MAY2013-02-02 - Checklist (Pre-Registration) Data Dictionary

TABLE OF CONTENTS

Document Summary

Property	Value
Document Title	MAY2013-02-02 - Checklist (Pre-Registration): Data Dictionary
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Sections	2
Entries	44
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MAY2013-02-02 - Checklist (Pre-Registration): Data Dictionary

Section 1: Identifiers

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

Section 2: Eligibility Checklist (Pre-Registration)

Class	Variable	Label	Description	Format Text
01. Principal	**age**	Age		Char
01. Principal	**auth_ca**	Participant Has Given Permission To Collect And Store Blood And Tissue For Future Use In Research To Learn About, Prevent, Treat Or Cure Cancer		"0"="No" "1"="Yes" "n"="No" "na"="N/A" "y"="Yes"
01. Principal	**auth_oth**	Participant Has Given Permission To Collect And Store Blood And Tissue For Future Use In Research About Other Health Problems)		"0"="No" "1"="Yes" "n"="No" "na"="N/A" "y"="Yes"
01. Principal	**auth_out**	Participant Has Given Permission To Send Blood And/Or Tissue Sample(s) To Researchers At An Outside Institution		"0"="No" "1"="Yes" "n"="No" "na"="N/A" "y"="Yes"
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		"0"="No" "1"="Yes" "n"="No" "na"="N/A" "y"="Yes"
01. Principal	**casedetailid**	Case Number		Numeric
01. Principal	**consntdt**	Date Informed Consent Signed		SAS Date
01. Principal	**ctep_arm**	TAC/TAD Code		"TAC-0"="TAC-0"
01. Principal	**date_mod**	Date Modified		SAS Date
01. Principal	**dc_num**	Protocol Number		"MAY2013-02-02"="MAY2013-02-02"
01. Principal	**EnrollDT**	Enrollment Date		SAS Date
01. Principal	**eresnum**	ERES Number		"0000-106261"="0000-106261"
01. Principal	**exclu001**	Any Prior Treatment With Erlotinib Or Other Agent Whose Primary Mechanism Of Action Is Known To Inhibit EGFR		"0"="No" "1"="Yes" "n"="No" "na"="N/A" "y"="Yes"
01. Principal	**exclu002**	Participants With A Known Diagnosis Of HIV		"0"="No" "1"="Yes" "n"="No" "na"="N/A" "y"="Yes"

Class	Variable	Label	Description	Format Text
01. Principal	**exclu003**	Participants Who Regularly (>=2 Times Per Week) Use Drugs That Alter The pH Of The GI Tract		"0"="No" "1"="Yes" "n"="No" "na"="N/A" "y"="Yes"
01. Principal	**exclu004**	Uncontrolled Intercurrent Illness		"0"="No" "1"="Yes" "n"="No" "na"="N/A" "y"="Yes"
01. Principal	**exclu005**	Use Of Potent CYP3A4 Inhibitors		"0"="No" "1"="Yes" "n"="No" "na"="N/A" "y"="Yes"
01. Principal	**exclu006**	Use Of CYP3A4 Inducers		"0"="No" "1"="Yes" "n"="No" "na"="N/A" "y"="Yes"
01. Principal	**exclu007**	History Of Allergic Reactions Attributed To Compounds Of Similar Chemical Or Biologic Composition To Erlotinib (Tarceva)		"0"="No" "1"="Yes" "n"="No" "na"="N/A" "y"="Yes"
01. Principal	**exclu008**	Participants Who Cannot Have Their Warfarin, Lovenox, Plavix, Or Other Comparable Medications Held For Percutanous Or Transjugular Liver Biopsy And Surgery If So Indicated		"0"="No" "1"="Yes" "n"="No" "na"="N/A" "y"="Yes"
01. Principal	**exclu009**	Non-Surgical Cohort Only: Pathology Report From Clinical Liver Biopsy Demonstrates No Histologic Abnormalities Associated With Chronic Hepatitis, Steatohepatitis, Fibrosis, Or Cirrhosis		"0"="No" "1"="Yes" "n"="No" "na"="N/A" "y"="Yes"
01. Principal	**form**	Form		-1="PreReg - chklist"
01. Principal	**hipaa_dt**	Date Of Authorization (mm/dd/yyyy)		SAS Date
01. Principal	**inclu001**	Individuals With A Clinical Diagnosis Fibrosis Or Cirrhosis Of The Liver		"0"="No" "1"="Yes" "n"="No" "na"="N/A" "y"="Yes"

Class	Variable	Label	Description	Format Text
01. Principal	**inclu002**	Age >=18 Years		"0"="No" "1"="Yes" "n"="No" "na"="N/A" "y"="Yes"
01. Principal	**inclu003**	Willingness To Discontinue Smoking During The Study Two Weeks Prior To Beginning The Study And Willingness To Not Smoke While Taking Study Medication		"0"="No" "1"="Yes" "n"="No" "na"="N/A" "y"="Yes"
01. Principal	**inclu004**	Not Pregnant Or Breast Feeding		"0"="No" "1"="Yes" "n"="No" "na"="N/A" "y"="Yes"
01. Principal	**inclu005**	Willingness To Use Adequate Contraception To Avoid Pregnancy Or Impregnantion Until 2 Weeks After Discontinuing Study Agent		"0"="No" "1"="Yes" "n"="No" "na"="N/A" "y"="Yes"
01. Principal	**inclu006**	Willingness To Provide Mandatory Blood Specimens As Specified In The Protocol		"0"="No" "1"="Yes" "n"="No" "na"="N/A" "y"="Yes"
01. Principal	**inclu007**	Able To Undergo: A. Percutaneous Or Transjugular Biopsy Of Cirrhotic Liver At Least 7 Days Prior To Liver Resection (Surgical Cohort), OR B. A Biopsy Of The Cirrhotic Liver (Non-Surgical Cohort)		"0"="No" "1"="Yes" "n"="No" "na"="N/A" "y"="Yes"
01. Principal	**inclu008**	Willingness To Authorize Collection Of Tissue From Surgically-Resected Liver Or Clinical Liver Biopsy For Analyses Specified In The Protocol		"0"="No" "1"="Yes" "n"="No" "na"="N/A" "y"="Yes"
01. Principal	**inclu009**	Ability To Understand And The Willingness To Sign A Written Informed Consent Document		"0"="No" "1"="Yes" "n"="No" "na"="N/A" "y"="Yes"

Class	Variable	Label	Description	Format Text
01. Principal	**pielig**	Is The Participant Eligible For Inclusion On This Study?		"0"="No" "1"="Yes" "n"="No" "na"="N/A" "y"="Yes"
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?		"0"="No" "1"="Yes" "n"="No" "na"="N/A" "y"="Yes"
01. Principal	**reg01**	Consent Form Signed And Dated		"0"="No" "1"="Yes" "n"="No" "na"="N/A" "y"="Yes"
01. Principal	**reg02**	Existence Of Authorization For Use And Disclosure Of Protected Health Information (USA Institutions Only)		"0"="No" "1"="Yes" "n"="No" "na"="N/A" "y"="Yes"
01. Principal	**reg03**	Screening And On-Study Evaluations Must Be Completed Within The Guidelines Specified On The Schedule Of Events		"0"="No" "1"="Yes" "n"="No" "na"="N/A" "y"="Yes"
01. Principal	**reg04**	All Baseline Symptoms Must Be Documented And Graded		"0"="No" "1"="Yes" "n"="No" "na"="N/A" "y"="Yes"
01. Principal	**reg05**	All Participants Will Be Automatically Registered To The Correlative Components Of This Study		"0"="No" "1"="Yes" "n"="No" "na"="N/A" "y"="Yes"
01. Principal	**reg06**	All Trial Activities Must Be Conducted At A CPN Member Institution Under The Supervision Of A CPN Physician		"0"="No" "1"="Yes" "n"="No" "na"="N/A" "y"="Yes"
01. Principal	**studyid**	Study ID		Numeric
01. Principal	**version**	Version Number		Numeric