A CRITICAL ANALYSIS OF INDIA'S LEGAL AND REGULATORY FRAMEWORK ON CLINICAL DATA MANAGEMENT: BRIDGING GAPS AND EXPLORING POSSIBILITIES

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ABSTRACT

Clinical Data Management (CDM) ensures the reliability and integrity of data collected from clinical trials. In India, however, the legal framework governing CDM is fragmented, with no single unified regulation addressing all aspects of data governance. This paper examines key instruments such as the Drugs and Cosmetics Act, 1940, the New Drugs and Clinical Trials Rules, 2019, the Indian Good Clinical Practice (GCP) Guidelines, 2001, the ICMR National Ethical Guidelines, 2017, the Digital Personal Data Protection Act, 2023, and the Health Data Management Policy, 2020. Through doctrinal analysis, the study identifies major gaps such as the absence of a statutory definition of CDM, overlapping institutional responsibilities, and lack of a central monitoring authority. It concludes that India requires a unified legal framework integrating ethical, procedural, and data protection principles to enhance consistency, accountability, and transparency in clinical research practices.

Keywords: Clinical Data Management (CDM), Drugs and Cosmetics Act, 1940, Good Clinical Practice (GCP) Guidelines, New Drugs and Clinical Trials Rules, 2019.

1) Introduction

India ranks first place in terms of population and it is known for its diversity in culture, food, customs, language, and attire. These differences play a crucial role in shaping health outcomes. For instance, the effect of a simple headache tablet may vary from person to person depending on their diet, lifestyle, and environment. Understanding such variations helps doctors assess the true impact of a medicine. Similarly, clinical trials which are conducted on humans generate valuable clinical data that records every aspect of the trial and its outcomes. This data is crucial because it provides insights into how a drug or treatment works across diverse populations. Proper collection, management, and sharing of clinical data are essential to ensure that the findings are transparent and reproducible. Making such data accessible allows researchers to learn from past failures, avoid repeating mistakes, and ultimately improve patient safety and the effectiveness of future trials.

There is no explicit definition laid down on clinical data management (CDM). However, the concept of data handling or record keeping was discussed in the Indian Good clinical practice guidelines. The lack of a clear definition for Clinical Data Management and ambiguity regarding what constitutes "clinical data" creates a significant gap. Without a precise framework, various stakeholders such as researchers, sponsors, and regulatory authorities may interpret the scope of CDM differently, leading to inconsistent and non-uniform practices in areas like data collection, storage, sharing, and protection. This inconsistency ultimately affects the reliability, accuracy, and integrity of clinical research outcomes. Furthermore, the absence of a clear definition creates legal and ethical challenges, particularly concerning issues of data ownership, patient consent, and confidentiality, because there is no standardized reference point available to determine specific responsibilities or liabilities.

CDM involves collection of data, erasure or correction of data in case of any errors and managing the data. It is a crucial phase of clinical research, as it ensures that data derived from clinical trials is accurate, reliable[1], and suitable for regulatory submissions. The primary goal of CDM is to provide high-quality data by minimizing errors and missing data while gathering the maximum amount of information possible for subsequent analysis. To meet this objective, best practices are to be implemented to ensure that data are complete, reliable, and processed

[1] ICMR – NIRBI, Data management division https://www.niced.org.in/divisions/DataManagement.htm accessed on 15 October 2025

correctly. High-quality data must be absolutely accurate and suitable for statistical analysis, adhering to protocol [2]specified parameters and complying with protocol requirements, aiming for minimal or no missing data.[3] It is essential as it reduces the time, cost and effort in managing large volumes of clinical data and it improves the authenticity of data which will be helpful to others researchers or clinicians.

The main objective of this paper is to examine the existing legal framework that governs CDM in India. This study is essential because to understand the CDM, we need to cover all fragmented framework. There is no one unified framework particular of CDM. Along with this increase of technology makes the CDM to get updated with all corners of privacy, storage of information. This study identifies gaps and inconsistencies among the framework. This paper follows the doctrinal research methodology which involves descriptive and historical research.

2) Evolution of Clinical Data Management

The history of Clinical Data Management (CDM) began with ancient medical systems like Ayurveda around 3000 BCE, which relied on careful observation to treat diseases but lacked standardized methods for collecting and analyzing data. Over time, people realized the importance of organized data when useful medical knowledge, such as using citrus fruits to prevent scurvy[4], was ignored for centuries due to poor data management. In the 18th century, doctors began manually recording and verifying patient data, as seen with Daniel Sutton's (surgeon) smallpox records. Frederick Akbar Mahomed who is a physician further advanced the idea by creating the Collective Investigation Record to share medical data among doctors. The modern era of CDM started in 1938, when the U.S. Food, Drug, and Cosmetic Act required that all new drugs be supported by safety and efficacy data before approval, marking the beginning of structured and regulated data handling in clinical research.[5]

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[2] Protocol is a document that states the background, objectives, rationale, design, methodology (including the methods for dealing with AEs, withdrawals etc.) and statistical considerations of the study. It also states the conditions under which the study shall be performed and managed.

[3] Krishnankutty B, Bellary S, Kumar NBR and Moodahadu LS, 'Data management in clinical research: An overview' (2012) 44(2) *Indian Journal of Pharmacology* 168–172 https://journals.lww.com/iphr/fulltext/2012/44020/data_management_in_clinical_research__an_overview.4.aspx accessed 17 October 2025

[4] Scurvy is a disease marked by swollen and bleeding gums, livid spots on the skin, prostration, etc., due to a diet lacking in vitamin C.

[5] Nidhi Bajpai, 'Clinical data management (CDM) process standardization for vaccine trials in an Indian pharmaceutical company, under Indian regulations' (Thesis, Jaypee Institute of Information Technology 2015) http://hdl.handle.net/10603/62185 accessed 30 October 2025.

The mid-20th century was a turning point for Clinical Data Management (CDM) as medical research became more structured and ethical. The Model Trial of streptomycin in 1946, the first randomized controlled trial, introduced systematic methods for patient enrolment and data collection which are core principles of modern CDM. Important ethical guidelines such as the Nuremberg Code (1948), the Declaration of Helsinki (1964), and the Belmont Report (1978) emphasized the need for proper data handling to protect human participants. The 1962 U.S.

Food and Drug Administration (FDA) amendments made it mandatory to prove a drug's effectiveness through controlled trials, leading to the creation of specialized CDM units in pharmaceutical companies. The majority of CDM was done by hand before to the development of computers. Case Report Forms (CRFs)[6] were used to record data, which were then transcribed into early electronic systems or simple databases, frequently without audit trails[7] or established validation. Data integrity and accuracy were impacted by this manual approach's lack of systematic quality control, appropriate training, and standard documentation procedures.[8].

Technological progress in the late 1970s transformed CDM when universities began using large mainframe computers for direct data entry. By the 1980s and 1990s, the use of personal computers (PCs) and Remote Data Entry (RDE) systems made data transfer faster and easier, though early storage devices like floppy disks sometimes caused data integrity issues. Today, CDM has become a specialized field that plays a crucial role in drug development and must follow strict global regulations[9]. The ICH-GCP guidelines set international ethical and scientific standards for clinical trials, while the Society for Clinical Data Management (SCDM) created the Good Clinical Data Management Practices (GCDMP) to outline quality and operational standards. Modern CDM involves a wide range of activities from designing CRFs

[6] CRF is a document which should be in accordance with protocol and it outlines the study's history, goals, justification, design, methods, and statistical concerns. It also specifies the guidelines for managing and carrying out the study.

[7] Metadata records that allow reconstruction of the course of events by capturing details on actions (manual or automated) performed relating to information and data collection and, where applicable, to activities in computerized systems. The audit trail should show activities, initial entry, and changes to data fields or records, by whom, when and, where applicable, why. In computerized systems, the audit trail should be secure, computer generated and timestamped.

[8] Bhatt A. Evolution of clinical research: a history before and beyond james lind. Perspect Clin Res. 2010 Jan;1(1):6-10. PMID: 21829774; PMCID: PMC3149409. https://pmc.ncbi.nlm.nih.gov/articles/PMC3149409/ (Accessed on 30 October 2025)

[9] Gluck B., "A Brief History and Look at the Future of Electronic Data Capture", http://www.datatrak.com/wpcontent/uploads/2014/07/Brief-History-and-Future-Look-of-EDC.pdf accessed on 30 October 2025

and validating data to medical coding and database locking managed by experts such as Data Managers, Programmers, and Medical Coders. Despite major technological and procedural improvements, CDM still faces challenges in achieving global uniformity in data standards and regulatory

3) Process of CDM

CDM is the data collected from a clinical trial where it involves collection of data in each and every step. Collection of data starts from trial and it will not be end even after completion of trial because in this process the data need to be stored even after completion of trial. The process of CDM involves multiple steps:

1. Case Report Form creation
2. Database system
3. Data collection
4. Data integrity
5. Quality control
6. Data base lock

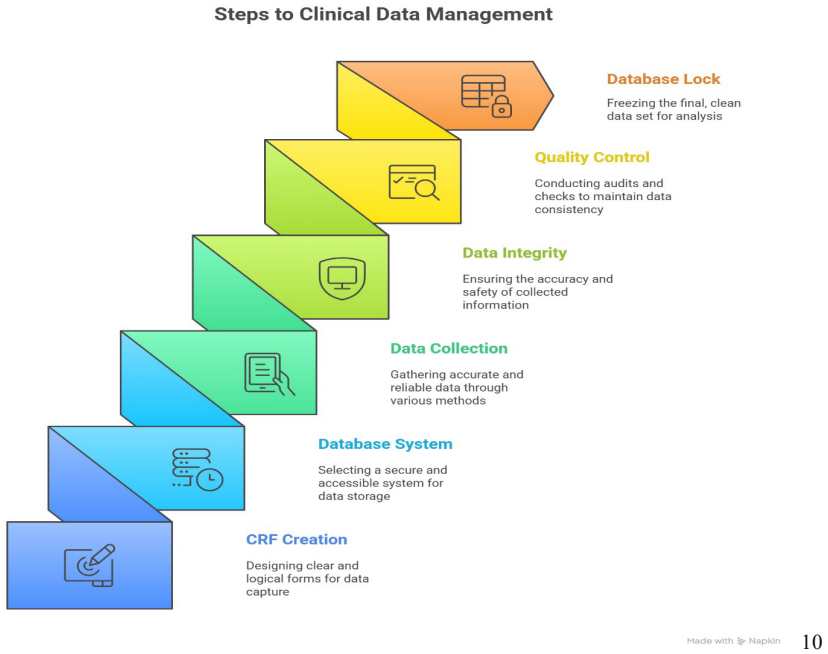

Fig 1 – Process of CDM

[10] The figure is obtained through Napkin AI

1. CRF is one of the important documents to record the trial data. CRF can be paper based or electronic[11]. CRFs ensure that all required data is captured correctly and consistently.

The data should match what's stated in the protocol and statistical plan. To prevent mistakes, CRFs should be designed clearly and logically.

2. The next step is choosing database system to store and manage data. That database system should match the size and complexity of the trial and make sure that the data is accurate, safe, and easily accessible.

3. Data collection is identified as a crucial part of any clinical trial. The data which is collected should be ensure the reliability and accuracy. Data collection can follow two main pathways:

1. Paper-Based Entry: Data may initially be recorded on paper and subsequently entered electronically.

2. Direct Electronic Entry: Data can be entered directly into electronic systems using various technologies, including web applications, secure connections, or handheld devices (Touch screen).

4. In clinical trials, ensuring data integrity is paramount, focusing on the accuracy, verifiability, and safety of all collected information. The data originates from source documents such as medical records, test reports, and patient diaries which are the first places where patient information and trial results are recorded. These documents are crucial for verifying that study participants are real, eligible, and treated according to the established protocol, enabling auditors to trace and confirm every step of a participant's treatment journey.

5. To maintain consistency and accuracy, quality control is rigorous, involving routine internal audits and internal quality checks that are carried out by someone other than the person who originally submitted the data (Monitor). Inconsistencies are

[11] The eCRF is an auditable electronic record of data that, in accordance with a clinical study protocol, is typically given to the sponsor on each trial subject. The systematic collection, review, management, storage, analysis, and reporting of clinical study data is made possible by the eCRF.

addressed through data queries, which are recognized as a normal part of verifying and clarifying the information. If an error is found on the CRF the correction must be done transparently. [12]

6. The database lock is the last step of CDM, marking the point where all data cleaning and fixing of issues are completely finished. When all problems are resolved, the final, clean set of information is frozen which means no one can make any changes to it anymore. This locking process requires approval from the stakeholders and sponsors. Once the database is officially locked, the statisticians are able to extract this finalized data set to begin their analysis, while the data management team completes all the required paperwork and prepares the information for safe, long-term storage.[13]

4) International Framework of CDM

International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) Good Clinical Practice (GCP) Guidelines

ICH – GCP Guidelines

ICH - GCP is recognized as an international, ethical, scientific, and quality standard for the conduct of trials that involve human participants[14]. It laid down the responsibilities of sponsor in cases of data management. The responsibilities of the sponsor for data handling are extensive, designed to ensure the quality, integrity, and protection of information throughout the clinical trial's full data life cycle. The sponsor must ensure the integrity and confidentiality of data generated and managed [15]by applying quality control [16](QC) to relevant stages of data handling, focusing QC activities on data of higher criticality to generate reliable results[17]. Before the trial begins, the sponsor must clearly define in the protocol what data needs to be

[12] Diane C St Germain, 'Data Management in Clinical Trials' in John I Gallin and Frederick P Ognibene (eds), *Principles and Practice of Clinical Research* (4th edn, Academic Press 2018) 91.
[13] Arputhadas G. Outline of clinical data management. International Journal of Science & Healthcare Research. ; 4(4): 79-82.
[14] International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), *E6(R3) Good Clinical Practice (Draft Guideline)* (Step 2b, 19 May 2023).
[15] ICH, *E6(R3) Good Clinical Practice (Draft Guideline)* (Step 2b, 19 May 2023) para 3.16.1(a).
[16] QC ensure that clinical data are generated, collected, managed, analyzed, and reported in accordance with protocol, SOPs, applicable regulations, and GCP guidelines, the process owners proactively conduct a periodic operational examination of the study/research related processes.
[17] ICH, *E6(R3) Good Clinical Practice (Draft Guideline)* (Step 2b, 19 May 2023) para 3.16.1(b).

collected[18] . They also have to ensure that the tools or systems used to collect this data (like software, devices, or forms) are validated[19]. Protecting the data is important, the sponsor must implement measures to prevent unauthorized access, disclosure, or alteration and ensure the privacy and confidentiality of participant's personal information according to applicable regulatory requirements.[20] In interactions with investigators, the sponsor must ensure they have timely access to the necessary data during the trial (including external sources like lab data) [21]and that procedures for correcting data are justified, supported by source records, and documented. Finally, the use of computerised systems imposes additional duties, requiring the sponsor to maintain records of important systems and their validation status[22] ensure the implementation of necessary requirements like audit trails and backup. They also need to check whether the systems used by investigators (like electronic health records, EHRs) are suitable and reliable for the clinical trial's purpose.

4.1) Data Cycle

The data cycle refers to the entire process by which clinical trial data is collected, recorded, reviewed, corrected, transferred, and finally stored or destroyed. It ensures that data is accurate, traceable, and dependable throughout its life cycle. Each stage of the cycle capture, verification, correction, transfer, and retention is critical to clinical research data integrity and regulatory compliance. ICH-GCP guidelines clearly laid down the procedure of data cycle in 4.2

1. **Data Capture** - This is the starting point where the data is collected. Data might be manually transcribed from paper into a computer system, or it might be directly entered into an electronic system. When data is captured, it must be accompanied by relevant metadata (information about how, when, and by whom it was collected). Systems should have automatic checks to detect data errors and raise queries these must be documented and controlled.[23]

2. **Relevant Metadata, Including Audit Trails –** This stage involves keeping detailed records, often called audit trails, of everything that happens to the data. The system

[18] ICH, *E6(R3) Good Clinical Practice (Draft Guideline)* (Step 2b, 19 May 2023) para 3.16.1(c).
[19] ICH, *E6(R3) Good Clinical Practice (Draft Guideline)* (Step 2b, 19 May 2023) para 3.16.1(d).
[20] ICH, *E6(R3) Good Clinical Practice (Draft Guideline)* (Step 2b, 19 May 2023) para 3.16.1(t).
[21] (ICH), *E6(R3) Good Clinical Practice (Draft Guideline)* (Step 2b, 19 May 2023) para 3.16.1(k)
[22] ICH, *E6(R3) Good Clinical Practice (Draft Guideline)* (Step 2b, 19 May 2023) para 3.16.1(x)(1)
[23] ICH, *E6(R3) Good Clinical Practice (Draft Guideline)* (Step 2b, 19 May 2023) para 4.2.1

must document the initial data entry. If data is changed or deleted, the system must document the change, and importantly, the reason for the change. The audit trails must record the date and time of entries or transfers unambiguously. These logs must be maintainable, interpretable, and generally should not be modified.[24]

3. **Review of Data and Metadata (Checking for Accuracy) -** This is the process of checking the data itself, along with the audit trails and other metadata, to ensure reliability. This review should be a planned activity. The extent of the review is often risk-based and adapted to the specific situation.[25]

4. **Data Corrections (Fixing Errors) -** If the review finds errors that could impact the reliability of the results, procedures must be in place to fix them. Any correction must be attributed to the person or system that made the fix. The correction must be justified and supported by source records. Corrections need to be performed in a timely manner[26].

5. **Data Transfer, Exchange, and Migration (Moving Data) -** This stage covers moving electronic data, including the relevant metadata, between different computer systems. Validated processes must be in place to ensure that the data maintains its integrity (completeness) and confidentiality during the transfer. The process must be documented for traceability. Data reconciliation is important to prevent data loss or unintended modifications during the move.[27]

6. **Finalisation of Data Sets Prior to Analysis (Cleaning Up)-** Before the data is used to draw conclusions, it must be finalized and confirmed to be of sufficient quality. Activities include fixing data errors and omissions that could impact safety or reliability. This stage can include medical coding and resolving noncompliance issues. Once finalized, the data is extracted for the planned statistical analysis. These activities must be documented.[28]

[24] ICH, *E6(R3) Good Clinical Practice (Draft Guideline)* (Step 2b, 19 May 2023) para 4.2.2
[25] (ICH), *E6(R3) Good Clinical Practice (Draft Guideline)* (Step 2b, 19 May 2023) para 4.2.3
[26] ICH, *E6(R3) Good Clinical Practice (Draft Guideline)* (Step 2b, 19 May 2023) para 4.2.4
[27] ICH, *E6(R3) Good Clinical Practice (Draft Guideline)* (Step 2b, 19 May 2023) para 4.2.5
[28] (ICH), *E6(R2) Good Clinical Practice – Integrated Addendum to E6(R1)* (Step 4, 9 November 2016) para 4.2.6

7. **Retention and Access (Safe Storage)** - After use, the finalized data and its metadata must be stored (archived) securely. The archived information must be protected from unauthorized access and alterations throughout the entire required retention period. It must be archived in a way that allows for easy retrieval and readability.[29]

8. **Destruction (End of Life)** - The final stage occurs when the data and metadata are no longer needed according to applicable regulations. At this point, the data may be permanently destroyed.[30]

5) National legal framework that governing the CDM

There is comprehensive legal framework that govern the CDM Process

1. Drugs and Cosmetics Act 1940 and New Drugs and clinical Trials Rules (NDCTR) 2019

2. Indian Good Clinical Practice (GCP) Guidelines 2001

3. Indian Council of Medical Research (ICMR) – National Ethical Guidelines, 2017

4. Digital Personal Data Protection Act, 2023

5. Health Data Management Policy

5.1) Drugs and Cosmetics Act 1940 and New Drugs and clinical Trials Rules 2019

The regulatory frameworks governing new drug and clinical trial processes in India are fundamentally established by the Drugs and Cosmetics Act, 1940, which give powers to the Central Government to regulate the import, manufacture, and clinical investigation of drugs and biologicals. The NDCTR were notified in 2019 under the Drugs and Cosmetics Act, 1940, and they constitute India's principal regulatory framework for clinical trials. The Rules detail the responsibilities of the sponsor, the investigator, and the ethics committee.

[29] ICH, *E6(R2) Good Clinical Practice – Integrated Addendum to E6(R1)* (Step 4, 9 November 2016) para 4.2.7
[30] ICH, *E6(R2) Good Clinical Practice – Integrated Addendum to E6(R1)* (Step 4, 9 November 2016) para 4.2.8

5.2) Indian GCP Guidelines 2001

The Indian Good Clinical Practice (GCP) Guidelines, 2001, issued by the Central Drugs Standard Control Organisation (CDSCO), are based on international best practices. These guidelines have a primary focus on safeguarding the rights, safety, and well-being of individuals participating in trials, while simultaneously working to ensure the reliability and credibility of the clinical data collected. To meet these objectives, the guidelines specifically emphasize several critical requirements, including strict adherence to safety protocols, ensuring the confidentiality of participant information, and maintaining transparency in both the recording and reporting of trial results. Crucially, the GCP Guidelines reinforce the requirement of obtaining informed consent, guaranteeing that every participant fully understands the nature of the study, its potential risks, and its anticipated benefits before providing agreement to take part.[31]

Here are the specific roles and responsibilities of the key players involved in the CDM Process, based on the framework mentioned above.

5.2.1) Sponsor

Sponsor includes a person, a company or an institution or an organisation responsible for initiation and management of a clinical trial.[32] The responsibilities of the sponsor are outlined in the Third Schedule, Clause 3(1) of the NDCTR and the CDSCO-GCP Guidelines. It specifies that the sponsor is responsible for implementing and maintaining quality assurance mechanisms to guarantee the study is carried out and data is reported in compliance with the protocol, GCP principles, and statutory obligations.[33] Sponsor must send a report to CLA, Chairperson of ethics committee and head of institution where trail took place within 14 days of knowing about the serious adverse event. [34]

Sponsor is responsible for securing agreement with all involved parties on the allocation of Protocol-related duties, which include specific tasks like monitoring, data processing, statistical analysis, breaking of the code, and reporting Adverse Drug Reactions (ADRs) or Adverse

[31] Central Drugs Standard Control Organisation (CDSCO), *Good Clinical Practice Guidelines for Clinical Research in India* (Ministry of Health and Family Welfare 2001) https://cdsco.gov.in accessed 5 November 2025.
[32] New Drugs and Clinical Trials Rules 2019, r 2(hh)
[34] New Drugs and Clinical Trials Rules 2019, sch III r 3(4).

Events (AEs) to the Ethics Committee[35]. The Sponsor must ensure that the study is operationally feasible, avoiding unnecessary complexity, and must establish, implement, and maintain appropriate quality assurance and quality control processes to ensure that the study is carried out in accordance with the protocol, Good Clinical Practice (GCP), and applicable regulatory requirements.

When computerised systems are used, the Sponsor must maintain detailed records of these systems, describing their use, functionality, validation status, and management responsibilities, alongside implementing crucial requirements such as audit trails, access controls, IT security, backup, and disaster recovery, ensuring documented procedures and adequate training are in place. Furthermore, the Sponsor must ensure the investigator has access to collected data (including external sources like central laboratory or ePRO data) necessary to make decisions on participant eligibility, treatment, and safety, while paying special attention to data that could potentially unblind the investigator.

Before starting to analyze the results, the Sponsor must clearly write down the specific steps they will take to manage the data and guarantee that every study participant has a unique and unambiguous identification code. They must also limit who can change the raw data, adjusting this restriction based on whether they are performing a preliminary (interim) review or the final assessment. It is vital that if any corrections are made to data originally entered by researchers or participants, these changes must be explained (justified), written down, and supported by the original paper records. Lastly, the Sponsor must ensure the safe and secure safekeeping (custody) of all study documents and materials. This includes keeping these materials for a minimum of five years after the study ends, or five years after the data is submitted to the regulatory authority, depending on which date is later.[36]

5.2.2) Ethics committee

The EC plays a vital role in ensuring ethical consent procedures. The informed consent form and the patient information sheet need to be approved by the EC. When an injury or death occurs during a trial, the EC makes sure investigators notify the subject of their right to

[35] CDSCO, *Good Clinical Practice Guidelines for Clinical Research in India* (Ministry of Health and Family Welfare 2001) para 3.1.5 https://cdsco.gov.in accessed 5 November 2025.
[36] Central Drugs Standard Control Organisation (CDSCO), *Good Clinical Practice Guidelines for Clinical Research in India* (Ministry of Health and Family Welfare 2001) para 3.1.5 https://cdsco.gov.in accessed 5 November 2025.

compensation. EC is required to keep data, records, registrations, and other documentation pertaining to its operations and evaluation for five years following the end of the study or clinical trial.[37]

5.2.3) CDSCO

CDSCO stands for Central Drugs Standard Control Organisation. It is the national regulatory authority for drugs, cosmetics, and clinical trials in India. It works under the Ministry of Health and Family Welfare, Government of India. It ensures that drugs and clinical trials in India are safe, effective, and ethically conducted. CLA stands for Central Licensing Authority. The CLA is not a separate body it is a specific authority within the CDSCO.

A person or institution can conduct a clinical trial of a new drug or investigational new drug with the permission granted by the CLA[38]. Applicants must submit applications (Form CT-04 for clinical trials) along with required documentation and fees. The CLA ensures trial integrity by setting conditions, including registering trials with the Clinical Trial Registry of India and ensuring compliance with the protocol and GCP guidelines. The sponsor must submit six monthly status reports of each clinical trial (ongoing, completed, or terminated) to the CLA electronically via the SUGAM portal[39]. The CLA maintains authority to impose additional conditions in writing for specific clinical trials regarding objective, design, subject population, and treatment. During inspection, officers have the authority to inspect, search, and seize any record, result, document, or investigational product related to the trial.

5.2.4) Investigator

An investigator is a person in charge of carrying out clinical trials at the trial location.[40] The investigator holds several key duties during a clinical trial, starting with the responsibility to run the study correctly according to the protocol and established guidelines. They must also

[37] CDSCO, *Good Clinical Practice Guidelines for Clinical Research in India* (Ministry of Health and Family Welfare 2001) r 13 https://cdsco.gov.in accessed 5 November 2025.
[38] Drugs and Clinical Trials Rules 2019, r 19(1)(i)
[39] India's Ministry of Health and Family Welfare's Central Drugs Standard Control Organization (CDSCO) created the SUGAM portal, an online e-Government platform. Sugam creates an extensive database of all the licenses and permits that State FDAs have granted. This contains information on the drug formulas, manufacturing location, and manufacturers. The manufacturer has access to their aggregated data regarding the authorizations granted by the State FDA.
[40] New Drugs and Clinical Trials Rules 2019, s 2(t).

create Standard Operating Procedures[41] for their work. A primary responsibility is to assure the correctness, completeness, legibility, and timeliness of all data presented to the sponsor, particularly in CRFs and other mandated reports. It is critical that the data documented on the CRF be consistent with the source papers, or any inconsistencies must be fully explained. Aside from documentation, the investigator should have timely access to and be accountable for the timely review of data, including relevant information from external sources such as central laboratories, imaging reads, or electronic patient-reported outcomes (ePRO data), particularly when such data may affect participant eligibility, treatment, or safety.[42]

5.3) ICMR – National Ethical Guidelines

Data management in clinical trials encompasses the entire lifecycle of handling research data, ensuring its integrity, and safeguarding the rights and privacy of human participants, as outlined in the National Ethical Guidelines for Biomedical and Health Research Involving Human Participants. Prior to beginning any study-related operations, the researcher must get the prospective participant's or Legally Acceptable/Authorized Representative's (LAR)[43] signed, informed permission.[44]This Informed Consent Document (ICD) must clearly explain the extent to which confidentiality will be maintained, the anticipated consequences of a breach of confidentiality, and include an account of the storage and maintenance of all data collected during the trial. Furthermore, research results, irrespective of outcome, should be published, making the information about the experiment, including the final data, freely available for others to check and use once published. This publicly shared data must generally be in a deidentified or anonymized form unless specific permissions or re-consent are obtained.

To provide ethical control over clinical trial data, all documentation and communications from an Ethics Committee (EC) must be dated, filed, and maintained in accordance with specified rules. While records are normally maintained for a minimum of 3 years following the completion or termination of the study, documentation pertaining to regulatory clinical trials

[41] Detailed written guidelines that are standard to provide uniformity in clinical study management.
[42] CDSCO, *Good Clinical Practice Guidelines for Clinical Research in India* (Ministry of Health and Family Welfare 2001) para 3.3.9
[43] Under applicable law or judicial authority, a person can provide consent on behalf of a prospective participant/subject who is unable to give consent due to legal or medical reasons to participate in research or undergo a diagnostic, therapeutic, or preventive procedure approved by the ethics committee.
[44] Indian Council of Medical Research (ICMR), *National Ethical Guidelines for Biomedical and Health Research Involving Human Participants* (2017) para 5.1.3

must be archived for 5 years after completion or termination, or as prescribed by laws.[45] The management of data also involves continuous review, including the reporting of safety data researchers are responsible for reporting all Serious Adverse Events (SAEs) to the EC within 24 hours of knowledge, followed by an analysis report within 14 days.[46]Additionally, all clinical trials must be registered prospectively with the Clinical Trials Registry India (CTRI) to ensure transparency, accountability, and accessibility of research information. [47]The EC also reviews the methods for ensuring physical safety and security of devices, password protection, differential access control, and data encryption for databases maintained in electronic/digital formats, especially those linked by networks or cloud computing, which pose risks to privacy.[48]

5.4) Digital Personal Data Protection Act, 2023

The Digital Personal Data Protection Act, 2023 ("DPDPA") introduces a new framework for data protection that significantly impacts India's healthcare and pharmaceutical sectors, which previously operated under fragmented sectoral regulations. A central feature of the DPDPA is the requirement for specific, informed, affirmative consent from individuals for the collection and processing of their health data, empowering patients to control how their information is used and providing them the right to withdraw consent at any time. While health data is not explicitly classified as sensitive personal data under the DPDPA, it is expected to be treated with a high level of protection. The Act allows for exceptions to consent, permitting data processing without explicit consent during medical emergencies involving threats to life or health, or for providing medical treatment during public health crises like epidemics. Entities that process large volumes of sensitive health data may be classified as Significant Data Fiduciaries (SDFs), which entails enhanced obligations such as conducting annual Data Protection Impact Assessments, ensuring algorithmic transparency, and adhering to strict data localization mandates. Crucially, the DPDPA emphasizes data minimisation, compelling healthcare providers to collect and process only the data strictly necessary for the specified medical purpose, while also requiring fiduciaries to implement stringent security measures,

[45] ICMR, *National Ethical Guidelines for Biomedical and Health Research Involving Human Participants* (2017) para 4.13
[46] ICMR, *National Ethical Guidelines for Biomedical and Health Research Involving Human Participants* (2017) para 2.61
[47] ICMR, *National Ethical Guidelines for Biomedical and Health Research Involving Human Participants* (2017) para 3.7.3
[48] ICMR, *National Ethical Guidelines for Biomedical and Health Research Involving Human Participants* (2017) para 11.8

including encryption and access controls, to safeguard personal data from breaches[49].

5.5) Health Data Management Policy

The Health Data Management Policy is the foundational guidance document for the National Digital Health Mission (NDHM), which aims to digitize India's entire healthcare ecosystem based on the National Health Policy, 2017. Its primary purpose is to realize the NDHM's guiding principle of "Security and Privacy by Design" for protecting individuals' personal digital health data, setting minimum data privacy standards across the National Digital Health Ecosystem (NDHE). The NDHE operates on a federated architecture to allow interoperability between decentralized systems while enhancing security and privacy.[50] Participation for individuals is completely voluntary, and those who join are issued a unique Health ID. Crucially, data fiduciaries must only collect or process personal data with the data principal's consent, [51]which must be free, informed, specific, and clearly given, and must also be capable of being withdrawn easily at any time. This Policy mandates that entities involved, including doctors, health facilities, and pharmaceutical manufacturers, follow strict data protection principles such as Accountability[52], Transparency,[53] and Privacy by Design.[54]

Findings

CDM plays an important role in the clinical trial. After having read through these comprehensive frameworks I found these findings.

1. There is no explicit definition for CDM in international and national framework.

2. It is very clear that the framework of CDM is fragmented where we need to look over many guidelines, Acts and policy to get proper understanding. Each framework focuses on specific aspects of data governance such as trial approval, participant protection, ethical consent, or data privacy but none provide a comprehensive and integrated

[49] JSA Prism, *Privacy and Data Protection – Digital Personal Data Protection Act, Edition XII* (JSA Law Jan 2025) https://www.jsalaw.com/wp-content/uploads/2025/01/JSA-Prism_Data-Privacy-DPDPA_Edition-12.Final_.pdf accessed 25 October 2025
[50] Purpose of Health Data Management Policy
[51] National Health Authority (NHA), *Health Data Management Policy*, s 9
[52] NHA, *Health Data Management Policy*, s 26.1
[53] NHA, *Health Data Management Policy*, s 26.2
[54] NHA, *Health Data Management Policy,* s 26.3

framework exclusively dedicated to Clinical Data Management.

3. Under third schedule of NDCTR, clinical trial needs to be conducted as per GCP guidelines. The act is talking about the clinical trial but not about data management

4. Furthermore, there is no single statutory authority exclusively responsible for monitoring and enforcing uniform standards in CDM.

Suggestions

1. India requires consolidated statute that integrates all aspects of CDM. This unified framework should clearly define "clinical data," assign responsibilities, and establish uniform compliance mechanisms. It is essential because majority framework that talks about CDM is guidelines which does not have binding value. In that case violation of that guideline will not have any sanction.

2. A dedicated body or specialized division under CDSCO or ICMR should be established to oversee and audit all CDM activities, ensuring uniform implementation of national and international standards.

3. Current guidelines like the Indian GCP Guidelines (2001) and ICMR National Ethical Guidelines (2017) provide valuable ethical direction, they should be formally incorporated into statutory rules (such as the NDCTR, 2019) to give them binding legal status. This would ensure consistency and accountability in CDM practices nationwide.

Conclusion

CDM plays an important role in ensuring information from clinical trials is accurate, reliable. Although there are several laws and guidelines in India they operate independently without forming single clear framework for CDM. Even though the NDCTR, 2019, mandates adherence to GCP guidelines, the Indian framework cannot be called fully unified because GCP is only referenced, not comprehensively incorporated into a single binding statute. Different aspects of CDM ethical review, data privacy, digital health, and trial conduct fall under separate authorities and documents, making the system only partially harmonized. This fragmented approach leads to gaps in accountability and consistency. To strengthen the integrity of clinical research, India needs a unified legal framework that clearly defines CDM procedures,

responsibilities, and data protection measures. Such a system would not only improve the quality of research outcomes but also enhance public trust in the country's clinical trial process.