Results schema of the SelfControlledCaseSeries package

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Contents

1 Introduction

This document describes the data model of the output of the SelfControlledCaseSeries (SCCS) package, generated by the `exportToCsv()` function. This vignette assumes you are already familiar with the `SelfControlledCaseSeries` package, and have read all other vignettes.

1.1 Exposures, covariates of interest, and controls

As described in the 'Single studies using the SelfControlledCaseSeries package' vignette, **eras** are cohorts or drug eras extracted from the database. **Covariates** can either be splines, for example representing age or season, or era covariates, derived from eras. When defining covariates using the `createEraCovariateSettings()` function we can either use verbatim era IDs (e.g. cohort IDs), or we can reference a variable (typically called 'exposureId'). When defining **exposures** using the `exposure()` function, we can define different era IDs to be used for this variable, thereby using the same analysis settings for different exposures and outcomes. For each exposure we can set the `trueEffectSize` if known. Any exposure with known true effect size is considered a

`control`, and will be used for empirical calibration. Some of our covariates can be marked as **covariates of interest** by setting `exposureOfInterest = TRUE` when calling `createEraCovariateSettings()`. This is especially relevant for the results model, since these covariates will be reported in the `sccs_result` table.

1.2 Exposures-outcome-sets, analysis IDs and models

Using the `createExposuresOutcome()` function we can define an outcome with one or more exposures, since an SCCS model can have multiple exposures (e.g. we could have separte exposures for the first and second dose of a vaccine). With the `createSccsAnalysis()` function we can create a set of settings for analysis describing which data to extract from the database, how to transform that data including which covariates to construct, and how to fit the SCCS model. Each analysis setting has a unique analysis ID. Each combination of an exposures-outcome-set and an analysis setting will correspond to one SCCS model. A model can have multiple covariates, and each covariates can be based on multiple eras.

1.3 Fields with minimum values

Some fields contain patient counts or fractions that can easily be converted to patient counts. To prevent identifiability, these fields are subject to a minimum value. When the value falls below this minimum, it is replaced with the negative value of the minimum. For example, if the minimum subject count is 5, and the actual count is 2, the value stored in the data model will be -5, which could be represented as '<5' to the user. Note that the value 0 is permissible, as it identifies no persons. These fields are identified below as having Min. count = 'Yes'.

2 Tables

In this section you will find the list of tables and their fields.

2.1 Table sccs_age_spanning

Field	Type	Key	Min. count	Description
analysis_id	int	Yes	No	A foreign key referencing the sccs_analysis table.
exposures_outcome_set_id	int	Yes	No	A foreign key referencing the sccs_exposures_outcome_set t
database_id	varchar	Yes	No	Foreign key referencing the database.
age_month	int	Yes	No	Age in months since birth.
cover_before_after_subjects	int	No	Yes	Number of subjects whose observation period covers this mon

2.2 Table sccs_analysis

Field	Type	Key	Min. count	Description
analysis_id	int	Yes	No	A unique identifier for an analysis.
description	varchar	No	No	A description for an analysis, e.g. 'Correcting for age and season'.
definition	varchar	No	No	A JSON object specifying the analysis.

2.3 Table sccs_attrition

Field	Type	Key	Min. count	Description
sequence_number	int	Yes	No	The place in the sequence of steps defining the final analysis
description	varchar	No	No	A description of the last restriction, e.g. 'Removing persons
analysis_id	int	Yes	No	A foreign key referencing the sccs_analysis table.

Field	Type	Key	Min. count	Description
exposures_outcome_set_id	int	Yes	No	A foreign key referencing the sccs_exposures_outcome_set
covariate_id	int	Yes	No	A foreign key referencing the sccs_covariate table. The iden
database_id	varchar	Yes	No	Foreign key referencing the database.
outcome_subjects	int	No	Yes	The number of subjects with at least one outcome.
outcome_events	int	No	Yes	The number of outcome events.
outcome_observation_periods	int	No	Yes	The number of observation periods containing at least one o
observed_days	bigint	No	Yes	The number of days subjects were observed.

2.4 Table sccs_calendar_time_spanning

Field	Type	Key	Min. count	Description
analysis_id	int	Yes	No	A foreign key referencing the sccs_analysis table.
exposures_outcome_set_id	int	Yes	No	A foreign key referencing the sccs_exposures_outcome_set t
database_id	varchar	Yes	No	Foreign key referencing the database.
calendar_year	int	Yes	No	Calendar year (e.g. 2022)
calendar_month	int	Yes	No	Calendar month (e.g. 1 is January).
cover_before_after_subjects	int	No	Yes	Number of subjects whose observation period covers this mon

2.5 Table sccs_censor_model

Field	Type	Key	Min. count	Description
analysis_id	int	Yes	No	A foreign key referencing the sccs_analysis table.
exposures_outcome_set_id	int	Yes	No	A foreign key referencing the sccs_exposures_outcome_set ta
database_id	varchar	Yes	No	Foreign key referencing the database.
parameter_id	int	Yes	No	The parameter number in the censor model (starting at 1).
parameter_value	float	No	No	The fitted parameter value.
model_type	varchar	No	No	The type of censor model. Can be 'Weibull-Age'. 'Weibull-Inte

2.6 Table sccs_covariate

Field	Type	Key	Min. count	Description
analysis_id	int	Yes	No	A foreign key referencing the sccs_analysis table.
exposures_outcome_set_id	int	Yes	No	A foreign key referencing the sccs_exposures_outcome_set ta
covariate_id	int	Yes	No	A unique identifier for a covariate.
covariate_name	varchar	No	No	A description for the covariate.
era_id	int	No	No	A foreign key referencing the sccs_era table.
covariate_analysis_id	int	No	No	A foreign key referencing the sccs_covariate_analysis table.
database_id	varchar	Yes	No	Foreign key referencing the database.

2.7 Table sccs_covariate_analysis

Field	Type	Key	Min. count	Description
analysis_id	int	Yes	No	A foreign key referencing the sccs_analysis table.
covariate_analysis_id	int	Yes	No	A unique identifier for a covariate analysis.
covariate_analysis_name	varchar	No	No	A name for a covariate analysis, e.g. 'Pre-exposure'.

Field	Type	Key	Min. count	Description
variable_of_interest	int	No	No	Is the variable of interest (1 = yes, 0 = no).
pre_exposure	int	No	No	Does the variable represent a pre-exposure period (1 = yes, 0
end_of_observation_period	int	No	No	Does the variable represent the end of the observation period

2.8 Table sccs_covariate_result

Field	Type	Key	Min. count	Description
analysis_id	int	Yes	No	A foreign key referencing the sccs_analysis table.
exposures_outcome_set_id	int	Yes	No	A foreign key referencing the sccs_exposures_outcome_set ta
database_id	varchar	Yes	No	Foreign key referencing the database.
covariate_id	int	Yes	No	The identifier for the covariate.
rr	float	No	No	The estimated relative risk (i.e. the incidence rate ratio).
ci_95_lb	float	No	No	The lower bound of the 95% confidence interval of the relative
ci_95_ub	float	No	No	The upper bound of the 95% confidence interval of the relative

2.9 Table sccs_diagnostics_summary

Field	Type	Key	Min. count	Description
analysis_id	int	Yes	No	A foreign key referencing the sccs_analysis table.
exposures_outcome_set_id	int	Yes	No	A foreign key referencing the sccs_exposures_outcom
covariate_id	int	Yes	No	The identifier for the covariate of interest.
database_id	varchar	Yes	No	Foreign key referencing the database.
time_stability_p	float	No	No	The p for whether the mean monthly ratio between o
time_stability_diagnostic	varchar(20)	No	No	Pass / fail / not evaluated classification of the time st
event_exposure_lb	float	No	No	Lower bound of the 95% CI for the pre-expososure es
event_exposure_ub	float	No	No	Upper bound of the 95% CI for the pre-expososure es
event_exposure_diagnostic	varchar(20)	No	No	Pass / fail / not evaluated classification of the event-e
event_observation_lb	float	No	No	Lower bound of the 95% CI for the end of observation
event_observation_ub	float	No	No	Upper bound of the 95% CI for the end of observation
event_observation_diagnostic	varchar(20)	No	No	Pass / fail / not evaluated classification of the event-o
rare_outcome_prevalence	float	No	No	The proportion of people in the underlying population
rare_outcome_diagnostic	varchar(20)	No	No	Pass / fail / not evaluated classification of the rare ou
ease	float	No	No	The expected absolute systematic error.
ease_diagnostic	varchar(20)	No	No	Pass / warning / fail / not evaluated classification of
mdrr	float	No	No	The minimum detectable relative risk.
mdrr_diagnostic	varchar(20)	No	No	Pass / warning / fail / not evaluated classification of
unblind	int	No	No	Is unblinding the result recommended? (1 = yes, 0 =
unblind_for_evidence_synthesis	int	No	No	Is unblinding the result for inclusion in evidence synth
time_trend_p	float	No	No	The p for whether the mean monthly ratio between o
pre_exposure_p	float	No	No	One-sided p-value for whether the rate before expore
time_trend_diagnostic	varchar(20)	No	No	Pass / warning / fail / not evaluated classification of
pre_exposure_diagnostic	varchar(20)	No	No	Pass / warning / fail / not evaluated classification of

2.10 Table sccs_era

Field	Type	Key	Min. count	Description
exposures_outcome_set_id	int	Yes	No	A foreign key referencing the sccs_exposures_outcome_set ta

Field	Type	Key	Min. count	Description
analysis_id	int	Yes	No	A unique identifier for an analysis.
era_type	varchar	Yes	No	The type of era (e.g. 'rx' for drugs).
era_id	int	Yes	No	A unique identifier, corresponding to the ID in the source tabl
era_name	varchar	No	No	A name for the era. Is NULL for eras derived from cohorts.
database_id	varchar	Yes	No	Foreign key referencing the database.

2.11 Table sccs_event_dep_observation

Field	Type	Key	Min. count	Description
analysis_id	int	Yes	No	A foreign key referencing the sccs_analysis table.
exposures_outcome_set_id	int	Yes	No	A foreign key referencing the sccs_exposures_outcome_set ta
database_id	varchar	Yes	No	Foreign key referencing the database.
months_to_end	int	Yes	No	Number of months until observation end.
censored	int	Yes	No	Whether the observation is censored (meaning, not equal to th
outcomes	int	No	Yes	Number of outcomes observed during the month.

2.12 Table sccs_exposure

Field	Type	Key	Min. count	Description
exposures_outcome_set_id	int	Yes	No	A foreign key referencing the sccs_exposures_outcome_set table
era_id	int	Yes	No	A foreign key referencing the sccs_era table.
true_effect_size	float	No	No	If known, the true effect size. For negatitive controls this equals

2.13 Table sccs_exposures_outcome_set

Field	Type	Key	Min. count	Description
exposures_outcome_set_id	int	Yes	No	A unique identifier for a set of exposures and an outcome.
outcome_id	int	No	No	A cohort ID.
nesting_cohort_id	int	No	No	A cohort ID.

2.14 Table sccs_likelihood_profile

Field	Type	Key	Min. count	Description
log_rr	float	Yes	No	The log of the relative risk where the likelihood is sampled.
log_likelihood	float	No	No	The normalized log likelihood.
gradient	float	No	No	The gradient of the log likelihood.
covariate_id	int	Yes	No	The identifier for the covariate of interest.
exposures_outcome_set_id	int	Yes	No	A foreign key referencing the sccs_exposures_outcome_set ta
analysis_id	int	Yes	No	A foreign key referencing the sccs_analysis table.
database_id	varchar	Yes	No	Foreign key referencing the database.

2.15 Table sccs_result

Field	Type	Key	Min. count	Description
analysis_id	int	Yes	No	A foreign key referencing the sccs_analysis table.
exposures_outcome_set_id	int	Yes	No	A foreign key referencing the sccs_exposures_outcome_set
covariate_id	int	Yes	No	A foreign key referencing the sccs_covariate table. The iden
rr	float	No	No	The estimated relative risk (i.e. the incidence rate ratio).
ci_95_lb	float	No	No	The lower bound of the 95% confidence interval of the relati
ci_95_ub	float	No	No	The upper bound of the 95% confidence interval of the relat
p	float	No	No	The two-sided p-value considering the null hypothesis of no
one_sided_p	float	No	No	The one-sided p-value considering the null hypothesis of IRI
outcome_subjects	int	No	Yes	The number of subjects with at least one outcome.
outcome_events	int	No	Yes	The number of outcome events.
outcome_observation_periods	int	No	Yes	The number of observation periods containing at least one o
covariate_subjects	int	No	Yes	The number of subjects having the covariate.
covariate_days	int	No	Yes	The total covariate time in days.
covariate_eras	int	No	Yes	The number of continuous eras of the covariate.
covariate_outcomes	int	No	Yes	The number of outcomes observed during the covariate time
observed_days	bigint	No	Yes	The number of days subjects were observed.
log_rr	float	No	No	The log of the relative risk.
se_log_rr	float	No	No	The standard error of the log of the relative risk.
llr	float	No	No	The log of the likelihood ratio (of the MLE vs the null hypo
calibrated_rr	float	No	No	The calibrated relative risk.
calibrated_ci_95_lb	float	No	No	The lower bound of the calibrated 95% confidence interval o
calibrated_ci_95_ub	float	No	No	The upper bound of the calibrated 95% confidence interval o
calibrated_p	float	No	No	The calibrated two-sided p-value.
calibrated_one_sided_p	float	No	No	The calibrated one-sided p-value considering the null hypoth
calibrated_log_rr	float	No	No	The log of the calibrated relative risk.
calibrated_se_log_rr	float	No	No	The standard error of the log of the calibrated relative risk.
database_id	varchar	Yes	No	Foreign key referencing the database.

2.16 Table sccs_spline

Field	Type	Key	Min. count	Description
analysis_id	int	Yes	No	A foreign key referencing the sccs_analysis table.
exposures_outcome_set_id	int	Yes	No	A foreign key referencing the sccs_exposures_outcome_set ta
database_id	varchar	Yes	No	Foreign key referencing the database.
spline_type	varchar	Yes	No	Either 'age', 'season', or 'calendar time'.
knot_month	float	Yes	No	Location of the knot. For age, the month since birth. For seas
rr	float	No	No	The estimated relative risk (i.e. the incidence rate ratio).

2.17 Table sccs_time_to_event

Field	Type	Key	Min. count	Description
analysis_id	int	Yes	No	A foreign key referencing the sccs_analysis table.
exposures_outcome_set_id	int	Yes	No	A foreign key referencing the sccs_exposures_outcome_set ta
database_id	varchar	Yes	No	Foreign key referencing the database.
era_id	int	Yes	No	A foreign key referencing the sccs_era table. The identifier for
week	int	Yes	No	The number of the week relative to exposure. Week 0 starts on
observed_subjects	int	No	Yes	The numer of people observed during the week.
outcomes	int	No	Yes	The number of outcomes observed durig the week.

2.18 Table sccs_time_trend

Field	Type	Key	Min. count	Description
analysis_id	int	Yes	No	A foreign key referencing the sccs_analysis table.
exposures_outcome_set_id	int	Yes	No	A foreign key referencing the sccs_exposures_outcome_set ta
database_id	varchar	Yes	No	Foreign key referencing the database.
calendar_year	int	Yes	No	The calendar year (e.g. 2022).
calendar_month	int	Yes	No	The calendar month (e.g. 1 for January).
observed_subjects	int	No	Yes	Number of people observed during the month.
ratio	float	No	No	Observed over expected ratio, where the expected count assum
adjusted_ratio	float	No	No	Observed over expected ratio, where the expected count is adj
outcome_rate	float	No	Yes	Number of outcomes divided by the number of subjects.
adjusted_rate	float	No	Yes	The outcome rate, adjusted for age, season, or calendar time, a
stable	int	No	No	Does the adjusted rate not deviate significantly from the mean
p	float	No	No	The two-sided p-value against the null hypothesis that the rat