

Eight Steps to Create a Winning Clinical Research Study Budget

Part 8 - Summarize the Study Budget and Determine the Profit Potential

By John P. Neal

About the Author

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In Part 7 of this series I explained how to determine the appropriate overhead rate to use for the study budget. Since the overhead line item is typically one of the single largest items in the study budget, it is one of the most crucial steps necessary to complete a study budget analysis.

Clinical personnel who have never received training in accounting or financial analysis, contract law, or negotiating strategies and tactics frequently are responsible for preparing and negotiating study budgets for investigative sites. Without proper training it is unlikely they will develop a study budget that properly captures all the costs involved in conducting a study. That is why I created a simple, eight step approach to developing a clinical research study budget modeled after the process I have successfully followed for years that has resulted in increased budgets, often exceeding 70% higher than what was originally offered by the Sponsor.

Following my eight step process will make your task of creating study budgets easier and give you the confidence you need to negotiate better budgets.

The Eight Steps

The process is broken down into the following distinct steps:

Step 1 - Determine the fully loaded, productivity adjusted cost of each staff member
(Part 1 of this series)

Step 2 - Identify all the study related tasks that must be performed per the protocol
(Part 2 of this series)

Step 3 - Identify all the non-staff costs of conducting the study visits
(Part 3 of this series)

Step 4 - Determine the time and cost of all the tasks necessary to start-up the study
(Part 4 of this series)

Step 5 - Determine the time and cost for each study visit
(Part 5 of this series)

Step 6 - Summarize all visits and add the totals for each visit
(Part 6 of this series)

Step 7 - Determine the appropriate overhead rate to use
(Part 7 of this series)

Step 8 - Summarize all the costs and expected revenue and determine whether the study, as budgeted, will be profitable

In this final article of the series I address **Step 8**, which is to summarize all the costs and expected revenue and determine whether the study, as budgeted, will be profitable.

Summarize the Study Budget and Determine the Profit Potential

The final step to create a winning clinical research study budget is to summarize all the costs and expected revenue from the study to determine whether the study, as budgeted will be profitable, and if not, determine what adjustments are necessary. Many assumptions go into this calculation, not the least of which is the approximate number of subjects you can reasonably expect to enroll and the approximate screen failure rate you anticipate.

The importance of conducting a critical review of the protocol and to thoughtfully consider the impact of the inclusion and exclusion criteria, along with your expected recruitment approach, on the likely result of your efforts cannot be overstressed. Too frequently sites struggle financially because they do not fully assess the challenges of recruiting and underestimate the impact of stringent inclusion/exclusion criteria (study selection and subject recruitment will be the topic of a future article). Together with inadequate assessment of overhead costs and the impact of productivity on staff costs, these can lead to disastrous results.

Part of the benefit of developing the budget using my eight step approach is that it gives you the ability to perform “what if” calculations to determine the impact of varying scenarios. For example, you can change the number of enrollments and see what impact it has on the bottom line. Or you can change the overhead percentage to see what happens. And of course, you can refine your time estimates and easily see the impact.

As with any new process, the first time through is the toughest and will take some time and persistence. Once you have completed one budget using this method you can easily use the resulting template to quickly create the next budget. In no time you will be budgeting like a pro. With the detailed information you created close at hand, defending your budget requests becomes easier. Sponsors and CRO’s appreciate that you have carefully considered the needs of the study and are willing to engage in discussions that ultimately result in your site being awarded better budgets.

*The entire clinical research budgeting model incorporating all **Eight Steps**, together with the book “**Clinical Research Budgeting Made Easy: The Step-by-Step Guide for Non-Accountants**” that leads you through the model, is available for purchase at The RAN Institute. **It would take hundreds of hours to create the same budgeting model from scratch!** In just a few hours you can create a winning clinical research budget. The model gives you the ability to perform “what if” calculations to determine the impact of varying scenarios so you can maximize the budget based on your site’s capabilities and unique requirements.*

Visit www.raninstitute.com today to purchase your copy!

Budget development and negotiation services are also available from Premier CMO. Visit www.premiercmo.com for more information.

As time goes by and you become familiar with the negotiation process (the topic of a future series of articles), you will become increasingly confident in your analysis and your knowledge of what is acceptable and customary in the industry. You will not only get better budgets than you have previously, but you will get increasingly better contract terms as well. Don't be surprised if you also get a few compliments from your boss – and just maybe a bonus along the way!

This is Part 8 of an eight part series that is available at www.premiercmo.com or www.raninstitute.com.
