MAY2013-01-01 - Checklist Registration Data Dictionary

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Document Summary

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MAY2013-01-01 - Checklist Registration: Data Dictionary

Section 1: Identifiers

Variable	Label	Description	Format Text
DCNTR_ID	Data Center ID	Data Center ID	Char

Section 2: Study-wide

Variable	Label	Description	Format Text
ARM	Arm	Arm	
CASE	Case Number	Case Number	Numeric
CREATED	Created Date	Created Date	SAS Date
CYCLE	Cycle	Cycle	Numeric
DATE_MOD	Date Modified	Date Modified	SAS Date
DC_NUM	Data Center Assigned Protocol Number	Data Center Assigned Protocol Number	"MAY2013-01-01"="MAY2013-01-01"
FORMCOMP	Form Complete	Form Complete	Char
FORMNAME	Form Name	Form Name	Char
SEQUENCE	Sequence	Sequence	Numeric
STUDY	Ingres Study Number	Ingres Study Number	Numeric
STUDY	Ingres Study Number	Ingres Study Number	Numeric
VERSION	Version	Version	Numeric

Section 3: Pre-Registration Checklist

Variable	Label	Description	Format Text
AGE	Age	Age	Numeric
ARM	Arm	Arm	Char
AUTH_CA	Authorized Sample	Participant has given permission to collect and store blood and/or tissue for future use in research to learn about, prevent, treat, or cure cancer.	1="Yes" 2="No"
AUTH_OTH	Authorized Sample Other	Participant has given permission to collect and store blood and/or tissue for future use in research about other health problems (for example: Barrett's esophagus, causes of diabetes mellitus, Alzheimer's disease, and heart disease).	1="Yes" 2="No"
AUTH_OUT	Authorized Sample OUT	Participant has given permission to send blood and/or tissue sample(s) to researchers at an outside institution.	1="Yes" 2="No"
AUTH_RES	Authorized contact research	Participant has given permission to his/her doctor (or someone from the Cancer Prevention Network) to contact them in the future to ask them to take part in more research.	"n"="No" "y"="Yes"
CONSNTDT	Consent Date	Date informed consent signed (mm/dd/yyyy)	SAS Date
CTEP_ARM	Arm Assigned CTEP	TAC/TAD Code:	Char
EXCLU001	History Of Colorectal Cancer	History of any colorectal cancer	"2"="No"
EXCLU002	History Of Other Malignancy Within 5 Years	History of other malignancy less than or equal to 5 years prior to the Registration/Randomization evaluation, with the exception of basal cell or squamous cell skin cancer.	"2"="No"

Variable	Label	Description	Format Text
EXCLU003	Presence Of Acute Or Chronic Infection Or Uncontrolled Illness	Presence of an active acute or chronic infection or uncontrolled illness including, but not limited to, unstable congestive heart failure, unstable angina pectoris, cardiac arrhythmia, or psychiatric illness/social situations that would limit compliance with study requirements	"2"="No"
EXCLU004	Acquired Immunosuppressive Diseases	Acquired immunosuppressive diseases such as active HIV infection or congenital diseases of immunity	"2"="No"
EXCLU005	History Of Heritable Cancer Syndrome	History of heritable cancer syndrome (FAP, HNPCC)	"2"="No"
EXCLU006	History Of Auto-Immune Disease	History of auto-immune disease such as, but not restricted to, inflammatory bowel disease, systemic lupus erythematosis, rheumatoid arthritis, ankylosing spondylitis, scleroderma, multiple sclerosis, Hashimoto's thyroiditis, or Grave's disease.	"2"="No"
EXCLU007	Current Or Planned Use Of Immunomodulators	Current or planed use of immunomodulators including: infliximab, 6-MP (mercaptopurine), methotrexate, cyclosporine, or other immunomodulatory drugs.	"2"="No"
EXCLU008	History Of Allergic Reactions To Compounds Similar To Agent	History of allergic reactions attributed to compounds of similar chemical or biologic composition to the study agent.	"2"="No"
EXCLU009	Pregnant Women	Pregnant women, because the teratogenic or abortifacient effects of the study agents remain incompletely defined.	"2"="No"
EXCLU010	Breastfeeding Women	Breastfeeding women, because there is an unknown but potential risk for adverse events in nursing infants secondary to treatment of the mother with the study agents.	"2"="No"

Variable	Label	Description	Format Text
EXCLU011	Diagnosis Of Non-Alcoholic Steatohepatitis	Diagnosis of nonalcoholic steatohepatitis (NASH) and a NAFLD (nonalcoholic fatty liver disease) activity score (NAS) >= 5. NOTES and EXCEPTIONS: NAS is based on findings from a liver biopsy. Participants with NAS of <= 2 are eligible for enrollment. Participants with NAS of 3-4 must be discussed with the Principal Investigator and DCP before enrollment to consider other risk factors (i.e., obesity, alcohol intake). Participants with a prior diagnosis of NASH and no available NAS must be discussed with	"2"="No"
FORM	Form	Form	Numeric
FORMTYPE	Form Type	Form Type	Char
HIPAA_DT	Date of Authorization For HIPA	If a USA institution - Date of authorization (mm/dd/yyyy)	SAS Date
IGNORE	Nothing	Nothing	Numeric
INCLU001	History Of Colorectal Adenomas	History of at least one of the following conditions in the previous 12 months: Colorectal adenoma(s) greater than or equal to 1 cm in maximal diameter Colorectal adenoma(s) with villous or tubulovillous histology Colorectal adenoma(s) with high grade (severe) dysplasia	"1"="Yes"
INCLU002	Presumptive Evidence That Adenomas Were Removed	Presumptive evidence that all adenomatous lesions, including qualifying advanced adenoma have been completely removed.	"1"="Yes"
INCLU003	Age 40-70 At Registration/Randomizatio n	Age 40-70 years of age at time of registration/randomization.	"1"="Yes"
INCLU004	Ability To Understand And Willing To Sign Informed Consent	Ability to understand and the willingness to sign a written informed consent document.	"1"="Yes"
INCLU005	Willingness To Undergo Screening Tests And Procedures	Willingness to undergo screening tests and procedures.	"1"="Yes"
INCLU006	Willingness To Provide Blood Samples For Toxicity	Willingness to provide blood samples for toxicity monitoring and research purposes.	"1"="Yes"

Variable	Label	Description	Format Text
INCLU007	Not Pregnant Or Nursing	Not pregnant or nursing. Note: A negative (serum or urine) pregnancy test must be documented less than or equal to 7 days prior to registration/randomization for women of childbearing potential. If not a woman of childbearing potential or male (select NA)	"1"="Yes" "3"="Not Available"
INCLU008	Willingness To Employ Adequate Contraception Through Week 53	Willingness to employ adequate contraception through Week 53 of the study. Note: The effects of the MUC1 vaccine on the developing human fetus at the dose specified in this study are unknown. For this reason, women of child-bearing potential and men must agree to use adequate contraception (hormonal, barrier method of birth contro,; abstinence) prior to study entry and for the period of active vaccination (through Week 53). Should a woman become pregnant or suspect she is pregnant while participating in	"1"="Yes"
NODE	Node	Node	Numeric
PIELIG	Participant Eligible for Study?	Is the patient eligible for inclusion on this study?	"1"="Yes"
REG01	Consent Form Signed And Dated?	Consent form signed and dated.	"1"="Yes"
REG02	Authorization For Use And Disclosure Of Protected Health Information	Authorization for use and disclosure of protected health information (USA institutions only) signed and dated. If not a USA institution (select NA)	"1"="Yes" "3"="Not Available"
REG03	Study Agent Is Available And Authorized To The Registering Site	Study agent is available and Drug Shipment Authorization has been granted to the registering site.	"1"="Yes"
REG04	Baseline Evaluations <= 28 Days Prior To Registration	Baseline (screening) evaluations must be completed less than or equal to 28 days prior to registration (See Section 7.1).	"1"="Yes"
REG05	Registration Office Personnel Will Automatically Register Participants	Registration Office personnel will automatically register participants separately to the translational components of the study (see Section 13.0).	"1"="Yes"