

# The CenterWatch Monthly

April 2011

A CenterWatch Article Reprint

Volume 18, Issue 04

## Surviving budget season

By Todd Reul

If you're in clinical operations or responsible for clinical budgeting for your company, you might be dreading the "budget season." However, there are some steps you can take to make preparing your study budgets easier. The following are tips gleaned from years of experience:

- Start with a road map. Get management to agree on core programs, with key studies that will be conducted next year. This will give you a framework in which to develop clinical study budgets.
- Agree upfront on key study metrics and timelines. Determine the number of subjects, sites and locations; and the start date, first-subject-in date and database lock date for each study.
- Keep the study objectives in sight at all times. Too often, study budgets get off track because they were preempted by "nice to have" endpoints or requirements inserted into the process versus must-have endpoints or requirements to meet key regulatory and operational objectives.
- Build your budget from the ground up. A budget based on your current study assumptions—rather than extrapolated from studies conducted in the past and with even slightly different assumptions—will be much more accurate. This approach will also ensure you have scoped your study budget based on your specific protocol design and will make it clear what cost drivers are impacting resources and budget.
- Prepare different options. Develop a range of scenarios including high-level budget summaries (expenses and FTEs per study by department is one way to report the study costs) to gather feedback on key objectives and timelines before developing full detailed budgets.



Todd Reul is director, clinical services, for ClearTrial, which makes software for planning, forecasting and tracking clinical project and financial performance. ClearTrial helps biopharmaceutical and medical device companies gain internal and supplier efficiencies, compress cycle-times and reduce costs. [www.cleartrial.com](http://www.cleartrial.com)



+1 312.460.3000 | [info@cleartrial.com](mailto:info@cleartrial.com) | [www.cleartrial.com](http://www.cleartrial.com)

And last but not least—plenty of coffee!