Group sequential designs

Why wait until you finish collecting data to analyze the results of your clinical trial?

Stata's **gsbounds** and **gsdesign** commands calculate efficacy- and futility-stopping boundaries, compute sample sizes for interim and final analyses, graph the stopping boundaries for your trial, and more.

- Hypothesis tests
  - One-sample mean
  - Two-sample means
  - One-sample proportion
  - Two-sample proportions
  - Log-rank test of survivor functions
- Add your own methods
- Automatic and customizable tables and graphs
- Stopping boundaries
  - Classical O'Brien–Fleming
  - Classical Pocock
  - Classical Wang–Tsiatis
  - Error-spending O'Brien–Fleming-style
  - Error-spending Pocock-style
  - Error-spending Kim–DeMets
  - Error-spending Hwang–Shih–de Cani

Stopping boundaries

gsbounds calculates efficacy and futility bounds based on the number of looks, the desired overall type I error, and the desired power.

For instance, calculate O'Brien–Fleming efficacy and futility bounds for a study with 5 looks, the default power of 0.8, and a type I error of 0.05.

```
. gsbounds, nlooks(5) efficacy(errobfleming) futility(errobfleming)
```

```
Group sequential boundaries

Efficacy: Error-spending O'Brien–Fleming style
Futility: Error-spending O'Brien–Fleming style, nonbinding

Study parameters:
      alpha = 0.0500  (two-sided)
      power = 0.8000

Info. ratio = 1.1618

Fixed-study crit. values = ±1.9600

Critical values and p-values for a group sequential design
```

Look	Info. frac.	Efficacy Lower	Efficacy Upper	Efficacy p-value	Futility Lower	Futility Upper	Futility p-value
1	0.20	-4.8769	4.8769	0.0000	-0.0130	0.0130	0.9896
2	0.40	-3.3570	3.3570	0.0008	-0.2929	0.2929	0.7696
3	0.60	-2.6803	2.6803	0.0074	-0.9245	0.9245	0.3552
4	0.80	-2.2898	2.2898	0.0220	-1.5186	1.5186	0.1289
5	1.00	-2.0310	2.0310	0.0423	-2.0310	2.0310	0.0423

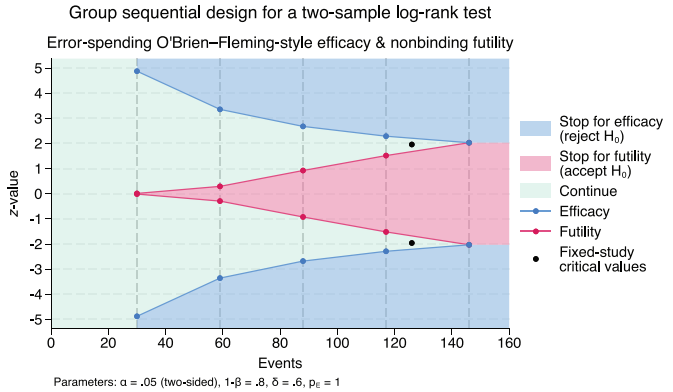
```
Note: Critical values are for z statistics; otherwise, use p-value
      boundaries.
```

Sample-size determination

gsdesign computes efficacy and futility boundaries and provides sample sizes at each look for a variety of tests.

Compute the required number of events for each look, and graph the O'Brien–Fleming efficacy and futility bounds for the log-rank test comparing the survivor functions of two groups and assuming a hazard ratio (effect size) of 0.6.

```
. gsdesign logrank, hratio(0.6) nlooks(5) efficacy(errobfleming) futility(errobfleming) graphbounds
```

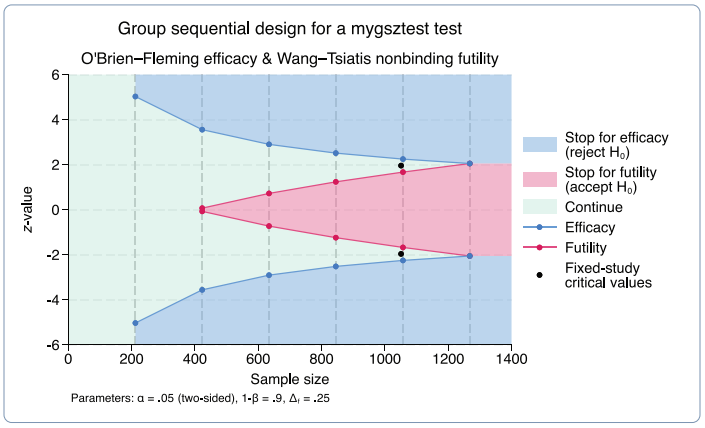


Add your own methods

In addition to **gsdesign**'s built-in methods, you can add your own methods to compute the required sample size such as when you use the **simulate** command to compute the sample size by simulation. All you need to do is write a program that computes sample size, and **gsdesign** will do the rest for you.

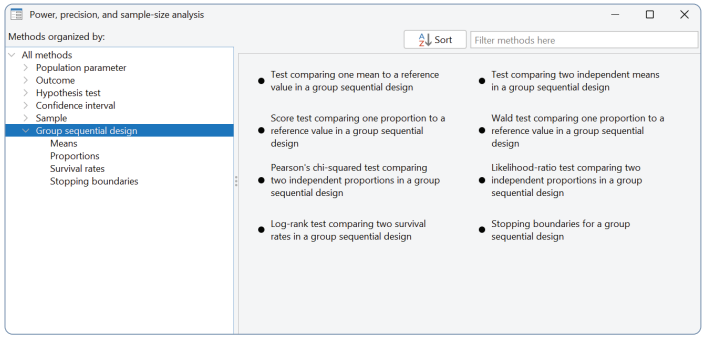
```
program power_cmd_mygsztest, rclass
    version 19.5
                        //  parse options
    syntax, STDDiff(real)    /// standardized diff.
          [ Alpha(real 0.05) /// significance level
            Power(real 0.8)  /// power
            NFRACtional      /// fractional sample size
          ]

                        //  compute sample size
    tempname N
    scalar `N' = ((invnormal(`power') + ///
                  invnormal(1 -`alpha'/2))/`stddiff')^2
    if ("`nfractional'" == "") {
              scalar `N' = ceil(`N')
    }

                        //  return results
    return scalar N       = `N'
    return scalar alpha   = `alpha'
    return scalar power   = `power'
    return scalar stddiff = `stddiff'
end
```

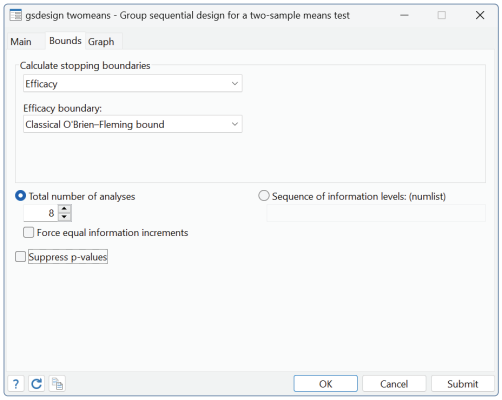
```
. gsdesign mygsztest, stddiff(0.1) alpha(0.05)
  power(0.9) nlooks(6) efficacy(obfleming)
  futility(wtsiatis(0.25)) graphbounds
```

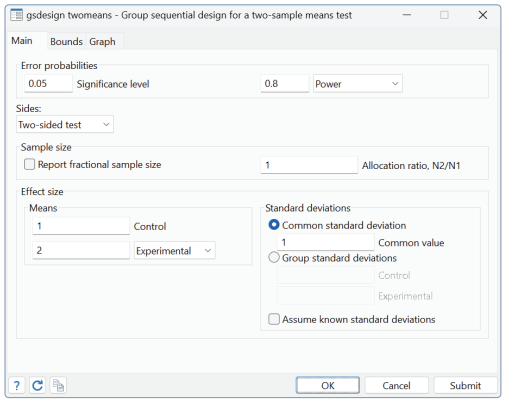


Perform analyses using point and click

You can perform your analyses interactively by typing the commands or by using a point-and-click GUI available via the PSS Control Panel.








```
. gsdesign twomeans 1 2, nlooks(6) graphbounds
```