User Guide for sparc_medication() Function

Crohn's and Colitis Foundation

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Contents

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] and XXX_ECRF for logic on determining is a participant was on a		If no medications are found at the index date +/- index range, then this is 1

[1] XXX = Medication Name

<table>
<tr><th>Column Header</th><th>Derived Variable (Y/N)</th><th>DDM Table</th><th>DDM Data Source</th><th>Other DDM Filters</th><th>DDM Variable</th><th>Notes</th></tr>
<tr><td></td><td></td><td></td><td></td><td>medication at the index date for each source respectively</td><td></td><td></td></tr>
<tr><td>BIOLOGIC_AT_INDEX_CONFIDENCE</td><td>Y</td><td>Prescription</td><td>ECRF_SPARC & EMR</td><td></td><td></td><td>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.
<table>
<tr><th>Rank</th><th>Logic</th></tr>
<tr><td>1</td><td>EMR and ECRF_SPARC agree that patient on medication at index</td></tr>
<tr><td>2</td><td>ECRF_SPARC says on medication or possibly on medication and no EMR information for this medication</td></tr>
<tr><td>3</td><td>EMR says on medication or possibly on medication and no ECRF_SPARC information for this medication</td></tr>
<tr><td>4</td><td>EMR and ECRF_SPARC both agree that Possibly on Medication (Index <</td></tr>
<tr><td>5</td><td>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)"</td></tr>
</table></td></tr>
</table>

Column Header	Derived Variable (Y/N)	DDM Table	DDM Data Source	Other DDM Filters	DDM Variable	Notes
						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.

<table>
<tr><th>Column Header</th><th>Derived Variable (Y/N)</th><th>DDM Table</th><th>DDM Data Source</th><th>Other DDM Filters</th><th>DDM Variable</th><th>Notes</th></tr>
<tr><td>XXX_STATUS</td><td>Y</td><td></td><td></td><td></td><td></td><td>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</td></tr>
<tr><td>XXX_LOADING_DATE_ECRF</td><td>Y</td><td>Prescriptions</td><td>ECRF</td><td></td><td>MED_START_DATE</td><td>For biologics only, the first date the medication was reported in the ECRF</td></tr>
<tr><td>XXX_LOADING_DATE_EMR</td><td>Y</td><td>Prescriptions</td><td>EMR</td><td></td><td>MED_START_DATE</td><td>For biologics only, the date the medication was first prescribed in the EMR.
<table>
<tr><th>Biologic</th><th>Criteria</th></tr>
<tr><td>Infliximab</td><td>Prescriptions at 0,2,6 and then every 8 weeks</td></tr>
<tr><td>Adalimumab</td><td>Every 2 weeks with the first dose as 160mg, then 80 mg, then 40mg going forward</td></tr>
<tr><td>Certolizumab</td><td>Prescriptions at 0,2,4 and then every 4 weeks</td></tr>
<tr><td>Vedolizumab</td><td>Prescriptions at 0,2,6 and then every 8 weeks</td></tr>
<tr><td>Ustekinumab</td><td>Initial dose as an IV and then subcutaneous injection every 8 weeks</td></tr>
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