

# MAY2013-01-01 - Checklist Pre-Registration Data Dictionary

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## Document Summary

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# MAY2013-01-01 - Checklist Pre-Registration: Data Dictionary

## Section 1: Identifiers

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Variable	Label	Description	Format Text
<b>DCNTR_ID</b>	Data Center ID	Data Center ID	Char

## Section 2: Study-wide

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Variable	Label	Description	Format Text
<b>ARM</b>	Arm	Arm	
<b>CASE</b>	Case Number	Case Number	Numeric
<b>CREATED</b>	Created Date	Created Date	SAS Date
<b>CYCLE</b>	Cycle	Cycle	Numeric
<b>DATE_MOD</b>	Date Modified	Date Modified	SAS Date
<b>DC_NUM</b>	Data Center Assigned Protocol Number	Data Center Assigned Protocol Number	Char
<b>FORMCOMP</b>	Form Complete	Form Complete	Char
<b>FORMNAME</b>	Form Name	Form Name	Char
<b>IGNORE</b>	Nothing	Nothing	Numeric
<b>NODE</b>	Node	Node	Numeric
<b>SEQUENCE</b>	Sequence	Sequence	Numeric
<b>STUDY</b>	Ingres Study Number	Ingres Study Number	Numeric
<b>VERSION</b>	Version	Version	Numeric

## Section 3: Registration Checklist

Variable	Label	Description	Format Text
<b>ADENOMA</b>	Number of advanced adenomas	Number of advanced adenoma on qualifying colonoscopy 1=greater than or equal to 3 2=less than 3	1="Greater >= 3" 2="< 3"
<b>ANA_VAL</b>	ANA ratio	ANA _____ : _____ The colon sign MUST be used for entry (i.e., 1:160). The less than symbol may be used if needed (i.e., <1:80)	Char
<b>CON_OTH</b>	Other	Preference for contact (select one) 1=fax number 2=email	1="Fax Number" 2="Email"
<b>CTEP_ARM</b>	Arm Assigned CTEP	TAC/TAD Code:	Char
<b>EARLY_DT</b>	Earliest Date	Earliest laboratory test date (mm/dd/yyyy) The earliest laboratory test date must be less than or equal to the latest laboratory test date.	SAS Date
<b>EXCLU001</b>	Receiving Any Other Investigational Agent <= 3 Months Prior To Registration	Receiving any other investigational agent less than or equal to 3 months prior to Registration/Randomization, except innocuous agents with no known interaction with the study agent (e.g., standard dose multivitamins or topical agents for limited skin conditions).	"2"="No"
<b>EXCLU002</b>	Any Use Of Oral Corticosteroids	Any use of oral corticosteroids less than or equal to 12 weeks prior to Registration/Randomization.	"2"="No"
<b>FORM</b>	Form	Form	Numeric
<b>FORMTYPE</b>	Form Type	Form Type	Char
<b>GENDER</b>	Gender	Gender 1=Male 2=Female	1="Male" 2="Female"
<b>INCLU001</b>	ECOG Performance Status <= 1	ECOG performance status less than or equal to 1 (Karnofsky greater than or equal to 70%; see Appendix A).	"1"="Yes"
<b>INCLU002</b>	Hemoglobin > 90% Of The Lower Limit Of Institutional Normal	Hemoglobin greater than 90% of the lower limit of institutional normal.	"1"="Yes"

Variable	Label	Description	Format Text
<b>INCLU003</b>	Normal Marrow And Organ Function <= 28 Days Prior To Registration	Normal marrow and organ function, obtained less than or equal to 28 days prior to Registration/Randomization, and defined as follows: NOTE: These dates pertain to the following labs only.	"1"="Yes"
<b>INCLU004</b>	Platelets >= 100 B/L (10 <sup>9</sup> /L)	Platelets greater than or equal to 100 B/L (10 <sup>9</sup> /L).	"1"="Yes"
<b>INCLU005</b>	WBC >= 2.5 B/L (10 <sup>9</sup> /L)	WBC greater than 2.5 B/L (10 <sup>9</sup> /L).	"1"="Yes"
<b>INCLU006</b>	Other Blood Chemistry Markers <= 1.5 x Upper Limit Of Institutional Normal	AST (SGOT), ALT (SGPT), alkaline phosphatase, total bilirubin, BUN, and creatinine less than or equal to 1.5 x upper limit of institutional normal.	"1"="Yes"
<b>INCLU007</b>	ANA <= 1:160	ANA less than or equal to 1:160.	"1"="Yes"
<b>LATE_DT</b>	Latest Date	Latest laboratory test date (mm/dd/yyyy) The latest laboratory test date must be greater than or equal to the earliest laboratory test date.	SAS Date
<b>PIELIG</b>	Participant Eligible for Study?	Is the patient eligible for inclusion on this study?	"1"="Yes"
<b>PLATELET</b>	Platelets	Platelets (10 <sup>9</sup> /L) =	Numeric
<b>PS</b>	Performance Score	ECOG performance status = (0 or 1)	Numeric
<b>REG01</b>	Intervention At CPN Institution Under CPN Clinician Supervision	Intervention on this protocol must commence at a CPN institution under the supervision of a CPN clinician.	"1"="Yes"
<b>REG02</b>	Intervention After Registration/Randomization And <= 14 Days After	Intervention cannot begin prior to Registration/Randomization and must begin less than or equal to 14 days after Registration/Randomization.	"1"="Yes"
<b>WBC</b>	WBC	WBC	Numeric