



Cross-Disciplinary Assessment of Clinical Trials Transparency and Patient Consent Practices

Rishabh Bhardwaj, Tusha, Dr. Arul Amutha Elizabeth, Dr. Pusparaj Samantsinghar, Dr Nirav Patel, Cong Yanxin, Kashish Gupta,

Centre of Research Impact and Outcome, Chitkara University, Rajpura- 140417, Punjab, India. rishabh.bhardwaj.orp@chitkara.edu.in
<https://orcid.org/0009-0009-6075-8837>

Quantum University Research Center, Quantum University, Roorkee, Uttarakhand, 247667, India. Email: tusha@quantumeducation.in, Orcid Id: 0009-0001-5904-2139

Professor and HOD, Department of Pharmacology, Sree Balaji Medical College and Hospital, amuthasathish@gmail.com. 0000-0002-9235-1603

Professor, Department of Forensic Medicine & Toxicology, IMS and SUM Hospital, Siksha 'O' Anusandhan (Deemed to be University), Bhubaneswar, Odisha, India, Email Id- pusparajsamantsinghar@soa.ac.in, Orcid Id- 0000-0001-7078-8735

Department of Pharmacology, Parul Institute of Medical Sciences & Research, Parul University, Vadodara, Gujarat, India, Email Id- nirav.patel40011@paruluniversity.ac.in, Orcid Id- 0009-0005-9420-4251

Research Scholar, School of Business Management, Lincoln University College, Malaysia. Email ID: cong.phdscholar@lincoln.edu.my

Department of Biotechnology and Microbiology, Noida International University, Uttar Pradesh, India. kashish.gupta@niu.edu.in. 0000-0001-5627-4792

ABSTRACT

The development of clinical research hinges on the fine line between open science and the autonomy of the participants. The current paper offers an interdisciplinary evaluation of the transparency of clinical trials to the dynamic nature of informed consent (IC). By combining opinions on medical ethics, law, and data science, the analysis reveals a major discrepancy between regulatory requirements (as specified by GDPR and ClinicalTrials.gov) and the actual reporting standards. The main theme of the research is the so-called transparency-privacy paradox, in which the demand to share data to make science reproducible frequently conflicts with technical challenges of de-identifying data and protecting patient privacy. The paper assesses how previous, passive, and non-interactive consent frameworks fail in the era of big data and secondary data process usage, and calls for a shift to the new era of Dynamic Consent. Evidence indicates that evidence-based medicine is still being sabotaged by selective reporting and the file drawer problem. The paper wraps up with strategic suggestions on reducing metadata standardization, improving regulatory compliance, and the adoption of digital-first approaches to consent in order to regain the trust of the people and to streamline the global research ecosystem.

Keywords: *Clinical Trials Transparency, Informed Consent, Open Science, Bioethics, Data Privacy (GDPR/HIPAA), Dynamic Consent, Scientific Reproducibility*

INTRODUCTION

Modern medicine depends on the fundamental idea that the data of the clinical trials should be available, provable, and acquired in an ethical manner [1]. The latest decades have seen the international research community move towards a "Transparency Mandate" as a result of the awareness that undisclosed trial outcomes and outcomes give rise to biased meta-analysis, and patient safety is put at risk [2]. The design of historical milestones, like the creation of ClinicalTrials.gov in the United States and the creation of the

EudraCT database in the European Union, was aimed at reducing the file drawer effect by ensuring that trials were pre-registered beforehand and the reporting of results was timely [9]. Nonetheless, even with these regulatory systems, there is a lack of compliance, which tends to be confused with corporate motives or bias in the publication of academics [4][5].

In line with the problem of transparency is a growing “Consent Crisis. Conventional informed consent (IC) was modeled after discrete interventions, which have a time limit [8]. With the modern era of Big Data and the utilization of secondary data, such paper-based models tend to fail to inform the participants of how their biological samples or digital health records may be used years after a trial is over [6][7]. The black box effect arises, which does not provide information about proprietary information, and external researchers find it almost impossible to verify their findings or patients to trace the lifecycle of their contributions due to the absence of standardized reporting.

Problem Statement

There is an extreme inconsistency with the global standards of reporting and the absence of transparency at the level of proprietary trial data. Not only do these gaps impede scientific progress, but they are also a threat to the ethical contract between scientists and subjects, as the existing mechanism of informed consent to participation is rapidly becoming inadequate to the full requirements of contemporary data sharing.

Research Questions

1. To what extent does the lack of transparency in clinical trial reporting impact scientific reproducibility and evidence-based clinical practice?
2. How do traditional consent practices undermine patient trust when applied to the secondary use of Big Data?
3. What cross-disciplinary frameworks can be implemented to reconcile the conflict between data privacy and the mandate for open science?

The rest of the paper is structured in the following way: Section 2 defines the theoretical framework by analyzing the point of bioethics, law, and data science. Part 3 examines the situation of transparency practices and report compliance. Section 4 discusses the development of informed consent with a special emphasis on the shift towards dynamic digital models. Section 5 is a critical assessment of the risks and incentives of open data. Lastly, Section 6 provides policy suggestions and closing remarks on the future of clinical research transparency.

Theoretical and Cross-Disciplinary Framework

The evaluation of the transparency of clinical trials involves the synthesis of disparate disciplines, and each of them displays a distinct prism of data sharing and rights of patients.

Bioethical Perspective: Autonomy vs. Collective Beneficence

The principle of autonomy states that the participants should be allowed to have control over their personal health information, but the principle of beneficence is applied not only to the individual but also to the rest of the population. It is possible to believe in a strong moral imperative to share information to eliminate duplication of unsuccessful experiments and to generate life-saving discoveries faster. The problems of ethical friction are found in the situation when the secondary use of data, which is usually crucial to scientific development, may violate the original intention of the consent of the participant. Such a framework must thus make a compromise between the right of an individual to privacy and the right of the collective to reliable, transparent scientific knowledge.

Legal Perspective: The Regulatory Constraints of GDPR and HIPAA

In Europe, the legal environment is mainly regulated by the General Data Protection Regulation (GDPR), whereas in the United States, the legal environment is controlled mainly by the Health Insurance Portability

and Accountability Act (HIPAA). GDPR puts in place strong demands of express consent and the right to forget, which may pose a challenge to long-term longitudinal studies and data archives. Its focus on lowering the amount of data usually contradicts the Big Data method in the example of modern genomics. Meanwhile, HIPAA dwells upon the de-identification of the Protected Health Information by the explicit Safe Harbor procedures. Although this offers a means through which data can be shared, the increasing likelihood of re-identification in the era of deep analytics is still a major legal and liability issue for research institutions across the world.

Economic and Industry Perspective: Intellectual Property vs. Public Health

There is a conflict that is at the core of intellectual property protection and the health of the people. Drug manufacturers and individual sponsors usually perceive uncooked clinical trial data as private property that can be used to gain a competitive edge. Full disclosure is often seen as a possible threat that can unveil trade secrets or allow competitors to avoid the expensive stages of research and development. On the other hand, withholding of data may result in duplication of a trial and putting more patients at risk of unnecessary exposure to experiments. The economic structure should hence find pre-competitive areas where the information can be exchanged without lowering the commercial feasibility that motivates the innovation of the private sector.

Technological Perspective: Blockchain and AI as Enablers

The technological advances can also be seen as the possible solution to the transparency-privacy paradox, as new methods are developed to protect and authenticate the data. The immutable audit trail of informed consent can be developed using blockchain technology, ensuring that all instances of access to the data are kept and clarified by the initial choices of the participant. At the same time, Artificial Intelligence is a threat and a remedy. Although AI contributes to the rise of the threat of re-identification, it also facilitates Federated Learning, whereby the algorithms can be trained on decentralized datasets, and the raw patient data does not need to leave secure local servers. Also, AI-based differential privacy methods are capable of introducing mathematical noise to data to maintain statistical utility and ensure individual anonymity.

Current State of Transparency Practices

A major gap between the regulatory expectations at the top level of clinical trial transparency and the reality of data reporting is the current state of the field.

Reporting Compliance: Quantitative Assessment of "Spin"

The presence of so-called spin often compromises reporting compliance, where the reporting of results is somehow biased to incorporate positive impacts and minimise the risks or non-significant results. The quantitative evaluation shows that in highly specialized studies such as psychiatry, about half of the abstracts of clinical trials are probably spin with researchers often focusing on secondary endpoints in case the primary ones do not reach a statistically significant result. Such distortion is especially common in trials funded by industries, whereby there is a high probability of arriving at a conclusion that favors the sponsor. The discrepancy between raw trial data, which is usually provided in extensive Clinical Study Reports (CSRs), and the refined stories presented in peer-reviewed journals indicates that the modern transparency model emphasizes whether something is being reported and not whether it is accurately reported.

Selective Reporting: The "File Drawer Problem"

Selective reporting is a seemingly unresolved obstacle to open science, sometimes known as the file drawer problem. This phenomenon consists of a non-publication of trials with a null or negative outcome on a systemic basis since researchers and sponsors might find such a result less prestigious or commercially demeriting. Although the law mandates the reporting of the results to databases such as ClinicalTrials.gov within one year of the study completion, a significant number of trials have not been reported in the open world. This processing of undesirable evidence generates a selective evidence base that makes the physicians and policymakers overevaluate the effectiveness and safety of the new interventions and disregard the unsuccessful experiences that may shape future studies.

Evolution of Informed Consent (IC)

The historical structure of the informed consent is witnessing a paradigm shift as clinical research takes a direction of long data acquisition and biomarking. With the change in the nature of data collection from single-use to perpetual storage, the mechanisms of securing participant autonomy would need to change accordingly so as to protect the integrity of ethics.

Broad vs. Specific Consent

One of the main conflicts in contemporary research is the specific consent, which restricts the use of the data to a specific study, and the broad consent, which opens the option of future and unspecified research. Whereas the greatest amount of protection is provided to the autonomy of the participants, specific consent poses considerable administrative and logistical challenges to longitudinal research, because in most cases, researchers are forced to re-contact thousands of participants each time they perform a secondary analysis. Broad consent has proven to be a practical solution but it has been vehemently criticized as being empty or ill-informed since participants cannot actually understand the dangers of future technologies or research agendas that are not yet realized. Such ambiguity can result in ethical conflicts, especially when the information is applied in controversial areas like behavioral genetics or commercial-driven AI creation without the express consent of the donor.

Dynamic Consent: A Digital-First Model

To overcome the drawbacks of both universal and targeted consent, the idea of Dynamic Consent has become popular as a solution being digital-first. Dynamic Consent uses a secure online interface, unlike the paper-based system, which requires a signature only once, and, unlike in the traditional one-and-done approach, the interface enables patients to have an open-ended discussion with the researchers. They have the freedom to join and quit particular modules of the research with time, change their preferences with the change in their health condition, and they are informed in real-time of how their information is being used. The model will change the participant into an active collaborator in the research ecosystem rather than a passive source of data. Dynamic Consent promotes greater trust and delivers a powerful audit trail which meets the demands of the stricter "granular consent" conditions of the current regulations such as GDPR due to the delivery of a transparent and flexible platform.

Critical Analysis: The Intersection of Consent and Open Data

The convergence of consent of the participants and the open sharing of data creates an intricate environment on which the technical constraints and the social forces tend to run into conflict. Although the drive towards open science is supposed to maximize the utility of a research, it brings in susceptibility that can destroy the entire basis of clinical ethics unless it is handled with accuracy.

De-identification Risks and the Anonymity Myth

One of the major issues with the open data movement is that it is technically difficult to ensure anonymity in the publicly available datasets. The conventional techniques of de-identification, where the explicit identifiers of a person such as names and social security numbers are eliminated, are becoming inadequate in a high-dimensional context. More complex methods of computation, including linkage attacks, enable investigators to make cross-checks between apparently anonymous clinical records and publicly available information, like voter registration or social media behavior, to re-identify individuals with a high precision [3]. This fact implies that anonymization of data is not always a permanent but a temporary process.

Trust Erosion and the Consequences of Data Misuse

The moral basis of clinical studies rests on a thin layer of the so called social license which can be easily discontinued when the social trust is compromised. Some of the warning examples of history include that the secondary use of data which was not completely and clearly agreed to resulted in major backlash and legal consequences of the use of data as they were. As an example, the Havasupai Tribe case had been able to point out the significant harm that resulted when DNA samples that were gathered in one instance to serve a specific purpose were utilized in a study of a different nature without the knowledge of the donors.

More recently, the scandals of selling patient information to giant technology companies have brought about the fear of so-called data harvesting. The occurrence of these incidences indicates that transparency is not just a bureaucracy, but a condition to act. Patients feel that their information is being sold as a commodity instead of a contribution to the common good and as a result, recruitment of them becomes lower and mistrust to the whole scientific process will be more pronounced.

Incentive Alignment and Rewarding Open Science

The solution to the transparency gap lies in the change of the very system of the scientific community that values research behavior. The academic incentive system, however, is currently structured in such a way that positive and novel findings, as opposed to the tedious task of data handling and sharing, are prioritized. To address this gap, institutional and editorial agencies are coming up with mechanisms to curb professional success and transparency. An example of such an initiative is the introduction of badges that are called Open Science badges that explicitly reward researchers who publish their raw data and analysis code. Moreover, transparency is becoming the equivalent of a currency because funding agencies are progressively requiring data-sharing plans as a condition to award grants, thereby making transparency a prerequisite to research in the future. By incorporating these measures into the tenure and promotion procedures, the scientific community can turn open data into an administration burden into a prestige of high quality and rigor scholarship.

Recommendations and Policy Implications

To have a more open clinical research environment, it is necessary to shift towards enforced global standards instead of voluntary guidelines. This change would necessitate the standardization of common metadata, e.g., the ones created by CDISC, so that the data can be interoperable and readable by a machine across different international registries [10].

Conclusion

The progress of contemporary medicine is inseparably connected with the purity, availability as well as the moral uprightness of clinical research. This multi-disciplinary evaluation has shown that, though the Transparency Mandate has taken considerable steps by instituting registries across the world, there are still considerable loopholes in the reporting obligations and autonomy of the participants. Dynamic Consent based on the shift towards using traditional and static consent models is a necessary development of keeping the ethical contract between the researchers and the participants in a Big Data era. The research community can curb the threat of de-identification, and encourage the culture of open science, by addressing the issue of the transparency-privacy paradox with technological solutions, such as Blockchain and AI. Finally, ensuring that the data transparency and patient privacy reconcile is an issue that cannot be resolved solely with the technical solutions, but one that necessitates the change of regulatory approaches and academic incentives. The adoption of standardized global metadata and the use of more severe punishment in case of non-disclosure are essential measures to make sure that the clinical trial data is used to the good of the people and is not locked in proprietary black boxes. The clinical research ecosystem, through empowering the participants with real-time access to their contributions towards their data and standardizing the results disclosure, can not only restore trust in the public but also increase the scientific reproducibility and speedy provision to the population with safe and evidence-based therapies.

Reference

- [1] Ng, J. Y., Wieland, L. S., Lee, M. S., Liu, J. P., Witt, C. M., Moher, D., & Cramer, H. (2024). Open science practices in traditional, complementary, and integrative medicine research: A path to enhanced transparency and collaboration. *Integrative medicine research*, 13(2), 101047.
- [2] Lawless, M. T., Tieu, M., Archibald, M. M., Pinero De Plaza, M. A., & Kitson, A. L. (2025). From promise to practice: how health researchers understand and promote transdisciplinary collaboration. *Qualitative Health Research*, 35(1), 3-16.

- [3] Tripathi, A. (2025). Artificial Intelligence in Public Health Surveillance: A Cross-Disciplinary Assessment of Predictive Analytics and Ethical Concerns. *Edulogic International Journal for Multi Disciplinary Research p-ISSN 3051-2395 e-ISSN 3051-2409*, 1(01), 13-26.
- [4] Simm, K., Parder, M. L., Tammelaht, A., & Lees, K. (2024). National cross-disciplinary research ethics and integrity study: methodology and results from Estonia. *Research Ethics*, 20(3), 514-538.
- [5] Farooq, M., & Rehmani, M. H. AI for Comprehensive Solutions-Cross-Disciplinary Applications in Mental Health, Cardiovascular Detection, and E-Commerce. *AlgoVista: Journal of AI and Computer Science*, 1(3), 592662.
- [6] Arvinth, N. (2025). Single-cell transcriptomic analysis reveals novel cell signaling networks in human embryonic development. *Frontiers in Life Sciences Research*, 1(1), 6–13.
- [7] Ritto, A. P., de Araujo, A. L., de Carvalho, C. R. R., De Souza, H. P., Favaretto, P. M. E. S., Saboya, V. R. B., ... & Busatto Filho, G. (2024). Data-driven, cross-disciplinary collaboration: lessons learned at the largest academic health center in Latin America during the COVID-19 pandemic. *Frontiers in Public Health*, 12, 1369129.
- [8] Fridas, A., Bourouliti, A., Touramanidou, L., Ivanova, D., Votis, K., & Katsaounis, P. (2025). Advanced Digital System for International Collaboration on Biosample-Oriented Research: A Multicriteria Query Tool for Real-Time Biosample and Patient Cohort Searches. *Computers*, 14(5), 157.
- [9] Russell, A. M., Shepherd, V., Woolfall, K., Young, B., Gillies, K., Volkmer, A., ... & Wade, J. (2023). Complex and alternate consent pathways in clinical trials: methodological and ethical challenges encountered by underserved groups and a call to action. *Trials*, 24(1), 151.
- [10] Koski, E., Das, A., Hsueh, P. Y. S., Solomonides, A., Joseph, A. L., Srivastava, G., ... & Quintana, Y. (2025). Towards responsible artificial intelligence in healthcare—getting real about real-world data and evidence. *Journal of the American Medical Informatics Association*, 32(11), 1746-1755.
- [11] Kvale, G., Wilhelmsen-Langeland, A., Jürgensen, M., Hystad, S. W., Öst, L. G., Søfteland, E., & Børtveit, T. (2022). Concentrated transdiagnostic and cross-disciplinary group treatment for patients with depression and with anxiety: a pilot study. *BMC Husen, T. K., Faris, M. N., & Taher, M. A. (2025). Multi-pollutants water cascade analysis for industrial water minimization. Current Topics in Nutraceutical Research*, 23(2). <https://doi.org/10.37290/ctnr.v23i2.25>
- [12] Albinsaad, L. S., Almubarak, E. A., Balkhair, R. M. A., Almana, K. A. A., Almuallim, R. M. A., Alkhamis, H. Y. H., & Alessa, M. Y. (2025). Diagnostic accuracy of artificial intelligence-assisted mammography interpretation vs. radiologist alone: A systematic review and meta-analysis. *Current Topics in Nutraceutical Research*, 23(2). <https://doi.org/10.37290/ctnr.v23i2.24>
- [13] Vallarino, D. (2024). Machine learning algorithms for survival analysis: Advantages, disadvantages, and examples. *International Journal of Artificial Intelligence & Machine Learning*, 4(1), 10–21. <https://doi.org/10.51483/IJAIML.4.1.2024.10-21>
- [14] Zhang, J., Abbas, Z., Ali, T., Liu, Q., & Wang, Y. (2024). The impact of ChatGPT on students' writing proficiency in second language acquisition: Students' perception and experiences: A qualitative analysis. *International Journal of Artificial Intelligence & Machine Learning*, 4(1), 1–9. <https://doi.org/10.51483/IJAIML.4.1.2024.1-9>and meta-analysis. *Current Topics in Nutraceutical Research*, 23(2). <https://doi.org/10.37290/ctnr.v23i2.24>
- [15] Vijaykumar, R., Gururaja, B. L., & Rajeswari, P. S. (2025). Integrating Green Orientation, Innovation, and Sustainability: Systematic Review Using the TCCM Framework. *Acta Innovations*, 56, 30-46.
- [16] Subba Naidu, S. G., & Tripathi, M. (2026). Designing biotechnological solutions for oil spill remediation and habitat restoration in coastal waters. *Natural and Engineering Sciences*, 10(2), 139–150. <https://doi.org/10.28978/nesciences.1714419>