2025
12(3), 1270

Chemical Biology
LETTERS

Cell therapy landscape in India: Current advances, opportunities, challenges, and future directions

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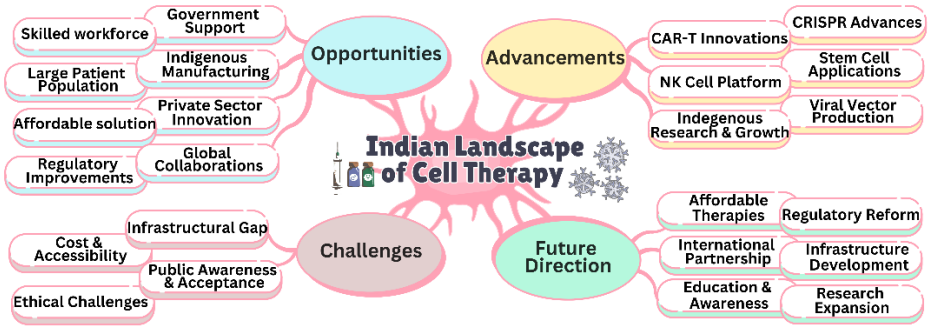
Submitted on: 21-Jan-2025, Accepted and Published on: 14-Mar-2025

Review

ABSTRACT

Cell and immunotherapy products are known for targeting the root cause of health ailments and potentially curing cancers and other degenerative indications. The rapid growth in cell therapy products, CRISPR-based gene editing, and stem cell applications in India is changing the face of personalized medicine, putting the country at the forefront of innovative product development. The therapy develops through strong regulatory guidelines and collaborative efforts among academia, industry, and government. However, high costs, less infrastructure, regulatory complexity, and ethics are hurdles in implementing the idea. This review emphasizes the progress made in cell therapy research in India and discusses the challenges as well as the possible strategies for overcoming them.



Keywords: Cell Therapy, Immunotherapy, CRISPR, CAR-T, Stem Cells

INTRODUCTION

Cell and gene therapy (CGT) are recent breakthroughs in medical science that provide new avenues for treating complex diseases[1]. These therapies provide a new dimension in medicine by treating symptoms and also by targeting the underlying causes of diseases. Cell therapy uses live cells to repair damaged tissues, can be produced from the patient (autologous) or a donor (allogeneic), it include cells that can differentiate into numerous cell types required for healing or treatment[1,2] and gene therapy refers to the process of insertion of therapeutic genes into a patient's cell in an attempt to compensate for or replace the dysfunctional gene, thereby treating the genetic disorder. This can be achieved by both in vivo and ex vivo procedures. During in-vivo, genetic material is supplied directly into the body, while in ex-vivo, the cells are modified outside of the body before reintroduction.[3] Among the most significant breakthroughs in these therapies are CAR-T cell therapies, which involve modifying a patient's immune cells to specifically target and destroy cancer cells, using various gene editing technologies like Clustered Regularly Interspaced Short Palindromic Repeats (CRISPR)-Cas (CRISPR-associated proteins) and other viral-based approaches, which allows for precise alterations to DNA sequences.[4,5] These advances have shown good results in clinical environments across the globe, providing hope for patients with previously untreatable conditions. However, they remain inaccessible in low- and middle-income countries (LMICs) due to several significant challenges.[6] India, with its vast and genetically diverse population, presents a unique opportunity for developing and applying cell therapies.[7] India broadly faces a high occurrence of genetic disorders like thalassemia and sickle cell anaemia, together with increasing incidences of haematological cancers like leukaemia and lymphoma.[8] The possible need for new and innovative treatments to tackle these serious health issues has never been a point of focus. Over the past few years, India has made great advancements in cell therapy, giving hope to many.[9] One of the most important milestones is India's first Indigenous CAR-T cell therapy trial designed explicitly for B-cell cancers like leukaemia and lymphoma.[10] Cell therapies have given encouraging effects in addressing spinal cord injuries and neurodegenerative diseases, which offer hope for patients.[11] Nevertheless, there are still considerable challenges, the first challenge is the incidence of the cost associated with these latest treatments, such as CAR-T cell therapy, which can cost 30-40 lakh at a minimum for every

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URN:NBN:sciencein.cbl.2025.v12.1270
DOI:10.62110/sciencein.cbl.2025.v12.1270

https://pubs.thesciencein.org/cbl

patient, making it unaffordable for many.[12] Second, India's infrastructure continues to develop even within the parameters of large-scale production and clinical trials, especially in the non-metropolitan area, which lacks sufficient healthcare resources, thereby limiting the reach of these advanced treatments to those who would otherwise require them considerably.[13] Although regulatory frameworks are evolving to accommodate new therapies, they continue to face delays that can prolong the time it takes for innovative treatments to reach patients.[14] The discussion will cover the recent developments that shows India as a potential leader in this field while specifying the significant hindrances that need to be tackled. Ethical concerns surrounding cell therapy also present additional barriers to progress. Consent issues, technology misapplication and the long-term implications of genetic interventions raise critical questions that have to be answered with due diligence through public ethics and discourse.[15] In India, public awareness and understanding of these advanced therapies remain low, and this constitutes a major hindrance to patient acceptance and participation in clinical trials.[16,17] Educational campaigns among healthcare professionals and the general population are important to create an understanding of the innovations.

This review attempts to provide an in-depth assessment of the position of cell and gene therapy / immunotherapeutic, presently in India. It also attempts to layout a roadmap to advance precision medicine opportunities available in India through research and development, regulatory reforms, and international collaborations for cooperation. By overcoming these challenges, India powerfully stands to enhance treatment accessibility to save lives and become a significant contributor in the field of global cell therapy.

CURRENT LANDSCAPE OF CELL THERAPIES

The worldwide spectrum of cell therapies is evolving rapidly, marked by exciting developments in research, regulation, and markets.[18] As recently estimated, the global cell therapy market is forecasted to develop from $13.81 billion in 2023 to $17.31 billion in 2024 at a 25.3% CAGR.[19, 20] This growth is driven by increasing research and development investments, advancements in cancer drug discovery, and rising healthcare expenditures. The Indian cell and immunotherapeutic industry is expected to expand quickly at a CAGR of 16.80% from 2024 to 2032, with an estimated size of $503.1 million by 2030. This expansion is being pushed by advances in biotechnology, growing healthcare costs, and an increased frequency of chronic illnesses. The market is characterized by a move towards personalized medicine and supporting regulatory frameworks allowing for speedier novel medication licensing. Collaboration between pharmaceutical corporations and academic institutes strengthens research and development activities, establishing India as a major participant in the global cell and immunotherapy scene. In the first half of 2024, the global regulatory environment has shown adaptability to the rapid advancements in cell therapies.[21] Non-genetically modified cell therapies dominate the market, accounting for 68% of approved products, while genetically modified therapies are experiencing robust growth, with over 1,008 therapies currently in development [Table 1].[22]

Table 1: List of FDA approved cell and gene therapy products.

S. No.	Therapy Name	Innovator (Company)	Technology Used	Indication	Autologous / Allogeneic	Virus Used	Year of Approval	Approval Status/Region	Notes
1	**Alhemo**	Novo Nordisk	Gene Therapy	Hemophilia with inhibitors	Allogeneic	Not specified	2024	FDA Approved (USA)	Approved for hemophilia patients with inhibitors.
2	**Casgevy™**	Vertex Pharmaceuticals	Ex Vivo Gene Editing	Sickle Cell Disease	Autologous	Lentivirus	2023	FDA Approved (USA)	World's first CRISPR-based gene-editing therapy.
3	**Lyfgenia™**	Bluebird Bio	Ex Vivo Gene Therapy	Sickle Cell Disease	Autologous	Lentivirus	2023	FDA Approved (USA)	Another therapy for sickle cell disease using ex vivo gene therapy techniques.
4	**Elevidys**	Sarepta Therapeutics	Gene Therapy	Duchenne Muscular Dystrophy	Allogeneic	AAV	2023	FDA Approved (USA)	AAV-based therapy for Duchenne Muscular Dystrophy.
5	**VYJUVEK™**	Krystal Biotech	Gene Therapy	Dystrophic Epidermolysis Bullosa	Allogeneic	HSV-1	2023	FDA Approved (USA)	HSV-1-based therapy for a rare skin disorder.
6	**HEMGENIX®**	CSL Behring	Gene Therapy	Hemophilia B	Allogeneic	AAV	2022	FDA Approved (USA)	The first approved gene therapy for hemophilia B.

7	**ZYNTEGLO™**	Bluebird Bio	Gene Therapy	Beta-Thalassemia	Autologous	Lentivirus	2022	FDA Approved (USA)	First approved gene therapy for transfusion-dependent beta-thalassemia.
8	**SKYSONA®**	Bluebird Bio	Gene Therapy	Cerebral Adrenoleukodystrophy	Autologous	Lentivirus	2022	FDA Approved (USA)	Therapy for a rare neurodegenerative disease affecting boys.
9	**ROCTAVIAN™**	BioMarin Pharmaceutical	Gene Therapy	Hemophilia A	Allogeneic	AAV	2022	FDA Approved (USA)	The first gene therapy for hemophilia A.
10	**Breyanzi**	Bristol Myers Squibb	CAR-T Cell Therapy	Large B-cell Lymphoma	Autologous	Lentivirus	2021	FDA Approved (USA)	A CAR-T cell therapy for aggressive forms of lymphoma.
11	**Abecma**	Bristol Myers Squibb	CAR-T Cell Therapy	Multiple Myeloma	Autologous	Lentivirus	2021	FDA Approved (USA)	The first CAR-T therapy for multiple myeloma.
12	**Tecartus**	Kite Pharma	CAR-T Cell Therapy	Mantle Cell Lymphoma	Autologous	Retrovirus	2020	FDA Approved (USA)	First CAR-T therapy for mantle cell lymphoma.
13	**Zolgensma®**	Novartis Gene Therapies	Gene Therapy	Spinal Muscular Atrophy	Allogeneic	AAV	2019	FDA Approved (USA)	A one-time treatment for spinal muscular atrophy in infants.
14	**Yescarta**	Kite Pharma	CAR-T Cell Therapy	Large B-cell Lymphoma	Autologous	Retrovirus	2017	FDA Approved (USA)	One of the first CAR-T therapies approved for large B-cell lymphoma.
15	**KYMRIAH®**	Novartis	CAR-T Cell Therapy	B-cell Acute Lymphoblastic Leukemia	Autologous	Lentivirus	2017	FDA Approved (USA)	The first CAR-T therapy for pediatric and young adult leukemia.
16	**LUXTURNA®**	Spark Therapeutics	Gene Therapy	RPE65 Mutation-associated Retinal Dystrophy	Allogeneic	AAV	2017	FDA Approved (USA)	First gene therapy for an inherited retinal disease.

The United States continues to be the leader in this area, with a plethora of clinical trials on cancers and rare diseases; however, Asia-Pacific countries such as China and Japan are emerging as front-runners. India also made a historic step forward by introducing the first indigenously developed CAR-T cell therapy for cancer, Actalycabtagene autoleucel (NexCAR19), developed through the joint efforts of IIT Bombay and Tata Memorial Hospital. This was part of the initiatives under national policies aimed towards increasing self-reliance in healthcare. Nonetheless, several challenges still abound in implementing these therapies at a larger scale within India. Most are the high costs, which limit access to a broader range of patients. The global cell therapy industry is growing and innovating quickly with solid market demands and changing regulations. India's picture has progressed but is still a reflection of serious challenges in developing cell therapies.

CURRENT ADVANCES IN CELL THERAPIES FROM INDIA

India is beginning to carve a niche for itself in this field through home-grown research efforts, clinical trials, and strong government backing. It is presently the United States, which, with over 20 approved products and more than 1,000 ongoing clinical trials, is leading the world in cell and immunotherapies. Focus areas in the global context are CAR-T cell therapy, gene therapy, and regenerative medicine. India is advancing in these fields with remarkable activities in the development of affordable and innovative treatments for similar indications. According to the count of over 10 products approved and approximately 700 ongoing trials, China is closely behind the U.S. with CAR-T therapies dedicated primarily to cancer treatments. Two countries, Japan and South Korea further, also contribute significantly towards regenerative medicine and oncology. European countries like Germany, UK, France, and Italy add up to a robust presence with more than 15 approved products in stock across the European Union (EU), where these European countries focus on CAR-T cell therapies and gene therapy for oncology applications. Another major player is Canada, which focuses on gene therapy for rare diseases. Meanwhile, India is beginning to enter this field step by step with relatively few approvals but a growing interest in CAR-T cell therapies, among others. [Table 2] [Figure 1, Figure 2].[17]

Table 2. Top 10 countries with the number of approved cell therapy products and clinical trials, (#) not in the rank.

Rank	Country	No. of Approved CGT Products	No. of Ongoing CGT Clinical Trials	Key Therapies / Focus Areas	Reference
1	**United States**	20+	1,000+	CAR-T, Gene Therapy, Regenerative	FDA, ClinicalTrials.gov
2	**China**	10+	700+	CAR-T, Cancer Therapies	NMPA, ClinicalTrials.gov
3	**Japan**	10+	200+	Regenerative Medicine, Rare Diseases	PMDA, ClinicalTrials.gov
4	**South Korea**	8+	150+	Regenerative Medicine, Oncology	MFDS, ClinicalTrials.gov
5	**European Union**	15+ (EU-wide)	400+	CAR-T, Gene Therapy, Oncology	EMA, ClinicalTrials.gov
6	**Germany**	5+	100+	Oncology, Gene Therapy	EMA, ClinicalTrials.gov
7	**United Kingdom**	5+	150+	Oncology, Gene Therapy, Rare Diseases	MHRA, ClinicalTrials.gov
8	**France**	5+	100+	Gene Therapy, Oncology	EMA, ClinicalTrials.gov
9	**Italy**	3+	80+	Oncology, Gene Therapy, Rare Diseases	EMA, ClinicalTrials.gov
10	**Canada**	3+	90+	Gene Therapy, Rare Diseases	Health Canada, ClinicalTrials.gov
#	**India**	2	**<50**	CAR-T, Gene Therapy, Regenerative Medicine	DBT, DCGI, ClinicalTrials.gov

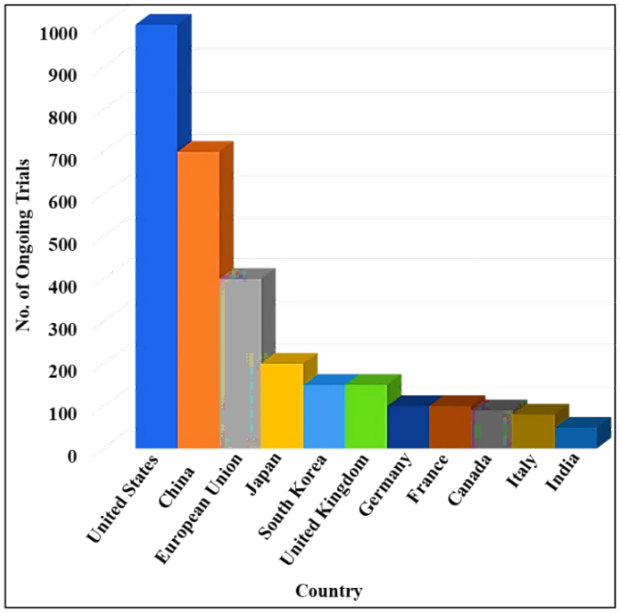

Figure 1. Graphical representation of Table 2 for ongoing clinical trials of cell therapy products in different countries.

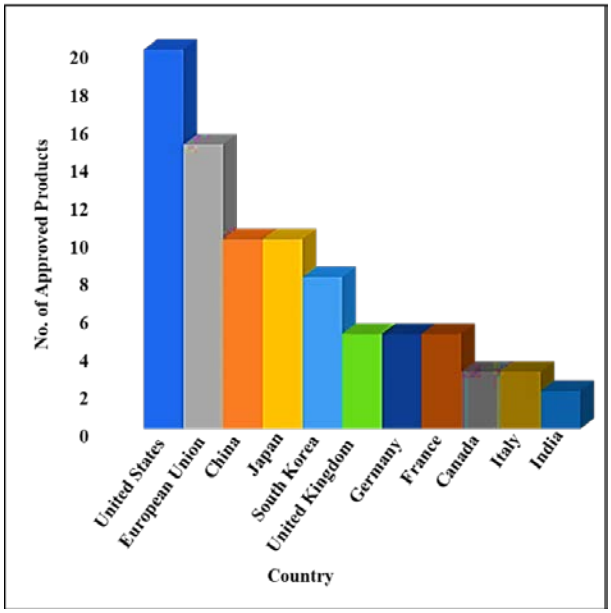

Figure 2. Graphical representation of approved cell therapy products in different countries as per Table 2.

The private sector in India is actively engaged in product development, with increasing investments in research, clinical trials, and the commercialization of cell therapies. Several leading Indian biotech firms and start-ups focus on gene editing, stem cell therapies, and cancer immunotherapies. Indian companies like Immuneel Therapeutics and ImmunoAct are making strides in developing CAR-T cell therapies, which are revolutionizing cancer treatment. Immuneel, in particular, has launched India's Autologous cell therapy Qartemi®, used in treating relapsed and refractory NonHodgkin's Lymphoma (NHL) [Table 3].

This significant development offers personalized treatment options and opens the door for affordable cancer therapies in India. APCEDEN®, APAC Biotech's dendritic cell-based tailored immunotherapy, is the first to be acknowledged and authorized by the Indian Health Regulatory Authority [Table 3].

Companies like Stempeutics (part of the Cipla Group) are working on stem cell-based therapies for various conditions, including cardiac diseases, neurological disorders, and diabetes.[23] Through collaborations with global partners, Stempeutics has advanced stem cell products, particularly for musculoskeletal diseases [Table 2]. Meril Lifesciences has made significant contributions through its unique medical devices and therapeutic solutions, notably in regenerative medicine and advanced cardiac treatments, such as Myval, India's first indigenously designed transcatheter aortic valve replacement (TAVR).[24]

India is also advancing gene editing technologies such as CRISPR/Cas9. Start-ups like Bioserve Biotechnologies are focused on developing CRISPR-based gene therapies for genetic disorders like thalassemia and sickle cell anaemia, both prevalent in India. NKure Therapeutics, a start-up company founded in 2022, has established a laboratory-scale NK cell platform and obtained licensing for specialized chimeric antigen receptor (CAR) technology, allowing for allogeneic cell therapy—the first in India. NKure recently received pre-series funding to finish its production methods and preclinical tests in preparation for an Investigational New Drug (IND) application. In India, NKure is also collaborating with Medigen Biotechnology Corp. to develop and commercialise Magicell®-NK, a natural killer cell treatment technology. MicroCRISPR has improved CRISPR methods for precise gene editing, which is critical for creating efficient gene treatments. This includes the capacity to do multiplexed gene knockouts and site-specific transgene insertions, which enable more precise treatments in various disorders.[25] It has developed different platforms of autologous and allogeneic CAR-T cell therapies like MyCARTTM, OmniCARTTM, NatasaTM for HIV, and AgafyaTM for Sickle Cell and β Thalassemia.

Indian researchers also work on genetic modifications to correct inherited conditions and improve therapeutic outcomes.[26] Such therapies critically depend on the viral vectors used to deliver genes into the cells of a patient.[27] With a view to fostering affordability and accessibility of gene therapy, India is striving hard to develop domestic capabilities for viral vector production. One example is Med Therapy, a Boston-based firm established as a worldwide leader in the contract manufacturing organization (CMO) field for cell and gene treatments. They offer complete manufacturing solutions, including generating viral vectors and finished CAR-T products, to assist other biotech companies in their therapeutic development. Their emphasis on lowering prices and manufacturing time makes them crucial in making these sophisticated therapies more accessible to a broader patient base, including India. India's academic and research institutions are at the forefront of cutting-edge CGT research.

IISc, IITs, National Institute of Immunology (NII), and AIIMS are conducting high-impact research in genetic disorders, immunotherapy, and bioprocessing for cell therapy. They also conduct clinical studies on stem cell-based therapies for neurodegenerative diseases, cardiac conditions, and autoimmune disorders. Key advancements include institutions like IIT Bombay and IISc Bengaluru, pioneering CRISPR-based innovations focusing on genome editing to correct mutations in genetic disorders. Researchers are also exploring gene therapies to treat rare genetic disorders.[28] NII and AIIMS are conducting clinical studies on stem cell-based therapies for neurodegenerative diseases, cardiac conditions, and autoimmune disorders.[29] These institutions partner with industry players to bring innovative stem cell therapies to the clinics. Pulse Pharmaceuticals has created a separate Gene and Cell Therapeutics Research and Development section at the Atal Incubation Centre - CCMB in Hyderabad. This division is dedicated to developing and commercializing gene and cell therapies for treating serious diseases. The Indian Institute of Technology Madras (IIT-M) is investigating CAR-T cell therapies and tumour-infiltrating lymphocyte (TIL) therapies to develop more effective cancer treatments. The Institute of Genomics and Integrative Biology (IGIB) contributes to cell therapy by developing CAR T and CRISPR-based cell and gene therapy for sickle cell anaemia.[30] Indian Institute of Technology Kanpur has created a ground-breaking gene therapy approach for treating genetic eye illnesses, which has been licensed to Reliance Life Sciences for future development. This approach improves the delivery of therapeutic genes using adeno-associated viral vectors and has shown promise in treating visual impairment in animal models. In addition, IIT Kanpur has also worked with Laurus Labs to bring innovative gene therapy products to market, and a GMP facility has been established to assist this partnership. The Mehta Family Centre for Engineering in Medicine at IIT Kanpur focuses on regenerative medicine and developing drugs for malignancies common in India, emphasizing a multidisciplinary approach to advancing local healthcare solutions.[31]

OPPORTUNITIES FOR CELL THERAPY IN INDIA

With an already strong foundation in biotechnology and life sciences, the country can leverage its skilled workforce, large patient population (Figure 3), and affordable healthcare solutions to majorly impact global cell therapy research and development. Government support for private sector innovation and growing clinical research drive India's way forward in the cell therapy landscape. India's strengths in biotechnology manufacturing and cost-effective production methods could allow it to become a leading manufacturer of affordable cell therapy products, helping to bridge the gap in access to advanced therapies for low- and middle-income countries (LMIC) and other developing nations.[32]

Indigenous raw material production end-to-end

The manufacturing process for cell therapy products comprises many steps, from the collection of patient cells and leukapheresis to drug product generation. The patient cells collected are then transported to a cell culture facility for further processing and cultured in sterile culture bags with suitable media for growth and expansion. The cells undergo genetic modifications (if needed), such as transduction using viral vectors, to achieve the desired therapeutic characteristics. The modified cells are expanded and undergo rigorous quality control testing, including purity, potency, and sterility assessments. The final product is packaged and cryopreserved. It undergoes a release testing phase to ensure its safety and efficacy before being administered to the patient.[35] However, none of these steps of cell

Table 3. Indian players in the field of cell therapy.

S. No.	Product Name	Therapy Type	Indication	Phase	Sponsor/ Institution	Principle
1	**Varnimcabtagene autoleucel (IMN-003A)**	CAR T-Cell Therapy	Relapsed/Refractory B-cell Malignancies	Phase II	Immuneel Therapeutics	An autologous second generation CAR-T cell therapy.
2	**NexCAR19**	CAR T-Cell Therapy	B-cell Malignancies	Approved	ImmunoACT/IIT Bombay	First CAR T-cell therapy designed and approved in India.
3	**Ribrecabtagene autoleucel (DRL-1801)**	CAR T-Cell Therapy	Relapsed/Refractory Multiple Myeloma	Phase II	Aurigene Oncology	Autologous anti-BCMA CAR-T therapy that utilises a humanized single-domain antibody
4	**Stempeucel®**	Mesenchymal Stem Cell Therapy	Critical Limb Ischemia	Phase II/III	Stempeutics Research Pvt. Ltd.	Consists of pooled, allogeneic, mesenchymal stromal cells derived from bone marrow of healthy adult volunteers against inflammation in critical limb ischemia due to Buerger's disease
5	**Stempeucel®**	Mesenchymal Stem Cell Therapy	Osteoarthritis	Phase II/III	Stempeutics Research Pvt. Ltd.	Ex vivo expanded mesenchymal stromal cells (MSCs)
6	**Nivolumab + TIL**	Adoptive Cell Therapy	Advanced Solid Tumors	Phase I	AIIMS, Delhi	Nivolumab (a PD-1 immune checkpoint inhibitor) and TIL (Tumor-Infiltrating Lymphocytes) therapy
7	**CardioRel®**	Mesenchymal Stem Cell Therapy	Cardiac Disorders	Clinical	Reliance Life Sciences	Autologous bone marrow derived mesenchymal stem cells for: Cardiac disorders
8	**NeuroRel**	Mesenchymal Stem Cell Therapy	Neurological Disorders	Clinical	Reliance Life Sciences	Autologous bone marrow mesenchymal stem cell therapy used to treat neurological disorders
9	**ReliNethra®**	Composite Limbal Epithelial Graft	Unilateral Limbal Stem Cell Deficiency	Clinical	Reliance Life Sciences	Autologous conjunctival epithelial graft for treating conjunctival disorders.
10	**Stem Cell Therapy for Type 1 Diabetes**	Mesenchymal Stem Cell Therapy	Type 1 Diabetes Mellitus	Approved for Clinical Trials	Reliance Life Sciences	Mesenchymal Stem Cells (MSCs) for Immunomodulation
11	**Gene Therapy for Hemophilia A**	Gene Therapy	Hemophilia A (FVIII deficiency)	Phase I	Christian Medical College (CMC), Vellore	Precise genome editing may provide permanent correction of the F8 gene.
12	**APCEDEN®**	Dendritic cell-based tailored immunotherapy	Prostate, Ovarian, Colorectal, and Non-small cell lung carcinoma.	Phase IV Clinical Development.	APAC Biotech Pvt. Ltd.	Autologous dendritic cell immunotherapy for treatment of solid tumors.

therapy production can currently be fully executed by raw materials made by Indian manufacturers without relying on imports. India is witnessing significant progress in cell and immunotherapy, where businesses such as VJ Biosciences and Kodo Lifescience Pvt. Ltd. are setting the standard for domestic manufacturing of vital raw materials.

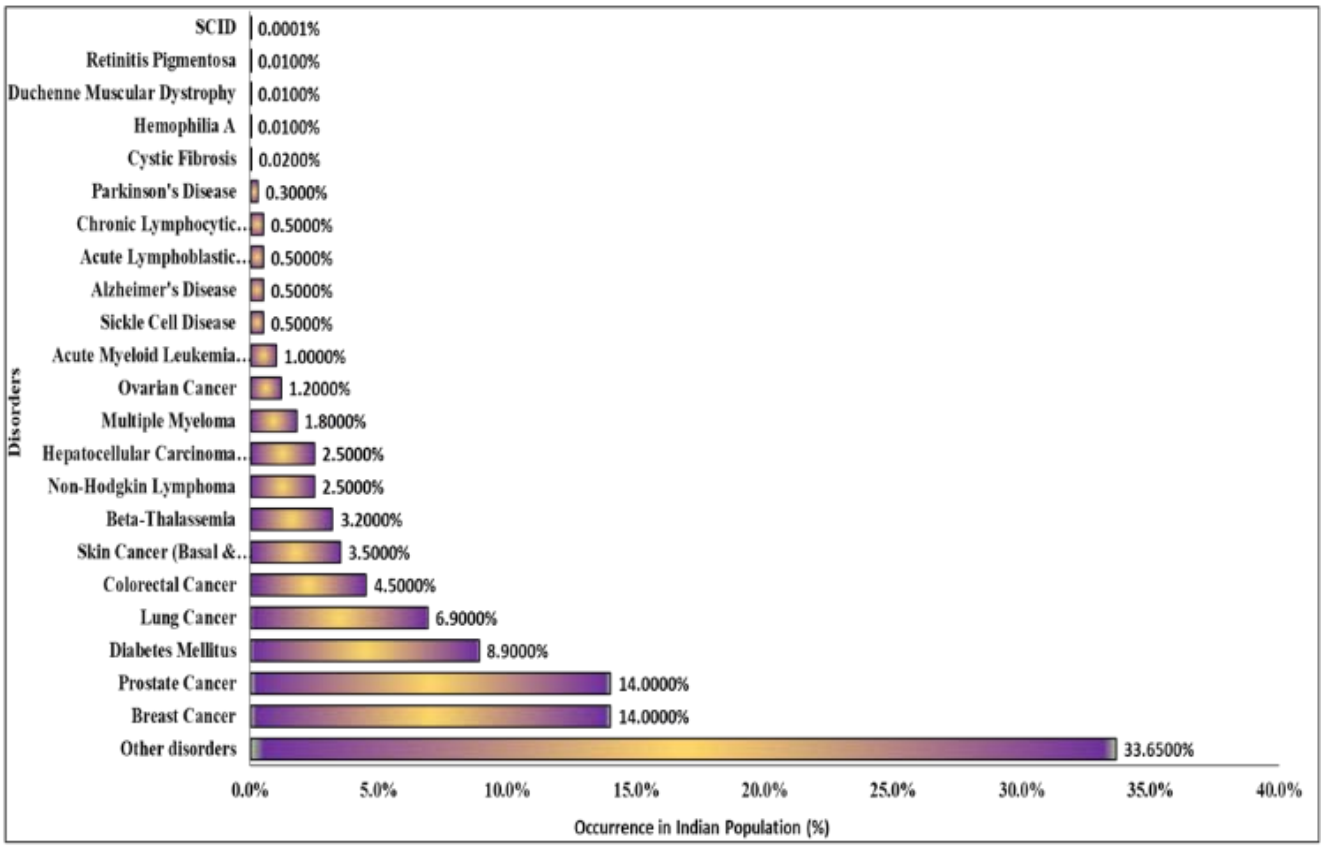

Figure 3. Disease occurrence in Indian population that has the potential to be cured with cell and gene therapy[26,33,34].

Government and private sector participation

The Indian government has taken several steps to support the growth of biotechnology and cell and immunotherapy, most notably through the Department of Biotechnology (DBT) and Biotechnology Industry Research Assistance Council (BIRAC), which provide funding and grants for R&D and technology commercialisation[36]. Initiatives like the Atal Innovation Mission (AIM) and the National Biopharma Mission aim to promote innovation and scale up biotech manufacturing in India.[37] Such endeavours have indeed set up an environment for advanced therapies to develop. The government's focus on making India a hub for biotechnology is also supported by policies such as "Make in India".

On the private sector side, India is witnessing growing involvement from established companies and start-ups in advancing cell and gene therapy products. Leading firms like Dr. Reddy Limited, Intas Pharmaceuticals, and others are investing in developing cell therapies and working on creating indigenous solutions for manufacturing critical raw materials such as viral vectors and culture media. Indian biotech companies such as ImmunoAct, Immuneel Therapeutics, and Stempeutics are innovating in the areas of CAR-T and stem cell therapies. Venture capital and private equity are driving the growth of biotech start-ups by further accelerating research and product development.

Clinical trials and research expansion

India's growing clinical trial network will speed up the global proliferation of cell therapy through the country's rich and diverse patient population [Figure 1]. This heterogeneity permits testing therapies in variegated genetic backgrounds, which, importantly, generates substantial intelligence for improving therapy efficacy and safety. Expanding research in areas such as CRISPR-based therapeutics, CAR-T treatments, and stem cell breakthroughs is critical for generating cost-effective medications adapted to the Indian healthcare environment. The Indian government has been really pushing research and developments in these areas and has invested considerable funds in programs like the National Biopharma Mission to support clinical trials and nurture innovation.

Regulatory advancements

Dedicated regulatory guidelines provide many opportunities for the growth of the global leadership of cell therapy in India. The government has realised that guidelines are required to promote innovations while safeguarding cell therapy products with safety, efficacy, and quality.[38] These regulatory improvements create an environment conducive to developing, manufacturing, and approving cutting-edge therapies. The

Biological Research Regulatory Approval Portal (BioRRAP) scheme is commissioned under the Department of Biotechnology (DBT), India. The project aims to establish a system that would facilitate streamlining of regulatory aspects concerning proceedings required for any biological research. The clearance process takes place by providing technology support, which enables tracking the entire progress in clearance and brings more accountability for the researcher. In India, the Central Drugs Standard Control Organization (CDSCO), which is associated with the licensing of drugs and pharmaceutical products, has positively improved its approval process for cell therapies. It has also streamlined the procedures for accelerating the clinical trial approval process for innovative therapy, facilitating more available access to patients at an earlier time.[39,40] Initiatives like the Clinical Trials Registry - India (CTRI) and the New Drug and Clinical Trial Rules 2019 have improved the transparency and efficiency of clinical trials in the country, making India an attractive destination for global clinical research.[41] India is actively working on aligning its regulatory processes with international standards through collaboration with global regulatory agencies such as the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA). This alignment enables Indian biotech firms to develop globally competitive cell therapy products and simplifies the process of entering international markets.

Talent pool and research institutions

India has equipped its talent assets and research institutions with an opportunity to emerge as a global leader in cell and gene therapy. It has a labour pool of various skilled professionals along with a budding yet extensive network of academic institutions, all set to create capacity in cell therapy innovation.[42] The country has a robust biotechnology workforce, including scientists, engineers, clinicians, and biotech entrepreneurs, many of whom are being trained at leading research institutions like the Indian Institutes of Technology (IITs), Indian Institute of Science (IISc), and National Institute of Immunology (NII) and Institutes of eminence (IoEs). These institutions provide world-class research in genetics, cell biology, bioprocessing, and gene editing. Research institutions in India are increasingly becoming centres of excellence for cutting-edge work in gene therapy, stem cell therapies, and gene editing technologies like CRISPR/Cas9.[43] Collaborative efforts between these institutions and the private sector, including companies such as Biocon, Immuneel Therapeutics, and Stempeutics, create a conducive environment for translational research, taking breakthroughs from the laboratory to clinical trials. The Indian Council of Medical Research (ICMR) and other public-private partnerships are helping accelerate the development of cell therapy products tailored to Indian and global markets.

CHALLENGES FOR CELL THERAPY IN INDIA

Cost and accessibility

The very high cost of advanced cell therapies such as immunotherapy and CAR-T cell therapies imposes a potentially massive barrier to their introduction in India. These therapies tend to exceed several million rupees per patient, making them financially unfeasible for most individuals.[44] Such high costs are due to imported raw materials, expensive manufacturing processes, and a limited production capacity within the country.[41] Cost is further inflated by the transportation of patient-specific cells across the production facility because of the centralized manufacturing model that is typically used for these therapies.[42] There is no reimbursement for the treatment cost from government funds or health insurance, thus making the large number of patients unaffordable. Accessibility is also complicated by the uneven distribution of healthcare facilities qualified to provide such complex procedures.

Infrastructure gaps

The cell therapy field still has a way to go for India as it has not developed an infrastructure that can support such developments. There are no specialized ones for the large-scale manufacturing of complex biologics such as CAR-T cells, which are very crucial elements needed for quality and scalability of the product.[14] Facilities constructed according to Good Manufacturing Practice (GMP) standards are expensive and technically complex. Another drawback is that India does not have a good logistics network designed for biological products, thus making the wider accessibility of these therapies impossible. Cell and immunotherapies often require stringent temperature controls and time-sensitive transportation to maintain their efficacy. Less infrastructural support for such specialized requirements restricts the geographic reach of these treatments, particularly to remote and rural areas.

Regulatory and ethical challenges

The regulatory environment for cell therapy in India remains complicated and slow-moving. Innovative requirements and complex treatment modalities are the reasons behind such conditions. The approval process lacks streamlined protocols and various clinical evidence, which delays the market launches of innovative therapies. Regulators face the challenge of encouraging inventions while ensuring patient safety through long evaluation times and decreased clarity for developers. Ethical consideration is yet another factor that complicates the use of these therapies, especially involving genetically modified cells in treatment. The manipulation of human cells raises ethical problems that might have unexpected consequences for people and their future generations. Genetically engineered germline treatments create irreversible genetic modifications that can be transmitted to the upcoming generations. Given our present understanding of long-term implications on health or society, this is a crucial concern. Fear of uncontrolled genetic modifications leading to potentially disastrous medical or societal outcomes have heightened public anxiety. Debates over embryonic versus induced pluripotent stem cell usage continue, and advances using the latter method potentially avoid certain controversies.[45]

Strong regulatory frameworks that address both scientific uncertainty and societal unease are necessary to navigate these complexities effectively; therefore, policymakers must involve stakeholders from a variety of disciplines to ensure that informed decision-making processes remain transparent while adequate safeguards are in place to prevent misuse, as it has the potential to create heritable genetic changes. Thus, policymakers and other

stakeholders are concerned about the balance between the transformation potential of new technologies and the possibility of unforeseen repercussions.

Public awareness and acceptance

The adoption of cell and immunotherapy in India continues to face several obstacles. This is majorly due to limited public awareness and understanding of these advanced treatments.[46] Many individuals remain unfamiliar with the science behind these therapies, which can lead to misconceptions and skepticism. There are also other inhibiting factors, such as efficacy, safety, and side effects. The perception that these therapies are highly priced adds to the misconception that it is only for the privileged part of society and can only decrease interest and trust in the therapy. Healthcare professionals, too, might sometimes face knowledge gaps regarding the latest advancements in cell therapy, which limits their ability to recommend these treatments to patients confidently. Primary care providers and clinicians working in rural or underserved areas are mainly affected by this limited knowledge about available therapies, with little or no exposure to these therapies. With the potential such therapies have, cancer treatments in India are revolutionized; still, they go underutilized.

Global collaborations

Global collaboration continues to play an important role in developing cell and immunotherapies in India, but the current extent of outreach remains limited. Much development, in fact, has been achieved through partnerships with biotechnology companies and research institutes from abroad, but this is very little against the immense possibilities. This lack of extensive collaboration restricts access to advanced technologies, innovative therapeutic platforms, and critical knowledge needed for these therapies' rapid development and deployment in India.[47] India struggles to bridge the expertise gap in cell engineering and large-scale manufacturing without strong global partnerships. These limitations slow the pace of technology transfer and impede the localization of advanced production techniques, essential for reducing costs and increasing accessibility. Limited exposure to global standards further deters India's clinicians and researchers from getting up-to-date innovations and modern best practices through participating in ongoing worldwide clinical trials and research. The very limited integration of India with the global community adversely affects the cell therapy sector. Without exposure to the established supply chains, regulatory practices, and quality standards of developed markets, India faces real challenges in making strides in global reach. Such exposure equally discourages foreign investors and companies from entering collaborative relations with Indian firms, creating a cycle of hampered growth.

FUTURE DIRECTIONS AND RECOMMENDATIONS

In order to unlock the total capabilities of cell therapies in India, a number of strategic fields require urgent priority and development[48]. Which are:

Development of affordable therapies

Reducing the high cost of cells and immunotherapies is the most important step in enhancing accessibility. Investment in domestic manufacturing plants and innovation for affordable production techniques is essential. Diligent control of producing critical materials like cell culture media, viral vectors, and gene-editing reagents consolidated the reliability of a supply chain while reducing import dependence and further reducing costs.[49] The localization of these therapies would make them available to more people and increase India's competitiveness globally. Through the development of innovation in scalable and effective manufacturing methods, India can become a global leader in the CGT industry, facilitating broader access to innovative treatments.

Infrastructure development

Expanding infrastructure for cell and immunotherapies is important in order to provide access to these treatments all over India. One such aspect of this is the creation of additional Good Manufacturing Practice (cGMP)-compliant facilities with large-scale production capability dedicated to these products.[50] The facilities need to be international-standard-compliant so that therapies remain safe, effective, and of good quality. They also need to allow for large-scale production to address increasing demand. These investments will increase local production and make India more competitive in the international market.

Improvement of the logistics network, especially the cold chain infrastructure, is going to be an essential requirement for intangible money conservation of biologics products since they are transported under controlled temperature conditions.[51] According to India's geography, a guarantee for treatment delivery is very much required in both urban and rural areas. Investments in regional distribution centres and transport will address these problems and lower the costs of logistics.

Public-private collaborations and government assistance in creating such infrastructure will be the key to speeding up the availability and accessibility of cell and gene therapies throughout the nation.[52] Augmenting infrastructure with other measures like cost reduction, regulatory harmonization, and workforce training will make India a global leader in the CGT industry.

Regulatory reform

Simplifying the approval process for new therapies and setting more clear-cut ethical guidelines are key measures to enable the quicker adoption of cell and gene therapies in India.[53] Although changing, CGT's existing regulatory framework is still convoluted and time-consuming. To speed up the entry of these revolutionary therapies, regulatory agencies need to establish clear, standardized routes for approval that take into account the novel nature of gene-editing and cell-based therapies.[54]

A Progressive regulatory framework that fosters innovation and patient safety will enhance access to cutting-edge care and make India a world leader in ethical and responsible cell and gene therapy research. Convergence of Indian regulation with global best practices will also enable global collaborations, bring foreign investment, and keep India at the vanguard of CGT innovation.

Education and awareness

Public and healthcare professionals' education campaigns will be vital to improving understanding and acceptance of advanced

cell and gene therapies (CGT) in India. Inadequate knowledge of the science behind these therapies contributes to their misconceptions and, thus, to the hesitance among some patients and healthcare providers.[9] Initiatives for public education should explain CGT's benefits, safety, and the rigorous processes by which they are developed and tested. These campaigns could use a host of platforms, like digital media, community outreach, and traditional media, to target urban and rural populations and generate a broad base of awareness.[55] In parallel, such teaching must also extend to primary care providers, clinicians, and specialists about the latest advances in cell therapy. Such an effort could include detailed instructions concerning gene-editing technologies, indications for therapy, and the process of administering the therapy. Well-informed healthcare providers will be able to help patients navigate the uncertainties surrounding their therapy options and clinical trials.[9]

Clinical trials are critical for promoting CGT, and growing public trust and engagement in these trials will further promote sustained research and access to new therapies. Whenever the general public and medical community are sufficiently educated, then India can expect increased acceptance and integration of these therapies into the healthcare system, improving patient outcomes while establishing itself as a pioneer in this flourishing field.

International partnerships

Stable partnerships with the world's top biotechnology organizations and research entities are important if India aims to continue leading innovation in cell and immunotherapy.[56] Such collaborations may enable knowledge exchange, technology sharing, and sharing of expertise, allowing the country to bring advanced therapies more quickly to its people.[57] Through collaboration with global leaders in the subject matter, Indian researchers and medical practitioners have access to advanced technologies, such as gene-editing tools and new therapeutic platforms, that may not be so easily accessed domestically.[58]

These collaborations might assist in overcoming local issues, including the high price of immunotherapeutic products, lack of infrastructure, and regulatory challenges.[59] With joint ventures as well as strategic partnerships, India can leverage common resources, such as access to international clinical trials, advanced manufacturing techniques, and patient care expertise.[47] Global alliances will also make India recognisable in the worldwide framework, enabling the country to attract foreign investment, which can help develop a robust indigenous industry.

Research and healthcare collaborations

An active partnership among healthcare professionals and researchers is critical for pushing forward cell and immunotherapy in India[60]. Partnerships will enable the transfer of new research into tangible practice and the proper implementation of new drugs in clinical practice. Integrating scientific understanding with realistic delivery of healthcare will enhance innovation and patient care in the rapidly evolving cell and immunotherapy arena.[61]

CONCLUSION

Cell therapies hold the potential to transform healthcare in India, offering personalized and curative treatments for a wide range of genetic and complex diseases. While India has made significant progress in developing and applying these therapies, challenges such as high costs, infrastructure limitations, and slow regulatory processes must be addressed. These therapies hold significant promise to revolutionize healthcare for a large mass of people in India and offer personalized and curative treatments for a huge basket of genetic and complex diseases. India has made great progress in developing and applying these therapies, but challenges such as very high costs, limitations imposed by infrastructure, and slow-moving regulatory processes need to be addressed. By fostering innovation, strengthening regulatory frameworks, and improving public awareness, India can become a global leader in regenerative medicine, ensuring that advanced therapies are accessible to all.

AUTHOR CONTRIBUTIONS

The original draft was prepared by TH and SV; PS and AB helped with the data extraction and background search; SG and DS reviewed and revised the overall manuscript. The final manuscript was read and approved by all the authors.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

ACKNOWLEDGMENTS

We sincerely thank our colleagues at Promea Therapeutics for their valuable insights and support. We also acknowledge the contributions of researchers and institutions advancing cell and gene therapy in India and worldwide. Lastly, we appreciate the encouragement from our collaborators, and peers.

REFERENCES AND NOTES

1. Wang, L. L. W., Janes, M. E., Kumbhojkar, N., Kapate, N., Clegg, J. R., Prakash, S., ... & Mitragotri, S. (2021). Cell therapies in the clinic. *Bioengineering & translational medicine*, *6*(2), e10214.
2. El-Kadiry, A. E. H., Rafei, M., & Shammaa, R. (2021). Cell therapy: types, regulation, and clinical benefits. *Frontiers in Medicine*, *8*, 756029.
3. Brooks, P. J., Urv, T. K., & Parisi, M. A. (2023). Gene-targeted therapies: Overview and implications. In *American Journal of Medical Genetics Part C: Seminars in Medical Genetics* (Vol. 193, No. 1, pp. 13-18).
4. Tao, R., Han, X., Bai, X., Yu, J., Ma, Y., Chen, W., ... & Li, Z. (2024). Revolutionizing cancer treatment: enhancing CAR-T cell therapy with CRISPR/Cas9 gene editing technology. *Frontiers in Immunology*, *15*, 1354825.
5. Sun, D., Shi, X., Li, S., Wang, X., Yang, X., & Wan, M. (2024). CAR-T cell therapy: A breakthrough in traditional cancer treatment strategies. *Molecular Medicine Reports*, *29*(3), 47.
6. Hendricks, C. L., Alessandrini, M., & Pepper, M. S. (2023). Equitable access to cell and gene therapies in South Africa: opportunities and hurdles. *Gene Therapy*, *30*(1), 180-186.
7. Aggarwal, S., & Phadke, S. R. (2015). Medical genetics and genomic medicine in India: current status and opportunities ahead. *Molecular genetics & genomic medicine*, *3*(3), 160.
8. Sharma, V., Kumar, B., Pandey, S. K., Choudhry, V. P., & Saxena, R. 49th Annual Conference of Indian Society of Hematology & Transfusion Medicine. *Indian J. Hematol. Blood Transfus*, *24*(3), 86-145.

9. Aiyegbusi, O. L., Macpherson, K., Elston, L., Myles, S., Washington, J., Sungum, N., ... & Calvert, M. J. (2020). Patient and public perspectives on cell and gene therapies: a systematic review. *Nature communications*, *11*(1), 6265.
10. Jain, H., Karulkar, A., Sharma, N., Sengar, M., Jaiswal, A., Shah, S., ... & Shah, N. N. (2022). Phase I trial of humanized CD19 CART-cell therapy developed in india: safe, active and feasible for outpatient therapy. *Blood*, *140*(Supplement 1), 10332-10334.
11. Ribeiro, B. F., da Cruz, B. C., de Sousa, B. M., Correia, P. D., David, N., Rocha, C., ... & Vieira, S. I. (2023). Cell therapies for spinal cord injury: a review of the clinical trials and cell-type therapeutic potential. *Brain*, *146*(7), 2672-2693.
12. Weng, L. (2023). Cell therapy drug product development: technical considerations and challenges. *Journal of Pharmaceutical Sciences*, *112*(10), 2615-2620.
13. Boopalan, D., Pandian, R., & Kesavan, G. (2021). Prospects for Stem Cell-Based Regenerative Therapies in India. *Stem Journal*, *3*(1), 11-21.
14. Ravindranath, A., Dubey, A., Suresh, S., Chaudhuri, G., & Chirmule, N. (2022). CAR-T cell therapy in India requires a paradigm shift in training, education and health care processes. *Cytotherapy*, *24*(2), 101-109.
15. Friedmann, T., & Roblin, R. (1972). Gene Therapy for Human Genetic Disease? Proposals for genetic manipulation in humans raise difficult scientific and ethical problems. *Science*, *175*(4025), 949-955.
16. Delhove, J., Osenk, I., Prichard, I., & Donnelley, M. (2020). Public acceptability of gene therapy and gene editing for human use: a systematic review. *Human gene therapy*, *31*(1-2), 20-46.
17. McFadden, B. R., Rumble, J. N., Stofer, K. A., & Folta, K. M. (2024). US public opinion about the safety of gene editing in the agriculture and medical fields and the amount of evidence needed to improve opinions. *Frontiers in Bioengineering and Biotechnology*, *12*, 1340398.
18. Iglesias-Lopez C, Agustí A, Vallano A, Obach M. Current landscape of clinical development and approval of advanced therapies. Mol Ther Methods Clin Dev. 2021;23: 606–618.
19. Ginn, S. L., Alexander, I. E., Edelstein, M. L., Abedi, M. R., & Wixon, J. (2013). Gene therapy clinical trials worldwide to 2012–an update. *The journal of gene medicine*, *15*(2), 65-77.
20. Palada, B. (2020). Bright Outlook for the Global Cell and Gene Therapy Market: Factors accelerating market growth include successful product launches, a favorable regulatory environment, and sizable investments in research and development. *Genetic Engineering & Biotechnology News*, *40*(S2), S6-S8.
21. Sainatham, C., Yadav, D., Dilli Babu, A., Tallapalli, J. R., Kanagala, S. G., Filippov, E., ... & Lutfi, F. (2024). The current socioeconomic and regulatory landscape of immune effector cell therapies. *Frontiers in Medicine*, *11*, 1462307.
22. Chen, K., Wang, S., Qi, D., Ma, P., Fang, Y., Jiang, N., ... & Li, N. (2022). Clinical investigations of CAR-T cell therapy for solid tumors. *Frontiers in immunology*, *13*, 896685.
23. Jayaraman, K. (2009). pagina 1 van 1 India's first true stem cell trials: Article: Nature Biotechnology. *Nature Biotechnology*, *27*, 498.
24. Kilic, T., Coskun, S., Mirzamidinov, D., Yilmaz, I., Yavuz, S., & Sahin, T. (2024). Myval Transcatheter Heart Valve: The Future of Transcatheter Valve Replacement and Significance in Current Timeline. *Journal of Clinical Medicine*, *13*(22), 6857.
25. Lei, T., Wang, Y., Zhang, Y., Yang, Y., Cao, J., Huang, J., ... & Wang, L. (2024). Leveraging CRISPR gene editing technology to optimize the efficacy, safety and accessibility of CAR T-cell therapy. *Leukemia*, 1-27.
26. Selot, R., & Ghosh, A. (2024). Recent developments in gene therapy research in India. *Journal of Biosciences*, *49*(1), 37.
27. Bulcha, J. T., Wang, Y., Ma, H., Tai, P. W., & Gao, G. (2021). Viral vector platforms within the gene therapy landscape. *Signal transduction and targeted therapy*, *6*(1), 53.
28. Bhattacharyya, P., Mehndiratta, K., Maiti, S., & Chakraborty, D. (2024). Rare genetic disorders in India: Current status, challenges, and CRISPR-based therapy. *Journal of Biosciences*, *49*(1), 28.
29. Srivastava, M. V. P., & Dash, D. (2015). History of neurology at All India Institute of Medical Sciences. *Neurology India*, *63*(5), 751-761.
30. Gupta, P., Goswami, S. G., Kumari, G., Saravanakumar, V., Bhargava, N., Rai, A. B., ... & Ramalingam, S. (2024). Development of pathophysiologically relevant models of sickle cell disease and β-thalassemia for therapeutic studies. *Nature Communications*, *15*(1), 1794.
31. Basu, B., & Basu, B. (2020). Scientists at Work in India. *Biomaterials Science and Implants: Status, Challenges and Recommendations*, 59-87.
32. Uppal, A., Chakrabarti, R., Chirmule, N., Rathore, A., & Atouf, F. (2021). Biopharmaceutical industry capability building in India: report from a symposium. *Journal of Pharmaceutical Innovation*, 1-8.
33. Bhattacharyya, P., Mehndiratta, K., Maiti, S., & Chakraborty, D. (2024). Rare genetic disorders in India: Current status, challenges, and CRISPR-based therapy. *Journal of Biosciences*, *49*(1), 28.
34. Kar, A., Sundaravadivel, P., & Dalal, A. (2024). Rare genetic diseases in India: Steps toward a nationwide mission program. *Journal of Biosciences*, *49*(1), 34.
35. Lipsitz, Y. Y., Bedford, P., Davies, A. H., Timmins, N. E., & Zandstra, P. W. (2017). Achieving efficient manufacturing and quality assurance through synthetic cell therapy design. *Cell Stem Cell*, *20*(1), 13-17.
36. Differding, E. (2023). Biotechnology in India: An Analysis of 'Biotechnology Industry Research Assistance Council'(BIRAC)-Supported Projects. *ChemBioChem*, *24*(21), e202300302.
37. Phatak, A., & Mane, V. (2022). Creativity, innovation, and cross-cultural collaboration in atal innovation mission. *International Journal of Academic Research and Development*, *7*(5), 53-56.
38. Dalal, V., Lata, H., Kharkwal, G., & Jotwani, G. (2023). Regulation of Clinical Research for Cellular and Gene Therapy Products in India. *Regulatory Aspects of Gene Therapy and Cell Therapy Products: A Global Perspective*, 135-154.
39. Pandit, K. R., & Nisar, A. (2024). Regulatory framework for developing cell & gene therapy products in India. *Cytotherapy*, *26*(6), S186.
40. Lohmor, S., Verma, R., Malik, V., & Kaushik, D. (2020). Current status of regulatory perspectives on stem cell therapy in India. *Chemical Biology Letters*, *7*(3), 176-182.
41. Rao, M. V. V., Maulik, M., Gupta, J., Panchal, Y., Juneja, A., Adhikari, T., & Pandey, A. (2018). Clinical Trials Registry–India: an overview and new developments. *Indian Journal of Pharmacology*, *50*(4), 208-211.
42. Gupta, R. (2009). Leveraging Indian talent pool and demographics to build competitive advantage. *Education, Knowledge & Economy*, *3*(3), 213-229.
43. Rajgharhia, A., Nandana, N., Parakh, P., Sachdev, S., Sravan, T., Singh, N., & Kaur, N. (2024). National innovation system for CRISPR genome editing research in India: an empirical analysis. *Current Science (00113891)*, *127*(6).
44. Cornetta, K., Patel, K., Wanjiku, C. M., & Busakhala, N. (2018). Equitable access to gene therapy: a call to action for the American Society of gene and cell therapy. *Molecular Therapy*, *26*(12), 2715-2716.
45. Kumar, R., Saha, T., Chaturvedi, A., Singh, A., & Kumar, D. (2024). Deciphering the frontiers of stem cell research in regenerative medicine. *Chemical Biology Letters*, *11*(4), 673-673.
46. Holland, S. M., Sohal, A., Nand, A. A., & Hutmacher, D. W. (2024). A quest for stakeholder synchronization in the CAR T-cell therapy supply chain. *Frontiers in Bioengineering and Biotechnology*, *12*, 1413688.
47. Mazumdar-Shaw, K. (2018). Leveraging affordable innovation to tackle India's healthcare challenge. *IIMB Management Review*, *30*(1), 37-50.
48. Gonçalves, G. A. R., & Paiva, R. D. M. A. (2017). Gene therapy: advances, challenges and perspectives. *Einstein (Sao Paulo)*, *15*, 369-375.
49. Mitchell, A. P., & Goldstein, D. A. (2022). Cost savings and increased access with ultra-low-dose immunotherapy. *Journal of Clinical Oncology*, *41*(2), 170.
50. Iancu, E. M., & Kandalaft, L. E. (2020). Challenges and advantages of cell therapy manufacturing under good manufacturing practices within the hospital setting. *Current opinion in biotechnology*, *65*, 233-241.

51. Pajic V, Andrejic M, Chatterjee P. Enhancing cold chain logistics: A framework for advanced temperature monitoring in transportation and storage. Mechatron Intell Transp Syst. 2024;3: 16–30.
52. Cornetta, K., Bonamino, M., Mahlangu, J., Mingozzi, F., Rangarajan, S., & Rao, J. (2022). Gene therapy access: Global challenges, opportunities, and views from Brazil, South Africa, and India. *Molecular Therapy*, *30*(6), 2122-2129.
53. StollElizabeth, A. (2017). A guide to approaching regulatory considerations for lentiviral-mediated gene therapies. *Human gene therapy methods*.
54. Drago, D., Foss-Campbell, B., Wonnacott, K., Barrett, D., & Ndu, A. (2021). Global regulatory progress in delivering on the promise of gene therapies for unmet medical needs. *Molecular Therapy Methods & Clinical Development*, *21*, 524-529.
55. Cornetta, K., Kay, S., Urio, F., Minja, I. K., Mbugi, E., Mgaya, J., ... & Jayandharan, G. R. (2023). Implementation of a gene therapy education initiative by the ASGCT and Muhimbili University of Health and Allied Sciences. *Molecular Therapy*, *31*(9), 2561-2565.
56. Vale, R. D., & Dell, K. (2009). The biological sciences in India: aiming high for the future. 342-353
57. Panda, S., Singh, P. K., Mishra, S., Mitra, S., Pattnaik, P., Adhikary, S. D., & Mohapatra, R. K. (2023). Indian biosimilars and vaccines at crossroads–replicating the success of pharmagenerics. *Vaccines*, *11*(1), 110.
58. Shukla-Jones, A., Friedrichs, S., & Winickoff, D. E. (2018). Gene editing in an international context: Scientific, economic and social issues across sectors. *OECD science, technology and industry working papers*, *2018*(4), 0_1-51.
59. Harrison, R. P., Ruck, S., Medcalf, N., & Rafiq, Q. A. (2017). Decentralized manufacturing of cell and gene therapies: Overcoming challenges and identifying opportunities. *Cytotherapy*, *19*(10), 1140-1151.
60. Poddar, A., & Rao, S. R. (2025). Overcoming barriers of cervical cancer elimination in India: A practice to policy level advocacy. *Journal of Cancer Policy*, *43*, 100521.
61. Proctor, E. K., McKay, V. R., Toker, E., Maddox, T. M., Hooley, C., Lengnick-Hall, R., ... & Evanoff, B. (2021). Partnered innovation to implement timely and personalized care: a case study. *Journal of Clinical and Translational Science*, *5*(1), e121.

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