



# CELL AND GENE CATALYST

ACCELERATING AUSTRALIA'S ADVANCED THERAPIES INDUSTRY

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Powered by Medicines Australia & AusBiotech

2025-2026 Pre-Budget Submission

January 2025

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**Australia's Cell and Gene Catalyst** (the Catalyst) is a national joint venture powered by Australia's leading health industry peak bodies, AusBiotech and Medicines Australia, and collaborates with an Expert Steering Group of industry professionals from its six (6) partner organisations and four (4) Expert Working Groups that represent the cell and gene ecosystem.

The Catalyst's vision is for people in Australia to have access to world-class innovation sustained by a thriving Australian cell and gene industry. Its mission is to work with the sector to enable an end-to-end value chain that can discover, develop, produce and distribute cell and gene therapies, creating an Australian Hub that delivers jobs, commercialises research and mostly importantly, benefits patients. This also creates an opportunity to export Australian therapies to the world.

Engaging with Australia's cell and gene ecosystem across the entire value chain, the Catalyst is enabling research and innovation in advanced therapies and endorses the pre-budget submissions from AusBiotech and Medicines Australia in full.

**The Catalyst calls on the Australian Government to commit to working with the cell and gene ecosystem to drive national coordination and collaboration, with the goal of accelerating the local cell and gene industry and increasing Australians' access to advanced therapies.**

The Catalyst recommends Australian Government budgetary measures that:

1. *Develop and implement specific access and regulatory pathways which are aligned with leading jurisdictions and will drive faster and broader patient access to cell and gene therapies in Australia.*
2. *Grow Australia's capacity and capability across the cell and gene therapies value chain.*

It is essential that together we secure the Australia's place in the growing global cell and gene industry as leaders across the entire value chain including R&D, manufacturing and commercialisation.

## The Cell and Gene Therapies Landscape

Cell and gene therapies are one of the world's greatest scientific achievements and are at the leading edge of advanced healthcare globally. These advanced therapies use genetic and cellular materials to treat or prevent disease and they are increasingly used in clinical practice within Australian hospitals.

There are currently 43 cell and gene therapies that have been approved by the United States Federal Drug Administration (FDA) and more than 4,000 cell and gene therapies in development, preclinical through pre-registration, around the world. Seven (7) are currently registered in Australia.<sup>1</sup>

Cell and gene therapies for oncology and rare diseases continue to lead in the development phase with the market diversifying – half of the newly initiated gene therapy trials target non-oncology indications. More than 1,300 cell and gene therapies will be available in the next few years, including gene-editing and cellular therapies in late-stage clinical trials today.

Cell and gene therapies have curative potential and are transforming healthcare in Australia. Enabling sustained growth of Australia's cell and gene ecosystem will ensure every Australian can access these world-class advanced therapies and cement Australia's position as a trusted cell and gene hub within the Asia-Pacific (APAC) region.

<sup>1</sup> American Society of Gene and Cell Therapy and Citeline, [Gene, Cell & RNA Therapy Landscape Report](#), Q3/2024.

## **Recommendation 1: Develop and implement specific access and regulatory pathways which are aligned with leading jurisdictions and will drive faster and broader patient access to cell and gene therapies in Australia.**

The Catalyst makes the following recommendations to the Australian Government:

### **1a) Commit to investing in the implementation of the package of Health Technology Assessment (HTA) reforms outlined in the HTA Review report.**

In their Pre-Budget Submission this year, Medicines Australia (MA) states implementation of the HTA Review recommendations will need to be phased over three years as many recommendations require co-design with a broad range of stakeholders. They also indicate several recommendations that can be implemented quickly to expedite patient access to medicines.

The Catalyst endorses the MA submission in full and reiterates that a commitment by the Australian Government to significantly invest in implementing the HTA package of reforms is essential.

The Catalyst further highlights the following recommendations critical to the cell and gene industry.

- Work with stakeholders (principally industry and government entities) to co-design a framework that supports the use of different contract and health technology funding mechanisms, in addition to the standard 'price per unit' approach around new funding model for advanced therapies.
- Work with stakeholders to co-design and implement sustainable funding pathways with a view to ensure equitable and expedited access to these advanced therapies within 60 days of the Therapeutic Goods Administration (TGA) registration.
- Invest in a robust horizon-scanning process, including analyses and forecasting of new and emerging therapies, to enable early implementation planning across the regulatory and reimbursement systems, as well as systems across the research and innovation pipeline.

Establishing streamlined access and sustainable funding models and pathways for cell and gene therapies is essential and is the first policy priority for the Catalyst. Australia's current systems were not set up for these innovative therapies and horizon-scanning enables forward planning for the ecosystem.

Addressing these priorities will enable health system readiness and industry growth, ensuring patients have equitable access to world-class innovation back by a thriving cell and gene industry in Australia.

#### **Estimated Investment**

**To be determined** by the Australian Government with advice from the HTA Review Implementation Advisory Group and stakeholders.

### **1b) Invest to enable the sector to increase the community's understanding of advanced therapies and support recruitment into cell and gene therapy clinical trials.**

Australian families are asking for help in understanding cell and gene therapies.<sup>2</sup> Investing in the development and delivery of patient education co-designed by a national network of research and clinical experts in cell and gene therapies across industry, hospital, academic and patient communities, will increase understanding of these innovative therapies and foster trust between the community and the cell and gene industry.<sup>3</sup>

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<sup>2</sup> [How Great a Risk Do You Take? A Qualitative Study Exploring Attitudes of Individuals with Friedreich Ataxia Toward Gene Therapy](#) 2023. *Human Gene Therapy*. PMID: 37624740

<sup>3</sup> [Patient and public perspectives on cell and gene therapies: a systematic review](#) 2020. *Nature Communications*, 11(1), 6265.

Increasing the knowledge and understanding of patients, especially within the context of a clinical trial, has demonstrated increased trial participation and retention.<sup>4</sup>

Failure to provide reliable information on the safety and effectiveness of innovative therapies can lead to Australians seeking out potentially exploitative, harmful and unproven treatments with damaging financial, physical and psychological consequences.

The Australian Government's National Preventative Health Strategy 2021 – 2030 identifies 'Information and Health Literacy' as one of seven principles underpinning its Framework for Action. It cites low health literacy as a structural barrier that must be overcome so individuals can access, understand, appraise and use information to make informed health-related decisions.

An accessible resource, such as a web portal, would provide patients and their families with fundamental knowledge so they can ask informed questions of their GP or specialist. A ripple effect is that such a resource could also be accessed by the broader ecosystem, including pharmacists, healthcare professionals, as well as educators.

**Case studies** of effective patient education programs in cell and gene therapies are provided below:

- **EuroGCT:** The European Consortium for Communicating Gene and Cell Therapy convenes 47 partner organisations and institutions across Europe with the goal of providing reliable and accessible information about using cells and genetic material to treat disease. The project (2021-26) received €1,999,783 in funding from the EU's Horizon 2020 research and innovation program (European Commission, 2020) and more than €3 million in total. EuroGCT seeks to provide patients, healthcare professionals and the public with information to assist better informed decision making about cell and gene therapies. It is coordinated by The University of Edinburgh.<sup>5</sup>
- **American Society of Gene and Cell Therapy (ASGCT):** The *Patient Education Program* through ASGCT serves to be a "trusted source of information on the science, technology and use of GCT".<sup>6</sup> This portal provides cell and gene therapy primer, information on clinical trials, diseases and cancers, and expert, evidence-based advice and guidance. Various resources are freely available.

The Catalyst has a comprehensive network across the cell and gene value chain, including industry, hospitals, patient groups, research and peak bodies. The Catalyst is keen to convene its key stakeholders and strategically partner with the sector to co-design and implement a portal and deliver on this recommendation.

#### **Estimated Investment**

**\$2.4 million** over forward estimates for the next 3 years to support one strategically aligned national program delivering on this recommendation, starting FY2025-26.

#### **1c) Commit to supporting the TGA to provide formal advice throughout the application and approval processes for cell and gene therapies.**

The TGA in the Department of Health and Aged Care provides excellent support to the cell and gene industry but has limited capacity to provide formal, written expert advice. To streamline review and approval processes, such advice can be extremely valuable, informative and important to include when submitting cell and gene products for approval in Australia.

Increasing the capacity and capabilities of the TGA to provide timely, expert advice will strengthen Australia's regulatory processes, reviews and approvals, meaning patients will have access sooner.

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<sup>4</sup> [How to strengthen trial retention through patient education](#) 2021, Medrio.

<sup>5</sup> EuroGCT, [European Consortium for Communicating Gene and Cell Therapy](#).

<sup>6</sup> The American Society of Gene and Cell Therapy (ASGCT), [Patient Education Program](#).

### Estimated Investment

**To be determined** by the Australian Government with advice from the TGA and stakeholders.

### **1d) Develop and promote a National Advanced Therapies Taxonomy to promote consistent definitions and language for educators, government and industry nationally and align with leading global markets.**

Cell and gene therapies is a broad term that includes multiple technologies and therapeutic approaches, and new technologies continue to be developed at pace. It can be challenging to be across all the latest advances. The terminology and taxonomy of medical, scientific and lay terms for cell and gene therapies vary across jurisdictions and agencies locally and globally. This contributes to unnecessary complexity and confusion for this emerging therapy area.

Nationally agreed language and definitions need to be developed to build trust and understanding in cell and gene therapies for patients and stakeholders as a proven treatment for disease.

A National Advanced Therapies Taxonomy could be led by the TGA in collaboration with the cell and gene industry to ensure national coordination. This taxonomy could then be used to standardise language, definitions and categorisation, and increase consistent use and understanding across industry, government, academia and education, within healthcare and in the general public.

The Catalyst has a comprehensive network across the cell and gene value chain and meets regularly with the TGA. Catalyst stakeholders are keen to work with the TGA in the development and dissemination of a National Advanced Therapies Taxonomy.

### Estimated Investment

**\$2 million** over forward estimates for the next 3 years to support one strategically aligned national project delivering on this recommendation, starting FY2025-26.

### **Recommendation 2: Invest to grow Australia's capacity and capability across the cell and gene therapies value chain.**

A thriving cell and gene industry requires a highly skilled workforce to ensure Australia can discover, develop, produce and translate world-class cell and gene therapies locally. The growth of this sector requires professionals with qualifications at both the vocational and/or higher education level, and diverse skills, expertise and lived experience.

The Catalyst makes the following recommendations to the Australian Government:

### **2a) Invest in targeted programs to develop an advanced therapies workforce across the value chain with high-demand skills, such as Good Manufacturing Practice (GMP), Quality Assurance (QA) and Commercialisation, and associated analysis and forecasting of immediate to mid-term skills.**

Through the production of world-class advanced therapies, Australia's cell and gene manufacturing industry will increase Australia's productivity and economic complexity, create jobs and future-proof our sovereign capability.

Australia's cell and gene industry is on a growth trajectory and accessing a skilled manufacturing workforce has been identified as the *greatest barrier* to the cell and gene manufacturing sector's growth and success.<sup>7</sup>

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<sup>7</sup> [Australia's Regenerative Medicines Manufacturing Capacity and Capability](#) 2021 and the [National Blueprint for Cell and Gene Therapy](#) 2023, AusBiotech.

Cell and gene manufacturing skills shortages, particularly in GMP, QA and Commercialisation, have been identified in the UK and the USA.<sup>8</sup>

As part of the Catalyst's Workforce Development project (*ongoing*), consultation with 47 leaders from 45 organisations in the cell and gene ecosystem indicates Australia's skills shortages in the short- to mid-term are consistent with those in the UK and the USA.

Australia's *RNA Blueprint* published by the Department of Industry, Science and Resources in 2024 reiterates this workforce skills need. RNA therapies are only one part of Australia's cell and gene industry.

The Catalyst has a comprehensive network across the cell and gene value chain, including industry, research, education, hospitals, patient groups and peak bodies. The Catalyst is keen to convene its key stakeholders and strategically partner with the sector to co-design a program for implementation and deliver on this recommendation.

#### **Estimated Investment**

**\$10 million** over forward estimates for the next 4 years to support one strategically aligned national program delivering on this recommendation, starting FY2025-26.

#### **2b) Invest in programs that increase researchers' understanding of the cell and gene value chain, including the patient perspective, and enable private partnerships with researchers with the goal of translating and commercialising cell and gene therapy research.**

For research to be successfully translated and commercialised, it is important to foster a connected and collaborative culture between industry and academia.

The Industry Mentoring Network in STEM (IMNIS) initiative of the Australian Academy of Technological Sciences and Engineering demonstrated that when researchers and developers in different sectors form enduring connections through mentorship, their willingness to collaborate and engage increased.<sup>9</sup> IMNIS provides industry engagement and education, as well as professional skills development for researchers to increase their understanding of the broader sector.

When developing a potentially life-changing treatment with the potential to cure an individual for the rest of their life, it is also vital to understand the patient perspective, including their understanding of such an advanced therapy and their appetite for an innovative treatment. Ideally, consumers will be involved throughout the course of research and development.

Forming long-term industry-academia partnerships to ensure relevant and timely industry expertise, advice and skills are part of the team designing, researching and developing the product will increase its likelihood for success.<sup>10</sup>

The Catalyst has a comprehensive network across the cell and gene value chain, including industry, research, education, hospitals, patient groups and peak bodies. The Catalyst is keen to convene its stakeholders and strategically partner with the sector to co-design a program and deliver on this recommendation.

#### **Estimated Investment**

**\$5 million** over forward estimates for the next 3 years to support one strategically aligned national program delivering on this recommendation, starting FY2025-26.

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<sup>8</sup> Cell and Gene Therapy UK Skills Demand Report 2023, UK Cell and Gene Therapy Catalyst; [The Workforce Report Gap Analysis for the Cell and Gene Therapy Sector](#) 2023, Alliance for Regenerative Medicine, USA.

<sup>9</sup> IMNIS [Impact Report](#) 2022-23, ATSE.

<sup>10</sup> [Strengthening the Bridge Between Academic and the Industry Through the Academia-Industry Collaboration Plan Design Model](#) 2022, *Frontiers in Psychology*.

## **2c) Work with cell and gene stakeholders to facilitate the development of a coordinated and collaborative advanced therapies manufacturing pipeline to service the nation and cement Australia's position as a trusted manufacturing hub for our region, accessing new export markets.**

At the AusBiotech 2024 conference in Melbourne, the Catalyst hosted the inaugural industry-led Cell and Gene Summit to discuss the challenges and opportunities for the sector. The expert panel on cell and gene manufacturing at this summit emphasised there is an urgent need for alignment, collaboration and coordination across Australia's cell and gene manufacturing sector.

It will be critical for the Australian Government to work collaboratively with the cell and gene sector to identify Australia's strengths and needs. In 2025, the Catalyst will introduce a new expert working group in Cell and Gene Manufacturing to convene the cell and gene manufacturing sector.

This work could be led by the Department of Industry, Science and Resources (DISR) in collaboration with the sector to ensure national coordination and engagement, as well as strategic alignment with the Australian Government's economic plan, a *Future Made in Australia*. The Department could leverage the Catalyst's working group to co-design a highly productive cell and gene manufacturing sector that services the nation and accesses new export markets, boosting Australia's profile as a cell and gene hub globally.

The Catalyst has a comprehensive network across the cell and gene value chain and meets regularly with DISR. Catalyst stakeholders are keen to work with the Department in establishing a coordinated and collaborative cell and gene manufacturing sector in Australia. This work could complement and work synergistically with the implementation of DISR's *RNA Blueprint*.

### **Estimated Investment**

**To be determined** by the Australian Government with advice from stakeholders.

## **Recommendation 3: Secure the future of Australia's cell and gene industry through an Advanced Therapies Strategy, as part of an overarching National Strategy for Life Sciences.**

The Australian Government's commitment to securing the nation's sovereign capability provides an opportunity for the cell and gene industry.

Through the Catalyst, Medicines Australia and AusBiotech provide a national platform for the cell and gene industry to engage, share knowledge, collaborate and coordinate as a connected sector, moving in one direction to service the nation and provide expert advice to decision-makers.

Driving this national-level activity with an Advanced Therapies Strategy underpinned by long-term strategic investment will be key to driving this sector's future growth and sustainability, and its impact on the international stage.

It is proposed that the Advanced Therapies Strategy be part of the National Strategy for Life Sciences, proposed in the AusBiotech and MTPConnect Pre-Budget Submission and aligned with the National Health and Medical Research Strategy and the Strategic Examination of R&D.

Working together, Australia can successfully navigate the barriers and leverage the opportunities the cell and gene industry presents – and Australia's Cell and Gene Catalyst and the advanced therapies ecosystem stands ready to coordinate and collaborate to make it happen.

**Case studies** of strategic initiatives that have contributed to growth of the cell and gene industry at a national level are provided below:

- **United Kingdom:** the UK government has invested in the Cell and Gene Therapy Catapult as part of the Catapult Network which is funded through Innovate UK. The Innovate UK Catapult network fosters cross-sector collaboration, including industry, academia and government to advance translation and commercialisation of research. The Cell and Gene Therapy Catapult supports the advanced therapy sector with expert advice to decision-makers, skills and training programs and access to a network of collaborators.<sup>11</sup>
- **South Korea:** the South Korean government's investment of more than \$1.7 billion USD is strengthening South Korea's biotechnology and biopharmaceutical sector, including regenerative medicine. South Korea was the first to commercialise stem cell therapy and is a key market in this sector. Korea is also adopting and developing cell and gene therapy products, facilitated by favourable legislation effective since 2020, the Act on the Safety and Support of Advanced Regenerative Medical and Advanced Biopharmaceuticals ("Advanced Regeneration Bio Act.") which allows conditional approval for commercial sale of phase II-completed drugs. This is expected to accelerate the growth of Korea's cell and gene manufacturing market.<sup>12</sup>

The Catalyst has a comprehensive network across the cell and gene value chain, including industry, research, hospitals, patient groups and peak bodies. The Catalyst is keen to convene its stakeholders and strategically partner with the sector to co-design a national-level Advanced Therapies Strategy and deliver on this recommendation.

#### Estimated Investment

**To be determined** by the Australian Government with advice from stakeholders.

## The Catalyst's Co-Leading Organisations

**AusBiotech** is Australia's leading national and global advocate for life sciences. With a more than 3,000 strong industry led member network, we leverage our unique national convening power to support our members' growth – by building an Australian life sciences ecosystem that leads in development and commercialisation, to create high-quality, innovative life sciences companies.

**Medicines Australia** leads the research-based medicines industry of Australia. Members discover, develop and manufacture prescription pharmaceutical products, biotherapeutic products and vaccines that bring health, social and economic benefits to Australia. Members invest in Australian medical research and take local discoveries and developments to the world.

## Contact

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<sup>11</sup> The Innovate UK [Catapult Network](#) and the [Cell and Gene Therapy Catapult](#), UK Government.

<sup>12</sup> Grand View Research – [Horizon Databook Portal](#) and Pharma to Market, [South Korea release new law on advanced regenerative medicine and biopharmaceuticals](#).