# Creating Analysis Specification

## Anthony G. Sena

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# 1 Creating an analysis specification

This walk through will show how to use Strategus to define an analysis specification on an example study using cohorts from the example problem What is the risk of gastrointestinal (GI) bleed in new users of celecoxib compared to new users of diclofenac? as described in the Book Of OHDSI Chapter 12 on Population Level Estimation

## 1.1 Setting up your R environment

Use renv and the renv.lock from the Strategus study template to set up your R environment. This is done by copying the renv.lock file into the root of a new project and the restore of the environment is done by calling renv::restore(). This will ensure that you have all of the R dependencies including the OHDSI HADES libraries and Strategus. The following code will download the renv.lock file to your machine, install renv and restore the R environment:

```
download.file("https://github.com/ohdsi-studies/StrategusStudyRepoTemplate/blob/main/renv.lock")
install.packages("renv")
renv::restore()
```

## 1.2 Cohorts for the study

To start, we'll need to define cohorts and negative control outcomes to use in our example analysis specification. We've included the cohorts and negative control outcomes in the **Strategus** package for this example and the code below will load them for use when assembling the analysis specification.

```
cohortDefinitionSet <- CohortGenerator::getCohortDefinitionSet(
   settingsFileName = "testdata/Cohorts.csv",
   jsonFolder = "testdata/cohorts",
   sqlFolder = "testdata/sql",
   packageName = "Strategus"
)
ncoCohortSet <- CohortGenerator::readCsv(file = system.file("testdata/negative_controls_concept_set.csv
   package = "Strategus"
))</pre>
```

# 2 Assembling HADES modules

The building blocks of the Strategus analysis specification are HADES modules. For purposes of this walk through, a module is a specific analytic task you would like to perform. As shown in the subsequent sections, the high-level pattern for using a module consists of:

- 1. Instantiate the module object. For example, CohortGenerator's module is created using: cg <- CohortGeneratorModule\$new()
- 2. Create the module specifications using the settings function(s) from the module. See the module list for more details.
- 3. Compose the analysis pipeline from one or more module settings.

#### 2.1 CohortGenerator Module Settings

The following code instantiates a new CohortGenerator module cgModule. cgModule then exposes functions we can use for creating the module specifications to add to the analysis specification. In the analysis specification, we will add the cohort definitions and negative control outcomes to the sharedResources section since these elements may be used by any of the HADES modules. To do this, we will use the createCohortSharedResourceSpecifications and createNegativeControlOutcomeCohortSharedResourceSpecification functions of the CohortGenerator module. In addition, we will use the createModuleSpecifications function to specify the cohort generation settings.

```
cgModule <- CohortGeneratorModule$new()

# Create the cohort definition shared resource element for the analysis specification
cohortDefinitionSharedResource <- cgModule$createCohortSharedResourceSpecifications(
    cohortDefinitionSet = cohortDefinitionSet
)</pre>
```

```
# Create the negative control outcome shared resource element for the analysis specification
ncoSharedResource <- cgModule$createNegativeControlOutcomeCohortSharedResourceSpecifications(
    negativeControlOutcomeCohortSet = ncoCohortSet,
    occurrenceType = "all",
    detectOnDescendants = TRUE
)

# Create the module specification
cohortGeneratorModuleSpecifications <- cgModule$createModuleSpecifications(
    generateStats = TRUE
)</pre>
```

#### 2.2 CohortDiagnostics Module Settings

The following code creates the cohortDiagnosticsModuleSpecifications to run cohort diagnostics on the cohorts in the study.

```
cdModule <- CohortDiagnosticsModule$new()
cohortDiagnosticsModuleSpecifications <- cdModule$createModuleSpecifications(
   runInclusionStatistics = TRUE,
   runIncludedSourceConcepts = TRUE,
   runOrphanConcepts = TRUE,
   runTimeSeries = FALSE,
   runVisitContext = TRUE,
   runBreakdownIndexEvents = TRUE,
   runIncidenceRate = TRUE,
   runCohortRelationship = TRUE,
   runTemporalCohortCharacterization = TRUE
)</pre>
```

## 2.3 CohortIncidence Module Settings

The following code creates the cohortIncidenceModuleSpecifications to perform an incidence rate analysis for the target cohorts and outcome in this study.

```
ciModule <- CohortIncidenceModule$new()
targets <- list(
   CohortIncidence::createCohortRef(id = 1, name = "Celecoxib"),
   CohortIncidence::createCohortRef(id = 2, name = "Diclofenac"),
   CohortIncidence::createCohortRef(id = 4, name = "Celecoxib Age >= 30"),
   CohortIncidence::createCohortRef(id = 5, name = "Diclofenac Age >= 30")
)
outcomes <- list(CohortIncidence::createOutcomeDef(id = 1, name = "GI bleed", cohortId = 3, cleanWindow
tars <- list(
   CohortIncidence::createTimeAtRiskDef(id = 1, startWith = "start", endWith = "end"),
   CohortIncidence::createTimeAtRiskDef(id = 2, startWith = "start", endWith = "start", endOffset = 365)
)
analysis1 <- CohortIncidence::createIncidenceAnalysis(
   targets = c(1, 2, 4, 5),
   outcomes = c(1),</pre>
```

```
tars = c(1, 2)
)

irDesign <- CohortIncidence::createIncidenceDesign(
    targetDefs = targets,
    outcomeDefs = outcomes,
    tars = tars,
    analysisList = list(analysis1),
    strataSettings = CohortIncidence::createStrataSettings(
        byYear = TRUE,
        byGender = TRUE
)
)

cohortIncidenceModuleSpecifications <- ciModule$createModuleSpecifications(
    irDesign = irDesign$toList()
)</pre>
```

#### 2.4 Characterization Module Settings

The following code creates the characterizationModuleSpecifications to perform an characterization analysis for the target cohorts and outcome in this study.

```
cModule <- CharacterizationModule$new()
characterizationModuleSpecifications <- cModule$createModuleSpecifications(
  targetIds = c(1, 2),
  outcomeIds = 3
)</pre>
```

#### 2.5 CohortMethod Module Settings

The following code creates the cohortMethodModuleSpecifications to perform a comparative cohort analysis for this study.

```
cmModule <- CohortMethodModule$new()
negativeControlOutcomes <- lapply(
    X = ncoCohortSet$cohortId,
    FUN = CohortMethod::createOutcome,
    outcomeOfInterest = FALSE,
    trueEffectSize = 1,
    priorOutcomeLookback = 30
)

outcomesOfInterest <- lapply(
    X = 3,
    FUN = CohortMethod::createOutcome,
    outcomeOfInterest = TRUE
)

outcomes <- append(
    negativeControlOutcomes,</pre>
```

```
outcomesOfInterest
tcos1 <- CohortMethod::createTargetComparatorOutcomes(</pre>
 targetId = 1,
  comparatorId = 2,
 outcomes = outcomes,
  excludedCovariateConceptIds = c(1118084, 1124300)
tcos2 <- CohortMethod::createTargetComparatorOutcomes(</pre>
  targetId = 4,
  comparatorId = 5,
 outcomes = outcomes,
  excludedCovariateConceptIds = c(1118084, 1124300)
targetComparatorOutcomesList <- list(tcos1, tcos2)</pre>
covarSettings <- FeatureExtraction::createDefaultCovariateSettings(addDescendantsToExclude = TRUE)</pre>
getDbCmDataArgs <- CohortMethod::createGetDbCohortMethodDataArgs(</pre>
  washoutPeriod = 183,
 firstExposureOnly = TRUE,
 removeDuplicateSubjects = "remove all",
 maxCohortSize = 100000,
  covariateSettings = covarSettings
createStudyPopArgs <- CohortMethod::createCreateStudyPopulationArgs(</pre>
 minDaysAtRisk = 1,
 riskWindowStart = 0,
 startAnchor = "cohort start",
 riskWindowEnd = 30,
  endAnchor = "cohort end"
)
matchOnPsArgs <- CohortMethod::createMatchOnPsArgs()</pre>
fitOutcomeModelArgs <- CohortMethod::createFitOutcomeModelArgs(modelType = "cox")</pre>
createPsArgs <- CohortMethod::createCreatePsArgs(</pre>
  stopOnError = FALSE,
  control = Cyclops::createControl(cvRepetitions = 1)
computeSharedCovBalArgs <- CohortMethod::createComputeCovariateBalanceArgs()</pre>
computeCovBalArgs <- CohortMethod::createComputeCovariateBalanceArgs(</pre>
  covariateFilter = FeatureExtraction::getDefaultTable1Specifications()
cmAnalysis1 <- CohortMethod::createCmAnalysis(</pre>
  analysisId = 1,
  description = "No matching, simple outcome model",
  getDbCohortMethodDataArgs = getDbCmDataArgs,
  createStudyPopArgs = createStudyPopArgs,
  fitOutcomeModelArgs = fitOutcomeModelArgs
```

```
cmAnalysis2 <- CohortMethod::createCmAnalysis(</pre>
  analysisId = 2,
  description = "Matching on ps and covariates, simple outcomeModel",
  getDbCohortMethodDataArgs = getDbCmDataArgs,
  createStudyPopArgs = createStudyPopArgs,
  createPsArgs = createPsArgs,
  matchOnPsArgs = matchOnPsArgs,
  computeSharedCovariateBalanceArgs = computeSharedCovBalArgs,
  computeCovariateBalanceArgs = computeCovBalArgs,
  fitOutcomeModelArgs = fitOutcomeModelArgs
cmAnalysisList <- list(cmAnalysis1, cmAnalysis2)</pre>
analysesToExclude <- NULL
cohortMethodModuleSpecifications <- cmModule$createModuleSpecifications(</pre>
  cmAnalysisList = cmAnalysisList,
  targetComparatorOutcomesList = targetComparatorOutcomesList,
  analysesToExclude = analysesToExclude
)
```

# 2.6 SelfControlledCaseSeries Module Settings

The following code creates the sccsModuleSpecifications to perform a self-controlled case series analysis for this study.

```
sccsModule <- SelfControlledCaseSeriesModule$new()</pre>
# Exposures-outcomes -----
negativeControlOutcomeIds <- ncoCohortSet$cohortId</pre>
outcomeOfInterestIds <- c(3)
exposureOfInterestIds <- c(1, 2)
exposuresOutcomeList <- list()</pre>
for (exposureOfInterestId in exposureOfInterestIds) {
  for (outcomeOfInterestId in outcomeOfInterestIds) {
    exposuresOutcomeList[[length(exposuresOutcomeList) + 1]] <- SelfControlledCaseSeries::createExposur
      outcomeId = outcomeOfInterestId,
      exposures = list(SelfControlledCaseSeries::createExposure(exposureId = exposureOfInterestId))
   )
  }
  for (negativeControlOutcomeId in negativeControlOutcomeIds) {
    exposuresOutcomeList[[length(exposuresOutcomeList) + 1]] <- SelfControlledCaseSeries::createExposur
      outcomeId = negativeControlOutcomeId,
      exposures = list(SelfControlledCaseSeries::createExposure(exposureId = exposureOfInterestId, true
    )
 }
```

```
# Analysis settings -----
getDbSccsDataArgs <- SelfControlledCaseSeries::createGetDbSccsDataArgs(</pre>
  studyStartDate = "",
  studyEndDate = "",
 maxCasesPerOutcome = 1e6,
 useNestingCohort = TRUE,
 nestingCohortId = 1,
 deleteCovariatesSmallCount = 0
)
createStudyPopulation6AndOlderArgs <- SelfControlledCaseSeries::createCreateStudyPopulationArgs(</pre>
 minAge = 18,
 naivePeriod = 365
covarPreExp <- SelfControlledCaseSeries::createEraCovariateSettings(</pre>
  label = "Pre-exposure",
 includeEraIds = "exposureId",
 start = -30,
 end = -1,
 endAnchor = "era start"
covarExposureOfInt <- SelfControlledCaseSeries::createEraCovariateSettings(</pre>
 label = "Main",
 includeEraIds = "exposureId",
 start = 0.
 startAnchor = "era start",
  end = 0,
  endAnchor = "era end",
 profileLikelihood = TRUE,
  exposureOfInterest = TRUE
calendarTimeSettings <- SelfControlledCaseSeries::createCalendarTimeCovariateSettings(</pre>
  calendarTimeKnots = 5,
 allowRegularization = TRUE,
  computeConfidenceIntervals = FALSE
seasonalitySettings <- SelfControlledCaseSeries::createSeasonalityCovariateSettings(</pre>
 seasonKnots = 5,
 allowRegularization = TRUE,
  computeConfidenceIntervals = FALSE
)
createSccsIntervalDataArgs <- SelfControlledCaseSeries::createCreateSccsIntervalDataArgs(</pre>
  eraCovariateSettings = list(covarPreExp, covarExposureOfInt),
  seasonalityCovariateSettings = seasonalitySettings,
  calendarTimeCovariateSettings = calendarTimeSettings,
  minCasesForTimeCovariates = 100000
)
```

```
fitSccsModelArgs <- SelfControlledCaseSeries::createFitSccsModelArgs(</pre>
  control = Cyclops::createControl(
    cvType = "auto",
   selectorType = "byPid",
   startingVariance = 0.1,
   seed = 1,
   resetCoefficients = TRUE,
   noiseLevel = "quiet"
  )
sccsAnalysis1 <- SelfControlledCaseSeries::createSccsAnalysis(</pre>
  analysisId = 1,
  description = "SCCS age 18-",
  getDbSccsDataArgs = getDbSccsDataArgs,
  createStudyPopulationArgs = createStudyPopulation6AndOlderArgs,
  createIntervalDataArgs = createSccsIntervalDataArgs,
  fitSccsModelArgs = fitSccsModelArgs
)
sccsAnalysisList <- list(sccsAnalysis1)</pre>
# SCCS module specs -----
                              _____
sccsModuleSpecifications <- sccsModule$createModuleSpecifications(</pre>
  sccsAnalysisList = sccsAnalysisList,
  exposuresOutcomeList = exposuresOutcomeList,
  combineDataFetchAcrossOutcomes = FALSE
```

#### 2.7 PatientLevelPrediction Module Settings

The following code creates the plpModuleSpecifications to perform a patient-level prediction analysis for this study.

```
plpModule <- PatientLevelPredictionModule$new()

makeModelDesignSettings <- function(targetId, outcomeId, popSettings, covarSettings) {
   invisible(PatientLevelPrediction::createModelDesign(
      targetId = targetId,
      outcomeId = outcomeId,
      restrictPlpDataSettings = PatientLevelPrediction::createRestrictPlpDataSettings(),
      populationSettings = popSettings,
      covariateSettings = covarSettings,
      preprocessSettings = PatientLevelPrediction::createPreprocessSettings(),
      modelSettings = PatientLevelPrediction::setLassoLogisticRegression(),
      splitSettings = PatientLevelPrediction::createDefaultSplitSetting(),
      runCovariateSummary = T
    ))
}

plpPopulationSettings <- PatientLevelPrediction::createStudyPopulationSettings(
    startAnchor = "cohort start",</pre>
```

```
riskWindowStart = 1,
  endAnchor = "cohort start",
  riskWindowEnd = 365,
  minTimeAtRisk = 1
plpCovarSettings <- FeatureExtraction::createDefaultCovariateSettings()</pre>
modelDesignList <- list()</pre>
for (i in 1:length(exposureOfInterestIds)) {
  for (j in 1:length(outcomeOfInterestIds)) {
    modelDesignList <- append(</pre>
      modelDesignList,
      list(
        makeModelDesignSettings(
          targetId = exposureOfInterestIds[i],
          outcomeId = outcomeOfInterestIds[j],
          popSettings = plpPopulationSettings,
          covarSettings = plpCovarSettings
      )
    )
 }
}
plpModuleSpecifications <- plpModule$createModuleSpecifications(</pre>
  modelDesignList = modelDesignList
)
```

# 3 Strategus Analysis Specifications

Finally, we will use the various shared resources and module specifications to construct the full set of analysis specifications and save it to the file system in JSON format.

```
analysisSpecifications <- createEmptyAnalysisSpecificiations() %>%
  addSharedResources(cohortDefinitionSharedResource) %>%
  addSharedResources(ncoSharedResource) %>%
  addModuleSpecifications(cohortGeneratorModuleSpecifications) %>%
  addModuleSpecifications(cohortDiagnosticsModuleSpecifications) %>%
  addModuleSpecifications(cohortIncidenceModuleSpecifications) %>%
  addModuleSpecifications(characterizationModuleSpecifications) %>%
  addModuleSpecifications(cohortMethodModuleSpecifications) %>%
  addModuleSpecifications(sccsModuleSpecifications) %>%
  addModuleSpecifications(splpModuleSpecifications)
```

ParallelLogger::saveSettingsToJson(analysisSpecifications, file.path(params\$analysisSettingsPath, param