Comparative effectiveness studies data model

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Contents

This document describes the data model for storing the output of the comparative effectiveness analyses.

1   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 have been marked with * in the preceding diagram, and are noted 'with min value' in the Type column in the table definitions below.

2   Study specification

The first set of tables are not specific to a database, but rather provide a reference for linking results generated in databases. These can be thought of as the study specifications.

2.1   Analyses

2.1.1   Table: cohort_method_analysis

Lists the analyses that will be executed by the CohortMethod package.

Field	Type	Description
analysis_id	integer	A unique identifier for an analysis.
description	varchar	A description for an analysis, e.g. 'On-treatment'.
definition	varchar	A CohortMethod JSON object specifying the analysis.

2.1.2   Table: covariate_analysis

Lists the covariate analyses that will be executed by the FeatureExtraction package. Each analysis can generate one or more covariates. For example, the age group analysis creates binary covariates for each 5-year age group.

Field	Type	Description
analysis_id	integer	A foreign key referencing the cohort_method_analysis table.
covariate_analysis_id	integer	A unique identifier for a covariate analysis.
covariate_analysis_name	varchar	A name for a covariate analysis, e.g. 'Demographics: age group'.

2.2   Exposures

Exposures can be exposures to drugs, procedures, or combinations of these. The exposure IDs used in the two exposure-of-interest tables do not overlap.

2.2.1   Table: exposure_of_interest

Lists all exposure cohorts considered in the study.

Field	Type	Description
exposure_id	integer	A unique identifier for an exposure.
exposure_name	varchar	A name for the exposure, e.g. 'Sertraline'.
definition	varchar	ATLAS cohort definition JSON for constructing the exposure cohort.

2.3 Outcomes

Outcomes can be distinguished into outcomes of interest, where the true effect size is unknown and of interest, negative control outcomes where the true effect size is known to be 1, and positive control outcomes where the true effect size is of a known magnitude greater than 1. The outcome IDs used in the three outcome tables do not overlap.

2.3.1 Table: outcome_of_interest

Field	Type	Description
outcome_id	integer	A unique identifier for an outcome.
outcome_name	varchar	A name for the outcome, e.g. 'Stroke.
definition	varchar	OHDSI SQL or JSON object defining the outcome.

2.3.2 Table: negative_control_outcomes

Negative control outcomes are derived from a single concept ID.

Field	Type	Description
outcome_id	integer	A unique identifier for an outcome.
outcome_name	varchar	A name for the outcome, e.g. 'Ingrown nail'.

2.3.3 Table: positive_control_outcomes

Positive controls are synthesized by injecting simulated outcomes into negative controls.

Field	Type	Description
outcome_id	integer	A unique identifier for an outcome.
outcome_name	varchar	A name for the outcome, e.g. 'Ingrown nail RR=2'.
exposure_id	integer	The exposure for which the signal is injected. A foreign key referencing the exposure_of_interest table.
negative_control_id	integer	The negative control used to create the positive control. A foreign key referencing outcome_id field in the negative_control_outcomes table.
effect_size	float	The simulated effect size for the positive control.

3   Generated results

The second set of tables contain the results generated on each database.

3.1   Metadata

For each database, some meta data is captured.

3.1.1   Table: database

Lists the databases that have contributed data. To identify meta-analyses estimates across databases, a dummy database record is created where the is_meta_analysis flag is set to 1.

Field	Type	Description
database_id	varchar	A unique identifier for a database, e.g. 'MDCD'.
database_name	varchar	The full name for the database, e.g. 'Truven MarketScan Multi-state Medicaid (MDCD)'.
description	varchar	A longer description, e.g. 'Truven Health MarketScan® Multi-State Medicaid Database (MDCD) adjudicated US health insurance claims for Medicaid enrollees from multiple states . . .'
is_meta_analysis	integer	Does the record pertain a meta-analysis across databases? (0=no, 1=yes)

3.1.2   Table: exposure_summary

Provides summary statistics for the exposure cohorts, independent of other exposure cohorts.

Field	Type	Description
database_id	varchar	Foreign key referencing the database.
exposure_id	integer	A foreign key referencing the exposure_of_interest table.
min_date	date	The earliest date when the exposure was observed in the database.
max_date	date	The latest date when the exposure was observed in the database.

3.1.3   Table: comparison_summary

Provides summary statistics for the comparison between two exposure cohorts.

Field	Type	Description
database_id	varchar	Foreign key referencing the database.
target_id	integer	A foreign key referencing the exposure_of_interest table.
comparator_id	integer	A foreign key referencing the exposure_of_interest table.

Field	Type	Description
min_date	date	The earliest date when both target and comparator were observed in the database.
max_date	date	The latest date when both target and comparator were observed in the database.

3.1.4   Table: attrition

Provides the number of people in the exposure cohorts after each step of the analyses. Because some steps are related to a specific comparison or even analysis, the target, comparator, and analysis ID can optionally also be specified.

Field	Type	Description
database_id	varchar	Foreign key referencing the database.
exposure_id	integer	A foreign key referencing the exposure_of _interest table.
target_id	integer nullable	A foreign key referencing the exposure_of _interest table.
comparator_id	integer nullable	A foreign key referencing the exposure_of _interest table.
outcome_id	integer nullable	A foreign key referencing the outcome_of_interest table.
analysis_id	integer nullable	A foreign key referencing the cohort_method_analysis table.
sequence_number	integer	The place in the sequence of steps defining the final analysis cohort. 1 indicates the original exposed population without any inclusion criteria.
description	varchar	A description of the last restriction, e.g. "Removing persons with the outcome prior".
subjects	integer with min value	The number of subjects in the cohort.

3.1.5   Table: covariate

Lists the covariates constructed in a database.

Field	Type	Description
database_id	varchar	Foreign key referencing the database.
analysis_id	integer	A foreign key referencing the cohort_method_analysis table.
covariate_id	integer	A unique identified for a covariate.
comparator_name	varchar	A name for a covariate, e.g. 'Age group: 20-25 years'.
covariate_analysis_id	integer	A foreign key referencing the covariate_analysis table.

3.1.6   Table: cm_follow_up_dist

Contains the distribution of follow up time in the target and comparator groups for a specific cohort method analysis. Only outcomes of interest are included.

Field	Type	Description
database_id	varchar	Foreign key referencing the database.
target_id	integer	A foreign key referencing the exposure_of_interest table.
comparator_id	integer	A foreign key referencing the exposure_of_interest table.
outcome_id	integer	A foreign key referencing the outcomes_of_interest, negative_control_outcome, or positive_control_outcome table.
analysis_id	integer	A foreign key referencing the cohort_method_analysis table.
target_min_days	integer	The minimum number of observation days for a person.
target_p10_days	integer	The 10th percentile of number of observation days for a person in the target group.
target_p25_days	integer	The 25th percentile of number of observation days for a person in the target group.
target_median_days	integer	The median number of observation days for a person in the target group.
target_p75_days	integer	The 75th percentile of number of observation days for a person in the target group.
target_p90_days	integer	The 90th percentile of number of observation days for a person in the target group.
target_max_days	integer	The maximum number of observation days for a person in the target group.
comparator_min_days	integer	The minimum number of observation days for a person in the comparator group.
comparator_p10_days	integer	The 10th percentile of number of observation days for a person in the comparator group.
comparator_p25_days	integer	The 25th percentile of number of observation days for a person in the comparator group.
comparator_median_days	integer	The median number of observation days for a person in the comparator group.
comparator_p75_days	integer	The 75th percentile of number of observation days for a person in the comparator group.
comparator_p90_days	integer	The 90th percentile of number of observation days for a person in the comparator group.
comparator_max_days	integer	The maximum number of observation days for a person in the comparator group.

3.2   Main results

These tables contain the main results.

3.2.1   Table: cohort_method_results

Contains the results produced by the CohortMethod package for the main effects. Also contains calibrated p-values and confidence intervals. Meta-analysis estimates are also stored in this table.

Field	Type	Description
database_id	varchar	Foreign key referencing the database.
target_id	integer	A foreign key referencing the exposure_of_interest table.
comparator_id	integer	A foreign key referencing the exposure_of_interest table.
outcome_id	integer	A foreign key referencing the outcomes_of_interest, negative_control_outcome, or positive_control_outcome table.
analysis_id	integer	A foreign key referencing the cohort_method_analysis table.
rr	float	The estimated relative risk (hazard ratio).
ci_95_lb	float	The lower bound of the 95% confidence interval of the relative risk.
ci_95_ub	float	The upper bound of the 95% confidence interval of the relative risk.
p	float	The two-sided p-value considering the null hypothesis of no effect.
i_2	float nullable	The I^2 measure of between-database heterogeneity (for meta-analyses estimates only).
log_rr	float	The log of the relative risk.
se_log_rr	float	The standard error of the log of the relative risk.
target_subjects	integer with min value	The number of subject in the target cohort.
comparator_subjects	integer with min value	The number of subject in the comparator cohort.
target_days	integer	The number of days observed in the target cohort.
comparator_days	integer	The number of days observed in the comparator cohort.
target_outcomes	integer with min value	The number of outcomes observed in the target cohort.
comparator_outcomes	integer with min value	The number of outcomes observed in the comparator cohort.
calibrated_p	float	The calibrated p-value.
calibrated_rr	float	The calibrated relative risk (hazard ratio).
calibrated_ci_95_lb	float	The lower bound of the calibrated 95% confidence interval of the relative risk.
calibrated_ci_95_ub	float	The upper bound of the calibrated 95% confidence interval of the relative risk.
calibrated_log_rr	float	The log of the calibrated relative risk.
calibrated_se_log_rr	float	The standard error of the log of the calibrated relative risk.

3.2.2 Table: cm_interaction_results

Contains the results produced by the CohortMethod package for the interaction effects. Also contains calibrated p-values. Meta-analysis estimates are also stored in this table.

Field	Type	Description
database_id	varchar	Foreign key referencing the database table.
target_id	integer	A foreign key referencing the exposure_of_interest table.

Field	Type	Description
comparator_id	integer	A foreign key referencing the exposure_of_interest table.
outcome_id	integer	A foreign key referencing the outcomes_of_interest, negative_control_outcome, or positive_control_outcome table.
analysis_id	integer	A foreign key referencing the cohort_method_analysis table.
interaction_covariate_id	integer	The covariate for which the interaction with the treatment variable was estimated. A foreign key referencing the covariate table.
rrr	float	The estimated relative risk ratio (hazard ratio ratio).
ci_95_lb	float	The lower bound of the 95% confidence interval of the relative risk ratio.
ci_95_ub	float	The upper bound of the 95% confidence interval of the relative risk ratio.
p	float	The two-sided p-value considering the null hypothesis of no effect.
i_2	float nullable	The I^2 measure of between-database heterogeneity (for meta-analyses estimates only).
log_rrr	float	The log of the relative risk ratio.
se_log_rrr	float	The standard error of the log of the relative risk ratio.
target_subjects	integer with min value	The number of subject in the target cohort having the covariate.
comparator_subjects	integer with min value	The number of subject in the comparator cohort having the covariate.
target_days	integer	The number of days observed in the target cohort having the covariate.
comparator_days	integer	The number of days observed in the comparator cohort having the covariate.
target_outcomes	integer with min value	The number of outcomes observed in the target cohort having the covariate.
comparator_outcomes	integer with min value	The number of outcomes observed in the comparator cohort having the covariate.
calibrated_p	float	The calibrated p-value.

3.3 Diagnostics

3.3.1 Table: covariate_balance

Contains the covariate balance statistics for each comparison. If the interaction_covariate_id is specified, the results pertain to the subgroup that has a non-zero value for that specific covariate. To save space, balance for all covariates is only computed once for each target-comparator pair, using propensity score matching and stratification. Only a subset of covariates is reported for each outcome-analysis combination.

Field	Type	Description
database_id	varchar	Foreign key referencing the database.
target_id	integer	A foreign key referencing the exposure_of_interest table.
comparator_id	integer	A foreign key referencing the exposure_of_interest table.

Field	Type	Description
outcome_id	integer nullable	A foreign key referencing the outcomes_of_interest table.
analysis_id	integer nullable	A foreign key referencing the cohort_method_analysis table.
interaction_covariate_id	integer nullable	For covariate balance within a subgroup: this covariate identifies the subgroup. A foreign key referencing the covariate table.
covariate_id	integer	A foreign key referencing the covariate table.
target_mean_before	float with min value	The mean value of the covariate in the target cohort before propensity score adjustment.
comparator_mean_before	float with min value	The mean value of the covariate in the comparator cohort before propensity score adjustment.
std_diff_before	float	The standardized difference of the means between the target and comparator cohort before propensity score adjustment.
target_mean_after	float with min value	The mean value of the covariate in the target cohort after propensity score adjustment.
comparator_mean_after	float with min value	The mean value of the covariate in the comparator cohort after propensity score adjustment.
std_diff_after	float	The standardized difference of the means between the target and comparator cohort after propensity score adjustment.

3.3.2   Table: preference_score_dist

Provides the preference score distribution for each comparison.

Field	Type	Description
database_id	varchar	Foreign key referencing the database.
target_id	integer	A foreign key referencing the exposure_of_interest table.
comparator_id	integer	A foreign key referencing the exposure_of_interest table.
analysis_id	integer	A foreign key referencing the cohort_method_analysis table.
preference_score	float	A preference score value.
target_density	float	The distribution density for the target cohort at the given preference score.
comparator_density	float	The distribution density for the comparator cohort at the given preference score.

3.3.3   Table: kaplan_meier_dist

Contains data to display as a Kaplan-Meier plot for each comparison. The number of subjects at risk in the target and comparator cohorts will only be provided for specific pre-defined time points.

Field	Type	Description
database_id	varchar	Foreign key referencing the database.

Field	Type	Description
target_id	integer	A foreign key referencing the exposure_of_interest table.
comparator_id	integer	A foreign key referencing the exposure_of_interest table.
outcome_id	integer	A foreign key referencing the outcomes_of_interest table.
analysis_id	integer	A foreign key referencing the cohort_method_analysis table.
time	integer	Time in days since cohort start.
target_at_risk	integer with min value nullable	The number of subjects still at risk in the target cohort.
comparator_at_risk	integer with min value nullable	The number of subjects still at risk in the comparator cohort.
target_survival	float	The estimated survival fraction in the target cohort.
target_survival_lb	float	The lower bound of the 95% confidence interval of the survival fraction in the target cohort.
target_survival_ub	float	The upper bound of the 95% confidence interval of the survival fraction in the target cohort.
comparator_survival	float	The estimated survival fraction in the comparator cohort.
comparator_survival_lb	float	The lower bound of the 95% confidence interval of the survival fraction in the comparator cohort.
comparator_survival_ub	float	The upper bound of the 95% confidence interval of the survival fraction in the comparator cohort.

3.3.4 Table: propensity_model

Contains the propensity models.

Field	Type	Description
database_id	varchar	Foreign key referencing the database.
target_id	integer	A foreign key referencing the exposure_of_interest table.
comparator_id	integer	A foreign key referencing the exposure_of_interest table.
analysis_id	integer	A foreign key referencing the cohort_method_analysis table.
covariate_id	integer	A foreign key referencing the covariate table.
coefficient	float	The coefficient (beta) for the covariate in the propensity model.