

United States Gene Therapy Market Assessment, By Type [Gene Augmentation, Gene Silencing, Others], By Vector [Viral Vectors, Non-Viral Vectors], By Gene Delivery Method [In vivo, Ex vivo], By Application [Oncological Diseases, Genetic Diseases, Cardiovascular Diseases, Neuromuscular Diseases, Hematological Diseases, Infectious Diseases, Others], By Route of Administration [Intravenous, Others], By End-user [Hospitals, Cancer and Research Institutes, Clinics, Others], By Region, Opportunities and Forecast, 2017-2031F

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Report description:

United States gene therapy market is projected to witness a CAGR of 21.53% during the forecast period 2024-2031, growing from USD 3,101.26 million in 2023 to USD 14,287.31 million in 2031. The growth of the market is bolstered by rising research activities, increasing approvals by regulatory bodies, growing cases of chronic and genetic diseases, and increasing investments by key market players.

Recent advancements in CRISPR-based genome editing technology are also expected to positively influence the market's expansion. Additionally, increasing emphasis is being placed on cardiovascular research due to the rising cases. According to the estimates of the American Heart Association, the age-adjusted death rate from cardiovascular diseases in 2023 increased by 4% from 2022. The emerging Cas nucleases are promoting the development of medicines and life sciences with the help of their extended applications that are allowing the expansion of the CRISPR-based genome editing toolbox. The genome editing technology is revolutionizing cardiovascular research by bolstering the generation of genetically modified models of cardiovascular diseases.

The government policies such as Medicaid and Medicare and laws including Affordable Care Act (ACA) have also impacted reimbursement and access to gene therapies in the United States. Federal funding for advancing biotechnology research from the Biomedical Advanced Research and Progress Authority (BARDA) and National Institutes of Health (NIH) are also fostering innovations in gene therapy.

Increasing Research Activities Boost Market Growth

The recent advancements in innovative technologies have propelled the development of novel therapeutic solutions and bolstered awareness about the potential of gene therapy for treating genetic disorders and rare diseases. Thus, this will bolster the investments towards research activities in gene therapy approaches across the country, which are ushering in a wide range of new therapeutic solutions to combat different diseases. In January 2024, a team of researchers from the Harvard Medical School and Massachusetts Eye and Ear Infirmary developed a novel gene therapy approach that allowed children with congenital deafness to hear for the first time. The project was the first to use gene therapy to treat the condition and has opened doors to support the development of other treatment solutions to reduce the burden of different types of genetic deafness. Such collaborations between the leading research organizations are expected to boost the market in the coming years. Rising Approvals by FDA Support Market Expansion

The increasing efforts of the key players in the market to bolster the development and availability of novel therapeutic solutions in the country are propelling the United States gene therapy market growth. In April 2024, the United States Food and Drug Administration (US FDA) approved fidanacogene elaparvovec (Beqvez), the second gene therapy for hemophilia B. The patients eligible for a one-time infusion include those with historical or current life-threatening hemorrhages, spontaneous and serious bleeding episodes, and those on clotting factor IX prophylaxis therapy. The first therapy to be approved by the FDA for the condition was etranacogene dezaparvovec (Hemgenix), in November 2022. The growing approvals for gene therapy for chronic diseases can be attributed to the efficacy and safety demonstrated by them in different trial phases. Such approvals are expected to provide lucrative growth opportunities to the market and aid the patient population in combating chronic diseases. Rising Cases of Genetic and Chronic Diseases to Increase Market Demand

The increasing prevalence of chronic and genetic diseases is propelling the demand for gene therapy in the United States. Genetic disorders, with often no effective conventional treatments, have become a main target for interventions involving gene therapy. Some of such disorders include cystic fibrosis, sickle cell anemia, muscular dystrophy, and hemophilia. Additionally, the expansion of the aging population is also one of the major reasons contributing to rising cases of chronic diseases and thus increasing the demand for gene therapies in the United States. Age-related disorders, including cardiovascular diseases, diabetes, and neurodegenerative disorders such as Parkinson's and Alzheimer's disease, require novel treatment modalities. Gene therapies offer symptom alleviation and modification of the disease process, thus providing effective long-term solutions. Meanwhile, the rise in cancer cases in the United States has drawn attention to gene therapy in oncology in the country. As per the estimates of the National Cancer Institute, approximately 2,001,140 new cases of cancer are expected to be diagnosed in the United States in 2024.

Oncological Diseases Hold Major Market Share

The rising cases of cancer in the country and the presence of a strong healthcare sector that is committed towards advancing the next generation of cancer treatment are propelling the growth of the United States gene therapy market. The gene therapy approach is deployed to either weaken the cancer cells or strengthen the immune system.

The increasing efforts towards the development of novel gene therapies to battle different types of cancer are also supporting the market's expansion. In July 2024, UC San Diego Health became the first health system in San Diego County to provide new gene therapy for treating localized bladder cancer. Such developments are expected to aid healthcare organizations in meeting the evolving requirements of patients with the help of gene therapy and provide lucrative growth opportunities to the market. Future Market Scenario (2024-2031F)

As per the United States gene therapy market analysis, the market is expected to witness significant growth in the coming years owing to the growing awareness about the potential of gene therapy in reducing the burden of different diseases, increasing investments by the key market players, and rising research activities in the country. Various research studies and clinical trials are underway to evaluate the safety and effectiveness of gene therapy. For instance, the Methodist Hospital Research Institute in Texas is conducting an interventional study to evaluate the efficacy and safety of chemotherapy, radiotherapy, valacyclovir, and

gene therapy in recurrent glioblastoma multiforme. The study aims to assess the toxicity and efficacy of the combination therapy in anaplastic astrocytoma or glioblastoma multiforme and comprises of patients who have previously failed standard-of-care treatment. The study is expected to conclude in December 2025.

Additionally, the growing efforts of the leading market players to bolster the production of different therapeutic solutions are also expected to boost the market's expansion. For instance, Gilead Sciences Inc. is actively working towards quadrupling the production of their cell therapy cancer treatments by 2026 by ensuring improvements in their manufacturing processes. Key Players Landscape and Outlook

Mergers and acquisitions aid the key players of the market to ensure the availability and development of innovative therapies, bolstering the market. In March 2024, Gilead Sciences Inc. announced that they had acquired CymaBay Therapeutics, Inc. for approximately USD 4.3 billion. The acquisition aligns with the former's long-term commitment to ensuring the availability of transformational medicines for patients by adding CymaBay's investigational candidate, seladelpar, to their existing liver portfolio. Such investments are expected to transform the treatment landscape for primary biliary cholangitis and allow companies to meet the unmet requirements of the patients.

Additionally, the rising investments by the key players towards the construction of manufacturing facilities in the country is also supporting the market's expansion. In February 2024, Amgen, Inc. announced the opening of a new manufacturing facility in Central Ohio. The site is expected to play a crucial role in aiding the company in combatting the threat of chronic diseases and ensuring the availability of innovative therapeutic solutions.

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*Companies mentioned above DO NOT hold any order as per market share and can be changed as per information available during research work.

17. Strategic Recommendations

18. About Us and Disclaimer



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