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

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UWI2016-07-01 - Exclusion (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_Exclusion_Criteria V3"="CP_DCP_Exclusion_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: Exclusion (Dataset 2)

Class	Variable	Label	Description	Format Text
01. Principal	**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"
01. Principal	**allergic429**	4.2.9 Participant Has A History Of Allergic Reactions Attributed To Compounds Of Similar Chemical Or Biologic Composition To ACTOplus Met® 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"
01. Principal	**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"
01. Principal	**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"
01. Principal	**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"
01. Principal	**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"

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

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

Class	Variable	Label	Description	Format Text
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	**Q4220Participant PGYNNA**	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"
01. Principal	**thiazoidinedione 4231**	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"
01. Principal	**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); Acetazolaminde (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"