

Servier Biometrics Intern Proposal

Bayesian Go/No-Go decision-making on study and portfolio level

Mentors: Jian Zhu and Paul Aubel.

Objective: To consolidate the Go/No-Go methodology in Servier early phase oncology trials.

Background and Motivation: Various versions of Bayesian Go/No-Go methodologies have been proposed in the literature and implemented in Servier projects. So far there is no internal guidance on which method is preferred. This results in duplicated evaluation efforts for each Servier project.

The implementation of Go/No-Go criteria is currently limited on study level, and its extension is needed to inform decision making for a portfolio or project level with multiple studies.

Methods: Currently there are three common methods for Bayesian Go/No-Go being implemented in Servier trials: 1. criteria based on posterior probabilities of exceeding Low Reference Value (LRV) and posterior probabilities of not achieving Target Reference Value (TRV); 2. criteria based on posterior probabilities of exceeding TRV and posterior probabilities of not achieving TRV; 3. criteria based on predictive probabilities of success. We aim to conduct extensive evaluation to understand the connection between these methods and compare the performance in various settings. Different priors will also be evaluated. The framework will also be extended to combining data from multiple studies to form the Go/No-Go decision for a portfolio.

Target Milestones:

- Bayesian Go/No-Go methodologies on study level
 - o Literature review and coding, including the three existing methods
 - Extensive simulation studies to compare performance
 - o Form recommendations based on evaluation
- Bayesian Go/No-Go methodologies on portfolio level
- R packages
- Internal/External presentations
- Potential implementation in Servier projects

Training / Skills:

- Student in last year of engineering school in statistics or applied mathematics (ENSAI, INSA) or in Master 2 of Biostatistics or equivalent.
- Good skills in the R language and an interest in life sciences are required.
- · A good level of English is required

To apply:

Contact (in english) Paul Aubel (Paul.aubel@servier.com) and Jian Zhu (Jian.zhu@servier.com).