

Budget Tool Helps Investigative Sites Calculate the Cost of a Coordinator's Time for a Typical Outpatient Study Visit - Part II

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Note: This is Part II of a two-part series introducing the Coordinator Cost Calculator (“CCC”) - a spreadsheet-based tool designed to help investigative sites calculate the cost of a study coordinator’s time for an uncomplicated, phase-III study visit.

In Part I of the series, we estimated that the total salary and benefits cost of a hypothetical study coordinator, making a nominal salary of \$45,000, was \$58,292. This equates to a benefit cost of approximately 29.5% of base pay. Then, we estimated that this coordinator was in the research clinic and available for work on 220 days out of the normal 260 day work year. The 40 paid days when the coordinator was not at work were due to holidays, vacation leave, educational and training days, and attendance at investigator meetings.

Part I of the series concluded with the calculation that while our hypothetical research coordinator was being paid at a nominal rate of \$21.63 per hour, his/her full cost per working hour was some 53% higher, or \$33.12 per hour.

So What’s the Problem?

With the full cost of the research coordinator calculated at \$58,292 (using a set of reasonable, but not universal, assumptions from Part I of this series), the question seems to be, “Why not just apply the cost figure to the work required of the research coordinator by the study protocol, and the result would be your budget for the coordinator’s time?”

The problem with this approach is simply that most clinical trial budgets don’t work like that. The budget for a typical phase-III clinical trial has one, or maybe two, line items to cover all the services of the clinical research coordinator, and that charge has to cover a smorgasbord of services. (Later on in the article, we will explore in greater detail the study coordinator’s clinical and non-clinical duties required in the conduct of an average clinical research trial.)

For our cost calculations, however, we will be taking a wide viewpoint of this issue by looking at the study coordinator’s total daily workload of study visits and study-related duties, and attempting to calculate the coordinator’s cost using this big picture approach.

The Workload Question

The workload of a study coordinator is a topic often touched upon in the popular literature, but rarely quantified. The influential clinical trials monthly publication, *CenterWatch*, ran a recent front-page story entitled “The Rising Tide of CRC Workload and Turnover.”¹ In this article, *CenterWatch* polled nearly 500 study coordinators and found that more than half of these CRCs had been in their current positions for less than three years, a sharp rise from the results of a similar survey done three years prior. The article reported that “burnout

due to heavy workload” was one of the three most common reasons for CRC turnover.

What did *CenterWatch* find out about CRC workload? The magazine, which measured study coordinator workload by the number of clinical trials actively managed by each CRC, reported:

*Full-time CRCs in dedicated and part-time investigative sites typically have the highest workload. Each coordinator in these settings manages the conduct of an average of five active clinical trials at any given time. Coordinators in academic institutions typically handle four active trials.*²

Unfortunately, knowing that the average study coordinator handles four to five active clinical trials at any one time doesn’t give us enough details to produce the coordinator’s

cost per study visit. We are left to ask: “How many study visits per day does a study coordinator average when that study coordinator has a workload of four or five active clinical trials?”

The Search for a Study Visit Standard

A search of the literature reveals little of direct relevance concerning the study visit workload for clinical research coordinators.³ In contrast to the scant amount of published articles, various unpublished opinions as to the optimal number of study visits per day for a study coordinator are put forth on specialized clinical research discussion boards such as “The IRB Forum”⁴ or the ACRP Site Managers Forum.⁵ These discussion boards are informal and their content is confidential, so direct citations are not appropriate. However, the optimum study-visit workload number frequently used on these boards for academic medical centers and large, research-based hospitals is 60 study visits per month per coordinator.

We can assume that “60 study visits per month” is equal to about 3 study visits per working day (using 21 working days per month), and because the previously quoted *CenterWatch* article said that the coordinator workload for academia was less than that of dedicated research sites, I will assume that coordinator workloads in private investigative sites exceed the three-per-day level – perhaps reaching four or five study visits per day. Again, this is an assumption based on unreferenced source data – but I think that you will see later in the article that the range of three to five study visits per day seems to fit in with other known data about the duties of a study coordinator.

Initial Cost Data

With only unpublished data on the number of study visits per month, we still can make our first estimation of the coordinator cost per study visit.

Here goes:

Our yearly cost for a hypothetical study coordinator, from Part I of this series, is \$58,292. Also from Part I, we know that this coordinator is in the research clinic for 220 workdays per year – with the other 40 days of the year taken up by leave, holidays, education, training and attendance at investigator meetings. Therefore, the cost per workday of our hypothetical study coordinator is \$58,292 divided by 220, or about \$265 per day.

To obtain the study coordinator cost per study visit, we then divide the \$265 coordinator cost per workday by the estimated three study visits per day, and the resulting coordinator cost per study visit is almost \$91. If we were to use the figure of four study visits per day, the resulting coordinator cost per study visit is approximately \$66, and a figure of five study visits per day decreases the coordinator cost per study visit to about \$51. Therefore, we have developed an initial range of \$50 to \$90 (using rounded numbers) for the coordinator cost of a study visit for a clinical research trial.

How reasonable is a range of \$50 to \$90 for the coordinator cost of a study visit? Again, I have found no published data on this aspect of clinical research budgets – but unpublished data and experiences related on discussion boards confirm that this range is reasonable for phase-III, uncomplicated clinical trials of mild-to-moderate conditions in chronic diseases (such as hypertension, diabetes, arthritis, irritable bowel, GERD, asthma and the like).

This is a Different Business

Wait just a minute! If a traditional private practice physician would step back and look at the financial information developed so far, the physician might be very surprised. After all, the clinical research financial model seems to be based on three to five study visits *per*

workday, whereas a busy private-practice physician easily may conduct that many clinic visits *each hour* – not just in a day! What is going on here?

Clearly, the research business is vastly different from the provision of normal medical services. What makes clinical research so different from a standard medical practice? Well, first the clinic visits are longer, with a 30-minute visit being about the minimum amount of time necessary for a phase-III study visit. Then, the paperwork and administrative support tasks for a research site are so much more comprehensive than for a regular medical practice. That the study coordinator’s day is filled with administrative and support duties is something that is well documented in the literature.⁶

In order to quantify the average daily routine of a research coordinator, the author has developed the “Coordinator Cost Calculator” (or “CCC”) which is a spreadsheet-based model that attempts to list and measure the many and varied tasks of a phase-III study coordinator. The CCC starts with the salary and workday calculations of an average study coordinator (as described in Part I of this series), and then breaks down the daily administrative and support duties of the coordinator. The “bottom line” of the CCC is its calculation of the coordinator’s cost per study visit.

The Clinical Day

The workplace assumptions for our study coordinator (which won’t fit every research center – you must adapt these assumptions to fit your circumstances) start with an investigative site that has dedicated study coordinator(s). We are not looking at an investigative site with a part-time coordinator – a coordinator splitting his/her time between research and regular clinic duties. Likewise, our model is not meant for a large investigative site where many operational functions (phlebotomy,

recruitment, CRF completion) are separated from the duties of the study coordinator and are performed by dedicated specialists.

Our base assumptions about a study coordinator's clinical day are listed at the top of Table 1. We assume that the study coordinator has about four study visits per day. This is presumed to be the average study visit rate per day for private investigative sites, and above the average study visit rate per day for academic medical research sites. As stated previously, there is no documentation of coordinator study visit rates in the literature, and this is simply an educated guess as to the coordinator's workload.

We also assume that the coordinator has two non-study clinic visits per day, which primarily are clinic visits with new or prospective research volunteers to review their medical history and to discuss the nature of clinical trials. Non-study clinic visits also occur when the sponsor contractually limits their reimbursement for subjects who fail to qualify for their study, even when those subjects met initial inclusion and exclusion criteria (so-called "screen failures"). The CCC also assumes that every other day there will be a patient "no-show" and that an available patient appointment time will go unfilled.

Next, the CCC assumes that the average clinic visit is 30 minutes in duration. Of course, clinic visit time varies greatly due to many factors: the study itself, the study visit involved (a consent visit versus a follow-up visit), and the therapeutic area, among other factors. However, a 30-minute clinic visit assumption is a convenient starting point, and this figure can easily be manipulated to account for differing scenarios.

Non-Clinical Duties

From our previous discussion of the study coordinator's day, we know that administrative and support duties are a major part of the coordinator's

workday. In our CCC, therefore, we list the major non-clinical duties of the research coordinator, and make reasonable assumptions as to the time required of each duty.

For the study coordinator's administrative and support duties listed in Table 1, the completion of study case report forms ("CRFs") is the primary administrative job of a study coordinator. Every study visit generates pages and pages of CRFs to document that visit, and a chunk of coordinator time each and every day is spent filling out CRFs. In our analysis, we assume that for every hour of study visit time, there will be another full hour needed for CRF completion. In Table 1, we have 4.0 half-hour study visits per day (2.0 hours per day of study visit time), and that equates to 2.0 hours per day of CRF completion time.

The next busiest daily job of a study coordinator is to ask and answer inquiries about the study, by phone, fax and/or email. What study coordinator goes through a day without initiating or receiving a study-related phone call, fax or email? We assume a half-hour will be spent each and every day communicating in some fashion about study related issues.

Weekly and Monthly Tasks

Some of the study coordinator's administrative and support tasks, such as completing CRFs and answering phone calls, are easily thought of as daily tasks. In Table 1, we have listed some of those coordinator tasks that, while occurring regularly, do not happen on a daily basis. For example, meeting with the sponsor's monitor to go over the progress of the clinical trial, and to inspect the study's CRFs may happen every other week or maybe only monthly. This is a task, however, that may take hours at a time to complete. In our model, we assume 2 hours per week (or about a full day each month) is devoted to preparing for and meeting with the study monitor. (Again, individual values such as the

time spent with study monitors can vary widely – and the individual user of the CCC spreadsheet is encouraged to enter whatever value reflects the reality of their research site.)

Patient recruitment activities also are listed in Table 1. For this important task, we assumed 1.5 hours per week would be spent on recruitment activities such as reviewing patient charts, checking lab values, and talking to prospective study volunteers about participating in clinical research.

There are other coordinator tasks that arise much less frequently than on a weekly basis. In Table 1, we have listed the coordinator's participation in a sponsor's site qualification visit, or in a study closeout meeting as examples of coordinator duties that may happen only on a monthly (or more infrequent) basis.

The CCC Fills in the Daily Details

Previously in this article, we calculated the coordinator cost per study visit at about \$66 per study visit, assuming the coordinator has four study visits per day. The actual math is the \$58,292 full cost of the study coordinator divided by his/her 220 workdays = \$265 which is the cost of the study coordinator per workday. Then \$265 is divided by four study visits per day, and the result is a study coordinator cost of \$66.25 per study visit.

As we also discussed earlier, if the coordinator has only four study visits per day, then what takes up the rest of his/her time during the normal workday? The CCC helps the user answer this important question, as it lists at least 16 other duties or tasks of the coordinator that more than fill the average working day (see Table 1). The actual math calculations involved in the CCC are summarized in Table 2, which again starts with the salary and benefit assumptions from Part I of this article, and then uses the administrative and support assumptions contained in Table 1 to document the coordinator cost per study visit of \$66.25.

Table 1:

Clinical Workday Assumptions

Study visits	4.0 clinic visits per day
Non-study and screening clinic visits	2.0 clinic visits per day
“No show” clinic appointment	0.5 clinic visits per day
Unfilled clinic appointment	0.5 clinic visits per day
Clinic visit duration	30 minutes per clinic visit

Administrative & Support Study Coordinator Tasks

Daily Tasks:

<u>Case Report Form or CRF Completion</u>	2.00 hour(s) per day
Phone, fax and/or email inquiries	<u>0.50 hour(s) per day</u>
Daily Tasks Subtotal	2.50 hours per day

Weekly Tasks:

Sponsor’s CRA monitoring visits	2.00 hour(s) per week
Patient recruitment/chart reviews	1.50 hour(s) per week
Lab shipments for studies	1.00 hour(s) per week
Protocol review & staff meetings	1.00 hour(s) per week
Data Correction Forms/Data queries	0.50 hour(s) per week
Regulatory Docs/IRB correspondence	0.50 hour(s) per week
Collect & process AE data	0.50 hour(s) per week
Read & implement protocol amendments	0.25 hour(s) per week
Read & comment on new protocols	0.25 hour(s) per week
Administer & explain informed consent	<u>0.50 hour(s) per week</u>
Weekly Tasks Subtotal	8.00 hours per week

Monthly Tasks:

Site qualification visits by sponsor	2.00 hour(s) per month
Study site initiation meetings	2.00 hour(s) per month
Study site close-out meetings	2.00 hour(s) per month
Answer telephone for newspaper ads	<u>2.00 hour(s) per month</u>
Monthly Tasks Subtotal	8.00 hours per month

Summary:

Study visits (4 @ 30 minutes)	2.00 hours per day
Other clinic appointments (3 @ 30 minutes)	1.50 hours per day
Administrative and Support duties	<u>4.50 hours per day</u>
<u>Total</u>	<u>8.00 hour workday</u>

Note: *The CCC spreadsheet translates all the above weekly and monthly frequencies into their daily equivalents.*

Table 2: Summary of Coordinator Cost per Study Visit

Total Salary and Benefits:

Nominal \$45,000 salary	\$45,000
Benefits	\$13,292
Total	\$58,292

Net Workdays per year:

5 days x 52 weeks	260 days
Less leave, holidays, training, etc.	-40 days
Net Workdays	220 days

Coordinator Clinic Day Assumptions:

Clinic visit duration	30 minutes
Study Visits	4.0 per day
Non-study & other visits	3.0 per day

Coordinator Administrative & Support Tasks:

Case report forms	2.0 hours per day
Phone, fax, emails	0.5 hours per day
<u>Weekly Tasks:</u> from Table 1	8.0 hours per week
<u>Monthly Tasks:</u> from Table 1	8.0 hours per month

Net Workday Breakdown in 30-minute Time Slots:

220 days x 16-30min slots	3,520 possible appointments
Study visits	880 25%
Non-study visits	660 19%
Admin & Support duties	1,980 56%

Coordinator Cost per Study Visit \$66.25

Note: See Part I of this series for a discussion of “Total Salary and Benefits” and “Net Workdays per Year” above.

“What If” Scenarios

Since no two clinical research investigative sites are run quite the same, perhaps the best feature of the CCC is its ability to be modified to suit individual variations. In Table 3 we have varied the workday assumptions of a research site to create a “Low,” “Medium” and “High” study visit scenario. The “Medium” study visit scenario is the one previously outlined in this article – using the assumption of four study visits per day and the coordinator tasks as described in Table 1.

Under the “Low” study visit scenario in Table 3, we have assumed that the site has only three study visits per day, and that its administrative load has increased. That is, the time devoted to CRF completion has increased by 15 minutes per day, the time for CRA monitoring visits has increased by a half-hour per week, and the time devoted to patient recruitment activities (both chart review and answering telephone inquiries) has significantly increased. With the coordinator doing more administrative work and conducting less study visits, the bottom line coordinator cost per study visit rises to \$90.83.

Under the “High” study visit scenario in Table 3, we have assumed that the study coordinator is relieved of some of his/her daily tasks. Most likely, this site has dedicated specialists in the fields of patient recruitment, phlebotomy, and regulatory compliance that allow the study coordinator to concentrate more directly on study visits. With this scenario, the study coordinator conducts five study visits per day, and the study coordinator’s cost per study visit falls to \$51.09.

Summary and Conclusions

Suppose, for a moment, you were naïve to clinical research budgeting. Would you think that a line item for the personnel charge of a study

coordinator with a nominal pay rate of about \$11 for a half-hour of work (based on a salary of \$45,000 per year) should have a charge rate of from \$50 to \$90 for that half-hour’s work? I think these figures would shock and astound most investigators, and I am reminded of the budget advice of the University of Washington as it counsels its clinical research budget makers:

Think carefully about personnel costs. This is the category most likely to include hidden costs. Although your study may be entitled “A Six-Month Double Blind, Randomized Study To Compare the Efficacy of Drug A with Drug B,” study staff will be involved much longer than six months. Study staff will spend significant reimbursable time with start-up tasks (such as IRB submission, budget development, patient recruitment, and patient consent) and closeout tasks (such as data clean-up and sponsor queries).

Look behind the study “label” -- although a study visit may be labeled as a “blood draw,” associated staff time may also include telephone reminders, call-backs, tube setup, lab paperwork, CRF entry and filing. Consider staff time associated with patient screening costs -- you may need to screen five patients in order to find one who can be randomized. Visits by study monitors will consume staff time and may occur several times during the trial. For all appropriate staff (P.I., the study coordinator, and administrative support) list both salaries and benefits....

Be sure that the sponsor understands that you expect to be paid for work performed.⁷

A copy of the Coordinator Cost Calculator is available via email from the author at guyjohnson@worldnet.att.net. The CCC is a Microsoft Excel 2000 based spreadsheet.

(Endnotes)

¹ Neuer A., The Rising Tide of CRC Workload and Turnover, CenterWatch 9:1, 4-7 (August 2002).

² Neuer A., The Rising Tide of CRC Workload and Turnover, CenterWatch 9:1, 4-7 (August 2002).

³ See Gwede C.K., Johnson D., Trotti A., Measuring the Workload of Clinical Research Coordinators: Part 1 – Tools to Study Workload Issues, Appl Clin Trials 9:4040-44, (January 2000).

⁴ “The IRB Forum” can be accessed at www.mcwirb.org.

⁵ The “ACRP Site Managers Forum” can be accessed at <http://www.acrpn.org/forums/index.html>.

⁶ Gwede C.K., Johnson D., Trotti A., Measuring the Workload of Clinical Research Coordinators: Part 1 – Tools to Study Workload Issues, Appl Clin Trials 9:4040-44, (January 2000); Ginsberg D., The Investigator’s Guide to Clinical Research, Chapter 7, 83-92 (Third Edition, 2002); University of Washington School of Medicine Clinical Trials Administrative Start-up Handbook: <http://www.hscer.washington.edu/clinicaltrialshandbook/>, accessed on 02/27/2003; ACRP Clinical Research Coordinator exam content: <http://www.acrpn.org/certification/handbookcrc/chcontent.html>, accessed on 03/15/2003.

⁷ University of Washington School of Medicine Clinical Trials Administrative Start-up Handbook: <http://www.hscer.washington.edu/clinicaltrialshandbook/>, accessed on 02/27/2003.

**Table 3: Coordinator Study Visit Costs under “Low,”
“Medium” and “High” Study Visit Scenarios**

Study Visit Scenario

	<u>Low</u>	<u>Medium</u>	<u>High</u>
Number of study visits per day (rounded)	3.00	4.00	5.00

Administrative & Support Study Coordinator Tasks

DailyTasks (in hours/day):	<u>Low</u>	<u>Medium</u>	<u>High</u>
Case Report Form or CRF Completion	2.25	2.00	2.00
Phone, fax and/or email inquiries	0.50	0.50	0.50

Weekly Tasks (in hours/week):

Sponsor’s CRA monitoring visits	2.50	2.00	2.00
Patient recruitment/chart reviews	2.00	1.50	0.50
Lab shipments for studies	1.00	1.00	0.00
Protocol review & staff meetings	1.00	1.00	1.00
Data Correction Forms/Data queries	0.50	0.50	0.50
Regulatory Docs/IRB correspondence	0.50	0.50	0.00
Collect & process AE data	0.50	0.50	0.50
Read & implement protocol amendments	0.25	0.25	0.25
Read & comment on new protocols	0.25	0.25	0.25
Administer & explain informed consent	0.50	0.50	0.50

Monthly Tasks (in hours per month):

Site qualification visits by sponsor	2.00	2.00	2.00
Study site initiation meetings	2.00	2.00	2.00
Study site close-out meetings	2.00	2.00	2.00
Answer telephone for newspaper ads	4.00	2.00	0.00

Summary:

<u>Coordinator Cost per Study Visit</u>	\$90.83	\$66.25	\$51.09
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Note: Changes in assumptions from the “Medium” scenario are bolded above.