# Package 'ctrdata'

May 5, 2025

Type Package

Title Retrieve and Analyze Clinical Trials Data from Public Registers

**Version** 1.22.1

**Imports** jsonlite, httr, curl (>= 5.1.0), clipr, xml2, nodbi (>= 0.10.7), stringi, lubridate, jqr, dplyr, zip, V8, readr, digest, rlang, countrycode, htmlwidgets, tibble, stringdist, tidyr

URL https://cran.r-project.org/package=ctrdata,
 https://rfhb.github.io/ctrdata/

BugReports https://github.com/rfhb/ctrdata/issues

Description A system for querying, retrieving and analyzing protocol- and results-related information on clinical trials from four public registers, the 'European Union Clinical Trials Register' ('EUCTR', <a href="https://www.clinicaltrialsregister.eu/">https://www.clinicaltrialsregister.eu/</a>), 'ClinicalTrials.gov' (<a href="https://clinicaltrials.gov/">https://clinicaltrials.gov/</a> and also translating queries the retired classic interface), the 'ISRCTN' (<a href="https://www.isrctn.com/">http://www.isrctn.com/</a>) and the 'European Union Clinical Trials Information System' ('CTIS', <a href="https://euclinicaltrials.eu/">https://euclinicaltrials.eu/</a>).

Trial information is downloaded, converted and stored in a database ('PostgreSQL', 'SQLite', 'DuckDB' or 'MongoDB'; via package 'nodbi'). Protocols, statistical analysis plans, informed consent sheets and other documents in registers associated with trials can also be downloaded. Other functions implement trial concepts canonically across registers, identify deduplicated records, easily find and extract variables (fields) of interest even from complex nested data as used by the registers, merge variables and update queries.

The package can be used for monitoring, meta- and trend-analysis of the design and conduct as well as of the results of clinical trials across registers.

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RoxygenNote 7.3.2

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<b>Suggests</b> devtools, knitr, rmarkdown, RSQLite, mongolite, tinytest (>= 1.2.1), RPostgres, duckdb
VignetteBuilder knitr
NeedsCompilation no
Encoding UTF-8
Language en-GB
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Repository CRAN

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**Date/Publication** 2025-05-05 06:00:02 UTC

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## Description

ctrdata is a package for aggregating and analysing data on clinical studies, and for obtaining documents, from public trial registers

#### 1 - Database connection

Package ctrdata retrieves trial data and stores it in a database collection. A database connection object has to be specified in parameter con for several ctrdata functions. The connection object is built using nodbi which allows to use different database backends in an identical way. Specifying a parameter collection = "<my collection's name>" is necessary for package ctrdata.

#### 2 - Operate on trial registers

ctrGenerateQueries (generate from simple user input specific queries for registers EUCTR, CTIS, CTGOV2 and ISRCTN), ctrOpenSearchPagesInBrowser (open queries in browser), see script (automatically copy user search in any register to clipboard), see ctrdata-registers for details on registers and how to search, ctrLoadQueryIntoDb (load trial records found with query into database collection).

#### 3 - Get data frame from collection

ctrShowOneTrial (show widget to explore structure, fields and data of a trial), dbFindFields (find names of fields of interest in trial records in a collection), dbGetFieldsIntoDf (create a data frame with fields of interest and calculated trial concepts from collection), ctrdata-trial-concepts (calculate pre-defined trial concepts for every register), dbFindIdsUniqueTrials (get de-duplicated identifiers of clinical trials' records to subset a data frame).

#### 4 - Operate on a trial data frame

dfTrials2Long (convert fields with nested elements into long format), dfName2Value (get values for variable(s) of interest), ctrdata-trial-concepts (calculate pre-defined trial concepts for every register).

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## Author(s)

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#### See Also

Useful links:

- https://cran.r-project.org/package=ctrdata
- https://rfhb.github.io/ctrdata/
- Report bugs at https://github.com/rfhb/ctrdata/issues

ctrdata-registers

Information on clinical trial registers

#### **Description**

Registers of the four clinical trial registers from which package ctrdata can retrieve, aggregate and analyse protocol- and result-related information as well as documents, last updated 2025-04-13.

#### 1 - Overview

- **EUCTR**: The EU Clinical Trials Register holds more than 44,300 clinical trials (at least one investigational medicinal product, IMP; in the European Union and beyond), including almost 25,000 trials with results, which continue to be added (can be loaded by ctrdata).
- CTIS: The EU Clinical Trials Information System, launched in 2023, holds more than 8,900 publicly accessible clinical trials, including around 100 with results or a report (only as PDF files). *No results in a structured electronic format are foreseeably available*, thus ctrdata cannot load any CTIS results. (To automatically get CTIS search query URLs, see here)
- CTGOV2: ClinicalTrials.gov holds more than 533,000 interventional and observational studies, including almost 66,000 interventional studies with results (can be loaded by ctrdata).
- **ISRCTN**: The ISRCTN Registry holds more than 26,000 interventional and observational health studies, including almost 14,200 studies with results (only as references). *No results in a structured electronic format are foreseeably available*, thus ctrdata cannot load any ISRCTN results.

## 2 - Notable changes

CTGOV "classic" was retired on 2024-06-25; ctrdata subsequently translates CTGOV queries to CTGOV2 queries. The new website ("CTGOV2") can be used with ctrdata since 2023-08-27. Database collections created with CTGOV queries can still be used since functions in ctrdata continue to support them. CTIS was relaunched on 2024-06-17, changing the data structure and search syntax, to which ctrdata was updated. CTIS can be used with ctrdata since 2023-03-25. EUCTR removed search parameter status= as of February 2025. More information on changes: here.

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## 3 - References

Material	<b>EUCTR</b>	CTGOV2	ISRCTN	CTIS
About	link	link	link	link
Terms & conditions, disclaimer	link	link	link	link
How to search	link	link	link	link
Search interface	link	link	link	link
Expert / advanced search	link	link	link	link
Glossary / related information	link	link	link	link
FAQ, caveats, issues	link	link, link	link	link
Data dictionaries / definitions / structure reference	link, link, link	link, link, link	link	link (XLSX files)
Example*	link	link	link	link

Some registers are expanding entered search terms using dictionaries (example).

# 4 - Example and ctrdata motivation

See vignette("ctrdata\_summarise") for several other examples.

\*This example is an expert search for interventional trials primarily with neonates, investigating treatments for infectious conditions. It shows that searches in the web interface of most registers are not sufficient to identify the trials of interest:

- EUCTR retrieves trials with neonates, but not only those exclusively in neonates.
- ISRCTN retrieves studies with interventions other than medicines.
- CTIS retrieves trials that mention the words neonates and infection. (To show CTIS search results, see <a href="here">here</a>)

To address this issue, trials can be retrieved with ctrLoadQueryIntoDb into a database collection and in a second step trials of interest can be selected based on values of relevant fields, for example:

- EUCTR field f115\_children\_211years and other age group criteria
- ISRCTN field interventions.intervention.interventionType for type of study
- CTIS fields ageGroup and authorizedApplication.authorizedPartI.medicalConditions.medicalCondition

ctrdata supports users with pre-defined ctrdata-trial-concepts and these cover the example above, and with functions dbFindFields and ctrShowOneTrial for finding fields of interest and reviewing data structure, respectively.

#### Author(s)

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ctrdata-trial-concepts

Trial concepts implemented across registers

## **Description**

ctrdata includes (since version 1.21.0) functions that implement selected trial concepts. Concepts of clinical trials, such as their start or status of recruitment, require to analyse several fields against various pre-defined values. The structure and value sets of fields differ between all ctrdata-registers. In this situation, the implemented trial concepts simplify and accelerate a user's analysis workflow and also increase analysis consistency.

#### **Details**

The implementation of trial concepts in ctrdata has not been validated with any formal approach, but has been checked for plausibility and against expectations. The implementation is based on current understanding, on public data models and on scientific papers, as relevant. As with other R functions, call help("f.startDate") or print its implementation code by entering the name of the function as command, e.g. f.startDate. Please raise an issue here to ask about or improve a trial concept.

The following trial concepts can be used by referencing their name when calling dbGetFieldsIntoDf (parameter calculate). Concepts will continue to be refined and added; last updated 2025-03-15.

- f.controlType (factor) which type of internal or concurrent control is used in the trial? ("none", "no-treatment", "placebo", "active", "placebo+active" or "other")
- f.isMedIntervTrial (logical) is the trial interventional and does it have one or more medicines (drugs or biological) as investigational (experimental) intervention? (irrespective of status of authorisation and of study design)
- f.isUniqueTrial (logical) is the trial record unique in the data frame of trial, based on default parameters of dbFindIdsUniqueTrials?
- f.likelyPlatformTrial (logical, list of likely related trials, and a list of possibly related trials) is the trial possibly a (research) platform trial, and what are related trials? (based on trial title, f.numTestArmsSubstances, number of periods; similarity of terms in parts of trial titles)
- f.numSites (integer) how many sites does the trial have?
- f.numTestArmsSubstances (integer) how many arms or groups have medicines that are investigational? (cannot be calculated for ISRCTN or for phase 1 trials)
- f.primaryEndpointDescription (list of character) string containing protocol definition, details and time frames, concatenated with " == "
- f.primaryEndpointResults (columns of number, character, integer) returning the statistical testing p value and method as well as the number of subjects included in the test, each in one new column, for the first primary endpoint only
- f.resultsDate (date) the planned or achieved date of results availability
- f.startDate (date) the planned, authorised or documented date of start of recruitment
- f.sampleSize (integer) the planned or achieved number of subjects or participants recruited

- f.sponsorType (factor) a type or class of main or lead sponsor that is simplified to "not for profit", "for profit" or "other"
- f.statusRecruitment (factor) a status that is simplified to "ongoing" (includes temporarily halted), "completed", "ended early" (includes terminated or ended prematurely) and "other" (includes planned, stopped, withdrawn)
- f.trialObjectives (string) identifies with letters those objectives that could be identified by text fragments, e.g. "E S PD D", with "E" (efficacy), "S" (safety), "D" (dose-finding)
- f.trialPhase (ordered factor) the phase(s) of medicine development with which a trial is associated
- f.trialPopulation (columns of factor, string and string) age groups (e.g., "P" for paediatric participants, "A" for adults, "E" for older than 65 years, or "P+A"), inclusion and exclusion criteria texts
- f.trialTitle (string) full or scientific title of the study

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ctrFindActiveSubstanceSynonyms

Find synonyms of an active substance

# Description

An active substance can be identified by a recommended international nonproprietary name (INN), a trade or product name, or a company code(s). To find likely synonyms, the function retrieves from CTGOV2 the field protocolSection.armsInterventionsModule.interventions.otherNames. Note this does not seem to be based on choices from a dictionary but may be manually filled, thus is not free of error and needs to be checked.

## Usage

ctrFindActiveSubstanceSynonyms(activesubstance = "", verbose = FALSE)

# **Arguments**

activesubstance

An active substance, in an atomic character vector

verbose Print number of studies found in CTGOV2 for 'active substance'

## Value

A character vector of the active substance (input parameter) and synonyms, or NULL if active substance was not found and may be invalid

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## **Examples**

```
## Not run:

ctrFindActiveSubstanceSynonyms(activesubstance = "imatinib")
# [1] "imatinib" "CGP 57148" "CGP 57148B"
# [4] "CGP57148B" "Gleevec" "GLIVEC"
# [7] "Imatinib" "Imatinib Mesylate" "NSC 716051"
# [10] "ST1571" "STI 571" "STI571"

## End(Not run)
```

ctrGenerateQueries

Generates queries that work across registers

## **Description**

From high-level search terms provided by the user, generate specific queries for each registers with which ctrdata works, see ctrdata-registers. Search terms that are expanded to concepts such as from MeSH and MedDRA by the search implementations in registers include the 'intervention' and 'condition'. Logical operators only work with 'searchPhrase'.

# Usage

```
ctrGenerateQueries(
   searchPhrase = NULL,
   condition = NULL,
   intervention = NULL,
   phase = NULL,
   population = NULL,
   recruitment = NULL,
   startBefore = NULL,
   startAfter = NULL,
   completedBefore = NULL,
   completedAfter = NULL,
   onlyMedIntervTrials = TRUE,
   onlyWithResults = FALSE,
   countries = NULL
)
```

## **Arguments**

searchPhrase String with optional logical operators ("AND", "OR") that will be searched in se-

lected fields of registers that can handle logical operators (general or title fields),

should not include quotation marks

condition String with condition / disease

intervention String with intervention

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phase	String, e.g. "phase 2" (note that "phase 2+3" is a specific category, not the union set of "phase 2" and "phase 3")						
population	String, e.g. "P" (paediatric), "A" (adult), "P+A" (adult and paediatric), "E" (elderly), "P+A+E" participants can be recruited						
recruitment	String, one of "ongoing", "completed", "other" (which includes "ended early" but this cannot be searched; use trial concept f.statusRecruitment to identify this status)						
startBefore	String that can be interpreted as date (for EUCTR, when trial was first registered)						
startAfter	String that can be interpreted as date (for EUCTR, when trial was first registered)						
completedBefore	completedBefore						
	String that can be interpreted as date (does not work with EUCTR)						
completedAfter	String that can be interpreted as date (does not work with EUCTR)						
onlyMedIntervTu	rials						
	Logical, default TRUE, which indicates if queries should search only for medicine interventional clinical trial						
onlyWithResults	onlyWithResults						
	Logical						
countries	Vector of country names, two- or three-letter ISO 3166 codes						

#### Value

Named vector of URLs for finding trials in the registers and as input to functions ctrLoadQueryIntoDb and ctrOpenSearchPagesInBrowser

```
urls <- ctrGenerateQueries(</pre>
  intervention = "antibody",
  phase = "phase 3",
  startAfter = "2000-01-01")
# open queries in register web interface
sapply(urls, ctrOpenSearchPagesInBrowser)
urls <- ctrGenerateQueries(</pre>
  searchPhrase = "antibody AND covid",
  recruitment = "completed",
# count trials found
sapply(urls, ctrLoadQueryIntoDb, only.count = TRUE)
# load queries into database collection
# sapply(urls, ctrLoadQueryIntoDb, con = dbc)
# find research platform and platform trials
urls <- ctrGenerateQueries(</pre>
  searchPhrase = paste0(
   "basket OR platform OR umbrella OR master protocol OR ",
```

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```
"multiarm OR multistage OR subprotocol OR substudy OR ",
   "multi-arm OR multi-stage OR sub-protocol OR sub-study"),
   startAfter = "01/31/2010",
   countries = c("DE", "US", "United Kingdom"))

# open queries in register web interface
sapply(urls, ctrOpenSearchPagesInBrowser)
```

ctrGetQueryUrl

Get register name and query parameters from search URL

## **Description**

Extracts query parameters and register name from parameter 'url' or from the clipboard, into which the URL of a register search was copied.

# Usage

```
ctrGetQueryUrl(url = "", register = "")
```

## **Arguments**

url

URL such as from the browser address bar. If not specified, clipboard contents will be checked for a suitable URL. For automatically copying the user's query of a register in a web browser to the clipboard, see <a href="here">here</a>. Can also contain a query term such as from <a href="here">dbQueryHistory()["query-term"]</a>. Can also be an identifier of a trial, which based on its format will indicate to which register it relates.

register

Optional name of register (one of "EUCTR", "CTGOV2" "ISRCTN" or "CTIS") in case 'url' is a query term but not a full URL

## Value

A data frame (or tibble, if tibble is loaded) with column names 'query-term' and 'query-register'. The data frame (or tibble) can be passed as such as parameter 'queryterm' to ctrLoadQueryIntoDb and as parameter 'url' to ctrOpenSearchPagesInBrowser.

```
# user copied into the clipboard the URL from
# the address bar of the browser that shows results
# from a query in one of the trial registers
if (interactive()) try(ctrGetQueryUrl(), silent = TRUE)
# extract query parameters from search result URL
# (URL was cut for the purpose of formatting only)
ctrGetQueryUrl(
   url = paste0(
        "https://classic.clinicaltrials.gov/ct2/results?",
```

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```
"cond=&term=AREA%5BMaximumAge%5D+RANGE%5B0+days%2C+28+days%5D",
        "&type=Intr&rslt=&age_v=&gndr=&intr=Drugs%2C+Investigational",
        "&titles=&outc=&spons=&lead=&id=&cntry=&state=&city=&dist=",
        "&locn=&phase=2&rsub=&strd_s=01%2F01%2F2015&strd_e=01%2F01%2F2016",
        "&prcd_s=&prcd_e=&sfpd_s=&sfpd_e=&rfpd_s=&rfpd_e=&lupd_s=&lupd_e=&sort="
)
# other examples
ctrGetQueryUrl("https://www.clinicaltrialsregister.eu/ctr-search/trial/2007-000371-42/results")
ctrGetQueryUrl("https://euclinicaltrials.eu/ctis-public/view/2022-500041-24-00")
ctrGetQueryUrl("https://classic.clinicaltrials.gov/ct2/show/NCT01492673?cond=neuroblastoma")
ctrGetQueryUrl("https://clinicaltrials.gov/ct2/show/NCT01492673?cond=neuroblastoma")
ctrGetQueryUrl("https://clinicaltrials.gov/study/NCT01467986?aggFilters=ages:child")
ctrGetQueryUrl("https://www.isrctn.com/ISRCTN70039829")
# using identifiers of single trials
ctrGetQueryUrl("70039829")
ctrGetQueryUrl("ISRCTN70039829")
ctrGetQueryUrl("NCT00617929")
ctrGetQueryUrl("2022-501142-30-00")
ctrGetQueryUrl("2012-003632-23")
```

ctrLoadQueryIntoDb

Load and store register trial information

# **Description**

Retrieves information on clinical trials from registers and stores it in a collection in a database. Main function of ctrdata for accessing registers. A collection can store trial information from different queries or different registers. Query details are stored in the collection and can be accessed using dbQueryHistory. A previous query can be re-run, which replaces or adds trial records while keeping any user annotations of trial records.

# Usage

```
ctrLoadQueryIntoDb(
  queryterm = NULL,
  register = "",
  querytoupdate = NULL,
  forcetoupdate = FALSE,
  euctrresults = FALSE,
  euctrresultshistory = FALSE,
  ctgov2history = FALSE,
  ctishistory = TRUE,
  documents.path = NULL,
  documents.regexp = "prot|sample|statist|sap_|p1ar|p2ars|icf|ctalett|lay|^[0-9]+ ",
  annotation.text = "",
```

```
annotation.mode = "append",
 only.count = FALSE,
  con = NULL,
  verbose = FALSE,
)
```

## **Arguments**

queryterm

Either a string with the full URL of a search query in a register, or the data frame returned by ctrGetQueryUrl or dbQueryHistory, or an 'id' in the format of one of the trial registers, or, together with register, a string with query elements of a search URL. The query details are recorded in the collection for later use to update records. For "CTIS", queryterm can be an empty string to obtain all trial records. For automatically copying the user's query of a register in a web browser to the clipboard, see here

register

String with abbreviation of register to query, either "EUCTR", "CTGOV2", "IS-RCTN" or "CTIS". Not needed if query term has a full URL to query results, or has a single trial identifier, or comes from ctrGetQueryUrl or dbQueryHistory.

querytoupdate

Either the word "last", or the row number of a query in the data frame returned by dbQueryHistory that should be run to retrieve any new or update trial records since this query was run the last time. This parameter takes precedence over queryterm. For "EUCTR", updates are available only for the last seven days; the query is run again if more time has passed since it was run last. Does not work with "CTIS" at this time.

forcetoupdate

If TRUE, run again the query given in querytoupdate, irrespective of when it was run last. Default is FALSE.

euctrresults

If TRUE, also download available results when retrieving and loading trials from EUCTR. This slows down this function. (For "CTGOV2" and "CTIS", available results are always retrieved and loaded into the collection.)

euctrresultshistory

If TRUE, download results and also the available history of results publication in "EUCTR." This somewhat time-consuming. Default is FALSE.

ctgov2history

For trials from CTGOV2, retrieve historic versions of the record. Default is FALSE, because this is a time-consuming operation. Use n for n from all versions (recommended), 1 for the first (original) version, -1 for the last-but-one version, "n:m" for the nth to the mth versions, or TRUE for all versions of the trial record to be retrieved. Note that for register CTIS, historic versions were available in the 'applications' field only before the register's relaunch on 2024-06-17.

ctishistory

If TRUE, and only when using querytoupdate, move the current CTIS record into an array history with the record which holds one or more historic versions, before updating the rest of the record from CTIS. Default is FALSE, because this is a time-consuming operation. See "Historic versions" in vignette ("ctrdata\_summarise").

documents.path If this is a relative or absolute path to a directory that exists or can be created, save any documents into it that are directly available from the register ("EUCTR", "CTGOV2", "ISRCTN", "CTIS") such as PDFs on results, analysis ctrLoadQueryIntoDb 13

plans, spreadsheets, patient information sheets, assessments or product information. Default is NULL, which disables saving documents. For "EUCTR", sets euctrresults = TRUE since documents are available only with results.

## documents.regexp

Regular expression, case insensitive, to select documents by filename, if saving documents is requested (see documents.path). If set to NULL, empty placeholder files are saved for every document that could be saved, which is useful to get an overview on the number and types of documents available for download. Default is "prot|sample|statist|sap\_|plar|p2ars|icf|ctalett|lay|^[0-9]+". Used with "CTGOV2", "ISRCTN" and "CTIS" (for "EUCTR", all documents are downloaded since they are few and have non-canonical filenames.)

#### annotation.text

Text to be including into the field "annotation" in the records retrieved with the query that is to be loaded into the collection. The contents of the field "annotation" for a trial record are preserved e.g. when running this function again and loading a record of a with an annotation, see parameter annotation. mode.

#### annotation.mode

One of "append" (default), "prepend" or "replace" for new annotation.text with respect to any existing annotation for the records retrieved with the query that is to be loaded into the collection.

only.count

Set to TRUE to return only the number of trial records found in the register for the query. Does not load trial information into the database. Default is FALSE.

con

A database connection object, created with nodbi. See section '1 - Database

connection' in ctrdata.

verbose

Printing additional information if set to TRUE; default is FALSE.

...

Do not use (capture deprecated parameters).

#### Value

A list with elements 'n' (number of trial records newly imported or updated), 'success' (a vector of \_id's of successfully loaded records), 'failed' (a vector of identifiers of records that failed to load) and 'queryterm' (the query term used). The returned list has several attributes (including database and collection name, as well as the query history of this database collection) to facilitate documentation.

```
## Not run:
dbc <- nodbi::src_sqlite(collection = "my_collection")
# Retrieve protocol- and results-related information
# on two specific trials identified by their EU number
ctrLoadQueryIntoDb(
   queryterm = "2005-001267-63+OR+2008-003606-33",
   register = "EUCTR",
   euctrresults = TRUE,
   con = dbc</pre>
```

```
)
# Count ongoing interventional cancer trials involving children
# Note this query is a classical CTGOV query and is translated
# to a corresponding query for the current CTGOV2 webinterface
ctrLoadQueryIntoDb(
 queryterm = "cond=cancer&recr=Open&type=Intr&age=0",
 register = "CTGOV",
 only.count = TRUE,
 con = dbc
)
# Retrieve all information on more than 40 trials
# that are labelled as phase 3 and that mention
# either neuroblastoma or lymphoma from ISRCTN,
# into the same collection as used before
ctrLoadQueryIntoDb(
 queryterm = paste0(
    "https://www.isrctn.com/search?",
    "q=neuroblastoma+OR+lymphoma&filters=phase%3APhase+III"),
 con = dbc
)
# Retrieve information trials in CTIS mentioning neonates
ctrLoadQueryIntoDb(
 queryterm = paste0("https://euclinicaltrials.eu/ctis-public/",
  "search#searchCriteria={%22containAll%22:%22%22,",
  "%22containAny%22:%22neonates%22,%22containNot%22:%22%22}"),
 con = dbc
)
## End(Not run)
```

ctrOpenSearchPagesInBrowser

Open register to show query results or search page

## **Description**

Open advanced search pages of register(s), or execute search in browser

# Usage

```
ctrOpenSearchPagesInBrowser(url = "", register = "", copyright = FALSE)
```

## **Arguments**

url

of search results page to show in the browser. To open the browser with a previous search, the output of ctrGetQueryUrl or dbQueryHistory can be used. Can be left as empty string (default) to open the advanced search page of register.

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register Register(s) to open, "EUCTR", "CTGOV2", "ISRCTN" or "CTIS". Default is

empty string, and this opens the advanced search page of the registers (including

the expert search page in the case of CTGOV).

copyright (Optional) If set to TRUE, opens only the copyright pages of all registers.

#### Value

(String) Full URL corresponding to the shortened url in conjunction with register if any, or invisibly TRUE if no url is specified.

## **Examples**

```
# Open all and check copyrights before using registers
ctrOpenSearchPagesInBrowser(copyright = TRUE)
# Open specific register advanced search page
ctrOpenSearchPagesInBrowser(register = "CTGOV2")
ctrOpenSearchPagesInBrowser(register = "CTIS")
ctrOpenSearchPagesInBrowser(register = "EUCTR")
ctrOpenSearchPagesInBrowser(register = "ISRCTN")
# Open all queries that were loaded into demo collection
dbc <- nodbi::src_sqlite(</pre>
 dbname = system.file("extdata", "demo.sqlite", package = "ctrdata"),
 collection = "my_trials",
 flags = RSQLite::SQLITE_RO)
dbh <- dbQueryHistory(con = dbc)</pre>
for (r in seq_len(nrow(dbh))) {
   ctrOpenSearchPagesInBrowser(dbh[r, ])
}
```

ctrShowOneTrial

Show full structure and all data of a trial

## **Description**

If used interactively, the function shows a widget of all data in the trial as a tree of field names and values. The widget opens in the default browser. Fields names and values can be search and selected. Selected fields can be copied to the clipboard for use with function dbGetFieldsIntoDf. The trial is retrieved with ctrLoadQueryIntoDb if no database con is provided or if the trial is not in database con.

# Usage

```
ctrShowOneTrial(identifier = NULL, con = NULL)
```

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## **Arguments**

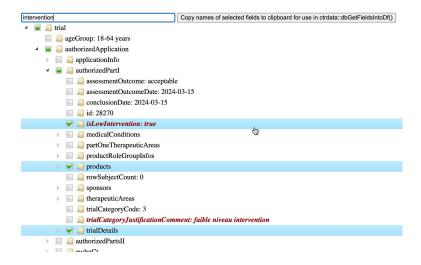
identifier A trial identifier string

con A database connection object, created with nodbi. See section '1 - Database

connection' in ctrdata.

#### **Details**

This is the widget for CTIS trial 2022-501142-30-00:



#### Value

Invisibly, the trial data for constructing an HTML widget.

```
dbc <- nodbi::src_sqlite(
   dbname = system.file("extdata", "demo.sqlite", package = "ctrdata"),
   collection = "my_trials",
   flags = RSQLite::SQLITE_RO)

# all such identifiers work
id <- "2014-003556-31"
id <- "2014-003556-31-SE"
id <- "76463425"
id <- "1SRCTN76463425"
id <- "NCT03431558"
id <- "2022-501142-30-00"

# the id also works with
# ctrGetQueryUrl(url = id) and
# ctrLoadQueryIntoDb(queryterm = id, ...)

# show widget for user to explore and search content as well as to</pre>
```

dbFindFields 17

```
# select fields of interest and to click on "Copy names of selected
# fields to clipboard..." to use them with dbGetFieldsIntoDf()
ctrShowOneTrial(identifier = id, con = dbc)
# get sample of identifiers of trials in database
sample(dbFindIdsUniqueTrials(con = dbc), 5L)
```

dbFindFields

Find names of fields in the database collection

## **Description**

Given part of the name of a field of interest to the user, this function returns the full field names used in records that were previously loaded into a collection (using ctrLoadQueryIntoDb). Only names of fields that have a value in the collection can be returned. Set sample = FALSE to force screening all records in the collection for field names, see below. See ctrShowOneTrial to interactively find fields.

## Usage

```
dbFindFields(namepart = ".*", con, sample = TRUE, verbose = FALSE)
```

## **Arguments**

namepart	A character string (can be a regular expression, including Perl-style) to be searched among all field names (keys) in the collection, case-insensitive. The default ".*" lists all fields.
con	A database connection object, created with nodbi. See section '1 - Database connection' in ctrdata.
sample	If TRUE (default), uses a sample of only 5 trial records per register to identify fields, to rapidly return a possibly incomplete set of field names. If FALSE, uses all trial records in the collection, which will take more time with more trials but ensures to returns all names of all fields in the collection.
verbose	If TRUE, prints additional information (default FALSE).

## **Details**

The full names of child fields are returned in dot notation (e.g., clinical\_results.outcome\_list.outcome.measure.class In addition, names of parent fields (e.g., clinical\_results) are returned. Data in parent fields is typically complex (nested), see dfTrials2Long for easily handling it. For field definitions of the registers, see "Definition" in ctrdata-registers. Note: When dbFindFields is first called after ctr-LoadQueryIntoDb, it will take a moment.

#### Value

Vector of strings with full names of field(s) found, ordered by register and alphabet, see examples. Names of the vector are the names of the register holding the respective fields. The field names can be fed into dbGetFieldsIntoDf to extract the data for the field(s) from the collection into a data frame.

## **Examples**

```
dbc <- nodbi::src_sqlite(
   dbname = system.file("extdata", "demo.sqlite", package = "ctrdata"),
   collection = "my_trials",
   flags = RSQLite::SQLITE_RO)

dbFindFields(namepart = "date", con = dbc)[1:5]

# view all 1880+ fields from all registers:

allFields <- dbFindFields(con = dbc, sample = FALSE)

if (interactive()) View(data.frame(
   register = names(allFields),
   field = allFields))</pre>
```

dbFindIdsUniqueTrials Get identifiers of deduplicated trial records

## **Description**

Records for a clinical trial can be loaded from more than one register into a collection. This function returns deduplicated identifiers for all trials in the collection, respecting the register(s) preferred by the user. All registers are recording identifiers also from other registers, which are used by this function to provide a vector of identifiers of deduplicated trials.

# Usage

```
dbFindIdsUniqueTrials(
  preferregister = c("CTGOV2", "EUCTR", "CTGOV", "ISRCTN", "CTIS"),
  prefermemberstate = "BE",
  include3rdcountrytrials = TRUE,
  con,
  verbose = FALSE
)
```

#### **Arguments**

preferregister A vector of the order of preference for registers from which to generate unique \_id's, default c("CTGOV2", "EUCTR", "CTGOV", "ISRCTN", "CTIS")

prefermemberstate

Code of single EU Member State for which records should returned. If not available, a record for BE or lacking this, any random Member State's record for the trial will be returned. For a list of codes of EU Member States, please see vector countriesEUCTR. Specifying "3RD" will return the Third Country record of trials, where available.

include3rdcountrytrials

A logical value if trials should be retained that are conducted exclusively in third countries, that is, outside the European Union. Ignored if prefermemberstate

is set to "3RD".

con A database connection object, created with nodbi. See section '1 - Database

connection' in ctrdata.

verbose If TRUE, prints out the fields of registers used to find corresponding trial records

#### **Details**

Note that the content of records may differ between registers (and, for "EUCTR", between records for different Member States). Such differences are not considered by this function.

Note that the trial concept ".isUniqueTrial" (which uses this function) can be calculated at the time of creating a data frame with dbGetFieldsIntoDf, which often may be the preferred approach.

#### Value

A named vector with strings of keys (field "\_id") of records in the collection that represent unique trials, where names correspond to the register of the record.

```
dbc <- nodbi::src_sqlite(
   dbname = system.file("extdata", "demo.sqlite", package = "ctrdata"),
   collection = "my_trials",
   flags = RSQLite::SQLITE_RO)

dbFindIdsUniqueTrials(con = dbc)[1:10]

# alternative as of ctrdata version 1.21.0,
# using defaults of dbFindIdsUniqueTrials()
df <- dbGetFieldsIntoDf(
   fields = "keyword",
   calculate = "f.isUniqueTrial",
   con = dbc)

# using base R
df[df[[".isUniqueTrial"]], ]

## Not run:</pre>
```

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```
library(dplyr)
df %>% filter(.isUniqueTrial)
## End(Not run)
```

dbGetFieldsIntoDf

Create data frame of specified fields from database collection

#### **Description**

Fields in the collection are retrieved from all records into a data frame (or tibble). Within a given trial record, a fields can be hierarchical and structured, that is, nested. Th function uses the field names to appropriately type the values that it returns, harmonising original values (e.g. "Information not present in EudraCT" to 'NA', "Yes" to 'TRUE', "false" to 'FALSE', date strings to dates or time differences, number strings to numbers). The function simplifies the structure of nested data and may concatenate multiple strings in a field using "/" (see example) and may have widened the returned data frame with additional columns that were recursively expanded from simply nested data (e.g., "externalRefs" to columns "externalRefs.doi", "externalRefs.eudraCTNumber" etc.). For an alternative way for handling the complex nested data, see dfTrials2Long followed by dfName2Value for extracting the sought variable(s).

#### Usage

```
dbGetFieldsIntoDf(fields = "", calculate = "", con, verbose = FALSE, ...)
```

## Arguments

fields	Vector of one or more strings, with names of sought fields. See function dbFind-Fields for how to find names of fields and ctrShowOneTrial for interactively selecting field names. Dot path notation ("field.subfield") without indices is supported. If compatibility with 'nodbi::src_postgres()' is needed, specify fewer than 50 fields, consider also using parent fields e.g., '"a.b" instead of 'c("a.b.c.d", "a.b.c.e")', accessing sought fields with dfTrials2Long followed by dfName2Value or other R functions.
calculate	Vector of one or more strings, which are names of functions to calculate certain trial concepts from fields in the collection across different registers.
con	A database connection object, created with nodbi. See section '1 - Database connection' in ctrdata.
verbose	Printing additional information if set to TRUE; (default FALSE).
	Do not use (captures deprecated parameter stopifnodata)

#### Value

A data frame (or tibble, if tibble is loaded) with columns corresponding to the sought fields. A column for the records' '\_id' will always be included. The maximum number of rows of the returned data frame is equal to, or less than the number of trial records in the database collection.

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## **Examples**

```
dbc <- nodbi::src_sqlite(</pre>
  dbname = system.file("extdata", "demo.sqlite", package = "ctrdata"),
  collection = "my_trials",
  flags = RSQLite::SQLITE_RO)
# get fields that are nested within another field
# and can have multiple values with the nested field
dbGetFieldsIntoDf(
  fields = "b1_sponsor.b31_and_b32_status_of_the_sponsor",
  con = dbc)
# fields that are lists of string values are
# returned by concatenating values with a slash
dbGetFieldsIntoDf(
  fields = "keyword",
  con = dbc)
# calculate new field(s) from data across trials
df <- dbGetFieldsIntoDf(</pre>
  fields = "keyword",
  calculate = c("f.statusRecruitment", "f.isUniqueTrial", "f.startDate"),
  con = dbc)
table(df$.statusRecruitment, exclude = NULL)
## Not run:
library(dplyr)
library(ggplot2)
df %>%
  filter(.isUniqueTrial) %>%
  count(.statusRecruitment)
df %>%
  filter(.isUniqueTrial) %>%
  ggplot() +
  stat_ecdf(aes(
   x = .startDate,
   colour = .statusRecruitment))
## End(Not run)
```

dbQueryHistory

Show history of queries loaded into a database collection

# **Description**

Show history of queries loaded into a database collection

## Usage

```
dbQueryHistory(con, verbose = FALSE)
```

#### **Arguments**

con A database connection object, created with nodbi. See section '1 - Database

connection' in ctrdata.

verbose If TRUE, prints additional information (default FALSE).

#### Value

A data frame (or tibble, if tibble is loaded) with columns: 'query-timestamp', 'query-register', 'query-records' (note: this is the number of records loaded when last executing ctrLoadQueryIntoDb, not the total record number) and 'query-term', with one row for each time that ctrLoadQuery-IntoDb loaded trial records into this collection.

# **Examples**

```
dbc <- nodbi::src_sqlite(
  dbname = system.file("extdata", "demo.sqlite", package = "ctrdata"),
  collection = "my_trials",
  flags = RSQLite::SQLITE_RO)

dbQueryHistory(con = dbc)</pre>
```

dfMergeVariablesRelevel

Merge variables, keeping type, and optionally relevel factors

## **Description**

Merge variables in a data frame such as returned by dbGetFieldsIntoDf into a new variable, and optionally also map its values to new levels. See ctrdata-trial-concepts for pre-defined cross-register concepts that are already implemented based on merging fields from different registers and calculating a new field.

## Usage

```
dfMergeVariablesRelevel(df = NULL, colnames = "", levelslist = NULL)
```

## **Arguments**

df A data frame with the variables (columns) to be merged into one vector.

colnames A vector of names of columns in 'df' that hold the variables to be merged, or a

selection of columns as per select.

levelslist A names list with one slice each for a new value to be used for a vector of old

values (optional).

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# Value

A vector, with the type of the columns to be merged

# **Examples**

```
dbc <- nodbi::src_sqlite(</pre>
  dbname = system.file("extdata", "demo.sqlite", package = "ctrdata"),
  collection = "my_trials",
  flags = RSQLite::SQLITE_RO)
df <- dbGetFieldsIntoDf(</pre>
  fields = c(
    "protocolSection.eligibilityModule.healthyVolunteers",
    "f31\_healthy\_volunteers",
    "eligibility.healthy_volunteers"
  ),
  con = dbc
)
table(
  dfMergeVariablesRelevel(
    df = df,
    colnames = 'matches("healthy")'
))
```

dfName2Value

Get value for variable of interest

# Description

Get information for variable of interest (e.g., clinical endpoints) from long data frame of protocol- or result-related trial information as returned by dfTrials2Long. Parameters 'valuename', 'wherename' and 'wherevalue' are matched using Perl regular expressions and ignoring case.

## Usage

```
dfName2Value(df, valuename = "", wherename = "", wherevalue = "")
```

# Arguments

df	A data frame (or tibble) with four columns ('_id', 'identifier', 'name', 'value') as returned by dfTrials2Long
valuename	A character string for the name of the field that holds the value of the variable of interest (e.g., a summary measure such as "endPoints.*tendencyValue.value")
wherename	(optional) A character string to identify the variable of interest among those that repeatedly occur in a trial record (e.g., "endPoints.endPoint.title")
wherevalue	(optional) A character string with the value of the variable identified by 'wherename' (e.g., "response")

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#### Value

A data frame (or tibble, if tibble is loaded) that includes the values of interest, with columns '\_id', 'identifier', 'name', 'value' and 'where' (with the contents of 'wherevalue' found at 'wherename'). Contents of 'value' are strings unless all its elements are numbers. The 'identifier' is generated by function dfTrials2Long to identify matching elements, e.g endpoint descriptions and measurements.

```
dbc <- nodbi::src_sqlite(</pre>
 dbname = system.file("extdata", "demo.sqlite", package = "ctrdata"),
 collection = "my_trials",
 flags = RSQLite::SQLITE_RO)
dfwide <- dbGetFieldsIntoDf(</pre>
    fields = c(
        ## ctgov - typical results fields
        # "clinical_results.baseline.analyzed_list.analyzed.count_list.count",
        # "clinical_results.baseline.group_list.group",
        # "clinical_results.baseline.analyzed_list.analyzed.units",
        "clinical_results.outcome_list.outcome",
        "study_design_info.allocation",
        ## euctr - typical results fields
        # "trialInformation.fullTitle",
        # "baselineCharacteristics.baselineReportingGroups.baselineReportingGroup",
        # "trialChanges.hasGlobalInterruptions",
        # "subjectAnalysisSets",
        # "adverseEvents.seriousAdverseEvents.seriousAdverseEvent",
        "endPoints.endPoint",
        "subjectDisposition.recruitmentDetails"
   ), con = dbc
)
dflong <- dfTrials2Long(df = dfwide)</pre>
## get values for the endpoint 'response'
dfName2Value(
   df = dflong,
   valuename = paste0(
        "clinical_results.*measurement.value|",
        "clinical_results.*outcome.measure.units|",
        "endPoints.endPoint.*tendencyValue.value|",
        "endPoints.endPoint.unit"
   ),
   wherename = paste0(
        "clinical_results.*outcome.measure.title|",
        "endPoints.endPoint.title"
   ),
    wherevalue = "response"
)
```

dfTrials2Long 25

dfTrials2Long

Convert data frame with trial records into long format

# **Description**

The function works with procotol- and results- related information. It converts lists and other values that are in a data frame returned by dbGetFieldsIntoDf into individual rows of a long data frame. From the resulting long data frame, values of interest can be selected using dfName2Value. The function is particularly useful for fields with complex content, such as node field "clinical\_results" from EUCTR, for which dbGetFieldsIntoDf returns as a multiply nested list and for which this function then converts every observation of every (leaf) field into a row of its own.

## Usage

```
dfTrials2Long(df)
```

## **Arguments**

df

Data frame (or tibble) with columns including the trial identifier (\_id) and one or more variables as obtained from dbGetFieldsIntoDf

## Value

A data frame (or tibble, if tibble is loaded) with the four columns: '\_id', 'identifier', 'name', 'value'

```
dbc <- nodbi::src_sqlite(
  dbname = system.file("extdata", "demo.sqlite", package = "ctrdata"),
  collection = "my_trials",
  flags = RSQLite::SQLITE_RO)

dfwide <- dbGetFieldsIntoDf(
  fields = "clinical_results.participant_flow",
  con = dbc)

dfTrials2Long(df = dfwide)</pre>
```

26 f.controlType

f.controlType

Calculate type of control data collected in a study

## **Description**

Trial concept calculated: type of internal control. ICH E10 lists as types of control: placebo concurrent control, no-treatment concurrent control, dose-response concurrent control, active (positive) concurrent control, external (including historical) control, multiple control groups. Dose-controlled trials are currently not identified. External (including historical) controls are so far not identified in specific register fields. Cross-over designs, where identifiable, have active controls.

## Usage

```
f.controlType(df = NULL)
```

# **Arguments**

df

data frame such as from dbGetFieldsIntoDf. If 'NULL', prints fields needed in 'df' for calculating this trial concept, which can be used with dbGetFieldsIntoDf.

## Value

data frame with columns '\_id' and '.controlType', which is a factor with levels 'none', 'no-treatment', 'placebo', 'active', 'placebo+active' and 'other'.

```
# fields needed
f.controlType()

# apply trial concept when creating data frame
dbc <- nodbi::src_sqlite(
   dbname = system.file("extdata", "demo.sqlite", package = "ctrdata"),
   collection = "my_trials", flags = RSQLite::SQLITE_RO)
trialsDf <- dbGetFieldsIntoDf(
   field = "ctrname",
   calculate = "f.controlType",
   con = dbc)
trialsDf</pre>
```

f.isMedIntervTrial 27

f.isMedIntervTrial

Calculate if study is a medicine-interventional study

# **Description**

Trial concept calculated: Calculates if record is a medicine-interventional trial, investigating one or more medicine, whether biological or not. For EUCTR and CTIS, this corresponds to all records as per the definition of the EU Clinical Trial Regulation. For CTGOV and CTGOV2, this is based on drug or biological as type of intervention, and interventional as type of study. For ISRCTN, this is based on drug or biological as type of intervention, and interventional as type of study.

# Usage

```
f.isMedIntervTrial(df = NULL)
```

## **Arguments**

df

data frame such as from dbGetFieldsIntoDf. If 'NULL', prints fields needed in 'df' for calculating this trial concept, which can be used with dbGetFieldsIntoDf.

#### Value

data frame with colums '\_id' and '.isMedIntervTrial', a logical.

# **Examples**

```
# fields needed
f.isMedIntervTrial()

# apply trial concept when creating data frame
dbc <- nodbi::src_sqlite(
   dbname = system.file("extdata", "demo.sqlite", package = "ctrdata"),
   collection = "my_trials", flags = RSQLite::SQLITE_RO)
trialsDf <- dbGetFieldsIntoDf(
   calculate = "f.isMedIntervTrial",
   con = dbc)
trialsDf</pre>
```

f.isUniqueTrial

Calculate if record is unique for a study

# Description

Trial concept calculated: Applies function dbFindIdsUniqueTrials() with its defaults.

28 f.likelyPlatformTrial

#### Usage

```
f.isUniqueTrial(df = NULL)
```

#### **Arguments**

df

data frame such as from dbGetFieldsIntoDf. If 'NULL', prints fields needed in 'df' for calculating this trial concept, which can be used with dbGetFieldsIntoDf.

#### Value

data frame with columns '\_id' and '.isUniqueTrial', a logical.

## **Examples**

```
# fields needed
f.isUniqueTrial()

# apply trial concept when creating data frame
dbc <- nodbi::src_sqlite(
   dbname = system.file("extdata", "demo.sqlite", package = "ctrdata"),
   collection = "my_trials", flags = RSQLite::SQLITE_RO)
trialsDf <- dbGetFieldsIntoDf(
   calculate = "f.isUniqueTrial",
   con = dbc)
trialsDf</pre>
```

f.likelyPlatformTrial Calculate if study is likely a platform trial or not

## Description

Trial concept calculated: platform trial, research platform. As operational definition, at least one of these criteria is true: a. trial has "platform", "basket", "umbrella", "multi.?arm", "multi.?stage" or "master protocol" in its title or description (for ISRCTN, this is the only criterion; some trials in EUCTR lack data in English), b. trial has more than 2 active arms with different investigational medicines, after excluding comparator, auxiliary and placebo medicines (calculated with f.numTestArmsSubstances; not used for ISRCTN because it cannot be calculated precisely), c. trial more than 2 periods, after excluding safety run-in, screening, enrolling, extension and follow-up periods (for CTGOV and CTGOV2, this criterion requires results-related data). Requires that EUCTR results have been included in the collection, using ctrLoadQueryIntoDb(queryterm = ..., euctrresults = TRUE, con = ...). Requires packages dplyr and stringdist to be installed; stringdist is used for evaluating terms in brackets in the trial title, where trials may be related if the term similarity is 0.7 or higher.

## Usage

```
f.likelyPlatformTrial(df = NULL)
```

f.numSites 29

## **Arguments**

df

data frame such as from dbGetFieldsIntoDf. If 'NULL', prints fields needed in 'df' for calculating this trial concept, which can be used with dbGetFieldsIntoDf.

#### **Details**

Publication references considered: E-PEARL WP2 2020 https://tinyurl.com/eupearld21terminology (which did not include all basket trials in the definition, as done here) Williams RJ et al. 2022 https://doi.org/10.1136/bmj-2021-067745

#### Value

data frame with columns '\_id' and '.likelyPlatformTrial', a logical, '.likelyRelatedTrials', a list (e.g., from CTIS' 'associatedClinicalTrials') and '.maybeRelatedTrials', a list (based on similar short terms within a first set of brackets or before a colon in the title).

# **Examples**

```
# fields needed
f.likelyPlatformTrial()

# apply trial concept when creating data frame
dbc <- nodbi::src_sqlite(
   dbname = system.file("extdata", "demo.sqlite", package = "ctrdata"),
   collection = "my_trials", flags = RSQLite::SQLITE_RO)
trialsDf <- dbGetFieldsIntoDf(
   calculate = "f.likelyPlatformTrial",
   con = dbc)
trialsDf</pre>
```

f.numSites

Calculate number of sites of a study

# **Description**

Trial concept calculated: number of the sites where the trial is conducted. EUCTR lacks information on number of sites outside of the EEA; for each non-EEA country mentioned, at least one site is assumed.

## Usage

```
f.numSites(df = NULL)
```

#### **Arguments**

df

data frame such as from dbGetFieldsIntoDf. If 'NULL', prints fields needed in 'df' for calculating this trial concept, which can be used with dbGetFieldsIntoDf.

#### Value

data frame with columns '\_id' and '.numSites', an integer.

#### **Examples**

```
# fields needed
f.numSites()

# apply trial concept when creating data frame
dbc <- nodbi::src_sqlite(
   dbname = system.file("extdata", "demo.sqlite", package = "ctrdata"),
   collection = "my_trials", flags = RSQLite::SQLITE_RO)
trialsDf <- dbGetFieldsIntoDf(
   calculate = "f.numSites",
   con = dbc)
trialsDf</pre>
```

f.numTestArmsSubstances

Calculate type of control data collected in a study

# **Description**

Trial concept calculated: number of active arms with different investigational medicines, after excluding comparator, auxiliary and placebo arms / medicines. For ISRCTN, this is imprecise because arms are not identified in a field. Most registers provide no or only limited information on phase 1 trials, so that this number typically cannot be calculated for these trials. Requires packages stringdist to be installed; stringdist is used for evaluating names of active substances, which are considered similar when the similarity is 0.8 or higher.

## Usage

```
f.numTestArmsSubstances(df = NULL)
```

## **Arguments**

df

data frame such as from dbGetFieldsIntoDf. If 'NULL', prints fields needed in 'df' for calculating this trial concept, which can be used with dbGetFieldsIntoDf.

#### Value

data frame with columns '\_id' and '.numTestArmsSubstances', an integer

# **Examples**

```
# fields needed
f.controlType()

# apply trial concept when creating data frame
dbc <- nodbi::src_sqlite(
   dbname = system.file("extdata", "demo.sqlite", package = "ctrdata"),
   collection = "my_trials", flags = RSQLite::SQLITE_RO)
trialsDf <- dbGetFieldsIntoDf(
   calculate = "f.numTestArmsSubstances",
   con = dbc)
trialsDf</pre>
```

f.primaryEndpointDescription

Calculate details of a primary endpoint of a study

#### **Description**

Trial concept calculated: full description of the primary endpoint, concatenating with " == " its title, description, time frame of assessment. The details vary by register. The text description can be used for identifying trials of interest or for analysing trends in primary endpoints, which among the set of all endpoints are most often used for determining the number of participants sought for the study.

#### Usage

```
f.primaryEndpointDescription(df = NULL)
```

#### **Arguments**

df

data frame such as from dbGetFieldsIntoDf. If 'NULL', prints fields needed in 'df' for calculating this trial concept, which can be used with dbGetFieldsIntoDf.

# Value

data frame with columns '\_id' and '.primaryEndpointDescription', which is a list (that is, one or more items in one vector per row; the background is that some trials have several endpoints as primary).

```
# fields needed
f.primaryEndpointDescription()

# apply trial concept when creating data frame
dbc <- nodbi::src_sqlite(
   dbname = system.file("extdata", "demo.sqlite", package = "ctrdata"),</pre>
```

```
collection = "my_trials", flags = RSQLite::SQLITE_RO
)
trialsDf <- dbGetFieldsIntoDf(
  calculate = "f.primaryEndpointDescription",
  con = dbc
)
trialsDf</pre>
```

f.primaryEndpointResults

Calculate type of control data collected in a study

## **Description**

Trial concept calculated: Calculates several results-related elements of the primary analysis of the primary endpoint. Requires loading results-related information. For CTIS and ISRCTN, such information is not available in structured format. Recommended to be combined with .controlType, .sampleSize etc. for analyses.

## Usage

```
f.primaryEndpointResults(df = NULL)
```

# **Arguments**

df

data frame such as from dbGetFieldsIntoDf. If 'NULL', prints fields needed in 'df' for calculating this trial concept, which can be used with dbGetFieldsIntoDf.

#### Value

data frame with columns '\_id' and new columns: '.primaryEndpointFirstPvalue' (discarding any inequality indicator, e.g. <=), '.primaryEndpointFirstPmethod' (normalised string, e.g. chisquared), '.primaryEndpointFirstPsize' (number included in test, across assignment groups).

```
# fields needed
f.primaryEndpointResults()

# apply trial concept when creating data frame
dbc <- nodbi::src_sqlite(
   dbname = system.file("extdata", "demo.sqlite", package = "ctrdata"),
   collection = "my_trials", flags = RSQLite::SQLITE_RO)
trialsDf <- dbGetFieldsIntoDf(
   calculate = "f.primaryEndpointResults",
   con = dbc)
trialsDf</pre>
```

f.resultsDate 33

f.resultsDate

Calculate date of results of a study

## **Description**

Trial concept calculated: earliest date of results as recorded in the register. At that date, results may have been incomplete and may have been changed later. For EUCTR, requires that results and preferrably also their history of publication have been included in the collection, using ctr-LoadQueryIntoDb(queryterm = ..., euctrresultshistory = TRUE, con = ...). Cannot be calculated for ISRCTN, which does not have a corresponding field.

#### Usage

```
f.resultsDate(df = NULL)
```

## **Arguments**

df

data frame such as from dbGetFieldsIntoDf. If 'NULL', prints fields needed in 'df' for calculating this trial concept, which can be used with dbGetFieldsIntoDf.

## Value

data frame with columns '\_id' and '.resultsDate', a date.

# **Examples**

```
# fields needed
f.resultsDate()

# apply trial concept when creating data frame
dbc <- nodbi::src_sqlite(
   dbname = system.file("extdata", "demo.sqlite", package = "ctrdata"),
   collection = "my_trials", flags = RSQLite::SQLITE_RO)
trialsDf <- dbGetFieldsIntoDf(
   calculate = "f.resultsDate",
   con = dbc)
trialsDf</pre>
```

f.sampleSize

Calculate sample size of a study

#### **Description**

Trial concept calculated: sample size of the trial, preferring results-related over protocol-related information.

f.sponsorType

## Usage

```
f.sampleSize(df = NULL)
```

## **Arguments**

df

data frame such as from dbGetFieldsIntoDf. If 'NULL', prints fields needed in 'df' for calculating this trial concept, which can be used with dbGetFieldsIntoDf.

#### Value

data frame with columns '\_id' and '.sampleSize', an integer.

## **Examples**

```
# fields needed
f.sampleSize()

# apply trial concept when creating data frame
dbc <- nodbi::src_sqlite(
   dbname = system.file("extdata", "demo.sqlite", package = "ctrdata"),
   collection = "my_trials", flags = RSQLite::SQLITE_RO)
trialsDf <- dbGetFieldsIntoDf(
   calculate = "f.sampleSize",
   con = dbc)
trialsDf</pre>
```

f.sponsorType

Calculate type of control data collected in a study

# **Description**

Trial concept calculated: type or class of the lead or main sponsor of the trial. Some information is not yet mapped (e.g., "NETWORK" in CTGOV2). No specific field is available in ISRCTN.

# Usage

```
f.sponsorType(df = NULL)
```

## **Arguments**

df

data frame such as from dbGetFieldsIntoDf. If 'NULL', prints fields needed in 'df' for calculating this trial concept, which can be used with dbGetFieldsIntoDf.

## Value

data frame with columns '\_id' and '.sponsorType', which is a factor with levels 'For profit', 'Not for profit' or 'Other'.

f.startDate 35

## **Examples**

```
# fields needed
f.sponsorType()

# apply trial concept when creating data frame
dbc <- nodbi::src_sqlite(
   dbname = system.file("extdata", "demo.sqlite", package = "ctrdata"),
   collection = "my_trials", flags = RSQLite::SQLITE_RO)
trialsDf <- dbGetFieldsIntoDf(
   calculate = "f.sponsorType",
   con = dbc)
trialsDf</pre>
```

f.startDate

Calculate start date of a study

# Description

Trial concept calculated: start of the trial, based on the documented or planned start of recruitment, or on the date of opinion of the competent authority.

## Usage

```
f.startDate(df = NULL)
```

## **Arguments**

df

data frame such as from dbGetFieldsIntoDf. If 'NULL', prints fields needed in 'df' for calculating this trial concept, which can be used with dbGetFieldsIntoDf.

#### Value

data frame with columns '\_id' and '.startDate', a date.

```
# fields needed
f.startDate()

# apply trial concept when creating data frame
dbc <- nodbi::src_sqlite(
   dbname = system.file("extdata", "demo.sqlite", package = "ctrdata"),
   collection = "my_trials", flags = RSQLite::SQLITE_RO)

trialsDf <- dbGetFieldsIntoDf(
   field = "ctrname",
   calculate = "f.startDate",
   con = dbc)

trialsDf</pre>
```

36 f.statusRecruitment

f.statusRecruitment Calculate status of recruitment of a study

## **Description**

Trial concept calculated: status of recruitment at the time of loading the trial records. Maps the categories that are in fields which specify the state of recruitment. Simplifies the status into three categories.

# Usage

```
f.statusRecruitment(df = NULL)
```

## **Arguments**

df

data frame such as from dbGetFieldsIntoDf. If 'NULL', prints fields needed in 'df' for calculating this trial concept, which can be used with dbGetFieldsIntoDf.

#### Value

data frame with columns '\_id' and '.statusRecruitment', which is a factor with levels 'ongoing' (includes active, not yet recruiting; temporarily halted; suspended; authorised, not started and similar), 'completed' (includes ended; ongoing, recruitment ended), 'ended early' (includes prematurely ended, terminated early) and 'other' (includes revoked, withdrawn, planned, stopped).

```
# fields needed
f.statusRecruitment()

# apply trial concept when creating data frame
dbc <- nodbi::src_sqlite(
   dbname = system.file("extdata", "demo.sqlite", package = "ctrdata"),
   collection = "my_trials", flags = RSQLite::SQLITE_RO)
trialsDf <- dbGetFieldsIntoDf(
   calculate = "f.statusRecruitment",
   con = dbc)
trialsDf</pre>
```

f.trialObjectives 37

f.trialObjectives

Calculate objectives of a study

## **Description**

Trial concept calculated: objectives of the trial, by searching for text fragments found in fields describing its purpose, objective, background or hypothesis, after applying .isMedIntervTrial, because the text fragments are tailored to medicinal product interventional trials. This is a simplification, and it is expected that the criteria will be further refined. The text fragments only apply to English.

# Usage

```
f.trialObjectives(df = NULL)
```

## **Arguments**

df

data frame such as from dbGetFieldsIntoDf. If 'NULL', prints fields needed in 'df' for calculating this trial concept, which can be used with dbGetFieldsIntoDf.

## Value

data frame with columns '\_id' and '.trialObjectives', which is a string with letters separated by a space, such as E (efficacy, including cure, survival, effectiveness); A (activity, including reponse, remission, seroconversion); S (safety); PK; PD (including biomarker); D (dose-finding, determining recommended dose); LT (long-term); and FU (follow-up).

```
# fields needed
f.trialObjectives()

# apply trial concept when creating data frame
dbc <- nodbi::src_sqlite(
   dbname = system.file("extdata", "demo.sqlite", package = "ctrdata"),
   collection = "my_trials", flags = RSQLite::SQLITE_RO)
trialsDf <- dbGetFieldsIntoDf(
   calculate = "f.trialObjectives",
   con = dbc)
trialsDf</pre>
```

38 f.trialPopulation

f.trialPhase

Calculate phase of a clinical trial

## **Description**

Trial concept calculated: phase of a clinical trial as per ICH E8(R1).

# Usage

```
f.trialPhase(df = NULL)
```

## **Arguments**

df

data frame such as from dbGetFieldsIntoDf. If 'NULL', prints fields needed in 'df' for calculating this trial concept, which can be used with dbGetFieldsIntoDf.

#### Value

```
data frame with columns '_id' and '.trialPhase', which is an ordered factor with levels 'phase 1', 'phase 1+2', 'phase 2', 'phase 2+4', 'phase 3', 'phase 3+4', 'phase 1+2+3', 'phase 4', 'phase 1+2+3+4'.
```

## **Examples**

```
# fields needed
f.trialPhase()

# apply trial concept when creating data frame
dbc <- nodbi::src_sqlite(
   dbname = system.file("extdata", "demo.sqlite", package = "ctrdata"),
   collection = "my_trials", flags = RSQLite::SQLITE_RO)
trialsDf <- dbGetFieldsIntoDf(
   calculate = "f.trialPhase",
   con = dbc)
trialsDf</pre>
```

 $f.\,trial Population$ 

Calculate in- and exclusion criteria and age groups

## **Description**

Trial concept calculated: inclusion and exclusion criteria as well as age groups that can participate in a trial, based on protocol-related information. Since CTGOV uses single text field for eligibility criteria, text extraction is used to separate in- and exclusion criteria. (See dfMergeVariablesRelevel with an example for healthy volunteers.)

f.trialTitle 39

## Usage

```
f.trialPopulation(df = NULL)
```

#### **Arguments**

df

data frame such as from dbGetFieldsIntoDf. If 'NULL', prints fields needed in 'df' for calculating this trial concept, which can be used with dbGetFieldsIntoDf.

#### Value

```
data frame with columns '_id' and new columns: '.trialPopulationAgeGroup' (factor, "P", "A", "P+A", "E", "A+E", "P+A+E"), '.trialPopulationInclusion' (string), '.trialPopulationExclusion' (string).
```

# **Examples**

```
# fields needed
f.trialPopulation()

# apply trial concept when creating data frame
dbc <- nodbi::src_sqlite(
   dbname = system.file("extdata", "demo.sqlite", package = "ctrdata"),
   collection = "my_trials", flags = RSQLite::SQLITE_RO)
trialsDf <- dbGetFieldsIntoDf(
   calculate = "f.trialPopulation",
   con = dbc)
trialsDf</pre>
```

f.trialTitle

Calculate the title of a study

## **Description**

Trial concept calculated: scientific or full title of the study.

## Usage

```
f.trialTitle(df = NULL)
```

# **Arguments**

df

data frame such as from dbGetFieldsIntoDf. If 'NULL', prints fields needed in 'df' for calculating this trial concept, which can be used with dbGetFieldsIntoDf.

#### Value

```
data frame with columns '_id' and '.trialTitle', a string.
```

40 f.trialTitle

```
# fields needed
f.resultsDate()

# apply trial concept when creating data frame
dbc <- nodbi::src_sqlite(
   dbname = system.file("extdata", "demo.sqlite", package = "ctrdata"),
   collection = "my_trials", flags = RSQLite::SQLITE_RO)
trialsDf <- dbGetFieldsIntoDf(
   calculate = "f.trialTitle",
   con = dbc)
trialsDf</pre>
```

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