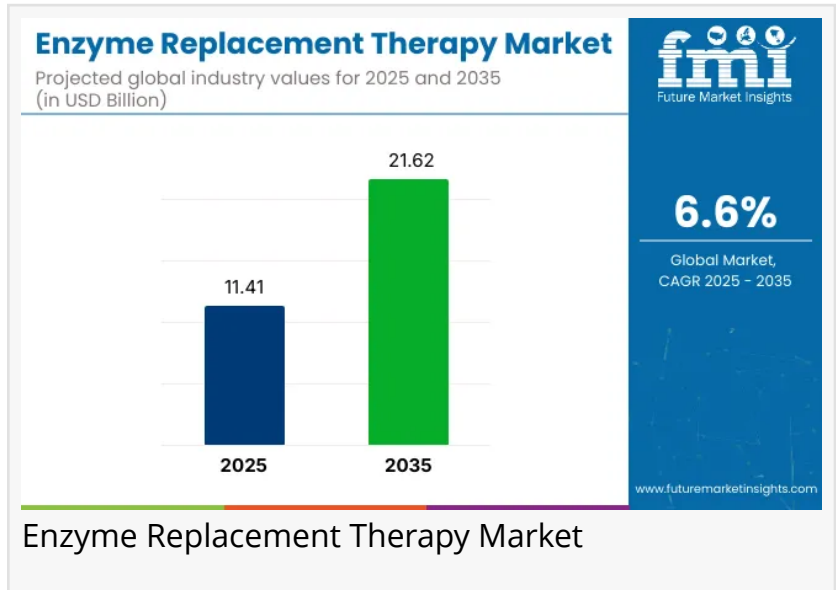


Enzyme Replacement Therapy Market to Accelerate Across USA, Europe, APAC & Saudi Arabia with 6.6% CAGR to 2035

Therapeutic innovation is reshaping rare disease care, bringing earlier diagnosis and improving global access to life-changing enzyme therapies.

UNITED KINGDOM, November 7, 2025 /EINPresswire.com/ -- The global [enzyme replacement therapy \(ERT\) market](#) is set for significant expansion, valued at USD 11.41 billion in 2025 and anticipated to reach USD 21.62 billion by 2035, reflecting a 6.6% CAGR throughout the forecast period. Growth is being driven by rising awareness of genetic and metabolic disorders, improved diagnostic capabilities, and sustained biopharmaceutical innovation.



ERT plays a central role in treating enzyme deficiency disorders, including Gaucher disease, Fabry disease, Pompe disease, and multiple forms of mucopolysaccharidosis (MPS). These therapies replace missing or malfunctioning enzymes, aiming to restore metabolic balance, alleviate symptoms, and enhance patient longevity and quality of life. Expanding newborn screening programs and access to genetic testing are enabling earlier diagnosis, which remains critical for clinical effectiveness.

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Therapeutic innovation is reshaping rare disease care, bringing earlier diagnosis and improving global access to life-changing enzyme therapies.”

Sabyasachi Ghosh

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Expanded Treatment Adoption Across Key Global Regions

Growth is notable across the USA, Europe, Asia-Pacific (APAC), and Saudi Arabia, driven by supportive healthcare frameworks and robust reimbursement models. Regulatory bodies like the U.S. FDA, EMA in Europe, Japan's PMDA, and health authorities across the Middle East continue to bolster orphan drug development through incentives such as tax credits, accelerated review programs, and market exclusivity benefits.

Emerging economies in the APAC region are increasingly investing in specialized care infrastructure, while Saudi Arabia and the broader GCC are prioritizing rare disease treatment capacity as part of national healthcare modernization programs.

Leading Therapeutic Segment: Mucopolysaccharidosis (MPS)

Among therapeutic applications, the mucopolysaccharidosis (MPS) segment is expected to hold a 42.3% share in 2025, making it the dominant area of ERT usage. Enzyme therapies for MPS target impaired glycosaminoglycan breakdown, supporting reductions in skeletal, respiratory, cardiac, and neurological symptoms. Companies including BioMarin, Sanofi, and JCR Pharmaceuticals remain central to advancing specialized MPS treatment pipelines.

Meanwhile, Gaucher disease therapies are projected to account for 27.9% of the market, supported by broad treatment familiarity and strong clinical outcomes from established ERT products.

Injectable Therapies Remain Standard, While Oral ERT Gains Research Momentum

In terms of delivery route, injectable enzyme replacement therapy will dominate with an 87.4% market share in 2025. Intravenous infusion remains the gold standard for ensuring systemic enzyme availability and effectiveness, particularly in lysosomal storage disorders. Pharmaceutical manufacturers are focusing on improving dosing intervals, reducing immunogenicity, and enhancing stability.

While oral ERT currently occupies a smaller share due to challenges in systemic absorption, research into encapsulation, enzyme engineering, and gut-targeted applications is rapidly advancing. Future innovations may enable home-based administration and reduced treatment burden.

Hospital Pharmacies to Lead Distribution

Hospital pharmacies are projected to account for 48.6% of ERT distribution in 2025, reflecting the need for clinical supervision, infusion infrastructure, and specialized monitoring. Specialty pharmacies continue to expand their role by coordinating home infusion support, strengthening supply chain security, and assisting with insurance navigation.

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Key Regional Growth Insights

- Japan is projected to grow at 8% CAGR, driven by advanced healthcare investment and an aging population at higher risk of metabolic disorders.
- China will grow at 7.3% CAGR, supported by government healthcare funding and improved diagnostic capabilities.
- Canada, Australia, New Zealand, and Brazil are also demonstrating strong investment and research-led momentum.

Competitive Landscape

The market is shaped by a concentrated group of specialized biopharmaceutical leaders, including:

Sanofi Genzyme, Takeda, BioMarin, Alexion, Amicus Therapeutics, Ultragenyx, Pfizer, AbbVie, Novartis, and CSL Behring.

Recent advancements include orphan drug approvals, gene therapy clinical trials for Hunter syndrome, newly approved Pompe therapies, and expanded treatment access via national healthcare systems.

Outlook

As precision medicine, real-world clinical data, and next-generation biologics continue to evolve, the enzyme replacement therapy market is positioned for sustained growth. The expanding diagnostic landscape and patient advocacy efforts worldwide are accelerating treatment access—offering meaningful improvements in the lives of individuals with previously untreatable rare disorders.

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