# ${\bf Package\ 'Self Controlled Case Series'}$

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Type Package

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<b>Description</b> SelfControlledCaseSeries is an R package for performing Self-Controlled Case Series (SCCS) analyses in an observational database in the OMOP Common Data Model.
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createAgeSettings createCovariateSettings createSccsEraData createSccsSimulationSettings createSeasonalitySettings

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createAgeSettings

Create age settings

# **Description**

Create age settings

# Usage

```
createAgeSettings(includeAge = FALSE, ageKnots = 5,
  allowRegularization = FALSE)
```

#### Arguments

includeAge

Should age be included in the model?

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 numer is provided these are assumed to be the exact location of the knots in age-days

 ${\it allow} {\it Regularization}$ 

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

#### **Details**

Create an object specifing 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 cubic spline.

#### Value

An object of type ageSettings.

createCovariateSettings

createCovariateSettings

Create covariate settings

#### **Description**

Create covariate settings

#### Usage

```
createCovariateSettings(includeCovariateIds = NULL,
  excludeCovariateIds = NULL, label = "Covariates", stratifyById = TRUE,
  start = 0, addExposedDaysToStart = FALSE, end = 0,
  addExposedDaysToEnd = FALSE, firstOccurrenceOnly = FALSE,
  splitPoints = c(), allowRegularization = FALSE)
```

# **Arguments**

includeCovariateIds

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.

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excludeCovariateIds

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.

The start of the risk window in days, relative to the exposure start date. start addExposedDaysToStart

Should the length of exposure be added to the start date?

The start of the risk window in days, relative to the exposure start date. end addExposedDaysToEnd

Should the length of exposure be added to the end date?

firstOccurrenceOnly

Should only the first occurrence of the exposure be used?

splitPoints

To split the risk window into several smaller windows, specify the end of each sub- window relative to the start of the main risk window. If addExposed-DaysToStart is TRUE, the split points will be considered to be relative to the end of the main risk window instead.

allowRegularization

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

#### **Details**

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

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#### Value

An object of type covariateSettings.

createSccsEraData

Create SCCS era data

#### **Description**

Create SCCS era data

#### Usage

```
createSccsEraData(sccsData, outcomeId = NULL, naivePeriod = 0,
  firstOutcomeOnly = FALSE, covariateSettings,
  ageSettings = createAgeSettings(includeAge = FALSE),
  seasonalitySettings = createSeasonalitySettings(includeSeasonality = FALSE),
  eventDependentObservation = FALSE)
```

# 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.

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.

firstOutcomeOnly

Whether only the first occurrence of an outcome should be considered.

covariateSettings

 $Either an object of type \ covariate Settings \ as \ created \ using \ the \ create Covariate Settings$ 

function, or a list of such objects.

ageSettings An object of type ageSettings as created using the createAgeSettings func-

tion.

seasonalitySettings

An object of type seasonalitySettings as created using the createSeasonalitySettings

function.

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 object, 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 sccsEraData.

#### 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

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, covariateIds = 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,
outcomeId = 10)
```

#### **Arguments**

meanPatientTime

Mean number of observation days per patient.

sdPatientTime Standard deviation of the observation days per patient.

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).

covariateIds 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.

 ${\it sdPrescriptionDurations}$ 

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

simulationRiskWindows

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.

includeSeasonality

Include seasonality for the outcome?

seasonKnots Number of knots in the seasonality 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.

createSeasonalitySettings

Create seasonality settings

# Description

Create seasonality settings

#### Usage

```
createSeasonalitySettings(includeSeasonality = FALSE, seasonKnots = 5,
   allowRegularization = FALSE)
```

# **Arguments**

includeSeasonality

Should seasonlaity be included in the model?

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 equaly spaced across the year. If more than one numer 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?

## **Details**

Create an object specifing 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 cubic spline.

# Value

An object of type seasonality Settings.

createSimulationRiskWindow

Create a risk window definition for simulation

#### **Description**

Create a risk window definition for simulation

## Usage

```
createSimulationRiskWindow(start = 0, end = 0, addExposedDaysToEnd = TRUE, splitPoints = c(), relativeRisks = c(0))
```

#### **Arguments**

start Start of the risk window relative to exposure start.

end End of risk window relative to exposure start, or if addExposedDaysToEnd is

TRUE, relative to the end date.

addExposedDaysToEnd

Should the length of exposure be added to the end date? In other words, should

the exposure end date be used as reference point for the risk window 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.

cyclicSplineDesign Create a design matrix for a cyclic spline

#### **Description**

Create a design matrix for a cyclic spline

# Usage

```
cyclicSplineDesign(x, knots, ord = 4)
```

#### **Arguments**

x Vector of coordinates of the points to be interpolated.

knots Location of the knots.

ord Order of the spline function.

# **Details**

This function is used by other functions in this package.

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Fit the SCCS model

#### **Description**

Fit the SCCS model

## Usage

```
fitSccsModel(sccsEraData, prior = createPrior("laplace", useCrossValidation =
   TRUE), control = createControl(cvType = "auto", selectorType = "byPid",
   startingVariance = 0.1, noiseLevel = "quiet"))
```

#### **Arguments**

sccsEraData An object of type sccsEraData as created using the createSccsEraData func-

tion.

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

control The control object used to control the cross-validation used to determine the

hyperparameters of the prior (if applicable). See createControl for details.

#### **Details**

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

#### Value

An object of type sccsModel. eneric function summary, coef, and confint are available.

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,
  oracleTempSchema = cdmDatabaseSchema,
  outcomeDatabaseSchema = cdmDatabaseSchema,
  outcomeTable = "condition_occurrence", outcomeIds,
  outcomeConditionTypeConceptIds = c(),
  exposureDatabaseSchema = cdmDatabaseSchema, exposureTable = "drug_era",
  exposureIds = c(), useCustomCovariates = FALSE,
  customCovariateDatabaseSchema = cdmDatabaseSchema,
  customCovariateTable = "cohort", customCovariateIds = c(),
  deleteCovariatesSmallCount = 100, cdmVersion = "4")
```

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#### **Arguments**

connectionDetails

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

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'.

oracleTempSchema

A schema where temp tables can be created in Oracle.

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 tablename that contains the outcome cohorts. If outcomeTable is not CON-DITION\_OCCURRENCE or CONDITION\_ERA, then expectation is outcomeTable has format of COHORT table: COHORT\_DEFINITION\_ID, SUBJECT\_ID,

COHORT\_START\_DATE, COHORT\_END\_DATE.

outcomeIds A list of ids used to define outcomes. If outcomeTable = CONDITION\_OCCURRENCE, the list is a set of ancestor CONCEPT\_IDs, and all occurrences of all descendant concepts will be selected. If outcomeTable <> CONDITION\_OCCURRENCE, the list contains records found in COHORT\_DEFINITION\_ID field.

outcomeConditionTypeConceptIds

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

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 cdmSchema. Requires read permissions to this database.

exposureTable The tablename that contains the exposure cohorts. If exposureTable <> DRUG\_ERA, then expectation is exposureTable has format of COHORT table: cohort\_concept\_id, SUBJECT\_ID, COHORT\_START\_DATE, COHORT\_END\_DATE.

exposureIds A unique identifier to define the exposures of interest. If exposureTable = DRUG\_ERA, exposureIds should be CONCEPT\_ID. If exposureTable <> DRUG\_ERA, exposureIds is used to select the cohort\_concept\_id in the cohort-like table. If no exposureIds are provided, all drugs or cohorts in the exposureTable are included as exposures.

useCustomCovariates

Create covariates from a custom table?

 $\verb|customCovariateDatabaseSchema| \\$ 

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.

customCovariateIds

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

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deleteCovariatesSmallCount

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

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

#### **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.

Four different database schemas can be specified, for four 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.

#### Value

Returns an object of type sccsData, containing information on the cases, their outcomes, exposures, and potentially other covariates. Information about multiple outcomes can be captured at once for efficiency reasons. This object is a list with the following components:

cases An ffdf object listing the persons that have the outcome(s), their age, and observation time.

eras An ffdf object listing the exposures, outcomes and other covariates.

covariateRef An ffdf object describing the covariates that have been extracted.

metaData A list of objects with information on how the sccsData object was constructed.

The generic summary() function has been implemented for this object.

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

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loadSccsData

Load the SCCS data from a folder

# **Description**

loadSccsData loads an object of type sccsData from a folder in the file system.

# Usage

```
loadSccsData(folder, readOnly = TRUE)
```

# **Arguments**

folder The name of the folder containing the data.

readOnly If true, the data is opened read only.

#### **Details**

The data will be written to a set of files in the folder specified by the user.

#### Value

An object of class cohortData.

loadSccsEraData

Load the SCCS era data from a folder

# **Description**

loadSccsEraData loads an object of type sccsEraData from a folder in the file system.

# Usage

```
loadSccsEraData(folder, readOnly = FALSE)
```

# **Arguments**

folder The name of the folder containing the data.

readOnly If true, the data is opened read only.

#### **Details**

The data will be written to a set of files in the folder specified by the user.

#### Value

An object of class sccsEraData

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# **Description**

Plot the age effect

#### Usage

```
plotAgeEffect(sccsModel, rrLim = c(0.1, 10), 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.

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.

plotSeasonality Plot the seasonality effect
---

### **Description**

Plot the seasonality effect

# Usage

```
plotSeasonality(sccsModel, rrLim = c(0.1, 10), 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.

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.

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# **Description**

sccsData saves an object of type sccsData to folder.

# Usage

```
saveSccsData(sccsData, folder)
```

# Arguments

sccsData An object of type sccsData as generated using getDbSccsData.

folder The name of the folder where the data will be written. The folder should not yet

exist.

# **Details**

The data will be written to a set of files in the specified folder.

# **Examples**

# todo

saveSccsEraData Save the SCCS era data to folder

# Description

saveSccsEraData saves an object of type sccsEraData to folder.

# Usage

```
saveSccsEraData(sccsEraData, folder)
```

# **Arguments**

sccsEraData An object of type sccsEraData as generated using createSccsEraData.

folder The name of the folder where the data will be written. The folder should not yet

exist.

#### **Details**

The data will be written to a set of files in the specified folder.

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SelfControlledCaseSeries

Self Controlled Case Series

# Description

SelfControlledCaseSeries

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

createSccsSim

# Value

An object of type sccsData.

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