

US Orphan Drugs Market, Drugs Sales, Price, Dosage & Clinical Trials Insight 2028

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Abstracts

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US Orphan Drugs Market, Drugs Sales, Price, Dosage & Clinical Trials Insight 2028
Report Highlights:

US Orphan Drugs Market Opportunity: > USD 150 Billion By 2028

Orphan Drugs Dosage, Price & Treatment Cost: > 350 Orphan Drug

Annual & Quarterly Sales Insight (2019 – Q1'2023):> 100 Orphan Drugs

US Orphan Drugs Reimbursement Scenario: Medicare, Medicaid, Private Insurers

Active Clinical Trials Insight By Company, Indication & Phase: 1000 Orphan Drugs

Marketed Orphan Drugs Clinical Insight By Company & Indication: > 400 Orphan Drugs

Competitive Landscape: 75 Companies

Considering the increasing burden of patients suffering from rare and orphan diseases, the US FDA has taken several steps to increase the interest of the research and pharmaceutical companies to these forgotten diseases. One of the fundamental actions

taken by the FDA is the assignment of the orphan drug designation, which gives developers benefits in the course of the research and development, clinical assessment and marketing of the drug. The orphan drug designation has been granted to over 6500 drugs and compounds, and around 100 of these have received regulatory approvals. Therefore, though the number is less, these drugs have been essential for improving the treatment outcomes of patients suffering from rare orphan diseases. Taking into account the continued success of several drugs in the US pharmaceutical market, it is evident these therapeutic products are faring well in spite of the small patient base, which makes it an interesting domain to explore.

Earlier rare diseases were neglected due to low profitability feasibility, but enactment of FDA's Orphan Drug Act 1983, succeeding regulatory reforms, government funding support and extensive research by pharmaceutical companies led to exponential growth in the US orphan drugs market. These favorable parameters resulted in more than 1000 orphan designated drugs in clinical trials and more than 400 orphan designated drugs being commercially available in the market. This number is further expected to surpass 500 orphan designated drugs in market by 2028 driven by increasing focus of pharmaceutical companies on rare diseases. The US orphan drugs market was valued around US\$ 100 Billion in 2022, and is further expected to surpass US\$ 180 Billion by 2028, making it one of the highest revenue-generating segments of the global orphan-designated drugs market.

Many drugs that were given the orphan designation for rare indications have already gained US FDA approval for a different, non-orphan indication. Observation studies, anecdotal evidence, or unexpected clinical results from clinical trials involving patients with unrelated indications are what lead researchers to the conclusion that the same drug may also be utilized for a rare indication. As a result, it frequently happens that pharmaceutical companies are unaware of the potential of their products as therapeutic treatments for rare diseases. On the plus side, completing clinical trials for uncommon diseases, and subsequently being given the orphan drug designation, can aid in growing the patient base for the company and the drug, which will later boost revenues.

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