

CENTER FOR STRATEGIC SCIENTIFIC INITIATIVES

Enabling Progress in Cancer Research Through Advanced Technologies, Trans-disciplinary Programs, and Foundational Resources

In the latter part of the 20th century, and especially in the last decade, advanced technologies have fueled an unprecedented period of discovery and driven progress in the molecular sciences that promises to revolutionize cancer medicine. To capitalize on advances in areas such as genomics and nanotechnology, and to ensure that state-of-the-art foundational resources are broadly available to all cancer researchers, the National Cancer Institute (NCI) created the Center for Strategic Scientific Initiatives (CSSI) in 2004. CSSI serves as a strategic focus for innovative programs that range from exploratory pilot programs to the development of national resources that serve the overall cancer research community. In aggregate, these efforts are designed to accelerate progress toward a future of personalized cancer medicine.

The Center's approach is embodied in its name. In close collaboration with the extramural cancer research and other scientific communities, CSSI examines the continuum of research to identify major barriers to progress, and organizes and conducts workshops and think tanks to devise strategies that address those barriers through carefully planned initiatives.

The CSSI mission is to remove barriers to progress in cancer research, replace obstacles with opportunities, and speed momentum toward clinical applications for people living with cancer, those who will be diagnosed, and most importantly, those who will benefit from prevention strategies.

CSSI adheres to a set of basic principles that define each program, including extensive conversations with the extramural communities; milestone-driven plans; trans-disciplinary team science; and publicly available, broadly accessible, multi-dimensional data. In all that the Center undertakes, innovation and new ideas are encouraged and rewarded.

CSSI OFFICE OF THE DIRECTOR

<http://cssi.cancer.gov>

Acting Director: Douglas Lowy, M.D.

Deputy Director: Jerry S.H. Lee, Ph.D.

The Center for Strategic Scientific Initiatives Office of the Director (CSSI OD) is responsible for providing oversight and coordination of scientific and programmatic activities within its offices to effectively carry out the mission of CSSI. This includes facilitating extensive reviews and approvals from the NCI Scientific Program Leaders, NCI Board of Scientific Advisors, and National Cancer Advisory Board.

The CSSI OD also oversees programmatic management of the NCI's Provocative Questions (PQ) Initiative and the Innovative Molecular Analysis Technologies (IMAT) Program. Both of these programs function as trans-divisional, highly collaborative efforts that span multiple disciplines in cancer research to most effectively achieve their goals.

PROVOCATIVE QUESTIONS (PQ) INITIATIVE

<http://provocativequestions.nci.nih.gov/>

Program Director: Emily Greenspan, Ph.D.

The PQ Initiative was established by the NCI's Director, Dr. Harold Varmus, in 2010 to support innovative research projects designed to solve specific problems in cancer research that have been identified by the extramural research community and the NCI as understudied, neglected, and paradoxical, or that have been difficult to address in the past. For the first time, the NCI asked extramural scientists from various fields relevant to cancer research to identify and propose cancer-relevant problems of

recognized high importance that had little existing research and required a renewed focus or different perspective. The first three issuances of the PQ RFAs have received an extremely positive response from the cancer research community, with over 170 distinct R01 and R21 awards being made to date. Future directions for the PQ initiative include expanding the workshops used to identify new questions to a global effort in order to continue to identify the most ignored or overlooked cancer-relevant problems throughout the world.

INNOVATIVE MOLECULAR ANALYSIS TECHNOLOGIES (IMAT) PROGRAM

<http://innovation.cancer.gov/>

Program Director: Tony Dickherber, Ph.D.

The IMAT Program was established to support the development of tools and methods to accelerate the ability of cancer researchers to make new discoveries, expand understanding of cancer etiology and proliferation, improve detection capabilities, develop diagnostic methods and treatment strategies, conduct large population studies, address and reduce disparities in clinical care, and assist in clinical decision-making. The program is unique by virtue of its exclusive focus on technology development and emphasis on both a high degree of innovation and potential for improved molecular and cellular analysis and targeting capabilities of cancers and their host environment. More than 600 distinct grant awards have been made toward supporting more effective instrumentation, platforms, techniques, devices, and analytical tools that represent a substantial improvement over the current state of the art.

OFFICE OF CANCER CLINICAL PROTEOMICS RESEARCH (OCCPR)

<http://proteomics.cancer.gov>

Director: Henry Rodriguez, Ph.D., M.B.A., M.S.

OCCPR through programs such as the Clinical Proteomic Tumor Analysis Consortium (CPTAC) is beginning to bridge the knowledge gap in cancer between genotype and phenotype through proteomics and generating unique public datasets that integrate proteomic and genomic data on tumor samples previously analyzed by The Cancer Genome Atlas (TCGA) Program. CPTAC adds to NCI's ongoing initiatives in clinical molecular biology that comprehensively characterize tumors and make its findings and resources publicly available. CPTAC is a comprehensive and coordinated effort to accelerate the understanding of the molecular basis of cancer through the application of robust, quantitative, proteomic technologies and workflows. CPTAC:

- Reported the first large-scale integrated proteomic and genomic analysis of a human cancer (colorectal) that demonstrated how proteomics can help explain how genomic abnormalities drive cancer (July 20, 2014, Nature).
- Released the largest public datasets covering the proteome integrated with the genome on ovarian cancer and breast cancer (tumors previously analyzed by TCGA).
- In cooperation with the NCI RAS Initiative, initiated the development of quantitative multiplexed proteomic assays against RAS protein/peptide targets of interest. Assays, reagents, and SOPs developed will be provided to the public as a community resource to enable studies by cancer researchers in unraveling the oncogenic role of the RAS proteins in many cancers.
- Streamlined the regulatory process for protein-based multiplex assays by coordinating with the U.S. Food and Drug Administration (FDA), American Association for Clinical Chemistry (AACC), academia, and industry to create the first-ever mock 510(k) pre-market submission documents. These documents help orient the FDA to protein-based multiplex assays in novel diagnostics and serve as a springboard for guidance to the proteomics community on properly designing studies that address the FDA's questions on protein-based in vitro diagnostic (IVD) device clearance.
- Led an international effort to develop data release/sharing policies for proteomics raw data files. The policies, known as the "Amsterdam Principles," align data-release practices for proteomics with those of genomics, and aspects have been adopted by journals.
- Established NCI's Antibody Characterization Program (<http://antibodies.cancer.gov>), which serves as a community resource of unbiased antibody

validation in a centralized location for a large variety of antibodies, with all reagents and characterization data made publicly available.

- Established NCI's Proteomics Data Portal, (<https://cptac-data-portal.georgetown.edu/cptacPublic/>), which provides a platform for researchers to search, download, and analyze raw datasets generated by CPTAC (with connectivity to TCGA's databases).
- Launched NCI's Proteomics Assay Portal, (<https://assays.cancer.gov/>), the first community Web-based portal of standardized multiplex proteomic targeted assays. This community Web-based repository for well-characterized quantitative proteomic assays serves as a public resource of methodologies and data related to cancer-associated targets – critical in protein characterization and understanding the basis of diseases.

OFFICE OF CANCER NANOTECHNOLOGY RESEARCH (OCNR)

<http://nano.cancer.gov>

Director: Piotr Grodzinski, Ph.D.

OCNR oversees the NCI Alliance for Nanotechnology in Cancer, a program pioneering the development and deployment of nanotechnology-based diagnostics and therapeutics. These new technologies make earlier and more effective disease diagnosis possible and deliver therapies with reduced side effects.

- Established a network of cancer nanotechnology research centers, stand-alone career development awards, and research projects across the United States. Individual projects developed new technologies, devices, and materials for innovative drug delivery, new imaging modalities, and in vitro diagnostics, while center infrastructure and resources were used to translate promising approaches into clinical practice.
- Established cancer nanotechnology training centers to educate and train early career researchers originating from diverse science and technology fields. Training centers relied on mentored laboratory-based training, courses, seminars, and career development activities.
- Academic researchers and entrepreneurs funded by the program formed more than 75 companies to enable clinical translation and commercialization of maturing nanotherapeutics and nanotechnology-based diagnostics by substantially leveraging NCI funds invested in the program.
- Established the Nanotechnology Characterization Laboratory (NCL) (<http://ncl.cancer.gov/>) within Frederick National Laboratory for Cancer Research to perform preclinical characterization of nanomaterials using a comprehensive battery of assays. The operation of NCL relies on collaboration with the FDA and the National Institute of Standards and Technology to aid regulatory approval of new nanotechnology-based therapeutics.
- Initiated Translation of Nanotechnology in Cancer (TONIC) Consortium (<http://nano.cancer.gov/collaborate/collaborating/nanotechnology.asp>), a public-private partnership promoting translational research and development opportunities for commercialized nanotechnology-based cancer solutions. TONIC facilitates collaborations involving government, academia, industry, and advocacy groups; membership has grown to include 19 companies and health care-related organizations.



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To learn more about funding opportunities, please visit:
http://cssi.cancer.gov/resources-current_funding.asp

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