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Global Orphan Drug Clinical Trials, Patent & Guidelines Insight 2026

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Abstracts

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'Global Orphan Drug Clinical Trials, Patent & Guidelines Insight 2026' Report Highlights:

- Global Orphan Drug Market Opportunity: US$ 300 Billion
- US Dominates Global Orphan Drug Market: 50% Market Share
- US Orphan Drug Opportunity To Surpass: US$ 150 Billion
- Global Orphan Drug Clinical Insight: More Than 900 Drugs
- Clinical Insight on Marketed Orphan Drugs: More Than 400 Drugs
- Oncology To Dominate Orphan Drug Development: 35% Share
- FDA & EMA Regulations For Orphan Drugs
- Orphan Drug Designation Criteria & Reimbursement Policy by Country

The research report “Global Orphan Drug Clinical Trials, Patent & Guidelines Insight 2026” discusses about the recent trends and opportunities that the orphan drug market has brought into the pharmaceutical sector. The information related to the current status of the evolving market strategies and ongoing clinical studies by the companies involved in development of the orphan drugs is elaborately discussed in the report. The research

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report shares the information related to drugs that have been successfully designated as orphan drugs by respective approval authorities, with an exclusive insight on clinical uniqueness and patent information. In addition to the commercial information, the report brings a deep insight about the efforts that have been put to establish the market as it is now.

' Global Orphan Drug Market Is Estimated To Witness 150% Market Growth By 2026 As Compare To 2018'

Orphan drugs market has been recently recognized as a promising therapeutic market as the diseases that are covered under the market are life-threatening diseases. The FDA & EMA have designated a drug as orphan drug for which the cases in the US are less than 0.2 Million and not more than 5 in 10,000 people across the EU. Earlier the orphan drug segment was overlooked by the big pharmaceutical companies as developing and marketing of these drugs was considered not so profitable. Majority of the research and development activities related to orphan drugs were done by small size pharmaceutical firms and less than 25% of the orphan drugs were being researched and developed by the big firms.

The enactment of 1983 US Orphan Drug Act, as well as similar Acts in 1991 in Singapore, 1993 in Japan, 1997 in Australia and in 2000 by the European Union led to rapid transformation of global orphan drug market landscape which was earlier neglected by the multiple stake holders of the pharmaceutical industry. The structured regulatory and policy framework favoring the research and development of orphan designated drugs resulted in the much needed thrust for the development of global orphan drug market. These laws allowed the various financial incentives, market exclusivity, patent protection, high price allotment and government grants, which resulted in favorable economic environment for the entry of big pharmaceutical companies in the orphan drug segment.

The entry of mid and large size pharmaceutical companies helped in the speeding up the clinical research activities related to orphan drugs. The number of clinical trials increased drastically in last 10 years to more than 500 for orphan drugs as compared to few hundred trials in beginning of 21st century. Currently, more than 400 orphan designated drugs are commercially available in the marketed and close to 1000 drugs are undergoing clinical trials. The number of clinical trials covering the rare diseases has been observed to increase in the recent years with a major participation of the players such as Roche, Celgene, AbbVie, Johnson & Johnson, Shire, Alexion, Novo Nordisk, Sanofi and Bayer. The various major key players and the rising demand of the orphan drugs clearly depicts about the escalation that the market will experience in the future.

The availability of large number of orphan drugs by limited firms provides an excellent fundamental benefit to the emerged market in the present as well as in future. The dynamic interest scenario that has been delivered by the users since its arrival has completely changed the landscape of the market. The drastic change from few users in the past to millions of users till now has been successful in proving the importance of orphan drugs in the market. It is well witnessed from analyzing the market value of orphan drugs that clinicians as well as rare disease patients are now more inclined towards its use, thereby, promoting a form of treatment that is more mainstream.

As per report findings, the orphan drug market is open to serve the globe with an approach that is about to bring a fresh new era for the life threatening diseases. The ongoing clinical research at preclinical and clinical levels and the major trends followed by the regions such as North America and Europe are about to introduce a drastic change in overall scenario of the approach. The market is driven by the anticipation of the players and the huge commercial success that the market has foreseen in few years. The enhancement and the shape that the market has developed since years is about to get evolved as a serious option for rare diseases.

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