



MESSAGE FROM DCTD'S DIRECTOR AND DEPUTY DIRECTOR



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As we begin a new year, we would like to express our appreciation for the cancer research community and the many talented DCTD staff members who remained dedicated to NCI's mission in 2021. Thank you to everyone who continues to work towards improving the lives of people with cancer during the challenges presented by the COVID-19 pandemic. Below we describe a few cancer research highlights

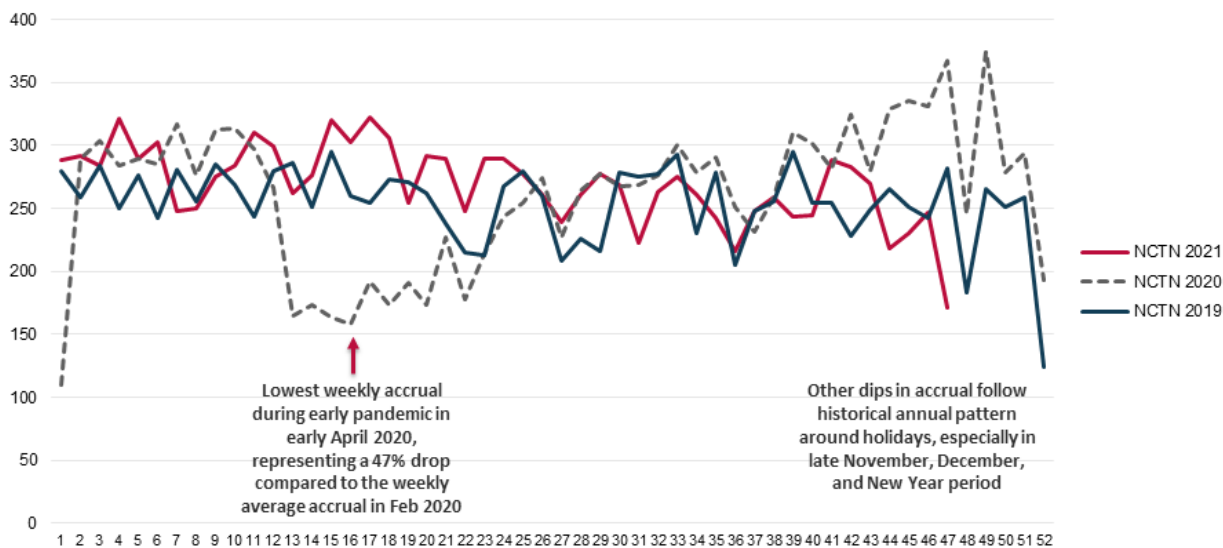
from the last 12 months that we hope will lead us strongly into 2022.

- Following a drop in accrual to the NCI's National Clinical Trials Network in the spring of 2020, accrual in the remainder of 2020 and through 2021 was consistent with pre-pandemic levels.

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Weekly NCTN Trial Intervention Accrual in 2019, 2020, & 2021 as of November 28, 2021



- In May 2021, the NCI Patient-Derived Models Repository (PDMR) reached a **milestone** when it surpassed development of its 500th patient-derived xenograft (PDX) model. Launched in 2017, the **PDMR** is a publicly accessible, national repository for early-passage, molecularly characterized patient-derived models developed from patients with solid tumors.
- In 2021, DCTD joined in the commemoration of the 50th anniversary of the National Cancer Act by reflecting on 50 years of advances in **drug development** and **cancer imaging**.
- Building upon its **initial efforts** over the last several years to support the production of CAR-T cells for clinical studies, the NCI Biopharmaceutical Development Program (BDP) at Frederick National Laboratory for Cancer Research **expanded its capabilities** to offer viral vector production. Investigators in need of clinical grade vector and/or cell therapy product manufacturing can apply through the **NCI Experimental Therapeutics (NExT) Program**.
- At the 2021 ASCO Annual Meeting, the Cancer Therapy Evaluation Program (CTEP) presented data on the **implementation of expanded eligibility criteria guidelines** in NCI trials. The analysis showed that more work is needed to ensure that eligibility criteria are as broad as safely possible to achieve diverse and representative populations in clinical trials.
- In the fall of 2021, NCI funded the **Glioblastoma Therapeutics Network**, which will work to drive the development of therapeutic agent(s) for glioblastoma from preclinical development, through IND studies, into pilot clinical studies in humans.

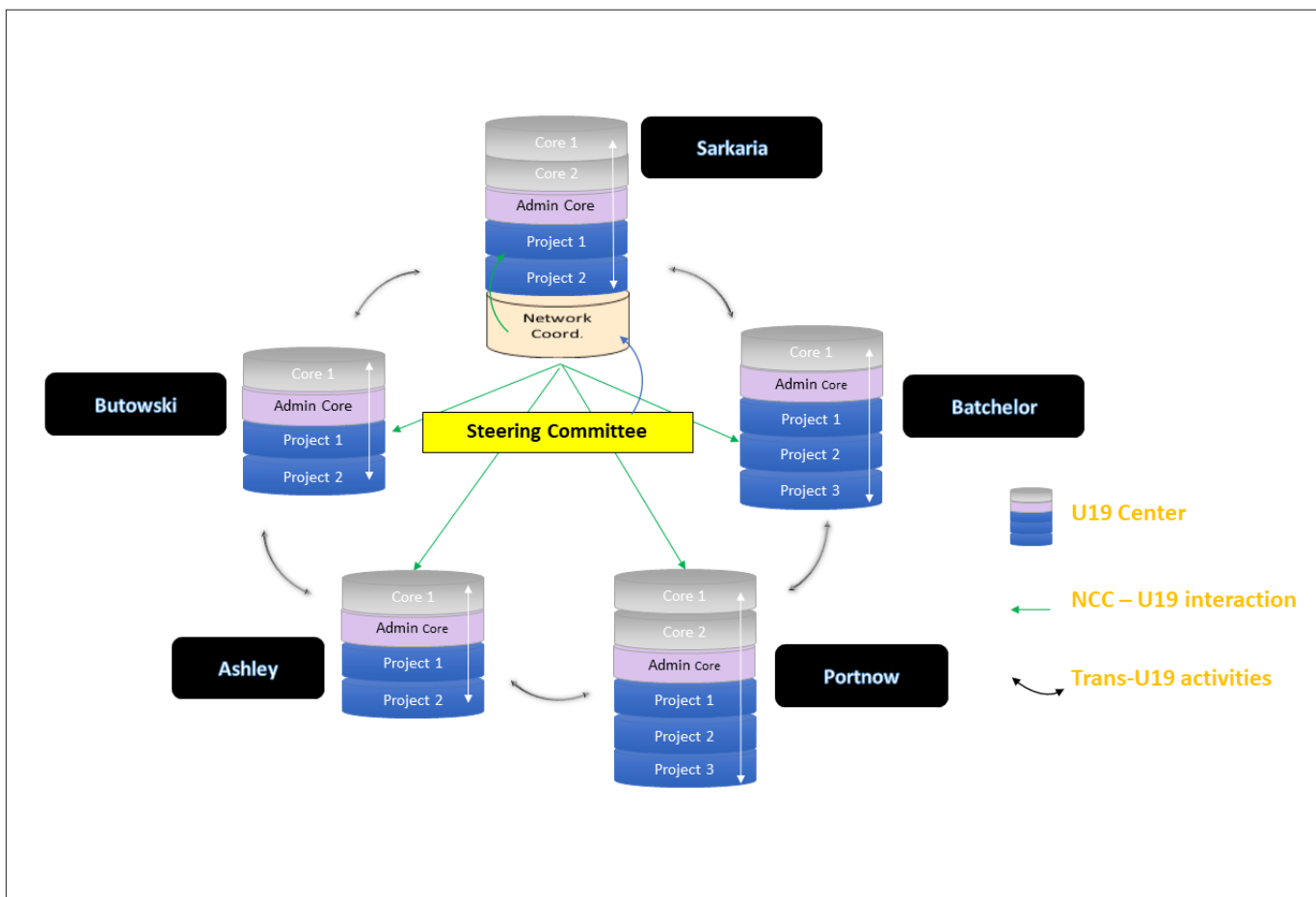


SPOTLIGHT - NCI-funded Glioblastoma Therapeutics Network (GTN) Is Working to Develop New Treatments

Despite enormous public and private investments into basic, translational, and clinical research for adult glioblastoma (GBM), treatment has not changed in 15 years due to significant challenges to progress. With the standard of care, the median survival is about 15 months and 5-year survival is less than 5%.

There is an urgent need to improve the treatment of adult GBM by developing novel, effective agents that can cross the blood-brain-barrier and testing them in the clinic.

The GTN comprises highly collaborative research teams ([RFA-CA-20-047](#)) that will drive therapeutic agent(s) from pre-clinical development, through IND studies, into pilot clinical studies in humans. Members cooperate between teams so that reagents, assay protocols, animal models, patient samples, technologies, and development of clinical protocols are shared. [Read more about this network.](#)



SPOTLIGHT - Drug Combination Helps Children with Acute Promyelocytic Leukemia Avoid Conventional Chemotherapy

A clinical trial recently found that the combination of all-trans retinoic acid and arsenic trioxide is highly effective in children with standard- and high-risk acute promyelocytic leukemia (APL). The results of the trial were published in [JAMA Oncology](#) on November 11, 2021.

Nearly all patients in the trial survived for two years without experiencing a relapse. None of

the children with standard-risk APL required conventional chemotherapy, and those with high-risk APL received just four doses of the chemotherapy drug idarubicin (Idamycin PFS). The Children's Oncology Group conducted and the NCI Cancer Therapy Evaluation Program funded this multi-institutional, nonrandomized phase 3 cooperative group trial. [Read the NCI press release.](#)



Dr. Matthew Kutny of Children's of Alabama and the University of Alabama at Birmingham examines Asher, who participated in the Children's Oncology Group trial that tested all-trans retinoic acid and arsenic trioxide for acute promyelocytic leukemia.

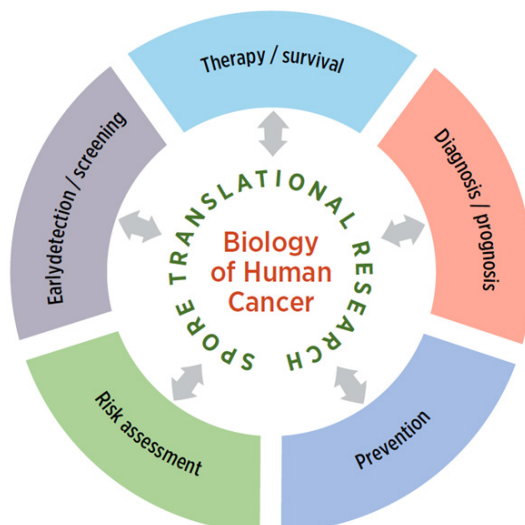
Credit: Patrick Deavours, Children's of Alabama

NEWS ABOUT DCTD PROGRAMS AND ACTIVITIES

Program Updates

The Translational Research Program (TRP) Announces Fiscal Year 2021 SPORE Grantees

TRP recently announced its successfully competed FY2021 SPORE grantees. The SPORE program uses the P50 and U54 grant funding mechanisms to promote collaborative, interdisciplinary, translational cancer multi-project research. SPOREs are primarily focused on organ site disease, but also on themes that cut across organ sites. [Read about the grantees and their projects.](#)



NCI Hosts FDA-NIH Workshop on Resource Requirements in Next Generation Sequencing and Radiomics



The NIH recently hosted the FDA-NIH Next Generation Sequencing and Radiomics Workshop: Resource Requirements for Acceleration of Clinical Applications Including AI. The goal was for the scientific community to discuss existing resource gaps and their impact on NGS and radiomics as well as strategies to

accelerate high-quality research, development, validation, and regulatory science. The workshop consisted of a keynote presentation by Anthony Kerlavage, PhD, NCI, on the NCI Research Data Commons and two plenary sessions on genomics and radiomics. [Read the meeting summary and view the recordings.](#)

NCI Convenes Workshop on Rational Drug Discovery



The Developmental Therapeutics Program held a workshop on Rational Drug Discovery to further understand the rapidly evolving scientific and technological advancements that are shaping cancer drug discovery. The workshop reviewed

the latest developments in the fields of structural biology, novel therapeutic modalities, target interrogation, and artificial intelligence in drug discovery. [Read the meeting summary and view the recordings.](#)

NCI Drug Development Workshop: How to Advance a Therapeutic Candidate from Bench to Bedside

NCI Drug Development Workshop:
How to Advance A Therapeutic Candidate from Bench to Bedside

Ten Discrete Webinars
Fridays, 12:00 pm – 2:30 pm ET · July 23, 2021 – December 10, 2021

Navigating through Investigational New Drug (IND)-enabling activities and acquiring the full set of resources for the preclinical stage of drug development are major research challenges. The Developmental Therapeutics Program convened a 10-part webinar series to provide

researchers with a guide to key IND-enabling activities and resources to facilitate successful translation of anti-cancer agents from the lab to the clinic. [Read the meeting summary and view the recordings.](#)

Updates from the Office of Cancer Clinical Proteomics Research

Cancer Diagnostic Devices Interagency Task Force

Memorandum of Understanding Signing Ceremony September 17, 2021 Establishes
Cancer Diagnostic Devices Interagency Task Force

Norman E. Sharpless, M.D.
Director, National Cancer Institute

Jeffrey E. Shuren, M.D., J.D.
Director, Center for Devices and Radiological Health
Food and Drug Administration

Richard Pazdur, M.D.
Director, Oncology Center of Excellence
Food and Drug Administration

Susan Monarez, Ph.D.
Director, Office of Planning, Analysis and Evaluation
Health Resources and Services Administration

Douglas R. Lowy, M.D.
Principal Deputy Director
National Cancer Institute

NIH NATIONAL CANCER INSTITUTE

FDA U.S. FOOD & DRUG ADMINISTRATION

HRSA Health Resources & Services Administration

On Friday, September 17, 2021, leadership from the NCI, Food and Drug Administration, and Health Resources and Services Administration signed a [Memorandum of Understanding \(MOU\)](#) to support solutions for early cancer detection and diagnosis to improve patient outcomes,

quality of life, and reduce health disparities among medically underserved, geographically isolated, and otherwise vulnerable populations. This MOU formalized a new Cancer Diagnostic Devices Interagency Task Force.

2021 CPTAC Virtual Scientific Symposium

The [Clinical Proteomic Tumor Analysis Consortium \(CPTAC\)](#) held the 2021 CPTAC Virtual Scientific Symposium on October 13, 2021. The goal was to learn about advances in the field of cancer proteogenomics and cancer research by

the CPTAC investigators. [Watch the recorded public session](#) for talks by [CPTAC researchers](#) from all over the country, sharing their newest discoveries in cancer research using the power of proteogenomics.

Updates from the Cancer Imaging Program

Two-volume Book Published on Quantitative Imaging



The American Institute of Physics recently published a two-volume book, [Quantitative Imaging in Medicine](#), edited by Robert Nordstrom, PhD. The first volume, *Background and Basics*, introduces the concept of quantitative imaging and provides the fundamentals of the methods. The second volume, *Applications and Clinical Translation*, provides specific examples of quantitative imaging in a variety of clinical applications.

Annual Biomarker Consortium Symposium of the FNIH Cancer Steering Committee

Janet Eary, MD, Associate Director, Cancer Imaging Program, and Marc Theoret, FDA, chaired the imaging session of the recent Annual Biomarker Consortium symposium of the FNIH Cancer Steering Committee, which included 11 imaging scientists. A second session, Image-Guided Surgery: Advances and Challenges Webinars, provided scientists and engineers an opportunity to discuss potential solutions to the issues raised in the first meeting. The

goal was to uncover areas where near- and long-term improvements will increase the impact that current and future image-guided techniques will have on the survival of people with cancer.

Keynote Presentation

Janet Eary, MD, associate director, Cancer Imaging Program, gave the [keynote presentation](#) at the NCCN Virtual Oncology Policy Summit: The Impact of Technology on Cancer Care in 2021 (September 9, 2021).



- Supporting Research/Researchers
- Supporting Innovation, clinical translation
- Facilitating Communication
- Understanding the Landscape

NCI Cancer Imaging Program

NIH NATIONAL CANCER INSTITUTE

Janet F. Eary, MD
National Cancer Institute

NCCN Virtual Oncology Policy Summit: The Impact of Technology on Cancer Care in 2021

Highlights from the Cancer Imaging Archive (TCIA)

TCIA Highlighted at the FDA-NIH Workshop on Next-Generation Sequencing (NGS) and Radiomics

The FDA-NIH Joint Leadership Council Next-Generation Sequencing and Radiomics Working Group recently hosted a [workshop](#) on resource requirements for acceleration of clinical applications of NGS and radiomics, including those using artificial intelligence. The workshop co-chairs were Lalitha Shankar, MD, PhD, Cancer Imaging Program, and Lyndsay Harris, MD,

Cancer Diagnosis Program. Ned Sharpless, MD, NCI director, noted TCIA in his opening remarks, emphasizing the central role it plays in cancer image data sharing and radiomic tool development and validation. TCIA collections were leveraged in several presentations at the workshop. Significantly, NIH has recently recognized TCIA as a High Value Data Asset.

National Lung Screening Trial Data



More than 70,000 CT scans from the [National Lung Screening Trial \(NLST\)](#) are now publicly available (no data access request needed). The data collection provides CT scans, some pathology slide images, and limited clinical data from approximately 26,000 heavy smokers who, at the start of the study, showed no signs, symptoms, or history of lung cancer. NLST followed participants for 7 years to compare two imaging methods for detecting lung cancer: low-dose CT scans and standard chest X-rays. Researchers can explore the data through [The Cancer Imaging Archive](#) as well as the [NCI Imaging Data Commons](#) and the [NCI Cancer Data Access System](#).

Publications, Blogs, and Press Featuring DCTD Staff

Publications

[Kaur G, Evans DM, Teicher BA, et al.](#) Complex tumor spheroids, a tissue-mimicking tumor model, for drug discovery and precision medicine. *SLAS Discov.* 2021 Dec;26(10):1298-1314.

[Kummar S, Srivastava AK, Navas T, et al.](#) Combination therapy with pazopanib and tivantinib modulates VEGF and c-MET levels in refractory advanced solid tumors. *Invest New Drugs.* 2021 Dec;39(6):1577-1586.

[Vega DM, Yee LM, McShane LM, et al.](#) Aligning tumor mutational burden (TMB) quantification across diagnostic platforms: Phase II of the Friends of Cancer Research TMB Harmonization Project. *Ann Oncol.* 2021 Dec;32(12):1626-1636.

[Hanna GS, Choo YM, Harbit R, et al.](#) Contemporary approaches to the discovery and development of broad-spectrum natural product prototypes for the control of coronaviruses. *J Nat Prod.* 2021 Nov 26;84(11):3001-3007.

Qi L, Lindsay H, Kogiso M, et al. Evaluation of an EZH₂ inhibitor in patient-derived orthotopic xenograft models of pediatric brain tumors alone and in combination with chemo- and radiation therapies. *Lab Invest*. 2021 Nov 20. Online ahead of print.

Grossman KF, Othus M, Patel SP, et al. Adjuvant pembrolizumab versus interferon alfa-2b or ipilimumab in resected high-risk melanoma. *Cancer Discov*. 2021 Nov 11. Online ahead of print.

Mao JJ, Pillai GG, Andrade CJ, et al. Integrative oncology: Addressing the global challenges of cancer prevention and treatment. *CA Cancer J Clin*. 2021 Nov 9. Online ahead of print.

Zou F, Faleck D, Thomas A, et al. Efficacy and safety of vedolizumab and infliximab treatment for immune-mediated diarrhea and colitis in patients with cancer: A two-center observational study. *J Immunother Cancer*. 2021 Nov;9(11):e003277.

Adams S, Othus M, Patel SP, et al. A multicenter phase II trial of ipilimumab and nivolumab in unresectable or metastatic metaplastic breast cancer: Cohort 36 of Dual Anti-CTLA-4 and Anti-PD-1 Blockade in Rare Tumors (DART, SWOG S1609). *Clin Cancer Res*. 2021 Oct 29. Online ahead of print.

O'Sullivan Coyne G, Kummar S, Hu J. Clinical activity of single-agent cabozantinib (XL184), a multi-receptor tyrosine kinase inhibitor, in patients with refractory soft tissue sarcomas. *Clin Cancer Res*. 2021 Oct 29. Online ahead of print.

Brem EA, Li H, Beaven AW, et al. SWOG 1918: A phase II/III randomized study of R-miniCHOP with or without oral azacitidine (CC-486) in participants age 75 years or older with newly diagnosed aggressive non-Hodgkin lymphomas – Aiming to improve therapy, outcomes, and validate a prospective frailty tool. *J Geriatr Oncol*. 2021 Oct 19. Online ahead of print.

El Touny LH, Hose C, Connelly J. ATR inhibition reverses the resistance of homologous recombination deficient MGMT^{low}/MMR^{proficient} cancer cells to temozolomide. *Oncotarget*. 2021 Oct 12;12(12):2114-2130.

Mitra A, Naqash AR, Murray JH, et al. Outcomes of pregnancy during immunotherapy treatment for cancer: Analysis of clinical trials sponsored by the National Cancer Institute. *Oncologist*. 2021 Oct;26(10)e1883-e1886.

Kaur G, Doroshow JH, Teicher BA, et al. Format (2D vs 3D) and media effect target expression and response of patient-derived and standard NSCLC lines to EGFR inhibitors. *Cancer Treat Res Commun*. 2021 Sep 25;29:100463. Online ahead of print.

Cao L, Huang C, Cui Zhou D, et al. Proteogenomic characterization of pancreatic ductal adenocarcinoma. *Cell*. 2021 Sep 16;184(19):5031-5052.e26.

Xia F, Allen J, Balaprakash P, et al. A cross-study analysis of drug response prediction in cancer cell lines. *Brief Bioinform*. 2021 Sep 14. Online ahead of print.

Shindiapina P, Pietrzak M, Seweryn M, et al. Immune recovery following autologous hematopoietic stem cell transplantation in HIV-related lymphoma patients on the BMT CTN 0803/AMC 071 Trial. *Front Immunol*. 2021 Sep 3;12:700045.

Press and Social Media

Drug Combination Helps Children with Acute Promyelocytic Leukemia Avoid Conventional Chemotherapy; *NCI Press Release*; November 11, 2021.

Racial Disparities in Cancer Clinical Trials: An Old Problem with New Implications; *Healio*; October 15, 2021.

U.S. Cancer Patients Gained 14 Million Life-years Since 1980 Because of NCI-funded Trials; *The Cancer Letter*; October 1, 2021.

Healthcast Podcast: 50 Years of Cancer: Collaboration in Combatting Childhood Cancer; September 28, 2021.



New DCTD Funding Opportunity and Funding Information

Funding Opportunity Announcements

Title	Announcement Number	First Available Due Date	Expiration Date	Activity Code
Integrating biospecimen science approaches into clinical assay development	PAR-22-049	December 11, 2021	September 14, 2024	U01
Toward Translation of Nanotechnology Cancer Interventions (TTNCI)	PAR-22-071	April 17, 2022	November 18, 2024	R01

Notices of Change

Title	Announcement Number
Notice of Correction to NOT-CA-21-101, "Notice of Special Interest (NOSI): Advancing the development of tumor site-activated small molecules"	NOT-CA-22-006
Notice of Correction to PAR-21-166 "Academic-Industrial Partnerships for Translation of Technologies for Diagnosis and Treatment"	NOT-CA-21-119