

REPORT FROM THE 2ND MEETING OF THE NATIONAL CANCER ADVISORY BOARD WORKING GROUP ON EXTRAMURAL RESEARCH CONCEPTS AND PROGRAMS

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INTRODUCTION

The second meeting of the National Cancer Advisory Board Working Group on Extramural Research Concepts and Programs (NCAB WG) was held virtually on April 8, 2026. The meeting was chaired by Dr. Cornelia M. Ulrich and attended by 31 NCAB WG members. Dr. Douglas R. Lowy, Principal Deputy Director, NCI, provided an update on the NCI budget and extramural funding landscape. Three concepts were reviewed by the NCAB WG to make recommendations for voting at the subsequent NCAB meeting.

CONCEPT REVIEW

RFP REISSUANCE: SURVEILLANCE, EPIDEMIOLOGY, AND END RESULTS (SEER) PROGRAM

Established in response to the National Cancer Act of 1971, the Surveillance, Epidemiology, and End Results (SEER) Program is the nation's primary population-based cancer surveillance system and the gold standard for cancer incidence and survival data. Currently covering approximately 46% of the U.S. population through 17 core registries, SEER collects nearly one million new cancer cases annually with nearly 500 data elements per case. The concept outlined in this reissuance seeks to fund up to 20 registry contracts over a 10-year period beginning in FY2028, with a first-year set-aside of \$52M and a total contract ceiling of \$600M, in pursuit of four primary goals: continued support of SEER's data collection infrastructure; enhanced research support infrastructure through activities that directly leverage that data; maintained geographic and demographic representation of the U.S. population in national cancer surveillance efforts; and the development of methods and technologies to improve registry operations and keep data readily accessible to researchers. New elements of the reissuance include the creation of an innovation center and an external advisory board, potentially operationalized as a subgroup of the NCAB. All registries would be required to use the SEER Data Management System (SEER*DMS), with those not currently on the platform required to migrate within two years of award at their own cost.

Working Group Feedback

The NCAB WG strongly endorsed the concept reissuance, emphasizing the irreplaceable role of SEER data across epidemiology, basic science, health policy, and clinical guidelines. Discussion highlighted the program's value as a comprehensive, population-based census with rigorous quality control that no other U.S. database rivals. Members raised concern about the 20% non-federal cost-sharing requirement given anticipated reductions to CDC funding for state cancer registries, and urged NCI to monitor the impact on registry sustainability. In addition, members recommended establishing a well-structured external advisory committee with clearly defined membership, meeting frequency, and responsibilities relative to NCI program staff. Members also encouraged expanding attention to underrepresented populations, including rural communities, and emphasized the potential for AI and data linkages to modernize and extend the program's reach.

Recommendation to NCAB: Approve

RFA REISSUANCE: INNOVATIVE MOLECULAR ANALYSIS TECHNOLOGIES (IMAT) PROGRAM (R61/R33)

The Innovative Molecular Analysis Technologies (IMAT) program, established in 1998, supports the development of highly innovative technologies with the potential to transform cancer research by addressing the complexity of cancer biology. The program fills a niche not addressed by traditional NIH funding mechanisms by supporting high-risk, high-reward technology development prior to the establishment of feasibility, spanning a broad range of technical disciplines including instrumentation, platforms, techniques, devices, methods, assays, and analytical tools. IMAT uses two grant mechanisms: R61 awards support proof-of-concept studies (up to \$150,000/year in direct costs for up to three years), and R33 awards support advanced-stage development and technical validation (up to \$300,000/year in direct costs for up to three years). The program receives 200–300 applications annually across all mechanisms, with a success rate of 9–13%. Beginning in FY2026, applications are reviewed by Special Emphasis Panels managed by the NIH Center for Scientific Review rather than NCI's DEA. In FY2027, IMAT will offer one R61 RFA and one R33 RFA. The reissuance requests \$12M in first-year total costs to fund new R61 and R33 grants across FY2028–2030.

Working Group Feedback

NCAB WG members expressed strong enthusiasm for the program, noting its unique and irreplaceable role in catalyzing technology development across disciplines — including chemistry, biomedical engineering, and physics — that might not otherwise engage with NCI. Members discussed the program's exceptional return on investment, noting that the cost per patent is two to three times lower than traditional R01/R21 mechanisms, and that IMAT has an outsized impact for the investment. Members endorsed the planned changes, including discontinuing the revision RFA and merging the two existing RFAs. There was also a brief discussion on ways to increase engagement from early-stage investigators, including the potential for program-specific challenges or special funding opportunities. There was broad support for expanding the program budget given its demonstrated value, and members encouraged NCI to explore mechanisms for connecting high-performing grantees with translation and commercialization resources.

Recommendation to NCAB: Approve

RFA REISSUANCE: RADIATION ONCOLOGY–BIOLOGY INTEGRATION NETWORK (ROBIN) (U54)

The Radiation Oncology–Biology Integration Network (ROBIN), launched in 2022, provides a coordinated national platform for real-time biological characterization during radiation therapy, with the goal of defining mechanistic treatment-response dynamics in human tumors and normal tissues and identifying actionable biological changes that can inform biomarker development, drug–radiation combinations, and adaptive treatment strategies. Traditional drug development has emphasized drug–drug combinations, leaving drug–radiation combinations comparatively underexplored despite their routine use in clinical practice; ROBIN aims to close this gap by defining treatment-induced biological dynamics and leveraging these insights to optimize sequencing, reduce toxicity, and improve patient outcomes across both adult

and pediatric cancers. Currently, the program funds five U54s, each focused on longitudinal biospecimen collection, multi-omic profiling, and imaging integration before, during, and after radiation treatment across multiple cancer types, including rectal, bladder, head and neck, prostate, cervical, pancreatic, and pediatric CNS cancers. The renewal would capitalize on the programmatic infrastructure developed during the first project period — including validated workflows, harmonized sampling protocols, multi-omic pipelines, and cross-institutional governance — to enable mechanistic discovery and translational testing at a scale and rigor not previously feasible. The renewal requests funding for five U54 centers with a first-year total cost of \$4.32M and a total cost of \$36M over five years. This would be an open competition RFA, with goals that include expanding disease coverage to breast, lung, sarcoma, and lymphoma; studying radiation in combination with chemotherapy, immunotherapy, and other agents; advancing longitudinal characterization of normal tissue and toxicity biology; and strengthening workforce development across radiation biology, oncology, and computational science.

Working Group Feedback

NCAB WG members expressed strong support for the renewal, noting that ROBIN addresses a critical and previously understudied area — dynamic molecular biology during radiation therapy — that no other national platform is pursuing. The Working Group underscored the importance of harmonized sample collection protocols and consistent use of standard operating procedures across centers to ensure data comparability and reproducibility. Members noted the value of incorporating short-course and hypofractionated radiation approaches, which are particularly relevant for patients in rural communities. Members recommended that performance metrics be clearly defined upfront, including publications, grant acquisition, clinical trial development, and workforce outcomes. The discussion also addressed the importance of articulating a clear rationale for expanding to new disease sites and establishing explicit governance structures for resolving disputes over shared resources. The Working Group recommended the establishment of an external review panel for a mid-cycle review to assess progress toward programmatic goals. The reissuance was noted as a model for how basic molecular science can be systematically integrated into clinical treatment platforms.

Recommendation to NCAB: Approve

RTP: CLINICAL TRIALS EVALUATION PROGRAM ENTERPRISE SYSTEM (CTEP ESYS)

The Clinical Trials Evaluation Program Enterprise System (CTEP-ESYS) is an NCI-wide enterprise platform that supports the conduct, oversight, coordination, and evaluation of NCI-sponsored oncology clinical trials across multiple programs and networks, including the NCTN, ETCTN, PEP-CTN, and others. CTEP-ESYS is a suite of interconnected systems that includes START for protocol review and management, CTEP-AERS for adverse event reporting, AURORA for investigational agent management, and IAM/RCR for identity and access management, that form the foundational infrastructure through which NCI reviews, activates, oversees, and manages its oncology clinical trials portfolio. Under the current contract (FY2022–2027 has a \$109.1M contract ceiling), the platform has matured into an integrated enterprise system capable of handling increasingly complex protocols, novel trial designs, expanded safety requirements, and growing data volumes. This recompetition seeks to sustain and significantly expand

these capabilities over a 10-year period with a proposed budget of \$223.7M, broadening the scope beyond mission-critical enterprise support to include a formal R&D component encompassing advanced analytics, artificial intelligence, and machine learning to improve protocol review, trial feasibility assessment, accrual oversight, and safety monitoring aligned with NIH's validated enterprise AI infrastructure to ensure governance consistency and avoid duplication across the clinical trials enterprise.

Working Group Feedback

The NCAB WG reviewed this concept outside of the in-person meeting. Primary reviewers met with the Program Officials to discuss the concept and provided feedback in writing to all the members of the NCAB WG for additional feedback and an email vote. Overall, reviewers strongly endorsed the concept and its importance to the NCI mission. They emphasized that a robust, modern, and interoperable CTEP-ESYS is essential for supporting efficient, high-quality cancer clinical trials and recommended that the concept be strengthened through additional detail regarding current performance, interoperability, innovation, evaluation strategies, user support, and the expected impact of modernization activities. Specifically, the reviewers recommended greater interoperability and seamless data flow across the enterprise — including tighter integration with external platforms such as ClinicalTrials.gov, OnCore, REDCap, and CTSU-supported applications with START elevated as the core protocol data hub. Reviewers were enthusiastic about the proposed use of AI, ML, and advanced analytics for protocol review, accrual monitoring, and safety surveillance, provided these efforts align with NIH governance frameworks, and requested concrete examples of new capabilities that modernization would make possible. The reviewers also encouraged the concept to explicitly address emerging trial models such as decentralized and hybrid designs, broader use of real-world data, and flexible infrastructure to keep NCI trials at the forefront of operational innovation. Reviewers raised questions about whether a 10-year contract term allows sufficient flexibility given the pace of technological change, and recommended stronger user engagement through enhanced support services and more frequent training opportunities.

Recommendation to NCAB: Approve

SUMMARY

The NCAB WG reviewed NCI concepts and made recommendations to approve, disapprove, or defer for NCAB consideration. Presentations by program officials were followed by reports by NCAB WG expert reviewers that were assigned in advance of the meeting to review the concept with the Program Official and robust discussion by the entire WG. Table 1 summarizes the recommendations from the NCAB WG to NCAB on each of the concepts.

Table 1: Summary of Recommendations

Concept Type	New/Reissue	Title	Recommendation
RFP	Reissue	Surveillance, Epidemiology, and End Results (SEER) Program	Approve
RFA	Reissue	Innovative Molecular Analysis Technologies (IMAT) Program (R61/R33)	Approve
RFA	Reissue	Radiation Oncology–Biology Integration Network (ROBIN) (U54)	Approve
RFA	Reissue	Clinical Trials Evaluation Program Enterprise System (CTEP ESYS)	Approve