Australian Cell and Gene Therapies Innovation Investment Report

Insights into Australia's investment priorities in the cell and gene therapies sector

Deloitte.

Global Investment and Innovation Incentives (G*i*³)

Contents

Authors

Australia's Cell and Gene Catalyst (the Catalyst) was 24-month joint venture of Australia's leading health industry peak bodies, AusBiotech and Medicines Australia.

The Cell and Gene Catalyst's former Director, Dr Marguerite Evans-Galea AM, championed and supported the development of this report, while serving as a passionate advocate for Australia's cell and gene sector during her time as Director.

Deloitte's Global Investment and Innovation Incentives (Gi^3) team provides specialised advisory services in life sciences and medical research, supporting both public and private sector clients. With deep industry expertise, we assist life sciences companies—from startups to global pharmaceutical leaders—in securing funding and establishing operations in Australia.

Our work includes business case development, ecosystem mapping, investment strategies, and tenant attraction. Leveraging strong government and industry connections, we help drive innovation and economic growth in Australia's life sciences sector, ensuring it remains globally competitive.

Enquiries

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Executive Summary

The Australian cell and gene therapy (CGT) sector is experiencing significant growth, driven by strong investment in research and development (R&D), emerging technologies, and enhanced collaboration across industry and academia. This report presents findings from a survey assessing the current and projected R&D investment pipeline for CGTs across Australia. The survey aimed to provide insights into investment strategies and priorities within Australia's CGT R&D sector, forming the basis for a forward-looking innovation investment report for the CGT landscape.

Investment outlook for CGT R&D in Australia

The investment outlook for CGT R&D is strong, with **62% of respondents planning to invest in CGT development** within the next 12 months. Additionally, 54% of respondents ranked raising capital for CGT investment as a top five organisational priority for 2025, while **79% believe that R&D investment will drive new revenue streams** over the next year. These results reflect a strong commitment to CGT investment despite broader economic challenges.

Beyond R&D, survey respondents identified manufacturing and supply chain, clinical development, and regulatory pathways as critical investment areas. Over the next five years, key investment actions include investing in core technologies, improving R&D productivity, and fostering strategic alliances. The growing emphasis on commercialisation, regulatory pathways, and market access underscores Australia's evolving CGT landscape, moving from early-stage innovation toward large-scale application and patient access.

CGT manufacturing

Australia's CGT manufacturing sector remains limited, with only eight TGA-licensed GMP facilities nationwide. **58% of respondents** believe that a **lack of onshore manufacturing capabilities** will **negatively impact CGT development** over the next five years, while 83% cite supply chain disruptions as a significant challenge. Strengthening domestic manufacturing capacity is crucial to reducing reliance on international facilities, avoiding delays, and maintaining Australia's global competitiveness.

Collaboration across the CGT sector

The survey highlights a **strong appetite for collaboration** across the CGT ecosystem, with stakeholders recognising the value of strategic alliances in advancing the sector. **91% of respondents advocate for a nationally coordinated approach** to strengthen Australia's CGT capabilities. Industry consolidation, licensing agreements, and stronger academia-industry collaboration will be essential for enhancing Australia's CGT research and development pipeline and improving international competitiveness.

CGT workforce challenges

A significant skills shortage threatens the expansion of Australia's CGT sector, with **83% of respondents** expecting **workforce talent shortages** to negatively impact their organisation's strategy over the next five years. The survey confirms **a severe lack of CGT training pathways (61%)**, an insufficient R&D workforce (42%), and a **critical gap in Good Manufacturing Practice (GMP) expertise (65%)**, all of which present major barriers to sector growth. Addressing these workforce deficiencies will require a collaborative effort between industry, government, and educational institutions.

Emerging technologies and patient perspectives

Artificial intelligence (AI) and digital technologies are poised to transform CGT R&D by enhancing efficiency across discovery, manufacturing, and clinical applications. With **83% of respondents expecting accelerated digital transformation to positively impact** their organisation's CGT strategy over the next five years and 79% identifying AI as a key driver of future growth, the industry is increasingly looking to technological advancements to streamline operations.

This is particularly relevant as **87% of respondents** emphasised the importance of **ensuring high-quality clinical care and timely CGT delivery**, highlighting the need for robust infrastructure and optimised processes. However, despite these advancements, equitable access remains a significant challenge, with 70% of respondents citing disparities between metropolitan and regional areas as a key concern.

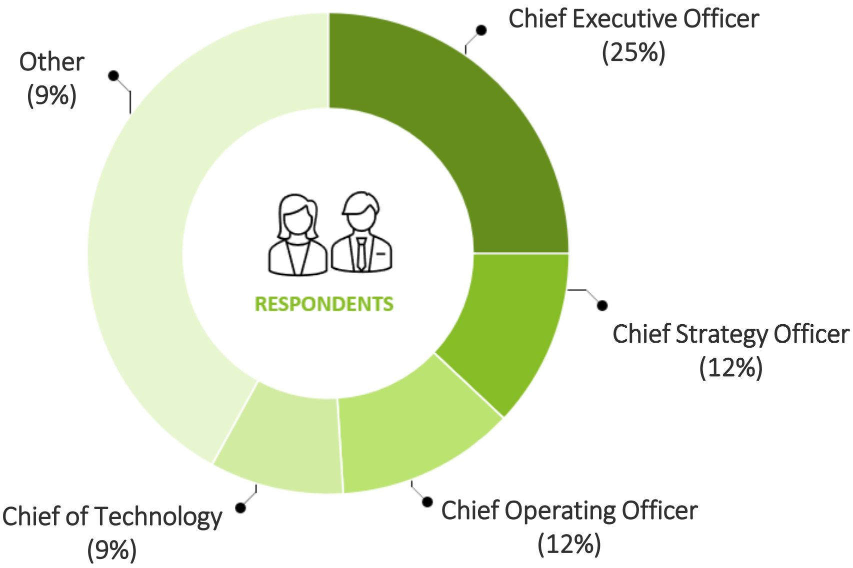
01 Methodology

Deloitte's Global Investment and Innovation Incentives (Gi³) team partnered with the joint venture formerly known as **Cell and Gene Catalyst** to conduct a survey mapping the current and projected R&D investment pipeline for CGTs across Australia in the short term (12 months) and medium term (five year) horizon. This survey was undertaken pre-tariffs. Although the post-tariff landscape may impact where CGT investments are taking place, globally these investments continue to rise and interest and engagement in Australia's R&D, manufacturing and clinical trials in cell and gene therapies remains strong.

A total of 24 respondents from the CGT industry participated in the survey, with respondents identified from the following types of organisations*:

48%	Pharmaceutical and biotechnology organisations
25%	Academic institutions and medical research institutes
20%	Medical device organisations and manufacturers
12.5%	Contract manufacturing organisations
4%	Contract research organisations
12.5%	Other

Respondents characterised themselves as key decision makers (50%) and strong influencers (38%) of strategic initiatives within their respective organisations. This included respondents with the following titles within



Most of the respondents' total global revenue in the last fiscal year was either pre-revenue (33%) or exceeded $250 million (38%).

Survey respondents operated in the following geographic markets:

66%	Australia
4%	Asia – Pacific
4%	United States
25%	Other

Respondents were invited to respond to 21 questions. Questions prompted respondents to provide insights into the current and future challenges and investment opportunities to increase Australia's competitiveness within the CGT R&D space.

Key themes explored included investment in R&D, manufacturing, workforce, collaboration, consumer perspectives, and emerging technologies.

Respondents were asked to respond as either:

- Positive impact, negative impact or no impact
- Not or somewhat important, (very) important or not applicable
- (Strongly) disagree, neutral or (strongly) agree
- Provide a ranking or estimate of future projections

Questions were presented as multiple-choice answers where some allowed respondents to select as many as applied.

*Total percentage exceeds 100% as some organisations selected multiple organisation types in their survey response.

02 Introduction

Global cell and gene therapies pipeline

Cell and gene therapies represent a rapidly expanding frontier in medical innovation, with transformative potential across a range of diseases. Globally, more than 4,400[1] cell and gene therapies are in development, and the United States FDA has already approved 45 treatments[2]. In contrast, only seven treatments are currently registered in Australia[3], despite 185 CGT clinical trials being conducted in Australia as of 2024[4].

4000 CGTs globally in development

43 FDA-approved CGTs

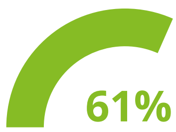
185 CGT clinical trials in Australia

7 CGTs registered in Australia

Australia's cell and gene therapies ecosystem

Australia's CGT ecosystem holds significant potential, but critical challenges remain. While 100% of survey respondents believe CGTs could revolutionise healthcare, 61% of respondents disagree that Australia's current capabilities are sufficient to support their development. Gaps in infrastructure, workforce expertise, and regulatory processes must be addressed to fully capitalise on the opportunities CGTs present. The low number of approved therapies in Australia compared to the growing global pipeline underscores the **urgency of building a stronger, more resilient CGT ecosystem** to meet future demand.

of respondents believe that CGT has the potential to revolutionise the way healthcare is delivered

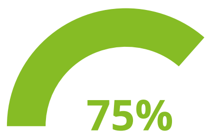


of respondents somewhat disagree or strongly disagree that Australia's current ecosystem has adequate capabilities to support development of CGT

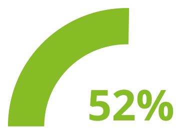
Strategic investment in CGT research, development, and supporting infrastructure will be key to strengthening Australia's capabilities and positioning it as a global leader in this field. Realising **the vision of Australia's Cell and Gene Catalyst**—for Australians to have access to world-class innovation supported by a **thriving domestic CGT industry**—requires an end-to-end value chain that enables the discovery, development, production, and distribution of these therapies.

Impact of economic climate on Australia's cell and gene therapies sector

Australia's CGT sector faces substantial challenges due to the current economic climate, with 75% of surveyed organisations anticipating that inflation and a potential recession will negatively impact their CGT strategy over the next five years. Additionally, 52% of respondents identified a lack of investment or funding as the greatest barrier to CGT development, highlighting financial constraints as a key risk to innovation and commercialisation. Given these pressures, **understanding Australia's investment priorities in CGTs** is crucial to ensuring the sector remains **globally competitive**, attracts **sustained funding**, and delivers **transformative therapies** to patients.



of respondents anticipate that **inflation and economic recession** will have a negative impact on their organisation's CGT strategy over the next 5 years



of respondents identified **lack of investment or funding** as their greatest challenge for the development of CGTs

1. Cell, Gene, & RNA Therapy Landscape
2. Approved Cellular and Gene Therapy Products | FDA
3. Statistics from Catalyst Pre-Budget submission 2025-2026,
4. HOYA and University of Melbourne Australian CGT Landscape report 2024

03 Investment in Research & Development

Investment outlook for R&D in cell and gene therapies

The investment outlook for R&D in cell and gene therapies (CGTs) is strong, with survey data highlighting that **investment in R&D is a high priority for industry stakeholders**. Enthusiasm for R&D investment is high, with 71% of respondents planning to invest in CGT development within the next 12 months. Additionally, 54% ranked raising capital for CGT investment as a top five organisational priority for 2025, while 79% believe that investing in R&D over the next 12 months will increase potential revenue streams in the future. These results reflect a strong commitment to R&D investment in Australia's CGT sector, despite broader economic challenges.

The survey data presented below indicates varying expectations for investment growth in CGTs across different organisation types over the next five years. A significant proportion of pharmaceutical and biotech companies, as well as contract research organisations (CROs), anticipate increasing their CGT investments by over 50%, reflecting **strong commercial confidence in the sector's potential**.

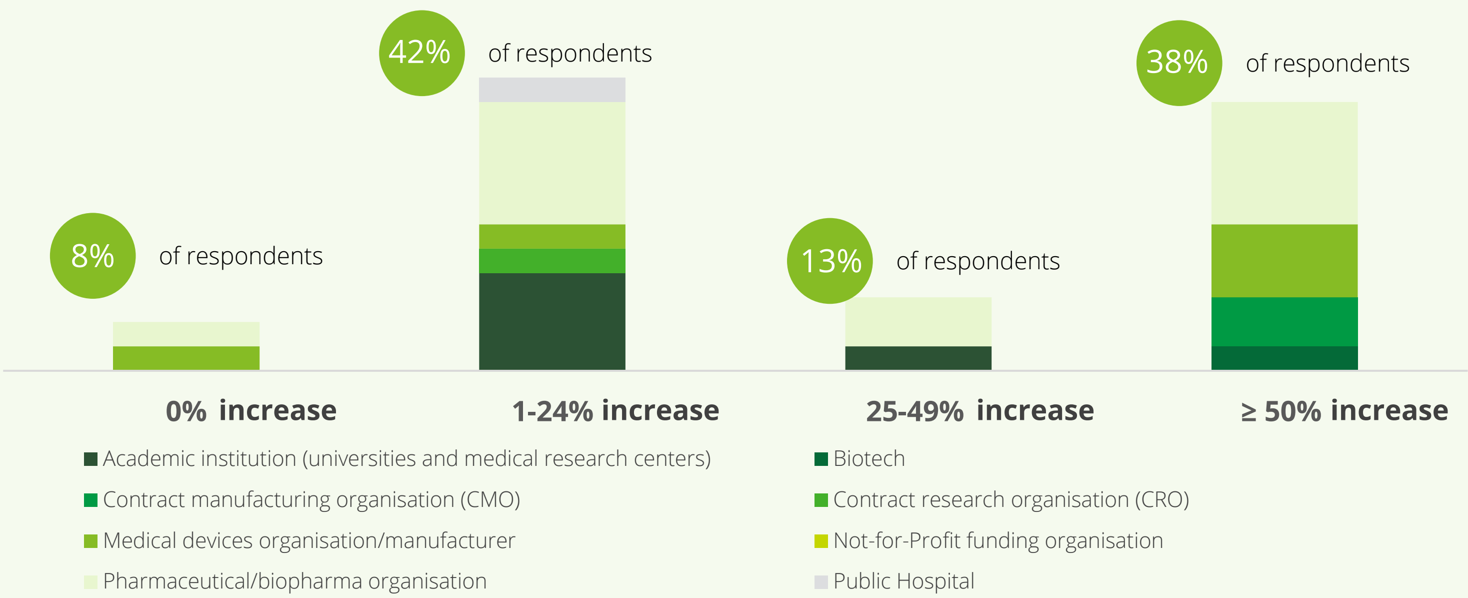
In contrast, academic institutions largely expect more modest investment growth, with most estimating increases of 1–24%. This disparity highlights the **differing funding landscapes and strategic priorities between industry and academia**, emphasising the need for targeted investment strategies to support CGT innovation across all stakeholders.

71%
of respondents are enthusiastic about **investing in R&D** for the development of cell and gene therapies within the next 12 months

54%
of respondents ranked **raising capital** for investment in CGT as a **top 5 priority** for their organisational goals in 2025

79%
of respondents believe that investing in R&D over the next 12 months will **increase potential revenue streams** in the future

Over the next 5 years, respondents estimated their **organisation's investments in cell and gene therapies to increase** by the following percentage ranges:



Note: *Some organisations listed multiple organisation types. These types have been counted and graphed separately.*

03 Investment in Research & Development

What are organisations in the CGT sector investing in?

The survey data reflected that **investment priorities in CGTs extend beyond research and development**, with organisations prioritising a range of areas critical to successful integration and commercialisation. In the next 12 months, the **top three investment priorities** identified by respondents are **manufacturing and supply chain, research and development,** and **clinical development**. Additionally, **market access and regulatory pathways**, such as pricing strategies and reimbursement, were ranked as the fourth investment priority (25% of respondents), reflecting the importance of ensuring timely market entry and commercial viability of new therapies.

The **top three priority areas** identified within organisations for integration of CGTs in the next **twelve months** included:

Manufacturing and supply chain

For example: Streamlining CGT production, ensuring product quality and consistency, and improving logistics

79% of respondents identified manufacturing and supply chain as a top 3 priority

Research and development

For example: CGT target identification, CGT design and development

71% of respondents identified research and development as a top 3 priority

Clinical development

For example: Optimisation of clinical trial protocols and trial documentation, pharmacovigilance

71% of respondents identified clinical development as a top 3 priority

Looking beyond the next twelve months, survey participants were asked to identify actions that they considered of high importance for their CGT investments in the **next five years**.

The top three actions identified were:

1. Investment in **core technologies**
2. Improving **R&D productivity** and investing in strategic alliances and **cross industry collaboration**
3. **Increased clinical trial activity**, namely, additional trials or trial sites

The emphasis on technological investment, R&D productivity, and clinical trial expansion signals a maturing CGT sector in Australia, with stakeholders focused on **strengthening the foundations needed for long-term growth**. This outlook suggests a shift from early-stage innovation to scalable, commercially viable solutions, underpinned by greater collaboration and strategic partnerships.

Increased clinical trial activity also points to efforts to **accelerate translation from research to patient access**, reinforcing Australia's position as a competitive player in the global CGT landscape. However, successfully executing these priorities will depend on sustained investment, regulatory agility, and the ability to attract both local and international funding.

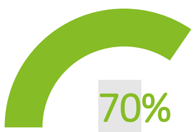
04 Manufacturing

Australia's CGT manufacturing ecosystem

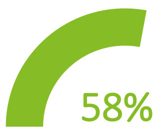
Australia's CGT manufacturing ecosystem currently consists of only **eight TGA-licensed Good Manufacturing Practice (GMP) facilities.** Although there is some capacity in the system among various CGT manufacturing facilities, more than half of survey respondents believe that the lack of onshore manufacturing capabilities will negatively impact their CGT development strategies over the next five years. A constrained onshore manufacturing capacity, coupled with supply chain vulnerabilities, poses a risk to the timely development and commercialisation of CGTs.

Without the necessary infrastructure, Australian organisations may struggle to scale up production efficiently, potentially leading to delays, increased costs, and reliance on international facilities. This could put **Australia at a competitive disadvantage compared to global markets** that have already prioritised advanced manufacturing capabilities.

Technology transfer issues also present a key bottleneck in the sector, limiting the ability of organisations to move CGT innovations from research to clinical and commercial applications. **Streamlining technology transfer processes,** including fostering stronger local collaboration between research institutions, biotech companies, and manufacturers, will be crucial for accelerating development timelines and ensuring Australian CGTs remain globally competitive.

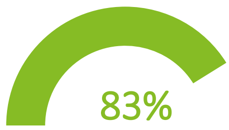


of respondents view **manufacturing challenges** (i.e. capacity, scalability and cost of raw materials) as a major consideration for their organisation impacting CGT development.

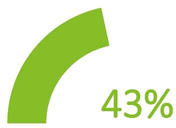


of respondents believe that a **lack of onshore manufacturing capabilities** will negatively impact their strategies for development of CGT in the next five years

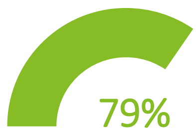
Encouragingly, the vast majority of respondents recognise that investment in a robust onshore manufacturing ecosystem is essential for enabling quicker progression in CGT development. This signals a **clear opportunity for both government and private sector stakeholders to prioritise funding and policy initiatives that enhance manufacturing capabilities.** By addressing these challenges, Australia can position itself as a leader in CGT innovation, ensuring that domestic advancements translate into real-world patient outcomes and economic benefits.



of respondents believe that **supply chain disruption** will negatively impact their CGT development strategies in the next five years.



of respondents consider **technology transfer-related issues** to be a current challenge within their organisation for CGT development



of respondents somewhat agree or strongly agree that investment in improving and establishing a robust ecosystem for onshore manufacturing capacity will allow for quicker progression in the development of CGT

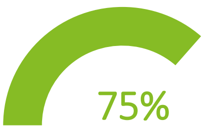
05 Collaboration

The role of collaboration in growing Australia's CGT ecosystem

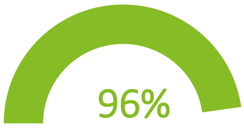
The survey findings highlight a strong appetite for collaboration within Australia's CGT ecosystem, with industry stakeholders recognising the **critical role of strategic alliances in advancing the sector**. The overwhelming recognition of collaboration as a priority suggests that stakeholders across manufacturing, academic research, and clinical development see shared resources, expertise, and infrastructure as critical to advancing CGT capabilities. This aligns with global trends where cross-industry partnerships and alliances have accelerated innovation and streamlined commercialisation pathways. The **Solutions for Manufacturing Advanced Regenerative Therapies (SMART) Cooperative Research Centre,** with the Catalyst as a partner, is playing a leading role in advancing national industry-academia collaboration to accelerate translation and sector growth.

Industry consolidation and mergers & acquisitions

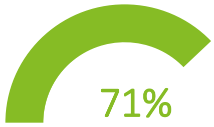
Industry consolidation through mergers, acquisitions, and licensing agreements is expected to play a crucial role in strengthening Australia's CGT sector. As companies seek to scale up and integrate capabilities across the value chain, consolidation may enable **more efficient translation of research into clinical and commercial outcomes**. This dynamic creates opportunities for emerging CGT companies to align with larger players, leveraging established networks and regulatory expertise to overcome barriers to market entry. Additionally, fostering stronger collaboration between academia and industry can enhance Australia's ability to compete internationally in advanced therapies.



of respondents expect **industry consolidation**, namely, mergers and acquisitions and cross-industry partnerships, to have a **positive impact** on their organisation's CGT strategy for the next five years



of respondents view **investing in strategic alliances and cross industry collaboration** relating to CGT over the next 5 years as **important** or **very important**

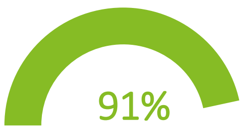


of respondents view **engaging in M&A, in-licensing and other partnerships** related to CGT over the next five years as **important** or **very important**

The need for a nationally coordinated CGT strategy

The survey findings also underscore the need for a nationally coordinated approach to ensure that Australia's CGT sector remains globally competitive. With 91% of respondents advocating for a structured, whole-of-sector strategy, there is a **clear mandate for greater policy alignment and investment in sector-wide infrastructure.**

This aligns with AusBiotech and Medicines Australia's call for a **National Life Sciences Strategy**[1] and highlights the need to prioritise CGTs as a key growth sector within that strategy. It presents a clear opportunity for the **Australian Government to play an active role in shaping the future of CGT** by fostering strategic partnerships, supporting translational research, and ensuring regulatory and funding mechanisms are optimised to attract global investment. A coordinated approach across manufacturing, research, and clinical applications could position Australia as a leader in CGT development while ensuring long-term patient access to innovative therapies.



of respondents agreed that a **national coordinated approach** across the entire value chain is required to ensure Australia's CGT needs are met.

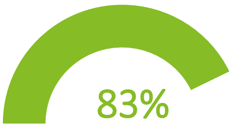
1. AusBiotech and MTP Connect: Pre-Budget Submission – 2025-26 Federal Budget

06 Workforce

Cell and gene therapies workforce challenges and gaps

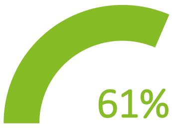
Australia's CGT sector faces a significant workforce challenge, with 83% of industry stakeholders expecting talent shortages to negatively impact their organisation's CGT strategy over the next five years.

A key factor driving this concern is the lack of CGT-specific training pathways, which 61% of respondents identified as a major issue contributing to the shortage of skilled professionals. The **absence of structured education and training programs** limits the ability to build a workforce equipped to meet the technical and regulatory demands of CGT development and manufacturing. Without intervention, this skills gap could constrain industry growth, hinder commercialisation efforts, and reduce Australia's attractiveness as a destination for CGT investment.



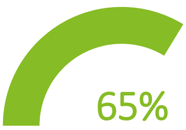
83%

of respondents expect **workforce talent challenges** and shortages **to negatively impact** their organisation's strategy for cell and gene therapies for the next 5 years



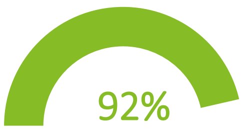
61%

of respondents agreed that **the lack of CGT training pathways** is a major workforce consideration for their organisation



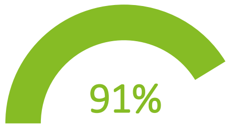
65%

of respondents agreed that the **lack of workforce with GMP expertise** is a major workforce consideration for their organisation



92%

of respondents agree that **investing in workforce** (retention, upskilling/reskilling) and education opportunities is an **important** or **very important** action



91%

of respondents agree that organisations need **to prioritise CGT-related workforce training**

Among the most pressing workforce gaps, 65% of respondents highlighted a shortage of professionals with GMP expertise, while 42% pointed to a lack of R&D workforce as a critical concern. These findings align with previous reports from the Cell and Gene Catalyst, including the National Cell and Gene Blueprint, which underscored **the urgent need to expand training opportunities for GMP-qualified cleanroom staff**. Without a workforce capable of supporting both early-stage research and large-scale manufacturing, Australia risks falling behind in the global CGT landscape.

Cell and gene therapies workforce training initiatives

Addressing these skills gaps requires proactive investment in workforce development, with 92% of respondents recognising **retention, upskilling, and education as critical priorities**. While industry organisations should explore ways to attract and retain skilled professionals through internal training initiatives and partnerships with academic institutions, a coordinated national effort is needed to develop a sustainable talent pipeline. Governments at both the state and federal levels could play a key role in funding initiatives that expand CGT training programs, support workforce reskilling, and create structured pathways into CGT careers.

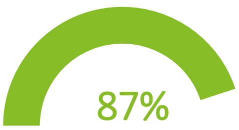
Ultimately, prioritising workforce development is a strategic imperative for Australia's CGT sector. Organisations that proactively invest in workforce training will be better positioned to navigate industry growth, while government support in developing structured training pathways will provide long-term benefits to the entire ecosystem. By addressing these workforce challenges now, Australia can build a **sustainable talent pipeline that supports the advancement of CGT therapies** and strengthens the country's reputation as a hub for advanced medical innovation.

07 Consumer Perspective

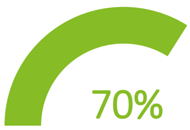
Consumer and patient perspectives

The survey findings highlight that patient considerations are central to the strategic priorities of organisations involved in Australia's CGT sector. With 87% of respondents emphasising the **importance of high-quality clinical care and timely delivery,** it is clear that ensuring efficient and effective patient access to CGTs is a critical focus.

Given the complexity of these therapies, which often involve highly personalised and time-sensitive treatments, investments in streamlining delivery pathways, improving healthcare infrastructure, and ensuring workforce readiness will be essential to meeting these expectations. Any delays in manufacturing, regulatory approvals, or clinical administration could compromise patient outcomes, making operational efficiency and healthcare system preparedness key areas for investment.



of respondents agree that ensuring patients receive **high quality clinical care and timely delivery of CGTs** is a major consideration for their organisation



of respondents agree that ensuring **equitable access to CGTs** (e.g. metropolitan versus regional access) is a major consideration for their organisation

of respondents believe that **patient experience** and consumer trust will **positively impact** their organisation's strategy for cell and gene therapies for the next 5 years.

Ensuring equitable access to CGTs

Equitable access remains a significant challenge, with 70% of respondents recognising disparities in CGT availability between metropolitan and regional areas as a major concern. Many advanced therapies require specialised facilities and highly trained staff, which are often concentrated in major cities, limiting access for patients in rural and remote areas.

Addressing these inequities will require coordinated efforts from industry, healthcare providers, and policymakers to expand infrastructure, develop innovative delivery models (e.g., decentralised manufacturing or telehealth-enabled follow-up care), and support regional healthcare professionals with CGT training. Failure to do so risks widening the healthcare gap, making it imperative that investment strategies consider equitable distribution of CGT resources across Australia.

Patient engagement and trust

Consumer trust and patient experience will play a pivotal role in shaping the future of the CGT sector, with 50% of respondents believing these factors will positively influence their organisation's strategy over the next five years. As CGTs represent a paradigm shift in treatment—often offering one-time, potentially curative solutions—it is crucial to ensure that patients and caregivers understand the science, risks, and long-term benefits.

This underscores the need for **greater patient engagement** throughout the research and development process, ensuring that consumer perspectives inform not only clinical trial design but also regulatory approvals, reimbursement models, and long-term care strategies. By actively involving patients in the CGT ecosystem, the sector can build confidence in these therapies, drive adoption, and ultimately improve health outcomes.

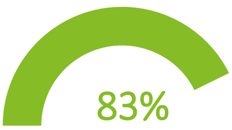
08 Emerging Technologies

Role of emerging technologies in CGT research & development

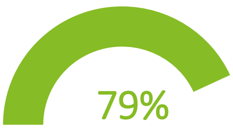
Artificial intelligence (AI) and **emerging digital technologies** are set to play a **transformative role in CGT R&D,** offering new efficiencies and capabilities across the entire value chain. AI-driven data analysis can accelerate the identification of therapeutic targets, optimise manufacturing processes, and enhance patient selection for clinical trials. Similarly, advancements in quantum computing and cloud technology have the potential to improve complex modelling and real-time data sharing, driving more precise and scalable CGT solutions. As these technologies continue to evolve, their integration into CGT R&D could reduce development timelines, lower costs, and improve the overall efficacy and accessibility of advanced therapies.

Strong industry confidence in AI and digital transformation

The strong industry confidence in AI and digital transformation suggests that **Australia's CGT sector is increasingly recognising the value of technological innovation**. Widespread adoption of AI could streamline both discovery and regulatory approval processes by automating data analysis, identifying optimal production methods, and supporting predictive modelling for patient outcomes. This presents significant opportunities for research institutions and biotech companies to leverage AI-driven insights, accelerating the transition from early-stage research to clinical application. Additionally, robotics and automation could enhance the efficiency and scalability of CGT manufacturing, addressing bottlenecks associated with manual production processes.



of respondents expect **accelerated digital transformation** will have a positive impact on their organisation's strategy for cell and gene therapies for the next five years



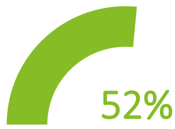
of respondents believe that the proliferation of **artificial intelligence** and its application in the development of cell and gene therapies will have a **positive impact** on their organisation's strategy for cell and gene therapies

What this means for Australia's CGT investment landscape

From an investment perspective, the growing prioritisation of AI and emerging technologies signals a shift in funding strategies within the CGT ecosystem. Investors and government stakeholders may look to support companies that are actively incorporating AI, robotics, and cloud-based solutions into their CGT pipelines.

However, with only a quarter of organisations currently progressing CGT development with plans to integrate AI or digital technologies, there remains a gap between awareness and implementation. This underscores the opportunity for targeted investment and incentives to drive adoption, ensuring Australia remains competitive in the rapidly evolving global CGT landscape.

of respondents are progressing development of relevant CGT with future plans to incorporate **use of AI, robotics or digital technologies**



of respondents view investment in emerging technologies like **AI, quantum computing** and cloud technology as **important** or **very important** over the next five years

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