

Package ‘faersquarterlydata’

June 23, 2024

Type Package

Title FDA Adverse Event Reporting System Quarterly Data Extracting Tool

Version 1.2.0

Maintainer Luis Garcez <luisgarcez1@gmail.com>

Description

An easy framework to read FDA Adverse Event Reporting System XML/ASCII files <<https://www.fda.gov/drugs/questions-and-answers-fdas-adverse-event-reporting-system-faers/fda-adverse-event-reporting-system-faers-latest-quarterly-data-files>>.

License GPL (>= 3)

Imports data.table, tibble, xml2, tableone, tidyr, dplyr, stringr, stats, utils

Encoding UTF-8

LazyData true

Depends R (>= 3.5.0)

Suggests testthat (>= 3.0.0)

Config/testthat/edition 3

RoxygenNote 7.2.3

NeedsCompilation no

Author Luis Garcez [aut, cre, cph] (<<https://orcid.org/0000-0002-8637-7946>>)

Repository CRAN

Date/Publication 2024-06-22 22:10:02 UTC

Contents

als_faers_data	2
als_faers_data_unified	3
arrange_date	3
estimate_chisq	4

estimate_infoc	4
estimate_prr	5
estimate_ror	6
estimate_ror_bygroup	6
faersxml_to_r	7
get_duplicate_caseids	8
products_fda	8
retrieve_faersascii	9
retrieve_faersxml	9
retrieve_faersxml_all	10
retrieve_unique_info	11
summary_faersdata	11
unify_tabular_ascii	12
unzip_faerszip	12

Index	13
--------------	-----------

als_faers_data	<i>List ASCII data example</i>
----------------	--------------------------------

Description

A list containing data from FDA website. The list only contains safety reports which the ADR primary suspect drug was indicated for ALS. List originated from [retrieve_faersascii](#)

Usage

```
als_faers_data
```

Format

A data frame with 200 rows and 38 columns:

Source

<<https://www.fda.gov/drugs/questions-and-answers-fdas-adverse-event-reporting-system-faers/fda-adverse-event-reporting-system-faers-latest-quarterly-data-files>>

`als_faers_data_unified`*Tabular ASCII data example*

Description

A subset of data from FAERS data. One row corresponds to one adverse drug reaction. All the ADR in this subset have a primary suspect drug indicated for ALS. Data frame originated from [unify_tabular_ascii](#)

Usage`als_faers_data_unified`**Format**

A data frame with 1635 rows and 40 columns.

`arrange_date`*Convert a date string into a date format*

Description

Convert a date string into a date format

Usage`arrange_date(date_string)`**Arguments**

`date_string` A string vector with multiple formats (8, 6 or 4 digits)

Value

A converted Date

Examples

```
arrange_date("2020")
arrange_date("202006")
arrange_date("20200601")
```

estimate_chisq	<i>Estimate Chi-Squared test with yates correction</i>
----------------	--

Description

Estimate Chi-Squared test with yates correction

Usage

```
estimate_chisq(n11, n10, n01, n00)
```

Arguments

n11	Number of events of interest within the group of interest
n10	Number of events of interest from all groups
n01	Number of all events within the group of interest
n00	Number of all events from all groups

Value

list with Chi-squared statistic and p-value

Examples

```
estimate_chisq(n11 = 20, n10 = 10, n01 = 200, n00 = 200)
```

estimate_infoc	<i>Estimate Information Component</i>
----------------	---------------------------------------

Description

Estimate Information Component

Usage

```
estimate_infoc(n11, n10, n01, n00)
```

Arguments

n11	Number of events of interest within the group of interest
n10	Number of events of interest from all groups
n01	Number of all events within the group of interest
n00	Number of all events from all groups

Value

List with Information Component estimate and its 0.95 IC

Examples

```
estimate_infoc(n11 = 20, n10 = 10, n01 = 200, n00 = 200)
```

estimate_prr	<i>Estimate Proportional Reporting Odds Ratio</i>
--------------	---

Description

Estimate Proportional Reporting Odds Ratio

Usage

```
estimate_prr(n11, n10, n01, n00, ic_range = 0.95)
```

Arguments

n11	Number of events of interest within the group of interest
n10	Number of events of interest from all groups
n01	Number of all events within the group of interest
n00	Number of all events from all groups
ic_range	Confidence Interval range

Value

Proportional Reporting Odds Ratio

Examples

```
estimate_prr(n11 = 20, n10 = 10, n01 = 200, n00 = 200)
```

estimate_ror	<i>Estimate Reporting Odds Ratio</i>
--------------	--------------------------------------

Description

Estimate Reporting Odds Ratio

Usage

```
estimate_ror(n11, n10, n01, n00, ic_range = 0.95)
```

Arguments

n11	Number of events of interest within the group of interest
n10	Number of events of interest from all groups
n01	Number of all events within the group of interest
n00	Number of all events from all groups
ic_range	Confidence Interval range

Value

list with ROR estimate and a vector with the IC boundaries

Examples

```
estimate_ror(n11 = 20, n10 = 10, n01 = 200, n00 = 200, ic_range = 0.90)
```

estimate_ror_bygroup	<i>Estimate Measures of Association</i>
----------------------	---

Description

Estimate Measures of Association

Usage

```
estimate_ror_bygroup(
  tabular_faers_data,
  group_of_interest_col = NULL,
  group_of_interest_ref = NULL,
  rename_vector = NULL,
  event_of_interest_col = NULL,
  ...
)
```

Arguments

`tabular_faers_data`
FAERS tabular format. Output of function [retrieve_faersxml](#) or [retrieve_faersxml_all](#)

`group_of_interest_col`
a string, specifying the group of interest. Must be a column name of 'tabular_faers_data', and this column should only contain two unique values.

`group_of_interest_ref`
a string, specifying the group of interest reference. Must be a value from the group of interest column.

`rename_vector` optional. named vector to rename the group of interest, in order to show up in a

`event_of_interest_col`
a string, specifying the event of interest. Must be a column name of 'tabular_faers_data'.

... arguments passed to 'estimate_ror' like 'ic_range'.

Value

tibble with the event of interest counts, group of interest counts and the respective estimated measures of association (ROR and its IC, PRR and its IC, Information Component and Chi-squared statistic with Yates correction).

Examples

```
estimate_ror_bygroup(tabular_faers_data = dplyr::filter(als_faers_data_unified,
sex %in% c("M", "F") ),
group_of_interest_col = "sex",
group_of_interest_ref = "M",
event_of_interest_col = "pt")
```

faersxml_to_r

Convert FAERS xml to an R list

Description

Convert FAERS xml to an R list

Usage

```
faersxml_to_r(xml_address)
```

Arguments

`xml_address` XML address file

Value

a list containing all the elements from 'xml_address'

get_duplicate_caseids *Get duplicated caseIDs*

Description

Retrieve the duplicated caseIDs to remove from the analysis.

Usage

```
get_duplicate_caseids(duplicates_dir = NULL)
```

Arguments

duplicates_dir directory path where the text files with the duplicates information are.

Value

an integer vector with all the caseids to be removed

products_fda *List of approved products by FDA*

Description

List of approved products by FDA

Usage

```
products_fda
```

Format

A data frame.

Source

<<https://www.fda.gov/drugs/drug-approvals-and-databases/drugsfda-data-files>>

retrieve_faersascii	<i>Read FAERS ascii files</i>
---------------------	-------------------------------

Description

Read ASCII files from a directory, removing the duplicates.

Usage

```
retrieve_faersascii(
  ascii_dir,
  cache_path = NULL,
  drug_indication_pattern = NULL,
  drug_pattern = NULL,
  primary_suspect = TRUE,
  ...
)
```

Arguments

ascii_dir	directory path where ascii files are
cache_path	(optional) a string. Must have a ".Rdata" extension to save the read tabular formats in each loop.
drug_indication_pattern	(optional) a string. filter ADRs with a specific drug indication pattern (**stringr** syntax)
drug_pattern	(optional) a string. filter ADRs with a specific drug name pattern (**stringr** syntax)
primary_suspect	(optional) a string.
...	directory with duplicate information to be passed to get_duplicate_caseids

Value

A list with binded tibbles retrieved from files.

retrieve_faersxml	<i>Convert FAERS xml to tabular format</i>
-------------------	--

Description

Convert FAERS xml to tabular format

Usage

```
retrieve_faersxml(
  xml_address,
  reaction_wise = TRUE,
  drug_wise = FALSE,
  drug_indication_pattern = NULL
)
```

Arguments

xml_address XML address to be read

reaction_wise each row corresponds to a reaction (if TRUE, drug_wise cannot be TRUE)

drug_wise each row corresponds to a drug (if TRUE, reaction_wise cannot be TRUE)

drug_indication_pattern
filter by ADR with a specific drug indication pattern (**stringr** syntax)

Value

A tibble corresponding to the XML file

retrieve_faersxml_all *Convert FAERS a number of xml files to tabular format*

Description

Convert FAERS a number of xml files to tabular format

Usage

```
retrieve_faersxml_all(xml_address_vector, ..., cache_path = NULL)
```

Arguments

xml_address_vector
Vector with XML addresses to be read

... arguments to be passed to [retrieve_faersxml](#)

cache_path a string. Must have a ".Rdata" extension to save the read tabular formats in each loop.

Value

A binded tibble with all the tibbles returned from 'retrieve_faersxml'

retrieve_unique_info *Retrieve unique drug and ADR information values from XML files*

Description

Retrieve unique drug and ADR information values from XML files

Usage

```
retrieve_unique_info(xml_address_vector, ...)
```

Arguments

xml_address_vector Vector with XML addresses to be read
... arguments to be passed to [retrieve_faersxml](#)

Value

A list with all the unique information on FAERS variables

summary_faersdata *FAERS description*

Description

FAERS description

Usage

```
summary_faersdata(tabular_faers_data)
```

Arguments

tabular_faers_data a tibble corresponding to the unified FAERS tabular format. Output of function [unify_tabular_ascii](#)

Value

A list with a findings summary

Examples

```
summary_faersdata(als_faers_data_unified)
```

`unify_tabular_ascii` *Unify the list to a tabular format*

Description

Turn the list elements returned from [retrieve_faersascii](#) into a tabular format

Usage

```
unify_tabular_ascii(ascii_list)
```

Arguments

`ascii_list` list from [retrieve_faersascii](#)

Value

A data frame representing FAERS data, with all components from the list joined.

Examples

```
unify_tabular_ascii(ascii_list = als_faers_data)
```

`unzip_faerszip` *Unzip FAERS zip folders*

Description

Unzip FAERS zip folders

Usage

```
unzip_faerszip(zip_folders_dir, ex_dir)
```

Arguments

`zip_folders_dir` directory containing FAERS zip folders
`ex_dir` directory to be exported the unzipped files

Value

None. Just unzips the folders to a specified location.

Index

* datasets

- als_faers_data, [2](#)
- als_faers_data_unified, [3](#)
- products_fda, [8](#)

als_faers_data, [2](#)
als_faers_data_unified, [3](#)
arrange_date, [3](#)

estimate_chisq, [4](#)
estimate_infoc, [4](#)
estimate_prr, [5](#)
estimate_ror, [6](#)
estimate_ror_bygroup, [6](#)

faersxml_to_r, [7](#)

get_duplicate_caseids, [8](#), [9](#)

products_fda, [8](#)

retrieve_faersascii, [2](#), [9](#), [12](#)
retrieve_faersxml, [7](#), [9](#), [10](#), [11](#)
retrieve_faersxml_all, [7](#), [10](#)
retrieve_unique_info, [11](#)

summary_faersdata, [11](#)

unify_tabular_ascii, [3](#), [11](#), [12](#)
unzip_faerszip, [12](#)