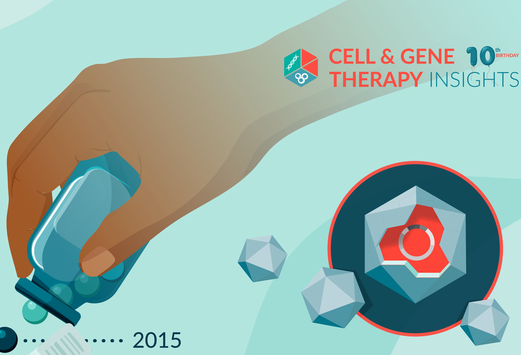
CELL & GENE THERAPY INSIGHTS 10 BIRTHDAY

A decade of breakthroughs

10 years of cell & gene therapy

Over the past ten years, cell and gene therapy has leapt from experimental trials to life-changing treatments. From the first CAR-T approvals to CRISPR's clinical debut, the field has redefined what's possible in medicine. In this infographic, we chart the milestones that transformed CGT from promise to practice.



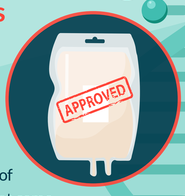
2015

Laying the groundwork

The field of cell and gene therapy (CGT) began to shift from promise to practice. Early clinical successes in CAR-T and AAV-based therapies were setting the stage for a wave of transformative approvals.

2017

First FDA CAR-T approvals

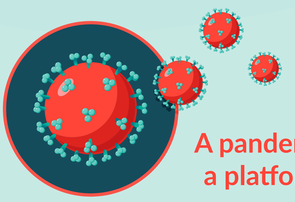


A landmark year for the field. The US FDA approved the first two CAR-T cell therapies: Kymriah (Novartis) for pediatric acute lymphoblastic leukemia, and Yescarta (Kite Pharma, later Gilead) for adult large B-cell lymphoma. These approvals marked the arrival of living drugs in mainstream oncology care. That same year, Gilead Sciences acquired Kite Pharma for $11.9 billion; the first major acquisition of a CGT-focused biotech, signaling growing commercial confidence in the space. Luxturna (Spark Therapeutics) also became the first FDA-approved directly administered gene therapy for a genetic disease, targeting inherited retinal dystrophy.

2018

Expansion into Europe

Kymriah and Yescarta received European Commission approval, expanding access to CAR-T therapies across the EU. Manufacturing and regulatory frameworks began to evolve rapidly to accommodate the unique demands of autologous cell therapies. The year also saw a surge in CGT-focused investment and infrastructure development globally.



2020

A pandemic and a platform shift

While the COVID-19 pandemic disrupted clinical trials and supply chains, it also accelerated innovation in viral vector and mRNA platforms. CGT trials surpassed 1,000 globally by the end of the year, and the industry began to explore decentralized manufacturing and digital solutions to support complex therapy delivery.

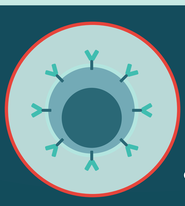
2019

Gene therapy goes systemic

The FDA approved Zolgensma (Novartis), a one-time gene therapy for spinal muscular atrophy delivered via systemic AAV9, and at $2.1 million, it became the most expensive drug ever approved. In Europe, Zynteglo (bluebird bio) was granted conditional approval for transfusion-dependent β-thalassemia, marking another step forward for lentiviral gene therapy.

2021

CAR-T diversifies



The CAR-T landscape expanded with the approval of Abecma (Bristol Myers Squibb/bluebird bio), the first CAR-T therapy for multiple myeloma, and Breyanzi (BMS) for large B-cell lymphoma. These approvals demonstrated the potential of CAR-T beyond initial indications and highlighted the growing role of dual partnerships in CGT commercialization.

2022

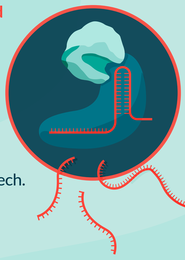
Hemophilia and beyond

Roctavian (BioMarin) received conditional EMA approval for hemophilia A, becoming the first gene therapy for this bleeding disorder. Meanwhile, Carvykti (Janssen/Legend Biotech) joined the CAR-T arsenal for multiple myeloma, and the field began to see increasing interest in allogeneic and off-the-shelf approaches. Upstaza (PTC Therapeutics) became the first approved gene therapy delivered directly into the brain, treating aromatic L-amino acid decarboxylase (AADC) deficiency.

2023

A CRISPR debut

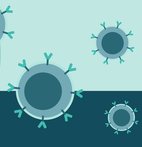
In a historic moment for gene editing, the FDA approved the first CRISPR-based therapies: Casgevy (Vertex/CRISPR Therapeutics) and Lyfgenia (bluebird bio) for sickle cell disease. These approvals validated years of research and opened the door to a new class of precision therapies. Blood cancer therapy NexCAR19 (ImmunoACT) became the first CAR T-cell therapy designed and approved in India, by a small Mumbai-based biotech.



2024

Decentralized CAR-T advances

Two new anti-BCMA CAR-T therapies for multiple myeloma were approved, each representing a milestone in regional innovation. In Spain, ARI0002h (Cesnicabtagene Autoleucel), developed by Hospital Clínic of Barcelona, became the first point-of-care CAR-T therapy approved in Europe. In China, Zevorcabtagene Autoleucel (CARsgen Therapeutics) received approval. Tecelra (Adaptimmune) also became the first engineered TCR therapy approved for a solid tumor indication, while Ryoncil (Mesoblast) was approved for steroid-refractory graft-versus-host disease – the first mesenchymal stem cell therapy of its kind.



2025

Individualized gene editing

The field of cell and gene therapy continued to expand both geographically and technologically. China approved Ruiboshen, its first MSC therapy, reflecting the field's growing global footprint. In a landmark for personalized medicine, clinicians at CHOP successfully treated an infant with CPS1 deficiency using a bespoke CRISPR base-editing therapy—the first case of personalized *in vivo* CRISPR gene editing. With over 4,000 CGT and RNA therapies in development, the field continues to evolve toward broader access and greater precision.

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