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Developing Regenerative Medicine Therapies with Artificial Intelligence: A Workshop

November 18, 2025

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

Anne Plant, Workshop Co-Chair
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Planning Committee Members

Anne Plant (*Workshop Co-Chair*), *Emerita*, National Institute of Standards and Technology

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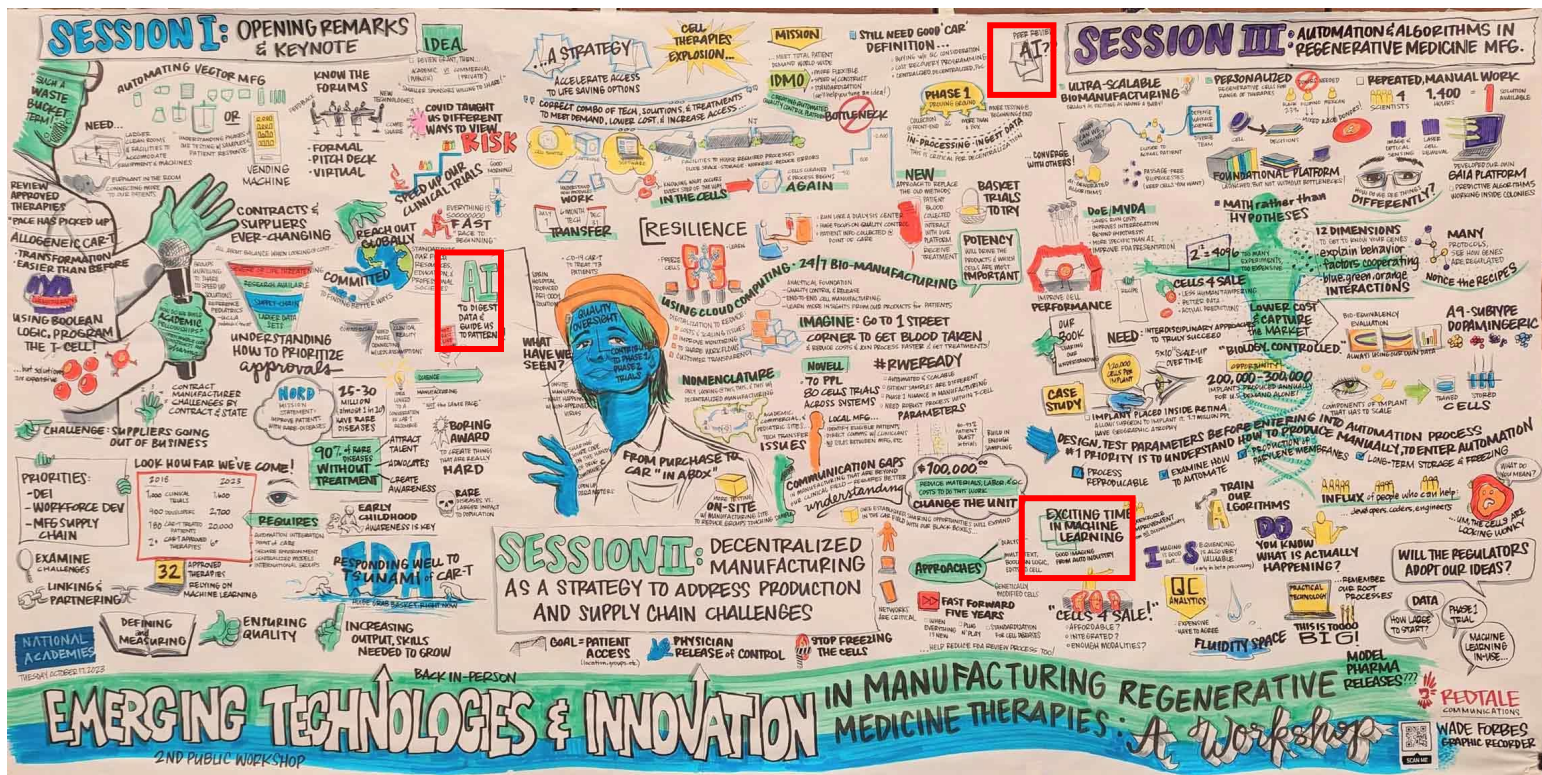
John Knighton, Johnson & Johnson

Jagdeep Podichetty, Critical Path Institute

Scott Steele, US Food and Drug Administration

Claudia Zylberberg, Kosten Digital

Most Recent Previous Workshop: Emerging Technologies and Innovation in Manufacturing Regenerative Medicine Therapies



Purpose of Today's Workshop: AI as Emerging Technology

To explore the potential applications of artificial intelligence (AI) in regenerative medicine throughout the product development pipeline, such as:

- Pre-clinical model systems for discovery and design of cell and gene therapies
- Innovating clinical trial practices and informing regulatory processes
- Analyzing large data sets to provide insight from clinical and nonclinical data
- Advancing biomanufacturing practices and regulation
- Predicting patient outcomes
- Assessing the reliability of AI to assure safe and effective therapies

The Nexus of AI and Regenerative Medicine

- **Regenerative Medicine:** iPSC-derived therapies, tissue engineering, cell- and gene-based treatments are approaching scale.
- **Artificial Intelligence (AI):** A powerful engine for modeling, automation, manufacturing, and drug discovery.
- **Future Imperative:** Near-term decisions made regarding AI/RM integration will shape the trajectory of medicine and regulatory science for the coming century.

Co-Chair Vision: Aligning for High-Impact Innovation

- **Patient-Centricity:** Access and patient outcomes are our unwavering North Star
- **Acceleration of patient accessibility through integration:** AI and Regenerative Medicine will work in concert to compress timelines, amplify precision, expand scale, and potentially reduce cost
- **AI Trust by Design:** Essential foundations for reliable AI are strong data governance, validation, and transparency to sustain public confidence.

Workshop Goal: Spark New Ideas For A Better Future

- **Pinpoint Opportunities and Challenges:** Identify the most promising, high-yield intersections of AI and Regenerative Medicine. Identify logistical and conceptual barriers that require community engagement.
- **Examine:** Consider the outstanding needs for essential infrastructure, standards, and regulatory frameworks for trust and translation.
- **Seed:** Foster long-lasting partnerships across academia, industry, and policy sectors.
- **Spark:** Help convert expert insights into scalable, validated, and patient-ready therapies.

Today's Agenda

- **SESSION I: Opening Remarks and Keynote**
- SESSION II: AI in the Pre-Clinical Development of Regenerative Medicine Therapies
- SESSION III: AI in Regenerative Medicine Clinical Trials and Manufacturing
- SESSION IV: Laying the Data Groundwork for Regenerative Medicine AI Tools
- SESSION V: Building Trust in AI for Regenerative Medicine
- SESSION VI: Final Reflections and Future Opportunities

How to Engage with Us Today

Asking Questions

Please state your question succinctly in ~30 sec after stating your name and affiliation

- **In-Person:** Speak into a microphone so those online can hear too
- **Remote:** Use the Slido box beneath the webcast to share your questions for the panelists

Other

- Speaker bios can be found in the briefing book located on the workshop webpage
- A survey will be shared with you after the workshop to collect your feedback
- A proceedings—in brief will be published based on the day's discussions

Thank you for joining us!

