

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

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## 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

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## MAY2016-07-01 - Pre-Registration Checklist: 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: Pre-Registration Checklist

Class	Variable	Label	Description	Format Text
01. Principal	<b>age</b>	Age		Char
01. Principal	<b>auth_res</b>	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	<b>casedetailid</b>	Case Number		Numeric
01. Principal	<b>consntdt</b>	Date Informed Consent Signed		SAS Date
01. Principal	<b>ctep_arm</b>	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	<b>date_mod</b>	Date Modified		SAS Date
01. Principal	<b>dc_num</b>	Data Center Assigned Protocol Number		"MAY2016-07-01"="MAY2016-07-01"
01. Principal	<b>elig</b>	Is The Participant Eligible For Inclusion On This Study?		"y"="y"
01. Principal	<b>EnrollIDT</b>	Enrollment Date		SAS Date
01. Principal	<b>eresnum</b>	ERES Number		"0000-107077"="0000-107077"
01. Principal	<b>exclu001</b>	Any Prior Treatment With Erlotinib Or Other Agent Whose Primary Mechanism Of Action Is Known To Inhibit EGFR		"n"="n"
01. Principal	<b>exclu002</b>	History Of Allergic Reactions Attributed To Compounds Of Similar Chemical Or Biologic Composition To Erlotinib		"n"="n"
01. Principal	<b>exclu003</b>	Use Of Potent CYP3A4 Inhibitors		"n"="n"
01. Principal	<b>exclu004</b>	Use Of CYP3A4 Inducers		"n"="n"
01. Principal	<b>exclu005</b>	Use Of Any Other Investigational Agents <=12 Weeks Prior To Pre-Registration		"n"="n"

Class	Variable	Label	Description	Format Text
01. Principal	<b>exclu006</b>	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	<b>exclu007</b>	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	<b>exclu008</b>	Use Of Anticoagulation Medications, Including But Not Limited To Coumadin, Warfarin, Plavix.		"n"="n" "na"="na"
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		"n"="n"
01. Principal	<b>form</b>	Form Number		Numeric
01. Principal	<b>FormName</b>	Form Name		"PreReg - chklist"="PreReg - chklist"
01. Principal	<b>inclus001</b>	Diagnosis Of Familial Adenomatous Polyposis (FAP) Or Attenuated Familial Adenomatous Polyposis (AFAP)		"y"="y"
01. Principal	<b>inclus002</b>	Age 18 To 69		"y"="y"
01. Principal	<b>inclus003</b>	Ability To Understand And The Willingness To Sign A Written Informed Consent Document.		"y"="y"
01. Principal	<b>inclus004</b>	Willing To Discontinue Taking NSAIDS For 30 Days Prior To Initiation Of And During Intervention.		"y"="y"
01. Principal	<b>inclus005</b>	Willing To Discontinue Smoking For The Duration Of Study Intervention		"y"="y"

Class	Variable	Label	Description	Format Text
01. Principal	<b>inclus06</b>	Willing To Provide Mandatory Biospecimens As Specified In The Protocol		"y"="y"
01. Principal	<b>permit1</b>	Participant Has Given Permission To Collect And Store Blood, Urine And Tissue For Research Specified In This Protocol.		"y"="y"
01. Principal	<b>permit2</b>	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	<b>permit3</b>	Participant Has Given Permission To Contact Him/Her Or His/Her Physician To Learn About The Results Of These Studies.		"y"="y"
01. Principal	<b>permit4</b>	Participant Has Given Permission To Send Blood, Urine, And Tissue Specimens To Researchers At Outside Institutions.		"y"="y"
01. Principal	<b>permit5</b>	Participant Has Given Permission For Information From The Alcohol And Tobacco Use Assessment To Be Used In Future Health Research.		"y"="y"
01. Principal	<b>prev_id</b>	If Yes: Prior Participant CPN ID Number:		Char
01. Principal	<b>previous</b>	Has The Participant Been Pre-Registered Previously To This Study?		"n"="n" "y"="y"
01. Principal	<b>reg01</b>	Consent Form Signed And Dated.		"y"="y"
01. Principal	<b>reg02</b>	Existence Of Authorization For Use And Disclosure Of Protected Health Information.		"na"="na" "y"="y"

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