

# MAY2017-09-01 - PRE-REGISTRATION CHECKLIST: DATA DICTIONARY

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## Document Summary

Property	Value
Document Title	MAY2017-09-01 - Pre-Registration Checklist: Data Dictionary
Date Created	02/26/2020
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Entries	54
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# MAY2017-09-01 - Pre-Registration Checklist: Data Dictionary

## Section 1: Identifiers

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Variable	Label	Description	Format Text
<b>subject</b>	Participant ID	Participant ID	Char

## Section 2: Pre-Registration Checklist

Variable	Label	Description	Format Text
<b>AGE</b>	Age	Age	Numeric
<b>AUTH_OUT</b>	Authorized Specimen Research	Authorized Specimen Research	Numeric
<b>AUTH_RES</b>	Authorized Doctor/Representative To Contact About Future Research	Authorized Doctor/Representative To Contact About Future Research	Numeric
<b>CASE</b>	Case Number	Case Number	Numeric
<b>CONSENTDT</b>	Consent Date	Consent Date	SAS Date
<b>CREATED</b>	Created Date	Created Date	SAS Date
<b>CTEP_ARM</b>	CTEP Arm	CTEP Arm	"TAC0"="TAC0"
<b>DATE_MOD</b>	Date Modified	Date Modified	SAS Date
<b>DC_NUM</b>	Data Center Assigned Prot Num	Data Center Assigned Prot Num	"MAY2017-09-01"="MAY2017-09-01"
<b>ELIG</b>	Is Participant Eligible?	Is Participant Eligible?	1="Yes"
<b>EXCLU001</b>	History Of Advanced Adenomas Or Colorectal Cancer	History Of Advanced Adenomas Or Colorectal Cancer	"2"="No"
<b>EXCLU002</b>	Family History Of Polyposis Syndrome Or Colorectal Cancer	Family History Of Polyposis Syndrome Or Colorectal Cancer	"2"="No"
<b>EXCLU003</b>	History Of Gastroparesis	History Of Gastroparesis	"2"="No"
<b>EXCLU004</b>	History Of G.I. Tract Surgery	History Of G.I. Tract Surgery	"2"="No"
<b>EXCLU005</b>	History Of Celiac Disease	History Of Celiac Disease	"2"="No"
<b>EXCLU006</b>	Inflammatory Bowel Disease	Inflammatory Bowel Disease	"2"="No"
<b>EXCLU007</b>	Previous Diagnosis Of Irritable Bowel Syndrome, Chronic Constipation, Bowel Disorders, or Colonic Motility Disorder	Previous Diagnosis Of Irritable Bowel Syndrome, Chronic Constipation, Bowel Disorders, or Colonic Motility Disorder	"2"="No"
<b>EXCLU008</b>	Any Malignancy Within 3 Years Of Baseline	Any Malignancy Within 3 Years Of Baseline	"2"="No"
<b>EXCLU009</b>	Any Other Investigational Agents Currently	Any Other Investigational Agents Currently	"2"="No"
<b>EXCLU010</b>	History Of Allergic Reactions To Similar Compounds	History Of Allergic Reactions To Similar Compounds	"2"="No"
<b>EXCLU011</b>	History Of Difficult Sigmoidoscopy Or Abnormal Colorectal Anatomy	History Of Difficult Sigmoidoscopy Or Abnormal Colorectal Anatomy	"2"="No"

Variable	Label	Description	Format Text
<b>EXCLU012</b>	Uncontrolled Current Illness	Uncontrolled Current Illness	"2"="No"
<b>EXCLU013</b>	Pregnant Or Lactating Women	Pregnant Or Lactating Women	"2"="No"
<b>EXCLU014</b>	Current Use Of Laxatives More Than 3 Times Per Week	Current Use Of Laxatives More Than 3 Times Per Week	"2"="No"
<b>EXCLU015</b>	Current Use Of >= 5 Cigarettes A Day	Current Use Of >= 5 Cigarettes A Day	"2"="No"
<b>EXCLU016</b>	Current Use Of >= 3 Alcoholic Drinks A Day	Current Use Of >= 3 Alcoholic Drinks A Day	"2"="No"
<b>EXCLU017</b>	Use Of Anti-Coagulants Or Anti-Platelet Within 5 Days Prior To Sigmoidoscopy	Use Of Anti-Coagulants Or Anti-Platelet Within 5 Days Prior To Sigmoidoscopy	"2"="No"
<b>EXCLU018</b>	History Of Bleeding/Coagulation Problems	History Of Bleeding/Coagulation Problems	"2"="No"
<b>EXCLU019</b>	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	"2"="No"
<b>EXCLU020</b>	Known Or Suspected Mechanical Gastrointestinal Obstruction	Known Or Suspected Mechanical Gastrointestinal Obstruction	"2"="No"
<b>FORM</b>	Form	Form	Numeric
<b>FORMNAME</b>	Form Name	Form Name	"MAY2017-09-01 Pre-Registration Elig Checklist (Step 0)"="MAY2017-09-01 Pre-Registration Elig Checklist (Step 0)"
<b>INCLU001</b>	Age Between 18 And 65	Age Between 18 And 65	"1"="Yes"
<b>INCLU002</b>	Able And Willing To Sign Consent	Able And Willing To Sign Consent	"1"="Yes"
<b>INCLU003</b>	Willing To Abstain From Grapefruit Juice	Willing To Abstain From Grapefruit Juice	"1"="Yes"
<b>INCLU004</b>	Willing To Use Adequate Contraception	Willing To Use Adequate Contraception	"1"="Yes"
<b>INCLU005</b>	Body Mass Index <35 kg/m3	Body Mass Index <35 kg/m3	"1"="Yes"
<b>INCLU006</b>	Willing To Provide Blood And Tissue Specimen	Willing To Provide Blood And Tissue Specimen	"1"="Yes"
<b>NODE</b>	Node	Node	Numeric
<b>PERMIT1</b>	Participant Permission To Collect And Use Specimens For Studies Described In This Protocol	Participant Permission To Collect And Use Specimens For Studies Described In This Protocol	"1"="Yes" "2"="No"
<b>PERMIT2</b>	Participnt Permission For Study Doctor To Contact Their Physician With Results	Participnt Permission For Study Doctor To Contact Their Physician With Results	"1"="Yes" "2"="No"

Variable	Label	Description	Format Text
<b>PERMIT3</b>	Participant Permission For Alcohol/Tobacco Information To Be Used For Future Research	Participant Permission For Alcohol/Tobacco Information To Be Used For Future Research	"1"="Yes" "2"="No"
<b>PERMIT4</b>	Participant Permission For Specimens To Be Kept In A Biobank For Use In Future Studies	Participant Permission For Specimens To Be Kept In A Biobank For Use In Future Studies	"1"="Yes" "2"="No"
<b>PREV_ID</b>	Previous Study ID	Previous Study ID	Char
<b>PREVIOUS</b>	Previous Study?	Previous Study?	"1"="Yes" "2"="No"
<b>REG01</b>	Consent Form Signed And Dated	Consent Form Signed And Dated	"1"="Yes"
<b>REG02</b>	Existence Of Authorization For Use And Disclosure Of Protected Health Information	Existence Of Authorization For Use And Disclosure Of Protected Health Information	"1"="Yes"
<b>REG03</b>	Study Agent Is Available And Drug Shipment Authorization Has Been Granted To The Registering Site	Study Agent Is Available And Drug Shipment Authorization Has Been Granted To The Registering Site	"1"="Yes"
<b>REG04</b>	Baseline Evaluations Must Be Completed Within Guidelines	Baseline Evaluations Must Be Completed Within Guidelines	"1"="Yes"
<b>REG05</b>	All Baseline Symptoms Must Be Documented	All Baseline Symptoms Must Be Documented	"1"="Yes"
<b>REG06</b>	Registration Office Personnel Will Automatically Register Participants Separately To The Translational Components Of The Study	Registration Office Personnel Will Automatically Register Participants Separately To The Translational Components Of The Study	"1"="Yes"
<b>SEQUENCE</b>	Sequence	Sequence	Numeric
<b>VERSION</b>	Version	Version	Numeric