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.

If finding medications at enrollment only the patient reported case report forms are used.

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".

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

Column Header	Derived Variable (Y/N)	DDM Table	DDM Data Source	Other DDM Filters	DDM Variable	Notes
						Present for index dates that are not at enrollment.
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		If no medications are found at the index date +/- index range, then this is 1
MEDICATION_AT_INDEX	Y	Prescription	ECRF_SPARC & EMR (for index dates outside of enrollment)	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 medication(s) that the patient is predicted to be on at the index date.
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

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[1] XXX = Medication Name

Column Header	Derived Variable (Y/N)	DDM Table	DDM Data Source	Other DDM Filters	DDM Variable	Notes
						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. <table><tr><td>Biologic</td><td>Criteria</td></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</td></tr></table>

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