${\bf Package\ 'Self Controlled Cohort'}$

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Title Population-Level Estimation Method that Estimates Incidence Rate Comparison of Exposed/Unexposed Time Within an Exposed Cohort
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Description A method to estimate risk by comparing time exposed with time unexposed among the exposed cohort.
<pre>URL https://github.com/OHDSI/SelfControlledCohort</pre>
BugReports https://github.com/OHDSI/SelfControlledCohort/issues
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R topics documented:
createExposureOutcome

$getSccRiskWindowStats \ \dots $	5
$load Exposure Outcome List \ldots \ldots \ldots \ldots \ldots \ldots \ldots \ldots$	6
$loadSccAnalysisList\dots$	7
$runSccAnalyses \ . \ . \ . \ . \ . \ . \ . \ . \ . \ $	7
$runSccRiskWindows \ \dots $	9
$run Self Controlled Cohort \ \dots $	11
saveExposureOutcomeList	14
saveSccAnalysisList	15
summarizeAnalyses	15

 ${\it createExposureOutcome\ }{\it Create\ exposure-outcome\ }{\it combinations.}$

Description

Create exposure-outcome combinations.

Usage

createExposureOutcome(exposureId, outcomeId)

Arguments

exposureId

A concept ID indentifying the drug of interest in the exposure table. If multiple strategies for picking the exposure will be tested in the analysis, a named list of numbers can be provided instead. In the analysis, the name of the number to be used can be specified using the exposureType parameter in the createSccAnalysis function.

 ${\tt outcomeId}$

A concept ID indentifying the outcome of interest in the outcome table. If multiple strategies for picking the outcome will be tested in the analysis, a named list of numbers can be provided instead. In the analysis, the name of the number to be used can be specified using the #' outcomeType parameter in the createSccAnalysis function.

Details

Create a hypothesis of interest, to be used with the runSccAnalyses function.

create Run Self Controlled Cohort Args

 $Create\ a\ parameter\ object\ for\ the\ function\ run Self Controlled Cohort$

Description

Create a parameter object for the function runSelfControlledCohort

Usage

```
createRunSelfControlledCohortArgs(
  firstExposureOnly = TRUE,
  firstOutcomeOnly = TRUE,
 minAge = "",
 maxAge = "",
  studyStartDate = "",
  studyEndDate = "",
  addLengthOfExposureExposed = TRUE,
  riskWindowStartExposed = 1,
  riskWindowEndExposed = 30,
  addLengthOfExposureUnexposed = TRUE,
 riskWindowEndUnexposed = -1,
  riskWindowStartUnexposed = −30,
 hasFullTimeAtRisk = FALSE,
 washoutPeriod = 0,
  followupPeriod = 0,
  computeTarDistribution = FALSE
)
```

Arguments

firstExposureOnly

If TRUE, only use first occurrence of each drug concept idfor each person

firstOutcomeOnly

If TRUE, only use first occurrence of each condition conceptid for each person.

minAge Integer for minimum allowable age.

maxAge Integer for maximum allowable age.

studyStartDate Date for minimum allowable data for index exposure. Dateformat is 'yyyymmdd'.

studyEndDate Date for maximum allowable data for index exposure. Dateformat is 'yyyymmdd'.

addLengthOfExposureExposed

If TRUE, use the duration from drugEraStart -; drugEraEnd as part of timeAtRisk.

riskWindowStartExposed

Integer of days to add to drugEraStart for start of timeAtRisk (0 to include index date, 1 to start the dayafter).

riskWindowEndExposed

Additional window to add to end of exposure period (ifaddLengthOf-ExposureExposed = TRUE, then add to exposure enddate, else add to exposure start date).

addLengthOfExposureUnexposed

If TRUE, use the duration from exposure start -; exposureend as part of timeAtRisk looking back before exposurestart.

riskWindowEndUnexposed

Integer of days to add to exposure start for end of timeAtRisk (0 to include index date, -1 to end the daybefore).

4 createSccAnalysis

riskWindowStartUnexposed

Additional window to add to start of exposure period (ifaddLengthOfExposureUnexposed = TRUE, then add to exposureend date, else add to exposure start date).

hasFullTimeAtRisk

If TRUE, restrict to people who have full time-at-risk exposed and unexposed.

washoutPeriod Integer to define required time observed before exposurestart.

 ${\tt followupPeriod} \ \ {\tt Integer} \ \ {\tt to} \ \ {\tt define} \ \ {\tt required} \ \ {\tt time} \ \ {\tt observed} \ \ {\tt after} \ \ {\tt exposurestart}.$

compute Tar Distribution

If TRUE, computer the distribution of time-at-risk and average absolute time between treatment and outcome. Note, may add significant computation time on some database engines. If set true in one analysis will default to true for all others.

Details

Create an object defining the parameter values.

createSccAnalysis

 $Create\ a\ Self Controlled Cohort\ analysis\ specification$

Description

Create a SelfControlledCohort analysis specification

Usage

```
createSccAnalysis(
  analysisId = 1,
  description = "",
  exposureType = NULL,
  outcomeType = NULL,
  runSelfControlledCohortArgs
)
```

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.

exposureType If more than one exposure is provided for each exposureOutcome, this

field should be used to select the specific exposure to use in this analysis.

outcomeType If more than one outcome is provided for each exposureOutcome, this

field should be used to select the specific outcome to use in this analysis.

run Self Controlled Cohort Args

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

Details

Create a set of analysis choices, to be used with the runSccAnalyses function.

 ${\tt getSccRiskWindowStats} \quad \textit{Get Self-Controlled Cohort Risk Window Statistics}$

Description

Compute statistics from risk windows.

Usage

```
getSccRiskWindowStats(
  connection,
  outcomeDatabaseSchema,
  tempEmulationSchema = getOption("sqlRenderTempEmulationSchema"),
  oracleTempSchema = NULL,
  outcomeIds = NULL,
  cdmVersion = 5,
  outcomeTable = "condition_era",
  firstOutcomeOnly = TRUE,
  resultsDatabaseSchema = NULL,
  riskWindowsTable = "#risk_windows"
)
```

Arguments

connection

DatabaseConnector connection instance

 ${\tt outcomeDatabaseSchema}$

The name of the database schema that is the location where the data used to define the outcome cohorts is available. If exposureTable = CON-DITION_ERA, exposureDatabaseSchema is not used by assumed to be cdmSchema. Requires read permissions to this database.

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.

oracleTempSchema

For Oracle only: the name of the database schema where you want all temporary tables to be managed. Requires create/insert permissions to this database.

outcomeIds

The condition_concept_ids or cohort_definition_ids of the outcomes of interest. If empty, all the outcomes in the outcome table will be included.

cdmVersion

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

outcomeTable

The tablename that contains the outcome cohorts. If outcomeTable ¡¿ CONDITION_OCCURRENCE, then expectation is outcomeTable has format of COHORT table: COHORT_DEFINITION_ID, SUBJECT_ID, COHORT_START_DATE, COHORT_END_DATE.

firstOutcomeOnly

If TRUE, only use first occurrence of each condition concept id for each person.

resultsDatabaseSchema

Schema to oputput results to. Ignored if results Table and risk Windows Table are temporary.

riskWindowsTable

String: optionally store the risk windows in a (non-temporary) table.

Details

Requires a risk window table to be created first with 'runSccRiskWindows'

Value

 $list\ containing\ data\ frames:\ treatment Time Distribution,\ time To Outcome Distribution,\ time To Outcome Distribution Exposed,\ time To Outcome Distribution Unexposed$

Examples

```
## Not run:
# First, create the risk windows table
connectionDetails <- Eunomia::getEunomiaConnectionDetails()</pre>
connection <- DatabaseConnector::connect(connectionDetails)</pre>
riskWindowsTable <- "computed_risk_windows"</pre>
runSccRiskWindows(connection,
                   cdmDatabaseSchema = "main".
                   exposureIds = c(1102527, 1125315),
            resultsDatabaseSchema = "main", # This is the schema where the results will be stored
                   riskWindowsTable = riskWindowsTable,
                   exposureTable = "drug_era")
# Get stats based on outcomes of interest
tarStats <- getSccRiskWindowStats(connection,</pre>
                                    outcomeDatabaseSchema = "main",
                                    resultsDatabaseSchema = "main",
                                    riskWindowsTable = riskWindowsTable,
                                    outcomeTable = "condition_era",
                                    outcomeIds = 192671)
## End(Not run)
```

loadExposureOutcomeList

 $Load\ a\ list\ of\ exposureOutcome\ from\ file$

Description

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

Usage

```
loadExposureOutcomeList(file)
```

Arguments

file

The name of the file

loadSccAnalysisList 7

Value

A list of objects of type exposureOutcome.

 ${\tt loadSccAnalysisList} \qquad {\tt Load~a~list~of~sccAnalysis~from~file}$

Description

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

Usage

```
loadSccAnalysisList(file)
```

Arguments

file

The name of the file

Value

A list of objects of type sccAnalysis.

runSccAnalyses

Run a list of analyses

Description

Run a list of analyses

Usage

```
runSccAnalyses(
 connectionDetails,
  cdmDatabaseSchema,
  tempEmulationSchema = getOption("sqlRenderTempEmulationSchema"),
 oracleTempSchema = NULL,
 exposureDatabaseSchema = cdmDatabaseSchema,
 exposureTable = "drug_era",
 outcomeDatabaseSchema = cdmDatabaseSchema,
 outcomeTable = "condition_occurrence",
 cdmVersion = 5,
 outputFolder = "./SelfControlledCohortOutput",
  sccAnalysisList,
 exposureOutcomeList,
 analysisThreads = 1,
  computeThreads = 1
)
```

8 runSccAnalyses

Arguments

connectionDetails

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

cdmDatabaseSchema

Name of database schema that contains the OMOP CDM and vocabulary.

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.

oracleTempSchema

For Oracle only: the name of the database schema where you want all temporary tables to be managed. Requires create/insert permissions to this database.

exposureDatabaseSchema

The name of the database schema that is the location where the exposure data used to define the exposure cohorts is available. If exposure Table = DRUG_ERA, exposureDatabaseSchema is not used by assumed to be cdmSchema. Requires read permissions to this database.

exposureTable

The tablename that contains the exposure cohorts. If exposure Table ;; DRUG_ERA, then expectation is exposure Table has format of COHORT table: cohort_concept_id, SUBJECT_ID, COHORT_START_DATE, CO-HORT_END_DATE.

outcomeDatabaseSchema

The name of the database schema that is the location where the data used to define the outcome cohorts is available. If exposure Table = CON-DITION_ERA, exposureDatabaseSchema is not used by assumed to be cdmSchema. Requires read permissions to this database.

outcomeTable

The tablename that contains the outcome cohorts. If outcome Table ;; CONDITION_OCCURRENCE, then expectation is outcome Table has format of COHORT table: COHORT_DEFINITION_ID, SUBJECT_ID, COHORT_START_DATE, COHORT_END_DATE.

cdmVersion

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

outputFolder

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

sccAnalysisList

A list of objects of type sccAnalysis as created using the createSccAnalysis function.

exposureOutcomeList

A list of objects of type exposureOutcome as created using the createExposureOutcome

analysisThreads

The number of parallel threads to use to execute the analyses.

computeThreads Number of parallel threads for computing IRRs with exact confidence intervals.

Details

Run a list of analyses for the drug-comparator-outcomes of interest. This function will run all specified analyses against all hypotheses of interest, meaning that the total number of outcome models is 'length(cmAnalysisList) * length(drugComparatorOutcomesList)'.

runSccRiskWindows 9

runSccRiskWindows

 $Run\ Self\mbox{-}Controlled\ Cohort\ Risk\ Windows$

Description

Compute time at risk exposed and time at risk unexposed for risk window parameters. See 'getSccRiskWindowStats' for example usage.

Usage

```
runSccRiskWindows(
 connection,
  cdmDatabaseSchema,
  cdmVersion = 5,
  tempEmulationSchema = getOption("sqlRenderTempEmulationSchema"),
 oracleTempSchema = NULL,
  exposureIds = NULL,
  exposureDatabaseSchema = cdmDatabaseSchema,
  exposureTable = "drug_era",
  firstExposureOnly = TRUE,
 minAge = "",
 maxAge = "",
  studyStartDate = "",
  studyEndDate = "",
  addLengthOfExposureExposed = TRUE,
  riskWindowStartExposed = 1,
 riskWindowEndExposed = 30,
 addLengthOfExposureUnexposed = TRUE,
 riskWindowEndUnexposed = -1,
  riskWindowStartUnexposed = -30,
 hasFullTimeAtRisk = FALSE,
 washoutPeriod = 0,
  followupPeriod = 0,
 riskWindowsTable = "#risk_windows",
  resultsDatabaseSchema = NULL
)
```

Arguments

 $\begin{array}{ll} connection & Database Connector \ connection \ instance \\ cdmDatabase Schema & \end{array}$

Name of database schema that contains the OMOP CDM and vocabulary.

 ${\tt cdmVersion} \qquad {\tt Define \ the \ OMOP \ CDM \ version \ used: \ currently \ support \ "4" \ and \ "5".}$ ${\tt tempEmulationSchema}$

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.

oracleTempSchema

For Oracle only: the name of the database schema where you want all temporary tables to be managed. Requires create/insert permissions to this database.

10 runSccRiskWindows

exposureIds A vector containing the drug_concept_ids or cohort_definition_ids of the exposures of interest. If empty, all exposures in the exposure table will be included.

exposureDatabaseSchema

The name of the database schema that is the location where the exposure data used to define the exposure cohorts is available. If exposureTable = DRUG_ERA, exposureDatabaseSchema is not used by assumed to be cdmSchema. Requires read permissions to this database.

exposureTable The tablename that contains the exposure cohorts. If exposureTable ¡¿ DRUG_ERA, then expectation is exposureTable has format of COHORT table: cohort_concept_id, SUBJECT_ID, COHORT_START_DATE, COHORT_END_DATE.

firstExposureOnly

If TRUE, only use first occurrence of each drug concept id for each person

minAge Integer for minimum allowable age.
maxAge Integer for maximum allowable age.

studyStartDate Date for minimum allowable data for index exposure. Date format is 'yyyymmdd'.

studyEndDate Date for maximum allowable data for index exposure. Date format is 'yyyymmdd'.

addLengthOfExposureExposed

If TRUE, use the duration from drugEraStart -; drugEraEnd as part of timeAtRisk.

riskWindowStartExposed

Integer of days to add to drugEraStart for start of timeAtRisk (0 to include index date, 1 to start the day after).

riskWindowEndExposed

Additional window to add to end of exposure period (if addLengthOf-ExposureExposed = TRUE, then add to exposure end date, else add to exposure start date).

add Length Of Exposure Unexposed

If TRUE, use the duration from exposure start -¿ exposure end as part of timeAtRisk looking back before exposure start.

riskWindowEndUnexposed

Integer of days to add to exposure start for end of timeAtRisk (0 to include index date, -1 to end the day before).

riskWindowStartUnexposed

Additional window to add to start of exposure period (if addLengthOf-ExposureUnexposed = TRUE, then add to exposure end date, else add to exposure start date).

hasFullTimeAtRisk

If TRUE, restrict to people who have full time-at-risk exposed and unexposed.

washoutPeriod Integer to define required time observed before exposure start.

 $\begin{tabular}{ll} follow up Period Integer to define required time observed after exposure start. \\ risk Windows Table \end{tabular}$

....

String: optionally store the risk windows in a (non-temporary) table.

resultsDatabaseSchema

Schema to oputput results to. Ignored if resultsTable and riskWindowsTable are temporary.

runSelfControlledCohort

11

runSelfControlledCohort

Run self-controlled cohort

Description

runSelfControlledCohort generates population-level estimation by comparing exposed and unexposed time among exposed cohort.

Usage

```
runSelfControlledCohort(
  connectionDetails = NULL,
  cdmDatabaseSchema,
  connection = NULL,
  cdmVersion = 5,
  tempEmulationSchema = getOption("sqlRenderTempEmulationSchema"),
 oracleTempSchema = NULL,
 exposureIds = NULL,
 outcomeIds = NULL,
 exposureDatabaseSchema = cdmDatabaseSchema,
  exposureTable = "drug_era",
 outcomeDatabaseSchema = cdmDatabaseSchema,
 outcomeTable = "condition_era",
 firstExposureOnly = TRUE,
 firstOutcomeOnly = TRUE,
 minAge = "",
 maxAge = "",
  studyStartDate = "",
  studyEndDate = "",
  addLengthOfExposureExposed = TRUE,
 riskWindowStartExposed = 1,
 riskWindowEndExposed = 30,
 addLengthOfExposureUnexposed = TRUE,
 riskWindowEndUnexposed = -1,
 riskWindowStartUnexposed = -30,
 hasFullTimeAtRisk = FALSE,
 washoutPeriod = 0,
  followupPeriod = 0,
 computeTarDistribution = FALSE,
  computeThreads = 1,
 riskWindowsTable = "#risk_windows",
  resultsTable = "#results",
  resultsDatabaseSchema = NULL,
 postProcessFunction = NULL,
 postProcessArgs = list(),
  returnEstimates = TRUE
)
```

12 runSelfControlledCohort

Arguments

connectionDetails

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

cdmDatabaseSchema

Name of database schema that contains the OMOP CDM and vocabulary.

connection DatabaseConnector connection instance

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

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.

oracleTempSchema

For Oracle only: the name of the database schema where you want all temporary tables to be managed. Requires create/insert permissions to this database.

exposureIds A vector containing the drug_concept_ids or cohort_definition_ids of the exposures of interest. If empty, all exposures in the exposure table will

be included.

outcomeIds The condition_concept_ids or cohort_definition_ids of the outcomes of interest. If empty, all the outcomes in the outcome table will be included.

exposureDatabaseSchema

The name of the database schema that is the location where the exposure data used to define the exposure cohorts is available. If exposureTable = DRUG_ERA, exposureDatabaseSchema is not used by assumed to be cdmSchema. Requires read permissions to this database.

exposureTable The tablename that contains the exposure cohorts. If exposureTable ¡¿ DRUG_ERA, then expectation is exposureTable has format of COHORT

table: cohort_concept_id, SUBJECT_ID, COHORT_START_DATE, CO-

HORT_END_DATE.

outcomeDatabaseSchema

The name of the database schema that is the location where the data used to define the outcome cohorts is available. If exposureTable = CON-DITION_ERA, exposureDatabaseSchema is not used by assumed to be cdmSchema. Requires read permissions to this database.

outcomeTable

The tablename that contains the outcome cohorts. If outcomeTable ¡¿ CONDITION_OCCURRENCE, then expectation is outcomeTable has format of COHORT table: COHORT_DEFINITION_ID, SUBJECT_ID, COHORT_START_DATE, COHORT_END_DATE.

firstExposureOnly

If TRUE, only use first occurrence of each drug concept id for each person

firstOutcomeOnly

If TRUE, only use first occurrence of each condition concept id for each person.

minAge Integer for minimum allowable age.

maxAge Integer for maximum allowable age.

studyStartDate Date for minimum allowable data for index exposure. Date format is 'yyyymmdd'.

runSelfControlledCohort 13

studyEndDate Date for maximum allowable data for index exposure. Date format is 'vvvvmmdd'.

add Length Of Exposure Exposed

If TRUE, use the duration from drugEraStart -; drugEraEnd as part of timeAtRisk.

riskWindowStartExposed

Integer of days to add to drugEraStart for start of timeAtRisk (0 to include index date, 1 to start the day after).

riskWindowEndExposed

Additional window to add to end of exposure period (if addLengthOf-ExposureExposed = TRUE, then add to exposure end date, else add to exposure start date).

addLengthOfExposureUnexposed

If TRUE, use the duration from exposure start -; exposure end as part of timeAtRisk looking back before exposure start.

riskWindowEndUnexposed

Integer of days to add to exposure start for end of timeAtRisk (0 to include index date, -1 to end the day before).

riskWindowStartUnexposed

Additional window to add to start of exposure period (if addLengthOf-ExposureUnexposed = TRUE, then add to exposure end date, else add to exposure start date).

hasFullTimeAtRisk

If TRUE, restrict to people who have full time-at-risk exposed and unexposed.

washoutPeriod Integer to define required time observed before exposure start.

followupPeriod Integer to define required time observed after exposure start.

computeTarDistribution

If TRUE, computer the distribution of time-at-risk and average absolute time between treatment and outcome. Note, may add significant computation time on some database engines.

computeThreads Number of parallel threads for computing IRRs with exact confidence intervals.

riskWindowsTable

String: optionally store the risk windows in a (non-temporary) table.

results Table String: optionally store the summary results (number exposed/ unexposed patients per outcome-exposure pair) in a (non-temporary) table. Note that this table does not store the rate ratios, only the values required to calculate rate ratios.

resultsDatabaseSchema

Schema to oputput results to. Ignored if resultsTable and riskWindowsTable are temporary.

postProcessFunction

Callback function to handle batches of data. Useful for massive result sets that overflow system memory. See example.

postProcessArgs

Arguments for post processing function callback.

returnEstimates

Boolean opt to not return estimates, only useful in the case where post-ProcessFunction is used

Details

Population-level estimation method that estimates incidence rate comparison of exposed/unexposed time within an exposed cohort. If multiple exposureIds and outcomeIds are provided, estimates will be generated for every combination of exposure and outcome.

Value

An object of type sccResults containing the results of the analysis.

References

Ryan PB, Schuemie MJ, Madigan D.Empirical performance of a self-controlled cohort method: lessons for developing a risk identification and analysis system. Drug Safety 36 Suppl1:S95-106, 2013

Examples

```
## Not run:
connectionDetails <- createConnectionDetails(dbms = "sql server",</pre>
                                               server = "RNDUSRDHIT07.jnj.com")
sccResult <- runSelfControlledCohort(connectionDetails,</pre>
                                      cdmDatabaseSchema = "cdm_truven_mdcr.dbo",
                                      exposureIds = c(767410, 1314924, 907879),
                                      outcomeIds = 444382,
                                      outcomeTable = "condition_era")
# Using a callback function that writes data to a csv file and not store in memory
csvFileName <- "D:/path/to/output.csv"</pre>
writeSccData <- function(data, position, csvFileName) {</pre>
  vroom::vroom_write(data, csvFileName, delim = ",", append = position != 1, na = "")
}
runSelfControlledCohort(connectionDetails,
                         cdmDatabaseSchema = "cdm_truven_mdcr.dbo",
                         exposureIds = c(767410, 1314924, 907879),
                         outcomeIds = 444382,
                         outcomeTable = "condition_era",
                         postProcessFunction = writeSccData,
                         postProcessArgs = list(csvFileName = csvFileName),
                         returnEstimates = FALSE)
## End(Not run)
```

save Exposure Outcome List

Save a list of exposureOutcome to file

Description

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

Usage

```
saveExposureOutcomeList(exposureOutcomeList, file)
```

saveSccAnalysisList 15

Arguments

exposureOutcomeList

The exposureOutcome list to be written to file

file The name of the file where the results will be written

saveSccAnalysisList $Save\ a\ list\ of\ sccAnalysis\ to\ file$

Description

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

Usage

```
saveSccAnalysisList(sccAnalysisList, file)
```

Arguments

sccAnalysisList

The sccAnalysis list to be written to file

file The name of the file where the results will be written

summarizeAnalyses

Create a summary report of the analyses

Description

Create a summary report of the analyses

Usage

```
summarizeAnalyses(resultsReference, outputFolder)
```

Arguments

resultsReference

A data.frame as created by the runSccAnalyses function.

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