DEPARTMENT OF HEALTH AND HUMAN SERVICES
NATIONAL INSTITUTES OF HEALTH
NATIONAL CANCER INSTITUTE
59TH CLINICAL TRIALS AND TRANSLATIONAL RESEARCH ADVISORY COMMITTEE MEETING

Summary of Meeting
March 18, 2026

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 59th meeting of the Clinical Trials and Translational Research Advisory Committee (CTAC) of the National Cancer Institute (NCI) was convened Wednesday, March 18, 2026, at 8:33 a.m. The CTAC chair, Dr. Julie M. Vose, presided.[1] The meeting was adjourned at 2:38 p.m.

Chair

Julie M. Vose

CTAC Members

Nilofer S. Azad
Smita Bhatia (virtual)
Gary C. Doolittle (absent)
Ken Kobayashi (virtual)
Seth P. Lerner (absent)
Robert S. Mannel (virtual)
Ruben A. Mesa
Carolyn Y. Muller
Raphael E. Pollock (virtual)
Suresh S. Ramalingam
Victor M. Santana (virtual)
Patricia A. Spears
George Wilding

Ex Officio Members

Michael J. Kelley, US Department of Veterans Affairs
Rebekah Zinn, US Food and Drug Administration

Designated Federal Official

Sheila A. Prindiville, NCI

Presenters

Jeffrey Buchsbaum, M.D., Ph.D., A.M., Medical Officer, Division of Cancer Treatment and Diagnosis, Radiation Research Program, NCI

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

Daphne R. Friedman, M.D., Staff Oncologist, Durham Veterans Affairs Health Care System and National TeleOncology Service, Director, Cancer Clinical Research Service National TeleOncology Service, Deputy Director, National Oncology Program Specialty Care Services, Veterans Health Administration, Professor, Medical Oncology, Duke University School of Medicine

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

Brandy Heckman-Stoddard, Ph.D., M.P.H., Chief Program Officer, Breast and Gynecologic Cancer, Acting Chief, Community Oncology and Prevention Trials, Division of Cancer Prevention, NCI

Anthony Letai, M.D., Ph.D., Director, NCI

Tamara P. Miller, M.D., M.S.C.E, Associate professor, Department of Pediatrics, Emory University School of Medicine

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

Robert E. Schoen, M.D., M.P.H, Professor of Medicine & Epidemiology, UPMC Endowed Chair in Gastroenterology, Hepatology and Nutrition, University of Pittsburgh | UPMC

Robin C. Vanderpool, Dr.P.H., Chief, Health Communication and Informatics Research Branch, Division of Cancer Control and Population Sciences

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

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

TABLE OF CONTENTS

Wednesday, March 18, 2026

I. Call to Order and Opening Remarks 1

II. NCI Director's Report 1

III. NCI Cancer Screening Trials 3

Implementation Update: CTAC Cancer Screening Trials Working Group Recommendations 3

Five- or Ten-Year Colonoscopy for 1-2 Non-Advanced Adenomatous Polyps (FORTE) 4

IV. Optimizing Electronic Health Records to Support Clinical Trials 7

Introduction 7

Accelerating Electronic Clinical Trial Activation Pilot 8

Automated Electronic Health Record Data Extraction and Curation Using ExtractEHR 10

V. NCI Cancer Information Service 13

VI. Facilitating Clinical Trials Enrollment 15

NCI's Virtual Clinical Trials Office: Update 15

Decentralized Clinical Trials: The Veterans Health Administration Experience 17

VII. Radiation Oncology-Biology Integration Network 19

VIII. Ongoing and New Business 21

IX. Adjourn 22

Appendix 23

I. Call to Order and Opening Remarks

Julie M. Vose, M.D.

Dr. Vose called the 59th meeting of CTAC to order at 8:33 a.m. She reviewed the confidentiality and conflict-of-interest practices required of CTAC members during the meeting and invited members of the public to send comments on any issues discussed during the meeting to Dr. Prindiville within 10 days of the meeting. Dr. Rebekah Zinn, Ph.D., Senior Advisor for Research Strategy and External Partnerships, Oncology Center of Excellence, U.S. Food and Drug Administration (FDA), attended as the FDA representative. 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/6e20485a-0cff-11f1-9f14-124f0a52e769.

Motion. A motion to accept the minutes of the 57th CTAC meeting, held on July 16, 2025, was approved.

II. NCI Director's Report

Anthony Letai, M.D., Ph.D.

Dr. Letai provided an overview of NCI priorities, focusing on stability, clinical trial efficiency and international competitiveness, research updates, and budget considerations.

Stability. Dr. Letai emphasized that NCI's mission to reduce the burden of cancer remains unchanged and that the institute continues to support a strong extramural research program. Fiscal year (FY) 2025 marked record support for the extramural program, and Dr. Letai noted that NCI anticipates continuing to devote approximately three-quarters of its budget to extramural research.

Clinical Trial Efficiency and International Competitiveness. Dr. Letai noted that early-phase clinical trials are increasingly being conducted outside the United States, particularly in China, Australia, and New Zealand. In Australia, several factors contribute to faster trial activation, including standardized contracting processes, use of centralized institutional review boards, and different regulatory requirements for early-phase studies. Together, these factors allow some trials to move from application to enrollment in a matter of weeks, substantially faster than is typical in the United States. Efforts are underway across the U.S. Department of Health and Human Services to better understand these differences and identify opportunities to improve efficiency in the US clinical trials system.

Research Updates. Dr. Letai highlighted two areas of scientific focus. The first is a new cancer vaccine program, established as a public–private partnership led by the Foundation for the National Institutes of Health with support from NCI. An expert panel was convened to identify areas in which cancer vaccines show the most promise for rapid advancement, specifically focusing on solid tumors. Next steps for the program include defining priority technologies and trial design.

The second topic highlighted was functional precision medicine. Dr. Letai noted that while genomic-based precision medicine has had important successes, it benefits

only a subset of patients. Functional precision approaches may provide additional information to guide treatment selection by testing therapeutic agents directly on patient-derived tumor samples to assess drug sensitivity. NCI plans to support further development of this area through engagement of both the intramural and extramural communities, including convening a workshop to help guide future efforts.

Dr. Letai also addressed the role of animal models in cancer research, noting that NCI aligns with NIH efforts to reduce animal use where appropriate while continuing to support scientifically justified animal research. He emphasized that justification for animal research should be explicit and clear and that investigators should consider whether research questions can be addressed using human-based approaches, while recognizing that animal models remain necessary in certain contexts.

Budget. NIH has adopted a unified funding strategy which considers several principles in addition to peer-review scores when making funding decisions, with scientific peer review continuing to remain the most important factor. Other principles include alignment with NIH and NCI priorities, programmatic and geographic balance, stewardship, and career stage. Dr. Letai noted that recent disruptions, including a 45-day government shutdown, contributed to delays in the funding cycle, but he expressed confidence that NCI will obligate its full extramural budget by the end of September 2026. He noted that NCI will make more awards through select pay rather than a fixed payline, and that NCI is prepared to manage the challenges that may arise with multi-year funding. In FY25, nearly half of NCI’s budget supported research project grants, and although the total dollar amount spent was higher than prior years, the number of grants funded was lower due to the upfront costs of multi-year funding. In FY26, this effect has lessened because future-year funding commitments have already been incorporated into the budget.

Questions and Discussion

Dr. Mesa asked about the implications of framing cancer as a chronic disease for NCI's cancer prevention and screening trial portfolio. Dr. Letai responded that cancer prevention and screening trials remain important, but he does not anticipate major programmatic changes in this area as NCI has long operated within a chronic disease paradigm given the approximately 20 million cancer survivors in the United States.

Ms. Spears expressed enthusiasm for the cancer vaccine program and encouraged robust patient advocate involvement throughout the process, including in clinical trial development. She also emphasized the importance of community engagement, specifically regarding access and affordability as the functional precision medicine initiative moves forward. Dr. Letai agreed, noting that patient advocates will be important allies in both programs and that their role will expand as the vaccine program moves towards implementation.

Dr. Ramalingam noted a shift in early-phase clinical trial activity from academia to industry and asked about NCI's role in funding these studies to advance drug development and developing early career investigators. Dr. Letai responded that NCI continues to fund early-phase trials and training for early-stage clinical investigators, emphasizing that NCI should focus on questions and disease contexts that would not be

pursued by industry. Dr. Kobayashi echoed the importance of NCI-sponsored early-phase trials for investigator training, noting that the scientific rigor and discipline developed through NCI-funded mechanisms is invaluable. Dr. Azad added that long activation timelines and limited access to investigational agents may contribute to reduced interest in NCI funding mechanisms among junior faculty. Dr. Doroshow acknowledged that some trials are developed through NCI mechanisms only to have the drug withdrawn for commercial reasons and noted the importance of improving access to agents.

Dr. Vose asked which diseases the functional precision medicine program would prioritize. Dr. Letai commented that while the vaccine program is focused on solid tumors, the functional precision medicine program is not disease specific and may be broadly applicable across cancer types. He added the approach may be particularly well suited to hematologic malignancies given the relative ease of tissue access.

Dr. Muller asked whether the cancer vaccine program would include a focus on cancer prevention. Dr. Letai acknowledged NCI's strong legacy in preventive vaccines, including the development of the HPV vaccine, but clarified that the program is therapeutic in nature and is focused on preventing relapse rather than prevention.

III. NCI Cancer Screening Trials

Implementation Update: CTAC Cancer Screening Trials Working Group Recommendations

Brandy Heckman-Stoddard, Ph.D., M.P.H.

Dr. Heckman-Stoddard presented an update on the implementation of recommendations from the CTAC *ad hoc* Working Group on Cancer Screening Trials (CSTWG), which was convened in November 2020 to assess the real-world impact of the COVID-19 pandemic on NCI-supported screening trials. The group initially focused on the Tomosynthesis Mammographic Imaging Screening Trial (TMIST), which is a large, randomized breast cancer screening trial comparing 3-dimensional tomosynthesis to 2-dimensional digital mammography. The CSTWG issued recommendations both specific to TMIST and broadly applicable to NCI cancer screening trials.

The CSTWG recommended TMIST continue but with modifications designed to accelerate accrual, ensure completion of primary study objectives, and maximize the potential for results to inform patient care and advance research. The trial closed to accrual in December 2024 after enrolling 108,908 participants. The final accrual reflects multiple reductions from the original sample size of 165,000 with a final sample size of 108,508 corresponding to 80% statistical power.

Optional biospecimen collection was incorporated into the study. The CSTWG recommended increasing the rate of biospecimen collection at the time of initial enrollment. However, rapid accrual limited baseline collection, and specimens are now being collected during follow-up visits.

The CSTWG also addressed NCI-supported cancer screening trials more broadly, recommending NCI develop a framework for the design and conduct of cancer screening trials that incorporated slow accrual guidelines and early termination criteria.

To implement these recommendations, NCI's Division of Cancer Prevention (DCP) formed a trans-DCP Clinical Trials Working Group to assess ongoing and planned DCP screening protocols against the CSTWG recommendations, identify challenges, and recommend ways to improve trial success. The group included program leadership from multiple screening trial networks as well as DCP statistical experts. The group recommended that DCP screening trials incorporate defined accrual milestones, monitoring plans, and criteria for addressing slow accrual. Additional recommendations included analyzing accrual data to establish standardized stopping rules for future trials and developing guidelines that clearly define roles and responsibilities for monitoring study performance and implementing corrective actions. The trans-DCP working group and an Executive Leadership Committee are tasked with reviewing corrective action plans, evaluating progress, and providing recommendations on trial remediation or closure.

As a result of the trans-DCP working group recommendations, new DCP screening trial requirements were implemented. These requirements include clearly justified sample sizes, explicit accrual targets and timelines, well-defined eligibility criteria, and predefined accrual milestones with periodic performance assessment and stopping rules if targets are not met. Additional requirements include participant advisory boards for trials enrolling more than 10,000 participants and inclusion of non-English-speaking populations. These guidelines have already informed decisions on DCP-supported screening trials. Dr. Heckman-Stoddard highlighted one case where insufficient accrual led to conversion from a randomized study design to a biomarker study. In another case, adjustments to sample size enabled successful accrual completion.

The Five- or Ten-Year Colonoscopy for 1-2 Non-Advanced Adenomatous Polyps (FORTE) trial provides another example of applying these principles. This NRG-led study was activated in 2021 with participation from all NCI National Clinical Trials Network (NCTN) groups. It has an accrual goal of 9,500 participants and has met its first accrual milestone, reaching 10% accrual within 25% of the enrollment period. However, because the NCI Community Oncology Research Program (NCORP) reimburses sites on a per-participant basis, increasing accrual rates would substantially increase trial costs in later stages of enrollment. As a result, revised accrual targets were established to balance scientific goals with resource constraints. To date, FORTE has enrolled more than 4,000 participants, and current accrual is exceeding the revised target of 130 patients per month. Dr. Heckman-Stoddard noted that Dr. Schoen would expand further on the changes made to FORTE to improve access and accrual to the study in the next presentation.

Five- or Ten-Year Colonoscopy for 1-2 Non-Advanced Adenomatous Polyps (FORTE)

Robert E. Schoen, M.D., M.P.H.

Dr. Schoen provided an overview of the NCI DCP-supported FORTE trial, describing the clinical context for the study, novel approaches used to ensure successful implementation, and the study's progress to date.

Approximately 15–16 million colonoscopies are performed annually in the United States, and about 25% of these are conducted for surveillance. More than 85% of adenomas detected during colonoscopy are non-advanced. Increased screening and emphasis on adenoma detection have led to a growing population of patients entering surveillance programs. FORTE is designed to evaluate surveillance colonoscopy intervals following identification of non-advanced adenomatous polyps, specifically assessing if follow-up colonoscopy at five years is necessary and beneficial. It enrolls individuals with one or two non-advanced adenomatous polyps and randomizes them to either a 5-year or 10-year surveillance colonoscopy interval, with colorectal cancer incidence as the primary endpoint.

The study uses several novel strategic approaches to enhance accessibility and accrual. The inclusion of a retrospective cohort allowed sites to identify and enroll patients who had been diagnosed with non-advanced adenomas within the past four years, allowing for rapid study initiation. Remote consent via approved electronic platforms allows enrollment of participants without an in-person visit, reducing barriers such as travel, geographic location, and socioeconomic factors. In addition, the trial incorporates mobile and remote phlebotomy for biospecimen collection. Through a centralized contract with a national provider, participants can have blood samples collected remotely and shipped directly to the study biobank, further enabling enrollment and specimen collection without in-person visits.

Another approach allows institutions to provide modest financial incentives for enrollment and specimen collection, which are approved by the Central Institutional Review Board (cIRB), to offset time and inconvenience associated with study participation. Funds for incentives come out of site reimbursement for the study. Dr. Schoen stressed that providing incentives has resulted in recruitment of individuals who would not otherwise participate in the trial.

In 2025, the FORTE trial lowered its eligibility age from 50-45 to align with updated U.S. Preventive Services Task Force recommendations, which lowered the age for colorectal cancer screening to 45. This reduction will maximize generalizability of study findings.

Study accrual reached 4,000 in January 2026, with an average enrollment rate of approximately 136 participants per month across more than 30 sites. Participation from 15 U.S. Department of Veterans Affairs (VA) sites has contributed more than 300 enrollments. Dr. Schoen highlighted that enrollment of Black and Hispanic participants currently exceeds expected targets, with approximately 9% identifying as Black or African American and 16% identifying as Hispanic or Latino. He emphasized that achieving representative enrollment is critical for ensuring the applicability of study findings.

Participant compliance is another important component of study conduct and success. Current completion rates are at 82.4% for patient-reported outcome questionnaires, 76.6% for blood samples, and 65.6% for stool samples. The rates are higher if excluding recently randomized participants who are still within the completion window for these tasks. Ensuring completion of the five-year follow-up colonoscopy is a key challenge. Among participants who are six or more years from their qualifying

colonoscopy, compliance is 79%, with some having had their follow-up procedure slightly before or after the five-year mark.

Dr. Schoen concluded by stating the FORTE trial is progressing successfully and has benefited from a combination of design adaptations, operational innovations, and targeted recruitment strategies.

CTAC members were asked to provide feedback on the following questions:

- Are there additions or modifications to the accrual monitoring process that DCP should consider?
- How can NCI continue to enhance the connection to primary care providers to improve screening trial accrual?

Questions and Discussion

Dr. Wilding asked about the potential role of emerging blood-based screening tests and whether such technologies could affect the long-term relevance of the trial. Dr. Schoen responded that current blood-based tests have limited ability to detect precursors such as adenomas. He noted that serial blood collection is not part of the study and would require increased funding.

Ms. Spears applauded the use of participant incentives and asked if enrollment at sites that do not offer incentives has been compared to sites that do. Dr. Schoen noted that the complexity of NCORP funding may make it more difficult for NCORP sites to provide incentives. Dr. Heckman-Stoddard added that participation in screening trials is often altruistic, but patients may receive reimbursement for their time.

Dr. Ramalingam asked about patient perspectives on longer surveillance intervals and whether assignment to less frequent screening could be a barrier to participation. Dr. Schoen responded that individual preferences vary and some choose not to participate due to the long surveillance interval. There are, however, enough individuals willing to enroll. Dr. Heckman-Stoddard noted that de-escalation trials aimed at improving quality of life and outcomes are unique to NCI's portfolio.

Dr. Muller commended the changes made to the study which allowed new sites to participate, including her own, and commented that the strategies used in FORTE to decentralize could inform others in their trial design.

Dr. Kelley noted that the VA is happy to collaborate with NCI on studies that are particularly important for their population, which often include adult men. He asked about the rate of compliance for participants randomized to the 10-year study arm and if intention-to-treat analysis would be conducted. Dr. Schoen responded that the focus thus far has been on ensuring follow-up with the 5-year participants. They do plan to look at the 10-year data in the future.

Dr. Kobayashi noted the strong representation of Black and Hispanic participants, as well as participation from American Indian/Alaska Native and Native Hawaiian/Pacific Islander populations. He asked about how the use of teleconsent impacts participation from individuals who are unable to communicate effectively using that method (e.g., those who speak other languages or who are hearing impaired). Dr. Schoen responded

that teleconsent does not work for everyone and that in-person consent remains available. The ability to use teleconsent to obviate the need for travel has, however, been a huge benefit for participants.

Dr. Kobayashi also asked whether the use of incentives improves data entry timeliness and accuracy. Dr. Schoen indicated that incentives are tied to completion of required study elements, including patient-reported outcomes and biospecimen collection. Dr. Heckman-Stoddard added that data timeliness across sites is routinely monitored and remains strong.

Dr. Vose asked about challenges in recruiting participants from community and rural settings. Dr. Schoen explained that because cancer centers do not generally conduct screening colonoscopies, establishing partnerships with the gastroenterologists and endoscopy practices performing these procedures is necessary to support enrollment. He noted that this remains an ongoing challenge. Dr. Heckman-Stoddard commented that rural accrual data are tracked for all NCORP studies, which is one of the benefits of opening a screening study under NCORP.

IV. Optimizing Electronic Health Records to Support Clinical Trials

Introduction

James H. Doroshow, M.D.

Dr. Doroshow introduced the session on optimizing electronic health records (EHRs) to support clinical trials by framing it within NCI's broader strategic vision for clinical trials for 2030 and beyond. This vision aims to develop flexible, faster, simpler, less expensive, and high-impact trials that seamlessly integrate with clinical practice by streamlining processes for trial design and execution, decreasing regulatory hurdles, focusing on essential endpoints, and increasing the efficiency of data collection.

The 2020 CTAC Strategic Planning Working Group (SPWG) made two recommendations to NCI on EHR optimization. The first was to accelerate EHR clinical trial builds through integration and standardization—specifically, engaging EHR and clinical trial management system vendors to create mechanisms for automatically integrating study-specific documents into local implementations of their products. Currently, each clinical trial requires manual configuration within local EHR systems at participating NCI sites. With approximately 2,000 sites, the cumulative financial and operational burden required for these study builds is substantial.

NCI has supported efforts to address this challenge. The Clinical Trials Support Unit Site Study Setup Initiative extracts key protocol information needed for EHR trial builds into structured Excel templates for NCI Cancer Therapy Evaluation Program-sponsored NCTN and Experimental Therapeutics Clinical Trials Network (ETCTN) protocols to reduce duplicative effort at clinical trial sites. Additionally, the Electronic Health Record Pilot Consortium (EPC) is exploring approaches to accelerate and standardize the EHR study build process. Dr. James Yao will provide an update on this initiative.

The second recommendation focused on EHR clinical trial data extraction—specifically, resolving the logistical and data quality challenges of extracting clinical trial

data from EHRs. CTAC encouraged NCI to support testing and implementation of tools targeting automated or semi-automated methods for extracting data directly from EHRs to clinical trial data systems within the NCI clinical trials networks. NCI released a Request for Information through the Childhood Cancer Data Initiative (CCDI) to assess available tools and workflows for structured prospective data capture in EHRs, capabilities for automated data ingestion, extraction, and harmonization at the point of care, and the utility of existing adult oncology tools for support of pediatric and rare cancer research. Thirty-four responses were received from clinical, technical, industry, and regulatory stakeholders, reflecting strong cross-sector interest in this area. Based on these responses, CCDI is identifying and assessing tools for further evaluation. Dr. Tamara Miller will present on one of these tools—ExtractEHR—and describe potential use cases.

Accelerating Electronic Clinical Trial Activation Pilot
James C. Yao, M.D.

Dr. Yao provided an update on the EPC, which aims to streamline and centralize the building of clinical trial treatment plans in EHR systems. Initial work began in 2020 through two consortia—the Clinical Trials Rapid Activation Consortium and The Big Ten Electronic Health Record Consortium. In 2023, the EPC was established as an expanded consortium, comprising seven core sites—MD Anderson Cancer Center (coordinating institute), Dana-Farber Cancer Institute, City of Hope, University of Michigan, University of Wisconsin, Indiana University, and University of Colorado. Memorial Sloan Kettering Cancer Center recently joined as a partner site to test how the technology can be incorporated into a site's workflow without having participated in the full multi-year development process.

Building clinical trial treatment plans in an EHR is a labor-intensive process. Unlike standard of care treatment plans, which can be reused across many patients, clinical trial builds typically serve only a few patients and must be configured separately for each site and EHR instance. The complexity has increased in the era of precision medicine. For example, a trial such as NCI's Molecular Analysis for Therapy Choice (NCI-MATCH) may include dozens of arms, potentially requiring tens of thousands of builds across participating sites if all arms are opened. Compounding this burden, 20-30% of clinical trials and 40-50% of treatment plans built in EHRs are rarely or never used due to early trial closure or limited accrual to specific arms.

The current build process begins with unstructured source documents such as study protocols, study calendars, investigational brochures, and pharmacy and lab manuals, from which staff must extract content, resolve information gaps, and reformat information to align with EHR conventions before the technical build and validation can proceed. Differences across sites—including formularies, procedures, data elements, and medication configurations—drive repetitive builds. The EPC aims to build a trial once and disseminate it broadly.

To address these challenges, the EPC has developed a structured content database and application to standardize the extraction of protocol content into a format that can support centralized EHR builds. Treatment plans are organized as tasks and timepoints. General tasks—such as antiemetic regimens—may vary across sites and

are managed in a task library to allow local customization, while protocol-specific tasks that do not vary across sites are standardized centrally. This enables a centralized build to be created and then exported as a package that sites can implement directly or adapt to local preferences.

To facilitate adoption, the consortium has worked with EHR vendors, particularly Epic, to enhance tools for detailed import and export of protocol content and to automate the application of site-specific preferences. A similar approach is being developed for Oracle Health. The consortium is also exploring structured protocol authoring and artificial intelligence (AI)-assisted content extraction to further streamline the process. Together, these efforts are designed to reduce the amount of manual work required at individual sites.

Dr. Yao noted several benefits of the EPC approach, including improved quality and reproducibility of EHR builds, greater standardization of clinical data elements, and progress toward structured protocol authoring. The modular design allows sites flexibility in adopting components of the build package while enabling centralization at NCI or the cooperative group level. To date, the EPC has completed production builds for six NCI-supported protocols, including early-phase trials from the ETCTN, randomized phase III trials from the NCTN, and both traditional and precision medicine trials. Results have demonstrated feasibility in real-world clinical settings, but further testing is needed to determine how best to scale implementation across the NCI networks.

CTAC members were asked to provide feedback on the following questions:

1) What are the most important priorities to advance this work in times of fiscal constraints?
    - What are the best ways to scale this nationally?
2) What other features would be helpful for streamlining study builds?
    - Engage EHR/clinical trial management systems (CTMS) vendors for tools to import structured study data into EHR systems?
    - Explore AI/large language model (LLM)-enabled assistance to reduce manual effort—starting with low-risk steps—while maintaining safety and quality?

Questions and Discussion

Dr. Mesa commended this work and noted that many institutional differences in EHR builds are clinically inconsequential, representing a significant opportunity for standardization at the national level. He emphasized the importance of engaging professional societies and addressing the role of EHR systems as a source of complexity.

Dr. Letai suggested engaging cancer centers more directly in standardization efforts and expressed willingness to communicate NCI's preference for harmonization directly to cancer center directors and institutional leadership. Dr. Mesa agreed, noting parallels with the adoption of the cIRB and highlighting NCI’s influence on driving standardization. Dr. Yao noted the EPC has taken a measured approach given the

limited number of protocols implemented but emphasized that standardizing protocol content—particularly medication and treatment plan data—would be beneficial. Dr. Azad noted that directives from NCI, particularly those embedded in grant requirements and requests for applications, have historically been effective in driving institutional change and encouraged NCI to consider a more prescriptive approach.

Dr. Kibbe commented that technologies for automating study builds have matured where implementation is feasible, and now it is important to reduce barriers, highlighting the importance of protocol standardization. Ms. Spears similarly noted that simplifying protocols and limiting data collection would support broader adoption and encouraged aiming for national implementation beyond cancer centers.

Dr. Wilding asked whether industry sponsors have expressed interest in supporting the EPC approach. Dr. Yao noted that the consortium has received inquiries from industry representatives at national meetings and that broader implementation of NCI protocols through the consortium would help establish the critical mass needed to attract industry participation. Dr. Wilding also asked about integration of CTMS within EHR platforms. Dr. Yao noted that Epic has announced a CTMS product but that it may require further development before having the functionality needed for the EPC initiative. Oracle Health is redesigning its EHR, so it is unclear whether the company will pursue this approach.

Dr. Kobayashi emphasized the importance of documenting the financial and data quality improvements to support broader adoption and highlighted the need to better align protocol design with downstream data capture requirements.

Dr. Ramalingam asked what protocol simplification steps, informed by the EPC's work, could be incorporated into NCI trial templates. Dr. Yao noted that following a standard day-cycle structure within protocols would significantly simplify builds, and that selecting from predefined tasks and standardized elements during the protocol authoring process would reduce downstream complexity. Dr. Radim Moravec, Biomedical Informatics Projects Officer, Clinical Trials Operations and Informatics Branch, NCI, added that the consortium plans to publish a series of white papers to share lessons learned with the broader community and called for advocates to help promote adoption of the EPC package at their institutions and within the scientific community.

Dr. Kelley noted the potential to leverage existing standardization efforts, including National Comprehensive Cancer Network chemotherapy templates and the federal health EHR consortium used by the VA, Department of Defense, and other federal agencies on the Oracle Health platform, as models for broader harmonization.

Automated Electronic Health Record Data Extraction and Curation Using ExtractEHR

Tamara P. Miller, M.D., M.S.C.E.

Dr. Miller presented an overview of the ExtractEHR+ toolkit, an open-source software package developed to automate the extraction and curation of clinical data from EHR systems for research purposes.

Clinical research has historically relied on manual abstraction of EHR data, a process that is time-consuming, costly, difficult to standardize across institutions, and prone to human error. To quantify these limitations, the accuracy of manual adverse event (AE) ascertainment was evaluated using data from a phase III NCI cooperative group study for pediatric de novo acute myeloid leukemia (AML) across 14 hospitals. Among 12 targeted AEs, 66% were missed, and 25% were incorrectly reported. In a second study focused on laboratory AEs, 85% of AEs were missed, and 50% were incorrectly reported. These discrepancies were attributed to manual transcription errors such as selecting incorrect AE names from dropdown menus and false positive reporting due to lack of clinical knowledge. These findings highlight the need for more reliable and scalable approaches to EHR data collection.

To help address these limitations, Dr. Miller described the ExtractEHR+ toolkit, which consists of three components: ExtractEHR, which extracts data from EHR data warehouses using Structured Query Language queries; CleanEHR, which cleans and processes extracted data by removing false or duplicate results and standardizing outputs across sites; and GradeEHR, which grades laboratory AEs according to Common Terminology Criteria for Adverse Events definitions. The toolkit is freely available through GitHub and can be implemented locally at each site, ensuring that protected health information remains within institutional systems. Extracted data elements are customizable and can include demographics, encounters, vital signs, laboratory results, medications, clinical notes, imaging results, pathology, and genomic data. Data can be used in raw form or further processed using CleanEHR and GradeEHR.

Use of ExtractEHR requires site-level technical expertise, including data analysts with access to EHR systems, as well as clinical or subject matter expertise to guide data use. ExtractEHR has already been implemented or is in the process of being implemented at multiple pediatric institutions across the United States, spanning several EHR vendors, including Epic, Cerner, and Allscripts. While initial implementation requires upfront effort, the system is reusable and can support multiple research applications once established.

Dr. Miller presented several use cases demonstrating application of ExtractEHR. The Leukemia Electronic Abstraction of Records Network (LEARN), a multicenter cohort of pediatric AML and acute lymphoblastic leukemia patients, was established using ExtractEHR where de-identified EHR data are shared and processed centrally and have been used to answer clinical epidemiology questions, including analyses of laboratory AEs. Processed EHR data from LEARN were shown to be more comprehensive than manually abstracted data from Children's Oncology Group trials. The toolkit has also been used to characterize complex phenotypes using natural language processing and machine learning. For example, in a study examining the AE typhlitis using EHR-derived data, the number of chemotherapy courses requiring manual review was reduced by 96%, from 961 to 37. Additionally, a pilot within the CCDI used ExtractEHR to extract and process chemotherapy exposure data, including height, weight, medication administration, and medication order data for over 1,200 patients. This approach enabled identification of unique exposures and cumulative dosing and produced more accurate and comprehensive data than manual abstraction. Finally, in a clinical trial pilot

(PEPN21EHR/PBTCN-15), ExtractEHR enabled automated extraction and direct upload of laboratory data into Medidata Rave across seven sites, demonstrating feasibility in cooperative group trials.

Building on these examples, Dr. Miller summarized the key benefits of the automated approach to EHR data extraction. These include improved standardization across institutions, reduced reliance on manual abstraction, enhanced data quality and harmonization, and the ability to scale data collection efficiently across large populations. Although implementation requires initial effort, the approach is reusable, adaptable across use cases, and more cost-effective over time.

CTAC members were asked to provide feedback on the following questions:

- Given the key challenges and lessons learned from implementing ExtractEHR across institutions, what would be required to scale this capability more broadly across the cancer research community?
- How can the cancer research community ensure EHR data extraction tools leverage or align with existing data standards and common data models so that extracted EHR data can be integrated with broader research data ecosystems?

Questions and Discussion

Dr. Mesa asked about the potential to scale ExtractEHR to capture data that historically has not been feasible to capture, such as imaging and digital pathology data. Dr. Miller noted that automated extraction could facilitate capture of additional data types, including concurrent medications. Dr. Kibbe added that the CCDI is working to integrate whole slide imaging and radiology imaging data alongside molecular and clinical data for pediatric patients, emphasizing the value of comprehensive datasets.

Dr. Bhatia asked about the timeline for broader availability and whether the toolkit would be made widely accessible. Dr. Miller noted that the toolkit is freely available via GitHub and that her team is actively seeking partnerships, including expansion into adult oncology settings. She estimated implementation requiring approximately 40 hours at sites using Epic, with additional time needed for other systems.

Dr. Muller commented on the challenges of capturing AE data from community hospitals that are not on the same EHR system as the enrolling institution, noting that PDF-based data transfers remain common in this context. Dr. Miller acknowledged this as a greater challenge in adult oncology settings than in pediatric settings, where patients are more commonly treated within a single hospital system. She noted that ongoing work to develop CleanEHR packages compatible with Fast Healthcare Interoperability Resources-based data extraction may offer a more broadly applicable solution for community practices.

Dr. Azad asked how ExtractEHR compares to commercial EHR extraction tools. Dr. Miller noted that while many tools focus on data extraction, ExtractEHR includes post-extraction processing, which transforms raw data into research-ready datasets. Dr. Kibbe added that the toolkit is freely available and encouraged institutions to explore its use.

Dr. Kobayashi noted that ExtractEHR, taken together with the EPC's work on EHR study builds, presents an opportunity to reconceptualize clinical trial conduct in the digital era by integrating plans for data extraction into study databases and protocols. He suggested that NCI is well positioned to advance this effort in a way that industry sponsors are not. Dr. Miller added that increased standardization of data entered into EHRs would further facilitate post-extraction processing.

Dr. Letai reminded the group that increased data availability should not lead to unnecessary data collection and should be balanced with maintaining focus on primary study objectives, noting that some earlier trials conducted with paper-based methods were able to initiate, enroll, and answer their primary objectives more quickly than many trials today.

V. NCI Cancer Information Service

Robin C. Vanderpool, Dr.P.H.

Dr. Vanderpool provided an overview of the NCI Cancer Information Service (CIS), a long-standing program established in 1975 to provide accurate, timely, and evidence-based cancer information to patients, caregivers, the public, and health professionals. She also described her own connection to CIS, beginning as an NCI fellow in the Office of Cancer Communication, then through her work in the Mid-South CIS Regional Office at the University of Kentucky Markey Cancer Center, and later returning to NCI in her current role as Chief of the Health Communication and Informatics Research Branch.

CIS was created in response to a congressional mandate under the National Cancer Act to disseminate cancer-related information to the public, which in turn has positive impacts on cancer-related outcomes by increasing knowledge, supporting informed decision making and disease self-management, enhancing patient–provider communication, promoting behavior change, facilitating engagement in clinical trials, and reducing cancer disparities.

Over the past five decades, the program has evolved from a network of regional phone lines into a centralized, multi-channel communication platform offering support via telephone, LiveHelp online chat, email, and social media in both English and Spanish. CIS is staffed by trained information specialists who undergo a rigorous certification program in patient-centered communication. The program maintains standardized protocols and quality assurance processes, routinely achieving user satisfaction scores above 90% across all access channels. Systematic collection of de-identified data from inquiries is used to guide program planning, evaluation, and training to ensure responsiveness to emerging public information needs.

More than 400,000 inquiries have been recorded since September 2018, and the volume continues to increase. Most inquiries are in English, with approximately 10% in Spanish. Nearly half occur through the LiveHelp online chat platform, which has surpassed telephone use. However, nearly 40% of interactions are still conducted by telephone, reflecting continued demand for direct, person-to-person communication. Based on limited available sociodemographic data, 53% of CIS users are female, 71% identify as White, and 39% are age 65 or older. Approximately 42% are college

graduates and 40% report annual incomes above $60,000. The vast majority have health insurance and reside in urban areas. Geospatial analysis of collected zip codes similarly shows that most inquiries originate from urban areas, often aligning with cancer centers, highlighting an opportunity to improve CIS utilization in rural communities.

Most CIS inquiries come from individuals who smoke cigarettes, caregivers, cancer survivors, and the general public, and approximately two-thirds of CIS inquiries are related to cancer treatment. The most common topics include tobacco cessation, general cancer questions, clinical trials, and cancer care management. Breast, lung, prostate, and colorectal cancers are the most frequently discussed, reflecting the cancers most commonly diagnosed in the United States.

Dr. Vanderpool highlighted three key areas of the CIS service that extend beyond the provision of general cancer information: tobacco cessation, clinical trial support, and health communication research. CIS information specialists trained in motivational interviewing help individuals develop plans for quitting tobacco and managing cravings and triggers. The program provides counseling and support through the 1-877-44U-QUIT line and partners with the VA to serve veterans through the 1-855-QUIT-VET line. Additionally, CIS connects clients to NCI resources through Smokefree.gov, including text messaging programs, smartphone applications, and web-based tools to support tobacco cessation.

To improve access to clinical trial information, CIS specialists assist clients with customized searches of ClinicalTrials.gov and provide follow-up support to address barriers to participation. CIS has historically contributed to recruitment to NCI-supported trials and is currently working with the NCI Center for Cancer Research to assist research nurse teams with collecting patient information related to potential eligibility and referral to open trials at the NCI Clinical Center. CIS can also support individuals who are not eligible for local trials by conducting nationwide searches and providing broader clinical trial education. During the government shutdown at the end of 2025, CIS remained operational and served as a critical communication channel for patients and providers.

The CIS inquiry database enables real-time analysis of public information-seeking behaviors and has been used to study patterns across topics including novel cancer therapies, COVID-19 and cancer, childhood cancer, prognosis, medical and nonmedical cannabis use, end of life, and complementary and alternative medicine. Findings from analyses of CIS inquiry data highlight opportunities to advance cancer communication research. A published analysis of clinical trial information seeking identified disparities across language, race and ethnicity, sex, age, socioeconomic status, insurance coverage, and urbanicity, consistent with known disparities in clinical trial enrollment. These findings underscore the need to develop and disseminate educational resources that address varying health literacy levels and are tailored to reach populations underrepresented in clinical trials.

Dr. Vanderpool concluded by emphasizing the CIS's role in providing human-centered communication in an environment where individuals increasingly encounter both helpful and harmful health information online. CIS will continue to serve the public

by supporting the public health priorities of NCI and other federal partners to enhance the well-being of Americans.

CTAC members were asked to provide feedback on how to better promote CIS and its clinical trials services among patient, caregiver, and provider constituencies.

Questions and Discussion

Ms. Spears asked whether CIS tracks instances in which individuals contact the service with misinformation and whether such trends are increasing. Dr. Vanderpool responded that while misinformation is not formally coded in the data system, CIS staff routinely encounter misconceptions during interactions, which provide opportunities for real-time education and clarification. As an example, she noted that some individuals perceive immunotherapies as “natural” treatments that may allow them to avoid chemotherapy or radiation, creating an opportunity to explain how these therapies work.

Dr. Santana asked whether a mechanism exists for gathering user feedback to inform future program priorities and whether contacts can remain anonymous. Dr. Vanderpool explained that contacts can be fully anonymous unless users request follow-up. She noted that user satisfaction data are routinely collected and that qualitative feedback from information specialists, along with trends in inquiry topics, help identify emerging issues, such as increasing public interest in multicancer early detection tests. She added that proactive approaches to soliciting user feedback could be considered in the future.

VI. Facilitating Clinical Trials Enrollment

NCI’s Virtual Clinical Trials Office: Update

James H. Doroshow, M.D.

Dr. Doroshow presented an overview of the NCI Virtual Clinical Trials Office (VCTO), a pilot program launched in Fall 2023 to provide centralized, remote support for clinical trial operations and to address workforce challenges affecting accrual at NCI-designated cancer centers following the COVID-19 pandemic. In 2020, accrual dropped for all categories of trials at NCI-designated cancer centers, but rebounded for national, externally peer reviewed, and industrial trials in the years following the pandemic. However, accrual to investigator-initiated trials did not return to pre-pandemic levels and remained approximately 20% below 2019 levels. A survey of all 64 cancer centers showed staffing shortages to be a major contributing factor to this decrease.

The VCTO pilot was established to respond to these staffing challenges by providing remote staff support to participating research sites, including research nurses, clinical research associates, and regulatory affairs personnel organized through the NCI-Frederick National Laboratory Clinical Research Directorate. The VCTO includes eighteen staff members organized into two teams, allowing flexible, site-specific support based on individual institutional needs. Services include patient eligibility screening, informed consent and enrollment, data entry and abstraction from EHRs into the clinical trial reporting system, coordination of study visits and procedures, regulatory support, and AE reporting. Initial participating research sites were selected based on their need for operational support and potential to accrue from underserved and rural populations.

Nine primary sites were initially selected. These sites included NCI-designated cancer centers, many of which also participate in the NCORP. To date, an additional 26 affiliated sites have come on board, for a total of 35 sites.

The VCTO currently supports 24 NCI-sponsored trials which were requested by the participating research sites. The protocols range in complexity and include cooperative group studies, precision medicine studies, and several NCORP symptom management studies. As of February 2026, the program has supported 92,404 protocol screenings resulting in 265 patient accruals, with 69 of those from underserved populations. Additionally, VCTO staff have entered 3,822 case report forms (CRFs), resolved 1,122 data queries, and reviewed 2,865 CRFs for quality control. These efforts have enabled several participating sites to improve compliance with data reporting requirements and maintain their standing with the cooperative groups.

Dr. Doroshow noted several key lessons from implementation of the VCTO pilot, first acknowledging that successful implementation requires early and sustained engagement of institutional stakeholders, including executive leadership, clinical trial offices, principal investigators (PIs), and information technology and legal teams. Active involvement of clinical trials teams is also necessary to ensure integration of remote support into local institutional workflows. Establishing remote access to EHR systems involves legal, contractual, and technical processes that vary across institutions and could take six to twelve months to complete. Smaller or community-based sites may face additional challenges stemming from reliance on third-party EHR vendors and intermediary systems.

Prior to implementation, site readiness for remote support should be assessed. Participating sites vary widely in infrastructure and workflow, and some sites still rely on paper-based processes and lack standardized electronic systems. Transition to digital workflows may require additional effort such as digitizing paper AE and concomitant medication logs and establishing secure file-sharing systems. Building trust between centralized VCTO teams and site personnel is essential as effective collaboration depends on strong working relationships and adapting support to site-specific needs.

Overall, the VCTO has proven to be a valuable resource to mitigate workforce challenges. By providing experienced remote staff that can be rapidly deployed, the model helps preserve trial continuity and data integrity when research sites face staffing challenges. Dr. Doroshow would like to see the program expanded to more community sites where this type of support could have a large impact on patient enrollment. Additionally, future plans include adding lead sites that use the Cerner EHR to determine if the VCTO can be applied beyond Epic, broadening access to additional types of trials, and providing support for long-term follow-up activities.

CTAC members were asked to consider what other services or activities the VCTO should consider in the future.

Questions and Discussion

Dr. Mesa noted he received positive feedback on the VCTO from his colleagues in San Antonio who reported the program addressed a significant staffing gap during the

pandemic. He asked about the use of remote consent and whether additional remote capabilities, such as AE assessments, may be incorporated into future iterations of the program. Dr. Doroshow responded that remote consent is already an integral part of the program and emphasized that building trust between VCTO staff and staff at participating sites is the priority.

Decentralized Clinical Trials: The Veterans Health Administration Experience

Daphne R. Friedman, M.D.

Dr. Friedman highlighted the issue of low clinical trial participation, noting that at Commission on Cancer accredited facilities, only 7% of patients with cancer participate in therapeutic clinical trials. Approximately 21% of these enrollments were at NCI-designated Cancer Centers and 4% at community practices, although most adults with cancer (approximately 80%) are treated in community settings. Clinical trials are concentrated in urban areas, and in 2022, 70% of counties lacked access to cancer clinical trials. Despite this, most eligible patients are willing to participate, emphasizing the need to bring clinical trials closer to patients.

Approximately 50,000 cases of invasive cancer are diagnosed annually within the VA, with care delivered across 139 VA facilities and community providers. To address variability in access to oncology expertise, the VA established the National Tele-Oncology (NTO) service in 2019. Based at the Durham VA, this hub-and-spoke model is connected to 124 VA facilities and provides remote access to subspecialized oncology care and clinical research services. Since its inception, the NTO has served approximately 31,000 veterans across roughly 130,000 encounters. Telehealth service agreements between the hub and the spoke sites facilitate access to these services.

NCI-VA Collaboration. The NCI and the VA collaborate through multiple mechanisms. Dr. Friedman noted that, through VA clinical trial navigation, veterans are referred to the NIH Clinical Center, with 15 veterans having been enrolled on studies between June 2024 and November 2025. Additional collaborations include an agreement between the VA and the NCI cIRB for NCTN and NCORP studies and a new agreement with the NIH cIRB for intramural studies, laying the groundwork for future trials to be implemented at both the NIH Clinical Center and the VA. Other collaborative activities include NCI investigator presentations at VA oncology office hours, second-opinion consultations, and participation in virtual tumor boards.

A key collaboration is the NCI and VA Inter-Agency Group to Accelerate Trial Enrollment (NAVIGATE) program. Initially funded by NCI to support 12 VA sites, the program has expanded to include four additional sites with VA investment. In 2024, three-quarters of VA enrollments in NCI-sponsored studies came from NAVIGATE-funded sites, with approximately 25% of participants from racially diverse groups. The VA and NCI work with NAVIGATE investigators to address enterprise-wide challenges and centralize processes where possible.

Decentralized Clinical Trials in the VA. There are multiple approaches to conducting clinical trials. Traditional trials are centered at a research site, whereas non-traditional approaches may incorporate remote staffing models or decentralized clinical

trials (DCTs). Examples of remote staffing models include NCI's VCTO and the Virtual Research Nurse program at the Louisiana State University and Louisiana Children's Medical Center Health Cancer Center (LSU LCMC). The VA has also received a five-year award from Blood Cancer United to evaluate remote research staff and educational interventions to support veteran enrollment in NCI-sponsored therapeutic trials for hematologic malignancies.

DCTs may be fully remote or hybrid with some activities conducted virtually and others at the research site. Observational studies are the simplest to decentralize, while therapeutic studies are more complex. In the VA, fully remote DCTs do not require participants to be located at the research site; instead, the NTO service coordinates with local sites to support recruitment, consent, enrollment, and delivery of clinical care.

Operationally, the VA supports DCTs through the use of multiple IRBs of record, standardized operating procedures, and site-level clinical champions. Oral investigational agents may be shipped directly to participants from a centralized pharmacy with temperature monitoring. Additionally, participants complete drug diaries remotely, data management is conducted electronically, and biospecimen kits are shipped between sites and the sponsor.

Between June 2020 and March 2025, the VA conducted 10 DCTs, enrolling 134 veterans from 31 states. Most were enrolled into non-therapeutic intervention or observational studies, with four enrolled into therapeutic intervention studies. Since March 2025, an additional eight veterans have been enrolled in therapeutic studies. DCT participants had a mean age of 71 which is older than those typically expected to participate in clinical trials. There was good representation from racially diverse groups and approximately one-third of participants were from rural areas. Only one of the 134 enrolled veterans withdrew consent.

There are numerous NCI studies that incorporate decentralized elements. For example, in SWOG S2312, a phase III prostate cancer study, most study activities can be done remotely except for imaging. While not fully decentralized, this design allows for accrual from a broader regional area as participants can receive most care locally and only need to travel for the imaging component. Dr. Friedman described two VA DCTs: an NCORP study evaluating text-based smoking cessation interventions among rural cancer survivors and an industry-sponsored therapeutic study of adagrasib in non-small cell lung cancer, in which physical examinations were observed remotely by the PI via video to support fully decentralized conduct. The two veterans enrolled in this industry study were the only participants from the United States.

Key barriers to conducting DCTs include industry hesitancy in incorporating decentralized elements in registrational trials, concerns about direct-to-patient drug shipment, variation in electronic medical record systems, and the difficulty of retrofitting traditionally designed protocols for DCT conduct. Potential solutions include FDA guidance encouraging sponsors to consider DCT elements, temperature monitoring for drug shipments, and conducting DCTs within integrated health systems that share an electronic medical record, such as the VA. Dr. Friedman emphasized that determining which trial elements to decentralize should occur during study design and encouraged

investigators to consider whether activities that are typically done in a traditional manner could instead be decentralized.

CTAC members were asked to provide feedback on the following questions:

- How can NCTN and NCORP trials incorporate more DCT conduct and flexibility in study design and documents?
- How can health care systems encourage implementation of non-traditional clinical trial conduct, including DCTs and remote staffing models?
- How can VA and NCI collaborate and innovate on cancer research and clinical trials beyond current state?

Questions and Discussion

Dr. Muller raised the question of whether PI oversight in DCT settings could be conducted fully remotely. Dr. Friedman explained that PI oversight in the VA is maintained through regular review of participant medical records and communication with onsite clinical staff. Dr. Heckman-Stoddard noted this is also the model used in the LSU LCMC Virtual Research Nurse program for the rural NCORP sites. Dr. Kelley commented that, in his role as a PI, he uses Microsoft Teams channels to coordinate patient care and oversight, enabling scheduling, documentation, and medication management to be done remotely. As the oncology workforce becomes more constrained, this model will likely be expanded to reach patients particularly in rural areas.

Dr. Ramalingam asked about lessons learned that could improve the viability of the DCT model for therapeutic studies. Dr. Friedman noted that while there is industry interest in decentralization, restrictive eligibility criteria remain a challenge. However, growing interest within the VA is leading investigators to design trials with decentralized components. Dr. Azad stated this model appears especially promising for low-prevalence, biomarker-driven studies requiring large screening populations. Dr. Friedman agreed, noting that identifying eligible patients across a national network can improve feasibility for such studies and reduce the burden on individual sites.

Ms. Spears encouraged the VA to share their insights on DCTs with protocol writers, particularly regarding barriers, to improve accessibility of interventional trials.

VII. Radiation Oncology-Biology Integration Network

Jeffrey C. Buchsbaum, M.D., Ph.D., A.M.

Dr. Buchsbaum provided an overview of the Radiation Oncology-Biology Integration Network (ROBIN), an NCI-supported initiative developed in response to the 2020 report from the CTAC Radiation Oncology Working Group, which identified opportunities for advancing the radiation oncology field. While radiation therapy is used in the treatment of approximately 75% of cancer patients, there has historically been limited understanding of its molecular mechanisms. While data exists before and after treatment, little is known about biological changes during radiation therapy, specifically in terms of both normal tissue response and treatment success or failure. It remains

unclear why some patients respond to treatment while others do not, and evolving changes during therapy may require a more dynamic treatment approach.

ROBIN was established to address these gaps as the only national platform conducting dose- and region-specific “before–during–after” (BDA) studies, collecting longitudinal clinical, molecular, and imaging data from patients receiving radiation therapy across multiple cancer types. ROBIN comprises of five U54 grants spanning multiple geographic regions and tumor types, including head and neck, bladder, rectal, cervix, pancreas, prostate, and pediatric cancers including neuroblastoma and diffuse midline glioma (DMG). BDA studies aim, in the short term, to identify biomarkers and inducible therapeutic targets and, over the longer term, to enable predictive models and more personalized, adaptive radiation therapy approaches.

The ROBIN network has produced more than 182 publications. On average, these papers are cited with much higher frequency than other NIH-funded papers in the same research areas, reflecting exceptional productivity and impact from ROBIN investigators.

Radiation oncology is facing a significant workforce shortage. In response to the CTAC recommendation on workforce development, ROBIN established a cross-training core to enhance knowledge in radiation biology and attract new investigators to the field. Cross-training core lectures have drawn high levels of participation from junior investigators, which was as a key goal of the initiative. Notably, 33% of participants across all five U54 sites came from outside of radiation oncology, and 96% reported improving their knowledge on radiation biology. Among non-radiation participants, 60% expressed interest in pursuing radiation biology research in their careers. In collaboration with ROBIN, the American Society for Radiation Oncology is working with NCI to evaluate hosting the cross-training core lectures at no cost and making the recorded lectures available on its platform for training purposes.

A key output of ROBIN is the generation of large, longitudinal datasets. For example, cervical cancer trials collect repeat biospecimens, imaging, and clinical data at multiple timepoints before, during, and after therapy. These data are being analyzed using genomic, imaging, and computational approaches, including machine learning and natural language processing. Eventually, data from over 200 patients will be submitted to the Cancer Research Data Commons, where they will be publicly available to support hypothesis generation and the development of future clinical trials.

There are opportunities for future collaboration with NCI partners, including the Radiation Oncology Branch, the Molecular Imaging Branch, the Division of Cancer Epidemiology and Genetics, as well as through mechanisms such as derivative grants, clinical trials, and associate memberships. The growing body of ROBIN data and the infrastructure developed through the program have established a new standard for radiation oncology science and are expected to reshape treatment approaches.

CTAC members were asked to consider ways that NCI’s Radiation Research Program can further enhance ROBIN.

Questions and Discussion

Dr. Mesa asked about hypofractionation, noting the significant shift in practice toward more condensed radiation schedules. He asked whether ROBIN is examining the biological differences associated with this approach. Dr. Buchsbaum noted different radiation fractionation approaches are being studied within ROBIN, including in prostate and rectal cancer studies. He noted that prior research, including his own early work, demonstrated substantially different genomic responses between single-fraction and multi-fraction radiation regimens, and that ROBIN investigators are now examining these differences using contemporary approaches such as single-cell sequencing and genomic analyses.

Dr. Santana asked about the potential for ROBIN to inform understanding of long-term radiation-related outcomes in pediatric cancer survivors, particularly with proton therapy, and whether the program's findings could be integrated with data from the Childhood Cancer Survivorship study. Dr. Buchsbaum acknowledged that the pediatric cancers currently included in ROBIN—neuroblastoma and DMG—are not well suited for long-term survivorship analyses given the prognosis, and that the program's findings in these tumors will be limited by the grants that were funded. Dr. Bhatia added that the absence of randomized trials comparing proton to photon therapy and the long latency of radiation-related late effects—typically ten or more years—have historically limited the ability to draw definitive conclusions in this area. Dr. Bhadrasain Vikram, Chief, Clinical Radiation Oncology Branch, and program director for ROBIN, noted that one of the ROBIN PIs is analyzing ependymoma trials from the Children's Oncology Group in which patients were treated with either proton or photon therapy, and that findings from this work may help inform the field.

VIII. Ongoing and New Business

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

Dr. Vose informed the committee that a letter addressed to CTAC had been received from Dr. Gabby Vidaurre, a research associate at the Science for Advancement and Outreach Division of People for the Ethical Treatment of Animals, urging CTAC to align its research and training priorities with NIH's commitment to prioritizing non-animal research methods. She noted that Dr. Letai had addressed NCI’s alignment with NIH’s policy on animal models earlier in the meeting, pointing out that NCI supports scientifically justified methods, prioritizing human-based approaches when possible and animal models when necessary and well justified. Members were invited to submit additional comments on the letter to Dr. Prindiville.

Dr. Azad expressed appreciation for the presentation on CIS, noting the importance of sharing information about cancer and ongoing research with the public.

Dr. Vose commented that it was gratifying to see projects discussed at prior CTAC meetings come to fruition.

Dr. Mesa reflected on the breadth of innovation presented during the meeting, highlighting the focus on improving the conduct of clinical trials as well as specialized

research programs. He suggested that a brief summary of these initiatives with links to key resources could be shared broadly across the NCI community to increase awareness of the work underway.

Dr. Prindiville noted that the next CTAC meeting, scheduled for July 15, 2026, is expected to be virtual. Topics under consideration for the agenda include the role of AI and LLMs in clinical trials and a presentation from NCI intramural investigators who have conducted pilot work addressing this topic, specifically focusing on protocol authoring. Dr. Kibbe added that a future presentation on using AI and machine learning for protocol authoring would be a timely complement to the day's discussions.

CTAC members were invited to submit suggestions for future CTAC agenda topics to Dr. Prindiville.

IX. Adjourn

Julie M. Vose, M.D.

There being no further business, the 59th meeting of CTAC was adjourned at 2:38 p.m. on Wednesday, March 18, 2026.

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

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

Appendix

March 2026

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

CHAIR

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