

## Eight Steps to Create a Winning Clinical Research Study Budget

### Part 6 - Summarize the Time and Cost for Each Study Visit

By John P. Neal

#### About the Author

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In Part 5 of this series I explained how to determine the time and cost of all the tasks required to perform each study visit. Understanding the true costs to conduct each visit, including phone follow-up as called for in the protocol, is essential to the budgeting process. Without understanding the cost of each visit, determining what fee is needed to cover all costs and provide a reasonable margin is impossible.

Non-accounting site 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, 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

**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 address **Step 6**. In each subsequent article I will cover the next step until we have covered them all.

### Summarize the Time and Cost for Each Study Visit

The **sixth step** is to summarize the time and cost for each study visit. These summaries will look similar to the Schedule of Procedures contained in the study protocol, except the X's are replaced with time and dollar values. This should look familiar, as it should mimic closely the Study Budget Spreadsheet often provided by the Sponsor or CRO. If a budget schedule is not provided by the Sponsor or CRO, create one based on following the first five steps presented previously in this series of articles.

Figure 1 provides an example of a study time summary.

**Figure 1 – Example Study Time Summary**

Study Task/Procedure	V1	V2	V3	V4	V5	V6	V7	V8	V9	V10	Total
Full screen Subject	1.00										1.00
Informed consent	1.20										1.20
Inclusion/Exclusion Criteria	0.35	0.35									0.70
Medical History	1.00		1.00								2.00
Randomization			1.00								1.00
Vital Signs	0.35	0.35	0.35	0.35	0.35	0.35	0.35	0.35	0.35	0.35	3.50
Physical examination - Complete		1.00							1.00		2.00
Physical examination - Brief			0.50								0.50
Wound Site Assessment	0.40	0.40	0.40	0.40	0.40	0.40	0.40	0.40	0.40	0.40	4.00
ECG - 12 Lead		0.40									0.40
Lab Draw & Processing	0.25	0.25	0.25	0.25	0.25	0.25	0.25	0.25	0.25	0.25	2.50
Adverse Events			0.20	0.20	0.20	0.20	0.20	0.20	0.20	0.20	1.60
Concomitant Meds	0.20	0.20	0.20	0.20	0.20	0.20	0.20	0.20	0.20	0.20	2.00
Drug Distribution and Accountability		0.20	0.20	0.20	0.20	0.20	0.20	0.20	0.20		1.60
Lab results review	0.10	0.10	0.10	0.10	0.10	0.10	0.10	0.10	0.10	0.10	1.00
Lab handling/Shipping	0.50	0.50	0.50	0.50	0.50	0.50	0.50	0.50	0.50	0.50	5.00
Subject progress notes	0.35	0.20	0.20	0.20	0.20	0.20	0.20	0.20	0.20	0.20	2.15
Subject source binder management	0.25	0.25	0.25	0.25	0.25	0.25	0.25	0.25	0.25	0.25	2.50
Protocol review	0.20	0.10	0.10	0.10	0.10	0.10	0.10	0.10	0.10	0.10	1.10
CRF transcription	0.50	0.50	0.50	0.50	0.50	0.50	0.50	0.50	0.50	0.50	5.00
Copying	0.15	0.15	0.15	0.15	0.15	0.15	0.15	0.15	0.15	0.15	1.50
Study Management system event input	0.50	0.50	0.50	0.50	0.50	0.50	0.50	0.50	0.50	0.50	5.00
Stipend processing	0.15	0.15	0.15	0.15	0.15	0.15	0.15	0.15	0.15	0.15	1.50
Coordinator Fee	1.50	1.50	1.50	1.25	1.25	1.25	1.25	1.25	1.25	1.25	13.25
Investigator Fee	0.75	0.50	0.50	0.30	0.30	0.30	0.30	0.30	0.30	0.30	3.85
Quality Assurance Fee	0.50	0.50	0.50	0.50	0.50	0.50	0.50	0.50	0.50	0.50	5.00
<b>Total Hours</b>	<b>10.20</b>	<b>8.10</b>	<b>9.05</b>	<b>6.10</b>	<b>6.10</b>	<b>6.10</b>	<b>6.10</b>	<b>6.10</b>	<b>7.10</b>	<b>5.90</b>	<b>70.85</b>

Adapted from John P. Neal, 2009, *Clinical Research Budgeting Made Easy*. Used with permission.

The time summary is derived from the individual study visit time estimates created in **Step 5** (see article 5 in this series) and represents all of the time involved by site personnel in conducting the study visits. A review of the time summary can identify any discrepancies in the time estimates for individual tasks as well as provide a high level reality check of the time estimates. If discrepancies are identified, or the time required to perform tasks appear out of line with expectations, individual study visit estimates can be adjusted accordingly and the summary updated.

After completing the study visit time summary, a study visit cost summary should be completed similar to that in Figure 2.

**Figure 2 – Example Study Cost Summary**

Study Task/Procedure	V1	V2	V3	V4	V5	V6	V7	V8	V9	V10	Total
Full screen Subject	93.33										93.33
Informed consent	96.27										96.27
Inclusion/Exclusion Criteria	35.47	35.47									70.93
Medical History	93.33		93.33								186.67
Randomization			93.33								93.33
Vital Signs	13.73	13.73	13.73	13.73	13.73	13.73	13.73	13.73	13.73	13.73	137.33
Physical examination - Complete		131.33							131.33		262.67
Physical examination - Brief			65.67								65.67
Wound Site Assessment	54.40	52.53	52.53	52.53	52.53	52.53	52.53	52.53	52.53	52.53	527.20
ECG - 12 Lead		15.47									15.47
Lab Draw & Processing	8.67	8.67	8.67	8.67	8.67	8.67	8.67	8.67	8.67	8.67	86.67
Adverse Events			27.87	27.87	27.87	27.87	27.87	27.87	27.87	27.87	222.93
Concomitant Meds	27.87	27.87	27.87	27.87	27.87	27.87	27.87	27.87	27.87	27.87	278.67
Drug Distribution and Accountability		17.60	17.60	17.60	17.60	17.60	17.60	17.60	17.60	17.60	140.80
Lab results review	22.80	22.80	22.80	22.80	22.80	22.80	22.80	22.80	22.80	22.80	228.00
Lab handling/Shipping	21.00	21.00	21.00	21.00	21.00	21.00	21.00	21.00	21.00	21.00	210.00
Subject progress notes	51.53	27.20	27.20	27.20	27.20	27.20	27.20	27.20	27.20	27.20	296.33
Subject source binder management	11.00	11.00	11.00	11.00	11.00	11.00	11.00	11.00	11.00	11.00	110.00
Protocol review	27.87	13.93	13.93	13.93	13.93	13.93	13.93	13.93	13.93	13.93	153.27
CRF transcription	25.33	25.33	25.33	25.33	25.33	25.33	25.33	25.33	25.33	25.33	253.33
Copying	6.60	6.60	6.60	6.60	6.60	6.60	6.60	6.60	6.60	6.60	66.00
Study Management system event input	19.33	19.33	19.33	19.33	19.33	19.33	19.33	19.33	19.33	19.33	193.33
Stipend processing	6.60	6.60	6.60	6.60	6.60	6.60	6.60	6.60	6.60	6.60	66.00
Coordinator Fee	76.00	66.00	66.00	55.00	55.00	55.00	55.00	55.00	55.00	55.00	593.00
Investigator Fee	125.00	114.00	114.00	68.40	68.40	68.40	68.40	68.40	68.40	68.40	831.80
Quality Assurance Fee	30.00	30.00	30.00	30.00	30.00	30.00	30.00	30.00	30.00	30.00	300.00
Subtotal of Procedure Costs	846.13	666.47	764.40	455.47	455.47	455.47	455.47	455.47	586.80	437.87	5,579.00
Blood Culture	25.00	25.00	25.00	25.00	25.00	25.00	25.00	25.00	25.00	25.00	250.00
Serum Chemistry Panel	22.00										22.00
Urinalysis	25.00										25.00
Serum Pregnancy Test	22.00										22.00
Subject Stipend	50.00	50.00	50.00	50.00	50.00	50.00	50.00	50.00	50.00	50.00	500.00
Subtotal	\$990	\$741	\$839	\$530	\$530	\$530	\$530	\$530	\$662	\$513	\$6,398

Adapted from John P. Neal, 2009, *Clinical Research Budgeting Made Easy*. Used with permission.

Included at the bottom of Figure 2 are the visit costs for any items for which an outside vendor is used or that represent a non-personnel out-of-pocket cost. The units and costs for these items for each visit would be identified during **Step 5** at the same time individual tasks and time estimates were determined.

You should have a good idea now of the actual costs of performing each of the tasks required by the study protocol and required by good clinical practice (GCP). As you can see, a thorough analysis of the protocol and inclusion of all tasks site staff must complete for each visit is vital to developing a complete understanding of the direct costs associated with conducting study visits.

In my next article I will explain **Step 7**, how to determine an appropriate overhead rate to apply to your cost analysis and ultimately the budget request you will submit to the Sponsor or CRO.

We are just two steps away from completing the entire budget analysis. 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 and defending your budget requests. Over time, as you continue to study budgeting and contracting best practices, you will become increasingly familiar with what is customary and possible. As a result, you will get increasingly better budgets and better contract terms.

The financial success of a study starts with negotiating a fair budget. By understanding your costs and the financial contribution each study must make to your organization, you are able to *Start with the Finish Line in Sight* and negotiate successful budgets.

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*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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