization" |
| 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 (i.e., baseline, Month 1, etc.) | "Randomization"="Randomization" |

# Section 3: Randomization

| Class | Variable | Label | Description | Format Text |
|---|---|---|---|---|
| 01. Principal | **EndWashOutDateNotApplicab** | End Wash Out Date Not Applicable | The indicator that represents that a specific test, exam, or specimen was not obtained, not examined, not applicable, unknown or not required, etc. | "Not Applicable"="Not Applicable" |
| 01. Principal | **FormNotApplicable** | Form Not Applicable? | The check box that represents that a form or section of a form is not filled out or nothing was reported/examined. | Char |
| 01. Principal | **MDS_RandomDate** | Randomization Date | Date of a process used in therapeutic trials or other research endeavors for allocating experimental subjects, human or animal, between treatment and control groups, or among treatment groups. | SAS Date |
| 01. Principal | **RandomizationNumber** | Randomization Number | The number given to participants and are randomized to a study to code them to the control or treatment groups. | Numeric |
| 01. Principal | **WashoutDateEnded** | Washout Date Ended | The start date of the washout or waiting period. | Char |
| 01. Principal | **WashOutDateNotApplicable** | Start Wash Out Date Not Applicable | The indicator that represents that a specific test, exam, or specimen was not obtained, not examined, not applicable, unknown or not required, etc. | "Not Applicable"="Not Applicable" |
| 01. Principal | **WashoutDateStarted** | Washout Date Started | The start date of the washout or waiting period. | Char |