

**BOARD OF SCIENTIFIC ADVISORS
NCI LISTENS Q & AS**

**Based on most frequently asked questions from research community attending NCI
Listens sessions at national meetings from 1997 to 2007.**

CLINICAL RESEARCH

- **Is there a source for information on the preparation of clinical research grant applications?**

The Center for Scientific Review (CSR) has developed a web site for [Advice to Investigators Submitting Clinical Research Applications](#). The web site also contains links to policies and institute contacts.

See [Conducting Clinical Trials](#) for links to NCI clinical trials resources.

- **Are there special initiatives to support clinical trials research?**

Yes. See [NCI Extramural Funding Opportunities](#) for all initiatives. Specific initiatives to support clinical trials include [Quick Trials for Novel Cancer Therapy and Prevention](#) (R21) and [Correlative Studies with Specimens from Multi-site Trials](#) (R01).

- **What resources and programs are available to assist clinicians in carrying out drug development and clinical research?**

The [Cancer Therapy Evaluation Program](#) (CTEP) provides access to a wide variety of resources, including Clinical Investigator forms and electronic applications for the standardization of trial data collection and reporting, including common toxicity criteria and common data elements. The [Investigator's Handbook](#) provides information on the policies and procedures for participants in clinical trials of investigational agents sponsored by NCI. The [Clinical Trials Support Unit](#) (CTSU) allows physicians who are not affiliated with a cooperative group to enroll patients on NCI sponsored clinical trials.

Information on [industry collaborations](#) is provided including guidelines for collaborations and a list of CTEP sponsored agents. The NCI and the Life Sciences Consortium of the CEO Roundtable on Cancer jointly developed a set of common clauses, or [START](#) (Standard Terms of Agreement for Research Trial) Clauses, that are accessible for any party to use when initiating a trial.

The [NCI Experimental Therapeutics \(NExT\)](#) Program supports drug discovery and development projects from preclinical development of an agent with a specific target through proof of concept clinical trials. Submission deadlines occur three times per year.

The NCI Special Translational Research Acceleration Projects (STRAP) Program was developed in response to recommendations from the Translational Research Working Group. The overall purpose of the STRAP Program is to accelerate integrated research and

development to move translational research projects to the point of initiating clinical studies. Current initiatives can be found on the [STRAP](#) web site.

Contact the [Division of Cancer Prevention](#) for information on prevention clinical trials. Contact the [Division of Cancer Control and Population Sciences](#) for information on behavior, clinical epidemiology and genetics, survivorship, and outcomes research.

The [Cancer Biomedical Informatics Grid \(caBIG™\)](#) is developing a comprehensive set of clinical trials management tools including an adverse event reporting module, a clinical trials participant registry, a clinical data exchange system and a patient study calendar.

Visit the [NCI Clinical Trials](#) web site for information on NCI sponsored clinical trials, clinical trial results, and education materials.

- **How can primary care physicians become involved in primary and secondary prevention studies?**

The [Community Clinical Oncology Program](#) (CCOP) supports a network linking academic institutions with community medical practitioners for conducting cancer prevention and treatment clinical trials. Primary care physicians are encouraged to become involved with their local CCOP program.

The [National Cancer Institute Community Cancer Centers Program](#) (NCCCP) is designed to encourage the collaboration of private-practice medical, surgical, and radiation oncologists with NCI supported cancer centers to provide state of the art cancer care and prevention.

- **Should the NCI support the development of clinical trial management tools that would allow researchers to access and use data to consider individual treatment, new trial designs, etc.?**

This issue was addressed in the [Clinical Trials Working Group](#) report published in 2005. In response to the report, the [Cancer Biomedical Informatics Grid \(caBIG™\)](#) is developing a comprehensive set of modular, interoperable and standards-based tools designed to meet clinical trials management needs. Examples of these tools include an adverse event reporting module, a clinical trials participant registry, a patient study calendar, and a lab information exchange module and may be viewed at the [Clinical Trials Management Systems \(CTMS\) Workspace](#).

The [Coordinating Center for Clinical Trials](#) is leading the effort to establish a comprehensive database containing information on all NCI-funded clinical trials to facilitate better planning and management across clinical trial venues.

- **Since physicians are not aware of many clinical trials, are there marketing tools to assist physicians and patients?**

The NCI [Clinical Trials](#) web site provides information on clinical trials, trial results, and education materials. The [PDQ](#) (Physician Data Query) is NCI's comprehensive cancer database on active clinical trials and includes peer-reviewed summaries. Clinical trials

information on all NIH sponsored clinical trials can be accessed through the web site, clinicaltrials.gov.

The Cancer Information Service (CIS) educates the public about [cancer prevention, risk factors, symptoms, diagnosis](#), treatment, and research. Fact Sheets are available at the [CIS web site](#) and cancer information specialists will answer questions at 1-800-4-CANCER. See the [NCI Publications Locator](#) to view and order NCI publications.

The [Clinical Trial Education Series](#) (CTES) is a group of thirteen different educational materials (books, booklets, slides, videos) to target education and outreach for health professionals and patients.

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- **Are NCI supported human specimen banks available to investigators?**

Yes. The [Specimen Resource Locator](#) is a database to help researchers locate human specimens (tissue, serum, DNA/RNA, other specimens) for cancer research. It includes tissue banks and tissue procurement systems with access to normal, benign precancerous and cancerous human tissue from a variety of organs.

In addition, the [Office of Biorepositories and Biospecimen Research \(OBBR\)](#) was established in 2005 to guide, coordinate, and develop the NCI's biospecimen resources and capabilities. OBBR activities include, establishment of the [Biospecimen Research Network](#) and the [Biospecimen Research Database](#), development of [NCI Best Practices for Biospecimen Resources](#), and sponsoring a series of [Biospeciman Best Practices Forums](#).

The [Cancer Biomedical Informatics Grid \(caBIG™\)](#) has developed tissue bank repository tools and supports the [Shared Biospecimen Data Directory](#).

Contact staff in the [Office of Biorepositories and Biospecimen Research](#) or [Cancer Diagnosis Program](#) for more information.

- **How do patient advocates participate in NCI's research activities and programs?**

The NCI has established the Consumer Advocates in Research and Related Activities (CARRA) program within the Office of Advocacy Relations (OAR). The CARRA program was created to integrate the perspective of people affected by cancer into a wide range of NCI's programs and activities, including peer review of clinical research. See [CARRA web page](#) for more information.

- **Is there a nomination process for the Clinical Trials and Translational Research Advisory Committee (CTAC) membership? How is this committee being constituted?**

There is not a nomination process. The CTAC includes current members from the major NCI boards/committees and representatives from the appropriate clinical and scientific areas. See CTAC web site for meeting schedule, minutes, and membership: <http://deainfo.nci.nih.gov/advisory/ctac/ctac.htm>

