

Package ‘RiskStratifiedEstimation’

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Type Package

Title Risk Stratified Effect Estimation

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Description RiskStratifiedEstimation is an R package for implementing risk stratified analyses of treatment effect in an observational database in the OMOP Common Data Model. It combines functionality of PatientLevelPrediction and CohortMethod R packages to extract and analyze data from a database in the OMOP Common Data Model format. Analyses are performed in two distinct steps. First, a prediction step is implemented, where personalized risks are derived from a large set of covariates applying one of various possible prediction methods. In the second step, risk stratified treatment comparisons are performed. Large scale regularized regression is used to fit the propensity model. Inverse probability of treatment weights are calculated and truncated within strata of predicted risk. Only weighted Cox regression models are supported for the outcome model.

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Encoding UTF-8

LazyData true

RoxygenNote 6.1.1

Imports PatientLevelPrediction,
CohortMethod,
Cyclops,
ParallelLogger,
DatabaseConnector,
SqlRender,
foreach,
FeatureExtraction,
dplyr,
ff,
reshape,
caret,
ffbase,
ggplot2,
gridExtra,
survival,
tidyr,
doSNOW,

ggpubr,
survminer

Suggests knitr,
rmarkdown

VignetteBuilder knitr

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absoluteRiskReduction	<i>Absolute risk reduction</i>
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Description

Calculates absolute risk reduction based on the Kaplan-Meier estimates within risk strata

Usage

```
absoluteRiskReduction(population, timePoint, psMethod)
```

Arguments

population	The study population generated by matchOnPs when using propensity score matching or by stratifyByPs when stratifying on the propensity score. In case of inverse probability of treatment weighting approach, it is a dataframe with a weights column.
timePoint	The time at which the absolute risk difference is estimated
psMethod	Can be one of "matchOnPs", "stratifyByPs" or "inversePtWeighted".

Value

A dataframe with the absolute risk-stratum specific absolute risk difference estimates, along with 95 percent confidence interval.

createGetPlpDataArgs *Create a parameter object for the function getPlpData*

Description

Create a parameter object for the function getPlpData

Usage

```
createGetPlpDataArgs(studyStartDate = "", studyEndDate = "",
  firstExposureOnly = FALSE, washoutPeriod = 0,
  excludeDrugsFromCovariates = FALSE)
```

Arguments

- | | |
|----------------------------|---|
| studyStartDate | A calendar date specifying the minimum date that a cohort indexdate can appear. Date format is 'yyyymmdd'. |
| studyEndDate | A calendar date specifying the maximum date that a cohort indexdate can appear. Date format is 'yyyymmdd'. Important: the studyend data is also used to truncate risk windows, meaning no outcomes beyond the study end date will be considered. |
| firstExposureOnly | Should only the first exposure per subject be included? Note that this is typically done in the createStudyPopulation function, but can already be done here for efficiency reasons. |
| washoutPeriod | The minimum required continuous observation time prior to indexdate for a person to be included in the at risk cohort. Note that this is typically done in the createStudyPopulation function, but can already be done here for efficiency reasons. |
| excludeDrugsFromCovariates | A redundant option |

Details

Create an object defining the parameter values.

createIPW	<i>Creates Inverse Probability Weights</i>
-----------	--

Description

Calculates inverse probability weights based on the propensity score

Usage

```
createIPW(ps, weightsType = "ATE", useStabilizedWeights = TRUE,
          truncationLevels = c(0.01, 0.99))
```

Arguments

ps	A propensity score data frame as created from createPs
weightsType	The type of the weights to be used. Allowed options are 'ATE' for average treatment effect and 'ATT' for average treatment effect on the treated weights
useStabilizedWeights	Should stabilized weights be used?
truncationLevels	The level of truncation expressed in percentiles of the propensity score.

Value

The ps data frame provided as input along with a weights column

createRunPlpArgs	<i>Create a parameter object for the function runPlp</i>
------------------	--

Description

Create a parameter object for the function runPlp

Usage

```
createRunPlpArgs(minCovariateFraction = 0.001, normalizeData = TRUE,
                 testSplit = "person", testFraction = 0.25, trainFraction = NULL,
                 splitSeed = NULL, nfold = 3, indexes = NULL, savePlpData = TRUE,
                 savePlpResult = TRUE, savePlpPlots = TRUE, saveEvaluation = TRUE,
                 verbosity = "INFO", timeStamp = FALSE, analysisId = NULL)
```

Arguments

minCovariateFraction	The minimum fraction of target population who must have a covariate for it to be included in the model training
normalizeData	Whether to normalise the covariates before training (Default: TRUE)

testSplit	Either 'person' or 'time' specifying the type of evaluation used. 'time' find the date where testFraction of patients had an index after the date and assigns patients with an index prior to this date into the training set and post the date into the test set 'person' splits the data into test (1-testFraction of the data) and train (validationFraction of the data) sets. The split is stratified by the class label.
testFraction	The fraction of the data to be used as the test set in the patientsplit evaluation.
trainFraction	A real number between 0 and 1 indicating the train set fraction of the data. If not set trainFraction is equal to 1 - test
splitSeed	The seed used to split the test/train set when using a person type testSplit
nfold	The number of folds used in the cross validation (default 3)
indexes	A dataframe containing a rowId and index column where the index value of -1 means in the test set, and positive integer represents the cross validation fold (default is NULL)
savePlpData	Binary indicating whether to save the plpData object (default is T)
savePlpResult	Binary indicating whether to save the object returned by runPlp (default is T)
savePlpPlots	Binary indicating whether to save the performance plots as pdf files (default is T)
saveEvaluation	Binary indicating whether to save the oerformance as csv files (default is T)
verbosity	Sets the level of the verbosity. If the log level is at or higher in priority than the logger threshold, a message will print. The levels are: DEBUGHighest verbosity showing all debug statements TRACEShowing information about start and end of steps INFOShow informative information (Default) WARNShow warning messages ERRORShow error messages FATALBe silent except for fatal errors
timeStamp	If TRUE a timestamp will be added to each logging statement. Automatically switched on for TRACE level.
analysisId	Identifier for the analysis. It is used to create, e.g., the result folder. Default is a timestamp.

Details

Create an object defining the parameter values.

```
createStudyPopulationCmSettings
```

Create a parameter object for the function createStudyPopulation

Description

Create a parameter object for the function createStudyPopulation

Usage

```
createStudyPopulationCmSettings(population = NULL,
  firstExposureOnly = FALSE, restrictToCommonPeriod = FALSE,
  washoutPeriod = 0, removeDuplicateSubjects = FALSE,
  removeSubjectsWithPriorOutcome = TRUE, priorOutcomeLookback = 99999,
  minDaysAtRisk = 1, riskWindowStart = 0,
  addExposureDaysToStart = FALSE, riskWindowEnd = 0,
  addExposureDaysToEnd = TRUE, censorAtNewRiskWindow = FALSE)
```

Arguments

population	If specified, this population will be used as the starting point instead of the cohorts in the cohortMethodDataobject.
firstExposureOnly	Should only the first exposure per subject be included? Note that this is typically done in the createStudyPopulation function,
restrictToCommonPeriod	Restrict the analysis to the period when both exposures are observed?
washoutPeriod	The minimum required continuous observation time prior to index date for a person to be included in the cohort.
removeDuplicateSubjects	Remove subjects that are in both the target and comparator cohort? See details for allowed values.
removeSubjectsWithPriorOutcome	Remove subjects that have the outcome prior to the risk window start?
priorOutcomeLookback	How many days should we look back when identifying prior outcomes?
minDaysAtRisk	The minimum required number of days at risk.
riskWindowStart	The start of the risk window (in days) relative to the index date (+ days of exposure if the addExposureDaysToStart parameter is specified).
addExposureDaysToStart	Add the length of exposure the start of the risk window?
riskWindowEnd	The end of the risk window (in days) relative to the index date (+ days of exposure if the addExposureDaysToEnd parameter is specified).
addExposureDaysToEnd	Add the length of exposure the risk window?
censorAtNewRiskWindow	If a subject is in multiple cohorts, should time-at-risk be censored when the new time-at-risk starts to prevent overlap?

Details

Create an object defining the parameter values.

fitOutcomeModels	<i>Fit outcome models</i>
------------------	---------------------------

Description

Fits outcome models within risk strata, estimating relative and absolute differences. Designed to be performed within a parallelized analysis.

Usage

```
fitOutcomeModels(outcomeId, analysisPath, cohortMethodDataFolder,
  outcomeIdList, compareAllOutcomes, timePoint, psMethod, weightsType,
  useStabilizedWeights, truncationLevels, populationCmSettings)
```

Arguments

outcomeId	The outcome of interest for which the estimation is performed. That is the outcome for which risk stratification is performed.
analysisPath	The path to the RSEE analysis results.
cohortMethodDataFolder	The directory where the cohortMethodData object is stored.
outcomeIdList	The other outcomes for which risk stratified estimates need to be derived. Only required if compareAllOutcomes is TRUE.
compareAllOutcomes	Compare all the outcomes within the outcomeIdList within risk strata of code-outcomeId?
timePoint	The time point at which absolute risk differences will be calculated.
psMethod	Select the propensity score method for the estimation of treatment effects within risk strata. It can be "matchOnPs", "stratifyByPs" or "inversePtWeighted".
weightsType	Only required if psMethod is "inversePtWeighted". The type of weights for the balancing of covariates. Should be either 'ATE' or 'ATT'
useStabilizedWeights	Only required if weightsType is "inversePtWeighted". Should stabilized weights be used?
truncationLevels	Only required if weightsType is "inversePtWeighted". The level of truncation expressed in percentiles of the propensity score.
populationCmSettings	A parameter object for the function createStudyPopulation . Can be generated from function createStudyPopulationCmSettings.

Value

NULL. The results are all saved.

fitPsModel	<i>Calculate propensity scores for a specific outcome</i>
------------	---

Description

Fits a large-scale regularized regression model to estimate propensity scores within predicted risk strata. Designed to be applied in a parallelized analysis.

Usage

```
fitPsModel(cohortMethodDataFolder, plpDataFolder, outcomeId,
  populationCmSettings, populationPlpSettings, saveDirectory, riskStrata,
  analysisId, analysisPath)
```

Arguments

cohortMethodDataFolder	The directory where the cohortMethodData object is stored.
plpDataFolder	The directory where the plpData object is stored.
outcomeId	The outcome of interest for which the risk stratification is performed.
populationCmSettings	A parameter object for the function createStudyPopulation . Can be generated from function createStudyPopulationCmSettings .
populationPlpSettings	A parameter object for the function createStudyPopulation . Can be generated from function createStudyPopulationSettings .
saveDirectory	The directory of the RSEE analysis where the prediction models are located.
riskStrata	The considered number of risk strata.
analysisId	The analysis ID of the prediction model used to stratify the population.
analysisPath	The directory where the propensity scores will be stored.

Value

NULL. The results are all saved.

loadRSEE	<i>Load the result of a risk stratified analysis</i>
----------	--

Description

Loads the result of a risk stratified analysis.

Usage

```
loadRSEE(file, mainOutcomes = NULL, loadOtherOutcomes = TRUE,
         otherOutcomes = NULL, loadPs = TRUE)
```

Arguments

file	The file location where the results are stored. It should point at the analysisId folder of a risk stratified analysis
mainOutcomes	The main outcomes for which the results should be loaded. If set to NULL the results for all the outcomes are loaded.
loadOtherOutcomes	Logical: Whether to load results for other outcomes. If FALSE, only the main outcome results are loaded.
otherOutcomes	The Ids of the other outcomes to be loaded.
loadPs	Should the propensity scores along with the matrices mapping risk stratification be loaded?

Value

The result of a previous risk stratified analysis.

outcomeModelWeighted	<i>Fits a weighted cox regression model</i>
----------------------	---

Description

Fits a weighted cox regression model using an inverse probability of treatment weighting approach

Usage

```
outcomeModelWeighted(ps, calculateWeights = TRUE, weightsType = "ATE",  
  useStabilizedWeights = TRUE, truncationLevels)
```

Arguments

ps	A dataframe wiht propensity scores as generated from createPs .
calculateWeights	Should weights be calculated?
weightsType	The type of weights for the balancing of covariates. Should be either 'ATE' or 'ATT'
useStabilizedWeights	Should stabilized weights be used?
truncationLevels	The level of truncation expressed in percentiles of the propensity score.

Value

A weighted cox regression model.

plotCovariateBalance	<i>Plots the covariate balance before and after balancing</i>
----------------------	---

Description

Plots covariate before and after weighting using the inverse of the propensity score

Usage

```
plotCovariateBalance(ps, cohortMethodData, calculateWeights = TRUE,  
  weightsType = "ATE", useStabilizedWeights = TRUE, truncationLevels,  
  showNotBalancedCovariateIds = TRUE)
```

Arguments

ps	A propensity score data frame as created from createPs
cohortMethodData	A cohortMethodData object
calculateWeights	Should the weights be calculated?
weightsType	The type of the weights to be used. Allowed options are 'ATE' for average treatment effect and 'ATT' for average treatment effect on the treated weights
useStabilizedWeights	Should stabilized weights be used?
truncationLevels	The level of truncation expressed in percentiles of the propensity score.
showNotBalancedCovariateIds	Show covariate ids that were not balanced after weighting?

Value

The covariate balance plot

plotRSEE	<i>Plot the results of a risk stratified analysis</i>
----------	---

Description

Plots the overall results of a risk stratified analysis.

Usage

```
plotRSEE(rseeResult, mapOutcomes = NULL, mapTreatments = NULL)
```

Arguments

rseeResult	The overall result of a risk stratified analysis.
mapOutcomes	A dataframe with the outcome labels. It should have 2 columns called "outcome" and "labelOutcome". The former should contain character values of the form "outcome_x" and the latter should contain the outcome label. If set to NULL, the outcome definition id's appear in the graphs.
mapTreatments	A dataframe with the treatment labels. It should have 2 columns named "cohort" and "labelTreatments". The former should contain the values "treatment" and "comparator" and the latter should contain the treatment labels. If set to NULL, the labels treatment and comaprator appear in the graph,

Value

A 3-level graph. In the first level observed outcome rates are presented for all treatment-outcome combinations across risk strata. In the second level, hazard ratios across risk strata are given. In the final level, absolute risk difference across risk strata are presented.

prepareForPlpData	<i>Prepares for the running the PatientLevelPrediction package</i>
-------------------	--

Description

Prepares for running the PatientLevelPrediction package by merging the treatment and comparator cohorts and defining a new covariate for treatment.

Usage

```
prepareForPlpData(treatmentCohortId, comparatorCohortId, targetCohortId,
  cohortDatabaseSchema, cohortTable, resultsDatabaseSchema,
  mergedCohortTable, attributeDefinitionTable, cohortAttributeTable,
  connectionDetails)
```

Arguments

treatmentCohortId	The treatment cohort id
comparatorCohortId	The comparator cohort id
targetCohortId	The id of the merged cohorts
cohortDatabaseSchema	The name of the database schema that is the location where the cohort data used to define the at risk cohort is available
cohortTable	The table that contains the treatment and comparator cohorts.
resultsDatabaseSchema	The name of the database schema to store the new tables. Need to have write access.
mergedCohortTable	The table that will contain the merged cohorts.
attributeDefinitionTable	The table that will contain the definition of the treatment variable.
cohortAttributeTable	The table that will contain the patients along with their new covariate values.
connectionDetails	The connection details required to connect to a database.

Value

Creates the tables resultsDatabaseSchema.mergedCohortTable, resultsDatabaseSchema.attributeDefinitionTable and resultsDatabaseSchema.cohortAttributeTable

A covariate settings object for the treatment covariate.

relativeRiskReduction	<i>Relative risk reduction</i>
-----------------------	--------------------------------

Description

Calculates hazard ratios within risk strata.

Usage

```
relativeRiskReduction(model)
```

Arguments

model	The model that was used to fit a cox regression model to the data.
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Value

A dataframe with hazard ratios for treatment effect across risk strata along with 95 percent confidence intervals

runRiskStratifiedEstimation	<i>Runs a risk stratified analysis</i>
-----------------------------	--

Description

Runs a risk stratified analysis in two stages. It first runs a prediction algorithm using PatientLevelPrediction to derive baseline patient risks and then derives estimates within risk strata using CohortMethod package.

Usage

```
runRiskStratifiedEstimation(plpDataFolder = NULL,
  cohortMethodDataFolder = NULL, cdmDatabaseSchema, cohortDatabaseSchema,
  outcomeDatabaseSchema, resultsDatabaseSchema, cohortTable, outcomeTable,
  mergedCohortTable, attributeDefinitionTable, cohortAttributeTable,
  treatmentCohortId, comparatorCohortId, outcomeIds, targetCohortId,
  connectionDetails, getDbCohortMethodDataArgs, covariateSettingsCm,
  populationCmSettings, exposureTable, psControl = NULL,
  psPrior = NULL, psMethod = "matchOnPs", createPsThreads = 1,
  exposureDatabaseSchema, getPlpDataArgs, covariateSettingsPlp,
  modelSettings, populationPlpSettings, cdmVersion = "5", runPlpArgs,
  riskStrata = 4, weightsType = "ATE", useStabilizedWeights = TRUE,
  truncationLevels = c(0.01, 0.99), timePoint,
  compareAllOutcomes = TRUE, predictionThreads = 1, saveResults,
  saveDirectory = NULL, fftempdir, fitOutcomeModelsThreads = 1,
  saveMapMatrix = TRUE, savePs = TRUE, verbosity = "INFO",
  analysisId = NULL)
```

Arguments

plpDataFolder	Folder where the plpData object is stored. If NULL, it will be constructed within the function.
cohortMethodDataFolder	Folder where the cohortMethodData object is stored. If NULL, it will be constructed within the function.
cdmDatabaseSchema	The name of the database schema that contains the vocabulary files. Requires read permissions to this database. On SQL Server, this should specify both the database and the schema, so for example 'cdm_instance.dbo'.
cohortDatabaseSchema	The name of the database schema that contains the treatment and comparator cohorts. Requires read permissions to this database.
outcomeDatabaseSchema	The name of the database schema that contains the outcome cohorts. Requires read permissions to this database.
resultsDatabaseSchema	The name of the database schema with write permissions.
cohortTable	The name of the table holding the treatment and comparator cohorts.
outcomeTable	The name of the table holding the outcome cohorts.
mergedCohortTable	The name of the table where the merged treatment and comparator cohorts will be stored.
attributeDefinitionTable	The table where the definition of the treatment covariate will be stored.
cohortAttributeTable	The table where the covariate values with regard to treatment will be stored.
treatmentCohortId	The cohort definition id of the treatment cohort in the cohortTable.
comparatorCohortId	The cohort definition id of the comparator cohort in the cohortTable.
outcomeIds	A list of cohort definition ids used to define the outcomes in the outcome table.
targetCohortId	The cohort definition id of the merged cohort in the mergedCohortTable.
connectionDetails	An R object of type connectionDetails created using function createConnectionDetails . Either the connection or the connectionDetails argument should be specified.
getDbCohortMethodDataArgs	A parameter object for the function getDbCohortMethodData . Can be generated from function createGetDbCohortMethodDataArgs .
covariateSettingsCm	An object of type covariateSettings as created using the createCovariateSettings to be used for the definition of the cohortMethodData object.
populationCmSettings	A parameter object for the function createStudyPopulation . Can be generated from function createStudyPopulationCmSettings .
exposureTable	Input of function getDbCohortMethodData : The tablename that contains the exposure cohorts.

psControl	An object of the type <code>cyclopsControl</code> generated from createControl .
psPrior	An object of the type <code>cyclopsPrior</code> generated from createPrior .
psMethod	Select the propensity score method for the estimation of treatment effects within risk strata. It can be "matchOnPs", "stratifyByPs" or "inversePtWeighted".
createPsThreads	The number of threads for the calculation of the propensity scores.
exposureDatabaseSchema	Input of function getDbCohortMethodData : The name of the database schema that is the location where the exposure data used to define the exposure cohorts is available.
getPlpDataArgs	A parameter object for the function getPlpData . It can be generated from function createGetPlpDataArgs .
covariateSettingsPlp	An object of type <code>covariateSettings</code> as created using the createCovariateSettings to be used for the definition of the <code>plpData</code> object. note that a covariate indicating treatment will be added.
modelSettings	An object of the class <code>modelSettings</code> to be used as input for runPlp .
populationPlpSettings	A parameter object for the function createStudyPopulation . Can be generated from function createStudyPopulationSettings .
cdmVersion	Define the OMOP CDM version used: currently supported is "5".
runPlpArgs	A parameter object for the function runPlp . Can be generated from function createRunPlpArgs .
riskStrata	The number of risk strata to divide the study population.
weightsType	Only required if <code>weightsType</code> is "inversePtWeighted". The type of weights for the balancing of covariates. Should be either 'ATE' or 'ATT'
useStabilizedWeights	Only required if <code>weightsType</code> is "inversePtWeighted". Should stabilized weights be used?
truncationLevels	Only required if <code>weightsType</code> is "inversePtWeighted". The level of truncation expressed in percentiles of the propensity score.
timePoint	The time point of interest for the calculation of the absolute risk reduction.
compareAllOutcomes	Should all the outcomes be analyzed within all stratifications?
predictionThreads	The number of threads to be used to run the predictions.
saveResults	Should the results of the entire analysis be saved?
saveDirectory	The file path to the directory where the results of the analysis will be saved.
fftempdir	The directory where the temporary ff files will be saved.
fitOutcomeModelsThreads	The number of threads to be used for the calculation of the risk stratified results.
saveMapMatrix	Should the map matrix with the risk stratum allocations be saved?
savePs	Should the propensity scores be saved?
verbosity	Sets the level of the verbosity. If the log level is at or higher in priority than the logger threshold, a message will print. The levels are:

- **DEBUG**Highest verbosity showing all debug statements
- **TRACE**Showing information about start and end of steps
- **INFO**Show informative information (Default)
- **WARN**Show warning messages
- **ERROR**Show error messages
- **FATAL**Be silent except for fatal errors

`analysisId` The identifier of the analysis.

Value

An object containing two large lists:

- The propensity scores within risk strata for each outcome in `outcomeIds`
- The results of the risk stratified analysis within risk strata for all outcomes in `outcomeIds`:
 - Weighted Kaplan-Meier estimates.
 - Relative risk reduction.
 - Absolute risk reduction.
 - Number of cases.

<code>singlePlotRSEE</code>	<i>Plot a single outcome</i>
-----------------------------	------------------------------

Description

Plots the result of a risk stratified analysis for a single outcome of interest

Usage

```
singlePlotRSEE(outcomeId, mapMatrix, title = NULL,
  overallResult = NULL, mapTreatments = NULL)
```

Arguments

<code>outcomeId</code>	The outcome Id of interest
<code>mapMatrix</code>	The matrix that maps patients to their risk quantiles
<code>title</code>	The title of the graph
<code>overallResult</code>	The hazard ratio from an analysis on the overall study population
<code>mapTreatments</code>	A dataframe with the treatment labels. It should have 2 columns named "cohort" and "labelTreatments". The former should contain the values "treatment" and "comparator" and the latter should contain the treatment labels. If set to <code>NULL</code> , the labels treatment and comaprator appear in the graph.

Value

A 3-level graph for a single outcome. In the first level observed outcome rates are presented for all treatment-outcome combinations across risk strata. In the second level, hazard ratios across risk strata are given. In the final level, absolute risk difference across risk strata are presented.

stratifiedKaplanMeier	<i>Calculate stratified Kaplan-Meier estimates</i>
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Description

Calculate stratified Kaplan-Meier estimates

Usage

```
stratifiedKaplanMeier(population, timePoint)
```

Arguments

population	The population of interest stratified using the stratifyByPs
timePoint	The point in time for which the absolute risk difference is required

Value

A vector of the absolute risk difference along with the lowest and highest limits of the the 95 percent confidence interval

weightedKM	<i>Calculates the weighted Kaplan-Meier estimates</i>
------------	---

Description

Calculates the weighted Kaplan-Meier estimates.

Usage

```
weightedKM(ps, calculateWeights = TRUE, weightsType = "ATE",
  useStabilizedWeights = TRUE, truncationLevels)
```

Arguments

ps	A data frame including the propensity scores as generated from createPs
calculateWeights	Whether to calculate the weights using createIPW
weightsType	The type of the weights to be used. Allowed options are 'ATE' for average treatment effect and 'ATT' for average treatment effect on the treated weights
useStabilizedWeights	Should stabilized weights be used?
truncationLevels	The level of truncation expressed in percentiles of the propensity score.

Value

A data frame with the Kaplan-Meier estimates

References

Xie J, Liu C. Adjusted Kaplan-Meier estimator and log-rank test with inverse probability of treatment weighting for survival data. *Statistics in Medicine* 2005; 24:3089–3110.

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