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CTEP (Cancer Therapy Evaluation Program)

CTEP was formed by the National Cancer Institute (NCI) within the Division of Cancer Treatment and Diagnosis (DCTD). Its mission is to improve the lives of cancer patients by finding better ways to treat, control, and cure cancer. To this end, CTEP funds a robust national program of cancer research and sponsors clinical trials to investigate new anti-cancer agents, placing importance on translational research, the practical application of scientific findings.

CTEP uses a scientific process to accomplish its goals. Basic scientific findings are first identified based on scientific criteria and therapeutic needs. New anti-cancer agents fitting specific criteria are then selected and clinical trials are developed. Next, the agents are investigated in clinical trials. Finally, promising new cancer treatments are meticulously compared to the most efficacious existing treatments in clinical trials to define the best treatments for specific types of cancer. Importantly, the goal is to find an effective treatment for a disease, rather than to find a function for a particular research agent.

CTEP is organized into nine distinct branches and offices, each with its own functions and responsibilities.

The Office of the Associate Director (OAD) oversees the other eight branches and CTEP as a whole. Since 2008, Jeffrey Abrams, MD, has served as the Associate Director. He also currently serves as the NCI's Acting Director for Clinical Research.

Each of the other eight branches has its own branch chief and specific duties and functions.

The Clinical Grants and Contracts Branch (CGCB) main function is to oversee translational research grants and cooperative agreements, specifically in the fields of clinical oncology, surgical oncology, and pharmacogenomics, that is, how a person's genes affect his or her response to drugs.

The Clinical Investigations Branch (CIB) function is the scientific oversight, coordination of, and collaboration with all programs, organizations, and forms of research supported by CTEP.

The monitoring and auditing of all clinical trials sponsored by CTEP/Division of Cancer Treatment, NCI, as well as some cancer prevention trials sponsored by the Division of Cancer Treatment, is the responsibility of the Clinical Trials Monitoring Branch (CTMB). In order to ensure that trial data is accurate and in compliance with regulatory guidelines, this branch provides guidance and oversight for the conduct of clinical trials and serves as a liaison with the Food and Drug Administration (FDA), among other regulatory groups.

The Investigational Drug Branch (IDB) manages a cutting edge research therapeutics program, including Phase I, Phase II, and Phase III trials. The branch is comprised of three sections, each with its own portfolio of research agents under study.

The Pharmaceutical Management Branch (PMB) is responsible for providing pharmaceutical assistance and oversight for CTEP-sponsored trials. Their main functions are providing information related to all aspects of IND (Investigational New Drug) agents, approving the use of IND agents and the subsequent distribution of these agents to participating investigators and institutions, and handling special situations involving the use and supply of CTEP IND agents. In addition, this branch registers all investigators and other staff taking part in CTEP clinical trials, and manages these records.

The Operations and Informatics Branch (OIB) was created in 2008 by combining the Protocol and Information Office and the CTEP Enterprise System (ESYS). In brief, this branch facilitates the process by which protocols are developed and operated, and manages data related to CTEP regulated protocols.

The Regulatory Affairs Branch (RAB) encompasses two separate groups: the Drug Regulatory Group and the Agreement Coordination Group. The Drug Regulatory Group provides support and oversight in the development of INDs, particularly with regard to FDA compliance. This group also provides regulatory assistance and information to NCI staff and external staff involved in the drug development process. The Agreement Coordination Group develops and coordinates pharmaceutical agreements to facilitate the evaluation of new drugs.

The Administrative Resource Center (ARC) is responsible for providing administrative services to aid the progress of cancer research. The Center lists its values as integrity, respect, perseverance, trust, and reliability.

CTEP as a whole works to develop collaborations within the research community and cooperates with the pharmaceutical and biotechnology industries to develop new treatments for cancer. When selecting trials for National Cancer Institute (NCI) sponsorship, CTEP considers unmet treatment needs and avoids duplication of research in the private sector.

Due in large part to its public and private partnerships, CTEP has become one of the largest sponsors of cancer studies in the world. As such, the organization provides oversight to a myriad of research groups, including the NCI Cooperative Group Program, the Experimental Therapeutics Clinical Trials Network (ETCTN), the National Clinical Trials Network (NCTN), and a number of additional NCI initiatives and collaborations.

The NCI Cooperative Group Program currently includes: COG (Children's Oncology Group), ECOG (Eastern Cooperative Oncology Group) - ACRIN (American College of Radiology Imaging Network), NRG, which itself is comprised of NSABP (National Surgical and Bowel Project), RTOG (Radiation Therapy Oncology Group), and GOG (Gynecologic Oncology Group), NCI-CCTG (National Cancer Institute of Canada, Clinical Trials Group), and SWOG (Southwest Oncology Group).

Other initiatives and collaborations supported by CTEP include the Adult Brain Tumor Consortium, the Pediatric Brain Tumor Consortium, the Pediatric Preclinical Testing Program, the Childhood Cancer Survivor Study, New Approaches to Neuroblastoma Therapy, Blood and Marrow Clinical Trials Network (BMT CTN), Myeloproliferative Disorders Research Consortium, The Children’s Oncology Group (COG) Phase I/Pilot Consortium, International Collaborations, the Phase 2 N01 Program, Early Drug Development Program (EDDP), Cancer Stem Cell (CSC) Therapeutics Initiative, the Michaele C. Christian Oncology Development Lectureship and Award, and Workshops on Adolescent and Young Adult Oncology.

Lorna Rogahn

See Also: Clinical Trials; Experimental Cancer Drugs; Food and Drug Administration; Government; National Cancer Institute.

Further Readings

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