

UWI2013-00-01 - OFF STUDY: DATA DICTIONARY

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Document Summary

| Property | Value |
|-------------------|--|
| Document Title | UWI2013-00-01 - Off Study: Data Dictionary |
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UWI2013-00-01 - Off Study: 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 | | "POMx 1000mg/Placebo daily"="POMx 1000mg/Placebo daily" |
| Cycle | Cycle | | Char, 1 |
| Day | Day | | Numeric |
| Form | Form | | "CP DCP OffStudy V1"="CP DCP OffStudy V1" |
| Form_Desc_ | Form Description | | "CP DCP Off Study"="CP DCP Off Study" |
| Form_Status | Form Status | | "Completed"="Completed" |
| Institution_Code | Institution Code | | "MA017"="MA017" "MN022"="MN022" "TX273"="TX273" "WI020"="WI020" |
| Level | Level | | Char, 1 |
| Not_Applicable_or_Missing | Not Applicable Or Missing | | Char, 1 |
| Phase | Phase | | "Treatment"="Treatment" |
| Segment | Segment | | "Baseline"="Baseline" "End of Study"="End of Study" "Randomization"="Randomization" |
| Visit_Date | Visit Date | | SAS Date |

Section 3: Off Study

| Variable | Label | Description | Format Text |
|-------------------------------|------------------------------|-------------|---|
| Agent_End_Date | Agent End Date | | SAS Date .="Missing" |
| Agent_End_Date_Ext | Agent End Date Extension | | "Day"="Day" |
| Date_of_Last_Contact | Date of Last Contact | | SAS Date |
| Date_Off_Follow_up | Date Off Follow-up | | Char, 1 |
| Date_Off_Follow_up_Ext | Date Off Follow-up Extension | | "Not Applicable"="Not Applicable" |
| Date_On_Follow_up | Date On Follow-up | | Char, 1 |
| Date_On_Follow_up_Ext | Date On Follow-up Extension | | "Not Applicable"="Not Applicable" |
| Form_Date | Form Date | | SAS Date |
| Off_Study_Date | Off Study Date | | SAS Date |
| Reason_Explanation | Reason Explanation | | Char, 308 |
| Reason_Off_Study | Reason Off Study | | "Ineligible"="Ineligible" "Participant Withdrawal"="Participant Withdrawal" "Study Complete"="Study Complete" |