

Eight Steps to Create a Winning Clinical Research Study Budget

Part 4 - Determine the Time and Cost of Tasks Necessary to Start-up and Close-out the Study

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About the Author

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In Part 3 of this series I explained how to determine the non-staff costs incurred in the course of preparing for and conducting a study per the protocol and to comply with good clinical practice (GCP). Sites perform many tasks related to starting a study, as well as closing a study, which are not included in the per subject study budget. Identifying and understanding the cost of these tasks is crucial to the overall financial evaluation of a study. 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 confidence 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
- 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 4**. In each subsequent article I will cover the next step until we have covered them all.

Determining the Time and Cost of Start-up and Close-out Activities

The **fourth step** is to consider all the tasks necessary to start-up the study, to close it out after the study is completed, and identify certain costs that will be treated as pass-throughs for purposes of reimbursement. This will prepare you to negotiate those items.

Start-up activities include items like the Site Selection Visit, review of the protocol, participation in the Investigator Meeting, preparing and negotiating the budget, negotiating the Clinical Trial Agreement (CTA), creating a blinding plan, and many more such tasks. As in earlier steps, determining all the tasks associated with start-up and close-out is a team effort. Brainstorming with your team will allow you to create a comprehensive schedule of tasks and determine who must perform each task. Figure 1 shows an example of a Schedule of Start-up and Close-out Tasks.

After creating a schedule of all start-up and close-out tasks and determining the time required by each staff member to perform each, you can calculate the total cost to start-up and close-out the study by multiplying the time for each staff member by their productivity adjusted hourly rate determined in Step 1.

By knowing the true costs to start-up and close-out a study, together with the research revenue per subject, revenue from screen failures, and non-

refundable start-up fees, you can determine the minimum number of subjects you must enroll and have complete the study in order for that study to be profitable. This will be addressed later in Step 7.

Please note that the list in Figure 1 is only a partial list. The actual list will be quite extensive and will involve additional personnel. The more thorough you are in identifying these tasks, the more accurate your analysis of the costs. Most non-financial personnel are shocked the first time they complete this analysis. Depending on a sites cost structure, start-up and close-out costs can easily exceed \$10,000 per study. With most Sponsors refusing to reimburse a majority of these costs, your per subject budget

Figure 1

Study Start-up & Close-out Time Estimates

Start-up/Close-out Step	Admin			Site Clinical Staff					Grand Total
	Regulatory	Accountant	Bus. Dev.	PI	Ops. Mgr.	CCRC	RA	Pharm. D	
Budget Development & negotiation		4.00		0.25	0.25				4.50
Business development contact			1.00	0.50					1.50
Consent development	2.00								2.00
Contract Editing & Negotiation		4.00							4.00
Feasibility questionnaire			1.00	0.25	0.25			0.25	1.75
General protocol review	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	10.00
Investigator meeting				8.00		8.00			16.00
IRB document development and submission	1.00								1.00
Ongoing regulatory compliance update	4.00								4.00
Subject packet preparation	1.00								2.00
Regulatory submission development	4.00								4.00
Site Initiation meeting	4.00			3.00	2.00	4.00		1.00	14.00
Site selection meeting	1.00		3.00	2.00	2.00	2.00	2.00	1.00	13.00
Source document review and development					1.00	2.00	4.00		8.00
Clinical Trial Management system study set-up					2.00				2.00
Study Team meetings - Initial	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	12.00
Study Team meetings - Follow-up	2.00	2.00	2.00	2.00	2.00	2.00	2.00	2.00	16.00
Recruitment Plan development				0.50	0.50	2.00			3.00
Recruitment Materials Development									2.00
Recruitment advertising placement									2.00
Close-out Processing	4.00			2.00		8.00		1.00	15.00
Total	28.00	12.00	9.25	22.10	12.00	40.00	11.50	8.75	152.10

Note: Multiple rows and columns were hidden in order to demonstrate the layout. Time estimates are for illustrative purposes only.

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must anticipate recovering the balance of these unreimbursed costs by earning sufficient revenue over a target number of enrollments in the study.

In addition to negotiating a non-refundable start-up fee, you will negotiate a refundable advance (intended to offset the long delays in payment typical in the industry), certain pass-through items like IRB submission fees, translation fees, and the cost of recruitment activity specific to the study.

To ensure you capture each of the pass-through items in your analysis, and ultimately in your budget request, create a separate table of pass-through costs and other invoiceable costs. The table will be used later when you prepare the budget request for submission to the Sponsor or CRO.

In my next article I will explain **Step 5, determining the time and cost by staff member for each study visit**. I will explain how to analyze and determine the amount of time required to perform each study related task and to calculate the cost to perform each task.

As we work through all **Eight Steps**, you will find that completing a budget analysis will become easier. Once you have created a defensible budget and understand the detail behind the costs, you can negotiate the budget with Sponsor's or CRO's with confidence. The negotiation itself is the topic of a future article that will include negotiating the budget as well as the Clinical Trial Agreement (CTA).

A well thought out budget analysis is critical to understanding the fair value for conducting a study. By continuing to study budgeting and contracting best practices, over time you will become increasingly familiar with what is customary and possible and you will get increasingly better budgets as well as better contract terms. The potential financial success of a study starts with negotiating a fair budget. Mistakes in budgeting can seal the fate of a study. Good budgeting practices establishes a strong foundation for financial success of the study so, KNOW YOUR NUMBERS!

*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 at The RAN Institute for the low introductory price of just \$169 for a limited time. **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 sites capabilities and unique requirements.*

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This is Part 4 of an eight part series that is available at www.premiercmo.com or www.raninstitute.com.
