

UWI2016-07-01 - Inclusion (Dataset 2) Data Dictionary

TABLE OF CONTENTS

Document Summary.....	2
UWI2016-07-01 - Inclusion (Dataset 2): Data Dictionary	3
Section 1: Identifiers	3
Section 2: Study-wide	4
Section 3: Inclusion (Dataset 2)	5

Document Summary

Property	Value
Document Title	UWI2016-07-01 - Inclusion (Dataset 2): Data Dictionary
Date Created	01/02/2026
Sections	3
Entries	35
Document Filename	dictionary_inclusion2.rtf

UWI2016-07-01 - Inclusion (Dataset 2): Data Dictionary

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 V2"="CP_DCP_Inclusion_Criteria V2"
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.	"UW12016-07-01"="UW12016-07-01"
01. Principal	MDS_Registering Institution	Registering Institution	Code that uniquely identifies the institution where the research participant was registered in the clinical trial	"MD017"="MD017" "MN022"="MN022" "WI020"="WI020"
01. Principal	NOT_APPLICABLE_OR_MISSING	Not Applicable Or Missing		"Not Applicable"="Not Applicable"
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 2)

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 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"
01. Principal	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"
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	ALTSGPTwithinnormal4111	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"
01. Principal	ASTSGOTwithinnormal4111	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"

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	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"
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 ≥ 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"

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	Totalbilirubin4111	4.1.9 Total Bilirubin ≤ 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	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"