

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

TABLE OF CONTENTS

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

Document Summary

Property	Value
Document Title	UWI2016-07-01 - Exclusion (Dataset 2): Data Dictionary
Date Created	07/10/2020
Sections	3
Entries	37
Document Filename	dictionary_exclusion2.rtf

UWI2016-07-01 - Exclusion (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_Exclusion_Criteria V3"="CP_DCP_Exclusion_Criteria V3"
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	"MN022"="MN022"
NOT_APPLICABLE_OR_MISSING	Not Applicable Or Missing		Char
PHASE	Phase		"Treatment"="Treatment"
SEGMENT	Segment		"Screening/Baseline"="Screening/Baseline"
VISIT_DATE	Visit Date		SAS Date

Section 3: Exclusion (Dataset 2)

Variable	Label	Description	Format Text
alcohol4215	4.2.15 Participant Is An Active Alcoholic Or Consumes Excessive Amounts Of Alcohol.	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.	"No"="No"
allergic429	4.2.9 Participant Has A History Of Allergic Reactions Attributed To Compounds Of Similar Chemical Or Biologic Composition To ACTOplus MetÂ® XR.	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.	"No"="No"
biguanide4232	4.2.3.2 Participant Has Taken A Biguanide [e.g. Metformin (Glucophage, Glumetza, Fortamet, Riomet), Or Proguanil (Paludrine)] In The Past 3 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.	"No"="No"
bladderca4217	4.2.17 Participant Has A History Of Bladder Cancer (Including In Situ Bladder 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.	"No"="No"
cationic427	4.2.7 Participant Is Currently Taking A Cationic Drug Or Multidrug And Toxin Extrusion [MATE] Inhibitor [e.g. Amiloride (Midamor); Cimetidine (Tagamet); Digoxin (Lanoxin, Digitek, Digox); Dolutegravir (Tivicay); Morphine (Roxanol, Duramorph, Kadian...]	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.	"No"="No"
chf4211	4.2.11 Participant Has A History Of Congestive Heart Failure Or New York Heart Association (NYHA) Class III Or IV Functional Status.	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.	"No"="No"

Variable	Label	Description	Format Text
combodrug4233	4.2.3.3 Participant Has Taken A Combination Drug Containing One Of The Agents Above (Brand Names Include: ACTOplus Met, Avandamet, Avandaryl, Duetact, Glucovance, Invokamet, Janumet, Jentadueto, Komboglyze, Metaglip, PrandiMet, Synjardy, Xigudo) In...	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.	"No"="No"
concurrentdiag422	4.2.2 Participant Has A Concurrent Diagnosis Of Type I Or Type II Diabetes That Is Being Treated With Insulin Or An Antidiabetic Agent.	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.	"No"="No"
contraindicationbiopsy4210	4.2.10 Participant Has A Contraindication To Biopsy.	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.	"No"="No"
ctcaegrade14213	4.2.13 Participant Has > CTCAE Grade 1 Limb Edema	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.	"No"="No"
cyp2c8424	4.2.4 Participant Is Currently Taking A Strong CYP2C8 Inhibitor [e.g. Gemfibrozil (Lopid)].	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.	"No"="No"
enzymeinducer425	4.2.5 Participant Is Currently Taking An Enzyme Inducer Of CYP2C8 [Carbamazepine (Carbatrol, Epitol, Equetro, Tegretol); Cortisol (Hydrocortisone); Dexamethasone (Decadron); Phenobarbital (Luminal Sodium); Phenytoin (Dilantin, Phenytek, Novaplus...	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.	"No"="No"
hasrecetx421	4.2.1 Participant Has Received Or Will Receive Some Form Of Treatment For Their Cancer Prior To Completing A Minimum Of 10 Days Of Study Agent Dosing.	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.	"No"="No"
hypoglycemia4214	4.2.14 Participant Has A History Of Hypoglycemia	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.	"No"="No"

Variable	Label	Description	Format Text
illness4219	4.2.19 Participant Has Uncontrolled Intercurrent Illness Including, But Not Limited To, Ongoing Or Active Infection, Unstable Angina Pectoris, Cardiac Arrhythmia, Or Psychiatric Illness/Social Situations That Would Limit Compliance With Study Requirements	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.	"No"="No"
invasiveca4218	4.2.18 Participant Has A History Of Invasive Cancer (Other Than Non-melanoma Skin Cancer Or Cervical Cancer In Situ) Active Within 18 Months Prior To The Baseline Study 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.	"No"="No"
investigationalagent428	4.2.8 Participant Is Taking Another Investigational Agent.	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.	"No"="No"
liverdx4212	4.2.12 Participant Has A History Of Liver 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.	"No"="No"
macularedema4216	4.2.16 Participant Has A History Of Macular Edema.	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.	"No"="No"
MeetCriteria	Meet Criteria	The indicator that asks the investigator to stipulate whether the patient is eligible for inclusion on this protocol	"Yes"="Yes"
Q4220ParticipantPGYNNA	4.2.20 Participant Is Pregnant, Breast Feeding Or Planning To Become Pregnant. (All Participants Of Childbearing Potential Regardless Of Method Of Birth Control Must Have A Negative Pregnancy Test At Baseline. A Woman Is Considered Not To Be Of Childbea...	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"
thiazoidinedione4231	4.2.3.1 Participant Has Taken A Thiazolidinedione [e.g. Pioglitazone (Actos) Or Rosiglitazone (Avandia)] In The Past 3 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.	"No"="No"

Variable	Label	Description	Format Text
topamax426	4.2.6 Participant Is Currently Taking Topiramate (Topamax) Commonly Used In Epilepsy Or To Prevent Migraines Or Other Carbonic Anhydrase Inhibitors [e.g. Zonisamide (Zonegran); Acetazolamidine (Diamox Sequels); Or Dichlorphenamide (Keveyis, Daranide)].	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.	"No"="No"