

Eight Steps to Create a Winning Clinical Research Study Budget

By John P. Neal

Study budgeting for the non-accountant

Do you wish you knew enough about developing a clinical research study budget to be confident you are getting your site the best possible budget on every study you negotiate? You aren't alone! From my experience, most people who work on clinical research study budgets, as well as the Clinical Trial Agreements (CTAs), don't have a background in accounting. Generally they're uncomfortable performing the budgeting function, but who else is going to do it when no one at the site is trained in accounting?

Wouldn't you like to feel confident in the budgets you create and feel good about getting great budgets for your site? Well, I think I can show you the way. I have worked with and observed many people like yourself and I understand what you go through each time you have to prepare another study budget. So I've created a simple eight step approach to developing a clinical research study budget that will aid you in your task of creating study budgets and give you the confidence to negotiate better budgets. Employing this process I have achieved an average increase in budgets of over 53%, with many in excess of 70% higher than what was originally offered by the Sponsor.

A key to the success of my approach is to *Start the Race with the Finish Line in Sight*. By this, I mean to know what you want and need to achieve before you get started, then work through the details, all the while knowing what the endpoint is. For clinical research budgeting, the endpoint is a budget that covers all direct costs, a reasonable portion of indirect costs, and provides a profit. Figure 1 is an example of a study summary page illustrating an endpoint for a study.

Figure 1 - Study Summary Page

Target Enrollment	12	→	Usually established by Sponsor/CRO. If not, assign based on your best judgement of how many subjects your site can reasonably expect to enroll over the course of the enrollment period given recruiting resources and methodologies available.
Billable Screen Failures	10		
Value per Screen Failure	\$1,037		
Overhead (excluding Profit)	25%	→	Based on detailed analysis or information provided by your finance or accounting department.
Target Profit %	10%	→	Set based on the goals of your institution.
Total Overhead used	35%		
Calculated Revenue Per Subject	\$9,512		
Target Research Revenue	\$114,139	→	Revenue per subject x the Target Enrollment
Target Screen Failure Revenue	\$10,370	→	Value per Screen Failure x Billable Screen Failures
Estimated Start-up Revenue	\$7,500	→	Set-based on the total amount of non-refundable start-up and other non-research visit based activity fees to be negotiated. See tab "Start-up & Close-Out Costs" for a detailed analysis of study start-up and other non-research visit related activities to consider.
Estimated Total Revenue	\$132,009		
Estimated Start-up & Close-out Costs	\$19,967	→	See "Start-up Costs" Tab
Estimated Direct Costs	\$84,547	→	See "All Visits Costs" tab
Estimated Overhead Costs	\$21,137	→	See "All Visits Costs" tab
Estimated Total Costs	\$125,651		
Estimated Profit (Loss)	\$6,358	→	This number should always be positive. A negative number here indicates that the study, as budgeted, will not cover all direct and indirect (overhead) cost plus provide for a profit on the study. See Chapter "Overhead and Profit" in the accompanying guide, <i>Clinical Research Study Budgeting Made Simple: A guide for non-accounting personnel</i> .
Estimated Profit (Loss) %	4.82%		
Profit Excess (Shortfall) from Target	-5.18%		

Generated by Premier Clinical Management Organization "Clinical Research Budget Development Tool" available through RAN Institute at

Knowledge is Power

Before I get into the individual budget development steps, let's take a short detour and explore the relationship between each party in the Clinical Trial. Knowledge is power, so if you know what each party wants and needs to feel they have "won", you already possess one of the key ingredients to getting great budgets! Sponsors and CRO's need sites that can recruit subjects into their studies within a practical timeframe and at a **reasonable** cost and will conduct the study in a professional manner that yields quality, evaluable data. Notice I didn't say at the **lowest** cost.

Contrary to what I hear from some sites, Sponsors and CRO's aren't interested in having your site accept a budget below your costs. Sponsors are required by the U.S. Department of Health and Human Services to demonstrate that they are paying fair market value for the services for which they payⁱⁱ. The Sponsor and CRO actually have a vested interest in the long-term financial health of each of the sites with which they do **recurring** business. Developing a compound and taking it to market is a long-term project that requires stability and longevity of all the companies in the chain, in particular clinical research sites. But, since the Sponsor and CRO don't know what your costs are, it's your responsibility to present to them a defensible budget based on knowledge of your costs.

Know Your Numbers

So, what are your costs? Conducting a study results in incurring three types of costs (yes, three!): direct costs, indirect costs (otherwise known as "overhead"), and opportunity cost. Direct costs are costs incurred specifically related to conducting a particular study at your site. Direct costs further break down into project related costs (non-study visit related costs for tasks like pre-study start-up and close-out tasks) and study visit/procedure costs. I'll address each of these later.

Indirect costs are costs allocable to the study that represent necessary infrastructure in order to be able to conduct research. Examples of such costs are rent, utilities, insurance, accounting, legal, etc.

Finally, there is opportunity cost. It may be simpler to think of this component as profit, but it represents a required return on the assets utilized to conduct the study (cash, property, furniture, equipment, supplies, overhead) that could otherwise be invested in some other activity or pursuit that could generate a return on those assets. Without some compensation for this "cost" your organization cannot sustain itself independent of outside contributions. In not-for-profit organizations, building in this element of cost reduces the burden of seeking outside funding for your activities. In for-profit sites, profit is the difference between success and failure.

Understanding the components of proper budgeting and the importance of each component to the budget is essential to the financial success of your site. It allows you to *Start the Race with the Finish Line in Sightⁱⁱⁱ*, so to speak. Once you know where you need to get to, you just have to plan out the steps to get from where you are to where you want to end up.

The Eight Steps

Developing a clinical research study budget can be overwhelming. Where do you start? How do you tackle such a big task? It can be a bit like trying to eat an elephant in one sitting. Instead, I have broken the process down into eight manageable steps so you can eat the elephant a bite at a time.

The steps are:

Step 1 - Determine the fully loaded, productivity adjusted cost of each staff member.

Step 2 - Identify all the study related tasks that must be performed per the protocol.

Step 3 - Identify all the non-staff costs of conducting the study visits.

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 1. Each month I will cover the next step until we have covered them all.

The **first step** to developing your budget is to understand your staff costs. Staff costs include direct compensation plus the costs for employer paid payroll taxes, health insurance and other benefits (such as vacation pay, pension contributions, and health savings accounts).

To start, obtain the base compensation amount for each staff position in your company. Add to that the amount the company pays for each of the benefits provided and the taxes required. Then, determine the actual number of hours available for performing clinical research tasks by subtracting from the total hours available all the time that the person won't be available (vacation, sick days, holidays, training time, investigator meetings etc. By dividing the adjusted compensation by the adjusted hours available, you will get the hourly compensation *prior to* adjustment for productivity.

Productivity is a sensitive topic at most sites, but must be accounted for in order to arrive at an accurate cost to use for budgeting. There are many approaches to evaluating productivity, all too long to address in this article, but it is safe to say that no one is 100% productive. Once you have decided on

*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.*

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

the productivity modifier, apply that to the rate per hour calculated previously and you get the productivity adjusted cost per hour. This will be used in all the rest of the budgeting steps. See Figure 2 below for an Example Staff Cost Calculation.

Figure 2 - Example Staff Cost Calculation

Compensation Components	Site Clinical Staff						
	PI	Sub-I (MD)	Ops. Mgr.	CCRC	RA	Lab Tech	AA
Wages ¹	\$250,000	\$125,000	\$85,000	\$50,000	\$45,000	\$40,000	\$30,000
Total Days	260	260	260	260	260	260	260
Vacation Days	20	15	15	10	10	10	10
Holidays	10	10	10	10	10	10	10
Sick days	6	6	6	6	6	6	6
Investigator Meetings, PSSV,SIV, & Training	45	30	20	20	15	15	15
Available Days	179	199	209	214	219	219	219
Adjusted Hours	1,432	1,592	1,672	1,712	1,752	1,752	1,752
Hourly Wage Before Benefits	\$120	\$60	\$41	\$24	\$22	\$19	\$14
Adjusted Employee Cost	\$306,625	\$155,813	\$107,553	\$65,325	\$59,293	\$53,260	\$41,195
Fully Loaded Employee Cost per Hour	\$214	\$97	\$64	\$38	\$33	\$30	\$23
Productivity Rate	75%	75%	75%	75%	75%	75%	75%
Productivity adjusted Cost per Hour	\$285	\$129	\$85	\$51	\$44	\$40	\$31

¹ NOTE: AMOUNTS ARE FOR ILLUSTRATIVE PURPOSES ONLY.

You are well on your way to creating a winning study budget!

As with any new process, the first time through is the toughest and will take some time and persistence. After you have completed **Step 1** once, you only have to update it periodically as compensation factors change.

Next month I will explain **Step 2** and walk through the process of identifying all the study related tasks that must be performed, including many that you won't find explicitly in protocol.

After you have completed all **Eight Steps**, you will become familiar with the negotiation process (I will cover this in a later article), 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 one of an eight part series that will be available at www.premiercmo.com or www.ranitstitute.com.

ⁱ Linda Pinson and John P. Neal. 2006. Develop an Exit Strategy: Start the Race with the Finish Line in Sight. *The Anatomy of a Business Plan*.

ⁱⁱ U.S. Department of Health and Human Services, Office of Inspector General. 2003. OIG compliance program for pharmaceutical manufacturers. *Federal Register* 68(86).

John P. Neal is CEO of Premier Clinical Management Organization, a leader in clinical research site consulting services, located in Encinitas, CA. He has served as the COO or CFO of several multi-site clinical research companies and has over twenty-five years experience working with biotech and pharmaceutical start-up companies. He received his BS in Accounting at San Diego State University and his CPA Certificate while with Deloitte Touche in San Diego, CA and is a certified Clinical Research Contracting Professional (CRCP). He can be reached at jneal@premiercmo.com.