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

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Document Title	MAY2016-07-01 - Pre-Registration Checklist: Data Dictionary
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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 Notpermit 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