

Current Initiatives

at the National Cancer Institute

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The National Cancer Institute (NCI) has developed several innovative programs to help reduce barriers to clinical trial participation. These initiatives are helping to ensure that health care professionals and the people they treat understand clinical trials, consider them an option, and can easily locate them in their communities.

In 1997 the NCI, with the help of many cancer experts and advocates, conducted a formal review of the national clinical trials program. The Clinical Trials Program Review Group recommended that the cancer trials system should be more flexible and more inclusive and should invite opinions from basic science and clinical researchers, community and research oncologists, patients and families, and all groups with a commitment to improving cancer care.

Cancer Trials Support Unit

To eliminate many of the barriers that physicians reported when they tried to access clinical trials, the NCI and the Clinical Trials Cooperative Group Program are collaborating in a five-year pilot project called the Cancer Trials Support Unit (CTSU). Among its objectives, the CTSU is working to reduce administrative burdens, standardize many of the financial and data submission tasks, and increase physician and patient access to clinical trials. Currently, the CTSU provides participating cooperative group members with a single access point to selected Phase III cancer treatment trials. Active CTSU members have access to protocols from other participating cooperative groups, as well as training and educational materials.

For the past two years, the CTSU has shared the information on its active treatment protocol "menu" with its member investigators. This menu is a cross-group listing of all lung and genitourinary cancer studies, and most

breast, gastrointestinal, and leukemia studies. Other benefits of joining the CTSU include:

- standardized reports of clinical trials data
- use of a web-based system to download protocol materials from other cooperative groups
- instruction on using the CTSU web site, including information on how to submit regulatory documents, data forms, and other materials
- opportunity to accrue membership credits from CTSU



enrollments and to designate them towards one's own cooperative group's requirements.

Another benefit of joining the CTSU is being able to use its four-page, protocol-specific education fact sheets written specifically for patients. Designed by the CTSU with help from NCI staff members and patient advocates, the fact sheets are available for each active protocol on the CTSU menu and contain information both about the patient's cancer and the treatment available as part of the clinical trial in question.

By mid-2002, CTSU membership will expand to include physicians who are not part of a cooperative group. Once they join the network, they will be able to enroll patients in any CTSU protocol.

Clinical Trials Education Series

In 2000 NCI's Office of Education and Special Initiatives (OESI) asked patient advocacy groups and health care professionals to tell them what they needed in the way of clinical trial education materials. Based on the responses they received, OESI has released a new Clinical Trials Education Series that can be adopted as the standard for cancer clinical trial education.

Several organizations are helping the NCI evaluate the series, which is designed to suit a variety of audiences and learning styles and can be used to educate patients, patient service and advocacy groups, and health care professionals. Workbooks and outreach materials have been developed, including:

Cancer Clinical Trials: The Basic Workbook. This workbook is designed for patients and explains why cancer clinical trials are important, how they work, how patient safety is protected, and reasons why so few adults currently participate.

Cancer Clinical Trials: The In-Depth Program. This textbook is designed for health care professionals and others who seek a more in-depth understanding of clinical trials. This resource has information on clinical trial design, resources for physician participation, and how to refer individual patients to studies.

Cancer Clinical Trials: A Resource Guide for Outreach, Education and Advocacy. This interactive workbook provides direction and guidance for individuals and organizations that would like to develop specific clinical trial outreach and education activities.

Trainer's Guide for Cancer Education. This manual is for planning and conducting educational sessions on cancer-related topics, including clinical trials.

Other tools include:

- Slide programs, which are available on CD-ROM with three complete PowerPoint presentations (designed both

for those not familiar with cancer clinical trials and those who are more knowledgeable).

- Two videos for patients: one on clinical trial awareness, and another on how to decide whether or not to take part in clinical trials.

- A low literacy brochure in English and Spanish entitled *If you have cancer...you need to know about clinical trials.*

In addition to NCI's new education series, its newly formatted web site (www.cancer.gov) provides online access to cancer information for patients and their families, health professionals, researchers, and the general public, and serves as the main gateway to all of the NCI's programs and divisions. The redesigned NCI web site, which launched early in 2002, provides easier navigation, new search functionality, and quicker access to NCI's most important information resources.

In its clinical trials area (formerly cancerTrials), www.cancer.gov offers:

- extensive information about the "what and how" of clinical trials participation, including a discussion of the patient protections that are in place

- timely reports about clinical research advances and features about new areas of clinical investigation

- information on more than 1,800 active clinical trials and an archive of 11,000 closed trials, many of which are linked to their resulting publications.

The Cancer Information Service

Since 1976, the NCI's Cancer Information Service (CIS) has helped people become active participants in their health care by providing the latest cancer information in understandable language.

In 2001, CIS responded to more than 50,000 inquiries on clinical trials (31 percent from the general public, 63 percent from patients and their families, and 4 percent from health professionals). The service helps recruit patients to clinical trials, educates patients about clinical trials, explains the results of trials, describes new drugs, and helps physicians locate research studies.

The CIS staff works one-on-one with callers to assess their current situation, then provides information on standard treatment options and proactively introduces them to studies for their condition. They also mail on request NCI educational materials. The CIS can produce customized clinical trial searches from the PDQ (Physician Data Query) database for both the public and health care professionals.

The CIS Partnership Program works with organizations that have an established presence in their region, are trusted within their communities, and serve minority and underserved populations to promote trial participation in

Resources

To find out more about NCI pilot projects, visit <http://cancertrials.nci.nih.gov/system>.

To order publications, including the Clinical Trials Education Series, call 1-800-4-CANCER or <http://cancer.gov/publications> (materials can also be viewed as PDF files from this web site.)

To find out more about the Cancer Trials Support Unit (CTSU), call the CTSU Help Desk at 1-888-823-5923 or log on at www.ctsu.org.

For clinical trials information or a customized clinical trials search, call 1-800-4-CANCER (1-800-422-6237), or 1-800-332-8615 for deaf and hard-of-hearing callers with TTY equipment. Or visit www.cancer.gov/cis. LiveHelp, an online instant messaging service, is available Monday through Friday from 9:00 a.m. to 4:30 p.m. Eastern time.

To search PDQ online, visit NCI's web site at www.cancer.gov.

these demographic groups. The Clinical Trial Education Series is used in the Partnership Program Train-the-Trainer sessions and as the basis for the material the new trainers present to their targeted audiences.

Barriers to Trial Participation

Clinical trials are a critical link between discoveries in the laboratory and advances in patient care, but studies have consistently shown that the public is unaware of clinical trials as either a prevention or treatment option in health care.

Patient barriers to clinical trial participation include language and literacy barriers, fear of medical research, and financial and personal concerns such as lack of insurance coverage.

Health care professional barriers to clinical trial participation include being unaware of appropriate studies, not wanting to refer people out of the practice, believing that standard therapy is best, or thinking that getting involved in clinical trials creates an undue administrative burden for the private practice office.

Because of both of these sets of barriers, fewer than 5 percent of adults with cancer participate in clinical trials (compared to 60 percent of children with cancer). Increasing adult clinical trial participation is crucial for advancing our knowledge of the disease and developing effective treatments in the future. ❏

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Articles of Interest

1. Lengacher CA, Gonzalez LL, Giuliano R, et al. The process of clinical trials: a model for successful clinical trial participation. *Oncol Nurs Forum*. August 2001;28(7):1115-1120.
2. Shavers VL, Lynch CF, Burmeister LF. Factors that influence African-Americans' willingness to participate in medical research studies. *Cancer*. January 1, 2001;91(S1):233-236.
3. Swanson GM, Ward AJ. Recruiting minorities into clinical trials: toward a participant-friendly system. *J Natl Cancer Inst*. December 6, 1995;87(23):1747-1759.
4. McCabe MS, Varricchio CG, Padberg RM. Efforts to recruit the economically disadvantaged to national clinical trials. *Semin Oncol Nurs*. May 1994;10(2):123-129.
5. Harris Interactive. *Health Care News*. 2001;1(3). [Poll]. Available from http://harrisinteractive.com/about/health-news/HI_HealthCareNews2001Vol_iss3.pdf.
6. Lara PN Jr, Higdon R, Lim N, et al. Prospective evaluation of cancer clinical trial accrual patterns: identifying potential barriers to enrollment. *J Clin Oncol*. March 15, 2001;19(6):1728-1733.
7. Klabunde CN, Springer BC, Butler B, et al. Factors influencing enrollment in clinical trials for cancer treatment. *South Med J*. December 1999;92(12):1189-1193.