

Eight Steps to Create a Winning Clinical Research Study Budget

Part 5 - Determine the Time and Cost for Each Study Visit

By John P. Neal

About the Author

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In Part 4 of this series I explained how to determine the time and cost of all the tasks necessary to start-up the study. It is important to understand the true costs to start-up and close-out a study in order to determine the minimum number of subjects you must enroll and have complete the study in order for that study to be profitable. Without understanding the cost of these tasks, it is impossible to accurately calculate the breakeven point of any particular study.

Clinical staff are frequently expected to negotiate budgets, but often don't know how to go about it in a way that leads to a fair budget. 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 of as much as 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
- Step 6** - Summarize all visits and add the totals for each visit
- Step 7** - Determine the appropriate overhead rate to use
- Step 8** - Summarize all the costs and expected revenue and determine whether the study, as budgeted, will be profitable

In this article I will address **Step 5**. In each subsequent article I will cover the next step until we have covered them all.

Determining the Time and Cost by Staff Member for Each Study Visit

The **fifth step** is to determine the time and cost by staff member for each study visit. This requires valuable input from your clinical research team and is critical to preparing your budget request.

Part of the work for this step was covered in Step 2 (see article 2 in this series) when I addressed creating the Study Task Dictionary. The next step is to create a schedule for each visit that identifies the staff time required for that visit along with the invoiceable cost for tasks or procedures that require outside processing for which your site will be billed. **Figure 1** shows an example of a Schedule of Staff Time for a study visit.

Figure 1 – Example Study Visit Time Estimate

Study Task/Procedure	Visit 1								Totals
	Admin Staff			Site Clinical Staff					
	Accountant	General Admin	Bus. Dev.	PI	Ops. Mgr.	CCRC	RA	Pharm. D	
Full screen Subject				0.25		0.50	0.25		1.00
Informed consent				0.20		1.00			1.20
Inclusion/Exclusion Criteria				0.10		0.25			0.35
Medical History				0.25		0.50	0.25		1.00
Randomization									
Vital Signs						0.10			0.35
Physical examination - Complete									
Physical examination - Brief									
Wound Site Assessment				0.20			0.20		0.40
ECG - 12 Lead									
Lab Draw & Processing									0.25
Adverse Events									
Concomitant Meds				0.10		0.10			0.20
Drug Distribution and Accountability									
Lab results review				0.10					0.10
Lab handling/Shipping							0.25		0.50
Subject progress notes				0.15			0.10		0.35
Subject source binder management							0.25		0.25
Protocol review				0.10		0.10			0.20
CRF transcription						0.50			0.50
Copying							0.15		0.15
Study Management system event input	0.25								0.50
Stipend processing							0.15		0.15
Coordinator Fee						1.50			1.50
Investigator Fee				0.50			0.25		0.75
Quality Assurance Fee					0.25				0.50
Total	0.3	0.0	0.0	1.7	0.3	4.1	1.6	0.0	10.2

Note: Multiple rows and columns were hidden for presentation purposes.

To be complete, the schedule above should be expanded to capture other non-staff costs related to the visit.

The time required for each task can be estimated by referring to the actual time to perform the same task on previous studies, by conducting “time and motion” studies (the basis for activity based costing), or by simple “guesstimates”. The method is employed will depend on the extent that time by task is

captured and tracked in your Clinical Trial Management System (CTMS) or other cost accounting method.

Sites that don't capture and track actual time can perform simple time and motion studies by conducting mock visits and capturing the time required to complete each task. The better job you do to capture this time, the more accurate your costs estimates will be.

After completing the schedule for Visit 1 the process is repeated for each study visit based on the Schedule of Activities contained in the protocol plus additional items identified necessary to carry out that visit and to comply with good clinical practice (GCP).

In my next article I will explain **Step 6**, summarizing all visits and calculating the total visit costs.

After we work through all **Eight Steps**, you will understand how to complete a thorough budget analysis and a defensible budget request. By understanding the detail behind the costs, you can negotiate with Sponsor's or CRO's with confidence. The negotiation itself is the topic of a future series of articles that will include negotiating the budget as well as the Clinical Trial Agreement (CTA).

A thorough budget analysis is essential to understanding the fair value for conducting a clinical research study. Over time, as you continue to study budgeting and contracting best practices, you will become increasingly familiar with what is customary and possible and you will get increasingly better budgets and better contract terms.

The potential financial success of a study starts with negotiating a fair budget. Mistakes in budgeting seal the fate of a study. That is why it is important to *Start with the Finish Line in Sight* by knowing your numbers and then negotiating successful 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 over 200 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.*

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This is Part 5 of an eight part series that is available at www.premiercmo.com or www.raninstitute.com.
