Quest Journals
Journal of Research in Pharmaceutical Science
Volume 9 ~ Issue 9 (2023) pp: 07-15
ISSN(Online) : 2347-2995
www.questjournals.org

Research Paper

Regulatory Process and Considerations for Gene Therapy Clinical Trials in India

Ganesh Ashok Chepuri[1], Gaurav SanjayraoMude[2]

1. *Clinical Research Department, School of Allied Health Sciences, DattaMeghe Institute of Higher Education and Research, Sawangi (Meghe), Wardha, Maharashtra, India. Pin code: 442001*
2. *Pharmacology Department, DattaMeghe College of Pharmacy, DattaMeghe Institute of Higher Education and Research, Sawangi (Meghe), Wardha, Maharashtra, India. Pin Code: 442001*

**Corresponding Author: Ganesh Ashok Chepuri[1]*
Clinical Research Department, School of Allied Health Sciences, DattaMeghe Institute of Higher Education and Research, Sawangi(Meghe), Wardha, Maharashtra, India. Pin code: 442001

ABSTRACT
Gene therapy is an emerging technology that has significant potential for treating a wide range of diseases in a novel way. Clinical trials for gene therapy have specific challenges that must be addressed in order to meet regulatory criteria. Gene Therapy Products (GTPs) are complicated biomedicines and require rigorous scientific evaluation to assess safety and efficacy.
Clinical trials play a curious role in the development of GTPs. Clinical Trials of GTPs are regulated under Drug and Cosmetic Act 1940, Drug and Cosmetic Rules 1945, and New Drugs and Clinical Trials Rules 2019. The following documents contain the set of rules, which are mandatory and that need to be followed while conducting the GTPs clinical trial. Permission for conducting the clinical trials of GTPs is granted by the Central Licensing Authority, which is a regulatory body in India.
Regulatory bodies should not be viewed as stumbling blocks, but rather as collaborators whose recommendations can considerably accelerate product development. Before and during the study, several committees and regulatory organizations analyze and approve gene therapy clinical studies, allowing for continuing risk evaluation of these novel products. The regulatory process for conducting clinical trials of gene therapy products is ambiguous. The regulatory process involves multiple steps including the submission of detailed applications, different committee approvals, and adherence to established guidelines. As gene therapy continues to evolve and expand, collaboration between researchers, regulatory authorities and ethical oversight bodies remains crucial.
Keywords: *Clinical Trials, Gene therapy products, Gene therapy, Guidelines, Regulatory*

***R**eceived 26 August, 2023; **R**evised 05 Sep., 2023; **A**ccepted 07 Sep., 2023 © The author(s) 2023.*
P**ublished with open access at **www.questjournals.org

I. INTRODUCTION

The science of gene therapy has gained momentum in recent decades as a result of the rapid discovery of a large number of genes that are mutated in a variety of disorders. To construct gene therapy for human applications, a vast depth of scientific knowledge is required, to establish an optimum strategy, to cure diverse diseases or disorders that are difficult to cure or incurable. [(1)] Looking at the evolution of gene therapy throughout the last century, it appears that we have entered a new age, as indicated by the increasing number of licensed gene therapy products in the recent decade. Bringing a promising GTP from the laboratory into the clinic can present unique challenges, as they are highly regulated. [(2)]

Gene is the fundamental and functional unit of heredity and inheritance. It is made up of a specific sequence of nucleotides in DNA or RNA that are found on chromosomes and encode for specific proteins. The human genome has around 20,000 genes. [(3)] The defects in an individual's genes cause inherited diseases. Down syndrome, sickle cell anemia, muscular dystrophies, blindness, thalassemia, etc. are common genetic diseases. [(4)]

Millions are impacted each year by inherited monogenic or complicated diseases with few or no treatment choices. Genetic disorders are linked to lifetime disability and pose a considerable economic burden on the community and the health care system. [(5, 6)] Monogenic diseases are more prevalent in India. These

include thalassemia (β thalassemia), haemophilia (haemophilia A), sickle-cell anemia, retinitis pigmentosa, muscular dystrophies, lysosomal storage disorders, primary immunodeficiency (PID) in children, etc. [7] Cancer and other multifactorial diseases are also very prevalent in India. [8]

In India, it is estimated that approximately 72 to 96 million individuals may be impacted by rare diseases. Rare diseases affect 6-8% of the world's population, according to international estimates. [9, 10] Gene therapy has begun to become an effective therapy for hereditary illnesses. Gene Therapy is the process of introducing, removing, or changing the composition of an individual's genetic material in order to treat a disease with the intent to achieve a long-term cure. Gene therapy product (GTP) is defined as any entity containing a nucleic acid component that is administered in multiple ways for therapeutic effect. Gene therapy works by inserting therapeutic genes into the cells of a patient to replace missing or faulty genes. [11, 12]

The introduction of a gene into a cell requires the use of a vector, which acts as a vehicle or agent that transports the gene. Because viruses have an inherent ability to deliver nucleic acid cargo to specific cell types, they are used as vectors or vehicles to move genetic material inside cells. In advance, these viruses are altered in order to eliminate their ability to infect the patient with any kind of infectious disease. Gene therapy has been neglected for a long time, due to the uncertain or poor commercial outcomes. Gene therapy is emerging in India and this article serves to outline the regulatory process and considerations for conducting gene therapy clinical trials in India.

CLINICAL TRIALS OF GENE THERAPEUTIC PRODUCTS (GTPs)

The initial successful gene therapy clinical study for severe combined immunodeficiency was undertaken in 1989 at the NIH Clinical Centre. [13, 14] As per recent data, worldwide over 3800 gene therapy clinical studies were approved. America accounted for 53.3%, Asia 20.2%, and Europe 17.9% (Table 1). In Asia, China contributed the major part in conducting the clinical studies on gene therapy, followed by Japan (Table 2). As far as India is considered 5 gene therapy clinical trials are approved (Table 3). [15]

Table 1 : Geographical Distribution of Gene Therapy Clinical Trials by Continent

Continent	No. of Trials	%
America	2039	53.3
Asia	773	20.2
Europe	683	17.9
Australia	43	1.1
Africa	7	0.2
Multi-Country	281	7.3
Total	**3826**	**100**

Table 2 : Geographical Distribution of Gene Therapy Clinical Trials by Top 10 Countries

Countries	No. of Trials	%
United States	2000	52.3
China	651	17
UK	245	6.4
Germany	115	3.0
France	66	1.7
Japan	55	1.4
Switzerland	50	1.3
Spain	45	1.2
Netherland	41	1.1
Italy	39	1.0
Other Countries	238	6.2
Multi-Country	281	7.3
Total	**3826**	**100**

Gene therapy clinical trials are mainly targeting cancer diseases (68.5%) followed by monogenic diseases (12.80%) (Figure 1). As it is a new emerging field, most of the gene therapy clinical trials are in Phase 1 and Phase 1/2 (Figure 2). [15] Gene therapy is permitted in India if it is carried out in an ethical, scientific, and safe manner in accordance with national guidelines and with the necessary regulatory licenses.

The Central Drugs Standard Control Organization (CDSCO) under the Ministry of Health and Family Welfare (MHFW) has issued the New Drugs and Clinical Trials Rules, 2019 (NDCT 2019), which describe gene therapy as a "new drug." Concurrently, the ICMR (Indian Council of Medical Research) and DBT (Department of Biotechnology) took the lead in developing the 'National Guidelines for Gene Therapy Product Development and Clinical Trials 2019'. In India, gene therapy can be developed with scientific advice from the Gene Therapy Advisory and Evaluation Committee (GTAEC) and financial backing from several funding

bodies such as the Indian Council of Medical Research (ICMR), the Department of Biotechnology (DBT), and the Department of Science and Technology (DST).

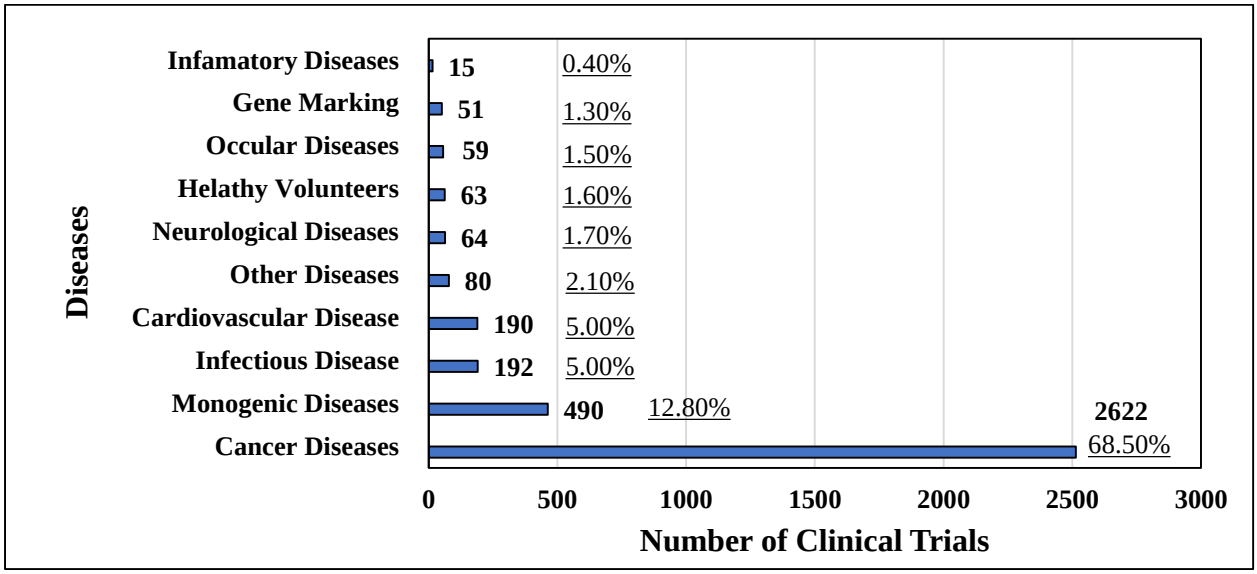


Figure 1: Indications Addressed by Gene Therapy Clinical Trials

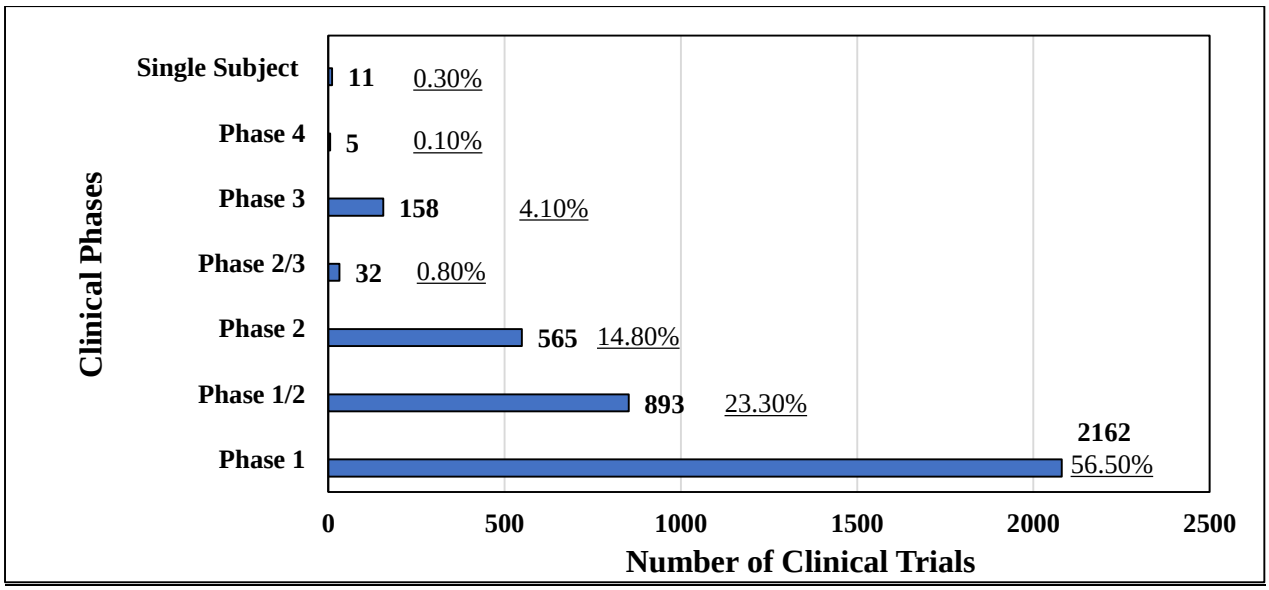


Figure 2: Clinical Phases of Gene Therapy Clinical Trials

Table 3 : India Status in Gene Therapy Clinical Trials			
Phase	**Diseases**	**No. of Trials**	**%**
Phase 1	Cancer Diseases	3	60
Phase 1/2	Monogenic Diseases	2	40
Total		**5**	**100**

REGULATORY PROCESS OF GTP CLINICAL TRIALS

Gene Therapeutic Product (GTP) intended to be used as a drug falls under the definition of 'new drug' as per NDCT 2019 guidelines. A person or institution or organization intends to conduct a clinical trial of a Gene

Therapeutic Product (GTP) shall be required to have permission granted by the Central Licensing Authority (i.e. Drug Controller General of India - DCGI) and Ethics Committee mainly. [16] [17]

Whoever is associated with the Gene Therapeutic Product (GTP) trial needs to follow the First Schedule of NDCT 2019 i.e. General principles and practices for clinical trial. This section mainly discusses about the general principles, approach in design and analysis, development methodology, the conduct of the clinical trial, analysis, and reporting. Clinical trial of gene therapy shall be conducted in accordance with the procedure prescribed under the provisions of the act and rules of NDCT 2019 and other applicable guidelines. [16] Figure 3 gives the overview of the entire regulatory approval pathway for gene therapy trials.

Steps involved in GTP clinical trial [18]

- Selection of patient as per protocol requirement and history of the disease.
- Background of genetic or family history
- Staging of disease or classification
- Drug administration route
- Immune response and GTP toxicity
- GTP Efficacy
- Analysis of risk and benefit

CENTRAL LICENSING AUTHORITY

The Central Licensing Authority (CLA) or National Regulatory Authority (NRA) of India is the Central Drugs Standard Control Organization (CDSCO) under the Directorate General of Health Services, Ministry of Health & Family Welfare, Government of India. CDSCO is in charge of approving new drugs and clinical trials, developing drug standards, monitoring the quality of imported drugs in the country, and coordinating the activities of State Drug Control Organizations by providing expert advice to achieve uniformity in the enforcement of the Drugs and Cosmetics Act. The DCGI (Drug Controller General of India) is responsible for giving permissions for the conduct of clinical trials of GTP.

Application for Permission to Conduct Clinical Trial of GTP

Any individual, institution, or organization that wishes to carry out a clinical trial of a Gene Therapeutic Product (GTP) shall be required to submit a duly filled 'Form CT-04' to Central Licensing Authority. Form CT-04 from 'Seventh Schedule' of NDCT 2019 is an 'Application for grant of permission to conduct a clinical trial of new drugs and investigational new drug'. The form must be accompanied by the information and documents as specified in the 'Second Schedule' of NDCT 2019. The second Schedule describes the 'Requirements and guidelines for permission to import or manufacture of a new drug for sales or to undertake clinical trial'. [16] [17]

- Application for permission
- Animal toxicology (Non-clinical toxicity studies)
- Animal Pharmacology
- Fixed Dose Combinations (FDCs)
- Stability Testing of New Drugs

Application Fees to Conduct Clinical Trial of GTP

There shall be no fees payable for the conduct of a clinical trial of gene therapy products by a person associated with an institution or organization that is funded or owned entirely or substantially by the central government or a state government. As per clause (x) of rule 2 of NDCT 2019, there would be no fees charged for applications to conduct clinical trials for orphan drugs. An orphan drug is one that is meant to treat an illness that affects not more than five lakh people in India. If an application is received from a Micro Small Medium Enterprises (MSME) firm for the conduct of a clinical trial of GTP, the fee charge shall be half of the fee mentioned (Table 4). [16] [17]

Table 4: Application fees as specified in the Sixth Schedule of NDCT 2019.

Rule	Subject		In INR
21	Application for permission to conduct clinical trial	Phase 1	3,00,000
		Phase 2	2,00,000
		Phase 3	2,00,000
		Phase 4	2,00,000
22	Reconsideration of application for permission to conduct clinical trial		50,000

Grant of Permission to Conduct Clinical Trial of GTP

The Central Licensing Authority (CLA) after scrutiny of the application Form CT-04 and such further enquiries -

- If satisfied, grant the permission to conduct a clinical trial of GTP in Form CT-06 - Permission to conduct a clinical trial of a new drug or investigational new drug.
- If any deficiencies are found in the application, the same will be informed to the applicant for rectification within a period specified by the CLA.
- If not satisfied, rejection of the application will take place.

The CLA takes the above decisions within 90 working days after submission of the application.

Validity Period

The permission to initiate clinical trial granted under rule 22 in Form CT-06 shall remain valid for a period of 2 years from the date of its issue unless extended by the CLA.

Inspection of premises relating to a clinical trial of GTP

A clinical trial site shall permit any officer authorized by the CLA (Central Licensing Authority) and SLA (State Licensing Authority) to enter the premises, with or without prior notice, to inspect, search, or seize any record, statistical result, document, investigational drug, and other related material; and respond to queries raised by the inspecting authority in relation to conditions. [16] [17]

Suspension or cancellation of permission to conduct a clinical trial of GTP

If a clinical trial site fails to comply with any provision of the act and rules, the Central Licensing Authority may, by written order, take one or more of the following actions, after providing a chance to demonstrate cause and an opportunity to be heard:

- Deliver a written notice outlining the flaw or fault discovered during inspection or otherwise, which may jeopardize a trial subject's rights or well-being, or the validity of the clinical study undertaken.
- Reject the clinical trial results.
- Suspend or cancel the permission granted under Rule 22 in Form CT-06 or Rule 23 in Form CT-4A for the relevant period of time.
- Prohibit the investigator or sponsor, including his agents, from conducting any clinical study in the future for such term as the Central Licencing Authority deems suitable. [16] [17]

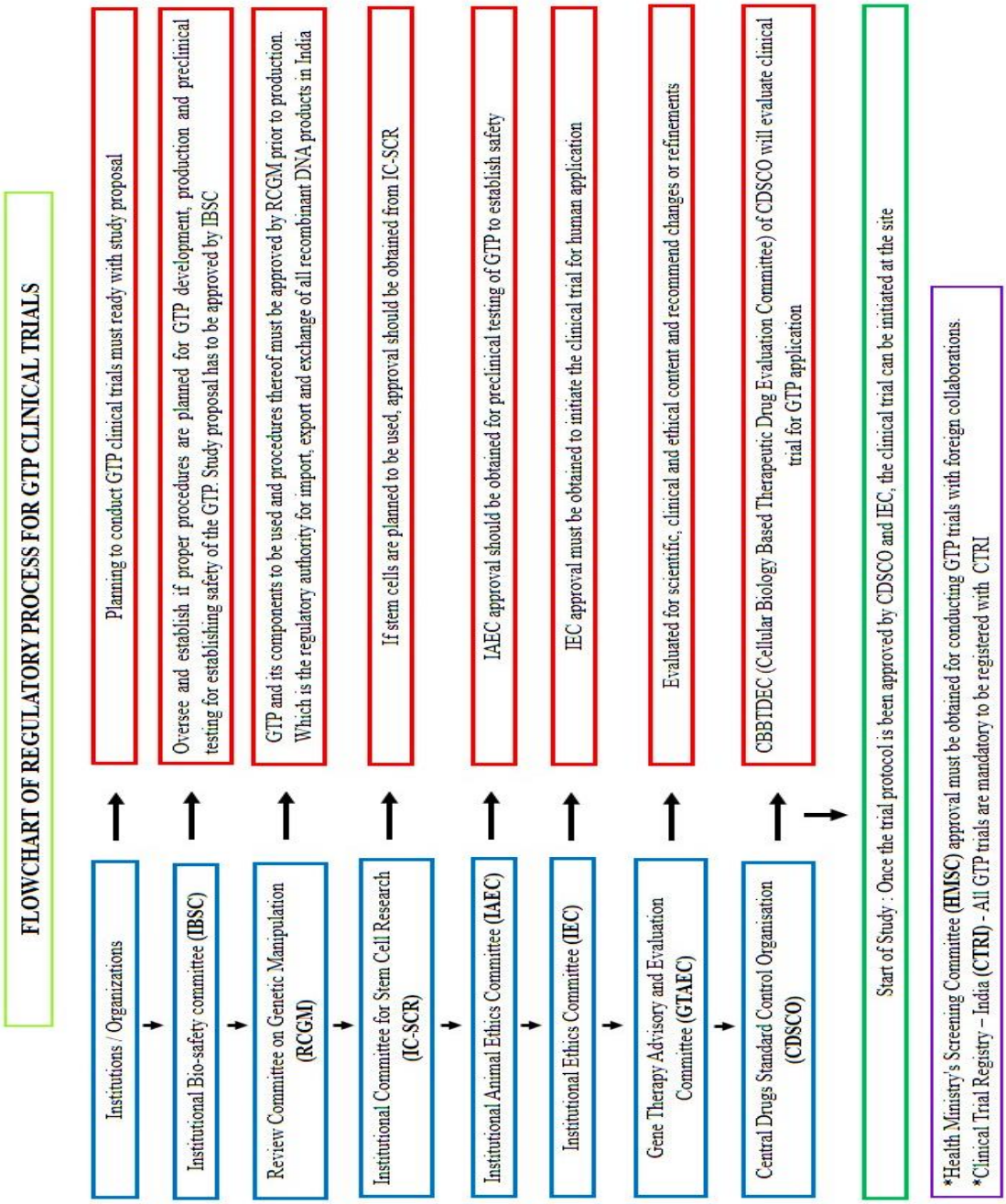
Table 5 : Important forms from Schedule 8 of NDCT 2019 for clinical trial of GTP	
CT-04	Application for grant of permission to conduct clinical trial of new drug or investigational new drug
CT-06	Permission to conduct clinical trial of new drug or investigational new drug
CT-10	Application for permission to manufacture of new drug or investigational new drug for clinical trial
CT-11	Grant of permission to manufacture of new drug or investigational new drug for clinical trial
CT-16	Application for grant of license to import new drug or investigational new drug for clinical trial
CT-17	License to import new drug or investigational new drug for the purpose of clinical trial

ETHICS COMMITTEE

Initiation of clinical trials of GTP at each site must be done after the approval of the clinical trial protocol and other study-related documents by the ethics committee of that site or an independent ethics committee. A parallel proposal to the ethics committee might be made in addition to the application to the DCGI of CDSCO.

In case the ethics committee approves or rejects the clinical trial protocol of GTP, the same must be informed to the Central Licensing Authority. The average approval time for an ethics committee is 4 to 6 weeks. Ethics committee approval must be informed within a period of fifteen working days to the Central Licensing Authority. [16, 19]

Figure 3: Flowchart of regulatory process for GTP Clinical Trial



CTRI

In India, Clinical Trial Registry-India (CTRI) is a record system where the registration of clinical trials related to gene therapy is done. The National Institute of Medical Statistics (NIMS) of Indian Council for Medical Research (ICMR), New Delhi manages this registry. Prospectively all clinical trials of gene therapy products must be registered on CTRI before the enrollment of the first subject into the trial.

The Drug Controller General of India (DCGI) of CDSCO has made it mandatory to register the trial on CTRI since 2009. Clinical trial registration in CTRI is free of charge. Trial document submission on CTRI is completely online i.e. paperless system. Verification is done through an email. Once a study is submitted to the CTRI, it undergoes review within 7 to 10 business days and is returned to the registrant for clarifications/modifications. As a result, the time required for trial registration is greatly dependent on the registrant's reaction. [20, 21]

RCGM

The Department of Biotechnology (DBT) under the Ministry of Science and Technology established the Review Committee on Genetic Manipulation (RCGM). The function of this committee is to monitor the safety of the ongoing clinical trials involving genetically altered organisms.

On the RCGM portal, different application formats are available related to the following subjects under the bio-pharmaceutical section.

- To import, export, transfer, and receiving of regulated material
- To carry out research and development
- To submit report of research trial(s) and/or safety study(ies)
- To conduct pre-clinical toxicity study(ies)
- To submit a report of pre-clinical toxicity study(ies)

RCGM is responsible for monitoring the safety-related aspects and ensuring that appropriate precautions and confinement conditions are followed as per the Guidelines and Standard Operating Procedures (SOPs) when they change. It establishes the measures to limit or prohibit the manufacture, sale, importation, and use of GTPs. It issues clearance letters or permits for the import or exchange of genes, DNA fragments, vectors, plasmids, and other biological materials for research purposes exclusively. It serves as a regulatory authority for accepting and reviewing applications for confined field trials. [(22)]

IBSC

The Institutional Biosafety Committee (IBSC) operates directly from the institutions' premises and ensures on-site assessment and monitoring of conformity to biosafety requirements, as well as overall management of the regulatory process. At the institutional level, IBSC is responsible for analyzing the research being undertaken, approving submissions, and proposing all research applications to the RCGM for consideration.

Before beginning research at the organization, Principal Investigators (PIs) must apply online by filling out the required application form. Application forms can be found on the IBKP (Indian Biosafety Knowledge Portal). The online application forms must be completed and submitted for review by the institute's IBSC and subsequently by the RCGM. According to the Rules of 1989, the IBSC shall assess and process applications for approval by the appropriate authorities. [(23)]

GTAEC

Gene Therapy Advisory and Evaluation Committee (GTAEC) is responsible for overseeing gene therapy research activities in India. An independent body of specialists representing many fields of biomedical research, as well as concerned government agencies and other stakeholders, formed and notified by the Department of Health Research and

- To act as an apex advisory body to the Government of India for gene therapy research and development in India.
- To conduct a thorough review of gene therapy product pre-IND (Investigational New Drug) and IND applications.
- To provide a venue for discussion of scientific and clinical research challenges, as well as advancements in the field of gene therapy.

Prior to Central Drugs Standard Control Organisation (CDSCO) approval, GTAEC reviews all GTP (Gene Therapy Product) clinical trial applications and makes recommendations. In collaboration with the CDSCO and other current rules, develop criteria for safety and efficacy, quality control, GTP processes, and licensing or approval. The investigator can submit the application on the GTAEC portal after successful user profile registration. [(24)]

HMSC

The Health Ministry's Screening Committee (HMSC) is run by the Department of Health Research/ICMR, Ministry of Health and Family Welfare, Government of India. For international collaboration projects, Indian investigators must acquire HMSC permission. According to Government of India guidelines, all overseas collaborations require clearance from the respective financial agencies, followed by approval from the HMSC. HMSC will assess and approve proposals involving international collaboration or funding in health research, including studies in humans, animals, plants, and the environment. The Government of India (GoI) has made it essential for each proposal submitted for HMSC consideration going forward to register through the Biological Research Regulatory Approval Portal (BioRRAP) for a unique BioRRAP ID and then submit the proposal on the HMSC portal with a valid BioRRAP ID. [(25)]

II. CONCLUSION

Gene therapy has emerged as a promising and innovative approach to treating a wide range of diseases, including both genetic and acquired conditions. The rapid advancements in this field have led to an increasing number of clinical trials worldwide, aimed at testing the safety and efficacy of gene therapy products (GTPs). Despite its potential, gene therapy clinical trials pose unique challenges due to their complex nature and the need for rigorous scientific evaluation. In India, the regulatory landscape for gene therapy clinical trials is evolving, with specific guidelines and rules in place to ensure ethical, scientific, and safe conduct. The Central Licensing Authority, under the Central Drugs Standard Control Organization (CDSCO), plays a pivotal role in granting permission for GTP clinical trials. The regulatory process involves multiple steps including the submission of detailed applications, different committee approvals, and adherence to established guidelines. As gene therapy continues to evolve and expand, collaboration between researchers, regulatory authorities and ethical oversight bodies remains crucial. A comprehensive and coordinated approach ensures that the development of gene therapy products follows rigorous scientific standards, ethical principles, and regulatory guidelines. Ultimately, these efforts contribute to the advancement of gene therapy as a viable treatment option for various diseases, improving the lives of patients worldwide.

DATA AVAILABILITY

No data are associated with this article.

COMPETING INTERESTS

No competing interests.

GRANT INFORMATION

Nil

REFERENCES

[1]. Aguilar LK, Aguilar-Cordova E. Evolution of a gene therapy clinical trial. Journal of Neuro-Oncology. 2003;65(3):307–15. doi:10.1023/b:neon.0000003659.04633.6e
[2]. Arabi F, Mansouri V, Ahmadbeigi N. Gene therapy clinical trials, where do we go? an overview. Biomedicine & Pharmacotherapy. 2022;153:113324. doi:10.1016/j.biopha.2022.113324
[3]. Maxwell O, UdokaChinedu I, Charles Ifeanyi A. Numbers in life: A statistical genetic approach. Scientific Review. 2019;(57):142–9. doi:10.32861/sr.57.142.149
[4]. Mohammad Afzal, YasirHasan, Tanveer Beg, GulshanAra, Jyoti Gupta. Genetics and public health in post-genomic era. Trends in Medical Research. 2008;3(1):41–63. doi:10.3923/tmr.2008.41.63
[5]. Verma IC, Puri RD. Global burden of genetic disease and the role of genetic screening. Seminars in Fetal and Neonatal Medicine. 2015;20(5):354–63. doi:10.1016/j.siny.2015.07.002
[6]. Ferreira CR. The burden of rare diseases. American Journal of Medical Genetics Part A. 2019;179(6):885–92. doi:10.1002/ajmg.a.61124
[7]. Venugopal A, Chandran M, Eruppakotte N, Kizhakkillach S, Breezevilla SC, Vellingiri B. Monogenic Diseases in India. Mutation Research/Reviews in Mutation Research. 2018;776:23–31. doi:10.1016/j.mrrev.2018.03.003
[8]. Smith RD, Mallath MK. History of the growing burden of cancer in India: From antiquity to the 21st century. Journal of Global Oncology. 2019;(5):1–15. doi:10.1200/jgo.19.00048
[9]. Taneja A, Shashidhara LS, Bhattacharya A. Rare diseases in India:time for cure-driven policy initiatives and action. Current Science. 2020;118(10):1500. doi:10.18520/cs/v118/i10/1500-1506
[10]. Pingali V, Das N. Rare diseases require support too. Vikalpa: The Journal for Decision Makers. 2021;46(2):129–34. doi:10.1177/02560909211024554
[11]. Mulligan RC. The basic science of gene therapy. Science. 1993;260(5110):926–32. doi:10.1126/science.8493530
[12]. Dunbar CE, High KA, Joung JK, Kohn DB, Ozawa K, Sadelain M. Gene therapy comes of age. Science. 2018;359(6372). doi:10.1126/science.aan4672
[13]. Cournoyer D, Caskey CT. Gene transfer into humans. New England Journal of Medicine. 1990;323(9):601–3. doi:10.1056/nejm199008303230909
[14]. Rosenberg SA, Aebersold P, Cornetta K, Kasid A, Morgan RA, Moen R, et al. Gene transfer into humans — immunotherapy of patients with advanced melanoma, using tumor-infiltrating lymphocytes modified by retroviral gene transduction. New England Journal of Medicine. 1990;323(9):570–8. doi:10.1056/nejm199008303230904
[15]. Wiley database on Gene Therapy Trials Worldwide. Available from: https://a873679.fmphost.com/fmi/webd/GTCT [Last accessed on 2023 Aug 10].
[16]. NDCT Rules 2019. Available from: https://www.cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=ODk1MA [Last accessed on 2023 Jul 10].
[17]. 2016 Drugs and Cosmetics Act 1940 Rules 1945. Available from:
[18]. https://gtaec.icmr.org.in//media_image/download/2016DrugsandCosmeticsAct1940Rules1945.pdf [Last accessed on 2023 Jul 10].
[19]. National Guidelines for Gene Therapy Product Development and Clinical Trials 2019, Guidelines_GTP.pdf. Available from: https://main.icmr.nic.in/sites/default/files/guidelines/guidelines_GTP.pdf [Last accessed on 2023 Jul 10].
[20]. Ethics Committee, Central Drugs Standard Control Organization, Government of India. Available from:https://cdsco.gov.in/opencms/opencms/en/Clinical-Trial/Ethics-Committee/ [Last accessed on 2023 Jul 10].
[21]. Clinical Trial Registry India, ICMR-National Institute of Medical Sciences. Available from :https://ctri.nic.in/Clinicaltrials/login.php [Last accessed on 2023 Jul 10].
[22]. Vardhana Rao M, Maulik M, Gupta J, Panchal Y, Juneja A, Adhikari T, et al. Clinical trials registry – india: An overview and new developments. Indian Journal of Pharmacology. 2018;50(4):208. doi:10.4103/ijp.ijp_153_18

[23]. Review Committee on Genetic Manipulation (RCGM), Department of Biotechnology, Ministry of Science and Technology, Government of India. Available from :https://ibkp.dbtindia.gov.in/Content/RCGMInfo [Last accessed on 2023 Jul 10].
[24]. The Institutional Biosafety Committee (IBSC), Department of Biotechnology, Ministry of Science and Technology, Government of India. Available from :https://ibkp.dbtindia.gov.in/Content/IbscInfo[Last accessed on 2023 Jul 10].
[25]. Gene Therapy Advisory and Evaluation Committee (GTAEC), Department of Health Research (DHR), Ministry of Health and Family Welfare, Government of India. Available from :https://gtaec.icmr.org.in/ [Last accessed on 2023 Jul 10].
[26]. Health Ministry's Screening Committee (HMSC), Department of Health Research (DHR), Ministry of Health and Family Welfare, Government of India. Available from :https://hmsc.dhr.gov.in/ [Last accessed on 2023 Jul 10].