Package 'MethodEvaluation'

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Type Package

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Description This package contains resources for the evaluation of the performance of methods that aim to estimate the magnitude (relative risk) of the effect of a drug on an outcome. These resources include reference sets for evaluating methods on real data, as well as functions for inserting simulated effects in real data based on negative control drug-outcome pairs. Further included are functions for the computation of the minimum detectable relative risks and functions for computing performance statistics such as predictive accuracy, error and bias.
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R topics documented: computeAucs computeCoverage

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computeAucs

Compute the AUCs for various injected signal sizes

Description

Compute the AUCs for various injected signal sizes

Usage

```
computeAucs(logRr, trueLogRr)
```

Arguments

logRr A vector containing the log of the relative risk as estimated by a method.

trueLogRr A vector containing the injected log(relative risk) for each estimate.

Value

A data frame with per injected signal size the AUC and the 95 percent confidence interval of the AUC.

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computeCoverage	Compute the coverage

Description

Compute the coverage

Usage

```
computeCoverage(logRr, seLogRr, trueLogRr, region = 0.95)
```

Arguments

logRr A numeric vector of effect estimates on the log scale.

seLogRr The standard error of the log of the effect estimates. Hint: often the standard

error = (log(<lower bound 95 percent confidence interval>) - log(<effect esti-

mate >))/qnorm(0.025).

trueLogRr A vector of the true effect sizes.

region Size of the confidence interval. Default is .95 (95 percent).

Details

Compute the fractions of estimates where the true effect size is below, above or within the confidence interval, for one or more true effect sizes.

computeMdrr	Compute minimal detectable relative risk (MDRR)	

Description

computeMdrr computes the minimal detectable relative risk (MDRR) for drug-outcome pairs.

Usage

```
computeMdrr(connectionDetails, cdmDatabaseSchema,
  oracleTempSchema = cdmDatabaseSchema, exposureOutcomePairs,
  exposureDatabaseSchema = cdmDatabaseSchema,
  exposureTable = "drug_era",
  outcomeDatabaseSchema = cdmDatabaseSchema,
  outcomeTable = "condition_era", cdmVersion = "5")
```

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Arguments

connectionDetails

An R object of type ConnectionDetails created using the function createConnectionDetails in the DatabaseConnector package.

cdmDatabaseSchema

Name of database schema that contains OMOP CDM and vocabulary.

oracleTempSchema

For Oracle only: the name of the database schema where you want all temporary tables to be managed. Requires create/insert permissions to this database.

exposureOutcomePairs

A data frame with at least two columns:

- "exposureId" or "targetId" containing the drug_concept_ID or cohort_definition_id of the exposure variable
- "outcomeId" containing the condition_concept_ID or cohort_definition_id of the outcome variable

exposureDatabaseSchema

The name of the database schema that is the location where the exposure data used to define the exposure cohorts is available. If exposureTable = DRUG_ERA, exposureDatabaseSchema is not used by assumed to be cdmSchema. Requires read permissions to this database.

exposureTable

The tablename that contains the exposure cohorts. If exposureTable <> DRUG_ERA, then expectation is exposureTable has format of COHORT table: COHORT_DEFINITION_ID, SUBJECT_ID, COHORT_START_DATE, COHORT_END_DATE.

outcomeDatabaseSchema

The name of the database schema that is the location where the data used to define the outcome cohorts is available. If exposureTable = CONDITION_ERA, exposureDatabaseSchema is not used by assumed to be cdmSchema. Requires read permissions to this database.

outcomeTable

The tablename that contains the outcome cohorts. If outcomeTable <> CONDITION_OCCURRENCE, then expectation is outcomeTable has format of COHORT table: COHORT_DEFINITION_ID, SUBJECT_ID, COHORT_START_DATE, COHORT_END_DATE.

cdmVersion

Define the OMOP CDM version used: currently support "4" and "5".

Details

Computes the MDRR using simple power-calculations using person-level statistics stratified by age and gender.

Value

A data frame containing the MDRRs for the given exposure-outcome pairs.

Examples

computeMetrics 5

```
"cdm_truven_mdcr",
exposureOutcomePairs,
outcomeTable = "condition_era")
```

End(Not run)

computeMetrics

Compute the AUC, coverage, MSE, and type 1 and 2 error

Description

Compute the AUC, coverage, MSE, and type 1 and 2 error

Usage

```
computeMetrics(logRr, seLogRr, trueLogRr)
```

Arguments

logRr A numeric vector of effect estimates on the log scale

seLogRr The standard error of the log of the effect estimates. Hint: often the standard

error = (log(<lower bound 95 percent confidence interval>) - log(<effect esti-

mate>))/qnorm(0.025)

trueLogRr A vector of the true effect sizes

Details

Compute the AUC, coverage, MSE, and type 1 and 2 error.

computeMse (Compute the	mean so	auared	error
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Description

Compute the mean squared error

Usage

```
computeMse(logRr, trueLogRr)
```

Arguments

logRr A numeric vector of effect estimates on the log scale.

trueLogRr A vector of the true effect sizes.

createReferenceSetCohorts

computeType1And2Error Compute type 1 and 2 error

Description

Compute type 1 and 2 error

Usage

```
computeType1And2Error(logRr, seLogRr, trueLogRr, alpha = 0.05)
```

Arguments

logRr A numeric vector of effect estimates on the log scale.

seLogRr The standard error of the log of the effect estimates. Hint: often the standard

error = (log(<lower bound 95 percent confidence interval>) - log(<effect esti-

mate>))/qnorm(0.025).

trueLogRr A vector of the true effect sizes.

createReferenceSetCohorts

Create cohorts used in a reference set.

Description

Create cohorts used in a reference set.

Usage

```
createReferenceSetCohorts(connectionDetails, oracleTempSchema = NULL,
    cdmDatabaseSchema, outcomeDatabaseSchema = cdmDatabaseSchema,
    outcomeTable = "outcomes", nestingDatabaseSchema = cdmDatabaseSchema,
    nestingTable = "nesting", referenceSet = "ohdsiMethodsBenchmark")
```

Arguments

connectionDetails

An R object of type ConnectionDetails created using the function createConnectionDetails in the DatabaseConnector package.

oracleTempSchema

Should be used in Oracle to specify a schema where the user has write priviliges for storing temporary tables.

cdmDatabaseSchema

A database schema containing health care data in the OMOP Commond Data Model. Note that for SQL Server, botth the database and schema should be specified, e.g. 'cdm_schema.dbo'

euadrReferenceSet 7

outcomeDatabaseSchema

The database schema where the target outcome table is located. Note that for SQL Server, both the database and schema should be specified, e.g. 'cdm_schema.dbo'

The name of the table where the outcomes will be stored.

nestingDatabaseSchema

outcomeTable

(For the OHDSI Methods Benchmark only) The database schema where the nesting outcome table is located. Note that for SQL Server, both the database

and schema should be specified, e.g. 'cdm_schema.dbo'.

nestingTable (For the OHDSI Methods Benchmark only) The name of the table where the

nesting cohorts will be stored.

referenceSet The name of the reference set for which outcomes need to be created. Currently

supported are "omopReferenceSet", "euadrReferenceSet", and "ohdsiMethods-

Benchmark".

Details

This function will create the outcomes of interest and nesting cohorts referenced in the various reference sets. The outcomes of interest are derives using information like diagnoses, procedures, and drug prescriptions. The outcomes are stored in a table on the database server.

euadrReferenceSet

The EU-ADR reference set

Description

A reference set of 43 drug-outcome pairs where we believe the drug causes the outcome (positive controls) and 50 drug-outcome pairs where we believe the drug does not cause the outcome (negative controls). The controls involve 10 health outcomes of interest. Note that originally, there was an additional positive control (Nimesulide and acute liver injury), but Nimesulide is not in RxNorm, and is not available in many countries.

Usage

data(euadrReferenceSet)

Format

A data frame with 399 rows and 10 variables:

exposureId Concept ID identifying the exposure

exposureName Name of the exposure

outcomeId Concept ID identifying the outcome

outcomeName Name of the outcome

groundTruth 0 = negative control, 1 = positive control

indicationId Concept Id identifying the (primary) indication of the drug. To be used when one wants to nest the analysis within the indication

indicationName Name of the indication

comparatorId Concept ID identifying a comparator drug that can be used as a counterfactual

comparatorName Name of the comparator drug
comparatorType How the comparator was selected

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References

Coloma PM, Avillach P, Salvo F, Schuemie MJ, Ferrajolo C, Pariente A, Fourrier-Reglat A, Molokhia M, Patadia V, van der Lei J, Sturkenboom M, Trifiro G. A reference standard for evaluation of methods for drug safety signal detection using electronic healthcare record databases. Drug Safety 36(1):13-23, 2013

filterOnMdrr

Filter data based on MDRR

Description

Filters a dataset to those exposure-outcome pairs with sufficient power.

Usage

```
filterOnMdrr(data, mdrr, threshold = 1.25)
```

Arguments

data

A data frame with at least two columns:

- "exposureConceptId" containing the drug_concept_ID or cohort_definition_id of the exposure variable
- "outcomeConceptId" containing the condition_concept_ID or cohort_definition_id of the outcome variable

mdrr

A data frame as generated by the computeMdrr function.

threshold

The required minimum detectable relative risk.

Value

A subset of the data object.

 ${\tt injectSignals}$

Inject signals in database

Description

Inject signals in database

Usage

```
injectSignals(connectionDetails, cdmDatabaseSchema,
  oracleTempSchema = cdmDatabaseSchema,
  exposureDatabaseSchema = cdmDatabaseSchema,
  exposureTable = "drug_era",
  outcomeDatabaseSchema = cdmDatabaseSchema, outcomeTable = "cohort",
  outputDatabaseSchema = outcomeDatabaseSchema,
  outputTable = outcomeTable, createOutputTable = FALSE,
  exposureOutcomePairs, modelType = "poisson",
```

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```
minOutcomeCountForModel = 100, minOutcomeCountForInjection = 25,
covariateSettings = FeatureExtraction::createCovariateSettings(useDemographicsAgeGroup
= TRUE, useDemographicsGender = TRUE, useDemographicsIndexYear = TRUE,
useDemographicsIndexMonth = TRUE, useConditionGroupEraLongTerm = TRUE,
useDrugGroupEraLongTerm = TRUE, useProcedureOccurrenceLongTerm = TRUE,
useMeasurementLongTerm = TRUE, useObservationLongTerm = TRUE,
useCharlsonIndex = TRUE, useDcsi = TRUE, useChads2Vasc = TRUE,
longTermStartDays = 365, endDays = 0), prior = createPrior("laplace",
exclude = 0, useCrossValidation = TRUE), control = createControl(cvType
= "auto", startingVariance = 0.1, noiseLevel = "quiet", threads = 10),
firstExposureOnly = FALSE, washoutPeriod = 183,
riskWindowStart = 0, riskWindowEnd = 0,
addExposureDaysToEnd = TRUE, addIntentToTreat = FALSE,
firstOutcomeOnly = FALSE, removePeopleWithPriorOutcomes = FALSE,
maxSubjectsForModel = 1e+05, effectSizes = c(1, 1.25, 1.5, 2, 4),
precision = 0.01, outputIdOffset = 1000,
workFolder = "./SignalInjectionTemp", cdmVersion = "5",
modelThreads = 1, generationThreads = 1)
```

Arguments

connectionDetails

An R object of type ConnectionDetails created using the function createConnectionDetails in the DatabaseConnector package.

cdmDatabaseSchema

Name of database schema that contains OMOP CDM and vocabulary.

oracleTempSchema

For Oracle only: the name of the database schema where you want all temporary tables to be managed. Requires create/insert permissions to this database.

exposureDatabaseSchema

The name of the database schema that is the location where the exposure data used to define the exposure cohorts is available. If exposureTable = DRUG_ERA, exposureDatabaseSchema is not used by assumed to be cdmSchema. Requires read permissions to this database.

exposureTable

The table name that contains the exposure cohorts. If exposure Table <> DRUG_ERA, then expectation is exposure Table has format of COHORT table: cohort_concept_id, SUBJECT_ID, COHORT_START_DATE, COHORT_END_DATE.

outcomeDatabaseSchema

The name of the database schema that is the location where the data used to define the outcome cohorts is available. If exposureTable = CONDITION_ERA, exposureDatabaseSchema is not used by assumed to be cdmSchema. Requires read permissions to this database.

outcomeTable

The table name that contains the outcome cohorts. When the table name is not CONDITION_ERA This table is expected to have the same format as the CO-HORT table: SUBJECT_ID, COHORT_START_DATE, COHORT_END_DATE, COHORT_CONCEPT_ID (CDM v4) or COHORT_DEFINITION_ID (CDM v5 and higher).

outputDatabaseSchema

The name of the database schema that is the location of the tables containing the new outcomesRequires write permissions to this database.

outputTable The name of the table names that will contain the generated outcome cohorts.

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createOutputTable

Should the output table be created prior to inserting the outcomes? If TRUE and the tables already exists, it will first be deleted. If FALSE, the table is assumed to exist and the outcomes will be inserted. Any existing outcomes with the same IDs will first be deleted.

exposureOutcomePairs

A data frame with at least two columns:

- "exposureId" containing the drug concept ID or cohort concept id of the exposure variable
- "outcomeId" containing the condition_concept_ID or cohort_concept_id of the outcome variable

modelType Can be either "poisson" or "survival"

minOutcomeCountForModel

Minimum number of outcome events required to build a model.

minOutcomeCountForInjection

Minimum number of outcome events required to inject a signal.

covariateSettings

An object of type covariateSettings as created using the createCovariateSettings function in the FeatureExtraction package.

prior The prior used to fit the outcome model. See createPrior for details.

> The control object used to control the cross-validation used to determine the hyperparameters of the prior (if applicable). See createControl for details.

firstExposureOnly

control

Should signals be injected only for the first exposure? (ie. assuming an acute effect)

washoutPeriod Number of days at the start of observation for which no signals will be injected,

but will be used to determine whether exposure or outcome is the first one, and

for extracting covariates to build the outcome model.

riskWindowStart

The start of the risk window relative to the start of the exposure (in days). When 0, risk is assumed to start on the first day of exposure.

riskWindowEnd

The end of the risk window relative to the start of the exposure. Note that typically the length of exposure is added to this number (when the addExposureDaysToEnd parameter is set to TRUE).

addExposureDaysToEnd

Should length of exposure be added to the risk window?

addIntentToTreat

If true, the signal will not only be injected in the primary time at risk, but also after the time at risk (up until the obseration period end). In both time periods, the target effect size will be enforced. This allows the same positive control synthesis to be used in both on treatment and intent-to-treat analysis variants. However, this will preclude the controls to be used in self-controlled designs that consider the time after exposure. Requires firstExposureOnly = TRUE.

firstOutcomeOnly

Should only the first outcome per person be considered when modeling the outcome?

removePeopleWithPriorOutcomes

Remove people with prior outcomes?

maxSubjectsForModel

Maximum number of people used to fit an outcome model.

effectSizes A numeric vector of effect sizes that should be inserted.

precision The allowed ratio between target and injected signal size.

outputIdOffset What should be the first new outcome ID that is to be created?

workFolder Path to a folder where intermediate data will be stored.

cdmVersion Define the OMOP CDM version used: currently support "4" and "5".

modelThreads Number of parallel threads to use when fitting outcome models.

generationThreads

Number of parallel threads to use when generating outcomes.

Details

This function will insert additional outcomes for a given set of drug-outcome pairs. It is assumed that these drug-outcome pairs represent negative controls, so the true relative risk before inserting any outcomes should be 1. There are two models for inserting the outcomes during the specified risk window of the drug: a Poisson model assuming multiple outcomes could occurr during a single exposure, and a survival model considering only one outcome per exposure.

It is possible to use bulk import to insert the generated outcomes in the database. This requires the environmental variable 'USE_MPP_BULK_LOAD' to be set to 'TRUE'. See 'PostabaseConnector::insertTable for details on how to configure the bulk upload.

Value

A data frame listing all the drug-pairs in combination with requested effect sizes and the real inserted effect size (might be different from the requested effect size because of sampling error).

References

Schuemie MJ, Hripcsak G, Ryan PB, Madigan D, Suchard MA. Empirical confidence interval calibration for population-level effect estimation studies in observational healthcare data. Proc Natl Acad Sci U S A. 2018 Mar 13;115(11):2571-2577.

launchMethodEvaluationApp

Launch the Method Evaluation Shiny app

Description

Launch the Method Evaluation Shiny app

Usage

launchMethodEvaluationApp(exportFolder, launch.browser = TRUE)

Arguments

exportFolder A folder where the data files for the Method Evaluation app are stored. Use the

prepareForEvidenceExplorer to populate this folder.

launch.browser Should the app be launched in your default browser, or in a Shiny window. Note:

copying to clipboard will not work in a Shiny window.

blind Should the user be blinded to the main results?

Details

Launches a Shiny app that allows the user to explore the results.

MethodEvaluation MethodEvaluation

Description

MethodEvaluation

ohdsiNegativeControls The OHDSI Method Evaluation Benchmark - Negative Controls

Description

A set of 200 negative controls, centered around four outcomes of interest (acute pancreatitis, GI bleeding, Stroke, and IBD), and 4 exposures of interest (diclofenac, ciprofloxacin, metformin, and sertraline), which 25 negative controls each. Each drug-outcome pair also includes a comparator drug (where the comparator is also a negative control), allowing for evaluation of comparative effect estimation, and a nesting cohort for evaluating methods such as the nested case-control design.

Usage

data(ohdsiNegativeControls)

Format

A data frame with 200 rows and 9 variables:

targetId Cohort ID identifying the target exposure

targetName Name of the target cohort

comparatorId Cohort ID identifying the comparator exposure

comparatorName Name of the comparator cohort **nestingId** Cohort ID identifying the nesting cohort

nestingName Name of the nesting cohortoutcomeId Cohort ID identifying the outcome

outcomeName Name of the outcome

type THe type of control: exposure or outcome

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Details

The exposure, outcome, and nesting cohorts can be created using the createReferenceSetCohorts function.

These negative controls can form the basis to generate positive controls using the injectSignals function.

omopReferenceSet

The OMOP reference set A reference set of 165 drug-outcome pairs where we believe the drug causes the outcome (positive controls) and 234 drug-outcome pairs where we believe the drug does not cause the outcome (negative controls). The controls involve 4 health outcomes of interest: acute liver injury, acute kidney injury, acute myocardial infarction, and GI bleeding.

Description

The OMOP reference set A reference set of 165 drug-outcome pairs where we believe the drug causes the outcome (positive controls) and 234 drug-outcome pairs where we believe the drug does not cause the outcome (negative controls). The controls involve 4 health outcomes of interest: acute liver injury, acute kidney injury, acute myocardial infarction, and GI bleeding.

Usage

data(omopReferenceSet)

Format

A data frame with 399 rows and 10 variables:

exposureId Concept ID identifying the exposure

exposureName Name of the exposure

outcomeId Concept ID identifying the outcome

outcomeName Name of the outcome

groundTruth 0 = negative control, 1 = positive control

indicationId Concept Id identifying the (primary) indication of the drug. To be used when one wants to nest the analysis within the indication

indicationName Name of the indication

comparatorId Concept ID identifying a comparator drug that can be used as a counterfactual

comparatorName Name of the comparator drug

comparatorType How the comparator was selected

References

Ryan PB, Schuemie MJ, Welebob E, Duke J, Valentine S, Hartzema AG. Defining a reference set to support methodological research in drug safety. Drug Safety 36 Suppl 1:S33-47, 2013

packageOhdsiBenchmarkResults

Package results of a method on the OHDSI Methods Benchmark

Description

Stores the results of a method on the OHDSI Methods Benchmark in a standardized format, for example for use in the Method Evaluation Shiny app.

Usage

packageOhdsiBenchmarkResults(estimates, controlSummary, analysisRef, databaseName, exportFolder)

Arguments

estimates A data frame containing the estimates. See details for required columns.

controlSummary A data frame with the summary of the controls as generated by the synthesizePositiveControls

function.

analysisRef A file describing the various analyses that were performed. See details for re-

quired columns.

databaseName A character string to identify the database the method was executed on.

exportFolder The folder where the output CSV files will written.

Details

The estimates argument should have the following columns: "targetId", "outcomeId", "analysisId", "logRr", "seLogRr", "ci95Lb", "ci95Ub".

The analysisRef argument should have the following columns: "analysisId", "method", "comparative", "nesting", "firstExposureOnly"

The targetId and outcomeId fields identify the specific control, and should correspond to those in the controlSummary object.

The analysisId field is an integer that identifies a specific variant of the method. For example, if the method is 'CohortMethod', analysisId = 1 could identify a set of settings using propensity score matching, and analysisId = 2 could identify a set of settings using stratification.

logRr, seLogRr, ci95Lb, and ci95Ub correspond to the log of the effect estimate (e.g. the hazard ratio), the standard error, and the upper and lower bound of the effect size estimate, as produced by the method.

method is a character string identifyign the method (e.g. "CohortMethod").

comparative is a boolean indicating whether the analysis can also be considerd to perform comparative effect estimation (comparing the target to the comparator).

nesting is a boolean indicating whether the analysis is nested in the nesting cohorts identified in the gold standard.

firstExposureOnly is a boolean indicating whether only the first exposure was used in the analysis.

plotCoverageInjectedSignals

Plot the coverage

Description

Plot the coverage

Usage

```
plotCoverageInjectedSignals(logRr, seLogRr, trueLogRr, region = 0.95,
    fileName = NULL)
```

Arguments

logRr A numeric vector of effect estimates on the log scale

seLogRr The standard error of the log of the effect estimates. Hint: often the standard

error = (log(<lower bound 95 percent confidence interval>) - log(<effect esti-

mate>))/qnorm(0.025)

trueLogRr A vector of the true effect sizes

region Size of the confidence interval. Default is .95 (95 percent).

fileName Name of the file where the plot should be saved, for example 'plot.png'. See the

function ggsave in the ggplot2 package for supported file formats.

Details

Plot the fractions of estimates where the true effect size is below, above or within the confidence interval, for one or more true effect sizes.

```
plotRocsInjectedSignals
```

Plot the ROC curves for various injected signal sizes

Description

Plot the ROC curves for various injected signal sizes

Usage

```
plotRocsInjectedSignals(logRr, trueLogRr, showAucs, fileName = NULL)
```

Arguments

logRr A vector containing the log of the relative risk as estimated by a method.
trueLogRr A vector containing the injected log(relative risk) for each estimate.

showAucs Should the AUCs be shown in the plot?

fileName Name of the file where the plot should be saved, for example 'plot.png'. See the

function ggsave in the ggplot2 package for supported file formats.

Value

A Ggplot object. Use the ggsave function to save to file.

synthesizePositiveControls

Synthesize positive controls based on negative controls

Description

Synthesize positive controls based on negative controls

Usage

```
synthesizePositiveControls(connectionDetails, cdmDatabaseSchema,
  oracleTempSchema = NULL, outcomeDatabaseSchema = cdmDatabaseSchema,
  outcomeTable = "cohort", referenceSet = "ohdsiMethodsBenchmark",
  maxCores = 1, workFolder, summaryFileName = file.path(workFolder,
  "allControls.csv"))
```

Arguments

connectionDetails

An R object of type ConnectionDetails created using the function createConnectionDetails in the DatabaseConnector package.

cdmDatabaseSchema

A database schema containing health care data in the OMOP Commond Data Model. Note that for SQL Server, botth the database and schema should be specified, e.g. 'cdm_schema.dbo'

oracleTempSchema

Should be used in Oracle to specify a schema where the user has write priviliges for storing temporary tables.

outcomeDatabaseSchema

The database schema where the target outcome table is located. Note that for SQL Server, both the database and schema should be specified, e.g. 'cdm_schema.dbo'

outcomeTable The name of the table where the outcomes will be stored.

referenceSet The name of the reference set for which positive controls need to be synthesized.

Currently supported are "ohdsiMethodsBenchmark".

maxCores How many parallel cores should be used? If more cores are made available this

can speed up the analyses.

workFolder Name of local folder to place intermediary results; make sure to use forward

slashes (/). Do not use a folder on a network drive since this greatly impacts

performance.

summaryFileName

The name of the CSV file where to store the summary of the final set of positive and negative controls.

Details

This function will synthesize positive controls for a given reference set based on the real negative controls. Data from the database will be used to fit outcome models for each negative control outcome, and these models will be used to sample additional synthetic outcomes during eposure to increase the true hazard ratio.

The positive control outcome cohorts will be stored in the same database table as the negative control outcome cohorts.

A summary file will be created listing all positive and negative controls. This list should then be used as input for the method under evaluation.

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