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CODE OF CARE: Volume II

FROM EXPERIMENT TO ENFORCEMENT: HOW INDIA REGULATES TESTING AND CLINICAL TRIALS

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1. Introduction

Clinical Trials have been critical to the healthcare sector, serving as the cornerstone of drug development and medical device safety. Without Clinical Trials, it would be impossible to characterize the benefits and risks of a treatment or evaluate the efficacy of a medicine. The market for Clinical Trials in 2024 has been valued at USD 1.42 billion and is expected to grow at a CAGR of approximately 8% (eight percent) until 2030.[1] The Indian government basis the trends of budgetary allocation has further been observed to have steadily increased its budget allocations for health research indicating a steady 11% increase in budgetary allocation in the past years currently making the sum total of the budgetary allocation to health research to INR 3,901 crores.[2]

Additionally, fiscal incentives under the Income Tax Act, 1961, such as allowing up to 100% tax deductions on expenditure for scientific research including clinical drug trials, coupled with the product patent regime under the Patents Act, 1970 ensuring strong protection for proprietary drugs, incentivized multinational corporations to establish and expand in-house research and development in India.

2. Foreign Direct Investments in India

Pursuant to the promotion of clinical research through financial incentives and requisite patent protection being provided, India has observed a steady influx of foreign direct investments in pharmaceutical and medical devices sector. For instance, in the previous financial year, India recorded foreign direct investment ("**FDI**") inflows of INR 19,134 crores.[3]

While the Consolidated FDI Policy, 2020 ("**FDI Policy**"), as well as the Foreign Exchange Management (Non-Debt Instruments) Rules, 2019 ("**NDI Rules**") do not provide a specific classification for clinical research organizations ("**CRO**")[4] under any business sectors explicitly, resulting in such unclassified activities to fall under the residual category for which 100% FDI is permitted under the automatic route, subject to applicable laws, regulations, security, and other conditionalities.

3. Regulatory Framework

With the growing emphasis on incentivizing clinical research in India, it became necessary to regulate and streamline clinical research processes with patient safety as the primary consideration. To this end, the licensing and regulatory framework in India was further strengthened through the introduction of the New Drugs and Clinical Trials Rules, 2019 ("**NDCT Rules**"). In the present regulatory framework, clinical research in India is primarily governed by the NDCT Rules, which have superseded the earlier provisions of Schedule Y of the Drugs Rules, 1945. These rules were introduced to streamline the regulatory process, enhance participant protection, and align India's clinical research regulations with international standards. This article provides an overview of the regulatory framework governing the conduct of clinical research under the NDCT Rules read with the Drugs and Cosmetics Act, 1940 and the emerging legal perspective and challenges in clinical research in India.

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[1] *India Clinical Trials Market Size, Share & Trends Analysis Report By Phase (Phase I, Phase II, Phase III, Phase IV), By Study Design, By Indication, By Service Type, By Sponsor, And Segment Forecasts, 2025 – 2030*, GRANDVIEWRESEARCH (2024) https://www.grandviewresearch.com/industry-analysis/india-clinical-trials-market.

[2] Demand for Grants 2025-26 Analysis, PRS INDIA (March 01, 2025) https://prsindia.org/files/budget/budget_parliament/2025/DFG_Analysis_2025-26-Health.pdf

[3] *FDI in India's pharma sector crosses Rs 19,134 crore during 2024-25*, ECONOMICTIMES (April 14, 2025) https://cfo.economictimes.indiatimes.com/news/corporate-finance/fdi-in-indias-pharma-sector-crosses-rs-19134-crore-during-2024-25/120268260.

[4] '*Clinical research organization*' or '*CRO*' wherever referred in this article means a legal entity by whatsoever name called, to which undertakes tasks, duties or obligations regarding clinical trial or bioavailability or bioequivalence study.

NDCT Rules regulates the following forms of clinical research: (i) clinical trials (as defined under NDCT Rules); (ii) bioequivalence and bioavailability studies; (iii) biomedical and health research.

Stakeholders of Clinical Research

Clinical research refers to the systematic study of pharmaceutical products in human participants to evaluate their safety, efficacy, and overall risk–benefit profile prior to regulatory approval and commercial distribution. The conduct of such research typically involves three key entities: the pharmaceutical companies ("**Sponsors**"), contract research organizations ("**CROs**"), and ethics committee. With the increasing complexity and scale of clinical research, Sponsors engaged in the manufacture of drugs for global distribution are increasingly relying on CROs to assist in the design, management and conduct of clinical research. To ensure that CROs possess the requisite competence, including infrastructure, qualified personnel, and quality systems to undertake clinical research-related activities, the revised regulatory framework prescribes specific obligations such as appointing responsible and trained personnel, maintaining documented standard operating procedures, ensuring proper delegation of trial-related duties, implementing quality assurance and control mechanisms, regularly training staff, ensuring investigator preparedness, maintaining comprehensive trial records for prescribed periods, and upholding strict confidentiality and regulatory compliance throughout the conduct of the study. To regulate and streamline the operations of CROs, the new regulatory framework mandates registration of the CROs with the Drugs Controller, India before conducting any Clinical Trial, bioavailability/ bioequivalence study or biomedical and health research. Applications for such registration must be made in Form CT-07B. Registered CROs must comply with good clinical practices guidelines for the conduct of clinical studies in India, formulated by the Central Drugs Standard Control Organization and adopted by the Drugs Technical Advisory Board and maintain proper documentation.

Stages of Clinical Research

Pre-clinical studies

Prior to undertaking human clinical research in India, one of the general principles under NDCT Rules is to first undertake animal clinical testing, such testing may include animal pharmacology data and toxicology data. However, the Indian government to ensure ethical pre-clinical studies ensures that ethical standards with minimal animal cruelty are undertaken and has established the Committee for the Purpose of Control and Supervision of Experiments on Animals ("**CPCSEA**"), which has the authority to regulate and oversee all animal experimentation in the country under Prevention of Cruelty to Animals Act, 1960.

For any pre-clinical studies requiring animal experimentation being undertaken, an entity requires the same to be registered with CPCSEA under the Breeding of and Experiments on Animals (Control and Supervision) Rules, 1998. Establishments registered under CPCSEA are further mandated to constitute an Institutional Animals Ethics Committee ("**IAEC**"). IAEC once constituted is required to review and approve all types of protocols for research involving small animal experimentation before the start of the study.[5] For approval of experimentation on large animals, the request should be forwarded to CPCSEA in the prescribed manner with recommendation of IAEC. The primary duty of IAEC is to focus mainly on ensuring ethical and methodical handling of animals during and after experiments, so that they have less suffering.

Furthermore, IAEC is required to maintain detailed records of experiments, including particulars about animals used, in specified formats and inspect the animal housing facilities from time to time.

[5] IAEC can only clear research project proposals that involve experiments on animals higher on the phylogenetic scale than rodents.

Human Clinical Research

I. Pharmaceutical Clinical Trials

(a) Phases of Clinical Trials

Under NDCT Rules, '*Clinical Trials'* are defined as systematic human studies that generate data on clinical, pharmacological, and adverse effects to determine safety, efficacy, and tolerance of new or investigational drugs. The development process consists of four phases as provided below:

Phase I: Tests safety and dosage in small groups of healthy volunteers; determines pharmacokinetics and maximum tolerated dose

Phase II: Evaluates effectiveness and side effects in limited patients with target condition

Phase III: Confirms efficacy and safety in larger, diverse patient populations; provides basis for marketing approval

Phase IV: Post-marketing surveillance to monitor long-term effects and rare adverse events in real-world settings

(b) Registration Requirements

Under the NDCT Rules, Clinical Trials require permission from the Drugs Controller, India. This centralized approval system ensures consistent application of standards across the country. Applications must be submitted in Form CT-04 with supporting documents as specified in the Second Schedule and fees as specified in the Sixth Schedule. Upon scrutiny, if the authority is satisfied that all requirements have been met, it may grant permission for conducting Clinical Trial. Such decisions must be taken within 90 working days, failing which the application shall be deemed to be approved. In such cases, the applicant must notify the Authority, which shall be taken on record as deemed approval and treated as legally valid authorization to initiate the Clinical Trial. All trials must be registered with the Clinical Trial Registry of India before enrolling the first subject. This registration requirement enhances transparency and allows public access to information about ongoing trials. Trials must follow the general principles and practices specified in the First Schedule of the NDCT Rules.

(c) Role of ethics committees and informed consent

Any entity intending to undertake Clinical Trials should obtain the approval of an ethics committee. Such ethics committees must be registered with the Drugs Controller, India in Form CT-01. This registration ensures that ethics committees meet minimum standards for protecting research participants. They must comprise at least seven members from diverse backgrounds including medical, non-medical, scientific, and non-scientific areas, with at least 50% (fifty) being non-affiliated with the institution. This composition requirement ensures independent oversight and diverse perspectives. The committee must include at least one lay person, one woman member, one legal expert, and one independent member from another related field. For reviewing protocols, a quorum of at least five specific members is required. Ethics committees are responsible for safeguarding the rights, safety, and well-being of trial subjects.

II. Additional types of clinical research

(a) Regulatory framework for Bioavailability and Bioequivalence

Under the NDCT Rules, any person, institution, or organization intending to conduct a bioavailability study or bioequivalence study of a new drug or investigational new drug in human subjects must obtain prior permission from the Drugs Controller, India. This centralized approval system ensures uniform standards of review and monitoring. Applications must be submitted in Form CT-05 with supporting documents as specified in the Second Schedule and the prescribed fees under the Sixth Schedule. Upon review, the Central Licensing Authority may grant permission in Form CT-07. In certain cases, deemed approval may arise under the proviso to the prescribed timelines, in which event the applicant must notify the Central Licensing Authority in Form CT-07A prior to initiating the study.

All bioequivalence and bioavailability studies must be reviewed and approved by a registered Ethics Committee before enrolment of the first subject. Ethics Committees are required to be registered with the Drugs Controller, India in Form CT-01 and must comply with the composition and quorum requirements under the Rules to ensure independence and adequate representation. The oversight of Ethics Committees is critical to safeguarding the rights, safety, and well-being of study participants. In addition, permissions granted under Form CT-07 remain valid for a period of one year, unless suspended or cancelled earlier, and all conditions applicable to Clinical Trials of new drugs apply mutatis mutandis to bioequivalence and bioavailability studies.

(b) Regulatory Framework for Biomedical and Health Research

For biomedical and health research not involving new drugs, the ethics committees must be registered with the National Ethics Committee Registry for Biomedical and Health Research. This separate registration pathway acknowledges the different risk profiles of such research.

(c) ICMR Guidelines

In addition to the above specified statutory regulations, ICMR has issued guidelines that govern research in specific domains such as stem cell research, gene therapy and other advanced biomedical areas. Where clinical research is undertaken in these specialised fields, the respective ICMR guidelines are required to be complied with, in addition to the general regulatory framework.

III. Alternative Medicine Research

Ayurvedic, Siddha, and Unani Clinical Research:

For traditional medicine systems, researchers must follow AYUSH guidelines including the Good Clinical Practice Guidelines for clinical research in Ayurveda, Siddha and Unani Medicine, 2013 and ICMR Guidelines for Biomedical and Health Research Involving Human Participants.

Inspection and Compliance

Clinical Trial sites and bioavailability or bioequivalence is subject to inspection by authorized officers from the Drugs Controller, India. Non-compliance can result in suspension or cancellation of trial permissions, rejection of trial results, or debarment of investigators and Sponsors conducting future trials. Accordingly, CRO is required to ensure that all necessary documentation is maintained for at least 5 (five) years after trial completion or 2 (two) years after marketing approval, whichever is later.

Serious Adverse Events

Under the NDCT Rules, an “adverse event” is defined as any untoward medical occurrence (including a symptom, disease, or abnormal laboratory finding) during treatment with an investigational drug or pharmaceutical product in a patient or trial subject, which does not necessarily have a relationship with the treatment. A SAE refers to any such occurrence during a trial or study that results in death,

permanent disability, hospitalization (or prolongation thereof), life-threatening events, congenital anomaly, or other significant incapacity. India's regulatory framework imposes stringent obligations on Sponsors, investigators, and Ethics Committees with respect to the reporting, review, and redressal of serious adverse events ("**SAEs**"), across all categories of clinical research including (i) Clinical Trials of new drugs or investigational new drugs, (ii) bioavailability and bioequivalence studies, and (iii) biomedical and health research.

(a) Clinical Trials of new drugs or investigational new drugs

Under the NDCT Rules, Sponsors are required to provide free medical management for any trial-related injury, for as long as required. In the event of a trial-related death or permanent disability, financial compensation must be paid to the subject or their legal heirs according to the formula specified in the rules. The initial report for serious adverse events must be reported to the Drugs Controller, India, Ethics committee within 24 (twenty four) hours and a detailed report would be required to be submitted within 14 (fourteen) days, in each case, from the time of occurrence of such event. This reporting requirement enables timely investigation and intervention. Further, post-trial access to investigational drugs may be provided free of cost under specific conditions.

(b) Bioavailability and bioequivalence studies

The same standards for medical management, SAE reporting, and compensation applicable to Clinical Trials will apply *mutatis mutandis* to bioavailability and bioequivalence studies.

(c) Biomedical and health research

Such research must comply with the National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, 2017 issued by the Indian Council of Medical Research. This regulation mandates registration with the Clinical Trial Registry of India prior to conducting any clinical research for biomedical and health research, obtaining informed consent from each participant, and maintaining quality assurance throughout the trial. Sponsors are also obligated to report SAEs within prescribed timelines, provide free medical management for adverse events (where such events are causally linked to the research), and offer compensation for trial-related injuries.

Manufacturing Permission for New Drugs and Investigational New Drugs

Under the NDCT Rules, no person may manufacture a new drug or an investigational new drug for the purposes of conducting a Clinical Trial, bioavailability or bioequivalence study, or for examination, test, and analysis, without prior permission from the Central Licensing Authority. An application for such permission must be submitted in Form CT-10, along with the documents prescribed in the Fourth Schedule and the applicable fee under the Sixth Schedule.

On receipt of the application, the Central Licensing Authority scrutinizes the information provided and may, if satisfied that the requirements of the Rules are met, grant permission in Form CT-11 within ninety working days. If deficiencies are noted, applicants are given an opportunity to rectify them within a specified period. Where no communication is received within ninety working days, permission is deemed to have been granted, subject to the filing of Form CT-11A for record. The permission remains valid for three years, extendable by one year in exceptional cases.

Emerging Legal Perspectives and Challenges in Clinical Research in India

While NDCT Rules have modernized India's clinical research ecosystem, new-age technologies and evolving research models bring fresh legal challenges. Policymakers, regulators, Sponsors, and CROs must anticipate and address these to sustain India's competitiveness while ensuring participant protection:

I. Personal Data Protection Framework

The present regulatory framework governs 'sensitive personal data' which includes medical records and history.[6]Sponsors and the CROs handling such sensitive personal data must obtain consent before collection, use the data only for the stated purpose, maintain reasonable security practices, and allow individuals to review, correct, or withdraw their data. They are also required to adopt a documented privacy policy, appoint a grievance officer, and ensure lawful transfer of such data outside India.

India has recently enacted the Digital Personal Data Protection Act, 2023 ("**Act**") and issued draft Digital Personal Data Protection Rules, 2025 ("**Draft Rules**"), which together create a comprehensive framework for safeguarding personal data in the digital space. However, these provisions are not yet in force. Clinical research activities may qualify for an exemption under the Act, where personal data is processed solely for research purposes.[7] This exemption is not automatic, the Draft Rules clarify that such processing must comply with standards set out in the Second Schedule of the Draft Rules, including lawful use of data, collecting only what is necessary, ensuring accuracy, limiting how long data is kept, and adopting reasonable security safeguards.[8] Further, the entity processing such data must maintain accountability for effective observance of these standards while ensuring the data is not used to make decisions specific to a Data Principal.[9] If these conditions are met, Sponsors or CROs conducting clinical research may be eligible for exemption from the provisions of the Act.

These regulations further assume particular significance in the context of genomic data-based trials, which are expanding in oncology and rare diseases such as lysosomal storage disorders, thalassemia, muscular dystrophies, and other neuromuscular conditions. Under the present regulatory framework, genetic data is regarded as sensitive under Indian jurisprudence[10], requiring informed consent that expressly addresses long-term storage, secondary uses, and potential commercialization. Since many genomic datasets are analyzed abroad, their transfer will be subject to government whitelists and the safeguards prescribed under the present regulatory framework i.e., Information Technology (Reasonable Security Practices and Procedures and Sensitive Personal Data or Information) Rules, 2011, as discussed above until the Act is brought into force. Moreover, because genomic findings may inadvertently reveal health risks for family members, such trials necessitate more sophisticated disclosure and counselling frameworks to uphold ethical standards.

Further, artificial intelligence ("**AI**") is increasingly used in clinical research for patient screening, risk prediction, and monitoring, but raises concerns of bias, liability, and ethical compliance. Unlike the US FDA[11], India has yet to establish AI-specific accountability frameworks, making regulatory clarity urgent.

II. Decentralized Clinical Trials

Another emerging concept within the landscape of Clinical Trials is decentralized clinical trials ("**DCTs**") leverage digital technologies to conduct research remotely, reducing participant burden and expanding access. Several emerging start-ups are moving into the DCT landscape. However, this emerging approach faces a significant regulatory vacuum in India. The regulations governing Clinical Trials in India lack specific provisions for governing the specific challenges in relation to virtual trials such as confidentiality, data privacy, maintenance of digital trail, electronic consent, acceptable mode of digital Clinical Trials. While telemedicine gained regulatory recognition in 2020[12], these

[6]Information Technology (Reasonable Security Practices and Procedures and Sensitive Personal Data or Information) Rules, 2011, R. 3.
[7]Digital Personal Data Protection Act, 2023, S. 17(2)(b).
[8]Digital Personal Data Protection Rules, 2025, Second Schedule.
[9]*Id.*
[10]Justice K.S. Puttaswamy v. Union of India 10 S.C.C. 1 (India).
[11]US FDA Discussion Paper on AI/ML in Drug Development, 2023.
[12]Telemedicine Practice Guidelines, 2020.

guidelines explicitly exempt research and evaluation activities, leaving DCTs without clear direction for remote participant interactions. While the regulations governing Clinical Trials do not specifically provide for safeguards of the sensitive data collected during the course of Clinical Trials, limited comfort can be drawn from the provisions of Information Technology (Reasonable Security Practices and Procedures and Sensitive Personal Data or Information) Rules, 2011, which prescribes certain safeguards as specified in the preceding paragraphs. With the global shift toward decentralized methodologies accelerated by COVID-19, this regulatory void presents both challenges and opportunities. Further, the ICMR's draft guidance on digital health and remote clinical trials (released in May 2025) is the first step toward recognizing e-consent, remote monitoring, and secure data storage as legitimate practices.[13] Yet, these are not binding, and hence, a lack of statutory recognition for e-consent raises enforceability concerns if challenged. Thus, companies must navigate uncertain requirements while regulators have the opportunity to develop forward-looking frameworks that balance innovation with participant protection in India's rapidly evolving clinical research landscape.

Technology-enabled trials tend to blur traditional lines of responsibility. As regards telemedicine trials, in case of an SAE, ambiguity continues to exist on whether liability rests with the principal investigator, the teleconsulting doctor, or the Sponsor. Further, malfunctioning of remote monitoring devices may raise product liability questions and thereby whether manufacturers, CROs, or Sponsors would need to bear responsibility for such liability remains to be clarified. Lastly, current Clinical Trial insurance frameworks may not adequately cover risks from digital interfaces and cross-border data handling[14], which may need to be considered while generally considering revision of frameworks to seamlessly adopt technology-enabled trials in India.

III. ESG and Responsible Innovation

Globally, pharma companies are being evaluated on ESG metrics.[15] Regulators and investors expect evidence that trials recruit across diverse populations and do not exclude marginalized groups. Trial sponsors may soon be required to disclose the carbon footprint of their operations, including trial site infrastructure and digital data centres. Transparent reporting of trial outcomes, adverse events, and data practices is also becoming part of ESG accountability, influencing investment decisions.

4. Conclusion

India's evolving regulatory ecosystem supports pharmaceutical development through streamlined clinical research rules, structured FDI treatment, and ethical oversight mechanisms. The 2019 reforms ensure participant safety, while sector-specific FDI policies encourage both Sponsor-led and CRO-led research. Additionally, the Act offers research exemptions for entities meeting prescribed data safeguards. Together, these legal, fiscal, and compliance frameworks make India a competitive, secure, and transparent destination for clinical research, medical device testing, and pharmaceutical innovation. However, with the growing global shift towards decentralized clinical trials, India's current regulatory framework remains silent on key aspects such as virtual participant engagement presenting both challenges and opportunities for policymakers to craft forward-looking regulations that enable innovation while ensuring robust participant protection. Given technological advancements world over, the future of clinical research will likely be shaped by the ability to integrate digital health technologies, AI, genomic safeguards, liability clarifications, and ESG principles. Policymakers must move quickly to align regulations with these global trends, ensuring India remains a hub for responsible and innovative clinical research.

[13] ICMR Draft Guidance on Digital Health Trials, May 2025.
[14] IRDAI (Health Insurance) Regulations, 2016, Regulation 17; see also IRDAI Circular on Clinical Trial Insurance (2021).
[15] World Economic Forum, ESG Metrics for Pharma & Biotech (2024).

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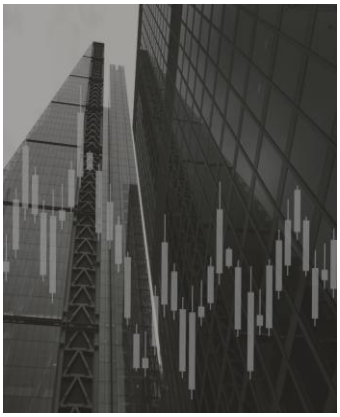

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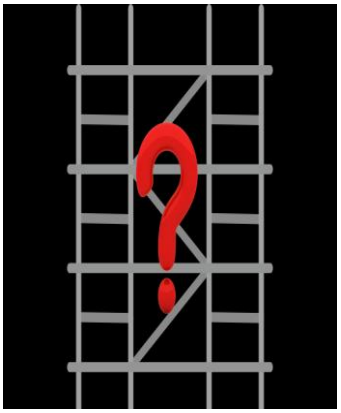

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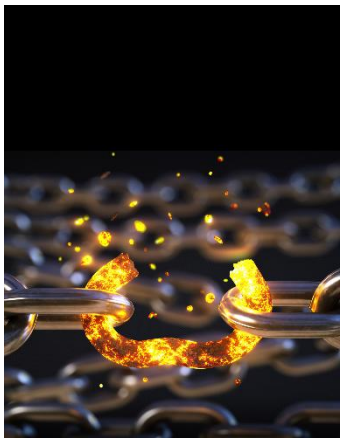

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