NIH NATIONAL CANCER INSTITUTE

pipeline news

November 2016

DCTD Division of Cancer Treatment and Diagnosis

DCTD Staff Highlight: Stephen Creekmore, PhD, MD

Stephen Creekmore, PhD, MD, who recently retired from NCI after 29 years, was Chief of the Biological Resources Branch (BRB), Developmental Therapeutics Program (DTP), Division of Cancer Treatment and Diagnosis (DCTD) since 1987. BRB is an extramural branch that supports clinical and laboratory research in biological therapeutics, using both grant- and contract-funded mechanisms. These programs include development of cytokines and other recombinant proteins, vaccines, monoclonal antibodies, and genetically modified viruses, bacteria, and mammalian cells. BRB oversees an NCI grant portfolio of biologic and immunotherapeutic approaches to treating cancer, with about 150 funded grants totaling approximately $35 million per year.

A unique feature of BRB, which distinguishes itself from other branches in DTP and DCTD, is the close proximity of the biological

Dinutuximab (Unituxin) – approved for use in combination with GM-CSF, IL-2 and 13-cis-retinoic acid for high-risk neuroblastoma in pediatric patients.

grants program with BRB contract resources for production. As a result of this relationship, and with Dr. Creekmore's critical support, the Biopharmaceutical Development Program (BDP) was established in 1993. Dr. Creekmore was also the Contracting Officer's Representative for BDP within the Operations and Technical Support Contract at the Frederick National Laboratory for Cancer Research (FNLCR). BDP was envisioned as an advanced development program, similar to a model used in other industries, where pilot concepts could be explored at relatively small scale with transfer of the most promising technologies to large-scale commercial production. Many BRB accomplishments were facilitated by this dual-functional setup, since senior BRB staff could identify potential biological drug candidates from the grants portfolio for referral to an independent review for access to clinical development resources. BDP supports a wide range of biological products in early clinical development for cancer, infectious disease, and other indications, has completed more than 100 projects, has released more than 225 lots of different products, and has seen more than 50 agents move to human clinical trials. Many former BDP clinical products are deposited in BRB's Preclinical Repository, which is a resource for academic investigators to obtain reagents.

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Dr. Creekmore's work has resulted in more than 50 publications, many on topics related to clinical development of cytokines, vaccines, and immunotoxins. During Dr. Creekmore's tenure at NCI, three biological drugs were FDA-approved for clinical use after obtaining BRB input through BRB grants, contracts, or the DTP Cooperative Agreement portfolio: Dinutuximab (2015), Erbitux (2004), and Ontak (1998). Dr. Creekmore has provided input to other technological activities at NIH, including serving on peer-review panels for drug development grants and contracts funded by NIH programs outside of NCI. Dr. Creekmore received his PhD in Physics from the California Institute of Technology and his MD from the University of California, San Francisco, and after completing his Medical Oncology Fellowship at NCI, he spent five years on the faculty at Loyola University Medical School. He returned to NCI in 1987 to join DTP. During his 32 years as a federal government employee, Dr. Creekmore received four NIH Merit Awards. Following his retirement, Dr. Creekmore continues his work as a DTP Special Volunteer to assist and troubleshoot scientific, technical, and management issues relating to preclinical and clinical development of novel biological agents.

DCTD staff are grateful that Dr. Creekmore remains a DCTD colleague, but staff are especially appreciative to continue to experience his sense of humor and infectious laugh. Congratulations on your retirement, Dr. Creekmore – we are happy that you are remaining part of the team.

Spotlight: The Precision Medicine Initiative: DCTD's Strategic Efforts

In 2016, President Obama announced a Precision Medicine Initiative® (PMI) to advance health and treatments for disease through research that considers an individual's genes, lifestyle, and environment. The PMI provided FY2016 resources to FDA and NIH, including funding for NCI to focus research on precision medicine in oncology. Discussions and collaborations across NCI's divisions led to the development of NCI's PMI oncology strategic areas. As part of NCI's contribution to this initiative, DCTD directed new funding towards expanding its portfolio of genomic-based clinical trials, improving our understanding of resistance to targeted agents and drug combinations, and developing a mechanistic understanding of immunotherapy. The PMI was also focused on improving pre-clinical models for evaluating targeted therapeutics. Finally, a major component of this overall effort was the 2016 launch of NCI's Genomic Data Commons (GDC), which is a data sharing platform for precision medicine in oncology. Molecular data from DCTD-supported clinical trials will be deposited into the GDC in order to foster and encourage data mining and secondary analyses by a broad range of investigators.

To begin this initiative, and to accelerate progress in multiple areas, DCTD announced a series of administrative 1-year supplement awards for 2016. Eligible parent grants for these supplements included P30 (Cancer Centers), P50 (SPORES), and UM1 / U10 Cooperative Agreements (Experimental Therapeutics Clinical Trials Network - ETCTN and National Clinical Trials Network - NCTN, respectively). In total, 53 awards were made (see tables below) for this supplement initiative from a total of 144 applications. In the coming years, DCTD hopes to spark increased activity in the areas that were supplemented in 2016 by issuing Requests for Applications (RFAs) on these topics.

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Improvements and Optimization of T-cell Therapies and cGMP Manufacturing Processes for Production of Autologous T-cell Therapy Products Targeting Solid Cancers

- Optimize an antigen-specific T-cell product against a solid tumor antigen (surface antigen or tumor specific MHC:peptide complex)
- Demonstrate that the tumor infiltrating lymphocyte, chimeric antigen receptor, or T-cell receptor autologous T-cell product can be prepared according to current Good Manufacturing Practices specifications, such that it could be utilized in a multi-center trial

PROJECT PI(s)	PARENT GRANT PI	INSTITUTION
Chantale Bernatchez, Elizabeth Shpall	Ronald DePinho	University of Texas, MD Anderson Cancer Center
Linda Kelley, James Mulé	Thomas A. Sellers	H. Lee Moffitt Cancer Center and Research Institute
Isabelle Rivière, Michel Sadelain	Craig B. Thompson	Sloan-Kettering Institute for Cancer Research

Biomarker Studies Associated with NCI-supported Clinical Trials of Immunotherapy

- Support biomarker assays and analysis in immunotherapy trials
- Support efforts to develop or facilitate data integration, and cross-trial analysis

PROJECT PI(s)	PARENT GRANT PI	INSTITUTION
Michael B. Atkins, Geoffrey T. Gibney	Louis M. Weiner	Georgetown University
Lisa H. Butterfield	Nancy E. Davidson	University of Pittsburgh
Martin (Mac) Cheever	Gary D. Gilliland	Fred Hutchinson Cancer Research Center
Sandra P. D'Angelo	Monica M. Bertagnolli	Brigham and Women's Hospital, Alliance for Clinical Trials in Oncology
Thomas Gajewski	Michelle M. Le Beau	University of Chicago
David Gerber	Melanie H. Cobb	University of Texas, Southwestern Medical Center
F. Stephen Hodi	Edward J. Benz	Dana-Farber Cancer Institute
Michael Lim	Stuart A. Grossman	Adult Brain Tumor Consortium
Patricia M. LoRusso	Peter G. Schulam	Yale University
Emanuel Maverakis, Joseph Tuscano	Ralph W. de Vere White	University of California, Davis Comprehensive Cancer Center
Kunle Odunsi	Kunle Odunsi	Roswell Park Cancer Institute
Ravi Salgia	Steven T. Rosen	Beckman Research Institute/City of Hope
Ignacio I. Wistuba	Ronald A. DePinho	University of Texas, MD Anderson Cancer Center

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Mechanisms of Cancer Sensitivity and Resistance to Therapy Utilizing Samples and Information from Human Clinical Trials

- Investigate mechanisms of intrinsic and acquired drug resistance in tumor biopsies, blood samples, or other biological material from patients on trials with targeted anti-cancer agents
- Understand the genetic and cellular basis for increased sensitivity of cancer to treatment with agents targeting DNA damage response, apoptosis, and epigenetic pathways, and corroborate with analysis of tumor specimens and clinical outcomes from trials

PROJECT PI(s)	PARENT GRANT PI	INSTITUTION
Nathalie Agar, Jann Sarkaria, Forest White	Tyler Jacks	Massachusetts Institute of Technology
Carlos L. Arteaga	Carlos L. Arteaga	Vanderbilt University Medical Center
Himisha Beltran, Martin Gleave, Susan Halabi, Alexander Wyatt	Monica M. Bertagnolli	Brigham and Women's Hospital, Alliance for Clinical Trials in Oncology
Brian J. Druker	Brian J. Druker	Oregon Health & Science University
Felix Fang	Alan Ashworth	University of California, San Francisco
Christos Hatzis, Lajos Pusztai	Peter G. Schulam	Yale University
Ross Levine	Craig B. Thompson	Sloan-Kettering Institute for Cancer Research
Don Nguyen, Katerina Politi, Narendra Wajapeyee	Roy S. Herbst	Yale University, SPORE grant
Katherine Pogue-Geile	Norman Wolmark	NRG Oncology Foundation, Inc.
Thomas Witzig	Robert B. Diasio	Mayo Clinic Cancer Center

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Administrative Supplements for Research in Canine Immunotherapy via Collaboration of NCI-designated Cancer Centers and Veterinary Medical Colleges

- Establish the suitability of canine models to study single and combination immunomodulating agents (with molecularly targeted drugs or chemotherapeutics)
- Sequence canine cancers and control specimens to determine the mutational load and identify neoantigens that could be used as targets for immunotherapy

PROJECT PI(s)	PARENT GRANT PI	INSTITUTION
Amy Heimberger	Ronald A. DePinho	University of Texas, MD Anderson Cancer Center
Katherine Janeway	Edward J. Benz	Dana-Farber Cancer Institute
Deborah Knapp	Timothy L. Ratliff	Purdue University
Richard Koya	Candace S. Johnson	Roswell Park Cancer Institute
Jonathan Levitt, David Wheeler	C. Kent Osborne	Baylor College of Medicine
Arta Monjazeb	Ralph W. de Vere White	University of California, Davis Comprehensive Cancer Center
Peter Shields	Michael A. Caligiuri	Ohio State University
Jill Slansky	Dan Theodorescu	University of Colorado, Denver

Studies of How the Microenvironment of Pancreatic Ductal Adenocarcinoma Affects Immunotherapy

- Understand the interaction between tumors and the microenvironment to design new immunotherapy interventions

PROJECT PI(s)	PARENT GRANT PI	INSTITUTION
Vinod Balachandran, Steven D. Leach	Craig B. Thompson	Sloan-Kettering Institute for Cancer Research
John Condeelis	I. David Goldman	Albert Einstein College of Medicine
Howard Crawford, Marina Pasca di Magliano	Theodore S. Lawrence	University of Michigan
David DeNardo	Timothy J. Eberlein	Washington University
Robert Vonderheide	Chi V. Dang	University of Pennsylvania
Sunil Hingorani	Gary D. Gilliland	Fred Hutchinson Cancer Research Center
Michael A. Hollingsworth	Michael A. Hollingsworth	University of Nebraska Medical Center
Richard Hynes	Tyler Jacks	Massachusetts Institute of Technology
Kenneth P. Olive	Stephen G. Emerson	Columbia University Health Sciences

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Collaborative Research Efforts to Enhance Preclinical Drug Development and Preclinical Clinical Trials Utilizing Patient Derived Xenograft (PDX) Models

- Develop and characterize new non-hematopoietic PDX models to test cancer therapies, including drug combinations and NCI-IND agents
- Demonstrate the capability to test existing PDX models against NCI-IND agents and combinations for tumor response, integrate and analyze PDX molecular characteristics against response to therapeutic regimens, and collaborate with NCI-funded investigators to study mechanisms of drugs sensitivity and resistance

PROJECT PI(s)	PARENT GRANT PI	INSTITUTION
Carol Bult	Edison Tak-Bun Liu	Jackson Laboratory
Eva Corey	Peter S. Nelson	Fred Hutchinson Cancer Research Center
Bingliang Fang	John D. Minna	University of Texas, Southwestern Medical Center
Barbara Foster	Candace S. Johnson	Roswell Park Cancer Institute
Michael Lewis	C. Kent Osborne	Baylor College of Medicine
Funda Meric-Bernstam	Funda Meric-Bernstam	MD Anderson Cancer Center
Ann Richmond	Jennifer A. Pietenpol	Vanderbilt-Ingram Cancer Center
Jann Sarkaria	Robert Diasio	Mayo Clinic Cancer Center
Alana Welm	Mary C. Beckerle	University of Utah
Agnieszka Witkiewicz	Andrew S. Kraft	University of Arizona

In addition to these supplements, the PMI provided DCTD with funds to enable several important additions to ongoing clinical trials and new initiatives:

- Increase screening to the NCI-MATCH trial from 5,000 to 6,000 patients
- Perform whole exome sequencing and RNA sequencing on approximately 1,000 patients treated with targeted agents on NCI-MATCH
- Perform genomic panel sequencing (somatic and germline) in patients screened for NCI-Pediatric MATCH
- Develop special initiatives to collect tumor specimens for generation of PDX models from minority and underserved patients
- Develop special initiatives to collect pre- and post-treatment specimens from NCORP sites treating patients with approved, molecularly-targeted regimens
- Launch an NCI Formulary program to provide novel targeted agents to investigators from pharmaceutical partners to enhance the development of combination therapy

News about DCTD Programs and Activities

Publications

- In collaboration with scientists from Cancer Research UK, EORTC, and academia, **Lalitha Shankar, MD, PhD** and **Laurence Clarke, PhD**, Cancer Imaging Program and **Lisa McShane, PhD** and **Erich Huang, PhD,** Biometric Research Program contributed to "Imaging Biomarker Roadmap for Cancer Studies." The paper was published online on October 11, 2016 in *Nature Reviews in Oncology* and presents 14 key recommendations to accelerate clinical translation of imaging biomarkers.

- DCTD staff published "Small Cell Lung Cancer Screen of Oncology Drugs, Investigational Agents, and Gene and microRNA Expression" in the *Journal of the National Cancer Institute* in October 2016. The full compound, gene expression, and microRNA data sets for the human small cell lung cancer lines discussed in the paper are publicly available at the Small Cell Lung Cancer Project Site Navigation site.

- The August 2016 issue of *Seminars in Oncology* focuses exclusively on pharmacodynamics in cancer drug development. NCI staff from DCTD and the Clinical Pharmacodynamics Program, Leidos Biomedical Research, Inc., Frederick National Laboratory for Cancer Research were invited to co-edit this special issue.

- DCTD staff contributed to five recent NCI *Cancer Currents* blog posts:

  CA-125 Testing, CT Scans Still Used for Ovarian Cancer Surveillance Despite Lack of Proven Benefit, **Elise Kohn, MD**, Cancer Therapy Evaluation Program

  Approach May Allow for Stem Cell Transplant without Radiation, Chemotherapy, **Richard Little, MD**, Cancer Therapy Evaluation Program

  Avelumab Induces Sustained Tumor Responses in Some Patients with Rare Skin Cancer, **Elad Sharon, MD, MPH**, Cancer Therapy Evaluation Program

  Educating Patients about Genetic Test Results: An Interview with Carol Weil about the COMET Study, **Carol Weil, JD**, Cancer Diagnosis Program

  Olaratumab Approved to Treat Advanced Soft Tissue Sarcoma, **Alice Chen, MD**, Developmental Therapeutics Clinic, and **Peter Ujhazy, MD, PhD**, Translational Research Program

Meeting Participation

- Several Cancer Diagnosis Program staff presented posters at the 2016 ISBER Regional Meeting (November 7-8, 2016; Bethesda, MD). The following abstracts are publicly available:
  - The National Cancer Institute's 2016 Best Practices for Biospecimen Resources: Revised Recommendations (P-13)
  - An Online Viewer for GTEx Histological Images (P-14)
  - Recruiting Biospecimen Resources to Participate in The National Cancer Institute's Specimen Resource Locator (P-23)
  - Building a Biobank for the NIH's Precision Medicine Initiative Cohort Program (P-25)
  - Making a Proven Vocabulary for Biobanking Available to the Research Community (P-50)

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Norm Coleman, MD
Associate Director, Radiation Research Program

- **Norm Coleman, MD**, Radiation Research Program, formally received the Failla Award at the 62nd Annual International Meeting of the Radiation Research Society (October 16-19, 2016; Big Island, Hawaii). Dr. Coleman presented a lecture entitled, "Radiation Stress Response: Of the People, By the People and for the People" with emphasis on the continuum of science, service, and society. The presentation discussed how radiation is an integral part of precision medicine, how radiation scientists could help society deal with the reality of radiation in our lives, including threats of radiation exposure from both accidental and intentional exposures, and how experts in cancer care can address the enormous gap in global cancer care.

- **Lalitha Shankar, MD, PhD,** Cancer Imaging Program, presented a Keynote lecture entitled, "Imaging and Genomics: Is There a Synergy?" at Thomas Jefferson University's 6th Annual Brain Tumor Symposium (October 28, 2016; Philadelphia, PA). The focus of the meeting was "Imaging the Brain for Diagnosis and Treatment Responses in Neuro-Oncology."

- **Ed Korn, PhD,** Biometric Research Program ("Phase III Design Considerations for Agents with a Potential Predictive Biomarker"), and **Elad Sharon, MD, MPH,** Cancer Therapy Evaluation Program ("A Global Picture of Immuno-Oncology Adverse Events"), presented at the FDA-AACR Immuno-oncology Drug Development Workshop (October 13-14, 2016; Washington, DC). Transcripts of all of the meeting presentations are available.

- **Geraldine O'Sullivan Coyne, MD, PhD,** Developmental Therapeutics Clinic, presented a poster at the ESMO 2016 Congress (October 7-11, 2016; Copenhagen, Denmark). The poster entitled, "First-in-human trial of 4'-thio-2'-deoxycytidine (TdCyd) in patients with advanced solid tumors,"* described the collaborative research of DCTD and Frederick National Laboratory for Cancer Research.

- **Carol Weil, JD,** Cancer Diagnosis Program recently presented two posters at NCI symposia: "Addressing Global Cancer Disparities through Biobanking" at NCI's Global Cancer Research Symposium (October 6, 2016; Rockville, MD) and "Barriers to Research Participation and Biospecimen Donation in Local Minority and Underserved Communities" at the Symposium on Cancer Health Disparities (October

Carol Weil, JD, Cancer Diagnosis Program

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18, 2016; Bethesda, MD). This work on cancer disparities, both domestically and globally, is a natural outgrowth of NCI's moonshot initiative and NIH's focus on precision medicine.

- Staff from the Cancer Diagnosis Program led the development of the "Workshop on Circulating Tumor DNA in Clinical Cancer Research" (September 29-30, 2016; Rockville, MD). The purpose of the meeting was to discuss and understand how to show clinical utility, clinical and analytical validation, and the potential use of circulating tumor DNA assays in NCI-supported clinical trials. The following DCTD staff were involved in the collaborative planning and implementation of this meeting:

  Cancer Diagnosis Program: **Lokesh Agrawal, PhD, Rodrigo Chuaqui, MD, Barbara Conley, MD, Sumana Dey, PhD, Ping Guan, PhD, Tracy Lively, PhD, Tawnya McKee, PhD, Miguel Ossandon, MS, Brian Sorg, PhD, James V. Tricoli, PhD**

  Cancer Imaging Program: **Gary Kelloff, MD**

  Radiation Research Program: **Eric Bernhard, PhD**

  Cancer Therapy Evaluation Program: **S. Percy Ivy, MD, Jeff Moscow, MD, John Wright, MD, PhD**

- The Cancer Therapy Evaluation Program convened its annual Early Drug Development meeting (September 26-27, 2016; Rockville, MD), which is an educational event focused on enhancing communications between NCI and the network of CTEP-supported Experimental Therapeutics Clinical Trials Network (ETCTN)-funded early clinical trial investigators. The meeting included a half-day educational session focused on improving research biopsy quality in the era of personalized medicine.

- **Lori Henderson, PhD,** Cancer Imaging Program, was invited by the President of the World Molecular Imaging Society to speak at the Presidential Opening session of the World Molecular Imaging Congress (WMIC) (September 6, 2016; New York, NY). As the Co-Chair appointed to the U.S. National Science and Technology Council's Subcommittee (NSTC) on Nanoscale Science, Engineering, and Technology, she presented the status of two Federal Initiatives: the *National Nanotechnology Initiative* (NNI) and the *Interagency Working Group on Medical Imaging* (IWGMI). The NNI was announced by President Clinton in 2000 and was signed into law by President Bush in December 2003. Federal Agencies are currently developing the NNI 2.0 Strategic Plan with guidance from the President's Council of Advisors on Science and Technology and in alignment with President Obama's goal for making Science and Technology a priority for the 21st century. Twenty departments and independent agencies work together towards "*a future in which the ability to understand and control matter at the nanoscale leads to a revolution in technology and industry that benefits society*." In FY2015, Congress called for the establishment of the IWGMI, which has been tasked with developing a strategic roadmap that identifies opportunities to advance imaging science research and technologies. NIH and the National Institute of Standards and Technology are leading this initiative with representation from DCTD's Imaging-related Programs (CIP and RRP) and the National Institute of Biomedical Imaging and Bioengineering colleagues.

- The Innovation in Biomarkers and Cancer Drug Development meeting was held on September 8-9, 2016 in Brussels, Belgium. Several DCTD staff members were involved in the planning and implementation of the meeting. Audio recordings of the presentations are available, and a review of the meeting was published in *Nature Reviews Clinical Oncology*.

Program Updates

- On October 19, 2016, FDA announced accelerated approval to combination olaratumab and doxorubicin in the treatment of adults with certain types of soft tissue sarcoma. This approval is the result, in part, of significant work performed by the Memorial Sloan-Kettering Cancer Center SPORE. The investigators published a paper in July 2016 reporting outcomes of a clinical trial of the drug combination. The achievements of this SPORE highlight NCI's and the Translational Research Program's impact on standard of care. A *Cancer Currents* blog describes the approval in more detail.

- The Translational Research Program recently announced its FY2016 SPORE grantees. There are now 54 active SPOREs located at academic centers in 21 states and one consortium across the country.

- On September 26-27, 2016, staff from the Office of Cancer Complementary and Alternative Medicine hosted a delegation of scientific collaborators from China to continue discussions of future collaborative initiatives and research.

- Patients who are newly enrolled to NCI's precision medicine clinical trial, NCI-Molecular Analysis for Therapy Choice (NCI-MATCH), may also choose to enroll in an ancillary study called COMET (COMmunication and Education in Tumor Profiling). The COMET study opened on September 26, 2016 and will gather data to determine whether informing cancer patients about the limitations and benefits of genetic testing will reduce distress levels by empowering patients with knowledge. A second component of COMET is a small pilot to assess the feasibility and preliminary outcomes of providing remote genetic counseling (by telephone) to patients in whom a potential inherited germline is found through their participation in NCI-MATCH.

- **Barry O'Keefe, PhD,** Developmental Therapeutics Program, was interviewed about natural products by New Hampshire Public Radio for their show, "Outside/In." The podcast was posted online on September 22, 2016.

- DCTD Researchers recently developed and validated immunoassays that measure MET (hepatocyte growth factor receptor) protein and phosphorylation levels at key amino acid residues. In late August 2016, DCTD announced that the MET Immunoassays were being transferred to the cancer research community, with training and certification provided at the Frederick National Laboratory for Cancer Research campus.

- The Cancer Diagnosis Program's educational video on cancer treatment and tissue donation received a silver National Health Information Award in August 2016. The awards program is coordinated by the Health Information Resource Center, a national clearinghouse for consumer health information programs and materials.

New Funding Opportunities

PAR-17-003: *Revision Applications for Validation of Biomarker Assays Developed through NIH-supported Research Grants (RO1)*

The purpose of this Funding Opportunity Announcement is to accelerate the pace of translation of NCI-supported methods/assays/technologies to the clinic, with a focus on the adaptation and clinical validation of molecular/cellular/imaging biomarkers for cancer detection, diagnosis, prognosis, monitoring, and prediction of response to treatment, as well as control and prevention.

Honors and Awards

Paula Jacobs, PhD, Cancer Imaging Program, was appointed to the Food and Drug Administration Medical Imaging Drugs Advisory Committee (MIDAC). The MIDAC reviews and evaluates data concerning the safety and effectiveness of marketed and investigational human drug products for use in diagnostic and therapeutic procedures using radioactive pharmaceuticals and contrast media used in diagnostic radiology and makes appropriate recommendations to the Commissioner of Food and Drugs. Dr. Jacobs' term on the MIDAC began on September 28, 2016 and will continue until June 30, 2020.

2016 NCI Director's Awards – Presented October 20, 2016

CGH and NCI Collaborative Group for Research in India – Exceptional leadership in marshaling trans-NCI collaboration to foster cooperation in cancer research between scientists in the U.S. and India

Mansoor Ahmed, PhD, Radiation Research Program
Barry O'Keefe, PhD, Developmental Therapeutics Program
Pushpa Tandon, PhD, Cancer Imaging Program
Bhadrasain Vikram, MD, Radiation Research Program
Jeffrey White, MD, Office of Cancer Complementary and Alternative Medicine

PRO-CTCAE Scientific Leadership Team – Outstanding leadership and achievement in the development, testing, and implementation of a novel electronic patient-reported outcomes adverse event measurement system for cancer clinical trials

Alice Chen, MD, Developmental Therapeutics Clinic
Andrea Denicoff, MS, RN, Cancer Therapy Evaluation Program
Richard Piekarz, MD, PhD, Cancer Therapy Evaluation Program

NCI-NHLBI Cancer Treatment-related Cardiotoxicity Team – Extraordinary contributions to cancer and cardiovascular research through the development and implementation of a comprehensive, multi-institute approach to improve outcomes in cancer treatment-related cardiotoxicity

Myrtle Davis, DVM, PhD, Developmental Therapeutics Program

Exceptional and sustained performance as leader of the Biometric Research Program and contributions to clinical trial methodology and biostatistics

Richard Simon, PhD, Biometric Research Program

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Chimeric 14.18 Group – Key contributions to the regulatory approval of the first therapy specific for high-risk neuroblastoma: dinutuximab, in combination with GM-CSF, IL-2, and 13-cis-retinoic acid

Sherry Ansher, PhD, Cancer Therapy Evaluation Program
Mathew Boron, Cancer Therapy Evaluation Program
Jan Casadei, PhD, Cancer Therapy Evaluation Program
Shanda Finnigan, MPH, RN, Cancer Therapy Evaluation Program
Rodney Howells, Cancer Therapy Evaluation Program
Martha Kruhm, Cancer Therapy Evaluation Program
Jeffrey Moscow, MD, Cancer Therapy Evaluation Program
Rocio Paul, MSHS, CCRP, Cancer Therapy Evaluation Program
Gary Smith, Cancer Therapy Evaluation Program
Malcolm Smith, MD, PhD, Cancer Therapy Evaluation Program

CTCAE Core Committee – Exceptional leadership and stewardship in the revision and ongoing maintenance of the NCI Common Terminology Criteria for Adverse Events (CTCAE)

Alice Chen, MD, Developmental Therapeutics Clinic
Shanda Finnigan, MPH, RN, Cancer Therapy Evaluation Program
Richard Piekarz, MD, PhD, Cancer Therapy Evaluation Program
Nita Seibel, MD, Cancer Therapy Evaluation Program

ETCTN UM1 Phase 2 Supplement Implementation Group – Redesign and implementation of the Phase 2 program of the Experimental Therapeutics Clinical Trials Network to strengthen its capabilities

Jeffrey Abrams, MD, Cancer Therapy Evaluation Program
S. Percy Ivy, MD, Cancer Therapy Evaluation Program
Martha Kruhm, Cancer Therapy Evaluation Program
Yolanda Lake, Cancer Therapy Evaluation Program
Jeffrey Moscow, MD, Cancer Therapy Evaluation Program
Donna Shriner, PharmD, MPH, Cancer Therapy Evaluation Program
Gary Smith, Cancer Therapy Evaluation Program
Kim Witherspoon, Cancer Therapy Evaluation Program
James Zwiebel, MD, Cancer Therapy Evaluation Program

Immunotherapy Clinical Trials and Biomarkers Initiative Group – Leadership in enabling progress in clinical cancer immunotherapy by supporting the development of biomarkers and databases that foster integration across clinical and biomarker datasets

Jeffrey Abrams, MD, Cancer Therapy Evaluation Program
Helen Chen, MD, Cancer Therapy Evaluation Program
Barbara Conley, MD, Cancer Diagnosis Program
Toby Hecht, PhD, Translational Research Program
Tracy Lively, PhD, Cancer Diagnosis Program
Lisa McShane, PhD, Biometric Research Program
William Merritt, PhD, Cancer Therapy Evaluation Program
Elad Sharon, MD, MPH, Cancer Therapy Evaluation Program
Min Kyung Song, PhD, Cancer Therapy Evaluation Program
Howard Streicher, MD, Cancer Therapy Evaluation Program
Magdalena Thurin, PhD, Cancer Diagnosis Program
James Zwiebel, MD, Cancer Therapy Evaluation Program

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Papillary Renal Cancer MET Inhibitor Trial (PAPMET) Initiation Team – Identifying a clinical need for new targeted therapies in rare papillary renal cancers and innovative multi-agent trial design and organizing partnerships with pharmaceutical companies

Jeffrey Abrams, MD, Cancer Therapy Evaluation Program
Sherry Ansher, PhD, Cancer Therapy Evaluation Program
Tali Johnson, PharmD, Cancer Therapy Evaluation Program
Ravie Kem, PharmD, Cancer Therapy Evaluation Program
Bhupinder Mann, MBBS, Cancer Therapy Evaluation Program
Bhanumati Ramineni, MS, MS, Cancer Therapy Evaluation Program
Jennifer Thompson, Cancer Therapy Evaluation Program
John Wright, MD, Cancer Therapy Evaluation Program
Jianqiao Zhang, PhD, Cancer Therapy Evaluation Program

CTEP-ESYS Group – Exceptional vision and leadership in project conception, development, and commencement of the re-engineering of CTEP's integral IT infrastructure

Jeffrey Abrams, MD, Cancer Therapy Evaluation Program
Shanda Finnigan, MPH, RN, Cancer Therapy Evaluation Program
Martha Kruhm, Cancer Therapy Evaluation Program
Michael Montello, PharmD, MBA, Cancer Therapy Evaluation Program

Extraordinary efforts supporting all Human Resource functions in DCTD

Mark Foltz