Oncology Issues

ISSN: 1046-3356 (Print) 2573-1777 (Online) Journal homepage: https://www.tandfonline.com/loi/uacc20

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**To cite this article:** Jo A. Scott (1998) Developing a Research Program…and How to Make it Work, Oncology Issues, 13:4, 18-21, DOI: 10.1080/10463356.1998.11904762

**To link to this article:** https://doi.org/10.1080/10463356.1998.11904762

Published online: 18 Oct 2017.

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# Developing a Research Program...and How To Make It Work

by Jo A. Scott, R.N., B.S.N., O.C.N.

Participation in clinical research has become a requisite of many community cancer programs for a variety of reasons. The American College of Surgeons now requires that 2 percent of an institution's patients be enrolled in clinical trials. Market forces are also playing a role. Many institutions, enticed by the marketing advantage gained by offering patients cutting-edge treatments, are developing clinical research programs to differentiate themselves in a competitive marketplace.

Clinical research can strengthen and enhance a cancer program by increasing the availability of state-of-the-art, quality care. However, limited funding, unnecessarily strict protocol eligibility requirements, and ever-increasing paperwork threaten to dampen enthusiasm for development or expansion of such programs. Many community hospitals are viewing clinical research as an investment that is too expensive and time-consuming to pursue.

Development of a community research program demands a substantial financial commitment from the institution and significant time and effort on the part of the principal investigator and other dedicated staff. For a clinical research program to flourish within a community setting, administration and investigators must view the program as an extension of the institution's mission to serve the community. The hospital must be willing to commit the facilities, equipment, and staff necessary to support the program. Investigators must be willing to commit the time to meet the demands of research, which can include reviewing literature, protocols, and investigators' brochures; attending industry-sponsored investigator meetings and meetings with the affiliated research bases (such as NSABP or ECOG); preparing for site visits and audits; and overseeing the informed consent process. Clearly, the institution and investigator must have the desire to advance science and promote cutting-edge care.

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## THE CLINICAL TRIALS MENU

Fortunately, even smaller community cancer programs have access to large national treatment and prevention trials offered through the NCI-sponsored Community Clinical Oncology Program (CCOP) and Cooperative Group Outreach Program (CGOP). Industry-sponsored trials that study a specific therapy may be accessed through pharmaceutical companies and contract research organizations. Participation in these programs allows patients in the community to receive the benefits of new treatments long before they are available to the general population.

NCI-sponsored research at the community level often begins via the CGOP, which links the community hospital and physicians with the cooperative groups responsible for implementing and monitoring the protocol. CGOPs provide a means for community hospitals and physicians to gain experience with the demands of clinical research without the burden of a competitive grant review application. However, the types of trials available may be limited. Funding is provided through the research base, based on per patient accrual, and is usually awarded quarterly. This payment mechanism may make it difficult to financially sustain a clinical research department on a daily basis.

CCOPs offer experienced investigators access to a wide variety of trials through affiliation with up to five of the major research bases (e.g., ECOG, SWOG, RTOG, NSABP, GOG). In order to qualify and be funded through the NCI as a CCOP, institutions must file a competing grant application. The application must undergo extensive peer and administrative review. NCI approval of a project may include recommended support for up to five years. However, awards are made annually and depend on

the project's progress and anticipated accrual for the next year. Awards are dependent upon appropriation of funds by Congress and generally cover only one-half or less of the total research expenses. The remaining expenses must be covered by the institution.

Many hospitals participate in research without actually having an established program in place. A hospital may affiliate with a CCOP institution via a consortium arrangement or purchased service contract. Typically a formal agreement exists between the grantee institution and the collaborating institution that allows the latter to participate in the scientific and administrative research activities of the CCOP. Third-party participants operating under consortium arrangements must track and account for the use of federal funds in the same manner as is required for the grantee institution.[1]

## FUNDING OPTIONS

Institutions wishing to conduct clinical research must think creatively to devise supplemental sources of funding. Building relationships within the community is essential. For example, partial support for the Breast Cancer Prevention Trial can be provided by the local Race for the Cure. In addition, private donations can be accepted by the hospital foundation and made available for specified research projects. The Cancer Care Institute at Decatur Memorial Hospital, for example, was recently awarded $15,000 by the Illinois Ladies Auxiliary to the Veterans of Foreign Wars to further the research of breast cancer. The key to successful collaboration among the institution, physicians, and community groups is continual assessment of community needs, especially as they relate to issues surrounding cancer care and prevention.

One of the fastest growing areas of clinical research are those funded by pharmaceutical companies. The clinical trials industry is growing rapidly as pharmaceutical companies seek to accelerate development of new drugs. Industry grants to U.S. investigators rose from $1.9 billion in 1992 to a projected amount of almost $3 billion in 1996, according to Ginsberg and Whitaker.[2] The increase in grant awards is accompanied by an increase in the number of investigators (25,000 in 1996, compared to 5,000 in 1990)[3] and has resulted in a highly competitive market.

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Institutions involved in NCI-sponsored research may choose to complement their clinical trials menu with pharmaceutical trials. Participation in industry-sponsored trials can expand the types of trials offered while providing additional revenue for the department. However, not all trials result in monetary profit. There are many reasons to conduct a trial, including the degree of potential benefit to the patient population and/or the scientific significance of a particular study. Pharmaceutical trials must be carefully selected based on the institution's need and balanced with federally funded trials. The research team should consult with the program specialist assigned to the grant to guard against overlap of program income or personnel support that could impact grant funding.

Investigators with proven expertise can often secure industry grants independently. The novice investigator may wish to work with site management or contract research organizations to gain access to clinical trials and experience with clinical research.

## MAPPING OUT A BUSINESS PLAN

The addition of clinical research to a cancer program is a significant financial investment. The ultimate goal is to balance grant income and research expenditures. However, a research program can expect to lose money for the first few years. There are several steps an institution can take to minimize losses prior to initiating a research program, including assessing the patient population, determining and allocating resources, and establishing a budget.

*Conduct a thorough assessment of the environment.* Assess what

types of patients the program is expected to attract and what trials those patients are likely to need. Study demographic and other information regarding patient population to determine how patients can best benefit from clinical trials. Relevant data can be obtained from the cancer registry or by assessing patient billing codes for specific disease sites.

It is also important to assess whether current trials compete for the same patient population. For example, track the number and frequency of referrals for investigational therapies in the last five years. This information will help an institution determine what needs are currently being met in the community and where new opportunities may exist. Also, remember to take into account managed care trends and the impact managed care can have on payment for clinical trials, as well as the possible changes in Medicare regulations that might impact income and cash flow. Many managed care plans explicitly exclude payment of costs associated with investigational treatments, effectively denying eligible patients access to clinical trials. In this case, supplemental sources of funding and selection of trials in which patient care costs are covered by the study sponsor are often necessary.

*Determine and allocate resources.* An assessment of the facilities and services currently offered will assist an institution in determining the types of clinical trials that could be readily implemented. Resources such as pharmacy, laboratory, radiology, and clerical support are frequently already in place. However, infrastructure to support activities specifically related to research functions, such as formation of an institutional review board (IRB), may have to be established to ensure compliance with state and federal regulations.

The institutional review board is responsible for protecting the rights and welfare of human research subjects as regulated by the Department of Health and Human Services (DHHS) and the Food and Drug Administration (FDA), as well as several states. Institutions must be familiar with the laws and regulations applicable to them. For instance, DHHS requires that institutions provide an Assurance of Compliance with Human Subject Regulations, which is negotiated with its Office for Protection from Research Risks. The FDA does not require an assurance, but does require that IRBs have in place written policies and procedures. When research involves products regulated by the FDA, such as investigational new drugs, and is funded by DHHS, both DHHS and FDA regulations apply. DHHS regulations are codified at Title 45, Part 46 of the Code of Federal Regulations; the FDA regulations are codified at Title 21, Parts 50 and 56.

*Set realistic goals and objectives.* Ideally, all programs and initiatives related to oncology should effectively complement one another. If warranted by assessment of the environment and resources, a reasonable goal might be to strengthen the cancer program through expansion of services. A reasonable objective for a new program would be to provide access to clinical trials with revenues to balance costs by the fifth year. This timeline facilitates development of the infrastructure as well as the community relationships necessary to support clinical trials.

*Establish a budget.* The actual start-up costs and budget are determined by the initial assessment of the environment and available resources. Start-up costs are significantly lower when using available facilities, services, and staff. Initially the research department at Decatur Memorial Hospital's Cancer Care

## Research Ramp-Up

by Consuelo Skosey, R.N., C.C.R.A.

In 1995 the University of Illinois at Chicago in Chicago, Ill., made a major commitment to establish an oncology program with recruitment of an internationally renown hematologist to head its Section of Hematology/Oncology. This commitment spurred efforts to recruit a diverse faculty with academic pursuits in clinical trials both basic and translational. A director for clinical oncology research was recruited to develop a clinical trials program and an administrative director was hired to develop the infrastructure required to organize, coordinate, and facilitate protocol development and activation. Management staff, laboratory technicians, research nurses, clinical research associates, and secretaries were hired to support the faculty in their development of disease-specific research programs. Construction of a ten-bed stem cell transplant unit led the initiative, followed by renovation of the Oncology Care Center and the inpatient unit.

In 1996 UIC became a main member of the Cancer and Leukemia Group B (CALGB), one of three multidisciplinary cooperative treatment groups funded by the National Cancer Institute. The UIC Clinical Trials Office was created to oversee the activation and submission of studies to the institutional review board; maintenance of the protocol and patient databases; central registration and randomization of patients onto all studies; and effective collection, receipt, and storage of data. In 1997 UIC applied for and was awarded funding for a Minority-Based Community Clinical Oncology Program. (MB-CCOP).

In the last two years, multidisciplinary disease programs have been established to aid in identifying appropriate clinical trials. These programs are instrumental in facilitating exchange of patient information between the disciplines and assist in evaluating the

Institute was staffed by one full-time RN. Our current staff consists of 9.8 FTEs and is structured to include ancillary personnel (2.8 FTEs) associated with IRB administration and cancer registry. To ensure that the budget accurately reflects the true cost of the program, the percentage of any services provided by other departments, such as shared clerical support, should be allocated to the budget. A typical budget might include personnel costs (salaries and benefits), supplies (medical and office), professional fees for consultants and lawyers, marketing, indirect costs, and travel and training for staff. Finally, remember that in any budget process, Murphy's Law applies. Plan for the unexpected!

## FEASIBILITY STUDIES AND COST ANALYSIS

Fundamental to research site management are ongoing assessments that judge the feasibility of activating specific clinical trials. For each trial considered, there must be a cost-benefit analysis weighing the costs of trial activation and operation against patient benefit, including the number of patients expected to participate. A community hospital's patient population should be reassessed each time a clinical trial is considered for activation. The goal is to maintain a comprehensive clinical trials menu that reflects the patient population served by the community hospital. As stated above, data can be gleaned from the cancer registry or patient billing codes for specific disease sites. Activation of trials that are underutilized places undue administrative time and expense on the department. However, it is important to remember that situations do arise in which trials are selected because of scientific importance or patient benefit, despite the added cost.

The costs of a particular trial must be studied to determine if the necessary resources are available to successfully conduct the study. Total study costs are determined by adding the direct expenses (salaries, assessments, and procedure costs) to the indirect costs (overhead). In addition, the protocol itself must be thoroughly assessed to determine the procedures for which the study pays and the cost for each service (e.g., a CT scan). Many of the procedures are often listed on the study calendar located in the protocol; however, it is important to review the entire protocol for any additional requirements. For instance, a CT may be required to confirm response to treatment. This requirement may be found in the section of the protocol that deals with response assessments but may not be listed in the calendar of procedures.

Determining the cost of the study-specific procedure is the next step. Factors to consider for a confirmatory CT, for example, might include:

- actual cost of procedure (with or without interpretation and tumor measurement)
- copy and mailing expenses associated with review by a central radiologist (if required)
- staff time.

When assessing the amount of time necessary to conduct the study, be certain to review the paperwork requirements. Department staff should assess the forms required for submission prior to accepting a study. A study that requires repeated documentation of concomitant medications, including indication, dose, route, frequency, and start-stop dates, or specific classification numbers assigned to adverse events will greatly increase the data management time necessary to conduct the study. Be certain to budget for this increased staff time.

Currently one-third of all patients placed on NCI-sponsored treatment trials are enrolled through the CCOP program.[4] This statistic alone is indicative of the critical role that community hospitals play in the advancement of cancer care. While it may be unrealistic to expect every community institution to operate a research program of its own, there are many avenues of participation available that enable smaller facilities to contribute to this valuable and essential component of cancer care.

results of treatment. They also provide a means for discussions surrounding the further investigation of cancer. Investigators from six UIC-affiliated community hospitals attend the weekly disease-specific conferences. Their CALGB membership allows them to activate cooperative group trials and other UIC studies of interest at their institutions. Registration of their patients to these studies is performed centrally through the UIC Clinical Trials Office.

Currently office staff coordinate the conduct of 130 protocols. These protocols include cooperative group, NCI-funded Phase II contract, investigator-initiated, and pharmaceutical studies as well as Phase I chemoprevention studies. The selection of studies to activate is made by the directors of each disease program using the criterion to prevent overlapping studies that would compete for the same subset of patients. Additionally, there must be an anticipated patient activity. The selection and prioritization of studies is discussed at a monthly clinical research meeting. NCI-sponsored studies are always given the highest priority.

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