# Package 'SelfControlledCaseSeries'

April 7, 2025

Type Package

```
Title Self-Controlled Case Series
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Maintainer Martijn Schuemie <schuemie@ohdsi.org>
Description SelfControlledCaseSeries is an R package for performing self-
      controlled case series (SCCS) analyses in an observational database in the OMOP
      Common Data Model. It 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.
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URL https://ohdsi.github.io/SelfControlledCaseSeries/, https:
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BugReports https://github.com/OHDSI/SelfControlledCaseSeries/issues
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```

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compute Mdrr

 $Compute \ the \ minimum \ detectable \ relative \ risk$ 

# 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.

exposureCovariateId

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

Compute P for pre-exposure risk gain

### Usage

computePreExposureGainP(sccsData, studyPopulation, exposureEraId = NULL)

# **Arguments**

sccsData An object of type SccsData as created using the getDbSccsData function.

studyPopulation

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.

computeTimeStability

#### **Details**

Compares the rate of the outcome in the 30 days prior to exposure to the rate of the outcome in the 30 days following exposure. If the rate before exposure is higher, this indicates there might reverse causality, that the outcome, or some precursor of the outcome, increases the probability of having the exposure.

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The resulting p-value is computed using a Poisson model conditioned on the person.

### Value

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

computeTimeStability Compute stability of outcome rate over time

### **Description**

Compute stability of outcome rate over time

# Usage

```
computeTimeStability(
  studyPopulation,
  sccsModel = NULL,
  maxRatio = 1.25,
  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 stable is TRUE if p is greater than alpha.

createAgeCovariateSettings

Create age covariate settings

### **Description**

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.

create Calendar Time Covariate Settings

Create calendar time settings

### **Description**

Create calendar time settings

```
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 seasonalitySettings.

 ${\tt createControlIntervalSettings}$ 

Create control interval settings

# **Description**

Create control interval settings

```
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 ControlSettings.

 $create {\tt Create Sccs Interval Data Args}$ 

Create a parameter object for the function createSccsIntervalData

# Description

Create a parameter object for the function createSccsIntervalData

```
createCreateSccsIntervalDataArgs(
  eraCovariateSettings,
  ageCovariateSettings = NULL,
  seasonalityCovariateSettings = NULL,
  calendarTimeCovariateSettings = NULL,
  minCasesForAgeSeason = NULL,
  minCasesForTimeCovariates = 10000,
  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.

seasonality Covariate Settings

An object of type seasonalityCovariateSettings as created using the createSeasonalityCovariateSettings() function.

calendarTimeCovariateSettings

An object of type calendarTimeCovariateSettings as created using the create-CalendarTimeCovariateSettings() function.

minCasesForAgeSeason

 $DEPRECATED: \ Use \ min Cases For Time Covariates \ instead.$ 

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.

eventDependentObservation

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

# Details

Create an object defining the parameter values.

createCreateScriIntervalDataArgs

Create a parameter object for the function createScriIntervalData

# **Description**

Create a parameter object for the function createScriIntervalData

### 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.

createCreateStudyPopulationArgs

Create a parameter object for the function createStudyPopulation

### **Description**

Create a parameter object for the function createStudyPopulation

# 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 after the minimum age (e.g. when a prescription was started just prior to reaching 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.

# restrict Time To Era Id

If provided, study time (for all patients) will be restricted to the calender 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.

# **Details**

Create an object defining the parameter values.

 ${\tt createDefaultSccsMultiThreadingSettings}$ 

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
)
```

#### **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".

firstOccurrenceOnly

Should only the first occurrence of the exposure be used?

allowRegularization

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

createExposure 13

# profileLikelihood

When fitting the model, should the likelihood profile be computed for the covariate defined here? The likelihood profile can be used to avoid making normal approximations on the likelihood and can be used in methods specifically designed 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().

### **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 createEraCovariateSetting

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().

nestingCohortId

(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))
)
```

#### **Arguments**

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 de-

tails.

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.

createGetDbSccsDataArgs

Create a parameter object for the function getDbSccsData

# **Description**

Create a parameter object for the function getDbSccsData

### Usage

```
createGetDbSccsDataArgs(
  useCustomCovariates = FALSE,
  useNestingCohort = FALSE,
  nestingCohortId = NULL,
  deleteCovariatesSmallCount = 0,
  studyStartDate = "",
  studyEndDate = "",
  studyEndDates = c(),
  studyEndDates = c(),
  maxCasesPerOutcome = 0,
  exposureIds = "exposureId",
  customCovariateIds = ""
```

# **Arguments**

useCustomCovariates

DEPRECATED. Set customCovariateIds to non-null value to use custom co-horts.

useNestingCohort

DEPRECATED. Set nestingCohortId to non-null value to use a nesting cohort.

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.

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studyStartDate DEPRECATED. Use studyStartDates instead. studyEndDate DEPRECATED. Use studyEndDates instead. studyStartDates

A character object specifying the minimum dates where data is used. Date format 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.

maxCasesPerOutcome

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.

customCovariateIds

A list of cohort definition IDs identifying the records in the customCovariateTable to use for building custom covariates.

#### **Details**

Create an object defining the parameter values.

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

# **Details**

Only PostgreSQL and SQLite servers are supported.

createSccsAnalysis 17

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.

getDbSccsDataArgs

An object representing the arguments to be used when calling the getDbSccs-Data function.

 ${\tt createStudyPopulationArgs}$ 

An object representing the arguments to be used when calling the getDbSccs-Data function.

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.

create Sccs Diagnostic Thresholds

Create SCCS diagnostics thresholds

# **Description**

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

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#### Usage

```
createSccsDiagnosticThresholds(
  mdrrThreshold = 10,
  easeThreshold = 0.25,
  timeTrendPThreshold = 0.05,
  preExposurePThreshold = 0.05
)
```

# **Arguments**

mdrrThreshold What is the maximum allowed minimum detectable relative risk (MDRR)? easeThreshold What is the maximum allowed expected absolute systematic error (EASE). timeTrendPThreshold

 $\label{p-value} What \ p-value \ threshold \ (alpha) \ will \ be \ used \ to \ determine \ temporal \ instability?$  preExposurePThreshold

What p-value threshold (alpha) will be used to determine whether the rate of the outcome was higher just before exposure initiation?

### Value

An object of type SccsDiagnosticThresholds.

createSccsIntervalData

Create SCCS era data

# Description

Create SCCS era data

#### Usage

```
createSccsIntervalData(
   studyPopulation,
   sccsData,
   eraCovariateSettings,
   ageCovariateSettings = NULL,
   seasonalityCovariateSettings = NULL,
   calendarTimeCovariateSettings = NULL,
   minCasesForAgeSeason = NULL,
   minCasesForTimeCovariates = 10000,
   eventDependentObservation = FALSE
)
```

# Arguments

studyPopulation

An object created using the createStudyPopulation() function.

sccsData An object of type SccsData as created using the getDbSccsData function.

### 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 createSeasonalityCovar function.

### calendar Time Covariate Settings

An object of type calendarTimeCovariateSettings as created using the createCalendarTimeCov function.

# minCasesForAgeSeason

DEPRECATED: Use minCasesForTimeCovariates instead.

### 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.

#### eventDependentObservation

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

### **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.

### 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

 ${\tt createSccsMultiThreadingSettings}$ 

Create SelfControlledCaseSeries multi-threading settings

# **Description**

Create SelfControlledCaseSeries multi-threading settings

```
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.

 ${\tt calibrationThreads}$ 

The number of parallel threads to use for empirical calibration.

# Value

An object of type SccsMultiThreadingSettings.

#### See Also

createDefaultSccsMultiThreadingSettings()

 ${\tt createSccsSimulationSettings}$ 

Create SCCS simulation settings

# Description

Create SCCS simulation settings

```
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),
 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,
 outcomeId = 10
)
```

# **Arguments**

sdPrescriptionDurations

meanPatientTime Mean number of observation days per patient. Standard deviation of the observation days per patient. sdPatientTime minAge The minimum age in days. maxAge The maximum age in days. minBaselineRate The minimum baseline rate (per day). maxBaselineRate The maximum baseline rate (per day). minCalendarTime The minimum date patients are to be observed. maxCalendarTime The maximum date patients are to be observed. eraIds The IDs for the covariates to be generated. patientUsages The fraction of patients that use the drugs. usageRate The rate of prescriptions per person that uses the drug. meanPrescriptionDurations The mean duration of a prescription, per drug.

The standard deviation of the duration of a prescription, per drug.

22 createScriIntervalData

simulationRiskWindows

One or a list of objects of type SimulationRiskWindow as created using the createSimulationRiskWindow() function. function.

includeAgeEffect

Include an age effect for the outcome?

ageKnots Number of knots in the age spline.

includeSeasonality

Include seasonality for the outcome?

seasonKnots Number of knots in the seasonality spline.

include Calendar Time Effect

Include a calendar time effect for the outcome?

calendarTimeKnots

Number of knots in the calendar time spline.

outcomeId The ID to be used for the outcome.

# **Details**

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,
   eraCovariateSettings,
   controlIntervalSettings)
```

# **Arguments**

studyPopulation

An object created using the createStudyPopulation() function.

sccsData An object of type SccsData as created using the getDbSccsData function.

eraCovariateSettings

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

 ${\tt controlIntervalSettings}$ 

An object of type ControlIntervalSettings as created using the createControlIntervalSettin 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.

 ${\tt create Seasonality Covariate Settings}$ 

Create seasonality settings

# Description

Create seasonality settings

### Usage

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

# **Arguments**

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.

 $\verb|allowRegularization| \\$ 

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 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 seasonalitySettings.

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)
)
```

### **Arguments**

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.

splitPoints have been defined a vector of relative risks, one for each sub-window.

# Value

An object of type SimulationRiskWindow.

createStudyPopulation 25

createStudyPopulation Create a study population

# **Description**

Create a study population

### Usage

```
createStudyPopulation(
  sccsData,
  outcomeId = NULL,
  firstOutcomeOnly = FALSE,
  naivePeriod = 0,
  minAge = NULL,
  maxAge = NULL,
  genderConceptIds = NULL,
  restrictTimeToEraId = NULL)
```

### **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.

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 after the minimum age (e.g. when a prescription was started just prior to reaching 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 calender 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.

26 exportToCsv

#### **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**

x 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.

exportToCsv

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,
  sccsDiagnosticThresholds = createSccsDiagnosticThresholds()
)
```

fitSccsModel 27

### **Arguments**

 $output Folder \qquad The \ folder \ where \ runCmAnalyses () \ generated \ all \ results.$ 

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.

sccsDiagnosticThresholds

An object of type SccsDiagnosticThresholds as created using createSccsDiagnosticThreshold

#### **Details**

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,
  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))
)
```

# **Arguments**

sccsIntervalData

An object of type SccsIntervalData as created using the createSccsIntervalData

function.

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 de-

tails.

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.

28 getAttritionTable

#### **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 user-defined 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

 ${\tt getAttritionTable}$ 

Get the attrition table for a population

# **Description**

Get the attrition table for a population

# Usage

getAttritionTable(object)

# **Arguments**

object

Either 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 29

getDataMigrator

Get database migrations instance

### **Description**

Returns ResultModelManager DataMigrationsManager instance.

### Usage

```
getDataMigrator(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_")
```

#### Value

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

getDbSccsData

Load data for SCCS from the database

### **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",
  exposureIds = c(),
 useCustomCovariates = FALSE,
  customCovariateDatabaseSchema = cdmDatabaseSchema,
  customCovariateTable = "cohort",
  customCovariateIds = c(),
 useNestingCohort = FALSE,
 nestingCohortDatabaseSchema = cdmDatabaseSchema,
 nestingCohortTable = "cohort",
```

30 getDbSccsData

```
nestingCohortId = NULL,
deleteCovariatesSmallCount = 0,
studyStartDate = "",
studyEndDate = "",
studyStartDates = c(),
studyEndDates = c(),
cdmVersion = "5",
maxCasesPerOutcome = 0
)
```

### **Arguments**

#### connectionDetails

An R object of type ConnectionDetails created using the function DatabaseConnector::createCofunction.

#### 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.

outcome Table

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).

outcomeIds

A list of IDs used to define outcomes. If outcomeTable is not "condition\_era" 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).

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.

### useCustomCovariates

#### customCovariateDatabaseSchema

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

getDbSccsData 31

customCovariateTable

Name of the table holding the custom covariates. This table should have the same structure as the cohort table (see details).

customCovariateIds

A list of cohort definition IDs identifying the records in the customCovariateTable to use for building custom covariates.

useNestingCohort

DEPRECATED. Set nestingCohortId to non-null value to use a nesting cohort.

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).

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.

studyStartDate DEPRECATED. Use studyStartDates instead.

studyEndDate DEPRECATED. Use studyEndDates instead.

studyStartDates

A character object specifying the minimum dates where data is used. Date format 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.

cdmVersion Define the OMOP CDM version used: currently supports "5". maxCasesPerOutcome

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.

### **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

32 getFileReference

• **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.

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 33

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.

 ${\tt getResultsDataModelSpecifications}$ 

 $Get\ specifications\ for\ Self Controlled Case Series\ results\ data\ model$ 

# Description

Get specifications for SelfControlledCaseSeries results data model

# Usage

getResultsDataModelSpecifications()

# Value

A tibble data frame object with specifications

34 hasAgeEffect

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.

has Age Effect

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 35

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.

36 isSccsIntervalData

isSccsData

Check whether an object is a SccsData object

# Description

Check whether an object is a SccsData object

# Usage

```
isSccsData(x)
```

# **Arguments**

Χ

The object to check.

# Value

A logical value.

 $\verb"isSccsIntervalData"$ 

Check whether an object is a SccsIntervalData object

# Description

Check whether an object is a SccsIntervalData object

# Usage

```
isSccsIntervalData(x)
```

# Arguments

Х

The object to check.

# Value

A logical value.

 ${\tt loadExposuresOutcomeList}$ 

 $Load\ a\ list\ of\ {\it ExposuresOutcome}\ from\ file$ 

# 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.

38 loadSccsIntervalData

loadSccsData

Load the cohort method data from a file

# 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.

 ${\tt loadSccsIntervalData} \quad \textit{Load the cohort method data from a file}$ 

# 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 39

nigrateDataModel 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

Plot the age ranges spanned by each observation period.

# Description

Plot the age ranges spanned by each observation period.

## Usage

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

#### **Arguments**

studyPopulation

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

#### 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**

studyPopulation

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.

plotEventObservationDependence

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**

studyPopulation

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.

#### 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

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

44 plotSeasonality

#### **Usage**

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

## **Arguments**

studyPopulation

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.

plotSeasonality Plot the seasonality effect

#### **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.

runSccsAnalyses 45

#### **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",
  cdmVersion = "5",
 outputFolder = "./SccsOutput",
  sccsAnalysisList,
  exposuresOutcomeList,
  analysesToExclude = NULL,
  combineDataFetchAcrossOutcomes = FALSE,
  sccsMultiThreadingSettings = createSccsMultiThreadingSettings(),
  controlType = "outcome"
)
```

# Arguments

connectionDetails

 $An\ R\ object\ of\ type\ {\tt ConnectionDetails}\ created\ using\ the\ function\ {\tt DatabaseConnector::creat$ 

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.

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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.

ett

Define the OMOP CDM version used: currently supports "5".

cdmVersion
outputFolder

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

sccsAnalysisList

A list of objects of 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.

sccsMultiThreadingSettings

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

control Type

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.

#### **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 mod-

els 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.

save Exposures Outcome List

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

The ExposuresOutcome list to be written to file

The name of the file where the results will be written

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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

sccsAnalysisList

The SccsAnalysis list to be written to file

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 49

saveSccsIntervalData Save the cohort method data to file

#### **Description**

Saves an object of type SccsIntervalData to a file.

## Usage

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

## **Arguments**

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.

50 simulateSccsData

```
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 ob

An object of type SccsIntervalData.

simulateSccsData

Simulate SCCS data

# Description

Simulate SCCS data

## Usage

```
simulateSccsData(nCases, settings)
```

#### **Arguments**

nCases Th

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 51

uploadResults $U_{I}$	load results to the database server.
-----------------------	--------------------------------------

## **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 connection Details 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 specifications have changed since the last upload.

 $\verb"purgeSiteDataBeforeUploading"$ 

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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