UWI2016-07-01 - Inclusion (Dataset 1) Data Dictionary

TABLE OF CONTENTS

Document Summary

Property	Value
Document Title	UWI2016-07-01 - Inclusion (Dataset 1): Data Dictionary
Date Created	01/02/2026
Sections	3
Entries	35
Document Filename	dictionary_inclusion1.rtf

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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 V1"="CP_DCP_Inclusion_Criteria V1"
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		"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 1)

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 Biopsy In The Outpatient Clinic Setting And The Participant Is Willing To Have Baseline And End Of Study (Day 15-26) 4 mm Punch Biopsies Of Tumor And Adjacent Visually Normal Appearing Tissue Obtained	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) Within Normal Institutional Limits	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) Within Normal Institutional Limits	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	**contraception41114**	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 Per Cockcroft-Gault	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 Of The Oral Cavity Or Oropharynx And Will Be Undergoing Definitive Surgical, Radiotherapy, Or Chemoradiation Treatment. Or Participant Has A Lesion...	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 Within Normal Institutional Limits (Or 1.5 x Institutional Upper Limit Of Normal If Participant Is 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"