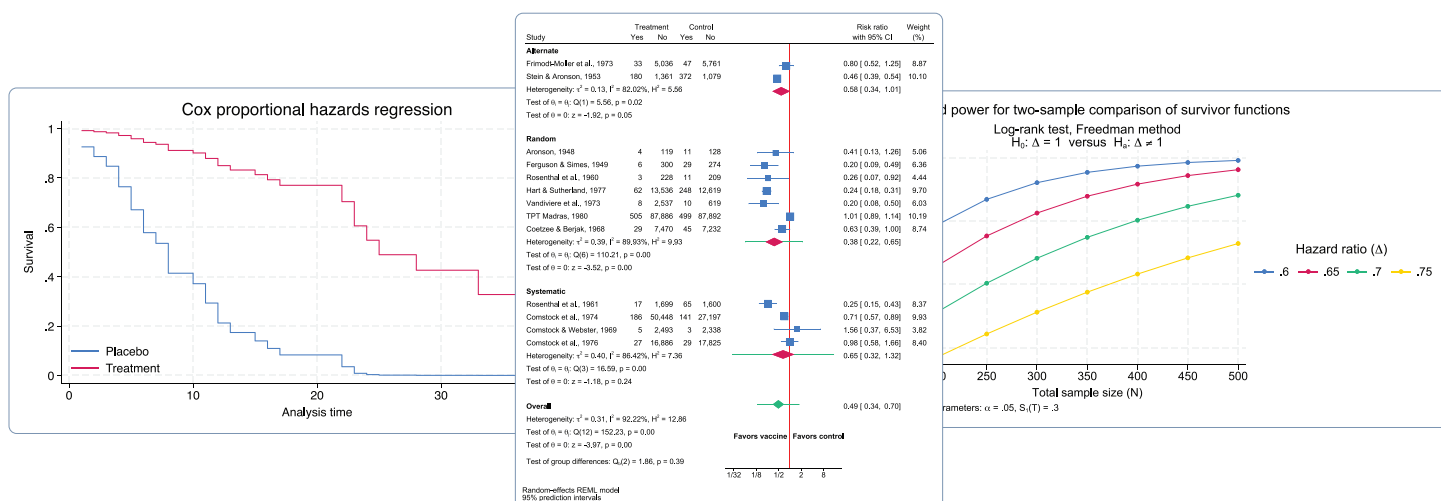


Clinical trials

Design and analysis

Stata provides a wide range of features to design and analyze clinical trials: power and sample-size determination using the **power** command, group sequential designs using the **gsdesign** command, evaluation of drugs' safety using the pharmacokinetic **pk** suite, analysis of survival-time outcomes by fitting a Cox model with the **stcox** command, combining results of multiple trials using the meta-analysis **meta** suite, and much more.



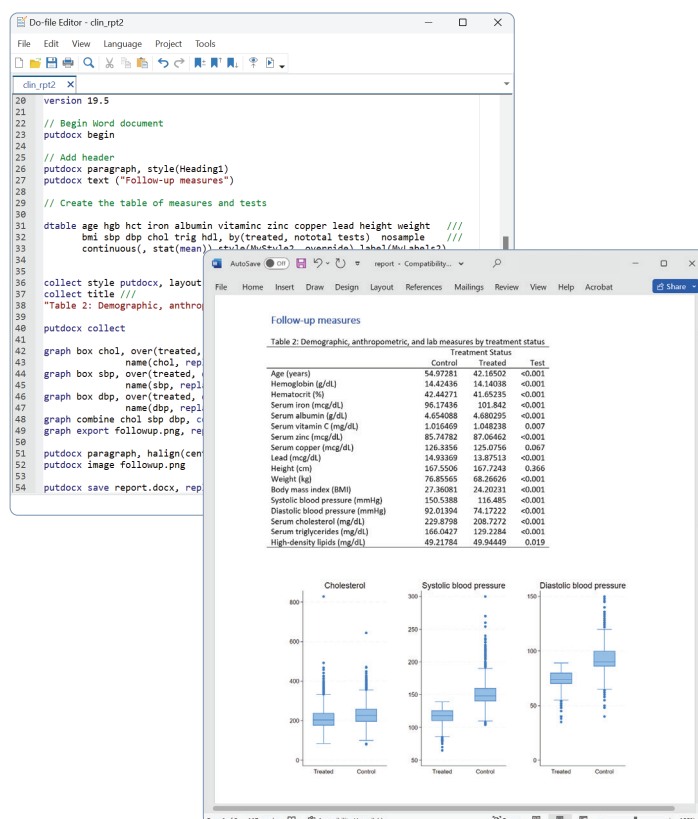
Create and automate reports

Stata offers powerful tools for clearly communicating your results.

From power curves to survivor functions to forest plots, Stata makes it easy to create publication-quality visualizations.

Customize tables reporting baseline characteristics, adverse events, regression results, and more.

With a single script, you can automate the creation of a reproducible report, complete with formatted text, tables, and graphs.



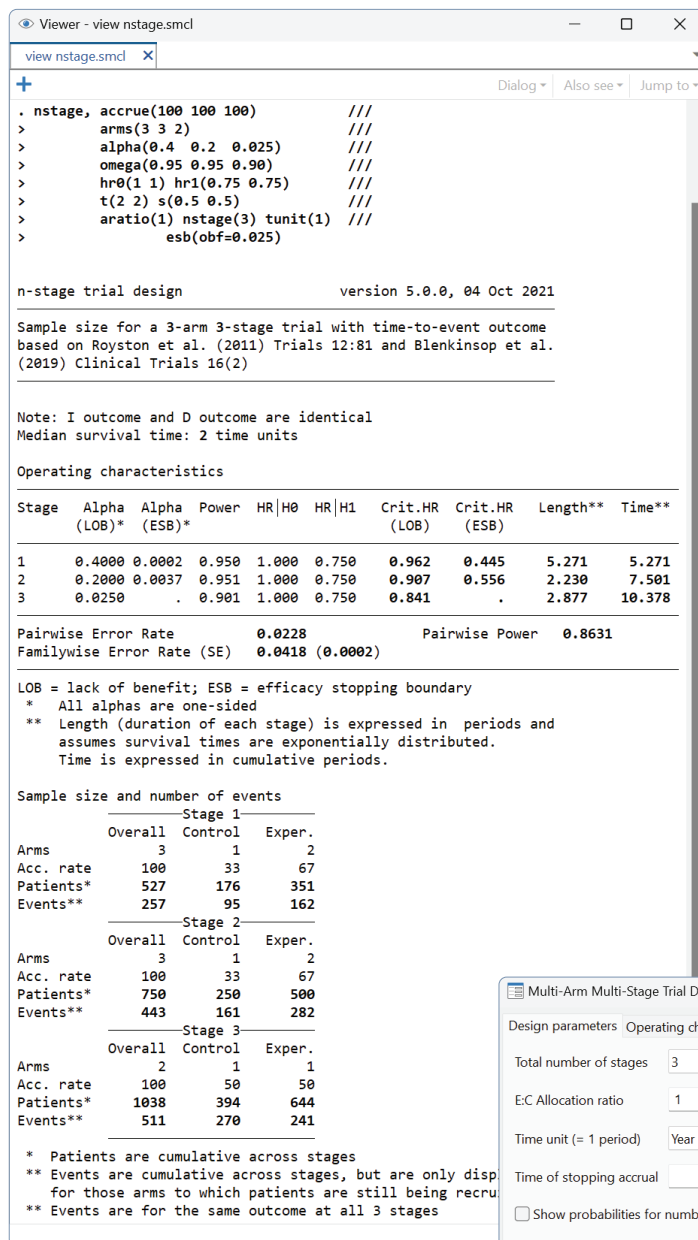
Community-contributed features

In addition to built-in features, Stata has a large and active community of researchers who are continuously adding new methods to Stata and often publish them in the *Stata Journal*. Finding and installing such commands is easy!

For instance, in Stata you can type

```
. search multi-stage design
```

You will see the **nstage** package in the list of other suitable commands. You can click on it to read more about it, install it, and use it like any other Stata command:



The screenshot shows the Stata Viewer window with the command `. nstage, accrue(100 100 100)` and its output. The output includes a table of operating characteristics and sample size calculations for a 3-arm 3-stage trial.

n-stage trial design version 5.0.0, 04 Oct 2021

Sample size for a 3-arm 3-stage trial with time-to-event outcome based on Royston et al. (2011) Trials 12:81 and Blenkinsop et al. (2019) Clinical Trials 16(2)

Note: I outcome and D outcome are identical
Median survival time: 2 time units

Operating characteristics

Stage	Alpha (LOB)*	Alpha (ESB)*	Power	HR H0	HR H1	Crit.HR (LOB)	Crit.HR (ESB)	Length**	Time**
1	0.4000	0.0002	0.950	1.000	0.750	0.962	0.445	5.271	5.271
2	0.2000	0.0037	0.951	1.000	0.750	0.907	0.556	2.230	7.501
3	0.0250	.	0.901	1.000	0.750	0.841	.	2.877	10.378

Pairwise Error Rate 0.0228 Pairwise Power 0.8631
Familywise Error Rate (SE) 0.0418 (0.0002)

LOB = lack of benefit; ESB = efficacy stopping boundary
* All alphas are one-sided
** Length (duration of each stage) is expressed in periods and assumes survival times are exponentially distributed.
Time is expressed in cumulative periods.

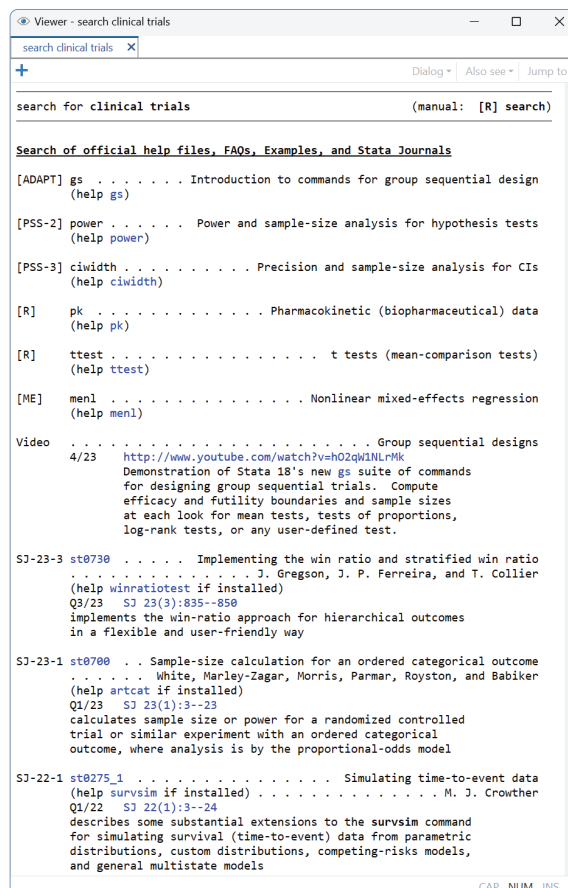
Sample size and number of events

Arms	Stage 1		
	Overall	Control	Exper.
Arms	3	1	2
Acc. rate	100	33	67
Patients*	527	176	351
Events**	257	95	162

Arms	Stage 2		
	Overall	Control	Exper.
Arms	3	1	2
Acc. rate	100	33	67
Patients*	750	250	500
Events**	443	161	282

Arms	Stage 3		
	Overall	Control	Exper.
Arms	2	1	1
Acc. rate	100	50	50
Patients*	1038	394	644
Events**	511	270	241

* Patients are cumulative across stages
** Events are cumulative across stages, but are only displayed for those arms to which patients are still being recruited
** Events are for the same outcome at all 3 stages



The screenshot shows the Stata Viewer window with search results for 'clinical trials'. The results include a list of commands and their descriptions, such as `[ADAPT] gs`, `[PSS-2] power`, `[PSS-3] ciwidth`, `[R] pk`, `[R] ttest`, `[ME] men1`, and `Video`.

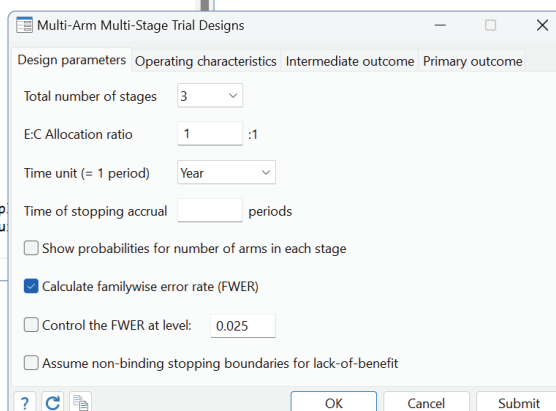
Easily access your data

Use ODBC or JDBC to access your data from password-protected databases, including Oracle, MySQL, Amazon Redshift, Snowflake, Microsoft SQL Server, and more.

```
. odbc sqlfile("query.sql"), dsn("TrialData")  
user(myid) password(mypass)
```

Stata and FDA regulatory compliance

Learn how Stata satisfies FDA requirements, including installation qualification, documentation, certification, and more, at [stata.com/stata-fda-compliance](https://www.stata.com/stata-fda-compliance).



The screenshot shows the 'Multi-Arm Multi-Stage Trial Designs' dialog box. It contains fields for design parameters, operating characteristics, intermediate outcome, and primary outcome. The 'Design parameters' tab is selected, showing fields for 'Total number of stages' (3), 'E:C Allocation ratio' (1:1), 'Time unit' (Year), and 'Time of stopping accrual' (periods). There are checkboxes for 'Show probabilities for number of arms in each stage', 'Calculate familywise error rate (FWER)', 'Control the FWER at level' (0.025), and 'Assume non-binding stopping boundaries for lack-of-benefit'.