

# **Regenerative Medicine Market Size and Forecast (2021 - 2031), Global and Regional Share, Trend, and Growth Opportunity Analysis Report Coverage: By Product Type [Cell-Based Products (Stem Cell and Cell-Based Immunotherapy), Gene Therapy, Tissue Engineering], Application (Oncology, Neurological Disorders, Wound Healing & Skin Regeneration, Ophthalmology, Orthopedics & Musculoskeletal, Immunology, Genetic Disorders, and Others), and Geography (North America, Europe, Asia Pacific, Middle East and Africa, and South and Central America)**

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## **Abstracts**

According to our new research study on “Regenerative Medicine Market Forecast to 2031 -Global Analysis - by Product Type, and Application,” the market is anticipated to grow from US\$ 20.55 billion in 2024 to US\$ 75.16 billion by 2031; the market is expected to register a CAGR of 20.3%. The regenerative medicine market growth is attributed to the rising prevalence of chronic disorders, an aging population, and the introduction of advanced regenerative therapies.

Regenerative medicine is a field of biomedical science focusing on repairing, replacing, or regenerating damaged or diseased cells, tissues, or organs to restore normal function. It combines approaches from stem cell therapy, tissue engineering, gene therapy, and biomaterials to promote healing and regeneration.

The regenerative medicine market in North America is segmented into the US, Canada,

and Mexico. The US holds the largest market share, followed by Canada. According to the Centers for Disease Control and Prevention (CDC), a heart attack occurs every 40 seconds in the US, with approximately 805,000 people experiencing it each year. Cancer is a major cause of morbidity and mortality, with significant healthcare costs and quality-of-life implications. The rising prevalence of chronic and degenerative conditions is increasing the demand for novel treatment approaches such as regenerative therapies.

Regenerative medicine holds transformative potential for prevalent diseases in North America, particularly cardiovascular diseases, diabetes, and certain types of cancer. Advances in stem cell therapies, gene editing, and tissue engineering are showing promise in these areas. Several CAR-T cell therapies have received FDA approval for treating hematological malignancies, such as multiple myeloma and lymphoma.

The rising burden of chronic and degenerative diseases is driving investments in research, biomanufacturing, and workforce development within the regenerative medicine sector. This ecosystem fosters rapid innovation and enhances the availability and sophistication of treatment options. In January 2022, Cellino Biotech, Inc., a US-based autonomous cell therapy manufacturing company, completed an US\$ 80 million Series A financing round led by Bayer AG's Leaps by Bayer, alongside 8VC and the Humboldt Fund. Cellino's innovative manufacturing platform combines artificial intelligence and laser technology to automate cell therapy production, aiming to lower costs and improve scalability. This investment offers Leaps by Bayer a unique opportunity to support the development of advanced therapies that enhance patient access to cell treatments.

In North America, the US holds a significant share of the regenerative medicine market. The US dominated the North America regenerative medicine market in 2024. According to the CDC, in 2023, 76.4% of US adults, over 194 million people, had at least one chronic condition. More than half of these individuals (51.4%, or 131 million) reported having two or more chronic conditions. The prevalence of at least one chronic condition among adults increased from 72.3% to 76.4%. The percentage of adults with two or more chronic conditions rose from 47.3% to 51.4%.

According to the Alzheimer's Association, by 2025, more than 7.2 million Americans aged 65 and older are projected to be living with Alzheimer's, with that number expected to grow to 12.7 million by 2050. Chronic illnesses such as cardiovascular diseases, cancer, and neurodegenerative disorders lead to irreversible damage to tissues or organs, making patients prime candidates for regenerative therapies such as

stem cell therapy, tissue engineering, and gene therapy. Regenerative medicine shows promise in restoring lost heart function after heart attacks, regenerating cartilage in cases of degenerative joint diseases, and replacing damaged neurons in neurodegenerative disorders. In the US, MSCs are commonly used to treat degenerative diseases and certain diseases of the skin, bone, and cartilage.

The US government is promoting the development and approval of regenerative therapies by utilizing regulatory innovation, expedited approval processes, direct funding, and collaborative technical support. As of mid-2025, more than 80 Regenerative Medicine Advanced Therapy (RMAT) designations have been awarded, which have helped speed up clinical advancements for conditions such as spinal cord injuries and heart failure. In 2023, the US FDA approved cell and gene therapies, including gene-editing treatments targeting rare diseases. Therapies such as exagamglogene autotemcel (Casgevy) and lovetibeglogene autotemcel for sickle cell disease, as well as valoctocogene roxaparvovec for severe hemophilia A, have received FDA approval, highlighting the potential of gene therapies in addressing rare disease challenges. Thus, the increasing incidence of chronic diseases, coupled with ongoing research and approval initiatives to promote the adoption of regenerative technologies, is fueling the market growth in the US.

### Integration of Artificial Intelligence in Regenerative Medicine to Provide Market Opportunities in Future

Integrating artificial intelligence (AI) into regenerative medicine enhances drug discovery, improves personalized therapies, and accelerates development timelines. AI-driven technologies facilitate handling complex biological data and optimizing manufacturing processes, leading to more efficient regenerative therapies. Aspen Neuroscience's ANPD-001, currently in Phase II clinical trials for Parkinson's disease, exemplifies a pioneering AI-enabled regenerative therapy. This therapy utilizes AI and machine learning (ML) to reprogram patient skin cells into dopamine-producing neurons. Proprietary AI-based genomic tests ensure cell quality, resulting in safer, more personalized treatments. This approach demonstrates how AI validation can enhance the precision and biological safety of regenerative medicine products while reducing the risk of rejection.

Several startups illustrate this trend further. The Argentinian company MesencHyal-T employs AI-powered cellular therapies aimed at bone regeneration. It uses machine learning in its scalable production processes to standardize stem cell expansion and improve the osteogenic potential of the cells. Additionally, it collaborates with hospitals

and research centers to facilitate quicker clinical deployment, showing how AI aids in discovery as well as real-world applications and outcome predictions. Similarly, the UK-based company Trogenix integrates genomics, bioinformatics, and machine learning into its synthetic super-enhancer viral immunotherapy for precise gene control and targeted regenerative treatments in cancer and age-related tissue repair.

AI-driven platforms contribute to product launches that accelerate drug candidate generation. Insilico Medicine, a leader in AI drug discovery, achieved a milestone with INS018\_055, a small-molecule drug candidate for idiopathic pulmonary fibrosis. This drug is the first entirely AI-discovered and AI-designed medication to enter Phase II trials. Insilico's collaboration with pharmaceutical giant Sanofi, a US\$1.2 billion deal, leverages Insilico's AI platform to identify novel targets and predict clinical outcomes, highlighting the ecosystem of partnerships centered around AI-driven regenerative solutions.

In manufacturing and therapy design, companies such as US-based Shinobi Therapeutics utilize AI-enabled platforms to develop immune-evasive induced pluripotent stem cell (iPSC) therapies, featuring genetic edits that evade immune detection. This strategy offers off-the-shelf regenerative treatments suitable for oncology, diabetes, and autoimmune disorders, showcasing how AI simplifies the complex genetic engineering required for advanced regenerative products.

AI helps overcome challenges in regenerative medicine, such as high developmental costs and lengthy timelines. It enhances predictive modeling, quality control, and scaling up production. AI algorithms analyze vast datasets to predict patient-specific responses to stem cell therapies, aiding in creating personalized treatment plans and improving clinical outcomes. Industry forecasts for 2025 suggest that AI adoption will increase dramatically, becoming foundational in personalizing regenerative protocols worldwide.

The integration of AI in regenerative medicine represents a groundbreaking trend. AI streamlines therapy development and enhances personalization, quality, and clinical effectiveness. This approach positions regenerative medicine for unprecedented growth and patient impact in the coming years, underscoring the convergence of cutting-edge technology with biological innovation to revolutionize the design, testing, and delivery of regenerative therapies.

The US Food and Drug Administration, Medicines and Healthcare Products Regulatory Agency (MHRA), Alliance for Regenerative Medicine (ARM) are among the primary and secondary sources referred to while preparing the regenerative medicine market report.

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