MAYO - PREREG CHKLIST HISTORY: DATA DICTIONARY

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Document Summary

Property	Value
Document Title	Mayo - Prereg Chklist History: Data Dictionary
Date Created	12/07/2017
For Dataset	chklist_history
Sections	2
Entries	60
Document Filename	dictionary_ChklistHistory.100617.rtf

Mayo - Prereg Chklist History: Data Dictionary

Section 1: Identifiers

Variable	Label	Description	Format Text
ARM	Arm		Char " "=" "
DCNTR_ID	Data Center ID		Char " "=" "

Section 2: Form Data

Variable	Label	Description	Format Text
AGE	Age		Num
AUTH_CA	Authorized Sample	The following will also be recorded: Participant has given permission to collect and store blood and tissue for at least 5 years for future use in research to learn about, prevent, treat, or cure cancer.	Num 1="Yes"
AUTH_OTH	Authorized Sample Other	Participant has given permission to collect and store blood and tissue for at least 5 years for future use in research about other health problems (for example: causes of diabetes, Alzheimer's disease, and heart disease).	Num 1="Yes"
AUTH_OUT	Authorized Sample OUT	Participant has given permission to send blood and/or tissue sample(s) to researchers at an outside institution.	Num 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.	Num ."Missing"
CASE	Case Number		Num
CONSNTDT	Consent Date	Date informed consent signed: (mm/dd/yyyy)	SAS Date
CREATED	Created Date		SAS Date ."Missing"
CTEP_ARM	Arm Assigned CTEP	TAC/TAD Code:	Char
CYCLE	Cycle		Num
DATE_MOD	Date Modified		Num ."Missing"
DC_NUM	Data Center Assigned Prot Num		Char " "=" "

Variable	Label	Description	Format Text
EXCLU001	Previous personal history of advanced adenomas (>= 1 cm in maximal diameter, >= 3 in total number, villous morphology, or high-grade dysplasia) or colorectal cancer).	Previous personal history of advanced adenomas (>= 1 cm in maximal diameter, >= 3 in total number, villous morphology, or high-grade dysplasia) or colorectal cancer).	Char "2"="No"
EXCLU002	Family history of polyposis syndrome (e.g., FAP, HNPCC) or colorectal cancer (first degree relatives younger than 60 years old).	Family history of polyposis syndrome (e.g., FAP, HNPCC) or colorectal cancer (first degree relatives younger than 60 years old).	Char "2"="No"
EXCLU003	History of gastroparesis.	History of gastroparesis.	Char "2"="No"
EXCLU004	History of surgery involving the luminal GI tract, including bariatric surgery.	History of surgery involving the luminal GI tract, including bariatric surgery.	Char "2"="No"
EXCLU005	History of celiac disease.	History of celiac disease.	Char "2"="No"
EXCLU006	Inflammatory bowel disease (Crohn's disease, ulcerative colitis).	Inflammatory bowel disease (Crohn's disease, ulcerative colitis).	Char "2"="No"
EXCLU007	Irritable bowel syndrome, chronic constipation, functional bowel disorders, or colonic motility disorder.	Irritable bowel syndrome, chronic constipation, functional bowel disorders, or colonic motility disorder.	Char "2"="No"
EXCLU008	Any malignancy within 3 years of baseline. Participants with a history of basal cell or squamous cell skin cancer may be enrolled at the discretion of the investigator.	Any malignancy within 3 years of baseline. Participants with a history of basal cell or squamous cell skin cancer may be enrolled at the discretion of the investigator.	Char "2"="No"
EXCLU009	Participants may not be receiving any other investigational agents.	Participants may not be receiving any other investigational agents.	Char "2"="No"
EXCLU010	History of allergic reactions attributed to compounds of similar chemical or biologic composition to linaclotide.	History of allergic reactions attributed to compounds of similar chemical or biologic composition to linaclotide.	Char "2"="No"
EXCLU011	History of difficulty with colonoscopy or abnormal colorectal anatomy.	History of difficulty with colonoscopy or abnormal colorectal anatomy.	Char "2"="No"
EXCLU012	Uncontrolled current illness including, but not limited to, ongoing or active infection, symptomatic congestive heart failure, unstable angina pectoris, cardiac arrhythmia, or psychiatric illness/social situations that would limit compliance	Uncontrolled current illness including, but not limited to, ongoing or active infection, symptomatic congestive heart failure, unstable angina pectoris, cardiac arrhythmia, or psychiatric illness/social situations that would limit compliance with study requirements.	Char "2"="No"

Variable	Label	Description	Format Text
EXCLU013	Pregnant or lactating women.	Pregnant or lactating women.	Char "2"="No"
EXCLU014	Use of laxatives more than 3 times per week.	Use of laxatives more than 3 times per week.	Char "2"="No"
EXCLU015	Intestinal motility agents, histamine-2 inverse agonists (H-2 blockers), or proton pump inhibitors.	Intestinal motility agents, histamine-2 inverse agonists (H-2 blockers), or proton pump inhibitors.	Char "2"="No"
EXCLU016	Current use of >= 5 cigarettes/day.	Current use of >= 5 cigarettes/day.	Char "2"="No"
EXCLU017	Current use of >= 3 alcoholic drinks/day.	Current use of >= 3 alcoholic drinks/day.	Char "2"="No"
EXCLU018	Use anti-platelet agents within two weeks of anticipated colonoscopy.	Use anti-platelet agents within two weeks of anticipated colonoscopy.	Char "2"="No"
EXCLU019	Use of anti-coagulants within two weeks of anticipated colonoscopy.	Use of anti-coagulants within two weeks of anticipated colonoscopy.	Char "2"="No"
EXCLU020	History of bleeding/coagulation problems.	History of bleeding/coagulation problems.	Char "2"="No"
EXCLU021	Prior intolerance of or contraindications for the use of sedation anesthetic agents, which would prevent the safe use of sedation for colonoscopy. This includes allergies to eggs and soy products.	Prior intolerance of or contraindications for the use of sedation anesthetic agents, which would prevent the safe use of sedation for colonoscopy. This includes allergies to eggs and soy products.	Char " "=" " "2"="No"
EXCLU022	Any medical condition judged by the investigator to constitute a risk to safe participation.	Any medical condition judged by the investigator to constitute a risk to safe participation.	Char "2"="No"
FORM	Form		Num 8="Pre-Registration Eligibilty Checklist"
FORMCOMP	Form Complete		Char " "=" "
FORMNAME	Form Name		Char " "=" "
FORMTYPE	Form Type		Char " "=" "
HIPAA_DT	Date of Authorization For HIPA	If a USA Institution - Date of authorization (mm/dd/yyyy)	SAS Date
IGNORE	Nothing		Num ."Missing"
INCLU001	Male and female participants with an age between 18 years and 65 years.	Male and female participants with an age between 18 years and 65 years.	Char "1"="Yes"

Variable	Label	Description	Format Text
INCLU002	Ability to understand and willingness to sign a written informed consent document and follow study procedures.	Ability to understand and willingness to sign a written informed consent document and follow study procedures.	Char "1"="Yes"
INCLU003	Willingness to abstain from grapefruit juice, alcohol and concomitant medications during study.	Willingness to abstain from grapefruit juice, alcohol and concomitant medications during study.	Char "1"="Yes"
INCLU004	Willingness to employ adequate contraception for men and women of childbearing potential. Acceptable methods include double barrier methods, intrauterine device (IUD), postmenopausal status documented by serum FSH, and/or documentation	Willingness to employ adequate contraception for men and women of childbearing potential. Acceptable methods include double barrier methods, intrauterine device (IUD), postmenopausal status documented by serum FSH, and/or documentation of surgical sterilization. If not of childbearing potential (select N/A)	Char "1"="Yes"
INCLU005	Body Mass Index <35 kg/m^2.	Body Mass Index <35 kg/m^2.	Char "1"="Yes"
INCLU006	Willingness to provide blood and tissue specimens for research purposes.	Willingness to provide blood and tissue specimens for research purposes.	Char "1"="Yes"
NODE	Node		Num
PIELIG	Participant Eligible for Study?	Is the patient eligible for inclusion on this study?	Char "1"="Yes"
PREV_ID	Previous ID	If yes: Prior participant CPN ID number:	Char " "=" "
PREVIOUS	Pre-Registered Previously	Has the participant been pre-registered previously to this study? y (Yes), n (No)	Char "1"="Yes" "2"="No"
REG01	Consent form signed and dated.	Consent form signed and dated.	Char
REG02	Authorization for use and disclosure of protected health information (USA Institutions only) signed and dated. If not a USA Insitution (select NA)	Authorization for use and disclosure of protected health information (USA Institutions only) signed and dated. If not a USA Insitution (select NA)	Char
REG03	Evaluations must be completed within the guidelines specified on the Schedule of Events.	Evaluations must be completed within the guidelines specified on the Schedule of Events.	Char
REG04	All baseline symptoms must be documented and graded.	All baseline symptoms must be documented and graded.	Char

Variable	Label	Description	Format Text
REG05	All Participants will automatically be registered to the correlative components of this study (see Section 9.0).	All Participants will automatically be registered to the correlative components of this study (see Section 9.0).	Char
SEQUENCE	Sequence		Num
STUDY	Ingres Study Number		Num .="Missing"
VERSION	Version		Num