

MAY2013-02-02 - [Checklist (Registration)] Data Dictionary

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Property	Value
Document Title	MAY2013-02-02 - [Checklist (Registration)]: Data Dictionary
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MAY2013-02-02 - [Checklist (Registration)]: Data Dictionary

Section 1: Identifiers

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

Section 2: [Checklist (Registration)]

Class	Variable	Label	Description	Format Text
01. Principal	alt	ALT/SGPT		"039"="039" "048"="048" "062"="062" "21"="21" "24"="24" "26"="26" "29"="29" "31"="31" "44"="44" "72"="72" "9"="9" "99"="99"
01. Principal	alt_unl	ALT/SGPT UNL		"033"="033" "055"="055" "33"="33" "38"="38" "52"="52" "54"="54" "55"="55"
01. Principal	Arm	Treatment Arm		"A"="A"
01. Principal	ast	AST/SGOT		"039"="039" "042"="042" "103"="103" "22"="22" "31"="31" "32"="32" "35"="35" "37"="37" "64"="64" "68"="68" "82"="82" "96"="96"
01. Principal	ast_unl	AST/SGOT UNL		"032"="032" "040"="040" "32"="32" "35"="35" "39"="39" "40"="40" "48"="48"
01. Principal	casedetailid	Case Number		Numeric
01. Principal	creat	Creatinine		".65"=".65" "0.55"="0.55" "0.7"="0.7" "0.74"="0.74" "0.75"="0.75" "0.87"="0.87" "1.0"="1.0" "1.04"="1.04" "1.1"="1.1" "1.3"="1.3"

Class	Variable	Label	Description	Format Text
01. Principal	creatunl	Creatinine UNL		"0.96"="0.96" "1.22"="1.22" "1.30"="1.30" "1.35"="1.35" "1.5"="1.5" "1.50"="1.50"
01. Principal	ctep_arm	TAC/TAD Code		"TAC-1 (Erlotinib 50 mg PO Q am x 7 days [empty stomach])"="TAC-1 (Erlotinib 50 mg PO Q am x 7 days [empty stomach])" "TAC-1B (Non-Surgical Cohort B: Erlotinib 50mg PO Qam x 7 days [empty Stomach])"="TAC-1B (Non-Surgical Cohort B: Erlotinib 50mg PO Qam x 7 days [empty Stomach])" "TAC-2A (Surgical Cohort A: Erlotinib 25mg PO Qam x 7 days [empty Stomach])"="TAC-2A (Surgical Cohort A: Erlotinib 25mg PO Qam x 7 days [empty Stomach])" "TAC-2B (Non-Surgical Cohort B: Erlotinib 25mg PO Qam x 7 days [empty Stomach])"="TAC-2B (Non-Surgical Cohort B: Erlotinib 25mg PO Qam x 7 days [empty Stomach])" "TAC1 (Erlotinib 75 mg PO Q am x 7 days [empty stomach])"="TAC1 (Erlotinib 75 mg PO Q am x 7 days [empty stomach])"
01. Principal	date_mod	Date Modified		SAS Date
01. Principal	dc_num	Protocol Number		"MAY2013-02-02"="MAY2013-02-02"
01. Principal	doselevl	Dose Level (+2, +1, 0, -1, -2)		"-1"="-1" "-2"="-2" "0"="0"
01. Principal	EnrollDT	Enrollment Date		SAS Date
01. Principal	eresnum	ERES Number		"0000-106261"="0000-106261"
01. Principal	exclu001	Receiving Any Other Investigational Agents <=6 Months Prior To Registration		"n"="n"
01. Principal	exclu002	Surgical Cohort (Cohort A Only): Percutaneous Or Transjugular Biopsy Incomplete Or Not Performed.		"n"="n" "na"="na"
01. Principal	form	Form		Numeric
01. Principal	group	Group: 1=Dose Escalation/De-Escalation Cohort 2=Expansion Cohort		"1=Dose Escalation/De-escalation Cohort"="1=Dose Escalation/De-escalation Cohort" "1=Dose escalation/de-escalation cohort"="1=Dose escalation/de-escalation cohort" "2=Dose expansion cohort"="2=Dose expansion cohort"
01. Principal	inclu001	ECOG Performance Status 0 Or 1 (Appendix A)		"y"="y"

Class	Variable	Label	Description	Format Text
01. Principal	inclu002	Participants Must Have Normal Organ And Marrow Function As Defined Below		"y"="y"
01. Principal	inclu003	 INR <=1.5		"y"="y"
01. Principal	inclu004	 Platelets >=50 B/L (10^9/L)		"y"="y"
01. Principal	inclu005	 Total Bilirubin <=3 X Institutional ULN		"y"="y"
01. Principal	inclu006	 AST (SGOT) And ALT (SGPT) <=5 X Institutional ULN		"y"="y"
01. Principal	inclu007	 Creatinine <=1.5 X Institutional ULN		"y"="y"
01. Principal	inclu008	Non-Surgical Cohort Only: Positive Phospho-EGFR Assessment		"na"="na" "y"="y"
01. Principal	inclu009	Pre-Intervention Biopsy Sample Collected		"y"="y"
01. Principal	inr	INR (Decimal Use Available With Entry, If Needed)		"0.9"="0.9" "1.0"="1.0" "1.1"="1.1" "1.3"="1.3"
01. Principal	pielig	Is The Participant Eligible For Inclusion On This Study?		"y"="y"
01. Principal	plt	Platelets, the absolute peripheral platelet count (units not specified).		"103"="103" "159"="159" "169"="169" "172"="172" "185"="185" "198"="198" "200"="200" "211"="211" "213"="213" "247"="247" "259"="259" "318"="318"
01. Principal	ps	ECOG Performance Status 0 Or 1		"0"="0" "1"="1"
01. Principal	reg01	Intervention Cannot Begin Prior To Registration And Must Begin <=14 Days From Registration		"y"="y"
01. Principal	studyid	Study ID		Numeric
01. Principal	tbiliunl	Total Bilirubin UNL		"1.0"="1.0" "1.2"="1.2" "1.3"="1.3"

Class	Variable	Label	Description	Format Text
01. Principal	tot_bili	Total Bilirubin		"0.4"="0.4" "0.5"="0.5" "0.6"="0.6" "0.7"="0.7" "0.9"="0.9" "1.0"="1.0" "1.4"="1.4"
01. Principal	version	Version Number		Numeric