



## 2023 CGT industry survey:

Reflections on and vision for the  
cell and gene therapy industry

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# Executive summary

Deloitte conducted a survey to assess the current state of the cell and gene therapy (CGT) industry and identify trends that are poised to shape the industry in the years ahead. The survey included respondents from more than 30 organizations with diverse representation from CGT innovators, health care providers, and contract development and manufacturing organizations (CDMOs). The findings reveal a shared optimism and recognition of the commercial potential of CGTs, while also highlighting areas of caution that resonate with stakeholders in the field. These findings provide valuable insights to guide decision-making and informing strategic planning for the future of the CGT industry.

## Survey highlights



**Positive outlook:** More than 80% of CGT leaders surveyed felt optimistic about the performance of the industry in the past 12–18 months, and 90% expressed a positive outlook for the next 12–18 months. CGT innovators and health care providers had a more positive outlook than CDMOs.



**Manufacturing challenges:** Nearly 40% of respondents lacked confidence in their current manufacturing capabilities to meet demand within the next two to three years. Short-term barriers to scaling up manufacturing included limited access to inputs (e.g., raw material supply), lack of standardized or proven manufacturing technology, and limited access to capital.



**Commercialization strategies:** Seeking partnerships, raising capital, and undertaking independent commercialization efforts were the top three options considered by CGT leaders to devise their commercialization strategy.



**Forces impacting future commercialization:** The top three forces expected to significantly impact commercialization of CGTs in the next 12–18 months are payer and reimbursement challenges, ability to raise capital, and manufacturing capacity or quality consistency constraints.



**Real-world evidence (RWE) collection barriers:** The lack of biomarkers and surrogate endpoints, burdensome data collection effort, and unclear regulatory guidelines constitute the top three barriers to RWE collection.



**Clinical-stage innovators:** More than 60% of clinical-stage CGT innovators are seeking partnerships, and more than 50% are looking to raise capital to support commercialization.



**Regulatory ambiguity:** The areas of the CGT value chain with the most significant regulatory ambiguity were chemistry, manufacturing, and control (CMC); comparability to reference products; and vector or plasmid guidelines.



**Critical aspects of clinical trial management:** The top three critical aspects of clinical trial management for CGTs were patient recruitment, site selection/trial design, and clinical trial management systems.

# Introduction

The survey aimed to understand CGT industry sentiment regarding past and future challenges, and across various functions in the value chain. The survey highlights key challenges and opportunities that organizations, their partners, and the broader CGT ecosystem face. The respondent pool consisted of 94% executive or senior leaders. Within this group, 55% represented CGT innovator companies, while the remaining 45% represented health care providers or contract development and manufacturing organizations (CDMOs), offering a range of perspectives. The roles of the participants spanned multiple functional areas, including commercial operations, manufacturing, regulatory affairs, digital/IT, clinical operations, and medical affairs/patient operations.

# Reflections and future sentiments toward the CGT industry

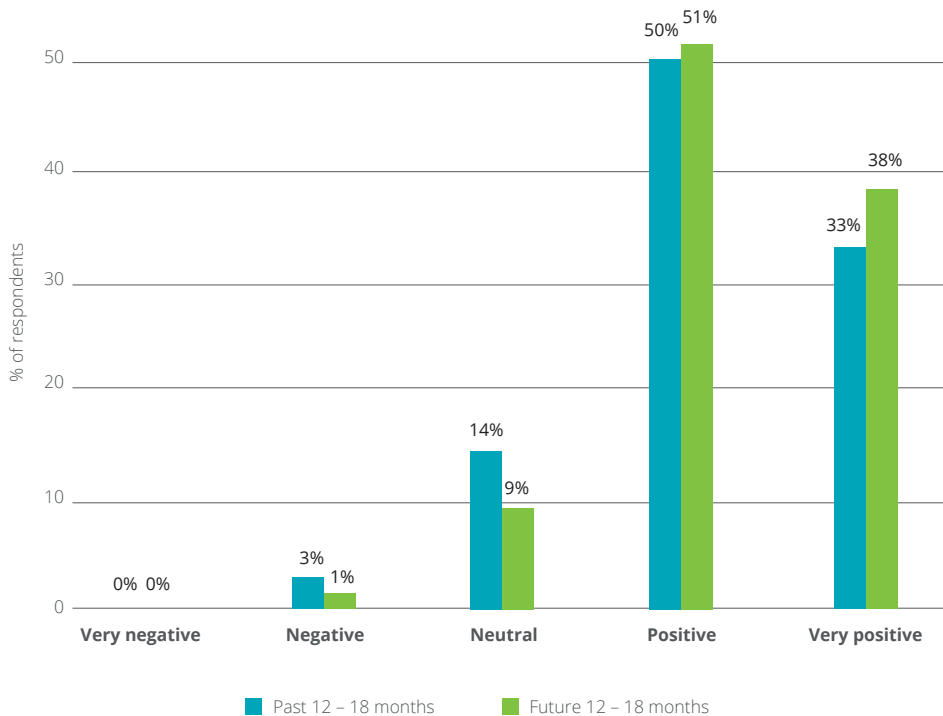
When examining the sentiments expressed by stakeholders, CGT innovators and health care providers had a positive sentiment about the industry over the past 12–18 months. Approximately 86% of CGT innovators and 83% of health care providers felt that this period had been positive for CGTs. In contrast, only 66% of CDMOs shared the same sentiment.

However, in looking ahead to the next 12–18 months, there is a more positive outlook across all stakeholder groups. CGT innovators (93%), health care providers (86%), and CDMOs (83%) expressed optimism, believing that the future will bring positive developments for the industry. This alignment and positive outlook reflects the overall potential and widespread optimism in the field.

Respondents had a more favorable outlook for gene therapies than autologous and allogeneic cell therapies when considering the next 12–18 months. Specifically, 86% of respondents expressed a positive outlook for gene therapies, while 76% and 72% expressed the same sentiment for autologous and allogeneic cell therapies, respectively.

Examining the perspectives of different roles within organizations, executives stand out as being substantially more optimistic about the future than about the previous 12–18 months. Around 90% of executives expressed optimism for the future, while only 70% felt the same about the past period, highlighting a belief in the transformative potential of CGTs among top-level decision-makers.

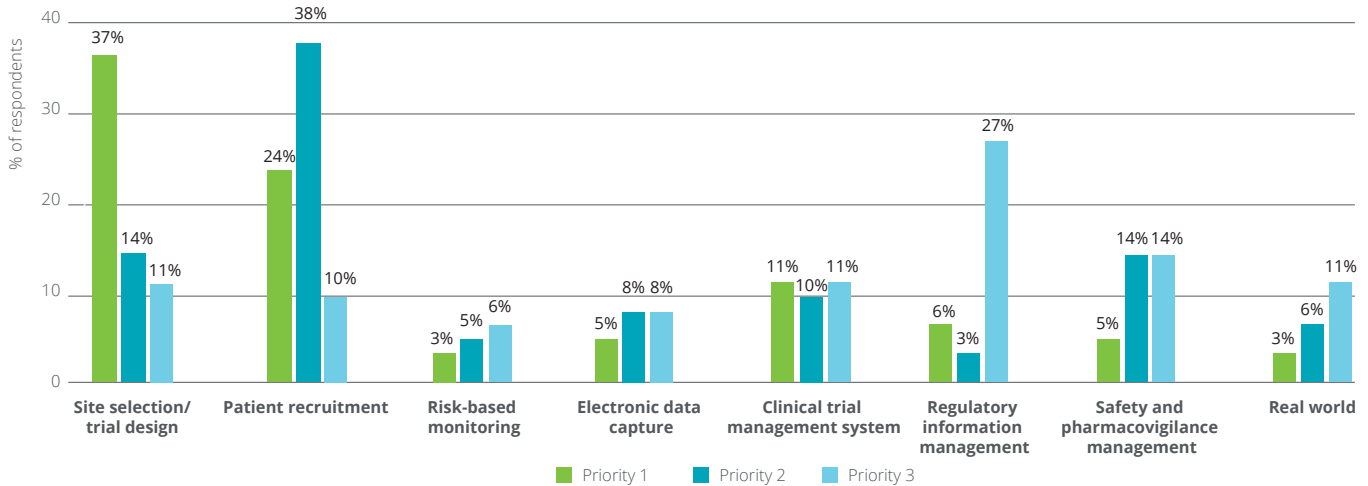
**Figure 1:**  
**Past and future sentiment regarding the development and commercialization of all cell and gene therapies**



## R&D

In considering the management of CGT clinical trials, the survey results highlighted the top three critical aspects of clinical trial management for CGTs to be: site selection/trial design, patient recruitment, and clinical trial management system. More than 35% of respondents chose site selection/trial design as the most critical aspect of clinical trial management for CGTs. These rankings were consistent with the perspectives of clinical operations respondents, highlighting the importance of these factors in effectively managing clinical trials. On the other hand, contrary to CGT innovators and health care providers, CDMOs selected electronic data capture as the third most critical aspect of clinical trial management. Overall, the findings underscore the need to effectively manage clinical trials to optimize the development of CGTs.

**Figure 2:**  
**What are your most critical aspects of clinical trial management in cell and gene therapy?**



## Manufacturing

The survey aimed to uncover industry sentiment on manufacturing capabilities, and the results revealed that nearly 40% of respondents are only somewhat confident, slightly confident, or not confident in their current manufacturing capabilities to meet demand within the next two to three years. The lack of confidence is likely a result of challenges faced when scaling manufacturing, which, per the survey results, included the need for more access to inputs, the absence of standardized or proven manufacturing technology, and inflated cost of capital or limited access to capital.

- 71% of CDMO's highlighted the absence of standardized or proven manufacturing technology as the primary barrier to scaling up manufacturing.
- 35% of respondents emphasized the critical role of good-quality apheresed and processed leukopaks as a limiting factor in their manufacturing capacity.

The survey shed light on the outsourcing dynamics within the manufacturing value chain. Overall, 56% of CGT innovators had contracted with CDMOs, where 94% of respondents reported they outsource some aspect of plasmid production and only 54% of respondents reported they outsource cell therapy manufacturing.

When selecting outsourcing partners, 79% of respondents identified a track record of regulatory compliance as the most or second most important factor. Furthermore, the survey results identified existing accreditations, prior experience collecting raw materials, and capacity as the top three factors driving the selection of apheresis centers. In fact, 33% of respondents selected existing accreditations as the most important factor driving apheresis center selection.

These results underscore the challenges and considerations associated with scaling up manufacturing in the CGT industry. Barriers such as limited access to inputs, lack of standardized technology, and capital constraints must be addressed. The dynamics of outsourcing within the manufacturing value chain highlight the reliance on external partners, particularly in plasmid production.

### The top three critical obstacles to scaling up manufacturing are:

- Limited access to resources (e.g., talent, supplies, raw material)
- Lack of standardized/proven manufacturing technology
- Inflated cost of capital and/or limited access to capital

## Commercialization

The survey illuminated the multifaceted nature of commercialization within the CGT industry. The survey results revealed the top three strategies organizations were considering to support the commercialization of their products to be: seeking partnerships, raising capital, and commercializing independently. These results highlight two diametrically opposed strategies between organizations, with almost half (48%) seeking partnerships and one-third (33%) choosing to commercialize independently.

The survey results also highlight a stark difference between how clinical-stage and commercial-stage CGT innovators approach commercialization. Clinical-stage innovators are more likely to seek partnerships (61%) and raise capital (54%) to support their commercialization efforts. In contrast, only 20% of commercial-stage innovators are seeking partnerships or raising capital for commercialization.

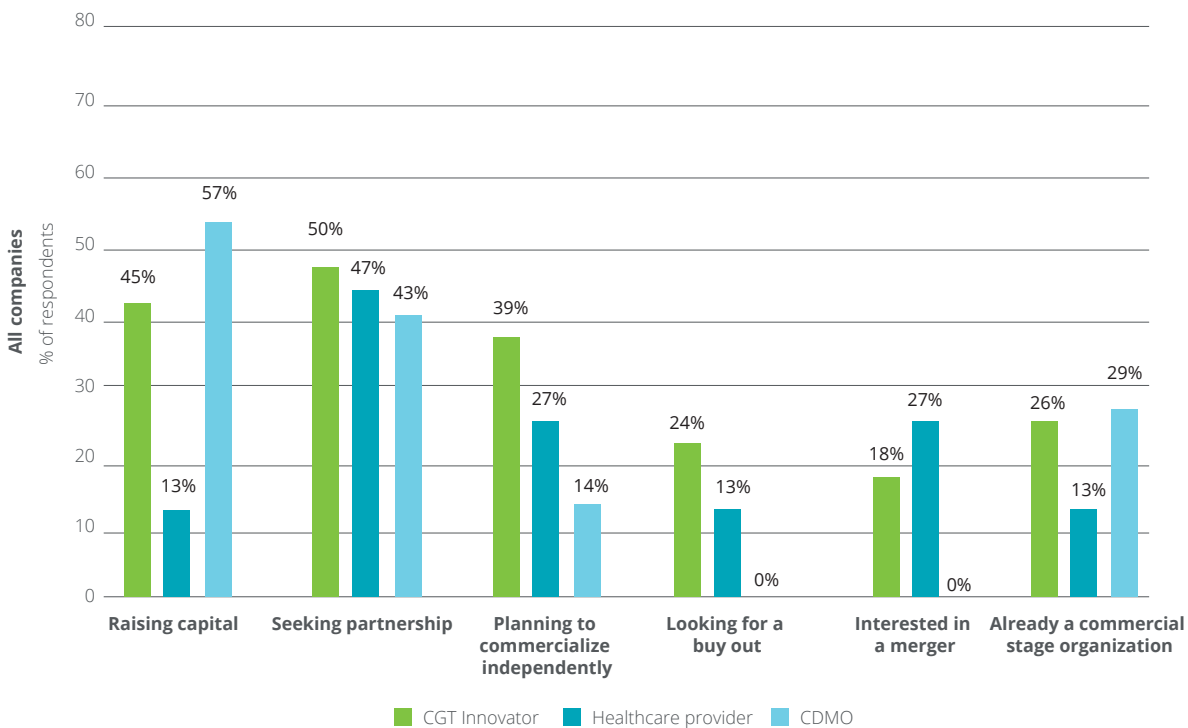
Looking ahead, respondents identified three key factors when considering the forces that will have the most impact on the commercialization of CGTs in the next 12–18 months: payer and reimbursement challenges, ability to raise capital from public and private sources, and manufacturing capacity or quality consistency constraints. These forces reflect the multifaceted nature of commercialization and the critical decision points organizations must navigate to succeed in the market.

**Top three forces expected to significantly impact commercialization of CGTs in the next 12 – 18 months are:**

- Payer and reimbursement challenges
- Ability to raise capital from public and private sources
- Manufacturing capacity or quality consistency constraints

**Figure 3:**

**When thinking about commercialization, which of these options is your organization considering?**





## Data and digital

The survey also explored respondents perspectives on the data and digital opportunities and challenges for CGTs. One of the crucial technological capabilities for CGT companies is the ability to capture and use real-world evidence (RWE) data for more informed decision-making. The survey results revealed the top three barriers for RWE collection to be: lack of biomarkers and surrogate endpoints to quantify efficacy, burden associated with data collection over time, and unclear regulatory guidelines.

Results also revealed that more than 33% of CGT innovators and CDMOs plan to establish their patient/therapy digital orchestration platform by leveraging partnerships. Another 33% of CGT innovators and CDMOs plan to develop end-to-end bespoke capabilities for their digital orchestration platform. The results demonstrate the varying approaches and priorities in embracing digital and technology advancements to improve patient-centric services.

Finally, the survey results revealed the top three digitally or hybrid-enabled processes to be: case management, order management, and patient support services. This finding indicates the increasing adoption of digital solutions to streamline and enhance these critical processes within the industry.

## Regulatory

The survey results revealed the top three areas in the CGT value chain that are perceived to have the most regulatory ambiguity as: chemistry, manufacturing, and control (CMC); comparability and biosimilarity to reference products; and vector or plasmid guidelines. More than 40% of respondents selected CMC as the area of the CGT value chain with the most regulatory ambiguity.

Results also revealed that 54% of CGT leaders either lack CGT-specific regulatory training or have no in-house CGT-specific regulatory expertise. Additionally, nearly 40% of health care providers have no in-house CGT-specific regulatory expertise. Developing and acquiring the necessary regulatory expertise and knowledge within organizations is crucial to meeting regulatory requirements and ensuring compliance. These insights underscore the importance of having clarity in regulatory requirements and the need to develop talent with this expertise within the CGT industry.



# Conclusion

Overall, responses tell a story of positive sentiment for the CGT industry, with most CGT leaders feeling positive about the past and expressing optimism for the future. However, differences emerged when considering specific therapy types, with gene therapies garnering the most positive outlook. While acknowledging the challenges ahead, the respondents expressed optimism about the potential of CGTs to transform health care and improve patient outcomes. The insights gathered from this survey highlight the challenges across various aspects of the CGT value chain, but also the collective industry sentiment about the potential of these therapies in the years to come. By navigating the hurdles and capitalizing on emerging opportunities, the CGT industry can continue to advance the development of transformational treatments and the broader health care industry.

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