DEPARTMENT OF HEALTH AND HUMAN SERVICES
NATIONAL INSTITUTES OF HEALTH
NATIONAL CANCER INSTITUTE
45th CLINICAL TRIALS AND TRANSLATIONAL RESEARCH ADVISORY COMMITTEE (CTAC) MEETING

Summary of Meeting
July 14, 2021

Webinar

CLINICAL TRIALS AND TRANSLATIONAL RESEARCH ADVISORY COMMITTEE
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The 45th meeting of the Clinical Trials and Translational Research Advisory Committee (CTAC) of the National Cancer Institute (NCI) was convened on Wednesday, July 14, 2021, at 11:00 a.m. ET. The CTAC chair, Dr. Loehrer, presided.[1] The meeting was adjourned at 2:27 p.m.

Chair
Patrick J. Loehrer, Sr.

CTAC Members
Debra L. Barton
Smita Bhatia (absent)
Charles D. Blanke
Edward Chu (absent)
Janet Ellen Dancey
Nancy E. Davidson
Anjelica Q. Davis
Adam P. Dicker
Ernest T. Hawk
Michael V. Knopp
Anne-Marie R. Langevin
Seth P. Lerner
Mia Levy
Sumithra J. Mandrekar
Lynn M. Matrisian
Neal J. Meropol
Carolyn Y. Muller
Raphael E. Pollock
Suresh S. Ramalingam
Steven T. Rosen (absent)
Victor M. Santana
Julie M. Vose

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

Executive Secretary
Sheila A. Prindiville, NCI

Presenters
Nancy E. Davidson, MD, Senior Vice President, Director, and Full Member, Clinical Research Division, Fred Hutchinson Cancer Research Center; President and Executive Director, Seattle Cancer Care Alliance; Head, Division of Medical Oncology, Department of Medicine, University of Washington
James H. Doroshow, MD, Deputy Director, Clinical and Translational Research; Director, Division of Cancer Treatment and Diagnosis, NCI
Janet Eary, MD, Associate Director, Cancer Imaging Program, Division of Cancer Treatment and Diagnosis, NCI

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

M.K. Holohan, JD, Director, Office of Government and Congressional Relations, Office of the Director, NCI

Patrick J. Loehrer, Sr., MD, Distinguished Professor, Indiana University; Joseph W. and Jackie J. Cusick Professor in Oncology; Director, Center of Global Oncology and Health Equity, Indiana University Melvin and Bren Simon Comprehensive Cancer Center

Norman E. Sharpless, MD, Director, NCI

Tiffany A. Wallace, PhD, Program Director, Center to Reduce Cancer Health Disparities, NCI

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I. Call to Order and Opening Remarks

Patrick J. Loehrer, Sr., MD

Dr. Loehrer called the 45th meeting of CTAC to order and welcomed participants. Dr. Schneider was welcomed as the U.S. Food and Drug Administration (FDA) representative in place of Dr. Pazdur at this meeting.

Dr. Loehrer 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=41971 after the meeting.

The next CTAC meeting, which will take place on November 10, 2021, will again be virtual.

Motion. A motion to accept the minutes of the 44th CTAC meeting, held on March 17, 2021, was approved.

II. NCI Director's Update

Norman E. Sharpless, MD

50th Anniversary of the National Cancer Act. The commemoration of the 50th anniversary of the National Cancer Act (NCA) is under way, and NCI will focus on this topic throughout the year. Dr. Sharpless noted that NCI was actually established more than 80 years ago, in 1937. However, the NCA modernized the institute, and celebration of the NCA provides an opportunity to inspire the next generation of cancer researchers and cancer research supporters. Commemoration activities will highlight progress in cancer research across the nation from basic science to translational and implementation science. The theme for this milestone is "Nothing will stop us."

NCI Budget. When CTAC last met in March 2021, NCI and the federal government were operating under a continuing resolution. Since then, Congress has completed the fiscal year (FY) 2021 appropriations process, and the President's proposed FY 2022 discretionary budget has been submitted. Under the FY 2021 budget, NCI received $6.56 billion, a $119 million increase from FY 2020. This appropriation includes $195 million for the 21st Century Cures Act, which funds the Cancer Moonshot, and $50 million for the second year of the Childhood Cancer Data Initiative (CCDI).

The President's proposed FY 2022 discretionary budget appropriates nearly $52 billion to NIH, including $6.73 billion to NCI, which is approximately 2.7 percent ($174) million more than the enacted FY 2021 NCI budget. The President's budget allocates $50 million to NCI for year 3 of the 10-year, $500 million CCDI and $194 million for the Cancer Moonshot, which will sunset in FY 2023. The NCI has begun planning the transition of funding for the initiatives supported through the Cancer Moonshot to the general NCI appropriation. The President's budget also establishes funding for a new agency, the Advanced Research Projects Agency for Health (ARPA-H), which is modeled after the Defense Advanced Research Projects Agency (DARPA) and would be housed within NIH. This new agency would be more flexible and nimble than other parts of NIH, and would work across disciplines and diseases, including cancer, Alzheimer's disease, diabetes, and other conditions. It is possible that ARPA-H will have some special capabilities, including being exempt from peer review for the agency's funding decisions and the ability to do multi-year contracting, which would be different from how NCI and other

NIH Institutes and Centers (ICs) function. A town hall to kick off a series of listening tours on ARPA-H involving various stakeholders has been organized by NIH and the White House Office of Science and Technology.

NCI's ability to support R01 paylines is determined by the number of applications received and appropriations from Congress. R01 paylines are currently at the 11th percentile range, but in its annual budget plan and proposal for FY 2022, NCI has established a goal of reaching a payline of the 15th percentile by FY 2025 (the "15 by 25" goal). NCI cannot determine if there will be an increase in paylines for FY 2022 until Congress finalizes the budget.

The appropriations process is currently ongoing, and a long Continuing Resolution is possible. Dr. Sharpless recently testified in Congress before the House and the Senate with NIH Director Dr. Collins and other NIH leaders in support of the President's proposed budget. Dr. Sharpless said the annual increase in funding for NIH and NCI, particularly over the past decade, reflects strong bipartisan support for cancer research.

Cancer Trends and Surveillance. Dr. Sharpless referenced two key documents on cancer progress that were recently released from the NCI. The first was the Cancer Trends Progress Report, which summarizes the nation's progress against cancer in relation to the Healthy People 2030 targets set forth by the U.S. Department of Health and Human Services (HHS), from prevention to end-of-life care. The online report, intended for policy makers, researchers, and public health professionals, includes key measures of progress along the cancer control continuum and uses national trend data to illustrate where improvements have been made as well as where there is still work to do.

The second document referenced by Dr. Sharpless was the Annual Report to the Nation on the Status of Cancer. The report was released on July 8, 2021, and shows some encouraging trends in cancer death rates. Data through 2018 show a steady decline of about 1.5 percent per year in overall cancer mortality going back to the 1990s and an accelerated decline of more than 2 percent per year more recently. Particularly substantial reductions in mortality have been seen for lung cancer and melanoma. In contrast, a few cancers, including endometrial cancer, are seeing an increase in mortality, and previously declining mortality rates for several major cancers, including prostate, colorectal, and female breast cancers, have slowed or leveled off. It is also important to note that incidence for many cancers is increasing or stable. Melanoma is the cancer that has the highest increase in incidence, but also has remarkably decreased mortality. This trend is thought to have resulted from a combination of increased screening and improvements in treatment.

Dr. Sharpless highlighted several recent updates to the Surveillance, Epidemiology, and End Results (SEER) program. With the awarding of new contracts, SEER now covers approximately half of the U.S., improving incidence and mortality data in general and for underrepresented populations across the country, including Alaska Natives, Arizona Indians, and Cherokee Nation. Data linkages have also been expanded under SEER; examples include linking cancer data in certain states to medication use/prescription data from national pharmacy chains or to insurance claims data from sources such as the SEER-Medicare registry. Novel technology is being developed in collaboration with the Department of Energy in which natural language processing and machine learning are being adapted to expedite and facilitate the reading of some 800,000 pathology reports SEER receives each year. The goal is to implement near real-time reporting using this and other technological solutions.

Bilateral Cancer Summit and International Collaborations. In advance of the G-7 meeting in June 2021, President Biden and the Prime Minister of the United Kingdom (U.K.), Boris Johnson, made a formal commitment to convene the first joint U.S.-U.K. Bilateral Cancer Summit. Dr. Sharpless pointed to the many longstanding relationships with U.K. organizations, including the Cancer Grand Challenges, a major collaborative funding initiative between NCI and Cancer Research United Kingdom (CRUK). A high-level meeting between NCI and its U.K. collaborators is being planned for early 2022 to build on joint research efforts.

NCI's COVID-19 Activities. Dr. Sharpless provided updates on NCI COVID-19 research projects, including the establishment of the Serological Sciences Network (SeroNet), which is funding translational research related to the immune response to COVID-19, resulting in a large contribution to the scientific literature and a better understanding of immunity to COVID-19.

The NCI COVID-19 in Cancer Patients Study (NCCAPS) aims to enroll 2,000 patients across 1,000 sites in the U.S. and follow them for 2 years to determine the natural history of COVID-19 in people with cancer. The study was launched in May 2020 and has a special emphasis on minority, underserved, and rural communities. To date, the study has activated 875 sites in all 50 states, the District of Columbia, Puerto Rico, and Canada and enrolled 1,150 participants, including 91 pediatric patients. However, accrual has slowed from approximately 50 patients per week at the height of the pandemic to approximately 10 patients per week. Two abstracts on the status of NCCAPS that were presented at ASCO 2021 described inpatient mortality and outcomes for patients with cancer and coronavirus, the ability to continue cancer care, and the occurrence of late-onset COVID-19 symptoms in patients with cancer.

NCI has also been tracking the impact of the COVID-19 pandemic on cancer screening in the U.S. through the Population-based Research Optimizing Screening through Personalized Regimens (PROSPR) consortium. A dramatic drop-off in screening for breast cancer (mammography) and colorectal cancer (colonoscopy) occurred in the spring of 2020, which far exceeded what had been expected through modeling. An estimated 10 million screening events were missed in 2020 and early 2021. In addition, there have been marked decreases in cancer surgeries and chemotherapies since the start of the pandemic. It is not clear whether the country has the capacity to fully catch up to these losses, and many experts are expecting an increase in the incidence of later-stage cancers.

One notable finding from the PROSPR data was that use of in-home screening tests for colorectal cancer (fecal immunochemical testing [FIT]) did not markedly decline during the pandemic, as in-office screening did. This outcome points to the merits of in-home screening within the current climate.

Several groups have provided clear guidelines for providing care to cancer patients during the pandemic. The community at large needs to focus on working collectively to make up screenings where possible, get patients with symptomatic cancer evaluated as quickly as possible, and ensure that care is not being delayed or triaged unnecessarily.

Cancer Moonshot. The Cancer Moonshot was given 7 years of funding from Congress beginning in FY 2017 and is now in its fifth year of funding. The initiative involves more than 70 consortia and programs and supports more than 240 projects. Moonshot projects conduct research across the cancer continuum but focus heavily on translational research. Projects are designed to, for example, increase fundamental understanding of the drivers of childhood cancers and develop targeted approaches to those drivers, increase genetic counseling and screening for individuals with inherited predispositions

to cancer, create new therapeutic approaches and identify biomarkers and responses to immunotherapy drugs, and engage people who have cancer more directly in research.

One project funded by the Cancer Moonshot is the Human Tumor Atlas Network (HTAN), which was launched in September 2018 and is designed to identify the cellular, morphological, and molecular features of human cancers as they evolve from precancerous lesions to advanced disease. The diverse set of cancer types under investigation includes tumors that affect minority and underserved populations, tumors with a hereditary component, and highly aggressive pediatric cancers. Access to and use of the data in HTAN are open to the scientific community. More than 10 papers describing the initial atlas across eight organ sites will be published this fall. Data generated through this initiative are available on the HTAN portal.

Funding for the Cancer Moonshot initiative will sunset in FY 2023. NCI is developing a plan to sustain the Moonshot programs, as appropriate, through the general appropriation after congressional funding ends.

Other NCI Research Programs and Initiatives. A study sponsored by NCI and AstraZeneca demonstrated the benefit of adjuvant treatment with olaparib after completion of chemotherapy in women with early-stage high-risk *BRCA*–mutated invasive breast cancer. Results show mortality benefit and significant 3-year disease-free survival and may lead to a new standard of care for this population. Dr. Sharpless noted that the study also illustrates the importance of genomic sequencing in breast cancer.

Dr. Sharpless cited several high-profile publications and projects from NCI's Clinical Proteomics Tumor Analysis Consortium (CPTAC). One notable publication identifies novel signaling modes in glioblastoma (GBM) and four distinct subtypes of glioma based on the immune profile of the disease. These data might inform immuno-oncology research and models on how to enhance the immune response of some cancers. To date, the consortium has comprehensively characterized 14 tumor types in 4.5 years, exceeding its goal of characterizing five tumor types over this time period. The program has fostered the International Cancer Proteogenome Consortium (ICPC) and supports NCI's RAS Initiative, established in 2013 to explore innovative approaches for attacking the proteins encoded by mutant forms of *RAS* genes and to ultimately create effective, new therapies for *RAS*-related cancer.

Recent results of an international consortium study on rhabdomyosarcoma (RMS), the most common soft tissue sarcoma of childhood, indicate that the presence of mutations in *tp53, myod1,* and *cdkn21* appear to be associated with a more aggressive form of the disease and a poorer chance of survival. This consortium has the largest genomic characterization of RMS with clinical annotation to date. Analysis of these data has identified distinct RMS populations with different prognoses and points to potential new therapeutic targets for this disease.

NCI Equity and Inclusion Program. NCI launched the Equity and Inclusion Program (EIP) with the goals of increasing the diversity of the cancer research workforce, building a more inclusive and equitable NCI community, addressing cancer disparities, and advancing health equity. The EIP is linked to the UNITE initiative and is overseen and supported by a steering committee called the NCI Equity Council (NEC), which is co-chaired by Dr. Sharpless and Dr. Gray. Five working groups have been formed under the EIP to address cancer health disparities, optimize the cancer research workforce, and provide an inclusive and equitable culture at NCI. The working groups are well under way and have already provided NCI with several recommendations that are being acted on, including innovative approaches to promote a diverse cancer research workforce and to support and retain underrepresented

minority scientists within NCI to create an inclusive culture. Presentations on EIP activities were recently given at a joint NCI Board of Scientific Advisors and National Cancer Advisory Board meeting.

Questions and Discussion

Dr. Loehrer asked about China's Thousand Talents Program, Congress's view of the program, and how congressional action might affect the status of the program. Dr. Sharpless said the Senate version of the Endless Frontier Act might include language with implications for academic institutions. He also pointed out that international collaborations, including those with China and Chinese scientists, are vital for cancer progress.

Ms. Holohan said Congress has placed some emphasis on concerns about competitiveness. She noted that the U.S. House and Senate are handling the Thousand Talents program and the Endless Frontier Act very differently and provided some additional information in her presentation.

III. Retiring Members Recognition

James H. Doroshow, MD

Dr. Doroshow thanked the retiring CTAC members—Drs. Dancey, Langevin, Loehrer, Matrisian, and Rosen, with special recognition to Dr. Loehrer, who served as CTAC Chair from 2019 to 2021—for their service on CTAC. Each retiring member was presented with a plaque in recognition of their contributions to the committee.

IV. Legislative Update

M.K. Holohan, JD

Fiscal Year 2022 Budget and Appropriations. The White House released the President's FY 2022 budget on May 28, 2021. The administration has proposed $131.7 billion for the Department of Health and Human Services (HHS), representing a 23.4 percent increase over FY 2021 enacted levels. The budget proposes $51 billion for NIH, a $9 billion increase over FY 2021 enacted levels.

Approximately $6.5 billion of the increase for NIH would go toward the establishment of the Advanced Research Projects Agency for Health (ARPA-H), which would be housed within NIH and would aim to develop breakthroughs in prevention, detection, and treatment of diseases including Alzheimer's, diabetes, and cancer. There is support for this agency among House and Senate Appropriations Subcommittee members, however, there were also questions around the specifics of how the program would work.

The President's budget proposes $6.73 billion for NCI. This includes an increase of approximately $174 million over the FY 2021 enacted funding level for NCI, which is part of the remaining $2.5 billion proposed increase to the NIH base budget.

Congress remains very divided and faces many challenges with the FY 2022 appropriations process. Neither the House nor the Senate has enacted a budget resolution for FY 2022. However, the House Appropriations Committee is moving quickly to mark up the House bill that includes the Department of Labor, all of HHS, and the Department of Education. They are under considerable time constraints to finalize and pass a budget, with an August recess pending and only 79 days of federal funding remaining as of the date of this CTAC meeting. Additionally, Congress needs to address the

existing debt limit suspension, which expires on July 31. The midterm elections in November 2022 present pressure for Congressional Democrats and the Biden Administration as, historically, the party that holds the White House almost always loses seats in the House in the midterms.

Other Major Funding Bills. The Senate passed the U.S. Innovation and Competition Act on June 8, 2021. The Senate bill, based on the Endless Frontier Act, authorizes $250 billion over 5 years and focuses on increasing competitiveness with China. The bill would provide more than $50 billion to the U.S. semiconductor industry; dramatically increase the budget of the National Science Foundation; and increase funding for the Department of Energy (DOE) National Labs, the National Aeronautics and Space Administration (NASA), and the Commerce Department. Funding for the Commerce Department would be used to establish regional technology hubs. The House passed two complementary alternatives that differ from the Senate legislation; further negotiation will be needed to reconcile the House and Senate bills.

The Senate also passed an amendment by Senator Ben Sasse (R-NE) that would double the budget for DARPA over a 5-year period. There were multiple amendments relevant to NIH on topics including foreign influence, "gain of function" research, and genomic data sharing. Ms. Holohan said the bill faces challenges in the House and that companion legislation has been stalled for weeks.

Questions and Discussion

Dr. Loehrer noted that the media tends to focus on division and partisan politics, but there appears to be ongoing bipartisan support for NIH and NCI that has been cultivated over the years. Ms. Holohan said members of Congress have become accustomed to working together on many issues and that bipartisan support of NCI has spanned multiple administrations and Congresses.

V. Cancer Clinical Investigator Team Leadership Award (CCITLA)—2021 Awardees and Program Update

James H. Doroshow, MD

CCITLA Program. Since 2009, the CCITLA program has recognized and supported outstanding clinical investigators who actively enroll patients and participate collaboratively in NCI-funded clinical trials at NCI-designated cancer centers. The program was designed to promote the retention of investigators in academic clinical research careers by providing salary support to individuals who do not have independent research grant funding as a principal investigator. The program is open to mid-career clinicians including physicians, oncology nurses, clinical psychologists, and similarly qualified clinicians with a doctoral degree who are practicing in the medical oncology field.

Supported activities include engaging fellows and new faculty in collaborative clinical research efforts; organizing courses, lecture/seminar series, educational sessions, and workshops related to clinical trials; participating on cancer center committees related to clinical trials; developing clinical trial(s); designing and implementing initiatives to better coordinate, support and integrate clinical trials efforts at the institution; and improving access, accrual and efficiency of clinical trials.

CCITLA is a competitive program, with 8 to 12 new awards made each year. To date, 143 awards have been made. Candidates are nominated annually by NCI cancer center directors. Awardees receive $60,000 per year for 2 years, with an institutional commitment to allow at least 15 percent of the

awardees' effort for proposed activities. To date, 96 percent of recipients who have completed the award (*n* = 124, 2009–2019) are still in academic clinical research positions.

CCITLA Awardees. The 2021 recipients are a diverse group of clinicians studying a broad range of cancers, including melanoma as well as breast, gastrointestinal, genitourinary, gynecologic, and pediatric and adult brain cancers. The 2021 awardees are:

- Brian Christopher Baumann, MD, Washington University, Siteman Cancer Center
- Daniel V. T. Catenacci, MD, MS, University of Chicago Comprehensive Cancer Center
- Kristen K. Ciombor, MD, MSCI, Vanderbilt University Medical Center, Vanderbilt-Ingram Cancer Center
- Bree Ruppert Eaton, MD, Emory University, Winship Cancer Institute
- Zeynep Eroglu, MD, University of South Florida, H. Lee Moffitt Cancer Center & Research Institute
- Joseph W. Kim, MD, Yale Cancer Center
- Mark V. Mishra, MD, University of Maryland, Marlene & Stewart Greenebaum Comprehensive Cancer Center
- Zahi Ibrahim Mitri, MD, MS, Oregon Health & Science University, Knight Cancer Institute
- Alison M. Schram, MD, Memorial Sloan Kettering Cancer Center
- Nataliya V. Uboha, MD, PhD, University of Wisconsin, Carbone Cancer Center

Clinician Scientist Research Award R50. There currently are no mechanisms offered by NCI that provide a clinical career path with *sustained* salary support. A new concept under development, the Clinician Scientist Research Award R50, which was recently approved by the NCI Board of Scientific Advisors, will help address this gap. The program will provide 5-year, renewable awards for up to 40 percent effort to approximately 25 established clinical investigators who carry out activities at their academic institutions that are critical to the success of NCI clinical trials but who do not seek independent research funding. The R50 program will be for more senior faculty and clinicians and fund a higher level of effort than the CCITLA program. The request for application (RFA) for the R50 is expected to be released in fall 2021.

NCI plans to seek CTAC input on the modification of applicant eligibility criteria for the CCITLA after release of the R50 funding announcement. Modifications under consideration include shifting the focus to investigators earlier in their career and expanding support of underrepresented oncologists involved in NCI-funded clinical trials.

Questions and Discussion

Ms. Davis asked whether these programs could encourage investigators to engage with research advocates or incorporate a health equity focus by having a relationship with a research advocate as a priority. Dr. Doroshow explained that, while the structure of the program is still in development, the NCI Board of Scientific Advisors provided input emphasizing that the award structure should encourage applications from individuals who would facilitate the development of trials appropriate for underrepresented minorities or who are themselves underrepresented minorities. In addition, NCI is focused on facilitating further accrual of underrepresented minorities in its clinical trials program that, in turn, would involve interactions with advocates.

Dr. Ramalingam inquired about the R50 application process, specifically asking whether candidates apply directly or are nominated, and if the number of applicants per center is limited. Dr. Doroshow replied that the details regarding the application process will be provided in the funding announcement, which is expected to be released later this year.

Dr. Loehrer suggested having the senior investigators under the R50 award serve as mentors to the more junior investigators who are CCITLA recipients, as a way of establishing a mentorship network.

Dr. Lerner asked about the mix of applicants for these programs, noting that surgeons are under considerable pressure from a time management standpoint to build research careers. Dr. Pollack agreed, and he and Dr. Lerner recommended promoting the R50 award to surgical oncology programs to engage surgical trainees and other early- and mid-career surgeons in order to foster this group of applicants. Dr. Muller said gynecologic oncologists should also be included in outreach efforts for the program. Dr. Doroshow said CCITLA recipients usually include one or two gynecologic oncologists each year but that very few surgical oncologists apply for these awards.

Dr. Santana suggested including global health researchers as part of outreach to underserved populations and investigators under the R50 program. One key focus area might be pediatric oncology because of the potential to have a major impact on curable diseases that occur worldwide.

Dr. Dicker noted the importance of clinicians in training seeing how their career path could unfold, whether through programs and awards from NIH/NCI or other organizations. Dr. Doroshow said that, after the R50 RFA is released, it might make sense for NCI to draft an informational document clarifying the various timelines and career development options for trainees who are early in their positions. This would include an outline of the opportunities for training, grant support, and other types of support available as an investigator moves through their career. Dr. Muller suggested getting feedback on the informational document from other relevant groups, including the American Society of Clinical Oncology (ASCO), the Society of Surgical Oncology (SSO), and the Society of Gynecologic Oncology (SGO).

Dr. Davidson suggested that NCI compile and publish the accomplishments of CCITLA recipients to date to demonstrate the success and value of the program, including how it supports the academic clinical research pipeline. Dr. Doroshow agreed with this idea and suggested writing a paper on the topic after getting input from CTAC members on modifications to the CCITLA program in response to the R50. Dr. Loehrer noted that many of the awardees have been from smaller institutions and he suggested including a map of the CCITLA recipients that shows the regions and institutions of the awardees in the publication. Dr. Doroshow said awards are typically set up so that an institution is limited to one award at a time.

VI. NCI Equity and Inclusion Activities

Tiffany A. Wallace, PhD

Equity and Inclusion Program (EIP). NCI launched the EIP with the goals of increasing the diversity of the cancer research workforce, building a more inclusive and equitable NCI community, addressing cancer disparities, and advancing health equity. EIP is overseen and supported by a steering committee called the NCI Equity Council (NEC), which is co-chaired by Dr. Sharpless and Dr. Gray. Five working groups have been formed under NEC:

- Working Group 1: Enhancing Research to Address Cancer Health Disparities

- Working Group 2: Ensuring Diversity of Thought and Background in the Cancer Research Workforce
- Working Group 3: Promoting an Inclusive and Equitable Community at NCI
- Working Group 4: Systemic Tracking and Evaluation of Equity Activities
- Working group 5: Communications and Outreach for Equity Activities

The first three working groups encompass the main goals of EIP. The two additional working groups address issues and activities that cut across all of the groups. Some activities of the working groups complement and/or address the recommendations made by the Strategic Planning Working Group, particularly as related to patient access and the oncology workforce. Dr. Wallace highlighted key NCI workforce data and summarized some of the efforts to date by Working Groups 2 and 3, and then presented activities to date for Working Group 1.

Working Groups 2 and 3. Data from Working Group 2—Ensuring Diversity of Thought and Background in the Cancer Research Workforce—show striking underrepresentation of Black/African American and Hispanic/Latinx R01 applicants and awardees. In FY 2020, only 1 percent and 5 percent of all R01-equivalent awardees identified as Black/African American and Hispanic/Latinx, respectively. Investigators identifying as more than one race, American Indian/Alaska Native, and Native Hawaiians/Pacific Islanders were combined and totaled an additional 1 percent. Application rates are also extremely low for these groups, from 1 percent for the combined group, 2 percent for Black/African American, and 5 percent for Hispanic/Latinx.

Working Group 2 has been focused on sustaining past efforts that have been successful at increasing diversity, such as NCI's Center to Reduce Cancer Health Disparities (CRCHD) Continuing Umbrella of Research Experiences (CURE) Program. The group is also working on new programs to address some of the structural barriers that have limited diversity.

Data from Working Group 3—Promoting an Inclusive and Equitable Community at NCI—show that the representation of scientists that identify as Black/African American or Hispanic/Latinx is strikingly low for senior positions within NCI's Intramural Research Program. Specifically, 2 percent or less of senior scientists, clinicians, or investigators within the NCI Intramural Research Program identify as Black or Hispanic. In comparison, approximately 75 percent or more of the institute's senior scientists, clinicians, and investigators identify as White.

Working Group 1. Working Group 1 is co-chaired by Dr. Wallace, Dr. Doroshow, and Worta McCaskill-Stevens, MD, MS, Chief, Community Oncology and Prevention Trials Research Group, NCI. The group is charged with developing research recommendations to determine the precursors to cancer disparities and implementing research programs to eliminate disparities and promote health equity across the continuum, from prevention to treatment and survivorship.

The group has identified three goals to fulfill its mission. Goal 1 involves conducting a landscape analysis and identifying key diverse stakeholders to provide input on the gaps and opportunities the group should prioritize. Goal 2 is to develop and prioritize research recommendations based on analysis and feedback. Goal 3 involves promotion and implementation of research recommendations and activities.

The working group has already undertaken several immediate actions in support of the working group's goals. Two NCI-specific requests for information (RFIs) have been released (NOT-CA-21-066 and NOT-CA-21-067). One RFI sought stakeholder input on how to enhance cancer disparities research,

and the other focused on how to increase diversity and inclusion in the cancer research workforce. Planning is under way for a summit that will bring together multiple stakeholders to develop innovative ideas around increasing inclusion and health equity in cancer clinical trials. The working group supported, in conjunction with the NCI Division of Cancer Epidemiology and Genetics and NCI Center for Cancer Research, postdoctoral fellowships and research project awards to enhance research on cancer disparities and minority health within the NCI intramural research program.

Furthermore, the working group also supported the development of the Connecting Underrepresented Populations to Clinical Trials (CUSP2CT) initiative, which is designed to implement and evaluate multi-level outreach and education interventions to increase referral of racial/ethnic populations to NCI-supported clinical trials. This concept was approved by the NCI Board of Scientific Advisors in June 2021. Lastly, the working group is also focused on reissuing/re-imagining NCI initiatives that have successfully advanced the field of cancer disparities research.

Consistent with Goal 1, a landscape analysis is currently under way and involves extracting key information from published reports (i.e., critical gaps, research opportunities, recommendations) and identifying overlapping and unique issues to help inform future working group priorities.

Consistent with Goals 2 and 3, the working group is conducting a survey and analysis to evaluate telemedicine usage in NCI clinical trials before and after the COVID-19 pandemic, with a particular interest in identifying lessons learned that could inform how to use telemedicine to increase equity in clinical trials going forward. Furthermore, a Notice of Special Interest (NOSI) soliciting new P01 applications proposing cancer control research in persistent poverty areas—defined as a county that has had poverty rates of 20 percent or more in U.S. Census data from 1980, 1990, and 2000—has been released (NOT-CA-21-071). Incidence and mortality from cancer is known to be higher in these areas. Current categorization of the data indicates that approximately 10 percent of U.S. counties meet the criteria for a persistent poverty area; most of these counties are in the rural South. The group is working with the U.S. Department of Agriculture (USDA) to expand the definition to the census tract level to make it more granular; under this expanded definition, each of the 50 states and the District of Columbia has a persistent poverty area.

Dr. Wallace concluded her presentation mentioning that the NCI's EIP is coordinating and synergizing with the NIH UNITE Initiative to most effectively achieve the goals of the two efforts.

Questions and discussions

LeeAnn Bailey, PhD, CRCHD, NCI, and co-chair of Working Group 2, said her group is focused on enhancing NCI's efforts to develop and train a diverse and balanced cancer workforce, at all levels both intramurally and extramurally, especially focusing on the R01 pipeline. She noted that workforce diversity issues and associated challenges are not unique to NCI and are relevant across NIH.

Satish Gopal, MD, MPH, Director, Center for Global Health, NCI, and co-chair of Working Group 3, highlighted actions already taken and under way by that group, including conducting a comprehensive landscape analysis of the workforce composition and climate at the NCI, with a focus on differences across groups. The working group has also promoted increased transparency about the workforce based on results of the annual Federal Employee Viewpoint Survey administered survey to all federal employees; this analysis included a breakdown of racial and ethnic categories by specific work units within NCI. Another project involves the development of a diversity, equity, and inclusion toolkit

that will be piloted in the near future across groups within the NCI to help facilitate conversations around some of these difficult topics. In addition, the working group has launched a new diversity, equity, and inclusion speaker series to address issues of equity and diversity within the NCI workforce.

Ms. Davis asked if there was a strategy planned for reviewing the diversity within NCI's leadership. Dr. Gopal noted the importance of this issue and indicated that activities within NIH UNITE and the EIP are aimed at addressing diversity in NCI's leadership.

Dr. Dicker inquired about initiatives for Historically Black Colleges and Universities (HBCUs) at NCI centers and/or other institutions to increase the investigator pipeline. Dr. Bailey pointed to CRCHD's Partnerships to Advance Cancer Health Equity (PACHE) program, which pairs a cancer center with minority-serving institutions, including not only HBCUs but also Hispanic-serving institutions, Tribal colleges, and others. The intent of the PACHE program is to support research, build capacity, and address gaps in cancer health disparities research across the cancer centers. Another immediate action taken by Working Group 2 is the implementation of the Early Investigator Advancement Program, which promotes the transition of extramural and intramural early career investigators to independent investigators. Dr. Dicker further noted that the geographic boundaries for mentorship and collaboration have expanded due to our ability to meet virtually. He suggested considering how this could help enhance the development of these relationships. Dr. Bailey said that several of the resources in development are intended to be made available to the public, including virtual participation and technical assistance where possible.

Dr. Hawk raised concerns about disparities among uninsured populations, particularly in states and regions where Medicaid expansion has not occurred, and asked about initiatives to assist cancer centers in improving recruitment of uninsured patients to clinical trials. Dr. McCaskill-Stevens noted that some institutions serve only underserved populations but acknowledged that these institutions alone are not sufficient to fully meet the needs of the uninsured. One potential way to address this problem is the passing and implementation of the Clinical Treatment Act, under which Medicaid would cover participation of otherwise uninsured patients in clinical trials, which has been a major barrier for this group. It is important that institutions are committed to receiving uninsured patients and have a pathway established through which these patients can navigate.

Ms. Davis said groups such as the NCI Patient Advocate Steering Committee (PASC) and NCI Council of Research Advocates (NCRA) have discussed how research advocates fit into the larger NCI workforce. She asked about assessing diversity and equity within the population of research advocates and the strengths and weakness of recruitment efforts regarding research advocate representation, as well as whether there is a way to help with succession planning for these advocates. Dr. Wallace said these suggestions are important to consider for the working group's next steps.

Dr. Loehrer noted that data on health care disparities in underserved and underrepresented populations show disproportionately high mortality rates, even with Medicaid coverage. Those outcomes are due in part to lack of access to oncology care and specialists. Landscape assessments should look at the specific cancer resources and workforce in place around the country, particularly in areas of poverty.

VII. CTAC Strategic Planning Working Group: Update on Implementation of Recommendations

James H. Doroshow, MD

COVID-19 and NCI-Supported Clinical Trials. Dr. Doroshow described several COVID-19–related roadblocks that limited accrual to clinical trials at the beginning of the pandemic. These roadblocks include the following:

- Limited ability to conduct in-person study activities, including collection of informed consent, patient visits to receive investigational study drugs, and assessments of patient safety and study adherence
- Requirement for exclusive use of imaging and laboratory facilities specified by trial documents and for the collection of abundant test data of limited importance
- Requirement to collect low-grade adverse events despite potential lack of clinical relevance to study endpoints
- Limited access to cancer care personnel/facilities and reprogramming of clinical research resources to clinical care, which further diminished the availability of trials for underserved populations

NCI's clinical trials programs, in consultation with the U.S. Food and Drug Administration, quickly identified several measures that could be taken to address these barriers and allow for the continuation of accrual to clinical trials. The response included use of electronic consenting; shipping oral investigational agents directly to local sites; initiating electronic, rather than in-person, study audits; facilitating use of telemedicine for study visits; limiting the impact of minor study deviations on trial conduct/evaluation for study sites; and implementing decentralized testing for required lab and imaging studies to reduce the travel burden to patients.

Accrual to studies in NCI's National Clinical Trials Network (NCTN), which dropped by about 50 percent in the first week of March 2020, appears to have recovered to pre-pandemic levels. Trials occurring at NCI-designated cancer centers, excluding NCTN and industrial trials, saw a similar drop in accrual in March 2020. While there was steady improvement throughout fall 2020 and the first couple months of 2021, these trials have only partially recovered compared to 2019.

NCI's 2030 Strategic Vision for Clinical Trials. The CTAC Strategic Planning Working Group's strategic vision for NCI clinical trials in 2030 and beyond focuses on developing flexible, faster, simpler, less expensive, high-impact trials that seamlessly integrate with clinical practice. The Working Group's November 2020 report included 15 recommendations and three operational initiatives spanning multiple themes.

Initial Implementation Plan. Six Working Group recommendations—focused on streamlining clinical trials, decentralized trial activities, and patient access to trials—were selected for initial implementation. These include limiting data elements collected, using electronic health records (EHRs) to support clinical trials, conducting study procedures locally and remotely, using telehealth in clinical trials, broadening eligibility criteria, and conducting trials that support minority and underserved patient needs. Dr. Doroshow described each of the recommendations as well as the anticipated timeline for activities related to their implementation.

Information gathering is under way for the recommendations and will continue through October 2021. Once the information-gathering phase is complete, experts will be convened to review findings,

identify any additional analyses, develop consensus on guidance, and identify procedures that should be standard practice.

Additionally, Dr. Doroshow described several activities already in process, including assessing the impact of trial modifications made in response to the pandemic, supporting Administrative Supplements to P30 Cancer Center Support Grants (CCSG)—awarded to the MD Anderson Cancer Center Consortium and the Big 10 Cancer Consortium—to study the feasibility of automatically integrating study-specific documents into local EHR and clinical trial management systems, conducting a survey on usage of telemedicine, analyzing the utilization of the American Society of Clinical Oncology (ASCO)/Friends of Cancer Research eligibility criteria in trials sponsored by NCI's Cancer Therapy Evaluation Program (CTEP), and communicating with professional societies such as ASCO to complement and leverage efforts for related activities.

Questions and Discussion

Dr. Santana noted significant changes in the workforce due to the pandemic, not only relating to adjustments for remote work but also to retention of experienced clinical research associates (CRAs) and study coordinators, many of whom are being pulled away for higher paying jobs. Several CTAC members expressed agreement that there are challenges with workforce retention. Dr. Loehrer said that a mandate for the COVID-19 vaccine at his institution has resulted in the loss of a number of young research nurses and CRAs. Dr. Muller noted that pandemic burnout and loss of women in the workforce have been issues at many cancer centers. Dr. Levy said that overall turnover in hospital systems has been high during the pandemic, largely among nursing and support staff and clinical trial coordinators. Dr. Santana asked whether data on this problem is being or can be collected to get a better understanding of what is happening and how to address this situation (e.g., higher salaries, retraining). Dr. Doroshow acknowledged the importance of this issue and its contribution to the slowed recovery of accrual to clinical trials.

Dr. Ramalingam added that the pandemic has had a greater impact on accrual to newer trials coming into the system compared to ongoing trials, because every step—from obtaining regulatory and other approvals to enrollment of subjects—has created backlogs at the centers. Dr. Muller said losses in the contract research organization (CRO) workforce have also impacted activation and management of trials and data. In contrast, Dr. Levy noted that new NRG Oncology studies are easier to get through the start-up process than other trials, even with fewer staff in the clinical trials office, because the budgets for those studies are non-negotiable.

Dr. Davidson asked if data on accrual to NCTN trials beyond the first quarter of 2021 are currently available and if there has been a change in the trend in the second quarter. Dr. Doroshow said accrual data are available for the first 6 months of the year and accrual has remained stable.

Dr. Davidson also commented on issues around physicians being told they are no longer able to treat out of state patients via telehealth due to potential legal liability concerns. Dr. Loehrer said telemedicine across state lines is especially important for patients with rare diseases and in underserved areas in states where clinicians or specialists are not available. Ms. Davis agreed, noting that many patients who are in the process of trying to accrue to a trial have to stop due to state telehealth laws expiring during this process. She said some patients end up driving across state lines to work around this obstacle. Dr. Loehrer suggested raising this issue with Congress to help create a national solution that addresses practicing across state lines, especially for patients trying to enroll in clinical trials. Ms.

Holohan said the current administration is working on guidance from the U.S. Centers for Medicare & Medicaid Services (CMS) but acknowledged that federal guidelines do not necessarily help with state licensee issues.

VIII. Ongoing and New Business

Patrick J. Loehrer, Sr., MD

Dr. Loehrer introduced the presenters for this session, who provided updates on two CTAC groups: the Quantitative Imaging Network (QIN) Working Group and the Translational Research Strategy Subcommittee (TRSS).

CTAC Group Updates

Quantitative Imaging Network Working Group: Implementation of Recommendations

Janet Eary, MD

CTAC QIN 2020 Working Group Report. Six recommendations to enhance the integration of quantitative imaging tools into National Clinical Trials Network (NCTN) protocols were included in the report, as follows:

1. Form a pipeline oversight committee with National Clinical Trials Network (NCTN), Imaging and Radiation Oncology Core (IROC), QIN leadership, and NCI program staff to assess advanced QIN tools for NCTN clinical trial validation.
2. Provide opportunities for QIN and NCTN scientific leadership engagement.
3. Promote and incentivize QIN tool development and readiness for NCTN deployment.
4. Ensure imaging scientists, clinical radiologists, and clinical trialists have clarity about the use of QIN tools in clinical trials and the assessment of realistic endpoints.
5. Ensure that NCTN sites are ready to open trials that include QIN tools.
6. Support image data banking and sharing, with accompanying metadata from NCTN trials, in an archive such as The Cancer Imaging Archive (TCIA).

Dr. Eary described the progress to date toward implementing these recommendations.

QIN Tool Development Support and Process. The estimated cost for development of each tool is $50,000. NCI provided a $125,000 administrative supplement in FY 2021 to the IROC U24 grant to provide funds to facilitate tool development.

To assist with the implementation of recommendation 1, the Cancer Imaging Program (CIP) formed an oversight committee for tool assessment and integration into clinical trials. The committee, in collaboration with CIP, established the IROC process for tool assessment.

1. Present the tool to the NCI-QIN oversight committee and determine the tool's fitness for the indicated purpose.
2. Assess and shortlist available trial image data sets.
3. Have the IROC team test the tool on two or more data sets with ongoing communication with the tool developer over 3 months with an initial status report at 6 weeks.
4. Assess performance in various scenarios.

Utilizing the process above, several tools ready for assessment were identified and are currently under evaluation.

QIN Tools Under Evaluation. Tools currently under evaluation include: ImagingBiometrics (IB) Clinic, an FDA-cleared suite of tools for processing MRI perfusion images; Lung Segmentation, a lung tumor automatic segmentation tool for identifying and quantifying tumor volume; and Miviewer, used to annotate, outline, and measure urinary bladder tumors. Other tools under consideration based on their fit-for-purpose documentation include autoPERCIST, which evaluates PET image tumor response criteria; qDWI Phantom; and ePAD, a quantitative imaging informatics platform to support clinical trials imaging.

The QIN Program continues to provide support to tool developers, investigators, and members of the business community to help commercialize these tools once they are tested for use in the wider clinical community. To facilitate this aspect of the program, a Notice of Special Interest (NOSI) was created to link imaging tool development with an Academic/Industrial Partnership (PAR-21-206), with the goal of bringing commercial interests to quantitative imaging tool clinical translation. A Small Business Research Innovation (SBIR) contract has been developed for business entry into clinical translation of quantitative imaging tools; to date, three SBIR contracts are being negotiated.

Dr. Eary concluded by noting that the process envisioned by the CTAC QIN Working Group is well under way and provides for dynamic interaction between IROC and investigators. The tools evaluated thus far are diverse across imaging modalities, workflow processes, and analysis types. Tools continue to be brought forward to the NCI-QIN oversight committee for fit-for-purpose consideration as delineated in the IROC process for tool assessment.

Questions and Discussion

Dr. Knopp acknowledged the challenges in translating a research tool into a tool considered essential for the clinical trial community. The QIN program takes an innovative approach to developing imaging tools for standard care of patients and informing the management of clinical trials using real-world clinical trials data. It ultimately will provide an opportunity to bridge beyond clinical trials to the clinical setting.

Dr. Dancey asked about plans for engaging the recipients of the tools (e.g., NCTN trialists, member centers) and whether that engagement will be done after IROC's evaluation. Dr. Eary said this type of activity is already part of the multi-focused approach of this program, wherein QIN investigators are working closely with researchers in disease-related groups in the NCTN and other organizations (e.g., NRG Oncology, ECOG-ACRIN) to incorporate QIN tools into new clinical trials, as appropriate, as the tools are being developed.

Dr. Knopp said the group is also exploring the specific training that would be necessary for the tools to be implemented from a practical implementation perspective (e.g., plug-and-play approaches) and what would be necessary to make those tools available within targeted communities.

Dr. Dancey also asked about the timeline for incorporating the imaging tools into the next NRG glioblastoma multiforme (GBM) trial. Dr. Knopp explained that the feasibility of using a tool or tools within the clinical workflow of a trial will be established as part of the tool assessment process. However, the ultimate use of the tool will be determined by the trialists and investigative teams.

Translational Research Strategy Subcommittee
Nancy E. Davidson, MD

The mission of the TRSS, which Dr. Davidson co-chairs with Chi Dang, MD, PhD, Professor, Molecular and Cellular Oncogenesis Program, Wistar Institute Cancer Center, is to survey scientific horizons and provide broad advice to NCI advisory boards (CTAC, Board of Scientific Advisors, and National Cancer Advisory Board) and leadership on enhancing and broadening the institute's translational research portfolio. TRSS has been active since 2019, and its members are current or former members of NCI advisory boards.

TRSS has met twice since the last CTAC meeting. The topic of the March 29, 2021, TRSS meeting was resistance to immunotherapy. The group identified the following research gaps and opportunities for this topic that might be addressed through NCI: pre-clinical models; combination immunotherapy; molecular mechanisms, genetics, and cellular basis of response and resistance; and the identification and validation of biomarkers of both response and resistance. The group then proceeded to identify immunotherapy research priorities that would be feasible. One priority area is development of better *in vivo* and *in vitro* immuno-oncology (IO) preclinical models, with a focus on immunocompetent murine models (e.g., genetically engineered mouse models [GEMMs], syngeneic tumor models) and human organoid models. Other immunotherapy research priorities included development of better IO predictive biomarkers, use of imaging methods to develop biomarkers, study of long-term responders, microbiome and tumor microenvironment studies, and better understanding of cellular and molecular mechanisms.

The discussion of immunotherapy research gaps and priorities continued during the June 17, 2021, TRSS meeting, which focused on the translational potential of organoid cultures and animal tumor models. Research gaps and opportunities identified included *in vivo* and *in vitro* IO preclinical models (GEMMs, syngeneic, patient-derived xenograft [PDX], humanized mouse); modeling the key role of the tumor microenvironment; developing individualized precision oncology models to determine which agents work best for patients and models for the preclinical drug discovery phase; and identifying multiple conceptual, technical, and administrative barriers to the advancement of preclinical models.

TRSS members agreed that this overarching area of research should be investigated further. They recommended that NCI convene a workshop that would bring together experts in the field to address the general principles of models, including personalized predictive models.

The next two TRSS meetings are scheduled for September 9, 2021, and December 16, 2021.

Motion. A motion carried to accept the minutes of the March 29, 2021, and June 17, 2021, TRSS meetings.

Questions and Discussion

Dr. Doroshow commented that the workshop will look at what the state of the art should or could be for preclinical models, particularly for immunotherapy, and explore what NCI might be able to do to promote and facilitate advancement of this field and standardization of resources and tools (e.g., develop models, establish a repository).

Another TRSS member, Dr. Matrisian, said that the TRSS discussions on this big and complex issue have been robust. The workshop and experts will be important in drilling down on the critical components to identify how to overcome some of the hurdles in this field and advance the potential of immunotherapy for patients.

IX. Adjourn

Patrick J. Loehrer, Sr., MD

There being no further business, the 45th meeting of CTAC was adjourned at 2:27 p.m. on Wednesday, July 14, 2021.

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Date Patrick J. Loehrer, Sr., MD, Chair

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

Appendix

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

CHAIR

Patrick J. Loehrer, Sr., MD 2021
Distinguished Professor
Indiana University
Joseph W. and Jackie J. Cusick Professor in Oncology
Director
Center of Global Oncology and Health Equity
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Professor of Nursing
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