UWI2016-07-01 - Inclusion (Dataset 3) Data Dictionary

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Section 1: Identifiers

Class	Variable	Label	Description	Format Text
01. Principal	**SEQUENCE_NO_**	Patient ID		Numeric

Section 2: Study-wide

Class	Variable	Label	Description	Format Text
01. Principal	**ARM**	Arm		Char
01. Principal	**CYCLE**	Cycle		Char
01. Principal	**DAY_1**	Day		Numeric
01. Principal	**FORM**	Form		"CP_DCP_Inclusion_Criteria V3"="CP_DCP_Inclusion_Criteria V3"
01. Principal	**FORM_DESC_**	Form Description		"Built for UW16110"="Built for UW16110"
01. Principal	**FORM_STATUS**	Form Status		"Completed"="Completed"
01. Principal	**LEVEL**	Level		Char
01. Principal	**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"
01. Principal	**MDS_Registering Institution**	Registering Institution	Code that uniquely identifies the institution where the research participant was registered in the clinical trial	"MN022"="MN022"
01. Principal	**NOT_APPLICABLE_OR_MISSING**	Not Applicable Or Missing		Char
01. Principal	**PHASE**	Phase		"Treatment"="Treatment"
01. Principal	**SEGMENT**	Segment		"Screening/Baseline"="Screening/Baseline"
01. Principal	**VISIT_DATE**	Visit Date		SAS Date

Section 3: Inclusion (Dataset 3)

Class	Variable	Label	Description	Format Text
01. Principal	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"
01. Principal	abletocomplete14daysdosing413	4.1.3 Participant Is Able To Complete A Minimum Of 10 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"
01. Principal	accessibletobiopsy412	4.1.2 The Participant's Primary Tumor Is Accessible For The Collection Of 4 mm Samples Of Tumor And Adjacent Visually Normal Appearing Tissue For Biomarker Analysis And The Participant Is Willing To Have These Samples Collected At Baseline And At The...	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"
01. Principal	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"
01. Principal	ALTSGPTwithinnorm4111	4.1.9 ALT (SGPT) â‰¤ 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"
01. Principal	ASTSGOTwithinnorm4111	4.1.9 AST (SGOT) â‰¤ 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"

Class	Variable	Label	Description	Format Text
01. Principal	**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"
01. Principal	**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"
01. Principal	**contraception41144**	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"
01. Principal	**eGFR45mLminpermin4111**	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"
01. Principal	**endofstudybiopsy414**	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"
01. Principal	**Glucoseserum200_4111**	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"
01. Principal	**Hemoglobin10gdl4111**	4.1.9 Hemoglobin â‰¥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"

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Class	Variable	Label	Description	Format Text
01. Principal	**Lifeexpectancyis6mos419**	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"
01. Principal	**MeetCriteria**	Meet Criteria	The indicator that asks the investigator to stipulate whether the patient is eligible for inclusion on this protocol	"Yes"="Yes"
01. Principal	**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"
01. Principal	**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"
01. Principal	**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"
01. Principal	**Platelets100000mic4111**	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"
01. Principal	**Totalbilirubin41111**	4.1.9 Total Bilirubin â‰¤ 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"

Class	Variable	Label	Description	Format Text
01. Principal	**Whitebloodcells4 111**	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"