

# **Primary Immunodeficiency Disorders Market - Global Industry Size, Share, Trends, Opportunity, and Forecast, Segmented By Disease (Antibody Deficiency, Cellular Immunodeficiency, Innate Immune Disorders, Others), By Treatment (Immunoglobulin Replacement Therapy, Antibiotic Therapy, Stem Cell/Bone Marrow Transplantation, Gene Therapy, Others), By Region and Competition, 2019-2029F**

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## **Abstracts**

Global Primary Immunodeficiency Disorders Market was valued at USD 7.03 Billion in 2023 and is expected to reach USD 9.88 Billion by 2029 with a CAGR of 6.01% during the forecast period.

The Global Primary Immunodeficiency Disorders (PIDD) Market is witnessing significant growth, driven by rising awareness, advancements in diagnostic technologies, and increased access to treatments. Primary immunodeficiency disorders are a group of genetic conditions that impair the immune system, making individuals susceptible to frequent infections. With over 400 types of PIDD identified, the market has been expanding due to the growing understanding of these conditions and their management. Key factors influencing the market include advancements in gene therapy, monoclonal antibody treatments, and immunoglobulin replacement therapies.

Government initiatives and support from non-profit organizations to promote early diagnosis and treatment are positively impacting the market. The development of newborn screening programs for PIDD is further enhancing early detection and timely intervention, boosting patient outcomes. Despite these advances, challenges such as

high treatment costs and limited awareness in low-income regions remain hurdles to market expansion. Nonetheless, ongoing research, coupled with new therapeutic developments, is anticipated to drive continuous growth in the Global Primary Immunodeficiency Disorders Market.

## Key Market Drivers

### Increasing Awareness and Diagnosis of Primary Immunodeficiency Disorders

One of the significant drivers for the Global Primary Immunodeficiency Disorders (PIDD) Market is the rising awareness and improved diagnosis of these conditions. Historically, PIDD has been underdiagnosed due to the complex and varied nature of the disorders, but recent advancements in medical research and education have brought more attention to these conditions. This has led to an increase in the identification and classification of various PIDD types, significantly contributing to market growth.

Medical communities, healthcare professionals, and patient advocacy groups have been instrumental in promoting awareness about PIDD. Organizations like the Immune Deficiency Foundation (IDF) and the Jeffrey Modell Foundation (JMF) play a vital role in educating the public and healthcare providers about the symptoms and treatment options available for PIDD. The rise in Primary Immunodeficiency (PI) disorders, affecting up to 1% of the population, poses significant challenges due to delayed diagnosis and treatment. The Jeffrey Modell Foundation established the Jeffrey Modell Centers Network (JMCN) to enhance awareness and improve patient outcomes. A recent analysis of physician-reported data revealed a 96.3% increase in patients followed in the U.S. from 2013 to 2021, with notable improvements in treatment accessibility. The JMCN continues to facilitate education, standardize care, and drive research advancements in immunology. These efforts have enabled earlier and more accurate diagnosis, which, in turn, has led to better management of the condition. With increased knowledge about the genetic factors and immunological profiles of PIDD, patients are more likely to seek medical attention sooner, driving the demand for diagnostic services and treatments.

Technological advancements in diagnostics, particularly genetic testing, have enabled clinicians to pinpoint the exact nature of immunodeficiency disorders with greater precision. Tests like next-generation sequencing (NGS) and whole exome sequencing have revolutionized the identification process, leading to faster and more comprehensive diagnoses. This has resulted in a surge of patients being diagnosed with PIDD, which is fueling the demand for therapies, further supporting market

expansion. In addition to patient advocacy, government initiatives in healthcare systems worldwide are also contributing to better diagnosis and treatment options. Several countries have implemented newborn screening programs that test for PIDD, ensuring early identification and immediate intervention. These programs significantly improve survival rates and quality of life for affected individuals, further propelling market demand for immunoglobulin therapies, gene therapy, and other innovative treatment options. As awareness continues to spread and diagnostic techniques evolve, healthcare providers are becoming better equipped to recognize the diverse manifestations of PIDD. This trend is expected to drive the growth of the PIDD market substantially, as earlier diagnoses lead to prompt therapeutic interventions. In developing regions, where healthcare access and diagnostic capabilities are improving, the diagnosis rate for PIDD is also expected to rise, expanding the market's reach.

### Advancements in Immunoglobulin Therapies

Immunoglobulin (IG) therapies, especially intravenous immunoglobulin (IVIG) and subcutaneous immunoglobulin (SCIG), have emerged as essential treatments for PIDD. The advancement of IG therapies is a major driver for the Global PIDD Market, as these treatments play a critical role in improving the quality of life for patients with weakened immune systems. IG therapies supplement the body's deficient antibodies, enabling patients to fight infections more effectively, which in turn drives demand. In recent years, significant progress has been made in the development and administration of IG therapies. The introduction of subcutaneous immunoglobulin (SCIG) as an alternative to intravenous treatments has been a game-changer. SCIG offers patients the convenience of at-home administration and reduces the need for frequent hospital visits, improving compliance and overall patient experience. This shift towards more patient-friendly treatment modalities has expanded the use of IG therapies globally, contributing to market growth.

Pharmaceutical companies are also investing in the development of more efficient and longer-acting IG formulations. These advancements have not only improved the efficacy of treatments but have also reduced the frequency of administration, leading to better patient adherence. Companies are exploring new delivery mechanisms, such as self-injectable devices and advanced formulations, to further enhance the convenience and accessibility of IG therapy. These innovations are expected to drive the market for PIDD treatments by providing patients with more effective and manageable therapeutic options. For instance, On July 20, 2023, Grifols, a leading global producer of plasma-derived medicines, announced that its recently completed Phase 4 trial (NCT04566692) evaluating biweekly dosing of XEMBIFY successfully met its primary endpoint. The trial

demonstrated that patients with primary immunodeficiencies (PIDs) treated with this subcutaneous 20% immunoglobulin (SCIg) product every two weeks achieved non-inferior total immunoglobulin (Ig) levels compared to those receiving weekly doses. Additionally, the Phase 4 trial revealed comparable safety and tolerability profiles for both biweekly and weekly administration. This multicenter, single-sequence, open-label clinical study involved 27 subjects across 18 sites in the United States.

Regulatory approvals and government support for IG therapies have bolstered the market's growth. Many countries have recognized the importance of ensuring a steady supply of IG products, given their critical role in managing PID. Governments and healthcare organizations have implemented measures to facilitate access to these therapies, including insurance coverage and subsidies. This regulatory backing encourages market expansion and ensures that more patients receive the necessary treatments.

### Emergence of Gene Therapy for PID

The emergence of gene therapy as a groundbreaking treatment for Primary Immunodeficiency Disorders (PID) represents one of the most transformative drivers for the market. Gene therapy holds the promise of correcting the genetic defects that underlie these disorders, potentially offering long-term or even permanent cures. This advancement has significantly shifted the focus of PID treatments from symptom management to addressing the root cause of the disease, creating a paradigm shift in the way these disorders are treated. The basic premise of gene therapy for PID involves introducing functional copies of faulty genes into a patient's cells, thereby restoring normal immune system functionality. Early successes in gene therapy have been especially evident in the treatment of Severe Combined Immunodeficiency (SCID), commonly known as 'bubble boy' syndrome, and Chronic Granulomatous Disease (CGD). These forms of PID, previously considered life-threatening and difficult to treat, have shown promising responses to gene therapy, paving the way for more research and broader applications.

SCID, which severely compromises the immune system from birth, has historically required treatments like bone marrow transplants or lifelong immunoglobulin therapy. However, gene therapy trials have demonstrated that replacing the defective gene responsible for SCID can effectively restore immune function in patients, significantly improving their quality of life. Similar breakthroughs have been observed in the treatment of CGD, where gene therapy has successfully reduced the severity and frequency of infections by correcting the defective genes that impair the immune

response.

The potential for gene therapy to address a broader range of PID types is driving further research and investment. Biopharmaceutical companies are actively pursuing clinical trials to explore the efficacy of gene therapy across various forms of PID, including X-linked agammaglobulinemia (XLA) and Wiskott-Aldrich syndrome. These developments have sparked significant interest from investors and healthcare providers, as gene therapy could revolutionize the treatment landscape for PID, offering hope for a permanent solution to these lifelong conditions. Regulatory agencies such as the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) have shown strong support for gene therapy development, granting fast-track designations and orphan drug status to promising candidates. This regulatory support accelerates the approval process and encourages companies to continue investing in the research and development of gene therapy for PID. The increased pace of innovation in this area is expected to drive substantial growth in the PID market in the coming years.

## Key Market Challenges

### High Cost of Treatment and Lack of Access to Advanced Therapies

One of the key challenges faced by the Global Primary Immunodeficiency Disorders (PID) market is the high cost associated with the treatment of these disorders, especially in regions with limited healthcare infrastructure. The advanced therapies, including immunoglobulin replacement therapy and gene therapy, can be prohibitively expensive, making them inaccessible to a significant portion of the global population. Many healthcare systems in developing regions are underfunded, lacking the financial resources to offer patients cutting-edge treatments that are common in more developed countries. As a result, individuals suffering from primary immunodeficiency disorders in these areas may not receive proper diagnosis or treatment, leading to increased morbidity and mortality rates. Insurance coverage is often limited for these costly treatments, placing a financial burden on patients and their families. Despite the potential for government programs to offset some of these costs, bureaucratic inefficiencies, as well as disparities in healthcare access between urban and rural areas, further exacerbate the issue. As innovative treatments emerge, like gene therapies that offer curative solutions, the financial barrier remains a critical challenge for the market, slowing down adoption and equitable treatment access on a global scale.

### Delayed Diagnosis and Misdiagnosis of Primary Immunodeficiency Disorders

A significant challenge in the Global Primary Immunodeficiency Disorders Market is the delayed diagnosis and frequent misdiagnosis of these disorders, which can lead to serious health complications and diminished quality of life for patients. Since many primary immunodeficiency disorders present with symptoms that are similar to common infections or autoimmune diseases, healthcare providers often overlook the underlying cause. In regions with limited medical resources, the availability of diagnostic tools, such as genetic testing and specialized immunological assessments, is scarce. This creates delays in proper diagnosis, which is critical for timely intervention and management. Even in well-developed healthcare systems, physicians may not be adequately trained to recognize or suspect primary immunodeficiency disorders, resulting in misdiagnosis or underdiagnosis. Inadequate awareness campaigns targeting both medical professionals and the general public contribute to this issue, causing patients to remain untreated or improperly treated for extended periods. As a result, these patients often experience recurrent infections and complications, further increasing healthcare costs and negatively affecting their long-term prognosis. Addressing this challenge will require greater awareness, education, and access to appropriate diagnostic technologies globally.

## Key Market Trends

### Expansion of Newborn Screening Programs

The expansion of newborn screening programs for Primary Immunodeficiency Disorders (PIDD) is a major driver for market growth, as early diagnosis leads to timely intervention and better management of these conditions. Newborn screening programs have been pivotal in identifying infants born with PIDD, allowing for early treatment and improving long-term outcomes. These programs are rapidly expanding across the globe, driven by increased awareness, government support, and advancements in screening technologies. In countries like the United States, newborn screening for Severe Combined Immunodeficiency (SCID) has become a standard practice. SCID, one of the most severe forms of PIDD, if left untreated, can result in life-threatening infections in early infancy. However, early detection through newborn screening allows for immediate interventions, such as bone marrow transplants or gene therapy, which can significantly improve survival rates. The inclusion of SCID in routine newborn screening programs across several states in the U.S. has led to a marked increase in early diagnoses, providing critical market growth for diagnostic tools, treatments, and follow-up care services.

Other regions, including Europe and Asia-Pacific, are following suit by expanding their newborn screening panels to include PIDD. For example, several European countries have initiated pilot programs to include PIDD in national newborn screening protocols. This trend is expected to drive significant growth in the PIDD market, as early identification of the disorder increases the demand for treatments and therapeutic interventions.

Technological advancements are also playing a key role in the expansion of newborn screening programs. Improved genetic testing technologies, such as next-generation sequencing (NGS), enable more accurate and efficient screening for a wider array of genetic disorders, including PIDD. These technologies allow healthcare providers to quickly and accurately diagnose PIDD in newborns, ensuring that affected infants receive appropriate treatment as early as possible. The increasing affordability of genetic testing is also making newborn screening programs more accessible in developing countries, further driving the market's growth. In addition to government-driven initiatives, non-profit organizations and advocacy groups have been actively promoting the expansion of newborn screening programs for PIDD. Organizations like the Jeffrey Modell Foundation and the Immune Deficiency Foundation (IDF) have played an essential role in raising awareness about the importance of early detection, funding research, and working with healthcare systems to implement screening protocols. These efforts are helping to push for wider adoption of newborn screening programs, which directly supports the growth of the PIDD market.

### Technological Advancements in Diagnostics

Technological advancements in diagnostics are reshaping the Global Primary Immunodeficiency Disorders (PIDD) Market by making it easier and faster to identify these conditions with greater accuracy. Given the complexity of PIDD, which includes over 400 types, diagnosis has traditionally been a time-consuming and challenging process. However, innovations in genetic testing and molecular biology are revolutionizing this landscape, enabling early detection and timely treatment, which are crucial for better patient outcomes.

Historically, diagnosing PIDD required healthcare providers to observe symptoms, conduct immunological tests, and analyze family histories. While these methods have been somewhat effective, they were often slow and imprecise. They relied on symptom patterns and clinical suspicion rather than direct identification of the genetic cause. The arrival of next-generation sequencing (NGS) technologies has drastically improved this process. NGS allows for a broad and detailed genetic analysis, identifying specific

mutations responsible for immunodeficiency disorders with much greater speed and accuracy. This approach facilitates a level of precision previously unattainable through traditional methods.

Whole exome sequencing (WES) and whole genome sequencing (WGS) have had a profound impact on diagnosing PIDD. These techniques examine either significant portions or the entirety of an individual's genome, enabling the identification of rare and complex mutations that cause immunodeficiencies. Patients who may have gone undiagnosed for years can now receive earlier and more accurate diagnoses, leading to quicker treatment interventions. In addition to improving diagnostic precision, these advancements reduce healthcare costs by avoiding unnecessary tests and prolonged hospitalizations due to undiagnosed or misdiagnosed cases. The expanding availability and affordability of genetic testing technologies are making these tools more accessible worldwide, further driving demand in the PIDD diagnostics market. This technological shift is ultimately contributing to better management and treatment of PIDD, positively impacting the market's growth.

## Segmental Insights

### Disease Insights

Based on the Disease, antibody deficiency segments disorders are currently dominating the Global PIDD Market. This category encompasses a range of conditions, primarily characterized by an impaired ability to produce immunoglobulins, which are essential for effective immune responses against infections. The prevalence and impact of antibody deficiency disorders, such as Common Variable Immunodeficiency (CVID), X-Linked Agammaglobulinemia (XLA), and Hyper-IgM Syndrome, have positioned them as significant contributors to the growth of the PIDD market. One of the primary factors contributing to the dominance of antibody deficiency disorders is their higher prevalence compared to other types of PIDD. Studies suggest that antibody deficiency disorders account for a substantial proportion of all PIDD cases, with CVID being one of the most common forms. This increased prevalence results in a higher patient population requiring diagnosis and treatment, thereby driving demand for therapeutic interventions, particularly immunoglobulin replacement therapy.

The strong clinical need for effective management of antibody deficiency disorders further solidifies their market dominance. Patients with these conditions are at a heightened risk of recurrent infections, autoimmune diseases, and malignancies due to their compromised immune systems. As a result, timely diagnosis and appropriate



therapeutic strategies are critical for improving patient outcomes.

## Regional Insights

North America is currently dominating the Global Primary Immunodeficiency Disorders (PID) Market, primarily driven by several key factors. The region boasts advanced healthcare infrastructure, high levels of research and development investment, and a growing awareness of PID among healthcare professionals and the general public. The United States, in particular, plays a crucial role in this dominance, given its extensive network of specialized healthcare providers and research institutions focused on immunological disorders. One significant contributor to North America's market leadership is the high prevalence of primary immunodeficiency diseases. As awareness increases and genetic testing becomes more accessible, more individuals are being diagnosed with PID, leading to a greater demand for effective treatment options. The presence of a large patient population coupled with a well-established healthcare system ensures that patients receive timely diagnosis and appropriate therapies.

North America is home to several key pharmaceutical and biotechnology companies that are at the forefront of developing innovative therapies for PID. These companies are investing heavily in research and development, contributing to a robust pipeline of new treatments, including immunoglobulin therapies, gene therapy, and other advanced therapeutic modalities. Regulatory agencies, such as the FDA, provide a supportive environment for the approval and commercialization of novel treatments, further propelling market growth.

## Key Market Players

Baxter International Inc.

CSL Behring LLC

Takeda Pharmaceutical Company Limited

Octapharma AG

Grifols, S.A

Kedrion S.p.A

Bio Products Laboratory Ltd.

LFB SA

ADMA Biologics, Inc.

Astellas Pharma Inc.

### Report Scope:

In this report, the Global Primary Immunodeficiency Disorders Market has been segmented into the following categories, in addition to the industry trends which have also been detailed below:

#### Primary Immunodeficiency Disorders Market, By Disease:

Antibody Deficiency

Cellular Immunodeficiency

Innate Immune Disorders

Others

#### Primary Immunodeficiency Disorders Market, By Treatment:

Immunoglobulin Replacement Therapy

Antibiotic Therapy

Stem Cell/Bone Marrow Transplantation

Gene Therapy

Others

#### Primary Immunodeficiency Disorders Market, By Region:

North America

United States

Canada

Mexico

Europe

France

United Kingdom

Italy

Germany

Spain

Asia-Pacific

China

India

Japan

Australia

South Korea

South America

Brazil

Argentina

Colombia

Middle East & Africa

South Africa

Saudi Arabia

UAE

Competitive Landscape

Company Profiles: Detailed analysis of the major companies present in the Global Primary Immunodeficiency Disorders Market.

Available Customizations:

Global Primary Immunodeficiency Disorders Market report with the given market data, TechSci Research offers customizations according to a company's specific needs. The following customization options are available for the report:

Company Information

Detailed analysis and profiling of additional market players (up to five).

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