

MAY2016-07-01 - Registration Checklist Data Dictionary

TABLE OF CONTENTS

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

Document Summary

Property	Value
Document Title	MAY2016-07-01 - Registration Checklist: Data Dictionary
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MAY2016-07-01 - Registration Checklist: Data Dictionary

Section 1: Identifiers

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

Section 2: Registration Checklist

Class	Variable	Label	Description	Format Text
01. Principal	alk_phos	Alkaline Phosphatase		Char
01. Principal	alk_unl	Alkaline Phosphatase UNL		Char
01. Principal	alt	ALT/SGPT		Char
01. Principal	alt_unl	ALT/SGPT UNL		Char
01. Principal	Arm	Arm		"A"="A"
01. Principal	ast	AST/SGOT		Char
01. Principal	ast_unl	AST/SGOT UNL		Char
01. Principal	casedetailid	Case Number		Numeric
01. Principal	creat	Creatinine		Char
01. Principal	creatunl	Creatinine UNL		Char
01. Principal	ctep_arm	TAC/TAD Code		"TAC1 (Erlotinib 350 mg PO Once Per Week x 6 months)"="TAC1 (Erlotinib 350 mg PO Once Per Week x 6 months)"
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	EnrollIDT	Enrollment Date		SAS Date
01. Principal	eresnum	ERES Number		"0000-107077"="0000-107077"
01. Principal	exclu001	Histologically-Confirmed High Grade Dysplasia (HGD), Cancer, Or Polyp Burden That Is Not Quantifiable.		"n"="n"
01. Principal	exclu002	Regular (>=2 Times Per Week) Use Of Drugs That Alter The pH Of The GI Tract		"n"="n"
01. Principal	exclu003	Gastrointestinal Bleeding.		"n"="n"
01. Principal	form	Form Number		Numeric
01. Principal	FormName	Form Name		"Main - chklist"="Main - chklist"
01. Principal	hgb	Hemoglobin (>=11.5)		Char
01. Principal	inclu001	ECOG Performance Status <=1		"y"="y"
01. Principal	inclu002	Adequate Bone Marrow And Organ Function:		"y"="y"

Class	Variable	Label	Description	Format Text
01. Principal	inclu003	Leukocytes (WBC) ≥3,000/mL (≥2,500/mL for African-American participants)		"y"="y"
01. Principal	inclu004	Platelet Count ≥100 x 10 ⁹ /L		"y"="y"
01. Principal	inclu005	Hemoglobin ≥11.5 g/dL		"y"="y"
01. Principal	inclu006	Total Bilirubin ≤1.5 x UNL		"y"="y"
01. Principal	inclu007	Alkaline Phosphatase ≤1.5 x UNL		"y"="y"
01. Principal	inclu008	AST/SGOT ≤2 x UNL		"y"="y"
01. Principal	inclu009	ALT/SGPT ≤2 x UNL		"y"="y"
01. Principal	inclu010	Creatinine UNL		"y"="y"
01. Principal	inclu011	Urinary Testing Results Within Institutional Limits Of Normal Or Deemed Clinically Significant		"y"="y"
01. Principal	inclu012	Spigelman 2-3		"y"="y"
01. Principal	inclu013	Not Pregnant Or Breast Feeding.		"y"="y"
01. Principal	inclu014	Willing To Use Adequate Contraception To Avoid Pregnancy Or Impregnation Until 2 Weeks After Discontinuing Study Agent		"na"="na" "y"="y"
01. Principal	leukocyt	If Yes, Leukocytes (WBC)		Char
01. Principal	nav1	Is this participant an African-American?		"1=Yes"="1=Yes" "2=No"="2=No"
01. Principal	platelet	Platelet count (≥100)		Char
01. Principal	ps	ECOG performance status 0 Or 1		"0"="0"
01. Principal	reg01	Intervention Cannot Begin Prior To Registration And Must Begin ≤14 Days From Registration.		"y"="y"
01. Principal	reg02	Intervention Must Take Place At A CPN Institution And Under The Supervision Of A CPN Clinician.		"y"="y"

Class	Variable	Label	Description	Format Text
01. Principal	reg03	Pathology Reports Confirming Diagnoses Must Be Sent <=30 Days Post Registration To The CPN QAS at CPN Operations Office		"y"="y"
01. Principal	studyid	Internal Study Number		Numeric
01. Principal	tbiliunl	Total bilirubin UNL		Char
01. Principal	tot_bili	Total bilirubin		Char
01. Principal	version	Version Number		Numeric