User Guide for SPARC Summary At Index Date Function

Crohn’s and Colitis Foundation

2/17/2021

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## Overview

Sparc\_summary\_at\_index.R is a script that reads in SPARC data from IBD Plexus. It finds the medications the participant is prescribed from the electronic medical record, patient reported case report forms and Smartform, lists other Smartform data fields, calculates diagnosis, phenotype, disease, and endoscopy scores and lists the encounter id or hist id at a specific (“index”) date.

## Requirements

## Requirements

* R Version 4.0.2 or above
* The following R packages are required and can be installed using install.packages(“package name”)
  + reshape2
  + tidyverse
  + lubridate
  + DT
  + readxl
  + openxlsx
* datadir = the directory where the unzipped SPARC site data from IBD Plexus is saved
  + .csv and .txt format are acceptable
  + If multiple extracts are saved in the same folder, the most recent files will be selected
* Index\_info = a data frame with DEIDENTIFIED\_MASTER\_PATIENT\_ID and a variable named index\_date.
  + The default index\_date is the DATE\_OF\_CONSENT
* Filename = the name of the output file.
  + Must be in .xlsx format
  + The default is SPARC\_SITE\_SUMMARY.xlsx
* Index\_range = the number of days to look out from index date.
  + The default is 14 days
  + For example, to see Smartform values and scores within +/- 30 days of enrollment, the index\_range = “30”.
* Emr\_codes = the codes to search through in the extract
  + Default is an empty vector
  + Usually an ICD10 code
  + For example, to search for Ankylosing spondylitis of multiple sites in spine and Ankylosing spondylitis of unspecified sites in spine, emr\_codes = c(“M45.0”, “M45.9”).
* MED\_CODES.csv = a file that has the medications of interest saved in the working directory
  + MEDICATION\_NAME= the medication of interest and includes the generic and brand names
  + Med\_type = the medication class (i.e. Biologic, Antibiotic, etc)
  + New\_med\_name = the generic name of the drug
* EIM\_CODES.csv = a file that has the codes for the EIMS in the Smartform saved in the working directory
  + EIM\_DX = the Extraintestinal manifestation of interest as it appears on the Smartform
  + Coding = if the code associated with the code is Yes/No or Unknown
  + DIAG\_CONCEPT\_CODE = the code associated with the EIM in the Smartform

## Output Table

The output file “SPARC\_SUMMARY.xlsx” includes the following columns. If more than the DEIDENTIFIED\_MASTER\_PATIENT\_ID and index\_date is in the index\_info data.frame, those columns will be included as well. Unless otherwise specified, the closest value to the index date is used if there are multiple reported values within the index range.

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Column Header** | **Derived Variable (Y/N)** | **DDM Table** | **DDM Data Source** | **Other DDM Filters** | **DDM Variable** | **Notes** | |
| **DEIDENTIFIED\_MASTER\_PATIENT\_ID** | N | Demographics | ECRF\_SPARC |  | DEIDENTIFIED\_MASTER\_PATIENT\_ID |  | |
| **INDEX\_DATE** | Y |  |  |  |  | A date of interest specified by the user. | |
| **DATE\_OF\_CONSENT** | N | Demographics | ECRF\_SPARC |  | DATE\_OF\_CONSENT |  | |
| **DATE\_OF\_CONSENT\_WITHDRAWN** | N | Demographics | ECRF\_SPARC |  | DATE\_OF\_CONSENT\_WITHDRAWN |  | |
| **BIRTH\_YEAR** | N | Demographics | ECRF\_SPARC |  | BIRTH\_YEAR |  | |
| **GENDER** | N | Demographics | ECRF\_SPARC |  | GENDER |  | |
| **ETHNICITY** | N | Demographics | EMR |  | ETHNICITY |  | |
| **RACE** | N | Demographics | EMR |  | RACE |  | |
| **DIAGNOSIS** | N | Diagnosis | SF\_SPARC > ECRF\_SPARC | DIAG\_CONCEPT\_NAME equals Crohn’s Disease, Ulcerative Colitis or IBD Unclassified. For SF only, | DIAG\_CONCEPT\_NAME | Chose diagnosis reported closest to index date from SF first, then ECRF. Use ECRF\_QORUS if consented to both studies. | |
|  |  |  |  | DIAG\_STATUS\_CONCEPT\_CODE equals Yes. |  |  | |
| **DIAGNOSIS\_DATE** | N | Diagnosis | SF\_SPARC | DIAG\_CONCEPT\_NAME equals Crohn’s Disease, Ulcerative Colitis, IBD Unclassified or Inflammatory Bowel Disease. | DIAGNOSIS\_DATE |  | |
| **CROHN'S DISEASE PHENOTYPE** | N | Observations | SF\_SPARC | For Crohn’s Disease patients only. OBS\_TEST\_CONCEPT\_NAME equals “Crohn’s Disease Phenotype”. | DESCRIPTIVE\_SYMP\_TEST\_RESULTS | Inflammatory, non-penetrating, non-stricturing phenotype can be pulled backward. All phenotypes can be pulled forward to the next reported phenotype. | |
| **IBD MANIFESTATIONS - ABDOMINAL ABSCESS, FISTULA, OR OTHER PENETRATING COMPLICATION** | N | Observations | SF\_SPARC | For Crohn’s Disease patients only. | DESCRIPTIVE\_SYMP\_TEST\_RESULTS |  | |
| **PHENOTYPE - ANAL STRICTURE** | N | Observations | SF\_SPARC | For Crohn’s Disease patients only. | DESCRIPTIVE\_SYMP\_TEST\_RESULTS |  | |
| **PHENOTYPE - DUODENAL STRICTURE** | N | Observations | SF\_SPARC | For Crohn’s Disease patients only. | DESCRIPTIVE\_SYMP\_TEST\_RESULTS |  | |
| **PHENOTYPE - ENTEROCUTANEOUS FISTULA** | N | Observations | SF\_SPARC | For Crohn’s Disease patients only. | DESCRIPTIVE\_SYMP\_TEST\_RESULTS |  | |
| **PHENOTYPE - ENTEROENTERIC FISTULA** | N | Observations | SF\_SPARC | For Crohn’s Disease patients only. | DESCRIPTIVE\_SYMP\_TEST\_RESULTS |  | |
| **PHENOTYPE - ENTEROVESICAL FISTULA** | N | Observations | SF\_SPARC | For Crohn’s Disease patients only. | DESCRIPTIVE\_SYMP\_TEST\_RESULTS |  | |
| **PHENOTYPE - ESOPHAGEAL STRICTURE** | N | Observations | SF\_SPARC | For Crohn’s Disease patients only. | DESCRIPTIVE\_SYMP\_TEST\_RESULTS |  | |
| **PHENOTYPE - GASTRIC STRICTURE** | N | Observations | SF\_SPARC | For Crohn’s Disease patients only. | DESCRIPTIVE\_SYMP\_TEST\_RESULTS |  | |
| **PHENOTYPE - ILEAL STRICTURE** | N | Observations | SF\_SPARC | For Crohn’s Disease patients only. | DESCRIPTIVE\_SYMP\_TEST\_RESULTS |  | |
| **PHENOTYPE - INTRA-ABDOMINAL ABCESS** | N | Observations | SF\_SPARC | For Crohn’s Disease patients only. | DESCRIPTIVE\_SYMP\_TEST\_RESULTS |  | |
| **PHENOTYPE - JEJUNAL STRICTURE** | N | Observations | SF\_SPARC | For Crohn’s Disease patients only. | DESCRIPTIVE\_SYMP\_TEST\_RESULTS |  | |
| **PHENOTYPE - LEFT COLONIC STRICTURE** | N | Observations | SF\_SPARC | For Crohn’s Disease patients only. | DESCRIPTIVE\_SYMP\_TEST\_RESULTS |  | |
| **PHENOTYPE - OTHER FISTULA** | N | Observations | SF\_SPARC | For Crohn’s Disease patients only. | DESCRIPTIVE\_SYMP\_TEST\_RESULTS |  | |
| **PHENOTYPE - RECTAL STRICTURE** | N | Observations | SF\_SPARC | For Crohn’s Disease patients only. | DESCRIPTIVE\_SYMP\_TEST\_RESULTS |  | |
| **PHENOTYPE - RIGHT COLONIC STRICTURE** | N | Observations | SF\_SPARC | For Crohn’s Disease patients only. | DESCRIPTIVE\_SYMP\_TEST\_RESULTS |  | |
| **PHENOTYPE - TRANSVERSE COLONIC STRICTURE** | N | Observations | SF\_SPARC | For Crohn’s Disease patients only. | DESCRIPTIVE\_SYMP\_TEST\_RESULTS |  | |
| **EXTENT OF MACROSCOPIC ULCERATIVE COLITIS** | N | Observations | SF\_SPARC | For Ulcerative Colitis patients only. OBS\_TEST\_CONCEPT\_NAME equals “Extent of Macroscopic Ulcerative Colitis” | DESCRIPTIVE\_SYMP\_TEST\_RESULTS | Ulcerative proctitis (rectum only) can be pulled backward. All phenotypes can be pulled forward to the next reported phenotype. | |
| **EXTENT OF MACROSCOPIC IBD UNCLASSIFIED** | N | Observations | SF\_SPARC | For IBD unclassified patients only. OBS\_TEST\_CONCEPT\_NAME equals “Extent of Macroscopic IBD Unclassified” | DESCRIPTIVE\_SYMP\_TEST\_RESULTS | Ulcerative proctitis (rectum only) can be pulled backward. All phenotypes can be pulled forward to the next reported phenotype. | |
| **HISTORY OF HOSPITALIZATION FOR SEVERE ULCERATIVE COLITIS** | N | Observations | SF\_SPARC | For Ulcerative Colitis patients only. | DESCRIPTIVE\_SYMP\_TEST\_RESULTS |  | |
| **HISTORY OF HOSPITALIZATION FOR SEVERE IBD UNCLASSIFIED** | N | Observations | SF\_SPARC | For IBD Unclassified patients only. | DESCRIPTIVE\_SYMP\_TEST\_RESULTS |  | |
| **ANAL PHENOTYPE** | N | Observations | SF\_SPARC |  | DESCRIPTIVE\_SYMP\_TEST\_RESULTS | Involved sites since disease onset for Crohn’s Disease | |
| **DUODENAL PHENOTYPE** | N | Observations | SF\_SPARC |  | DESCRIPTIVE\_SYMP\_TEST\_RESULTS | Involved sites since disease onset for Crohn’s Disease | |
| **ESOPHAGEAL PHENOTYPE** | N | Observations | SF\_SPARC |  | DESCRIPTIVE\_SYMP\_TEST\_RESULTS | Involved sites since disease onset for Crohn’s Disease | |
| **GASTRIC PHENOTYPE** | N | Observations | SF\_SPARC |  | DESCRIPTIVE\_SYMP\_TEST\_RESULTS | Involved sites since disease onset for Crohn’s Disease | |
| **ILEAL PHENOTYPE** | N | Observations | SF\_SPARC |  | DESCRIPTIVE\_SYMP\_TEST\_RESULTS | Involved sites since disease onset for Crohn’s Disease | |
| **JEJUNAL PHENOTYPE** | N | Observations | SF\_SPARC |  | DESCRIPTIVE\_SYMP\_TEST\_RESULTS | Involved sites since disease onset for Crohn’s Disease | |
| **LEFT COLONIC PHENOTYPE** | N | Observations | SF\_SPARC |  | DESCRIPTIVE\_SYMP\_TEST\_RESULTS | Involved sites since disease onset for Crohn’s Disease | |
| **RECTAL PHENOTYPE** | N | Observations | SF\_SPARC |  | DESCRIPTIVE\_SYMP\_TEST\_RESULTS | Involved sites since disease onset for Crohn’s Disease | |
| **RIGHT COLONIC PHENOTYPE** | N | Observations | SF\_SPARC |  | DESCRIPTIVE\_SYMP\_TEST\_RESULTS | Involved sites since disease onset for Crohn’s Disease | |
| **TRANSVERSE COLONIC PHENOTYPE** | N | Observations | SF\_SPARC |  | DESCRIPTIVE\_SYMP\_TEST\_RESULTS | Involved sites since disease onset for Crohn’s Disease | |
| **PERIANAL FISTULA** | N | Observations | SF\_SPARC |  | DESCRIPTIVE\_SYMP\_TEST\_RESULTS | History of Perianal Disease for Crohn’s Disease | |
| **ANAL CANAL STRICTURE** | N | Observations | SF\_SPARC |  | DESCRIPTIVE\_SYMP\_TEST\_RESULTS | History of Perianal Disease for Crohn’s Disease | |
| **ANAL CANAL ULCER** | N | Observations | SF\_SPARC |  | DESCRIPTIVE\_SYMP\_TEST\_RESULTS | History of Perianal Disease for Crohn’s Disease | |
| **ANAL FISSURE** | N | Observations | SF\_SPARC |  | DESCRIPTIVE\_SYMP\_TEST\_RESULTS | History of Perianal Disease for Crohn’s Disease | |
| **LARGE SKIN TAGS** | N | Observations | SF\_SPARC |  | DESCRIPTIVE\_SYMP\_TEST\_RESULTS | History of Perianal Disease for Crohn’s Disease | |
| **PERIANAL ABCESS** | N | Observations | SF\_SPARC |  | DESCRIPTIVE\_SYMP\_TEST\_RESULTS | History of Perianal Disease for Crohn’s Disease | |
| **PERIANAL FISTULA - COMPLEX FISTULA** | N | Observations | SF\_SPARC |  | DESCRIPTIVE\_SYMP\_TEST\_RESULTS | History of Perianal Disease for Crohn’s Disease | |
| **RECTOVAGINAL FISTULA** | N | Observations | SF\_SPARC |  | DESCRIPTIVE\_SYMP\_TEST\_RESULTS | History of Perianal Disease for Crohn’s Disease | |
| **NUMBER OF IBD SURGERIES** | N | Procedures | SF\_SPARC | PROC\_CONCEPT\_NAME = IBD Surgeries | PHYSICIAN\_NOTES\_PROC\_AVAIL | If 0 surgeries reported greater than the index range after the index date, then pulled back. | |
| **YEAR OF FIRST IBD SURGERY** | N | Procedures | SF\_SPARC | PROC\_CONCEPT\_NAME = IBD Surgeries | PROC\_START\_DATE | Year the same as or before the index date | |
| **YEAR OF MOST RECENT IBD SURGERY** | N | Procedures | SF\_SPARC | PROC\_CONCEPT\_NAME = IBD Surgeries | PROC\_END\_DATE | Year the same as or before the index date | |
| **ESOPHAGEAL SURGERY** | N | Procedures | SF\_SPARC |  | PHYSICIAN\_NOTES\_PROC\_AVAIL |  | |
| **GASTRODUODENAL SURGERY** | N | Procedures | SF\_SPARC |  | PHYSICIAN\_NOTES\_PROC\_AVAIL |  | |
| **SMALL BOWEL RESECTION** | N | Procedures | SF\_SPARC |  | PHYSICIAN\_NOTES\_PROC\_AVAIL |  | |
| **SMALL BOWEL RESECTION - DUODENUM** | N | Procedures | SF\_SPARC |  | PROC\_STATUS\_CONCEPT\_CODE |  | |
| **SMALL BOWEL RESECTION - ILEUM** | N | Procedures | SF\_SPARC |  | PROC\_STATUS\_CONCEPT\_CODE |  | |
| **SMALL BOWEL RESECTION - JEJUNUM** | N | Procedures | SF\_SPARC |  | PROC\_STATUS\_CONCEPT\_CODE |  | |
| **COLON RESECTION** | N | Procedures | SF\_SPARC |  | PHYSICIAN\_NOTES\_PROC\_AVAIL |  | |
| **COLON RESECTION - CECUM** | N | Procedures | SF\_SPARC |  | PROC\_STATUS\_CONCEPT\_CODE |  | |
| **COLON RESECTION - RECTUM** | N | Procedures | SF\_SPARC |  | PROC\_STATUS\_CONCEPT\_CODE |  | |
| **COLON RESECTION - SIGMOID** | N | Procedures | SF\_SPARC |  | PROC\_STATUS\_CONCEPT\_CODE |  | |
| **COMPLETE COLECTOMY** | N | Procedures | SF\_SPARC | PROC\_CONCEPT\_NAME = Complete Colectomy | PROC\_STATUS\_CONCEPT\_CODE |  | |
| **YEAR OF COMPLETE COLECTOMY** | N | Procedures | SF\_SPARC | PROC\_CONCEPT\_NAME = Complete Colectomy | PROC\_START\_DATE |  | |
| **INDICATION FOR TOTAL COLECTOMY** | N | Procedures | SF\_SPARC | PROC\_CONCEPT\_NAME = Complete Colectomy | INDICATION |  | |
| **ILEOSTOMY/COLOSTOMY** | N | Procedures | SF\_SPARC |  | PHYSICIAN\_NOTES\_PROC\_AVAIL and PROC\_STATUS\_CONCEPT\_NAME |  | |
| **J-POUCH** | N | Procedures | SF\_SPARC |  | PHYSICIAN\_NOTES\_PROC\_AVAIL and PROC\_STATUS\_CONCEPT\_NAME |  | |
| **STRICTUROPLASTY** | N | Procedures | SF\_SPARC |  | PHYSICIAN\_NOTES\_PROC\_AVAIL and PROC\_STATUS\_CONCEPT\_NAME |  | |
| **PHYSIOLOGICAL SHORT GUT SYNDROME** | N | Diagnosis | SF\_SPARC |  | DIAG\_STATUS\_CONCEPT\_NAME |  | |
| **TOBACCO USE WITHIN LAST 3 MONTHS** | N | Observations | SF\_SPARC |  | DESCRIPTIVE\_SYMP\_TEST\_RESULTS |  | |
| **TOBACCO USE WITHIN LAST 7 DAYS** | N | Observations | SF\_SPARC |  | DESCRIPTIVE\_SYMP\_TEST\_RESULTS |  | |
| **ORAL NARCOTIC INTAKE WITHIN LAST 30 DAYS** | N | Observations | SF\_SPARC |  | DESCRIPTIVE\_SYMP\_TEST\_RESULTS |  | |
| **ORAL NARCOTIC INTAKE WITHIN LAST 7 DAYS** | N | Observations | SF\_SPARC |  | DESCRIPTIVE\_SYMP\_TEST\_RESULTS |  | |
| **APHTHOUS ULCER** | N | Diagnosis | SF\_SPARC |  | DIAG\_STATUS\_CONCEPT\_NAME | Extraintestinal Manifestation | |
| **ERYTHEMA NODOSUM** | N | Diagnosis | SF\_SPARC |  | DIAG\_STATUS\_CONCEPT\_NAME | Extraintestinal Manifestation | |
| **IBD - ASSOCIATED ARTHROPATHY** | N | Diagnosis | SF\_SPARC |  | DIAG\_STATUS\_CONCEPT\_NAME | Extraintestinal Manifestation | |
| **IRITIS/UVEITIS** | N | Diagnosis | SF\_SPARC |  | DIAG\_STATUS\_CONCEPT\_NAME | Extraintestinal Manifestation | |
| **PRIMARY SCLEROSING CHOLANGITIS** | N | Diagnosis | SF\_SPARC |  | DIAG\_STATUS\_CONCEPT\_NAME | Extraintestinal Manifestation | |
| **PYODERMA GANGRENOSUM** | N | Diagnosis | SF\_SPARC |  | DIAG\_STATUS\_CONCEPT\_NAME | Extraintestinal Manifestation | |
| **THROMBOTIC COMPLICATIONS** | N | Diagnosis | SF\_SPARC |  | DIAG\_STATUS\_CONCEPT\_NAME | Extraintestinal Manifestation | |
| **INTESTINAL DYSPLASIA** | N | Diagnosis | SF\_SPARC |  | DIAG\_STATUS\_CONCEPT\_NAME | Cancer History | |
| **MALIGNANT NEOPLASM OF COLON, UNSPECIFIED** | N | Diagnosis | SF\_SPARC |  | DIAG\_STATUS\_CONCEPT\_NAME | Cancer History | |
| **PERSONAL HISTORY OF CERVICAL DYSPLASIA** | N | Diagnosis | SF\_SPARC |  | DIAG\_STATUS\_CONCEPT\_NAME | Cancer History | |
| **SKIN CANCER** | N | Diagnosis | SF\_SPARC |  | DIAG\_STATUS\_CONCEPT\_NAME | Cancer History | |
| **ABDOMINAL.PAIN.SCORE** | N | Observations | SF\_SPARC; ECRF\_SPARC | FOR SF, OBS\_TEST\_CONCEPT\_NAME equals Abdominal Pain-Pain Scale; For ECRF, OBS\_TEST\_CONCEPT\_NAME equals Abdominal Pain | DESCRIPTIVE\_SYMP\_TEST\_RESULTS | Use to calculate *A* for sCDAI equation.   |  |  | | --- | --- | | DESCRIPTIVE\_SYMP\_TEST\_RESULTS | A | | None | 0 | | Mild | 1 | | Moderate | 2 | | Severe | 3 | | |
| **DAILY.BM** | N | Observations | SF\_SPARC; ECRF\_SPARC | FOR SF, OBS\_TEST\_CONCEPT\_NAME equals Current Average Number of Daily Bowel Movements or Current Maximum Number of Daily Bowel Movements. For ECRF, OBS\_TEST\_CONCEPT\_NAME equals Current Average Number of Daily Bowel Movements or Current Average Number of Daily Liquid Bowel Movements. For ECRF, if OBS\_TEST\_RESULT\_DATE before August 1, 2018 use Current Average Number of Daily Bowel Movements. | TEST\_RESULT\_NUMERIC; DESCRIPTIVE\_SYMP\_TEST\_RESULTS | This is *B* for the sCDAI equation. This is N/A for anyone with an ostomy. 20+ was treated as 20 in the sCDAI equation. | |
| **DAILY.BM.VERSION** | Y |  |  |  |  | Refers to the question used to determine the daily.bm variable in the sCDAI equation.   |  |  | | --- | --- | | 1 | Current Average Number of Daily Bowel Movements | | 2 | Current Average Number of Daily Liquid Bowel Movements | | 3 | Current Maximum Number of Daily Bowel Movements | | |
| **GENERAL.WELL.BEING.SCORE** | N | Observations | SF\_SPARC; ECRF\_SPARC | FOR SF, OBS\_TEST\_CONCEPT\_NAME equals Constitutional - General Well-Being; For ECRF, OBS\_TEST\_CONCEPT\_NAME equals General Well-Being | DESCRIPTIVE\_SYMP\_TEST\_RESULTS | Use to calculate *G* for sCDAI equation.   |  |  | | --- | --- | | DESCRIPTIVE\_SYMP\_TEST\_RESULTS | G | | Generally well | 0 | | Slightly under par | 1 | | Poor | 2 | | Very poor | 3 | | Terrible | 4 | | |
| **SCDAI.DATE** | N | Observations | SF\_SPARC; ECRF\_SPARC |  | OBS\_TEST\_RESULT\_DATE |  | |
| **SCDAI.SCORE[[1]](#footnote-1)** | Y | [Calculated] | SF\_SPARC; ECRF\_SPARC |  |  | Crohn’s Disease Only.  Only use SF or ECRF to calculate; Do not combine from multiple sources to calculate. If one variable is missing from equation, leave blank for that source. | |
| **SCDAI.SOURCE** | Y |  | SF\_SPARC; ECRF\_SPARC |  |  | If SF variables used, then put SF, if ECRF variables used then put ECRF. | |
| **GLOBAL.ASSESSMENT.SCORE** | N | Observations | SF\_SPARC | OBS\_TEST\_CONCEPT\_NAME equals Physician's Global Assessment of Current Disease Status | DESCRIPTIVE\_SYMP\_TEST\_RESULTS | This is *T* for the UCDAI.9.SCORE.   |  |  | | --- | --- | | DESCRIPTIVE\_SYMP\_TEST\_RESULTS | T | | Quiescent | 0 | | Mild | 1 | | Moderate | 2 | | Severe | 3 | | |
| **RECTAL.BLEEDING.SCORE** | Y | Observations | SF\_SPARC; ECRF\_SPARC; | FOR SF, OBS\_TEST\_CONCEPT\_NAME Blood in Stool - Recent Change in Rectal Bleeding Amount  . For ECRF, OBS\_TEST\_CONCEPT\_NAME equals Blood in Stool and/or Blood Passed Alone | DESCRIPTIVE\_SYMP\_TEST\_RESULTS | If from both sources at baseline separate by semicolon. This is *R* for the UCDAI.6 & UCDAI.9 SCORE.   |  |  | | --- | --- | | DESCRIPTIVE\_SYMP\_TEST\_RESULTS | R | | None; No blood seen | 0 | | Visible blood in stool less than half the time; Blood less than 50% of the time | 1 | | Visible blood in stool half the time or more; Blood 50% or more of the time | 2 | | Passing blood alone; ECRF: Blood Passed Alone = Yes | 3 | | |
| **STOOL.FREQ.SCORE** | N | Observations | SF\_SPARC; ECRF\_SPARC; | FOR SF, OBS\_TEST\_CONCEPT\_NAME equals Recent Change in Daily Stool Frequency. For ECRF, OBS\_TEST\_CONCEPT\_NAME equals Recent Change in Daily Stool Frequency | DESCRIPTIVE\_SYMP\_TEST\_RESULTS | If from both sources at baseline separate by semicolon. This is *S* for the UCDAI.6 & UCDAI.9 SCORE.   |  |  | | --- | --- | | DESCRIPTIVE\_SYMP\_TEST\_RESULTS | S | | Normal | 0 | | 1-2 stools/day more than normal | 1 | | 3-4 stools/day more than normal | 2 | | >4 stools/day more than normal; 5 or more stools per day more than normal | 3 | | |
| **UCDAI.6.SCORE** | Y | [Calculated] |  |  |  | Ulcerative Colitis Only.  Only use SF or ECRF to calculate; Do not combine from multiple sources to calculate. If one variable is missing from equation, leave blank for that source. | |
| **UCDAI.9.SCORE** | Y | [Calculated] |  |  |  | Ulcerative Colitis Only.  Only use SF or ECRF to calculate; Do not combine from multiple sources to calculate. If one variable is missing from equation, leave blank for that source. | |
| **UCDAI.DATE** | N | Observations | SF\_SPARC; ECRF\_SPARC |  | OBS\_TEST\_RESULT\_DATE |  | |
| **UCDAI.SOURCE** | Y |  | SF\_SPARC; ECRF\_SPARC |  |  | If SF variables used, then put SF, if ECRF variables used then put ECRF. | |
| **ILEUM** | N | Procedures | ECRF\_SPARC | PROC\_CONCEPT\_NAME equals Colonoscopy/Sigmoidoscopy | LOCATION |  | |
| **DESCENDING COLON** | N | Procedures | ECRF\_SPARC | PROC\_CONCEPT\_NAME equals Colonoscopy/Sigmoidoscopy | LOCATION |  | |
| **LEFT COLON** | N | Procedures | ECRF\_SPARC | PROC\_CONCEPT\_NAME equals Colonoscopy/Sigmoidoscopy | LOCATION |  | |
| **RECTUM** | N | Procedures | ECRF\_SPARC | PROC\_CONCEPT\_NAME equals Colonoscopy/Sigmoidoscopy | LOCATION |  | |
| **RIGHT COLON** | N | Procedures | ECRF\_SPARC | PROC\_CONCEPT\_NAME equals Colonoscopy/Sigmoidoscopy | LOCATION |  | |
| **SIGMOID COLON** | N | Procedures | ECRF\_SPARC | PROC\_CONCEPT\_NAME equals Colonoscopy/Sigmoidoscopy | LOCATION |  | |
| **TRANSVERSE COLON** | N | Procedures | ECRF\_SPARC | PROC\_CONCEPT\_NAME equals Colonoscopy/Sigmoidoscopy | LOCATION |  | |
| **SES\_SCORE** | Y | Procedures | ECRF\_SPARC | PROC\_CONCEPT\_NAME equals Colonoscopy/Sigmoidoscopy | SES.CD\_Subscore | Sum of SES.CD\_Subscore from each location from same colonoscopy. If segment is “Not reached” then treated as 0. For Crohn’s Disease patients only. | |
| **SES.DATE** | N | Procedures | ECRF\_SPARC | PROC\_CONCEPT\_NAME equals Colonoscopy/Sigmoidoscopy | PROC\_START\_DATE | Date of colonoscopy with SES scoring. | |
| **MAX\_EXTENT\_ACTIVE\_DISEASE** | N | Procedures | ECRF\_SPARC | PROC\_CONCEPT\_NAME equals Colonoscopy/Sigmoidoscopy | MAX\_EXTENT\_ACTIVE\_DISEASE | Units = cm | |
| **MAYO\_ENDOSCOPY\_SCORE[[2]](#footnote-2)** | Y | Procedures | ECRF\_SPARC | PROC\_CONCEPT\_NAME equals Colonoscopy/Sigmoidoscopy | MAYO\_ENDOSCOPIC\_SUBSCORE | Maximum MAYO\_ENDOSCOPIC\_SUBSCORE from each location from same colonoscopy. For Ulcerative Colitis patients only. | |
| **MODIFIED\_MAYO\_SCORE2** | Y | Procedures | ECRF\_SPARC | PROC\_CONCEPT\_NAME equals Colonoscopy/Sigmoidoscopy | MAYO\_ENDOSCOPIC\_SUBSCORE | Sum of MAYO\_ENDOSCOPIC\_SUBSCORE from each location from same colonoscopy. For Ulcerative Colitis patients only. | |
| **EXTENDED\_MODIFIED\_MAYO\_SCORE2** | Y | [Calculated] |  |  |  |  | |
| **MODIFIED\_MAYO\_ENDOSCOPIC\_SCORE2** | Y | [Calculated] |  |  |  |  | |
| **MES.DATE** | N | Procedures | ECRF\_SPARC | PROC\_CONCEPT\_NAME equals Colonoscopy/Sigmoidoscopy | PROC\_START\_DATE | Date of colonoscopy with Mayo Scoring. | |
| **ABDOMINAL.PAIN.SCORE** | N | Observations | SF\_SPARC; ECRF\_SPARC | FOR SF, OBS\_TEST\_CONCEPT\_NAME equals Abdominal Pain-Pain Scale; For ECRF, OBS\_TEST\_CONCEPT\_NAME equals Abdominal Pain | DESCRIPTIVE\_SYMP\_TEST\_RESULTS | Use to calculate *A* for sCDAI equation.   |  |  | | --- | --- | | DESCRIPTIVE\_SYMP\_TEST\_RESULTS | A | | None | 0 | | Mild | 1 | | Moderate | 2 | | Severe | 3 | | |
| **DAILY.BM** | N | Observations | SF\_SPARC; ECRF\_SPARC | FOR SF, OBS\_TEST\_CONCEPT\_NAME equals Current Average Number of Daily Bowel Movements or Current Maximum Number of Daily Bowel Movements. For ECRF, OBS\_TEST\_CONCEPT\_NAME equals Current Average Number of Daily Bowel Movements or Current Average Number of Daily Liquid Bowel Movements. For ECRF, if OBS\_TEST\_RESULT\_DATE before August 1, 2018 use Current Average Number of Daily Bowel Movements. | TEST\_RESULT\_NUMERIC; DESCRIPTIVE\_SYMP\_TEST\_RESULTS | This is *B* for the sCDAI equation. This is N/A for anyone with an ostomy. 20+ was treated as 20 in the sCDAI equation. | |
| **DAILY.BM.VERSION** | Y |  |  |  |  | Refers to the question used to determine the daily.bm variable in the sCDAI equation.   |  |  | | --- | --- | | 1 | Current Average Number of Daily Bowel Movements | | 2 | Current Average Number of Daily Liquid Bowel Movements | | 3 | Current Maximum Number of Daily Bowel Movements | | |
| **GENERAL.WELL.BEING.SCORE** | N | Observations | SF\_SPARC; ECRF\_SPARC | FOR SF, OBS\_TEST\_CONCEPT\_NAME equals Constitutional - General Well-Being; For ECRF, OBS\_TEST\_CONCEPT\_NAME equals General Well-Being | DESCRIPTIVE\_SYMP\_TEST\_RESULTS | Use to calculate *G* for sCDAI equation.   |  |  | | --- | --- | | DESCRIPTIVE\_SYMP\_TEST\_RESULTS | G | | Generally well | 0 | | Slightly under par | 1 | | Poor | 2 | | Very poor | 3 | | Terrible | 4 | | |
| **SCDAI.DATE** | N | Observations | SF\_SPARC; ECRF\_SPARC |  | OBS\_TEST\_RESULT\_DATE |  | |
| **SCDAI.SCORE[[3]](#footnote-3)** | Y | [Calculated] | SF\_SPARC; ECRF\_SPARC |  |  | Crohn’s Disease Only.  Only use SF or ECRF to calculate; Do not combine from multiple sources to calculate. If one variable is missing from equation, leave blank for that source. | |
| **SCDAI.SOURCE** | Y |  | SF\_SPARC; ECRF\_SPARC |  |  | If SF variables used, then put SF, if ECRF variables used then put ECRF. | |
| **GLOBAL.ASSESSMENT.SCORE** | N | Observations | SF\_SPARC | OBS\_TEST\_CONCEPT\_NAME equals Physician's Global Assessment of Current Disease Status | DESCRIPTIVE\_SYMP\_TEST\_RESULTS | This is *T* for the UCDAI.9.SCORE.   |  |  | | --- | --- | | DESCRIPTIVE\_SYMP\_TEST\_RESULTS | T | | Quiescent | 0 | | Mild | 1 | | Moderate | 2 | | Severe | 3 | | |
| **RECTAL.BLEEDING.SCORE** | Y | Observations | SF\_SPARC; ECRF\_SPARC; | FOR SF, OBS\_TEST\_CONCEPT\_NAME Blood in Stool - Recent Change in Rectal Bleeding Amount  . For ECRF, OBS\_TEST\_CONCEPT\_NAME equals Blood in Stool and/or Blood Passed Alone | DESCRIPTIVE\_SYMP\_TEST\_RESULTS | If from both sources at baseline separate by semicolon. This is *R* for the UCDAI.6 & UCDAI.9 SCORE.   |  |  | | --- | --- | | DESCRIPTIVE\_SYMP\_TEST\_RESULTS | R | | None; No blood seen | 0 | | Visible blood in stool less than half the time; Blood less than 50% of the time | 1 | | Visible blood in stool half the time or more; Blood 50% or more of the time | 2 | | Passing blood alone; ECRF: Blood Passed Alone = Yes | 3 | | |
| **STOOL.FREQ.SCORE** | N | Observations | SF\_SPARC; ECRF\_SPARC; | FOR SF, OBS\_TEST\_CONCEPT\_NAME equals Recent Change in Daily Stool Frequency. For ECRF, OBS\_TEST\_CONCEPT\_NAME equals Recent Change in Daily Stool Frequency | DESCRIPTIVE\_SYMP\_TEST\_RESULTS | If from both sources at baseline separate by semicolon. This is *S* for the UCDAI.6 & UCDAI.9 SCORE.   |  |  | | --- | --- | | DESCRIPTIVE\_SYMP\_TEST\_RESULTS | S | | Normal | 0 | | 1-2 stools/day more than normal | 1 | | 3-4 stools/day more than normal | 2 | | >4 stools/day more than normal; 5 or more stools per day more than normal | 3 | | |
| **UCDAI.6.SCORE** | Y | [Calculated] |  |  |  | Ulcerative Colitis Only.  Only use SF or ECRF to calculate; Do not combine from multiple sources to calculate. If one variable is missing from equation, leave blank for that source. | |
| **UCDAI.9.SCORE** | Y | [Calculated] |  |  |  | Ulcerative Colitis Only.  Only use SF or ECRF to calculate; Do not combine from multiple sources to calculate. If one variable is missing from equation, leave blank for that source. | |
| **UCDAI.DATE** | N | Observations | SF\_SPARC; ECRF\_SPARC |  | OBS\_TEST\_RESULT\_DATE |  | |
| **UCDAI.SOURCE** | Y |  | SF\_SPARC; ECRF\_SPARC |  |  | If SF variables used, then put SF, if ECRF variables used then put ECRF. | |
| **ILEUM** | N | Procedures | ECRF\_SPARC | PROC\_CONCEPT\_NAME equals Colonoscopy/Sigmoidoscopy | LOCATION |  | |
| **DESCENDING COLON** | N | Procedures | ECRF\_SPARC | PROC\_CONCEPT\_NAME equals Colonoscopy/Sigmoidoscopy | LOCATION |  | |
| **LEFT COLON** | N | Procedures | ECRF\_SPARC | PROC\_CONCEPT\_NAME equals Colonoscopy/Sigmoidoscopy | LOCATION |  | |
| **RECTUM** | N | Procedures | ECRF\_SPARC | PROC\_CONCEPT\_NAME equals Colonoscopy/Sigmoidoscopy | LOCATION |  | |
| **RIGHT COLON** | N | Procedures | ECRF\_SPARC | PROC\_CONCEPT\_NAME equals Colonoscopy/Sigmoidoscopy | LOCATION |  | |
| **SIGMOID COLON** | N | Procedures | ECRF\_SPARC | PROC\_CONCEPT\_NAME equals Colonoscopy/Sigmoidoscopy | LOCATION |  | |
| **TRANSVERSE COLON** | N | Procedures | ECRF\_SPARC | PROC\_CONCEPT\_NAME equals Colonoscopy/Sigmoidoscopy | LOCATION |  | |
| **SES\_SCORE** | Y | Procedures | ECRF\_SPARC | PROC\_CONCEPT\_NAME equals Colonoscopy/Sigmoidoscopy | SES.CD\_Subscore | Sum of SES.CD\_Subscore from each location from same colonoscopy. If segment is “Not reached” then treated as 0. For Crohn’s Disease patients only. | |
| **SES.DATE** | N | Procedures | ECRF\_SPARC | PROC\_CONCEPT\_NAME equals Colonoscopy/Sigmoidoscopy | PROC\_START\_DATE | Date of colonoscopy with SES scoring. | |
| **MAX\_EXTENT\_ACTIVE\_DISEASE** | N | Procedures | ECRF\_SPARC | PROC\_CONCEPT\_NAME equals Colonoscopy/Sigmoidoscopy | MAX\_EXTENT\_ACTIVE\_DISEASE | Units = cm | |
| **MAYO\_ENDOSCOPY\_SCORE[[4]](#footnote-4)** | Y | Procedures | ECRF\_SPARC | PROC\_CONCEPT\_NAME equals Colonoscopy/Sigmoidoscopy | MAYO\_ENDOSCOPIC\_SUBSCORE | Maximum MAYO\_ENDOSCOPIC\_SUBSCORE from each location from same colonoscopy. For Ulcerative Colitis patients only. | |
| **MODIFIED\_MAYO\_SCORE2** | Y | Procedures | ECRF\_SPARC | PROC\_CONCEPT\_NAME equals Colonoscopy/Sigmoidoscopy | MAYO\_ENDOSCOPIC\_SUBSCORE | Sum of MAYO\_ENDOSCOPIC\_SUBSCORE from each location from same colonoscopy. For Ulcerative Colitis patients only. | |
| **EXTENDED\_MODIFIED\_MAYO\_SCORE2** | Y | [Calculated] |  |  |  |  | |
| **MODIFIED\_MAYO\_ENDOSCOPIC\_SCORE2** | Y | [Calculated] |  |  |  |  | |
| **MES.DATE** | N | Procedures | ECRF\_SPARC | PROC\_CONCEPT\_NAME equals Colonoscopy/Sigmoidoscopy | PROC\_START\_DATE | Date of colonoscopy with Mayo Scoring. | |
| **OSTOMY** | N | Procedures & Observations | SF\_SPARC, ECRF\_SPARC | For SF, PROC\_CONCEPT\_NAME equals Ileostomy/colostomy ; For ECRF, OBS\_TEST\_CONCEPT\_NAME equals Baseline Number of Daily Bowel Movements or Current Average Number of Daily Bowel Movements or Recent Change in Daily Stool Frequency or Current Average Number of Daily Liquid Bowel Movements equals Not applicable, I have an ostomy | DESCRIPTIVE\_SYMP\_TEST\_RESULTS | Only populated for those missing sCDAI or UCDAI scores. | |
| **NO\_IBD\_MEDICATION\_AT\_ENROLLMENT** | Y | Observations | ECRF\_SPARC | OBS\_TEST\_CONCEPT\_NAME == "Are you currently taking any medication for your IBD?" & DESCRIPTIVE\_SYMP\_TEST\_RESULTS == "No" |  | 1 = First Survey with Are you Currently Taking Any Medication = NO) Does not include antibiotics/probiotics within +/- index range of the date of consent; 0 = Question not available or did not answer No | |
| **NO\_IBD\_MEDICATION\_AT\_INDEX** | Y | Prescription | ECRF\_SPARC & EMR | [See XXX\_EMR[1] and XXX\_ECRF for logic on determining is a participant was on a medication at the index date for each source respectively](file:///C:\\Users\\tdhingra\\AppData\\Roaming\\Microsoft\\Excel\\Book1%20(version%201).xlsb" \l "RANGE!A193) |  | If no medications are found at the index date +/- index range, then this is 1 | |
| **BIOLOGIC\_AT\_INDEX\_CONFIDENCE** | Y | Prescription | ECRF\_SPARC & EMR |  |  | Rank of confidence in choice of Biologic at index date. The lowest score (green) indicates high confidence in the choice, while a higher score (orange) indicates less confidence.   |  |  | | --- | --- | | Rank | Logic | | 1 | EMR and ECRF\_SPARC agree that patient on medication at index | | 2 | ECRF\_SPARC says on medication or possibly on medication and no EMR information for this medication | | 3 | EMR says on medication or possibly on medication and no ECRF\_SPARC information for this medication | | 4 | EMR and ECRF\_SPARC both agree that Possibly on Medication (Index < | | 5 | EMR and ECRF\_SPARC both agree that individual  "Possibly on Medication (Index Performed <= 12 Months After Last Reported Medication)" or "Possibly on Medication (Index Performed > 1 Year After Last Reported Medication)" or "Possibly on Medication (Index Performed <= 6 Months After Last Reported Medication)" | | 6 | EMR says possibly on medication and ECRF\_SPARC says yes on medication | | 7 | EMR says yes on medication and ECRF\_SPARC says possibly on medication | | 8 | EMR says not on medication but ECRF\_SPARC says yes or possibly on medication | | 9 | EMR says yes or possibly on medication but ECRF\_SPARC says no | | |
| **BIOLOGIC\_AT\_INDEX** | Y | Prescription | ECRF\_SPARC & EMR | See XXX\_EMR and XXX\_ECRF for logic on determining is a participant was on a medication at the index date for each source respectively |  | The biologic that the patient is predicted to be on at the index date. For EMR, if two biologics reported at the same time, chose the most recently prescribed. For ECRF, if two biologics reported at the same time, chose the most recently reported | |
| **XXX\_SF** | N | Prescriptions | SF\_SPARC | MEDICATION\_NAME | MEDICATION\_ADMINISTRATED\_CODE | Reports of “Never” used medication after index\_date can be pulled backward. Otherwise only data up until the index date was used. | |
| **XXX\_ECRF** | Y | Prescriptions; Observations | ECRF\_SPARC | In the observation table, OBS\_TEST\_CONCEPT\_NAME equals "In the last 90 days, have you had any changes in your Medication(s)?" & DESCRIPTIVE\_SYMP\_TEST\_RESULTS == "No" |  | The status of the medication using the ECRF source. If a patient reported no changes to medication in the past 90 days, then the previously entered medication data can be pulled forward to that survey encounter. This column reflects if the index date is within the MED\_START\_DATE and MED\_END\_DATE before the MED\_START\_DATE or after the MED\_END\_DATE. For the “Possibly” categories, the time between patient reported being on the medication and the index date is captured in the following groups (<=3 months, <= 6 months, <= 12 months & > 1 year). | |
|  |  |  |  |  |  |  | |  |
| **XXX\_EMR** | Y | Prescriptions | EMR |  |  | The status of the medication using the EMR source. For each medication, the most recently prescribed was picked. | |  |
| **XXX\_STATUS** | Y |  | EMR & ECRF |  |  | Summary based on both sources | |  |
|  |  |  |  |  |  | Yes = patient on medication | |  |
|  |  |  |  |  |  | Possible = patient possibly on medication | |  |
|  |  |  |  |  |  | Contradicts = ECRF\_SPARC and EMR sources disagree | |  |
|  |  |  |  |  |  | No = patient not on medication | |  |
| **XXX\_LOADING\_DATE\_ECRF** | Y | Prescriptions | ECRF |  | MED\_START\_DATE | For biologics only, the first date the medication was reported in the ECRF | |  |
| **XXX\_LOADING\_DATE\_EMR** | Y | Prescriptions | EMR |  | MED\_START\_DATE | For biologics only, the date the medication was first prescribed in the EMR. | |  |
|  |  |  |  |  |  | Biologic | Criteria |  |
|  |  |  |  |  |  | Infliximab | Prescriptions at 0,2,6 and then every 8 weeks |  |
|  |  |  |  |  |  | Adalimumab | Every 2 weeks with the first dose as 160mg, then 80 mg, then 40mg going forward |  |
|  |  |  |  |  |  | Certolizumab | Prescriptions at 0,2,4 and then every 4 weeks |  |
|  |  |  |  |  |  | Vedolizumab | Prescriptions at 0,2,6 and then every 8 weeks |  |
|  |  |  |  |  |  | Ustekinumab | Initial dose as an IV and then subcutaneous injection every 8 weeks |  |
|  |  |  |  |  |  |  | |  |
|  |  |  |  |  |  |  | |  |

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2. Triana Lobatón, Talat Bessissow, Gert De Hertogh, Bart Lemmens, Chelsea Maedler, Gert Van Assche, Séverine Vermeire, Raf Bisschops, Paul Rutgeerts, Alain Bitton, Waqqas Afif, Victoria Marcus, Marc Ferrante, The Modified Mayo Endoscopic Score (MMES): A New Index for the Assessment of Extension and Severity of Endoscopic Activity in Ulcerative Colitis Patients, Journal of Crohn's and Colitis, Volume 9, Issue 10, October 2015, Pages 846–852, <https://doi.org/10.1093/ecco-jcc/jjv111> [↑](#footnote-ref-2)
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4. Triana Lobatón, Talat Bessissow, Gert De Hertogh, Bart Lemmens, Chelsea Maedler, Gert Van Assche, Séverine Vermeire, Raf Bisschops, Paul Rutgeerts, Alain Bitton, Waqqas Afif, Victoria Marcus, Marc Ferrante, The Modified Mayo Endoscopic Score (MMES): A New Index for the Assessment of Extension and Severity of Endoscopic Activity in Ulcerative Colitis Patients, Journal of Crohn's and Colitis, Volume 9, Issue 10, October 2015, Pages 846–852, <https://doi.org/10.1093/ecco-jcc/jjv111> [↑](#footnote-ref-4)