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Forum on Regenerative Medicine: 2024-2025 Combined Annual Report (2026)

DETAILS

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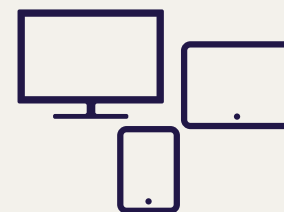
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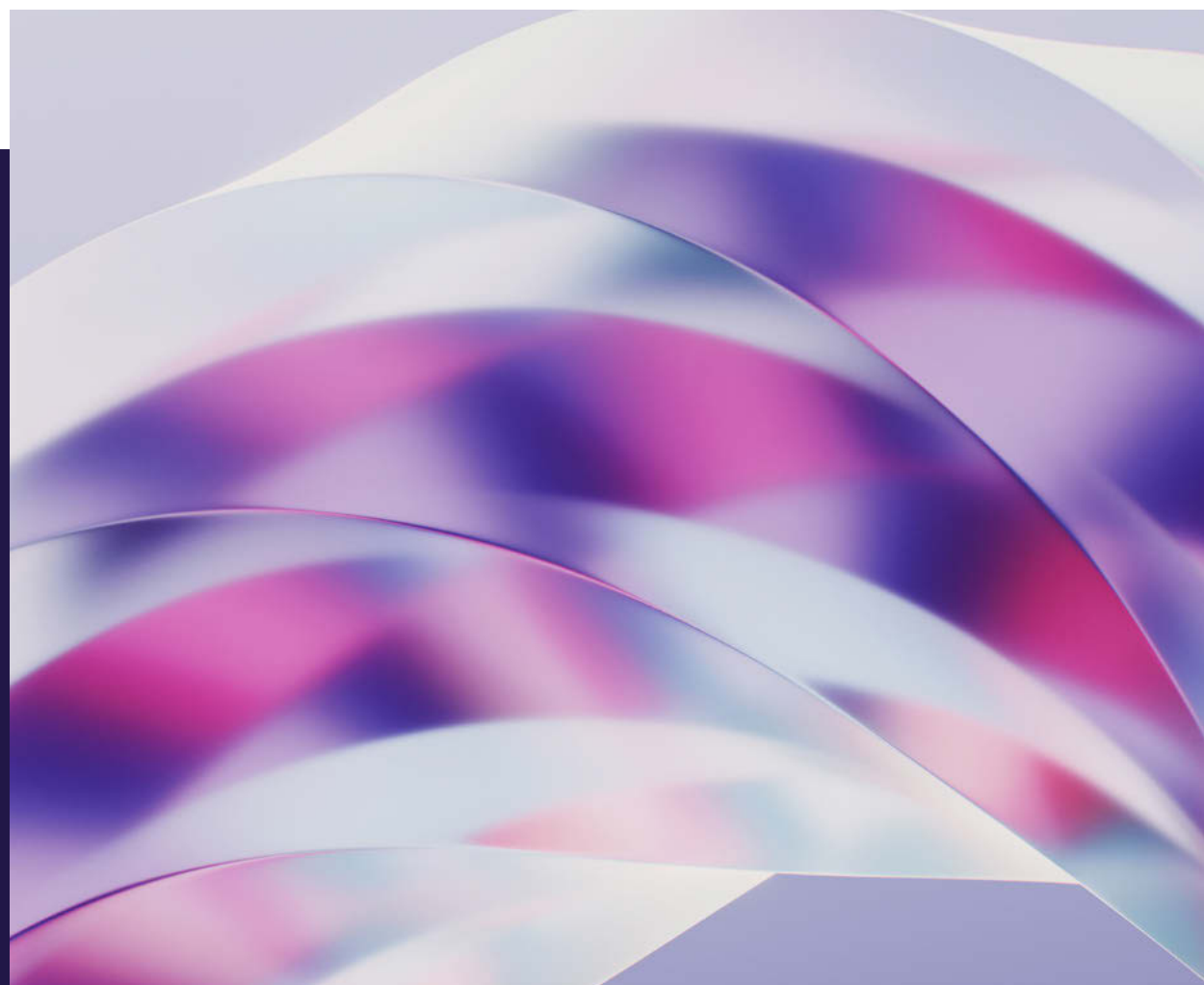
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BIOMEDICAL AND HEALTH SCIENCES

Forum on Regenerative Medicine

2024–2025 Combined Annual Report





About the Forum

The National Academies of Sciences, Engineering, and Medicine's (National Academies') Forum on Regenerative Medicine (the forum) was established in 2016 and provides a convening mechanism for interested parties from academia, industry, government, patient and provider organizations, regulatory bodies, foundations, societies, associations, and others. The purpose of the forum is **to spark exchange and inspire action among interested parties to advance regenerative medicine for the benefit of all**. To achieve this goal, members discuss sensitive and difficult issues in a neutral setting and engage in dialogue that addresses the challenges facing the application of and 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; discusses opportunities to assist in facilitating more effective partnerships among interested parties; examines the impact that current policies have on the discovery, development, and translation of regenerative medicine therapies; considers the unique challenges of identifying, validating, and bringing regenerative medicine applications to market; and explores the ethical, legal, and social issues posed by advances in regenerative medicine.

Over the past several years, the forum has identified important questions and challenges in the field of regenerative medicine that have led the group to explore a broad array of issues ranging from the application of artificial intelligence (AI) and systems-thinking approaches to develop and optimize regenerative medicine products, to the evolving manufacturing models for therapy production, to the challenge of regulating a rapidly changing field. By bringing together experts and leveraging multiple perspectives and knowledge, forum members have collaborated to identify strategic opportunities to advance the field of regenerative medicine through hosting public workshops, publishing perspective papers and workshop proceedings, and serving as a resource for the community to foster the advancement of high-quality science and work towards safe and effective therapies for patients.

<https://www.nationalacademies.org/regenmedforum>

Strategic Areas of Focus

The forum has working groups to focus on the main aspects of regenerative medicine: Clinical Translation and Implementation, Innovation and Emerging Technologies, and Workforce Development. The members and staff of the Forum on Regenerative Medicine also continue to work toward the forum's vision by exploring challenges and discussing possible solutions to areas relevant to the development of regenerative medicines, including communication, cost of and access to therapies, and regulatory and legislative affairs.

In alignment with the forum's purpose and strategic plan, a core group coordinates activities across the forum and identifies topics and speakers of interest for upcoming forum meetings. The group also monitors scientific and technological advancements in regenerative medicine and develops sessions on updates in policies and ethics surrounding the field.

Clinical Translation and Implementation

The forum's working group on Clinical Translation and Implementation aims to highlight and facilitate opportunities to accelerate and improve the clinical translation, implementation, and access to regenerative medicine therapies. This group is interested in examining obstacles to accessing therapies and plans to host a workshop on this topic in late 2026.

Innovation and Emerging Technologies

The forum's working group on Innovation and Emerging Technologies explores 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. The group held a public workshop in late 2025 to understand the role of AI and related technologies on the development of regenerative medicine therapies and products.

Workforce Development

The forum's working group on Workforce Development examines gaps in workforce development and opportunities for expanding, retaining, and engaging with the regenerative medicine workforce. During previous work, this group explored gaps in regenerative medicine workforce training to learn about needs from companies in the pre-investigational new drug (IND), IND, and post-IND stages of development. This work was presented at the International Society for Cell & Gene Therapy annual meeting in May 2025 and was developed into a white paper to be published in early 2026 along with an accompanying webinar, Strengthening the Regenerative Medicine Workforce.

Public Workshops

THE INTERSECTION OF REGENERATIVE MEDICINE AND WOMEN'S HEALTH: A WORKSHOP

- October 1, 2024
- This public workshop examined opportunities in regenerative medicine to address current gaps in basic science, translational research, and related therapies for women. Presentations and discussions explored strategies to better understand the underlying biology that would enable development of regenerative medicine therapies for women.
- Learn more about this workshop here: <https://www.nationalacademies.org/our-work/the-intersection-of-regenerative-medicine-and-womens-health-a-workshop>

DEVELOPING REGENERATIVE MEDICINE THERAPIES WITH ARTIFICIAL INTELLIGENCE: A WORKSHOP

- November 18, 2025
- This public workshop considered the opportunities and challenges with using AI to enhance the translation of regenerative medicine therapies. Presentations and discussions explored the potential applications of AI as a tool in regenerative medicine throughout the product development pipeline.
- Learn more about this workshop and view the interactive webpage, including a video featuring key messages from workshop speakers, here: <https://www.nationalacademies.org/projects/HMD-HSP-24-22>

Meetings

March 19–20, 2024 (virtual)

Forum members held the first session in the three-part series, *Exploring Gaps in Regenerative Medicine Workforce Training*, which focused on the perspective of companies in the pre-IND stage of product development. Members learned of 2024 priorities for the U.S. Food and Drug Administration (FDA)/Center for Biologics Evaluation and Research Office of Therapeutic Products and explored current gaps in women's health care and research and began examining opportunities in regenerative medicine to address these gaps in preparation for the fall workshop.

June 4–5, 2024 (virtual)

Forum members continued examining gaps in the regenerative medicine workforce training in the second session of the series, this time learning about industry needs at the IND-enabling stage of development. The members also learned from the field of cellular agriculture manufacturing and started exploring the uses of AI technologies in regenerative medicine.

October 1–2, 2024 (in-person)

Following the public workshop The Intersection of Regenerative Medicine and Women's Health, the members debriefed, discussed next steps for the forum, and reflected on the forum's strategic plan.

November 14, 2024 (virtual)

Forum members learned more about gaps in the regenerative medicine workforce training during this final session of the three-part series from those working at companies in the post-IND stage of development.

March 18–19, 2025 (virtual)

Forum members explored data sharing in regenerative medicine, examining systems developed to foster sharing of biological data for research and clinical trials. Members learned about ongoing work in regenerative medicine standards development and standards training programs, discussed opportunities to translate cell and gene therapies into the clinic, and welcomed our new academic members to the forum.

July 23–24, 2025 (virtual)

Forum members convened a joint listening session with the Roundtable on Genomics and Precision Health to learn more about partnering with patients to implement cell and gene therapies. Several members also shared updates from their organizations' work on incorporating the community perspective in research funding, oversight of human stem cell-based embryo model research, and stem cell deregulation. Members also examined strategies for public–private partnerships in regenerative medicine and heard from members about how their organizations are exploring collaboration models.

November 18–19, 2025 (in-person)

Following the public workshop Developing Regenerative Medicine Therapies with Artificial Intelligence, the members debriefed, continued their discussion from the summer on collaborative models and partnerships, and discussed next steps for the forum and plans for 2026.

Publications

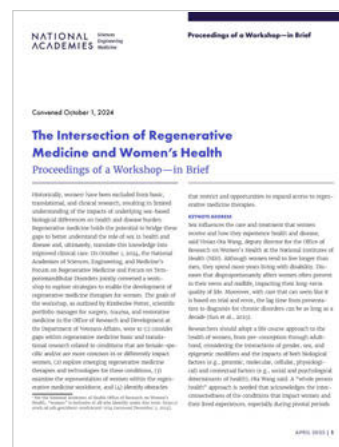
Emerging Technologies and Innovation in Manufacturing Regenerative Medicine Therapies: Proceedings of a Workshop—in Brief (2024)

- **View publication here:** <https://doi.org/10.17226/27483>
- View the graphic illustrations here: https://www.nationalacademies.org/event/40391_10-2023_emerging-technologies-and-innovation-in-manufacturing-regenerative-medicine-therapies-a-workshop



The Intersection of Regenerative Medicine and Women's Health: Proceedings of a Workshop—in Brief (2025)

- View publication here: <https://www.nationalacademies.org/publications/29088>.
- View interactive webpage here: <https://nap.nationalacademies.org/resource/29088/interactive/>
- Watch the recording of this workshop here: <https://www.nationalacademies.org/projects/HMD-HSP-24-02/event/43007>.



RELATED ACTIVITIES AND ENGAGEMENT

The forum continued to strengthen its community and advance work between meetings through membership growth, workforce initiatives, mentorship, and cross-disciplinary collaboration.

In 2024, the forum launched a search to expand its academic representation. As a result, Karen Christman (University of California San Diego), Constance Chu (Stanford University), Erika Moore (University of Maryland), and Jessica Weaver (Arizona State University) joined the forum in 2025, bringing new expertise and perspectives to the membership.

Building on the forum's 2024 listening session series, *Exploring Gaps in Regenerative Medicine Workforce Training*, a subgroup of members began developing a white paper in early 2025 to further examine workforce challenges and opportunities. The group also shared preliminary findings through a poster presentation at the International Society for Cell & Gene Therapy Annual Meeting in New Orleans in May 2025.

The forum hosted a Mirzayan Fellow in spring 2025 who supported forum activities and contributed to the workforce initiative. Members shared their expertise, professional experiences, and mentorship, providing valuable exposure to careers at the intersection of regenerative medicine, cell and gene therapies, and health policy.

Looking ahead, the forum's co-chairs joined other National Academies forum and roundtable leaders in summer 2025 to identify opportunities for cross-disciplinary collaboration and shared programming. These discussions highlighted new avenues for partnership and reinforced the forum's commitment to addressing emerging challenges and opportunities across the regenerative medicine ecosystem.

Forum Membership

(AS OF DECEMBER 2025)

Krishnendu Roy, Ph.D. (Co-Chair)
Vanderbilt University

Katherine Tsokas, J.D. (Co-Chair)
Syracuse University

Ginny Beakes-Read, J.D.
Johnson & Johnson Innovative Medicine

Karen Christman, Ph.D.
University of California San Diego

Constance Chu, Ph.D.
Stanford University

Tiziana P. Cogliati, Ph.D.
National Institute on Aging

Tammy Collins, Ph.D.
Burroughs Wellcome Fund

Ashley Fortress, Ph.D.
National Eye Institute

Uta Grieshammer, Ph.D.
California Institute for Regenerative Medicine

Tim Hunt, J.D.
Alliance for Regenerative Medicine

Albert Hwa, Ph.D.
National Institute of Diabetes and Digestive and Kidney Diseases

Cato T. Laurencin, M.D., Ph.D.
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Aron Marquitz, Ph.D.
National Institute of Arthritis and Musculoskeletal and Skin Diseases

Michael May, Ph.D.
Centre for Commercialization of Regenerative Medicine

Richard McFarland, Ph.D., M.D.
Advanced Regenerative Manufacturing Institute

Erika Moore, Ph.D.
University of Maryland

Jack T. Mosher, Ph.D.
International Society for Stem Cell Research

Steven Oh, Ph.D.
U.S. Food and Drug Administration

Amy Patterson, M.D.
National Heart, Lung, and Blood Institute

Thomas Petersen, M.D., Ph.D.
United Therapeutics Corporation

Kimberlee Potter, Ph.D.
U.S. Department of Veterans Affairs

David Rampulla, Ph.D.
National Institute of Biomedical Imaging and Bioengineering

Derek Robertson, M.B.A., J.D.

Maryland Sickle Cell Disease Association

Krishanu Saha, Ph.D.

University of Wisconsin–Madison

Nabiha Saklayen, Ph.D.

Cellino

Rachel Salzman, D.V.M.

American Society of Gene & Cell Therapy

Sumona Sarkar, Ph.D.

National Institute of Standards and Technology

Eric Sid, M.D.

National Center for Advancing Translational Sciences

Jessica Weaver, Ph.D.

Arizona State University

Daniel Weiss, M.D., Ph.D.

International Society for Cell & Gene Therapy

Kathleen Zackowski, Ph.D.

National Multiple Sclerosis Society

Claudia Zylberberg, Ph.D.

Kosten Digital

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(AS OF DECEMBER 2025)

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American Society of Gene & Cell Therapy

Burroughs Wellcome Fund

California Institute for Regenerative Medicine

Cellino Biotech, Inc.

Centre for Commercialization of Regenerative Medicine

International Society for Cell & Gene Therapy

International Society for Stem Cell Research

Johnson & Johnson

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National Institute of Standards and Technology

United Therapeutics Corporation

U.S. Department of Veterans Affairs

U.S. Food and Drug Administration

Forum Timeline

2016 June 28 Meeting 1

October 13 The State of the Science in the Field of Regenerative Medicine: Challenges of and Opportunities for Cellular Therapies Workshop

October 14 Meeting 2

2017 March 28–29 Meeting 3

June 26 Navigating the Manufacturing Process and Assuring the Quality of Regenerative Medicine Therapies Workshop

June 27 Meeting 4

October 26 Meeting 5

2018 February 26–27 Meeting 6

July 23–24 Meeting 7

October 18 Exploring Sources of Variability Related to the Clinical Translation of Regenerative Engineering Products Workshop

October 19 Meeting 8

2019 February 26 Meeting 9

July 17–18 Meeting 10

November 13 Exploring Novel Clinical Trial Designs for Gene-Based Therapies Workshop

November 14 Meeting 11

2020 March 11–12 Meeting 12

July 21–22 Meeting 13

October 22–23 Applying Systems Thinking to Regenerative Medicine Workshop

October 28 Meeting 14

2021 February 23–24 Meeting 15

June 14–15 Meeting 16

November 2–3 Understanding the Role of the Immune System in Improving Tissue Regeneration Workshop

November 10 Meeting 17

2022 February 4 Meeting 18 – strategic planning begins

March 15 Meeting 19

May 10–11 Meeting 20

July 21 Meeting 21 – strategic plan adoption

November 15 Training the Regenerative Medicine Workforce for the Future Workshop

November 16 Meeting 22

2023 March 21–22 Meeting 23

July 18–19 Meeting 24

October 17 Emerging Technologies and Innovation in Manufacturing Regenerative Medicine Therapies Workshop

October 18 Meeting 25

2024 March 19–20 Meeting 26

June 4–5 Meeting 27

October 1 The Intersection of Regenerative Medicine and Women's Health Workshop

October 2 Meeting 28

November 14 Meeting 29

- 2025

March 18–19

Meeting 30

July 23–24

Meeting 31

November 18

Developing Regenerative
Medicine Therapies with Artificial Intelligence
Workshop

November 19

Meeting 32
-

- 2026

March 10–11

Meeting 33

June 16–17

Meeting 34

October 14

Workshop TBA

October 15

Meeting 35
-

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ABOUT THE NATIONAL ACADEMIES

The National Academy of Sciences, the National Academy of Engineering, and the National Academy of Medicine work together as the National Academies of Sciences, Engineering, and Medicine (the National Academies) to provide independent, objective analysis and advice to the nation and conduct other activities to solve complex problems and inform public policy decisions. The National Academies also encourage education and research, recognize outstanding contributions to knowledge, and increase public understanding in matters of science, engineering, and medicine.

The Health and Medicine Division (HMD) is a division of the National Academies. HMD's aim is to help those in government and the private sector make informed health decisions by providing evidence upon which they can rely. Each year, more than 3,000 individuals volunteer their time, knowledge, and expertise to advance the nation's health through the work of HMD.

Many of the studies that HMD undertakes are requested by federal agencies and independent organizations; others begin as specific mandates from Congress. While expert, consensus committees are vital to its advisory role, HMD also convenes a series of forums, roundtables, and standing committees, as well as other activities, to facilitate discussion, discovery, and cross-disciplinary thinking.



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