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Research

Genomics in India

Paving the Way for Precision Health

March 2026

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Contents

List of Abbreviations

Abbreviation	Description
Biotech-PRIDE Guidelines	Framework for Exchange of Data Protocols under the Biotech-PRIDE Guidelines
BIRAC	Biotechnology Industry Research Assistance Council
CDSCO	Central Drugs Standard Control Organization
CE Act	Clinical Establishment (Registration and Regulation) Act, 2010
CMO	Contract Manufacturing Organization
D2C	Direct-to-Consumer
DACs	Data Access Committees
DBT	Department of Biotechnology
DCA	Drugs & Cosmetics Act, 1940
DLC	District Level Committee
DNA	Deoxyribonucleic Acid
DNA Bill	DNA Technology (Use and Application) Regulation Bill, 2019 DNA Technology (Use and Application) Regulation Bill, 2019
DPDP Act	Digital Personal Data Protection Act, 2023
Draft GEO Guidelines	Genome Edited Organisms: Regulatory Framework and Guidelines for Risk Assessment
Drugs Rules	Drugs Rules, 1945
EPA	Environment Protection Act, 1986
FDA	US Food and Drug Administration
FDCA	US Food, Drug, and Cosmetic Act
FeED	Framework for Exchange of Data
GDPR	General Data Protection Regulation
GEAC	Genetic Engineering Appraisal Committee
GEO Rules	Rules for the manufacture, use/import/export & storage of hazardous microorganisms/genetically engineered organisms or cells, 1989
GEOs	Genetically Engineered Organisms
GINA	Genetic Information Non-discrimination Act, 2008
GMP	Good Manufacturing Practices
GTAEC	Gene Therapy Advisory and Evaluation Committee

List of Abbreviations

Abbreviation	Description
GTP Guidelines	National Guidelines for Gene Therapy Product Development & Clinical Trials, 2019
IBDC	the Indian Biological Data Centre Indian Biological Data Centre
IBSC	Institutional Biosafety Committee
ICMR	Indian Council of Medical Research
ICMR Guidelines	National Ethical Guidelines for Biomedical and Health Research involving Human Participants, 2017
IT Act	Information Technology Act, 2000
MDR	Medical Device Rules, 2017
MoEFCC	Ministry of Environment, Forest and Climate Change
NBDS	National Biotechnology Development Strategy
NDCTR	New Drugs & Clinical Trials Rules, 2019
NIBMG	National Institute of Biomedical Genomics
NIH	National Institute of Health
Patents Act	Patents Act, 1970
PCPNDT	Pre-Conception and Pre-Natal Diagnostic Techniques Act, 1994
RCGM	Review Committee on Genetic Manipulation
RDAC	rDNA Advisory Committee
SBCC	State Biotechnology Coordination Committee
SPDI	Sensitive Personal Data or Information
SPDI Rules	Sensitive Personal Data or Information Rules, 2011
TRIPS Agreement	The Agreement on Trade-Related Aspects of Intellectual Property Rights
UNESCO	United Nations Educational, Scientific and Cultural Organization
WHO	World Health Orgianization

Introduction

The emergence of genomics signifies a pivotal moment in the advancement of science and healthcare. Genomics represents an interdisciplinary domain of molecular biology that concentrates on the structure, function, evolution, mapping, and modification of genomes where a genome encompasses the complete set of DNA instructions present within a cell.

Worldwide, genomics is transforming the medical landscape by facilitating personalized drug therapies and predictive diagnostics. It has also opened new pathways for gene therapy and disease prevention. The genomics market in India is expected to reach a projected revenue of USD 1,861.6 million by 2033. A compound annual growth rate of 16.6% is expected of India's genomics market from in the coming. The global genomics market size was valued at USD 32.65 billion in 2023 and is projected to reach USD 94.86 billion by 2030, growing at a CAGR of 16.5% from 2024 to 2030.[1]

In the pharmaceutical industry, genomics is becoming increasingly integral to strategies for drug discovery and development. The incorporation of genomic data into clinical trials is supporting patient stratification, improving efficacy, and minimizing adverse drug reactions. Over the past two decades, with the completion of the Human Genome Project in USA and subsequent breakthroughs in next-generation sequencing, this field has rapidly transitioned from basic research to real-world application with far-reaching implications for healthcare and legal governance.[2]

In an exceptionally diverse and heterogeneous nation such as India, there is significant potential for genomic medicine. As infant mortality rates decline, genetic disorders are becoming increasingly recognized as a significant category of diseases. Approximately one-third of all rare diseases are found in India, and a report from the Ministry of Health and Family Welfare in 2021 indicates that the number of diseases classified as rare in India may range from about 7,000 to 8,000.[3] The Organization of Rare Diseases in India states that roughly 1 in 20 people in the country is impacted by a rare disorder.[4]

India is a leading producer of pharmaceuticals and is emerging as a prominent center for biomedical research and clinical trials. With the increasing establishment of biobanks and genetic testing companies, India's involvement in genomics is becoming extensive. However, there is a notable absence of a comprehensive legal framework that governs genomic research, data collection, clinical applications, and commercialization. Instead, the field is regulated in a fragmented manner through a patchwork of laws and guidelines, which include environmental biosafety regulations, ethical guidelines, data protection laws, and intellectual property statutes.

The direct-to-consumer testing market is also rapidly expanding in India. Genetic tests such as single-gene, multi-gene, exome and genome sequencing, prenatal testing, and pre-implantation genetic diagnosis are readily available.

1 Accessible at: https://www.fortunebusinessinsights.com/industry-reports/genomics-market-100941, last accessed on February 18, 2026.

2 Accessible at: https://www.genome.gov/human-genome-project, last accessed on February 18, 2026.

3 Accessible at: https://rarediseases.mohfw.gov.in/uploads/Content/1624967837_Final-NPRD-2021.pdf, last accessed on February 18, 2026.

4 Accessible at: https://frontlinegenomics.com/world-of-genomics-india/, last accessed on February 18, 2026.

The primary issue lies in the lack of regulatory oversight to supervise such direct-to-consumer industry in India. It inadvertently allows companies to promote their services directly to consumers without considerable regulation on the manner in which such information may be transmitted to the end user. This absence of oversight raises concerns as accurate interpretation of such gene-related test results is crucial to ensure that individuals are adequately educated and informed about the implications of their results.[5]

From an industry standpoint, genomics is a double-edged sword. On one hand, it offers significant economic and therapeutic benefits. Conversely, the industry encounters substantial legal hurdles due to the lack of clear regulations. Complications may arise from issues such as the secondary use of data, data breaches, genomic equity and access, as well as the absence of standardized patent protection for gene-based innovations.[6]

Furthermore, as public scrutiny of biomedical research intensifies especially concerning vulnerable populations or tribal groups, the legal compliance demands on pharmaceutical and healthcare organizations are expected to increase. Any legal framework must strive to reconcile scientific freedom with fair public health outcomes. For pharmaceutical and healthcare organizations, it is essential to anticipate and understand these regulatory changes because it is vital for compliance as well as realizing the complete scientific and commercial potential of genomics in a responsible way.

5 Supra note 3.

6 Accessible at: https://www.cambridge.org/core/journals/journal-of-law-medicine-and-ethics/article/doubleedged-sword-a-brief-history-of-genomic-data-governance-and-genetic-researcher-perspectives-on-data-sharing/E9796A86C2417BDE010572AF2C1EF7AB, last accessed on February 18, 2026.

Trends and Applications

A. Personalized Medicine and Predictive Medicine

In clinical practice, personalized medicine and predictive medicine analyses inherited variants in humans/animals to assess disease susceptibility through genome mapping. Instead of treating patients based on generalized population data, genomics allows healthcare providers to customize treatments according to individual genetic profiles.

The global market for personalized genomics was valued at USD 12.6 billion in 2025 and is expected to hit around USD 52.58 billion by 2034, with projections indicating an increase to USD 38 billion by 2032 at CAGR of 17%. The swift reduction in sequencing costs and the advancement of pharmacogenomics are driving this growth.[1] Certain medications which targets the HER2 mutation in breast cancer, represent an early success in this field.[2]

In India, the adoption of personalized and predictive medicine is relatively recent but is rapidly gaining traction. Institutions like the National Institute of Biomedical Genomics ("**NIBMG**") and various private companies are concentrating on pharmacogenomics and genetic disorders. Key areas of focus include oncology, cardiology, and metabolic diseases. This approach aims to reduce trial-and-error prescribing and lower hospitalization rates caused by adverse drug reactions, thereby providing both therapeutic accuracy and systemic efficiency.[3] The legal challenge lies in how such information is framed and acted upon. As personalized medicine expands to population health models, the pressure increases to ensure that genomic tools are deployed responsibly.

B. Ancestry Testing and Identity

Ancestry testing represents one of the most commercially successful uses of genomics. It attracts individuals who are interested in exploring their genealogical roots, ethnic heritage, or cultural identity.

Fundamentally, ancestry testing entails the comparison of an individual's DNA against reference populations that are maintained in proprietary databases. Ancestry data is increasingly utilized in biomedical and population health research to gain insights into how genetic diversity differs across various regions, and how such differences may relate to disease prevalence or responses to medication. This practice aids medical initiatives aimed at creating more inclusive genomic databases and enhancing diagnostic precision for populations that are often underrepresented.

However, these databases frequently suffer from unequal representation and a bias towards specific populations. Consequently, the results of these tests can vary based on the entity conducting them, and the data sets available to such entity for training the databases.

1 Accessible at: https://www.coherentmarketinsights.com/market-insight/personalized-genomics-market-6210?utm_source, last accessed on February 18, 2026.

2 Accessible at: https://www.cancer.org/cancer/types/breast-cancer/treatment/targeted-therapy-for-breast-cancer.html, last accessed on February 18, 2026.

3 Accessible at: https://zocto.in/emerging-trends-in-personalized-medicine-and-genomics-in-india/, last accessed on February 18, 2026.

Additionally, consumer genomics companies typically retain ownership rights over users' data and may repurpose it for research or commercial purposes. Users might unknowingly contribute to datasets that are sold or licensed to pharmaceutical companies or utilized in machine learning applications, often with little transparency or meaningful consent.[4]

C. Pharmacogenomics

Pharmacogenomics examines the impact of genetic variations on drug responses and seeks to tailor therapies while minimizing adverse drug reactions. It provides a framework for rational prescribing, allowing for the optimization of treatment from the outset rather than relying on trial and error.

As of 2024, the global market for pharmacogenomics technology was valued at USD 7.6 billion and is anticipated to grow to USD 12.4 billion by 2030, particularly driven by advancements in oncology applications.

Regulatory bodies in numerous countries, including the US Food and Drug Administration (**"FDA"**), have begun to include pharmacogenomic data in drug labeling. This advancement holds significant relevance for nations like India, where the use of generic medications is prevalent and pharmacogenomic diversity is substantial. The implementation of pharmacogenomics has the potential to significantly alleviate the incidence of adverse drug reactions and enhance treatment protocols in a cost-effective manner.[5]

D. Drug Discovery and Development

By utilizing genetic information, we can now pinpoint new drug targets based on the genes associated with diseases. Traditional drug discovery was laborious, expensive, and often driven by chance. In contrast to it, genomics has brought about both speed and accuracy. Genomics allows researchers to uncover disease mechanisms at the molecular level, categorize patient populations, and validate drug targets with greater efficiency. The identification of BRCA1/2 mutations serves as a notable example.

What truly sets genomics apart is its synergy with artificial intelligence. Many machine learning and deep learning algorithms that have been trained on genomic and clinical data are now adept at forecasting drug responses, side effect profiles, and even synergistic combinations of drugs. Both startups and large pharmaceutical companies are investing in AI-genomics platforms, which are anticipated to reduce development timelines by half and significantly lower costs.[6]

Ethical concerns arise regarding the collection of samples and data from diverse populations, particularly when the benefits primarily favor pharmaceutical companies. Nevertheless, with suitable models for benefit-sharing, genomics continues to enhance the efficiency and precision of drug development.

4 Accessible at: https://pmc.ncbi.nlm.nih.gov/articles/PMC8202415/#:~:text=These%20tests%20provide%20information%20about,know%20their%20genealogical%20ancestry%20(eg, last accessed on February 18, 2026

5 Accessible at: https://pmc.ncbi.nlm.nih.gov/articles/PMC10289244/, last accessed on February 18, 2026.

6 Accessible at: https://www.sciencedirect.com/science/article/pii/S2707368823001061, last accessed on February 18, 2026.

E. Genomic Biobanking

The potential of genomics is significantly enhanced when it is associated with extensive, well-organized datasets. Biobanks serve as repositories for genetic materials and related health information. From the UK Biobank[7] to India's IndiGen,[8] these infrastructures support large-scale research that connects genomic variations to health outcomes. Furthermore, biobanking promotes research on rare diseases by consolidating cases that would otherwise be too infrequent for individual study.

Biobanks are increasingly recognized as a strategic national resource. They enable nations to create population-specific reference genomes, refine health policy planning, and lessen dependence on Western datasets that may not accurately reflect local genetic diversity.

The legal and ethical considerations surrounding biobanking involve long-term data management, the distinction between broad and specific consent, and the reuse of samples.[9] When managed responsibly, biobanks provide an essential foundation for equitable, science-based healthcare.

F. Genome Editing

Genome editing technologies, especially technologies like CRISPR-Cas9, have revolutionized the possibilities within genetic medicine. In the field of agriculture, it has led to increased yields and enhanced disease resistance. In medicine, they present the opportunity to rectify genetic mutations at their origin. Clinical trials utilizing CRISPR to address sickle cell disease, beta-thalassemia, and specific cancers are already yielding encouraging outcomes. Researchers are also advancing gene therapies that are aimed at preventing and treating diseases in humans.

Gene therapies can be classified into two distinct categories: germline therapy and somatic therapy. Germline therapies alter DNA in reproductive cells, impacting future generations, while somatic therapies only affect the individual being treated. Genome editing has introduced the potential for making enduring changes not only to the individual but also to their descendants, a prospect that remains highly contentious. Currently, most countries including India have banned clinical germline editing; however, gene editing is poised to play a transformative role in global healthcare.[10]

G. Designer Babies

Closely associated with genome editing is the intriguing concept of "designer babies." Although still predominantly theoretical, the possibility of selecting or modifying traits in embryos such as intelligence, height, and athletic ability has fascinated both the public and academics alike.

7 Accessible at: https://www.ukbiobank.ac.uk/, last accessed on February 18, 2026.

8 Accessible at: https://clingen.igib.res.in/indigen/, last accessed on February 18, 2026.

9 Accessible at: https://pmc.ncbi.nlm.nih.gov/articles/PMC11887102/, last accessed on February 18, 2026.

10 Accessible at: https://www.genome.gov/about-genomics/policy-issues/what-is-Genome-Editing, last accessed on February 18, 2026.

Most countries' legal frameworks prohibit non-therapeutic germline editing. The primary ethical question revolves around the morality of altering the human germline for enhancement purposes, even if such modifications become technologically viable and safe, given the fine line that exists between disease prevention and enhancement.

The He Jiankui case in China, where gene-edited babies were born sparked global calls for stronger governance.[11] In response, many jurisdictions have reaffirmed bans or moratoria on germline editing. Meanwhile, the World Health Organization (**"WHO"**), United Nations Educational, Scientific and Cultural Organization (**"UNESCO"**), and national ethics councils have been working toward global consensus on safe and equitable genome editing practices. To effectively address this delicate issue, regulatory clarity and international collaboration will be crucial.[12]

Our detailed analysis on the designer babies concept is **accessible here**.

H. Forensic Applications

Beyond the realm of medicine, genomics has established a significant presence in the field of criminal justice. Forensic genomics utilizes DNA analysis to identify individuals, reconstruct events, or determine familial connections in criminal investigations.

Law enforcement agencies in the US and other countries have resolved cold cases by correlating crime scene DNA with public ancestry databases, resulting in the apprehension of individuals based on distant familial ties. A notable example is the arrest of the Golden State Killer in USA, which generated considerable interest in this technique.[13]

Key concerns involve the extent of consent, whether individuals who upload their DNA to genealogy websites comprehend that it may be utilized by law enforcement, and the risks associated with genetic surveillance.[14]

In India, forensic genomics is still in its nascent stages, yet it is increasingly applied in paternity disputes, disaster victim identification, and criminal investigations. Despite ongoing privacy concerns, the forensic application of genomics, when managed with transparency and accountability will emerge as a valuable asset within the justice system.

11 Accessible at: https://www.bbc.com/news/world-asia-china-50944461, last accessed on February 18, 2026.

12 Accessible at: https://www.who.int/health-topics/human-genome-editing#tab=tab_1, last accessed on February 18, 2026.

13 Accessible at: https://pmc.ncbi.nlm.nih.gov/articles/PMC10876674/#:~:text=Although%20the%20technique's%20first%20reported,%5D%2C%20%5B16%5D%5D, last accessed on February 18, 2026.

14 Accessible at: https://pmc.ncbi.nlm.nih.gov/articles/PMC5608170/, last accessed on February 18, 2026.

Legal Framework in India

India's genomic landscape is expanding rapidly from public genome sequencing projects to a growing private market in consumer testing and biotech innovation. Yet, the pace of legal and regulatory development has not always kept up with the scientific momentum.

At present, India does not have a single, unified law governing genomics. Instead, regulation is fragmented across several legal instruments and each address different facets of the field.

A. Regulation of Gene Therapy

I. Regulation of Gene Products as "New Drugs"

The New Drugs and Clinical Trials Rules of 2019 (**"NDCTR"**) replaced Schedule Y of the Drugs Rules, 1945 (**"Drugs Rules"**) to provide a detailed regulatory mechanism for clinical trials in India. NDCTR defines the scope of products included in the definition of "new drugs" that are required to undergo clinical trials in India.[1] The Central Drugs Standard Control Organization (**"CDSCO"**) is the regulatory body that oversees the approval process for new drugs in India.

Under Rule 2(w)(iv) of the NDCTR, a "new drug" is defined to include gene therapy products intended to be used as a drug, and gene therapy products shall always be deemed new drugs for the purposes of applicable laws and compliances in India. This reflects the regulator's recognition that genomics- and gene-based products are inherently novel forms of drugs involving direct modification or targeting of genetic material, with evolving safety, efficacy and ethical considerations. Consequently, gene-based and genomics-driven therapies continue to remain subject to the full "new drug" regulatory pathway, including prior approval requirements, clinical trials, and post-approval regulatory controls, irrespective of how long they have been in use globally. Any entity intending to import or manufacture a gene therapy product must obtain prior approval from CDSCO if it has not been approved for marketing in India and would also be required to undertake clinical trials for the drug in India.

The trials must be done in consonance with the Third Schedule of the NDCTR which mandates voluntary and informed consent to be obtained from the participants of a clinical trial. Additionally, adherence to Good Clinical Practice is mandatory for entities undertaking clinical trials along with other conditions.[2]

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1 "New Drug" means - (i) a drug, including active pharmaceutical ingredient or phytopharmaceutical drug, which has not been used in the country to any significant extent, except in accordance with the provisions of the Act and the rules made thereunder, as per conditions specified in the labelling thereof and has not been approved as safe and efficacious by the Central Licencing Authority with respect to its claims; or.
(ii) a drug approved by the Central Licencing Authority for certain claims and proposed to be marketed with modified or new claims including indication, route of administration, dosage and dosage form; or.
(iii) a fixed dose combination of two or more drugs, approved separately for certain claims and proposed to be combined for the first time in a fixed ratio, or where the ratio of ingredients in an approved combination is proposed to be changed with certain claims including indication, route of administration, dosage and dosage form; or.
(iv) a modified or sustained release form of a drug or novel drug delivery system of any drug approved by the Central Licencing Authority; or.
(v) a vaccine, recombinant Deoxyribonucleic Acid (r-DNA) derived product, living modified organism, monoclonal anti-body, 4[cell or stem cell derived product], gene therapeutic product or xenografts, intended to be used as drug;.

2 Rule 25 of the New Drugs and Clinical Trial Rules, 2019.

After the marketing authorization is granted by the CDSCO, upon successful completion of Phase III of the clinical trials, the new gene therapy product can be imported or manufactured. This may be done after obtaining the prior approvals under the NDCTR, the Drugs and Cosmetics Act, 1940 (**"DCA"**) and the Drugs Rules. Such approved gene therapy products must be manufactured in facilities compliant with Good Manufacturing Practices (**"GMP"**) under the revised Schedule M of the Drugs Rules and such facilities are subject to inspection by CDSCO.

It must be noted that after the receipt of the marketing authorization, manufacturers of gene therapy products are required to engage in post-marketing surveillance i.e. Phase IV studies where the manufacturers are required to undertake post-marketing surveillance to generate real-world safety and effectiveness data. These studies are crucial to detect long-term effects, especially when the genetic alteration may result in permanent or long-lasting effects. Unlike conventional drugs, the effects of such products may evolve over time, with potential risks emerging years after administration, including unintended genetic changes or impacts on future health outcomes. Long-term follow-up through Phase IV studies therefore becomes essential to continuously assess real-world safety, durability of therapeutic benefit, and any unforeseen consequences.[3]

The NDCTR also provides a waiver for certain new drugs from the local Indian clinical trial requirements if they have been approved for marketing in notified countries under Rule 101 of the NDCTR.[4] Stringent conditions[5] need to be satisfied for obtaining a waiver under Rule 101 of the NDCTR and it is available for certain categories for new drugs which includes "Gene and cellular therapy products".

Additionally, NDCTR mandates compliance with additional guidance provided by the Indian Council of Medical Research (**"ICMR"**) and Department of Biotechnology (**"DBT"**), especially when dealing with novel mechanisms like gene technology.[6]

II. Rules for the Manufacture, Use, Import, Export and Storage of Hazardous Micro-organisms/ Genetically Engineered Organisms or Cells, 1989

In India, the Ministry of Environment, Forest and Climate Change (**"MoEFCC"**) established the Environment Protection Act, 1986 (**"EPA"**) as a comprehensive law aimed at safeguarding and enhancing the environment.

MoEFCC under the EPA also issued the Rules for the manufacture, use/import/export & storage of hazardous microorganisms/genetically engineered organisms or cells, 1989 (**"GEO Rules"**) for the regulation of genetically engineered organisms (**"GEOs"**), microorganisms and the application of genetic technology in terms of their manufacture, import and storage. The GEO Rules mandate adherence to biosafety safeguards, and any violations or non-compliance in this domain incur punitive measures as stipulated under the EPA.[7]

Gene technology is defined under the GEO Rules to mean the application of the gene technique called genetic engineering, include self-cloning, deletion and cell hybridisation. Genetic engineering refers to -

3 Supra note 20.

4 Accessible at: https://cdsco.gov.in/opencms/resources/UploadCDSCOWeb/2018/UploadPublic_NoticesFiles/Orde101%20NDCT.pdf.

5 FAQ 79, available at: https://cdsco.gov.in/opencms/resources/UploadCDSCOWeb/2018/UploadPublic_NoticesFiles/faqnd.pdf.

6 Accessible at: https://www.icmr.gov.in/icmrobject/custom_data/pdf/resource-guidelines/guidelines_GTP.pdf, last accessed on February 18, 2026.

7 Rule 15 of the Rules for the Manufacture, Use, Import, Export and Storage of Hazardous Micro-organisms/ Genetically Engineered Organisms or Cells, 1989.

"Technique by which heritable material, which does not usually occur or will not occur naturally in the organism or cell concerned, generated outside the organism or the cell is inserted into said cell or organism. It shall also mean the formation of new combinations of genetic material by incorporation of a cell into a host cell, where they occur naturally (self-cloning) as well as modification of an organism or in a cell by deletion and removal of parts of the heritable material".[8]

The GEO Rules are applicable to new gene technologies, genetically-engineered organisms, microorganisms, cells and their corresponding products and food stuffs. The regulatory intent under the GEO Rules is to govern the application of genetic engineering in practice, where such techniques result in genetically engineered organisms, microorganisms, cells or products, and where such activities involve manufacture, use, import, export or storage with potential biosafety and environmental concerns.

The GEO Rules are enforced by the MoEFCC in collaboration with DBT, the Ministry of Science and Technology, and the respective state governments. Under the GEO Rules, six competent authorities have been designated:[9]

- rDNA Advisory Committee (**"RDAC"**)
- Institutional Biosafety Committee (**"IBSC"**)
- Review Committee on Genetic Manipulation (**"RCGM"**)
- Genetic Engineering Appraisal Committee (**"GEAC"**)
- State Biotechnology Coordination Committee (**"SBCC"**)
- District Level Committee (**"DLC"**)

The RDAC serves an advisory role, while the IBSC, RCGM, and GEAC are tasked with regulatory functions, with GEAC acting as the apex authority for GEOs. Substances and products that contain GEOs, cells, or microorganisms cannot be produced, sold, imported, or utilized without the approval of the GEAC.[10] The GEAC also oversees the enforcement of the terms and conditions established in relation to the approvals granted by it. Further, the SBCC and DLC are established for monitoring activities. RCGM and GEAC may form various sub-committees and expert committees as needed for specific cases.

Although the GEO Rules do not directly address the scientific process on how to conduct genetic engineering, genomic data, privacy, or clinical outcomes, they are essential for compliance during the research phase, biocontainment, and institutional oversight of GEOs in India in the absence of a specific legislation regulating such technologies and data outcomes.

III. National Guidelines for Gene Therapy Product Development & Clinical Trials, 2019

In light of lack of statutory framework regulating genomic research that involves human subjects in India, the National Guidelines for Gene Therapy Product Development & Clinical Trials, 2019 (**"GTP Guidelines"**) issued by ICMR are crucial.

8 Rule 3(iv) of the Rules for the Manufacture, Use, Import, Export and Storage of Hazardous Micro-organisms/ Genetically Engineered Organisms or Cells, 1989.

9 Rule 4 of the Rules for the Manufacture, Use, Import, Export and Storage of Hazardous Micro-organisms/ Genetically Engineered Organisms or Cells, 1989.

10 Rule 10 of the Rules for the Manufacture, Use, Import, Export and Storage of Hazardous Micro-organisms/ Genetically Engineered Organisms or Cells, 1989.

The GTP Guidelines provide guidance for the research and development of Gene Therapy Products (**"GTPs"**) that involve human participants, including clinical trials. These guidelines also act as a reference standard for CDSCO and other regulatory bodies when evaluating the ethical feasibility of clinical trials that incorporate gene therapy.

All GTPs that are being developed with the aim of potential human applications are required to comply with these guidelines and should only be used within the framework of defined and approved clinical trials as per the NDCTR.[11]

Under the GTP Guidelines, gene therapy is defined as the process of introducing, removing, or altering an individual's genetic material with the aim of treating a disease and potentially achieving a long-term cure, which also encompasses gene editing within its scope. However, germline gene therapy is expressly prohibited in India.[12]

The GTP Guidelines also propose to establish Gene Therapy Advisory and Evaluation Committee (**"GTAEC"**) with the secretariat at ICMR and the GTAEC currently guide sponsors in undertaking clinical trials and offers pre-investigational new drug consultations in India. It is also tasked with reviewing all GTP clinical trial applications and monitoring ongoing trials to ensure compliance with regulatory and safety standards. Additionally, it maintains a centralized database by collecting and archiving clinical trial data related to gene therapies.[13]

It is mandatory for all entities engaged in development of GTPs to establish an IBSC, constituted as per the Regulations and Guidelines on Bio-safety of recombinant DNA Research and Biocontainment, 2017[14] along with an Ethics Committee.

The pre-clinical evaluation of an investigational GTP (i.e. a GTP not approved for marketing in any country) needs to conducted as per the requirements under GTP Guidelines which includes testing on a non-human model before moving to clinical trials on humans. Following the pre-clinical stage, GTP clinical trials should only be carried out in institutions and hospitals that possess sufficient tertiary care facilities. Biological materials from humans for GTPs can be procured only from clinics/hospitals that have an Ethics Committee.

Additionally, GTPs are required to adhere to the considerations outlined for Chemistry, Manufacturing and Control, Quality Assurance, and Product Attributes as specified in the GTP Guidelines along with the other requirements for clinical trials. These processes must also comply with the GMP guidelines.[15]

Although the guidelines place significant emphasis on patient consent, they only outline a general consent model that permits individuals to opt out of clinical trials.

11 National Guidelines for Gene Therapy Product Development & Clinical Trials, 2019.

12 Para 4.1 of the National Guidelines for Gene Therapy Product Development & Clinical Trials, 2019.

13 Para 6 of the National Guidelines for Gene Therapy Product Development & Clinical Trials, 2019.

14 Accessible at: https://dbtindia.gov.in/sites/default/files/uploadfiles/Regulations_%26_Guidelines_for_Reocminant_DNA_Research_and_Biocontainment%2C2017.pdf, last accessed on February 18, 2026.

15 Para 9 of the National Guidelines for Gene Therapy Product Development & Clinical Trials, 2019.

IV. Regulation of Genetic Testing Labs / Clinics

Any entity that conducts genetic research or testing through laboratory or medical equipment may be classified as a clinical establishment and is obligated to adhere to the Clinical Establishment (Registration and Regulation) Act, 2010 (**"CEA"**), which serves as a central legislation.

The central legislation seeks to standardize and regulate all clinical establishments in India, encompassing diagnostic and pathological laboratories. It grants state governments the authority to set minimum standards for facilities, personnel, record-keeping, and services. Given that 'health' is a state subject, certain states have implemented the CEA with modifications to it. Consequently, the compliance process for genetic testing laboratories and clinics will differ from one state to another.

However, the CEA does not delineate specific standards or requirements that are customized for genetic or molecular diagnostic facilities. Therefore, its application to genetic laboratories remains broad and inconsistent across different jurisdictions.

It is also important to note that under Pre-Conception and Pre-Natal Diagnostic Techniques Act, 1994 (**"PCPNDT Act"**), genetic clinics and genetic labs are defined to include, laboratories, clinics and any other such places used for conducting pre-natal diagnostic procedures conducting analysis or tests of samples received from clinics for pre-natal diagnostic test.[16] They are required to be registered under the PCPNDT Act to conduct their functions.[17] Such labs and clinics are permitted to conduct genetic testing to identify: chromosomal abnormalities, genetic metabolic disorders, haemoglobinopathies, sex-linked genetic disorders, or congenital anomalies. However, genetic testing conducted exclusively for the purpose of determining sex is not allowed.[18]

V. National Ethical Guidelines for Biomedical and Health Research involving Human Participants, 2017

Research and testing of human genetics are encompassed under the National Ethical Guidelines for Biomedical and Health Research involving Human Participants, 2017 (**"ICMR Guidelines"**) notified by the ICMR. The ICMR Guidelines are enforced by the registered Ethics Committee of the institution. These guidelines recognize the ethical risks associated with genomic research and testing on humans which include likelihood of social stigmatization and discrimination.

The registration of clinical trials for biomedical research is mandatory. Specifically, in the context of genetic testing, the ICMR Guidelines state that pre- and post-test non-directive counselling should be given to the participants and the nature of confidentiality of data generated should be explained.[19]

It also states that written informed consent of the participant is mandatory for procedures like genomic studies, however, for routine genetic diagnostic testing, written consent may or may not be needed as per institutional policies.[20]

16 Section 2(d) & (e) of the Pre-Conception and Pre-Natal Diagnostic Techniques Act, 1994.

17 Section 3 of the Pre-Conception and Pre-Natal Diagnostic Techniques Act, 1994.

18 Section 3A of the Pre-Conception and Pre-Natal Diagnostic Techniques Act, 1994.

19 Para 10 of National Ethical Guidelines for Biomedical and Health Research involving Human Participants, 2017.

20 Supra note 49.

The ICMR Guidelines also address the functioning of biobanks which are organized collections of human biological materials with usually associated dataset stored for years in appropriate facilities for research and potential commercial purposes. They are required to comply with safety requirements and the relevant regulatory standards.[21]

B. Regulation of Genetic Testing Technologies

I. Regulation of Genetic Testing Sequencers and Kits

Genetic testing sequencers and kits are increasingly gaining commercial traction in both clinical testing and direct-to-consumer (**"D2C"**) markets. Therefore, it is essential to comprehend the regulatory framework that governs these products. They are governed under the DCA and the Medical Device Rules, 2017 (**"MDR"**) issued under the DCA.

Pursuant to the 2020 notification issued by the Ministry of Health and Family Welfare, medical devices were brought within the definition of "drug" under the DCA. As a result, medical devices became subject to the overarching regulatory framework applicable to drugs, in addition to the device-specific regulatory requirements prescribed under the MDR.[22]

A medical device is defined to include -

"All devices including an instrument, apparatus, appliance, implant, material or other article, whether used alone or in combination, including a software or an accessory, intended by its manufacturer to be used specially for human beings or animals which does not achieve the primary intended action in or on human body or animals by any pharmacological or immunological or metabolic means, but which may assist in its intended function by such means for one or more of the specific purposes of -

- *diagnosis, prevention, monitoring, treatment or alleviation of any disease or disorder;*
- *diagnosis, monitoring, treatment, alleviation or assistance for, any injury or disability;*
- *investigation, replacement or modification or support of the anatomy or of a physiological process;*
- *supporting or sustaining life;*
- *disinfection of medical devices; and*
- *control of conception."*[23]

While MDR does not specify use of genetic technologies, if any such device (including in-vitro devices) deploying genomics such as genetic testing kits, performs the purposes stated above for a medical device, it will be classified as a medical device.

21 Para 11 of National Ethical Guidelines for Biomedical and Health Research involving Human Participants, 2017.

22 Available at: https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NTU0OA==.

23 Supra note 52.

The MDR has implemented a risk-based framework to categorize and regulate medical devices, thus enhancing regulatory clarity. The regulations categorize devices into four classes (Class A to D), according to their risk level—from low to high. Manufacturers and importers of Class C and D devices are required to meet more stringent documentation and inspection standards compared to those for Class A and B devices.

Additionally, it establishes licensing and approval criteria for the devices based on their risk classification. This risk categorization is determined by the intended use of the device and the associated risks, along with other factors outlined in the First Schedule of the MDR.

If a genetic technology medical device has not been classified by the CDSCO, the applicant must submit a separate request to the CDSCO, including the product's technical specifications and regulatory status in other countries for obtaining clarity on the risk classification for the product. Furthermore, the MDR stipulates specific requirements for the labeling and packaging of medical devices.

CDSCO has not yet issued comprehensive regulations specifically targeting the D2C genomics space. However, under the general provisions of the DCA, any device that is found to be misbranded, adulterated, or falsely advertised may be liable for penalties.

C. Data Sharing and Protection

I. Framework for Exchange of Data Protocols under the Biotech-PRIDE Guidelines

The Framework for Exchange of Data Protocols under the Biotech-PRIDE Guidelines (**"Biotech-PRIDE Guidelines"**) were established by the DBT in 2021, offering direction on biological data acquired via biotechnological techniques. These guidelines are solely focused on facilitating data exchange in accordance with FAIR principles (Findable, Accessible, Interoperable, Reusable) and do not govern the practices of genetic testing, clinical genomics, or gene therapy research and applications.

Essentially, it deals with data management by creating a framework for the large-scale sharing and exchange of biological data.

The implementation of the Biotech-PRIDE Guidelines will take place through the Indian Biological Data Centre (**"IBDC"**) at the Regional Center for Biotechnology. Additional datasets and data centers will be connected to the IBDC, forming what will be known as the Bio-Grid. The Bio-Grid is intended to serve as a National Repository for all biological knowledge, information, and data produced through research conducted within the country.[24]

The Framework for Exchange of Data (**"FeED"**) protocols were established in accordance with the Biotech-PRIDE Guidelines in 2021. This initiative marks India's inaugural formal effort to create a national data-sharing framework for research in biological and life sciences sector, including genomic data.

The FeED protocols are designed to implement the Biotech-PRIDE guidelines by specifying the procedures and standards necessary for the exchange of biological data, thus promoting a secure and ethical data-sharing infrastructure among both public and private research institutions.

24 Accessible at: https://dbtindia.gov.in/sites/default/files/Biotech%20Pride%20Guidelines%20July%202021_0.pdf.

Key categories of datasets encompassed by the FeED protocol include genomic data, particularly from sequencing projects, clinical research, biobanks, and public health surveillance. The FeED outlines the roles and responsibilities of various stakeholders, including data generators (such as research laboratories and sequencing centers), data repositories (for instance, IBDC), and data users (including academia, industry, and policymakers).

A significant aspect of the FeED protocols is the categorization of data into three tiers: Open Access, Registered Access, and Controlled Access. Genomic datasets are likely to fall under the Controlled Access category due to their potential implications concerning privacy, consent, and misuse.

Consequently, the FeED stipulates that access to such data is contingent upon review and approval by designated Data Access Committees (**"DACs"**), thereby ensuring ethical oversight in accordance with data protection standards. This is particularly important in the context of large-scale genomic projects or population-scale biobanks.[25]

II. Sensitive Personal Data or Information Rules and the Digital Personal Data Protection Act

Under the Sensitive Personal Data or Information Rules, 2011 (**"SPDI Rules"**) notified under the Information Technology Act, 2010, sensitive personal data or information (**"SPDI"**) is defined to include biometric information, medical records and histories[26] where "biometrics" means –

"technologies that measure and analyse human body characteristics, such as 'fingerprints', 'eye retinas and irises', 'voice patterns', 'facial patterns', 'hand measurements' and 'DNA' for authentication purposes."

While the term genetic data has not been explicitly mentioned under the SPDI Rules, it is generally understood to fall within the broader scope of medical and biometric data.

Any body corporate or person processing such data is required to obtain prior written consent, implement reasonable security practices, and disclose data only with the individual's permission or under legal obligation. Transfer of such data is permitted only if the data subject has consented to such transfer, or if the transfer is necessary for the performance of a lawful contract between the transferring organisation (or any organisation on its behalf) and the data subject.

These requirements are limited in scope as they apply only to corporate entities, not to government agencies or academic institutions.

Additionally, they do not establish criteria for anonymization, data retention and secondary usage. These issues are especially concerning in relation to genomic data, given that the FeED protocols and Biotech-PRIDE Guidelines lack legal binding force. The Biotech-PRIDE Guidelines represent normative obligations rather than enforceable responsibilities.

25 Accessible at: https://ibdc.dbtindia.gov.in/documents/Framework_for_Exchange_of_Data(FeED)_Protocol.pdf.

26 Rule 3 of the Information Technology (Reasonable security practices and procedures and sensitive personal data or information) Rules, 2011.

Similarly, the recently notified Digital Personal Data Protection Act, 2023 (**"DPDP Act"**) and Digital Personal Data Protection Rules, 2025 do not specifically address genetic data. It introduces the concept of 'personal data' to mean "any data about an individual who is identifiable by or in relation to such data"[27], which would broadly include genetic data within its ambit.

The DPDP Act is intended to apply uniformly to all personal data without creating a specific subcategory for highly sensitive data or SPDI such as genetic information. The DPDP Act empowers the Central Government to notify certain types of data for additional safeguards in future rulemaking, but as of now, genetic data is not separately notified or protected under the act.

The DPDP Act provides that all data fiduciaries i.e. entities determining the purpose and means of data processing, are required to obtain free, informed, specific, and unambiguous consent from data principals (i.e., individuals) before collecting and processing their personal data. This consent must be accompanied by a notice that clearly communicates the purpose of processing, the nature of data collected, and the individual's rights.

In the context of genomics, this poses challenges in biobanking or secondary use research, where future purposes may not always be precisely defined at the time of obtaining consent. The DPDP Act also allows for "deemed consent" in certain contexts, such as public health or scientific research[28] which is not suitable for genetic data given its highly sensitive nature.

India's current data protection regime adopts a broad approach to personal data that is ill-suited to the unique risks and sensitivities of genetic information. The absence of clear and specific statutory protections for genomic data weakens individual autonomy and undermines ethical standards in biomedical research. As genomic technologies become more integrated into clinical care and public health, India must move beyond generalist privacy laws and develop a dedicated regulatory architecture for genetic data.

D. Intellectual Property

I. Patents Act, 1970

India's Patents Act, 1970 (**"Patents Act"**) plays a crucial role in shaping the innovation landscape for genomics, biotechnology, and life sciences. The patent protection framework in India, post the adoption of The Agreement on Trade-Related Aspects of Intellectual Property Rights (**"TRIPS Agreement"**) reflect a delicate balance between incentivizing innovation and safeguarding public interest especially in the healthcare sector.

The threshold requirements for patentability under the Patents Act are novelty, inventive step, and industrial applicability. However, certain statutory exclusions are imposed that limit the scope of patent protection for certain categories of biological material. Section 3(c) of the Patents Act excludes from patentability "the mere discovery of a scientific principle or the formulation of an abstract theory." Subsequently, Section 3(d) of the Patents Act prohibits the patenting of new forms or uses of known substances unless they show enhanced efficacy. This means that the isolation of naturally occurring gene sequences, without demonstrating significant functional modification or industrial utility is not patentable in India.

27 Section 2(t) of the Digital Personal Data Protection Act, 2023.

28 Section 8(1) of the Digital Personal Data Protection Act, 2023.

However, Section 3(j) of the Patents Act specifically excludes microorganisms from the ambit of non-patentability which may be interpreted to mean that the gene technologies that create genetically modified microorganisms can be patented. Additionally, genetically modified microorganisms that fulfil requirements of patentability which are novelty, inventive step, and industrial applicability may be patented as there is no express bar against it.

Despite this, there remains considerable legal ambiguity on the patentability of GMOs and gene technologies. A more coherent statutory framework or judicial clarification for the same is needed to resolve these uncertainties and provide clearer guidance to the industry to foster innovation while maintaining public interest safeguards.

E. Proposed Law

I. Draft document on Genome Edited Organisms: Regulatory Framework and Guidelines for Risk Assessment

In 2020, a draft document on Genome Edited Organisms: Regulatory Framework and Guidelines for Risk Assessment (**"Draft GEO Guidelines"**) was formed by the DTB that aimed at providing guidance on the regulation of genome editing technologies and its products such as GMOs.

The Draft GEO Guidelines propose a tiered risk assessment framework depending on various factors such as the nature of genome editing, complexity of modification created, and the trait introduced in the organism/product.

It also identifies potential ways through which unintended harm to humans, animals, plants, or the environment could occur based on type of such genetically edited organism.[29] However, there has not been any update on the notification or implementation of the Draft GEO Guidelines.

II. DNA Technology (Use and Application) Regulation Bill, 2019

The DNA Technology (Use and Application) Regulation Bill, 2019 (**"DNA Bill"**) represents a significant legislative step towards formalizing the use of DNA-based technologies for forensic and identification purposes in India.

It seeks to establish a comprehensive regulatory framework for the use of DNA profiling in cases involving missing persons, unidentified victims, and criminal investigations. Central to the proposed legislation is the creation of a National DNA Data Bank along with regional databases, to systematically store and manage DNA profiles. To ensure accountability and oversight, the DNA Bill provides for the establishment of a DNA Regulatory Board, which will be responsible for supervising DNA laboratories and the functioning of data banks across the country.

29 Available at: https://dbtindia.gov.in/sites/default/files/Draft_Regulatory_Framework_Genome_Editing_9jan2020a.pdf, last accessed on February 18, 2026.

It also places strong emphasis on consent and individual rights, mandating that DNA samples be collected only with proper authorization, except in cases explicitly exempted by law. It includes provisions for the removal of DNA profiles from the database under specified conditions.

Importantly, the DNA Bill recognizes the sensitive nature of genetic information and outlines penalties for offences such as unauthorized disclosure of DNA information or collection and use of DNA samples without consent.[30]

As of now, the DNA Bill has not been enacted and there have been no substantive developments or updates on its approval since its introduction in the Parliament in 2019.

30 Accessible at: https://prsindia.org/files/bills_acts/bills_parliament/2019/The%20DNA%20Technology%20(Use%20and%20Application)%20Regulation%20Bill,%202019%20Bill%20Text.pdf, last accessed on February 18, 2026.

Policy Initiatives

A. The GenomeIndia Project

The GenomeIndia Project represents a landmark initiative in India's pursuit of genomic self-reliance and precision medicine. It was launched in January 2020 by the DBT and it aims at a creating comprehensive catalogue of genetic variation across India's diverse population groups by sequencing the genomes of at least 10,000 healthy individuals from varied linguistic, ethnic, and geographic backgrounds.

Existing global reference genomes, including those used in international projects such as the 1000 Genomes Project or UK Biobank, fail to capture the genetic variation specific to Indian populations. This lack of representation impairs the accuracy of disease prediction, pharmacogenomic analysis, and identification of rare disorders in the Indian context. The GenomeIndia Project addresses this gap by aiming to establish a population-specific Indian reference genome.

It is led by the Indian Institute of Science (**"IISc"**), Bengaluru, in collaboration with over 20 national institutions making this initiative India's first large-scale, publicly funded human genome sequencing effort. Additionally, Indian Biological Data Centre (**"IBDC"**) serves as the national data custodian for biological data generated from publicly funded research in India, including the GenomeIndia Project. IBDC is responsible for secure storage, management, and controlled access to the data collected from this project.[1]

On April 30, 2025, the Government confirmed the completion of whole-genome sequencing for over 10,000 individuals as part of the GenomeIndia project.[2]

The DBT has also issued a formal call for proposals from researchers to exploit the opportunities of translational research using GenomeIndia data and continues to accept independent data access requests, all subject to the Biotech-PRIDE Guidelines and FeED Protocols.[3] The next phase of GenomeIndia will expand sequencing efforts to include disease-specific studies, focusing on rare disorders, cancer, lifestyle diseases, and neurological conditions.[4]

This is expected to significantly strengthen India's drug discovery and development ecosystem by enabling identification of population-specific genetic markers, therapeutic targets and pharmacogenomic variations. For the pharmaceutical and healthcare industries, this facilitates the development of more precise, targeted and preventive therapies tailored to Indian genetic profiles, thereby enhancing clinical outcomes and reducing adverse drug reactions.

1 Accessible at: https://dbtindia.gov.in/sites/default/files/GenomeIndia-Digest-27-02-2024_1.pdf, last accessed on February 18, 2026.

2 Accessible at: https://www.pib.gov.in/PressReleasePage.aspx?PRID=2125504&reg=3&lang=2, last accessed on February 18, 2026.

3 Accessible at: https://www.pib.gov.in/PressReleasePage.aspx?PRID=2125504, last accessed on February 18, 2026.

4 Accessible at: https://www.nature.com/articles/d44151-025-00024-2#:~:text=The%20dataset%2C%20archived%20at%20the,through%20a%20managed%20access%20system., last accessed on on February 18, 2026.

B. National Biotechnology Development Strategy (Part I and II)

The National Biotechnology Development Strategy (**"NBDS"**) was formulated by DBT and it is India's flagship policy framework aimed at transforming the country into a global hub for biotechnology innovation, research, and entrepreneurship. It was issued in two successive phases— NBDS Part I (2007–2015) and NBDS Part II (2015–2020).

NBDS Part I focused on capacity building and establishing the basic research infrastructure required to catalyze the growth of Indian biotechnology by establishing Centers of Excellence (**"CoEs"**) in priority areas such as genomics, bioinformatics, agriculture, and medical biotechnology along with creation of biotech parks.

By 2015, India had established more than 10 biotech parks and initiated large-scale programs such as Biotechnology Information System Network (**"BTIS"**) and Biotechnology Industry Research Assistance Council (**"BIRAC**").

NBDS Part II launched in December 2015 sought to elevate India to the status of a global Bio-Manufacturing Hub. It focuses on leveraging biotechnology for various sectors like agriculture, healthcare, and energy, with a goal to achieve a USD 100 billion bio-economy by 2025. It proposed the creation of National Biological Data Centres, later realized as the IBDC, and supported the expansion of GenomeIndia, India International Bioenergy Platforms, and large-scale biobanking initiatives.

It also highlighted the need for evolving ethical frameworks for genomics, gene editing, and synthetic biology, foreseeing the challenges posed by new technologies such as CRISPR.[5] Collectively, the NBDS strategies have had a transformative impact on India's biotech landscape. Several institutions established during NBDS phases now serve as anchors for national genomics. However, certain gaps remain. The lack of a unified legislative framework for regulation of genomics, genomic data protection and uneven state-level biotech implementation continue to pose challenges.

5 Accessible at: https://www.pib.gov.in/PressNoteDetails.aspx?NoteId=149965#:~:text=Department%20of%20Biotechnology%20has%20prepared,Vardhan%20presided%20over%20the%20meeting., last accessed on February 18, 2026.

India Entry Strategies

India offers substantial opportunities for genomics-led research and commercial deployment, supported by national initiatives and a rapidly maturing life sciences ecosystem. Effective market entry strategies must be designed around India's evolving regulatory landscape, institutional oversight mechanisms, and data governance requirements.

A. Technology Transfer and Licensing

Genomics companies frequently enter the Indian market by licensing proprietary sequencing platforms, software, algorithms, reagents or gene-editing tools to Indian entities through licensing agreements. These entities may include Indian subsidiaries, hospital networks, diagnostic laboratories, research institutions and contract manufacturing organizations (**"CMO"**).

The licensing agreements should clearly define the permitted scope of use (e.g., research-only, clinical use, or commercial deployment), territorial limits, and whether sublicensing to affiliates or third parties is permitted. In practice, ambiguity in the licensing structure often leads to compliance and IP risks.

Subsequently, provided that genomics workflows generate valuable datasets, licensing agreements should expressly address ownership and permitted use of data generated using the licensed technology, and rights over derivative works.

From a regulatory perspective, licensing terms should therefore be aligned with the scope of regulatory permissions obtained in India, with clear obligations on the Indian partner as the licensee to secure and maintain applicable approvals and to comply with local labelling, quality and use restrictions.

B. Import of Genomic Products and Outputs

Entry into the Indian genomics market often requires import of sequencing instruments, reagents, diagnostic kits, consumables, vectors, biological materials, and, in some cases, investigational gene-based products. The regulatory pathway for import depends on the classification of the product being imported and its intended use in India.

Imports involving biological materials, genetically engineered organisms or genetically modified cells may attract additional regulatory scrutiny under India's regulatory framework where prior approvals from the relevant authorities may be required before such materials can be received, stored, handled or used at Indian facilities. If imported materials are intended for clinical research or therapeutic use, regulatory permissions for clinical trials will be required to be obtained as detailed above.

Failure to obtain the relevant permissions and clearances for import purposes can result in the inability to operationalise the materials post-import, leading to project delays and regulatory non-compliance.

Jurisdictional Comparison

As the genomics revolution gathers pace, countries across the world are attempting to align, policy, ethics, and legal frameworks with the rapid pace of scientific advancement. While the underlying science may be global, the governance of genomics remains deeply shaped by national priorities and public health goals.

A. United States of America (USA)

The USA is home to one of the most developed and commercially vibrant genomics industries globally. The Human Genome Project was spearheaded by the USA and since its completion, both federal and private initiatives have maintained the nation's leadership in genomic innovation.

The Genetic Information Nondiscrimination Act (**"GINA"**) of 2008 represents a significant legislative landmark that forbids genetic discrimination in health insurance and employment. However, it does not apply to life insurance, disability insurance, or housing. GINA safeguards the genetic privacy of the public, including research participants, by making it unlawful for health insurers or employers to request or mandate genetic information from individuals or their family members, and it further prohibits the discriminatory application of such information.[1]

The FDA oversees genetic tests marketed for clinical purposes. It assesses both analytical and clinical validity and has permitted direct-to-consumer genetic tests under specific conditions. The US Food, Drug, and Cosmetic Act (**"FDCA"**) and the Medical Device Amendments enacted in 1938, placed the regulation of medical devices under the FDA's authority. However, it was not until the 1976 Medical Device Amendments to the FDCA that the term "medical device" was clearly defined. According to this definition, diagnostic tests are categorized as medical devices which would include genetic testing kits and devices under its ambit in most cases.

The Centers for Medicare & Medicaid Services under the Clinical Laboratory Improvement Amendments guarantees the quality of laboratory testing but does not evaluate the efficacy of such tests. The National Institute of Health (**"NIH"**) provides funding for research and establishes ethical standards which are adhered to by Institutional Review Boards.[2]

Moreover, there is currently no federal legislation that prohibits covert testing. At present, numerous USA states have enacted laws or regulations that address genomic privacy and the improper use of genomic data. However, these laws differ significantly. While some states ban the unauthorized acquisition or analysis of genetic information, others only prohibit unauthorized disclosure.[3]

1 Supra note 20.

2 Accessible at: https://www.ncbi.nlm.nih.gov/books/NBK209639/, last accessed on February 18, 2026.

3 Supra note 27.

B. European Union

The European Union (**"EU"**) has established one of the most thorough and ethically sound frameworks for genomics regulation. This initiative is significantly bolstered by public funding, international research collaborations, and a strong legal framework that prioritizes fundamental rights of its people. At the heart of the EU's regulatory structure is the General Data Protection Regulation (**"GDPR"**)which designates genetic data as a unique category of 'personal data' that requires enhanced protection. The GDPR necessitates explicit and informed consent for the processing of genetic data, restricts secondary usage, and imposes stringent conditions for data sharing, particularly across national borders. Additionally, it empowers individuals with the rights to access, amend, and delete their genetic information.

Clinical and research endeavors are further regulated by instruments such as the EU Clinical Trials Regulation that incorporates the principles of the Oviedo Convention (concerning human rights and biomedicine).[4] These regulations underscore the importance of ethical review, proportionality, and protections against discrimination and commercial exploitation. While gene-editing technologies are allowed in research contexts, germline modification for reproductive purposes is largely prohibited by most national laws.

The European Medicines Agency (**"EMA"**) oversees the regulatory framework for gene therapies and advanced therapy medicinal products. The approval processes for genomic diagnostics and therapies are stringent, focusing on safety, efficacy, and adherence to ethical standards.[5]

The EU's regulatory approach has received praise for its human-centered model. However, it has also faced criticism for its regulatory complexity it presents to innovation, especially for smaller enterprises attempting to navigate the multi-tiered compliance landscape.

C. China

China has a state-directed genomics strategy and it has established itself as a global frontrunner in public health genomics and industrial biotechnology. Various organizations are at the forefront of extensive population sequencing initiatives, agricultural genomics, and AI-driven biomedicine. The Chinese model is marked by centralized state control over biological data.

Genomics serves as a fundamental component of China's "Healthy China 2030" initiative, integrating into public hospitals, AI health platforms, and pandemic monitoring systems. The government plays a pivotal role in financing, infrastructure development, and regulatory oversight, fostering a highly coordinated genomics ecosystem.

The primary legislation governing this field is the Regulations on the Administration of Human Genetic Resources of 2019, which imposes strict regulations on the collection, storage, export, and utilization of Chinese genetic materials. Foreign organizations are required to collaborate with local institutions for research purposes, and any cross-border data transfers necessitate governmental approval. This approach reflects a commitment to protecting national genetic sovereignty alongside increasing concerns regarding

4 Accessible at: https://www.coe.int/en/web/human-rights-and-biomedicine/oviedo-convention, last accessed on February 18, 2026.

5 Europe's Evolving Landscape for New Genomic Techniques and Precision Breeding Technologies, Science Speaks, accessible at: https://www.isaaa.org/blog/entry/default.asp?BlogDate=5/7/2025, last accessed on February 18, 2026.

bio-surveillance and foreign exploitation.[6]Following the 2018 He Jiankui incident, in which a scientist edited embryos resulting in the birth of gene-edited twins, China has instituted more stringent ethical review processes for gene editing and human clinical trials. Institutional review boards are required to be registered, and any clinical application of gene-editing technology must obtain central approval.[7]

While somatic editing is permitted under regulated conditions, germline editing continues to be officially banned. The Personal Information Protection Law in China classifies genetic data as sensitive personal information and establishes principles of consent, purpose limitation, and controls on cross-border transfers. The State access to genomic databases for public health or surveillance purposes is also allowed.[8]

6 Demystifying China's regulation of 'human genetic resources', Fresh Fields, accessible at: https://riskandcompliance.freshfields.com/post/102iml7/demystifying-chinas-regulation-of-human-genetic-resources, last accessed on February 18, 2026.

7 After He Jianku: China's biotechnology regulation reforms, Sage Journals, accessible at: https://journals.sagepub.com/doi/full/10.1177/0968533221993504, last accessed on February 18, 2026.

8 Protecting Your Personal Information in the Age of the Personal Information Protection Law (PIPL) by the People's Republic of China, accessible at: https://secureprivacy.ai/blog/china-pipl-personal-information-protection-law#:~:text=The%20PIPL%20in%20China%20places,the%20Cyberspace%20Administration%20of%20China, last accessed on February 18, 2026

Challenges Worldwide

As genomics increasingly occupies a central role in contemporary medicine and biotechnology, it highlights a range of intricate legal and ethical issues, from the management of sensitive personal data to the potential for discrimination, especially in a nation as diverse as India. With genomic data becoming more pivotal to diagnosis, treatment, and research, the necessity to reconcile innovation with rights, risks, and responsibilities grow ever more pressing.

A. Data Privacy

Genomic data is profoundly personal. It contains sensitive information regarding not just the individual but also their biological relatives. This implies that breaches of genomic data represent more than mere privacy violations as it can put entire families, ethnic groups, or communities at risk of medical, social, or legal repercussions.

The concern extends beyond data theft or unauthorized access. A more urgent issue is the secondary use of data in situations where individuals agree to genetic testing for clinical reasons, yet their data is subsequently repurposed for research, commercial collaborations, or AI training models without their explicit awareness or consent due to uncertainty on data privacy in genomics.

In the direct-to-consumer genetic testing sector, this ambiguity is even more evident as companies reserve the right to store, analyse, and share genetic user data in anonymized or even identifiable formats, often through fine print terms and conditions.[1]

In India, the lack of a dedicated genomic privacy law results in protections being largely derived from broader data protection regulations such as the Information Technology Act, 2000 (**"IT Act"**) and the SPDI Rules, which reference medical data as SPDI and biometrics but do not specifically cover genomic data.[2] Additionally, the newly notified Digital Personal Data Protection Act, 2023 (**"DPDPA"**) and its Digital Personal Data Protection Rules, 2025 (**"DPDP Rules"**) that are intended to come into force from May 2027 represent a significant overhaul of India's data protection regime. It aims to create a comprehensive statutory structure for the protection of personal data and blurs the lines between general personal information and sensitive personal. However, despite its broad reach, the current DPDPA and DPDP Rules do not specifically carve out genomic data as a distinct category, nor do they explicitly classify genomic sequences or derived genetic information as a separate sub-class of data requiring enhanced safeguards. This creates regulatory ambiguity for genomics research and commercial activities. While genomic data may be captured as personal data when linked to identified or identifiable individuals, there is no specific provision in the DPDPA that recognises the unique nature of genomic information such as its irreversibility, familial implications, potential for re-identification, and long-term sensitivity.

1 Privacy in Genomics, National Human Genome Institute, accessible at: https://www.genome.gov/about-genomics/policy-issues/Privacy, last accessed on February 18, 2026.

2 Rule 2(b) of Information Technology (Reasonable security practices and procedures and sensitive personal data or information) Rules, 2011.

On a global scale, frameworks like the European Union's GDPR have attempted to categorize genetic data as a distinct type of personal data.[3] However, the enforcement of these regulations has struggled to keep up with the swiftly changing environment of bioinformatics, cloud storage, and international data sharing.

B. Informed Consent

In the realm of genomics, informed consent should not be regarded as a simple administrative procedure. It is essential that it serves as a significant process, ensuring that individuals comprehend what is being done with their genetic material, the reasons behind it, the potential outcomes, and how their data will be utilized both now and in the future.

This issue is particularly pronounced in India, where health literacy varies significantly, and patients may not fully understand the long-term consequences of genetic testing. In rural areas, the consent process is further complicated by language barriers, cultural beliefs, and the hierarchical nature of doctor-patient relationships. Even in urban environments where private healthcare providers and direct-to-consumer companies are prevalent in the genomics sector, consent practices frequently reduce to mere checkbox agreements found in applications or websites.

On an international scale this has resulted in the implementation of 'broad consent' or 'dynamic consent' models. Broad consent permits data processors to undertake future research with the datasets within general parameters, while dynamic consent employs digital platforms to enable participants to modify their preferences over time. Nevertheless, both models present challenges: the former may be excessively vague, while the latter could be overly demanding in terms of ongoing engagement. [4]

In India, the consent frameworks for biomedical research are typically guided by the ICMR Guidelines. Although these guidelines acknowledge the complexities associated with genomic research, their implementation remains inconsistent, as they are non-binding.

In practice, many participants, especially those in rural or low-income areas, may not fully understand the long-term implications of donating biological material or data. Therefore, consent frameworks must be integrated within broader systems of transparency, accountability, and participant engagement to ensure ongoing control for consumers.[5] It is evident that there is increasing inclination towards the dynamic consent model under the new data law requiring data processors to take specific consent and to enable participants to modify consent terms over time.

C. Genetic Discrimination

The risk of discrimination stemming from genetic predisposition is an urgent issue as understanding one's genetic susceptibility to diseases can enhance clinical care, however, it may also lead to stigmatization, exclusion, or the denial of opportunities. This concern has already manifested in subtle ways, particularly within high-risk insurance pools, prenatal screening initiatives, and social environments that associate genetic markers with stigma.

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3 Rules for processing genetic data for research purposes in view of the new EU General Data Protection Regulation, European Journal of Human Genetic, accessible at: https://www.nature.com/articles/s41431-017-0045-7, last accessed on February 16, 2026.

4 Informed Consent in Direct-to-Consumer Personal Genome Testing: The Outline of A Model between Specific and Generic Consent 2012, Research Gate, accessible at: https://www.researchgate.net/publication/233382995_Informed_Consent_in_Direct-to-Consumer_Personal_Genome_Testing_The_Outline_of_A_Model_between_Specific_and_Generic_Consent, last accessed on February 16, 2026.

5 National Ethical Guidelines for Biomedical and Health Research involving Human Participants, 2017.

In 2008, USA implemented GINA to prevent discrimination based on genetic information in health insurance and employment sectors. Other nations, including Canada and South Korea, have integrated genetic protections into existing legislations. Nevertheless, numerous jurisdictions, such as India, lack specific laws that directly tackle the threat of genetic discrimination.

While the Equal Remuneration Act (ERA) and the Persons with Disabilities Act (PDA) in India address broader workplace discrimination, but they do not consider the emerging challenges posed by genomic profiling. This legislative gap in the Indian context results in considerable vulnerability.

In the absence of explicit legal prohibitions and public awareness initiatives, these risks are likely to escalate as genomic testing becomes increasingly prevalent and accessible.[6]

D. Ethical Use of AI and Genomics

As genomic data expands, its analysis increasingly depends on artificial intelligence and machine learning technologies. These tools are crucial for interpreting extensive genetic information and tailoring treatment protocols. However, the convergence of AI and genomics introduces a unique set of ethical and legal dilemmas.

Firstly, there is the concern of algorithmic bias. If AI models are trained on datasets that inadequately represent specific ethnic or regional groups, the predictions they produce may be less accurate or potentially harmful for those populations. In a nation as genetically diverse as India, this is not merely a theoretical issue. Genomic tools created using Western data may misclassify or overlook variants that are prevalent in Indian populations, resulting in misdiagnosis or exclusion from research.

Another issue is explainability, as most AI systems function as "black boxes"—yielding results that are challenging to comprehend or audit. When these outcomes influence clinical decision-making, both patients and providers may find themselves without a clear explanation for why a particular diagnosis was reached or a treatment was suggested.

AI systems also frequently necessitate substantial amounts of data, encompassing genomic, clinical, and behavioral information. This generates a feedback loop where the demand for data may surpass ethical safeguards. In the absence of clear boundaries, patients may inadvertently become data sources for models that prioritize commercial interests over clinical ones. Accountability also remains unclear because if an AI system misclassifies a gene variant or fails to identify a risk, who bears responsibility—the developer, the data provider, or the clinician? Current legal frameworks struggle to determine liability in such situations.[7]

6 Genes, Behavior, and the Social Environment: Moving Beyond the Nature/Nurture Debate, National Library of Medicine, accessible at: https://www.ncbi.nlm.nih.gov/books/NBK19932/#:~:text=In%20many%20ways%2C%20we%20are,our%20ecologies%20to%20model%20risk, last accessed on February 16, 2026.

7 A plea for caution and guidance about using AI in genomics 2024, Nature Machine Intelligence, accessible at: https://www.nature.com/articles/s42256-024-00947-y, last accessed on February 16, 2026.

Recommendations

Despite the significant strides made in genomics and its growing relevance in personalized medicine, agriculture, and biotechnology, India's current legal and policy architecture remains fragmented and inadequate.

A. Unified Legislative Framework

There is an urgent need for a dedicated Genomics Regulation Act that defines the scope of permissible genomic research and applications, including gene editing, genetic engineering synthetic biology, and personalized medicine.

Such legislation should address risk assessment, informed consent, data protection, liability, and benefit-sharing in a unified legal framework. It should regulate clinical, agricultural, forensic, and DTC genomic applications along with defining legally permissible and prohibited uses of genomics. This would reduce regulatory fragmentation across different laws and bring in much needed legal clarity for stakeholders.

B. Data Protection and Privacy for Genetic Data

SPDI Rules and DPDP Act does not explicitly define or protect genetic data which causes ambiguity and leaves genetic information vulnerable to misuse. To prevent this, either the existing regulations should be amended to specifically deal with genetic data or a new law on genetic data protection is required due to its highly sensitive nature.

It should define and classify genetic data, as well as provide specific data privacy protections accompanied by enhanced obligations for processing. It should also impose a prohibition on discrimination based on genomic traits modelled on the GINA in the US.

C. Clarification on Patent Eligibility for Gene Technologies

The Patents Act as interpreted through Section 3(c), 3(d), and 3(j), prohibits patents on discoveries of natural substances, mere admixtures, and plants or animals in whole or in part. While this has traditionally been used to exclude naturally occurring gene sequences, it has also caused confusion over whether this would include gene technologies and GMOs.

Therefore, clarification for the same needs to be issued under the Patents Act, keeping in mind that genomics has become a high-priority growth sector in India.

D. Incentivize Responsible Innovation Through Policy Measures

Innovation in genomics must be matched by incentives that also encourage ethical conduct and legal compliance. This can be done by allowing patentability of GMOs and gene technologies if they satisfy the criteria set out in the Patents Act. Additionally, tax benefits or R&D credits can be offered to companies and research labs developing indigenous genetic diagnostics, therapeutic solutions, or bioinformatics tools aligned with Indian population needs. Focus should also be laid on the development of public-private partnership models for ethical biobanking that ensures benefit-sharing and data protection.

Conclusion

India stands at a pivotal moment in the evolution of genomic science. With large-scale initiatives like the GenomeIndia Project and the establishment of the IBDCs, India has demonstrated both scientific capacity and policy intent to participate meaningfully in the global genomics revolution. Yet, the legal and regulatory frameworks have struggled to keep pace with the ethical, technological, and commercial complexities posed by genomics.

India's current legal architecture spanning biotechnology, data protection, health regulation, patent law, and environmental governance remains fragmented, outdated, and often silent on critical issues such as gene editing, biobanking, genomic discrimination, and direct-to-consumer testing.

One of the most pressing areas of concern is the regulation of genetic engineering and GMOs. As gene-editing technologies such as CRISPR redefine what is scientifically possible in both healthcare and agriculture, India must ensure that its laws provide clear guidelines on their treatment.

The potential of these technologies cannot be denied, but nor can the risks they pose to biosafety, genetic diversity, and fundamental rights. In the absence of robust regulation, the dangers of irreversible harm, exploitation, or erosion of public trust remain prominent.

Therefore, a coherent and forward-looking legal framework is imperative to balance innovation with public interest which will give India the opportunity to align itself with global biotech leaders such as USA, China and EU, all of which have well-defined regulations for genomics. This will promote cross-border collaboration by ensuring data interoperability, and encouraging foreign and domestic investment in genomics research and biotechnology.

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Management by Trust in a Democratic Enterprise: A Law Firm Shapes Organizational Behavior to Create Competitive Advantage

NISHITH DESAI

The founder of Mumbai-based Nishith Desai Associates (NDA) built his law firm on a few powerful ideas: a trust-based, nonhierarchical, democratically managed organization that leverages research and knowledge to deliver premium-service, high value, and a unique employer proposition that shatters many negative law-firm stereotypes. The author discusses the rationale behind NDA's business model and its organization and talent framework, and tracks the firm's philosophical genesis, which includes ideas from Mahatma Gandhi on democracy and from Charles Handy on trust in virtual organizations. He examines the implications of Handy's Rules of Trust for HR policies and practices, and then he describes NDA's approaches for creating challenge, growth, and rewards in a nonhierarchical structure; building behavioral competencies; balancing control with freedom; and other management practices that empower employees to act in the best interests of the firm and its clients. © 2009 Wiley Periodicals, Inc.

Think of a profession that, by its very nature and craft, tends to ingrain such attitudes as low trust, skepticism, and dispassion, where the personal interest and goals of individualistic, ambitious, self-driven, ego-led professionals supersede any commitment to the organization's goals. Chances are that the legal profession will be at the top of your list. If not, just think of a lawyer—and the description fits effortlessly. (As a lawyer, I have no qualms making this statement.)

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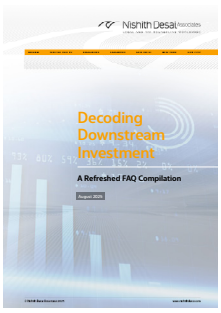

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