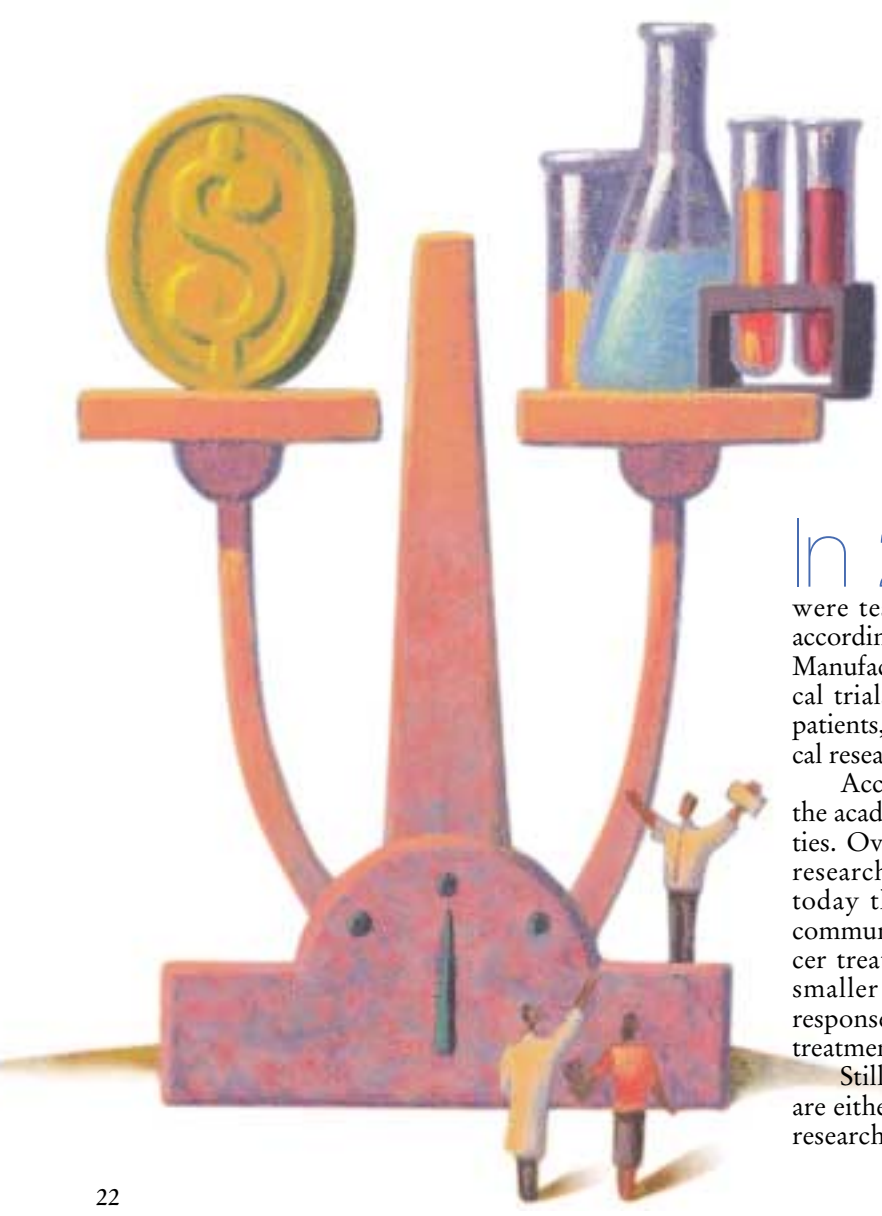
Planning to Succeed

Developing and Maintaining a Community Research Program

by Sharon Jameson, R.N., M.B.A.



In 2001 more than 400 anticancer drugs were tested in 722 clinical trials in the United States, according to a survey by the Pharmaceutical Research and Manufacturers of America (PhRMA). Making these clinical trials a reality requires the constant recruitment of patients, as well as oncologists and their staffs, into clinical research.

Accrual into clinical trials has typically taken place in the academic setting at large medical centers and universities. Over the last two decades, however, clinical cancer research has expanded to the community setting, and today thousands of patients are accrued into trials at community cancer centers where they are receiving cancer treatment. Increased research participation at these smaller hospitals and physician practices is partly in response to informed patients wanting access to the latest treatments without having to travel far from their home.

Still, many community cancer centers and practices are either hesitant to initiate or quick to abandon clinical research, finding participation to be both financially and

logistically overwhelming. Today's volatile medical reimbursement climate contributes to an already risky financial atmosphere surrounding clinical research. Although community cancer centers do not enter clinical research to make money, no cancer center can afford to let its research program drain resources from patient care and practice expenses. Indeed, over time a consistent financial loss would have a negative effect on the delivery of quality patient care.

Developing and maintaining a viable research program require adequate planning and staffing. In a highly competitive health care market, offering participation in clinical trials and access to novel anticancer drugs and therapies sets a facility a notch above other centers that cannot provide such opportunities. A research program also serves to attract and retain qualified staff members that want to participate in the future of cancer treatment.

Understanding the components of a research program and financial planning for all the services provided in clinical trials are essential if your program is to thrive.

WHAT YOU NEED TO KNOW

Usually, industry (drug manufacturers) initiates the clinical drug process. Depending on the particular drug and the purpose of the study, the drug manufacturer can choose to set up a clinical trial in three possible venues—hospitals or institutions, private practices, or cooperative groups. Often industry will accrue patients in more than one setting in order to raise awareness and ensure wide physician access to the new drug.

There are two main types of clinical trials—cooperative group trials, which are usually funded through the National Cancer Institute (NCI), and pharmaceutical registration trials. Two other types of clinical trials—investigator-initiated and compassionate use trials (typically sponsored by industry)—comprise a much smaller percentage of clinical trials. Any research portfolio should contain a mix of these different types of trials.

Cooperative group trials. These trials are usually standard of care. Physicians purchase trial drugs and bill drugs and services directly to insurance companies for reimbursement. If a component of the cooperative group trial is not standard of care, the practice site must absorb the cost of these services. Some programs may choose not to participate in a specific cooperative trial based solely on nonstandard of care costs.

Recently, Medicare has instituted a payment system to ensure that standard of care costs for patients on clinical trials are reimbursed. When billing for research patient reimbursement, cancer programs must use the QV modifiers for standard of care, which guarantee payment for standard of care services.

While some cooperative group trials may pay physicians from $500 to $1,000 for every patient accrued to a trial, this amount is usually less than cost. In fact, the May 1999 Clinical Trial Practice Cost Study, sponsored by the American Society of Clinical Oncology, found that the average total cost per trial patient was $10,491 at an academic center and $6,924 in a private physician practice.[1]

Most cooperative group trials are funded through NCI's Community Clinical Oncology Program (CCOP). To participate in this program, community cancer centers must file a competing grant application, which undergoes extensive peer and administrative review. NCI may recommend supporting a study for up to five years, but awards are made annually and depend on the project's progress and anticipated accrual for the next year. It is important to note that awards cover only one-half or less of the total research expenses, the remainder of which must be covered by the participating facility.[2]

Although streamlining operations and precise budgeting can lower and help recoup the costs of participation in a cooperative group clinical trial, a cancer center can lose money by participating in such trials. To offset their costs, some hospitals contribute a portion of the salaries and benefits for the CCOP manager, the research nurse, and/or the principal investigator. Successful research programs may balance these losses by participating in appropriately funded clinical trials—usually industry registration trials.

Pharmaceutical or industry trials. These trials are usually conducted for registration purposes and may involve some nonstandard of care services. Physicians bill insurance carriers for allowable standard of care amounts; any nonstandard of care service provided is paid for by industry as part of the per patient fee. If the trial drug is not on the market yet or is a marketed drug that is not approved for the indication being studied, industry should be asked to provide the drug for the study.

In comparison to what they receive for cooperative group trials, hospitals and physicians participating in industry trials will usually be reimbursed a higher amount of money for every patient they accrue to the study. On average, physicians participating in industry trials receive from $6,000 to more than $10,000 per patient. This number is dependent on a variety of factors, including the trial complexity, nonstandard of care costs, and the physician and staff time involved.

Investigator-initiated trials. These clinical trials may also include nonstandard of care services and usually occur

ILLUSTRATION BY ROB COLVIN

So You Want to *Start a Research Program!*

The experience of a community cancer center in Jupiter, Fla.

BY BRENDA GORDON, R.N., M.S., OCN®

Your physician office or cancer program has gotten its feet on the ground and now you want to start a research program. Excellent. The only way to find the best treatments for patients is through research.

We started the research program at Jupiter Medical Center in 2001. Our first step was to hire a research nurse/coordinator and that should be the first step you take, too. Your research coordinator is the backbone of your new program, and finding the right person for the job goes a long way to ensure the success of your research program. Find someone with an oncology background and previous research experience. Your coordinator should also be extraordinarily detail-oriented, able to deal with people, and able to establish good working relationships with the departments of the hospital (radiology, pathology, and the clinical lab) that will provide services for your trial patients. The Society of Clinical Research Associates and The Association of Clinical Research Trial Professionals have a certification process. Talk to them about finding the right candidate for your facility.

Our next step was connecting with a community clinical oncology program (CCOP). CCOPs are regional clearinghouses for the federally sponsored cooperative group trials, and we now participate actively in the CCOP headquartered at Mt. Sinai Hospital in Miami. You can obtain information about CCOPs at *www.cancer.gov* or *www.ctsu.org*, which are funded by the National Cancer Institute (NCI). You can also learn about NCI trials that might be appropriate for your patient population by visiting *www.clinicaltrials.gov*, a service of the National Institutes of Health developed by the National Library of Medicine.

If you are involved with a CCOP and prove you can enroll patients and keep up with the paperwork, the clinical research organizations (CROs) that broker pharmaceutical company trials will come looking for you. Contact them first if you can, because pharmaceutical trials are lucrative and will help your new research program get on its feet. We work with CROs such as Pharmatech, Theradex, PRA International, and ParExel, all of which can be contacted through the Internet.

Pharmaceutical trials are less complicated to administer than CCOPs and reimburse participating entities at a much higher level. A good mix of pharmaceutical and cooperative group trials will keep your research program solvent.

What essentials will you need to start? First, of course, is your coordinator, followed by a dedicated phone line for a computer with Internet access and a CD-ROM port, a printer, answering service capability, and room for files. If your hospital or office does not have the money for these start-up essentials, look for philanthropic or grant money. As your program grows, you will need more physical space for new staff members, patient management, and the files to house your reports to study sponsors and your own Institutional Review Board (IRB). Each protocol is a detailed recipe for subject care with logarithms for both follow-up visits and reports to the sponsors and the IRB.

Your expenses will include $24-$26/hour for your coordinator; space rental; funds to cover faxing, long-distance phone calls, paper, postage, and other supplies; and money for your coordinator to attend cooperative group meetings, which are required and are usually held out of state. Our research budget at Jupiter is around $65,000 a year and we have 65 open clinical studies.

Start slowly with one or two trials that will accrue well to get your physicians and staff used to the research process. Educate your staff about the new department and how it will interact with them once patients are enrolled, and educate your physicians on what is expected from principal and sub-investigators.

Our last recommendation is to keep your sense of humor in good working order and have a supply of aspirin in your top desk drawer. Good luck!

Brenda Gordon, R.N., M.S., OCN®, is the cancer program administrator at Jupiter Medical Center in Jupiter, Fla.

when a physician uses an approved drug in an off-label indication. For example, an oncologist familiar with the mechanisms of a drug approved for lung cancer might believe that using it on a patient with breast cancer may prove beneficial. If the oncologist sees patient benefit, the physician may approach the drug manufacturer about the possibility of conducting a clinical trial to study these potential benefits. Investigator-initiated clinical trials can also occur after a physician finds that using a new dosing schedule or using a drug in combination with other drugs has therapeutic benefit to the patient.

If the drug being studied is on the market but not yet approved for the study indication, practice sites may not be reimbursed for use of the drug in the trial. For

A research program that does not account and budget for development activities will lose money…

this reason, any study budget should include the cost of the drug to ensure appropriate reimbursement from the manufacturer.

Compassionate use trials. This type of clinical trial refers to the use of a scientifically tested drug outside of a registration trial and prior to FDA approval. The pharmaceutical industry provides the drug in compassionate use trials; however, they typically do not cover any other expenses incurred at the site participating in the trial (i.e., IRB expenses, patient screening and registration, data management, drug accountability, etc.). Sites involved in a compassionate use trial must ensure that their mix of trials can support both the loss of operating revenue and the increase in staff time and effort necessary to manage the trial.

Table 1: Sample Practice Trial Portfolio of Research Program*

Total Open Trials: 43

Type	Number	Percentage	Annual Accrual
NCI-sponsored	27	63%	19
Industry sponsored	9	21%	13
Investigator initiated	6	14%	11
Compassionate use	1	2%	29

**Here is an example of an existing program, however, it does not assume to be an appropriate portfolio for this or any other research program. A successful portfolio of clinical research trials will vary widely depending on patient mix, access to trials, and the financial stability of the cancer program, among other indicators.*

The mix of a successful clinical trial portfolio varies widely among cancer centers based on patient mix, access to trials, and the financial stability of the organization, among other indicators. Table 1 offers a sample trial portfolio from an actual practice. Although this practice had access to a large number of trials for patient accrual, the practice was spending maximum effort (time and resources) opening trials that were difficult to accrue patients. Most importantly, the practice's patient reimbursement per study did not cover its operating costs. Out of 72 total accruals, 59 (82 percent) were accrued to minimally funded trials.

Generally, a cancer center establishing a new research program would be better off balancing its initial research portfolio with a mixture of approximately 65 percent industry trials and 35 percent cooperative trials. As the cancer program evolves and staff members become more familiar with the patient and trial mix and the budgetary process, the portfolio of clinical trials may change. Successful research programs that are financially viable can participate in a greater number of minimally funded clinical trials.

GETTING STARTED: KNOW YOUR DEVELOPMENTAL COSTS

Sound budget principles must be established at the start of any new research program. Billable and non-billable services must be identified *prior* to the start of any trial to ensure that these costs will be recouped. Research program administrators must budget correctly for the internal costs of services provided to a patient who is participating in a clinical trial, paying particular attention to those services that are nonstandard of care. Services such as trial development expenditures and nonstandard care costs should be billed to the sponsoring company.

Developmental costs are fixed expenses and are the most misunderstood and frequently overlooked budgetary line item of a research program. A research program that does not account and budget for developmental activities will lose money and place unnecessary burdens on staff. While development costs are not covered or reimbursed by insurers, these costs should be accounted for in the study cost estimate to ensure reimbursement from industry.

Table 2 offers a sample calculation of the developmental costs of a single trial amount that totals more than $5,475. From this snapshot, it is easy to see how failure to budget for or recoup these developmental costs can have a negative impact on the bottom line of the research program. For example, if this cancer center were to conduct 10 similar trials per year, the loss in developmental costs alone would total more than $54,750.

Developmental activities, as shown in Table 2, include:

- Reviewing the study contract or proposal
- Analyzing the study economics
- Negotiating payment amounts

Table 2: Sample Developmental Costs for a Research Program

Activity	Staff Performing Action	Estimated Staff Time on "Typical" Trial	Total Cost*
Review study contract/proposal	Physician, Research Nurse	2-3 hours	$435
Internal economic analysis of study	Physician Assistant	1-2 hours	$80
Protocol review/changes	Physician, Research Nurse	8 hours	$1,160
Negotiate payment amounts with sponsor	Physician, Research Nurse	4 hours	$580
IRB activities	Research Nurse	16-24 hours	$960
IRB approval	Physician	(Fee for service)	$1,000+
Complete regulatory documentation	Research Nurse	8-16 hours	$640
Participation in pharmaceutical-sponsored activities	Physician	2 hours	$500
Periodic meetings with pharmaceutical monitor	Research Nurse, Data Manager	3 hours	$120
Billing and collection	Research Nurse, Controller, Accounting Personnel	Varies according to size of trial, nonstandard care of costs, etc.	
Total Practice Start-up Cost Per Registration Trial			**$5,475 + billing/collection costs**

**Assumes physician charges at $250/hour and non-physician charges at $40/hour. Fully loaded for benefits and overhead.*

- Reviewing and changing protocols
- Supervising and coordinating IRB activities and approvals
- Participating in pharmaceutical-sponsored activities
- Documenting
- Billing and collecting.

Before adding a clinical trial to any research portfolio, here's how to calculate your development costs. The first step is to conduct scientific protocol assessment. Usually the research nurse and the physician who will be accruing patients to the study will spend about eight hours reviewing the protocol.

The second step is to conduct an internal economic analysis of the study, which typically takes between one to two hours.

After that, budget and contract negotiations begin. The research nurse and the physician will typically spend six to eight hours doing a second review of the research proposal and implementing the necessary protocol changes. An additional four hours will often be spent negotiating an adequate payment amount with the sponsor.

After an agreement is reached with the sponsor, the research nurse typically spends between 16 to 24 hours on institutional review board (IRB) activities, including developing, updating, or adapting patient consent forms based on IRB and sponsor feedback. (These tasks are just the beginning of an ongoing and regular dialogue among the research nurse, the sponsor, and the IRB.) The physician will then pay at least $1,000 to obtain IRB approval of the planned study.

Once IRB approval has been obtained, which can be a lengthy and tedious process, the research nurse may spend between 8 to 16 hours gathering and completing the necessary regulatory documentation including: the FDA Statement of Investigator (Form 1275), lab certifications, curriculum vitae of the principal investigator and other members of the research team, and other necessary licenses.

Finally, trial administration begins. The lead investi-

What Does a New Drug **Really Cost** *to Develop?*

The average cost to develop a new prescription drug is $802 million, according to a 2001 study by the Tufts Center for the Study of Drug Development.[1] Based on information obtained directly from research-based drug companies, the $802 million estimate includes expenses incurred from project failures and the impact that long development times have on investment costs.

The study found that it takes between 10 to 15 years to develop a new prescription drug and gain approval to market it in the United States.

Out-of pocket clinical costs, out-of-pocket discovery and preclinical development costs, clinical success and phase attrition rates, and the cost of capital (the cost of using money for drug research rather than on other lucrative investments) are also accounted for in the study.

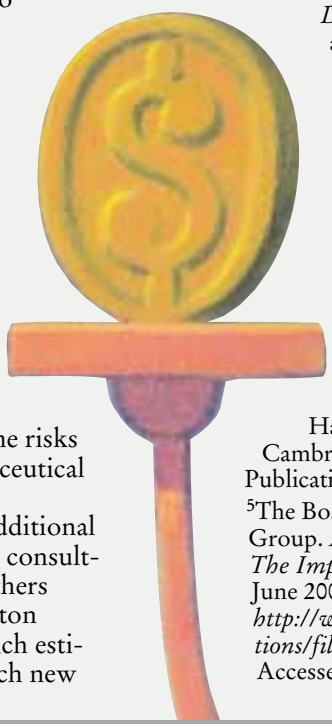
In comparison with a 1987 study by DeMasi and colleagues[2] that estimated the average cost to develop a drug to be $231 million, the costs of drugs far outstripped the rate of inflation. Much of this increase can be attributed to rising clinical trial costs, said DiMasi, lead author and director of economic analysis at the Tufts Center.

Although the Pharmaceutical Research and Manufacturers Association (PhRMA), among others, has cited the Tufts' Center comprehensive studies as the most reliable estimate of the total cost of new drug development, the 2001 study has met with some controversy.

In a report released to coincide with the Tufts' study, the Consumer Project on Technology, a Washington, D.C.-based consumer advocacy group, said that it could not reconcile industry figures on the cost of drug development with the pharmaceutical industry's IRS filings. According to Ralph Nader's group, Public Citizen, the $802 million is misleading because approximately half of this number represents the opportunity cost of capital.[3] Further, Public Citizen questioned whether the Tufts' study accounted for research and development (R&D) tax deductions. In its own analysis of new drug development, Public Citizen found the after-tax estimate (or actual cash outlay) to be only $240 million.

PhRMA was quick to defend the DeMasi data in an eight-page report prepared by Ernst & Young, LLP. Among other issues, PhRMA said that the Public Citizen's study deviated from standard methodologies, presented selective evidence, and lacked an understanding of R&D tax deductions, new chemical entities, and the risks associated with pharmaceutical R&D.

PhRMA also cited additional research by two private consulting firms, Lehman Brothers Healthcare and the Boston Consulting Group, which estimated that R&D for each new drug now exceeds $500 million. The Lehman Brothers study[4] found R&D costs of $675 million per new drug, while the Boston Consulting Group's study[5] put current average development costs between $590-$800 million for a new drug.



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gator can expect to spend a few hours participating in a study kick-off (usually a pharmaceutical-sponsored investigator meeting or conference call). The research nurse and the data manager can expect to spend about three hours each on periodic meetings with the pharmaceutical monitor, providing updates on the clinical trial.

Throughout the course of the clinical trial, the research nurse, controller, and accounting personnel will spend additional hours on billing and collection activities. The exact amount of hours will vary depending on the size of the trial and nonstandard of care costs, among other issues.

Once you have calculated your developmental costs (the fee for staff time spent on development tasks for a "typical" trial), take this amount and multiply it by the number of trials your cancer program expects to participate in that year. This number will provide an estimate of the total developmental costs for your research program.

Again, for example, Table 2 shows a developmental cost of $5,475 per patient/per trial. (Keep in mind this

estimate does not include the time spent on billing and collection.) If your cancer program anticipates participating in 40 trials this year, a good estimate of your total developmental costs would be $218,840.

GETTING STARTED: KNOW YOUR OPERATIONAL COSTS

Certain operational research costs such as salaries and overhead (rent, supplies, equipment) are also fixed expenses and do not change from trial to trial. To calculate your fixed operational costs related to clinical trials, first identify which staff members are working on the clinical trial, how much time each staff member is spending on research, and the overhead expenses related to the clinical trial. Taking that total figure and dividing it by the number of patients you anticipate accruing into clinical trials that year will provide the per patient cost.

Table 3 provides an example of how to calculate fixed operational costs. This particular cancer center employs 1.5 full-time equivalent (FTE) research nurses and a FTE data manager to assist the principal investigator (physician) with the research program. Calculating staff hours and overhead expenses, this cancer center spends $166,000/year on operating expenses relating to clinical trials. Dividing that cost among the 72 patients projected to be accrued into 10 trials that year results in a fixed operational cost of $2,400 per person for each trial. This number represents the *minimum* per patient cost and does not account for fixed variable costs. To ensure that you recoup your *total* per patient cost, you must also account and budget for the variable operational costs listed below.

The other operational costs of conducting clinical research differ greatly from trial to trial and are referred to as variable costs. On a per-study basis, these variable costs can include: 1) nonstandard of care costs, 2) unique study requirements or procedures, 3) data management, and 4) equipment and supplies (shipping, copies, telephone).

In particular, cancer centers should ensure that unique study requirements such as centralized laboratory testing, special radiology studies, and/or novel methods and schedules of drug administration are factored into budgetary estimates. Once the cancer center accurately identifies the fixed and variable operational costs of individual trials, the total cost to the center can be calculated and an accurate budget can be developed.

This sound financial planning process must be carried out for each clinical trial in which your cancer center would like to participate. While study costs should be determined on an individual basis, a cancer research program that wants to meet its yearly budget and recoup its total costs must not assess any study budget in isolation. Cancer research programs will lose money on some studies, break even on others, and even make money on some studies. The only way to protect the bottom line of the research program is to look at the portfolio of research studies as a whole.

Table 3: Sample of Fixed Operational Costs for a Research Program

Full-time Employee Benefits	Costs
■ Principal Investigator	$7,200
■ Research Nurse (1.5 FTE: 80%)	$66,000
■ Data Manager (1 FTE)	$40,000
Overhead (Typically 20%)	$60,000
■ Rent	
■ Supplies	
■ FedEx Shipping	
■ Equipment/Phone	
TOTAL	**$166,000**
Cost Per Patient @ 72 patients/year	**$2,400**

GETTING STARTED: KNOW YOUR STAFFING NEEDS

Regardless of the size of your research program, developing an accurate staffing model is essential. An accurate staffing model justifies current and future staff volume, stabilizes workflow, reduces turnover, and accurately predicts variable study costs. The first step in developing a staffing model is to evaluate the complexity of each clinical trial. You do this by looking at the hours your staff spends on data management, clinical coordination, regulatory issues, and other miscellaneous activities for each clinical trial.

The hours spent on data management functions will depend on the complexity of the case report form and the number of patients. For each clinical trial, rank the case report from 1 (least complex) to 3 (most complex) based on the frequency of patient visits, the intensity of the screening process, and the number of cycles or months the study is expected to last.

Once you have ranked the case report, take that number and multiply it by the number of patients participating in the trial. For example, a clinical trial with a case report form ranked as a 3 and an accrual of 30 patients will result in approximately 90 hours of work. Identify which staff member will be doing what work, multiply the corresponding hourly salary by 90 hours, and you have a good estimate of your data management costs for the clinical trial.

A similar process is used to estimate clinical coordination activities. For every clinical trial, assign a ranking from 1 (least complex) to 3 (most complex) to each clinical protocol based on the following criteria:

- Type of agent or drug (i.e., is it a simple or complex agent?)

Clinical Trials and **Conflict of Interest**

BY MONIQUE J. MARINO

In the last decade, cancer clinical research has become increasingly dominated by private rather than public investment, a trend that has raised concerns about the financial ties between clinical investigators and private industry. According to the American Society of Clinical Oncologists (ASCO), conflict of interest (or even the *appearance* of conflict of interest) represents the greatest threat to the integrity of clinical research, whether the conflict is financial, academic, or scientific.[1]

ASCO, among others, released a conflict of interest policy in 1996 to establish standards for clinical research that included:

- Uniform requirements for all clinical research, regardless of the trial sponsor
- Full disclosure of all financial interests of investigators, research staff, and members of the research oversight committee
- A summary conflict of interest report issued to the central or local institutional review board
- Consent forms documenting how the clinical investigator, research staff, and the institution are being compensated by the research sponsor for the time and effort of conducting the clinical trial.

This year ASCO added revisions to that policy that outline new financial disclosure levels, restrict activities for researchers in leadership roles, and identify general prohibitions for all clinical investigators. These revisions take effect April 29, 2004.

ASCO's research efforts prior to the 2003 policy revision found a wide range of disclosure requirements that depended on the trial sponsor. The National Institutes of Health (NIH) requires financial disclosure of payments or holdings of stock in excess of $10,000, while some universities had thresholds as high as $100,000. FDA-sponsored trials fell somewhere in the middle, requiring financial disclosure of payments in excess of $25,000 during the trial and for a one-year period after the conclusion of the trial, and holdings of more than $50,000 equity interest in the trial sponsor.

ASCO's existing policy calls for financial disclosure of ownership of more than $1,000 in publicly traded trial sponsors and honoraria in excess of $2,000 per year or $5,000 over a five-year period.

The 2003 update has additional requirements for researchers submitting abstracts or making presentations at ASCO meetings, authors submitting papers to ASCO publications, and anyone serving on an ASCO board or committee, including financial disclosure of:

- Money earned through an advisory role, employment, leadership position, or expert testimony
- All stock ownership (except when invested in a diversified fund not controlled by the individual)
- All honoraria
- Research funding
- Any other remuneration that is not research-related, including travel and gifts with a value of more than $100.

The 2003 revisions also place new restrictions on individuals having "a leadership role" in the clinical trial. Such individuals cannot receive or hold stock or equity in the industry sponsor (except when the stock is invested in a diversified mutual fund not controlled by the individual). Royalty, licensing fees, or patents from the product or novel treatment under investigation cannot be received or held by individuals with leadership roles in the clinical trial. These individuals are also not allowed to hold positions as officer, board of directors' member, or employee of the trial sponsor.

Tighter restrictions have also been placed on travel or trips to attend scientific or educational meetings paid by the trial sponsor. Now, the only acceptable instances of sponsor-paid travel or trips are to widely-attended and independently sponsored scientific meetings (with the primary purpose of making a presentation on the clinical trial) or investigator meetings related to the conduct of the trial. Finally, these individuals are restricted from receiving research-related payments substantially exceeding actual research costs from the trial, including honoraria or gifts from the trial sponsor.

Along with the disclosure guidelines and restricted activities, ASCO identified the following activities as inappropriate for *any* cancer researcher: accepting any payments for referral or accrual to a clinical trial; accepting payments contingent on particular research outcomes; and signing research contracts that allow the sponsor to override the decision to publish or present trial results.

Monique J. Marino is managing editor at the Association of Community Cancer Centers.

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- Nonstandard of care (i.e., does the trial require a number of staff hours and services that will not be reimbursed?)
- Number of modalities (i.e., studies that involve more than one modality are more labor intensive and require additional staff time.)
- Novel administration techniques
- Registration process (i.e., how long does it take to register one patient?)
- Central labs (i.e., the number of lab visits will affect the time staff must spend on activities such as drawing

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A flourishing research program should include a full range of trials that matches the center's size, location, capabilities, expertise, and budget.

blood and packaging and sending the blood for analysis)
- Number of patient visits each month
- Number of treatments administered each month
- Quality of life diaries (i.e., how much staff time is spent ensuring that patients are completing these materials? Longer diaries mean more explanation and more follow-up phone calls to patients.)
- Tumor assessments each month
- Pharmacy requirements (i.e., how much support must the pharmacy provide during this trial?)

To estimate the staff hours spent on each of these clinical activities, you must take the ranking assigned to each activity and multiply it by the number of patients in the study.

Identify which staff member (i.e., data manager, research nurse, research coordinator) will be doing what tasks, multiply the corresponding hourly salary by the number of hours you estimated these tasks to take, and you have a good estimate of the clinical protocol costs for the clinical trial.

You can estimate the number of hours your staff will spend each month on regulatory tasks by evaluating each clinical trial in terms of how long staff spends on local IRB submission, how many regulatory forms must be filled out, the number of site profile updates that are required, and the time spent on quality assurance efforts.

Finally, don't forget to account for the miscellaneous activities your staff is spending time on. Take each clinical trial and evaluate how much time your staff spends on activities such as:
- Travel time between sites
- Drug accountability (i.e., stocking, measuring, storing, and tracking drugs)
- Tumor assessment with offsite radiology
- Meetings at off-site radiation facilities.

DESIGNING YOUR RESEARCH PROGRAM

Now that you have a comprehensive cost estimate for your research program, you need to ensure that the trials you initiate will cover those costs. As you begin to develop or restructure your research program, consider the following factors—all of which are essential for a successful research program:
- The portfolio (balance or mixture) of trials needed for the research program to be financially viable
- The projected patient accrual for the year
- Development needs
- Physician buy-in
- Dedicated staffing.

A flourishing research program should include a full range of trials that matches the center's size, location, capabilities, expertise, and budget. The research portfolio should include a broad range of Phase I through Phase IV trials for various disease sites and include investigator-initiated, pharmaceutical registration, cooperative, and compassionate group trials. Cancer research programs should select trials that will benefit its patient mix and program size, allowing realistic expectations of accrual. Selected trials should not compete with one another, thereby greatly diminishing possible accruals or potentially engendering unintentional investigator bias.

Understanding your center's capabilities and capacities is also essential. Each trial must be evaluated according to the burden its protocol, pharmacy needs, and regulatory requirements will have on the cancer center or practice. Physician buy-in for all potential trials is obviously essential, and all staff participating in research should review and approve all clinical trials that have been pre-identified as meeting the needs of the center.

Although less than 5 percent of patients with cancer participate in clinical trials,[3] it is vital for patients to have clinical trials as an option in their treatment plan.

Everyone wins when a community cancer center or practice has a successful research program—the patients, the physicians, and the cancer center. Patients have access to the latest investigational anticancer agents close to home, physicians have the satisfaction of participating in cancer research and offering more advanced treatment options to their patients, and the center's prestige and marketability are enhanced, setting it apart from competitors.

Research programs do not have to be a financial drain on the community cancer center's bottom line. Taking the time to develop a balanced research portfolio that is buttressed by sound budgeting will ensure that the research program remains efficient, cost-effective, and successful.

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