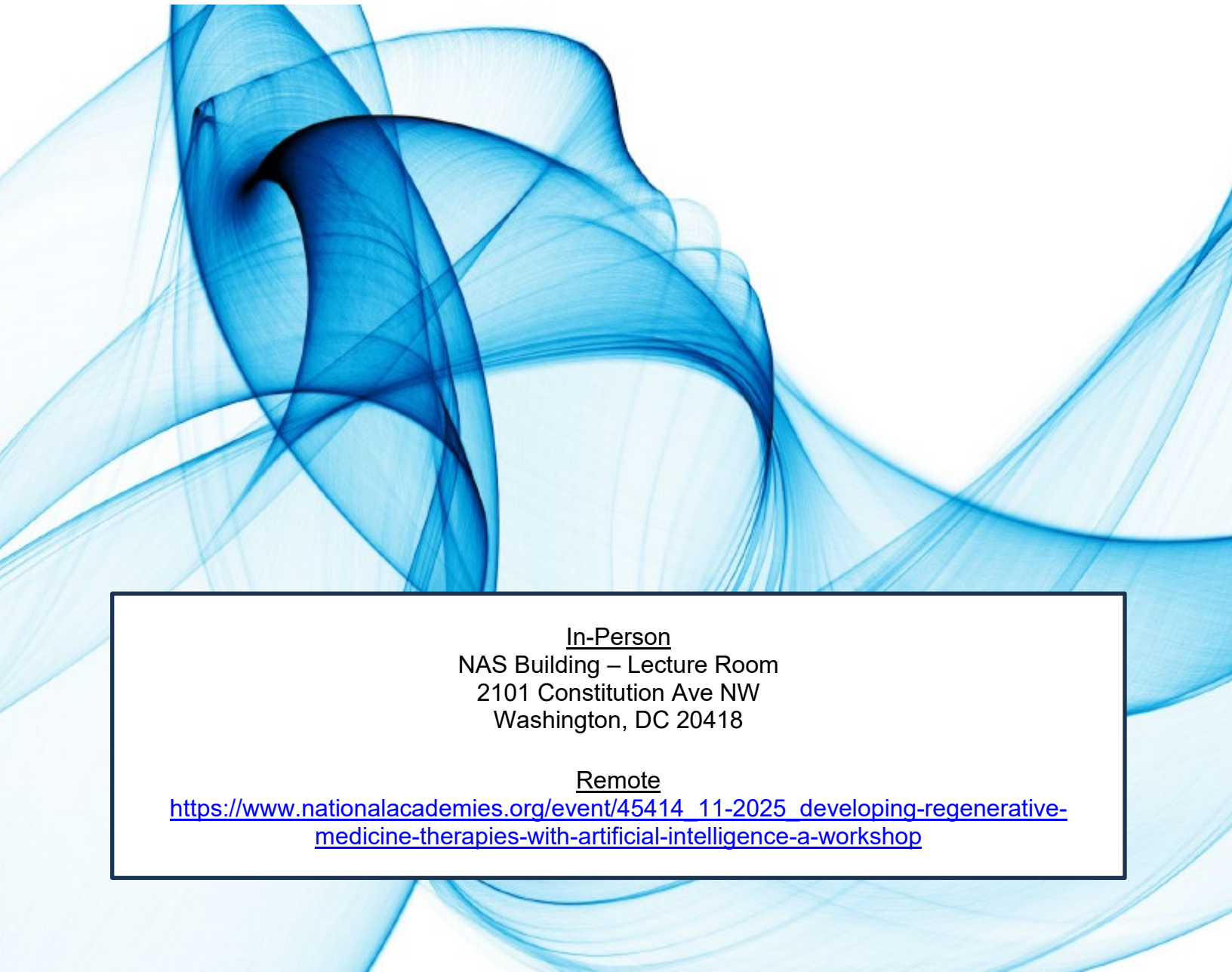
NATIONAL ACADEMIES Sciences Engineering Medicine

Developing Regenerative Medicine Therapies with Artificial Intelligence: A Workshop

November 18, 2025



In-Person
NAS Building – Lecture Room
2101 Constitution Ave NW
Washington, DC 20418

Remote
https://www.nationalacademies.org/event/45414_11-2025_developing-regenerative-medicine-therapies-with-artificial-intelligence-a-workshop

NATIONAL ACADEMIES Sciences Engineering Medicine

Developing Regenerative Medicine Therapies with Artificial Intelligence: A Workshop

Convened by the Forum on Regenerative Medicine
In Collaboration with the Forum on Drug Discovery, Development, and Translation

November 18, 2025

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AGENDA

Developing Regenerative Medicine Therapies with Artificial Intelligence: A Workshop

Tuesday, November 18, 2025

Statement of Task

A planning committee of the National Academies of Sciences, Engineering, and Medicine will organize and conduct a public workshop to explore the potential applications of AI as a tool in regenerative medicine throughout the product development pipeline. The overarching goal of this workshop is to consider the opportunities and challenges with using AI to enhance the translation of regenerative medicine therapies. The public workshop may include invited presentations and discussions to:

- Explore how AI can be used to improve the discovery of regenerative medicine therapies and the development of related technologies that improve therapy efficacy.
- Consider the applications of AI with pre-clinical models in translational research to more effectively optimize these systems and analyze large data sets derived from these systems, including opportunities to provide supplemental nonclinical data.
- Examine the potential uses of AI to support regenerative medicine clinical trials and regulatory processes by understanding the role of AI in informing innovative trial designs and predicting and evaluating clinical outcomes, such as in pharmacovigilance.
- Explore the growing opportunities to leverage AI in the manufacturing process for regenerative medicine products, including in combination with other advanced biomanufacturing methods.
- Discuss the ethical and legal implications for AI in regenerative medicine and the ways AI can improve safe and effective regenerative medicine therapies.

The planning committee will organize the workshop, develop the agenda, select and invite speakers and discussants, and moderate or identify moderators for the discussions. A proceedings - in brief of the presentations and discussions at the workshop will be prepared by a designated rapporteur in accordance with institutional guidelines.

SESSION I: Opening Remarks & Keynote

8:30 – 8:35 AM ET

Welcoming Remarks

Katherine Tsokas, *Forum Co-Chair*
Adjunct Professor
College of Engineering and Computer Science
Syracuse University

Krishnendu Roy, *Forum Co-Chair*
Bruce and Bridgitt Evans Dean of Engineering and University
Distinguished Professor
Vanderbilt University

8:35 – 8:40 AM

Introduction and Charge to the Workshop Speakers and Participants

Anne Plant, *Workshop Planning Committee Co-Chair*
Emeritus Fellow

National Institute of Standards and Technology

Nabiha Saklayen, *Workshop Planning Committee Co-Chair*
CEO & Co-Founder
Cellino

8:40 – 9:10 AM **Keynotes**

Su-In Lee
Boeing Endowed Professor, Paul G. Allen School of Computer Science & Engineering
Director, Computational Molecular Biology Program
AI Core Director, Nathan Shock Center for Basic Biology of Aging
University of Washington, Seattle

Seth Ettenberg
President and CEO
BlueRock Therapeutics

9:10 – 9:25 AM **Keynote Reflections**

Barbara J. Evans
Professor of Law and Stephen C. O'Connell Chair
University of Florida Levin College of Law
Professor of Engineering
Glenn and Deborah Renwick Faculty Fellow in AI & Ethics
University of Florida Wertheim College of Engineering
Associate Director, AI Alignment
Intelligent Clinical Care Center at University of Florida

Christopher Hartshorn
Chief of Digital & Mobile Technologies Section
National Center for Advancing Translational Sciences
National Health Institutes

Steven Oh
Acting Director
Office of Cellular Therapy and Human Tissue
Office of Therapeutic Products
Center for Biologics Evaluation and Research
Food and Drug Administration

9:25 – 9:55 AM **Keynote Panel Discussion**

Moderator: *Kapil Bharti, National Eye Institute*

9:55 – 10:00 AM **Reflections on the Discussion**

SESSION II: AI in the Pre-Clinical Development of Regenerative Medicine Therapies

Moderator: *John Knighton, Johnson & Johnson*

Session Objectives:

- Examine recent advances and potential future uses of AI in pre-clinical model systems and the design and development of regenerative medicine therapies.
- Discuss the practical considerations for effective, ethical, and reproducible implementation of these tools at the pre-clinical stage of product development.

10:00 – 10:15 AM
Susanne Rafelski
Deputy Director
Scientific Programs
Allen Institute for Cell Science

10:15 – 10:30 AM
Kyle G. Daniels
Assistant Professor of Genetics and, by courtesy, of Neurosurgery
Stanford University

10:30 – 10:45 AM
Sam Sinai
Co-Founder and Head of Machine Learning
Dyno Therapeutics

10:45 – 11:00 AM
Johnny Lam
Associate Director of Policy
Center for Biologics Evaluation and Research
Food and Drug Administration

11:00 – 11:25 AM **Panel Discussion**

11:25 – 11:30 AM **Reflections on the Discussion**
John Knighton, Johnson & Johnson

11:30 – 12:30 PM **Break for Lunch**

SESSION III: AI in Regenerative Medicine Clinical Trials and Manufacturing

Moderator: *Claudia Zylberberg, Kosten Digital; Anne Plant, National Institute of Standards and Technology*

Session Objectives:

- Explore recent advances and potential future applications of AI to support regenerative medicine clinical trials, regulatory processes, and manufacturing.
- Discuss the practical considerations for effective, ethical, and reproducible implementation of these tools at the clinical and post-market stage of product development.

12:30 – 12:45 PM ET
Marshall Summar
Executive Officer
Uncommon Cures

12:45 – 1:00 PM
Andrés Bratt-Leal
Co-Founder and Senior Vice President of Research
Aspen Neuroscience

1:00 – 1:15 PM
Ken Harris
Chief Strategy Officer & Head of AI
Omnia Bio

1:15 – 1:30 PM
Vera Mucaj
Mayo Venture Partner
Mayo Clinic

1:30 – 1:55 PM **Panel Discussion**

1:55 – 2:00 PM **Reflections on the Discussion**
Claudia Zylberberg, Kosten Digital

SESSION IV: Laying the Data Groundwork for Regenerative Medicine AI Tools

Moderator: *Timothy A. Chan, Cleveland Clinic & Case Western School of Medicine*

Session Objectives:

- Discuss the current opportunities and challenges to collecting, curating, and sharing the data necessary for AI applications in regenerative medicine.
- Explore the ethical and legal considerations of sharing regenerative medicine-associated data.

2:00 – 2:30 PM **Fireside Chat**

Elaine O. Nsoesie
Associate Professor
School of Public Health
Boston University

Klaus Romero
Chief Executive Officer
Critical Path Institute

Eric J. Rubin
Editor-in-Chief
The New England Journal of Medicine
Adjunct Professor of Immunology and Infectious Diseases
Harvard T.H. Chan School of Public Health
Professor of Medicine
Brigham and Women's Hospital
Harvard Medical School

Shawn M. Sweeney
Senior Director
American Association for Cancer Research

2:30 – 2:55 PM **Panel Discussion**

2:55 – 3:00 PM **Reflections on the Discussion**
Timothy A. Chan, Cleveland Clinic & Case Western School of Medicine

3:00 – 3:15 PM **Brief Break**

SESSION V: Building Trust in AI for Regenerative Medicine

Moderator: *Rosario Isasi, University of Miami*

Session Objectives:

- Discuss the current limitations of AI trustworthiness and explore opportunities to address these gaps and build

trust in AI within the regenerative medicine field.

- Consider practical approaches to helping the regenerative medicine workforce navigate the current AI landscape and developing AI literacy skills.

3:15 – 3:45 PM **Fireside Chat**

Susan Ariel Aaronson
Research Professor of International Affairs
GWU Public Interest Technology Scholar
co-PI, NSF-NIST Trustworthy AI Institute for Law and Society
Elliott School of International Affairs
George Washington University

Peter Bajcsy
Project Lead
Software and Systems Division
Information Technology Laboratory
National Institute of Standards and Technology

Shannon Eaker
Chief Technology Officer
Xcell Biosciences Inc.

George Eastwood
Executive Director
Emily Whitehead Foundation

3:45 – 4:10 PM **Panel Discussion**

4:10 – 4:15 PM **Reflections on the Discussion**
Rosario Isasi, University of Miami

SESSION VI: Final Reflections and Future Opportunities

4:15 – 4:45 PM **Envisioning the Future of AI and Regenerative Medicine: Fireside Chat**
Moderator: *Ronald J. Bartek, Friedreich's Ataxia Research Alliance*

Peter Bajcsy, National Institute of Standards and Technology
Seth Ettenberg, BlueRock Therapeutics
Barbara J. Evans, University of Florida
Su-In Lee, University of Washington
Sam Sinai, Dyno Therapeutics
Marshall Summar, Uncommon Cures

4:45 – 5:00 PM **Closing Remarks**
Anne Plant, Workshop Planning Committee Co-Chair
Nabiha Saklayen, Workshop Planning Committee Co-Chair

5:00 PM **Adjourn**

WORKSHOP INFORMATION

NATIONAL ACADEMIES Sciences Engineering Medicine

Convened by the Forum on Regenerative Medicine
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Planning Committee Member Roster

Co-Chairs

Anne Plant, Ph.D.
Emeritus Fellow
National Institute of Standards and Technology

Nabiha Saklayen, Ph.D.
CEO & Co-Founder
Cellino

Members

Ronald Bartek
President and Co-Founder
Friedreich's Ataxia Research Alliance (FARA)

Kapil Bharti, Ph.D.
Scientific Director
Senior Investigator
Ocular and Stem Cell Translation Research Center
NIH National Eye Institute

Timothy Chan, M.D., Ph.D.
Chair, Center for Immunotherapy & Precision Immuno-Oncology
Director, Global Center for Immunotherapy, Cleveland Clinic
Co-Director, National Center for Regenerative Medicine
Program Leader, Immune Oncology Program, Case Comprehensive Cancer Center
Sheikha Fatima bint Mubarak Endowed Chair in Immunotherapy
Cleveland Clinic

Christopher Hartshorn, Ph.D.
Chief of Digital & Mobile Technologies Section
NIH National Center for Advancing Translational Sciences

Rosario Isasi, J.D., M.P.H.
Associate Professor of Human Genetics
Adjunct Professor of Law
Director, Program in Genome Ethics and Policy
Dr. John T. Macdonald Foundation Department of Human Genetics
John P. Hussman Institute for Human Genomics
Interdisciplinary Stem Cell Institute
Leonard M. Miller School of Medicine
University of Miami

Amritha Jaishankara, Ph.D.
Executive Director, Cell and Gene Therapy Center
Global Head, Cell and Gene Therapy Lifecycle Strategy
IQVIA

John Knighton, D.B.A.
Vice President, Cell & Gene Therapy API Development
Johnson & Johnson

Jagdeep Podichetty, Ph.D.
Senior Director of Predictive Analytics (AI/ML), Quantitative Medicine
Critical Path Institute

Scott Steele, Ph.D.
Acting Deputy Center Director
Center for Biologics Evaluation and Research
US Food and Drug Administration

Claudia Zylberberg, Ph.D.
Co-Founder & Advisor
Kosten Digital

Planning Committee Member Biographies

Anne Plant, Ph.D., an Emerita Fellow at the National Institute of Standards and Technology (NIST), where she was previously Chief of the Biosystems and Biomaterials Division. She has served in the White House Office of Science and Technology Policy, as the NIST Representative to the National Science and Technology Council Life Science Sub-Committee, as an *ex officio* member of the National Advisory Council for Biomedical Imaging and Bioengineering of NIH, as reviewer for the California Institute of Regenerative Medicine and as a member of the National Academies Forum on Regenerative Medicine. She is a Fellow of the American Institute for Medical and Biological Engineering (AIMBE) and a Fellow of the American Association for the Advancement of Science. She has coauthored of over 100 articles on biosensors, light microscopy, and measurement science in biological systems. Dr. Plant's most recent research has focused on robust quantification of stem cell response through quantitative cell imaging, and theoretical approaches for prediction of complex biological response. She received her Ph.D. from Baylor College of Medicine in Houston, TX in Biochemistry.

Nabiha Saklayen, Ph.D., is CEO and co-founder of Cellino, where her team is spearheading the biomanufacturing of regenerative medicines to make "Your Cells, Your Cure" a reality for patients in an aging world. As a purpose-driven physicist, she focused her Ph.D. research on inventing bio/nanophotonics technologies to unlock precision cellular engineering for human health applications. Nabiha's expertise and passion for patient impact inspired Cellino's proprietary approach: an autonomous, optical bioprocess that unlocks the ultra-scalable manufacturing of regenerative medicines. Nabiha is a TED speaker and the inaugural Tory Burch Foundation Fellow in Genomics at the Innovative Genomics Institute, led by Nobel Laureate Dr. Jennifer Doudna. She received her Ph.D. in Physics from Harvard University as a Howard Hughes Medical Institute International Fellow. Nabiha also co-created I Am A Scientist, an educational program in 50 states that inspires children to explore science. She is a global citizen who grew up in Saudi Arabia, Bangladesh, Germany, and Sri Lanka.

Ronald Bartek is co-founder and president of Friedreich's Ataxia Research Alliance. A former partner and president of a business development/government affairs firm, he also served 20 years in the US government, including on the US House Armed Services Committee staff, at the US State Department, on the US delegation to the Intermediate-Range Nuclear Forces Treaty talks in Geneva, and as a CIA analyst. Bartek serves on the boards of the National Organization for Rare Disorders, Alliance for a Stronger FDA, and Alliance for Regenerative Medicine. He's a member of the NIH/NCATS National Advisory Council, NIH/NCATS Cures Acceleration Network Review Board, and NIH National Advisory Neurological Disorders and Stroke Council.

Kapil Bharti, Ph.D., obtained his Ph.D. from J.W. Goethe University, Frankfurt, Germany, *graduating summa cum laude*. His Ph.D. work involved research in the areas of molecular chaperones and epigenetics. He did his postdoc at the National Institutes of Health, where he published numerous papers in the areas of transcription regulation, pigment cell biology, and developmental biology of the eye. His lab at the National Eye Institute recently received started the first U.S. phase I/IIa trial to test autologous iPSC-derived RPE patch in AMD patients. Currently, he is co-developing a dual RPE/photoreceptor cell therapy with Opsis Therapeutics. He has published over 100 peer reviewed manuscripts and reviews, given over 30 keynote and named lectures, won several awards including the two times winner of the Public Service Award for the International Society for Stem Cell Research (ISSCR), two times winer of the NIH Director's award, NEI Directors Dr. Karl Kupfer Visionary award, and Sayer Vision Research lecture at NEI for his pioneering role in advancing the field of stem cell based therapies. He has filed 18 patents; six have been issued already. He serves on the advisory board *(pro bono)* of several stem cell therapy-based companies and patient-advocacy groups. His current work as a Senior Investigator at NEI involves understanding mechanism of retinal degenerative diseases using induced pluripotent stem cell derived eye cells and tissues, and developing cell-based and drug-based therapies for such diseases. He is the Scientific Director of the NEI Intramural Research Program where he oversees 21 research labs, 6 core facilities, and a staff of over 350 people.

Timothy A. Chan, M.D., Ph.D., is a physician scientist, Professor of Medicine, and attending physician at the Cleveland Clinic and the Case Comprehensive Cancer Center. He is PI of a cancer research laboratory. Dr. Chan is Chair of the Global Center for Immunotherapy and Precision Immuno-Oncology at the Cleveland Clinic, which is an institution focused on immunotherapy research and translational sciences. He is co-director of the National Center for Regenerative Medicine and a program director of the Case Comprehensive Cancer Center Immuno-Oncology Program. Dr. Chan received an MD and, a PhD, completed a residency in radiation oncology, and finished a fellowship at the Johns Hopkins School of Medicine. Dr. Chan was previously at the Memorial Sloan Kettering for over a decade.

Christopher Hartshorn, Ph.D., is an established leader at the National Center for Advancing Translational Science (NCATS) of the NIH, where he heads a dynamic team advancing innovation at the intersection of digital health, AI, data science, and biomedical technologies. As Acting Chief of the NCATS CTSA Program Branch, he directs efforts to advance the U.S. clinical trial infrastructure and training of its workforce via translational science. With over two decades of experience spanning translational research, data science, nanotechnology, and digital health, Dr. Hartshorn has led high-impact R&D portfolios across academia, industry, and federal agencies. He has played pivotal roles in launching NIH and interagency initiatives and serves as a subject matter expert for the NIH Common Fund's Nutrition for Precision Health initiative. Dr. Hartshorn's government service includes strategic partnership roles with NSF, DoD, and DOE, and liaison appointments to the National Nanotechnology Initiative and the National Information Technology R&D Program (NITRD). His multidisciplinary scientific contributions and commitment to public health continue to shape national strategies for innovation, collaboration, and impact in biomedical research. Prior to the NIH, Dr. Hartshorn was at NIST and Pfizer.

Rosario Isasi, J.D., M.P.H., is an Associate Professor of Human Genetics and Director of the Institute of Bioethics and Health Policy at the University of Miami Miller School of Medicine. An internationally recognized scholar, Prof. Isasi's research examines the social, ethical, and policy dimensions of disruptive biotechnologies, including precision medicine, genomics and

regenerative medicine. From 2017 to 2019, she served as a President's International Fellow of the Chinese Academy of Sciences, recognized for her global contributions to comparative law and ethics in stem cell research and regenerative medicine. Prof. Isasi holds leadership roles in major national and international initiatives. She chairs the Ethics Committee of the International Society for Stem Cell Research and serves as Ethics Advisor to the European Commission's European Human Pluripotent Stem Cell Registry. She also co-chairs the American Society of Human Genetics' Professional Practice & Social Implications Committee and chairs the Research Access Board of the NIH All of Us Research Program.

Amritha Jaishankara, Ph.D., is the Executive Director of the Cell and Gene Therapy (CGT) Center and Global Head of CGT Lifecycle Strategy at IQVIA. In this role she is responsible for driving an integrated and collaborative end-to-end CGT strategy to accelerate the development and commercialization of advanced therapies for biotechs, academic innovators, healthcare systems, and patients worldwide.

With over 20 years of experience across academia, government, non-profits, and industry-spanning R&D, program/policy, products/services and grants/investments, Dr. Jaishankar brings a uniquely holistic perspective to the CGT landscape.

She has supported more than 500 CGT and stem cell programs, helped launch and scale over 30 companies, and overseen more than $200 million in grants and strategic investments. Her leadership has directly contributed to the creation of platforms that support discovery, clinical development, regulatory navigation, manufacturing, commercialization, workforce training, and ecosystem growth. As a former stem cell scientist and architect of transformative funding initiatives, Dr. Jaishankar is known for combining deep scientific insight with bold, systems-level thinking. Her initiatives increased annual funding for a major state stem cell program by over 160%, and she continues to influence the field through board service, global partnerships, and her thought leadership. A trusted leader and champion in the field, Dr. Jaishankar is driven by a mission to translate CGT innovation into patient impact—anchored by robust infrastructure, equitable access, and disciplined execution across the product lifecycle.

John Knighton, D.B.A., is the Vice President of Cell & Gene Therapy Development API at Johnson & Johnson and has been with J&J for 19 years and with over 30 years of biopharmaceutical development experience. John leads a diverse and dedicated team of scientists and engineers in biopharmaceutical viral vector & gene therapy drug substance and CAR-T process development and global technology transfer. John started his career at GlaxoSmithKline in various roles of biopharmaceutical research and development. John holds his BS degree in Microbiology from The Pennsylvania State University, an MBA from Villanova University, and a Doctorate from Temple University.

Jagdeep Podichetty, Ph.D., is the Senior Director of Predictive Analytics in the Quantitative Medicine Program at the Critical Path Institute, where he is developing quantitative solutions such as disease progression models, survival models, clinical trial simulation, and artificial intelligence models to advance the field of drug discovery and development. He is also an Amazon Web Services (AWS) Certified Cloud Practitioner.

Prior to joining C-Path, he worked in academia and the pharmaceutical industry in both research and manufacturing of pharmaceutical products. He has received several awards for his research and leadership. He has numerous publications in peer reviewed journals and conference proceedings. He is also an active member of the International Society of Pharmacometrics

(ISoP) and American Society for Clinical Pharmacology and Therapeutics (ASCPT). He is currently serving as the Vice Chair of ASCPT Translational Informatics Community. Dr. Podichetty has an MS and PhD in Engineering from Oklahoma State University, and specialized postdoctoral training in Computational Biology and AI/ML from the University of Michigan and Indiana University. He received his Bachelor of Technology in Chemical Engineering from Jawaharlal Nehru Technological University in India.

Scott Steele, Ph.D., joined the FDA Center for Biologics Evaluation and Research (CBER) in 2022 as the Senior Advisor for Translational Science in the Office of the Center Director, and currently serves as the Acting Deputy Center Director. At CBER, he has led horizon scanning and translational science programs, external partnerships, and policy initiatives, including in areas such as artificial intelligence and cellular and gene therapies. Prior to joining CBER, he served on an assignment in CDER where he advised on policies and programs focused on artificial intelligence, digital health, and real world evidence. Before coming to the FDA, Dr. Steele was at the University of Rochester where he served as the Director of Regulatory Science and Personalized Medicine Programs at the Clinical and Translational Science Institute, Founding Director of the Data Science Center of Excellence, and Associate Professor of Public Health Sciences. Earlier in his career, he served in the White House Office of Science and Technology Policy, initially as a policy analyst focused on medical countermeasures and emerging biotechnology, and then as the Executive Director of the President's Council of Advisors on Science and Technology. He received his BS in Biology from Union College and then performed research at the General Electric Center for Research and Development and at the University of Geneva, followed by a fellowship at the National Institutes of Health. Dr. Steele completed his MA and PhD in Molecular Biology at Princeton University.

Claudia Zylberberg, Ph.D., is a biotech entrepreneur, innovator, and author dedicated to advancing science, healthcare, and education. She is the Founder and Chair of Akron Bio, a leading supplier of cGMP tools and materials for cell and gene therapies; the Founder of Kosten Digital, a global AI and digital health company integrating advanced data solutions into hospitals and healthcare systems; and the Co-Founder of ARScience Bio, which develops cytokine-based therapeutics. She has authored numerous peer-reviewed publications and holds multiple issued patents spanning biologics, cell therapy, and advanced manufacturing technologies. Her work has been widely cited and adopted in the cell and gene therapy field, where she has been an influential voice since the industry's formative years. Beyond her companies, Claudia has played a central role in shaping regenerative medicine and decentralized CGT. She is a past Board Member of ISCT (International Society for Cell & Gene Therapy) and the Alliance for Regenerative Medicine (ARM), both of which she helped guide during critical stages of their growth. She currently serves on the boards of the Standards Coordinating Body (SCB), CCRM (Toronto), and the AMM Alliance for mRNA Foundation, among others. She contributes to the National Academies of Sciences, Engineering, and Medicine (NASEM) Regenerative Medicine Forum, where she has organized and co-chaired workshops on decentralization of CGT manufacturing and the role of AI in advanced therapies. Claudia also advises several companies and leading hospital institutions, helping to shape next-generation healthcare infrastructure. Deeply committed to education and outreach, Claudia supports philanthropic initiatives that build regenerative medicine ecosystems and expand STEM programs in Florida and worldwide. As the author of children's books such as "You're Full of Genes" and "You're Full of RNA!", she brings science to life through storytelling, inspiring the next generation of scientists.

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Speaker Biographies

Susan Ariel Aaronson, Ph.D., is Research Professor of International Affairs at George Washington University (GWU). Aaronson is also co-principal investigator with the NSF -NIST (National Science Foundation and (National Institute of Standards and Technology Institute for Trustworthy AI in Law & Society, TRAILS, where she leads research on data and AI governance. Aaronson is also named one of GWU's Public Interest Technology Scholars, where she works to encourage interdisciplinary research on technology in the public interest. Aaronson is a Senior Fellow at the think tank CIGI in Canada and a Balsilie Scholar in Canada. Susan is also director of the Digital Trade and Data Governance Hub at GWU. The Hub was founded in 2019 and educates policy makers, the press and the public about data governance and data-driven change through conferences, webinars, study groups, primers and scholarly papers. It is the only organization in the world that maps the governance of public, proprietary and personal data at the domestic and international levels. The Hub is currently updating its metric to reflect the changes to data governance wrought by AI. The Hub's research has been funded by foundations such as Ford and Minderoo. Susan currently directs projects on responsible AI; national security and the free flow of data; participatory AI; AI and trade and AI protectionism. She regularly writes op-eds for Barron's and Fortune, and was a commentator on economics for NPR's Marketplace, All Things Considered and Morning Edition, and for NBC, CNN, the BBC and PBS.

Peter Bajcsy, Ph.D., received his Ph.D. in Electrical and Computer Engineering in 1997 from the University of Illinois at Urbana-Champaign (UIUC) and a M.S. in Electrical and Computer Engineering in 1994 from the University of Pennsylvania (UPENN). He worked for machine vision, government contracting, and research and educational institutions before joining NIST in June 2011. At NIST, Peter has been leading efforts focusing on the application of computational science in metrology, specifically live cell and material characterization at very large scales.

Andrés Bratt-Leal, Ph.D., is the Co-Founder and leads the research and development at Aspen Neuroscience. He served as a post-doctoral fellow in Jeanne Loring's lab where he helped develop the core technology producing dopaminergic neurons from iPSCs that formed the basis for the creation of Aspen. Andrés also served as Senior Science Advisor and Director of Research and Development at Summit for Stem Cell Foundation during which he led a team on the pre-clinical development of an autologous cell-based cell therapy for Parkinson's disease. Andrés obtained his PhD in Biomedical Engineering from the Georgia Institute of Technology and his BS in Bioengineering from the University of Washington.

Kyle G. Daniels, Ph.D., obtained his BS in Biochemistry from the University of Maryland College Park in 2010, conducting undergraduate research with Dr. Dorothy Beckett, PhD. He

obtained his PhD in Biochemistry with a certificate in Structural Biology and Biophysics. His dissertation is titled "Kinetics of Coupled Binding and Conformational Change in Proteins and RNA" and was completed in the laboratory of Dr. Terrence G. Oas, PhD. Kyle performed postdoctoral training with Dr. Wendell A. Lim, PhD at UCSF studying how CAR T cell phenotype is encoded by modular signaling motifs within chimeric antigen receptors.

The Daniels laboratory is working to create powerful immune cell therapies for breast cancer, glioblastoma, and HIV. Our approach is to decode natural signaling systems, understand their functions, then encode specific instructions in synthetic signaling systems to engineer therapeutic immune cells. To do this, we use synthetic biology, high-throughput library screening, and machine learning to decode how various signaling modules control cell function (as in Daniels KG, Wang S, et al. Science. 2022). We are particularly interested in understanding how modular domains can be recombined in new combinations and arrangements to give rise to diverse cellular behaviors that will enhance therapeutic efficacy. In the lab we curate a toolkit of modular domains involved in cell signaling, combine them in novel arrangements to make combinatorial libraries of hundreds to thousands of synthetic signaling molecules, and test these libraries for their effects on human immune cell (T cell, macrophage, natural killer cell) phenotypes. Next, we use neural networks to build predictive models to quantitatively and systematically understand cell signaling networks, decode structure-function relationships, and design new immune cell therapeutics. Our vision for AI-enabled rational design of improved cell therapies is discussed in our review article (Capponi S & Daniels KG, Immunol. Rev. 2023). In recent work, we've shown that this approach can be used to build synthetic receptors that greatly improve the efficacy of CAR T cells against difficult-to-treat solid tumors (Cho W, Daniels KG, bioRxiv. 2023). We are working with clinicians at Stanford to apply this approach to build safer, more powerful cell therapies.

Shannon Eaker, Ph.D. is currently the Chief Technology Officer (CTO) for Xcell Biosciences. Shannon received his PhD from the University of Tennessee, Knoxville in Biochemistry, Cellular and Molecular Biology. His expertise is around T-cell, HSC, and ES/iPSC cell biology, and was formerly with Cytiva/GE Healthcare in the Cell and Gene Therapy Division. He is a member of the International Society for Cell Therapy (ISCT) Process Development and Manufacturing (PDM) Committee, has authored numerous papers within the field of cell biology and manufacturing, and sits on Scientific Advisory Boards for numerous companies in the field of cell and gene therapy and regenerative medicine. Shannon lives with his wife and 2 kids in Knoxville, TN.

George Eastwood is the Executive Director of the Emily Whitehead Foundation, an organization created by the Whitehead family after their daughter Emily became the first pediatric patient to receive CAR-T cell therapy. Under his leadership, the foundation is focused on expanding access to advanced therapies, influencing policy to remove barriers to care, and supporting patients and families throughout their treatment journey, work that builds on its original mission of funding groundbreaking research for less-toxic cancer treatments.
A mission-driven innovator in cell and gene therapy, George has spent much of his career creating products, tools, and services to accelerate the development and delivery of cell-based therapeutics. As an early employee at HemaCare, he partnered with pioneering CAR-T companies like Kite and Novartis to help bring their therapies from development to commercialization. He later held leadership roles in the start-up space, including Vice President of Business Development and Partnerships at Kytopen and co-founder of Excellos, a cell and gene therapy company spun out of the San Diego Blood Bank. In addition to his role at the Emily Whitehead Foundation, George serves on the Board of Directors for the Alliance for

Regenerative Medicine, where he works alongside global leaders to advance policies, standards, and innovations that ensure more patients can benefit from next-generation therapies.

Seth Ettenberg, Ph.D., is the President and Chief Executive Officer at BlueRock Therapeutics. Seth joined BlueRock as Chief Scientific Officer in 2020 and led the rapid expansion and advancement of BlueRock's pipeline. Prior to joining BlueRock, Seth was a founding member of Unum Therapeutics where he served as Chief Scientific Officer. At Unum Seth built and lead the strategy team that supported strategic partnerships, four first in class clinical trials, several rounds of fundraising, and a successful NASDAQ IPO listing. Previously Seth led the Cambridge site of Novartis' Oncology Biotherapeutics group where he was responsible for developing and leading the strategy and implementation for oncology drug development projects at the Novartis Institutes for Biomedical Research (NIBR). In addition, Seth was responsible for building and leading the Novartis Cell and Gene Therapy research team in collaboration with the University of Pennsylvania to develop chimeric antigen receptor T-cell therapeutics. Seth received his formal scientific training at the Genetics Branch of the National Cancer Institute. He sits on the board of directors of Kano Therapeutics.

Barbara J. Evans, Ph.D., J.D., LL.M., is Professor of Law and Stephen C. O'Connell Chair at the University of Florida Levin College of Law and holds a joint appointment as Professor of Engineering and Glenn and Deborah Renwick Faculty Fellow in AI and Ethics at UF's Herbert Wertheim College of Engineering. Her research focuses on data privacy and regulation of AI/ML medical software, genomic technologies, and diagnostic testing. Currently she is part of the ethics and legal studies teams for the NIH Bridge2AI Program in Clinical Care AI through the Patient-Focused Collaborative Hospital Repository Uniting Standards (CHoRUS) Network and the NIH/NIGMS-funded Artificial Intelligence Passport for Biomedical Research (AIPassportBMR) program. She is an elected member of the American Law Institute, a Senior Member of the Institute of Electrical and Electronics Engineers and was named a Greenwall Foundation Faculty Scholar in Bioethics for 2010-2013. Before coming to academia, she was a partner in the international regulatory practice of a large New York law firm and is admitted to the practice of law in New York and Texas. She holds a BS in electrical engineering from the University of Texas at Austin, an MS & PhD from Stanford University, a JD from Yale Law School, an LLM in Health Law from the University of Houston Law Center, and she completed a post-doctoral fellowship in Clinical Ethics at the MD Anderson Cancer Center.

Ken Harris brings over 35 years of leadership experience across the healthcare ecosystem, with the last six years dedicated to advancing the strategic application of artificial intelligence in clinical, translational, and manufacturing contexts. As former Head of Academic Medicine at Amazon Web Services, Ken led initiatives integrating cloud-based AI solutions into academic, provider, and biopharma use-cases. Most recently, as Chief AI Officer at OmniaBio, he has focused on deploying AI-driven platforms to industrialize personalized medicine, with emphasis predictive modeling to improve costs, quality, and throughput. His work spans the intersection of data science, healthcare delivery, and cellular manufacturing.

Christopher Hartshorn, Ph.D., is an established leader at the National Center for Advancing Translational Science (NCATS) of the NIH, where he heads a dynamic team advancing innovation at the intersection of digital health, AI, data science, and biomedical technologies. As Acting Chief of the NCATS CTSA Program Branch, he directs efforts to advance the U.S. clinical trial infrastructure and training of its workforce via translational science. With over two decades of experience spanning translational research, data science, nanotechnology, and

digital health, Dr. Hartshorn has led high-impact R&D portfolios across academia, industry, and federal agencies. He has played pivotal roles in launching NIH and interagency initiatives and serves as a subject matter expert for the NIH Common Fund's Nutrition for Precision Health initiative. Dr. Hartshorn's government service includes strategic partnership roles with NSF, DoD, and DOE, and liaison appointments to the National Nanotechnology Initiative and the National Information Technology R&D Program (NITRD). His multidisciplinary scientific contributions and commitment to public health continue to shape national strategies for innovation, collaboration, and impact in biomedical research. Prior to the NIH, Dr. Hartshorn was at NIST and Pfizer.

Johnny Lam, Ph.D., is the Associate Director of Policy for the U.S. Food and Drug Administration Center for Biologics Evaluation and Research.

Su-In Lee, Ph.D., is the Boeing Endowed Professor of Computer Science at the University of Washington (UW). She earned her Ph.D. from Stanford University in 2009 under Professor Daphne Koller and joined UW in 2010 after serving as a Visiting Assistant Professor at Carnegie Mellon University.

She is renowned for her groundbreaking research at the intersection of AI, biology, and medicine, and widely recognized as a pioneer in explainable AI (XAI). Among her seminal contributions is the SHAP framework (Lundberg and Lee, NeurIPS'17 oral; cited over 40,000 times), which has transformed the interpretation of machine learning models across disciplines.

She has been honored with major awards, including the Samsung Ho-Am Prize in Engineering (the "Korean Nobel Prize," as its first woman recipient in 34 years), the ISCB Innovator Award, and the NSF CAREER Award. She is an American Cancer Society Research Scholar, an AIMBE Fellow, and an ISCB Distinguished Fellow.

Her recent work advances fundamental principles of XAI and applies them to biomedicine—from uncovering molecular drivers of disease to auditing clinical AI systems—fundamentally reshaping how AI is integrated into biomedical research and healthcare. This integration has enabled novel discoveries and produced numerous awards and highly cited publications spanning AI, molecular biology, and clinical medicine.

Vera Mucaj, Ph.D., is a biotech executive, scientist, and entrepreneur with over a decade of experience in healthcare data, digital biology, and translational science. As an entrepreneur in residence with Mayo Clinic, Vera leads the institution's efforts to translate world-class science and medicine into new independent businesses. Her key area of focus is regenerative medicine and organogenesis, with the goal of developing therapies that target healthspan and longevity. Previously, she served as Chief Scientific Officer of Datavant, where she joined as employee #8 and helped scale the company into one of the largest healthcare data interoperability platforms in the U.S.. Her product development expertise spans Real World Evidence, Data Privacy (HIPAA, CCPA, GDPR) and Clinical Research. Vera also advises and invests in early-stage health tech, biotech, and AI startups. She previously worked at McKinsey & Company, advising clients on strategy and growth across biopharma and private equity. She holds a PhD in Cell and Molecular Biology from the University of Pennsylvania and a BA in Biochemistry from Harvard. Her scientific research focused on the tumor microenvironment, developmental biology, synthetic biology, and applied mathematics.

Elaine O. Nsoesie, Ph.D., is an Associate Professor at Boston University School of Public Health and was a founding member of the Boston University Faculty of Computing & Data Sciences. Â She is an expert in the application of data science methods (including artificial intelligence (AI)) to global health problems, with a particular focus on developing approaches and technology that use data from non-traditional public health sources (such as mobile phones, satellites, and social media) for public health surveillance and to advance global health equity. She led the Racial Data Tracker project at Boston University's Center for Antiracist Research which aimed to collect, analyze, and disseminate publicly available racial data that points to the structural nature of racism. She also served as a program lead and a senior advisor to the Artificial Intelligence/Machine Learning Consortium to Advance Health Equity and Researcher Diversity (AIM-AHEAD) program at the National Institutes of Health. She is the founder of Rethé, an initiative that aims to increase representation of Africans in scientific research publications. She co-edited the book, Urban Health in Africa, published in 2025 by Johns Hopkins University Press. Her research and service have been recognized with awards from Boston University School of Public Health, Mozilla, Boston Congress of Public Health and others. She is on the advisory boards of Data Science Africa and Data Scientists Network organizations working to build data science capacity in Africa. She was born and raised in Cameroon.

Steven Oh, Ph.D., oversees product quality reviews, policy development, and regulatory science research programs focused on cellular therapy, tissue-engineered products, and xenotransplantation products at Center for Biologics Evaluation and Research (CBER) in U.S. Food and Drug Administration (FDA). He also heads the regulatory bioinformatics group in CBER. His scientific and regulatory interests include emerging novel technologies in regenerative medicine therapies and individualized medicine, standards development and use, and global regulatory convergence in advanced therapy products. Over 18 years in FDA, Dr. Oh has served in leadership roles including Acting Director and Deputy Director of Office of Cellular Therapy and Human Tissue, Director and Deputy Director of Division of Cellular and Gene Therapies, and Chief of Cell Therapies Branch. Before joining FDA, Dr. Oh served on the faculty of Tufts University School of Medicine. He was trained as a cell biologist and biochemist at the University of Michigan, Johns Hopkins University School of Medicine, and Massachusetts Institute of Technology.

Susanne Rafelski, Ph.D., is the Deputy Director of the Allen Institute for Cell Science, which aims to understand the principles by which human induced pluripotent stem cells (hiPSC)organize themselves across scales to form complex cell communities and tissues essential for life through a holistic understanding of cell states and dynamics. Prior to joining the Institute in 2016, Susanne was an Assistant Professor position in the Department of Developmental and Cell Biology, the Department of Biomedical Engineering, and the Center for Complex Biological Systems at UC Irvine. There, her lab studied the principles of intracellular organization, via the control of size, topology, and function of mitochondrial networks in budding yeast and mammalian cells. Susanne takes an interdisciplinary, quantitative approach to cell biology, combining live-cell image-based assays, molecular genetics, and computational methods.

Klaus Romero, M.D., is a prominent clinician scientist and scholar, who serves as both the Chief Executive Officer and Chief Science Officer at Critical Path Institute. As a recognized thought-leader, Dr. Romero established C-Path's Quantitative Medicine Program and has been an instrumental leader in the growth of the organization's portfolio of transformative consortia and public-private-partnerships across more than 16 therapeutic development areas. As both a

scientist and an executive, Dr. Romero led the generation of actionable drug development tools in Alzheimer's disease, which introduced a transformation in the drug development process for this indication. In tuberculosis, Romero's leadership was instrumental in generating a drug development infrastructure that allowed the approval of the first new individual drug and the first new regimen for this disease, in more than 50 years. Dr. Romero's leadership has also resulted in the transformation of therapeutic development paradigms for many other diverse areas, like polycystic kidney, Parkinson's and Huntington's diseases, as well as type 1 diabetes prevention, kidney transplantation, Duchenne muscular dystrophy, and several other rare and orphan indications. As a trained clinical pharmacologist and epidemiologist, Dr. Romero is a fellow of the American College of Clinical Pharmacology, a founding member of the International Society of Pharmacometrics, as well as a member of the American Society for Clinical Pharmacology and Therapeutics, and the International Society of Pharmacoepidemiology. He is also an Associate Research Professor at the University of Arizona, as well as an Adjunct Professor at the University of Southern California and Arizona State University.

Eric J. Rubin, M.D., Ph.D., is the current Editor-in-Chief, New England Journal of Medicine and NEJM Group, having been appointed in 2019 after serving as an Associate Editor since 2012. He is Adjunct Professor of Immunology and Infectious Disease and a tuberculosis researcher at the Harvard T.H. Chan School of Public Health. Dr. Rubin is an Associate Physician at Brigham & Women's Hospital in Boston. A native of Brockton, Massachusetts, Dr. Rubin earned a Bachelor of Arts degree from Harvard, an M.D. from Tufts University School of Medicine, and a Ph.D. from Tufts University.

Sam Sinai, Ph.D., is a scientist-entrepreneur and co-founder of Dyno Therapeutics, an AI-driven company pioneering next-generation gene therapies. He has led groundbreaking innovations in applying generative AI to biology, publishing his work in famous venues including Science, Nature Biotechnology, and NeurIPS. Sam holds graduate degrees from Harvard and MIT.

Marshall Summar, M.D., is a leading figure in rare disease care and research, with more than 40 years of experience. As a board-certified pediatrician and geneticist, he specializes in clinical and biochemical genetics, focusing on genetic-environmental interactions. His expertise extends to rare disease clinical trials, where he has driven innovations in trial design, therapies, and patient outcomes. In 2022, Dr. Summar founded Uncommon Cures, where he serves as Chief Executive Officer. The company aims to enhance rare disease clinical trials by consolidating resources and incorporating technology to streamline processes. His career began at Vanderbilt University, where he held leadership roles in the Center for Human Genetic Research, the Medical Genetics Division, the CTSA grant, the Cancer Center, the General Clinical Research Center (GCRC) and was promoted to Tenured Professor. At Children’s National Medical Center, he served as Director of the Clinical Research Center, Division Chief for Genetics and Metabolism, and was the founding director of the Rare Disease Institute—the first dedicated clinical center for patients with genetic rare diseases—and the inaugural NORD-designated Rare Disease Center of Excellence as well as serving as a tenured professor at George Washington University and awarded Emeritus Status. Dr. Summar’s contributions include over 180 peer-reviewed publications and more than 100 international patents on therapies, devices, and software. His work has yielded FDA-approved treatments and supported ongoing trials for conditions like sickle cell anemia, organic acidemias, congenital heart disease, and premature birth. Beyond research, Dr. Summar has held leadership positions, including President of the National Organization for Rare Disorders (NORD) Board of Directors and the Society for Inherited Metabolic Disorders. He helped develop NORD’s IAMRARE patient registry platform

and the Rare Disease Centers of Excellence program. He also advises organizations such as PHLOW Pharmaceuticals, NIH's National Center for Advancing Translational Sciences, and the Pediatric Inclusion Alliance. In 2022, NORD honored him with its Lifetime Achievement Award for his dedication to rare diseases.

Shawn M. Sweeney, Ph.D., is a scientist, educator, and servant leader. He is the senior director of the AACR Project GENIE Coordinating Center and project lead, having served the project since its inception in 2015. Prior roles at the AACR include project lead and content developer for the AACR Cancer Progress Report series (2011- 2016); and as an internal scientific consultant. Before joining the AACR, Sweeney was a researcher in the Cardiovascular Institute and the Institute for Medicine and Engineering at the University of Pennsylvania. His more than 15-year career in research focused on the role of the microenvironment in angiogenesis/lymphangiogenesis, as well as in breast cancer metastasis with an active drug development program. Sweeney was also an adjunct associate professor of medicine at the School of Medicine of the International University of the Health Sciences (2008-2017) where he taught first and second year medical students medical embryology and pharmacology. Sweeney firmly believes in the transformative power of both real-world data and bicycles and looks forward to contributing to the learning healthcare system the world needs.

Developing Regenerative Medicine Therapies with Artificial Intelligence: A Workshop

November 18, 2025

Speaker Guidance: Context and Key Questions

The Forum on Regenerative Medicine on Regenerative Medicine, in collaboration with the Forum on Drug Discovery, Development, and Translation, is hosting this workshop to consider the opportunities and challenges with using artificial intelligence (AI) to enhance the translation of regenerative medicine therapies. The workshop will explore the potential applications of AI as a tool in regenerative medicine throughout the product development pipeline. The questions listed below were developed by the workshop planning committee to provide some guidance to the speakers as they prepared for the workshop and their presentations and the moderated panel discussions.

SESSION I: OPENING REMARKS & KEYNOTE

Guidance and Key Questions for AI Keynote Speaker

1. Please provide a brief level-setting introduction to the fundamental principles of how AI works for an audience that is highly interested in AI, but likely using it to varying degrees in their day-to-day work in regenerative medicine.
2. What are some of the major AI advancements currently shaping the drug development and health care fields? What are some lessons learned and best practices from these advancements that could be applied along the translational research pathway and through to clinical care for regenerative medicine, such as the cell and gene therapy fields?
3. What are some best practices in rigor, generalizability, and explainability for AI that you have adopted in your work? How could they be applied to the regenerative medicine field?
4. What are some challenges in the adoption and implementation of these new AI tools? What are some of the major bottlenecks to implementation at the pharma-scale?
5. As AI use becomes more prevalent in regenerative medicine, how can the field help prepare its workforce for AI and promote collaboration?
6. Considering the future of AI in the drug development and health care fields, what are you looking forward to and are excited about the most?

Guidance and Key Questions for Regenerative Medicine Keynote Speaker

1. What are some challenges in regenerative medicine that AI could potentially help address? What kinds of AI tools do you see as having the largest potential in regenerative medicine at the different stages of therapy development?
2. What ethical or accountability issues do you anticipate arising as AI tools are deployed in the development and manufacturing of regenerative medicine therapies and in clinical trials?
3. What challenges to the adoption, implementation, and regulation of these new AI tools do you anticipate? What actions could be taken to help the field prepare for these challenges?
4. As AI use becomes more prevalent in regenerative medicine, how can the field help prepare its workforce for AI and promote collaboration?
5. Within the next five years, what do you see as the most immediate opportunity and most pressing risk of applying AI to regenerative medicine? What can AI realistically achieve in this field, and what is needed to get there?

Guidance and Key Questions for Keynote Reflection Speakers

1. Please provide a brief introduction of your expertise within AI and regenerative medicine to provide context for your keynote reflections.
2. Reflecting on the keynote addresses, what are some of your key takeaways and what would you add to the topics discussed in terms of major advancements for the field and opportunities and areas of potential caution for using AI in regenerative medicine?
3. Within the next five years, what do you see as the most immediate opportunity and most pressing risk of applying AI to regenerative medicine? What can AI realistically achieve in this field, and what is needed to get there?
4. How are regulatory agencies/bodies preparing to regulate AI applied in regenerative medicine and advanced therapy products?

SESSION II: AI IN THE PRE-CLINICAL DEVELOPMENT OF REGENERATIVE MEDICINE THERAPIES

Session Objectives

- Examine recent advances and potential future uses of AI in pre-clinical model systems and the design and development of regenerative medicine therapies.
- Discuss the practical considerations for effective, ethical, and reproducible implementation of these tools at the pre-clinical stage of product development.

Questions for Speakers – Case Study

1. How are you currently using AI in pre-clinical research and the design and development of regenerative medicine therapies? Please use a case study approach to provide a

proof-of-concept example of an AI application in the pre-clinical stage of regenerative medicine therapy and cellular/disease model development.
2. What types AI models do you employ? What data do your AI tools use and how do you curate these data?
3. How do you validate and ensure reproducible implementation of your AI models? How do you factor in generalizability, bias migration, and regulatory considerations when designing and implementing your models?
4. What ethical or accountability issues have arisen or are anticipated to arise as your AI tools are deployed?

Questions for Speakers – Future Opportunities

1. What are some challenges in the pre-clinical stage of regenerative medicine therapy and model development that AI could potentially help address?
2. How can pre-clinical AI innovations anticipate or influence downstream clinical or regulatory applications?
3. What do you see as the most immediate opportunity and most pressing risk of applying AI to the pre-clinical stage of regenerative medicine therapy and cellular/disease model development in the next five years? What can AI realistically achieve, and what is needed to get there?

SESSION III: AI IN REGENERATIVE MEDICINE CLINICAL TRIALS AND MANUFACTURING

Session Objectives

- Explore recent advances and potential future applications of AI to support regenerative medicine clinical trials, regulatory processes, and manufacturing.
- Discuss the practical considerations for effective, ethical, and reproducible implementation of these tools at the clinical and post-market stage of product development.

Questions for Speakers – Case Study

1. How are you currently using AI to support regenerative medicine clinicals trials, regulatory processes, or manufacturing? Please use a case study approach to provide a proof-of-concept example of an AI application in the clinical and post-market stage of product development.
2. What types of AI models do you employ? What data do your AI tools use and how do you curate these data?
3. What are some challenges and lessons learned from integrating AI into pre-existing clinical, manufacturing, or quality control pipelines?
4. How do you validate and ensure reproducible implementation of your models? How do you assure and test in generalizability, bias, and regulatory considerations when designing and implementing your models?

5. What ethical or accountability issues have arisen or are anticipated to arise as your AI tools are deployed?

Questions for Speakers – Future Opportunities

1. What are some challenges in the clinical and post-market stages of regenerative medicine therapy development that AI could potentially help address?
2. What downstream impacts do you anticipate will arise from the increased use of AI in regenerative medicine clinical trials and manufacturing?
3. What do you see as the most immediate opportunity and most pressing risk of applying AI to the regenerative medicine therapy clinical trials, manufacturing, and regulation in the next five years? What can AI realistically achieve, and what is needed to get there?

SESSION IV: LAYING THE DATA GROUNDWORK FOR REGENERATIVE MEDICINE AI TOOLS

Session Objectives

- Discuss the current opportunities and challenges to collecting, curating, and sharing the data necessary for AI applications in regenerative medicine.
- Explore the ethical and legal considerations of sharing regenerative medicine-associated data.

Questions for Moderated Fireside Chat:

1. What are some of the challenges the regenerative medicine field needs to address to collect, curate, and share data for AI-driven systems? Please provide any promising solutions or lessons learned from your work that can help address these challenges.
2. What are some of the challenges associated with identifying, collecting, and curating sufficient and relevant data that are needed for training models that will have an impact on the field? Additionally, what are some of the challenges associated with validating and employing those models? Please also address any proposed solutions to these challenges.
3. What ethical and legal considerations, such as patient privacy and protecting proprietary information, are unique to this field, and how do you approach these concerns in your work?

SESSION V: BUILDING TRUST IN AI FOR REGENERATIVE MEDICINE

Session Objectives

- Discuss the current limitations of AI trustworthiness and explore opportunities to address these gaps and build trust in AI within the regenerative medicine field.
- Consider practical approaches to helping the regenerative medicine workforce navigate the current AI landscape and developing AI literacy skills.

Questions for Moderated Fireside Chat

1. What are some of the challenges the regenerative medicine field needs to address to improve the trustworthiness of AI tools? Please provide any promising solutions or lessons learned from your work that can help address these challenges.
2. How can the field navigate the hype around AI and build confidence in these technologies?
3. What educational strategies can be implemented to prepare the workforce for implementing AI within regenerative medicine?

SESSION VI: FINAL REFLECTIONS AND FUTURE OPPORTUNITIES

Questions for Moderated Fireside Chat

1. Please briefly discuss one takeaway from the workshop that can help the field better use AI to develop regenerative medicine therapies.
2. What advancements, such as new research, policies, implementation practices, or governance, are needed to propel this space forward and could make a significant impact on developing effective and accessible regenerative medicine therapies?
3. What topic or issue wasn't covered here today, or wasn't covered in enough detail, that should be considered for a future discussion?

NATIONAL ACADEMIES Sciences Engineering Medicine

PREVENTING DISCRIMINATION, HARASSMENT, AND BULLYING:
POLICY FOR PARTICIPANTS IN NASEM ACTIVITIES

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Discrimination is prejudicial treatment of individuals or groups of people based on their race, ethnicity, color, national origin, sex, sexual orientation, gender identity, age, religion, disability, veteran status, or any other characteristic protected by applicable laws.

Sexual harassment is unwelcome sexual advances, requests for sexual favors, and other verbal or physical conduct of a sexual nature that creates an intimidating, hostile, or offensive environment.

Other types of harassment include any verbal or physical conduct directed at individuals or groups of people because of their race, ethnicity, color, national origin, sex, sexual orientation, gender identity, age, religion, disability, veteran status, or any other characteristic protected by applicable laws, that creates an intimidating, hostile, or offensive environment.

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REPORTING AND RESOLUTION

Any violation of this policy should be reported. If you experience or witness discrimination, harassment, or bullying, you are encouraged to make your unease or disapproval known to the individual at the time the incident occurs, if you are comfortable doing so. You are also urged to report any incident by:

- Filing a complaint with the Office of Human Resources at 202-334-3400 or hrservicecenter@nas.edu, or
- Reporting the incident to an employee involved in the activity in which the member or volunteer is participating, who will then file a complaint with the Office of Human Resources.

Complaints should be filed as soon as possible after an incident. To ensure the prompt and thorough investigation of the complaint, the complainant should provide as much information as is possible, such as names, dates, locations, and steps taken. The Office of Human Resources will investigate the alleged violation in consultation with the Office of the General Counsel.

If an investigation results in a finding that an individual has committed a violation, NASEM will take the actions necessary to protect those involved in its activities from any future discrimination, harassment, or bullying, including in appropriate circumstances **the removal of an individual from current NASEM activities and a ban on participation in future activities**.

CONFIDENTIALITY

Information contained in a complaint is kept confidential, and information is revealed only on a need-to-know basis. NASEM will not retaliate or tolerate retaliation against anyone who makes a good faith report of discrimination, harassment, or bullying.

Updated December 2, 2021

FORUM INFORMATION

NATIONAL ACADEMIES Sciences Engineering Medicine

Forum on Regenerative Medicine

The National Academies of Sciences, Engineering, and Medicine's Forum on Regenerative Medicine provides a convening mechanism for interested parties from academia, industry, government, patient and provider organizations, regulators, foundations, and others to meet and discuss sensitive and difficult issues in a neutral setting in order to engage in dialogue and discussions that address the challenges facing the application of, and the opportunities for, regenerative medicine to improve health through the development of effective new therapies. The Forum identifies existing and potential barriers to scientific and therapeutic advances; identifies and discusses opportunities to assist in facilitating more effective partnerships among key interested parties; examines the impact that current policies have on the discovery, development, and translation of regenerative medicine therapies; examines the unique challenges of identifying, validating, and bringing regenerative medicine applications to market; and explores the ethical, legal, and social issues posed by regenerative medicine advances.

Regenerative medicine holds the potential to create living, functional tissues which can be used to repair or replace those that have suffered irreparable damage due to disease, age, traumatic injury, or congenital defects. Whether through tissue-engineering, synthetic constructs, or cellular therapies, the field holds the promise of providing relief to those suffering from traumatic injuries to neurodegenerative diseases. However, the enormous potential health and economic benefits this relatively new field could potentiate upon society must be balanced by the enactment of the proper policies and procedures to assure these therapies are safe and effective for use.

There are a number of key issues that must be explored and illuminated in order to realize the full potential of regenerative medicine. Ethical, legal, and social issues pose potential challenges with much debate still taking place around the use of adult, embryonic, and induced pluripotent stem cells for research and therapy. Additionally, many prospective advances, while developed for disease treatment, have the potential to be used for enhancement of physical attributes or anti-aging therapy. There is also a concern about possible unanticipated consequences of these treatments and products and the potential for stockpiling of and unequal access to organs. Ensuring the ethical application of regenerative medicine advances will be critical to not only progress the field but also to improve the health of individuals and the public.

Scientific and technical hurdles also exist for which a better fundamental understanding of the underlying cell biology is necessary. This knowledge will allow for more specific engineering of tissues and organs and will diminish the chance of transplant rejection by ensuring biocompatibility with the host tissue. Similarly, it is necessary to understand the cellular response to biomaterials and scaffolds to ensure that the desired biological function is developed and retained. While great advances have been realized to date, to take full advantage of regenerative medicine, the barriers to scientific advance will need to be delineated and potential solutions discussed.

Guidelines for the safe and proper use of regenerative medicine advances will need to be developed, translational barriers identified, and the regulatory environment clearly defined. Commercial aspects will need to be addressed including: the development of cost-effectiveness strategies for growing cells and organs at an industrial capacity; assessments of effectiveness, quality, and biosafety developed; and products certified. Greater dialogue and coordination of efforts between the public and private sectors will enable regenerative medicine products to be brought to market in a safe, effective, and swift manner.

Forum sponsors include federal agencies, medical and scientific associations, foundations, research organizations, patient groups, and industry representatives. For more information about the Forum on Regenerative Medicine, please visit our website at nas.edu/RegenMedForum or contact Sarah Beachy at 202-334-2217 or by email at sbeachy@nas.edu.

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Forum on Regenerative Medicine Membership

Co-Chairs
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Katherine Tsokas, JD, Syracuse University

Ginny Beakes-Read, JD, Johnson & Johnson Innovative Medicine

Karen Christman, PhD, University of California San Diego

Constance Chu, MD, Stanford University

Tammy Collins, PhD, Burroughs Wellcome Fund

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NATIONAL ACADEMIES Sciences Engineering Medicine

FORUM ON REGENERATIVE MEDICINE

Our **purpose** is to spark exchange and inspire action among interested parties to advance regenerative medicine for the benefit of all.

Our actions are guided by the following principles:

Innovation | **Intention** | **Collaboration** | **Integrity**

We effect change using these strategies:

» Foster future generations of thinkers and doers in the field

» Proactively discern critical scientific, medical, and social issues and provide fit-for-purpose venues for reflection and response

» Engage and collaborate with those whose work aligns with ours

» Translate and disseminate what we learn to catalyze action in the field

The priorities of our work:

Clinical Translation and Implementation	Innovation and Emerging Technologies	Workforce Development	Core Group
Highlight and facilitate opportunities to accelerate and improve the clinical translation, implementation, and access to regenerative medicine therapies.	Explore the innovations and emerging technologies that enable the development, manufacturing, and delivery of safe and effective regenerative medicine products and platforms to patients faster, at scale, and more efficiently.	Examine gaps in workforce development and opportunities for expanding, retaining, and engaging with the regenerative medicine workforce.	Track emerging scientific, policy-related, or other issues in the field and coordinate activities across the Forum.

To learn more, visit http://www.nationalacademies.org/our-work/forum-on-regenerative-medicine
or contact Forum Director, Sarah Beachy, at sbeachy@nas.edu

Forum activities—including public workshops, membership meetings, and other information-gathering activities—provide opportunities to discuss important questions and challenges in the field of regenerative medicine and foster the advancement of high-quality science toward safe and effective therapies for patients.

Forum on
DRUG DISCOVERY, DEVELOPMENT,
and TRANSLATION

ABOUT THE FORUM

The Forum on Drug Discovery, Development, and Translation (the forum) of the National Academies of Sciences, Engineering, and Medicine (the National Academies) was created in 2005 by the National Academies Board on Health Sciences Policy to foster communication, collaboration, and action in a neutral setting on issues of mutual interest across the drug research and development lifecycle. The forum membership includes leadership from the National Institutes of Health, the U.S. Food and Drug Administration, industry, academia, consortia, foundations, journals, and patient groups.

Through the forum's activities, participants have been better able to bring attention and visibility to important issues, explore new approaches for resolving problem areas, share information and find common ground, and work together to develop ideas into concrete actions and new collaborations.

Forum work is based on four thematic priorities:

Spurring INNOVATION and IMPLEMENTATION

Revolutionary advances in biomedical research and technology present new and exciting opportunities for the discovery and development (R&D) of new therapies for patients. The evolution of health care is expanding possibilities for integration of clinical research into the continuum of clinical care and new approaches are enabling the collection of data in real-world settings. Innovative modalities, such as digital health technologies and artificial intelligence applications, can now be leveraged to overcome challenges and advance clinical research. The forum unites key stakeholders to identify opportunities, address bottlenecks, and spur innovation in drug discovery, development, and translation.

Increasing PERSON-CENTEREDNESS

There is much greater awareness around the need for more person-centered approaches that prioritize lived experience and justice in the discovery, development, and translation of new treatments. The forum seeks to center priorities of people living with disease and those who have been traditionally excluded from the clinical trials enterprise, advance the science of patient input, and help bring to fruition innovations that better address the needs of patients.

Promoting COLLABORATION and HARMONIZATION

The forum provides a neutral platform for communication and collaboration across sectors and disciplines to better harmonize efforts throughout the drug R&D life cycle. It does this by convening a broad and evolving set of stakeholders to help integrate patients, caregivers, researchers, trialists, community practitioners, sponsors, regulators, payers, patient groups, and others into the continuum of research and clinical care. The forum also strives to enable shared decision-making and ensure that patients have input into research questions, researchers have insight into clinical practice, and practitioners are engaged in the clinical trials enterprise.

Enhancing the WORKFORCE and INFRASTRUCTURE

The forum has fostered the development of strategies to improve the discipline of innovative regulatory science and continues to focus on building a workforce that is adaptable and resilient. Considerable opportunities remain to improve and expand the evolving clinical trials workforce and infrastructure, integrate community-based practices, and engage early-career scientists and clinicians in drug discovery, development, and translation. The forum will continue to anticipate and promote adaptation to changes in the infrastructure of health care delivery.

For more information about the Forum on Drug Discovery, Development, and Translation, please visit at:

NATIONALACADEMIES.ORG/DRUGFORUM

NATIONAL ACADEMIES Sciences Engineering Medicine

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NATIONAL ACADEMIES Sciences Engineering Medicine

BACKGROUND INFORMATION

Developing Regenerative Medicine Therapies with Artificial Intelligence: A Workshop

November 18, 2025

Links to Additional Resources

Session I: Keynote

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Session II: AI in the Pre-Clinical Development of Regenerative Medicine Therapies

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Session V: Building Trust in AI for Regenerative Medicine

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ANNOUNCEMENTS

NATIONAL ACADEMIES Sciences Engineering Medicine

Exploring Applications of AI in Genomics and Precision Health: A Workshop

October 28, 2025

Stream Workshop Recordings:
https://www.nationalacademies.org/event/44932_10-2025_exploring-applications-of-ai-in-genomics-and-precision-health-a-workshop

A planning committee of the National Academies of Sciences, Engineering, and Medicine organized and conducted a public workshop to explore the role of artificial intelligence (AI) in advancing genomics and precision health. The overarching goal of the workshop was to explore current and potential future applications for AI in genomics and precision health along the continuum from translational research to clinical applications.

The workshop included invited presentations and panel discussions to:

- Explore how AI has been implemented in genomics and precision health settings to date (e.g., variant interpretation, data integration, patient and participant identification, return of results, treatment selection).
- Discuss ways in which AI may be applied in the near future, including for multi-modal diagnostics and translational genomics research, while considering the potential benefits and challenges related to data harmonization and security, workforce, and usefulness for all.
- Consider how the accuracy of, and bias inherent to, AI technologies are evaluated and their potential impacts on AI applications in genomics-related research and clinical care.
- Examine lessons learned from applications of AI in other fields that may be transferable to genomics and precision health throughout the translational research process.

NATIONAL ACADEMIES *Sciences Engineering Medicine*

New Consensus Study Report

Simplifying Research Regulations and Policies: Optimizing American Science

https://nap.nationalacademies.org/catalog/29231/simplifying-research-regulations-and-policies-optimizing-american-science

More resources are available through the project page

A recording of the report release webinar can be found here

The U.S. scientific enterprise has produced countless discoveries that have led to significant advances in technology, health, security, safety, and economic prosperity. However, concern exists that excessive, uncoordinated, and duplicative policies and regulations surrounding research are hampering progress and jeopardizing American scientific competitiveness. Estimates suggest the typical U.S. academic researcher spends more than 40 percent of their federally funded research time on administrative and regulatory matters, wasting intellectual capacity and taxpayer dollars. Although administrative and regulatory compliance work can be vital aspects of research, the time spent by researchers on such activities continues to increase because of a dramatic rise in regulations, policies, and requirements over time.

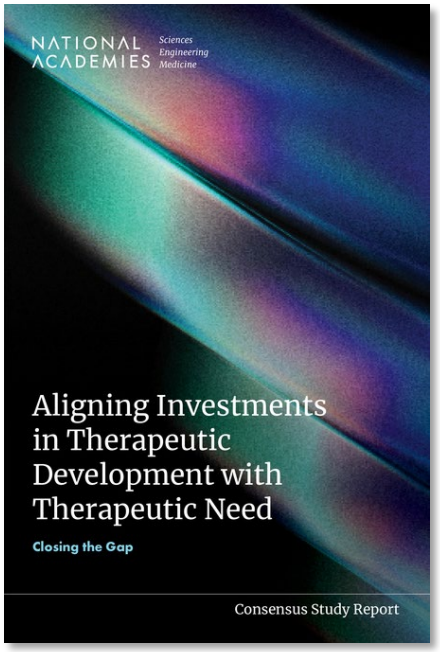
To better ensure that the research community is maximally productive while simultaneously ensuring the safety, accountability, security, and ethical conduct of publicly funded research, Simplifying Research Regulations and Policies: Optimizing American Science examines current federal research regulations. This report identifies ways to improve regulatory processes and administrative tasks, reduce or eliminate unnecessary work, and modify and remove policies and regulations that have outlived their purpose while maintaining necessary and appropriate integrity, accountability, and oversight. Simplifying Research Regulations provides a roadmap for establishing a more agile and resource-effective regulatory framework for federally funded research.

NATIONAL ACADEMIES *Sciences Engineering Medicine*

New Consensus Study Report

Aligning Investments in Therapeutic Development with Therapeutic Need: Closing the Gap

https://nap.nationalacademies.org/catalog/29157/aligning-investments-in-therapeutic-development-with-therapeutic-need-closing-the



More resources are available through the project page

A recording of the report release webinar can be found here

The United States is a global leader in biomedical research, generating therapeutic breakthroughs that advance the health of the nation and the world. The public and private sectors contribute to this advancement by funding biomedical research and development. The current level of investment in pharmaceutical development in the United States, while substantial, does not always yield desired health outcomes or meet the needs of patients. Public and private funders face a myriad of challenges that affect their funding decisions and hinder the ability of the drug development system to prioritize disease burden and unmet need - often leaving critical gaps in available treatment options.

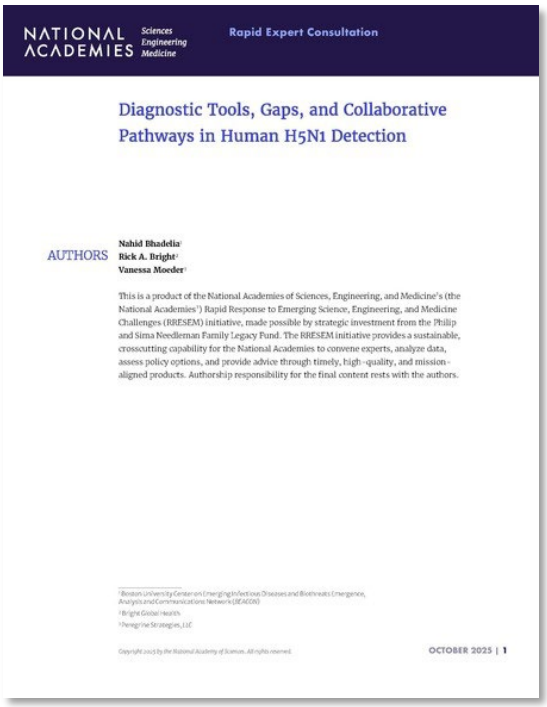
To better understand these gaps, Gates Ventures and the Peterson Center on Healthcare asked the National Academies to examine current challenges and offer strategies and recommendations for improvement. The resulting report emphasizes that current research prioritization does not systematically account for disease burden and unmet needs, and describes how a robust, timely, accessible data system is needed. It also explores the ways in which implementing recommended policy changes could deliver better health outcomes.

NATIONAL ACADEMIES Sciences Engineering Medicine

New Rapid Expert Consultation Release

State of Human H5N1 Diagnostics

https://nap.nationalacademies.org/catalog/29273/diagnostic-tools-gaps-and-collaborative-pathways-in-human-h5n1-detection


NATIONAL ACADEMIES Sciences Engineering Medicine

Rapid Expert Consultation

Diagnostic Tools, Gaps, and Collaborative Pathways in Human H5N1 Detection

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This is a product of the National Academies of Sciences, Engineering, and Medicine's (the National Academies') Rapid Response to Emerging Science, Engineering, and Medicine Challenges (RRESEM) initiative, made possible by strategic investment from the Philip and Sima Needleman Family Legacy Fund. The RRESEM initiative provides a sustainable, crosscutting capability for the National Academies to convene experts, analyze data, assess policy options, and provide advice through timely, high-quality, and mission-aligned products. Authorship responsibility for the final content rests with the authors.

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The Overview of the Rapid Expert Consultation can be found here: https://nap.nationalacademies.org/resource/29273/H5N1_Diagnostics_One_Pager.pdf

Diagnostics are the first line of defense to infectious disease outbreaks. The rapid spread of Influenza A (H5N1) or "Bird Flu" into U.S. dairy cattle, poultry, and humans underscores the urgent need for stronger diagnostic readiness. While sustained human-to-human transmission has not yet occurred with H5N1, the risk is growing. Currently there are knowledge gaps around early case identification measures, clinical management, and coordinated public health efforts.

In response, the National Academies produced a rapid expert consultation providing a strategic and actionable analysis for strengthening domestic diagnostic capacity and infrastructure. This is the first publication of the institution's new Rapid Response to Emerging Science, Engineering, and Medicine Challenges initiative, which provides a formal platform for proactively building sustainable, crosscutting rapid response capabilities.

NATIONAL ACADEMIES *Sciences Engineering Medicine*

New NAS, NAM, & NAE Presidents

Neil H. Shubin to be the next NAS President. He will succeed Marcia McNutt when her second and final term ends on June 30, 2026.

Monica Bertagnolli to be the next NAM President. Bertagnolli will succeed Victor J. Dzau when his second and final term as president ends on June 30, 2026.

Tsu-Jae King Liu began her term as the 13th president of the NAE on July 1, 2025.