BY DENISE MYSHKO

Accurately Costing a CLINICAL TRIAL

Streamlining the budget process **NOT ONLY LEADS TO MORE ACCURATE RESOURCE ALLOCATION, IT ALSO ALLOWS FOR BETTER PREDICTIONS AND CREATES MORE ACCURATE CLINICAL-TRIAL PLANNING.**

CLINICAL-TRIAL SPENDING has increased considerably over the past decade. Today, the average per-patient cost of a clinical trial ranges from about $5,500 for Phase I trials, $6,500 for Phase II trials, and $7,600 for Phase III trials, according to a recent report from Cutting Edge Information.

In 2004, some pharmaceutical companies' clinical-affairs budgets exceeded $400 million, and clinical-affairs spending averaged 37% of total research and development spending, according to Cutting Edge Information.

"Extremes exist in determining clinical-trial budgets," says Lisa Grimes, R.Ph., a member of the executive advisory group at Campbell Alliance. "On one end, there are companies that have very sophisticated clinical-trial budget and resource modeling tools. On the other end, are companies that have little to no formal process for determining trial budgets. Instead, companies make assumptions based on information from their previous experiences with similar trials."

While the process varies widely, most companies implement some type of formal budget negotiation process, Ms. Grimes says. This involves various groups within the company, including finance and multiple clinical development functions. Forecasts are made and validated using budget-estimating tools, spending benchmarks, and comparative analyses of bid proposals from CROs.

Faiz Kermani, Ph.D., a marketing executive with Chiltern International Ltd., says budgets vary according to the services required.

"From a general perspective, our budgets will start with what is required in the clinical development, data management, biostatistical, regulatory, and quality assurance fields and accommodate additional services based on

DR. FAIZ KERMANI

Large, global studies often have country-specific costs that may be unfamiliar to sponsors new to operating internationally. **A GOOD WAY TO PREPARE FOR THESE POTENTIAL COSTS IS TO CARRY OUT AN INITIAL FEASIBILITY STUDY FOR THE PROPOSED TRIAL IN THE GLOBAL REGIONS OF INTEREST.**

CLAIRE DRISCOLL

BETTER BUDGET FORECASTS FROM VENDORS will make it easier for sponsors to outsource and to trust their vendors.

AVERAGE PER-PATIENT CLINICAL-TRIAL COST BY THERAPEUTIC AREA AND TRIAL PHASE

THERAPEUTIC AREA	PHASE I	PHASE II	PHASE III
Antibiotics	$4,500	$6,500	$9,500
Antiviral	$3,500	$5,000	$6,750
Cardiovascular	$2,500	$7,000	$9,333
CNS	$3,500	$4,833	$7,333
Gastrointestinal	$4,000	$6,000	$7,500
Inflammation	$9,500	$9,750	$10,000
Oncology	$8,750	$9,125	$9,125

Source: Cutting Edge Information, Durham, N.C.
For more information, visit cuttingedgeinfo.com.

discussions with the clients about what their objectives are for the clinical trial," he says. "Different clients will have different requirements about what services they would like to have included in the budget."

He says CROs should recommend certain services to the client if they believe them to be appropriate to the study, but they must explain their reasoning in doing so.

"Client trust in the CRO is essential so that the budget can be negotiated in good faith," Dr. Kermani says. "Laying down a good foundation for the budget in this manner, where the costs of each component are clear, avoids misunderstanding between the client and the CRO. As a trial evolves, there may well be changes to the budget, but because each party understands the other, this can be carried out in an atmosphere of trust. People often underestimate the value of open communications and what can be achieved by setting up a good relationship early on in the process. This means that both parties understand the assumptions that are being used for the budget and are absolutely clear about what the costs actually reflect."

BUDGETING FOR RECRUITMENT AND MONITORING

Many executives interviewed by researchers at Cutting Edge Information believe that budgeting for patient recruitment should occur during the protocol-development stage.

Patient-recruitment budgeting should receive extra attention because it is one of the most challenging, time-consuming, and costly aspects of clinical trials. Patient-recruitment budgets should include the costs associated with project planning and analysis, study branding and message development, advertising collateral development, IRB approvals, media outlet fees, call centers, site support and recruitment program roll outs, and investigator and patient incentives. (See box on page 24 for more information.)

"Many companies fail to include adequate allowances for subject recruiting, such as ads and direct mailings, even though trial delays are primarily due to slower-than-expected recruitment," Ms. Grimes says. "Significant enrollment delays can have a huge impact on the overall budget, a fact that is not often taken into account up front."

In terms of evaluating the costs associated with call centers, pricing models are based heavily on the recruitment funnel, which examines the number of calls that need to be received to obtain enough patients for a particular trial.

"Pricing should be primarily based on how many calls will be generated by the advertising and the average length of the call," says Claire Driscoll, founder and president of Claire Driscoll & Associates Inc.

"Other charges may include setup and project maintenance, which is determined by the protocol and the extent of services provided," she says. "A complex protocol will mean more extensive training, a more involved call script, and more agent supervision."

Additionally, since patient recruitment is not a predictable science, it's often difficult to absolutely forecast how many calls will be received and the associated costs.

"While we can help determine an estimate of how many calls to expect, the success of

PREVENTING BUDGET CREEP IN PATIENT RECRUITMENT

USING ACCURATE DATA DURING THE BUDGETING PROCESS TO DETERMINE WHAT IS SPENT WHERE helps build more accurate, transparent budgets, says **ELIZABETH MOENCH**, Founder, President, and CEO of MediciGroup.

Creating a realistic study budget can be difficult, especially when it comes to recruiting patients. Even when done right, it may look as though costs have been overestimated. On the surface it appears that a company is taking into account more patients than the study needs. But underestimating the true number of patients required to flow through the course of a study can lead to "budget creep," or outspending the budget allotment later when patients drop out of a study and re-enrollment is required.

Detailed recruitment forecasting and estimation of patient-recruitment requirements up front and real-time performance metrics during implementation mean better fiscal risk management, which can help sponsors quickly identify nonperforming sites. These are key factors in developing an accurate budget and keeping the study within its budget parameters.

Using accurate data during the budgeting process to determine what is spent where helps build more accurate, transparent budgets. Even though the budget of one recruitment provider may be higher than its competitors, justifying the cost difference with the specific projection of subjects to be delivered and the commitment of preventing budget creep on the back end should be a powerful motivation for budget approval.

Budget creep occurs in situations when companies are bidding on price. Recruitment vendors deliver a price that is going to be competitive, yet it may increase after the project is awarded because it fails to deliver the required number of patients. This scenario is common and can be frustrating to both vendors and clinical teams. Companies that are just focused on price fail to realize that they are getting what they pay for: budgets based on the delivery of fewer patients and/or budgets that fail to be tied to any projection forecasts.

FORECASTING

Patient forecasting is essential to accurate budgeting. If recruitment companies and clinical teams do not know how many patients will flow through the study, given its particular protocol specifications, then an accurate plan and budget cannot be developed. But these projections need to account for the loss of subjects for a variety of reasons, from health problems to not granting informed consent to moving away from the research site.

If a study needs 150 patients to produce sufficient results, clinical operations and project managers may need to recruit 1,500 patients. This 10:1 ratio may seem high but it can be affected by many factors, some of which include the prevalence of the condition, the risk involved in participating in the study, and the competition for the type of patients in the study. If clinical teams only budget for 150 patients, they will run into problems; the study will miss its timeline, the budget will have been expensed, and the study will be at a standstill.

Not only do recruitment companies and clinical teams need to plan for attrition, the process of recruiting patients can be more difficult when the study protocol demands low-population types, such as people with migraine headaches who are on certain types of pain relievers. For example, if the study calls for drug-naive, serious Alzheimer's patients, about 75% of callers will be screened out.

MARKET-BY-MARKET BUDGETS

A major patient recruiting expense is advertising in local newspapers, radio, and other media. Severing ties with nonperforming sites before additional recruitment investment occurs preserves the budget and eliminates wasted money. Clinical teams must also take into account the cost of buying advertising in different markets. A one-size budget does not fit all sites. The classic mistake companies make is to allot a fixed amount for each site, such as $2,000 or, usually, the "magic" $5,000. This is a major *faux pas*. What advertising buys for $5,000 in Birmingham, Ala., is quite different from what it buys in Los Angeles.

Instead of making an average-based estimate of advertising costs, a recruitment budget must determine how many patients each market is projected to deliver and then estimate how much advertising will be required to reach this number of patients. This must be done on a market-by-market basis until the big picture equals the number of patients needed.

ACCOUNT FOR NONPERFORMANCE

One-third of study sites will not perform. This fact must be accounted for in recruitment budgets and plans. One-third will overachieve, turning in more results and recruiting more patients, possibly ahead of schedule. The middle third will perform as expected.

Create realistic budgets by assuming that support will be given to 100% of the study sites selected, but within two or three weeks real-time performance metrics will guide continued recruitment investment decisions to two-thirds of them.

Fiscal risk management for recruitment requires clinical teams to not grant a site all or part of its advertising budget until staff at that site have a least done groundwork on their own by recruiting from the site's patient database, even if this has involved screening without a patient yet enrolled. This effort demonstrates study commitment, as well as a behavior that is likely to continue over the course of the study.

Source: MediciGroup Inc., King of Prussia, Pa. For more information, visit medicigroup.com.

If a study is set up for "competitive enrollment," it only makes sense to have "competitive recruitment resources." With only a limited recruitment budget, clinical teams cannot afford to invest in nonperformers who have zero or limited returns. Those who enroll are rewarded with additional support to help them get to the finish line faster. It means targeting the recruitment budget for the greatest return on investment.

UNDERSTANDING THE BIG PICTURE

Using this model to more accurately estimate patient recruitment needs will probably inflate part of the recruitment budget. But with real-time metrics, the budget is often decreased by weeding out nonperformers early, which requires the daily monitoring of study sites. Clinical procurement teams need to understand the big picture when considering recruitment budget proposals and the differences between them.

One is example is a budget with comprehensive planning and forecasting — a budgets based on this model — is more likely to complete recruitment on time. As a result, these sites are much less likely to incur unbudgeted costs for extra time and monitoring as they compensate for patients who drop out.

Smaller companies appear to be more understanding of the zero-based budget approach. They understand the budget's composition and clearly understand how financial consequences for ill-planned studies can affect their ability to stay in business. They understand that time is money — often venture capital money; and they cannot afford to exceed their projected burn rate.

The costs of maintaining a delayed study with ongoing monitoring with a contract research organization far outweigh the costs of a comprehensive recruitment plan and a budget that is focused on completing that study on time.

advertising and the referral rate greatly influence the number of calls we receive," Ms. Driscoll says. "Underestimating the ratio and number of people it takes to ultimately enroll and randomize one patient can cause problems as well. I think that better budget forecasts from vendors will make it easier for sponsors to outsource and to trust their vendors. We work very hard to stick to the established budget with respect to those things that are under our control."

Other crucial players in the recruitment process are the sites, which, according to Norman M. Goldfarb, managing partner of First Clinical Research and chairman of the Model Agreement Group Initiative (MAGI), often don't have experience negotiating budgets or know their own costs.

"Budgets from the same sponsor can be inconsistent; sites receive similar studies with different fees for the same line item," Mr. Goldfarb says. "A lot of site costs are up front, but sponsors want to pay for performance; 30% of the sites in a typical study enroll zero subjects."

Harold Glass, Ph.D., director of the Pharmaceutical Business Graduate program at the University of the Sciences in Philadelphia, says companies also have to allow for different budgets for physician recruitment.

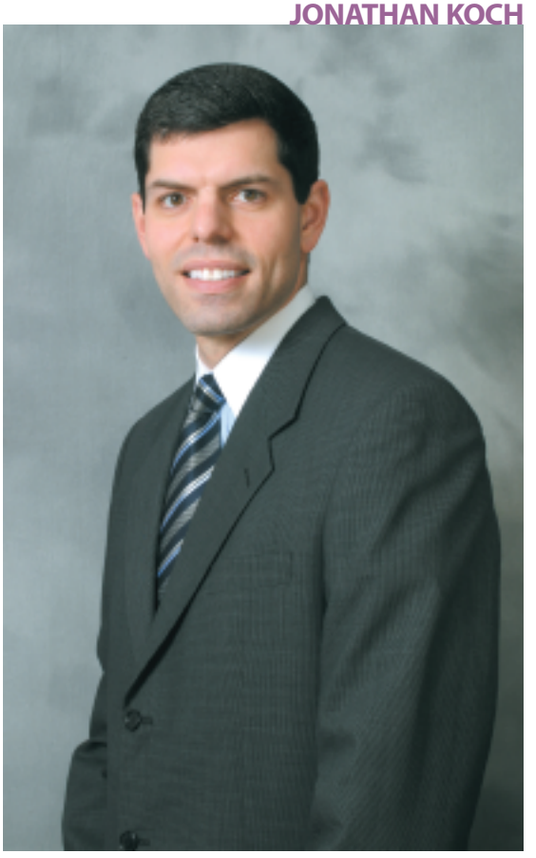
"There are relative differences in how much investigators are paid to do comparable levels of work," he says. "Market and business forces are at work. For example, more prestigious academic institutions have higher rates, and they can often command a premium price. Most study sites in the United States, though, are actually run by physicians in their private practices, and their rates are often lower."

Dr. Glass says when there are many studies competing at the same time for investigators, the grant levels usually go up.

"If the investigator has extensive experience in a specific study area, the physicians can usually command a premium price," he says. "Conversely, if the compound is a novel one, investigators will usually work for less."

In addition to the costs associated with patient and physician recruitment, the cost of monitors has to be factored in. About 30% of the cost of conducting a clinical trial is attributed to monitoring, accounting for about $1 billion of a clinical-study budget annually, says Scott Freedman, president of monitorforhire.com.

JONATHAN KOCH



The use of a thorough internal development plan or a well-constructed external RFP can provide the sponsor with responses that are accurate, complete, and consistent with their intent. **BUT SERIOUS BUDGETARY ISSUES CAN STILL ARISE IF THERE ARE FLAWS IN THE DEVELOPMENT PLAN OR PROTOCOL.**

He adds that by outsourcing the monitoring function, CROs can reduce the risk as well as the fixed costs for hiring a full-time monitor, such as recruiting, interviewing, training, salary, benefits, 401(k), ongoing management, and human resources.

Tapping into local resources is probably the single most important benefit of outsourcing the monitoring function, he says.

"Since there is a finite pool of monitors, CROs look for monitors around the clock," Mr. Freedman says. "For example, a small CRO with staff in Austin can add monitors to its existing staff in New Orleans and Oklahoma City by outsourcing. The outsourced monitors will be able to reach sites located in those cities with far less consumption of trav-

Sound Bites from the Field

PHARMAVOICE ASKED EXPERTS TO IDENTIFY THE CHALLENGES ASSOCIATED WITH DEVELOPING A CLINICAL BUDGET AND TO PROVIDE BEST PRACTICES FOR OVERCOMING THESE OBSTACLES.

DIANA ANDERSON is President, CEO, and Founder of D. Anderson & Co., Dallas, a provider of patient recruitment and retention services for clinical trials. For more information, visit dandersoncompany.com.

"Three challenges that come to mind almost immediately are the absence of proactive planning, failing to give due consideration to those variables that are outside of the sponsor's control, and falling for the misconception that patient recruitment equals advertising.

We have to remember that a sponsor's work cannot begin until a budget has been developed and approved. For this reason, our clients must do their best to estimate what the scope and depth of their patient-recruitment needs will be almost in a complete vacuum before the protocol is refined, before sites are selected, and, of course, before screening begins. Proactive planning means making a concerted effort to understand how the disease state, the patient population, and the protocol will affect the rate of enrollment. Even with planning aimed at mitigating some of these enrollment factors, there are many uncontrollable variables that impact the outcomes of the study.

Another challenge revolves around the common perception that patient recruitment equals advertising. While advertising is a viable option for stimulating enrollment, the nature of patient recruitment has evolved far beyond this in the past five years. The key question related to all patient-recruitment planning is: how do we close the gap between marketing, advertising, technology, and so on, resulting in actual study participation? The answer is developing a proactive recruitment plan that encompasses a variety of resources and aids DTC strategies to yield actual participants.

Over the last five years, there has been a shift in thinking from recruitment equals rescue to recruitment equals proactive planning, which equals cost savings. There are significant cost savings that can be achieved if companies develop plans that anticipate inherent challenges related to the uncontrollable variables each study possesses."

SCOTT H. CONNOR is Director of Marketing at Acurian Inc., Horsham, Pa., a full-service provider of clinical-trial patient and investigator recruitment solutions for the life-sciences industry. For more information, visit acurian.com.

"Trial managers still find it difficult to add a budget line item for patient recruitment beyond site grants because the prevailing attitude is that sites will enroll without outside assistance. But as we all know, sites rarely meet their enrollment projections. The trial manager then has the unenviable task of requesting additional budget to employ recruitment campaigns in rescue mode, which also puts that manager in a poor negotiating position with a vendor. We recommend that trial managers make a case for a patient-recruitment budget as part of the plan and perform the necessary due diligence to find a vendor that understands the challenges and costs of recruiting a specific patient population. They need to know exactly what they are going to get for that budget and hold their vendor accountable for the deliverables. The incremental cost of proactively budgeting for recruitment far outweighs the cost of trial overruns and adding sites when enrollment falls short and panic starts. At the very least, they need to build in a recruitment contingency. If the money isn't needed, the trial comes in under budget, and the trial manager is a hero for having the foresight to plan accordingly."

RICHARD D. PURCELL is President of ClinPro Inc., Bound Brook, N.J., an, independent, full-service CRO offering veteran clinical researchers with expertise in a variety of therapeutic areas. For more information, visit clinpro.com.

"The biggest challenge in the budgeting process is to determine — up front — the actual effort that will be required to complete the study.

So many factors come into play: targeting investigators and sites; IRB interactions and timelines; drug supply; investigator meeting logistics and training in general; patient enrollment; data-collection methods; capabilities of, and staffing at, the site; project management and sponsor/CRO relationship expectations.

Too often, sponsors underestimate the workload that will be required to minimize the budget requirements for the study. In response, CROs bid projects based on these reduced up-front expectations. This results in inaccurate bidding, cost overruns, and changes of scope. It is really important to set realistic expectations right from the start.

By evaluating the clinical-development and trial-management process through a business approach of process improvement, the bottlenecks in the logistical management of a clinical trial can be broken down. The three primary focal points include investigators, patients, databases, and data reports."

el time than could a monitor centrally based in Austin."

BUDGETING FOR GLOBAL TRIALS

"As more and more trials become global and are conducted in emerging markets, there may be additional costs that are not associated with running a trial in a well-established market," Dr. Kermani says. "Large global studies often require country-specific costs that may be unfamiliar to clients new to operating internationally. Sponsors should be aware of these costs to ensure that the trial is run to the required international standard. Accounting for such additional factors at the initial stage of the budgeting process can be beneficial in the long run, since this can help entrants to a market more easily tackle problems they may encounter.

"For example, emerging markets, such as Asia, Africa, and Latin America are vast and encompass a range of countries with myriad cultures, customs, languages, and communications systems that vary widely," Dr. Kermani continues. "Therefore, any number of things can impact the cost of the trial. For example, in emerging markets the monitoring costs may be very different from those in established countries because of accessibility issues regarding sites, and extra time may be needed for the appropriate visits to be carried out. Some of these countries also have more than one language, so translation may be required for different parts of the clinical-trial process, which can then be higher than anticipated."

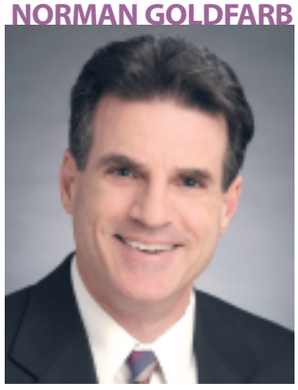
In addition, he says different regulatory procedures may mean additional costs for the work to be carried out effectively. For example, in the European Union, the introduction of the Clinical Trial Directive, which came into force in May 2004, has meant additional costs for companies.

BUDGETING FOR OUTSOURCED TRIALS

According to the Cutting Edge report, internally run clinical projects accounted for 32% of 2004 clinical budgets, and clinical work outsourced to CROs accounted for 28% of 2004 clinical budgets.

Ms. Grimes says many companies estimate their internal costs and then secure multiple bids from CROs. A comparison of those bids is then used to determine the final budget.

NORMAN GOLDFARB



Many sites need to understand their costs better, including **THE HIDDEN COSTS THAT ARE NOT IN THE STUDY BUDGET;** 94% of studies are delayed by subject recruiting, and most recruiting costs are hidden.

Paul Bleicher, M.D., Ph.D., chairman and founder of Phase Forward, says it's important for executives to consider what components of a trial a CRO will be used when determining the budget.

Several areas should be taken into consideration, Dr. Bleicher says, including the design of the trial, creation of the protocol, monitoring and site management, data management, medical monitoring, regulatory monitoring, statistics, and report generation.

"Most CROs have budget models that include standard rates for sites, data management, and report writing," he says.

Pharmaceutical and biotechnology sponsors using external service providers such as CROs, start the budgeting process by creating a request for proposal (RFP) document, says Jonathan C. Koch, VP of operations, Americas, at Charles River Laboratories — Clinical Services.

The RFP, he says, is based on the final trial protocol or a synopsis, if the trial is still in the concept stage. In response, CROs create a study plan and budget reflecting the assumptions and parameters called for.

DR. PAUL BLEICHER

By applying cost-accounting principles and technology, sponsors can collect information that is normally not collected. **THEY WILL THEN HAVE THE OPPORTUNITY TO BRING THIS KNOWLEDGE INTO THE COSTING OF THE OVERALL PROCESS TO BRING EFFICIENCY, QUALITY, AND TIMELINESS TO THE PROCESS.**

"The estimates are consolidated to form the study budget submitted for approval or funding," Mr. Koch says. "Regardless of whether internal or external resources are used, R&D managers, program managers, and outsourcing departments can use a number of metrics to estimate trial costs even at the earliest stages."

He says one frequently used metric is cost-per-patient. By conducting an analysis of the cost-per-patient in previously conducted trials, companies can derive an average cost per patient that can be adjusted based on differences between the new trial and those in the historical pool.

Mr. Koch says adjustments may reflect differences in study phase; therapeutic indication; number of patients; number of sites and resulting patients/site ratio; enrollment rate and duration; number and type of countries where sites will be located; number of case report form (CRF) pages per patient; services

DR. HAROLD GLASS

IF AN INVESTIGATOR HAS EXTENSIVE EXPERIENCE IN A SPECIFIC AREA OF THE STUDY, he or she can usually command a premium price.

to be included in the estimate, for instance, full service, multiservice, or single function; and expected investigator grant.

He says there are two tools that can reduce the likelihood of planning and budgeting mistakes, the first of which is objective feasibility.

"Given the strategic importance and expense of human trials, early-stage feasibility work to gauge the viability of trial execution has increased in importance," Mr. Koch says. "Feasibility assessments have become common practice for some companies. If conducted in a manner that realistically reflects the planned trial, feasibility work can validate clinical and financial assumptions and act as a channel to initiate communications with investigators who are likely to participate in the trial. In the event that the feasibility assessment reveals potential issues in the current plan, the relatively small cost of the exercise will be justified and may provide insight into a more effective or efficient trial design."

Secondly, Mr. Koch says, the lack of early involvement in the planning process from management, key suppliers, therapeutic leaders, investigators, and service providers commonly leads to problems later on in the trial.

"Involving the right parties during the planning stage can identify potential challenges that can be avoided or managed proactively, leading to increased buy-in," he says. "Comparing the actual costs of an internally conducted trial versus the expense incurred when using a CRO can also provide insights for more accurate budgeting."

Key to improving the budgeting process is to implement a three-tiered scenario plan, Mr. Koch says.

"Often only one version or scenario of a development plan and associated budget is created, which means that limited forethought is given to actions or contingency paths in the event that something unexpected occurs," he says. "Creating best, most probable, and worst-case scenarios up front can prove invaluable if each scenario is supported with indicators, such as red flags, and contingency actions."

Additionally, Mr. Koch adds, identifying areas of budget risk also will help enhance the budgeting process.

"While most people tend to avoid dealing with risks and concerns, those accountable for planning and budgeting have to face these factors head-on," he says. "Identifying areas of budget risk or variability, estimating their cost implications up front, and monitoring them closely are keys to knowledgeable and accurate budgeting. When using external providers such as CROs, sponsors should explicitly request that they identify areas of budget risk and potential variability up front and provide cost estimates for each area."

IMPROVING THE BUDGETING PROCESS

There are many benefits to be realized by simply improving the budget process, Ms. Grimes says.

FACTORS TO CONSIDER WHEN BUDGETING CLINICAL TRIALS

"EXPERIENCE IS A GREAT TEACHER AND CAN YIELD SIGNIFICANT BENEFITS WHEN PREDICTING FUTURE BUDGETS," SAYS LISA GRIMES, EXECUTIVE ADVISORY GROUP MEMBER, CAMPBELL ALLIANCE. **"WHEN ESTIMATING BUDGETS, IT IS IMPORTANT TO USE EXPERIENCE IN SIMILAR TRIALS CONDUCTED IN THE SAME THERAPEUTIC AREAS."**

1. **STUDY TYPE:** Phase of clinical research; overall purpose of the study, for example desired clinical endpoint; therapeutic area being studied; and nature of trial — outsourced vs. internally conducted
2. **PROTOCOL DESIGN:** Number of subjects and sites to be included; inclusion/exclusion criteria; length of the study; and number of arms in the study
3. **SUBJECT RECRUITMENT:** Ease of participant identification and recruitment; cost of recruitment efforts, for example advertising; use of honoraria, typical stipend for trial type; subject drop-out rate; payments for screen failures; and budgetary impact of missing enrollment deadlines
4. **INVESTIGATOR COSTS:** Frequency of follow-up visits; type/level of evaluation per visit; format of investigator meeting — face-to-face meeting or via video-conference; fee to investigator per subject; and competitiveness of investigator fee
5. **TRAVEL COSTS:** Geographic scope — areas/countries — of the sites, subjects, and monitoring staff; length of the study; frequency of monitoring visits; numbers of sites in the study; and technology being used to conduct the study that may increase/decrease need for travel
6. **MONITORING REQUIREMENTS:** Use of electronic data capture; number of sites included in study; frequency of monitoring visits; location of monitors — regionally or centrally based; and number of monitors required
7. **SPECIAL EQUIPMENT/TESTS:** Special lab tests that must be done — pulmonary function tests, MRIs, and CTs; and equipment needed at the site — centrifuge or refrigerator — to comply with study requirements

Source: Campbell Alliance, Raleigh, N.C. For more information, visit campbellalliance.com.

SCOTT FREEDMAN

TRAVEL COSTS ASSOCIATED WITH MONITOR VISITS ARE A MAJOR LINE ITEM WHEN SETTING UP A TRIAL BUDGET and need be factored into the overall cost of the trial.

"Streamlining the process not only leads to more accurate budgets, it minimizes the resources required to develop future budgets," she says. "Use of a more formalized forecasting process allows better predictions for various 'what-if' scenarios and allows for more accurate resource planning. Once the trial is under way, a better understanding of resource use can also be gained. When companies can track the areas that fall out of line with the original forecast, then they can focus on improving those areas. Companies also can use this information to determine if it is better for them to conduct more trials internally or through CROs."

Another way to improve the budget process is to do a better job of knowledge management, Ms. Grimes says.

"Effective knowledge management systems could help identify sites that are consistently poor enrollers, thus reducing the cost of site initiation, site closeout, and monitoring; track site performance; identify key reasons for screening failures; and the cost of advertising expenditures," she says. "This historical information can be plugged into the budget tool to create more accurate cost assessments for future trials."

Additionally, she says, when measuring trial performance, it is imperative to keep the big picture in mind.

"Sponsor companies should establish metrics up front for each of the individual functions and within the overall parameter of the trial timeline," she says. "It is also critical to measure each site's performance with actual patient-recruiting numbers versus projected numbers within a defined timeline. It is equally important to measure how quickly and timely the site enters its data, especially if EDC is being used, as well as the cleanliness of the data."

Once these processes and tools are in place, Ms. Grimes says, company sponsors can evaluate the pros and cons of various pricing models. For example, a pharmaceutical company can decide whether it wants to make payments based on performance, milestones, or a blend of the two.

"Finally, comparing the final costs with the forecasted budget can improve the accuracy of future budgets by identifying hidden or unexpected costs and the overall impact of delays," she says. ✦

PharmaVOICE welcomes comments about this article. E-mail us at feedback@pharmavoice.com.

Experts on this topic

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