

MAY2017-09-01 - REGISTRATION CHECKLIST: DATA DICTIONARY

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Document Summary

Property	Value
Document Title	MAY2017-09-01 - Registration Checklist: Data Dictionary
Date Created	02/26/2020
Sections	2
Entries	39
Document Filename	dictionary_chklist_reg.rtf

MAY2017-09-01 - Registration Checklist: Data Dictionary

Section 1: Identifiers

Variable	Label	Description	Format Text
subject	Participant ID		Char

Section 2: Registration Checklist

Variable	Label	Description	Format Text
ABANC	ANC Value		Numeric
ALT	ALT		Numeric
ALT_UNL	ALT Upper Limit		Numeric
AST	AST Value		Numeric
AST_UNL	AST Upper Normal Limit		Numeric
CASE	Case Number		Numeric
CREAT	Creatinine Value		Numeric
CREATED	Created Date		SAS Date
CREATUNL	Creatinine Upper Normal Limit		Numeric
CTEP_ARM	CTEP Arm		"TAC1"="TAC1"
DATE_MOD	Date Modified		SAS Date
DC_NUM	Data Center Assigned Prot Num		"MAY2017-09-01"="MAY2017-09-01"
ELIG	Is Participant Eligible?		1="Yes"
EXCLU001	Sigmoidoscopy Findings Requiring Clinical Intervention		"2"="No"
EXCLU002	Use Of Any Illicit Or Illegal Substances Detected By Urinary Drug Screen		"2"="No"
FORM	Form		Numeric
FORMNAME	Form Name		"MAY2017-09-01 Randomization Elig Checklist (Step 1)"="MAY2017-09-01 Randomization Elig Checklist (Step 1)"
INCLU001	Normal Organ Function And Normal Lab Findings		"1"="Yes"
INCLU002	Leukocytes >= 3x10 ³ /microliter (B/L)		"1"="Yes"
INCLU003	Absolute Neutrophil Count >= 1.5x10 ³ /microliter (B/L)		"1"="Yes"
INCLU004	Platelets >= 100x10 ³ /microliter (B/L)		"1"="Yes"
INCLU005	AST (SGOT) <= 1.5 x Institutional Upper Limit Of Normal (ULN)		"1"="Yes"
INCLU006	ALT (SGPT) <= 1.5 x Institutional Upper Limit Of Normal (ULN)		"1"="Yes"

Variable	Label	Description	Format Text
INCLU007	Creatinine <= Institutional Upper Limit Of Normal (ULN)		"1"="Yes"
INCLU008	Body Mass Index < 35Kg/m		"1"="Yes"
INCLU009	No Findings In Rectum Of Advanced Adenoma, Chronic Inflammation, Or Cancer		"1"="Yes"
LEUKOCYT	Leukocytes		Numeric
NODE	Node		Numeric
PLATELET	Platelets		Numeric
REG01	Intervention Cannot Begin Prior To Registration And Must Begin <= 14 Days After		"1"="Yes"
REG02	Intervention Must Commence At A CPN Institution Under CPN Clinician Supervision		"1"="Yes"
REG03	Baseline Evaluations Must Be Completed Within Guidelines		"1"="Yes"
REG04	All Baseline Symptoms Must Be Documented And Graded		"1"="Yes"
SEQUENCE	Sequence		Numeric
TBILILNL	Bilirubin Lower Limit		Numeric
TBILIUNL	Bilirubin Upper Limit		Numeric
TOT_BILI	Bilirubin Value		Numeric
VERSION	Version		Numeric