DEPARTMENT OF HEALTH AND HUMAN SERVICES
NATIONAL INSTITUTES OF HEALTH
NATIONAL CANCER INSTITUTE
47TH CLINICAL TRIALS AND TRANSLATIONAL RESEARCH ADVISORY COMMITTEE (CTAC) MEETING

Summary of Meeting
March 16, 2022

Webinar

CLINICAL TRIALS AND TRANSLATIONAL RESEARCH ADVISORY COMMITTEE
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The 47th meeting of the Clinical Trials and Translational Research Advisory Committee (CTAC) of the National Cancer Institute (NCI) was convened on Wednesday, March 16, 2022 at 12:00 p.m. The CTAC chair, Dr. Meropol, presided.[1] The meeting was adjourned at 2:55 p.m.

Chair
Neal J. Meropol

CTAC Members
Smita Bhatia
Charles D. Blanke
Edward Chu
Nancy E. Davidson (absent)
Anjelica Q. Davis (absent)
Adam P. Dicker
Gary C. Doolittle
Ernest T. Hawk
Michael V. Knopp
Seth P. Lerner
Mia Levy
Sumithra J. Mandrekar
Robert S. Mannel
Ruben A. Mesa
Carolyn Y. Muller
Raphael E. Pollock
Suresh S. Ramalingam
Victor M. Santana
Patricia A. Spears
Julie M. Vose
George Wilding

***Ex Officio* Members**
Terri Armstrong, NCI (alternate for William L. Dahut)
James H. Doroshow, NCI
Paulette S. Gray, NCI
Michael J. Kelley, U.S. Department of Veteran Affairs
Anthony Kerlavage, NCI
Julie Schneider, U.S. Food and Drug Administration (alternate for Richard Pazdur)
Xiufen Sui, Centers for Medicare and Medicaid Services

Designated Federal Official
Sheila A. Prindiville, NCI

Presenters
James H. Doroshow, MD, Deputy Director, Clinical and Translational Research; Director, Division of Cancer Treatment and Diagnosis, NCI
Oren Grad, MD, PhD, Consultant, Science and Technology Policy Institute (STPI)
M.K. Holohan, JD, Director, Office of Government and Congressional Relations, Office of the Director, NCI
Grant Huang PhD, MPH, Director, VA Cooperative Studies Program
Michael J. Kelley, MD, FACP, VA National Program Director for Oncology
Neal J. Meropol, MD, Vice President of Research Oncology; Scientific and Clinical Lead, Clinical Research, Flatiron Health
Norman E. Sharpless, MD, Director, NCI

[1] A roster of CTAC members and their affiliations is included as an appendix.

TABLE OF CONTENTS
Wednesday, March 16, 2022

I. Call to Order and Opening Remarks

Neal. J. Meropol, MD

Dr. Meropol called the 47th meeting of CTAC to order at 12:00 p.m. He welcomed new CTAC members: Drs. Doolittle, Mannel, Mesa, Wilding, and Ms. Spears. He recognized Terri S. Armstrong, PhD, who was attending in place of Dr. Dahut, and Julie Schneider, PhD, who was representing the U.S. Food and Drug Administration (FDA) in place of Dr. Pazdur, at this meeting.

Dr. Meropol reviewed the confidentiality and conflict-of-interest practices required of CTAC members during their deliberations. He invited members of the public to send written comments on issues discussed during the meeting to Dr. Prindiville within 10 days of the meeting. National Institutes of Health Events Management was videocasting the meeting, and the videocast became available for viewing at https://videocast.nih.gov/watch=44627 after the meeting.

The next CTAC meeting, which will take place on July 13, 2022, is currently expected to be virtual.

Motion. A motion to accept the minutes of the 46th CTAC meeting, held on November 10, 2021, was approved.

II. NCI Director's Update

Norman E. Sharpless, MD

Dr. Sharpless reported that the 50th anniversary celebration of the National Cancer Act in 2021 galvanized the national conversation about the past five decades of cancer research and its future directions. In early February, the White House announced that ending cancer as we know it is a top domestic priority and noted the importance of having trans-governmental support to achieve this goal.

NCI Appropriations. NCI's base budget appropriation for Fiscal Year (FY) 2022 under the newly approved Omnibus spending bill is $6.913 million, including $194 million for the 21st Century Cures Act that will support the original Cancer Moonshot for one additional year and $50 million for the Childhood Cancer Initiative. Congress has also appropriated $1 billion to support the Advanced Research Projects Agency for Health (ARPA-H) over FY 2022-2024. ARPA-H is expected to play an important role in a new Cancer Moonshot.

NCI Paylines. Because NCI has been operating under a continuing resolution until very recently, it has maintained very conservative paylines (i.e., 9th percentile for R01 grants for established and new investigators as well as R21s and 14th percentile for R01 grants for early-stage investigators) and funded non-competing grants at 90 percent. NCI is currently analyzing the FY 2022 budget and will be issuing new paylines and non-competing grant funding in the near future.

Leadership Changes. President Biden announced the appointments of Alondra Nelson, PhD, as Director of the White House Office of Science and Technology Policy, and of former NIH Director Francis Collins, MD, PhD, as Science Advisor to the President and Co-Chair of the President's Council of Advisors on Science and Technology. To help make progress on childhood cancer, Dr. Sharpless has appointed pediatric oncologist Brigitte C. Widemann, MD, NCI Center for Cancer Research, as Special Advisor to the Director for Childhood Cancer.

Cancer Moonshot. The White House, as President Biden reiterated in his State of the Union address, is committed to reducing cancer mortality by 50 percent in 25 years. It is supercharging the Cancer Moonshot with a "whole government" approach that includes convening a "cancer cabinet" of

nineteen federal agencies that have important interests in cancer, such as the U.S. Departments of Defense and Energy, in addition to Health and Human Services. The progress to date in reducing cancer mortality can be attributed to multiple factors, including better prevention and screening, improved therapies, and tobacco control, among others. While these need to be continued, an important new emphasis is on fairness and the promotion of health equity for all Americans, regardless of wealth, race, or access to health care.

The President has also drawn attention to disruptions in cancer care during the COVID-19 pandemic, including missed screenings. NCI is working with First Lady Jill Biden to support a "Returning to Screening" initiative that she is promoting across the nation.

The original Cancer Moonshot, initiated in 2016, had three ambitious goals: to accelerate scientific discovery in cancer research, foster greater collaboration, and improve the sharing of data. This first Moonshot has one additional year of funding (FY 2023) before its sunset in 2024. Between 2017-2020, the initiative built a strong platform for future cancer research, funding more than 70 consortia and programs and over 240 projects.

NCI Clinical Trials. For patients with early stage, non-small cell lung cancer, NCI launched ALCHEMIST (Adjuvant Lung Cancer Enrichment Marker Identification and Sequencing Trials). For this population, there is a 50 percent chance that the cancer will reoccur following standard treatment. ALCHEMIST's goal is to determine if adding targeted treatment based on a patient's tumor genetics will help prevent the cancer from returning and lead to better outcomes. Currently, there are 6,855 patients enrolled; two-thirds are assigned to a discovery cohort and one-third to a validation cohort. At present, 6,476 tissues have been processed to extract analytes and 3,656 cases have been fully characterized genomically. Analyses are ongoing. All data will be deposited in the NCI Genomics Data Commons.

The Tomosynthesis Mammographic Imaging Screening Trial (TMIST) is testing the hypothesis that 3-D imaging will decrease the cumulative incidence of advanced cancers, compared to standard 2-D digital mammography. TMIST is an academic-community partnership funded through the NCI Community Oncology Research Program (NCORP) and conducted by the Eastern Cooperative Oncology Group (ECOG)-American College of Radiology Imaging Network (ACRIN) Research Base. The trial was hit hard during the pandemic because cancer screening rates plummeted. To address the issue, a CTAC working group was convened to review the trial. The group's recommendation was to leave the trial's endpoints unchanged, but to modify the approach. The original design addressed the occurrence of advanced cancer within a fixed timeframe of four and a half years; the revised design calls for the occurrence of advanced cancer any time up to seven years after randomization. The power was slightly decreased from 90 percent to 85 percent for a 20 percent relative reduction in advanced cancer at 4.5 years after randomization. The study duration is now ten years with a projected completion date of August 30, 2027. Since those changes were made, enrollment has reached 65,508 patients, with an average of 2,100 new enrollees per month in 2021.

The pandemic has had a significant impact on clinical trial enrollment. Fortunately for the NCI National Clinical Trials Network (NCTN), accrual is now back on track. Accrual has also held up for NCORP. Despite this good news, NCI remains concerned about the impact of the pandemic on accrual across its entire clinical trials portfolio and will continue to closely monitor it.

A new analysis of cancer treatment side effects examined 202 clinical trials conducted by SWOG. It found that, overall, women had a 34 percent higher risk of severe side effects compared with men. The sex disparity was most pronounced for immunotherapy: Women had a nearly 50 percent increased risk of

serious side effects compared with men. The study was published in the *Journal of Clinical Oncology* (February 4, 2022).

Colorectal cancer incidence is increasing in younger individuals, and there is a substantial racial disparity between White and Black Americans. FORTE (Five-or Ten-Year Colonoscopy for 1-2 Non-Advanced Adenomatous Polyps) is an NCORP trial to examine colorectal cancer incidence in participants with one to two non-advanced adenomas randomized to surveillance colonoscopy at 10 years or surveillance colonoscopy at five and 10 years. This trial began in October 2021 and is currently recruiting with a desired sample size of 9,500 patients.

The purpose of CUSP2CT (Connecting Underrepresented Populations to Clinical Trials) is to implement and evaluate multi-level and culturally tailored outreach and education interventions with the primary goal of increasing referral of racial/ethnic minority populations to NCI-supported clinical trials. There is a new Funding Opportunity Announcement (RFA-CA-22-014) for a Data, Evaluation, and Coordinating Center for CUSP2CT. Submissions for this U24 cooperative agreement are due March 28, 2022.

Childhood Cancer Data Initiative (CCDI). Dr. Sharpless updated the Committee on CCDI, noting that it just launched the Childhood Molecular Characterization Initiative that will characterize approximately 3,000 children with hard-to-treat cancers and provide clinical and molecular data to all children with cancer. It is piggybacking on the Children's Oncology Group (COG)'s Project: EveryChild. Lessons learned from the initiative's large-scale data aggregation from multiple sources and patient privacy protections will be applicable to the study of adult cancers as well. CCDI is also operating the National Childhood Cancer Registry (NCCR) that will integrate multi-source data to generate an accurate count of child cancer cases. Its database will expand to include genomic and tumor characteristics, treatment information, recurrence indicators, etc., from multiple sources. An NCCR Explorer application is available for researchers to mine the database.

Questions and Discussion

Dr. Mesa said he was testifying before the House Energy and Commerce Committee about the cancer community's perspective on the Diverse and Equitable Participation in Clinical Trials Act (DEPICT) and the Diversifying Investigations Via Equitable Research Studies for Everyone Trials Act (DIVERSE). Dr. Sharpless encouraged Dr. Mesa to help the House Committee understand the research opportunities for reducing health disparities at NCI as well as at other government agencies.

Dr. Hawk shared sentiments from the prevention community in regard to the new Cancer Moonshot initiative. He expressed gratitude that the importance of addressing cancer prevention and screening will be emphasized in the overall mission of the Federal Government and noted the importance of drawing attention to the role of lifestyle factors (including tobacco, alcohol, nutrition, physical activity, and obesity) as a way of preventing cancer and reducing health disparities. Dr. Sharpless concurred that prevention is important to ensuring that the Moonshot's goals are met.

Ms. Spears commented that the Moonshot is a great opportunity for public engagement in cancer education; science communication to the public needs to be improved. She recommended framing the 50 percent reduction in cancer mortality in 25 years in the context of what has been accomplished in the past 25 years. Dr. Sharpless said the President made the point in his remarks that all the progress made since 1991 (about a 30 percent reduction in cancer rates) can lead to further reductions in mortality. The "all government" approach can help make that possible, as well as the leadership of the White House and the Office of Science and Technology Policy.

Dr. Ramalingam inquired about how cancer-related priorities will be set in ARPA-H and what the NCI's role will be. Dr. Sharpless responded that it is too soon to predict; Congress has appropriated the funds, but they are not yet authorized. There are still many open questions, such as where it will be located, if its grants will be exempt from peer review, and what capabilities the agency will have. It is expected that the ARPA-H director will have wide latitude on deciding the agency's research portfolio. All that is known at this time is that it will work on cancer, Alzheimer's disease, and diabetes, in addition to other diseases.

III. Legislative Update

M.K. Holohan, JD

Ms. Holohan addressed funding and policy issues for Fiscal Year (FY) 2022 and FY 2023.

Omnibus Spending Bill. On March 15, 2022, President Biden signed the $1.5 trillion FY 2022 Omnibus appropriations bill following four continuing resolutions that held federal government spending at FY 2021 levels. The legislation includes $45 billion in funding for NIH overall, an increase of $2.25 billion over FY 2021. The NIH total also includes $6.9 billion for NCI, which represents a $353 million increase over FY 2021. The Omnibus spending bill provides $1 billion for the Advanced Research Projects Agency for Health (ARPA-H) within the HHS Office of the Secretary and gives the Secretary the authority to transfer funding and administration of ARPA-H to any part of the Department, including NIH, within 30 days of enactment of the Omnibus bill.

The Omnibus bill was delayed due to earlier congressional consideration of the infrastructure and Build Back Better bills. Major issues of debate in the Omnibus spending bill included parity between defense spending and non-defense spending; Congress settled on a 5.6 percent increase in defense spending and a 6.7 percent increase in non-defense spending. This represents one of the biggest increases in discretionary spending in recent years that will support several White House priorities. Another issue that delayed negotiations was inclusion of the Hyde Amendment that forbids federal spending on abortion services. The bill included $13.6 billion in humanitarian and defense aid to Ukraine, as well as over 4,000 earmarks, which had been banned since 2011. It is unknown when President Biden will release his FY 2023 budget.

President Biden handed the first pen used in the Omnibus spending bill signing ceremony to Shalanda Young, who had just been confirmed as director of the Office of Management and Budget after serving as its acting director. She is the third woman and first African American woman to be appointed to this job.

COVID-19 Funding. Controversy over a proposed $15.6 billion in COVID-19 response funding derailed the first attempt at a FY22 Omnibus bill due to concerns about funding offsets that would subsume previously appropriated COVID-19 funds that had not yet been distributed to states. The COVID-19 response aid was then introduced in separate legislation that will need to be considered at another time. The White House has announced that it will need $22.5 billion to respond to the pandemic.

Telehealth Proposals. Over 50 telehealth proposals were introduced in Congress during the present session; of these, Creating Opportunities Now for Necessary and Effective Care Technologies (CONNECT) has the greatest number of bipartisan sponsors. The FY22 Omnibus bill extends Medicare telehealth flexibilities for 151 days past the COVID-19 public health emergency but does not make these changes permanent. One legislative issue is what role the federal government can play in terms of state laws and state licensure requirements. There are ongoing congressional discussions about how to incentivize states to create more flexible reciprocity in licensing and to make patient access easier.

Cures 2.0 and ARPA-H. Telehealth is also included in Cures 2.0, introduced in November 2021. It has provisions to increase diversity and access in clinical trials as well as authorize funding for ARPA-H and other research efforts, such as Long COVID-19 and antibiotic resistance. The House Energy and Commerce Committee held hearings in February 2022 on the proposed bill. At the hearings, all witnesses agreed that ARPA-H would have a distinct culture and authorities, independent of where it is placed. Congresswoman Anna Eshoo, who introduced the ARPA-H bill, and Representative Fred Upton, who introduced Cures 2.0, announced they would move their bills closer together in a synergistic fashion.

The Senate has authorized the Prepare for and Respond to Existing Viruses, Emerging New Threats (PREVENT) and Pandemics Act. Although its main focus is on preparedness, it also authorizes establishment of ARPA-H within NIH.

Other Legislation. The next big priority for Senate Democrats is American competitiveness legislation. The House passed its version of this legislation in February, the Senate in June; each bill has different emphases. As it moves to conference, other bills are expected to be attached to the final legislative package.

Congressional Retirements: Several longtime biomedical research champions have announced their retirements from Congress, including Senators Roy Blunt (R-MO), Richard Shelby (R-AL), and Patrick Leahy (D-VT), and Representatives. Jackie Speier (D-CA), G.K. Butterfield (D-NC), and Fred Upton (R-MI).

IV. NCI & VA Interagency Group to Accelerate Trials Enrollment (NAVIGATE) Update

Michael J. Kelley, MD, FACP
Grant Huang, MPH, PhD

The NCI and VA Interagency Group to Accelerate Trials Enrollment (NAVIGATE) program is a partnership between NCI and the Department of Veterans Affairs (VA) to facilitate enrollment of veterans with cancer into NCI-funded clinical trials. This agreement began in 2018 with the goals of 1) increasing veteran participation in NCI national clinical trials; 2) enhancing operational activities to reduce barriers and facilitate participation of VA sites in NCI National Clinical Trials Network (NCTN) and NCI Community Oncology Research Program (NCORP) trials; and 3) enabling sustained long-term capability for VA participation in NCTN and NCORP trials beyond the initial NAVIGATE support period. Twelve VA medical centers spanning the United States were selected to participate in NAVIGATE and received funding, including support for dedicated research coordinators. A Coordinating Center was also established to centrally address barriers to trial activation and coordinate research activities.

Overview. Dr. Kelley began his presentation with an overview of patients in the VA, the nation's largest integrated healthcare system and one of the largest cancer care providers. He noted that a 2017 survey of cancers among veterans at all VA facilities revealed that prostate cancer in men and breast cancer in women (30 percent each) are almost double that of the next most frequently occurring cancer, lung and bronchus (18 and 15 percent, respectively). An estimated 46,000 veterans are diagnosed with cancer annually. Of these, 79 percent are White, 19 percent are Black, and 1 percent represent other races. Veterans are 2.5 times as likely as other Americans to live in a rural area.

Barriers to VA participation in NCI trials include trial activation challenges, such as regulatory and policy compliance; use of technology, data sharing, and associated information security; tissue banking; and the single biggest barrier, lack of personnel and resources for recruitment. Barriers to participation in NCI trials among veterans are travel and financial considerations, awareness of trials and patient resources, and restrictive eligibility criteria (including comorbidities).

The benefits of the NAVIGATE consortium approach include development of Investigator and Coordinator groups to allow for sharing of resources, advice, and support; "strength in numbers" when issues arise that require escalation to the national level; avoiding duplication of efforts based on shared institutional knowledge; and identification of new ideas and areas for innovation for collaboration. In general, VA hospitals are smaller institutions than NCI cancer centers so this sharing across VA facilities has been useful to creating a critical mass of colleagues.

Select Tools, Processes, and Best Practices. Implementation of centralized information security approvals, central Institutional Review Board (IRB) processes, local/facility approval process mapping to identify areas for improved efficiency, and sharing of best practices among the NAVIGATE sites and beyond, have contributed to making NAVIGATE sites leaders in the VA. Workgroups have been established, focusing on community building and expansion, recruitment, infrastructure, and sustainability. Because of its success, this model is being used with the National Institute on Aging for its Alzheimer's Disease clinical research network.

NAVIGATE is one of many partnerships and networks that make up the VA's cancer clinical research enterprise, including the Cooperative Studies Program/Network of Dedicated Enrollment Sites, Lung Cancer Precision Oncology Program (LPOP), ***A***pplied ***P***roteogenomics ***O***rganizationa***L*** ***L***earning and ***O***utcomes (APOLLO), Prostate Cancer Foundation Centers of Excellence, and a Genitourinary Precision Oncology Program (POPCaP/GU). Within the bioinformatics domain, the VA uses electronic health records (EHRs) to identify patients who meet trial eligibility criteria. It maintains a Big Data Scientist Training and Enhancement Program to develop a bioinformatics workforce, and a cloud computing environment with its VA Informatics and Computing Infrastructure (VINCI). There is also a partnered research program to facilitate clinical trial partnerships with mostly for-profit partners in any disease area.

Accrual. Between 2018-2021, VA accrual to NCTN and NCORP clinical trials amounted to 536 patients from the 12 NAVIGATE sites and 222 patients from 18 non-NAVIGATE sites. Of the patients accrued by NAVIGATE sites, 25.5 percent were minorities, a modestly higher percentage than in the VA population as a whole.

Future Directions. Future directions for NAVIGATE include engagement with other networks (LPOP, POPCaP/GU, etc.) under an enterprise-wide strategy toward research activities aimed at improving veteran health; continued efforts with key partners, including NCI; dissemination of best practices to all VA sites wishing to engage in NCTN/NCORP trials; and ongoing use of the NAVIGATE Coordinating Center as the primary source of guidance and support for sites developing their NCI trials portfolios.

The VA National TeleOncology Service provides direct clinical care to veterans in centers/locations that lack disease-specific oncologists. This service has grown rapidly and now comprises 16 active sites and 8 engaged sites. This network can be used to recruit veterans from across the country for clinical trials. The VA views telehealth as a key component of its future activities. The VA decentralized clinical trial model consists of partnerships between academic institutions, the TeleOncology service, and patient sites around the country.

Questions and Discussion

Dr. Meropol invited CTAC members with experience with NAVIGATE to share their perspectives on the program.

Dr. Ramalingam indicated that the NAVIGATE program has been very impactful at the Atlanta VA Health Care System. Enrollments in clinical research have grown and the infrastructure for cancer clinical trials has improved across the system (i.e., the center hired research coordinators and regulatory specialists and instituted mechanisms for biospecimen collection during the early days of NAVIGATE). This VA system has been a partner in NCTN trials and other clinical research initiatives previously, but VA leadership moved from engagement to active participation (e.g., leading clinical meetings) as a result of NAVIGATE. Thus, the results of the program have not only been an increase in accrual in cancer clinical trials at the Atlanta VA, but also increased support and buy-in from the local VA that has allowed cancer research to thrive. This experience has led to this VA's participation in the nation-wide LPOP program as well as the POPCaP/GU. Local researchers have also had the opportunity to present their work at national NAVIGATE meetings, giving them opportunities to extend their leadership and influence. Further, the Atlanta VA is now looking at applying the lessons learned in NAVIGATE to other, non-cancer clinical trials at the center. He noted that a critically important future direction is tailoring eligibility criteria to veterans (e.g., in regard to prior or concomitant malignancies which are deal-breakers for veteran participation in clinical trials). Another issue for consideration is that radiation oncology services are not offered at all VA hospitals so trials involving radiation therapy may not be fully accessible by veterans.

Dr. Blanke reported on the Portland VA NAVIGATE effort, but also tied in the SWOG Cancer Research Network's pre-NAVIGATE VA effort that clearly demonstrated that the NAVIGATE program's goals are achievable. SWOG invested $750,000 across a number of well-dispersed VAs, which led to dramatic increases in accrual. SWOG also established a formal VA committee, the first of its kind. The financial investment has gone toward clinical research associates (CRAs) and other support positions to decrease the administrative burden of conducting NCTN trials. This has been cited by researchers and VA staff as the single biggest need for VA participation in trials. Both SWOG and the Portland VA have suggested that the biggest "bang for the buck" would come from holding routine meetings at as many VA sites as possible and formalizing the sharing of best practices with non-NAVIGATE sites. At every site, there is a serious appetite for VA participation in clinical research, but VA needs support and access to trials. Dr. Blanke closed with a quote from a Principal Investigator at his VA: "The VA here has seen a shift in perception from clinical research only helping someone else's goals and careers to being a true patient benefit to veterans."

Dr. Kelley concurred with Dr. Blanke that the SWOG effort was the spark that led to the creation of NAVIGATE and agreed on the importance of widespread dissemination of best practices. Dr. Huang also acknowledged the contributions of both SWOG and CTAC to the NAVIGATE program, noting that it has transformed how people are thinking about clinical trials and has become a national model for how clinical and research sites can work together. In regard to Dr. Ramalingam's earlier point about the availability of radiation, Dr. Kelley said that expansion of radiation oncology services represents a large investment for the VA, but the system is moving in that direction.

Dr. Levy said that she was impressed with the progress that NAVIGATE has made and particularly excited about the decentralized clinical trial model. She requested that Dr. Kelley return in the future to update CTAC on the lessons learned from its implementation.

Dr. Hawk lauded the impressive amount of minority representation in clinical trials that NAVIGATE has achieved. He asked if the VA collects and reports data on its cancer patient population and cancer treatment and prevention clinical trials as the NCI centers do, suggesting that doing so would be highly informative to identify representation, participation, and unmet needs. He also suggested that there may be many opportunities to advance healthy lifestyles among cancer patients/trial participants,

(e.g., tobacco cessation). He suggested that NCI could issue funding supplements to address unmet needs that are identified.

Dr. Mesa stated that his institution, the Mays Cancer Center at UT Health San Antonio MD Anderson, is one of the NAVIGATE sites. He reached out to Michael Liss, MD, who is one of its local Principal Investigators as well as the Medical Director for the Clinical Trials Office at the cancer center, for comments about NAVIGATE. Dr. Liss said that NAVIGATE was a very impactful program in terms of stewarding clinical trial efforts across both the cancer center and the VA. He identified key lessons learned from the experience to date: 1) the need to further delve into the design aspects of the trials in terms of feasibility within the VA system, 2) positive aspects such as increased patient access through outreach and overcoming geographic barriers; improved care delivery; and, especially, 3) the cultural impact of NAVIGATE on the VA care teams who have pivoted to a clinical trial focus.

Dr. Doolittle inquired about oncologist preparation and site training for those working in the VA TeleOncology Services program. He also asked how the VA managed consent issues with patients located at a distance. Dr. Kelley responded that the VA uses electronic consent; he reads the informed consent document to the patient who signs online. The VA's infrastructure for telehealth was very mature prior to the pandemic and offers robust training for standard clinical care and telehealth processes. It is expected that every patient will be offered multiple modalities for their care. Each local site is evaluated during the start-up of services to ensure that all staff have the correct training and certifications.

Dr. Wilding inquired if the VA's Information Technology group has worked on optimizing collection of trial data from the VA's EHR. Dr. Huang responded that the VA has a bioinformatics team that has developed workflows for data collection and sharing. Data collection procedures depend on the protocol. The information system security team has enabled the VA to use Clinical Trial Management Systems (CTMS) outside the VA firewall.

V. Strategic Planning Activities

James Doroshow, MD
Oren Grad, MD, PhD

Dr. Doroshow reviewed the CTAC Strategic Planning Working Group's *Strategic Vision for Clinical Trials*, which envisioned the development of flexible, faster, simpler, and less expensive high-impact clinical trials that seamlessly integrate with clinical practice. The Working Group's report included 15 recommendations and three operational initiatives to help achieve this vision. NCI's initial focus has been on six recommendations, falling under the following themes: streamlining clinical trials, decentralizing clinical trials, and increasing patient access to trials. Dr. Grad's presentation addressed the recommendation to expand the use of telehealth in clinical trials as well as emerging workforce issues.

Telehealth for Clinical Trials.

Dr. Grad provided an update on NCI's telehealth initiative, noting that NCI does not make a distinction between the terms "telehealth" and "telemedicine." The pandemic renewed interest in telemedicine, and NCI has been actively developing funding opportunity announcements (FOAs) on telemedicine in cancer care. The first—RFA-CA-21-029: Centers on Telehealth Research for Cancer-Related Care—will fund P50 centers to leverage clinical practice networks able to support multiple cancer-focused telehealth research studies, including two rapid-cycle pilot projects and one large-scale pragmatic randomized control trial with a focus on improving cancer-related care and outcomes across the cancer control continuum. Proposals are currently under review and an awards announcement is expected in spring 2022. The second—NOT-CA-21-043: Telehealth in Cancer Care—solicits investigator-initiated

applications for conducting research on the use of telehealth in cancer-related care. It has a broad scope encompassing both patient-provider and provider-provider interactions and any aspects of care across the continuum from prevention to end-of-life care. This Notice of Special Interest (NOSI) expires on March 8, 2024.

In addition, the NCI Division of Cancer Control and Population Sciences (DCCPS) is offering a monthly webinar series, "Telehealth and Cancer: Studying its Role in Cancer Control and Care Delivery", from February to June 2022. Topics include "Patient-Provider Communication and Cancer-Related Telehealth," "Telehealth Models of Cancer Care Delivery," "Telehealth Research to Address Cancer Disparities," and "Overview of NCI's Telehealth Research Centers of Excellence (TRACE)." The webinars may be accessed by registering for the series at https://healthcaredelivery.cancer.gov/telehealth/webinar-series.html.

NCI Community Oncology Research Program (NCORP) Survey. An online survey of NCORP sites was conducted between July 29-August 27, 2021 on telemedicine use during the pandemic and community sentiment about its continuation. Sixty-one responses were received from 46 NCORP sites, including at least one response from 44 NCORP sites.

The survey revealed that there was very little use of telemedicine across NCORP sites prior to the pandemic, but substantial use during it. Over 50 percent of respondents reported that their institution and most or all of its affiliates used telemedicine in NCI clinical trials following the pandemic's onset. When queried about the use of telemedicine at different trial stages, respondents reported limited use with new patients enrolled in trials (mean=7.0 percent) and patients in active treatment (mean=9.4 percent), but increased use for patients in follow-up (mean=23.8 percent). However, the distribution of telemedicine use with patients varied widely across centers, and less than a majority of sites used it at all.

The perceived usefulness of telemedicine varied by type of trial. It was considered moderately useful for studies of screening, prevention, cancer care delivery, disparities, and follow-up but less useful for investigational new drug (IND) treatment trials and, least of all, for tissue acquisition.

Acceptance of telemedicine varied by stakeholder. Oncologists, research staff, and patients indicated a moderate level of acceptance; administrators and institutional leaders indicated very little acceptance. In terms of the utility of telemedicine for patients, respondents suggested it was most useful for rural patients and least useful for children.

In their responses to open-ended questions, the most commonly noted benefits of telemedicine were that it improves trial access, reducing patient visit burden and extending participation to more diverse and/or remotely situated patients, and it enables remote screening/consent and more flexible and tailored consent processes. Three-quarters of respondents noted adverse impacts of telemedicine on the "patient/provider component of care." The most common concern was that certain clinical assessments must be done or are more informative in-person. An adverse impact on the personal relationship between provider and patient was also noted.

Opinion was divided regarding the impact of state licensing restrictions on cross-state telemedicine. Commenters noted that this is a particular challenge for health systems with catchment areas that cross state lines. Dr. Grad noted that the survey did not probe the specific problems faced by specific sites and that state licensing restrictions are in flux.

When asked what kinds of reimbursement changes are needed to facilitate telemedicine in a community setting, the most common response was reimbursement at similar levels to in-person visits.

Other responses indicated a need for clarity about reimbursement rates, reimbursement reflecting clinician time and effort, parity of reimbursement rates across different modalities (e.g., video vs. telephone), appropriate level-of-care coding, and the likelihood that private insurance industry will follow if Medicare endorses telehealth.

Cancer Center Survey. The cancer centers conducted a survey on the impact of the pandemic on the workforce and the use of operational flexibilities for clinical trials put in place during the pandemic, including the use of telemedicine. The survey was open between November 8-26, 2021 and achieved a 100 percent response rate (i.e., all 64 clinical cancer centers responded). Nearly 80 percent of respondents ranked the use of telemedicine for virtual study visits during follow-up as "very important", followed by remote consent (over two-thirds), and virtual study visits during active treatment (fewer than half). This finding is consistent with the NCORP survey results.

Questions and Discussion

Dr. Meropol opened the discussion by posing the following questions to CTAC members:

- What are the obstacles to broader use of telemedicine in NCI-sponsored clinical trials?
- What are specific activities or initiatives that NCI could undertake to address these obstacles or otherwise facilitate use of telemedicine in NCI-sponsored clinical trials?
- Should there be controlled empirical studies of the utility of telemedicine procedures for NCI clinical trial conduct?
- If so, what questions should those studies address?

Worta McCaskill-Stevens, MD, Chief of the Community Oncology and Prevention Trials Research Group at NCI, kicked off the discussion by commenting that NCI wanted to understand what modifications might be needed at the site level to make telehealth successful. Increased broadband and support from clinical leadership were two needs that stood out. There has been concern about information technology requirements and crosstalk with electronic health record systems. She noted that training and staff education would be required and that staffing issues have been exacerbated during the pandemic. One shortcoming of the telehealth NCORP survey is that there was no direct input from patients.

Dr. Doolittle, a principal investigator of a minority/underserved NCORP site at the University of Kansas Medical Center, with a special focus on the rural population, explained that telemedicine has been used for cancer care and evaluation in Kansas for over 20 years to meet the needs of patients in a largely rural state. He found the survey findings to be provocative but urged consideration of the context in which telemedicine was rolled out: His institution at the health system level planned on a two-year rollout but accomplished that in nine days instead because of the pandemic. There was no time for training or for addressing the barrier issues that are so prevalent in telemedicine. Medicare has paid for rural evaluations if the provider is urban but not for urban populations. The lifting of license requirements was particularly important for his site as it sits at the Kansas/Missouri border. In the University of Kansas model, visits between a sub-specialist provider at the university are typically conducted with a patient in a clinical office setting. Thus, they relied on the local health care provider (a general practitioner or advanced practice nurse) to be with the patient. During the pandemic, the model shifted to visiting the patient in his or her home where day-to-day cancer management could be observed, and family members from across the country could be engaged in the conversation. This provided a clear advantage to the use of telemedicine. Some of the NCORP survey findings reflected the rapid adoption of telemedicine without time to train as well as a model of care that was very different from standard care. Another issue was the physical exam. For successful implementation of telemedicine, it is necessary to determine when the

physical exam is absolutely necessary and when imaging and laboratory tests can provide sufficient data in its place. Finally, Dr. Doolittle noted that it is critical to have a provider on site with the patient, particularly for support when bad news must be shared, as it frequently is in the cancer world. That model can be accomplished with a nurse making a home visit or an active caregiver.

Dr. Mesa agreed that telemedicine has been a "big plus", particularly because it is very helpful in screening patients to determine if the patient is not interested or eligible without the patient needing to travel. During a trial, some interim visits and longer-term follow-up are all very impactful.

Dr. Levy echoed earlier sentiments regarding the need for training and for lifting state licensure requirements. She observed that one of the biggest remaining challenges is the new patient opportunity (i.e., whether a patient can participate in a trial given their ability to travel and licensure issues now that most special exceptions have expired). Accrual is an area that can be improved by telemedicine, but barriers continue to exist. She suggested that NCI develop training modules about designing clinical trials using telehealth (e.g., best practices for incorporating virtual visits into trial design) for investigators and study staff by convening a group of experienced practitioners to reflect on lessons learned from the shift to telemedicine during the pandemic. Dr. Levy also asked if there should be empirical studies of virtual trials, including issues of data quality and quantifiable assessments of cross-state licensing issues. She agreed with the earlier comments about designing clinical trials to reduce patient burden; if this could be successfully accomplished, it would broaden patient access to clinical trials.

Dr. Dicker remarked that his institution has been using telemedicine for seven years. He suggested there is a need for quality metrics (i.e., what is a high-quality telemedicine encounter?). It is important that it be of the same level of quality as an in-person visit. The Agency for Healthcare Research and Quality (AHRQ) and others are beginning to examine this issue. Telemedicine has a role to play but cannot do everything. It is one data stream that must be integrated with others. His institution has had a grant from the Federal Communications Commission (FCC) to study how certain Bluetooth devices are complementing telehealth (e.g., by collecting data on weight and blood pressure, among other measures).

Dr. Bhatia commented that one area that has benefited the most from telemedicine is survivorship. NCI could help mitigate the challenges of telemedicine by allowing quantitative studies (e.g., via Requests for Applications [RFAs]) so that researchers can study the benefits of telemedicine objectively.

Ms. Spears said that telemedicine has been very positive for many patients. She suggested that studies are needed to learn how patients feel about telemedicine (e.g., whether it increases or decreases their anxiety/comfort levels) and their preferences so that telemedicine can become an option rather than a requirement. Thus, it is important to incorporate the patient voice in post-pandemic telemedicine studies. She endorsed the hybrid model of telemedicine where the patient has support from a local provider as well access to a clinical trial.

Dr. Blanke commented that he was struck by the low acceptance of telemedicine in pediatrics; he said that federally funded research is important for this population; therefore, he recommended that a "deep dive" is needed into the use of telehealth in pediatrics. He stated that trials on whether telehealth "works" are not needed as much as a focus on better telehealth operations.

Dr. Lerner pointed out that surgical trials and those that require years of long treatment and procedures for ongoing disease assessment pose particular challenges for telemedicine. Patients are very willing to come to the clinic for these visits. Telemedicine can be quite helpful for trial consent and registration, adverse event (AE) assessment, and long-term follow-up post-treatment. These strategies

need to be built into clinical trial protocols. Dr. Mandrekar agreed with this point, noting that telehealth can optimize the conduct of trials and improve participation, compliance, and satisfaction. Dr. Lerner also suggested that demonstration projects via grants specific to such trials would be useful. Lastly, it would be helpful to engage institutional leaders who struggle with accountability and data verification issues.

Dr. Muller echoed Dr. Lerner's point about the need to educate institutional leaders about telehealth in clinical trials. She suggested that best practices for the use of high-quality telehealth for clinical trials specifically would be very helpful to investigators and for engaging institutional leaders. She also suggested the best practices for integrating certified translators in encounters with non-English-speaking patients would be useful; at her institution, translators may be conducting translations for three visits simultaneously.

Challenges with the Clinical Trials Operations Workforce.

Dr. Grad noted that CTAC members recently identified emerging issues for the oncology clinical trials workforce, particularly related to staff attrition during the COVID-19 pandemic. In follow-up, NCI conducted an online survey of the 64 NCI-designated cancer centers between November 8-26, 2021, to assess the extent of this issue. As mentioned earlier, the survey achieved a 100 percent response rate.

Workforce Attrition. The major impact of the pandemic on clinical trial capacity reported by the centers was limited research staff capacity which prevented trials from opening and forced accrual holds. Additional factors effecting clinical trial capacity included staff shortages in ancillary clinical services, such as pathology, imaging, and nursing, as well as in university central services, such as Institutional Review Boards (IRBs) and legal/contracting services; institutional policies, such as limits on new clinical trials and hiring freezes/practices; and state and local government policies (e.g., lockdowns). Overall, institutional and local policies had a greater impact on staffing during the pandemic than the overall size of the research operation.

The survey revealed a wide variation in the ability of cancer centers to maintain research staff capacity. Two-thirds reported minimal to severe staff reductions, while one-third maintained or increased staff during the pandemic. Overwhelmingly, those staff who have left their jobs have departed from the institution, rather than having their responsibilities reassigned. Higher pay/career advancement and a greater ability to work remotely were cited as key reasons staff members left their positions. Most departing staff members took positions in the pharmaceutical industry or in a contract research organization (CRO).

The great majority of centers intend to return to their pre-pandemic research staff capacity once the pandemic is over and most expect this can be accomplished in less than one year. The majority of centers said they expect to raise compensation between 10 and 30 percent in order to fill their current vacancies.

Additional observations from cancer center respondents were collected via open-ended questions in the survey, including the observation that staff impacts first observed in 2020 persisted into 2021. Centers that maintained at least 100 percent or more of their staff are finding that they have to "run harder" to maintain the status quo. In regard to staff "poaching" by the pharmaceutical industry and CROs, cancer center staff reported that it resulted in a loss of staff, both senior and recently trained, and a smaller pool of qualified candidates for replacement hires. The higher compensation that centers need to offer in order to compete makes centers less cost-effective for pharmaceutical/CRO work, thereby threatening an important income stream for the centers.

Clinical Trials Leadership. Another emerging issue identified by CTAC was the need to diversify clinical trial leadership for NCI-sponsored trials. NCI plans to collect demographic data about clinical trials leadership to address this issue.

Questions and Discussion

Dr. Meropol posed the following questions to CTAC members:

- What specific actions could NCI take that would help mitigate these challenges?
- Although retention appears to be the primary issue, would there be any value in expanding clinical trial workforce training to increase the workforce pool?
- Would operational changes in NCI-sponsored clinical trials to reduce staff workloads help to improve retention?
- If so, what are examples of changes that would be helpful?

Henry Ciolino, PhD, Director of NCI's Office of Cancer Centers, reported that the Association of American Cancer Institutes (AACI) has formed a staff retention task force that has held two meetings and is surveying the NCI-designated cancer centers. Forty-three responses have been received to date. When their report is done, NCI will meet with AACI to consider potential actions. Dr. Ciolino has also been in communication with cancer center directors and administration directors regarding feedback on the workforce issues. For example, Robert A. Winn, M.D., Virginia Commonwealth University Massey Cancer Center, suggested a campaign to raise the visibility of clinical trials research as a career path. Dr. Ciolino also noted that some cancer centers have hired headhunters and become more flexible in terms of compensation.

Dr. Lerner commented that the data presented is insightful. Noting that activating clinical trials can be a burdensome process, he asked if there are ways to minimize the burden by streamlining and standardizing activation processes. He also asked if funding to cancer centers could be increased and allocated for finding and retaining top talent. He suggested that streamlining adverse event reporting to the local IRB would reduce burden and went on to state that the field needs a remote work model that incorporates best practices and lessons learned from the corporate world. There needs to be alignment between the institutional level and the cancer center on clinical trial staff recruiting and support. There is often a disconnect between clinical trial job descriptions/training and retention, so there is an opportunity for an improved human resources strategy. Dr. Lerner also commented that there is a disconnect between these workforce attrition issues and the recovery of clinical trial enrollment that was reported by Dr. Sharpless. He suggested a deeper analysis of the data to examine this relationship further.

Ms. Spears commented that workforce issues are important for patients. When trials have to pause or stop accrual due to staffing issues, patients' access to clinical trials is reduced and they miss the opportunity to obtain the latest treatments.

Dr. Muller asked if NCI has an idea of what the general supply and demand for the clinical trials workforce is at CROs nationally. She suggested that the field might benefit from supporting education and training in high school and college as well as offering mechanisms for financial support (e.g., loan forgiveness in exchange for time served in an academic center, especially in a minority/underserved institution).

Dr. Meropol asked if any CTAC members had had success with career development and skill-building as a method for enhancing the engagement of clinical trial operational staff. Dr. Blanke responded that his institution is piloting educational programs for senior personnel. He also reported on a

survey of research staff who all said that they do what they do to support the NCTN mission, and they continued to do so until financial and work/life demands interfered. Dr. Blanke suggested that reducing the staff burdens of conducting clinical trials would be helpful, but the real answer lies in higher compensation. Dr. Chu stated that the University of Pittsburgh Medical Center's (UPMC) Hillman Cancer Center experienced significant retention problems. In response, the institution created a career ladder which really helped to address the issue. At the Albert Einstein Cancer Center, there is an effort to identify employees with leadership skills. The Center is also offering high salaries but finding it difficult to recruit individuals who want to work at an academic center.

Dr. Knopp concurred that workforce issues are an extremely important discussion topic. He pointed out that one issue that has evolved rapidly is the ability to work remotely. This has resulted in many team members moving to industry because their human resources policies are more flexible and accommodating to family needs. He argued that academic medicine needs to develop a better understanding of best practices for remote work arrangements and offer greater flexibility to employees.

Dr. Mandrekar commented that losing statisticians to the pharmaceutical industry is a real concern at her institution. The Mayo Clinic has lost 6-7 biostatisticians who are moving to pharmaceutical companies or CROs. She attributed these losses to the fact that clinical trials have become so complex that staff members are burning out from the increased demand. For example, the pharmaceutical company tells its potential employees that they will only need to work on three trials at a time, not the 30 trials expected at the cancer center. It is difficult to recruit and train new statisticians.

Dr. Pollack called attention to the fact that the workforce attrition issue is a national problem. His institution has been approved by its graduate school to create a virtual degree program for clinical trial personnel. He suggested that others could join them to collectively address the problem.

Dr. Ramalingam commented that being a research coordinator or investigator has become incredibly stressful due to excessive paperwork and protocols that may be 100 pages long and difficult to follow. He suggested that NCI could identify the most important considerations in carrying out a protocol so staff can prioritize their efforts accordingly.

Dr. Doroshow concluded the discussion by stating that the field is at a tipping point in terms of workforce attrition. He looks forward to assistance from CTAC to identify the best solutions and resources needed to address the current clinical trial workforce crisis.

IV. Adjourn

Neal J. Meropol, MD

There being no further business, the 47th meeting of CTAC was adjourned at 2:55 p.m. on Wednesday, March 16, 2022.

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Date Neal J. Meropol, MD, Chair

_____

Date Sheila A. Prindiville, MD, MPH, Executive Secretary

NATIONAL INSTITUTES OF HEALTH
National Cancer Institute
Clinical Trials and Translational Research Advisory Committee

CHAIR

Neal J. Meropol, M.D. 2023
Vice President of Research Oncology
Scientific and Clinical Lead, Clinical Research
Flatiron Health
New York, New York

MEMBERS

Smita Bhatia M.D., M.P.H. 2025
Vice Chair of Outcomes for Pediatrics
Professor
Division of Hematology/Oncology
Department of Pediatrics
University of Alabama at Birmingham
Birmingham Alabama

Charles D. Blanke, M.D. 2024
Chair, SWOG Cancer Research Network
Professor
Knight Cancer Institute
Oregon Health and Sciences University
Portland, Oregon

Edward Chu, M.D. 2025
Director
Albert Einstein Cancer Center
Carol and Roger Einiger Professor of Cancer Medicine
Department of Medicine
Albert Einstein College of Medicine
Bronx, New York

Nancy E. Davidson, M.D. (BSC) 2022
Senior Vice President, Director and Full Member Clinical Research Division
Fred Hutchinson Cancer Research Center
President & Executive Director
Seattle Cancer Care Alliance Head, Division of Medical Oncology Department of Medicine
University of Washington
Seattle, Washington

Anjelica Q. Davis, M.P.A. (NCRA) 2022
President
Fight Colorectal Cancer
Springfield, Missouri

Adam P. Dicker, M.D., Ph.D. 2024
Professor and Chair
Department of Radiation Oncology
Sidney Kimmel Cancer Center
Thomas Jefferson University
Philadelphia, Pennsylvania

Gary C. Doolittle, M.D.* 2026
Capitol Federal Masonic Professor
Division of Medical Oncology
University of Kansas Medical Center
Westwood, Kansas

Ernest T. Hawk, M.D. 2024
Vice President and Head
Division of Cancer Prevention and Population Sciences
T. Boone Pickens Distinguished Chair for Early Prevention of Cancer
The University of Texas MD Anderson Cancer Center
Houston, Texas

Michael V. Knopp, M.D. 2023
Professor of Radiology
Department of Radiology
Novartis Chair of Imaging Research
The Ohio State University
Columbus, Ohio

Seth P. Lerner, M.D., F.A.C.S. 2025
Vice Chair for Faculty Affairs
Beth and Dave Swalm Chair in Urologic Oncology
Professor
Scott Department of Urology
Baylor College of Medicine
Houston, Texas

Mia Levy, M.D., Ph.D. **2024**
Chief Medical Officer
Foundation Medicine, Inc.
Cambridge, Massachusetts

Sumithra J. Mandrekar, Ph.D. **2024**
Professor of Biostatistics and Oncology
Group Statistician, Alliance for Clinical Trials in Oncology
Department of Quantitative Health Sciences
Mayo Clinic
Rochester, Minnesota

Robert S. Mannel, M.D.* **2026**
Director
Peggy and Charles Stephenson Cancer Center
College of Medicine
University of Oklahoma Health Sciences Center
Oklahoma City, Oklahoma

Ruben A. Mesa, M.D.* **2026**
Executive Director
Mays Cancer Center
UT Health San Antonio MD Anderson
San Antonio, Texas

Carolyn Y. Muller, M.D., F.A.C.O.G. **2025**
Associate Director of Clinical Research
The Judy Putman Dirks Endowed Professor in Gynecologic Cancer Care
Department of Obstetrics and Gynecology
The University of New Mexico Health Sciences Center
Albuquerque, New Mexico

Raphael E. Pollock, M.D., Ph.D., F.A.C.S. **2025**
Kathleen Wellenreiter Klotz Chair in Cancer Research
Director
The Ohio State University Comprehensive Cancer Center
Columbus, Ohio

Suresh S. Ramalingam, M.D., F.A.S.C.O. **2025**
Executive Director
Winship Cancer Institute
Roberto C. Goizueta Chair for Cancer Research
Emory University School of Medicine
Atlanta, Georgia

Victor M. Santana, M.D. **2023**
Associate Director for Clinical Research
Vice President, Clinical Trials Administration
St. Jude Children's Research Hospital
Memphis, Tennessee

Patricia A. Spears **2026**
Scientific Research Manager
Patient Advocate
Lineberger Comprehensive Cancer Center
University of North Carolina at Chapel Hill
Chapel Hill, North Carolina

Julie M. Vose, M.D. **2023**
Neumann M. and Mildred E. Harris Professor
Chief, Division of Oncology/Hematology
Department of Internal Medicine
University of Nebraska Medical Center
Omaha, Nebraska

George Wilding, M.D.* **2026**
Professor Emeritus and Director Emeritus
University of Wisconsin, Madison
Albuquerque, New Mexico

Ex Officio Members

William L. Dahut, M.D.
Scientific Director for Clinical Research
Center for Cancer Research
National Cancer Institute
National Institutes of Health
Bethesda, Maryland

James H. Doroshow, M.D.
Deputy Director
Clinical and Translational Research
Director, Division of Cancer Treatment and Diagnosis
National Cancer Institute
National Institutes of Health
Bethesda, Maryland

Paulette S. Gray, Ph.D.
Director
Division of Extramural Activities
National Cancer Institute
National Institutes of Health
Bethesda, Maryland

Michael J. Kelley, M.D., F.A.C.P.
National Program Director for Oncology Veterans Health Administration
Department of Veterans Affairs
Durham, North Carolina

Anthony Kerlavage, Ph.D.
Director, Center for Biomedical
Informatics and Information Technology
Office of the Director
National Cancer Institute
National Institutes of Health
Bethesda, Maryland

Richard Pazdur, M.D., F.A.C.P.
Director
Oncology Center of Excellence
U.S. Food and Drug Administration
Silver Spring, Maryland

Xiufen Sui, M.D, M.S.
Biostatistician
Center for Clinical Standards and Quality
Center for Medicare and Medicaid Innovation
Baltimore, Maryland

Designated Federal Official

Sheila A. Prindiville, M.D., M.P.H.
Director
Coordinating Center for Clinical Trials
Office of the Director
National Cancer Institute
National Institutes of Health
Bethesda, Maryland

*** pending appointment**