

Package ‘eudract’

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Type Package

Title Creates Safety Results Summary in XML to Upload to EudraCT

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Version 0.9.2

URL <https://eudract-tool.medschl.cam.ac.uk/>

BugReports <https://github.com/shug0131/eudraCT/issues>

Description The remit of the European Clinical Trials Data Base (EudraCT <<https://eudract.ema.europa.eu/>>) is to provide open access to summaries of all registered clinical trial results; thus aiming to prevent non-reporting of negative results and provide open-access to results to inform future research. The amount of information required and the format of the results, however, imposes a large extra workload at the end of studies on clinical trial units. In particular, the adverse-event-reporting component requires entering: each unique combination of treatment group and safety event; for every such event above, a further 4 pieces of information (body system, number of occurrences, number of subjects, number exposed) for non-serious events, plus an extra three pieces of data for serious adverse events (numbers of causally related events, deaths, causally related deaths). This package prepares the required statistics needed by EudraCT and formats them into the precise requirements to directly upload an XML file into the web portal, with no further data entry by hand.

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Language en-GB

Encoding UTF-8

LazyData true

Imports tidy, xslt, dplyr, xml2, utils, magrittr

Depends R (>= 3.5.0)

RoxygenNote 7.0.1

Suggests testthat, knitr, rmarkdown, stringr

VignetteBuilder knitr

NeedsCompilation no

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R topics documented:

create.safety_summary	2
eudract_convert	3
safety	4
safety_summary	4
simple_safety_xml	6
soc_code	7

Index	8
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create.safety_summary *function that creates a safety_summary object from individual data.frames*

Description

function that creates a safety_summary object from individual data.frames

Usage

```
create.safety_summary(group, non_serious, serious)
```

Arguments

group	a data frame that contains the group-level statistics
non_serious	a data frame that contains the non-serious term-group level statistics
serious	a data frame that contains the serious term-group level statistics

Value

a safety_summary object

eudract_convert	<i>applies a conversion using xslt from a simple xml file to a eudract compatible file, and checks against the schema</i>
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Description

applies a conversion using xslt from a simple xml file to a eudract compatible file, and checks against the schema

Usage

```
eudract_convert(  
  input,  
  output,  
  xslt = system.file("extdata", "simpleToEudraCT.xslt", package = "eudract"),  
  schema_input = system.file("extdata", "simple.xsd", package = "eudract"),  
  schema_output = system.file("extdata", "adverseEvents.xsd", package = "eudract")  
)
```

Arguments

input	a character string giving the file path to the simple xml file
output	a character string naming the output file
xslt	a character string giving the file path to the xslt script. Defaults to the script provided in this package
schema_input	a character string giving the file path to the schema for the simple xml file. Defaults to the schema provided in this package
schema_output	a character string giving the file path to the schema. A copy was downloaded and is provided in this package as the default.

Value

the output from the validation against the schema. A new file is created as a side-effect, which is suitable to upload into eudraCT.

See Also

[safety_summary](#) [simple_safety_xml](#)

Examples

```
safety_statistics <- safety_summary(safety,  
                                  exposed=c("Experimental"=60,"Control"=67))  
simple <- tempfile(fileext = ".xml")  
eudract <- tempfile(fileext = ".xml")  
simple_safety_xml(safety_statistics, simple)  
eudract_convert(input=simple,  
               output=eudract)
```

 safety

Example of safety data

Description

A dataset containing some example data of safety event in raw source format

Usage

safety

Format

a data frame with 8 columns and 16 rows

pt meddra preferred term code

subjid a unique subject identifier

related a logical indicating if the event is related to the treatment

soc the meddra code for the System Organ Class

fatal a numerical 0/1 to indicate if the event was fatal

serious a numerical 0/1 to indicate if the event was serious

group the treatment group for the subject

term a text description of the event. Needs to be matching 1-1 with the pt code

Details

The data contains one row per patient-event. So the numbers exposed in each arm cannot be inferred from these data, as patients with no events will not be included in these data.

The variable names and formats are those required by [safety_summary](#). The variable pt is not strictly required. An alternative to soc would be the equivalent character string from [soc_code](#)

 safety_summary

Calculate frequency tables from a rectangular data frame with one row per subject-event

Description

Calculate frequency tables from a rectangular data frame with one row per subject-event

Usage

```
safety_summary(
  data,
  exposed,
  excess_deaths = 0,
  freq_threshold = 0,
  soc_index = c("meddra", "soc_term")
)
```

Arguments

<code>data</code>	a data set containing the following columns: <code>subjid</code> , <code>term</code> , <code>soc</code> , <code>serious</code> , <code>related</code> , <code>fatal</code> , <code>group</code> . See safety for more details.
<code>exposed</code>	a numeric vector giving the numbers of subjects exposed in each group. This needs to be supplied directly by the user, and cannot be inferred from the input data with one row per patient-event. To ensure the ordering is correct either, name the vector with names matching the values in <code>data\$group</code> , or ensure that the <code>data\$group</code> is an ordered factor, or relying on alphabetical ordering of the values in <code>data\$group</code>
<code>excess_deaths</code>	a numeric vector giving the number of extra deaths not reported within data. Defaults to 0.
<code>freq_threshold</code>	a value on a percentage scale at which to remove events if the incidence falls below. Defaults to 0
<code>soc_index</code>	a character vector either "meddra" or "soc_term", which is used to identify if the soc variable in data gives the numerical meddra code or the description in English.

Value

a list of three dataframes: `GROUP`, `SERIOUS`, `NON_SERIOUS`. Each contains the summary statistics required by EudraCT, and is suitable for export.

See Also

[eudract_convert_simple_safety_xml](#)

Examples

```
safety_statistics <- safety_summary(safety,
                                   exposed=c("Experimental"=60, "Control"=67))
simple <- tempfile(fileext = ".xml")
eudract <- tempfile(fileext = ".xml")
simple_safety_xml(safety_statistics, simple)
eudract_convert(input=simple,
                output=eudract)
```

simple_safety_xml *creates a simple xml file from the input of a safety_summary object*

Description

creates a simple xml file from the input of a safety_summary object

Usage

```
simple_safety_xml(  
  x,  
  file,  
  schema = system.file("extdata", "simple.xsd", package = "eudract")  
)
```

Arguments

x an object of class safety_summary, as created by [safety_summary](#).

file a character string name the file to be created

schema a character string giving the file path to the schema for the outputxml file. Defaults to the schema provided in this package.

Value

no output is returned, but a file is created as a side-effect.

See Also

[eudract_convert safety_summary](#)

Examples

```
safety_statistics <- safety_summary(safety,  
                                   exposed=c("Experimental"=60,"Control"=67))  
simple <- tempfile(fileext = ".xml")  
eudract <- tempfile(fileext = ".xml")  
simple_safety_xml(safety_statistics, simple)  
eudract_convert(input=simple,  
                output=eudract)
```

soc_code	<i>System Organ Class coding</i>
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Description

A dataset containing text descriptions and medDRA and EudraCT codes for each system organ class

Usage

soc_code

Format

a data frame with 3 columns and 27 rows

soc_term a text description

euctId the eudraCT coding

meddra the meddra code

Source

<https://www.meddra.org/>, <https://spor.ema.europa.eu/rmswi/#/>

Index

*Topic **datasets**

safety, [4](#)

soc_code, [7](#)

create_safety_summary, [2](#)

eudract_convert, [3](#), [5](#), [6](#)

safety, [4](#), [5](#)

safety_summary, [3](#), [4](#), [4](#), [6](#)

simple_safety_xml, [3](#), [5](#), [6](#)

soc_code, [4](#), [7](#)