

# UWI2016-07-01 - Specimen Information (Blood) Data Dictionary

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## Document Summary

| Property          | Value                                                         |
|-------------------|---------------------------------------------------------------|
| Document Title    | UWI2016-07-01 - Specimen Information (Blood): Data Dictionary |
| Date Created      | 01/02/2026                                                    |
| Sections          | 3                                                             |
| Entries           | 24                                                            |
| Document Filename | dictionary_spec_bld.rtf                                       |

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## UWI2016-07-01 - Specimen Information (Blood): Data Dictionary

### Section 1: Identifiers

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| Class         | Variable            | Label      | Description | Format Text |
|---------------|---------------------|------------|-------------|-------------|
| 01. Principal | <b>SEQUENCE_NO_</b> | Patient ID |             | Numeric     |

## Section 2: Study-wide

| Class         | Variable                           | Label                     | Description                                                                                                       | Format Text                                                                                                                                                     |
|---------------|------------------------------------|---------------------------|-------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 01. Principal | <b>ARM</b>                         | Arm                       |                                                                                                                   | "ACTOplus XR/Placebo"="ACTOplus XR/Placebo"                                                                                                                     |
| 01. Principal | <b>CYCLE</b>                       | Cycle                     |                                                                                                                   | Char                                                                                                                                                            |
| 01. Principal | <b>DAY_1</b>                       | Day                       |                                                                                                                   | Numeric                                                                                                                                                         |
| 01. Principal | <b>FORM</b>                        | Form                      |                                                                                                                   | "CP_DCP_Specimen_Acquistion_Blood V2"="CP_DCP_Specimen_Acquistion_Blood V2"                                                                                     |
| 01. Principal | <b>FORM_DESC_</b>                  | Form Description          |                                                                                                                   | "Built for UW16110"="Built for UW16110"                                                                                                                         |
| 01. Principal | <b>FORM_STATUS</b>                 | Form Status               |                                                                                                                   | "Amended"="Amended"<br>"Completed"="Completed"                                                                                                                  |
| 01. Principal | <b>LEVEL</b>                       | Level                     |                                                                                                                   | Char                                                                                                                                                            |
| 01. Principal | <b>MDS_DCPProtocolNumber</b>       | 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 | <b>MDS_Registering Institution</b> | Registering Institution   | Code that uniquely identifies the institution where the research participant was registered in the clinical trial | "MD017"="MD017"<br>"MN022"="MN022"<br>"WI020"="WI020"                                                                                                           |
| 01. Principal | <b>NOT_APPLICABLE_OR_MISSING</b>   | Not Applicable Or Missing |                                                                                                                   | "Not Applicable"="Not Applicable"                                                                                                                               |
| 01. Principal | <b>PHASE</b>                       | Phase                     |                                                                                                                   | "Treatment"="Treatment"                                                                                                                                         |
| 01. Principal | <b>SEGMENT</b>                     | Segment                   |                                                                                                                   | "Day 15-22 (max day 26)"="Day 15-22 (max day 26)"<br>"Final Dosing Reminder Call"="Final Dosing Reminder Call"<br>"Screening/Baseline"="Screening/Baseline"     |
| 01. Principal | <b>VISIT_DATE</b>                  | Visit Date                |                                                                                                                   | SAS Date                                                                                                                                                        |
| 01. Principal | <b>VisitType</b>                   | Visit Type                | The visit at which the data reported on the form was collected (i.e., baseline, Month 1, etc.)                    | "Baseline"="Baseline"<br>"Day 11-22 or Early Termination"="Day 11-22 or Early Termination"<br>"Day 15-22 or Early Termination"="Day 15-22 or Early Termination" |

## Section 3: Specimen Information (Blood)

| Class         | Variable                        | Label                       | Description                                                                                                                                         | Format Text                   |
|---------------|---------------------------------|-----------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------|
| 01. Principal | <b>CommentsSpecAcqBlood</b>     | Comments                    | The free text field for general notes.                                                                                                              | Char                          |
| 01. Principal | <b>DateLastStudyAgentTaken</b>  | Date Last Study Agent Taken | The last date the participant took study agent.                                                                                                     | SAS Date                      |
| 01. Principal | <b>DateSpecimenCollected</b>    | Date Specimen Collected     | The date when the sample (specimen) was collected.                                                                                                  | SAS Date                      |
| 01. Principal | <b>NotObtained</b>              | 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 | <b>SpecimenShippingDate</b>     | Specimen Shipping Date      | The date on which the specimen for pharmacokinetic or other correlative study was transported from one location to another.                         | SAS Date                      |
| 01. Principal | <b>StorageTemperature</b>       | Storage Temperature         | The temperature at which the specimen was stored expressed in degrees Celsius.                                                                      | Numeric                       |
| 01. Principal | <b>StorageTemperature_UNITS</b> | Storage Temperature Units   |                                                                                                                                                     | "C"="C"                       |
| 01. Principal | <b>TimeLastStudyAgentTaken</b>  | Time Last Study Agent Taken | The time the participant finished taking the agent for the specified visit period.                                                                  | Numeric                       |
| 01. Principal | <b>TimeSpecimenCollected</b>    | Time Specimen Collected     | The time at which a specimen was collected.                                                                                                         | Numeric                       |