

MAY2016-07-01 - Pre-Registration Eligibility Criteria Data Dictionary

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Document Summary

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MAY2016-07-01 - Pre-Registration Eligibility Criteria: Data Dictionary

Section 1: Identifiers

Class	Variable	Label	Description	Format Text
01. Principal	SUBJECT	Participant Identifier		Char

Section 2: Study-wide

Class	Variable	Label	Description	Format Text
01. Principal	FOLDERINSTANCENAME	Dataset Folder Name		"Baseline"="Baseline"
01. Principal	MAXUPDATED	Last Updated		SAS Date
01. Principal	MINCREATED	Created Time		SAS Date
01. Principal	PAGEREPEATNUMBER	Page Repeat Number		Numeric
01. Principal	PROJECT	Protocol		"MAY2016-07-01"="MAY2016-07-01"
01. Principal	RAVEID	Rave ID		Numeric
01. Principal	RECORDPOSITION	Record Position		Numeric
01. Principal	SITE	Site		"Cleveland Clinic Foundation"="Cleveland Clinic Foundation" "Huntsman Cancer Institute/University of Utah"="Huntsman Cancer Institute/University of Utah" "M D Anderson Cancer Center"="M D Anderson Cancer Center" "Mayo Clinic in Arizona"="Mayo Clinic in Arizona" "Mayo Clinic"="Mayo Clinic" "University of Michigan Comprehensive Cancer Center"="University of Michigan Comprehensive Cancer Center" "University of Pittsburgh Cancer Institute (UPCI)"="University of Pittsburgh Cancer Institute (UPCI)" "University of Puerto Rico"="University of Puerto Rico"
01. Principal	SITENUMBER	Site Number		"AZ020"="AZ020" "MI014"="MI014" "MN026"="MN026" "OH027"="OH027" "PA015"="PA015" "PR008"="PR008" "TX035"="TX035" "UT003"="UT003"
01. Principal	TARGETDAYS	Target Days From Baseline		Numeric

Section 3: Pre-Registration Eligibility Criteria

Class	Variable	Label	Description	Format Text
01. Principal	AGEINLCU003	Age At Entry		Numeric
01. Principal	CONTCTCONSNT	Participant Has Given Permission For His/Her Doctor To Contact Them In The Future To Ask Them To Take Part In More Research		Numeric
01. Principal	EXCLU001	Any Prior Treatment With Erlotinib Or Other Agent Whose Primary Mechanism Of Action Is Known To Inhibit EGFR		2="No"
01. Principal	EXCLU002	History Of Allergic Reactions Attributed To Compounds Of Similar Chemical Or Biologic Composition To Erlotinib		2="No"
01. Principal	EXCLU003	Use Of Potent CYP3A4 Inhibitors, Including But Not Limited To Ketoconazole, Atazanavir, Clarithromycin, Indinavir, Itraconazole, Nefazodone...		2="No"
01. Principal	EXCLU004	Use Of Potent CYP3A4 Inducers, Including But Not Limited To Rifampicin, Rifabutin, Rifapentine, Phenytoin, Carbamazepine, Phenobarbital, And St. John's Wort'		2="No"
01. Principal	EXCLU005	Use Of Any Other Investigational Agents 12 Weeks Prior To Pre-Registration		2="No"
01. Principal	EXCLU005A	Uncontrolled Intercurrent Illness Or Recent Surgical Procedure That Would Limit Compliance With Study Requirements		2="No"
01. Principal	EXCLU006	History Of Invasive Malignancy D 3 Years Prior To Pre-Registration.		2="No"

Class	Variable	Label	Description	Format Text
01. Principal	EXCLU007	Individuals On Anticoagulation Medications Who Cannot Safely Discontinue The Medication For At Least 48 Hours Prior To The Study Endoscopy		2="No"
01. Principal	EXCLU009	History Of Any Upper GI Surgery That Does Not Permit Access To Or Evaluation Of A 10 cm Segment Of The Duodenum That Includes The Duodenal Bulb		1="Yes" 2="No"
01. Principal	INCLU001	Diagnosis Of Familial Adenomatous Polyposis (FAP) Or Attenuated Familial Adenomatous Polyposis (AFAP)		1="Yes" 2="No"
01. Principal	INCLU003	Age (18 To 69)		1="Yes"
01. Principal	INCLU004	Able To Understand And The Willingness To Sign A Written Informed Consent Document		1="Yes"
01. Principal	INCLU005	Willing To Discontinue Taking Nsaids For 30 Days Prior To Initiation Of And During Intervention.		1="Yes"
01. Principal	INCLU006	Willing To Discontinue Smoking For The Duration Of Study Intervention		1="Yes"
01. Principal	INCLU007	Willing To Provide Mandatory Biospecimens As Specified In The Protocol		1="Yes"
01. Principal	OTHALCTOBCO NSNT	Participant Has/Has Not Given Permission For Information From The Alcohol And Tobacco Use Assessment To Be Used In Future Health Research		1="Yes" 2="No"
01. Principal	OTHCONTCONS NT	Participant Has Given Permission To Contact Him/Her Or His/Her Physician To Learn About The Results Of These Studies.		1="Yes" 2="No"

Class	Variable	Label	Description	Format Text
01. Principal	OTHHLTHCONSN T	Participant Has Given Permission To Collect And Store Blood, Urine, And/Or Tissue Specimens And Related Information In A Biobank For Future Use In Research To Learn About, Prevent, Treat, Or Cure Cancer		1="Yes" 2="No"
01. Principal	OTHRSRCHCON SNT	Participant Has Given Permission To Give His/Her Blood, Urine, And/Or Tissue Specimens And Related Information To Researchers At Outside Institutions.		1="Yes" 2="No"