DEPARTMENT OF HEALTH AND HUMAN SERVICES
NATIONAL INSTITUTES OF HEALTH
NATIONAL CANCER INSTITUTE
60TH CLINICAL TRIALS AND TRANSLATIONAL RESEARCH ADVISORY COMMITTEE MEETING

Summary of Meeting
July 15, 2026

Virtual

CLINICAL TRIALS AND TRANSLATIONAL RESEARCH ADVISORY COMMITTEE
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The 60th meeting of the Clinical Trials and Translational Research Advisory Committee (CTAC) of the National Cancer Institute (NCI) was convened Wednesday, July 15, 2026, at 1:02 p.m. The CTAC chair, Dr. Julie M. Vose, presided.[1] The meeting was adjourned at 3:54 p.m.

Chair
Julie M. Vose

CTAC Members
Nilofer S. Azad
Smita Bhatia (absent)
Gary C. Doolittle
Ken Kobayashi
Seth P. Lerner
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 Veterans Affairs
R. Angelo de Claro, US Food and Drug Administration

Designated Federal Official
Sheila A. Prindiville, NCI

Presenters
Stacey Adam, Ph.D., Senior Vice President, Chief Clinical Officer, Translational Science, Foundation for the National Institutes of Health
Vinod P. Balachandran, M.D., Director, The Olayan Center for Cancer Vaccines, Hutham S. Olayan and Robert F. Raucci Chair, Memorial Sloan Kettering Cancer Center
James H. Doroshow, M.D., Director, Division of Cancer Treatment and Diagnosis, NCI
James L. Gulley, M.D., Ph.D., Acting Co-Director, Center for Cancer Research, Co-Director, Center for Immuno-Oncology, Center for Cancer Research, Clinical Director, NCI
Warren A. Kibbe, Ph.D., Deputy Director for Data Science and Strategy, NCI
Anthony Letai, M.D., Ph.D., Director, NCI
Tanna Nelson, Ph.D., R.N., NI-BC, Informatics Clinical Trials Bioinformatician, Clinical and Translational Research Informatics Branch, NCI
Sheila A. Prindiville, M.D., M.P.H., Director, Coordinating Center for Clinical Trials, Office of the Director, NCI

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

Umit Topaloglu, Ph.D., F.A.M.I.A., Chief, Clinical and Translational Research Informatics Branch, Center for Biomedical Informatics and Information Technology, 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

Jeremy L. Warner, M.D., M.S., F.A.M.I.A., F.A.S.C.O., Professor of Medicine and Biostatistics, Brown University, Director, Center for Clinical Cancer Informatics and Data Science (CCIDS), Associate Director of Data Science, Legorreta Cancer Center

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I. Call to Order and Opening Remarks

Julie M. Vose, M.D.

Dr. Vose called the 60th meeting of CTAC to order at 1:02 p.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. R. Angelo de Claro, Director, Oncology Center of Excellence, US 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/25ac171c-6a90-11f1-82c0-124f0a52e769.

II. NCI Director's Report

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

Leadership Updates. Dr. Letai highlighted several leadership transitions at NCI. Dr. Sanya Springfield retired after more than 30 years of service to NCI. Following her retirement, Dr. Nelson Aguila will serve as Acting Director of the NCI Center to Reduce Cancer Health Disparities. Dr. Dinah Singer retired after more than 50 years of service to NCI, having provided scientific leadership across numerous initiatives, including the Cancer Moonshot. He also announced the appointment of Dr. Senthil Muthuswamy as Director of the Center for Cancer Research (CCR), effective July 26, 2026, and thanked Drs. James Gulley and Carol Thiele for serving as acting CCR Co-Directors over the past two years. Finally, he welcomed Dr. Jay Schnitzer as Interim President of Leidos Biomedical Research and Director of the Frederick National Laboratory for Cancer Research.

Budget and Funding. Dr. Letai reported that NCI received a $128 million increase in fiscal year (FY) 2026, bringing its total appropriation to $7.3 billion. For FY27, the President's budget proposal includes a modest increase above the FY26 enacted level, while the US House of Representatives has proposed an additional $110 million. The US Senate's position remains pending. Dr. Letai noted that NCI received an enacted funding increase in FY26 and that additional funding has been proposed for FY27, emphasizing that reports of funding cuts do not reflect NCI's enacted appropriations. He also acknowledged that funding increases have not kept pace with inflation, reducing NCI's purchasing power.

Dr. Letai reviewed the status of FY26 grant awards, noting that although grant awards were delayed by the government shutdown and changes to the NIH review process, NCI remains on track to fully obligate its extramural budget by the end of the fiscal year. FY26 is expected to support record levels of extramural funding, including increases in both new research project grants and awards to early-stage investigators compared with FY25. He also noted that NCI expects to invest more than $400 million in its clinical trial networks during FY26. Notices of funding opportunity have been issued to ensure uninterrupted support for the National Clinical Trials Network, Experimental Therapeutics Clinical Trials Network, NCI Community Oncology Research Program, and Cancer Screening Research Network.

NCI Priorities. Dr. Letai noted that clinical trials are increasingly moving overseas, citing lower costs and faster activation timelines in other countries, particularly for multicenter trials. He stated that improving the efficiency of US clinical trials has become a priority for NCI and the US Department of Health and Human Services (HHS). As part of this effort, HHS launched Operation TrialBlazer on June 22, 2026, with the goal of accelerating clinical trials. Dr. Letai also highlighted recent FDA proposals to reduce pre-investigational new drug (IND) requirements

and simplify IND regulations for early-phase trials, noting that further FDA actions may follow. He added that NCI continues to work with cancer centers and other stakeholders, including patient advocates, biopharmaceutical companies, contract research organizations, and government partners, to improve communication and reduce activation timelines.

Dr. Letai also discussed opportunities to apply artificial intelligence (AI) across the entire clinical trial lifecycle. NCI is actively evaluating how AI can be applied to the clinical trials ecosystem. He emphasized NCI's role in coordinating efforts, reducing duplication, and maintaining interoperability as AI-enabled solutions are developed across cancer centers.

Dr. Letai provided an update on the cancer therapeutic vaccine initiative, a public–private partnership led by the Foundation for the National Institutes of Health (FNIH). He stated that an implementation plan developed by an expert advisory panel is expected soon and will outline clinical trials with defined go/no-go criteria to evaluate multiple vaccine platforms. NCI will continue to provide expertise and resources to support this initiative.

Research Advances. Dr. Letai highlighted several recent advances supported by NCI. He discussed a presentation at the American Society of Clinical Oncology by Dr. Brian Wolpin from the Dana-Farber Cancer Institute demonstrating improved survival with daraxonrasib in people with pretreated, advanced pancreatic cancer. Dr. Letai noted that NCI's RAS initiative contributed to advances in RAS-targeted therapies through both intramural research and foundational work supported by NCI extramural grants.

Dr. Letai also highlighted NCI’s Self-collection for HPV testing to Improve Cervical Cancer Prevention (SHIP) trial, which demonstrated the effectiveness of at-home HPV screening and supported FDA approval of at-home HPV testing. He also discussed recent NCI-supported findings demonstrating that a single dose of HPV vaccine is as effective as two doses. Dr. Letai noted that broader adoption of at-home HPV screening together with HPV vaccination has the potential to substantially reduce cervical cancer and highlighted the foundational research on the HPV vaccine conducted at NCI by Drs. Douglas Lowy and John Schiller.

Upcoming Initiatives. Dr. Letai encouraged CTAC members to respond to the NIH Request for Information (RFI) on measuring and rewarding scientific impact. Responses can be submitted through August 19, 2026.

Dr. Letai reflected on his recent visits to major scientific meetings, NCI-Designated Cancer Centers, the Children’s Inn Pediatric Cancer Research Panel, and other professional organizations and foundations. He highlighted enhanced NCI communications, including increased social media activity and a weekly update, "Tuesdays with Tony," featuring topics of interest to the broader NCI community.

Dr. Letai discussed the recent Precision in Practice workshop, which focused on functional precision medicine. He described functional precision medicine as testing therapeutics directly on a patient's living tumor tissue to support discovery, guide treatment decisions, stratify patients in clinical trials, and identify therapies for patients with limited or no treatment options. Dr. Letai stated that broader implementation of functional precision medicine is an NCI priority, while noting that genomic precision medicine will continue to play an important role.

Dr. Letai also announced the upcoming Childhood Cancer Data Initiative (CCDI) symposium on September 18, 2026, at NCI’s Shady Grove campus, with an option for virtual attendance. He noted that the initiative has received federal support, including a presidential executive order directing an additional $50 million for AI deployment through CCDI.

Questions and Discussion

Ms. Spears expressed interest in Operation TrialBlazer, particularly patient advocate involvement. She also asked about the additional NIH and HHS review processes for grant applications and the Office of Management and Budget (OMB) proposal regarding grant funding decisions. Dr. Letai responded that the additional review adds approximately 7 to 10 days to the processing time but has not affected funding decisions. He also noted that the OMB proposal is not expected to change how NCI reviews and funds grants, although its implementation remains uncertain.

Dr. Mesa encouraged NCI to continue using its communication platform and partnerships with professional organizations to promote the impact of cancer research, particularly among trainees. Dr. Letai agreed and encouraged CTAC members to help communicate that NCI continues to fund and support training programs for investigators.

Dr. Lerner asked whether broader efforts to accelerate clinical trials would affect the Cancer Therapy Evaluation Program peer review process for large phase III studies. Dr. Letai indicated he was not aware of any planned changes, and Dr. Doroshow confirmed that NCI remains committed to rigorous peer review while continuing efforts to make the process faster and more flexible.

Dr. de Claro noted that the FDA, NCI, Centers for Medicare & Medicaid Services (CMS), and HHS are collaborating to facilitate clinical trials in the United States. He highlighted an open RFI on Operation TrialBlazer and encouraged interested stakeholders to submit comments by July 22, 2026.

III. Retiring Member Recognition

James H. Doroshow, M.D.

Dr. Doroshow recognized outgoing CTAC members Drs. Smita Bhatia, Seth Lerner, Carolyn Muller, Raphael Pollock, Suresh Ramalingam, Victor Santana, and Julie Vose for their service to NCI and CTAC. In addition, Dr. Vose was recognized for her service as CTAC Chair.

IV. Creation of a New Public–Private Partnership for a Therapeutic Cancer Vaccines Initiative

Stacey Adam, Ph.D.
Vinod P. Balachandran, M.D.

Drs. Adam and Balachandran presented an update on a public–private partnership organized by NCI and the FNIH to establish a National Therapeutic Cancer Vaccine Initiative (NTCVI). They reviewed the scientific rationale for the initiative, described the development of a national roadmap, and outlined the proposed program structure along with recommended demonstration projects and long-term vision.

Scientific Rationale. Dr. Balachandran explained that cancer immunotherapy harnesses T cells' ability to detect neoantigens, mutation-derived proteins found on cancer cells but not in normal tissues. While current immunotherapies are generally most effective in cancers with large numbers of neoantigens, cancer vaccines have the potential to generate tumor-specific immune responses even in cancers with fewer neoantigens that have historically not responded to existing immunotherapies. Recent advances in genomic sequencing, RNA vaccine technologies, lipid nanoparticle delivery systems, AI/machine learning, and biomanufacturing now enable rapid development and delivery of personalized cancer vaccines at scale. Early clinical studies have demonstrated encouraging results in both immunotherapy-

sensitive cancers, such as melanoma, and historically treatment-resistant cancers, including pancreatic cancer. Together, these findings suggest that therapeutic cancer vaccines may have broad applicability across solid tumors and that the field is at a point where coordinated national acceleration may be warranted.

Dr. Adam noted that despite converging advances and promising early signals, progress is hindered by fragmented efforts, insufficient focus on cancers with the greatest unmet need, and technologies that remain largely siloed within biopharmaceutical companies.

At Dr. Letai's request, the FNIH convened an expert advisory committee in December 2025 to develop a roadmap to accelerate testing of cancer vaccine hypotheses from discovery through clinical evaluation. The advisory committee delivered a high-level roadmap at the end of February 2026, which was approved by the NCI National Cancer Advisory Board on March 17, 2026. The initiative has since entered an accelerated design phase with a white paper expected by the end of August 2026.

Program Structure. Dr. Adam provided an overview of the FNIH, the congressionally authorized nonprofit organization that supports NIH through public–private partnerships. She explained that the FNIH brings together government, academia, industry, foundations, and patient organizations to provide governance, project management, fundraising, and other activities needed to support large collaborative initiatives.

The NTCVI is organized around a national learning framework in which data from each vaccinated patient are integrated to continuously improve future vaccine design, platform selection, and clinical development. Four guiding principles govern the initiative: targeting high-risk, high-reward indications that complement industry efforts; placing scientific discovery and clinical innovation at the center of program design; prioritizing shovel-ready concepts capable of generating actionable clinical and immunologic evidence; and executing at scale with predefined go/no-go criteria to identify the strongest concepts for expansion.

Implementation of the NTCVI will occur in two stages. Stage one, approximately years 1 through 3, focuses on generating clinical and biological data through demonstration studies in high-need cancers, while building a scalable foundation for vaccine manufacturing, clinical trials, and continuous learning. Stage two, approximately years 4 through 10, would scale successful approaches identified in stage one through a national network with the goal of increasing patient access and accelerating clinical implementation.

Recommendations: Demonstration Projects. The NTCVI includes stage one demonstration projects designed to generate clinical and immunologic data within approximately 3 years. Initial clinical trials would focus on high-risk cancers with poor disease-free survival following surgery and evaluate clinically mature vaccine platforms, including personalized RNA vaccines in the adjuvant setting and off-the-shelf vaccines in the neoadjuvant setting. Successful approaches would be positioned for expansion through national clinical trial networks or partnerships with biopharmaceutical companies.

The initiative is organized around four interconnected tracks that address critical field bottlenecks. Track one focuses on vaccine platform innovation, with an emphasis on accelerating evaluation of clinically mature vaccine platforms, generating comparative evidence, establishing national evaluation standards, and informing manufacturing and regulatory strategies.

Track two focuses on antigen discovery and immune monitoring powered by longitudinal immunological data from vaccinated patients that will be used to improve computational

prediction, enable rational vaccine design, establish standardized antigen evaluation frameworks, and support biomarker development.

Track three focuses on clinical evidence generation using a master basket trial framework to evaluate prioritized vaccines in up to four adult cancers and one pediatric cancer. The recommended initial indications are adjuvant vaccines in pancreatic, liver (hepatocellular carcinoma and biliary), colorectal, or fusion-positive pediatric cancers, and exploratory neoadjuvant treatment in pancreatic, colorectal, and ovarian cancers. Shared primary and co-primary endpoints include safety, feasibility, relative immunogenicity, recurrence-free survival, and overall survival. Secondary and exploratory immunologic endpoints are included to support future vaccine development.

Track four encompasses the initiative's learning engine, powered by a National Cancer Vaccine Knowledge Commons—a shared data repository to harmonize data across the ecosystem, analyze patterns, discover new biology, and use this information to inform vaccine platform selection, antigen discovery, and clinical development.

All four tracks are supported by shared infrastructure for manufacturing, biobanking, immune monitoring, regulatory science, workforce development, and patient and community engagement. Dr. Balachandran noted that decentralized Good Manufacturing Practice (GMP) manufacturing capacity for personalized vaccines represents the principal operational challenge to national implementation. To address this challenge, the roadmap proposes establishing centralized manufacturing capabilities at academic centers together with a framework for regional satellite facilities to support future national expansion.

The proposed stage one budget totals $200 million with clinical trials representing the largest allocation.

Stage Two. Stage two will build directly on findings from stage one by expanding platforms and indications that meet the predefined go/no-go criteria through a broader network of sites. Development of decentralized GMP manufacturing infrastructure during stage one is intended to support expansion beyond comprehensive cancer centers to regional academic and community oncology settings.

Dr. Balachandran concluded that recent advances in immunology, vaccine technology, and computational methods have created an opportunity to accelerate therapeutic cancer vaccine development. He noted that the public–private partnership is intended to establish a national cancer vaccine ecosystem that coordinates scientific priorities, harmonizes data collection, expands patient access, and continuously informs future vaccine development through a shared learning framework.

Questions and Discussion

Dr. Kobayashi asked how vaccines would advance from stage one given the time required to evaluate survival endpoints and what controls would be used in demonstration studies. Dr. Balachandran explained that the roadmap prioritizes high-risk cancers with median disease-free or recurrence-free survival of one year or less to enable go/no-go assessments within the 3-year stage one timeframe. He also noted that immune activity, recurrence outcomes, and matched historical controls would help identify promising approaches for evaluation in larger phase II or phase III clinical trials.

Dr. Azad expressed enthusiasm but raised concern about whether focusing initial studies on immunologically cold tumors could limit the ability to demonstrate early success. Dr. Balachandran noted that the selected cancers have shown early evidence of vaccine-induced

immune responses and were chosen because they represent high unmet need and are not the focus of current industry efforts.

Ms. Spears emphasized the importance of engaging patients and the public early, particularly given public perceptions of vaccines. She also asked whether a patient-friendly version of the white paper would be developed. Dr. Adam confirmed that a lay language executive summary could be generated for broad distribution.

Dr. Santana encouraged consideration of pediatric cancers with favorable survival outcomes where vaccines might reduce treatment intensity and long-term treatment-related toxicities, even if survival endpoints would require longer follow-up. Dr. Kibbe agreed and encouraged consideration of diseases with good initial survival but poor long-term outcomes related to treatment sequelae.

Dr. Ramalingam asked whether a separate safety cohort would be needed before evaluating investigational vaccines in patients with potentially curable disease. Dr. Balachandran responded that platform selection criteria explicitly require clinical efficacy of a platform in a particular disease and mature safety evidence both as a single agent and in combination, mitigating the need for a separate dose-escalation evaluation.

Dr. Lerner asked about the ability to expand or modify the program based on emerging data. Dr. Balachandran confirmed that the basket design was built to allow this flexibility, with decentralized GMP manufacturing infrastructure developed in parallel to support rapid scaling if a positive signal emerges early.

Dr. Muller emphasized incorporating decentralized trial elements into stage one to facilitate implementation in community settings during stage two. Dr. Balachandran noted that the proposed trial designs are intended to serve as flexible frameworks that will be refined with disease-specific expertise. Dr. Adam added that emerging technologies may simplify vaccine distribution to community sites. Additionally, Dr. Letai stated that NCI would prioritize broad access should an effective vaccine emerge.

V. Artificial Intelligence for Clinical Trials

Introduction

Warren A. Kibbe, Ph.D.

Dr. Kibbe introduced the AI session, noting that two presentations would follow. The first, from Dr. Jeremy Warner, would provide a broad framework for understanding opportunities to apply AI in clinical trials. The second, from Drs. Gulley, Topaloglu, and Nelson, would describe NCI's efforts to apply AI to clinical trial processes within the intramural program and discuss how those tools can be made accessible across the broader cancer research community.

AI in Clinical Trials: Current Landscape and Future Opportunities

Jeremy L. Warner, M.D., M.S., F.A.M.I.A., F.A.S.C.O.

Dr. Warner provided an overview of the current and potential applications of AI in late-stage interventional cancer clinical trials, framing his remarks around six areas: real-world data (RWD) and real-world evidence (RWE), recruitment and clinical trial matching, eligibility criteria, remote monitoring, reporting of trial results, and predicting trial success. He noted that AI has the potential to make clinical trials faster, less expensive, and more likely to succeed, while cautioning that technology gaps, implementation costs, and ethical considerations must also be addressed.

RWD and RWE. Clinical trials have long been informed by clinical observations and experience, but AI, particularly natural language processing (NLP), has the potential to scale this process while reducing the resource burden and potential bias associated with manual approaches. Dr. Warner emphasized the importance of considering the entire cancer continuum, from early-stage to advanced disease, together with the full spectrum of treatment-related toxicities, including immediate side effects, sequelae, and late effects.

Although electronic health records (EHRs) contain substantial information that NLP can help unlock, many variables important for research remain absent or inconsistently captured, including social determinants of health, treatment burden, treatment response, and imaging and pathology data. A study of 68 CancerLinQ sites demonstrated that while interoperability within individual EHR vendor systems was high, interoperability across vendors was as low as 1% for common medications and laboratory values.

Data ambiguity presents an additional challenge. A study of more than 2,000 patient records found that 84% contained some degree of cancer stage discordance, while a more recent AI-enabled analysis scaled this work to extract over 2.7 million staging records for 217,768 patients from more than 2.1 million clinical notes. Differences between AI-derived stage distributions and cancer registry statistics underscore the importance of data quality when using AI to inform trial design. Dr. Warner also noted that institutions often adopt different approaches to data standardization, making harmonization across organizations difficult.

Recruitment and Clinical Trial Matching. EHR certification requirements, administered by the Office of the National Coordinator for Health Information Technology (ONC), have served as an indirect mechanism for improving data standardization because most healthcare institutions purchase certified EHR systems. However, certification requirements address only a core set of data elements and do not extend to many cancer-specific variables. The United States Core Data for Interoperability (USCDI) defines this core set of data elements, including demographics, allergies, and health insurance information, and is updated periodically across certified EHR systems. To address disease-specific data needs beyond the core set, ONC partnered with NCI, CMS, the Centers for Disease Control and Prevention, and FDA to develop an extension called USCDI+ Cancer. The initiative focuses on cancer-specific data elements across four initial use cases, one of which is clinical trial matching.

AI-enabled clinical trial matching systems have the potential to identify eligible patients more efficiently and at greater scale than manual approaches. However, Dr. Warner cautioned that barriers to enrollment are not experienced equally across patient populations. Although AI-based site selection models have demonstrated improved demographic representation in other settings, comparable evidence has not yet been established in cancer clinical trials.

Eligibility Criteria. AI also has a role in rethinking eligibility criteria. Dr. Warner highlighted a study using Flatiron registry data to emulate non-small cell lung cancer trials, demonstrating that relaxing selected laboratory eligibility criteria could substantially increase the eligible patient population without meaningfully affecting trial results. Since this study was conducted, regulators and professional societies have encouraged broader eligibility criteria, but whether those recommendations have been widely implemented remains unclear.

Dr. Warner highlighted FaceAge, an AI tool that estimates biological age from facial photographs, reflecting physiologic age rather than chronological age. Early studies suggest that biological age may predict survival more accurately than chronological age. However,

whether FaceAge can complement or replace existing measures such as Eastern Cooperative Oncology Group (ECOG) performance status remains uncertain because comparative data are limited. Widespread adoption would also raise important questions regarding fairness in its application.

Trial Operations and Remote Monitoring. AI has clear potential applications across trial operations including site startup and administration costs, enrollment and treatment scheduling, visit documentation, audits, data safety monitoring, and closeout. Wearable technologies also create new opportunities for remote patient monitoring by enabling AI to analyze physiologic data such as gait, heart rate variability, sleep patterns, and activity. Early studies suggest wearable-derived measures, including daily steps and distance walked, may predict survival more accurately than ECOG performance status. Patient adherence to wearable devices, however, remains an important practical limitation.

Reporting of Trial Results. Dr. Warner highlighted the importance of complete and unbiased trial reporting and described work evaluating AI's ability to summarize clinical trial publications and regulatory documents. Performance varied substantially across models, particularly with respect to accuracy and completeness. Model selection, therefore, should be guided by performance for the intended task rather than assuming equivalent capabilities across large language models (LLMs).

Predicting Trial Success. Approximately half of phase III trials fail to meet their primary endpoints, and structural design factors likely play a significant role. Dr. Warner described work from his group suggesting that phase III trial success can be predicted to a meaningful degree using factors available during trial design, including cancer type, intervention characteristics, and study design features. Predicting enrollment failure remains considerably more difficult because data describing why patients decline participation are rarely available.

Increasingly accurate predictive models also raise ethical considerations. Certainty in predicting trial outcomes would undermine the ethical justification for randomization, meaning some uncertainty is inherent to randomized clinical trials. Dr. Warner suggested that future AI applications may include dynamically modifying trial design mid-study when standards of care evolve, adapting trial allocation based on local conditions, detecting trial futility earlier than current approaches, and developing new methods to measure toxicities that matter most to patients.

Dr. Warner concluded by noting that while AI has the potential to touch every aspect of clinical trials, the analytic approaches chosen are only as good as the underlying data, and that both the benefits and potential harms of AI applications must be carefully considered.

Questions and Discussion

Dr. Vose asked whether the FaceAge tool is open source or proprietary. Dr. Warner responded that he believes it is open source.

Ms. Spears commented that AI has many potential applications in clinical trials but also emphasized that output from LLMs still requires human review to ensure quality and reliability. She noted that evidence supporting broader eligibility criteria already exists, but implementation has been slow, suggesting that changing practice patterns may be as important as generating additional evidence. Dr. Warner agreed that demonstrating the case analytically is not sufficient

on its own and noted that AI-driven patient communication tools, such as interactive avatars capable of answering patient questions beyond what is feasible in a clinical appointment, may help address barriers to trial participation.

Dr. Lerner noted that trial failure is not always a negative outcome, citing a SWOG surgical trial in which demonstrating no difference between treatment arms established an important standard of care. He also discussed ongoing work using implementation science to identify factors contributing to poor trial accrual and asked whether AI could help predict enrollment success during trial design. Dr. Warner noted that limited data on why patients decline participation make enrollment prediction difficult. Dr. Muller added that AI could also be used to assess patient burden within a trial and help identify reasons why eligible patients choose not to enroll. Dr. Kibbe highlighted that institutions frequently overestimate the size of the eligible patient population and that competing trials further reduce accrual, making enrollment prediction as much an operational planning challenge as a technical one. Dr. Vose noted that pharmaceutical companies often overpredict enrollment as well.

Dr. Kobayashi agreed that AI is a powerful enabler for improving trial success but emphasized that its impact depends on successfully integrating it with human behavior. He highlighted the potential of AI to model and simulate trial designs before activation as a particularly promising application.

Dr. Ramalingam raised concerns about the growing number of AI vendors, each offering solutions to individual components of the clinical trial process. He asked how cancer centers should approach vendor selection. Dr. Warner acknowledged this as a significant challenge and suggested NCI may be well positioned to assist. Dr. Kibbe noted that NCI is working with the Association of American Cancer Institutes to engage NCI-Designated Cancer Centers in evaluating AI platforms and identifying broadly applicable solutions for the cancer research community. Cancer center representatives are encouraged to participate in these discussions.

From Protocol to Patient: Leveraging Large Language Models to Streamline Clinical Trials
James L. Gulley, M.D., Ph.D.
Tanna Nelson, Ph.D., R.N., NI-BC
Umit Topaloglu, Ph.D., F.A.M.I.A.

Overview. Dr. Gulley described inefficiencies in the current clinical trial development process, noting that consent forms are often filled with technical jargon, protocols contain inconsistencies, and many administrative tasks are repetitive and error-prone. Structured protocols and LLMs could reduce administrative burden by supporting tasks such as EHR treatment plan development, clinical trial management system (CTMS) calendar creation, eligibility abstraction, regulatory document preparation, and consent drafting. Informed consent is central to clinical research, and LLMs can improve consent documents by simplifying language, reducing length, identifying inconsistencies, and facilitating translation into multiple languages. Together, these capabilities can enhance participant understanding, build trust, increase accessibility, and improve the efficiency of the informed consent process.

Clinical trial activation timelines have continued to increase, with a recently published study reporting a median activation time of 167 days, even longer for investigator-initiated trials. Increasing protocol complexity has contributed to these delays, with the number of distinct procedures per study reaching 115–120, a 70% increase over the past decade. Up to 50% of

EHR treatment plans are never used despite requiring substantial resources to develop, and site activation processes are repeated across institutions at great expense. Each day of delay in a phase III trial is estimated to cost over $55,000, or approximately $1.7 million per month. Dr. Gulley noted that LLMs could streamline site activation by generating study documents using site-specific templates and extracting protocol content for validated EHR builds. The goal is to build a study once and disseminate it across participating sites, reducing redundant work, lowering costs, and improving efficiency for both research teams and patients. He added that NCI plans to share these capabilities broadly with cancer centers and has already begun engaging with several institutions.

Structured Protocols and Semantic Interoperability. Dr. Topaloglu described NCI's vision for a unified cancer intelligence ecosystem built on structured, semantically consistent clinical trial data. Although AI can extract and generate text, standardized terminology and common data elements are necessary to ensure that information is interpreted consistently across EHRs, CTMS applications, clinical trial matching tools, and analytic platforms. This framework supports downstream applications such as precision medicine and trial automation. Across all applications, AI is intended to support researchers and study teams while preserving expert oversight.

Implementing this vision begins with structured protocol authoring, which reduces ambiguity at the source and enables consistent interpretation and reuse of information throughout the clinical trial lifecycle. If a protocol starts as ambiguous narrative text, every downstream system inherits that ambiguity, making structured authoring at the source essential.

Protocols are currently distributed as unstructured PDF or Microsoft Word documents, requiring multiple teams to independently extract and reinterpret the same information for downstream activities such as building EHR treatment plans, CTMS calendars, consent forms, and eligibility criteria. Rather than relying on unstructured protocol documents that require repeated manual interpretation, the proposed approach uses structured protocol authoring to create reusable, machine-readable content that supports downstream trial operations, participant-facing materials, data capture, and clinical trial matching. This approach also simplifies amendments by allowing changes to be registered once and propagated simultaneously to all sites rather than being independently rebuilt at each site. Dr. Topaloglu reiterated that the goal is to improve consistency and traceability, not to transfer accountability to AI.

The structured protocol framework supports both clinical trial matching and trial operations. For matching, it enables computable eligibility criteria and consistent representation of cancer type, stage, histology, biomarkers, prior therapy, laboratory results, and performance status. For operations, it supports schedules of activities, treatment procedures, medication details, visit windows, study calendars, and electronic case report form design. The NCI Thesaurus provides a common oncology vocabulary, while Fast Healthcare Interoperability Resources (FHIR) enables structured exchange of information between systems. Together with USCDI+ Cancer, these standards support semantic interoperability across clinical trial matching and operational systems.

Dr. Topaloglu described efforts to improve clinical trial matching by combining standardized patient data with computable eligibility criteria. NCI is working with federal partners to standardize cancer data exchange and has begun testing the USCDI+ Cancer clinical trial

matching implementation guide across EHR systems. However, standardizing patient data alone is insufficient for reliable clinical trial matching. Eligibility criteria must also be converted from narrative text into structured, computable data by identifying and coding key eligibility elements. Combined with standardized patient data, this approach supports more transparent clinical trial matching by identifying why a patient is eligible, why a patient is ineligible, or what additional information is needed. This approach is currently being validated through a multi-institutional federated learning pilot, where sites maintain local control of patient data and only share AI model updates.

Tools in Development. Dr. Nelson reiterated that the protocol is the primary source of information for the many downstream processes required to activate and conduct a clinical trial. By addressing the primary source, rather than applying AI to each downstream task, investigators can enter protocol data once and have all downstream outputs generated in parallel from a single structured document with full traceability. This approach would also transform the amendment process. Instead of requiring each site to independently identify changes and rebuild study documentation, amendments could be propagated simultaneously to sites for review and acceptance, reducing implementation time from weeks or months to hours.

Several tools currently under development illustrate this approach. The first tool is an AI-assisted informed consent drafting tool that generates an initial draft of the consent form from the protocol document at an eighth-grade reading level. Required regulatory language is preserved and clearly distinguished from AI-generated content, which study teams can then review and modify before Institutional Review Board submission. The tool is currently available across NIH and is expected to be publicly available in 2027.

The second tool is a one-page layperson's research summary designed to communicate high-level study information to participants in accessible language. Developed in collaboration with patient advocates and based on a template developed by Dr. Mary Politi, Professor of Public Health, Washington University in St. Louis, the summary is intended to improve participant understanding of clinical trials. This tool is also currently available at NIH and is planned to be made publicly available in 2027.

The third tool supports AI-assisted translation of informed consent documents, with initial implementation focused on Spanish. AI generates a first draft of the translation, which is then reviewed and certified by an in-house human translator. A multi-step quality evaluation using LLMs assesses structural accuracy, translation quality, and cultural appropriateness, with comparisons between AI-generated and human-certified versions used to produce more accurate and culturally appropriate first-draft translations.

The fourth tool is a clinical trial matching engine that integrates LLM-assisted extraction of eligibility criteria from protocol documents, structured protocol data, including inclusion and exclusion criteria, together with FHIR-based data exchange to support patient-trial matching.

All tools are being developed within NIH's secure Amazon Web Services cloud infrastructure using NIH-approved LLMs. Dr. Nelson emphasized that humans remain central to the process, with AI used to generate drafts and extract content that human experts then review, validate, and approve before any content reaches patients or clinical sites.

Questions and Discussion

Dr. Warner raised the challenge of achieving an eighth-grade reading level for complex medical topics, noting that an analysis of medical content on Wikipedia found that nearly all articles are written well above that level. Dr. Nelson agreed and explained that AI provides a starting point that study teams can then refine where clinical nuance is needed. Dr. Gulley added that in his own experience drafting consent forms, the LLM-generated drafts were not perfect but provided a framework that could be modified to improve accessibility for patients.

Ms. Spears expressed strong support for the protocol-to-consent drafting tool, noting that it standardizes the quality of consent forms across institutions while reducing workload for sites. She also expressed enthusiasm for the one-page layperson's summary and noted ongoing efforts at her institution to implement Dr. Politi's key information section template as a standard component of consent forms.

Dr. Mesa welcomed NCI's leadership role in this space, noting that cancer centers currently risk developing dozens of organically grown, incompatible AI solutions. He emphasized that NCI's effort to provide a unifying, interoperable platform could prevent fragmentation and reduce barriers to conducting large-scale clinical trials.

Dr. Wilding asked how the NCI informatics effort is being coordinated with the Electronic Health Record Pilot Consortium’s work on EHR trial builds, given the many points of intersection between the two projects. Dr. Topaloglu confirmed that active coordination is underway, noting that the consortium's code is being integrated into the NCI platform with the goal of creating shared, reusable artifacts that can serve all NCI-Designated Cancer Centers. He added that AI tools can help accelerate the harmonization the consortium has been working toward.

VI. Ongoing and New Business

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

Dr. Prindiville indicated that NCI is working to appoint new CTAC members. She also provided an update on the formation of the CTAC Innovation in Clinical Trials Working Group. The group will focus on identifying transformative strategies to modernize the design, conduct, and efficiency of NCI clinical trials, including strategies to streamline data collection for IND studies and reduce trial activation timelines, building on CTAC's prior work while supporting HHS's Operation TrialBlazer initiative.

Dr. Prindiville also highlighted a forecasted funding opportunity for the NCI Research Specialist (Clinician Scientist) Award (R50), anticipated to reissue the recently expired funding opportunity for this program. The program has made 55 awards to date and provides salary support and a career pathway for clinician scientists who focus on the design and conduct of NCI-funded clinical trials but do not hold independent research grants. Interested applicants are encouraged to monitor the forthcoming announcement because the next funding opportunity is expected to open in fall 2026 with applications anticipated to be due on November 2, 2026.

Dr. Prindiville reviewed upcoming CTAC meeting dates, including November 18, 2026, March 10, July 14, and November 17, 2027. She invited CTAC members to submit suggestions for future meeting agenda topics.

VII. Adjourn

Julie M. Vose, M.D.

There being no further business, the 60th meeting of CTAC was adjourned at 3:54 p.m. on Wednesday, July 15, 2026.

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

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

Appendix

July 2026

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

CHAIR

Julie M. Vose, M.D. 2026
Neumann M. and Mildred E. Harris Professor
Chief, Division of Hematology/Oncology
Department of Internal Medicine
University of Nebraska Medical Center
Omaha, Nebraska

MEMBERS

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Professor of Oncology
Co-Director, Developmental Therapeutics Group
Co-Leader, Cancer Genetics and Epigenetics Program
Sidney Kimmel Comprehensive Cancer Center
Johns Hopkins University
Baltimore, Maryland

Smita Bhatia, M.D., M.P.H. 2026
Vice Chair of Outcomes for Pediatrics
Professor
Division of Hematology/Oncology
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University of Alabama at Birmingham
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Gary C. Doolittle, M.D. 2027
Capitol Federal Masonic Professor
Division of Medical Oncology
University of Kansas Medical Center
Westwood, Kansas

Ken Kobayashi, M.D., F.A.C.P. 2028
Chief Medical Officer
Pyxis Oncology
Boston, Massachusetts

Seth P. Lerner, M.D., F.A.C.S. 2026
SWOG GU Committee Chair
Vice Chair for Faculty Affairs
Beth and Dave Swalm Chair in Urologic Oncology
Professor
Scott Department of Urology
Baylor College of Medicine
Houston, Texas

Robert S. Mannel, M.D. 2027
Director
Peggy and Charles Stephenson Cancer Center
College of Medicine
University of Oklahoma Health Sciences Center
Oklahoma City, Oklahoma

Ruben A. Mesa, M.D. 2027
President, Advocate Health Cancer National Service Line
President, Atrium Health Levine Cancer
Executive Director, Atrium Health Wake Forest Baptist Comprehensive Cancer Center
Senior Vice President, Advocate Health
Vice Dean for Cancer Programs
The Charles L. Spurr MD Professor of Medicine
Wake Forest School of Medicine
Winston-Salem, North Carolina

Carolyn Y. Muller, M.D., F.A.C.O.G. **2026**
Associate Director of Clinical Research
The Judy Putman Dirks Endowed Professor in Gynecologic Cancer Care
Department of Obstetrics and Gynecology
The University of New Mexico Health Sciences Center
Albuquerque, New Mexico

Raphael E. Pollock, M.D., Ph.D., F.A.C.S. **2026**
Kathleen Wellenreiter Klotz Chair in Cancer Research
Director
The Ohio State University Comprehensive Cancer Center
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Roberto C. Goizueta Chair for Cancer Research
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Victor M. Santana, M.D. **2026**
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Patient Advocate
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University of North Carolina at Chapel Hill
Chapel Hill, North Carolina

George Wilding, M.D. **2027**
Professor Emeritus and Director Emeritus
University of Wisconsin, Madison
Albuquerque, New Mexico

Ex Officio Members

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

Richard Pazdur, M.D., F.A.C.P.
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Designated Federal Official

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