

# 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

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Class	Variable	Label	Description	Format Text
01. Principal	<b>SUBJECT</b>	Participant Identifier		Char

## Section 2: Study-wide

Class	Variable	Label	Description	Format Text
01. Principal	<b>FOLDERINSTAN CENAME</b>	Dataset Folder Name		"Baseline"="Baseline"
01. Principal	<b>MAXUPDATED</b>	Last Updated		SAS Date
01. Principal	<b>MINCREATED</b>	Created Time		SAS Date
01. Principal	<b>PAGEREPEATNU MBER</b>	Page Repeat Number		Numeric
01. Principal	<b>PROJECT</b>	Protocol		"MAY2016-07-01"="MAY2016-07-01"
01. Principal	<b>RAVEID</b>	Rave ID		Numeric
01. Principal	<b>RECORDPOSITIO N</b>	Record Position		Numeric
01. Principal	<b>SITE</b>	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	<b>SITENUMBER</b>	Site Number		"AZ020"="AZ020" "MI014"="MI014" "MN026"="MN026" "OH027"="OH027" "PA015"="PA015" "PR008"="PR008" "TX035"="TX035" "UT003"="UT003"
01. Principal	<b>TARGETDAYS</b>	Target Days From Baseline		Numeric

## Section 3: Pre-Registration Eligibility Criteria

Class	Variable	Label	Description	Format Text
01. Principal	<b>AGEINLCU003</b>	Age At Entry		Numeric
01. Principal	<b>CONTCTCONSNT</b>	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	<b>EXCLU001</b>	Any Prior Treatment With Erlotinib Or Other Agent Whose Primary Mechanism Of Action Is Known To Inhibit EGFR		2="No"
01. Principal	<b>EXCLU002</b>	History Of Allergic Reactions Attributed To Compounds Of Similar Chemical Or Biologic Composition To Erlotinib		2="No"
01. Principal	<b>EXCLU003</b>	Use Of Potent CYP3A4 Inhibitors, Including But Not Limited To Ketoconazole, Atazanavir, Clarithromycin, Indinavir, Itraconazole, Nefazodone...		2="No"
01. Principal	<b>EXCLU004</b>	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	<b>EXCLU005</b>	Use Of Any Other Investigational Agents 12 Weeks Prior To Pre-Registration		2="No"
01. Principal	<b>EXCLU005A</b>	Uncontrolled Intercurrent Illness Or Recent Surgical Procedure That Would Limit Compliance With Study Requirements		2="No"
01. Principal	<b>EXCLU006</b>	History Of Invasive Malignancy D 3 Years Prior To Pre-Registration.		2="No"

Class	Variable	Label	Description	Format Text
01. Principal	<b>EXCLU007</b>	Individuals On Anticoagulation Medications Who Cannot Safely Discontinue The Medication For At Least 48 Hours Prior To The Study Endoscopy		2="No"
01. Principal	<b>EXCLU009</b>	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	<b>INCLU001</b>	Diagnosis Of Familial Adenomatous Polyposis (FAP) Or Attenuated Familial Adenomatous Polyposis (AFAP)		1="Yes" 2="No"
01. Principal	<b>INCLU003</b>	Age (18 To 69)		1="Yes"
01. Principal	<b>INCLU004</b>	Able To Understand And The Willingness To Sign A Written Informed Consent Document		1="Yes"
01. Principal	<b>INCLU005</b>	Willing To Discontinue Taking Nsaids For 30 Days Prior To Initiation Of And During Intervention.		1="Yes"
01. Principal	<b>INCLU006</b>	Willing To Discontinue Smoking For The Duration Of Study Intervention		1="Yes"
01. Principal	<b>INCLU007</b>	Willing To Provide Mandatory Biospecimens As Specified In The Protocol		1="Yes"
01. Principal	<b>OTHALCTOBCO NSNT</b>	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	<b>OTHCONTCONS NT</b>	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	<b>OTHHLTHCONSN T</b>	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	<b>OTHRSRCHCON SNT</b>	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"