

# README

## About CountSMART

Longitudinal count data are often collected in a variety of health domains. This repository contains code to estimate sample size needed to compare dynamic treatment regimens using longitudinal count outcomes from a Sequential Multiple Assignment Randomized Trial (SMART). A particular focus of this repository is on longitudinal count data having overdispersion.

A pair of dynamic treatment regimens embedded in a planned SMART (aka. ‘EDTRs’) can be compared using differences in end-of-study means, or more generally, differences in a weighted average of means across various time points, which we denote as  $\Delta_Q$ ;  $Q$  is simply shorthand for ‘quantity’, e.g.,  $\Delta_{EOS}$  denotes the quantity *difference in end-of-study means*.

CountSMART is about a Monte Carlo simulation-based approach developed to estimate sample size required to attain power of  $1 - \eta$  to the test of the null  $H_0 : \Delta_Q = 0$  against the alternative  $H_a : \Delta_Q \neq 0$  at type-I error rate  $\alpha$ .

## About this repository

This repository contains code implementing CountSMART methodology and simulation studies examining the validity of the approach.

### 1. Setting up this repository

#### 1.1 Packages used in the project

1. The collection of packages and their version numbers used for this repository are recorded in the `renv.lock` file. The package, `renv`, can facilitate installation of these packages in the machine of end-users of this repository. See `renv` package documentation here for more details: <https://rstudio.github.io/renv/articles/renv.html>

#### 1.2 Tell R where to pull code from from and where to push data to

1. Create a new R file named ‘`paths.R`’ and save this file within the root directory of the repository (usually where the `.Rproj` file is located).
2. Within ‘`paths.R`’, set the value of the following variables below by replacing the three dots ‘`...`’ with the appropriate directory.
  - `path.output_data = “.../output”`
  - `path.code = “.../code”`
  - `path.plots = “.../plots”`

Note that ‘`paths.R`’ is included in the ‘`.gitignore`’ file, preventing any user-specific directories from being displayed in the repository. Also, since ‘`paths.R`’ is included in the ‘`.gitignore`’ file, a new ‘`paths.R`’ file would need to be created by each end-user of the repository.

## 2. The code folder

### 2.1 Collection of functions for input-checking, simulation, and data analysis

File Name	Brief Description
input-utils.R	Contains a function for checking validity of time-specific means and proportion of zeros provided as inputs to the sample size estimation procedure.
datagen-utils.R	Collection of functions to generate potential outcomes and observed outcomes.
analysis-utils.R	Collection of functions to ‘analyze’ data from a SMART.

### 2.2 Collection of functions for executing calculations

File Name	Brief Description
calc-covmat.R	Calculate estimated covariance matrix.
calc-corr-params-curve.R	Implement simulation to estimate relationship between $\rho$ and $\tau_{MAX}$ and the relationship between $\rho$ and $\tau_{MIN}$ .
calc-truth-beta.R	Calculate true value of parameters in a model for the mean trajectory of dynamic treatment regimens embedded in a SMART, implied by inputs provided to Monte Carlo simulation.
calc-truth-contrasts.R	Calculate true value of $\Delta_Q$ in a model for the mean trajectory of dynamic treatment regimens embedded in a SMART, implied by inputs provided to Monte Carlo simulation.
plot-truth-deltaQ.R	Wrapper for calc-truth-beta.R and calc-truth-contrasts.R. Visualize true mean trajectory of each dynamic treatment regimen embedded in a SMART, implied by inputs provided to Monte Carlo simulation.
geemMod.R	Modification of the <code>geem.R</code> script from the R package <code>geem</code> : setting the additional argument <code>fullmat=TRUE</code> allows custom specification of working correlation matrix for each participant-time.

## 3. The output folder

### Results using an autoregressive structure

File Name	Brief Description
create-scenarios-ar.R	A script to create simulation study scenarios.
calculate-dispersion-param.R	A script to calculate the value of the negative binomial dispersion parameter in the different simulation scenarios.
simulation-study-pipeline-ar.R	A script to document and run steps in the simulation study pipeline.
sim_size_test	A directory containing a collection of scripts to execute simulation studies concerning empirical type-I error rate. Results of simulation studies are also provided here (e.g., <code>power.csv</code> file).
sim_vary_effect	A directory containing a collection of scripts to execute simulation studies investigating how power changes as specific choices of $\Delta_Q$ are increased across a grid of total sample sizes $N=100, 150, 200, \dots, 550$ . Results of simulation studies are also provided here (e.g., <code>power.csv</code> file).

File Name	Brief Description
sim_vary_n4	A directory containing a collection of scripts to execute simulation studies investigating whether power is sensitive to a violation in our working assumption on the number of individuals who would not respond to either first-stage intervention option. Results of simulation studies are also provided here (e.g., <code>power.csv</code> file).
sim_vary_eta	
	A directory containing a collection of scripts to execute simulation studies investigating whether power is sensitive to the actual value of $\eta$ , given fixed value of $\rho$ and $N$ . Results of simulation studies are also provided here (e.g., <code>power.csv</code> file).

### Results using an exchangeable structure

File Name	Brief Description
create-scenarios-exch.R	A script to create simulation study scenarios.
calculate-dispersion-param.R	A script to calculate the value of the negative binomial dispersion parameter in the different simulation scenarios.
simulation-study-pipeline-exch.R	A script to document and run steps in the simulation study pipeline.
sim_vary_effect	A directory containing a collection of scripts to execute simulation studies investigating how power changes as specific choices of $\Delta_Q$ are increased across a grid of total sample sizes $N=100, 150, 200, \dots, 550$ . Results of simulation studies are also provided here (e.g., <code>power.csv</code> file).

## 4. The plots folder

### Plot results using an autoregressive structure

File Name	Brief Description
data-viz-pipeline-ar.R	A script to document and run steps in the data visualization pipeline.
plot-sim-size-test.R	A script to plot results in <code>sim_size_test</code>
plot-sim-vary-effect.R	A script to plot results in <code>sim_vary_effect</code>
plot-sim-vary-n4.R	A script to plot results in <code>sim_vary_n4</code>
plot-sim-vary-eta.R	A script to plot results in <code>sim_vary_eta</code>
corviz_sim_vary_effect	A directory containing visualization of empirical correlation matrices corresponding to each scenario considered. These results accompany those in the directory <code>sim_vary_effect</code> . Values of parameters identical to those used to obtain results in the directory <code>sim_vary_effect</code> were used to calculate the values displayed, except that $N$ was fixed to 1000.
corviz_sim_vary_eta	
	A directory containing visualization of empirical correlation matrices corresponding to each scenario considered. Values of parameters identical to those used to obtain results in the directory <code>sim_vary_eta</code> were used to calculate the values displayed, except that $N$ was fixed to 1000.

### Plot results using an exchangeable structure

File Name	Brief Description
data-viz-pipeline-exch.R	A script to document and run steps in the data visualization pipeline.
plot-sim-vary-effect.R	A script to plot results in sim_vary_effect