User Guide for sparc\_medication() Function

Crohn’s and Colitis Foundation

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## Overview

Sparc\_medication() is a function that reads in SPARC data from IBD Plexus, and finds the medications the participant is prescribed from the electronic medical record and patient reported case report forms at a specific (“index”) date.

## Requirements

* R Version 4.0.0 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 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\_MEDICATION.xlsx
* Index\_range = the number of days to look out from index date.
  + The default is 14 days
  + For example, to see medications within +/- 30 days of the index date, the index\_range = “30”.
* 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

## Output Table

The output file “SPARC\_MEDICATION.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 |  |
| DIAGNOSIS | N | Diagnosis | SF\_SPARC > ECRF\_SPARC | DIAG\_CONCEPT\_NAME equals Crohn’s Disease, Ulcerative Colitis or IBD Unclassified. For SF only,  DIAG\_STATUS\_CONCEPT\_CODE equals Yes. | DIAG\_CONCEPT\_NAME | Chose diagnosis reported closest to index date from SF first, then ECRF. Use ECRF\_QORUS if consented to both studies. |
| 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]](#footnote-1) and XXX\_ECRF for logic on determining is a participant was on a medication at the index date for each source respectively |  | 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\_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 |  |  |  |  | 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 | |

1. XXX = Medication Name [↑](#footnote-ref-1)