

Title

stpower — Sample-size, power, and effect-size determination for survival analysis

Syntax

Sample-size determination

```
stpower cox [...] [, ...]
```

```
stpower logrank [...] [, ...]
```

```
stpower exponential [...] [, ...]
```

Power determination

```
stpower cox [...], n(numlist) [...]
```

```
stpower logrank [...], n(numlist) [...]
```

```
stpower exponential [...], n(numlist) [...]
```

Effect-size determination

```
stpower cox, n(numlist) { ppower(numlist) | beta(numlist) } [...]
```

```
stpower logrank [...], n(numlist) { ppower(numlist) | beta(numlist) } [...]
```

See [ST] **stpower cox**, [ST] **stpower logrank**, and [ST] **stpower exponential**.

Description

stpower computes sample size and power for survival analysis comparing two survivor functions using the log-rank test or the *exponential test* (to be defined later), as well as for more general survival analysis investigating the effect of a single covariate in a Cox proportional hazards regression model, possibly in the presence of other covariates. It provides the estimate of the number of events required to be observed (or the expected number of events) in a study. The minimal effect size (minimal detectable difference, expressed as the hazard ratio or the log hazard-ratio) may also be obtained for the log-rank test and for the Wald test on a single coefficient from the Cox model.

This entry provides an overview of the relevant terminology, theory, and a few examples. For more details, see the entries specific to each **stpower** subcommand.

Remarks

Remarks are presented under the following headings:

Theory and terminology

Introduction to stpower subcommands

Sample-size determination for survival studies

Creating output tables

Power curves

Theory and terminology

The prominent feature of survival data is that the outcome is the time from an origin to the occurrence of a given event (failure), often referred to as the analysis time. Analyses of such data use the information from all subjects in a study, both those who experience an event by the end of the study and those who do not. However, inference about the survival experience of subjects is based on the event times and therefore depends on the number of events observed in a study. Indeed, if none of the subjects fails in a study, then the survival rate cannot be estimated and survivor functions of subjects from different groups cannot be compared. Therefore, power depends on the number of events observed in a study and not directly on the number of subjects recruited to the study. As a result, to obtain the estimate of the required number of subjects, the probability that a subject experiences an event during the course of the study needs to be estimated in addition to the required number of events. This distinguishes sample-size determination for survival studies from that for other studies in which the endpoint is not measured as a time to failure.

All the above leads us to consider the following two types of survival studies. The first type (a type I study) is a study in which all subjects experience an event by the end of the study (no censoring), and the second type (a type II study) is a study that terminates after a fixed period regardless of whether all subjects experienced an event by that time. For a type II study, subjects who did not experience an event at the end of the study are known to be right-censored. For a type I study, when all subjects fail by the end of the study, the estimate of the probability of a failure in a study is one and the required number of subjects is equal to the required number of failures. For a type II study, the probability of a failure needs to be estimated and therefore various aspects that affect this probability (and usually do not come into play at the analysis stage) must be taken into account for the computation of the sample size.

Under the assumption of random censoring (Lachin 2011, 431; Lawless 2003, 52; Chow and Liu 2004, 388), the type of censoring pattern is irrelevant to the analysis of survival data in which the goal is to make inferences about the survival distribution of subjects. It becomes important, however, for sample-size determination because the probability that a subject experiences an event in a study depends on the censoring distribution. We consider the following two types of random censoring: administrative censoring and loss to follow-up.

Under administrative censoring, a subject is known to have experienced either of the two outcomes at the end of a study: survival or failure. The probability of a subject failing in a study depends on the duration of the study. Often in practice, subjects may withdraw from a study, say, because of severe side effects from a treatment or may be lost to follow-up because of moving to a different location. Here the information about the outcome that subject would have experienced at the end of the study had he completed the course of the study is unavailable, and the probability of experiencing an event by the end of the study is affected by the process governing withdrawal of subjects from the study. In the literature, this type of censoring is often referred to as subject loss to follow-up, subject withdrawal, or sometimes subject dropout (Freedman 1982, Machin and Campbell 2005). Generally, great care must be taken when using this terminology because it may have slightly different meanings in different contexts. `stpower logrank` and `stpower cox` apply a conservative adjustment to the estimate of the sample size for withdrawal. `stpower exponential` assumes that losses to follow-up are exponentially distributed.

Another important component of sample-size and power determination that affects the estimate of the probability of a failure is the pattern of accrual of subjects into the study. The duration of a study is often divided into two phases: an accrual phase, during which subjects are recruited to the study, and a follow-up phase, during which subjects are followed up until the end of the study and no new subjects enter the study. For a fixed-duration study, fast accrual increases the average analysis time (average follow-up time) and increases the chance of a subject failing in a study, whereas slow accrual decreases the average analysis time and consequently decreases this probability. `stpower logrank`

and `stpower exponential` provide facilities to take into account uniform accrual, and for `stpower exponential` only, truncated exponential accrual.

All sample-size formulas used by `stpower` rely on the proportional-hazards assumption, that is, the assumption that the hazard ratio does not depend on time. See the documentation entry of each subcommand for the additional assumptions imposed by the methods it uses. In the case when the proportional-hazards assumption is suspect, or in the presence of other complexities associated with the nature of the trial (for example, lagged effect of a treatment, more than two treatment groups, clustered data) and with the behavior of participants (for example, noncompliance of subjects with the assigned treatment, competing risks), one may consider obtaining required sample size or power by simulation. Feiveson (2002) demonstrates an example of such simulation for clustered survival data. Barthel et al. (2006); Barthel, Royston, and Babiker (2005); Royston and Babiker (2002); Barthel, Royston, and Parmar (2009); and Royston and Barthel (2010) present sample-size and power computation for multiarm trials under more flexible design conditions.

Introduction to `stpower` subcommands

`stpower cox` provides estimates of sample size, power, or the minimal detectable value of the coefficient when an effect of a single covariate on subject survival is to be explored using Cox proportional hazards regression. It is assumed that the effect is to be tested using the partial likelihood from the Cox model (for example, score or Wald test) on the coefficient of the covariate of interest.

`stpower logrank` reports estimates of sample size, power, or minimal detectable value of the hazard ratio in the case when the two survivor functions are to be compared using the log-rank test. The only requirement about the distribution of the survivor functions is that the two survivor functions must satisfy the proportional-hazards assumption.

`stpower exponential` reports estimates of sample size or power when the disparity in the two exponential survivor functions is to be tested using the exponential test, the parametric test comparing the two exponential hazard rates. In particular, we refer to (exponential) hazard-difference test as the exponential test for the difference between hazards and (exponential) log hazard-ratio test as the exponential test for the log of the hazard ratio or, equivalently, for the difference between log hazards.

All subcommands share a common syntax. Sample-size determination with a power of 80% or, equivalently, a probability of a type II error, a failure to reject the null hypothesis when the alternative hypothesis is true, of 20% is the default. Other values of power or type II error probability may be supplied via the `power()` or `beta()` options, respectively. If power determination is desired, sample size `n()` must be specified. If the minimal detectable difference is of interest, both sample size `n()` and `power()` (or type II error probability `beta()`) must be specified.

For sample-size and power computations, the default effect size corresponds to a value of the hazard ratio of 0.5 and may be changed by specifying the `hratio()` option. The hazard ratio is defined as a ratio of hazards of the experimental group to the control group (or the less favorable of the two groups). Other ways of specifying the effect size are available, and these are particular to each subcommand.

The default probability of a type I error, a rejection of the null hypothesis when the null hypothesis is true, of a test is 0.05 but may be changed by using the `alpha()` option. Results for one-sided tests may be requested by using the `onesided` option. To change the default setting of equal-sized groups in `stpower logrank` and `stpower exponential`, one of the `p1()` or `nratio()` options must be specified.

By default, all subcommands assume a type I study, that is, perform computations for uncensored survival data. The censoring information may be taken into account by specifying the appropriate

arguments or options. See [ST] **stpower cox**, [ST] **stpower logrank**, and [ST] **stpower exponential** for details.

All subcommands can report results in a table. Results may be tabulated for various values of input parameters. See *Creating output tables* for examples. An example of how to produce a power curve is given in *Power curves*.

Also see Cleves et al. (2010, chap. 16) for more details.

Sample-size determination for survival studies

Here we demonstrate using **stpower** to obtain an estimate of the sample size for three different survival studies.

► Example 1: Sample size for the test of the effect of a covariate in the Cox model

Consider a hypothetical study for which the goal is to investigate the effect of the expression of one gene on subject survival with the Cox proportional hazards regression model. Suppose that the Wald test is to be used to test the coefficient on the gene after fitting the Cox model. Gene expression values measure the level of activity of the gene. Consider the scenario described in Simon, Radmacher, and Dobbin (2002) in which the hazard ratio of 3 associated with a one-unit change in the \log_2 intensity of a gene (or, respectively, with a twofold change in gene expression level) is desired to be detected with 95% power using a two-sided, 0.001-level test. The estimate of the standard deviation of the \log_2 -intensity level of the gene over the entire set of samples is assumed to be 0.75.

```
. stpower cox, hratio(3) sd(0.75) power(0.95) alpha(0.001)
Estimated sample size for Cox PH regression
Wald test, log-hazard metric
Ho: [b1, b2, ..., bp] = [0, b2, ..., bp]
Input parameters:
      alpha =    0.0010   (two sided)
      b1 =     1.0986
      sd =     0.7500
      power =    0.9500
Estimated number of events and sample size:
      E =        36
      N =        36
```

Provided that all subjects experience an event in this study, a total of 36 events is required to be observed in the study to ensure the specified power.

See [ST] **stpower cox** for more details.

► Example 2: Sample size for the log-rank test

Consider an example from Machin and Campbell (2005) of a study comparing two forms of surgical resection for patients with gastric cancer. From a prestudy survey, the baseline 5-year survival rate was expected to be 20% and an anticipated increase in survival in the experimental group expressed as a hazard ratio of 0.6667 (corresponding to a 5-year survival rate of approximately 34%) was desired to be detected with 90% power using a two-sided, 0.05 level, log-rank test under 1:1 randomization. To obtain the estimate of the sample size for this study, we use **stpower logrank** with survival proportion in the control group 0.2 supplied as an argument, the **hratio(0.6667)** option to request a hazard ratio of 0.6667, and the **power(0.9)** option to request 90% power.

```

. stpower logrank 0.2, hratio(0.6667) power(0.9)
Estimated sample sizes for two-sample comparison of survivor functions
Log-rank test, Freedman method
Ho: S1(t) = S2(t)
Input parameters:
      alpha =    0.0500  (two sided)
       s1 =    0.2000
       s2 =    0.3420
    hratio =    0.6667
      power =    0.9000
       p1 =    0.5000
Estimated number of events and sample sizes:
      E =      264
      N =      362
     N1 =      181
     N2 =      181

```

From the output, 264 events (failures) are required to be observed in this study to ensure 90% power to detect a hazard ratio of 0.6667 by using the log-rank test. The respective estimate of the total number of subjects required to observe 264 events in a 5-year study is 362 with 181 subjects per surgical group. Our estimate, 181, of each group's sample size is close to the manually computed estimate of 180 from Machin and Campbell (2005). This study is an example of a type II study as previously described, because 20% of subjects were expected to survive (be censored) by the end of the study.

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See [ST] **stpower logrank** for more detailed examples and other available methods of sample-size computation for this type of analysis.

▷ Example 3: Sample size for two-sample test of exponential survivor functions

Consider an example from Lachin (2011, 490) of a study comparing two therapies, the combination of a new therapy with the standard one versus the standard alone, in the treatment of lupus nephritis patients. From previous studies, the survivor function of the control group treated with the standard therapy was log linear with a constant yearly hazard rate of 0.3. The number of events (failures) required to ensure 90% power to detect a 50% risk reduction, $\Delta = 0.5$, (or, respectively, the log hazard-ratio of $\ln(0.5) = -0.6931$) with a one-sided test at a 0.05 significance level was obtained to be 72 under equal-group allocation. In the absence of censoring, Lachin (2011) determined that a total of 72 subjects (36 per group) would have to be recruited to the study. To obtain this same estimate with `stpower exponential`, we supply the control hazard rate 0.3 as an argument and specify the power (0.9), `onesided`, and `loghazard` options to request 90% power, a one-sided test, and sample-size determination for the exponential log hazard-ratio test (or, test for the log-hazard difference), respectively.

```
. stpower exponential 0.3, power(0.9) onesided loghazard
Note: input parameters are hazard rates.

Estimated sample sizes for two-sample comparison of survivor functions
Exponential test, log-hazard difference, conditional
Ho: ln(h2/h1) = 0

Input parameters:
    alpha =    0.0500 (one sided)
    h1 =    0.3000
    h2 =    0.1500
ln(h2/h1) =   -0.6931
    power =    0.9000
    p1 =    0.5000

Estimated sample sizes:
    N =        72
    N1 =       36
    N2 =       36
```

Further, the study was planned to continue for 6 years with a recruitment period of 4 years. Subjects who did not experience an event by the end of 6 years were censored. For this fixed-duration study with uniform entry (recruitment), the estimate of the sample size increases from 72 to 128. We specify the length of the accrual and the follow-up periods in the `aperiod()` and `fperiod()` options, respectively. We also request to display the expected number of events by using the `detail` option.

```
. stpower exponential 0.3, power(0.9) onesided loghazard aperiod(4) fperiod(2) detail
Note: input parameters are hazard rates.

Estimated sample sizes for two-sample comparison of survivor functions
Exponential test, log-hazard difference, conditional
Ho: ln(h2/h1) = 0

Input parameters:
    alpha =    0.0500 (one sided)
    h1 =    0.3000
    h2 =    0.1500
ln(h2/h1) =   -0.6931
    power =    0.9000
    p1 =    0.5000

Accrual and follow-up information:
    duration =    6.0000
    follow-up =    2.0000
    accrual =    4.0000 (uniform)

Estimated sample sizes:
    N =        128
    N1 =       64
    N2 =       64

Estimated expected number of events:
    E|Ha =       72      E|Ho =       74
    E1|Ha =       44      E1|Ho =       37
    E2|Ha =       28      E2|Ho =       37
```

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Under the alternative hypothesis of $H_a: \ln(\Delta) = -0.6931$, we expect to observe 44 events in the control group and 28 events in the experimental group. A total of 128 subjects (64 per group) is required to be enrolled into the study to observe an expected total of 72 events under the alternative.

See [ST] **stpower exponential** for more examples.

Creating output tables

stpower subcommands offer the `table` and `columns()` options to display results in a table. All tables in the examples below are produced for a default screen width of 79 characters. You may need to resize your Results window if you wish to clearly reproduce these tables.

► Example 4: Displaying results in a table with default columns

Continuing example 1, we display results in a table with the default columns.

```
. stpower cox, hratio(3) sd(0.75) power(0.95) alpha(0.001) table
Estimated sample size for Cox PH regression
Wald test, log-hazard metric
Ho: [b1, b2, ..., bp] = [0, b2, ..., bp]
```

Power	N	E	B1	SD	Alpha*
.95	36	36	1.09861	.75	.001

* two sided

Suppose we now believe that only 90% of subjects will experience an event by the end of the study. We account for this by using the `failprob(0.9)` option.

```
. stpower cox, hratio(3) sd(0.75) power(0.95) alpha(0.001) failprob(0.9) table
Estimated sample size for Cox PH regression
Wald test, log-hazard metric
Ho: [b1, b2, ..., bp] = [0, b2, ..., bp]
```

Power	N	E	B1	SD	Alpha*	Pr(E)
.95	40	36	1.09861	.75	.001	.9

* two sided

The specified options determine what table columns are displayed by default. See the documentation entry of each command for the details on the default columns.



► Example 5: Producing tables when options contain multiple values

Recall example 2. Suppose that we would like to tabulate values of power for sample-size values of 200, 250, and 300 and for three different values of the survival probability in the experimental group, 0.34, 0.5, and 0.65. To fit the table on a screen of width 79, we specify the `colwidth(7)` option, requesting a width of 7 for all table columns.

```
. stpower logrank 0.2 (0.34 0.5 0.65), n(200 250 300) colwidth(7)
Estimated power for two-sample comparison of survivor functions
Log-rank test, Freedman method
Ho: S1(t) = S2(t)
```

Power	N	N1	N2	E	S1	S2	HR	Alpha*
.6646	200	100	100	146	.2	.34	.6703	.05
.7601	250	125	125	183	.2	.34	.6703	.05
.8318	300	150	150	219	.2	.34	.6703	.05
.995	200	100	100	130	.2	.5	.4307	.05
.9991	250	125	125	163	.2	.5	.4307	.05
.9998	300	150	150	195	.2	.5	.4307	.05
1	200	100	100	115	.2	.65	.2677	.05
1	250	125	125	144	.2	.65	.2677	.05
1	300	150	150	173	.2	.65	.2677	.05

* two sided

Optionally, the width of each column may be changed by specifying respective column widths in `colwidth()`, as we demonstrate in example 6. Using `colwidth(7)` is equivalent to `colwidth(7 7 7 7 7 7 7)` in the above.

By default, the results are displayed for all possible combinations of values of `n()` and the second argument list. If a table is desired instead with results for sequential pairs of values (0.34, 200), (0.5, 250), and (0.65, 300), one can specify the `parallel` option.

```
. stpower logrank 0.2 (0.34 0.5 0.65), n(200 250 300) colwidth(7) parallel
Estimated power for two-sample comparison of survivor functions
Log-rank test, Freedman method
Ho: S1(t) = S2(t)
```

Power	N	N1	N2	E	S1	S2	HR	Alpha*
.6646	200	100	100	146	.2	.34	.6703	.05
.9991	250	125	125	163	.2	.5	.4307	.05
1	300	150	150	173	.2	.65	.2677	.05

* two sided

If the `parallel` option is specified, options with multiple values must each contain the same number of values.

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► Example 6: Customized tables

In example 4, we used the `table` option to display the default columns. One can construct a customized table by specifying `colnames` within `columns()`. The columns will be displayed in the same order as they are specified in `columns()`. Continuing example 3, we display the total and per-group expected number of events under the null and under the alternative hypotheses for two values of the hazard ratio, 0.5 and 0.6. To obtain this table, we also specify the `hratio(0.5 0.6)` and `columns(power ea ea1 ea2 eo eo1 eo2 hr alpha)` options and omit the `detail` option in the earlier syntax. We request that the column widths of the first six columns be as specified in `colwidth(7 6 7 7 6 7)`. Remaining columns will be displayed with the width of 7 (the last specified column width). If the widths of the remaining columns are desired to be unchanged, a missing (`.`), denoting the default column width of 9, may be specified as the last column width.

```
. stpower exponential 0.3, power(0.9) hratio(0.5 0.6) onesided loghazard
> aperiod(4) fperiod(2) columns(power ea ea1 ea2 eo eo1 eo2 hr alpha)
> colwidth(7 6 7 7 6 7)
Note: input parameters are hazard rates.
Estimated sample sizes for two-sample comparison of survivor functions
Exponential test, log-hazard difference, conditional
Ho: ln(h2/h1) = 0
```

Power	E Ha	E1 Ha	E2 Ha	E Ho	E1 Ho	E2 Ho	HR	Alpha*
.9	72	44	28	74	37	37	.5	.05
.9	132	76	56	134	67	67	.6	.05

* one sided

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The displayed table values may be saved to a Stata data file by using the `saving()` option. Also `table` and `columns()` in conjunction with `noheader` and `continue` may be used to produce tables for various values in options that do not allow specifying a number list. This task may be done by issuing an `stpower` subcommand repeatedly within a `forvalues` loop. See example 5 in [ST] `stpower exponential`.

Power curves

Here we demonstrate how to produce a graph of a power curve as a function of sample size.

▶ Example 7: Plotting a simple power curve

Continuing example 2, we plot power for sample-size values in a range from 200 to 400 for this study. We supply the integers in this range with a step size of 1 to the `n()` option and use the `saving()` option to save table values in a Stata dataset named `mypower.dta`.

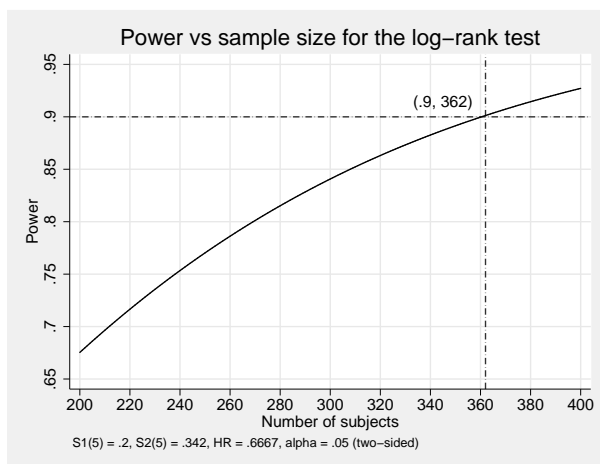
```
. quietly stpower logrank 0.2, hratio(0.6667) n(200(1)400) saving(mypower)
```

We specify `quietly` to avoid displaying the resulting table. The values of columns of the table are saved in `mypower.dta`. We generate the power graph by plotting the values of power and sample size saved in variables `power` and `n`:

```

. use mypower
. line power n,
> title("Power vs sample size for the log-rank test")
> ytitle("Power") xtitle("Number of subjects")
> yline(.9, lpattern("-.-")) xline(362, lpattern("-.-"))
> xlabel(200(20)400, grid) text(.915 345 "(.9, 362)")
> ylabel(.65(.05).95, grid)
> note("S1(5) = .2, S2(5) = .342, HR = .6667, alpha = .05 (two sided)")

```



Power curves may also be plotted for combinations of values of different options. For an example of plotting two power curves, see example 7 in [ST] **stpower logrank**.

Methods and formulas

stpower is implemented as an ado-file.

stpower cox adopts the method of Hsieh and Lavori (2000) to compute sample size and power for the test of a covariate obtained after the Cox model fit.

stpower logrank uses the approach of Freedman (1982) and Schoenfeld (1981) for sample-size and power computation. The approach of Schoenfeld (1983) is used to obtain the estimates in the presence of uniform accrual.

stpower exponential implements methods of Lachin (1981); Lachin and Foulkes (1986); George and Desu (1974); and Rubinstein, Gail, and Santner (1981) for the two-sample test of exponential survivor functions. The explicit sample-size formula for the last method was given in Lakatos and Lan (1992).

See *Methods and formulas* in [ST] **stpower cox**, [ST] **stpower logrank**, and [ST] **stpower exponential** for more details.

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Also see

- [ST] **stpower cox** — Sample size, power, and effect size for the Cox proportional hazards model
- [ST] **stpower exponential** — Sample size and power for the exponential test
- [ST] **stpower logrank** — Sample size, power, and effect size for the log-rank test
- [R] **sampsi** — Sample size and power for means and proportions
- [ST] **Glossary**