

UWI2013-00-01 - INCLUSION CRITERIA: DATA DICTIONARY

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Document Summary

Property	Value
Document Title	UWI2013-00-01 - Inclusion Criteria: Data Dictionary
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UWI2013-00-01 - Inclusion 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 InclusionCriteria(CO11378) V2"="CP DCP InclusionCriteria(CO11378) V2"
Form_Desc_	Form Description		"CP DCP InclusionCriteria(CO11378)"="CP DCP InclusionCriteria(CO11378)"
Form_Status	Form Status		"Completed"="Completed" "Validated"="Validated"
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"
Visit_Date	Visit Date		SAS Date
Visit_Type	Visit Type		"Baseline"="Baseline" "Randomization"="Randomization"

Section 3: Inclusion Criteria

Variable	Label	Description	Format Text
Participant_is_21_years_of_a	Participant Is >= 21 Years Of Age.		"Yes"="Yes"
Participant_is_not_planning_on	Participant Is Not Planning On Receiving Concurrent Treatment (Hormonal, Radiation Or Systemic Chemotherapy) For Prostate Cancer During The Study Period.		"No"="No" "Yes"="Yes"
The_participant_agrees_to_foreg	The Participant Agrees To Forego Foods, Beverages And Supplements Containing Pomegranate For The Duration Of The Study.		"Yes"="Yes"
The_participant_agrees_to_use_a	The Participant Agrees To Use A Medically-Approved Method Of Birth Control Or Abstinence If His Sexual Partner Is Of Child-Bearing Potential.		"N/A"="N/A" "Yes"="Yes"
The_participant_has_an ECOG_perf	The Participant Has An Ecog Performance Status Of < Or = 1.		"Yes"="Yes"
The_participant_has_normal_orga	The Participant Has Normal Organ And Marrow Function As Follows: WBC > 3,000/mm ³ AST < 1.5 x ULN Platelets >100,000/mm ³ ALT < 1.5 x ULN Hemoglobin > 10g/dL Serum Creatinine within 1.5 x ULN Total Bilirubin < 1.5 x ULN Sodium 135-144 mmol/L (Inclusive) Alka		"No"="No" "Yes"="Yes"
The_participant_is_able_to_unde	The Participant Is Able To Understand, And Willing To Sign, A Written Informed Consent Document.		"Yes"="Yes"
The_participant_must_be_male_an	The Participant Must Be Male And Has Either: A) Had A Prostate Biopsy Within 3 Months Of The Baseline Visit, And Has Been Diagnosed With Low-Grade, Clinically Localized Prostate Cancer, With A Gleason Score Of < Or = 3 + 3, And A PSA < Or = 10ng/ml In Men		"No"="No" "Yes"="Yes"