NATIONAL ACADEMIES Sciences Engineering Medicine

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

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

Moderators: *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**