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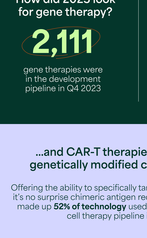
The ramarketing spotlight: CAR-T therapies in 2024

The cell and gene therapy (C&GT) space saw a period of instability in recent years, with the US FDA approving only four gene therapies in the five years prior to 2022.

But 2023 saw a re-ignition, resulting in seven C&GT approvals. With no signs of this momentum slowing, **2024 is set to see an estimated 17 approvals in the US and EU.**

Gene and genetically modified cell therapies from preclinical through pre-registration Q4 2023

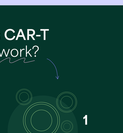


How did 2023 look for gene therapy?

2,111

gene therapies were in the development pipeline in Q4 2023

Oncology and rare diseases

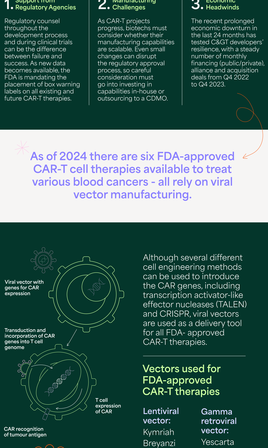


were the top areas of gene therapy development in both the overall pipeline and in clinical stage

...and CAR-T therapies dominated the genetically modified cell therapy space.

Offering the ability to specifically target and destroy cancer cells it's no surprise chimeric antigen receptor (CAR) T cell therapies made up **52% of technology** used in the genetically modified cell therapy pipeline in **Q4 of 2023.**

How does CAR-T therapy work?



The CAR-T cell therapy market is expected to grow at a compound annual growth rate (CAGR) of **28.5%** between 2022 and 2032 to reach a value of **$35.9 billion.**

What's influencing CAR-T cell therapy biotechs?

1. Support from Regulatory Agencies

Regulatory counsel throughout the development process and during clinical trials, can be the difference between failure and success. As new data becomes available, the FDA is mandating the placement of box warning labels on all existing and future CAR-T therapies.

2. Manufacturing Challenges

As CAR-T projects progress, biotechs must consider whether their manufacturing capabilities are scalable. Even small changes can disrupt the regulatory approval process, so careful consideration must go into investing in capabilities in-house or outsourcing to a CDMO.

3. Economic Headwinds

The recent prolonged economic downturn in the last 24 months has tested C&GT developers' resilience, with a steady number of monthly financing (public/private), alliance and acquisition deals from Q4 2022 to Q4 2023.

As of 2024 there are six FDA-approved CAR-T cell therapies available to treat various blood cancers - all rely on viral vector manufacturing.

Although several different cell engineering methods can be used to introduce the CAR genes, including transcription activator-like effector nucleases (TALEN) and CRISPR, viral vectors are used as a delivery tool for all FDA- approved CAR-T therapies.

Vectors used for FDA-approved CAR-T therapies

Lentiviral vector:
Kymriah
Breyanzi
Abecma
Carvykti

Gamma retroviral vector:
Yescarta
Tecartus

The global viral vector manufacturing market size was valued at **$5.5 billion** in 2023 - by 2028, it's expected to reach **$12.8 billion.**

What trends are we seeing in viral vector manufacturing?

1. The drive for broader patient access

Many producer cell lines require fetal bovine serum (FBS) for growth, but this brings variability and can impact the safety of the final product. Serum-free media options are offering an attractive alternative.

2. Adherent vs suspension cell lines

Although adherent cell lines are commonly used for viral vector production, their need for extensive manual handling and difficulty scaling is driving the trend towards the use of suspension cell lines.

3. Allogeneic vs autologous therapies

"Off-the-shelf" allogeneic C&GTs could offer the advantage of being more easily scalable than their autologous counterparts, but immunogenicity risks remain a challenge in bringing these products to market.

4. Supporting start-ups

A surge of venture capital investment in biotech in the past decade has meant many C&GTs in the pipeline have been developed by start-ups. As many of these companies lack necessary capacity and facilities, CDMOs are increasingly relied on for support.

5. Rise of gene editing therapeutics

The approval of the first CRISPR-based therapy, Casgevy, in 2023 signals a surge in gene editing treatments, necessitating improved manufacturing practices to address cost and access challenges.

C&GTs: 2024 and beyond

We can expect **2024** to be an exciting year for C&GTs, especially CAR-T therapies. Biotechs and CDMOs in the area are poised to rise to the challenges of C&GT development and manufacturing to deliver revolutionary new therapies to the patients that need them.

Find out how ramarketing can help your CDMO company grow in the C&GT space by contacting ramarketing today.

Contact us