

MAY2017-09-01 - PRE-EXCLUSION: DATA DICTIONARY

TABLE OF CONTENTS

| | |
|--|---|
| Document Summary..... | 2 |
| MAY2017-09-01 - Pre-Exclusion: Data Dictionary | 3 |
| Section 1: Identifiers | 3 |
| Section 2: Study-wide | 4 |
| Section 3: Pre-Exclusion | 5 |

Document Summary

| Property | Value |
|-------------------|--|
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MAY2017-09-01 - Pre-Exclusion: Data Dictionary

Section 1: Identifiers

| Variable | Label | Description | Format Text |
|----------------|----------------|----------------|-------------|
| SUBJECT | Participant ID | Participant ID | Char |

Section 2: Study-wide

| Variable | Label | Description | Format Text |
|--------------------------------|-----------------------------------|-----------------------------------|--|
| FOLDERINSTANCE NAME | Folder Name | Folder Name | "Screening"="Screening" |
| MAXUPDATED | Last Updated | Last Updated | Numeric |
| MINCREATED | Time Created | Time Created | Numeric |
| PAGEREPEATNUM BER | Page Repeat Number | Page Repeat Number | Numeric |
| PROJECT | Protocol | Protocol | "MAY2017-09-01"="MAY2017-09-01" |
| RAVEID | Rave ID | Rave ID | Numeric |
| RECORDPOSITION | Record Position | Record Position | Numeric |
| SITE | Study Institution | Study Institution | "Thomas Jefferson University Hospital"="Thomas Jefferson University Hospital" |
| SITENUMBER | Study Institution ID Number | Study Institution ID Number | "PA121"="PA121" |
| TARGETDAYS | Target Days From Randomization | Target Days From Randomization | Numeric |

Section 3: Pre-Exclusion

| Variable | Label | Description | Format Text |
|----------|---|---|-------------------|
| EXCLU001 | History Of Advanced Adenomas Or Colorectal Cancer | History Of Advanced Adenomas Or Colorectal Cancer | 2="No" |
| EXCLU002 | Family History Of Polyposis Syndrome Or Colorectal Cancer | Family History Of Polyposis Syndrome Or Colorectal Cancer | 2="No" |
| EXCLU003 | History Of Gastroparesis | History Of Gastroparesis | 2="No" |
| EXCLU004 | History Of G.I. Tract Surgery | History Of G.I. Tract Surgery | 2="No" |
| EXCLU005 | History Of Celiac Disease | History Of Celiac Disease | 2="No" |
| EXCLU006 | Inflammatory Bowel Disease | Inflammatory Bowel Disease | 2="No" |
| EXCLU007 | 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" |
| EXCLU008 | Any Malignancy Within 3 Years Of Baseline | Any Malignancy Within 3 Years Of Baseline | 2="No" |
| EXCLU009 | Any Other Investigational Agents Currently | Any Other Investigational Agents Currently | 2="No" |
| EXCLU010 | History Of Allergic Reactions To Similar Compounds | History Of Allergic Reactions To Similar Compounds | 2="No" |
| EXCLU011 | History Of Difficult Sigmoidoscopy Or Abnormal Colorectal Anatomy | History Of Difficult Sigmoidoscopy Or Abnormal Colorectal Anatomy | 2="No" |
| EXCLU012 | Uncontrolled Current Illness | Uncontrolled Current Illness | 2="No" |
| EXCLU013 | Pregnant Or Lactating Women | Pregnant Or Lactating Women | 2="No" 3="N/A" |
| EXCLU014 | Current Use Of Laxatives More Than 3 Times Per Week | Current Use Of Laxatives More Than 3 Times Per Week | 2="No" |
| EXCLU015 | Current Use Of >= 5 Cigarettes A Day | Current Use Of >= 5 Cigarettes A Day | 2="No" |
| EXCLU016 | Current Use Of >= 3 Alcoholic Drinks A Day | Current Use Of >= 3 Alcoholic Drinks A Day | 2="No" |
| EXCLU017 | 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" |
| EXCLU018 | History Of Bleeding/Coagulation Problems | History Of Bleeding/Coagulation Problems | 2="No" |

| Variable | Label | Description | Format Text |
|-----------------|---|---|-------------|
| EXCLU019 | 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" |
| EXCLU020 | Known Or Suspected Mechanical Gastrointestinal Obstruction | Known Or Suspected Mechanical Gastrointestinal Obstruction | 2="No" |