

UWI2016-07-01 - INCLUSION (DATASET 2): DATA DICTIONARY

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Document Summary

Property	Value
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UWI2016-07-01 - Inclusion (Dataset 2): 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
CYCLE	Cycle		Char
DAY_1	Day		Numeric
FORM	Form		"CP_DCP_Inclusion_Criteria V2"="CP_DCP_Inclusion_Criteria V2"
FORM_DESC_	Form Description		"Built for UW16110"="Built for UW16110"
FORM_STATUS	Form Status		"Completed"="Completed"
LEVEL	Level		Char
MDS_DCPProtocolNumber	DCP Protocol Number	Unique alphanumeric identifier assigned to a protocol by the National Cancer Institute for reporting of data.	"UWI2016-07-01"="UWI2016-07-01"
MDS_RegisteringInstitution	Registering Institution	Code that uniquely identifies the institution where the research participant was registered in the clinical trial	"MD017"="MD017" "MN022"="MN022" "WI020"="WI020"
NOT_APPLICABLE_OR_MISSING	Not Applicable Or Missing		"Not Applicable"="Not Applicable"
PHASE	Phase		"Treatment"="Treatment"
SEGMENT	Segment		"Screening/Baseline"="Screening/Baseline"
VISIT_DATE	Visit Date		SAS Date

Section 3: Inclusion (Dataset 2)

Variable	Label	Description	Format Text
Abilitytounderstand4115	4.1.13 Ability To Understand And The Willingness To Sign A Written Informed Consent Document.	The complete text of an individual question/criterion on the eligibility checklist of a protocol with a response of Yes, No, N/A to each item.	"Yes"="Yes"
abletocomplete14daysdosing413	4.1.3 Participant Is Able To Complete A Minimum Of 14 Days Of Study Agent Dosing Prior To Initiation Of Definitive Treatment For Their Cancer.	The complete text of an individual question/criterion on the eligibility checklist of a protocol with a response of Yes, No, N/A to each item.	"Yes"="Yes"
accessibletobiopsy412	4.1.2 The Participant's Primary Tumor Is Accessible To Tissue Sample Collection In The Outpatient Clinic Setting And The Participant Is Willing To Have Baseline And End Of Study (Day 15-26) 4 mm Samples Of Tumor And Adjacent Visually Normal Appearing...	The complete text of an individual question/criterion on the eligibility checklist of a protocol with a response of Yes, No, N/A to each item.	"Yes"="Yes"
Age18years417	4.1.5 Age >= 18 Years	The complete text of an individual question/criterion on the eligibility checklist of a protocol with a response of Yes, No, N/A to each item.	"Yes"="Yes"
ALTSGPTwithinnorm4111	4.1.9 ALT (SGPT) ≤ Within 1.2 x Institutional Upper Limit Of Normal.	The complete text of an individual question/criterion on the eligibility checklist of a protocol with a response of Yes, No, N/A to each item.	"Yes"="Yes"
ASTSGOTwithinnorm4111	4.1.9 AST (SGOT) ≤ Within 1.2 x Institutional Upper Limit Of Normal.	The complete text of an individual question/criterion on the eligibility checklist of a protocol with a response of Yes, No, N/A to each item.	"Yes"="Yes"
BodymassindexBMI4110	4.1.8 Body Mass Index (BMI) Is >= 18.5.	The complete text of an individual question/criterion on the eligibility checklist of a protocol with a response of Yes, No, N/A to each item.	"Yes"="Yes"
COGperformancestatus0or1_418	4.1.6 ECOG Performance Status = 0 Or 1	The complete text of an individual question/criterion on the eligibility checklist of a protocol with a response of Yes, No, N/A to each item.	"Yes"="Yes"

Variable	Label	Description	Format Text
contraception4114	4.1.12 Participant Of Childbearing Potential Agrees To Use Adequate Contraception (A Hormonal Method That Has Been In Continual Use For A Minimum Of 3 Months Prior To The Study Screening Visit, A Barrier Method, Or Abstinence) For The Duration Of Their...	The complete text of an individual question/criterion on the eligibility checklist of a protocol with a response of Yes, No, N/A to each item.	"N/A"="N/A"
eGFR45mLminperm in4111	4.1.9 eGFR >45 mL/min	The complete text of an individual question/criterion on the eligibility checklist of a protocol with a response of Yes, No, N/A to each item.	"Yes"="Yes"
endofstudybiopsy41 4	4.1.4 Participant Is Scheduled For An End Of Study Biopsy Within 22 Days Of Starting Study Agent And Within 52 Days Of Their Study Screening Visit.	The complete text of an individual question/criterion on the eligibility checklist of a protocol with a response of Yes, No, N/A to each item.	"Yes"="Yes"
Glucoseserum200_4 111	4.1.9 Glucose, Serum < 200 mg/dL	The complete text of an individual question/criterion on the eligibility checklist of a protocol with a response of Yes, No, N/A to each item.	"Yes"="Yes"
Hemoglobin10gdl41 11	4.1.9 Hemoglobin \neq 10 g/dl	The complete text of an individual question/criterion on the eligibility checklist of a protocol with a response of Yes, No, N/A to each item.	"Yes"="Yes"
Lifeexpectancyis6m os419	4.1.7 Life Expectancy Is > 6 Months.	The complete text of an individual question/criterion on the eligibility checklist of a protocol with a response of Yes, No, N/A to each item.	"Yes"="Yes"
MeetCriteria	Meet Criteria	The indicator that asks the investigator to stipulate whether the patient is eligible for inclusion on this protocol	"Yes"="Yes"
newlydiagnosed411	4.1.1 Participant Has A Newly Diagnosed, Histologically Confirmed, Stage I-IV Squamous Cell Carcinoma Or Squamous Cell Carcinoma In-Situ Of The Oral Cavity Or Oropharynx And Will Be Undergoing Definitive Surgical, Radiotherapy, Or Chemoradiation Treat...	The complete text of an individual question/criterion on the eligibility checklist of a protocol with a response of Yes, No, N/A to each item.	"Yes"="Yes"

Variable	Label	Description	Format Text
Participantduration4113	4.1.11 Participant Is Willing And Able To Participate For The Duration Of The Study.	The complete text of an individual question/criterion on the eligibility checklist of a protocol with a response of Yes, No, N/A to each item.	"Yes"="Yes"
Participantisabletoswallow4112	4.1.10 Participant Is Able To Swallow A Tablet Whole.	The complete text of an individual question/criterion on the eligibility checklist of a protocol with a response of Yes, No, N/A to each item.	"Yes"="Yes"
Platelets10000mic4111	4.1.9 Platelets >= 100,000/microliter	The complete text of an individual question/criterion on the eligibility checklist of a protocol with a response of Yes, No, N/A to each item.	"Yes"="Yes"
Totalbilirubin4111	4.1.9 Total Bilirubin \leq 1.2 x Institutional Upper Limit Of Normal (1.5 x Institutional Upper Limit Of Normal In Participants Diagnosed With Gilbert's Disease)	The complete text of an individual question/criterion on the eligibility checklist of a protocol with a response of Yes, No, N/A to each item.	"Yes"="Yes"
Whitebloodcells4111	4.1.9 White Blood Cells >= 3,000/microliter	The complete text of an individual question/criterion on the eligibility checklist of a protocol with a response of Yes, No, N/A to each item.	"Yes"="Yes"