

The gsDesign Package

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The gsDesign package supports group sequential clinical trial design. While there is a strong focus on designs using α - and β -spending functions, Wang-Tsiatis designs, including O'Brien-Fleming and Pocock designs, are also available. The ability to design with non-binding futility rules is an important feature to control Type I error in a manner acceptable to regulatory authorities when futility bounds are employed.

The routines are designed to provide simple access to commonly used designs using default arguments. Standard, published spending functions are supported as well as the ability to write custom spending functions. A **gsDesign** class is defined and returned by the **gsDesign()** function. A plot function for this class provides a wide variety of plots: boundaries, power, estimated treatment effect at boundaries, conditional power at boundaries, spending function plots, expected sample size plot, and B-values at boundaries. Using function calls to access the package routines provides a powerful capability to derive designs or output formatting that could not be anticipated through a gui interface. This enables the user to easily create designs with features they desire, such as designs with minimum expected sample size.

Thus, the intent of the gsDesign package is to easily create, fully characterize and even optimize routine group sequential trial designs as well as provide a tool to evaluate innovative designs.