Available online on 15 Dec, 2025 at https://ijdra.com/index.php/journal
International Journal of Drug Regulatory Affairs
Published by Diva Enterprises Pvt. Ltd., New Delhi
Associated with Delhi Pharmaceutical Sciences & Research University

Review Article

Open Access

Clinical Research Regulation in India and Brazil: An Overview of Current Frameworks and Implementation Gaps

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Abstract

Clinical research in emerging economies has expanded significantly over the past two decades, necessitating robust, transparent, and ethical regulatory systems. India and Brazil two major middle-income countries with rapidly growing clinical trial sectors have implemented substantial reforms aimed at strengthening participant protection, streamlining approval pathways, and improving regulatory oversight. This review provides a comparative examination of the current clinical trial regulatory frameworks in India and Brazil, highlighting their legal foundations, governance structures, ethical oversight mechanisms, and operational requirements. In India, the New Drugs and Clinical Trials Rules (NDCTR) 2019 established a consolidated, clearer, and more time-bound regulatory pathway, with mandatory ethics committee registration and enhanced safety reporting obligations. Brazil, through ANVISA regulations and the National Research Ethics Commission (CONEP), has progressively harmonized ethical and scientific review processes, with noteworthy reforms introduced by Law No. 14,874/2024 and updated ANVISA Resolutions. Despite these advances, both countries continue to face implementation gaps, including delays in multicenter trial approvals, variations in ethics committee capacity, limited inspection resources, and challenges in transparency and post-trial access. Comparative analysis reveals opportunities for regulatory convergence, digitalization of review processes, and strengthened collaboration between national authorities to support global clinical research. Addressing these systemic gaps will be essential for building public trust, enhancing research quality, and positioning India and Brazil as reliable hubs for ethical and scientifically sound clinical trials.

Keywords: Clinical Research Regulation; NDCTR 2019; ANVISA; ICH-GCP; WHO guidelines; CIOMS ethical principles; Institutional Ethics Committees (IECs); ICMR; New Drugs & Clinical Trials Rules; CTRI; CDSCO; National Committee (CONEP)

Article Info: Received 25 Nov 2025; Review Completed 12 Dec 2025; Accepted 15 Dec 2025

Cite this article as:
Shinde RK, Kothari LP. Clinical Research Regulation in India and Brazil: An Overview of Current Frameworks and Implementation Gaps. Int. J. Drug Reg. Affairs [Internet]. 2025 Dec15 [cited 2025 Dec 15]; 13(4):62-71. Available from: https://ijdra.com/index.php/journal/article/view/826

DOI: 10.22270/ijdra.v13i4.826
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1. Introduction

Clinical research forms the backbone of evidence-based medicine and is essential for the development, evaluation, and approval of new therapeutic interventions. As the global burden of disease evolves and the demand for innovative health solutions increases, emerging economies have become significant contributors to multinational clinical trial activity. Among these, India and Brazil two of the largest and fastest-growing healthcare markets offer substantial opportunities for clinical investigation due to their diverse populations, epidemiological profiles, expanding biomedical industries, and skilled scientific workforce. (1) Their participation in clinical research is not only vital for global drug development but also for ensuring local access to new therapies and building national research capacity. However, with increased clinical trial activity comes heightened responsibility to protect human participants, promote ethical conduct, ensure scientific robustness, and align national systems with international standards such as ICH-GCP, WHO guidelines, and CIOMS ethical principles. India has restructured its regulatory environment through the New Drugs and Clinical Trials Rules (2019), operationalized digital regulatory platforms, and standardized ethics committee accreditation processes. (2) The country has moved toward faster, more transparent approvals and clearer compensation rules. Meanwhile, Brazil has enhanced ethical governance through a dual-tier system under CONEP and CEPs, refined regulatory procedures through ANVISA's Resolution RDC 9/2015, and embraced guidelines for complex trials including stem cell, vaccine, and advanced therapy studies. Despite these advancements, both nations continue to face substantial implementation challenges, including administrative bottlenecks, regional disparities in research capacity, inconsistent ethics oversight, and logistical issues related to import, export, and monitoring of investigational products. (3)

This review presents a comprehensive, section-wise comparison of clinical research regulations in India and Brazil, with a focus on their governance frameworks, ethics systems, approval processes, operational

requirements, and safety oversight. Tables and conceptual figures are incorporated to highlight key similarities and differences. The analysis further identifies persistent implementation gaps and proposes potential strategies for improving regulatory efficiency and harmonization with international standards. By synthesizing current knowledge on regulatory landscapes in both countries, this article aims to support stakeholders in navigating complex approval environments and enhancing the quality and competitiveness of clinical research in emerging markets.

2. Regulatory Frameworks in India and Brazil

The regulatory frameworks governing clinical research in India and Brazil have evolved considerably over the past two decades, driven by the need to improve ethical oversight, ensure participant safety, and strengthen scientific credibility. Both countries occupy critical positions in global clinical development due to their large populations, high disease burden, and rapidly growing pharmaceutical markets. Despite these similarities, their regulatory systems differ substantially in structure, operational philosophy, and degree of centralization. (4)

Table 1. Overview of Regulatory Authorities in India and Brazil (5,6)

Aspect	India – CDSCO / ICMR	Brazil – ANVISA / CONEP
Main regulatory authority	Central Drugs Standard Control Organization (CDSCO)	National Health Surveillance Agency (ANVISA)
Ethics oversight	Institutional Ethics Committees (IECs) under ICMR	National Committee (CONEP) + Institutional CEPs
Key legislation	New Drugs & Clinical Trials Rules (2019)	Resolution 466/2012; RDC 9/2015
Registry	CTRI (mandatory)	ReBEC (mandatory)

2.1 India: Evolution Toward a Structured, Modern Clinical Trial Governance System

India's clinical research regulatory environment is primarily governed by the Central Drugs Standard Control Organization (CDSCO) under the Ministry of Health and Family Welfare. Historically criticized for ambiguity and delays, the regulatory landscape underwent major reforms between 2013 and 2019 following public concerns about participant protection and trial oversight. The most significant reform was the introduction of the New Drugs and Clinical Trials (NDCT) Rules, 2019, which replaced outdated Schedule Y provisions and consolidated all clinical trial requirements into a unified structure. The NDCT Rules emphasize expedited approvals, stricter ethical governance, standardized compensation frameworks, and enhanced transparency. (7)

India's regulatory reforms have significantly increased predictability and accountability while reducing procedural ambiguity. The country's framework continues to evolve with emerging guidance on biologics, biosimilars, medical devices, and digital health trials.

2.2 Brazil: A Dual Ethics–Regulatory System with Strong Central Oversight

Brazil's clinical research governance is anchored in a dual regulatory structure involving:

- **ANVISA (Agência Nacional de Vigilância Sanitária)** – regulatory authority for clinical trials, investigational products, and drug approvals
- **CONEP (Comissão Nacional de Ética em Pesquisa)** – national ethics oversight body under the National Health Council

Brazil follows a bioethics-driven regulatory philosophy, with a strong emphasis on participant rights, post-trial access, and protection of vulnerable populations. This is reflected in its major ethical and regulatory documents:

- **Resolution 466/2012** – comprehensive ethical guidelines for human research
- **Resolution RDC 9/2015** – ANVISA's clinical trial regulation
- **Genetic Heritage Law (2015)** – strict governance of biological sample export and genetic research

Unlike India's decentralized IEC system allowing parallel reviews, Brazil employs a sequential review model where local ethics committees (CEPs) review the protocol first, followed by mandatory review by CONEP for studies involving special populations or sensitive thematic areas. Only after CONEP approval does ANVISA initiate its regulatory assessment. This sequential structure ensures thorough ethical scrutiny but often leads to prolonged timelines. Digital systems like Plataforma Brasil have improved transparency and tracking, but administrative bottlenecks persist, particularly for complex trials. (8)

2.3 Structural Differences Between India and Brazil

Although both countries operate within international ethical frameworks such as ICH-GCP and CIOMS, their systems reflect distinct priorities:

- India prioritizes speed, operational flexibility, and decentralization, with shorter approval timelines and wider distribution of ethics committees.
- Brazil prioritizes ethical rigor, central oversight, and social accountability, with more layers of review and strict national governance.

These differences shape the overall research environment, affecting sponsor decision-making, site participation, and trial initiation metrics. (9)

2.4 Legal and Guideline Foundations

India

- New Drugs & Clinical Trials (NDCT) Rules, 2019

- Indian GCP Guidelines (2001)
- ICMR National Ethical Guidelines (2017, updated 2023)
- Drugs & Cosmetics Act, 1940 and Rules, 1945 (historic basis)

Brazil

- Resolution 466/2012 (National Health Council)
- Resolution RDC 9/2015 (ANVISA)
- Brazilian Code of Medical Ethics
- Genetic Heritage Law (Law No. 13,123/2015)

These documents collectively define regulatory jurisdiction, ethical standards, trial conduct, oversight mechanisms, and legal responsibilities of investigators and sponsors. (10)

3. Ethical Oversight and Governance

Ethical oversight is a critical component of clinical research regulation, ensuring that participant safety, autonomy, privacy, and well-being are upheld throughout the research lifecycle. India and Brazil have established comprehensive ethical governance structures, yet they differ markedly in their organizational architecture, review processes, levels of centralization, and enforcement mechanisms. These differences stem from distinct historical, cultural, and regulatory philosophies related to research ethics and public health governance. (11)

3.1 Ethical Governance in India: A Decentralized Committee-Driven System

India's ethical oversight is primarily managed through Institutional Ethics Committees (IECs) operating under the guidance of the Indian Council of Medical Research (ICMR) and regulated through the New Drugs and Clinical Trials (NDCT) Rules, 2019. IECs serve as gatekeepers of participant protection and scientific validity at the institutional level. (12)

3.1.1 Institutional Ethics Committees (IECs)

IECs in India operate under a decentralized model, where each academic institution, hospital, or research center maintains an independent committee. Key features include: Mandatory registration with the Central Drugs Standard Control Organization (CDSCO), Multidisciplinary membership, including clinicians, pharmacologists, legal experts, scientists, social workers, and laypersons, Compliance with ICMR Ethical Guidelines, which outline core principles such as autonomy, beneficence, non-maleficence, equity, and social justice, Oversight of protocol review, informed consent, compensation, and safety reporting The decentralized nature allows for rapid ethics review, parallel regulatory processing, and broader accessibility across the country. However, it introduces variability in quality, experience, and decision-making rigor across committees. (13)

3.1.2 Accreditation and Quality Assurance

To enhance consistency, India promotes accreditation of ethics committees through: National Accreditation Board for Hospitals (NABH), Clinical Development Services Agency (CDSA) under the Translational Health Science and Technology Institute (THSTI) Accredited IECs must meet stringent standards in documentation, training, operating procedures, and quality assurance. While accreditation is not mandatory nationally, it is increasingly recommended for multicenter and industry-sponsored trials. (14)

3.1.3 Ethical Challenges and Strengths in India

Strengths:

- Faster ethics review due to decentralization
- Flexibility to manage institution-specific concerns
- Standardized guidance through ICMR and NDCT Rules
- Growth of trained ethics professionals and GCP-certified reviewers

Challenges:

- Inconsistencies in training, quality, and decision-making across IECs
- Limited monitoring of IEC performance at national level
- Documentation and SOP variability
- Challenges in ensuring independence from institutional influence (15)

3.2 Ethical Governance in Brazil: A Dual National–Local Oversight Model

Brazil has one of the most structured and centralized ethical governance systems among emerging economies, grounded in robust bioethical principles developed by the National Health Council (CNS). Ethical oversight is implemented through a dual-tier committee system:

- Local Ethics Committees: CEP (Comitês de Ética em Pesquisa)
- National Committee: CONEP (Comissão Nacional de Ética em Pesquisa)

3.2.1 Local Committees (CEPs)

CEPs operate across universities, hospitals, and research institutions. Their responsibilities include: Evaluating research protocols for ethical and methodological rigor, ensuring informed consent completeness and cultural suitability, monitoring risk–benefit ratios and participant protections, Reviewing amendments, safety reports, and protocol deviations

3.2.2 National Committee (CONEP)

CONEP provides **centralized oversight** for: Studies involving vulnerable populations (children, pregnant women, indigenous groups), High-risk or novel technologies (genetics, stem cells, advanced therapies), Multicenter international trials, Research involving biosafety or public health significance. CONEP reviews protocols after CEP approval, contributing to Brazil's sequential ethics workflow. While this ensures thorough review and national consistency, it significantly extends overall approval timelines. (16)

3.2.3 Ethical Regulations and Digital Systems

Ethical oversight is regulated through:

- **Resolution 466/2012 (CNS)** – Comprehensive ethical framework
- **Resolution 510/2016 (CNS)** – Social sciences and humanities research
- **Plataforma Brasil**– Centralized digital platform for submission, tracking, and archiving of all ethics committee reviews

Brazil's digital ethics platform is one of the most advanced globally, enabling transparency, traceability, and audit readiness across thousands of research protocols. (17)

3.3 Comparative Perspective: India vs. Brazil

While both systems prioritize participant protection, their approaches differ significantly:

Table 2. Comparative Perspective: India vs. Brazil (18)

Aspect	India	Brazil
Structural model	Decentralized IECs	Centralized CONEP + local CEPs
Review process	Parallel ethics + regulatory	Sequential ethics (CEP → CONEP)
National oversight	Limited (advisory role by ICMR)	Strong national authority (CONEP)
Speed	Faster, but variable	Slower, but consistent
Training	Not uniform nationwide	Structured, mandatory in many institutions
Digitalization	CTRI + SUGAM (partial integration)	Fully integrated Plataforma Brasil

3.4 Key Challenges in Ethical Oversight

India

- Variability in IEC composition and competence
- Occasional conflict of interest in institutional IECs
- Overburdened committees in high-volume research centers
- Need for uniform accreditation and digital harmonization

Brazil

- Lengthy, sequential ethical review
- Complex bureaucracy for multicenter and international studies
- Low flexibility for adaptive or decentralized trial designs
- Regulatory bottlenecks in CONEP for high-risk research (19)

3.5 Summary

India and Brazil share strong commitments to participant protection and ethical integrity, but their systems differ in structure and execution: India's decentralized model prioritizes operational efficiency and accessibility, enabling faster research turnaround but facing challenges in standardization. Brazil's centralized CEP/CONEP system ensures rigorous oversight and ethical uniformity, though at the cost of longer review timelines. Together, these frameworks illustrate two distinct but effective paradigms for ethical governance in emerging research economies. (20)

4. Clinical Trial authorization processes

The clinical trial authorization (CTA) process determines the efficiency, predictability, and attractiveness of a country's clinical research environment. Both India and Brazil have developed structured pathways for regulatory submissions, yet they differ significantly in procedural design, approval timelines, and the degree of centralization. Understanding these systems is critical for global sponsors, investigators, and regulatory professionals seeking to initiate research in these major emerging markets. (21)

4.1 India's Clinical Trial Authorization System

India's CTA process is governed by the Central Drugs Standard Control Organization (CDSCO) and is operationalized under the New Drugs and Clinical Trials (NDCT) Rules, 2019. The system focuses on procedural clarity, accelerated timelines, and digital submission workflows. (22)

4.1.1 Submission Pathways

Sponsors submit clinical trial applications through SUGAM, an online portal for regulatory submissions. The application must include: Investigational brochure, Chemistry–Manufacturing–Control (CMC) data, non-clinical safety package, Protocol and case report forms, ICD (Informed Consent Document), Evidence of IEC approval, Compensation and medical management plans. India allows parallel submission to CDSCO and Institutional Ethics Committees (IECs), which substantially reduces overall approval timelines.

4.1.2 Approval Timelines

Under the NDCT Rules:

- New drug clinical trial applications must be reviewed within 90 days
- Drugs approved outside India (e.g., US/EU-approved APIs) may receive approval in 30 days
- Academic clinical trials not intended for commercialization may receive expedited review

If no response is issued within the stipulated timeline, deemed approval is granted, increasing predictability for sponsors.

4.1.3 Review Structure and Decision Criteria

CDSCO evaluates applications based on:

- Risk–benefit assessment
- Quality of non-clinical and prior clinical evidence
- Unmet medical needs in India

- Adequacy of safety monitoring and SAE management
- Investigational product quality and stability

The Drugs Controller General of India (DCGI) may seek expert committee review for high-risk studies, including first-in-human trials, biologics, and vaccines.

4.1.4 Clinical Trial Site and Investigator Requirements

Sponsors must secure: IEC approval for each site, Qualified investigators with relevant therapeutic expertise, Adequate infrastructure for patient safety and data integrity, Periodic status updates to CDSCO and CTRI. The NDCT Rules require all registered trials to maintain post-trial access (PTA) provisions when applicable. (23)

4.2 Brazil's Clinical Trial Authorization System

Brazil's CTA process is managed jointly by:

- **ANVISA** (Agência Nacional de Vigilância Sanitária) – regulatory review
- **CONEP/CEPs** – ethical review

The process is inherently sequential, with ethics approval required before ANVISA can initiate scientific and regulatory assessment.

4.2.1 Submission Pathways

All submissions occur through Plataforma Brasil (for ethics review) and ANVISA's electronic system. Submission components include:

- Protocol
- Investigator's brochure
- IMP Dossier (DICD – Dossiê de Investigação Clínica de Medicamento)
- Non-clinical evidence package
- Informed consent and recruitment materials
- CTA form and sponsor declaration

4.2.2 Sequential Review Model

Brazil mandates:

1. CEP review (local ethics committee)
2. CONEP review (for high-risk or sensitive studies)
3. ANVISA regulatory authorization

ANVISA issues a Special Clinical Trial Dossier (DEEC) approval for high-risk products and a Clinical Development Dossier (DDC) for subsequent submissions.

4.2.3 Decision Criteria for Clearance

ANVISA reviews applications based on:

- Regulatory compliance with RDC 9/2015
- Non-clinical pharmacology and toxicology evidence
- Quality and stability of investigational products
- Safety monitoring plan
- Ethical feasibility and post-trial access
- Data from international trials and comparator relevance

Brazil places strong emphasis on post-trial access commitments and local laboratory/infrastructure capability. (24)

4.3 Comparative Overview of India vs. Brazil CTA Systems

Table 3. Key Differences in CTA Processes (25,26)

Parameter	India	Brazil
Review structure	Parallel IEC + CDSCO	Sequential CEP → CONEP → ANVISA
Digital platforms	SUGAM + CTRI	Plataforma Brasil + ANVISA systems
Average approval time	30–90 days	180–240 days
Deemed approval	Yes (if no decision within timeline)	No
Post-trial access requirements	Required but flexible	Strict and mandatory
Role of ethics committee	Independent IEC at each site	Centralized CONEP regulates high-risk studies
International study alignment	Priorities on speed and efficiency	Priorities on ethics & participant rights

4.4 Operational Bottlenecks and System Challenges

India

- Variability in IEC competence
- Occasional delays in expert committee evaluations
- Inconsistent investigator site readiness
- Need for harmonization of digital documentation formats

Brazil

- Sequential model lengthens initiation timelines
- High burden on CONEP for complex trials
- Regulatory bottlenecks in high-volume therapeutic areas
- Complex requirements for genetic and biological sample research. (27)

4.5 Summary: Diverging Models with Complementary Strengths

India's system emphasizes efficiency, decentralization, and predictability, making it attractive for global clinical development, especially for Phase II–III trials. Brazil's model prioritizes ethical thoroughness, participant protection, and central oversight, making it uniquely strong for trials requiring high ethical scrutiny, such as

genetics, vaccines, and biologics. Together, these systems illustrate two successful yet contrasting approaches to clinical trial governance in large emerging markets. (28)

5. Safety Reporting and Pharmacovigilance

Effective safety reporting mechanisms are essential to ensuring participant protection, early detection of risks, and regulatory oversight during clinical trials. Both India and Brazil follow internationally accepted safety-reporting frameworks guided by ICH-GCP, WHO pharmacovigilance standards, and national regulatory requirements. While both countries have strengthened their systems over the last decade, they differ in reporting structures, timelines, and the responsibilities placed on investigators, sponsors, and regulatory authorities. (29)

5.1 Safety Reporting in India

India has established a well-defined safety reporting system under the New Drugs and Clinical Trials (NDCT) Rules, 2019, supplemented by detailed guidance from CDSCO and ICMR. The safety reporting obligations apply to all stakeholders, including investigators, sponsors, institutional ethics committees (IECs), and regulatory agencies.

5.1.1 Reporting of Serious Adverse Events (SAEs)

Under NDCT Rules:

- Investigators must report all SAEs to CDSCO, the sponsor, and their IEC within 24 hours.
- A detailed SAE report must be submitted within 14 calendar days.
- The IEC reviews and provides an opinion on causality and compensation.
- The Expert Committee constituted by CDSCO finalizes compensation decisions, ensuring consistency.

This multi-level review ensures accountability, although differences in IEC expertise may occasionally affect evaluation quality.

5.1.2 Sponsor Responsibilities

Sponsors must:

- Report unexpected Serious Adverse Reactions (SUSARs) within 7 days (fatal/life-threatening) or 15 days (others)
- Maintain an updated Investigator's Brochure and safety database
- Implement risk minimization and Data Safety Monitoring Board (DSMB) structures when required

5.1.3 National Pharmacovigilance Systems

India operates:

- Pharmacovigilance Programme of India (PvPI)
- Vigiflow/VigiBase reporting, integrated with WHO-UMC
- A national ADR monitoring system with >500 centers

The integration of clinical trial safety reporting with post-marketing surveillance enhances traceability and signal detection. (30)

5.2 Safety Reporting in Brazil

Brazil's safety reporting system is governed primarily by ANVISA's RDC 9/2015, complemented by guidance from CONEP and the National Health Council (CNS). The system places strong emphasis on ethical oversight, transparency, and participant rights.

5.2.1 Role of CONEP and CEPs

Ethics oversight bodies review: SAE narratives, Investigator causality assessments, Risk–benefit ratio reassessments, need for protocol modifications CONEP may request trial suspension or modification if risks outweigh potential benefits. (31)

5.3 Digital Safety Reporting Platforms

Brazil's Notivisa is centrally integrated but sometimes faces functionality challenges. India uses multiple platforms, enhancing redundancy but requiring improved harmonization.

Table 4. Reporting Platform India vs Brazil (32)

Country	Platform	Purpose
India	SUGAM, PvPI, Vigiflow	Reporting SAEs, regulatory communication, ADR submissions
Brazil	Notivisa, Plataforma Brasil	SAE reporting, tracking ethics reviews, safety updates

5.4 Data Safety Monitoring Boards (DSMBs)

Both countries require DSMBs for: High-risk trials, First-in-human studies, Gene therapy, oncology, and vaccine trials, Studies with vulnerable populations

Brazil's CONEP often mandates DSMBs for sensitive research areas, while India generally follows international best practices without additional national requirements. (33)

5.5 Common Challenges in Safety Reporting

India- Variability in IEC expertise in assessing SAE causality, Delays in finalizing compensation decisions due to multilayered committees, Differences in site-level understanding of reporting timelines, Need for platform integration (SUGAM–PvPI–CTRI).

Brazil- Complex administrative flow between CEPs, CONEP, and ANVISA**,** Occasional delays in Notivisa reporting synchronization**,** High burden of documentation for multicenter trials**,** Need for clearer guidelines for adaptive and decentralized trials. (34)

Table 5. Comparative Overview of Safety Reporting in India and Brazil (35,36)

Parameter	India	Brazil
SAE initial reporting timeline	24 hours by investigator	Immediate to sponsor; timelines follow SUSAR rules
Regulator submission	CDSCO + PvPI	ANVISA via Notivisa
Ethics committee roles	Strong role in compensation	Strong role in risk–benefit reassessment
Compensation system	Highly structured and rule-based	Less codified; ethics-driven
DSMB requirements	Based on global norms	Often more stringent for sensitive areas
System complexity	Moderate	High due to sequential ethics + regulatory flow

6. International Harmonization & Global Guidelines

International harmonization plays a pivotal role in ensuring that clinical research conducted across different countries adheres to unified standards of ethics, quality, and scientific integrity. As clinical trials increasingly become globalized, emerging economies like India and Brazil have progressively aligned their regulatory systems with globally recognized frameworks such as ICH-GCP, CIOMS, and WHO guidelines. Harmonization also facilitates smoother collaboration between regulatory authorities, enhances cross-border data reliability, and improves the efficiency of multinational drug development programs. (37) Both India and Brazil have strengthened their alignment with international expectations through structured reforms, digitalization, and modernization of trial oversight. India's NDCT Rules, 2019 incorporate several ICH-GCP principles, promote transparency through CTRI registration, and mandate clear safety reporting timelines consistent with global norms. Brazil's ANVISA and the CEP–CONEP system similarly integrate ethical frameworks guided by CIOMS principles, emphasizing participant rights, informed consent quality, and protection of vulnerable populations. Furthermore, participation in international regulatory networks such as ICH, PAHO-RHIS, and WHO-UMC encourages technical convergence, capacity building, and the adoption of harmonized review processes across regions. These steps ensure that both countries remain globally competitive and compliant with evolving scientific, ethical, and technological standards. (38)

In addition, global guidelines emphasize the modernization of clinical research processes through digital tools, risk-based monitoring, and decentralized trial models, promoting greater data integrity and operational transparency. WHO's ICTRP framework has strengthened global requirements for clinical trial registration, compelling countries to establish accessible platforms like CTRI and ReBEC. Safety-reporting standards based on ICH E2A/E2B further harmonize pharmacovigilance workflows, enabling faster detection and mitigation of emerging risks in clinical trials. Together, these harmonized principles and guidelines form the backbone of modern clinical governance, ensuring that India and Brazil advance in parallel with global scientific and regulatory progress. (39)

Key Points:

- **Strengthened Adoption of ICH-GCP Principles**- India and Brazil increasingly adhere to ICH-GCP guidelines, implementing structured processes for trial conduct, monitoring, documentation, and investigator responsibilities to ensure global acceptability of clinical trial data.
- **Integration with WHO & CIOMS Ethical Frameworks**- Both countries utilize WHO ethics standards and CIOMS guidance to shape policies related to informed consent, vulnerable populations, community involvement, compensation rules, and equitable risk–benefit assessment.
- **Convergence Through International Regulatory Collaboration**- Participation in global platforms such as the International Council for Harmonisation (ICH), WHO-UMC, PAHO, and regional regulatory harmonization initiatives supports consistent regulatory expectations and faster cross-border approvals.
- **Global Standardization of Safety Reporting Systems**- Implementation of ICH E2A/E2B guidelines enable harmonized SAE, SUSAR, and annual safety reporting through digital systems like PvPI, VigiBase, Notivisa, and ANVISA's electronic portals, improving international signal detection.
- **Facilitation of Multicountry Trial Efficiency**- Harmonized guidelines reduce redundancy in documentation, streamline cross-country submission processes, and enhance the predictability of approval timelines for multinational Phase II–IV clinical trials. (40,41)

7. Digital Transformation, Data Integrity & Modernization

Digital transformation has become a defining element of modern clinical research regulation, fundamentally reshaping how trials are planned, monitored, and reported. Both India and Brazil have accelerated the adoption of digital tools including electronic submissions, remote monitoring, electronic informed consent (e-consent), and centralized data repositories to enhance transparency, improve data integrity, and reduce administrative burden. These reforms are particularly relevant in the context of multinational research, where standardized digital workflows enable smoother collaboration between global teams, faster regulatory decision-making, and improved real-time oversight. (42)

In India, several digital platforms such as SUGAM (regulatory submissions), CTRI (trial registration), and PvPI/VigiFlow (pharmacovigilance reporting) contribute

to an integrated oversight ecosystem. Recent advancements include the adoption of digital consent, risk-based monitoring (RBM) tools, and increased use of electronic data capture (EDC) systems in compliance with ICH E6(R3) guidelines. (43) These systems strengthen data integrity through audit trails, secure electronic signatures, and structured metadata, which reduce protocol deviations and enhance quality assurance across trial sites. Digital innovations also support decentralized clinical trials (DCTs), enabling telemedicine consultations, remote patient monitoring, and home-based sample collection approaches that gained prominence during the COVID-19 pandemic. (44)

Brazil, through Plataforma Brasil, has established one of the world's most advanced centralized ethics-review portals, enabling digital submission, tracking, and approval of research protocols nationwide. ANVISA's electronic submission systems further support digitalized regulatory communication, ensuring standardized formatting, traceability, and integrity of clinical data. Adoption of digital consent solutions, mobile health applications, and electronic safety-reporting systems (Notivisa) reflects Brazil's commitment to integrating patient-centered technological innovations. These digital mechanisms improve transparency, facilitate rapid communication between investigators and regulators, and enhance public trust through easily accessible research information. (45)

Overall, modernization initiatives anchored in digital transformation are central to improving efficiency, data quality, and compliance in clinical research. By adopting global best practices in data integrity such as ALCOA+ principles, secure digital workflows, and real-time risk-based oversight India and Brazil are steadily advancing toward harmonized, technology-driven regulatory ecosystems capable of supporting complex, adaptive, and multinational trial designs. (46)

Key Features:

- **Centralized Digital Platforms** India's SUGAM/CTRI and Brazil's Plataforma Brasil enable standardized online submissions, protocol tracking, and regulatory communication, reducing administrative delays. (47)
- **Digital Informed Consent (e-Consent)** Adoption of multimedia-enabled, electronically signed consent forms increases participant comprehension, supports remote participation, and strengthens documentation integrity. (48)
- **Data Integrity Frameworks (ALCOA+)** Use of audit trails, electronic signatures, version control, and secure databases ensures data are attributable, legible, contemporaneous, original, accurate, complete, and consistent. (49)
- **Risk-Based & Remote Monitoring** Implementation of centralized risk-based monitoring (RBM), remote source-data verification, and virtual site audits enhances oversight efficiency and reduces trial-site burden. (50)
- **Support for Decentralized & Hybrid Trial Models** Mobile health apps, teleconsultation platforms, wearable devices, and cloud-based EDC systems support decentralized clinical trials, expanding patient access and operational flexibility. (51)

8. Conclusion

This review highlights the evolving regulatory environments governing clinical research in India and Brazil, two rapidly emerging economies with significant potential to contribute to global drug development. Both countries have demonstrated strong commitment to strengthening ethical oversight, improving regulatory clarity, and enhancing participant protection through substantial reforms, including India's New Drugs and Clinical Trials (NDCT) Rules, 2019, and Brazil's continued updates to the CEP–CONEP system and ANVISA frameworks. These reforms collectively align their systems more closely with international standards, particularly ICH-GCP, CIOMS, and WHO guidelines. Nevertheless, critical implementation gaps persist that limit full operational efficiency. Variability in ethics committee performance, infrastructural constraints at clinical trial sites, delays in regulatory and ethics approvals, fragmented digital systems, and inconsistencies in safety reporting mechanisms continue to impede progress. Moreover, regional disparities in research capacity and limited workforce training create additional barriers to high-quality and timely trial conduct.

Ultimately, by addressing these systemic challenges and capitalizing on ongoing reforms, India and Brazil can further enhance their roles as competitive, ethically robust, and globally integrated environments for clinical research. This progression will not only accelerate access to innovative therapies for their populations but also bolster global health research through diverse participation, regulatory reliability, and scientific excellence.

Acknowledgements

We would like to express my sincere gratitude to Dr. Kothari Sir and the editorial team and reviewers of International Journal of Drug Regulatory Affairs for their valuable feedback and support throughout the review and publication process. Their constructive comments have significantly enhanced the quality of article.

Conflict of Interest

he author declares that there is no conflict of interest regarding the publication of this article.

Financial Disclosure statement:

The authors have no relevant affiliations or financial involvement with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript. This includes employment, consultancies, honoraria, stock ownership or options, expert testimony, grants or patents received or pending, or royalties.

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