Cell and Gene Therapy Summit

June 15, 2025 | Washington, DC

Overview

In January 2024, DIA held a multi-stakeholder executive roundtable on this topic, which resulted in a publication with specific recommendations that came out in May 2024. We are excited to continue the important work by inviting the broader community from academia, government, industry, and nonprofit organizations to join us in June 2025 – the day before the start of our Global Annual Meeting in Washington, DC. Together, we'll unravel the potential and address the hurdles of this dynamic frontier in regulatory science and come up with an action plan and recommendations for how to most effectively advance the field of cell and gene therapy development in order to increase patient access and ultimately improve health outcomes.

Event Goals and Offerings

- Facilitate collaboration among academia, industry, regulators, and patient advocacy groups to address key barriers in cell and gene therapy development and access
- Develop a consensus on best practices for regulatory harmonization, including CMC hurdles and adapting regulatory processes for innovation
- Provide a platform for knowledge exchange through panels, case studies, and roundtable discussions, culminating in actionable recommendations
- Highlight updates from leading initiatives in cell and gene therapy

Why You Can't Miss It

- Hear from esteemed speakers, including global regulators and industry leaders
- Gain exclusive insights into groundbreaking case studies that span critical therapeutic areas and showcase cutting-edge science
- Contribute to shaping the future of cell and gene therapy regulations through interactive roundtable discussions and collaborative planning
- Network with a diverse array of stakeholders at a premier venue in Washington, DC, and be part of transformative discussions that will influence the DIA Global Annual Meeting

Who Should Attend

- Academia
- Biotechnology
- Clinical Pharmacology
- Clinical Research and Development
- Clinical Operations
- CMC
- CROs/Vendors
- Drug Discovery
- Drug Safety/Pharmacovigilance
- Government Affairs
- Policy and Intelligence
- Preclinical
- Quality Assurance
- Regulatory Agencies
- Regulatory Affairs, Operations, and Strategy
- Research and Development
- Risk Management, including Risk Evaluation and Mitigation Strategies (REMS)
- Strategic Sourcing/Planning

Schedule-At-A-Glance (All times listed are Eastern Time)

Day One | June 15	
7:15 - 8:00AM	**Meeting Registration and Continental Breakfast**
8:00 - 8:10AM	**Welcome and Opening Remarks from the Program Chairs: The Importance of Global Harmonization in Cell and Gene Therapies**
8:10 - 8:40AM	**Session 1:** An Overview of the Evolution and Impact of Cell and Gene Therapy Field
8:40 - 10:00AM	**Session 2:** Panel Discussion on the Challenges of Global Development for Cell and Gene Therapies
10:00 - 10:15AM	**Refreshment and Networking Break**
10:15 - 10:45AM	**Session 3:** Cells as Living Medicines: A New Approach to Treat Type 1 Diabetes
10:45AM - 12:05PM	**Session 4:** Case Studies: Discussing the Challenges and Opportunities of Cell and Gene Therapy Development in Different Therapeutic Areas **Case Study 1:** The Development of CAR T to Serve Patients Needs **Case Study 2:** Gene Therapy for Pediatric Hematology Disorders
12:05 - 12:25PM	**Session 5:** Platform Technologies: An Approach to Development and Regulation
12:25 - 12:40PM	**Session 6:** Enabling Innovation: Regulatory and Cross-Sector Strategies from the AMP BGTC to the Future of Cell Therapies
12:40 - 1:40PM	**Networking Luncheon**
1:40 - 3:50PM	**Session 7:** Roundtable Discussions **Topic 1:** CMC Hurdles with Cell and Gene Therapy Manufacturing **Topic 2:** Regulatory Challenges **Topic 3:** Ensuring Timely Access to Approved Therapies in Developing Countries
3:50 - 4:20PM	**Session 8:** Report-Outs on Recommendations
4:20 - 4:30PM	**Closing Remarks**
4:30PM	**Summit Adjourns**

Learning Objectives

At the conclusion of this conference, participants should be able to:

- Understand the latest advancements in cell and gene therapy, including the journey from translational research to patient access
- Explore challenges in global regulatory harmonization and strategies to align regulatory requirements across different regions
- Hear real-world case studies from leading companies to identify practical lessons and opportunities in oncology (CAR T therapy), Type 1 diabetes and pediatric hematological disorders
- Engage in multi-stakeholder dialogues to craft actionable recommendations for regulatory and clinical advancements in advanced therapies

DIA Disclosure Policy

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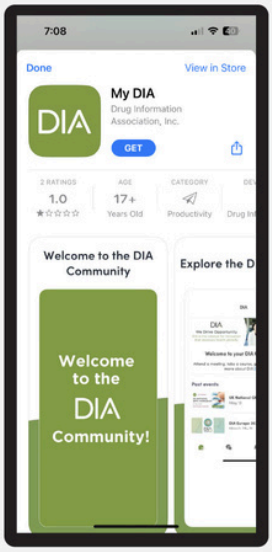
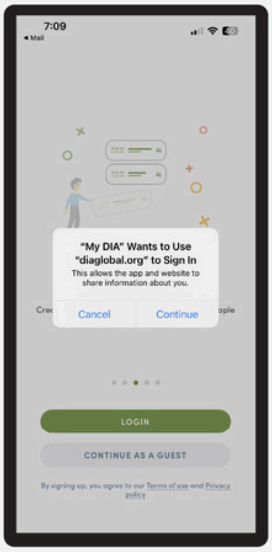
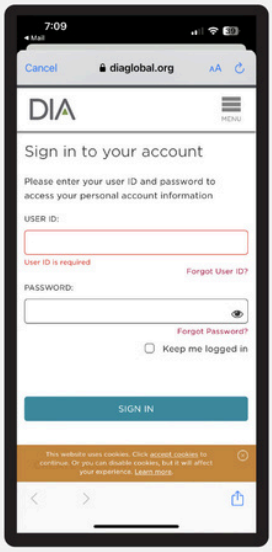
Want to view the detailed agenda? Download DIA's Mobile App!

- **Agenda at your fingertips**
- **Network with Attendees and Speakers**
- **Ask questions live during sessions through the session chat function**







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