Cell and Gene Therapy Summit 2026

25 February, 2026
Sydney Harbour Marriott Hotel

Event Overview

The DIA/ARCS Cell and Gene Therapy Summit unites Australia's regional leaders with international experts and regulators for a powerful exchange on advancing the science, policy, and promise of cell and gene therapies. Together, we'll explore solutions to accelerate innovation and expand global access to transformative treatments. As investment, regulation, and innovation evolve globally, Australia stands at a pivotal moment ready to connect leading world-class research and clinical excellence with the opportunities of global manufacturing, regulatory harmonisation, and patient access.

This summit brings together diverse stakeholders to explore how Australia can strengthen its position as a regional hub for advanced therapies, align with global standards, and build sustainable systems for equitable access. At its core, the meeting seeks to answer:

- How can we work more effectively as an integrated ecosystem?
- What are the right approaches to building lasting partnerships, leveraging resources to ensure fast progress and global competitiveness?

Meeting participants will explore what it takes to move from basic research to clinical reality, build sustainable systems for equitable access, and position Australia as a leader and a central world hub for advanced therapies within the broader Asia-Pacific region.

Through interactive sessions and strategic discussions, participants will examine key trends, global insights, and practical pathways to connect research, regulation, and clinical delivery. Together, we will define how Australia can collaborate, compete, and lead in this transformative field ensuring the regional ecosystem is ready to deliver the next generation of precision cures to local, emerging and global markets.

Who Should Attend

Senior to middle management experts focused on basic research, clinical research, drug development, manufacturing, quality, regulatory science and reimbursement policy across the following sectors:

- Industry
- Academia
- Patients/Patient Advocacy Organizations
- Government

Drug Information Association

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Program Highlights

Session 1: Charting Australia's Advanced Therapies Landscape - Momentum, Challenges, and Opportunities

This opening session will examine the current state of play for cell and gene therapies in Australia, highlighting progress made, remaining challenges, and insights from the ongoing HTA review. Speakers will explore how to sustain momentum and strengthen coordination across the ecosystem to enable future scale.

Session 2: Global Perspectives – Translating International Insights into Local Action

Featuring leading regulators and international experts, this session will explore global trends and regulatory innovations shaping the future of cell and gene therapies. Discussion will focus on lessons from the US FDA, UK (MHRA), EU (EMA), Asia–Pacific (China, Japan) and the Middle East (Saudi FDA), including regulatory agility, platform technology approvals, and models of public–private collaboration.

Session 3: Bridging Innovation and Access - Advancing Equitable and Sustainable Delivery of Cell and Gene Therapies

Australia's cell and gene therapy ecosystem is rapidly evolving, with significant progress in innovation, regulatory readiness, and infrastructure development. Yet questions remain: Who gets to benefit, and how can we ensure equitable and sustainable access? This interactive session will explore models that enable patient-centered access while addressing economic and logistical constraints.

Session 4: Building the Engine for Scale - Activating Australia's Advanced Therapies Ecosystem within the APAC Region

This session will explore what it takes to scale and sustain a robust advanced therapies ecosystem in Australia, from manufacturing and infrastructure to regulatory alignment and patient access. Connecting diagnostics, data, therapeutics, and workforce.

Program Committee

Erin Evans, Ph.D
CEO, InGeNA

Marguerite Evans-Galea AM, Ph.D
Deputy Director, Strategy & Planning, Australian Regenerative Medicine Institute, Monash University

James Wabby
Global Head, Regulatory Affairs (CoE) Emerging Technologies, Devices & Combination Products, AbbVie (US)

Lesbeth Rodriguez, MS
Director, Regulatory Policy & Science, Bayer

Maria Vassileva, Ph.D
Chief Science and Regulatory Officer, DIA

Tamei Elliott, MS
Director, Global Scientific Contents, DIA

Young Joo Park, Ph.D.,
VP for Asia Pacific, DIA

Registration Fee

Early Bird rates only available up to 25 Jan 2026. All prices are in AUD and inclusive of GST.

- Early Bird member price - $600
- Early Bird non-member price - $900
- Standard member price - $750
- Standard non-member price - $1250

VISIT ARCS REGISTRATION PAGE

Sponsorship and Exhibition

For more details on sponsorship and exhibiting opportunities, pricing, and booth availability, please refer to the Summit Prospectus and contact **emacmahon@arcs.com.au**

ARCS AUSTRALIA

DIA
Drug Information Association

8:30-8:45AM	**Opening Remarks from DIA and ARCS**
	DIA Representative ARCS Representative
8:45-10:00AM	**Opening Keynote** **Session 1: Charting Australia's Advanced Therapies Landscape - Momentum, Challenges, and Opportunities**
	Session Chairs **Tim Boyle, PhD, ChMPP** CEO, ARCS **Tamei Elliott, MS,** Director, Global Scientific Content, DIA
	This opening session will examine the current state of play for cell and gene therapies in Australia, highlighting progress made, remaining challenges, and insights from the ongoing HTA review. Speakers will explore how to sustain momentum and strengthen coordination across the ecosystem to enable future scale
	Speakers: **Simon Cool,** Professor of Bioengineering and Director of the UQ Advanced Cell Therapy Manufacturing Initiative in the School of Chemical Engineering, University of Queensland; Smart CRC, **Chris Alma**, Director of External Innovation, Genetic Medicines, CSL Limited **TGA representative** (invited)
10:00-10:20AM	**Morning Break**
10:20AM-12:00PM	**Session 2: Global Perspectives - Translating International Insights into Local Action**
	Session Chairs **Maria Vassileva, PhD,** Chief Science and Regulatory Officer, DIA **Lesbeth Rodriguez, MS,** Director, Regulatory Affairs, Bayer
	Featuring leading regulators and international experts, this session will explore global trends and regulatory innovations shaping the future of cell and gene therapies. Discussion will focus on lessons from global stakeholders and regulators, including regulatory agility, platform technology approvals, and models of public–private collaboration. Speakers will identify how Australia can adopt and adapt these insights to create a globally aligned and investment-ready framework for innovation and access. • Regulatory convergence with FDA/EMA/APAC frameworks. • Platform technology designation (reduce duplication, enable shared data and manufacturing). • Cross-border data sharing and ethical frameworks for CGT trials. • International patient access collaboration models (e.g., the "Baby KJ" case).
	Speakers: **Ana Hidalgo-Simon, PhD**, Professor, Leiden University **Maria Vassileva, PhD**, Chief Science and Regulatory Officer, DIA **Josephine Lembong,** Associate Director Scientific Affairs, ARM **Lesbeth Rodriguez, MS,** Director, Regulatory Affairs, Bayer
	Panelists: **John Beaman**, Deputy Director, Innovative Medicines in our Healthcare Quality and Access, MHRA **New Zealand Medicines and Medical Devices Safety Authority (MEDSAFE)** (invited) **FDA** (invited) **Warwick Shaw**, Market Access, Cell & Gene Therapies, Johnson & Johnson (invited) **TGA representative**
12:00-1:00PM	**Networking Luncheon**

1:00-2:30PM	**Session 3: Bridging Innovation and Access - Advancing Equitable and Sustainable Delivery of Cell and Gene Therapies**
Session Chair	**Erin Evans, PhD,** CEO, InGeNA Ltd **Tamei Elliott, MS,** Director, Global Scientific Content, DIA
	Australia's cell and gene therapy ecosystem is rapidly evolving, with significant progress in innovation, regulatory readiness, and infrastructure development. Yet questions remain: Who gets to benefit, and how can we ensure equitable and sustainable access? This interactive session will explore models that enable patient-centered access while addressing economic and logistical constraints.
	Speakers: **Marco Barsanti, PhD**, Sales Director, Integrated DNA Technologies **Colman Taylor**, Chief Vision Officer, HTAnalysts **Laura Issa, PhD,** Patient Advocate, Director of Scientific and Medical Affairs and Chief Scientific Officer, FSHD Global Research Foundation and Facio Bio Therapies Pty Ltd **Industry representative** (Invited)
2:30-3:00PM	**Break**
3:00-4:40PM	**Session 4: Building the Engine for Scale - Activating Australia's Advanced Therapies Ecosystem within the APAC Region**
Session Chairs	**Marguerite (Maggie) Evans-Galea, PhD,** Deputy Director, Strategy and Planning, Australian Regenerative Medicine Institute, Monash University **James Wabby** Head, Global Regulatory Affairs, Emerging Technologies, Combination Products, and Devices, Volwiler Senior Research Industry Fellow – Regulatory Science, AbbVie
	This session will explore what it takes to scale and sustain a robust advanced therapies ecosystem in Australia, from manufacturing and infrastructure to regulatory alignment and patient access. Connecting diagnostics, data, therapeutics, and workforce. Through presentations and roundtable discussions, participants will examine models for harmonization, centralization versus decentralization, and how Australia can position itself as a center of excellence and regional hub for cell and gene therapies across the Asia-Pacific.
	Speakers: **Leanna Read**, Chair, SMART CRC **Toshihiko Okazaki, MD**, Professor and Head of the Cell and Gene Medicine Unit at the Osaka University Center for Future Medicine **Hassan Chaudry,** Senior Consultant, IQVIA **Stephen Thompson,** CEO, VVMF **Bev Menner**, CEO, CTPL
4:40-5:00PM	**Closing Remarks and Key Takeaways**
	DIA Representative ARCS Representative