

Gene Therapy Market Fueled by CRISPR Advances & Regulatory Momentum | DataM Intelligence

Gene therapy market surges on breakthroughs in genome editing, rising chronic & genetic disease cases, regulatory approvals, and expanded manufacturing capacity

TEXAS, TX, UNITED STATES, July 31, 2025 /EINPresswire.com/ -- [Gene therapy treatments](#) using genetic material to correct or treat diseases is gaining traction, particularly in rare genetic disorders, oncology, and beyond. According to DataM

Intelligence, the market size reached US\$ 4.80 Billion in 2024 and is estimated to reach US\$ 35.91 Billion by 2033, growing at a CAGR of 23.1% during the forecast period 2025-2033.

Drivers include regulatory approvals (e.g. exa-cel, Zolgensma), increasing gene editing R&D, and significant pharmaceutical investment. Innovation in viral vector design, CRISPR platforms, and specialized CDMO capacity underpin this growth.

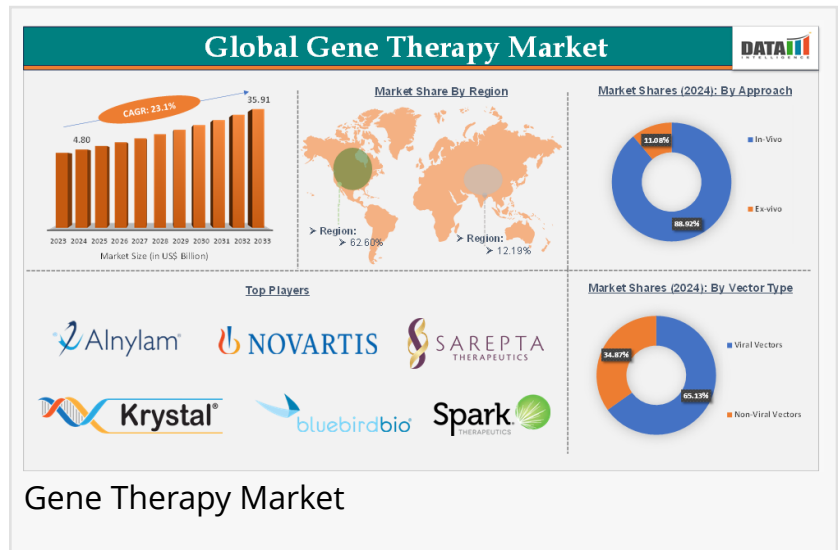
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Gene Therapy Market Segments

By Vector Type:

Viral vectors account for over 65% of revenue in 2024, led by adeno-associated virus (AAV) and lentiviral systems. Non viral vectors are growing fastest due to safety and scalability advantages in newer gene-editing trials.

By Therapeutic Area:



Oncology is the fastest-growing segment, driven by CAR-T and gene-editing cancer therapies. Neurological and rare genetic conditions currently hold the largest share, with approved products like Zolgensma and exa-cel setting precedent and expanding adoption.

Key Players & Collaborations

Leading gene therapy developers include Novartis, Bluebird Bio, Spark Therapeutics (Roche), CRISPR Therapeutics (with Vertex), Sangamo Therapeutics, Orchard Therapeutics (Kyowa Kirin), Gilead/Kite, Biogen, Amgen, and BioMarin.

Notable innovations:

- CRISPR Therapeutics gained approval for exa cel (CTX001) in sickle cell disease and beta thalassemia in late 2023, advancing gene editing commercialization.
- Bluebird Bio's Lyfgenia, FDA allowed outcomes-based pricing and expanded coverage agreements in U.S. Medicare contracts.

Regional Market Dynamics in Gene Therapy Market

- North America dominates thanks to advanced regulatory frameworks, insurance coverage for rare diseases, and concentration of biotech innovation hubs.
- Asia-Pacific led by China, Japan, and India is the fastest-growing region, powered by increasing genetic disease awareness, CDMO infrastructure expansion (e.g. Japan's automated iPS cell manufacturing), and favorable government biotech programs.
- Europe is supported by advanced gene therapy approval pathways, collaborative research networks, and recent acquisitions, including BioNTech's takeover of CureVac to build mRNA and RNA therapy platforms in Germany.
- Latin America, Middle East & Africa remain nascent, but growth is emerging via research partnerships and increasing access to rare disease treatments in Brazil, GCC countries, and South Africa.

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Recent Investments & Key Developments

United States

- June 2024: Sarepta's DMD gene therapy Elevidys earned broader FDA approval for children ≥ 4 and non-ambulatory patients, elevating potential market coverage to ~90% of U.S. DMD cases and driving a ~33% spike in share price, despite growing FDA scrutiny.

Japan

- April 2025: Kyoto University's CiRA began fully automated production of autologous iPS cells for

regenerative and gene therapy applications, reducing cost barriers and speeding personalized therapy workflows.

Europe

- June 2025: Bluebird Bio agreed to be acquired by Carlyle Group and SK Capital in a bailout deal valued at up to USD\$960million, aimed at sustaining rare disease gene therapy R&D despite financial pressures.

Innovation & Trends

- CRISPR and ex vivo editing therapies are emerging as key growth paths; platforms from CRISPR Therapeutics and Precision BioSciences (using ARCUS technology) target disorders like sickle cell and muscular dystrophy.
- Enhanced vector design collaborations, notably Roche's >USD\$1billion partnership with Dyno Therapeutics to develop next-generation AAV for neurologic conditions, are shaping safe and efficient delivery systems.
- Outcomes based contracting is taking hold, particularly with ultra-costly therapies like Lyfgenia, where payers only pay full price upon long-term benefit verification.

Challenges & Market Outlook

Challenges:

- Safety Concerns & Public Trust: Recent fatalities linked to Sarepta's Elevidys trials have raised investor and regulatory scrutiny, dampening sentiment despite scientific promise.
- Cost & Access: With therapies priced at USD\$2–3million per treatment, scaling access outside wealthy healthcare systems remains challenging.
- Investor Confidence: A steep pullback in gene therapy dealmaking and M&A over the past 18 months reflects reduced risk appetite and caution following technical setbacks.

Future Outlook:

Despite volatility, the pipeline of ex-vivo gene editing, oncology-targeted treatments, and safer viral vectors continues to grow. Stakeholders investing in scalable manufacturing, regional clinical trials (especially in Asia), and reimbursement innovation are best placed to lead global expansion toward a multi billion-dollar gene therapy market by 2033.

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