DEPARTMENT OF HEALTH AND HUMAN SERVICES
NATIONAL INSTITUTES OF HEALTH
NATIONAL CANCER INSTITUTE
57TH CLINICAL TRIALS AND TRANSLATIONAL RESEARCH ADVISORY COMMITTEE MEETING

Summary of Meeting
July 16, 2025

Virtual

CLINICAL TRIALS AND TRANSLATIONAL RESEARCH ADVISORY COMMITTEE

Summary of Meeting

July 16, 2025

The 57th meeting of the Clinical Trials and Translational Research Advisory Committee (CTAC) of the National Cancer Institute (NCI) was convened Wednesday, July 16, 2025, at 11:01 a.m. The CTAC chair, Dr. Julie M. Vose, presided.[1] The meeting was adjourned at 1:12 p.m.

Chair

Julie M. Vose

CTAC Members

Nilofer S. Azad
Smita Bhatia
Charles D. Blanke
Adam P. Dicker
Gary C. Doolittle
Ernest T. Hawk
Ken Kobayashi
Seth P. Lerner
Sumithra J. Mandrekar (absent)
Robert S. Mannel
Ruben A. Mesa
Carolyn Y. Muller
Raphael E. Pollock
Suresh S. Ramalingam
Victor M. Santana
Patricia A. Spears
George Wilding

Ex Officio Members

Michael J. Kelley, US Department of Veteran Affairs (absent)
Richard Pazdur, US Food and Drug Administration (absent)

Designated Federal Official

Sheila A. Prindiville, NCI

Presenters

Jeff Allen, Ph.D., President and CEO, Friends of Cancer Research

Andrea M. Denicoff, R.N., M.S., Head, National Clinical Trial Network Clinical Trials Operations, Cancer Therapy Evaluation Program, Division of Cancer Treatment and Diagnosis, NCI

James H. Doroshow, M.D., Director, Division of Cancer Treatment and Diagnosis, NCI

Douglas R. Lowy, M.D., Principal Deputy Director, NCI

Sheila A. Prindiville, M.D., M.P.H., Director, Coordinating Center for Clinical Trials, Office of the Director, NCI

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

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

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Wednesday, July 16, 2025

I. Call to Order and Opening Remarks

Julie M. Vose, M.D.

Dr. Vose called the 57th meeting of CTAC to order at 11:01 a.m. She welcomed Rebekah Zinn, Ph.D., Senior Advisor for Research Strategy and External Partnerships, Oncology Center of Excellence, US Food and Drug Administration (FDA), who attended as the FDA representative.

Dr.Vose reviewed the confidentiality and conflict-of-interest practices required of CTAC members during the meeting. She invited members of the public to send comments on any issues discussed during the meeting to Dr. Prindiville within 10 days of the meeting. The National Institutes of Health (NIH) Events Management provided a videocast of the meeting. The videocast recording is available for viewing at https://videocast.nih.gov/watch=56862.

Motion. A motion to accept the minutes of the 55th CTAC meeting, held on November 6, 2024, was approved.

II. NCI Principal Deputy Director's Remarks

Douglas R. Lowy, M.D.

Dr. Lowy began by emphasizing the important role advisory boards such as CTAC play in responding to the needs of the public and research communities.

Leadership Updates. Dr. Lowy shared that Dr. Paulette Gray retired as director of NCI's Division of Extramural Activities (DEA) in June 2025. Dr. Dinah Singer, NCI deputy director for scientific strategy and development, is now serving as acting DEA director. Dr. Shamala Srinivas, NCI associate director for scientific review and policy, was in attendance and will represent the DEA at future CTAC meetings.

Upfront Funding. In June 2025, the Office of Management and Budget notified NIH that each institute must allocate at least 50% of its remaining research program grant (RPG) funds using upfront funding. This funding approach obligates the full amount of an award in the fiscal year (FY) it is issued. The 50% upfront funding requirement is included in The President's proposed FY 2026 budget with a shift to 100% upfront funding anticipated in the FY 2027 budget proposal.

Dr. Lowy explained the potential implications of this shift. While upfront funding allows greater predictability for grantees, it initially results in fewer research-years because funds are concentrated into fewer awards. Reaching a "steady state," where the number of research-years and awards align with previous levels, may require 5 or more years. During this transition period, the reduced number of awards could result in loss of principal investigators and research staff.

New National Cancer Advisory Board (NCAB) Working Group. During the June 2025 NCAB meeting, the board approved the formation of the *ad hoc* Working Group on Extramural Research Concepts and Programs. This group will take on selected responsibilities previously managed by the Board of Scientific Advisors and will comprise a broad spectrum of cancer researchers and advocates, including current CTAC members. Dr. Lowy expressed his enthusiasm that CTAC would be considering the formation of three new working groups focused on streamlining data collection, advancing clinical trial innovation, and strengthening the role of the patient perspective in cancer research.

New NCI Chief Science Advisor. George Sigounas, Ph.D., presidential appointee, is the new chief scientific advisor for NCI. He has several years of experience as a doctoral fellow at NIH and has spent more than 20 years as a professor of medicine at East Carolina University. Additionally, he is the former administrator of the Health Resources and Services Administration (HRSA). Dr. Sigounas will serve as a liaison between NCI and the Administration.

US Cancer Mortality Rate Trends. Since the 1990s, US cancer mortality rates have steadily declined for both men and women. Estimates for 2025 suggest that 300,000 fewer Americans will die from cancer compared to the number expected based on 1990 mortality rates. However, approximately 600,000 cancer deaths will still occur this year, so urgent work remains. Mortality rates for most cancer types are declining, particularly for melanoma and lung cancer, largely due to advances in prevention, early detection, and treatment. However, these improvements are not evenly distributed across the United States. States including Arkansas, Kentucky, Mississippi, Oklahoma, and West Virginia continue to have the highest cancer mortality rates, which remain 20% or more above the national average.

Dr. Lowy concluded by acknowledging the hard work and dedication of NCI staff to continue to advance NCI's mission to make progress in cancer research.

Questions and Discussion

Dr. Mesa asked about the classification of cancer as a chronic disease and its relationship to other chronic conditions such as obesity and metabolic syndrome. Dr. Lowy responded that this is recognized as an important topic and there have been discussions with representatives from the Make America Healthy Again initiative about NCI's efforts to address this.

Ms. Spears raised concerns about how funding changes may affect clinical trials, workforce stability, and the continuity of research. She noted the potential role of advocacy in supporting NCI's efforts and asked how advocates might contribute. Dr. Lowy acknowledged the importance of ongoing engagement from the advocacy community.

Dr. Ramalingam asked if upfront funding will affect grants broadly or if certain initiatives will be prioritized to receive more funding. Dr. Lowy noted that details are still under discussion but cautioned that with 100% upfront funding, success rates might drop to the second or third percentile, necessitating careful portfolio balancing.

Dr. Azad asked about the potential impact of funding shifts on early-stage investigators. Dr. Lowy indicated that while early-stage investigators may receive a higher proportion of available funding in FY 2025, the total number of awards could decline. He noted that discussions are ongoing regarding the continuity of support for training programs and early-career development.

Dr. Wilding asked if existing grants would be affected. Dr. Lowy responded that NCI intends to fund existing grants at or above 95% of their commitment levels but noted the challenge of maintaining support for research areas outside of the RPG pool.

Dr. Lowy encouraged those interested in contributing to NCI's mission to connect with Ms. Mary Holohan, J.D., director, NCI Office of Government and Congressional Relations.

III. Strategic Planning Initiatives Overview

James H. Doroshow, M.D.

Dr. Doroshow reviewed NCI's strategic vision for clinical trials for 2030 and beyond, which aims to develop flexible, faster, simpler, less expensive, high-impact clinical trials that can rapidly translate to clinical practice. Key components to achieving these objectives include streamlining processes for trial design and execution, decreasing regulatory barriers, focusing on essential endpoints, and increasing efficiency of data collection.

In 2020, the CTAC Strategic Planning Working Group (SPWG) released a report identifying 15 recommendations, many of which have been implemented by NCI. During this CTAC meeting, members will hear updates on certain recommendations, including the status of refining NCI's audit process, decentralized clinical trial elements, streamlining clinical trial data collection, and the use of external control arms in a pilot project being conducted by Friends of Cancer Research (FOCR). NCI has previously explored the use of control arms, and there is particular interest in CTAC's input on how to proceed with this initiative as the FOCR pilot study progresses.

IV. Friends of Cancer Research: External Control Arm Pilot Project

Jeff Allen, Ph.D.

Dr. Allen provided an overview of a proof-of-concept pilot project led by FOCR exploring the use of external control arms (ECAs) constructed from existing patient-level data as a clinical research tool. An ECA provides a "virtual" control group, offering a potential alternative to traditional randomized control arms by comparing investigational therapies against standard treatment using real-world data sources. Preliminary work has involved collaboration with several data partners to assess the ability to reliably and consistently collect data across different datasets with an ultimate goal of developing methods to support the use of ECAs across a broad range of oncology clinical trials.

The goal of the pilot project is to establish a methodology for constructing ECAs using patient-level data that closely matches the control arm of a target randomized controlled trial (RCT) based on known prognostic and demographic characteristics. A key objective is to evaluate whether results can be consistently replicated across diverse data sources, thereby supporting methodological rigor. Additional objectives are to identify criteria such as data source type, data completeness, eligibility criteria, timing of treatment, and outcome measures that influence whether a dataset is fit for ECA construction. Statistical and study design methods will also be assessed to inform future best practices.

For this pilot, the RESOLVE RCT comparing the safety and efficacy of ibrutinib with nab-paclitaxel and gemcitabine (investigational arm) versus placebo with nab-paclitaxel and gemcitabine (control arm) in metastatic pancreatic adenocarcinoma (mPDAC) was selected as the target trial. mPDAC was chosen as a use case because of its low incidence, well-defined prognostic factors, limited treatment options, and availability of different data sources to construct an ECA.

In order to replicate the control arm, data partners were asked to isolate patients in their respective cancer databases and extract data using a standardized protocol. Eligible patient data were received from six data partners, which includes five real-world (electronic health record) datasets and one prior clinical trial. A minimum of 171 patients (approximately 80% of the control arm sample size in the target trial) is needed to construct the ECA and perform propensity score matching.

To isolate the patient population of interest, the datasets were aligned to the inclusion and exclusion criteria of the RESOLVE trial. As anticipated, when additional criteria were applied to the data pool, the number of eligible patients decreased. However, after all criteria were applied, two-thirds of the data partners still had over 171 eligible patients for direct propensity score matching. For the datasets that have fewer than 171 eligible patients, a weighted approach or modified exclusion criteria will be considered. The data analysis will provide insight into the extent of data completeness and variability among the data sources, offering insight into the characteristics of data needed to accurately construct an ECA.

Once eligible patient cohorts are finalized, overall survival will be analyzed and compared between the RESOLVE trial control patients and post-matching ECA patients. Kaplan-Meier curves and hazard ratios will be used to determine concordance between RESOLVE patients and each ECA cohort.

Dr. Allen concluded with a summary of the project's current status and next steps. Project scoping, which included identifying the six data partners, assessing data availability and feasibility to determine use case, and selecting the target trial has been completed. The pilot study design is also complete, and the study populations have been identified by adapting trial eligibility criteria to the available datasets. The pilot execution phase is currently underway. In the coming months, the protocol for propensity score matching will be finalized, and statistical analysis will be conducted for outcomes comparison. Dr. Allen acknowledged the important contributions of the pilot project's data partners and noted that initial study results are expected to be available in early 2026.

Questions and Discussion

Dr. Ramalingam expressed enthusisam for the pilot and its practical applications to treatment for rare cancers. He asked how differences that occur in practice such as adding radiation or delaying treatment for patient-specific reasons are accounted for to ensure ECA data aligns as closely as possible with the clinical trial. Dr. Allen acknowledged that this is an inherent challenge when working with real-world retrospective data. He noted that while prospective data collection may be ideal, the pilot aims to "pressure test" existing real-world data to evaluate how well it can replicate clinical trial controls. The goal is to determine whether real-world variability may have less impact, thereby potentially supporting the use of ECAs.

Dr. Vose commented that ECAs based on real-world data may prove to be helpful because they are more realistic representations of the patient experience.

Dr. Muller raised a point about ensuring that ECAs adequately represent diverse populations and are not overly homogeneous. She emphasized the importance of matching the efforts seen in diverse clinical trial enrollment and suggested that large datasets could allow for hypothesis-driven questions to compare differences between population-specific external controls. Dr. Allen agreed that there may be possibilities to explore these types of questions with the pilot results. He acknowledged the value in also analyzing patients who did not qualify for the ECA to assess potential differences and better understand the broader real-world population.

Ms. Spears applauded the initiative and asked about the concordance required for the pilot to be considered successful and unbiased. Dr. Allen noted that the specific threshold for concordance has not yet been determined. The focus of the pilot is to develop the methodology to reliably replicate clinical trial controls. The findings will help assess if the data are fit for purpose for an ECA and inform how the methodology can be refined.

Dr. Dicker was enthusiastic about use of these methods for accelerating trials in rare orphan diseases. He asked if data from Project Data Sphere can also be used in this pilot. Dr. Allen noted that Project Data Sphere does not currently have sufficient data in the mPDAC setting. If successful, this pilot could support pooling of high quality data to improve ECA development.

Dr. Mesa commented that this work will be critical in clinical trials for diseases such as myelofibrosis, where limited approved therapies make traditional randomized trials challenging, especially for long-term endpoints like survival. He highlighted that patients often hesitate to remain on control arms indefinitely, making real-world control arms essential.

Dr. Kobayashi commented that this methodology could provide a good resource for trial planning or post-approval activities.

Dr. Vose noted that CTAC was considering a similar initiative in response to the 2020 CTAC SPWG report on the use of external control arms to facilitate clinical trials. Given the progress of the FOCR pilot, CTAC members agreed that waiting for the pilot's findings would be a prudent approach prior to considering new projects.

V. Streamlining Clinical Trials Implementation Update

a. Auditing of Late-Phase Clinical Trials: Opportunities for Streamlining

James H. Doroshow, M.D.

Dr. Doroshow provided a summary of recent NCI efforts to identify ways to improve the current NCI National Clinical Trial Network (NCTN) audit process including an exploratory analysis of CTEP audit data and discussions with NCTN quality assurance and regulatory staff.

Exploratory analysis of CTEP Clinical Trials Monitoring Branch data. In their 2020 report, the CTAC SPWG identified the clinical trial audit process as a source of operational burden for NCTN sites and that a retrospective analysis of past audit results should be conducted to better understand challenges in the audit process. NCI conducted a review of CTEP Clinical Trials Monitoring Branch (CTMB) audit deficiency reports spanning 3 years from January 1, 2022 to January 1, 2025 to identify patterns in audit findings and to assess the feasibility of using the data for process improvement. The CTMB reports dataset included site audit deficiency data for NCTN phase III Investigational New Drug (IND) and IND-exempt studies. Deficiencies recorded in the audit reports were categorized into three components: patient case review, pharmacy review, and regulatory document review. Deficiencies within each component were further categorized into multiple subcategories and classified according to severity.

Overall, the high-level analysis did not reveal evidence of disproportionate or unnecessary reporting of specific deficiency types. IND studies had more deficiencies reported than non-IND studies. This difference is likely attributable to the increased complexity of IND studies and the corresponding heightened level of regulatory scrutiny applied to these trials.

Certain limitations were identified that made the data challenging to use for evaluating the audit process. Notably, the dataset was not originally designed for an analysis on burden of the audit process. Deficiencies were categorized with varying levels of detail across different audit components. In some cases, a single deficiency record could include multiple issues, which made efforts to analyze the data in a consistent manner difficult. Additionally, relevant contextual information was often included in free-text comment fields, which, while informative, would require substantial manual effort to interpret systematically. These factors suggest that further analysis of these data would require significant effort and would be unlikely to yield additional meaningful insights.

Summary of NCTN quality assurance and regulatory staff discussions. Quality assurance and regulatory staff from each of the NCTN groups were asked to provide feedback on their current audit processes and potential areas for improvement. In summarizing these discussions, the following key takeaways were identified:

- Collecting only essential data elements may help reduce the overall burden of the audit process.
- In addition to the audit itself, significant effort can be required to navigate the Audit Information System and to prepare for the audit.
- Differentiating the burden attributable to NCTN audits from that of industry audits can be challenging.
- There is variability in the degree of deficiency classification (e.g., lesser vs. major) across NCTN groups and specific auditors, which can add to the complexity and burden of audits.
- The COVID-19 pandemic has resulted in a notable loss of experienced staff, highlighting the importance of training for new auditors and research personnel.
- While greater standardization of audit processes across NCTN groups is generally supported, flexibility remains necessary to accommodate group-specific practices.

Next steps. NCI plans to continue to explore opportunities to streamline data collection and work with NCTN groups to harmonize audit processes across the groups where feasible in order to reduce audit burden. Direct data transmission from electronic health records to trial databases and centralizing the auditing process could save significant time and effort but would require extensive resources. Dr. Doroshow noted that the next version of the CTMB audit guidelines will include several updates, including clarification to better capture deficiencies related to documentation and reporting, and creation of a separate category for deficiencies related to correlatives. Additional suggestions can be emailed to GeneralQuestionsforCTMB@nih.gov. CTMB welcomes all feedback on methods to improve the process.

Questions and Discussion

Dr. Mannel commented that the NCTN audit process is largely a volunteer effort and can provide an important learning opportunity for the audit team to improve their own clinical trial sites. He noted that if the NCTN group auditing process were centralized, there would be a reduction in training opportunities for the next generation of auditors.

Dr. Santana highlighted feedback from quality assurance staff indicating that incremental improvements, such as harmonizing processes across NCTN groups, could enhance the audit process. He suggested the groups work together to develop a training program aimed at promoting consistent use of the CTMB audit manual to support process harmonization.

Dr. Blanke suggested that developing a new, simplified audit process with clear instructions for sites may be more effective than attempting to harmonize existing processes. This could make it easier to centralize audits with fewer resources. He further suggested piloting a streamlined audit system at a limited number of sites.

Dr. Muller emphasized that the primary objectives of audits are to ensure patient safety and maintain scientific integrity. Corrective and preventative action plans are implemented to address issues identified during the audit. Therefore, allowing sufficient time to monitor and ensure that corrective action plans are successfully adapted is important.

Dr. Kobayashi agreed that the key purpose of an audit is to ensure scientific integrity and patient safety. He asked if certain data elements could be deprioritized in a risk-based approach to simplify the audit process. He also commented that the follow-up to an audit can sometimes be more onerous and challenging than the audit itself, partly due to concerns for a study pause or study termination. Increasing transparency can help sites with the audit process.

Dr. Vose reaffirmed that significant variability exists in the way audits are conducted and concurred that harmonization and simplification of the audit process would be helpful to clinical sites.

b. Decentralized Clinical Trial Elements

Andrea M. Denicoff, R.N., M.S.

Ms. Denicoff provided an update on efforts to implement decentralized clinical trial (DCT) elements in NCI studies, many of which had been implemented during the COVID-19 pandemic. As the FDA was developing their 2024 guidance on Conducting Clinical Trials With Decentralized Elements, NCTN groups and NCI Community Oncology Research Program (NCORP) research bases collaborated with NCI CTEP and the Division of Cancer Prevention to develop a checklist to specify elements that could be decentralized and to create sample protocol language which could be used across NCI studies. The checklist topics include remote consent, administration of standard of care commercial agents by a local provider, telehealth appointments, and shipment of oral agents. These tools aim to help study teams identify which trial components can be decentralized and ensure consistent implementation across sites.

SWOG S2312, “A Phase III Study of Cabazitaxel with or without Carboplatin in Patients with Metastatic Castrate-Resistant Prostate Cancer, Stratified by Aggressive Variant Signature,” is an IND-exempt study, and serves as an example of how DCT elements can be incorporated into a clinical trial. The study successfully incorporates elements including remote consent, telehealth, local lab testing, and administration of commercial agents by a local oncologist. Since radiographic progression-free survival is a primary endpoint, imaging must be done at the clinical trial site and cannot be decentralized. The extent of decentralization is determined on a study-by-study basis and is also dependent on the study design and regulatory requirements.

An important component for enabling administration of commercial agents by a local provider is establishing an agreement between the enrolling site investigator and the local health care provider. This requirement is included in the site’s annual NCI Central Institutional Review Board (CIRB) signatory institution worksheet. Certain elements, such as the administration of investigational agents via intravenous or intraperitoneal routes, are generally not decentralized in NCTN IND trials. However, the FDA has indicated that full decentralization may be feasible for investigational products with well-characterized safety profiles, pending regulatory review and approval.

Questions and Discussion

Dr. Kobayashi highlighted the potential of remote informed consent to enhance accessibility and robustness of the consent process, particularly for patients with special needs, disabilities, or language barriers. Ms. Denicoff agreed that this is an important perspective.

Ms. Spears expressed support for the development of sample protocol language to describe DCT elements, noting that such activities are not always clearly identified in existing protocols. She asked if sample informed consent language was being developed as well to denote DCT elements. Ms. Denicoff responded that decentralized activities are typically described in a protocol appendix, sometimes under headings such as “continuity of care” or “decentralized activities.” For the informed consent form, Ms. Denicoff explained that such language is generally not necessary as informed consent forms do not typically specify the locations where individual trial activities take place.

Dr. Ramalingam asked about the requirements for a local health care provider to administer standard of care commercial agents. Ms. Denicoff explained that a simple written agreement between the responsible investigator and the local provider is adequate. The information must also be reported to the CIRB on the annual signatory worksheet indicating the relationship with a local oncologist to provide the agent.

c. Streamlining Clinical Trial Data Collection

Andrea M. Denicoff, R.N., M.S.

In their 2024 report, the CTAC Streamlining Clinical Trials Working Group outlined a set of standard practices for data collection aimed at reducing operational burden in NCTN trials. The primary goal of the standard practices is to limit data collection to information necessary for patient safety or to support key study objectives. The initial scope of the new standards applies to late phase (i.e., phase II/III and phase III) IND-exempt trials managed by NCI CTEP, which account for approximately 35% of NCTN trials. Ms. Denicoff presented an update on the implementation of the new standard practices, which are now required for NCTN studies activated after January 1, 2025.

Under the new standard practices for data collection, only grade 3 or higher adverse events (AEs) must be submitted along with the Common Terminology Criteria for Adverse Events (CTCAE) term and grade. Lower grade and solicited AEs should be collected only if they are required for pre-specified analyses indicated in the protocol statistical analysis plan. AE attribution and start and stop times should not be submitted. Additional data categories including medical history, concomitant medications, physical exam, laboratory testing, imaging, and patient-reported outcomes should only be submitted as needed for pre-specified analyses, patient characterization, and eligibility determination. Any deviation from these standard practices requires scientific justification, NCTN group-level approval, and CTEP review.

To support implementation, the NCTN Streamlining Clinical Trials Implementation Committee (SCTIC) was established, co-chaired by Dr. Sumithra Mandrekar (Alliance) and Ms. Andrea Denicoff (NCI CTEP). The committee, which includes representatives from all NCTN groups and NCI, meets quarterly to discuss implementation progress, emerging challenges, and best practices for site staff education and training. In addition, the committee has identified areas for operational improvement including standardizing serious AE reporting and creating a frequently asked questions document to capture and share relevant information.

Since January 1, 2025, there have been 15 new NCTN IND-exempt therapeutic trials with streamlined data collection:

- nine activated phase III trials
- three approved phase III trials (pending activation)
- three trials in review (two phase III and one phase II)

To date, no NCTN groups have requested exemptions from the streamlined data practices for IND-exempt trials.

Future plans for the SCTIC include exploring the application of streamlined data collection in non-treatment NCORP studies such as those focused on prevention and cancer care delivery. The committee also plans to assess whether data collected to document administration of pharmacologic therapies in treatment trials can be further streamlined, while acknowledging the need for tailored approaches depending on the agent, regimen, and safety requirements.

Ms. Denicoff concluded by noting that while IND-exempt trials are well-suited for streamlined data collection practices, IND trials continue to present the greatest data collection burden. The Pragmatica-Lung (S2302) trial serves as a precedent for implementing context-driven, streamlined data collection in IND trials through collaboration with the FDA. She suggested CTAC consider ways to extend streamlined data collection principles to IND trials, taking into account the necessary scientific, regulatory, and operational contexts.

Questions and Discussion

Ms. Spears supported the streamlining initiative, noting that limiting data collection to elements needed for scientific and safety objectives could reduce protocol deviations. She emphasized that reducing deviations would not only lessen audit burden but also enable the inclusion of patient-reported outcomes (PROs) which are sometimes avoided due to concerns about multiple deviations.

Dr. Lerner emphasized the need to increase awareness among cancer centers regarding implementation of streamlined data collection. He also asked how the success of the streamlining initiatives would be evaluated. Ms. Denicoff noted that formal data collection to assess implementation impact has not been planned. However, feedback is being gathered from NCTN groups along with ongoing dialogue with site staff.

Dr. Lerner also voiced support for expanding streamlined data collection to IND studies. Dr. Mannel agreed, stressing that IND trials remain a major source of data collection burden and audit complexity.

Dr. Blanke highlighted the importance of continued education to ensure that investigators and research staff fully understand the new data collection standard practices.

VI. New Business

Julie M. Vose, M.D.
Sheila A. Prindiville, M.D., M.P.H.

Dr. Prindiville reminded CTAC that working groups may be established to address specific topics and provide recommendations to CTAC and NCI. During this meeting, CTAC members considered the formation of three new working groups.

Streamlining Data Collection in Clinical Trials Working Group. The purpose of the Streamlining Data Collection in Clinical Trials Working Group is to advise CTAC and NCI on additional strategies for limiting data collection. This includes potentially developing standard practices for data collection in IND studies, while taking into account necessary clinical, scientific, and regulatory contexts. Membership will include representatives from CTAC and other individuals with relevant expertise. Given the focus on IND studies, participation from the FDA will be an important component.

Dr. Mannel recommended also including industry representation in the working group.

Motion. A motion to form a Streamlining Data Collection in Clinical Trials Working Group was approved.

Patient Perspectives in Cancer Research Working Group. The purpose of the Patient Perspectives in Cancer Research Working Group is to establish a venue for meaningful patient engagement to inform CTAC and NCI on clinical and translational research initiatives with particular emphasis on emerging areas of research. Membership will include CTAC representatives and other members of the cancer community with relevant expertise.

Dr. Mesa inquired whether the group's scope includes obtaining patient input broadly across research initiatives or specifically in the design and conduct of individual trials. Dr. Prindiville clarified that the group's aim is to provide a forum to share NCI research activities with the patient community and to obtain patient insight into new clinical and translational initiatives.

Ms. Spears highlighted the value of bidirectional communication to incorporate patient perspectives across relevant areas. She noted that the group could serve as a platform to coordinate patient input within CTAC and enhance transparency in the research process.

Dr. Hawk emphasized the importance of having a broad patient perspective on the working group, including patients undergoing treatment, survivors, community members, and those involved in prevention and screening trials.

Motion. A motion to form a Patient Perspectives in Cancer Research Working Group was approved.

Clinical Trials Innovation Working Group. In 2023, NCI established the Clinical Trials Innovation Unit (CTIU) to advance innovative science, trial designs, and operational efficiencies for high priority research. The group facilitated the development of PROSPECT-Lung, a highly pragmatic trial being conducted through the NCTN and led by Alliance and SWOG. The purpose of the proposed Clinical Trials Innovation Working Group is to integrate the CTIU activity under CTAC, providing a forum for ongoing discussions of research opportunities and to build upon prior progress with the extramural community. The working group will advise NCI and CTAC on transformative approaches to clinical trials, including advancing pragmatic clinical trials and use of real-world data. Membership will include representatives from CTAC as well as other individuals with relevant expertise, including NCTN leadership, representatives from the FDA, and NCI.

Dr. Hawk expressed his support for the working group and commented on the importance of trial innovation given new research guidelines on the use of animal models that may impact the scope of future clinical trials. He again noted that membership should be broadly inclusive.

Motion. A motion to form a Clinical Trials Innovation Working Group was approved.

Dr. Lerner asked how membership of the three new working groups will be determined. Dr. Prindiville replied that it will vary by group depending on the specific expertise needed. Each group will include CTAC members as well as individuals identified from the broader community with appropriate expertise.

Dr. Prindiville noted that the next CTAC meeting will be held on November 19, 2025.

VII. Adjourn

Julie M. Vose, M.D.

There being no further business, the 57th meeting of CTAC was adjourned at 1:12 p.m. on Wednesday, July 16, 2025.

Date	Julie M. Vose, M.D., Chair

Date	Sheila A. Prindiville, M.D., M.P.H., Executive Secretary

Appendix

April 2025

NATIONAL INSTITUTES OF HEALTH

National Cancer Institute
Clinical Trials and Translational Research Advisory Committee

CHAIR

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University of Kansas Medical Center
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