U.S. Department of Health and Human Services
National Institutes of Health
National Center for Advancing Translational Sciences
41st Meeting of the
Advisory Council

Minutes of Virtual Meeting
January 29, 2026

The National Center for Advancing Translational Sciences (NCATS) Advisory Council held a meeting in open session on January 29, 2026, from 1:07 p.m. to 4:45 p.m. EST, via National Institutes of Health (NIH) VideoCast and on MS Teams. Joni L. Rutter, Ph.D., NCATS Advisory Council Chair, led the meeting. In accordance with Public Law 92-463, the session was open to the public.

NCATS ADVISORY COUNCIL MEMBERS PRESENT

Chair

Joni L. Rutter, Ph.D., Director, NCATS

Executive Secretary

Anna L. Ramsey-Ewing, Ph.D., Director, Division of Extramural Activities (DEA), NCATS

Council Members

Sergio A. Aguilar-Gaxiola, M.D., Ph.D.
Jonathan Himmerfarb, M.D.
Robin J. Mermelstein, Ph.D.

***Ad Hoc* Council Members**

None present

Ex Officio Members

Jayanta "Jay" Bhattacharya, M.D., Ph.D.

Others Present

NCATS leadership and staff

I. CALL TO ORDER, OPEN SESSION

Joni L. Rutter, Ph.D., called the meeting to order and welcomed members and guests to the 41st meeting of the National Center for Advancing Translational Sciences (NCATS) Advisory Council. Anna L. Ramsey-Ewing, Ph.D., conducted the roll call and reviewed the meeting agenda. She noted the meeting logistics and reminded attendees that the open session was being livestreamed on NIH VideoCast.

APPROVAL OF 2026 NCATS ADVISORY COUNCIL GENERAL OPERATING PROCEDURES: Anna L. Ramsey-Ewing, Ph.D., Director, Division of Extramural Activities, NCATS; Executive Secretary, NCATS Advisory Council

Members unanimously approved the 2026 NCATS Advisory Council General Operating Procedures.

CONFIRMATION OF DATES FOR FUTURE NCATS ADVISORY COUNCIL MEETINGS: Anna L. Ramsey-Ewing, Ph.D., Director, Division of Extramural Activities, NCATS; Executive Secretary, NCATS Advisory Council

Anna L. Ramsey-Ewing, Ph.D., confirmed the schedule for the meetings of the NCATS Advisory Council for 2026 and 2027:

- May 21–22, 2026
- September 17–18, 2026 (virtual meeting)
- May 20–21, 2027
- September 16–17, 2027 (virtual meeting)
- January 28–29, 2027 (virtual meeting)

II. NIH DIRECTOR'S REPORT: Jayanta "Jay" Bhattacharya, M.D., Ph.D., Director, National Institutes of Health

Jayanta "Jay" Bhattacharya, M.D., Ph.D., NIH Director, began by expressing appreciation for National Center for Advancing Translational Sciences' (NCATS') efforts and its vital role within NIH. He communicated his gratitude to the Advisory Council members for their integral role at NCATS. Dr. Bhattacharya highlighted updates and initiatives related to advancing the NIH mission through a unified strategy.

NIH Priorities

Replication and reproducibility. Researchers' careers are rewarded for favorable results, but the published findings can be hard to reproduce. The NIH Common Fund will support replication efforts. The Center for Scientific Review and peer review groups will identify research to replicate. Replication studies should encourage collaborative discussion if different results are obtained. The Office of Metascience will be established to oversee a new peer-reviewed journal for replication studies, and PubMed will undergo revisions so that the replication is linked to the original study.

Real-World Data Platform. NIH will make investments to provide seamless availability of government and external data sets to researchers. Protecting patient privacy and data partners is vital throughout this process. Real-world data sets will provide new research opportunities while enhancing rigor, transparency, and integrity.

Furthering understanding of autism. The Autism Data Science Initiative (ADSI) is an example of NIH's investment in providing and linking real-world data sets to advance science and understand chronic diseases.

Artificial intelligence (AI). NIH is advancing AI research in many areas, including target identification and validation, predictive technology, and repurposing drugs. AI use in clinical settings will require guardrails to ensure outputs are accurate. In addition, the PubMed replication feature will be powered by AI. Dr. Bhattacharya highlighted that NCATS contributes to AI advances through open data sources and partnerships.

NIH News

Budget updates. Congress is proposing a budget increase of approximately 1% for NIH programs. There is widespread congressional recognition regarding the value of NCATS, resulting in a proposed NCATS budget increase of $14 million (M).

Updates to NIH peer review. The NIH peer review process has been modified, and new guidance has been provided to address the backlog of applications caused by the government shutdown. Grant applications are scored based on three criteria. Evaluation of the combined investigator(s) and environment criterion results in a binary score to ensure that Early Stage Investigators (ESIs) who have access to institutional resources for conducting the research are not at a disadvantage. Review meetings will discuss the top one-third of applications. The second third will be considered "competitive but not discussed," and the bottom third will be "not discussed." The top two-thirds (those that are scored and those that are competitive but not discussed) may be considered for potential funding. All applications will receive summary statements.

Grants policy updates. NIH has terminated grants that do not align with the current administration's priorities. Dr. Bhattacharya highlighted that investigators should clearly articulate the alignment of their research with NIH's mission to advance health. Common forms have been implemented for investigator biosketches. Compliance expectations for aim, title, and abstract revisions have been reinforced.

NIH Unified Funding Strategy. Funding strategies in recent years have become averse to risk. Institute, Center, and Office (ICO) Directors will make funding decisions to ensure the research portfolio includes innovative research that has the potential to transform the field if successful. Paylines have been removed for transparency and to allow ICOs to consider all peer-review feedback in combination with strategic priorities when making funding decisions.

NIH policy modernization. Policies are being simplified to support innovation, minimize investigator burden, and streamline applications and funding processes. Letters of intent have been removed from the application process; investigators do not need to seek permission to apply for budgets over $0.5 M; and notices of funding opportunities (NOFOs) are being centralized and simplified. Highlighted topics will clearly indicate Institute/Center (IC) priorities. Dr. Bhattacharya noted that NIH is open to investigator suggestions and feedback regarding how to maximize modernization.

Conclusion

Dr. Bhattacharya noted that short-term goals include scaling successful translational models, integrating AI and emerging technologies, and building large data resources that support the research community.

Long-term goals include implementing efficient translational systems, modifying the research culture toward replication and collaboration, and aligning research with NIH-wide and IC strategic goals. Achieving these goals will result in better health for people.

Discussion

Robin J. Mermelstein, Ph.D., commended the focus on health of the population and reiterated that NCATS plays a fundamental role in accelerating translation to ensure advancements are provided to the community. She emphasized that life expectancy represents a mean for the total population. Precision medicine approaches should be tailored to the needs of different populations. Dr. Mermelstein requested clarification on whether research and language that focus on specific populations is acceptable. Dr. Bhattacharya explained that he is committed to improving the health of minority populations, and NIH will support research that focuses on health outcomes and actionable results for practitioners to use. He noted that broad population health is achieved by tailoring research and medicine to different populations.

Sergio A. Aguilar-Gaxiola, M.D., Ph.D., appreciated that NIH is committed to improving the health of all populations, including minority populations. To do this effectively, it is critical to meaningfully engage the community. He highlighted that NCATS has successfully done this while creating the NCATS Strategic Plan 2025–2030. Dr. Aguilar-Gaxiola requested that Dr. Bhattacharya comment on community engagement efforts for NIH initiatives. Dr. Bhattacharya agreed that community engagement is critical and provided examples. American Indian populations want to be involved in research rather than being studied by others, and implementation science strategies should be culturally sensitive to effectively reduce HIV transmission.

Dr. Bhattacharya noted that individuals could reach out to him through email with additional questions.

III. DIRECTOR'S REPORT PRESENTATION AND DISCUSSION: Joni L. Rutter, Ph.D., Director, NCATS, Chair, NCATS Advisory Council

Joni L. Rutter, Ph.D., began by summarizing the discussions from the September 2025 Advisory Council meeting. After this review of the previous meeting, Dr. Rutter provided updates regarding leadership changes, and she highlighted recent news and announcements. Dr. Rutter shared engagement updates, described implementation of the (NCATS Strategic Plan 2025–2030, emphasized outcomes of rare disease efforts, and reviewed challenges with strategic transitions.

NCATS Staff Changes

Dr. Rutter outlined recent changes in NCATS leadership. Danilo Tagle, Ph.D., Director, Office of Special Initiatives (OSI), has retired. Cristine Colvis, Ph.D., Director, Office of Drug Development Partnership Programs, is serving as the Acting Director of OSI. Dr. Rutter expressed her appreciation to Dr. Colvis for assuming this additional leadership position within NCATS.

News and Announcements

Dr. Rutter highlighted recent NIH and NCATS-specific announcements and events.

NCATS Budget

NCATS currently is operating under a continuing resolution for fiscal year 2026 (FY26). The appropriations bills for FY26 provide a $14 M increase for NCATS, of which $10 M will be allocated to the rare diseases research portfolio and $4 M to the National Clinical Cohort Collaborative (N3C) program.

NIH News

NIH Unified Funding Strategy. NCATS continues to ensure that proposed research aligns with its strategic priorities, supports the NIH-Wide Strategic Plan, displays strong scientific merit, and has program relevance. NCATS confirmed that funding decisions provide program balance and support a variety of different disciplines. Dr. Rutter emphasized the importance of the peer review process and noted that the reviewers' scores and comments are considered during funding procedures. NCATS already utilizes many of the tenets of the NIH Unified Funding Strategy to inform funding decisions, which demonstrates the Center's alignment with the administration's requested changes.

Multi-year funding. If the scope of multi-year funding is extended to include large-scale programs, including the Rare Diseases Clinical Research Network and Clinical and Translational Science Awards, these initiatives would be negatively impacted. Multi-year awards are funded in full at the start of the project period from a single fiscal year's appropriations. This constraint would result in NCATS supporting fewer awards and researchers. NCATS is evaluating the impact of this potential requirement for FY26.

Foreign subawards. NCATS and NIH remain committed to supporting international scientific collaboration with foreign scientists when research is aligned with U.S. interests. A new application and award structure—the PF5 funding opportunity—has been implemented. Dr. Rutter emphasized the importance of international collaborations for rare diseases research. The international component is structured as an independent sub-project to provide accountability to the American public.

Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR). Legislative authority for the SBIR and STTR programs expired on October 1, 2025. Until authorization is renewed, NCATS cannot publish NOFOs, accept applications, or offer new or noncompeting continuation awards. Currently active grants and contracts are not affected by the expired legislative authorization.

Quick-response (QR) codes. Dr. Rutter highlighted QR codes to webpages that will help the community easily access relevant information, including funding opportunities and notices of NIH policy changes.

External and Internal NCATS Engagement

Dr. Rutter highlighted NCATS activities that involved congressional staff. On September 5, 2025, a group of congressional staff members from the offices of Senators John Boozman, Shelley Moore Capito, and Mike Rounds, as well as Representative Diana DeGette, toured the NCATS laboratories. Dr. Rutter expressed appreciation to NCATS staff for organizing the tour.

NCATS has been involved in Capitol Hill briefings, including the Rare Disease Congressional Caucus, which is chaired by Representative Gus Bilirakis. NCATS was invited to speak with the GOP Doctors Caucus about the center's role in drug repurposing and use of AI. Dr. Rutter noted that these conversations allow Congress to understand the importance of NCATS' initiatives.

NIH leadership toured the NCATS laboratories. This tour provided intramural program staff and trainees with an opportunity to have an interactive discussion with NIH leadership. The NCI Director and NCI

Chief Science Officer were provided with a tour of the NCATS laboratories. Dr. Rutter commented that NCATS has overlapping interests with the National Cancer Institute in New Approach Methodologies (NAMs) for precision medicine. An exchange tour with REGENXBIO was conducted to foster future partnerships in gene target therapies.

Rare Disease Initiatives

Dr. Rutter highlighted rare disease efforts at NCATS and their impact on the community.

Personalized Gene Editing. KJ Muldoon was selected as one of *Nature's* top ten people who helped shape science in 2025. KJ is a baby who was the first in human study to receive a hyper-personalized CRISPR gene-editing therapy, demonstrating the potential benefit of personalized therapies for treating a wide range of disorders.

Building Evidence and Collaboration for GenOmics in Nationwide Newborn Screening (BEACONS). NCATS has collaborated on an NIH Common Fund Venture Initiative with the National Human Genome Research Institute (NHGRI) and the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD) to the BEACONS program. This program will assess the feasibility of incorporating whole-genome sequencing into U.S. public health newborn screening programs through partnerships with state public health laboratories. Dr. Rutter emphasized the importance of whole-genome screening to find rare mutations in newborns.

Biomedical Data Translator Program. The broader scientific community is using NCATS' Biomedical Data Translator tool, called "Translator" for short, for their research and clinical efforts.

- **Baby Functional Omics Resource (BabyFORce).** Mayo Clinic has launched BabyFORce, which uses Translator to interpret identified variants and uncover targeted therapeutics for neonatal intensive care unit patients. Jorie Kraus was a patient suffering from a WW domain-containing adaptor with coiled coil (WAC) protein-induced disorder. Clinicians identified a potential treatment, and Jorie's WAC protein levels have been restored to normal levels using this treatment.

Rare Disease Clinical Research Network (RDCRN). The RDCRN has overcome several challenges to establish its fifth cohort. Because of administrative challenges, the cohort is split into two subgroups across two funding cycles. Dr. Rutter appreciated the teamwork and flexibility shown by the RDCRN community and ICO partners throughout this process. To achieve faster diagnosis and better treatments for rare disease patients, 21 research teams are collaborating with the RDCRN.

Oligonucleotide Toxicity Open Data Challenge. NCATS announced a prize competition to reward and foster effective approaches in predicting toxicity for antisense oligonucleotide technology. The competition was launched on December 10, 2025. The second phase will be launched on May 1, 2026.

Translational Science Education and Training Challenge. NCATS announced a prize competition in 2024 to reward and spur innovative strategies that develop a robust translational science workforce. The competition was launched on September 30, 2024, and the submission deadline for year 1 was April 30, 2025. The winners were New York University Langone Health's Clinical and Translational Science Institute, the Physicians Committee for Responsible Medicine, University of Minnesota, and Washington University School of Medicine. Dr. Rutter expressed excitement at disseminating the future findings from these efforts to the translational science community.

Quantum Biomedical Innovations and Technologies Program Challenges (Qu-BIT). NCATS announced two prize competitions in 2024 to advance the use of quantum computing and sensing in translational science. The competitions were launched in September 2024. Ten stage 1 winners for the quantum computing challenge have been selected in three topic categories: imaging and genomics, clinical predictions, and drug discovery. Twelve stage 1 winners have been selected to test quantum-enabled sensing and imaging methods that detect and diagnose a variety of different health outcomes. Dr. Rutter expressed appreciation to NCATS staff for coordinating these efforts.

Complement Animal Research in Experimentation (Complement-ARIE). NCATS co-leads this program to catalyze the development and use of NAMs in basic, translational, and clinical science. The incorporation of *in silico* and *in chemico* methods is of interest. The program launched the Reduction-to-Practice Challenge on September 30, 2025, and the submission deadline is March 1, 2026. Winners will be announced in July 2026. This challenge will deliver prototypes of innovative combinatorial NAMs to the Validation and Qualification Network for further evaluation.

N3C Strategic Transition

NCATS is committed to providing the National Clinical Cohort Collaborative (N3C) platform to the research community and recognizes that it is a powerful and unique resource. The center has overcome significant challenges to reopen access to the N3C platform. Dr. Rutter recognized the community's frustration from the lack of access. She briefly outlined events related to N3C hurdles. The N3C platform went offline on September 27, 2025. While N3C was unavailable, researchers could not access their data, complete analyses, or continue publication processes. Researchers were able to briefly access their data December 1–12, 2025. The new N3C platform was internally launched on January 12, 2026, and it will be available to the public in February 2026.

The N3C disruption occurred because of U.S. Department of Health and Human Services (HHS) efforts to consolidate platforms. During the government shutdown, NCATS staff securely backed up 80 terabytes of harmonized health data and code—more than 1,000 research projects—to the NCATS N3C Data Enclave. N3C data remain under the exclusive management of NCATS to ensure the data are safe, secure, and private. NCATS worked closely with HHS and NIH leadership to rapidly resolve these challenges.

Dr. Rutter emphasized that the N3C disruption resulted in several positive outcomes, including the development of an access dashboard, creation of communication materials, and facilitation of a technical meeting to discuss future efforts. N3C has increased visibility across HHS and Congress, which has resulted in an additional $4 M in funding appropriations for FY26. Developing N3C and making it sustainable took five years of collaboration among hundreds of researchers, clinicians, data scientists, and institutional partners. NCATS is developing a strategic partners workgroup composed of key stakeholders from the external community to guide future strategies for scaling N3C.

NCATS Strategic Plan 2025–2030

The NCATS Strategic Plan 2025–2030 was published in September 2024, and NCATS leadership is planning to hold an implementation retreat in January 2026. NCATS' implementation efforts will generate and track evidence to measure progress, which in turn will guide NCATS operations. The framework for NCATS' implementation efforts focuses on three main activities. NCATS has developed

eight center-wide outcome measures of success around the strategic plan goals. NCATS is considering methods to efficiently monitor progress, such as tracking and reporting tools, and creating a central dashboard to effectively communicate progress and disseminate important information to the public. Dr. Rutter noted that more information on this topic is forthcoming.

Upcoming Events

Dr. Rutter highlighted Rare Disease Day at NIH. The event will be held on February 27, 2026. This event features panel discussions, rare disease stories, scientific posters, and an art exhibition. Rare Disease Day brings together a broad range of individuals, including clinicians, patients, patient advocates, and researchers.

Discussion

Sergio A. Aguilar-Gaxiola, M.D., Ph.D., commented that the follow-up information regarding the proposed implementation of the strategic plan was beneficial. He noted the importance of NCATS' community engagement and applauded the roundtable listening sessions. He looks forward to receiving updates on NCATS' progress in implementing the strategic plan. Dr. Rutter replied that NCATS' success is because of the coordination efforts of NCATS staff. She added that roundtable discussions with a broad range of communities are extremely valuable for disseminating NCATS updates and receiving feedback.

Robin J. Mermelstein, Ph.D., appreciated the comprehensive report and thanked the NCATS staff for supporting the research community through recent hurdles. She commended NCATS' efforts to engage numerous institutional leaders rather than selecting a limited number of researchers. Dr. Rutter agreed that including institutional leadership and principal investigators in conversations is important. These engagement efforts hopefully will expand intra-institutional and inter-institutional relationships in translational science.

Jonathan Himmelfarb, M.D., complimented NCATS staff for their efforts and for developing a clear direction for implementing the strategic plan. Dr. Rutter responded that NCATS was methodical and invested time to develop a thorough implementation strategy that is adapted to the recent administrative changes.

IV. PROGRAM UPDATE PRESENTATION AND DISCUSSION: Office of Drug Development Partnership Programs (ODDPP): Christine M. Colvis, Ph.D., Director, ODDPP, NCATS; Acting Director, Office of Special Initiative (OSI), NCATS

Christina M. Colvis, Ph.D., provided an update on ODDPP activities. Dr. Colvis highlighted efforts to address bottlenecks within the research pipeline to promote translational efficiency. Under the Illuminating the Druggable Genome (IDG) program, R03 grants were awarded to researchers to expand the rare disease target landscape, and she provided examples of funded cutting-edge research projects.

Expanding the Target Landscape

Dr. Colvis presented on efforts within the IDG program to explore understudied druggable proteins. She highlighted Karlie Sharma, Ph.D. who oversaw the small grants program and had given a recent update on them. These small grants provide $0.1 M in direct costs to researchers for one year to investigate G protein-coupled receptors (GPCRs), ion channels, and protein kinases that had limited literature available. From FY19 to FY23, 98 grants were awarded, and 29 awards went to Early Stage Investigators

(ESIs) and new principal investigators. The awardees have published 143 publications, and approximately 30% of awardees went on to obtain follow-on awards such as research project grants.

In FY23, the IDG program launched an R03 pilot project opportunity focused on understudied proteins associated with rare diseases. Since this pilot project began, 27 grants have been funded, and 5 of these grantees have obtained follow-on awards to continue their research endeavors. Awardees have published 12 publications.

- **R03 Awardee.** Dr. Colvis highlighted Benjamin Myers, Ph.D., The University of Utah, who previously observed kinase regulation from a GPCR. His proposed research focused on developing a new functional screen to systematically identify GPCRs and kinase interactions to reveal new signaling paradigms and potential therapeutic targets.

- **Rare Disease R03 Awardee.** Mortimer Poncz, M.D., Children's Hospital of Philadelphia, focused on familial platelet disorder with associated myeloid malignancy (FPDMM). FPDMM affects approximately 130 individuals, and 40% of these patients will develop myelodysplastic syndromes or acute myeloid leukemia. No treatments are available for patients with FPDMM. Dr. Poncz collaborated with the National Center for Advancing Translational Sciences (NCATS) intramural program to obtain a proof of concept R21 exploratory research grant, under RFA-TR-25-002, to test the efficacy of a small molecule inhibitor, RepSox, and its analog in a preclinical model of FPDMM.

Awards Supporting Cutting-Edge Technologies for Translational Science (ASCETTS) Program

The ASCETTS program is focused on developing innovative technologies to overcome costly and time-consuming limitations in therapeutic development. The program includes special provisions in the application instructions to ensure technologies are brought to the market.

- **Total Inhalable Deposition in an Actuated Lung (TIDAL).** This project, led by Catherine A. Fromen, Ph.D., University of Delaware, has developed a full-volume, pulmonary deposition 3-D printed lung model to understand regional infiltration of inhalable therapeutics. The structural architecture of the 3-D model can be customized to a specific patient or patient population.

LitCoin and Lit2Graph

Knowledge graphs (KGs) explain the relationships between two or more entities. KGs are machine-readable, reusable, and portable; they enable inference; and the connections between entities are robust and traceable. Dr. Colvis provided a family tree as a KG example to provide context on how a KG is developed.

A research team at the Hugh Kaul Precision Medicine Institute, The University of Alabama at Birmingham used Translator to treat an adolescent patient with SHINE syndrome. Translator connected Discs Large Membrane Associated Guanylate Kinase Scaffold Protein 4 (DLG4) and alpha-2A adrenergic receptor and identified guanfacine as a potential treatment. Large Language Models (LLMs) would not be able to identify guanfacine as a drug to upregulate DLG4 because information is limited and direct connections between these molecules have not been identified, which highlights the importance of KGs in such research areas as rare diseases. This program is focused on building KGs from mining information

in literature, and these KGs will help researchers design studies and identify new research opportunities to explore.

Discussion

Jonathan Himmelfarb, M.D., commented that one challenge is the assumption that all publications are reproducible. Using publications that are not reproducible may affect the knowledge graph outputs. He cautioned NCATS to consider this when assembling the medical literature. Dr. Colvis explained that researchers can review the sources of the results generated by Translator to determine whether they agree with the inferences. LitCoin will utilize published research findings, which include experiments to confirm reproducibility, to help researchers extract information that is relevant to their query. She highlighted that these KGs are tools to help researchers, but the researchers make the final decision.

Sergio A. Aguilar-Gaxiola, M.D., Ph.D., remarked that the family tree example used by Dr. Colvis to explain KGs was effective. He appreciated that LitCoin is a tool that uses AI to identify patterns that connect entities.

V. CLEARANCE OF CONCEPTS: Presentation and Discussion

The Council received presentations on two concepts that National Center for Advancing Translational Sciences (NCATS) is considering issuing. After each presentation, the members discussed the concepts and voted on whether NCATS should move forward with the initiatives. Discussants for the concepts were assigned prior to the meeting.

Introduction of Office of Drug Development Partnership Programs (ODDPP) Concept: Christine M. Colvis, Ph.D., Director, ODDPP, NCATS; Acting Director, Office of Special Initiative (OSI), NCATS

Christine M. Colvis, Ph.D., introduced a concept for clearance that she had presented in the preceding session. She noted that the program has two main parts: LitCoin and Lit2Graph. LitCoin focuses on implementing a new publication format that incentivizes the sharing of robust research findings and case reports, which includes miscellaneous results, negative results, and replication studies. Lit2Graph generates Knowledge graphs (KGs) from existing literature. Dr. Colvis provided a brief overview of previous efforts related to the concept.

LitCoin and Lit2Graph: Piloting the LitCoin System with Open-Source Publishers: Tyler F. Beck, Ph.D., Program Director, ODDPP, NCATS

Tyler F. Beck, Ph.D., presented a concept on LitCoin and Lit2Graph that enables synthesis of knowledge from rare disease publications. This initiative is aligned with four of the five NCATS strategic goals. Dr. Beck explained that knowledge within publications is not ready for AI use; PubMed is not integrated with a knowledge network; and most rare disease information originates from case reports and unique publications. He explained that this program will make rare disease data ready for AI use to accelerate patient treatment. Dr. Beck presented an example using corticosterone and Fraser extracellular matrix complex subunit 1. PubMed and ChatGPT are unable to identify the connection between these two entities because direct connections have not been published in the literature.

Dr. Beck discussed pilot phase progress. Modifications to the LitCoin Large Language Models (LLM) to improve abstract intake have been completed, and approximately 2,300 publications related to the NIH Helping to End Addiction Long-Term® Initiative have been ingested by the LLM. The resulting KG and

curation dashboard have been transferred to NCATS. After deployment and testing on NCATS' cloud services are complete, LitCoin will be paused indefinitely until funding is obtained.

Program aims include making the LitCoin knowledge extraction pipeline accessible to the research community, ensuring that rare diseases publications are in the KG before integrating all PubMed abstracts, and supporting automated graph figure generation from extracted KGs. The curation dashboard will allow authors to validate and modify the generated knowledge assertions for accuracy. The LitCoin program enables researchers to reveal novel connections within the data and quickly identify new potential treatments for patients. NCATS plans to partner with PubMed and open-access publishers to ensure widespread use of this resource.

Discussion

Jonathan Himmelfarb, M.D., noted several potential limitations for the program. He explained that research findings that demonstrate a proposed connection between variables are more likely to be published than if the findings point to no connection, creating a positive publication bias in the literature. In addition, high-impact studies are not consistently reproducible, and the quality of abstracts can vary. Some abstracts may not include the relevant details or may make assertions that are not supported by the study results. In addition, abstracts do not include metadata needed for reproducibility. Dr. Himmelfarb emphasized that not all published data should be considered equal, and that is a concern when integrating the data into KGs. He concluded that the KGs are useful for generating hypotheses and will support investigators to develop hypothesis-driven ideas, especially for rare diseases research. Dr. Beck clarified that the KGs will support researchers in developing hypotheses and will help in extracting information from literature. He noted that the variable quality of abstracts depends on several factors, including the formatting requirements of the journal. The goal is to extract the main ideas from the abstracts and connect researchers to the publications for additional details. A future objective is to expand the KGs to include the full text from publications. Joni L. Rutter, Ph.D., questioned whether guardrails could be implemented to help reduce these concerns. Dr. Beck agreed that guardrails could be implemented into the program moving forward.

Sergio A. Aguilar-Gaxiola, M.D., Ph.D., appreciated the presentations, which were helpful for understanding the proposed concept. He highlighted that the meeting is open to the public, so NCATS should emphasize how the program aligns with strategic goals and initiatives. Dr. Beck explained that the proposed program aligns with four of the five strategic goals. LitCoin will empower researchers to contribute to translational science, and it will leverage crosscutting strategies. Dr. Aguilar-Gaxiola expressed concern over the concept title. LitCoin sounds similar to Bitcoin, although the two are not connected. He understands the importance of piquing curiosity and communicating the concept to the public. However, he suggested that the name be revised and recommended that NCATS conduct a focus group with different audiences to identify a better name for the program. Dr. Beck explained that the LitCoin title was developed from the idea that this is a smaller currency for literature but agreed that the name could be changed. Dr. Colvis explained that the concept title has received mixed reviews. She does not want it to be a barrier for the program, so she agreed it could be changed. Dr. Rutter appreciated the feedback.

Members unanimously approved the LitCoin and Lit2Graph concept.

Introduction of Division of Clinical Innovation (DCI) Concept: Michael G. Kurilla, M.D., Ph.D., Director, DCI, NCATS

Michael G. Kurilla, M.D., Ph.D., provided an overview of the NCATS Division of Clinical Innovation (DCI) and the Clinical and Translational Science Award (CTSA) Program. DCI focuses on innovating clinical and translational science through several approaches, such as supporting training programs that are relevant to clinical phases of translational science. The CTSA Program supports DCI's initiatives through several grant mechanisms, and the program provides single-site, multisite, and consortium-level awards. The R03 Small Grant Program will support Early Stage Investigators (ESIs).

Limited Competition: Small Grant Program for the NCATS Clinical and Translational Science Award (CTSA) Program: Patrick H. Brown, Ph.D., Chief, Education and Training Section, DCI, NCATS

Patrick H. Brown, Ph.D., presented a renewal concept for the Small Research Grants for the CTSA Program initiative. The NCATS Director's message in the NCATS Strategic Plan 2025–2030 highlights three key needs for translating science into practice more effectively. He explained that this program helps to address those needs by developing and sustaining a research workforce of physician–scientists and scientists skilled in clinical and translational science. Current CTSA Programs support institutional cohort-based training efforts, whereas the proposed renewal concept would fund individual investigators to complete smaller translational science research projects. The research projects will address translational efficiency and efficacy roadblocks, promote innovative solutions, and result in preliminary data that would help former K scholars transition from mentored training to independent research. To align with administration priorities, diversity re-entry reintegration supplement recipients are not eligible.

The NCATS Advisory Council approved this concept in September 2020, and awards were issued in FY22. The maximum awarded budget was $50,000 in direct costs, and the project period was two years. The primary objective was for awardees to submit an R01 or equivalent grant application using R03 data. NCATS awarded 31 R03 grants with an overall award rate of 34%. Dr. Brown highlighted that 100% of FY22 awardees submitted a subsequent R01-equivalent grant application, and approximately one-third were successful in obtaining this additional funding. He emphasized that the program is supporting a broad translational workforce based on comparable funding rates across physician–scientists and scientists. Dr. Brown shared two examples of previous R03 awardees, Olena Taratula, Ph.D., Oregon State University, and Moises A. Huaman, M.D., University of Cincinnati, who received R01 grants from the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development and the National Heart, Lung, and Blood Institute, respectively, following completion of the R03-funded research.

Dr. Brown noted that the proposed modification is to increase the direct cost budget to $75,000. Objectives of the renewal concept are to increase interest among former CTSA K scholars in applying for small research grants, sustain a high level of subsequent submissions of research project grant applications, and improve the proportion of awardees who successfully obtain subsequent funding. Key focus areas are to provide commensurate funding to awardees, support awardee navigation through the NIH grant submission process, and ensure research projects continue to align with NCATS' priorities. He explained that the program is aligned with the NCATS Strategic Plan 2025–2030 and the NIH Unified Funding Strategy to train future biomedical scientists.

Discussion

Robin J. Mermelstein, Ph.D., commended the concept and emphasized its importance for scholars. In response to a query from Dr. Mermelstein, Dr. Brown explained that K scholars can apply for the R03 grant during their second year of the KL2/K12 training program. Dr. Mermelstein requested additional clarification regarding the program eligibility criteria. Dr. Brown commented that applicants cannot have an R01 award, but they can submit proposals for several grant opportunities simultaneously.
Dr. Mermelstein noted the R03 grant would be useful if applicants need to gather additional data to support their R01 application. She continued that the proposed concept was beneficial and would support trainees in successfully obtaining R01 awards.

Sergio A. Aguilar-Gaxiola, M.D., Ph.D., emphasized the success of the program as observed by the outcomes and return on investment, and he agreed with the proposed budget increase.
Dr. Aguilar-Gaxiola noted that there was a discrepancy between the concept clearance worksheet and presentation. The worksheet discusses concept applicability to all five NCATS strategic goals, but the presentation did not address how the concept applies to goal 5. Dr. Brown explained that the concept is aligned with Goals 1, 2, 3, 4, and 5 of the *NCATS Strategic Plan 2025*–2030. Dr. Aguilar-Gaxiola noted that Goal 5 focuses on championing effective stewardship of translational science through transparency, integrity, and accountability. If this presentation will be used elsewhere, he recommended that the presentation slide include this goal because of its importance to the public.

Jonathan Himmelfarb, M.D., noted his support for R03 programs and that it is an important funding mechanism to help researchers obtain an R01 grant. He questioned whether this program would be accessible to K-funded scholars from other NIH ICOs. Dr. Brown explained that this is a closed competition and only available to current and former NCATS CTSA K scholars. In response to a question regarding overlap of the KL2/K12 and R03 funding, Dr. Brown clarified that scholars cannot have the two awards simultaneously. He recommended that scholars apply at a time that would not cause them to terminate the K award prematurely.

Members unanimously approved the CTSA small grant program concept.

VI. PUBLIC COMMENTS

A comment was received from the Physicians Committee for Responsible Medicine. Joni L. Rutter, Ph.D., explained that the comment focuses on strategies to advance human-based research at the NIH, collaborations with the Center for Scientific Review to increase the pool of New Approach Methodologies (NAMs) experts in review groups, and to partner with other ICOs to develop NAMs infrastructure. Dr. Rutter noted that NAMs are a research priority and growth in this research area at NIH will occur.

Comments from the public were accepted until February 13, 2026 (15 days after the meeting) and will be appended to the minutes.

VII. ADJOURNMENT OF THE OPEN MEETING

Joni Rutter, Ph.D., thanked the participants for their input. The next meeting is scheduled for May 21–22, 2026, and is planned as an in-person session. Dr. Rutter adjourned the meeting on January 29, 2026, at 4:45 p.m. EST.

VIII. CERTIFICATIONS

We hereby certify that, to the best of our knowledge, the foregoing minutes and supplements are accurate and complete.

Joni L. Rutter, Ph.D. — Date
Chair, NCATS Advisory Council
Director, National Center for Advancing Translational Sciences, NIH

Anna L. Ramsey-Ewing, Ph.D. — Date
Executive Secretary, NCATS Advisory Council
Director, Division of Extramural Activities, NCATS