U.S. Department of Health and Human Services
National Institutes of Health
National Center for Advancing Translational Sciences
40th Meeting of the
Advisory Council

Minutes of Meeting
September 18, 2025

The National Center for Advancing Translational Sciences (NCATS) Advisory Council held a meeting in open session on September 18, 2025, from 1–5:04 p.m. ET, 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 117-286, the session was open to the public.

Prior to the meeting, the NCATS Advisory Council met in closed session on September 18, 2025, from 11a.m. to 12 p.m. ET, for the review and consideration of grant applications.

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, NCATS

Council Members

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

***Ad Hoc* Council Members**

None present

Ex Officio Members

None present

Others Present

NCATS leadership and staff

I. CLOSED SESSION OF THE NCATS ADVISORY COUNCIL

This portion of the Advisory Council meeting was closed to the public in accordance with the provisions of Public Law 117-286.

Advisory Council members discussed procedures and policies regarding voting and the confidentiality of application materials, committee discussions and recommendations. Members did not participate in the discussion of and voting on applications from their own institutions or other applications in which there was a potential conflict of interest, real or apparent.

Review of Grant Applications

The Council reviewed 77 research, research-related and training grant applications with primary assignment to NCATS for a requested amount of $82,762,439 in first-year direct costs. The Council concurred with the recommendations of the initial review groups. For the record, it is noted that applications with secondary assignment to NCATS were also considered.

II. ADJOURNMENT OF CLOSED SESSION OF THE NCATS ADVISORY COUNCIL MEETING

Joni L. Rutter, Ph.D., adjourned the closed session of the NCATS Advisory Council meeting on September 18, 2025, at 1 p.m. ET.

III. CALL TO ORDER, OPEN SESSION

Joni L. Rutter, Ph.D., called the meeting to order and welcomed members and guests to the 40th meeting of the 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.

IV. 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:

- January 29–30, 2026 (virtual meeting)
- May 21–22, 2026
- September 17–18, 2026
- January 28–29, 2027 (virtual meeting)
- May 20–21, 2027
- September 16–17, 2027

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

Joni L. Rutter, Ph.D., began by expressing appreciation to NCATS staff for their efforts in obligating the NCATS budget over the past several months. She summarized the discussions from the April 2025 Advisory Council meeting, which focused on the new administration and priorities, the new NIH director, NIH and NCATS staffing changes, the fiscal year 2025 (FY25) budget continuing resolution and the President's budget, and congressional briefings. During the meeting, several impactful advances also were highlighted: the renaming of the National COVID Cohort Collaborative (N3C) to the National Clinical Cohort Collaborative, NCATS' contributions to Investigational New Drug clearances and New Drug Application approvals, a Common Fund Venture proposal for the Newborn Screening by Whole

Genome Sequencing Collaboratory and the NIH Quantum Biomedical Innovations and Technologies (Qu-BIT) program.

NCATS News and Announcements

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

- **Personalized gene editing.** A first-in-human study, published in May 2025, demonstrated potential for personalized gene-editing treatments for a wide range of disorders. This work was supported by the Somatic Cell Genome Editing (SCGE) program. Researchers developed a customized lipid nanoparticle–delivered base-editing therapy to treat severe carbamoyl phosphate synthetase 1 deficiency, a disease with an estimated 50% mortality in early infancy.
- **SCGE–U.S. Food and Drug Administration (FDA) regulatory interactions.** The SCGE program is creating guides for interactions between SCGE investigators and FDA. These guides are intended to help foster more productive discussions. This effort also is intended to help FDA become more familiar with SCGE's programs and approaches. Publications on this topic are forthcoming and will provide a resource for the scientific community. These efforts reflect the SCGE program's notable progress since its initiation.
- **NCATS in the news.** NCATS' rare diseases research recently was featured in *Newsweek*. The article, "Research Moves Slowly. Rare Diseases Don't—So Patients Aren't Waiting," focused on opportunities for patients and families to partner with researchers to enable progress on their rare diseases. NCATS speeds the development of new rare disease treatments by focusing on approaches that can address more than one disease at a time.
- **Rare Diseases Are Not Rare! 2025 Challenge.** NCATS announced a prize competition to reward and spur innovative approaches for effectively communicating with and educating people about the broad spectrum of rare diseases using simple, widespread communication vehicles. The competition was launched on September 15, 2025, and the submission deadline is January 2, 2026. Winners will be announced in February 2026.
- **Charles A. Sanders, M.D., Partnership Award.** The Foundation for the National Institutes of Health (FNIH) awarded the 2025 Charles A. Sanders, M.D., Partnership Award to NCATS. The Partnership Award recognizes people or organizations that have made significant contributions to FNIH's work in support of NIH's mission. Dr. Rutter expressed appreciation to NCATS staff for their collaborative efforts.
- **Congressional staff tour of NCATS laboratories.** A group of congressional staff members from the offices of Senators Shelley Capito, John N. Boozman, and Mike Rounds, as well as Representative Diana L. DeGette, recently toured the NCATS laboratories. Dr. Rutter expressed appreciation to NCATS staff for organizing the tour and noted that similar activities may be planned in the future.

NCATS Staff Changes

Dr. Rutter recognized Dominique C. Pichard, M.D., who recently stepped down as the director of NCATS' Division of Rare Diseases Research Innovation (DRDRI). PJ Brooks, Ph.D., is serving as the acting director of DRDRI. Dr. Rutter also noted that Gregory P. Jarosik, Ph.D., recently retired as deputy director of NCATS' Division of Extramural Activities (DEA). B. Duane Price, Ph.D., is serving as the acting deputy director of DEA.

Dr. Rutter also noted that three NCATS staff, Jennifer M. Beierlein, Ph.D., Stephen G. Seidel and Jessica C. Walrath, Ph.D., are being transferred to the NIH Office of Legislative and Public Affairs. She explained that this change is part of a larger process to centralize NIH's policy efforts.

NCATS Budget

The House and Senate appropriations bills for FY26 have passed committees but not the full chambers. The House bill proposes flat funding for NCATS, and the Senate bill proposes a $10 million increase directed at rare diseases. The House bill also dictates that $75 million be spent on the National Clinical Cohort Collaborative (N3C) program. Dr. Rutter noted that she will provide an update on the FY26 budget at the next Advisory Council meeting.

NCATS Strategic Plan 2025–2030

The *NCATS Strategic Plan 2025–2030* was published in September 2024, and NCATS leadership held an implementation retreat in November 2024. NCATS' implementation efforts will include developing center-wide outcome measures of success around the Strategic Plan goals, as well as using goal outcome measures to drive NCATS operations. Dr. Rutter noted that more information on this topic is forthcoming.

NCATS Program Updates

Dr. Rutter provided an update on NCATS programs and research outcomes.

- **A new way to discover drugs.** NCATS researchers recently published "A General Assay Platform to Study Protein Pharmacology Using Ligand-Dependent Structural Dynamics" in *Nature Communications*. This approach is effective for identifying "undrugged targets." This assay platform is generalizable and can be used to discover molecules that bind to purified proteins or proteins in cellular contexts. Multiple pharmaceutical companies have used the technique.
- **Tissue chips to fly on Artemis II.** NCATS-supported tissue chips will be part of the Artemis II launch, representing a partnership among NCATS, the National Aeronautics and Space Administration (NASA), and the Biomedical Advanced Research and Development Authority (BARDA). The tissue chips will be used to study the effects of increased radiation and microgravity on human health.

NIH Priorities

Jayanta Bhattacharya, M.D., Ph.D., NIH director, recently released a statement on Advancing NIH's Mission Through a Unified Strategy. This statement identified a list of NIH priorities. Dr. Rutter commented that several of these priorities are notably important for NCATS' mission.

- **Training future biomedical scientists.** NCATS' Clinical and Translational Science Awards (CTSA) Program offers training opportunities for early career investigators. K-award recipients from this program demonstrate increased success in subsequent NIH funding compared with K-award recipients from other programs.
- **Replication and reproducibility.** NCATS' *Assay Guidance Manual* program is a valuable resource for many assays and experimental designs. This resource is helping to advance replication and reproducibility in biomedical research. The CTSA Program is helping organize a symposium on the science of reproducibility of real-world data, which will further progress in this space across the field.

- **Artificial intelligence (AI).** NCATS is advancing AI research in many areas, and the CTSA Program is supporting the development of new AI models. NCATS also contributes to the NSF National Artificial Intelligence Research Resource Pilot.
- **Real-world data platforms.** The N3C program plays a key role in determining the future of real-world data at NIH, with considerations of many types of data and a robust governance structure.
- **Nutrition.** The CTSA Program is examining nutrition and diet from various perspectives, including weight loss, cardiometabolic health and type 2 diabetes.
- **Furthering understanding of autism.** The CTSA Program has contributed to autism research and will continue to do so. Research topics have included audiovisual integration and reading comprehension in autistic and non-autistic school-age children, as well as theta activity at sleep onset in children with autism.
- **Solution-oriented approaches in health disparities research.** The CTSA Program and DRDRI are helping to advance NCATS' efforts in this area, including modeling the cost effectiveness of doula care and reductions in preterm birth and cesarean delivery, as well as detecting, characterizing and mitigating implicit and explicit racial biases in health care datasets.

NIH News

- **Funding information.** NIH's terminated grants can be viewed via the U.S. Department of Health and Human Services website. The NIH Grants and Funding Information Status webpage highlights information on applications, review, awards and other related information.
- **Multi-year funding.** The Office of Management and Budget required NIH to use 50% of its remaining competing research project grant funds for full-year funded competing awards. Multi-year funded awards are funded in full at the start of the project period from a single fiscal year's appropriations. Funding for future years, as well as effects on NCATS' funding success rate, currently is unknown.
- **Foreign subawards.** NCATS and NIH remain committed to supporting international scientific collaboration with foreign scientists when it is in the Nation's interest. These efforts must be conducted in a secure, justifiable and responsible manner. NIH is currently finalizing the implementation of a new award structure to provide accountability to the American public while continuing to enable important foreign collaborations to accelerate scientific discovery and improve the lives of all Americans. NIH also recently implemented a short-term solution that allows recipients to remove a foreign subaward involving human subjects from an existing award and renegotiate it as an administrative supplement.
- **New resource: Highlighted Topics.** NIH released a tool, Highlighted Topics, to inform the research community about NIH areas of scientific interest. This resource encourages investigator-initiated applications in those topic areas, which may include emerging areas. Highlighted Topics will help reduce effort to search and apply for funding opportunities. Researchers can search topics by keyword and filter by participating NIH institutes, centers and offices. Dr. Rutter noted that she is interested in feedback on this resource, which she will relay to NIH leadership.
- **Prioritizing human-based research.** NIH recently announced that it will no longer develop new funding opportunities based solely on animal models of human disease. New funding

opportunities involving animal models will be designed more broadly with language that also encourages various approaches to be considered. Researchers may propose any model that they deem appropriate, including a combination of approaches, to answer a research question. The goal of this effort is to accelerate progress, encourage innovation, and ultimately improve the quality and validation of new approach methodologies. Dr. Rutter noted that NCATS has been involved in this space for many years and will continue to contribute to NIH's progress in this area.

- **Supporting fairness and originality in NIH research applications.** NIH will not consider applications that are either substantially developed by AI, or that contain sections substantially developed by AI, to be original ideas of applicants. NIH will only accept six new, renewal, resubmission or revision applications from an individual principal investigator (PI) or multi-PI for all Council rounds in a calendar year.

Summary

Dr. Rutter summarized her presentation and highlighted rare diseases in the news, the congressional staff NCATS laboratory tour, the FY26 budget outlook, NCATS' strategic plan implementation, and NIH priorities and changes. Impactful advances include the role of the N3C program in NIH's Real-World Data Platform, the structural dynamics response assay, the first funded award of the Newborn Screening by Whole Genome Sequencing Collaboratory, the launch of the Rare Diseases Are Not Rare! 2025 Challenge and the upcoming tissue chips flight on Artemis II.

Discussion

Robin J. Mermelstein, Ph.D., requested clarification on the implementation of the new multi-year funding policy, particularly regarding larger programs (e.g., CTSA Program). Dr. Rutter replied that she is hopeful that the policy will not be applicable to this program, as NCATS' capacity to support the program would be significantly reduced.

Sergio A. Aguilar-Gaxiola, M.D., Ph.D., commended NCATS on its responsiveness to community feedback, particularly regarding its strategic planning activities. He noted that he looks forward to receiving updates on NCATS' progress in implementing its strategic plan. Dr. Rutter replied that this topic could be addressed at the next Council meeting. She noted that NCATS is ultimately striving to work in alignment with NIH's mission and vision.

Jonathan Himmelfarb, M.D., inquired about NCATS' most impactful upcoming activities. Dr. Rutter noted that the SCGE program's progress is particularly exciting, as it represents the confluence of many areas in which NCATS has been involved (e.g., extracellular vesicles, precision medicine, new approach methodologies). She added that the SCGE program will play a significant role in many areas, including rare diseases research and clinical trial design.

VI. PROGRAM UPDATE PRESENTATION AND DISCUSSION: Division of Clinical Innovation (DCI) Michael G. Kurilla, M.D., Ph.D., Director, DCI, NCATS

Michael G. Kurilla, M.D., Ph.D., provided an update on DCI activities and focused on the current state of the Clinical and Translational Science Awards (CTSA) Program. Dr. Kurilla highlighted the proposed NCATS appropriations for fiscal year 2026 (FY26). Under the UM1 mechanism, 10 new CTSA Program awards were awarded in FY25. A total of 65 CTSA Program awards are active, including cost extensions and no-cost extensions. Dr. Kurilla discussed alignment with agency priorities and remarked that the average cost reduction in CTSA Program awards was about 2%.

DCI Staff Updates

Dr. Kurilla presented a summary of staff updates for FY25; staff retirements include Kenneth R. Gersing, M.D., director of informatics; Robin M. Wagner, Ph.D., director, Office of Program Evaluation, Analysis, and Reporting; and David Wilde, M.D., program director, medical officer. New staff include Dale R. Burwen, M.D., M.P.H., medical officer, Clinical Research Resources Section, Trial Innovation Network, and Katherine C. Patel, M.S.P.H., lead mathematical statistician, Office of Program Evaluation, Analysis and Reporting. Dr. Kurilla announced that Erica K. Rosemond, Ph.D., was promoted to deputy director, DCI. Staff that joined DCI from other NCATS' offices and divisions include Cynthia B. González, M.S., as a health science policy analyst, and Yanji Xu, Ph.D., as a data scientist.

Digital Health Technology

Dr. Kurilla emphasized a special communication publication, "Digital Health Technology Research Funded by the National Institutes of Health," in *JAMA Network* about digital health technology research funded by NIH. Digital health technology is an evolving application with innovative implications in health care and health care delivery.

Recognition and Awards

Dr. Kurilla highlighted recent accomplishments by CTSA Program investigators, scholars and trainees.

- **National Academy of Medicine.** On October 21, 2024, five CTSA Program investigators were elected for membership in the National Academy of Medicine: Christopher G. Chute, Dr.P.H., M.D., M.P.H., Johns Hopkins University; David Huang, M.D., Ph.D., Oregon Health & Science University; Shawna Veleura Hudson, Ph.D., Rutgers Health; Funda Meric-Bernstam, M.D., The University of Texas Health MD Anderson Cancer Center; and Jeffrey D. Rothstein, M.D., Ph.D., Johns Hopkins University.

- **Investigator awards.** Margarita L. Dubocovich, Ph.D., Jacobs School of Medicine and Biomedical Sciences, University at Buffalo, received the Presidential Award for Excellence in Science, Mathematics and Engineering Mentoring in January 2025 for her innovation and commitment to mentoring future generations of scientists. Muredach P. Reilly, M.D., Columbia University Irving Medical Center, was inducted into the Association of American Physicians for his pioneering work in precision cardiovascular medicine and his transformative leadership at Columbia University. Cara E. Stepp, Ph.D., professor, Department of Speech, Language and Hearing Sciences, Boston University, was inducted into the American Institute for Medical and Biological Engineering. Niroshana Anandasabapathy, M.D., Ph.D., vice chair for research in dermatology, institutional associate director, Tri-Institutional Medical Scientist Training Program, Weill Cornell Medicine, was elected to the American Society for Clinical Investigation.

- **Presidential Early Career Award for Scientists and Engineers.** Jason L. Vassy, M.D., M.P.H., M.S., primary care internist, VA Boston Healthcare System, and associate professor, Harvard Medical School, director, Genomes2Veterans, Brigham and Women's Hospital, was recognized for his research and application of genomic science to enhance veteran health care. Kavita Shah Arora, M.D., M.B.E., M.S., director, Division of General Obstetrics, Gynecology, and Midwifery, professor, Department of Obstetrics and Gynecology, University of North Carolina School of Medicine, was recognized for her national advocacy efforts in reproductive bioethics and health policy.

- **Other recognitions.** Lauren A. Dalvin, M.D., associate professor, Department of Ophthalmology, Mayo Clinic, was honored as a 2025 Research All-Star by Avant Garde Health. Henry A. Palfrey, Ph.D., postdoctoral fellow, University of Arkansas for Medical Sciences, is investigating the role of eicosanoids in kidney and cardiovascular function. His startup, PulseArk Technologies, reached the semifinals in the Bangkok Business Challenge, one of the world's leading student startup competitions, and Dr. Palfrey received a Best Presentation award.

CTSA Program Impact

Dr. Kurilla summarized the impact of the CTSA Program on policy, clinical guidance and workforce development. From 2006 to 2024, more than 30,000 publications included a CTSA Program trainee in the authorship list. Among those publications, 16% have been referenced in policy documents. These publications have received strong media attention, with more than 64,000 news articles, more than 7,000 blog posts and more than 480,000 X posts. Dr. Kurilla highlighted that the strong media attention allows scientists to convey research in a meaningful way to the public.

- **K12/KL2 Scholars Grant Activity.** NCATS-supported scholars apply for and receive a higher percentage of awards after completing their K-funded training than other NIH-supported scholars. Dr. Kurilla highlighted that this demonstrates the CTSA Program hubs' ability to prepare the next generation of cutting-edge scientists.

- **FY25 R03 Awardees.** Dr. Kurilla summarized the current FY25 R03 awards, which are intended to support previous K-funded scholars. Five awards were granted, and the current awardees reflect a broad clinical research portfolio, including a novel ultrasound score to improve the assessment of joint inflammation in children with chronic musculoskeletal pain and advancing catheter electrochemical impedance spectroscopy for precision medicine of embolotherapy.

CTSA Program Collaborative Innovation Awards

Dr. Kurilla highlighted a CTSA Program Collaborative Innovation Awards (CCIA) award, funded from 2020 to 2025, that focused on clinical genomic characterization to accelerate translational advances for patients with intellectual and developmental disabilities (IDDs). He summarized the efforts and results of the study, including the establishment of a National Brain Gene Registry and enrollment of patients across 12 IDD research centers. As of August 2025, the investigators have identified more than 100 gene variants that are associated with IDDs, and they have partnered with ClinGen to curate and share data with more than 1,500 collaborators across at least 35 countries.

Multimodal Artificial Intelligence (AI)–Based Predictive Medicine

Dr. Kurilla summarized the PRediction Of Glycemic RESponse Study (PROGRESS). PROGRESS is a decentralized clinical trial incorporating wearable devices and a digital platform. Data were collected from 1,137 participants within the United States. The study developed and validated a multimodal machine-learning model that computes glycemic profiles for type 2 diabetes. Dr. Kurilla noted that the CTSA Program community is moving toward utilizing decentralized clinical trials and wearable devices.

Trial Innovation Network

- **REDCap Advanced Randomization Module.** The REDCap Advanced Randomization Module is advancing complex clinical trials. The randomization module streamlines implementation, improves trial efficiency, ensures robust data integrity and supports adaptive clinical trials for institutional REDCap users. As of June 2025, 1,543 institutions have installed the REDCap

Advanced Randomization Module, and 1,415 projects across 105 institutions have utilized the module.

- **Training Program for Multicenter Clinical Trial Management.** The virtual cohort-based training program has eight sessions and is designed to prepare investigators and clinical research project managers to effectively lead complex multicenter clinical trials. Multicenter clinical trials face operational, regulatory and collaborative challenges. Participants of the training program gain practical knowledge and tools to navigate these challenges.

Streamlined, Multisite, Accelerated Resources for Trials (SMART) Institutional Review Board (IRB) Platform

Dr. Kurilla summarized the SMART IRB Platform, which was launched in 2018. The SMART IRB platform enables reliance on a study-by-study basis and eliminates the need to sign reliance agreements for each study. The SMART IRB platform has transformed multisite clinical research by reducing IRB reliance time from 6–9 months to fewer than 3 months for 90% of studies. SMART IRB 3.0, launched in 2025, is being used by 1,397 participating institutions. The new version has also engaged investigators conducting clinical trials at the U.S. Department of Defense, U.S. Department of Veterans Affairs (VA) and U.S. Department of Energy (DOE).

HEAL Pain Management Effectiveness Research Network (ERN)

Four clinical trials were awarded in FY19, and one clinical trial was awarded in FY20. These five clinical trials received full ERN support and have completed enrollment. Numerous NIH institutes and centers (ICs) have been involved in this research; pain encompasses many different diseases that are areas of interest for different NIH ICs. Having a centralized location where these clinical trials can be managed and administered has helped to optimize efficiency and operational efforts. Due to the value and achievements of this program, the National Institute of Neurological Disorders and Stroke plans to continue this research effort.

National Clinical Cohort Collaborative (N3C) Ecosystem

Dr. Kurilla noted that the COVID-19 study is still open, and investigators continue to advance research on COVID-19 to improve patient outcomes. NCATS is collaborating with the Office of Data Science Strategy through the AIM-AHEAD program to develop an educational resource on data training. A pilot study with the National Science Foundation and DOE is focused on developing synthetic electronic health record datasets. The research community and external partners are interested in utilizing synthetic data to develop products and conduct training. Two limited-access pilot collaborations are testing the feasibility of interagency data sharing and multi-source data linkage. Concerns for successful scaling of these efforts include infrastructure and resources.

An NCATS and AIM-AHEAD partnership helped train 104 clinicians and data scientists in data analysis. The training program includes 6 months of online courses, live classes and mentorship. Outcomes of the program to date include 10 publications; 40 awards, media highlights and other distinctions; 14 new grant awards; and 8 career positions and promotions in health-related AI technologies.

Building a Research-Ready Professional Workforce

Dr. Kurilla noted that the Association of Clinical Research Professionals (ACRP) received an R13 conference grant, which is the first NIH-funded grant for ACRP. ACRP will highlight innovative models for career entry, advancement and retention that will scale workforce development across the research enterprise. To promote recognition of clinical research professionals, collaborative discussions will

define professional standards and advocate for formal validation of clinical research professionals as an essential occupation.

CTSA Program Researcher Spotlight

Dr. Kurilla highlighted rising leaders within the CTSA Program.

- **Institutional Mentored Career Development Award (KL2) scholars.** Angela Lombardi, Ph.D., M.Sc., is assistant professor of medicine, Division of Endocrinology, Albert Einstein College of Medicine. She is harnessing immunological interventions for type 1 diabetes, including peptide therapeutics that block the interaction between HLA-DQ8$^+$ antigen-presenting cells and CD4$^+$ T cells to prevent beta cell death. Karan R. Chhabra, M.D., M.Sc., is assistant professor, Department of Surgery and Population Health, New York University Grossman School of Medicine. He completed a retrospective study to evaluate the outcomes and affordability of bariatric surgery and pharmacotherapy for weight management.

- **Former Institutional Mentored Career Development Award (KL2) scholars.** Laura B. Eisenmenger, M.D., is associate professor, associate chief of MRI, medical director of imaging services, Wisconsin Institutes for Medical Research, Department of Radiology, University of Wisconsin School of Medicine and Public Health. She is an author for position papers for ACRP on vessel wall imaging and continues imaging development research in cerebral autosomal dominant arteriopathy with subcortical infarcts and leukoencephalopathy (CADASIL) imaging.

- **Clinical Research Training Awards (TL1) trainees.** Dillon G. Pruett, Ph.D., is assistant professor, School of Communication Sciences and Disorders, Florida State University. He is examining the genetic basis of stuttering and how the disorder is characterized in electronic health records. Geoffrey M. Gusoff, M.D., M.B.A., M.S., is assistant professor, Department of Family Medicine, University of California, Los Angeles. His research focuses on caregiver-owned home care cooperatives to identify the methods that have resulted in reduced turnover rates and increased patient retention compared with traditional home care agencies. Ryan Blaustein, Ph.D., is assistant professor, Department of Nutrition and Food Science, College of Agriculture and Natural Resources, University of Maryland. While he was a TL1 trainee, Dr. Blaustein's research focused on developing a human gut model to study the interactions between microbiota and chemotherapeutics. His current research is on biobased innovations for viticulture and fermentation.

- **CTSC Summer Intensive Scholar.** Karena Zhao, M.D., conducted research at Memorial Sloan Kettering (MSK) Cancer Center while attending medical school at Weill Cornell Medical College; she was first author of a high-impact study published in *Nature Genetics*. The study provided new insights into the genetic complexity of cancer metastasis.

CTSA Program Research Spotlight

Dr. Kurilla emphasized thought-provoking research that is being conducted within the CTSA Program.

- **Extracellular vesicles prime tolerance.** Researchers demonstrated that extracellular vesicles from human semen induce unique tolerogenic phenotypes in vaginal dendritic cells and regulatory T cells. This may be a potential mechanism to prime tolerance of partner-specific allogenic material to support a successful pregnancy.

- **Biostatistics, Epidemiology, and Research Design core.** Loss of Y chromosome (LOY) in peripheral blood mononuclear cells increases cancer mortality. LOY in CD4$^+$ and CD8$^+$ T cells

results in immunosuppression. LOY has implications for tumor-infiltrating T cells and chimeric antigen receptor T-cell therapies. The results were published in *Nature*.

- **Fructose fuel for tumors.** Using a mouse model, investigators showed that dietary fructose enhances tumor growth indirectly through interorgan lipid transfer. The study demonstrates complex metabolic interactions between cancer cells and healthy tissues. Potential implications from this research include targeting metabolism of healthy cells to treat cancer, as well as regulations on sweeteners in processed food.

- **Connection between dementia and liver health.** Investigators completed a retrospective analysis of a national cohort of patients using TriNetX©. An unexpected link between dementia and liver health was discovered, and the investigators confirmed that the results obtained from a VA-supported study were mirrored in the general population of non-veterans. In this analysis of non-veterans, 13% of patients with dementia had a potential undiagnosed case of cirrhosis. This research highlighted that cognitive impairment may be reversed if these contributors to cognitive decline are treated.

- **Psilocybin.** Investigators demonstrated in aged mice that psilocin, the active metabolite of psilocybin, extends cellular lifespan and improves overall survival. Psilocybin may be a potent geroprotective agent.

- **Wearable microfluidic sweat biomarkers.** Cystic fibrosis (CF) leads to abnormal ion transport and sweat concentrations. To use sweat as a diagnostic and biomarker of treatment adherence for CF, a specialized sweat laboratory is required. Investigators at a spinout company, Epicore, created a sweat patch for CF patients that is portable and allows repeat measurements. The sweat patch is advantageous compared with macroduct sweat collection system chloridometry. Gatorade has licensed the sweat patch for athlete use.

- **Pistachios as a potential nutritional intervention.** Investigators examined how eating pistachios as a nighttime snack influences gut bacteria in prediabetic adults. The study demonstrated that eating pistachios over other carbohydrate-based foods as a nighttime snack may serve as a nutritional intervention to help regulate overnight and morning blood glucose levels.

- **Fecal metabolic profiling in critically ill patients.** Investigators collected fecal samples from 196 critically ill patients who were admitted to the intensive care unit for non-COVID-19 respiratory failure or shock. A fecal metabolic dysbiosis score was created and predicted 30-day mortality in critically ill patients. This study identified fecal metabolites as a potential therapeutic target to improve survival in critically ill patients and demonstrated a strong link between microbial dysbiosis and increased mortality risk. Dr. Kurilla called attention to a recent news article to demonstrate how the media portrayed the fecal dysbiosis study. He noted that it highlights the importance of investigators engaging with the public about findings in a clear and meaningful way.

Discussion

Robin J. Mermelstein, Ph.D., noted her appreciation for the researcher highlights across the career spectrum. She stated that Dr. Kurilla's attention to a recent news article highlights the importance of the public as a key partner in research. Additional training in communication skills and incorporation of community advisory boards to preview the science could be implemented to ensure that the research results will be interpreted correctly. Dr. Kurilla commented that the CTSA Program provides

opportunities for scholars to meet and explain their research to investigators who are not in their respective areas of research.

Sergio A. Aguila-Gaxiola, M.D., Ph.D., requested clarification on how NCATS is communicating the impact of the CTSA Program to congressional members and other key partners. Dr. Kurilla responded that NIH previously held a Lunch and Learn event to brief congressional staffers on the CTSA Program. He noted that his presentation focused on how the CTSA Program is advancing all clinical trials, as well as other broad themes (e.g., impact across NIH and the research enterprise). When communicating with individual congressional staff members, Dr. Kurilla provides distinct examples of scholars and investigators who are constituents of the state they represent. He continued that NCATS has an opportunity to relay the importance of its programs and emphasize the impacts and measurable outcomes of its programs for a variety of diseases. Dr. Rutter added that NCATS is prohibited from funding Phase III clinical trials, but this could be an area of advancement for the CTSA Program in the future.

Jonathan Himmelfarb, M.D., discussed the importance of community engagement. A disconnect exists between scientists and the way their research is perceived by the public. Scientists can learn how to effectively communicate with the public by engaging patient communities. Dr. Kurilla agreed on the importance of community engagement and active listening.

VII. PROGRAM UPDATE PRESENTATION AND DISCUSSION: OFFICE OF SPECIAL INITIATIVES (OSI): Danilo A. Tagle, Ph.D., M.S., Director, OSI, NCATS

Danilo A. Tagle, Ph.D., M.S., presented an update on OSI. OSI's mission is to address translation problems with innovative solutions through the development and implementation of disruptive technologies resulting in paradigm shifts in the field. The OSI team includes expertise from many disciplines, including molecular biology, genetics, neuroscience, organic and medicinal chemistry, bioengineering and biophysics.

OSI's initiatives span all aspects of the translational science spectrum, from fundamental research to clinical development and regulatory acceptance. OSI's work includes many disciplines, including artificial intelligence (AI), diagnostics and disease detection, quantum science, regenerative medicine and new approach methodologies (NAMs). All these efforts adhere to NCATS' principles of developing technologies, demonstrating their utility and disseminating the technology for community use and adoption.

Quantum Biomedical Innovations and Technologies (Qu-BIT) Program

NIH established the Qu-BIT program to support the development of biomedical and translational use cases for the new generation of quantum technologies. Under the Qu-BIT program, NCATS launched two prize challenge competitions in partnership with other NIH institutes and centers (ICs) to spur development in the fields of quantum sensing and quantum computing for biomedical applications.

Topics for the first Qu-BIT challenge, launched in February 2025, included quantum algorithms for drug discovery; quantum machine algorithms for clinical risk predictions, diagnosis and therapeutics; and quantum algorithms for biomedical imaging and genomic data analysis. Topics for the second Qu-BIT challenge, launched in April 2025, included quantum sensing approaches for disease diagnostics and monitoring, quantum approaches for early detection and prognosis, and quantum biosensing and imaging devices.

Tissue Chips Program

Representing more than a decade of investment, NCATS' Tissue Chips program has been launched across several stages: safety and pharmacology, disease models and efficacy, clinical trials on chips and precision medicine, building confidence and community, and regulatory acceptance. Program partners include other NIH ICs, FDA, NASA, BARDA, the U.S. Environmental Protection Agency and pharmaceutical companies. NCATS has previously supported an annual microphysiological systems (MPS) world summit to develop the community; the meeting will be held by the International Microphysiological Systems Society going forward.

Dr. Tagle outlined FDA's qualification process for regulatory acceptance, which involves assessing whether a model or assay can be relied upon to have a specific interpretation and application in product development and regulatory decision making. Qualification evaluates the fitness of a model for a specific context and identifies the boundaries of the available data that adequately justify the tool's use. Components in this process include a letter of intent, qualification plan, full qualification package and qualification recommendation.

The Translational Centers for Microphysiological Systems (TraCE MPS) were established in the spring of 2024 to accelerate the translational use of tissue chips in drug development through regulatory acceptance and adoption for industrial use. The goal of this effort is to develop qualifying MPS that are a fit for purpose of industry needs and have specific contexts of use that will meet regulatory qualification requirements. Dr. Tagle briefly outlined the FDA qualification submission process for biomarkers, clinical outcome assessments and animal models. In 2020, FDA launched the Innovative Science and Technology Approaches for New Drugs (ISTAND) Program for NAMs, including tissue chips, AI algorithms and novel digital health technologies. He highlighted TraCE MPS submissions, which include a liver system for determining candidate dosing in clinical trials, a human kidney chip for assessment of relative nephron-toxicology and an organ-on-a-chip modality for derisking rodent studies of investigational new drug candidates. Dr. Tagle explained that early engagement with FDA is vital for informing and facilitating early regulatory submissions, ultimately shortening the qualification process.

The Tissue Chips in Space 2.0 program was launched to create tissue and organ-on-chip platforms that can be sent to the International Space Station National Laboratory so that scientists can better understand the role of microgravity on human health and diseases and translate those findings to improve human health on Earth. These studies provided insight into the biology of aging and space flight–induced diseases while also advancing tissue chip technology through automation and miniaturization of instruments. The second phase of projects is being conducted to further the community's understanding of how microgravity can provide a unique platform to study the aging process more efficiently than can be accomplished on Earth. NASA recently announced support for tissue chips to study the effects of deep space radiation on human health through the A Virtual Astronaut Tissue Analog Response (AVATAR) program.

NIH Common Fund Program

The NIH Common Fund Program supports several NCATS-led programs. The Common Fund supports bold scientific programs that catalyze discoveries across all areas of biomedical and behavioral research. These programs advance cross-cutting areas of biomedical and behavioral research that are important to the missions of multiple NIH ICs and spur subsequent biomedical advances that would not be possible without an initial strategic investment.

- **Complement Animal Research In Experimentation (Complement-ARIE) Program.** The Complement-ARIE program was established to catalyze the development, standardization,

validation and use of human-relevant NAMs and to transform basic, translational and clinical research. The goals of this program are to better model and understand human health and disease outcomes across varied populations, develop NAMs that provide mechanistic insight into specific biological processes or disease states, validate mature NAMs and support regulatory use and standardization, complement traditional models, and make biomedical research more efficient and effective. Examples of NAMs include complex *in vitro* models emulating disease states and population variabilities, *in silico* multiscale systems simulating healthy and diseased individuals, *in chemico* cell-free systems capturing biochemical changes, and combinatorial NAMs that integrate multiple model elements into a synergistic approach. Data from these efforts will be made available through a public portal. Components of the program include technology development centers, a data hub and coordinating center, a validation and qualification network, community engagement and training, and prize competitions.

- **Extracellular RNA (ExRNA) Communication Program.** The ExRNA Communication Program was launched in 2013 to address scientific and technical challenges that exist in the field. In the past, RNA was viewed only as functioning within cells. A paradigm shift occurred when RNA was observed to be released from cells into various body fluids, carrying information and facilitating cell-to-cell communication. This paradigm shift sparked intense scientific interest and spurred questions regarding what types of cellular RNAs are released as exRNAs, how exRNAs are protected from outside the source cell to affect target cells in distant organs, the impacts of exRNAs in healthy and disease states, and the potential of exRNA communication for diagnosis and treatment. The ExRNA Communication Program was launched in two stages (2013–2019, 2019–2025) to unravel the fundamental biological principles of how exRNAs are produced and transported, as well as how they function in both health and disease states and their potential for clinical utility. The program has supported data, software, protocols and reagent resources for the research community. Links to these resources are available at the ExRNA Research Portal.

- These efforts have yielded more than 950 publications that have been cited more than 100,000 times. The ExRNA Atlas contains more than 10,000 human extracellular RNA profiles that have been downloaded more than 550,000 times. The Extracellular Vesicle Antibody Database has been accessed nearly 9,000 times since its launch in 2020. The exceRpt tool has included nearly 150,000 samples being processed and analyzed; 91% of data submitted were from non-consortium users. Furthermore, the MicroRNA Data Resource has been accessed nearly 1,500 times since the resource was launched in 2019. The program has enabled significant advances in clinical research across many areas, including cancer, COVID-19 and HIV. The team pivoted to a single-vesicle isolation protocol during the COVID-19 pandemic to develop technologies for detecting SARS-CoV-2. From these efforts, four projects were supported, resulting in 32 publications, 14 patent filings, and several FDA filings and submissions.

- In summary, the ExRNA Communication Program teams have helped establish extracellular RNA an intercellular communication vehicle, showed the potential for extracellular RNA as novel therapeutics, discovered vesicular and non-vesicular carriers with distinct extracellular RNA cargo, and showed that extracellular RNA molecules can be obtained as liquid biopsies and could be a source of biomarkers. The consortium also has developed methods to separate and characterize extracellular RNA carriers from vesicular and non-vesicular forms, helped develop diagnostic tests for COVID-19 using extracellular RNA carrier technologies, helped dispel the role

of food-derived microRNA in human health, and demonstrated potential for extracellular RNA molecules as drug-delivery vehicles.

Discussion

Sergio A. Aguila-Gaxiola, M.D., Ph.D., observed that community engagement and training have been identified as key components of the Complement-ARIE program. He expressed support for these efforts and requested additional details on plans for progress in this area. Dr. Tagle noted that these components were developed thoughtfully and involved community listening sessions, workshops, focus group discussions, landscape analysis and discussions with the NIH director. Community engagement and training emerged as key topics in those discussions. This theme has been embedded across the other program components. Community members include patients, nonprofit organizations, contract research organizations, industry regulators, journal editors and peer reviewers. Dr. Tagle also noted that the program is still actively seeking community input on this topic to identify areas of need, as well as research gaps and opportunities.

VIII. CLEARANCE OF CONCEPTS: Presentation and Discussion

The Council received presentations on two concepts for initiatives that NCATS is considering re-issuing. After each presentation, the members discussed the proposal and voted on whether NCATS should move forward with the initiatives. Discussants for the concept were assigned prior to the meeting.

Introduction of Office of Special Initiatives (OSI) Concepts: Danilo A. Tagle, Ph.D., M.S., Director, OSI, NCATS

Danilo A. Tagle, Ph.D., M.S., noted that the two OSI concepts would focus on advanced 3-D tissue models for drug screening and screening for conditions by electronic nose technology. The initial approvals of these two concepts occurred in 2017 and 2020, respectively.

Intramural–Extramural Collaboration for Advanced 3-D Tissue Models for Drug Screening: Dobrila D. Rudnicki, Ph.D., Program Director, OSI, NCATS

Dobrila D. Rudnicki, Ph.D., presented a re-issue concept on intramural–extramural collaboration for advanced 3-D tissue models for drug screening. She explained that this initiative is aligned with the NIH director's prioritization of new approach methodologies (NAMs). The program involves partnerships between the intramural NCATS 3-D Bioprinting Laboratory and extramural researchers to jointly develop models and execute initial screening. The extramural team is providing expertise in diseases and biofabrication, and the intramural team is providing expertise related to adoption of models for drug screening platforms. The program was launched in 2017 through a pilot initiative. Achievements from this program to date have included a 3-D bioprinted cutaneous cell carcinoma model to quantify chemotherapeutic effects, a 3-D model of the fetal–maternal interface for discovery of preterm birth therapies, identification of potent herpes simplex virus antivirals using 3-D bioprinted human skin equivalents and a human 3-D liver tissue model of metabolic dysfunction.

Dr. Rudnicki highlighted remaining challenges in this space. She noted that early steps of the drug discovery process require predictive assays to increase efficiency at the later stages of preclinical drug development. Additionally, current 3-D tissue models include different modalities, e.g., organoids, spheroids, bioprinted tissues, each with varying degrees of physiological complexity, throughput and technical difficulty of assembly and use. Furthermore, advanced drug screening tissue models are needed that are only as complex as necessary and as simple as possible for a specific context of use, and that are reliable and reproducible, and scalable and practical for drug discovery. Dr. Rudnicki also noted

that drug screening models are lacking in representation of population variability and complexity, including immune components, vascularization and innervation.

Next, Dr. Rudnicki outlined the program objectives and areas of emphasis: (1) Create advanced 3-D tissue models with the complexity necessary to make them physiologically, pathologically and pharmacologically useful for modeling relevant aspects of a disease and amenable for medium- to high-throughput drug screening; (2) integrate multiple 3-D tissue modalities (e.g., bioprinted/biofabricated tissues, spheroids, organoids, tissue chips) to mimic complex physiology and multi-organ pathology of human tissue and organ structure (e.g., flow, vascularization, innervation) as needed; (3) incorporate patient variability in the models, depending on the disease studies (e.g., sex, age, disease severity); (4) open opportunities for a wider spectrum of therapeutic modalities and perform screens (e.g., small molecules, biologics, peptides, oligonucleotides); and (5) in accordance with NIH priorities, institute the highest levels of rigor and reproducibility to ensure that the experiments are properly designed and executed, the results are disseminated, and the technologies are adopted beyond NCATS.

This proposal is aligned with Goals 1, 3, 4 and 5 of the *NCATS Strategic Plan 2025–2030*. The initiative will prioritize projects in the NCATS Intramural Laboratories for early lead discovery and Investigational New Drug Application–enabling preclinical development pipelines to facilitate application and demonstrate usefulness of the models. The program will also prioritize several areas of emphasis at NCATS, including rare diseases, approaches to treat more than one disease at a time, and models to evaluate therapeutics for infectious diseases and diseases that lack animal models. Dr. Rudnicki briefly highlighted NCATS' intramural portfolio of engineered 3-D tissue models, which includes models of the retina, skin, lung, placenta and fetal barrier, cardiac system, neurovascular unit, brain, liver, and muscles and neuromuscular junctions.

The program will establish multiple drug screening models with a fine line between the tissue complexity needed to mimic physiological conditions and over-engineering that would hinder the adoption of such models for drug screening. Applied innovative biofabrication approaches and biomaterials will support advanced design and application of 3-D disease models for drug screening. Validated multiple drug screening models will be created for chronic or rare diseases that incorporate population variability. The program will also demonstrate the utility of the models by identifying therapeutic hits for multiple diseases and validating them in appropriate secondary models. Through lessons learned, this work will inform the development of physiologically relevant 3-D models beyond those intended for drug screening, including for the development of vaccines, adjuvants and drug formulations, as well as for tissue regeneration.

Discussion

Robin J. Mermelstein, Ph.D., requested additional details on the melanin levels used in the skin tissue models. Marc Ferrer, Ph.D., clarified that the models do not include melanocytes. The disease under study should be considered when developing models; for some diseases, melanocytes are unnecessary to include.

Sergio A. Aguilar-Gaxiola, M.D., Ph.D., remarked that Goal 2 of the NCATS' Strategic Plan is also relevant to the program but was not checked off. He underscored the importance of engaging community partners in this work. Dr. Rudnicki agreed on the importance of this point and that community partnerships will be essential for the program. She noted that Goal 2 was not checked off because she feels that more work in this space still is needed. Joni L. Rutter, Ph.D., added that this point could be incorporated into future funding opportunity announcements. She added that the Complement Animal Research In Experimentation program can provide valuable insights for future initiatives. Dr. Ferrer

added that the 3-D Tissue Models program has established partnerships with patient advocacy organizations. He agreed on the importance of including specific language on this topic.

Jonathan Himmelfarb, M.D., commended NCATS for its efforts in this field over the past decade. He noted that an opportunity exists to apply these technologies to the drug development pipeline. Dr. Himmelfarb also remarked that many challenges still are present in this space, particularly balancing throughput and complexity. He added that biotechnology and pharmaceutical partners must be involved in these discussions. Other NIH efforts can provide insights for future program planning. Dr. Himmelfarb cautioned the team on challenges regarding cell source, which might be a limiting factor. Dr. Ferrer agreed on the importance of this point.

Members unanimously approved the concept of intramural–extramural collaboration for advanced 3-D tissue models for drug screening concept.

Screening for Conditions by Electronic Nose Technology (SCENT III): Leah Tolosa Croucher, Ph.D., Program Officer, OSI, NCATS

Leah Tolosa Croucher, Ph.D., presented a re-issue concept on SCENT III. She noted that this technology is intended to replace disease-sniffing dogs, mimicking the canine olfactory system via a combination of advanced technologies. Limitations on the use of dogs for this service include variation (e.g., among breeds, within breeds, among individuals), training costs, time required, lack of scalability and skill maintenance needs. This program is aligned with NIH's initiative to replace the use of animals in research. The objective of this program is to mimic the biological sense of smell for disease diagnosis, resulting in a more robust, standardizable and mechanized platform that can be validated and regulated for patient use. Dr. Croucher briefly outlined the function of biological olfactory systems. The artificial intelligence model (i.e., "e-nose") would use a sensor array, sensor response, feature extraction and pattern recognition to achieve a comparable outcome.

The proof of concept for this technology was piloted during the COVID-19 pandemic. From 2020 to 2022 (i.e., SCENT I), researchers developed a platform to screen for COVID-19-based volatile organic compound (VOC) detection in skin and breath. From 2022 to present (i.e., SCENT II), researchers have used the platform to screen 20 disease conditions based on VOCs emanating from the skin. The current concept is a renewal to move SCENT devices toward regulatory acceptance via a partnership with the U.S. Food and Drug Administration (FDA). Dr. Croucher shared a list of diseases and conditions currently being tested via the SCENT II platform; these include neurological disorders, skin conditions, respiratory and infectious diseases, metabolic disorders, and cancers.

Dr. Croucher presented data that illustrate the sensitivity and specificity of VOC compound detection using the SCENT I and II platforms. She explained that SCENT III is intended to build on the successes of these efforts and address gaps in this space. NCATS has established partnerships with the FDA Center for Devices and Radiological Health, National Institute of Standards and Technology, and U.S. Department of Defense for this effort. These partnerships will help NCATS improve sensitivity, specificity, and reliability of devices based on VOC analysis to meet FDA standards for submission; develop reference standards specific to VOCs from breath and skin; and set benchmarks for healthy VOCs. Dr. Croucher also noted that the platform has improved over the years alongside advancements in technology. This program is aligned with Goals 3 and 4 of the *NCATS Strategic Plan 2025–2030*.

Discussion

Drs. Himmelfarb and Mermelstein commended the team for its progress in developing the SCENT platform. Dr. Himmelfarb noted that he previously was unfamiliar with the program and was impressed by its accomplishments.

Dr. Aguilar-Gaxiola wondered about opportunities for making the technology as relevant as possible for end users. Dr. Croucher noted that feedback from patients has been positive, as the approach is noninvasive and painless. This is particularly beneficial for both pediatric and older patients. Dr. Aguilar-Gaxiola remarked that this outcome is aligned with Goal 2 of the strategic plan. It was also noted that the program has pivoted to meet the current needs of the community.

Members unanimously approved the SCENT III concept.

IX. PUBLIC COMMENTS

Public comments were accepted until October 3, 2025 (15 days after the meeting) and will be appended to the minutes.

X. ADJOURNMENT OF THE OPEN MEETING

Joni L. Rutter, Ph.D., thanked the participants for their input. The next meeting will be scheduled for January 2026 and is planned to be a virtual session. She noted that Jayanta Bhattacharya, M.D., Ph.D., NIH director, has agreed to speak at the next meeting. Dr. Rutter adjourned the meeting on September 18, 2025, at 5:04 p.m. ET.

XI. CERTIFICATIONS

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

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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