Package 'SelfControlledCaseSeries'

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Type Package

Title Self-Controlled Case Series

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Description Execute the self-controlled case series (SCCS) design using observational data in the OMOP Common Data Model. Extracts all necessary data from the database and transforms it to the format required for SCCS. Age and season can be modeled using splines assuming constant hazard within calendar months. Event-dependent censoring of the observation period can be corrected for. Many exposures can be included at once (MSCCS), with regularization on all coefficients except for the exposure of interest. Includes diagnostics for all major assumptions of the SCCS.

VignetteBuilder knitr

URL https://ohdsi.github.io/SelfControlledCaseSeries/,

https://github.com/OHDSI/SelfControlledCaseSeries

BugReports https://github.com/OHDSI/SelfControlledCaseSeries/issues

- **Depends** R (>= 4.1.0), Cyclops (>= 3.4.0), DatabaseConnector (>= 6.0.0), Andromeda (>= 1.0.0)
- Imports SqlRender (>= 1.16.0), dplyr (>= 1.0.0), Rcpp (>= 1.0.9), ParallelLogger (>= 3.4.0), EmpiricalCalibration, splines, ggplot2 (>= 3.4.0), methods, utils, checkmate, readr, ResultModelManager, jsonlite, digest, R6

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Contents

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checkEventExposureIndependenceAssumption Check diagnostic for event-dependent exposure

Description

This diagnostic tests whether there is a dependency between the event and subsequent exposures. This requires you have indicated one of the era covariates to be a pre-exposure window. This function simply checks whether the confidence interval for the effect estimate of that pre-exposure window overlaps with the nullBounds.

To designate an era covariate to be the pre-exposure window, set preExposure = TRUE when calling createEraCovariateSettings(). Note that, by default, preExposure will be TRUE if start is smaller than 0.

Usage

```
checkEventExposureIndependenceAssumption(sccsModel, nullBounds = c(0.8, 1.25))
```

Arguments

| sccsModel | A fitted SCCS model as created using fitSccsModel(). |
|------------|--|
| nullBounds | The bounds for the null hypothesis on the incidence rate ratio scale |

Value

A tibble with one row per pre-exposure window and four columns: ratio indicates the estimates incidence rate ratio for the pre-exposure window. 1b and ub represent the upper and lower bounds of the 95 percent confidence interval, and pass is TRUE if the confidence interval intersects the null bounds.

checkEventObservationIndependenceAssumption

Check diagnostic for event-dependent observation end

Description

This diagnostic tests whether there is a dependency between the event and the end of observation. It does so by adding a probe window at the end of observation, and checking whether the rate of the outcome is elevated (or decreased) during this window.

The end of observation probe window will automatically be added to the model by the createSccsIntervalData() function, unless the endOfObservationEraLength argument is set to 0. This function extracts the estimate for that window from the model, and compares it to the nullBounds.#'

Usage

```
checkEventObservationIndependenceAssumption(sccsModel, nullBounds = c(0.5, 2))
```

Arguments

| sccsModel | A fitted SCCS model as created using fitSccsModel(). |
|------------|---|
| nullBounds | The bounds for the null hypothesis on the incidence rate ratio scale. |

Value

A tibble with one row and four columns: ratio indicates the estimates incidence rate ratio for the probe at the end of observation. 1b and ub represent the upper and lower bounds of the 95 percent confidence interval, and pass is TRUE if the confidence interval intersects the null bounds.

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checkRareOutcomeAssumption

Check if rare outcome assumption is violated

Description

Check if rare outcome assumption is violated

Usage

```
checkRareOutcomeAssumption(
   studyPopulation,
   firstOutcomeOnly = NULL,
   maxPrevalence = 0.1
)
```

Arguments

studyPopulation

An object created using the createStudyPopulation() function.

firstOutcomeOnly

Was the analysis restricted to the first outcome only? If left at NULL, will be determined by whether firstOutcomeOnly was set to TRUE when calling createStudyPopulation() or whether each person only had one outcome when pulling the data from the server.

maxPrevalence The maximum allowed prevalence (proportion of people with the outcome) allowed when restricting to first outcome only.

Details

Most SCCS analyses restrict to the first outcome occurrence per person to avoid violating the assumption that subsequent occurrences are independent. This is fine, as long as the outcome is rare. According to Farrington et al., the magnitude of the bias from violating this assumption is 0.5p, where p is the prevalence. By default we set the threshold for p at 0.1, corresponding to at most 5 percent bias.

The prevalence was computed in the getDbSccsData() function, within the population defined by the observation_period table, and restricted to the study period(s) and nesting cohort if used.

Value

A tibble with one row and three columns: outcomeProportion indicates the proportion of people having the outcome at least once. firstOutcomeOnly indicated whether the analysis was restricted to the first outcome only. rare is TRUE if the rare outcome assumption is met, or the analysis was not restricted to the first outcome.

References

Farrington P, Whitaker H, Ghebremichael-Weldeselassie Y, Self-Controlled Case Series Studies: A Modelling Guide with R, CRC Press, 2018

checkTimeStabilityAssumption

Check stability of outcome rate over time

Description

Check stability of outcome rate over time

Usage

```
checkTimeStabilityAssumption(
   studyPopulation,
   sccsModel = NULL,
   maxRatio = 1.1,
   alpha = 0.05
)
```

Arguments

studyPopulation

| | An object created using the createStudyPopulation() function. |
|-----------|--|
| sccsModel | Optional: A fitted SCCS model as created using fitSccsModel(). If the model contains splines for seasonality and or calendar time these will be adjusted for before computing stability. |
| maxRatio | The maximum global ratio between the observed and expected count. |
| alpha | The alpha (type 1 error) used to test for stability. |

Details

Computes for each month the observed and expected count, and computes the (weighted) mean ratio between the two. If splines are used to adjust for seasonality and/or calendar time, these adjustments are taken into consideration when considering the expected count. A one-sided p-value is computed against the null hypothesis that the ratio is smaller than maxRatio. If this p-value exceeds the specified alpha value, the series is considered stable.

Value

A tibble with one row and three columns: ratio indicates the estimated mean ratio between observed and expected. p is the p-value against the null-hypothesis that the ratio is smaller than maxRatio, and pass is TRUE if p is greater than alpha. computeMdrr

Description

Compute the minimum detectable relative risk

Usage

```
computeMdrr(
   object,
   exposureCovariateId,
   alpha = 0.05,
   power = 0.8,
   twoSided = TRUE,
   method = "SRL1"
)
```

Arguments

| object | An object either of type SccsIntervalData as created using the createSccsInter- |
|----------------|---|
| | valData function, or an object of type SccsModel as created using the fitSccsModel() |
| | function. |
| exposureCovari | ateId |
| | Covariate Id for the health exposure of interest. |
| alpha | Type I error. |
| power | 1 - beta, where beta is the type II error. |
| twoSided | Consider a two-sided test? |
| method | The type of sample size formula that will be used. Allowable values are "pro- portion", "binomial", "SRL1", "SRL2", or "ageEffects". Currently "ageEffects" is not supported. |

Details

Compute the minimum detectable relative risk (MDRR) for a given study population, using the observed time at risk and total time in days and number of events. Five sample size formulas are implemented: sampling proportion, binomial proportion, 2 signed root likelihood ratio methods, and likelihood extension for age effects. The expressions by Musonda (2006) are used.

Value

A data frame with the MDRR, number of events, time at risk, and total time.

References

Musonda P, Farrington CP, Whitaker HJ (2006) Samples sizes for self-controlled case series studies, Statistics in Medicine, 15;25(15):2618-31

```
computePreExposureGainP
```

Compute P for pre-exposure risk gain

Description

This function is deprecated. Use computePreExposureGain() instead.

Usage

```
computePreExposureGainP(sccsData, studyPopulation, exposureEraId = NULL)
```

Arguments

| sccsData | An object of type SccsData as created using the getDbSccsData function. |
|----------------|---|
| studyPopulatio | n |
| | An object created using the createStudyPopulation() function. |
| exposureEraId | The exposure to create the era data for. If not specified it is assumed to be the one exposure for which the data was loaded from the database. |

Value

A one-sided p-value for whether the rate before exposure is higher than after, against the null of no change.#'

computeTimeStability Check stability of outcome rate over time

Description

Check stability of outcome rate over time

Usage

```
computeTimeStability(
   studyPopulation,
   sccsModel = NULL,
   maxRatio = 1.1,
   alpha = 0.05
)
```

| studyPopulatio | n An object created using the createStudyPopulation() function. |
|----------------|--|
| sccsModel | Optional: A fitted SCCS model as created using fitSccsModel(). If the model contains splines for seasonality and or calendar time these will be adjusted for before computing stability. |
| maxRatio | The maximum global ratio between the observed and expected count. |
| alpha | The alpha (type 1 error) used to test for stability. |

Details

DEPRECATED. Use checkTimeStabilityAssumption() instead.

Value

A tibble with one row and three columns: ratio indicates the estimated mean ratio between observed and expected. p is the p-value against the null-hypothesis that the ratio is smaller than maxRatio, and pass is TRUE if p is greater than alpha.

convertJsonToSccsAnalysesSpecifications Convert JSON to SccsAnalysesSpecifications

Description

Convert JSON to SccsAnalysesSpecifications

Usage

convertJsonToSccsAnalysesSpecifications(json)

Arguments

json A string containing the JSON representation.

Value

An object of type SccsAnalysesSpecifications.

convertSccsAnalysesSpecificationsToJson Convert SccsAnalysesSpecifications to JSON

Description

Convert SccsAnalysesSpecifications to JSON

Usage

convertSccsAnalysesSpecificationsToJson(sccsAnalysesSpecifications)

Arguments

```
sccsAnalysesSpecifications
```

An object of type SccsAnalysesSpecifications as created by the createSccsAnalysesSpecificatio function.

Value

A string containing the JSON representation.

convertUntypedListToSccsAnalysesSpecifications Convert untyped list to SccsAnalysesSpecifications

Description

Convert untyped list to SccsAnalysesSpecifications

Usage

```
convertUntypedListToSccsAnalysesSpecifications(untypedList)
```

Arguments

untypedList A list of untyped objects. For example, these could be objects from a call to jsonlite::fromJSON(). Importantly, simplifyDataFrame must be set to FALSE when doing so.

Value

An object of type SccsAnalysesSpecifications.

createAgeCovariateSettings

Create age covariate sesettings#' Create age covariate settings

Description

Create age covariate sesettings#' Create age covariate settings

Usage

```
createAgeCovariateSettings(
   ageKnots = 5,
   allowRegularization = FALSE,
   computeConfidenceIntervals = FALSE
)
```

Arguments

ageKnots If a single number is provided this is assumed to indicate the number of knots to use for the spline, and the knots are automatically spaced according to equal percentiles of the data. If more than one number is provided these are assumed to be the exact location of the knots in age-days

allowRegularization

When fitting the model, should the covariates defined here be allowed to be regularized?

```
computeConfidenceIntervals
```

Should confidence intervals be computed for the covariates defined here? Setting this to FALSE might save computing time when fitting the model. Will be turned to FALSE automatically when allowRegularization = TRUE.

Details

Create an object specifying whether and how age should be included in the model. Age can be included by splitting patient time into calendar months. During a month, the relative risk attributed to age is assumed to be constant, and the risk from month to month is modeled using a quadratic spline.

Value

An object of type AgeCovariateSettings.

createCalendarTimeCovariateSettings Create calendar time settings

Description

Create calendar time settings

Usage

```
createCalendarTimeCovariateSettings(
   calendarTimeKnots = 5,
   allowRegularization = FALSE,
   computeConfidenceIntervals = FALSE
)
```

Arguments

calendarTimeKnots

If a single number is provided this is assumed to indicate the number of knots to use for the spline. See details on how knots are placed. If a series of dates is provided these are assumed to be the exact location of the knots.

allowRegularization

When fitting the model, should the covariates defined here be allowed to be regularized?

computeConfidenceIntervals

Should confidence intervals be computed for the covariates defined here? Setting this to FALSE might save computing time when fitting the model. Will be turned to FALSE automatically when allowRegularization = TRUE.

Details

Create an object specifying whether and how calendar time should be included in the model. Calendar time can be included by splitting patient time into calendar months. During a month, the relative risk attributed to calendar time is assumed to be constant, and the risk from month to month is modeled using a quadratic spline.

Whereas the seasonality covariate uses a cyclic spline, repeating every year, this calendar time covariate can model trends over years.

If a number of knots is specified, knots are automatically spaced according to equal percentiles of the data (people observed). If more than one study period is provided, two more knots (start and end) are automatically added for each additional study period. So if calendarTimeKnots = 5 and there are 3 study periods, the total number of knots will be 5 + 2 * (3 - 1) = 9.#

Value

An object of type CalendarTimeCovariateSettings.

createControlIntervalSettings Create control interval settings

Description

Create control interval settings

Usage

```
createControlIntervalSettings(
    includeEraIds = NULL,
    excludeEraIds = NULL,
    start = 0,
    startAnchor = "era start",
    end = 0,
    endAnchor = "era end",
    firstOccurrenceOnly = FALSE
)
```

Arguments

| includeEraIds | One or more IDs of variables in the SccsData object that should be used to construct this covariate. If no IDs are specified, all variables will be used. | |
|---------------------|---|--|
| excludeEraIds | One or more IDs of variables in the [SccsData] object that should not be used to construct this covariate. | |
| start | The start of the control interval (in days) relative to the startAnchor. | |
| startAnchor | The anchor point for the start of the control interval. Can be "era start" or "era end". | |
| end | The end of the control interval (in days) relative to the endAnchor. | |
| endAnchor | The anchor point for the end of the control interval. Can be "era start" or "era end". | |
| firstOccurrenceOnly | | |
| | Should only the first occurrence of the exposure be used? | |

Details

Create an object specifying how to create a control interval for the self-controlled risk interval (SCRI) design.

Value

An object of type ControlIntervalSettings.

```
createCreateSccsIntervalDataArgs
```

Create a parameter object for the createSccsIntervalData() function

Description

Create a parameter object for the createSccsIntervalData() function

Usage

```
createCreateSccsIntervalDataArgs(
    eraCovariateSettings,
    ageCovariateSettings = NULL,
    seasonalityCovariateSettings = NULL,
    calendarTimeCovariateSettings = NULL,
    minCasesForTimeCovariates = 10000,
    endOfObservationEraLength = 30,
    eventDependentObservation = FALSE
)
```

Arguments

eraCovariateSettings

Either an object of type EraCovariateSettings as created using the createEraCovariateSettings() function, or a list of such objects.

ageCovariateSettings

An object of type AgeCovariateSettings as created using the createAgeCovariateSettings() function.

seasonalityCovariateSettings

An object of type SeasonalityCovariateSettings as created using the createSeasonalityCovariate function.

calendarTimeCovariateSettings

An object of type CalendarTimeCovariateSettings as created using the createCalendarTimeCovaria function.

minCasesForTimeCovariates

Minimum number of cases to use to fit age, season and calendar time splines. If needed (and available), cases that are not exposed will be included.

endOfObservationEraLength

Length in days of the probe that is inserted at the end of a patient's observation time. This probe will be used to test whether there is event- dependent observation end. Set to 0 to not include the probe.

eventDependentObservation

Should the extension proposed by Farrington et al. be used to adjust for eventdependent observation time?

Create an object defining the parameter values.

Value

An object of type CreateSccsIntervalDataArgs.

References

Farrington, C. P., Anaya-Izquierdo, A., Whitaker, H. J., Hocine, M.N., Douglas, I., and Smeeth, L. (2011). Self-Controlled case series analysis with event-dependent observation periods. Journal of the American Statistical Association 106 (494), 417-426

createCreateScriIntervalDataArgs

Create a parameter object for the createScriIntervalData() function

Description

Create a parameter object for the createScriIntervalData() function

Usage

createCreateScriIntervalDataArgs(eraCovariateSettings, controlIntervalSettings)

Arguments

eraCovariateSettings

Either an object of type EraCovariateSettings as created using the createEraCovariateSettings() function, or a list of such objects.

controlIntervalSettings

An object of type ControlIntervalSettings as created using the createControlIntervalSettings() function.

Details

Create an object defining the parameter values.

Value

An object of type CreateScriIntervalDataArgs.

```
createCreateStudyPopulationArgs
```

Create a parameter object for the createStudyPopulation() *function*

Description

Create a parameter object for the createStudyPopulation() function

Usage

```
createCreateStudyPopulationArgs(
  firstOutcomeOnly = FALSE,
  naivePeriod = 0,
  minAge = NULL,
  maxAge = NULL,
  genderConceptIds = NULL,
  restrictTimeToEraId = NULL
)
```

Arguments

firstOutcomeOnly

| | Whether only the first occurrence of an outcome should be considered. | |
|---------------------|--|--|
| naivePeriod | The number of days at the start of a patient's observation period that should not be included in the risk calculations. Note that the naive period can be used to determine current covariate status right after the naive period, and whether an outcome is the first one. | |
| minAge | Minimum age at which patient time will be included in the analysis. Note that information prior to the min age is still used to determine exposure status af- ter the minimum age (e.g. when a prescription was started just prior to reach- ing the minimum age). Also, outcomes occurring before the minimum age is reached will be considered as prior outcomes when using first outcomes only. Age should be specified in years, but non-integer values are allowed. If not specified, no age restriction will be applied. | |
| maxAge | Maximum age at which patient time will be included in the analysis. Age should be specified in years, but non-integer values are allowed. If not specified, no age restriction will be applied. | |
| genderConceptIds | | |
| | Set of gender concept IDs to restrict the population to. If not specified, no restriction on gender will be applied. | |
| restrictTimeToEraId | | |
| | If provided, study time (for all patients) will be restricted to the calendar time when that era was observed in the data. For example, if the era ID refers to a drug, study time will be restricted to when the drug was on the market. | |

Create an object defining the parameter values.

Value

An object of type CreateStudyPopulationArgs.

createDefaultSccsMultiThreadingSettings Create default SelfControlledCaseSeries multi-threading settings

Description

Create SelfControlledCaseSeries multi-threading settings based on the maximum number of cores to be used.

Usage

createDefaultSccsMultiThreadingSettings(maxCores)

Arguments

maxCores Maximum number of CPU cores to use.

Value

An object of type SccsMultiThreadingSettings.

See Also

createSccsMultiThreadingSettings()

Examples

settings <- createDefaultSccsMultiThreadingSettings(10)</pre>

createEraCovariateSettings

Create era covariate settings

Description

Create era covariate settings

Usage

```
createEraCovariateSettings(
    includeEraIds,
    excludeEraIds = NULL,
    label = "Covariates",
    stratifyById = FALSE,
    start = 0,
    startAnchor = "era start",
    end = 0,
    endAnchor = "era end",
    firstOccurrenceOnly = FALSE,
    allowRegularization = FALSE,
    profileLikelihood = FALSE,
    exposureOfInterest = FALSE,
    preExposure = start < 0
)
```

Arguments

| includeEraIds | One or more IDs of variables in the SccsData object that should be used to construct this covariate. If set to NULL, all variables will be used. |
|---------------|---|
| excludeEraIds | One or more IDs of variables in the [SccsData] object that should not be used to construct this covariate. |
| label | A label used to identify the covariates created using these settings. |
| stratifyById | Should a single covariate be created for every ID in the SccsData object, or should a single covariate be constructed? For example, if the IDs identify exposures to different drugs, should a covariate be constructed for every drug, or a single covariate for exposure to any of these drugs. Note that overlap will be considered a single exposure. |
| start | The start of the risk window (in days) relative to the startAnchor. |
| startAnchor | The anchor point for the start of the risk window. Can be "era start" or "era end". |
| end | The end of the risk window (in days) relative to the endAnchor. |
| endAnchor | The anchor point for the end of the risk window. Can be "era start" or "era end". |

createExposure

| firstOccurrenceOnly | | |
|---------------------|-----------------|---|
| | | Should only the first occurrence of the exposure be used? |
| | allowRegulariza | ation |
| | | When fitting the model, should the covariates defined here be allowed to be regularized? |
| profileLikelihood | | |
| | | When fitting the model, should the likelihood profile be computed for the co- variate defined here? The likelihood profile can be used to avoid making normal approximations on the likelihood and can be used in methods specifically de- signed to make use of the profile, but may take a while to compute. |
| exposureOfInterest | | |
| | | If TRUE, the fitted coefficient for this variable will be reported when using runSccsAnalyses(). Requires includeEraIds to be a exposure reference ID as defined in createExposure(). |
| | preExposure | If TRUE, this variable will be used for the pre-exposure diagnostic. |

Details

Create an object specifying how to create a (set of) era-based covariates.

Value

An object of type EraCovariateSettings.

createExposure Create exposure definition

Description

Create exposure definition

Usage

```
createExposure(exposureId, exposureIdRef = "exposureId", trueEffectSize = NA)
```

Arguments

| exposureId | An integer used to identify the exposure in the exposure cohort table. |
|----------------|---|
| exposureIdRef | A string used to refer to the exposure when defining covariates using the createEraCovariateSettings(function. |
| trueEffectSize | For negative and positive controls: the known true effect size. To be used for empirical calibration. Negative controls have trueEffectSize = 1. If the true effect size is unknown, use trueEffectSize = NA. |

Details

Create an exposure definition, to be used with the createExposuresOutcome function.

Value

An object of type Exposure.

createExposuresOutcome

Create a exposures-outcome combination.

Description

Create a exposures-outcome combination.

Usage

```
createExposuresOutcome(outcomeId, exposures, nestingCohortId = NULL)
```

Arguments

| outcomeId | An integer used to identify the outcome in the outcome cohort table. |
|-----------------|--|
| exposures | A list of object of type Exposure as created by createExposure(). |
| nestingCohortIc | 1 |
| | (Optional) the nesting cohort ID |

(Optional) the nesting cohort ID.

Details

Create a set of hypotheses of interest, to be used with the runSccsAnalyses() function.

Value

An object of type ExposuresOutcome.

createFitSccsModelArgs

Create a parameter object for the function fitSccsModel

Description

Create a parameter object for the function fitSccsModel

Usage

```
createFitSccsModelArgs(
  prior = createPrior("laplace", useCrossValidation = TRUE),
 control = createControl(cvType = "auto", selectorType = "byPid", startingVariance =
    0.1, seed = 1, resetCoefficients = TRUE, noiseLevel = "quiet"),
 profileGrid = NULL,
  profileBounds = c(log(0.1), log(10))
)
```

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| prior | The prior used to fit the model. See Cyclops::createPrior for details. |
|---------------|---|
| control | The control object used to control the cross-validation used to determine the hyperparameters of the prior (if applicable). See Cyclops::createControl for details. |
| profileGrid | A one-dimensional grid of points on the log(relative risk) scale where the likeli- hood for coefficient of variables is sampled. See details. |
| profileBounds | The bounds (on the log relative risk scale) for the adaptive sampling of the like- lihood function. |

Details

Create an object defining the parameter values.

Value

An object of type FitSccsModelArgs.

```
createGetDbSccsDataArgs
```

Create a parameter object for the function getDbSccsData

Description

Create a parameter object for the function getDbSccsData

Usage

```
createGetDbSccsDataArgs(
  nestingCohortId = NULL,
  deleteCovariatesSmallCount = 0,
  studyStartDates = c(),
  studyEndDates = c(),
  maxCasesPerOutcome = 0,
  exposureIds = "exposureId",
  customCovariateIds = NULL
)
```

Arguments

```
nestingCohortId
```

A cohort definition ID identifying the records in the nestingCohortTable to use as nesting cohort.

deleteCovariatesSmallCount

The minimum count for a covariate to appear in the data to be kept.

| studyStartDates | 6 |
|-----------------|--|
| | A character object specifying the minimum dates where data is used. Date for- mat is 'yyyymmdd'. Use "" to indicate all time prior. See section for more information. |
| studyEndDates | A character object specifying the maximum dates where data is used. Date format is 'yyyymmdd'. Use "" to indicate to the end of observation. See section for more information. |
| maxCasesPerOuto | come |
| | If there are more than this number of cases for a single outcome cases will be sampled to this size. maxCasesPerOutcome = 0 indicates no maximum size. |
| exposureIds | A list of identifiers to extract from the exposure table. If exposureTable = DRUG_ERA, exposureIds should be CONCEPT_ID. If exposureTable = "drug_era", exposureIds is used to select the drug_concept_id. If no exposure IDs are provided, all drugs or cohorts in the exposureTable are included as exposures. |
| customCovariate | eIds |
| | A list of cohort definition IDs identifying the records in the customCovari- ateTable to use for building custom covariates. |
| | |

Create an object defining the parameter values.

Value

An object of type GetDbSccsDataArgs.

```
createResultsDataModel
```

Create the results data model tables on a database server.

Description

Create the results data model tables on a database server.

Usage

```
createResultsDataModel(
  connectionDetails = NULL,
  databaseSchema,
  tablePrefix = ""
)
```

Arguments

connectionDetails

DatabaseConnector connectionDetails instance @seealsoDatabaseConnector::createConnectionDetails databaseSchema The schema on the server where the tables will be created.

tablePrefix (Optional) string to insert before table names for database table names

Only PostgreSQL and SQLite servers are supported.

createSccsAnalysesSpecifications Create full SCCS analysis specifications

Description

Create full SCCS analysis specifications

Usage

```
createSccsAnalysesSpecifications(
  sccsAnalysisList,
  exposuresOutcomeList,
  analysesToExclude = NULL,
  combineDataFetchAcrossOutcomes = FALSE,
 sccsDiagnosticThresholds = SelfControlledCaseSeries::createSccsDiagnosticThresholds(),
  controlType = "outcome"
)
```

Arguments

sccsAnalysisList A list of objects of type SccsAnalysis as created using the createSccsAnalysis() function. exposuresOutcomeList

> A list of objects of type ExposuresOutcome as created using the createExposuresOutcome() function.

analysesToExclude

Analyses to exclude. See the Analyses to Exclude section for details.

combineDataFetchAcrossOutcomes

Should fetching data from the database be done one outcome at a time, or for all outcomes in one fetch? Combining fetches will be more efficient if there is large overlap in the subjects that have the different outcomes.

sccsDiagnosticThresholds

An object of type SccsDiagnosticThresholds as created using createSccsDiagnosticThresholds().

controlType Type of negative (and positive) controls. Can be "outcome" or "exposure". When set to "outcome", controls with the same exposure (and nesting cohort) are grouped together for calibration. When set to "exposure", controls with the same outcome are grouped together.

Analyses to Exclude:

Normally, runSccsAnalyses will run all combinations of exposures-outcome-analyses settings. However, sometimes we may not need all those combinations. Using the analysesToExclude argument, we can remove certain items from the full matrix. This argument should be a data frame with at least one of the following columns:

- exposureId
- outcomeId
- nestingCohortId
- analysisId

This data frame will be joined to the outcome model reference table before executing, and matching rows will be removed. For example, if one specifies only one exposure ID and analysis ID, then any analyses with that exposure and that analysis ID will be skipped.

Value

An object of type SccsAnalysesSpecifications.

createSccsAnalysis Create a SelfControlledCaseSeries analysis specification

Description

Create a SelfControlledCaseSeries analysis specification

Usage

```
createSccsAnalysis(
    analysisId = 1,
    description = "",
    getDbSccsDataArgs,
    createStudyPopulationArgs,
    createIntervalDataArgs,
    fitSccsModelArgs
)
```

Arguments

| analysisId | An integer that will be used later to refer to this specific set of analysis choices. |
|-----------------|---|
| description | A short description of the analysis. |
| getDbSccsDataAr | gs |
| | An object representing the arguments to be used when calling the getDbSccs- |
| | Data function. |
| createStudyPopu | llationArgs |
| | An object representing the arguments to be used when calling the getDbSccs- |
| | Data function. |
| | |

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```
createIntervalDataArgs
```

An object representing the arguments to be used when calling the createSccsIntervalData or createScriIntervalData function.

fitSccsModelArgs

An object representing the arguments to be used when calling the fitSccsModel function.

Value

An object of type SccsAnalysis, to be used with the runSccsAnalyses function.

createSccsDiagnosticThresholds

Create SCCS diagnostics thresholds

Description

Threshold used when calling runSccsAnalyses() to determine if we pass or fail diagnostics.

Usage

```
createSccsDiagnosticThresholds(
  mdrrThreshold = 10,
  easeThreshold = 0.25,
  timeTrendMaxRatio = 1.1,
  rareOutcomeMaxPrevalence = 0.1,
  eventObservationDependenceNullBounds = c(0.5, 2),
  eventExposureDependenceNullBounds = c(0.8, 1.25)
)
```

Arguments

```
mdrrThreshold
                 What is the maximum allowed minimum detectable relative risk (MDRR)?
easeThreshold
                 What is the maximum allowed expected absolute systematic error (EASE).
timeTrendMaxRatio
                 The maximum global ratio between the observed and expected count for the
                 time stability diagnostic.
rareOutcomeMaxPrevalence
                 The maximum allowed prevalence (proportion of people with the outcome) al-
                 lowed when restricting to first outcome only.
eventObservationDependenceNullBounds
                 The bounds for the null hypothesis for the incidence rate ratio of the end-of-
                 observation probe window.
eventExposureDependenceNullBounds
                 The bounds for the null hypothesis for the incidence rate of the pre-exposure
                 window.
```

Value

An object of type SccsDiagnosticThresholds.

createSccsIntervalData

Create SCCS era data

Description

Create SCCS era data

Usage

createSccsIntervalData(studyPopulation, sccsData, createSccsIntervalDataArgs)

Arguments

studyPopulation

An object created using the createStudyPopulation() function.

| sccsData An object of type SccsData as created using th | e getDbSccsData function. |
|---|---------------------------|
|---|---------------------------|

createSccsIntervalDataArgs

An object of type CreateSccsIntervalDataArgs as created by the createCreateSccsIntervalDataAr function.

Details

This function creates covariates based on the data in the sccsData argument, according to the provided settings. It chops patient time into periods during which all covariates remain constant. The output details these periods, their durations, and a sparse representation of the covariate values.

Value

An object of type SccsIntervalData.

createSccsMultiThreadingSettings Create SelfControlledCaseSeries multi-threading settings

Description

Create SelfControlledCaseSeries multi-threading settings

Usage

```
createSccsMultiThreadingSettings(
  getDbSccsDataThreads = 1,
  createStudyPopulationThreads = 1,
  createIntervalDataThreads = 1,
  fitSccsModelThreads = 1,
  cvThreads = 1,
  calibrationThreads = 1
)
```

Arguments

getDbSccsDataThreads The number of parallel threads to use for building the SccsData objects. createStudyPopulationThreads The number of parallel threads to use for building the studyPopulation objects. createIntervalDataThreads The number of parallel threads to use for building the SccsIntervalData objects. fitSccsModelThreads The number of parallel threads to use for fitting the models. cvThreads The number of parallel threads to use for the cross- validation when estimating the hyperparameter for the outcome model. Note that the total number of CV threads at one time could be fitSccsModelThreads * cvThreads. calibrationThreads The number of parallel threads to use for empirical calibration.

Value

An object of type SccsMultiThreadingSettings.

See Also

createDefaultSccsMultiThreadingSettings()

createSccsSimulationSettings Create SCCS simulation settings

Description

Create SCCS simulation settings

Usage

```
createSccsSimulationSettings(
 meanPatientTime = 4 * 365,
  sdPatientTime = 2 * 365,
 minAge = 18 * 365,
 maxAge = 65 * 365,
 minBaselineRate = 0.001,
 maxBaselineRate = 0.01,
 minCalendarTime = as.Date("2000-01-01"),
 maxCalendarTime = as.Date("2010-01-01"),
  eraIds = c(1, 2),
  patientUsages = c(0.2, 0.1),
  usageRate = c(0.01, 0.01),
  usageRateSlope = c(0, 0),
  meanPrescriptionDurations = c(14, 30),
  sdPrescriptionDurations = c(7, 14),
  simulationRiskWindows = list(createSimulationRiskWindow(relativeRisks = 1),
    createSimulationRiskWindow(relativeRisks = 1.5)),
  includeAgeEffect = TRUE,
  ageKnots = 5,
  includeSeasonality = TRUE,
  seasonKnots = 5,
  includeCalendarTimeEffect = TRUE,
  calendarTimeKnots = 5,
  calendarTimeMonotonic = FALSE,
  outcomeId = 10
)
```

Arguments

meanPatientTime

| Mean number of observation days per patient. | | |
|--|--|--|
| Standard deviation of the observation days per patient. | | |
| The minimum age in days. | | |
| The maximum age in days. | | |
| | | |
| The minimum baseline rate (per day). | | |
| | | |
| The maximum baseline rate (per day). | | |
| minCalendarTime | | |
| The minimum date patients are to be observed. | | |
| maxCalendarTime | | |
| The maximum date patients are to be observed. | | |
| The IDs for the covariates to be generated. | | |
| The fraction of patients that use the drugs. | | |
| The rate of prescriptions per person that uses the drug. | | |
| | | |

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| usageRateSlope | The change in the usage rate from one day to the next. <code>usageRate</code> is the intercept at day 0 | |
|---------------------------|---|--|
| meanPrescriptic | onDurations | |
| | The mean duration of a prescription, per drug. | |
| sdPrescriptionD | Durations | |
| | The standard deviation of the duration of a prescription, per drug. | |
| simulationRiskW | /indows | |
| | One or a list of objects of type SimulationRiskWindow as created using the createSimulationRiskWindow() function. | |
| includeAgeEffect | | |
| | Include an age effect for the outcome? | |
| ageKnots | Number of knots in the age spline. | |
| includeSeasonal | ity | |
| | Include seasonality for the outcome? | |
| seasonKnots | Number of knots in the seasonality spline. | |
| includeCalendarTimeEffect | | |
| | Include a calendar time effect for the outcome? | |
| calendarTimeKnots | | |
| | Number of knots in the calendar time spline. | |
| calendarTimeMor | notonic | |
| | Should the calender time effect be monotonic? | |
| outcomeId | The ID to be used for the outcome. | |

Create an object of settings for an SCCS simulation.

Value

An object of type SccsSimulationSettings.

createScriIntervalData

Create Self-Controlled Risk Interval (SCRI) era data

Description

Create Self-Controlled Risk Interval (SCRI) era data

Usage

createScriIntervalData(studyPopulation, sccsData, createScriIntervalDataArgs)

| studyPopulatio | n | |
|----------------------------|---|--|
| | An object created using the createStudyPopulation() function. | |
| sccsData | An object of type SccsData as created using the getDbSccsData function. | |
| createScriIntervalDataArgs | | |
| | An object of type CreateScriIntervalDataArgs as created by the createCreateScriIntervalDataAr function. | |

Details

This function creates interval data according to the elf-Controlled Risk Interval (SCRI) design. Unlike the generic SCCS design, where all patient time is used to establish a background rate, in the SCRI design a specific control interval (relative to the exposure) needs to be defined. The final model will only include time that is either part of the risk interval (defined using the eraCovariateSettings argument, or the control interval (defined using controlIntervalSettings).

Value

An object of type SccsIntervalData.

References

Greene SK, Kulldorff M, Lewis EM, Li R, Yin R, Weintraub ES, Fireman BH, Lieu TA, Nordin JD, Glanz JM, Baxter R, Jacobsen SJ, Broder KR, Lee GM. Near real-time surveillance for influenza vaccine safety: proof-of-concept in the Vaccine Safety Datalink Project. Am J Epidemiol. 2010 Jan 15;171(2):177-88. doi: 10.1093/aje/kwp345.

createSeasonalityCovariateSettings Create seasonality settings

Description

Create seasonality settings

Usage

```
createSeasonalityCovariateSettings(
  seasonKnots = 5,
  allowRegularization = FALSE,
  computeConfidenceIntervals = FALSE
)
```

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| seasonKnots | If a single number is provided this is assumed to indicate the number of knots to use for the spline, and the knots are automatically equally spaced across the year. If more than one number is provided these are assumed to be the exact location of the knots in days relative to the start of the year. |
|----------------|---|
| allowRegulariz | wation When fitting the model, should the covariates defined here be allowed to be regularized? |
| computeConfide | e |
| | |

Details

Create an object specifying whether and how seasonality should be included in the model. Seasonality can be included by splitting patient time into calendar months. During a month, the relative risk attributed to season is assumed to be constant, and the risk from month to month is modeled using a cyclic quadratic spline.

Value

An object of type SeasonalityCovariateSettings.

createSimulationRiskWindow

Create a risk window definition for simulation

Description

Create a risk window definition for simulation

Usage

```
createSimulationRiskWindow(
  start = 0,
  end = 0,
  endAnchor = "era end",
  splitPoints = c(),
  relativeRisks = c(0)
)
```

| start | Start of the risk window relative to exposure start. |
|---------------|--|
| end | The end of the risk window (in days) relative to the endAnchor. |
| endAnchor | The anchor point for the end of the risk window. Can be "era start" or "era end". |
| splitPoints | Subdivision of the risk window in to smaller sub-windows. |
| relativeRisks | Either a single number representing the relative risk in the risk window, or when splitPoints have been defined a vector of relative risks, one for each sub-window. |

Value

An object of type SimulationRiskWindow.

createStudyPopulation Create a study population

Description

Create a study population

Usage

```
createStudyPopulation(sccsData, outcomeId = NULL, createStudyPopulationArgs)
```

Arguments

| sccsData | An object of type SccsData as created using the getDbSccsData function. | |
|---------------------------|---|--|
| outcomeId | The outcome to create the era data for. If not specified it is assumed to be the one outcome for which the data was loaded from the database. | |
| createStudyPopulationArgs | | |
| | An object of type CreateStudyPopulationArgs as created using the createCreateStudyPopulationAr function. | |

Details

Create a study population for a specific outcome, applying several restrictions.

Value

A list specifying the study population, with the following items:

- cases: A tibble with one row per observation period of a person with the outcome.
- outcomes: A tibble listing the days when a case has the outcome.
- metaData: A list with meta data about the study population, including the attrition.

cyclicSplineDesign Create a design matrix for a cyclic spline

Description

Create a design matrix for a cyclic spline

Usage

```
cyclicSplineDesign(x, knots, ord = 3)
```

Arguments

| х | Vector of coordinates of the points to be interpolated. |
|-------|--|
| knots | Location of the knots. |
| ord | Order of the spline function. ord = 3 implies quadratic. |

Details

This function is used by other functions in this package.

Export SCCSresults to CSV files

Description

Export SCCSresults to CSV files

Usage

```
exportToCsv(
   outputFolder,
   exportFolder = file.path(outputFolder, "export"),
   databaseId = 1,
   minCellCount = 5,
   maxCores = 1
)
```

Arguments

| outputFolder | The folder where runCmAnalyses() generated all results. |
|--------------|--|
| exportFolder | The folder where the CSV files will written. |
| databaseId | A unique ID for the database. This will be appended to most tables. |
| minCellCount | To preserve privacy: the minimum number of subjects contributing to a count before it can be included in the results. If the count is below this threshold, it will be set to -minCellCount. |
| maxCores | Maximum number of CPU cores to use. |

This requires that runSccsAnalyses() has been executed first. It exports all the results in the outputFolder to CSV files for sharing with other sites.

Value

Does not return anything. Is called for the side-effect of populating the exportFolder with CSV files.

fitSccsModel Fit the SCCS model

Description

Fit the SCCS model

Usage

fitSccsModel(sccsIntervalData, fitSccsModelArgs)

Arguments

```
sccsIntervalData
```

An object of type SccsIntervalData as created using the createSccsIntervalData function.

fitSccsModelArgs

An object of type FitSccsModelArgs as created by the createFitSccsModelArgs() function.

Details

Fits the SCCS model as a conditional Poisson regression. When allowed, coefficients for some or all covariates can be regularized.

Likelihood profiling is only done for variables for which profileLikelihood is set to TRUE when calling createEraCovariateSettings(). Either specify the profileGrid for a completely userdefined grid, or profileBounds for an adaptive grid. Both should be defined on the log IRR scale. When both profileGrid and profileGrid are NULL likelihood profiling is disabled.

Value

An object of type SccsModel. Generic functions print, coef, and confint are available.

References

Suchard, M.A., Simpson, S.E., Zorych, I., Ryan, P., and Madigan, D. (2013). Massive parallelization of serial inference algorithms for complex generalized linear models. ACM Transactions on Modeling and Computer Simulation 23, 10

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getAttritionTable Get the attrition table for a population

Description

Get the attrition table for a population

Usage

```
getAttritionTable(object)
```

Arguments

objectEither an object of type SccsData, a population object generated by functions
like createStudyPopulation(), or an object of type outcomeModel.

Value

A tibble specifying the number of people and exposures in the population after specific steps of filtering.

getDataMigrator Get database migrations instance

. .

Description

Returns ResultModelManager DataMigrationsManager instance.

Usage

```
getDataMigrator(connectionDetails, databaseSchema, tablePrefix = "")
```

Arguments

| connectionDetai | ls |
|-----------------|--|
| | DatabaseConnector connection details object |
| databaseSchema | String schema where database schema lives |
| tablePrefix | (Optional) Use if a table prefix is used before table names (e.g. "cd_") |

Value

Instance of ResultModelManager::DataMigrationManager that has interface for converting existing data models

getDbSccsData

Description

Load all data needed to perform an SCCS analysis from the database.

Usage

```
getDbSccsData(
    connectionDetails,
    cdmDatabaseSchema,
    tempEmulationSchema = getOption("sqlRenderTempEmulationSchema"),
    outcomeDatabaseSchema = cdmDatabaseSchema,
    outcomeTable = "condition_era",
    outcomeIds,
    exposureDatabaseSchema = cdmDatabaseSchema,
    exposureTable = "drug_era",
    customCovariateDatabaseSchema = cdmDatabaseSchema,
    customCovariateTable = "cohort",
    nestingCohortDatabaseSchema = cdmDatabaseSchema,
    nestingCohortTable = "cohort",
    getDbSccsDataArgs
)
```

Arguments

connectionDetails An R object of type ConnectionDetails created using the function DatabaseConnector::createConne function. cdmDatabaseSchema The name of the database schema that contains the OMOP CDM instance. Requires read permissions to this database. On SQL Server, this should specify both the database and the schema, so for example 'cdm_instance.dbo'. tempEmulationSchema Some database platforms like Oracle and Impala do not truly support temp tables. To emulate temp tables, provide a schema with write privileges where temp tables can be created. outcomeDatabaseSchema The name of the database schema that is the location where the data used to define the outcome cohorts is available. If outcomeTable = "condition_era", outcomeDatabaseSchema is not used. Requires read permissions to this database. outcomeTable The table name that contains the outcome cohorts. If outcomeTable is not "condition_era", then expectation is outcomeTable has format of cohort table (see details).

| <pre>the list contains records found in the cohort_definition_id field. exposureDatabaseSchema The name of the database schema that is the location where the exposure data used to define the exposure eras is available. If exposureTable = "drug_era", exposureDatabaseSchema is not used but assumed to be equal to cdmDatabaseSchema. Requires read permissions to this database. exposureTable The tablename that contains the exposure Cohorts. If exposureTable is not "drug_era", then expectation is exposureTable has format of a cohort table (see details). customCovariateDatabaseSchema The name of the database schema that is the location where the custom covariate data is available. customCovariateTable Name of the table holding the custom covariates. This table should have the same structure as the cohort table (see details). nestingCohortTable Name of the table holding the nesting cohort. This table should have the same structure as the cohort table (see details). getDbSccsDataArgs An object of type GetDbSccsDataArgs as created by the createGetDbSccsDataArgs() </pre> | | | |
|--|-----------------------------|--|--|
| exposureDatabaseSchema The name of the database schema that is the location where the exposure data used to define the exposure eras is available. If exposureTable = "drug_era", exposureDatabaseSchema is not used but assumed to be equal to cdmDatabaseSchema. Requires read permissions to this database. exposureTable The tablename that contains the exposure cohorts. If exposureTable is not "drug_era", then expectation is exposureTable has format of a cohort table (see details). customCovariateDatabaseSchema The name of the database schema that is the location where the custom covariate data is available. customCovariateTable Name of the table holding the custom covariates. This table should have the same structure as the cohort table (see details). nestingCohortDatabaseSchema The name of the database schema that is the location where the nesting cohort is defined. nestingCohortTable Name of the table holding the nesting cohort. This table should have the same structure as the cohort table (see details). nestingCohortTable Name of the table holding the nesting cohort. This table should have the same structure as the cohort table (see details). getDbSccsDataArgs An object of type GetDbSccsDataArgs as created by the createGetDbSccsDataArgs() | outcomeIds | | |
| used to define the exposure eras is available. If exposureTable = "drug_era", exposureDatabaseSchema is not used but assumed to be equal to cdmDatabaseSchema. Requires read permissions to this database. exposureTable The tablename that contains the exposure cohorts. If exposureTable is not "drug_era", then expectation is exposureTable has format of a cohort table (see details). customCovariateDatabaseSchema The name of the database schema that is the location where the custom covariate data is available. customCovariateTable Name of the table holding the custom covariates. This table should have the same structure as the cohort table (see details). nestingCohortDatabaseSchema The name of the database schema that is the location where the nesting cohort is defined. nestingCohortTable Name of the table holding the nesting cohort. This table should have the same structure as the cohort table (see details). nestingCohortTable Name of the table holding the nesting cohort. This table should have the same structure as the cohort table (see details). getDbSccsDataArgs An object of type GetDbSccsDataArgs as created by the createGetDbSccsDataArgs() | exposureDatabas | | |
| <pre>"drug_era", then expectation is exposureTable has format of a cohort table (see details). customCovariateDatabaseSchema The name of the database schema that is the location where the custom covariate data is available. customCovariateTable Name of the table holding the custom covariates. This table should have the same structure as the cohort table (see details). nestingCohortDatabaseSchema The name of the database schema that is the location where the nesting cohort is defined. nestingCohortTable Name of the table holding the nesting cohort. This table should have the same structure as the cohort table (see details). getDbSccsDataArgs An object of type GetDbSccsDataArgs as created by the createGetDbSccsDataArgs()</pre> | | used to define the exposure eras is available. If exposureTable = "drug_era", exposureDatabaseSchema is not used but assumed to be equal to cdmDatabaseSchema. | |
| The name of the database schema that is the location where the custom covariate data is available. ccustomCovariateTable Name of the table holding the custom covariates. This table should have the same structure as the cohort table (see details). nestingCohortDatabaseSchema The name of the database schema that is the location where the nesting cohort is defined. nestingCohortTable Name of the table holding the nesting cohort. This table should have the same structure as the cohort table (see details). getDbSccsDataArgs An object of type GetDbSccsDataArgs as created by the createGetDbSccsDataArgs() | exposureTable | "drug_era", then expectation is exposureTable has format of a cohort table | |
| data is available. customCovariateTable Name of the table holding the custom covariates. This table should have the same structure as the cohort table (see details). nestingCohortDatabaseSchema The name of the database schema that is the location where the nesting cohort is defined. nestingCohortTable Name of the table holding the nesting cohort. This table should have the same structure as the cohort table (see details). getDbSccsDataArgs An object of type GetDbSccsDataArgs as created by the createGetDbSccsDataArgs() | customCovariate | DatabaseSchema | |
| Name of the table holding the custom covariates. This table should have the same structure as the cohort table (see details). nestingCohortDatabaseSchema The name of the database schema that is the location where the nesting cohort is defined. nestingCohortTable Name of the table holding the nesting cohort. This table should have the same structure as the cohort table (see details). getDbSccsDataArgs An object of type GetDbSccsDataArgs as created by the createGetDbSccsDataArgs() | | | |
| same structure as the cohort table (see details). nestingCohortDatabaseSchema The name of the database schema that is the location where the nesting cohort is defined. nestingCohortTable Name of the table holding the nesting cohort. This table should have the same structure as the cohort table (see details). getDbSccsDataArgs An object of type GetDbSccsDataArgs as created by the createGetDbSccsDataArgs() | customCovariate | Pable | |
| The name of the database schema that is the location where the nesting cohort is defined. nestingCohortTable Name of the table holding the nesting cohort. This table should have the same structure as the cohort table (see details). getDbSccsDataArgs An object of type GetDbSccsDataArgs as created by the createGetDbSccsDataArgs() | | • | |
| is defined. nestingCohortTable Name of the table holding the nesting cohort. This table should have the same structure as the cohort table (see details). getDbSccsDataArgs An object of type GetDbSccsDataArgs as created by the createGetDbSccsDataArgs() | nestingCohortDatabaseSchema | | |
| Name of the table holding the nesting cohort. This table should have the same structure as the cohort table (see details). getDbSccsDataArgs An object of type GetDbSccsDataArgs as created by the createGetDbSccsDataArgs() | | - | |
| structure as the cohort table (see details). getDbSccsDataArgs An object of type GetDbSccsDataArgs as created by the createGetDbSccsDataArgs() | nestingCohortTable | | |
| An object of type GetDbSccsDataArgs as created by the createGetDbSccsDataArgs() | | | |
| | getDbSccsDataArgs | | |
| Tuletion. | | An object of type GetDbSccsDataArgs as created by the createGetDbSccsDataArgs() function. | |

Details

This function downloads several types of information:

- Information on the occurrences of the outcome(s) of interest. Note that information for multiple outcomes can be fetched in one go, and later the specific outcome can be specified for which we want to build a model.
- Information on the observation time and age for the people with the outcomes.
- Information on exposures of interest which we want to include in the model.

Five different database schemas can be specified, for five different types of information: The

- cdmDatabaseSchema is used to extract patient age and observation period. The
- · outcomeDatabaseSchema is used to extract information about the outcomes, the
- exposureDatabaseSchema is used to retrieve information on exposures, and the
- **customCovariateDatabaseSchema** is optionally used to find additional, user-defined covariates. All four locations could point to the same database schema.
- **nestingCohortDatabaseSchema** is optionally used to define a cohort in which the analysis is nested, for example a cohort of diabetics patients.

All five locations could point to the same database schema.

Cohort tables are assumed to have the following fields: cohort_definition_id, subject_id, cohort_start_date, and cohort_end_date.

Value

An SccsData object.

Study period start and end dates

A study start and end date define a period when patient data will be included in the analysis. Multiple non-overlapping periods can be defined, which for example will allow for excluding the time of the COVID pandemic, when most outcome rates were unstable.

getDiagnosticsSummary Get a summary report of the analyses diagnostics

Description

Get a summary report of the analyses diagnostics

Usage

```
getDiagnosticsSummary(outputFolder)
```

Arguments

outputFolder Name of the folder where all the outputs have been written to.

Value

A tibble containing summary diagnostics for each outcome-covariate-analysis combination.

getFileReference Get file reference

Description

Get file reference

Usage

getFileReference(outputFolder)

Arguments

outputFolder Name of the folder where all the outputs have been written to.

Value

A tibble containing the names of the files for various artifacts created for each outcome-exposures set.

getModel

Output the full model

Description

Output the full model

Usage

getModel(sccsModel)

Arguments

sccsModel An object of type SccsModel as created using the fitSccsModel() function.

Value

A tibble with the coefficients and confidence intervals (when not-regularized) for all covariates in the model.

getResultsDataModelSpecifications Get specifications for SelfControlledCaseSeries results data model

Description

Get specifications for SelfControlledCaseSeries results data model

Usage

```
getResultsDataModelSpecifications()
```

Value

A tibble data frame object with specifications

getResultsSummary Get a summary report of the analyses results

Description

Get a summary report of the analyses results

Usage

```
getResultsSummary(outputFolder)
```

Arguments

outputFolder Name of the folder where all the outputs have been written to.

Value

A tibble containing summary statistics for each outcome-covariate-analysis combination.

hasAgeEffect Does the model contain an age effect?

Description

Does the model contain an age effect?

Usage

```
hasAgeEffect(sccsModel)
```

Arguments

sccsModel An object of type SccsModel as created using the fitSccsModel() function.

Value

TRUE if the model contains an age effect, otherwise FALSE.

hasCalendarTimeEffect *Does the model contain an age effect?*

Description

Does the model contain an age effect?

Usage

```
hasCalendarTimeEffect(sccsModel)
```

Arguments

sccsModel An object of type SccsModel as created using the fitSccsModel() function.

Value

TRUE if the model contains an age effect, otherwise FALSE.

hasSeasonality Does the model contain an age effect?

Description

Does the model contain an age effect?

Usage

```
hasSeasonality(sccsModel)
```

Arguments

sccsModel An object of type SccsModel as created using the fitSccsModel() function.

Value

TRUE if the model contains an age effect, otherwise FALSE.

isSccsData

Description

Check whether an object is a SccsData object

Usage

isSccsData(x)

Arguments

x The object to check.

Value

A logical value.

isSccsIntervalData Check whether an object is a SccsIntervalData object

Description

Check whether an object is a SccsIntervalData object

Usage

```
isSccsIntervalData(x)
```

Arguments

x The object to check.

Value

A logical value.

loadExposuresOutcomeList

Load a list of ExposuresOutcome from file

Description

Load a list of objects of type ExposuresOutcome from file. The file is in JSON format.

Usage

loadExposuresOutcomeList(file)

Arguments

file The name of the file

Value

A list of objects of type ExposuresOutcome.

loadSccsAnalysisList Load a list of sccsAnalysis from file

Description

Load a list of objects of type SccsAnalysis from file. The file is in JSON format.

Usage

```
loadSccsAnalysisList(file)
```

Arguments

file The name of the file

Value

A list of objects of type SccsAnalysis.

loadSccsData

Description

Loads an object of type SccsData from a file in the file system.

Usage

```
loadSccsData(file)
```

Arguments

file The name of the file containing the data.

Value

An object of class SccsData.

loadSccsIntervalData Load the cohort method data from a file

Description

Loads an object of type SccsIntervalData from a file in the file system.

Usage

```
loadSccsIntervalData(file)
```

Arguments

file The name of the file containing the data.

Value

An object of class SccsIntervalData.

migrateDataModel Migrate Data model

Description

Migrate data from current state to next state

It is strongly advised that you have a backup of all data (either sqlite files, a backup database (in the case you are using a postgres backend) or have kept the csv/zip files from your data generation.

Usage

```
migrateDataModel(connectionDetails, databaseSchema, tablePrefix = "")
```

Arguments

| connectionDetails | | |
|-------------------|--|--|
| | DatabaseConnector connection details object | |
| databaseSchema | String schema where database schema lives | |
| tablePrefix | (Optional) Use if a table prefix is used before table names (e.g. "cd_") | |

| plotAgeEffect | Plot the age effect | |
|---------------|---------------------|--|
|---------------|---------------------|--|

Description

Plot the age effect

Usage

```
plotAgeEffect(sccsModel, rrLim = c(0.1, 10), title = NULL, fileName = NULL)
```

Arguments

| sccsModel | An object of type sccsModel as created using the fitSccsModel function. |
|-----------|--|
| rrLim | The limits on the incidence rate ratio scale in the plot. |
| title | Optional: the main title for 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. |

Details

Plot the spline curve of the age effect.

Value

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

plotAgeSpans

Description

Plot the age ranges spanned by each observation period.

Usage

```
plotAgeSpans(
   studyPopulation,
   maxPersons = 10000,
   title = NULL,
   fileName = NULL
)
```

Arguments

studyPopulation

| 5 | An object created using the createStudyPopulation() function. |
|------------|---|
| maxPersons | The maximum number of persons to plot. If there are more than this number of persons a random sample will be taken to avoid visual clutter. |
| title | Optional: the main title for the plot |
| fileName | Name of the file where the plot should be saved, for example 'plot.png'. See the function ggplot2::ggsave() for supported file formats. |

Details

Plots a line per patient from their age at observation start to their age at observation end.

Value

A ggplot object. Use the ggplot2::ggsave() function to save to file in a different format.

plotCalendarTimeEffect

Plot the calendar time effect

Description

Plot the calendar time effect

plotCalendarTimeSpans

Usage

```
plotCalendarTimeEffect(
  sccsModel,
  rrLim = c(0.1, 10),
  title = NULL,
  fileName = NULL
)
```

Arguments

| sccsModel | An object of type sccsModel as created using the fitSccsModel function. |
|-----------|---|
| rrLim | The limits on the incidence rate ratio scale in the plot. |
| title | Optional: the main title for 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. |

Details

Plot the spline curve of the calendar time effect.

Value

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

plotCalendarTimeSpans Plot the calendar time ranges spanned by each observation period.

Description

Plot the calendar time ranges spanned by each observation period.

Usage

```
plotCalendarTimeSpans(
   studyPopulation,
   maxPersons = 10000,
   title = NULL,
   fileName = NULL
)
```

Arguments

| studyPopulati | on |
|---------------|---|
| | An object created using the createStudyPopulation() function. |
| maxPersons | The maximum number of persons to plot. If there are more than this number of persons a random sample will be taken to avoid visual clutter. |
| title | Optional: the main title for the plot |
| fileName | Name of the file where the plot should be saved, for example 'plot.png'. See the function ggplot2::ggsave() for supported file formats. |

Details

Plots a line per patient from their observation start to their observation end.

Value

A ggplot object. Use the ggplot2::ggsave() function to save to file in a different format.

| plotEventObservationD | ependence |
|-----------------------|---|
| | Plot time from event to observation end for censored and uncensored time. |

Description

Plot time from event to observation end for censored and uncensored time.

Usage

```
plotEventObservationDependence(studyPopulation, title = NULL, fileName = NULL)
```

Arguments

| studyPopulatio | n |
|----------------|--|
| | An object created using the createStudyPopulation() function. |
| title | Optional: the main title for the plot |
| fileName | Name of the file where the plot should be saved, for example 'plot.png'. See the |
| | function ggplot2::ggsave() for supported file formats. |

Details

This plot shows whether there is a difference in time between (first) event and the observation period end for periods that are 'censored' and those that are 'uncensored'. By 'censored' we mean periods that end before we would normally expect. Here, we define periods to be uncensored if they end at either the study end date (if specified), database end date (i.e. the date after which no data is captured in the database), or maximum age (if specified). All other periods are assumed to be censored.

As proposed by Farrington et al., by comparing the two plots, we can gain some insight into whether the censoring is dependent on the occurrence of the event.

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Value

A ggplot object. Use the ggplot2::ggsave() function to save to file in a different format.

References

Farrington P, Whitaker H, Ghebremichael Weldeselassie Y (2018), Self-controlled case series studies: A modelling guide with R, Taylor & Francis

```
plotEventToCalendarTime
```

Plot the ratio of observed to expected events over calendar time.

Description

Plot the ratio of observed to expected events over calendar time.

Usage

```
plotEventToCalendarTime(
   studyPopulation,
   sccsModel = NULL,
   title = NULL,
   fileName = NULL
)
```

Arguments

studyPopulation

| 5 1 | An object created using the createStudyPopulation() function. |
|-----------|---|
| sccsModel | Optional: A fitted SCCS model as created using fitSccsModel(). If the model contains splines for seasonality and or calendar time a panel will be added with outcome counts adjusted for these splines. |
| title | Optional: the main title for the plot |
| fileName | Name of the file where the plot should be saved, for example 'plot.png'. See the function ggplot2::ggsave() for supported file formats. |

Details

Plot the ratio of observed to expected events over calendar time. The expected count expected rate considers which persons were observed during that month, and if specified in the model, the adjustment for season and calendar time.

Value

A ggplot object. Use the ggplot2::ggsave() function to save to file in a different format.

plotExposureCentered Plot information centered around the start of exposure

Description

Plot information centered around the start of exposure

Usage

```
plotExposureCentered(
  studyPopulation,
  sccsData,
  exposureEraId = NULL,
  highlightExposedEvents = TRUE,
  title = NULL,
  fileName = NULL
)
```

Arguments

| studyPopulation | I |
|--|---|
| | An object created using the createStudyPopulation() function. |
| sccsData | An object of type SccsData as created using the getDbSccsData function. |
| exposureEraId | The exposure to create the era data for. If not specified it is assumed to be the one exposure for which the data was loaded from the database. |
| highlightExposedEvents Highlight events that occurred during the exposure era using a different color | |
| title | Optional: the main title for the plot |
| fileName | Name of the file where the plot should be saved, for example 'plot.png'. See the function ggplot2::ggsave() for supported file formats. |

Details

This plot shows the number of events and the number of subjects under observation in week-sized intervals relative to the start of the first exposure.

Value

A ggplot object. Use the ggplot2::ggsave() function to save to file in a different format.

Description

Plot the seasonality effect

Usage

```
plotSeasonality(sccsModel, rrLim = c(0.1, 10), title = NULL, fileName = NULL)
```

Arguments

| sccsModel | An object of type sccsModel as created using the fitSccsModel function. |
|-----------|---|
| rrLim | The limits on the incidence rate ratio scale in the plot. |
| title | Optional: the main title for 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. |

Details

Plot the spline curve of the seasonality effect.

Value

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

runSccsAnalyses Run a list of analyses

Description

Run a list of analyses

Usage

```
runSccsAnalyses(
  connectionDetails,
  cdmDatabaseSchema,
  tempEmulationSchema = getOption("sqlRenderTempEmulationSchema"),
  exposureDatabaseSchema = cdmDatabaseSchema,
  exposureTable = "drug_era",
  outcomeDatabaseSchema = cdmDatabaseSchema,
  outcomeTable = "cohort",
  customCovariateDatabaseSchema = cdmDatabaseSchema,
```

```
customCovariateTable = "cohort",
nestingCohortDatabaseSchema = cdmDatabaseSchema,
nestingCohortTable = "cohort",
outputFolder,
sccsMultiThreadingSettings = createSccsMultiThreadingSettings(),
sccsAnalysesSpecifications
```

Arguments

)

```
connectionDetails
```

An R object of type ConnectionDetails created using the function DatabaseConnector::createConne cdmDatabaseSchema

The name of the database schema that contains the OMOP CDM instance. Requires read permissions to this database. On SQL Server, this should specify both the database and the schema, so for example 'cdm_instance.dbo'.

tempEmulationSchema

Some database platforms like Oracle and Impala do not truly support temp tables. To emulate temp tables, provide a schema with write privileges where temp tables can be created.

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 but assumed to be cdmDatabaseSchema. Requires read permissions to this database.

exposureTable The table name that contains the exposure cohorts. If exposureTable <> "DRUG_ERA", then expectation is exposureTable 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. Requires read permissions to this database.

outcomeTable The table name that contains the outcome cohorts.

customCovariateDatabaseSchema

The name of the database schema that is the location where the custom covariate data is available.

customCovariateTable

Name of the table holding the custom covariates. This table should have the same structure as the cohort table.

nestingCohortDatabaseSchema

The name of the database schema that is the location where the nesting cohort is defined.

nestingCohortTable

Name of the table holding the nesting cohort. This table should have the same structure as the cohort table.

outputFolder Name of the folder where all the outputs will written to.

sccsMultiThreadingSettings

An object of type SccsMultiThreadingSettings as created using the createSccsMultiThreadingSett or createDefaultSccsMultiThreadingSettings() functions.

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An object of type SccsAnalysesSpecifications as created using the createSccsAnalysesSpecificat function

Details

Run a list of analyses for the exposures-outcomes of interest. This function will run all specified analyses against all hypotheses of interest, meaning that the total number of outcome models is length(sccsAnalysisList) * length(exposuresOutcomeList) When you provide several analyses it will determine whether any of the analyses have anything in common, and will take advantage of this fact.

Analyses to Exclude:

Normally, runSccsAnalyses will run all combinations of exposures-outcome-analyses settings. However, sometimes we may not need all those combinations. Using the analysesToExclude argument, we can remove certain items from the full matrix. This argument should be a data frame with at least one of the following columns:

- exposureId
- outcomeId
- nestingCohortId
- analysisId

This data frame will be joined to the outcome model reference table before executing, and matching rows will be removed. For example, if one specifies only one exposure ID and analysis ID, then any analyses with that exposure and that analysis ID will be skipped.

Value

A tibble describing for each exposure-outcome-analysisId combination where the intermediary and outcome model files can be found, relative to the outputFolder.

saveExposuresOutcomeList

Save a list of ExposuresOutcome to file

Description

Write a list of objects of type ExposuresOutcome to file. The file is in JSON format.

Usage

saveExposuresOutcomeList(exposuresOutcomeList, file)

Arguments

| exposuresOutcomeList | |
|----------------------|--|
| | A list of objects of type ExposuresOutcome as created using the createExposuresOutcome() |
| | function. |
| file | The name of the file where the results will be written |

saveSccsAnalysisList Save a list of SccsAnalysis to file

Description

Write a list of objects of type SccsAnalysis to file. The file is in JSON format.

Usage

```
saveSccsAnalysisList(sccsAnalysisList, file)
```

Arguments

| sccsAnalysisLi | st |
|----------------|--|
| | A list of objects of type SccsAnalysis as created using the createSccsAnalysis() function. |
| file | The name of the file where the results will be written |

| saveSccsData | Save the cohort method data to file |
|--------------|-------------------------------------|
|--------------|-------------------------------------|

Description

Saves an object of type SccsData to a file.

Usage

```
saveSccsData(sccsData, file)
```

Arguments

| sccsData | An object of type SccsData as created using the getDbSccsData function. | |
|----------|--|--|
| file | The name of the file where the data will be written. If the file already exists it | |
| | will be overwritten. | |

Value

Returns no output.

saveSccsIntervalData Save the cohort method data to file

Description

Saves an object of type SccsIntervalData to a file.

Usage

```
saveSccsIntervalData(sccsIntervalData, file)
```

Arguments

f

sccsIntervalData

| | An object of type SccsIntervalData as created using the createSccsIntervalData function. |
|------|---|
| file | The name of the file where the data will be written. If the file already exists it will be overwritten. |

Value

Returns no output.

SccsData-class SCCS Data

Description

SccsData is an S4 class that inherits from Andromeda. It contains information on the cases and their covariates.

A SccsData is typically created using getDbSccsData(), can only be saved using saveSccsData(), and loaded using loadSccsData().

Usage

S4 method for signature 'SccsData'
show(object)

S4 method for signature 'SccsData'
summary(object)

Arguments

object An object of type SccsData.

SccsIntervalData-class

SCCS Interval Data

Description

SccsIntervalData' is an S4 class that inherits from Andromeda. It contains information on the cases and their covariates, divided in non-overlapping time intervals.

A SccsIntervalData is typically created using createSccsIntervalData(), can only be saved using saveSccsIntervalData(), and loaded using loadSccsIntervalData().

Usage

S4 method for signature 'SccsIntervalData'
show(object)

S4 method for signature 'SccsIntervalData'
summary(object)

Arguments

object An object of type SccsIntervalData.

simulateSccsData Simulate SCCS data

Description

Simulate SCCS data

Usage

simulateSccsData(nCases, settings)

Arguments

| nCases | The number of cases to simulate. |
|----------|--|
| settings | An object of type SccsSimulationSettings as created using the createSccsSimulationSettings() function. |

Value

An object of type SccsData.

uploadResults

Description

Requires the results data model tables have been created using the createResultsDataModel function.

Usage

```
uploadResults(
  connectionDetails,
  schema,
  zipFileName,
  forceOverWriteOfSpecifications = FALSE,
  purgeSiteDataBeforeUploading = TRUE,
  tempFolder = tempdir(),
  tablePrefix = "",
  ...
)
```

Arguments

```
connectionDetails
                   An object of type connectionDetails as created using the createConnectionDetails
                  function in the DatabaseConnector package.
schema
                  The schema on the server where the tables have been created.
zipFileName
                  The name of the zip file.
forceOverWriteOfSpecifications
                  If TRUE, specifications of the phenotypes, cohort definitions, and analysis will
                  be overwritten if they already exist on the database. Only use this if these spec-
                  ifications have changed since the last upload.
purgeSiteDataBeforeUploading
                   If TRUE, before inserting data for a specific databaseId all the data for that site
                   will be dropped. This assumes the input zip file contains the full data for that
                  data site.
tempFolder
                   A folder on the local file system where the zip files are extracted to. Will be
                  cleaned up when the function is finished. Can be used to specify a temp folder
                  on a drive that has sufficient space if the default system temp space is too limited.
tablePrefix
                   (Optional) string to insert before table names for database table names
                  See ResultModelManager::uploadResults
. . .
```

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