

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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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) V1"="CP DCP ExclusionCriteria(CO11378) V1"
Form_Desc_	Form Description		"CP DCP ExclusionCriteria(CO11378)"="CP DCP ExclusionCriteria(CO11378)"
Form_Status	Form Status		"Completed"="Completed"
Institution_Code	Institution Code		"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"
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"
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_NSAIDs_on	Participant Is Taking Nsaids On A Regularly Scheduled Basis, Except For Cardioprotective Aspirin (81 Mg). Participants May Take Acetaminophen For Pain.		"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-Reducataase Inhibitors Within 6 Months Of The Pre-Study Prostate Biopsy.		"No"="No"