

Case Report Paper

## Evaluating Gene Therapy and Immunotherapy for Cancer and Genetic Disorders

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**Abstract:** Gene therapy and immunotherapy have emerged as revolutionary treatments in medicine, offering hope for previously untreatable diseases, particularly cancer and genetic disorders. This study aims to analyze the progress and challenges in gene therapy and immunotherapy in the US healthcare system during 2022 and 2023, with a focus on their effectiveness, barriers to implementation, and regulatory hurdles. The methodology used in this study is a descriptive qualitative approach, using literature reviews, case study analysis, and data from clinical trials at institutions such as the NIH and Mayo Clinic. The findings highlight significant advances in gene therapies such as CRISPR for genetic disorders and cancer treatment, as well as the success of CAR-T cell therapy in hematologic cancers. However, both therapies face challenges, including high treatment costs, regulatory delays, and limited accessibility. Despite these challenges, this study highlights the promising future of these therapies, with advances in gene editing and immunotherapy expected to expand their applications. Future research should focus on long-term safety and efficacy, cost reduction strategies, and improved delivery systems for both therapies. Addressing these gaps will be critical to the widespread adoption of gene therapy and immunotherapy in clinical practice. **Keywords:** cancer, CRISPR, gene therapy, immunotherapy, regulatory barriers, cost of care.

**Keywords:** Cancer, CAR-T Cell, CRISPR, Gene Therapy, Immunotherapy.



## 1. Introduction

In the 21st century, significant advances in biotechnology and medicine have opened up new possibilities for treating diseases that were once considered incurable. Two innovative approaches that are gaining increasing attention are gene therapy and immunotherapy. Gene therapy aims to repair or replace defective genes in the human body to treat genetic disorders and certain types of cancer. Immunotherapy, on the other hand, harnesses the body's immune system to fight disease, particularly cancer, by enhancing the immune response to infected cells or tumors [1]. Both therapies are seen as revolutionary solutions because of their potential to treat diseases that were previously untreatable using conventional therapies.

In addition, gene therapy and immunotherapy have the potential to change the paradigm of treating chronic diseases and cancer, two categories of diseases that continue to affect millions of people worldwide. Technologies such as CRISPR take gene therapy to the next level, enabling precise gene editing with unmatched accuracy [2]. In contrast, immunotherapies, such as CAR-T cell therapy and checkpoint inhibitors, have shown promising results in treating difficult-to-treat cancers such as lung cancer and lymphoma [3]. However, despite their great potential, the development and implementation of these therapies face several challenges, including cost, regulation, and limited patient access.

As attention to these approaches increases, several clinical trials conducted in the United States have shown positive findings, demonstrating the effectiveness of these therapies in treating cancer and other diseases. Immunotherapy treatments for cancer are rapidly evolving, and gene therapy can be applied to several genetic disorders that were previously considered incurable [4]. In this context, the US health care system is at the forefront of developing and regulating the use of these therapies, both in clinical settings and in research laboratories [5] [6].

This study examines the implementation of gene therapy and immunotherapy in the United States in 2022. The primary goals are to analyze the effectiveness of these therapies in treating specific diseases, such as cancer and genetic disorders, and to understand the challenges of their implementation in the US health care system. The study also aims to identify opportunities that arise from further development of gene-based and immunological therapies.

This study is important in the context of medical and biotechnological advances. With the increasing prevalence of genetic disorders and cancer worldwide, including in the United States, gene therapy and immunotherapy offer more effective alternatives to conventional treatments. The findings of this study provide new insights that enrich the medical literature and suggest future research directions. Furthermore, this study guides healthcare professionals, scientists, and policymakers in developing and implementing these therapies for patients worldwide, taking into account the challenges and opportunities that exist. The results of this study contribute to a better understanding of how gene therapy and immunotherapy are integrated into global healthcare systems, particularly in addressing emerging public health problems such as cancer. This study also provides insight into how future advances in technology and medical research will overcome the barriers faced in treating more complex and diverse diseases. Therefore, this study is relevant not only to scientists and medical researchers but also to policymakers in facilitating the development of therapies that become more accessible and affordable in the future.

### 1) Historical Developments, Technologies, and Applications in Genetic Diseases and Cancer

Gene therapy, an innovative technique that aims to modify the genetic material of living cells to treat or prevent disease, has undergone significant development over the past few decades. Originally proposed in the 1970s, gene therapy began with the idea of replacing defective genes with healthy ones to treat genetic disorders. Early trials faced many challenges, such as vector delivery issues and immune system reactions. However, significant progress has been made since then, largely due to advances in gene editing technologies such as CRISPR, which allows for precise changes in DNA sequences. CRISPR-Cas9 technology has revolutionized the field by offering a more accurate, efficient, and cost-effective method of gene editing [6].

CRISPR-Cas9 works by using a guide RNA to direct the Cas9 enzyme to specific locations in the genome, where it produces double-strand breaks. These breaks allow for the insertion, deletion, or alteration of specific genes. The precision and simplicity of CRISPR-Cas9 have paved the way for its use in treating genetic disorders such as cystic fibrosis, sickle cell anemia, and Duchenne muscular dystrophy. Researchers are also exploring its potential in cancer therapy, where it can be used to target and modify immune cells, making them more effective at attacking cancerous tumors [7].

Another emerging technology is the use of viral vectors to deliver therapeutic genes to patient cells. Adenoviruses, lentiviruses, and retroviruses have been engineered to carry specific genes into human cells, providing vehicles for gene therapy. The use of viral vectors in clinical trials has shown success in treating congenital blindness, severe combined immunodeficiency (SCID), and hemophilia [8]. Despite these successes, challenges remain in ensuring safe and effective gene delivery and avoiding immune responses that can cause complications.

In cancer treatment, gene therapy works by targeting cancer cells directly or by modifying immune cells to better fight cancer. For example, scientists have explored the use of gene therapy to insert tumor suppressor genes into cancer cells or to repair defective genes that contribute to cancer development. Furthermore, the combination of gene therapy with immunotherapy, such as chimeric antigen receptor (CAR) T-cell therapy, has shown promise in overcoming the limitations of current cancer treatments, such as chemotherapy and radiation [9].

## **2) Basic Principles, Types, and Effectiveness in Cancer and Autoimmune Diseases**

Immunotherapy is an innovative approach to cancer treatment that stimulates the body's immune system to recognize and destroy cancer cells. Unlike traditional cancer treatments, such as chemotherapy and radiation, immunotherapy aims to enhance the natural immune response, making it a less toxic and more targeted approach [10]. The basic principle of immunotherapy involves the use of monoclonal antibodies, immune checkpoint inhibitors, or cancer vaccines to enhance the immune system's ability to identify and fight cancer cells.

One of the most well-known types of immunotherapies is immune checkpoint inhibition. Checkpoints are molecules on immune cells that need to be activated or inhibited in order to initiate an immune response. In cancer, these checkpoints can be hijacked by tumors to evade immune detection. By using immune checkpoint inhibitors such as pembrolizumab and nivolumab, the immune system can be reactivated to attack cancer cells. This therapy has been successful in treating cancers such as melanoma, non-small cell lung cancer, and renal cell carcinoma [11].

Another promising form of immunotherapy is CAR-T cell therapy, in which a patient's T cells are genetically modified to express specific receptors for cancer cells. Once infused back into the patient, these engineered cells can more effectively target and kill cancer cells. CAR-T cell therapy has shown significant success in hematologic cancers, particularly in treating leukemia and lymphoma [12]. However, its application to solid tumors, which are more difficult to treat, still faces several hurdles, including tumor heterogeneity and the tumor microenvironment, which can suppress immune activity.

Immunotherapy is not only effective in treating cancer, but is also being explored in the treatment of autoimmune diseases. The use of immunomodulating drugs has shown promise in diseases such as rheumatoid arthritis, lupus, and multiple sclerosis. By modulating the immune response, these therapies can prevent the immune system from attacking healthy tissue. While this approach is still under investigation, it offers new hope for patients with autoimmune conditions [13].

## **3) Research and Clinical Trials in the United States (2022).**

In 2022, significant advances in gene therapy and immunotherapy emerged from clinical trials and research conducted in the United States. Researchers are increasingly focused on optimizing existing gene editing technologies, such as CRISPR-Cas9, for clinical applications. One prominent study conducted in 2022 explored the use of CRISPR-Cas9 to treat sickle cell anemia by editing the genes of hematopoietic stem cells. The results were promising, as the edited cells showed increased production of fetal hemoglobin, thereby alleviating symptoms of the disease [14]. This study marks an important step forward in the clinical application of gene therapy for genetic diseases.

Immunotherapy has also made significant progress, particularly in the treatment of cancers that were once considered untreatable. A 2022 study of the use of CAR-T cell therapy in treating solid tumors showed early-stage success, particularly in patients with melanoma and glioblastoma [15]. While challenges remain in optimizing CAR-T cell therapy for solid tumors, this study highlights the potential of immunotherapy as a viable treatment option beyond hematologic cancers.

Additionally, a 2022 study conducted by the National Institutes of Health (NIH) evaluated the combination of gene therapy and immunotherapy in treating advanced cancer. The study involved using CRISPR technology to edit immune cells and enhance their ability to recognize and attack tumor cells. Early results suggest that combining these therapies may provide a more effective treatment option for patients with metastatic cancer, including those who do not respond to conventional treatments [16].

The US Food and Drug Administration (FDA) also approved several new immunotherapy drugs in 2022, expanding the treatment options available to patients with a variety of cancers. These approvals reflect growing confidence in the effectiveness of immunotherapy and its ability to significantly improve patient outcomes. The clinical success of this therapy has led to wider acceptance of immunotherapy as a first-line treatment for a wide range of cancers, making it a cornerstone of modern oncology [17] [18].

## 2. Method

This study uses a descriptive qualitative approach with data collection through literature review and case study analysis. This study focuses on analyzing the application of gene therapy and immunotherapy in the United States during 2022 and 2023. This study examines the effectiveness of these therapies in treating specific diseases such as cancer and genetic disorders, and aims to understand the challenges and opportunities for further development in the US healthcare system. This study used data from clinical trials conducted at major research institutions and hospitals in the United States, including the National Institutes of Health (NIH), Mayo Clinic, and the University of California, Los Angeles (UCLA). These data included clinical trials involving patients with a variety of diseases, including cancer and genetic disorders, who were treated with gene therapy and immunotherapy. The total number of participants across the clinical trials reviewed varied, with some clinical trials involving hundreds of participants. These participants included cancer patients, individuals with genetic disorders, and other patients receiving gene-based and immunology-based treatments. The data collected from these clinical trials serve as a baseline for analyzing the implementation and challenges of these therapies in the U.S. health care system during 2022–2023.

Data sources for this study include:

- 1) Peer-reviewed articles  
Scientific articles published in 2022 in medical and pharmaceutical journals. These articles provide insight into the latest developments in gene therapy and immunotherapy, with a focus on their application in clinical trials and treatments.
- 2) Clinical Trial Reports  
Reports from clinical trials relevant to gene therapy and immunotherapy. These reports detail the results of clinical trials, including success rates, side effects, and response to treatment for diseases such as cancer and genetic disorders.
- 3) Regulatory Data  
Data from US health agencies, including the Food and Drug Administration (FDA), provide information on the regulatory approval process for gene and immunotherapies, as well as associated challenges and regulatory frameworks.

Research procedures are follows:

- 1) Literature Collection  
Data collection involved reviewing literature on gene therapy and immunotherapy from multiple academic databases. The focus was on articles published between 2022 and 2023 to ensure the most current information was used.
- 2) Data Analysis  
Data were analyzed to identify trends in gene therapy and immunotherapy development. The study also evaluated clinical outcomes, treatment efficacy, and challenges in the regulatory environment.
- 3) Challenge Mapping  
The study identified challenges to the implementation of gene therapy and immunotherapy in the US. These challenges include regulatory barriers, access to treatment, cost, and patient eligibility. Challenges were mapped based on findings from clinical trials, academic literature, and FDA reports.

## 3. Finding and Discussion

### 3.1. Findings

Based on the analysis of clinical trials, articles, and regulatory reports, the key findings of gene therapy and immunotherapy studies in the United States during 2022 and 2023 are as follows:

### 1) Successes and Challenges in Gene Therapy and Immunotherapy Development

- **Gene Therapy**  
 The application of gene therapy, particularly in the treatment of genetic disorders and cancer, has shown substantial progress. Technologies such as CRISPR enable precise gene editing, providing an innovative approach to repairing defective genes. However, challenges related to the high cost of treatment, long-term effects, and regulatory hurdles remain significant. Regulatory agencies such as the FDA carefully review these therapies to ensure their safety and efficacy, but the approval process is time-consuming and expensive.
- **Immunotherapy**  
 Immunotherapy, particularly CAR-T cell therapy, has made impressive strides in treating cancers such as lymphoma and leukemia. While promising, its accessibility is limited by the high cost of treatment and the complex nature of the therapy, which requires personalized care for each patient.

Table 1. Overview of Challenges and Successes in Gene Therapy and Immunotherapy

Therapy Type	Successes	Challenges
Gene Therapy	Gene editing with CRISPR; treatment for genetic disorders and cancer	High costs, regulatory delays, long-term effects
Immunotherapy	CAR-T cell therapy success in treating cancers	High cost, individualized treatment, limited access

### 2) Recent Developments in CRISPR Technology and CAR-T Cell Therapy

- **CRISPR Technology in Gene Therapy**  
 CRISPR-Cas9 technology continues to show revolutionary potential in gene therapy. In clinical trials, CRISPR has been used to edit genes responsible for inherited diseases such as sickle cell anemia and muscular dystrophy, with encouraging results. However, challenges in off-target effects and delivery mechanisms remain.
- **CAR-T Cell Therapy in Immunotherapy**  
 CAR-T cell therapy, which involves modifying a patient’s T cells to better recognize and attack cancer cells, has been a breakthrough, especially for blood cancers. However, this therapy is still in its infancy for solid tumors, and its high cost limits its accessibility.

### 3) Comparison of Gene Therapy and Immunotherapy in Effectiveness, Risks, and Success Rates

- **Effectiveness**  
 Both therapies have shown high efficacy in certain diseases, particularly cancers and genetic disorders. However, gene therapy is more established in treating inherited diseases, while immunotherapy, such as CAR-T therapy, shows particular promise in hematologic malignancies (blood cancers).

Table 2. Comparison of Gene Therapy and Immunotherapy on Various Criteria

Criteria	Gene Therapy	Immunotherapy (CAR-T)
Effectiveness	High success in genetic disorders	High success in blood cancers
Risks	Risk of off-target effects, immune rejection	Risk of cytokine release syndrome, neurotoxicity
Success Rate	Promising results for inherited diseases	High success rate for blood cancers

- **Risks**  
 Risks of gene therapy include unwanted genetic mutations, immune reactions, and long-term complications. Immunotherapy, particularly CAR-T, has risks associated with cytokine release syndrome, neurotoxicity, and severe immune responses.
- **Success Rates**  
 Success rates vary by disease and therapy. For example, CAR-T therapy has high success rates in treating some types of blood cancers, but is still experimental for solid tumors. Gene therapy has shown promising success in treating genetic disorders such as sickle cell anemia, with long-term benefits observed in clinical trials.

### 3.2. Discussion

#### 1) Efficacy and Safety

Clinical trials and patient experiences have shown that gene therapy and immunotherapy have great potential to treat previously untreatable conditions. The ability of gene therapy to treat genetic disorders and correct gene defects presents an innovative approach, while immunotherapy has revolutionized cancer treatment. In terms of safety, gene therapy still faces challenges related to long-term effects and genetic instability, while immunotherapy requires careful monitoring for immune-related side effects, especially with CAR-T therapy.

#### 2) Implementation Challenges

The main challenges in implementing gene therapy and immunotherapy lie in accessibility, cost, and regulatory constraints. While both therapies offer revolutionary potential, their high production costs and the need for individualized care limit widespread adoption. Regulatory agencies such as the FDA are working to streamline the approval process, but the complexity and risks associated with these therapies require rigorous testing and oversight. Lack of infrastructure in some health care systems also presents challenges in getting these treatments to all patients who need them.

#### 3) The Future of Gene Therapy and Immunotherapy

As research continues, the development of gene therapies, such as CRISPR, and immunotherapies, such as CAR-T, is expected to grow rapidly. New delivery methods, including improved vectors for gene therapy and combination treatments for immunotherapy, may help address some of the current challenges. As clinical trials continue to yield positive results, these therapies will likely become more commonplace in treating not only cancer but also a variety of genetic and chronic diseases. Additionally, advances in healthcare systems, improved patient access programs, and cost-reduction strategies will increase the availability of these treatments.

Table 3. Future Prospects in Gene Therapy and Immunotherapy

Therapy Type	Current Challenges	Future Prospects
Gene Therapy	High cost, long-term effects, delivery issues	Improved delivery systems, reduced costs, broader applications
Immunotherapy	High cost, individualization, side effects	Combination therapies, increased access, better targeting

The findings of this study suggest that although gene therapy and immunotherapy show great potential, their widespread use faces major challenges related to cost, access, and regulatory approval. However, technological advances and ongoing clinical research provide hope that these therapies will become a mainstay in the treatment of a variety of diseases shortly.

Future research in gene therapy and immunotherapy should focus on several key areas to address current limitations and maximize their potential. First, further investigation of the long-term efficacy and safety of these therapies is needed, particularly through long-term patient follow-up to assess potential risks and benefits in later stages. Second, cost-reduction strategies should be explored, as the

high cost of treatment remains a significant barrier to accessibility. Research into scalable manufacturing processes and more affordable delivery systems could make these therapies accessible to a broader patient population. Additionally, while immunotherapy, particularly CAR-T cell therapy, has shown efficacy in treating blood cancers, its application to solid tumors is still in its infancy. Research should aim to optimize CAR-T cell therapy to be more effective in solid tumors. Finally, improved gene therapy delivery systems are needed to ensure precise gene editing and reduce off-target effects, which are critical to improving treatment outcomes and reducing associated risks. Addressing these research gaps will be critical to advancing the clinical application of gene therapy and immunotherapy, making them more accessible, effective, and safer for patients in the future.

#### 4. Conclusion

The study concludes that gene therapy and immunotherapy represent significant advances in the treatment of previously untreatable diseases, particularly in cancer therapy. Both therapies have demonstrated substantial potential in clinical trials, with gene therapy showing promise in treating genetic disorders and cancer, and immunotherapy—particularly CAR-T cell therapy—showing efficacy in treating hematologic malignancies. However, despite these advances, challenges such as high cost, regulatory delays, and limited accessibility continue to hinder widespread adoption and implementation of these therapies. Addressing the research question on the effectiveness and challenges of gene therapy and immunotherapy in the U.S. healthcare system during 2022 and 2023, the study identified that while both therapies offer substantial promise, their broader implementation is still limited by regulatory, cost, and infrastructure barriers. Therefore, while these therapies are effective in treating certain conditions, further research and development is needed to overcome these challenges and expand access to more patients.

To further advance gene therapy and immunotherapy, several key recommendations should be considered. First, there is a need to increase research efforts, particularly long-term studies, to assess efficacy, potential side effects, and strategies to mitigate risks in real-world settings. Second, interdisciplinary collaboration between scientists, medical professionals, and regulatory agencies is essential to ensure the safe and effective implementation of these therapies. Streamlining the regulatory process while prioritizing patient safety will be critical to future success. Third, addressing the high costs associated with these therapies is critical. Efforts to increase accessibility through improved healthcare systems and patient support programs will allow more patients to benefit from these revolutionary treatments. In conclusion, while gene therapy and immunotherapy represent groundbreaking medical advances, overcoming challenges related to cost, regulation, and access will be vital to realizing their full potential for a broader range of diseases. As research continues, these therapies will likely play an increasingly significant role in global medical care.

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