DEPARTMENT OF HEALTH AND HUMAN SERVICES
NATIONAL INSTITUTES OF HEALTH
NATIONAL CANCER INSTITUTE
51ST CLINICAL TRIALS AND TRANSLATIONAL RESEARCH ADVISORY COMMITTEE MEETING

Summary of Meeting
July 19, 2023

NCI Shady Grove, Conference Room TE406/408/410
9609 Medical Center Drive
Rockville, MD 20850

CLINICAL TRIALS AND TRANSLATIONAL RESEARCH ADVISORY COMMITTEE
Summary of Meeting
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The 51st meeting of the Clinical Trials and Translational Research Advisory Committee (CTAC) of the National Cancer Institute (NCI) was convened Wednesday, July 19, 2023, at 10:00 a.m. The CTAC chair, Dr. Neal J. Meropol, presided.[1] The meeting was adjourned at 3:10 p.m.

Chair
Neal J. Meropol

CTAC Members
Smita Bhatia (virtual)
Charles D. Blanke
Edward Chu
Nancy E. Davidson (virtual)
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 (virtual)
Victor M. Santana
Patricia A. Spears
Julie M. Vose
George Wilding (virtual)

Ex Officio Members
James H. Doroshow, NCI
Paulette S. Gray, NCI
James L. Gulley, NCI (absent)
Michael J. Kelley, U.S. Department of Veteran Affairs
Anthony Kerlavage, NCI
Richard Pazdur, U.S. Food and Drug Administration (absent)
Xiufen Sui, Centers for Medicare and Medicaid Services (absent)

Designated Federal Official
Sheila A. Prindiville, NCI

Presenters

Monica Bertagnolli, MD, Director, NCI

James H. Doroshow, MD, Deputy Director for Clinical and Translational Research; Director, Division of Cancer Treatment and Diagnosis, NCI

Judith A. Hautala, PhD, Research Staff Member, IDA Science & Technology Policy Institute

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

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

Neal J. Meropol, MD, Vice President of Research Oncology, Scientific and Clinical Lead, Clinical Research, Flatiron Health

Michael J. Morris, MD, Co-Director, Clinical Trials Innovation Unit

Sheila A. Prindiville, MD, MPH, Director, Coordinating Center for Clinical Trials, Office of the Director, NCI

James C. Yao, MD, Professor and Chair, Department of Gastrointestinal Medical Oncology, The University of Texas MD Anderson Cancer Center

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I. Call to Order and Opening Remarks

Neal J. Meropol, MD

Dr. Meropol called the 51st meeting of CTAC to order at 10:00 a.m.

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 provided a videocast of the meeting. The videocast recording is available for viewing at https://videocast.nih.gov/watch=49822.

Motion. A motion to accept the minutes of the 49th CTAC meeting, held on November 9, 2022, was approved.

II. NCI Director's Update

Monica Bertagnolli, MD

NCI News and Events. Presentations on major trials supported by the NCI Division of Cancer Treatment and Diagnosis/Cancer Therapy Evaluation Program were conducted at the American Society of Clinical Oncology meeting in June. These presentations highlight the critical importance of CTAC and NCI support for studies that transform health care and achieve results for cancer patients.

Funding and Appropriations. Research Project Grants account for 44 percent of NCI spending; followed by intramural research, including the clinical center, at 18 percent; Research and Development contracts (e.g., Frederick National Laboratory [FNL]) at 12 percent; other research grants (e.g., K awards, resource grants) at 9 percent; and research management and support at 7 percent. Overall, extramural funding that directly supports extramural investigators accounts for 74 percent of the institute's spending.

Since 2016, NCI has seen steady appropriations, and paylines are back up to the 12th percentile in Fiscal Year (FY) 2023. Despite sustained NCI budget increases, the institute's purchasing power in 2023 is $1.1 billion lower than 20 years ago (adjusted for inflation), which represents a significant challenge to NCI's ability to fund research, invest in critical infrastructure, and support trainees. A flat budget in FY 2024 would exacerbate this critical problem.

Cancer Drug Shortages. Recent and recurring shortages of oncology agents are having a negative impact on research, ongoing clinical trials, and patient care, particularly in smaller community sites. An estimated 170 government-sponsored cancer clinical trials are potentially affected by these shortages; 104 trials are affected by a shortage of one protocol agent, and 47 are affected by shortages of two agents. The National Institutes of Health (NIH), the White House, and the U.S. Food and Drug Administration (FDA) are working together to mitigate the effects of these shortages.

National Cancer Plan. A recently published analysis indicates that progress must accelerate to achieve the President's reignited Cancer Moonshot goal of reducing cancer mortality by at least 50 percent by 2047. The current rate of mortality decline is 2.3 percent per year; to meet the 50 percent goal, the rate of decline must be 2.7 percent per year. Recognizing that achieving this goal will require active change not only in the biomedical research community and the federal government but also the whole of society, the National Cancer Plan was created to communicate clearly to the community what is necessary to succeed. The plan's eight major goals are accompanied by strategies put forward by NCI.

Dr. Bertagnolli acknowledged the leadership of the President's Cancer Panel, which is tracking progress of the plan's implementation over time through annual reporting and in-depth progress reviews as well as engaging the community in public sessions. She commended the University of Colorado's report on how its cancer center is embracing the plan through collaborations, partnerships, studies, events, outreach, and the creation of a community advisory council to engage community members across the state.

NCI Program Updates. The Clinical Trials Innovation Unit (CTIU) is a collaboration between NCI, the FDA Oncology Center of Excellence, and the National Clinical Trials Network (NCTN) Group Chairs. The CTIU is designed to be a nimble, problem-solving collaboration unit that will select a few high-priority studies to pilot new study designs and operational procedures in order to demonstrate capability of achieving better, faster, more

accessible cancer clinical trials. The Pragmatica-Lung Study is a registration trial testing two drugs from two pharmaceutical sponsors in patients with advanced lung cancer. The study is a streamlined model that moved from concept presentation in August 2022 to first patient accrual in 7 months (March 2023). ComboMATCH is a combination therapy platform trial with molecular analysis for therapy choice. Three ComboMATCH trials are currently open for enrollment, and six additional trials will be available in the coming months. The aim is to enroll 2,000 patients in ComboMATCH.

Dr. James L. Gulley has been selected as NCI Clinical Director at the Center for Cancer Research, pending NIH approval. In this role, he will oversee day-to-day operations of more than 350 active clinical trials in the intramural program. Dr. Gulley will continue his role as co-director of the Center for Immuno-Oncology.

NCI would like to highlight and increase awareness of various core FNL resources, programs, advanced biomedical technologies, and unique sample and data repositories available to the extramural research community. These resources include 15 million biological specimens, frozen tumor samples, research reagents, and genetically engineered mouse models of human cancers. NCI is expanding the cell therapy manufacturing that is vital for the development of many new cell therapy innovations.

NCI-Designated Cancer Centers Updates. The University of Florida Health Cancer Center in Gainesville became NCI's 72nd designated cancer center. It serves North Central Florida, a region with the highest cancer mortality rate in the state. The Massey Cancer Center at Virginia Commonwealth University in Richmond has gained comprehensive status. Serving central, southern, and eastern Virginia, the center is making community engagement a major focus in their work to serve those who have the most to overcome in their fight against cancer.

NCI Deputy Director for Data Science. NCI is seeking a highly qualified visionary leader to serve as deputy director for data science. Responsibilities of this new position include guiding key data science initiatives, leading NCI efforts to collect, store, analyze, and share basic, translational, and clinical research data, and building strategic partnerships to develop and disseminate advanced technologies and methods.

Questions and Discussion

Ms. Spears asked what steps NCI and FDA are taking to prevent the addition of more drugs to the shortage list. Dr. Bertagnolli explained that a mitigation unit at the FDA monitors the supply chain to anticipate the next shortage and supports manufacturing to keep facilities online and producing needed drugs. Communicating with pharmacists at the cancer centers about shortages has been helpful.

Dr. Mesa commented on the value patient navigation offers toward helping patients join clinical trials, managing complexities of multi-step care, and addressing disparities and inequities. The White House and Centers for Medicare & Medicaid Services have been discussing coverage for navigation services, which could have a major impact on all aspects of the NCI mission. He asked how NCI can weigh in to support this. Dr. Bertagnolli responded that NCI has supported research that demonstrates the incredible value of navigation to patients. For example, the Childhood Cancer–Data Integration for Research, Education, Care, and Clinical Trials public–private partnership aims to ensure that the family of every child with cancer is connected with the knowledge and resources required to access proven treatments and participate in research. The initiative helps families who have a child with cancer obtain the child's medical record and put it into a standard, interoperable format, creating a standard health record. A navigation component helps tie children to care, and another component engages the child and family in research. Findings are expected soon.

Dr. Knopp applauded the emphasis on data science in Dr. Bertagnolli's presentation and asked for her direction to facilitate increased use of patient data. Dr. Bertagnolli described an approach that involves partnering with the data users and data scientists to build the infrastructure necessary to optimize access and use of data. NCI is committed to partnering to build this infrastructure while also strategically considering the complexities and costs needed to create and maintain it.

Dr. Levy expressed excitement for the National Cancer Plan and asked about intermediate endpoints that can be used to quantify progress. Dr. Bertagnolli responded that reduction in cancer mortality and incidence are obvious measures, as well as well-being, quality of life for people with cancer, and reduction of cancer incidence. The President's budget includes requests for investments in clinical trials, data infrastructure, and a host of other resources that would support advancement toward intermediate endpoints. She highlighted the need for expanded

community outreach and engagement and education to train a generation of clinicians and others to continue doing such work.

Recognition of Outgoing Committee Members

Dr. Bertagnolli recognized three outgoing committee members—Drs. Davidson, Knopp, and Meropol—for their outstanding and dedicated service to NCI and CTAC. In addition, Dr. Meropol was recognized for serving as Chair from 2021 to 2023.

III. Legislative Update

M.K. Holohan, JD

The debt ceiling agreement reached by Congress and the Biden administration suspends the debt ceiling until January 2025. This agreement is part of the Fiscal Responsibility Act (FRA) that was signed into law on June 3, 2023. Key provisions of the FRA include a cap on nondefense discretionary spending (which includes National Institutes of Health [NIH] and NCI funding) for FY 2024 at FY 2023 levels and a cap on discretionary spending growth at 1 percent for FY 2025.

Following passage of the FRA, 11 Republican members of the House Freedom Caucus (HFC) formally objected to the funding caps agreed upon in the FRA and derailed House activities for several days to express their dissatisfaction. The House deadlock ended after HFC meetings with Speaker Kevin McCarthy (CA) redefined the Majority's view of the FRA funding caps as "ceilings, not floors." House Appropriations Chair Kay Granger (TX) then announced that the House Appropriations Committee will write spending bills to a total of $119 billion below the FRA level. In contrast, both the Chair (Senator Patty Murray - WA) and Ranking Member (Senator Susan Collins - ME) confirmed that the Senate Appropriations Committee will write its bills according to the spending cap agreed to in the FRA (topline kept at the FY 2023 level).

The FY 2023 Enacted budget included $47.7 billion for NIH (a $2.5 billion increase), $7.3 billion for NCI (a $386 million increase to the base, plus $216 million for the Moonshot), and $1.5 billion for the Advance Research Projects Agency for Health (ARPA-H) (an increase of $500 million).

The FY 2024 President's Budget would increase allocations for NIH ($48.6 billion, an increase of $920 million), NCI ($7.8 billion, an increase of $500 million, and sustaining $216 million for the Moonshot), and ARPA-H ($2.5 billion, an increase of $1 billion).

The FY 2024 House Labor–HHS bill that was passed out of the subcommittee would decrease allocations to NIH ($44.7 billion, minus $2.99 billion) and ARPA-H ($500 million, minus $1 billion) and to NCI ($7.10 billion, a decrease of $216 million as Appropriators chose not to sustain Cancer Moonshot funding for the expiring Cures funding stream that ends after FY 2023).

"Must Pass" legislation with authorities expiring September 30, 2023, include FDA User Fee Programs for animal drugs and animal generic drugs, the Pandemic and All-Hazards Preparedness Act, a farm bill, and the National Defense Authorization Act.

IV. Clinical Trials Innovation Unit

Michael Morris, MD
Sheila A. Prindiville, MD, MPH

The current cancer clinical trials model is unsustainable. Trials are overly complex, expensive, and inefficient due to onerous trial design and the excess collection of data and biospecimens. Slow review and activation processes delay delivery of treatment to patients, prolonging their suffering, and high participant burden leads to inequities in trial participation.

NCI's strategic vision for clinical trials in 2030 and beyond calls for streamlining trial design and execution processes, focusing on essential endpoints, decreasing regulatory hurdles, broadening trial access, and increasing efficiency of data collection. The goal is to build flexible, faster, simpler, less expensive, high-impact clinical trials that seamlessly integrate with clinical practice.

The Clinical Trials Innovation Unit (CTIU) is one of several tools designed to execute NCI's strategic vision. It aims to radically transform how clinical trials are conducted by rapidly identifying and testing the most

innovative approaches while preserving current infrastructure and trials already underway. Overarching goals include rapid design and activation of trials that focus on innovative science, designs, data analysis, and collaborations; promotion of equitable clinical trials participation; and furtherance of the National Cancer Plan and Cancer Moonshot goals by working with partners in government, industry, advocacy, and other organizations to modernize trials that bring results to patients faster.

CTIU is an interagency platform, comprising representatives from NCI, the U.S. Food and Drug Administration (FDA), and the extramural cancer clinical research community. It brings required expertise to the same table to advance clinical care and equitable clinical trials through innovative science, trial designs, and operational efficiencies for a few high-priority clinical research studies. The extramural cancer clinical research community brings forth scientific ideas and priorities. NCI provides expertise on feasibility and operations. FDA Oncology Center of Excellence provides guidance on design and strategy.

For the first round of ideas, CTIU focused on the NCI National Clinical Trials Network (NCTN), asking each group to submit three to four proposals for innovative studies that "break the mold," which could include interventions that nonincrementally alter standards of care, biomarkers that dramatically shorten trial endpoints, new tools for data extraction and management that streamline trial conduct, and collaborations that conjoin resources and expertise. In the future, CTIU plans to engage the NCI Community Oncology Research Program, industry, and foundations to ensure there is a wide pool from which to draw ideas.

CTIU's own processes reflect its goals of simplification and speed of execution. Evaluation, approval, and activation processes are rapid, and stakeholders come to the table early in the proposal design stage. Since its inception in February 2023, CTIU has solicited, received, and evaluated proposals, and is in the process of selecting proposals to advance.

Questions and Discussion

Dr. Bertagnolli commended several NCI staff for their contributions to CTIU's rapid progress. She noted that CTIU is a problem-solving unit focused not only on clinical trials but also on enhancing collaborations and thinking about innovative ways to use existing resources.

Dr. Santana praised CTIU's rapid submission and approval process and asked how speedy implementation within the NCTN will be ensured. Dr. Morris responded that once studies are reviewed and activated, the NCTN and other NCI networks are able to implement them expertly and efficiently; the review process can often be lengthy and inefficient. Protocols typically go through numerous internal and external review committees. Involving key stakeholders early in the review and design process ensures their familiarity with the protocol, which has already benefited from their input. He acknowledged that some fundamental regulatory requirements such as institutional review boards and safety reviews cannot be changed. Dr. Santana suggested adapting lessons learned from cancer centers that have units focused on expediting trials. Dr. Morris agreed that this was an excellent suggestion.

Ms. Spears expressed enthusiasm for the promise and progress that CTIU has shown. Noting that the terms "high priority," "high impact," and "innovation" mean different things to different stakeholders, she recommended including advocates to provide a patient perspective. Dr. Morris agreed and pointed out the current CTIU submission process includes advocate participation to ensure appropriateness, acceptability, and innovation from the patient perspective. Disease-specific advocates are involved in each review, and there is advocate input at the NCTN level. Dr. Prindiville added that the unit also works with the NCI Office of Advocacy Relations and the NCI National Council of Research Advocates.

Dr. Ramalingam commended the effort to simplify the processes and wondered whether having FDA at the table provides opportunities to reduce regulatory burden that complicates trial conduct at the site level. Dr. Morris described the tension between innovation and impact; innovative proposals may have low impact, and high-impact proposals may not be very innovative. He referred to a recent joint ASCO presentation of the NCI and FDA that articulated an approach to simplifying regulatory burden. FDA priorities demonstrate the agency's strong interest in assuring that regulatory concerns are not the bottleneck for getting effective drugs to patients.

Dr. Meropol noted CTAC's interest in the CTIU and the opportunities the initiative affords. He encouraged NCI to report back on CTIU progress.

V. Representation of Women and Underrepresented Groups in Clinical Trials Leadership: A Survey of NCTN, NCORP, and Scientific Steering Committees

James Doroshow, MD
Judith Hautala, PhD

The National Institutes of Health and NCI are united in efforts to end structural racism and racial inequities in biomedical research. The need to address these issues can be seen in selected 2020 data that indicate significant underrepresentation of women, as well as Black/African American and Hispanic/Latinos in the oncology workforce. The NCI Equity and Inclusion Program (EIP) strives to increase workforce diversity, build a more inclusive and equitable NCI community, address cancer disparities, and advance health equity.

The NCI EIP created a subcommittee to understand and make recommendations to improve representation of women and other underrepresented groups in clinical trials leadership. Working in consultation with the National Clinical Trials Network (NCTN) Group and NCI Community Oncology Research Program (NCORP) Research Base chairs, as well as the Institute for Defense Analysis Science and Technology Policy Institute (STPI), the EIP subcommittee developed a voluntary and confidential survey to establish a baseline of demographic and professional attributes of individuals in these leadership groups.

Survey Methodology. To ensure confidentiality, the survey was pilot-tested and administered by STPI, an impartial third party. An email invitation was sent to 1,500 members of NCTN Group and NCORP Research Base leadership committees, NCI Scientific Steering Committees (SSCs), including chairs of Steering Committee Task Forces, and chairs of studies approved by an SSC between April 2017 and September 2022. The survey opened on January 12, 2023, and closed on March 17, 2023. Results were encrypted and saved on a secure network in a password-protected file. A de-identified response file was created for analytic purposes.

The overall survey response rate was 61 percent. The 39 percent non-response rate raises concern about potential effects of response bias. Thus, survey findings may differ to some degree from actual attributes of the overall survey population.

Demographic Findings. Respondent sex assigned at birth and self-described gender was about 52 percent female and 47 percent male. About 60 percent of respondents were between 45 and 64 years old, with a median age of 53; 19 percent were in the younger 35–44 group, and 14 percent in the older 65–74 group. In terms of sexual orientation, 92 percent of respondents self-identified as heterosexual. In terms of race, 72 percent were White, 16 percent Asian, 2 percent African American; 5 percent reported Other race, and 3 percent reported more than one race. Those who reported Other race were primarily Indian Subcontinent/South Asian and Arab/Middle Eastern/North African. For ethnicity, 4 percent reported Hispanic/Latino. Additionally, 1 percent reported they had a disability that affected their work activities.

Professional Findings. The majority of respondents (75 percent) reported their occupation as physician or physician-scientist, and the remainder reported they were research scientists, statisticians, administrators, advocates, or retired. Most respondents (82 percent) reported working at academic institutions; the remaining institutions were either community health care organizations or other nonresearch and research organizations. In terms of faculty status, 86 percent of respondents reported having a faculty appointment; of these, 60 percent were nontenure track. More than half (55 percent) were full professors.

Four states (New York, California, Pennsylvania, Texas) account for 33 percent of institutional ZIP Codes; 13 states account for 70 percent of the institutional locations. Based on United States Department of Agriculture Rural-Urban Continuum Codes, 95 percent of the respondents were in counties with populations of 250,000 or more, and 5 percent were in metro counties of fewer than 250,000. Half of the latter category were from Olmsted County, Minnesota, the location of the Mayo Clinic.

Findings Reported by Leadership Role. Demographic characteristics were presented by leadership role. About one-third of respondents (31 percent) reported holding more than one leadership position. Their responses were included in the data for each of these roles unless their multiple positions fall within a given leadership role. In that case, their responses were included only once within that leadership role. Gender identity was about 50 percent female across all categories. Age distribution was similar across all categories, except study chairs were younger (median age 45) than other roles. Race distribution was similar across all categories. For faculty status, full professors were more heavily represented than associate or assistant professors across all leadership

committees, with the exception of study chairs, where assistant professors accounted for 20 percent and the distribution of full and associate professors was nearly equal.

Questions and Discussion

Dr. Mandrekar asked whether any comparisons were made between survey responders versus nonresponders. Dr. Hautala said that the nonresponders were not characterized. Dr. Muller noted that insights about the nonresponders will be critical. Dr. Blanke also expressed concern about the 39 percent nonresponse rate and recommended consulting survey experts to eliminate or reduce concerns about potential for response bias. Dr. Hawk pointed out that a 61 percent response rate is not bad for a survey of this nature.

Dr. Mannel applauded the decision to collect baseline data, and, noting that other NCTN groups are gathering and interpreting similar statistics, he recommended trying to harmonize the baseline data across organizations. The survey results suggest that the presence of women in the various categories is better than what is observed at NCI Cancer Centers. Going forward, the challenge will be deciding what to do with the data and how to address the inequities for individuals in underrepresented groups. For example, innovative programs to engage younger investigators will be important. NRG Oncology has term limits for leadership roles in order to create room for others to lead. Dr. Mannel stated that the underrepresentation of certain minority populations in clinical trial leadership reflects underrepresentation of those populations in the pathways leading to those positions, starting with science, technology, engineering, and mathematics programs. He went on to point out that NCTN groups conduct clinical trials in several states with large populations where the notion of proactive diversity, equity, and inclusion (DEI) is being challenged. He asked how belonging and inclusion can be achieved without becoming mired in political debate.

Dr. Muller commented that although the survey showed that women represent 50 percent of most leadership positions, she has not observed this parity. The age group and academic representation statistics were not surprising. The lack of racial and ethnic diversity was eye-opening and disheartening. Dr. Muller was encouraged to see the minority/underserved community sites represented, given their critical role in clinical trial efforts; engaging with these facilities is more challenging due to their lack of academic focus, but their participation as leaders would be valuable. She encouraged thinking about how to gauge community partner interest in leadership and the possibility of providing protected time for engagement.

Dr. Mesa agreed that the data reflect the pipeline process. He wondered how to encourage or facilitate participation of younger study chairs from more underrepresented groups. Perhaps establishing vice-chairs to create a stepwise process would help to engage them in senior leadership before they attain full professor status.

Dr. Meropol commented on the low proportion of leaders from rural settings. He asked Dr. Blanke to what extent increasing rural representation should be prioritized. Dr. Blanke responded that the SWOG Cancer Research Network is trying to capture that data via a survey. To date, their focus has been on care of rural patients, but engagement in leadership will be a priority going forward. Dr. Mandrekar noted that for most of those in leadership positions in the statistics and data management centers of the cooperative groups and cancer centers, most will be at large academic centers.

Dr. Mannel added that some of the populations included in the NCI definition of underrepresented groups are not included on this survey; for example, many of those in leadership roles are coming from large academic centers and outside of the Mayo Clinic. These centers are not in rural areas. However, some in leadership roles at these large academic centers came from disadvantaged backgrounds in either rural or urban settings. He acknowledged that obtaining those valuable details adds to survey complexity, which could have an impact on response rate.

Dr. Hawk expressed interest in seeing iterative updates of the survey data and suggested NCI monitor the trends over time. Given the efforts to enhance diversity over the past 5 years, he said he is hopeful those data might show improvement.

Dr. Chu reported that his cancer center convened a DEI subcommittee focused on training the next generation of cancer center leaders. Most of the approximately 5 subcommittee members are at the junior faculty level. Some are attending strategic retreats and working groups, and there is a plan for two or three to attend advisory meetings.

Ms. Spears commented that there is a lot of room for improvement in the inclusion of underrepresented minorities in the leadership positions. She asked how many individuals from underrepresented groups are actually attending NCTN meetings and whether that is changing over time. Those meetings are an entry point to the leadership pathway.

Dr. Doroshow stated that at the time of the survey there was no baseline at the national level and expressed delight to have these survey findings. He urged regular ongoing collection of these data, noting that a lack of change will be a stimulus to do more.

VI. Strategies for Enhancing the Clinical Trials Workforce

James Doroshow, MD

The COVID-19 pandemic heightened existing workforce issues in clinical trial personnel recruitment and retention. NCI has created several initiatives to address these issues.

Cancer Centers Data Collection. In November 2021, NCI surveyed all 64 active clinical trial cancer centers to learn more about staffing shortages. The results indicated that personnel were leaving for positions in the pharmaceutical industry and at clinical research organizations (CROs) that offered higher pay and remote work opportunities. In follow-up to those findings, NCI met with leaders from 12 cancer centers—representing a wide range of clinical research staff sizes and a broad geographic distribution—between March and May of 2023 to discuss current issues with the clinical trials workforce, steps taken to address these issues, lessons learned, and the scope and value of potential new NCI initiatives. The cancer centers proved highly resourceful in adapting to the disruptions associated with the pandemic. Although the strategies taken differed depending on local environment, institutional policies, local labor markets, and educational resources, there were several common approaches, which included implementing salary adjustments, allowing remote work options, differentiating positions and clarifying paths to career growth, improving burdensome hiring procedures, and collaborating with local institutions to build pipelines for entry-level positions. Cancer centers considered data entry and data management services to be the most useful and feasible remote service. Developing training programs and remote activities that will enable clinical research sites to recruit and retain personnel will be an important next step.

NCI Virtual Clinical Trials Office (VCTO) Initiative. The Gulf South Minority Underserved NCI Community Oncology Research Program (NCORP), which is a high enrolling site, faced great difficulty retaining staff for clinical trials work in the early days of the pandemic. The Gulf South site successfully piloted an NCI-supported program to enable remote data collection.

The Frederick National Laboratory (FNL) operates with significant support from National Institute of Allergy and Infectious Diseases funds, much of which is earmarked for clinical trials. In 2021 and 2022, in response to the COVID-19 pandemic, the laboratory dramatically expanded its program for recruiting and training staff for infectious disease studies. The program provided both on-site and virtual support, including trial auditing of electronic health records (EHRs) housed at academic health systems and private practices.

NCI recently initiated a pilot with FNL to hire research nurses, clinical research associates, and regulatory personnel to centrally provide support to NCI-designated cancer centers and NCORP sites. Services could include eligibility screening and study coordination; assistance with informed consent, enrollment, protocol queries, and other “help desk” functions; data entry and abstraction from EHRs; coordination of study visits, procedures, and reminders; regulatory support; and adverse event reporting.

An NCI request for expression of interest sent to all NCI-designated cancer centers in February of 2023 was met with a strong response from both large and small centers. Three cancer centers and three NCORP sites with robust accrual in underserved communities have been selected to participate. It is anticipated that the program will begin in early Fall 2023. Dr. Doroshow will report on the pilot’s progress at a future CTAC meeting.

Potential NCI Clinical Research Training Initiatives. Sites emphasized the need for support in the development of a pipeline for training entry-level clinical trials personnel. Potential future NCI training initiatives include providing awards to cancer center consortia, partnerships, and local educational institutions to support the development and implementation of curricula and materials for entry-level clinical research skills, as well as a campaign to increase awareness of clinical research as a career opportunity. A separate initiative would provide cancer centers with supplemental awards to support mentorship and internships as well as tuition support for community college students who commit to service in clinical trials research.

Questions and Discussion

CTAC members were asked to consider and provide feedback on the following:

- Factors NCI should consider as the VCTO program is implemented
- Comments on potential NCI training initiatives
  - Importance of expanding entry-level training pipeline
  - Awards to consortia to develop training and communication initiatives targeted at entry level candidates
  - Supplemental awards to cancer centers for student mentorship and tuition support
- Other steps NCI should consider in the area of clinical trials workforce training

Dr. Dicker commented that the prevalence of decentralized clinical trials has increased significantly in recent years. He suggested that NCI draw on multi-disciplinary expertise within the community on decentralized trials in order to produce a series of position papers on current and future clinical trial models and conduct.

Dr. Pollock applauded the NCI initiatives and shared that his organization has lost approximately 35 percent of its clinical trials workforce due to non-competitive salaries and a lack of remote work flexibility. In response to personnel emphasizing a desire for a professional designation, The Ohio State University Comprehensive Cancer Center created a master's degree program in clinical research nursing and provided funding for five students. The program was met with great interest. NCI could support this type of model by providing centralized organization around remote learning, training, and other investments that demonstrate a commitment to the workforce.

Dr. Santana observed that remote work can lead to a diminished sense of unity within a team. To support cohesion and teamwork, his organization has begun providing opportunities for staff to convene and connect. He encouraged NCI to consider this "human" aspect when developing initiatives and to regularly collect metrics about job satisfaction and turnover rates.

Dr. Mesa shared that his organizations have seen dramatic rates of turnover, in some instances as much as 85 percent. As with other organizations, personnel left for higher salaries and more flexible remote-work options. He agreed that training opportunities are essential, and that new curricula and trainings should focus on creating a career path for clinical trials staff. A certain amount of turnover is inevitable, particularly in entry-level positions, which underlines the importance of supporting the pipeline. He supported NCI's plan to create centralized and standardized resources and agreed that many aspects of clinical trial conduct can be centralized. Dr. Meropol asked whether the proposed VCTO would include patient-facing work such as informed consent and education. Dr. Doroshow said that in the pilot program, individuals from the centralized resource support those in the field as well as clinical trial participants.

Dr. Bhatia noted that, since the beginning of the pandemic, there has been a shift in priorities across all fields and industries. Workers increasingly value higher salaries and remote work, which academic clinical trials offices have limited ability to provide. Dr. Doolittle concurred. He commended NCI's proposed research training initiatives and said that personnel would be more likely to stay in their positions if they had more training opportunities, particularly in the rural sector, where the pipeline is even more limited.

Dr. Lerner commented that institutional finance policies and human resources (HR) departments are often the greatest barriers to successful workforce recruitment and retention. To ensure success, HR departments should be included in the development of any new initiatives. Dr. Mannel said that part of the challenge arises from tension between a national workforce and local HR policies related to compensation. It would be helpful for research organizations to have set benchmarks for compensation that could be used to encourage their HR departments to make salary offerings competitive. NCI could consider partnering with the Association of American Cancer Institutes or the American Society of Clinical Oncology to conduct a compensation survey, including data from industry and CROs, so the scope of the differences in compensation can be fully appreciated.

Dr. Doroshow closed by highlighting that remote work is a central issue, and salary concerns may be secondary to the ability to work remotely for many in the clinical trials workforce.

VII. Strategic Planning Activities Update

Neal J. Meropol, MD
James Doroshow, MD

Drs. Meropol and Doroshow provided an update on the implementation of the CTAC Strategic Planning Working Group (SPWG) recommendations related to two topics: streamlining clinical trials and decentralized trial activities.

Streamlining Clinical Trials. The CTAC Streamlining Clinical Trials Working Group (SCTWG) was formed to address three SPWG recommendations, related to data collection and the use of electronic health records (EHRs) to support clinical trials:

Limiting Data Collection

- Limit clinical trial data collection in late phase trials to essential data elements.

Optimizing Use of Electronic Health Records (EHRs) to Support Clinical Trials

- Resolve the logistical and data quality challenges of extracting clinical trial data from EHRs.
- Engage EHR and Clinical Trials Management System vendors to create mechanisms for automatically integrating study-specific documents into local implementations of their products.

In their November 2022 interim report, the SCTWG, co-chaired by Drs. Mandrekar and Meropol, recommended standards for limiting clinical trial data collection in National Clinical Trials Network (NCTN) adult late-phase, Investigational New Drug (IND)-exempt, interventional treatment trials. Categories for these standards include adverse events, medical history, concomitant medications, physical exam, laboratory tests, imaging and other assessment procedures, and patient-reported data. The standards are expected to reduce operational burden and increase efficiency.

Progress to date includes the formation of an implementation committee comprising representatives from NCI's Cancer Therapy Evaluation Program (CTEP) and all NCTN groups. Led by co-chairs Dr. Mandrekar and Ms. Andrea Denicoff, RN, MS, ANP, Head, NCTN Clinical Trial Operations, NCI, the committee first met in May 2023 and will meet monthly through September 2023 to develop implementation plans for the proposed standards as well as timelines and milestones. Actual implementation among the groups is anticipated to begin in January 2024.

NCI plans to continue discussions with the U.S. Food and Drug Administration (FDA) about extending the SCTWG proposed standards to IND trials. The Pragmatica-Lung Study, an NCTN trial lead by SWOG, is piloting a highly streamlined, pragmatic approach including minimal data collection to IND trials of approved agents with well understood adverse events.

The SCTWG recommended resolving logistical and data-quality challenges of extracting clinical trial data from EHRs and engaging EHR and clinical trial management software vendors to create mechanisms for automatically integrating study-specific documents into local implementations of their products.

Progress on the recommendations related to optimizing EHRs has included identifying current initiatives in the private and public sectors aimed at developing tools for automated extraction of data from EHRs. Within NCI, discussions are ongoing concerning pilot studies using one or more of these tools for data extraction in an NCTN trial. The NCI Cancer Center consortium is developing tools to address the challenge of automating EHR study builds. [Note: Later in the meeting, Dr. James Yao presented an update on this initiative.]

Decentralized Trial Activities. The SPWG recommended identifying study procedures that were modified due to COVID-19, such as informed consent and auditing, to be performed locally or remotely that are sufficiently beneficial for adoption as standard clinical trial practice.

On March 13, 2020—soon after recognition of the pandemic—NCI CTEP issued initial interim guidance related to transfer of patient care to a different participating study site (i.e., closer to the patient); continuity of care (short-term or intermittent care) provided by nonresearch staff with responsible principal investigator (PI) oversight; and mailing CTEP IND oral agents from a site dispensing pharmacy to a local pharmacy closer to the patient. On March 23, 2020, additional guidance was provided on alternative procedures for ongoing trials,

including minor protocol deviations (e.g., virtual visits; reasonable delays in treatments, imaging, and laboratory tests; and local storage of blood collection); alternative procedures for auditing/monitoring of trials (i.e., modest audit delays, remote audits); and remote informed consent for trials.

A number of these modified policies have been approved for continuation post the pandemic public health emergency. Shipping of CTEP IND oral agents to local sites for distribution to patients will continue as a permanent option. Remote consent was made a permanent option by the NCI central Institutional Review Board. Remote auditing will remain a site option. Virtual study visits by investigators are permitted depending upon licensing and protocol requirements and appropriateness.

Policies on the intermittent and short-term use of local physicians, with responsible investigator oversight, are in place and covered by Office for Human Research Protections (OHRP) and FDA regulations (short-term permitted by OHRP, intermittent by FDA). Laboratory testing may be performed locally, unless specific tests must be conducted at a central laboratory, and imaging may be done locally, unless qualified site imaging is required. Study visit requirements may vary for IND versus IND-exempt trials, depending on protocol specifications.

To date, NCI implementation of decentralized trial activities has included establishing a CTEP working group to develop sample protocol language aligned with FDA and OHRP regulations to facilitate site understanding of parameters for decentralized trial activities. NCI is promoting routine consideration of decentralized activities during trial design and protocol development. NCI also is monitoring related developments underway at other organizations (e.g., FDA, American Society of Clinical Oncology [ASCO]). For example, ASCO is working to clarify interpretation issues on the completion of the FDA Form 1572. Recent FDA draft guidance on decentralized clinical trials addresses the role of Form 1572 for local health care providers and clinical laboratories; public comment is open until August 1, 2023.

Questions and Discussion

Streamlining Clinical Trials. Dr. Mandrekar noted that the recommendations from the SCTWG currently focus on non-IND studies, but by engaging FDA early in the implementation process, there is hope of expanding the proposed standards for limiting data collection to IND studies in the future. Implementation of streamlined trials will require a fundamental change in trial design, protocol development, and workflow, as well as structure of forms and the NCI reporting systems. It will need to be clear which trials are considered "streamlined" and what data elements do not need to be collected and reported for these trials. The goal is for implementation to begin for new trials that have not yet been activated, and then the committee will consider whether any current trials can be converted to these standards.

Ms. Denicoff described an important need for education at the study chair and PI level. Protocol staff have expressed concerns about pushback from PIs wanting to continue to collect data outside what is recommended by the SCTWG. Dr. Ramalingam commented that publishing the recommendations, especially the rationale for these changes, would be an important step. Having the recommendations in the public domain could help with investigator education. Dr. Meropol responded that a publication is under development.

Dr. Dicker recommended looking at collected patient-reported outcome data to clarify what a meaningful minimal dataset includes and whether added layers that increase patient burden provide actual value.

Dr. Meropol noted that simplifying data collection has been a topic for decades, and it is satisfying to see the recommendations gaining traction toward institutionalizing implementation.

Dr. Knopp commented that patients want to know that the data they share will be used as much as possible and suggested incentivizing electronic availability of data to reduce burden on study coordinators. Dr. Levy asked if there is a relationship between the CTIU and the SCTWG. Dr. Meropol responded that there is no official relationship at this point and agreed this connection should be made.

Decentralized Trial Activities. Dr. Meropol noted that "decentralization" has different meanings in different contexts. For purposes of this discussion, "decentralization" refers to elements of an operational model that may be fit-for-purpose in a particular setting. He encouraged CTAC members to think about decentralization as a spectrum. CTAC members should consider obstacles to implementation of decentralized operational elements in NCTN studies, steps NCI should take to promote broader use of decentralized approaches, and trial types that are good candidates for decentralization.

Ms. Spears described decentralization as an important means to get more trials to more patients. One way to do this is to allow more to be done at local sites rather than requiring patients to travel to main sites. She also suggested considering how to build trust between main institutions and local sites.

Dr. Kelley noted that many of the goals of the Clinical Trials Innovation Unit (CTIU), including access, efficiency, and equity, can be addressed by some elements of decentralized clinical trials. Veterans Affairs (VA) is doing a lot of work in this area, particularly around telehealth, as one-third of VA patients reside in rural areas. He said that the only way to get trials to these patients will be through a decentralized mechanism. To address this, VA has developed an implementation manual for decentralized clinical trials. Dr. Kelley suggested that protocols must spell out which procedures can be done by telehealth or some other remote mechanism, which means that sponsors must be on board. However, sponsors are risk averse. Dr. Kelley stated that NCI NCTN investigators should consider decentralized elements and how others might enroll patients in their study rather than focusing on how the trial will be conducted at their academic institution. There must be a change in perspective. CTIU may be able to help with that. Dr. Kelley said that the Pragmatica-Lung study, for example, would be even better if he could provide assessments to patients via telehealth, but he cannot do so because telehealth is not included as an option in the protocol. Adoption of decentralized trial concepts must begin by engaging people at the disease and concept level.

Dr. Meropol asked Dr. Mandrekar whether the implementation committee has discussed protocol templates and prompts in protocols for adoption of decentralized trial elements. Dr. Mandrekar responded that there is interest from all the groups for protocol language and standard templates, but there is no agreement on how and where that language would be integrated as each group wanted autonomy on how this would be implemented. There has been interest in minimizing data collection beyond the working group recommendations; for example, limiting collection of treatment-related information for non-IND studies.

Dr. Levy commented that the concept of a virtual workforce being experts on a particular study could offset some aversion to a decentralized approach. Often, studies are distributed to numerous sites in the nation; however, each site may only accrue a few patients. Therefore, one cannot know how well the local site team really knows the study. Utilization of a virtual expert could be a new model for ensuring that distributed studies maintain the highest levels of quality.

Dr. Bertagnolli stated that the culture of clinical trials must change to prioritize access for everyone. A key consideration for every protocol should be, “Who will not have access to this trial? Can we do something to ensure that they will have the opportunity to benefit from this treatment?”

Dr. Dicker pointed out examples of decentralized trials where phlebotomists come to a patient’s home. Another emerging area is how to do imaging in the home. New ultrasound technologies require less skill, and artificial intelligence combines the images so that they can be read almost instantaneously. He suggested thinking about which trials might be appropriate for pioneering imaging and blood collections in the home. Hybrid models of conducting clinical trials are possible as well. He suggested incentives that may help nudge culture such as receiving extra accrual credit for getting more rural enrollment or for the use of telehealth when appropriate.

Dr. Vose described the Nebraska Lymphoma Study Group that has conducted studies in community oncology centers for several decades. The studies are very pragmatic; the pathology review and data collection are done centrally, but oncologists provide care locally.

Dr. Santana applauded ASCO efforts to address interpretation of Form 1572 language. In the future, it would be interesting to consider how to align audit program policy with pragmatic approaches. Dr. Doroshow added that, as data collection requirements are reduced, there is less data to be audited.

VIII. Accelerating Electronic Clinical Trial Study Builds

James C. Yao, MD

The 2020 report from the Strategic Planning Working Group included a recommendation for NCI to engage electronic health record (EHR) and clinical trials management system vendors to create mechanisms for automatic integration of study-specific documents into local implementations of their products. The Clinical Trial Rapid Activation Consortium (CTRAC)—a collaboration between five cancer centers (MD Anderson, Dana Farber, City of Hope, University of Wisconsin, and University of Colorado), Epic (EHR vendor), and NCI—aims to address this need by creating and disseminating standard treatment plan builds for NCI-supported clinical trials.

CTRAC members analyzed existing workflows and builds and found room for greater efficiency at every stage of the process. Currently, each study protocol requires a unique implementation of study documents and forms into the local EHR. This process is time-consuming, costly, and inefficient, especially for precision medicine trials, which require rare populations and enroll few patients per site. The duplication of effort is necessitated by differences across sites in drug formulary, standard operating procedures, and style.

To maximize the efficiency of data collection, CTRAC sites came to an agreement on the data that are needed for a build and created an Investigational Drug Data Sheet for use across institutions. Information from the data sheet will flow into an eRX build tool that will allow for site-specific configuration.

Further analysis of existing NCI clinical trial builds and workflows revealed two types of treatment plan orders: protocol-specific orders, which are less variable, and general orders, which are more variable. The group also determined that, at present, the faithful capture of protocol content is insufficient for a comprehensive build. There is a lack of standardized content and a lack of standardized locations in the protocol for that content; additionally, the existing build process incorporates micro-decisions that are largely undocumented. CTRAC members used the Order Groups function in Epic to construct a standard representation of the treatment plan that could be mapped to local EHR installations. A pilot test of this approach—using an arm of the NCI Molecular Analysis for Therapy Choice study—built by MD Anderson Cancer Center and implemented at the four other CTRAC member sites—was successful. Even with this centralized offering, sites must still adjust the build to fit their local standards. The group is working on tools to make this tailoring process easier. A protocol treatment plan is, at its core, about tasks and when to complete them; therefore, delineating tasks and timepoints in a database will ensure that users have a clear and consistent view of the underlying data.

Future Directions. CTRAC's work is continuing under the newly expanded EHR Pilot Consortium, which has seven sites. The group is standardizing content extraction to the database with a focus on tasks and timepoints. They are generating a task library for general tasks and building an application that will deliver more tailored content to sites. The group is working with Epic to minimize post-import work for sites. They are also exploring the feasibility of expanding to other EHR vendors.

Long-term goals include conducting structured authoring of protocols; leveraging task libraries and content templates; creating a structured representation of treatment plan tasks and timepoints; delivering tailored content to sites; developing and maturing a data standard for treatment plan content; and reimagining how protocols should be represented in the electronic era.

Questions and Discussion

Dr. Meropol asked about existing barriers to conduct an NCI pilot project using actual study orders. Currently, the largest hurdle is the lack of standardization across sites. It will take time to resolve these issues. Flexibility from sites will help.

Dr. Meropol commented that change adoption and new solutions are challenging to integrate. One way to encourage adoption is to emphasize cost savings. Dr. Yao said that a metrics subgroup within CTRAC is collecting baseline data on current protocols to demonstrate how the new system would result in greater efficiency.

Dr. Lerner observed that many community health organizations do not use Epic. Dr. Yao said that much of the work is about the harmonization and tailoring of clinical content, which is vendor-agnostic, and that CTRAC is working to incorporate other EHR platforms, including Cerner.

Dr. Levy observed that CTRAC's build document itself has value, as this step will reduce the cognitive load for sites and variance in processes. CTRAC could assess how much time sites might save by using this document. Dr. Yao agreed that CTRAC's build document is an important output from the group.

Dr. Meropol commented that an area that is often prone to error in the current decentralized build process is protocol amendments and deviations that may not be reflected in the build. Digitizing the protocol can ensure consistency between study schema and scheduled tasks. This can be harmonized with the participants' EHR.

Dr. Knopp noted that lack of resources is a barrier not only for cancer clinical trials but also for clinical trials across all diseases and conditions. He suggested that a National Institutes of Health (NIH) initiative to convene stakeholders would help accelerate progress. Dr. Bertagnolli concurred and noted NCI is considering

collaborations within NIH and the Advanced Research Projects Agency for Health to build tools to facilitate data management; some are specific to clinical trials.

IX. Adjourn

Neal J. Meropol, MD

There being no further business, the 51st meeting of CTAC was adjourned at 3:10 p.m. on Wednesday, July 19, 2023.

Date Neal J. Meropol, MD, Chair

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

June 2023

NATIONAL INSTITUTES OF HEALTH

National Cancer Institute
Clinical Trials and Translational Research Advisory Committee

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