

UWI2013-00-01 - EXCLUSION CRITERIA: DATA DICTIONARY

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Document Summary

| Property | Value |
|-------------------|---|
| Document Title | UWI2013-00-01 - Exclusion Criteria: Data Dictionary |
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| Sections | 3 |
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UWI2013-00-01 - Exclusion Criteria: 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, 1 |
| Cycle | Cycle | | Char, 1 |
| Day | Day | | Numeric |
| Form | Form | | "CP DCP ExclusionCriteria(CO11378) V2"="CP DCP ExclusionCriteria(CO11378) V2" |
| Form_Desc_ | Form Description | | "CP DCP ExclusionCriteria(CO11378)"="CP DCP ExclusionCriteria(CO11378)" |
| Form_Status | Form Status | | "Amended"="Amended" "Completed"="Completed" "Validated"="Validated" |
| Institution_Code | Institution Code | | "MA017"="MA017" "MN022"="MN022" "TX273"="TX273" "UWI"="UWI" "WI020"="WI020" |
| Level | Level | | Char, 1 |
| Not_Applicable_or_Missing | Not Applicable Or Missing | | Char, 1 |
| Phase | Phase | | "Treatment"="Treatment" |
| Segment | Segment | | "Baseline"="Baseline" |
| Visit_Date | Visit Date | | SAS Date |
| Visit_Type | Visit Type | | "Baseline"="Baseline" |

Section 3: Exclusion Criteria

| Variable | Label | Description | Format Text |
|---|--|-------------|--------------------------|
| Any_significant_cardiac_event_s | Any Significant Cardiac Event(s) Within The 12 Months Prior To Registration | | "No"="No" |
| Participant_has_a_history_of_all | Participant Has A History Of Allergic Reaction Attributed To Compounds Of Similar Chemical Or Biologic Composition To Pomegranate Fruit Extract | | "No"="No" |
| Participant_has_evidence_of_othe | Participant Has Evidence Of Other Cancer(S) (Excluding Non-Melanoma Skin Cancer) Within The Past 5 Years. | | "No"="No" |
| Participant_has_had_pelvic_radi | Participant Has Had Prior Pelvic Radiation, For Any Reason. | | "No"="No" |
| Participant_has_had_surgery_to_t | The Participant Has Had Surgery To The Prostate Within 30 Days Of Baseline Procedures (Biopsies Are Not Considered Surgeries). | | "No"="No" |
| Participant_has_uncontrolled_in | Participant Has Uncontrolled Intercurrent Illness. | | "No"="No" "Yes"="Yes" |
| Participant_is_receiving_other_i | Participant Is Receiving Other Investigational Agents | | "No"="No" |
| Participant_is_taking_carbamazep | Participant Is Taking Carbamazepine | | "No"="No" |
| Participant_is_taking_or_is_plan | Participant Is Taking Or Is Planning To Take 5-A-Reductase Inhibitors Or Has Taken 5-A-Reducatase Inhibitors Within 6 Months Of The Pre-Study Prostate Biopsy. | | "No"="No" |