

Keeping Device Study Costs under Control: Building a Realistic Budget

By Nancy J. Stark

A Modest Device Study for a Million Dollars

A modest device study costs \$1 million and a major study \$10 million or more. These costs are divided between investigative sites, service providers like CROs and consultants, and costs internal to the sponsor company. In this article, we'll discuss common mistakes made in estimating study costs and steps you can take to keep spending under control. This article is a basic introduction for readers who are familiar with medical device study design but not with creating the budgets to conduct those studies.

It Starts with the Protocol

Consider the following study plan: 100 subjects will be implanted with a vascular access port. They will use the port for the duration of their primary treatment and then have the port removed. The protocol requires a radiologist's report at the time of implant to confirm catheter and port position, still photographs from a final fluoroscopy, and another radiologist's report at the time of explant to determine possible migration. These procedures are outside the normal standard of care.

Mistake 1. The first mistake sponsors make is to ask for information that is unnecessary for the study objective. Do not ask for nice-to-have procedures, lab tests, or other information. Limit your requests to information that is essential to analyzing your primary hypothesis. Resist the temptation to ask marketing questions like, "What features are most important in devices of this type?"

Know Your Investigators' Costs

Begin by creating a study overview that summarizes the study in a paragraph or two, describes the subject selection criteria, and includes a list of tasks the sites must perform to fulfill the study requirements. The list of tasks for each subject is often called the "schedule of events." Think in terms of verbs or action items for the site, organized by the site's pre-study, study and post-study tasks.

Based on the study overview, build a realistic model budget for the investigative sites. Most sites expect the sponsor to provide a budget template (spreadsheet) to help them understand the proposed budget and to use during negotiations.

Mistake 2. The Site's Task List is more than just a procedure list for the subjects. It includes other activities the site must perform to implement the study. Such tasks as "review the protocol," "prepare the IRB application," "screen patient medical records," "meet with monitor," "enter data onto case report forms," and other administrative tasks should be included in the list. Many of these tasks are known as "hidden costs" because they are not listed in the typical study budget. Sites add hidden costs to the budget during negotiations, include them in overhead, or absorb them (with potentially fatal ramifications for the sites). The Site's Pre-study Task List might look like this:

Site Pre-study Tasks (Study Start-Up):

1. Submit protocol and consent form to IRB for review
2. Meet with monitor for study training
3. Set up regulatory binder
4. Set up subject binders x number of subjects
5. Perform administrative activities

Mistake 3. Our human tendency is to underestimate the time required to perform a task; however long you think it will take, multiply by your characteristic correction factor. I usually underestimate the actual time by half. It's hard to get firm numbers because investigative sites don't invoice sponsors by the hour.

Site Study Tasks:

1. Screen patient records
2. Offer study to patients
3. Obtain informed consent
4. Implant vascular access port (procedure not paid by sponsor)
5. Take implant fluoroscopy and still image; write radiology report
6. Treat subject (procedures not paid by sponsor)
7. Investigate adverse events
8. Take explant fluoroscopy and still image; write radiology report

Mistake 4. It is easy to underestimate the cost of study procedures because accurate estimations are hard to find. Third-party payers rarely disclose their fee databases, and professional medical associations are prevented by federal antitrust legislation from disclosing fee survey results.¹ However, Medicare fee information is available from the Centers for Medicare & Medicaid Services (CMS) (https://www.cms.gov/PhysicianFeeSched/01_overview.asp) and various companies, such as PMIC (MEDFEES) and Ingenix (EncoderPro.com). Medidata (Grants Manager) and TTC (Grant Plan) offer extensive databases of drug study site fees. Accurate clinical research cost data is valuable, and these databases are costly to create, so access to the data is not cheap. The poor-man's approach is to ask around.

Site Post-study Tasks:

1. Transcribe/enter data from source files to case report forms/EDC screens
2. Be available for monitoring visits
3. Answer data queries
4. Notify IRB of study close-out

Other:

1. Overhead, about 30% of total site budget

Mistake 5. No one likes to pay overhead. My own clients argue over a 10% overhead. A quick search in Google found overhead rates of 20%, 25% and 30%. Overhead rates are higher if calculated on procedure fees only, lower if based on total direct costs. Depending on the mix of sites, plan on 25-30% average overhead charges against the total site budget.

The Task Table

Put the task list into a spreadsheet and create a Task Table by assigning hours, hourly rates, and amounts to each task. For tasks that require time, like preparing the IRB submission, imagine in your own mind how long it would take you to perform the task; these numbers will be only rough estimates, but can serve as sanity checks against estimates from other sources. Then decide if the investigator must perform this task or if a trained member of the study staff can perform it. This will help you determine "fair market

value” for the hourly rate. Fair market value for a physician/surgeon is about \$250-\$350/hour and for a study nurse about \$70-\$90/hour.

Finally, sites like to discuss study costs in terms of costs per subject. Some sites have a minimum per subject. One hospital in Chicago considers any study that pays less than \$2,000 per subject as a money-loser and will not participate.

Service-Provider Budgets

First, you need to identify the service provider(s) that will contribute to your study. Service providers might include central IRBs, central laboratories, contract research organizations, independent monitors, independent professionals, contract research organizations, data management centers, and anyone else whose time you will charge against the study.

You begin in the same way. Service provider budgets are built around the protocol, so make a task list of all the activities you want each service provider to perform.

Mistake 6. Too many sponsors wait until after they have designed the protocol and contracted with the sites to discuss study issues. Bring a competent clinical research professional into the project early on. CROs can often save you money by suggesting better regulatory strategies, study designs, or sample size calculations.

Once you have a protocol, you'll go through it page by page, as before, and make a table of tasks you want to contract and which service provider you want to have perform the task.

Mistake 7. Don't choose your service provider by cost alone. Look at references, experience in the device world, reputation, sub-contractor network, and size. Time and again I see service providers hired because their estimates were lowest; and then cost over-runs come in when it is too late to switch to another.

Mistake 8. Don't hire a big firm for a small job, or a small firm for a big job. In the first scenario, your study will be lost in the shuffle; in the latter scenario, the service provider will not have the resources to implement your project.

Then, estimate a budget for each service provider. Some service providers, such as central IRBs, have fixed fees; others, such as central laboratories, charge a fee per test; data management centers charge by the number of data fields; and professional consultants charge an hourly rate. As before, you divide the service provider's activities into pre-study, study and post-study tasks, and then assign a number of hours and hourly rate (or fixed fee) to each task.

Mistake 9. Don't cut corners by not monitoring poorly enrolling sites. Clinical studies are market-driven, and there is always a reason for poor performance. If enrollment is slow at an apparently good site, a competing study may be paying more than yours. Or, there may be a problem with the protocol. Or, there may be any number of other problems that will cost you money until they are addressed. You won't know until you have a face-to-face conversation at the site.

Sponsor Budgets

As the sponsor, your own budget fits into the equation, too. Sponsor costs aren't just the clinical trial department's costs; they are costs spread throughout the company but that rightfully should charge back to the clinical trial project. Statistical functions, data management functions, product modification and tracking functions, comparator devices, and manufacturing the investigational devices are all costs that should be included in the sponsor budget. And, of course, don't forget the salaries and benefits of in-house employees.

As before, organize the activities that in-house personnel will perform by pre-study, study and post-study tasks. Create a separate category for data management tasks because they span the entire study project timeline.

Mistake 10. Task lists, line items, and budgets are tricky to make. A “splitter” personality will easily find a couple of hundred things for people to do. A “lumper” personality may whittle a study down to 30-40 tasks. When splitter personnel work for lumper bosses, or vice versa, sparks fly. Learn the personality preferences of your workmates and accommodate them with sub-lists and summary lists.

Total Study Budget

Finally, add the budgets for each investigative site, each service provider, and yourself (the sponsor) to make a total study budget. By getting a good estimate ahead of time, you can assess the scale of the study, re-evaluate the cost of a testing a hypothesis, plan for expenditures, give realistic information to top management, and scale back when necessary.

Mistake 11. First-time sponsors are always surprised that as much as 50% of the study budget may be spent before the first subject enters the study. Good budget planning, organized by study timing, prepares top management for what lies ahead and helps keep middle-managers out of the “you didn’t tell me” hot-seat.

Reference

1. “PMIC Digital Book Series: Medical Fees in the United States 2010,” Practice Management Information Corporation, www.pmiconline.com

Author

Nancy J. Stark, PhD, is founder and President of Clinical Device Group, a consulting and contracting firm for medical device pre-approval issues. Clinical Device Group is a CRO and conducts workshops on medical device clinical and regulatory issues. (<https://www.clinicaldevice.com/mall/Workshops.aspx>) Contact her at 1.773.489.5706 or cdginc@clinicaldevice.com.