

# **Regulatory T-cells (Tregs) therapies Market – Global Industry Size, Share, Trends, Opportunity, & Forecast 2023-2035 Segmented By Type (Autologous, Allogenic), By Applications (Autoimmune Diseases, Organ Transplantation, Graft-versus-Host Disease (GVHD), Others), By End-User (Hospitals & Clinics, Academic & Research Institutions, Others), By Region, Competition**

<https://marketpublishers.com/r/R1A6FF497A73EN.html>

Date: October 2023

Pages: 181

Price: US\$ 4,900.00 (Single User License)

ID: R1A6FF497A73EN

## **Abstracts**

Global Regulatory T-cells (Tregs) therapies Market is anticipated to project robust growth in the forecast period. The Global Regulatory T-cells (Tregs) therapies market encompasses a rapidly evolving landscape in the field of immunotherapy and cell-based treatments. It is characterized by innovative therapies designed to harness the potential of Tregs, a specialized subset of immune cells, for therapeutic purposes.

Regulatory T-cells (Tregs) are a subset of T-cells in the immune system responsible for maintaining immune tolerance and suppressing excessive immune responses. Treg therapies involve the isolation, expansion, and modification of Tregs for therapeutic purposes, targeting various diseases, including autoimmune conditions, cancer, and transplant-related complications.

### **Key Market Drivers**

#### **Increasing Prevalence of Autoimmune Diseases**

The increasing prevalence of autoimmune diseases is a significant market driver for the

growth of the global Regulatory T-cells (Tregs) therapies market. Autoimmune diseases are a class of disorders in which the immune system mistakenly attacks and damages healthy tissues and organs in the body. This phenomenon has been on the rise globally, and it has a profound impact on the healthcare industry, particularly the development and adoption of Tregs-based therapies. Autoimmune diseases have shown a steady increase in their prevalence over the past few decades. This upward trend can be attributed to various factors, including genetic predisposition, environmental triggers, and lifestyle changes. As more people are diagnosed with autoimmune diseases, there is a growing patient population in need of effective treatments.

Autoimmune diseases encompass a broad spectrum of conditions, ranging from rheumatoid arthritis, multiple sclerosis, and systemic lupus erythematosus to type 1 diabetes and inflammatory bowel disease. This diversity in autoimmune diseases means that Tregs-based therapies have the potential to address a wide array of medical conditions, creating a substantial market opportunity. Many autoimmune diseases currently lack curative treatments, and existing therapies often focus on managing symptoms and suppressing the immune system, which can have significant side effects. Tregs therapies offer a novel approach by modulating the immune response rather than simply suppressing it. This addresses the unmet medical needs of patients, making Tregs therapies an attractive option.

The increasing prevalence of autoimmune diseases places a significant burden on healthcare systems worldwide. These diseases often require long-term management, which can be costly and resource-intensive. Tregs-based therapies have the potential to reduce the need for frequent hospitalizations, long-term medication use, and the associated healthcare costs, making them economically appealing. As information about autoimmune diseases becomes more accessible through the internet and patient advocacy groups, individuals are becoming more aware of these conditions. This heightened awareness leads to increased patient demand for advanced and innovative treatment options, including Tregs-based therapies.

### Advancements in Immunotherapy

Advancements in immunotherapy play a pivotal role as a market driver for the growth of the global Regulatory T-cells (Tregs) therapies market. Immunotherapy has emerged as a transformative approach in the field of medicine, offering new avenues for the treatment of various diseases, including autoimmune disorders and cancer. Immune checkpoint inhibitors (ICIs) have revolutionized the field of cancer immunotherapy.

Drugs like pembrolizumab and nivolumab have shown remarkable success in treating various types of cancer by enhancing the immune system's ability to target and destroy cancer cells. These advancements have demonstrated the potential of manipulating the immune system to achieve therapeutic goals, paving the way for Tregs therapies.

Tregs play a critical role in maintaining immune homeostasis by suppressing excessive immune responses. Combining Tregs-based therapies with existing immunotherapies, such as ICIs, can lead to synergistic effects. By modulating the immune response and enhancing the efficacy of immunotherapies, Tregs therapies can be integrated into comprehensive treatment strategies.

Chimeric antigen receptor T-cell (CAR-T) therapies have been groundbreaking in the treatment of certain cancers. These therapies involve genetically modifying a patient's T-cells to recognize and attack cancer cells. However, CAR-T cell therapies can sometimes lead to severe immune-related side effects. Tregs therapies hold promise in managing these side effects by regulating the immune response and improving the safety profile of CAR-T therapies. Advancements in gene editing technologies, such as CRISPR-Cas9, have enabled precise modifications of Tregs. This allows for the engineering of Tregs with enhanced suppressive capabilities or specific targeting of autoimmune disease-related antigens. Gene-edited Tregs can be tailored to address individual patient needs, increasing the therapeutic potential of Tregs-based treatments.

### Growing Transplantation Procedures

The growth of transplantation procedures serves as a significant market driver for the global Regulatory T-cells (Tregs) therapies market. Transplantation involves the transfer of organs or tissues from one individual (the donor) to another (the recipient), often to save a recipient's life or improve their quality of life. Regulatory T-cells, or Tregs, play a crucial role in the body's immune response, particularly in maintaining immune tolerance and preventing immune reactions against transplanted organs or tissues. The demand for organ transplants has been steadily increasing worldwide due to factors such as aging populations, greater awareness about transplantation, and improvements in surgical techniques. However, the shortage of available donor organs remains a challenge. Tregs therapies offer the potential to improve the success rates of transplantation and expand the pool of potential donors by reducing the risk of graft rejection.

One of the primary challenges in transplantation is graft rejection, where the recipient's immune system recognizes the transplanted organ or tissue as foreign and mounts an

immune response to attack it. Tregs have the unique ability to suppress these immune responses, promoting immune tolerance. Incorporating Tregs therapies into transplantation procedures can help reduce the risk of graft rejection and improve the long-term survival of transplanted organs. After transplantation, patients typically receive immunosuppressive drugs to prevent graft rejection. These medications, while effective, have significant side effects and long-term health risks. Tregs therapies offer an alternative or complementary approach to immunosuppression, potentially allowing for the reduction of immunosuppressive drug dosages and their associated adverse effects.

Tregs can be isolated and expanded from a patient's own cells, making them a candidate for personalized medicine in transplantation. These patient-specific Tregs can be tailored to address the unique immunological challenges of each transplant recipient, improving the compatibility and outcomes of transplantation procedures. Chronic rejection, which can occur months or years after transplantation, remains a significant concern in the field. Tregs-based therapies hold promise in mitigating chronic rejection by promoting long-term immune tolerance. This potential application further expands the market for Tregs therapies in the context of transplantation.

### Regulatory Support and Clinical Trials

Regulatory support and clinical trials are crucial market drivers for the growth of the global Regulatory T-cells (Tregs) therapies market. Regulatory support from government agencies and the conduct of clinical trials are essential in demonstrating the safety and efficacy of Tregs-based therapies, facilitating their development and eventual market adoption. Regulatory agencies, such as the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA), recognize the potential of Tregs therapies to address unmet medical needs. They offer expedited pathways, like Fast Track, Breakthrough Therapy, and Orphan Drug designations, to streamline the development and approval processes for innovative therapies. These designations accelerate the market entry of Tregs-based treatments.

Regulatory authorities provide clear guidance and frameworks for the development and testing of Tregs therapies. This guidance ensures that companies and researchers follow established standards and protocols, promoting consistency and transparency in the development process. It also reduces regulatory uncertainty, encouraging investment in Tregs therapy development. To foster research and development in the field of Tregs therapies, regulatory agencies may offer incentives and grants. These financial incentives can significantly lower the financial burden of conducting clinical

trials and securing regulatory approvals, making it more attractive for companies and research institutions to invest in Tregs therapies. Regulatory agencies often collaborate with academic institutions, industry stakeholders, and patient advocacy groups to advance the development of innovative therapies. Such collaborations can expedite the availability of Tregs-based treatments by providing expertise, resources, and a supportive environment for research and development.

### Clinical Trials:

Clinical trials are critical for establishing the safety and efficacy of Tregs-based therapies. These trials provide robust data on the therapeutic potential of Tregs, helping to build confidence among healthcare providers, patients, and investors. Positive trial outcomes can accelerate market adoption.

Clinical trials explore a wide range of applications for Tregs therapies, including autoimmune diseases, transplantation, and cancer. By addressing multiple medical conditions, Tregs-based therapies can cater to a broad patient population, thereby increasing their market potential.

Clinical trials involve patient enrollment and data collection, helping researchers gather valuable insights into the effectiveness of Tregs therapies. This data can be used to refine treatment protocols, optimize dosages, and identify potential side effects, enhancing the overall therapeutic profile of Tregs-based treatments.

Positive clinical trial results are often seen as milestones that attract investors and partners. The demonstration of efficacy and safety in clinical trials can lead to increased investment in Tregs therapy development, which is essential for scaling up production and commercialization.

As Tregs therapies progress through clinical trials and receive regulatory approvals, they expand the treatment options available to patients and healthcare providers. This, in turn, drives market growth by meeting the unmet medical needs of various patient populations.

### Key Market Challenges

#### Complex Regulatory Landscape

Developing and gaining regulatory approval for new therapies, including Tregs-based

treatments, involves navigating a complex and rigorous process. Regulatory agencies such as the FDA and EMA have high standards for safety and efficacy, which can lead to lengthy and expensive clinical trial processes.

The regulatory pathway for Tregs therapies may not always be well-defined, leading to uncertainty and potential delays. Determining the appropriate endpoints, patient populations, and trial designs can be challenging, causing delays in development and market entry. Ensuring consistent and compliant manufacturing processes for Tregs-based therapies is crucial. Meeting good manufacturing practice (GMP) standards is essential, and any manufacturing deviations can lead to regulatory setbacks and production issues.

### Limited Clinical Data and Evidence

Building a robust body of clinical evidence for Tregs therapies can be time-consuming and costly. The limited availability of long-term clinical data on the safety and efficacy of these therapies can hinder their adoption by healthcare providers and payers.

Tregs therapies may not have consistent responses across all patients due to individual variations in immune systems and disease characteristics. Understanding and addressing this heterogeneity is a challenge and may require personalized treatment approaches. Conducting clinical trials and collecting sufficient data for regulatory approval can take several years. This prolonged development timeline can slow down the introduction of Tregs therapies to the market, especially for patients with urgent medical needs.

### Market Access and Reimbursement

Tregs therapies, like many advanced therapies, can be expensive to develop and manufacture. The high cost of production and limited patient populations for certain indications may result in high treatment prices, potentially limiting patient access.

Reimbursement for novel therapies, including Tregs-based treatments, can be challenging. Payers may be hesitant to cover these therapies due to their cost and the need for substantial clinical evidence. Navigating reimbursement hurdles is critical for market adoption. As the Tregs therapies market grows, competition among different treatments and technologies may intensify. This competition can influence pricing strategies and market access, potentially affecting the growth of individual therapies.

## Key Market Trends

### Advancements in Gene Editing and Cell Engineering Technologies:

Advances in gene editing technologies, such as CRISPR-Cas9, are enabling precise modifications of Tregs. Researchers can engineer Tregs to enhance their suppressive capabilities, target specific antigens, or improve their overall therapeutic potential. This trend is leading to the development of personalized Tregs therapies tailored to individual patients and their unique immune profiles.

While autologous Tregs (derived from the patient's own cells) have been a focus, the field is increasingly exploring allogeneic Tregs (derived from healthy donors). Gene editing techniques allow for the creation of universal donor Tregs, which can be used in multiple patients, potentially reducing manufacturing costs and expanding access to treatment. Continuous research is focused on enhancing the safety profile of gene-edited Tregs. This includes minimizing off-target effects and ensuring the stability of engineered cells over time. These advancements are crucial for gaining regulatory approvals and ensuring the long-term effectiveness of Tregs therapies.

### Combination Therapies and Synergy with Immunotherapies

Tregs therapies are increasingly being explored in combination with ICIs like pembrolizumab and nivolumab to enhance the efficacy of cancer immunotherapy. By modulating the immune response with Tregs while simultaneously blocking immune checkpoints, researchers aim to achieve better tumor control and improved patient outcomes.

The trend towards personalized medicine is driving the development of combination therapies that integrate Tregs with other immunotherapies. These approaches take into account individual patient characteristics, tumor types, and disease stages to design customized treatment regimens. Clinical trials investigating combination therapies are generating valuable data on safety, efficacy, and the optimal sequencing of treatments. This trend is expected to expand as researchers seek to maximize the therapeutic potential of Tregs-based therapies in various disease settings.

### Diversification of Therapeutic Applications

While autoimmune diseases have been a primary focus, Tregs therapies are expanding their reach to address a wider range of autoimmune conditions, such as rheumatoid

arthritis, multiple sclerosis, and Crohn's disease. The increasing understanding of immune dysregulation in autoimmune disorders is driving this trend.

Tregs-based therapies are gaining prominence in transplantation medicine. These therapies aim to improve graft acceptance, reduce the need for immunosuppressive drugs, and prevent graft-versus-host reactions in stem cell and solid organ transplantation. This application is becoming more refined as clinical trials progress. Tregs therapies are being explored for the treatment of chronic inflammatory conditions, including inflammatory bowel disease (IBD), psoriasis, and asthma. These therapies offer the potential to provide long-term symptom relief and improve patients' quality of life.

## Segmental Insights

### Type Insights

Based on the category of Type, the autologous segment emerged as the dominant player in the global market for Regulatory T-cells (Tregs) therapies in 2022. Autologous Tregs are derived from the patient's own cells. This ensures a high degree of safety and compatibility, as there is no risk of graft rejection or graft-versus-host disease (GVHD) associated with allogeneic therapies. Since autologous Tregs are genetically identical to the patient's immune system, the likelihood of immune reactions against the infused cells is significantly lower. This reduces the risk of adverse events and complications.

Autologous Tregs therapies align with the trend of personalized medicine. Each patient's Tregs can be isolated and expanded to create a personalized treatment approach that addresses their specific disease and immune profile. Personalized therapies have the potential to be more effective because they are tailored to the patient's unique immune system. This approach maximizes the therapeutic benefit while minimizing potential side effects. Regulatory approval for autologous therapies is often less complex compared to allogeneic treatments. Since the patient's own cells are used, there are fewer concerns about compatibility, leading to a smoother regulatory pathway. The streamlined regulatory process for autologous therapies can result in shorter development timelines, enabling quicker market entry and patient access. These factors are expected to drive the growth of this segment.

### Application Insight

Based on the category of Application, the Organ Transplantation segment emerged as



the dominant player in the global market for Regulatory T-cells (Tregs) therapies in 2022. Preventing Graft Rejection: Organ transplantation involves the transfer of donor organs or tissues to recipients, which can trigger immune responses leading to graft rejection. Tregs play a crucial role in promoting immune tolerance, dampening immune reactions against transplanted tissues, and increasing the likelihood of graft acceptance.

Current transplantation protocols often require patients to take immunosuppressive drugs for extended periods to prevent graft rejection. However, these drugs can have significant side effects and long-term health risks. Tregs therapies offer an alternative approach by modulating the immune system, potentially reducing the reliance on immunosuppressive medications.

Chronic rejection, which can occur months or years after transplantation, remains a significant concern in the field. Tregs-based therapies hold promise in mitigating chronic rejection by promoting long-term immune tolerance. This application is particularly attractive as it addresses a critical issue in organ transplantation. Tregs therapies can be tailored to address the challenges associated with allogeneic transplantation, where organs or tissues come from a different donor. By infusing recipient specific Tregs alongside the transplant, it may be possible to promote immune tolerance even in cases of allogeneic transplantation, expanding the pool of potential donors. These factors are expected to drive the growth of this segment.

## End-User Insights

The Hospitals & Clinics segment is projected to experience rapid growth during the forecast period. Hospitals and clinics are well-equipped with specialized infrastructure and medical expertise to handle complex and advanced therapies like Tregs-based treatments. These facilities have the necessary equipment, personnel, and experience to administer and monitor Tregs therapies effectively. Hospitals often employ multidisciplinary teams of healthcare professionals, including transplant surgeons, immunologists, hematologists, and nurses, who collaborate to provide comprehensive care to patients undergoing Tregs therapies. This expertise is critical for ensuring the safe and effective delivery of these treatments.

Hospitals and clinics typically have a high patient volume, including individuals with autoimmune diseases, cancer, and those in need of organ transplantation. As Tregs therapies are relevant to these patient populations, healthcare facilities are natural hubs for providing such treatments. Many patients with complex medical conditions are referred to specialized hospitals and clinics by primary care physicians or other

healthcare providers. This referral network ensures that patients who can benefit from Tregs therapies are directed to appropriate facilities with the expertise to administer these treatments. Hospitals and clinics have access to advanced diagnostic tools and imaging equipment that are essential for assessing the eligibility of patients for Tregs therapies. Additionally, they can monitor patients closely during treatment to ensure safety and efficacy. Many healthcare facilities have on-site laboratories capable of processing blood samples and performing necessary tests to assess patients' immune profiles and response to Tregs therapies. These factors collectively contribute to the growth of this segment.

## Regional Insights

North America emerged as the dominant player in the global Regulatory T-cells (Tregs) therapies market in 2022, holding the largest market share in terms of value. The United States has one of the most advanced healthcare infrastructures in the world, with top-tier hospitals, research institutions, and clinics. This infrastructure is crucial for the development, clinical trials, and administration of Tregs therapies. The U.S. is a hub for biomedical research, including immunotherapy research. It has a large number of research institutions and pharmaceutical companies actively involved in Tregs therapies development and clinical trials. Regulatory agencies such as the U.S. Food and Drug Administration (FDA) have been supportive of innovative therapies like Tregs-based treatments. Expedited pathways and designations (e.g., Fast Track) have facilitated the development and approval of these therapies. North America has a significant burden of diseases that can potentially be treated with Tregs therapies, including autoimmune diseases and cancer. The prevalence of these conditions has driven the demand for innovative treatment options. The availability of venture capital, private investments, and government funding for research in the United States has spurred innovation in the field of Tregs therapies.

The Asia-Pacific market is poised to be the fastest-growing market, offering lucrative growth opportunities for Regulatory T-cells (Tregs) therapies players during the forecast period. Factors such as The Asia-Pacific region has seen an increase in the prevalence of autoimmune diseases, cancer, and other conditions that can benefit from Tregs therapies. This growing patient population is driving demand. Clinical trials for Tregs therapies have expanded into APAC countries due to the availability of a diverse patient pool and lower clinical trial costs. This has accelerated the introduction of these therapies in the region. Some APAC governments have shown interest in supporting innovative therapies, including Tregs-based treatments, through funding, incentives, and streamlined regulatory pathways. Greater patient and healthcare provider

awareness of Tregs therapies and their potential benefits has contributed to market growth in the APAC region.

### Key Market Players

Abata Therapeutics

Atara Biotherapeutics Inc

Bastion Therapeutics

Cellenkos, Inc.

Coya Therapeutics, Inc.

GentiBio Inc

Kyverna Therapeutics Inc

PoITREG S.A.

Teralmmune, Inc

Tr1X TRACT Therapeutics, Inc.

Roche AG

### Report Scope:

In this report, the Global Regulatory T-cells (Tregs) therapies Market has been segmented into the following categories, in addition to the industry trends which have also been detailed below:

#### Regulatory T-cells (Tregs) therapies Market, By Type:

Autologous

Allogenic

### Regulatory T-cells (Tregs) therapies Market, By Applications:

Autoimmune Diseases

Organ Transplantation

Graft-versus-Host Disease (GVHD)

Others

### Regulatory T-cells (Tregs) therapies Market, End-User:

Hospitals & Clinics

Academic & Research Institutions

Others

### Regulatory T-cells (Tregs) therapies 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

Kuwait

Turkey

Egypt

Competitive Landscape

Company Profiles: Detailed analysis of the major companies present in the Global

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Regulatory T-cells (Tregs) therapies Market.

Available Customizations:

Global Regulatory T-cells (Tregs) therapies market report with the given market data, Tech Sci 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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