# Package 'MethodEvaluation'

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Type Package

Title Package for evaluation of estimation methods

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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. Furthe 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.
License Apache License 2.0
Depends R (>= 3.1.0), ffbase, DatabaseConnector (>= 1.1.2), CohortMethod (>= 1.0.3)
Imports RJDBC, SqlRender (>= 1.1.0)
Suggests testthat,
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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",
  outcomeConditionTypeConceptIds = c())
```

## **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:

- "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

#### 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.

outcomeConditionTypeConceptIds

A list of TYPE\_CONCEPT\_ID values that will restrict condition occurrences. Only applicable if outcomeTable = CONDITION\_OCCURRENCE.

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#### **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**

```
## Not run:
    connectionDetails <- createConnectionDetails(dbms="sql server", server="RNDUSRDHIT07.jnj.com")
    exposureOutcomePairs = data.frame(exposureConceptId = c(767410,1314924,907879), outcomeConceptId = c(44438
    mdrrs <- computeMdrr(connectionDetails, "cdm_truven_mdcr" exposureOutcomePairs, outcomeTable = "condition_
## End(Not run)</pre>
```

## **Description**

Create outcomes of interest

## Usage

```
createOutcomeCohorts(connectionDetails, cdmDatabaseSchema,
  createNewCohortTable = FALSE, cohortDatabaseSchema = cdmDatabaseSchema,
  cohortTable = "cohort", referenceSet = "omopReferenceSet")
```

#### **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'

createNewCohortTable

Should a new cohort table be created, or should the outcomes be inserted in a existing table?

cohortDatabaseSchema

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

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

## **Details**

This function will create the outcomes of interest 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.

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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 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:

exposureConceptId Concept ID identifying the exposure

exposureConceptName Name of the exposure

outcomeConceptId Concept ID identifying the outcome

outcomeConceptName Name of the outcome

**groundTruth** 0 = negative control, 1 = positive control

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

indicationConceptName Name of the indication

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

comparatorDrugConceptName Name of the comparator drug

comparatorType How the comparator was selected

## References

Coloma PM, Avillach P, Salvo F, Schuemie MJ, Ferrajolo C, Pariente A, Fourrier-RC)glat A, Molokhia M, Patadia V, van der Lei J, Sturkenboom M, TrifirC2 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

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injectSignals

Inject signals in database

## **Description**

Inject signals in database

## Usage

```
injectSignals(connectionDetails, cdmDatabaseSchema,
  oracleTempSchema = cdmDatabaseSchema,
  exposureDatabaseSchema = cdmDatabaseSchema, exposureTable = "drug_era",
  outcomeDatabaseSchema = cdmDatabaseSchema, outcomeTable = "condition_era",
  outcomeConditionTypeConceptIds = c(),
  outputDatabaseSchema = cdmDatabaseSchema,
  outputTable = "generated_outcomes", exposureOutcomePairs,
  modelType = "poisson", buildOutcomeModel = TRUE,
  firstExposureOnly = FALSE, washoutWindow = 183, riskWindowStart = 0,
  riskWindowEnd = 0, addExposureDaysToEnd = TRUE, firstOutcomeOnly = TRUE,
  effectSizes = c(1, 1.25, 1.5, 2, 4, 8))
```

## **Arguments**

connectionDetails

 $An\ R\ object\ of\ type\ {\tt ConnectionDetails}\ created\ using\ the\ function\ create{\tt ConnectionDetails}\ in\ the\ {\tt DatabaseConnector}\ package.$ 

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 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.

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 $outcome {\tt ConditionTypeConceptIds}$ 

A list of TYPE\_CONCEPT\_ID values that will restrict condition occurrences. Only applicable if outcomeTable = CONDITION\_OCCURRENCE.

exposureOutcomePairs

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

## **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 several models for inserting the outcomes during the specified risk window of the drug.

omopReferenceSet

The OMOP reference set

## **Description**

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:

exposureConceptId Concept ID identifying the exposure

exposureConceptName Name of the exposure

outcomeConceptId Concept ID identifying the outcome

outcomeConceptName Name of the outcome

**groundTruth** 0 = negative control, 1 = positive control

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

indicationConceptName Name of the indication

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

comparatorDrugConceptName Name of the comparator drug

**comparatorType** How the comparator was selected

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## 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

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