Alliance for Regenerative Medicine

Advanced Manufacturing and Industrialization of the CGT Sector:

Takeaways from a scientific workshop

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INTRODUCTION

The field of cell and gene therapy (CGT) is rapidly advancing, and innovative manufacturing solutions are required to improve the scalability and commercial viability of therapeutic drug development. From June 12th-13th, 2025, the **Alliance for Regenerative Medicine (ARM) and the Cell and Gene Therapy Catapult** hosted a 2-day workshop in Stevenage, UK, to explore the use of advanced technologies and manufacturing strategies to industrialize and achieve future growth within the CGT sector. Bringing together therapeutic and technology developers, regulatory representatives, and other key stakeholders from across the industry (see the Appendix for a full list of presenters and panelists), this workshop represented ARM's continued commitment to advancing global CGT manufacturing, extending momentum from a US-based workshop in the spring of 2024 (see whitepaper from this event here).[1]

The goals of the workshop were to explore the following areas for advancing CGTs:

01 Artificial intelligence (AI), big data, and digitization

02 Strategies for scaling of manufacturing

03 Applications of robotics, automation, and AI

04 Decentralized manufacturing

General themes and specific case studies were shared, providing learnings from previous experience and inspiration for future efforts. In addition, regulatory perspectives on decentralized manufacturing and platform technologies were gathered from the MHRA. In-person attendees were also given the chance to tour the Cell and Gene Therapy Catapult's recently opened Digital and Automation Testbeds and participate in demonstrations of automated devices and robotic systems for bioprocessing of CGT manufacturing.

For definition of all abbreviations used in this whitepaper, please see the appendix.

[i] Cell and gene therapies (CGTs) are included in the broader definition of advanced therapy medicinal products (ATMPs) in the UK and the EU. The current definition of 'ATMP' also include tissue-engineered products, which were not discussed during the workshop.

[ii] Except where noted (e.g., publications cited), the information presented at the workshop and included in this whitepaper has not been subject to peer review. Case studies included in this report are not intended to show preference for any one developer's technology or product by the meeting's organizers or sponsors.

SUCCESS AND CHALLENGES WITHIN THE CGT INDUSTRY

The CGT industry is expanding year after year, with significant increases in the number of developers, clinical trials, and investment (**Box 1**). This growth reflects increasing patient demand and the higher likelihood of clinical trial success rates with CGTs compared to other types of therapies. Of candidates entering phase 1 trials, durable orphan gene therapies (defined as a candidate with the promise of conferring at least 18 months of clinical effect from a single administration) have an 18.5% overall likelihood of FDA approval, a rate 2.5 times higher than that for the average drug.[2-4] Between 2011 and 2020, cell therapies (eg, CAR-T, TCR-T) that reached phase 2 or later clinical trials were 40% more likely to receive U.S. FDA approval than other hematology/oncology drugs.[3-5]

BOX 1 **RISING GLOBAL COMPETITION IN THE CGT SECTOR (2024 DATA).**

CELL AND GENE THERAPY SECTOR DATA H1 2025

	North America	Asia Pacific	Europe	Total
Developers (Snapshot value)	770	750	453	2,070*
Clinical Trials (Snapshot value)	844	838	304	1,905*
Investment (Aggregate value)	$4.4B	$0.5B	$0.8B	$5B*

More data breakdowns available at: www.alliancerm.org/data

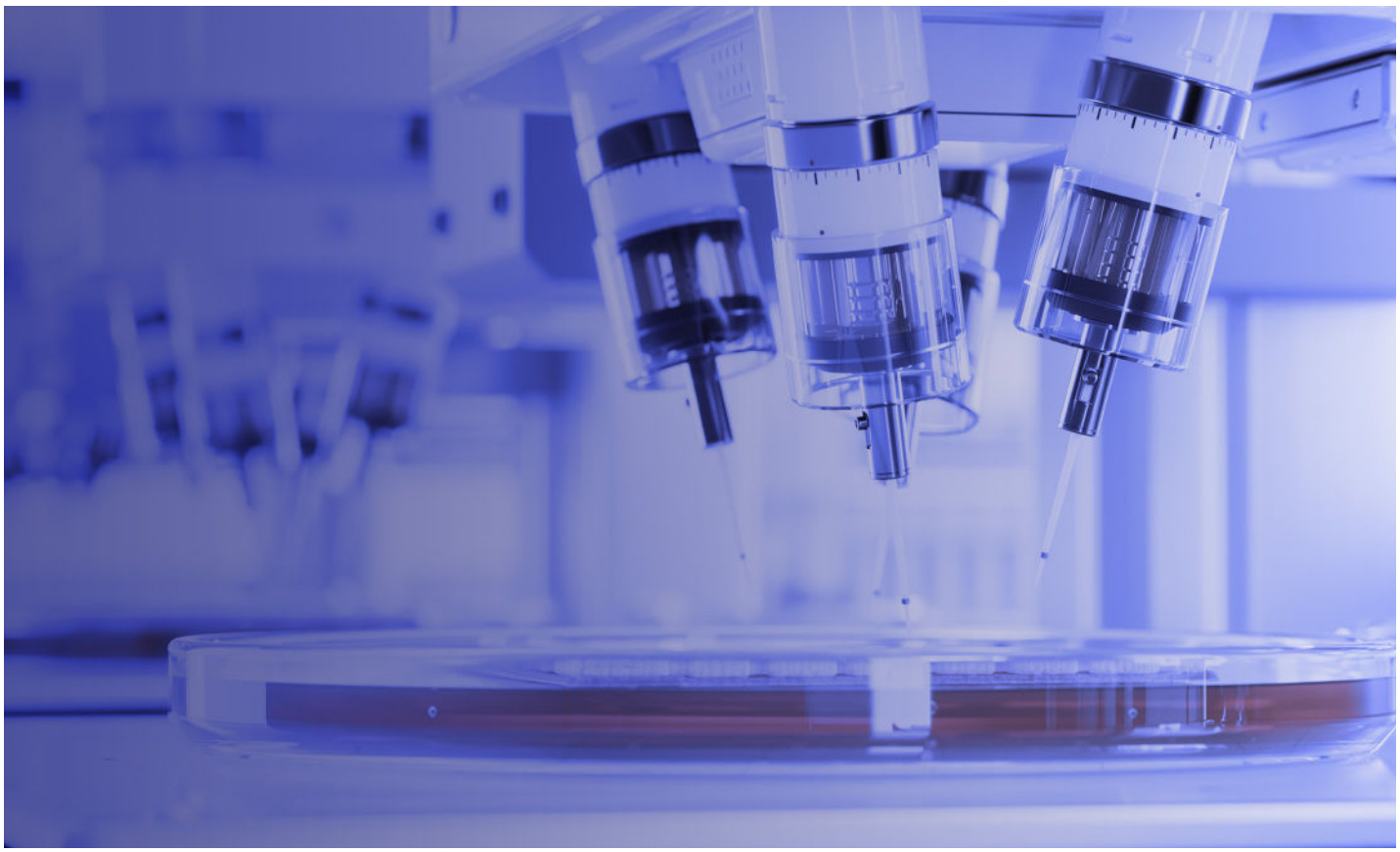
Source: GlobalData.[6]

*Totals refer to unique quantities and include data from other regions not shown.

In 2018, global CGT revenue totaled approximately $450 million US dollars. Two CGTs (Zolgensma® and Yescarta®) reached "commercial blockbuster" status (defined by ARM as estimated >$1 billion US dollars in worldwide sales) between 2018 and 2024, with an additional two (Carvykti® and Elevidys®) added in 2025 and at least 10 more expected by 2030.

Despite these positive trends, capital markets have been challenging for CGTs, with several developers and CDMOs closing doors, not bringing approved therapies to market, or downsizing CGT workforces due to funding difficulties. For CGTs to be attractive to investors and increase their commercial and economic viability, the industry needs creative manufacturing approaches capable of producing affordable therapies at scale.[7]

With current autologous therapies, manufacturing at scale is generally limited by a reliance on highly skilled experts for in-process decision making, manual operations, and the use of open processing in separate cleanrooms or isolators for each patient. A move toward automated, closed, and digitized manufacturing processes is necessary to reduce product variability, decrease cost of goods sold (COGS), and achieve appropriate scale. Ultimately, alongside the anchors of safety and efficacy, scalability/commercial viability should be thought of as the third pillar supporting any CGT endeavor. To this end, elements of scalable process design, keeping in mind requirements for an eventual commercial launch, should be incorporated early-on (perhaps even during R&D stages) for the greatest chance of success. Having end goals in mind also strengthens the investment thesis, as investors want to know how a product will be made and how quickly it could be made.



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