

MAY2016-07-01 - Pre-Registration Checklist Data Dictionary

TABLE OF CONTENTS

Document Summary.....	2
MAY2016-07-01 - Pre-Registration Checklist: Data Dictionary	3
Section 1: Identifiers	3
Section 2: Pre-Registration Checklist	4

Document Summary

Property	Value
Document Title	MAY2016-07-01 - Pre-Registration Checklist: Data Dictionary
Date Created	08/11/2025
Sections	2
Entries	42
Document Filename	dictionary_chklist_prereg.rtf

MAY2016-07-01 - Pre-Registration Checklist: Data Dictionary

Section 1: Identifiers

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

Section 2: Pre-Registration Checklist

Class	Variable	Label	Description	Format Text
01. Principal	age	Age		Char
01. Principal	auth_res	Participant Has Given Permission To His/Her Doctor To Contact Them In The Future To Ask Them To Take Part In More Research.		"y"="y"
01. Principal	casedetailid	Case Number		Numeric
01. Principal	consntdt	Date Informed Consent Signed		SAS Date
01. Principal	ctep_arm	TAC/TAD Code		"TAC-0 (Signed informed consent document and before intervention)"="TAC-0 (Signed informed consent document and before intervention)" "TAC0 (Signed informed consent document and before intervention)"="TAC0 (Signed informed consent document and before intervention)"
01. Principal	date_mod	Date Modified		SAS Date
01. Principal	dc_num	Data Center Assigned Protocol Number		"MAY2016-07-01"="MAY2016-07-01"
01. Principal	elig	Is The Participant Eligible For Inclusion On This Study?		"y"="y"
01. Principal	EnrollDT	Enrollment Date		SAS Date
01. Principal	eresnum	ERES Number		"0000-107077"="0000-107077"
01. Principal	exclu001	Any Prior Treatment With Erlotinib Or Other Agent Whose Primary Mechanism Of Action Is Known To Inhibit EGFR		"n"="n"
01. Principal	exclu002	History Of Allergic Reactions Attributed To Compounds Of Similar Chemical Or Biologic Composition To Erlotinib		"n"="n"
01. Principal	exclu003	Use Of Potent CYP3A4 Inhibitors		"n"="n"
01. Principal	exclu004	Use Of CYP3A4 Inducers		"n"="n"
01. Principal	exclu005	Use Of Any Other Investigational Agents <=12 Weeks Prior To Pre-Registration		"n"="n"

Class	Variable	Label	Description	Format Text
01. Principal	exclu006	Uncontrolled Intercurrent Illness Or Recent Surgical Procedure That In The Opinion Of The Investigative Team Would Limit Compliance With Study Requirements?		"n"="n"
01. Principal	exclu007	History Of Invasive Malignancy <=3 Years Prior To Pre-Registration. Exception: Adequately Treated Carcinoma Of The Cervix, Carinoma In Situ, Or Basal Or Squamous Cell Carcinomas Of The Skin.		"n"="n"
01. Principal	exclu008	Use Of Anticoagulation Medications, Including But Not Limited To Coumadin, Warfarin, Plavix.		"n"="n" "na"="na"
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		"n"="n"
01. Principal	form	Form Number		Numeric
01. Principal	FormName	Form Name		"PreReg - chklist"="PreReg - chklist"
01. Principal	inclu001	Diagnosis Of Familial Adenomatous Polyposis (FAP) Or Attenuated Familial Adenomatous Polyposis (AFAP)		"y"="y"
01. Principal	inclu002	Age 18 To 69		"y"="y"
01. Principal	inclu003	Ability To Understand And The Willingness To Sign A Written Informed Consent Document.		"y"="y"
01. Principal	inclu004	Willing To Discontinue Taking NSAIDS For 30 Days Prior To Initiation Of And During Intervention.		"y"="y"
01. Principal	inclu005	Willing To Discontinue Smoking For The Duration Of Study Intervention		"y"="y"

Class	Variable	Label	Description	Format Text
01. Principal	inclu006	Willing To Provide Mandatory Biospecimens As Specified In The Protocol		"y"="y"
01. Principal	permit1	Participant Has Given Permission To Collect And Store Blood, Urine And Tissue For Research Specified In This Protocol.		"y"="y"
01. Principal	permit2	Participant Has Given Permission To Collect And Store Blood, Urine, And Tissue For Future Use In Research To Learn About, Prevent, Treat, Or Cure Cancer And Other Health Problems.		"n"="n" "y"="y"
01. Principal	permit3	Participant Has Given Permission To Contact Him/Her Or His/Her Physician To Learn About The Results Of These Studies.		"y"="y"
01. Principal	permit4	Participant Has Given Permission To Send Blood, Urine, And Tissue Specimens To Researchers At Outside Institutions.		"y"="y"
01. Principal	permit5	Participant Has Given Permission For Information From The Alcohol And Tobacco Use Assessment To Be Used In Future Health Research.		"y"="y"
01. Principal	prev_id	If Yes: Prior Participant CPN ID Number:		Char
01. Principal	previous	Has The Participant Been Pre-Registered Previously To This Study?		"n"="n" "y"="y"
01. Principal	reg01	Consent Form Signed And Dated.		"y"="y"
01. Principal	reg02	Existence Of Authorization For Use And Disclosure Of Protected Health Information.		"na"="na" "y"="y"

Class	Variable	Label	Description	Format Text
01. Principal	reg03	Study Agent Is Available And Drug Shipment Authorization Has Been Granted To The Registering Site.		"y"="y"
01. Principal	reg04	Baseline (Screening) Evaluations Must Be Completed Within The Guidelines Specified On The Schedule Of Events.		"y"="y"
01. Principal	reg05	Registration Office Personnel Will Automatically Register Participants Separately To The Translational Research Components Of The Study.		"y"="y"
01. Principal	studyid	Internal Study Number		Numeric
01. Principal	version	Version Number		Numeric