

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

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Document Summary

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UWI2016-07-01 - Exclusion (Dataset 1): 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 V2"="CP_DCP_Exclusion_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.	"UWI2016-07-01"="UWI2016-07-01"
01. Principal	MDS_RegisteringInstitution	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: Exclusion (Dataset 1)

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 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"
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	comborug4233	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, Xigduo) 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	contraindicationsbiopsy4210	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 Pheny...]	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 14 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" "No"="No"
01. Principal	thiazolidinedione 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); Acetazolamide (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"