

# UWI2013-00-01 - INCLUSION CRITERIA: DATA DICTIONARY

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## Document Summary

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## UWI2013-00-01 - Inclusion Criteria: Data Dictionary

### Section 1: Identifiers

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Variable	Label	Description	Format Text
<b>Sequence_No_</b>	Patient ID		Numeric

## Section 2: Study-wide

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Variable	Label	Description	Format Text
<b>Arm</b>	Arm		Char, 1
<b>Cycle</b>	Cycle		Char, 1
<b>Day</b>	Day		Numeric
<b>Form</b>	Form		"CP DCP InclusionCriteria(CO11378) V1"="CP DCP InclusionCriteria(CO11378) V1"
<b>Form_Desc_</b>	Form Description		"CP DCP InclusionCriteria(CO11378)"="CP DCP InclusionCriteria(CO11378)"
<b>Form_Status</b>	Form Status		"Completed"="Completed"
<b>Institution_Code</b>	Institution Code		"MN022"="MN022" "TX273"="TX273" "WI020"="WI020"
<b>Level</b>	Level		Char, 1
<b>Not_Applicable_or_Missing</b>	Not Applicable Or Missing		Char, 1
<b>Phase</b>	Phase		"Treatment"="Treatment"
<b>Segment</b>	Segment		"Baseline"="Baseline"
<b>Visit_Date</b>	Visit Date		SAS Date
<b>Visit_Type</b>	Visit Type		"Baseline"="Baseline"

## Section 3: Inclusion Criteria

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Variable	Label	Description	Format Text
<b>Participant_is_21_years_of_a</b>	Participant is >= 21 years of age.		"Yes"="Yes"
<b>Participant_is_not_planning_on</b>	Participant Is Not Planning On Receiving Concurrent Treatment (Hormonal, Radiation Or Systemic Chemotherapy) For Prostate Cancer During The Study Period.		"Yes"="Yes"
<b>The_participant_agrees_to_forego</b>	The Participant Agrees To Forego Foods, Beverages And Supplements Containing Pomegranate For The Duration Of The Study.		"Yes"="Yes"
<b>The_participant_agrees_to_use_a</b>	The Participant Agrees To Use A Medically-Approved Method Of Birth Control Or Abstinence If His Sexual Partner Is Of Child-Bearing Potential.		"Yes"="Yes"
<b>The_participant_has_an ECOG_perf</b>	The Participant Has An Ecog Performance Status Of < Or = 1.		"Yes"="Yes"
<b>The_participant_has_normal_organ</b>	The Participant Has Normal Organ And Marrow Function As Follows: WBC > 3,000/mm <sup>3</sup> AST < 1.5 x ULN Platelets >100,000/mm <sup>3</sup> 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		"Yes"="Yes"
<b>The_participant_is_able_to_understand</b>	The Participant Is Able To Understand, And Willing To Sign, A Written Informed Consent Document.		"Yes"="Yes"
<b>The_participant_must_be_male_and</b>	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		"Yes"="Yes"