

Attributes of Exemplary Research

Basic Steps to Building a Research Program

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Background

Establishing a clinical trial infrastructure is one of the most challenging, yet important, steps when developing a successful research program. Two areas required for success include financial oversight and sustaining a qualified research team. This article, part of the Attributes of Exemplary Research series,¹ targets new investigators and those expanding their research programs and provides practical advice from successful experts.

Planning From Within

Taking an entrepreneurial approach is a successful mechanism when developing a clinical research program. Maintaining a sustainable program requires fiscal planning, much like a business. When developing the financial infrastructure, it is helpful to consider budgeting from both broad and narrow perspectives. For example, a study budget must be developed for each individual trial, whereas the program itself requires a budget that manages indirect costs required regardless of patient enrollment. The amount dedicated to indirect costs and the mechanisms by which the funds are used vary by institution and are pre-established at some sites. Sites that do not have a pre-established rate make this determination by calculating overhead costs not directly related to the study protocol, including space, utilities, information technology, and staff compensation. The amount varies by program, but many sites require roughly 25% from each study budget to cover the total of all indirect costs.

It is important to remain realistic when considering the amount of money needed for both direct and indirect costs, and to plan meticulously before initiating a new clinical trial, negotiating for industry trials, or establishing a budget within the institution. Institutions with a clinical trials office usually have guidance regarding budgeting and have contracts established with the National Cancer Institute (NCI) regarding the institute's indirect cost requirement. In contrast, practitioners in community settings have increased autonomy to predict costs and negotiate accordingly. Finding a mentor or establishing an institutional partnership can be helpful for physicians in this situation. Greater detail regarding cost-neutral budgeting is discussed in a previous article in the Attributes of Exemplary Research series published March 2009, entitled "Cost-Neutral Clinical Research Enterprise."²

Thinking Globally

Researchers are often frustrated that per-patient reimbursement does not always cover the actual costs of conducting a trial and that reimbursement is usually given after patient enrollment. With NCI cooperative group trials, inadequate federal funding

is well documented, including an ASCO study that determined the average cost of each patient in a clinical trial to be \$6,000, whereas per-patient reimbursement is only \$2,000.³ The key to success is awareness of alternative funding mechanisms and using them to supplement program needs.

A good place to start is within an institution. Some physicians and their staff members receive salaries through a hospital or clinic that supports clinical research, a great employment option for individuals dedicated to conducting trials. These physicians are under less pressure to increase patient volume and are able to dedicate additional time to clinical research. This model has a record for success and is often cited as a reason pediatric clinical trials accrue so well. Physicians who are not salaried can build a similar mechanism into their practice. For example, because research requires additional time not reimbursed by insurance or Medicare, consider adding physician reimbursement as a cost covered by the study budget. Reimbursing physicians for their time is a reasonable study cost and helps create a research culture within the institution.

Sites also benefit from offering a broad menu of clinical trials. If the program is not breaking even conducting federally funded trials, adding industry trials may be a good option. Though investigators are generally pleased by the higher reimbursement rates provided by industry, some complain that industry trials are less stimulating and provide fewer opportunities for publication. Using a combination of trials from industry and the NCI Cooperative Groups can help clinical researchers get the best of both worlds. Always be selective before choosing trials and consider the question being investigated as well as patient demographics. If researchers open a trial that cannot accrue, they tax the program budget by wasting time and resources. Before initiating a new trial, also be mindful of the degree of trial complexity a practice can facilitate, such as the ability to properly prepare biospecimens, manage unstable investigational agents, and meet all eligibility criteria. Financial balance will certainly fail if there are unexpected equipment upgrades required to support the conduct of a trial.

Though NCI per-patient reimbursement alone is often insufficient, many additional options are available through NCI and other federal sources.⁴ Becoming a community clinical oncology program (CCOP) is a great option for community sites dedicated to research. CCOPs benefit from having access to numerous phase I, II, and III trials and have autonomy to choose with which research bases they wish to partner. CCOPs also manage their own budgets and receive some funding before patient enrollment, unlike standard cooperative group partnerships. Becoming a CCOP requires a previous record of success.

Learn More

For additional literature on this topic, read the article “Clinical Research by Community Oncologists,” published by the American Cancer Society and available free online at <http://caonline.amcancersoc.org/cgi/content/full/53/2/73>.

For more information about the National Cancer Institute (NCI) Community Clinical Oncology Program, visit the Web site at <http://prevention.cancer.gov/programs-resources/programs/ccop>.

View free NCI education modules entitled “Incorporating Cancer Clinical Trials into Your Practice” at <http://cme.cancer.gov/clinicaltrials/learning/course7.asp>.

Learn about grant and award opportunities offered through ASCO at <http://www.asco.org/ASCOv2/Research+Resources/Grants+%26+Awards>.

Formal staff training and certification is offered via the Society of Clinical Research Associates and the Association of Clinical Research Professionals.

If a program is still in initial stages, consider becoming an affiliate member of a cooperative group instead. This enables a researcher to partner with a member institution and participate in all trials offered through the institution’s cooperative group affiliation. In this mechanism, reimbursement is provided after patients are enrolled and is initially given to the member institution, which is then responsible for channeling funds to partner institutions. Joining the NCI Clinical Trials Support Unit is also an option worth pursuing for programs at all levels. Also, NCI has many investigator-initiated funding opportunities, including training grants and administrative supplements, all of which are listed on the NCI Web site.

In addition to federal options, enhancing knowledge of funding opportunities offered through philanthropic organizations can be beneficial. From professional societies to advocacy organizations, most offer varying levels of grants, and some exceed several million dollars in annual funding. Many of the grants can be used to supplement the research one is already pursuing, such as ASCO’s community oncology research grants.⁵ Be clear about the requirements associated with grants funded by nonprofit organizations. Most researchers find these grants helpful, but some are not applicable because of conflicts of interest or inability to meet associated requirements.

If a researcher thinks it necessary to cut items from the budget, plan strategically. For example, an easy expenditure to cut may be the funds allocated to conferences and poster presentations. However, name recognition is an important aspect of peer review, and establishing oneself in the research community is imperative for future success. Consider instead applying for an employer travel grant or fee waiver, or through an external organization, such as the one conducting the conference. Also, do not automatically dismiss grants for small amounts of funding; instead, consider realistic ways to incorporate these mechanisms into your program. Smaller grants can be useful to fund feasibility studies or pilot projects. Using supplemental funding mechanisms can greatly enhance a clinical research program.

Developing the Research Team

Physicians dedicated to clinical research are the key to successful programs. Many physicians have endorsed the importance of clinical trials, but few enroll 10% of their patients, an attribute of an exemplary clinical trial site.¹ In the Eastern Cooperative Oncology Group (ECOG), 80% of ECOG community hospital accrual comes from only 20% of registered investigators, indicating that most oncologists do not fully integrate research into their practice. When identifying new staff, it is important to recognize individuals who see clinical trials as an important treatment option. Training physicians who do not already value research is difficult.

Conducting clinical trials in a community setting presents challenges that novice researchers may not have confronted while training at academic institutions.⁶ One example is the sheer number of trials onto which community researchers enroll their patients. Whereas academic physicians generally have narrow areas of expertise and accrue to a subset of studies, community physicians typically treat a variety of primary tumors and participate in a broader range of trials. Some physicians overcome this barrier by carrying a booklet that includes a brief explanation of each trial their practice offers. Community physicians may also have to spend more time educating patients and assuring informed consent because patients in the community setting may be less familiar with clinical trial options. In general, it is important to realize that conducting clinical research in a community setting takes time and adaptation. Hiring physicians committed to research and providing them with site-specific training is key to creating a successful research program and sets the tone for other clinical and support staff.

Although the physician is vital to creating a research culture and enrolling patients on trials, nonphysician staff are imperative to the overall success of the program. An ASCO study completed in 2003 found that physicians accounted for only 9% of the overall time required to conduct a clinical trial, whereas nurses and data managers contributed more than 30% each.³ At least one dedicated research staff member is critical to ensuring studies receive necessary attention. The clinical research associate (CRA), who may or may not be a nurse, is responsible for research study tasks and assuring all deadlines are met. Study success relies heavily on this person because they are responsible for everything from meeting submission deadlines and reviewing inclusion/exclusion criteria to collecting data and serving as the main source of interaction with patients on study, which can substantially influence participant enrollment and retention. The CRA is also responsible for maintaining the program’s regulatory compliance, which is essential to the research program and requires dedicated time beyond the scope of clinical practice.

If the program is small and only one staff person is supported, it is generally best to select a nurse because there are clinical components of research that only nurses are qualified to do. However, if more than one staff person is available, it becomes important to consider the tasks that need completed to determine the best mix of clinical and nonclinical staff. For example, it makes no sense to pay a nurse to photocopy papers or extract data from medical records when appropriately qualified but lower-salaried individuals can be assigned to the task.

Training staff is imperative when developing a research team and should combine on-the-job instruction with formal training. Training within the institution may include mentorship from se-

nior staff, active observation of study tasks, participation during industry initiation visits, and involvement during monitoring/audit preparation. Formal research training can be obtained through professional societies, universities, and online. If the program is new, it may be helpful to gradually build the research portfolio so the CRA has time to learn properly the many responsibilities associated with specific research projects. If a new CRA is starting at an established program, consider initiating incremental advancements so the CRA can be promoted as responsibilities increase. In either situation, the goal should be to prevent overwhelming the individual and providing achievable goals that lead to job satisfaction. These extra steps are important for staff retention. Considering that it takes roughly 6 to 12 months to fully train research staff, frequent job turnover can affect data quality and impede program development.

Other staff that cannot be overlooked include pharmacy staff and those responsible for reimbursement. From the study initiation, clear roles must be established assuring all study tasks are accomplished. Development of standard operating procedures, which are written instructions regarding study responsibilities, are often a good way to be certain that all tasks are consistently met.¹ Although this step requires time up front, it can be highly beneficial during audits and staffing changes and may be required by the study sponsor. Pharmacy staff members, for example, need procedures regarding proper storage and handling of study drugs. Reimbursement specialists need to know how to submit research claims properly and what to charge against the study budget versus the patient insurance. Some practices find it useful to schedule regular meetings to educate staff regarding research and provide updates regarding new protocols. Incremental auditing is also a helpful way for a new program to ensure the quality of research at the institution. Occasional external audits provide feedback not available through internal auditing alone and assure the program is meeting Good Clinical Practice guidelines. Developing a successful research program can be challenging but can provide great personal satisfaction and offers a wide range of treatment options for patients.

Upcoming Events

ASCO plans to offer online educational opportunities in which content providers to the series will discuss these topics in more detail. See ASCO's Web site at www.asco.org/

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ASCO Statement on Minimum Standards and Exemplary Attributes of Clinical Trial Sites

The ASCO statement addresses the minimum requirements for sites conducting quality clinical trials as well as the attributes of exemplary sites. Both minimum requirements and exemplary attributes were based on a review of the literature, current regulatory requirements, and consensus among community and academic clinical researchers. To conduct quality clinical research, sites should meet the minimum requirements. It should be noted, however, that the exemplary attributes are voluntary and suggested as goals, not requirements. Not all attributes will apply to all clinical trial sites, and many sites may be able to conduct high-quality clinical trials without accomplishing all attributes.

ClinicalTrialResources for more information and access the entire Attributes of Exemplary Research series at <http://jop.ascopubs.org/>. The next article in this series, which will provide practical tips regarding contracting, will be published in the March issue of *Journal of Oncology Practice*.

Feedback Request

Suggest future topic ideas for the series and provide your feedback by sending an e-mail to researchresources@asco.org.

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Editor's Desk

Seeking Serenity With Influence

John V. Cox 1

Feature Articles

Filling the Gap: Development of the Oncology Nurse Practitioner Workforce

- A new strategy for oncology care delivery that includes increasing the numbers and expanding the roles of nonphysician practitioners is critically important to meet the current and potential cancer care needs of the US population.

Brenda Nevidjon, Paula Rieger, Cynthia Miller Murphy, et al 2

Ensuring Quality Cancer Care Through the Oncology Workforce

- A summary of the discussion at the Institute of Medicine National Cancer Policy Forum Workshop to examine oncology workforce shortages and describe current and potential solutions.

Laura Levit, Alison P. Smith, Edward J. Benz Jr, et al 7

Original Research

i Cost Effectiveness of Evidence-Based Treatment Guidelines for the Treatment of Non–Small-Cell Lung Cancer in the Community Setting

- Results of this study suggest that treating patients according to evidence-based guidelines is a cost-effective strategy for delivering care to those with non–small-cell lung cancer treated in the outpatient community setting.

Marcus A. Neubauer, J. Russell Hoverman, Michael Kolodziej, et al 12

Who Is Responsible? The Role of Family Physicians in the Provision of Supportive Cancer Care (see commentary on page 24)

- Many family physicians do not view coordinating patients' supportive cancer care as a primary responsibility and do not wish to assume this role. Models involving them as team members in care coordination are more feasible for reducing patient need.

Kevin Brazil, Jonathan Sussman, Daryl Bainbridge, et al 19

Commentary: Who Should Follow Our Patients? (see article on page 19)

Patricia Legant 24

i Understanding the Role of Physician Assistants in Oncology

- A descriptive study using a Web-based questionnaire was undertaken to understand the deployment of physician assistants in oncology, as we face a significant shortage of oncology providers by 2020.

Alicia C. Ross, Maura N. Polansky, Patricia A. Parker, et al 26

Physician Assistant Perspective on the ASCO Workforce Study Regarding the Use of Physician Assistants and Nurse Practitioners

- A shortage of 2,350 to 3,800 oncologists by 2020 has been predicted, and increased use of physician assistants and nurse practitioners is one proposed solution. This report examines their role in oncology.

Maura Polansky, Alicia C. Ross, and David Coniglio 31

Practical Model for Psychosocial Care

- The delivery of economically feasible psychosocial care is critical for patients with cancer and their families. Creative partnering enables such comprehensive care to be provided effectively and efficiently.

Susan S. Hendrick and Everardo Cobos 34

Role of Advanced Nurse Practitioners and Physician Assistants in Washington State

- A survey in response to Washington oncology practices' workforce shortage on employment patterns for advanced nurse practitioners and physician assistants found that practices have embraced these roles.

Jonathan C. Britell 37

i Online content

Current Clinical Issues

Guideline Summary

American Society of Clinical Oncology Clinical Practice Guideline Update on Chemotherapy for Stage IV Non–Small-Cell Lung Cancer

- ASCO published a guideline on use of chemotherapy in advanced stage non–small-cell lung cancer in 1997. The latest update covers treatment with chemotherapy and biologic agents and reviews literature from 2002 to 2009.

Christopher G. Azzoli, Giuseppe Giaccone, and Sarah Temin 39

Business of the Business

Practical Tips

Changes in Medicare Rules Pertaining to Consignment Closets or Stock/Bill Arrangements 44

Practice of Research

Attributes of Exemplary Research

Basic Steps to Building a Research Program

- Establishing a clinical trial infrastructure is an important step when developing a successful research program. Two areas required for success include financial oversight and a qualified research team.

Allison Baer, Naftali Bechar, Gary Cohen, et al 45

The Voice of ASCO

ASCO’s Clinical Practice Committee

Collaboration

Michael Neuss 48

State Affiliate News

Georgia Society of Clinical Oncology Forms a Patient Navigator Affiliate 49

Focus on Quality

How the Federal Trade Commission Is Fighting Cancer Treatment Scams

- A cancer diagnosis can tempt a patient to turn to miraculous cancer-fighting products, but the Federal Trade Commission says it is good to be skeptical—most of these products are scams.

Carol Kando-Pineda 50

Perspective

Make Quality Cancer Survivorship Care Possible in the Era of Workforce Shortage

Jianqing Lin and Ross C. Donehower 52

Erratum 53

 Online content

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