

Gene Therapy Clinical Trial Services Market Trends and Analysis by Application, Vertical, Region, and Segment to 2029

The Business Research Company's Gene Therapy Clinical Trial Services Global Market Report 2025 – Market Size, Trends, And Global Forecast 2025-2034

LONDON, GREATER LONDON, UNITED KINGDOM, September 11, 2025 /EINPresswire.com/ -- What Is The Estimated Industry Size Of Gene Therapy Clinical Trial Services Market?



The scale of the gene therapy clinical trial services market has been on a rapid rise in recent years, expanding from a market size of \$1.53 billion in 2024, to a predicted \$1.82 billion one year later in 2025. This represents a compound annual growth rate (CAGR) of 19.6%. Various factors

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have contributed to this surge in the historical period, including an uptick in research and development funding, an increased prevalence of rare genetic disorders, broader acceptance of precision medicine practices, heightened regulatory support through expedited approval pathways, and an increasing number of gene therapy candidates.

The market for gene therapy clinical trial services is forecasted to exhibit robust expansion in the upcoming years, ballooning to a size of \$3.69 billion in 2029, with a compound annual growth rate (CAGR) of 19.2%. The surge expected in the prediction period is influenced by

advancements in gene-editing technology, an increase in clinical trials, the swelling demand for custom treatments, expanded investment in cell and gene therapy manufacturing infrastructure, and intensified efforts for patient recruitment. The forecast period will be marked by trends such as progress in gene-editing technologies, enhancement in vector manufacturing capabilities, development in patient recruitment techniques, the integration of real-world evidence, and the adoption of the decentralized trial model.

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What Are The Major Factors Driving The Gene Therapy Clinical Trial Services Global Market Growth?

The surge in the necessity for individualized healthcare solutions is projected to stimulate the expansion of the gene therapy clinical trial services market in the future. Customized healthcare strategies are designed to align treatments with patient-specific factors, including genetic, biomarker, and lifestyle influences. As a result of advancements in the fields of genomics and biotech, the personalized medicine sector is booming, due to the enhanced accuracy of therapeutic targeting. Gene therapy clinical trial services cater to individualized medicine by examining the genetic patterns unique to each patient, and tailoring treatments accordingly. These services utilize biomarker analysis and companion diagnostics to fine-tune therapy protocols for every patient to maximize safety and efficacy. For example, in February 2024, it was reported by the Personalized Medicine Coalition, a healthcare organization based in the US, that in 2023, the FDA gave their approval for 16 new customized treatment options for patients suffering from rare diseases. This number was a notable increase from the six that were approved the year before in 2022. Consequently, the escalating demand for tailored healthcare solutions is fuelling the progression of the gene therapy clinical trial services market.

Who Are The Leading Companies In The Gene Therapy Clinical Trial Services Market? Major players in the Gene Therapy Clinical Trial Services Global Market Report 2025 include:

- Thermo Fisher Scientific Inc.
- Sharp Services LLC
- Labcorp
- Pharmaceutical Product Development LLC
- ICON plc
- Syneos Health Inc.
- WuXi AppTec
- Franklin Biolabs
- Catalent Inc.
- Charles River Laboratories International Inc.

What Are Some Emerging Trends In The Gene Therapy Clinical Trial Services Market? Leading enterprises in the gene therapy clinical trial services market are directing their efforts towards the creation of novel strategies such as the long-term follow-up (LTFU) model for cell and gene therapy (CGT) trials. The goal is to speed up the overall trial procedure while still upholding mandatory regulatory compliance and safety protocols. A Long-Term Follow-Up (LTFU) model for CGT trials represents a systematic approach designed to supervise patients for an extended duration, mostly up to 15 years post the CGT treatment. To exemplify, Medable Inc., an American SaaS firm, introduced a digital-first Long-Term Follow-Up (LTFU) model in May 2025, conceived explicitly for CGT trials. This model facilitates CGT trials by lessening patient and site pressure whilst guaranteeing scientific exactness over the FDA-mandated 15-year observation

period. It enhances patient accessibility, participation, and continuity of data via remote and hybrid follow-up techniques, thereby, boosting long-term safety and effectiveness tracking.

What Are The Primary Segments Covered In The <u>Global Gene Therapy Clinical Trial Services</u> Market Report?

The gene therapy clinical trial services market covered in this report is segmented

- 1) By Type: Clinical Trial Design And Planning, Supply And Logistics Services, Regulatory Services, Data Management And Biostatistics, Site Management And Monitoring, Other Types
- 2) By Application: Oncology, Hematology, Endocrine or Metabolic Disorders, Musculoskeletal Diseases, Cardiovascular Diseases, Neurology Disorders, Infectious Diseases, Ophthalmology, Immunology, Other Applications
- 3) By End-User: Pharmaceutical Companies, Biotechnology Companies, Academic Institutions, Government Research Institutes, Contract Research Organizations (CROs)

Subsegments:

- 1) By Clinical Trial Design And Planning: Protocol Development, Feasibility Studies, Patient Recruitment Strategy Design
- 2) By Supply And Logistics Services: Cold Chain Management, Investigational Product Packaging And Labeling, Controlled-Temperature Storage
- 3) By Regulatory Services: Regulatory Consulting And Strategy, Ethics Committee Submissions, Regulatory Compliance Monitoring
- 4) By Data Management And Biostatistics: Clinical Data Capture And Database Design, Data Validation And Quality Control, Statistical Analysis And Modeling
- 5) By Site Management And Monitoring: Site Selection And Qualification, Investigator Training And Support, On-Site Monitoring Visits
- 6) By Other Types: Pharmacovigilance And Safety Reporting, Quality Assurance And Auditing, Patient Engagement And Retention

View the full gene therapy clinical trial services market report:

https://www.thebusinessresearchcompany.com/report/gene-therapy-clinical-trial-services-global-market-report

Which Region Is Forecasted To Grow The Fastest In The Gene Therapy Clinical Trial Services Industry?

In the 2025 Global Market Report for Gene Therapy Clinical Trial Services, North America held the position of the leading region in 2024. The anticipated fastest-growing region is projected to be Asia-Pacific. This comprehensive report encompasses all significant regions including Asia-Pacific, Western Europe, Eastern Europe, North America, South America, Middle East, and Africa.

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