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Sr. No.	CONTENTS	Page No.
1	New Electricity (Amendment) Bill, 2025 and Its Possible Impact on Indian Economy Ankush Budha Patil , Dr.Vishal Deshmukh	1-5
2	Women Empowerment and Gender Equality in India: A Strategic Imperative for Viksit Bharat Harshita Deepak Talreja	6-15
3	The Evolution of Indian Democracy: Historical Phases, Institutions, and Contemporary Challenges Rahul Manohar Suralkar	16-18
4	Demographic and cultural differences that may influence engagement levels in diverse workplaces Yamini S. Bhatiya	19-22
5	Financial Inclusion, Fintech, and Digital Transformation: Reshaping Global Finance Shinde Vijay Bhausaheb, Kavayitri Bahinabai Chaudhari	23-28
6	Globalization and the politics of urban space in the fiction of Neel Mukherjee. Mangesh Kamble ,Dr. Anil Kshirsagar	29-31
7	AI as an Emerging Mental Health Tool in Digital India: Implications for India's Social and Health Transformation Akshay Kharat, Dr. Lalita D. Nikam	32-36
8	Study of Graphene Based Functional Materials for Energy System to Healthcare Applications in India Bhawana A. Manekar, Suhas R. Patil	37-43
9	India-Japan Double Taxation Avoidance Agreement (DTAA) An All-Encompassing Study on the Provisions & Importance Prabhu Sanjay Bagul, Dr. Samir Narkhede	44-46
10	A Study Of Indian Workforce Industry And Skill Development After Globalization Nisha Guruprasad Kulkarni	47-52
11	The Role of Geographical Indication Tags in Enhancing Regional Development in India Tejas Guruprasad Kulkarni	53-59
12	The Role of Emerging Technologies in Boosting Digital India: A Study of Opportunities and Challenges Dr. Vijay Pandit Palve	60-65
13	An Analytical Study of Palghar District's Contribution to the Implementation of the Maharashtra State Rural Livelihood Mission (MSRLM). Dr. Shobha Menon, Prachi Lad Research Scholar	66-72
14	A Post Colonial study in the novels of Mulk Raj Anand Dr. Jahagirdar Zinga Salunkhe, Dinesh Gotya Vasave	73-75
15	Creamy Layer in SC and ST Reservations: Power, Intra-Group Inequality, and the Politics of Social Justice in India Ravindra Mohan Bhosale	76-78
16	Challenges of Technology Ethics and Cybersecurity (A Defence Studies Perspective) Dr. Kamble Surendra Bhimrao	79-82
17	Educational Reforms in Post-Independence India: Achievements, Challenges, and the Road Ahead Nitin Mohanani	83-85
18	Clinical Trials and Artificial Intelligence: Legal, Ethical, and Regulatory Challenges in India Kalichand Govardhan, Dr. Pratima R. Lokhande	86-89
19	Economic Transformation in Post-Independence India: Growth, Structural Change, and Future Challenges Dr.Nasiket Govindrao Suryavanshi	90-93
20	Beyond the App: The Human Cost of Digital Money in India Vishal ChandrakantPatil	94-96
21	भारतीय स्वतंत्रता के पश्चात आदिवासी समाज : परिवर्तन, उपलब्धियाँ, चुनौतियाँ , एवं भविष्य। रणजित शाम आडे , प्रो. सुनील बाबुराव कुलकर्णी	97-102
22	हरिवंशराय बच्चन के साहित्य में स्वतंत्र भारत का प्रतिबिंब। अंकिता दुबे, डॉ.मनोज एकनाथ महाजन	103-105



Original Article

Clinical Trials and Artificial Intelligence: Legal, Ethical, and Regulatory Challenges in India

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Abstract

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Artificial Intelligence (AI) is rapidly transforming the design, conduct, and analysis of clinical trials by enhancing efficiency, accuracy, and predictive capabilities. AI-driven tools are increasingly used for patient recruitment, risk stratification, trial monitoring, adverse event detection, and data analysis. While these innovations promise to accelerate drug development and improve patient outcomes, they also raise complex legal, ethical, and regulatory concerns. Issues relating to data privacy, algorithmic bias, transparency, accountability, and medical negligence pose significant challenges within the existing legal framework. This paper critically examines the application of AI in clinical trials and evaluates its implications under Indian law. It analyzes the regulatory landscape governing clinical research, data protection, and medical negligence, with reference to the Drugs and Cosmetics Act, 1940, the New Drugs and Clinical Trials Rules, 2019, the Bharatiya Sakshya Adhinyam, 2023, and emerging data protection norms. The study further explores the role of expert testimony in AI-related disputes and assesses the need for adaptive legal standards. Based on doctrinal research and secondary sources, the paper argues for the development of a comprehensive AI-specific regulatory framework to ensure ethical innovation while safeguarding participant rights.

Keywords: Artificial Intelligence, Clinical Trials, Medical Negligence, Algorithmic Accountability, Expert Evidence, Data Protection

Introduction

Clinical trials are essential for validating the safety and efficacy of new medical interventions. In recent years, Artificial Intelligence has emerged as a disruptive force in clinical research, reshaping traditional trial methodologies. AI technologies enable predictive analytics, real-time monitoring, automated decision-making, and large-scale data integration, thereby improving trial efficiency and reducing costs. However, the integration of AI into clinical trials also raises concerns regarding participant safety, informed consent, transparency, and legal accountability. The absence of clear regulatory standards governing AI-assisted clinical trials creates uncertainty in determining liability when harm occurs. In India, the clinical trials ecosystem has undergone significant transformation over the past decade, particularly following judicial scrutiny and public concern over unethical trials and participant exploitation. Regulatory reforms, such as the introduction of the New Drugs and Clinical Trials Rules, 2019, sought to strengthen ethical oversight, participant safety, and accountability. The integration of AI into clinical trials, however, presents new legal complexities that existing regulations do not adequately address. Unlike conventional medical negligence, AI-assisted clinical trials involve multiple stakeholders, including investigators, sponsors, software developers, data scientists, and technology providers. This diffusion of responsibility complicates the determination of liability when harm occurs. Furthermore, algorithmic opacity, data bias, and automated decision-making raise serious concerns regarding informed consent, transparency, and participant autonomy. This paper seeks to examine how Indian law responds to the challenges posed by AI in clinical trials, particularly in the context of medical negligence.

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It explores whether traditional negligence principles, such as the Bolam test, remain adequate in assessing AI-related harm and how expert testimony can assist courts in resolving complex technical disputes. By analysing statutory provisions, ethical guidelines, and judicial precedents, the study aims to propose a balanced legal framework that promotes innovation while safeguarding human rights.

Research Objectives

The objectives of this research paper are as follows:

- To examine the role and application of Artificial Intelligence in clinical trials.
- To analyse the legal framework governing clinical trials in India.
- To assess how medical negligence is determined in AI-assisted clinical research.
- To evaluate the adequacy of informed consent mechanisms in AI-driven trials.
- To study the role of expert testimony in adjudicating AI-related clinical trial disputes.
- To identify regulatory gaps and ethical challenges associated with AI in clinical trials.
- To propose legal and policy reforms to strengthen accountability and participant protection.

Research Methodology

This study adopts a **doctrinal and analytical research methodology**, relying primarily on secondary sources of data. The research draws upon statutes, rules, judicial decisions, ethical guidelines, policy documents, international conventions, and scholarly articles published in peer-reviewed journals.

Key legal sources analysed include the Drugs and Cosmetics Act, 1940, the New Drugs and Clinical Trials Rules, 2019, the Bharatiya Sakshya Adhinyam, 2023, and relevant provisions of the Indian Penal Code and consumer protection laws. Ethical standards prescribed by the Indian Council of Medical Research and international instruments such as the Declaration of Helsinki have also been examined.

Comparative references to foreign jurisprudence, particularly from the United States and the European Union, are incorporated to highlight best practices in regulating AI in healthcare research. The study does not involve empirical data collection and is limited to doctrinal analysis. However, it aims to contribute normative recommendations for law and policy reform.

Artificial Intelligence in Clinical Trials

AI in clinical trials encompasses machine learning algorithms, natural language processing, computer vision, and predictive analytics. Its applications include:

- AI-based patient recruitment and eligibility screening
- Predictive modeling for trial outcomes
- Real-time monitoring of adverse events
- Automated data analysis and reporting
- Decentralized and virtual clinical trials

While AI improves efficiency, its reliance on complex algorithms and large datasets introduces new risks, including data bias, algorithmic opacity, and system errors. Artificial Intelligence refers to computational systems capable of performing tasks that typically require human intelligence, such as learning, reasoning, pattern recognition, and decision-making. In clinical trials, AI is deployed across various stages of research. AI-driven algorithms are used in patient recruitment by analysing electronic health records to identify eligible participants more efficiently than traditional methods. Predictive models assist researchers in forecasting trial outcomes, identifying potential risks, and optimizing trial design. Real-time monitoring systems powered by AI can detect adverse events earlier, thereby enhancing participant safety. Decentralized and virtual clinical trials have also emerged as a result of AI integration, reducing geographical barriers and increasing participant diversity. However, the reliability of AI systems depends heavily on the quality of data used for training algorithms. Biases in datasets may result in discriminatory outcomes, undermining the scientific validity and ethical integrity of trials.

Legal Framework Governing Clinical Trials in India

Clinical trials in India are regulated under:

- Drugs and Cosmetics Act, 1940
- New Drugs and Clinical Trials Rules, 2019
- ICMR National Ethical Guidelines
- Good Clinical Practice (GCP) Guidelines

These frameworks were primarily designed for human-led trials and do not explicitly address AI-driven decision-making. The absence of AI-specific regulations poses challenges in determining responsibility when AI systems influence trial outcomes. Clinical trials in India are primarily regulated under the Drugs and Cosmetics Act, 1940, and the New Drugs and Clinical Trials Rules, 2019. These rules mandate regulatory approval, ethics committee clearance, informed consent, adverse event reporting, and compensation for trial-related injury or death. While these regulations



establish a robust framework for human-led trials, they do not explicitly address AI-assisted decision-making. There is no statutory guidance on algorithm validation, transparency, or liability allocation in AI-driven trials. This regulatory silence creates uncertainty regarding accountability when AI systems contribute to participant harm.

AI, Medical Negligence, and Liability

Medical negligence traditionally involves a breach of the standard of care by a healthcare professional. In AI-assisted clinical trials, determining negligence becomes complex due to shared responsibility among investigators, sponsors, developers, and technology providers.

Key legal questions include:

- Who is liable for AI-induced errors—the investigator, sponsor, or AI developer?
- Can algorithmic decisions be subjected to the Bolam test?
- Does reliance on AI dilute professional responsibility?

Courts may need to evolve the standard of care to include reasonable oversight of AI systems rather than blind reliance on algorithmic outputs. While medical professionals may rely on AI recommendations, ultimate responsibility for patient safety cannot be abdicated. Failure to understand algorithmic limitations or to intervene when necessary may constitute negligence.

Informed Consent in AI-Driven Clinical Trials

Informed consent assumes heightened importance in AI-based trials. Participants must be informed not only about medical risks but also about the role of AI, data usage, automated decision-making, and potential algorithmic limitations. Consent obtained without disclosing AI involvement may be considered invalid and unethical.

- Use of AI systems
 - Nature of automated decision-making
 - Data usage and secondary analysis
 - Limitations and risks of algorithms
- Failure to disclose AI involvement may invalidate consent and constitute negligence.

Data Protection and Privacy Concerns

AI systems require large volumes of personal and health data. In India, data protection in clinical trials is governed by emerging legal principles under data protection legislation and ethical guidelines. Issues such as data anonymization, cross-border data transfer, and secondary use of trial data remain inadequately regulated, posing risks to participant autonomy and privacy.

Role of Expert Testimony in AI-Related Clinical Trial Disputes

Disputes involving AI in clinical trials involve technical issues beyond judicial expertise. Under Sections 39–45 of the Bharatiya Sakshya Adhiniyam, 2023, expert testimony is essential to:

- Explain algorithmic functioning
 - Assess reliability and bias of AI systems
 - Establish causation between AI use and harm
- Courts must develop standards to critically evaluate both medical and technological expert evidence.

Ethical Challenges of AI in Clinical Trials

Ethical concerns include:

- Algorithmic bias affecting participant selection
 - Lack of explainability (black-box models)
 - Reduced human oversight
 - Potential exploitation of vulnerable populations
- Ethics Committees must be equipped with technological expertise to assess AI-driven trial protocols.

Challenges and Gaps in the Existing Framework

- Absence of AI-specific clinical trial regulations
- Unclear liability allocation
- Limited technical capacity of regulatory bodies
- Over-dependence on foreign guidelines
- Lack of judicial precedents on AI negligence

Suggestions and Recommendations

- Introduction of AI-specific provisions in clinical trial regulations
- Mandatory algorithmic transparency and auditability
- Clear allocation of liability among stakeholders
- Specialized training for Ethics Committees and judges



- Adoption of adaptive standards for expert evidence

Conclusion

Artificial Intelligence holds immense potential to revolutionize clinical trials, making them faster, safer, and more efficient. However, without an adaptive legal and ethical framework, AI-driven research risks undermining participant rights and accountability. Indian law must evolve to address algorithmic decision-making, redefine standards of care, and strengthen regulatory oversight. A balanced approach that encourages innovation while safeguarding human dignity is essential for the sustainable integration of AI into clinical trials. AI has the potential to revolutionize clinical trials, but its integration must be accompanied by robust legal safeguards. Indian law must evolve to address algorithmic accountability, redefine standards of care, and enhance regulatory oversight. A balanced approach that promotes innovation while protecting participant rights is essential for ethical and sustainable clinical research.

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