Dissertation Report

On

"Experiences and Perspectives of Clinical Research Professionals on Remote Monitoring in Clinical Trials in India: A Qualitative Exploratory Study"

At

The George Institute for Global Health India
(1st May - 31st June)

By
Name: Piyush Dutt
Enroll No.: PG/24/075

Under the guidance of
Dr. Shikha Bassi

PGDM (Hospital & Health Management) 2024-26



International Institute of Health Management Research New Delhi

Internship Training

On

Experiences and Perspectives of Clinical Research Professionals on Remote Monitoring in Clinical Trials in India: A Qualitative Exploratory Study

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Name: Piyush Dutt
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Dr. Shikha Bassi

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International Institute of Health Management Research New Delhi

The certificate is awarded to

Name: Piyush Dutt

in recognition of having successfully completed his internship

Title: Remote Monitoring in Clinical Trials

and has successfully completed his Project on

Experiences and Perspectives of Clinical Research Professionals on Remote Monitoring in Clinical Trials in India: A Qualitative Exploratory Study

Organization: George Institute for Global Health India

He comes across as a committed, sincere & diligent person who has a strong drive & zeal for learning.

We wish him all the best for future endeavors.

Aishwarya nair

Aishwarya Nair
Project Manager
GIS

TO WHOMSOEVER IT MAY CONCERN

This is to certify that **Piyush Dutt** student of PGDM (Hospital & Health Management) from International Institute of Health Management Research, New Delhi has undergone internship training at **George Institute for Global Health India** from **April to June**. The Candidate has successfully carried out the project designated to him during internship training and his approach to the study has been sincere, scientific and analytical. The Internship is in fulfillment of the course requirements.

I wish her success in all her future endeavors.

Dr. Punit Yadav
Academic and Student Affairs
IIHMR, New Delhi

Mentor-
Dr. Shikha Bassi
IIHMR, New Delhi

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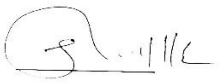
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Dissertation Examination Committee for evaluation of dissertation.

Name	Signature
Dr. Sumesh Kumar	
Dr. Supen	

INTERNATIONAL INSTITUTE OF HEALTH MANAGEMENT RESEARCH, NEW DELHI

CERTIFICATE BY STUDENT

This is to certify that the dissertation titled **Experiences and Perspectives of Clinical Research Professionals on Remote Monitoring in Clinical Trials in India: A Qualitative Exploratory Study and** submitted by Piyush Dutt Enrollment No. **PG/24/075** under the supervision of **Dr. Shikha Bassi** for award of PGDM (Hospital & Health Management) of the Institute carried out during the period from **May** to …**June**… embodies my original work and has not formed the basis for the award of any degree, diploma associate ship, fellowship, titles in this or any other Institute or other similar institution of higher learning.



Signature

FEEDBACK FORM (IIHMR Mentor)

Name of the Student: Piyush Dutt

Name of the Organization in Which Dissertation Has Been Completed: George Institute Services India Pvt. Ltd. (GIS India)

Area of Dissertation: Clinical Research Operations, Remote Monitoring, Risk-Based Monitoring (RBM), and GCP Compliance

Title of Dissertation: *Experiences and Perspectives of Clinical Research Professionals on Remote Monitoring in Clinical Trials in India: A Qualitative Exploratory Study*

Attendance: The student maintained consistent attendance

Objectives achieved: Piyush conducted an in-depth qualitative study capturing key stakeholder perspectives across site and CRO environments.

Deliverables: A comprehensive dissertation report titled

Strengths: Piyush Dutt shows great openness to academic guidance and mentor suggestions,

Suggestions for Improvement: Publish this work

Suggestions for Institute (course curriculum, industry interaction, placement, alumni):

Signature of the Officer-in-Charge/ IIHMR Mentor

Date:

Place: New Delhi

INTERNATIONAL INSTITUTE OF HEALTH MANAGEMENT RESEARCH (IIHMR)
Plot No. 3, Sector 18A, Phase- II, Dwarka, New Delhi- 110075
Ph. +91-11-30418900, www.iihmrdelhi.edu.in

CERTIFICATE ON PLAGIARISM CHECK

Name of Student (in block letter)	**Piyush Dutt**		
Enrollment/Roll No.	PG/24/075	**Batch Year**	2024-2026
Course Specialization (Choose one)	Hospital Management	Health Management	Healthcare IT ✓
Name of Guide/Supervisor	Dr. Shikha Bassi		
Title of the Dissertation Assignment	Experiences and Perspectives of Clinical Research Professionals on Remote Monitoring in Clinical Trials in India: A Qualitative Exploratory Study		
Plagiarism detect software used	**"TURNITIN"**		
Similar contents acceptable (%)	Up to **15** Percent as per policy		
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Guide/Supervisor
Name: Dr. Shikha Bassi
Signature: Bassi

Student
Name: Piyush Dutt
Signature: Piyush

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The George Institute for Global Health India

The George Institute for Global Health is an independent, not-for-profit medical research organisation working to improve the health of people across the world. Established in Australia in 1999, the Institute has grown into a global organisation with major centres in Australia, India, China and the United Kingdom. Its work focuses on developing practical, evidence-based solutions to major health problems and strengthening healthcare systems, particularly for vulnerable and underserved populations.

The George Institute for Global Health India was established in 2007 and operates through offices in New Delhi and Hyderabad, along with research and field activities across several Indian states. The organisation works closely with governments, hospitals, academic institutions, healthcare professionals, civil-society organisations and communities. Its aim is not only to generate high-quality research evidence but also to translate that evidence into better healthcare practices, effective public-health programmes and stronger health policies.

The Institute follows a multidisciplinary approach by bringing together clinicians, epidemiologists, public-health professionals, statisticians, data scientists, health economists, project managers and community researchers. These teams design and conduct clinical trials, implementation studies, population-based research and health-system evaluations. Its major areas of work include cardiovascular disease, kidney and metabolic disorders, mental health, injury and trauma, women's health, multiple chronic conditions, nutrition, health equity, digital health and planetary health.

Clinical research is an important part of the Institute's work. It supports and conducts large-scale clinical trials to evaluate treatments, models of care and health-system interventions. These studies are designed to maintain high standards of participant safety, data quality, ethical conduct and regulatory compliance. The organisation also provides operational support through functions such as data management, quality assurance, research governance, monitoring, project coordination and capacity building.

A major strength of The George Institute is its focus on innovation and digital health. The organisation uses digital platforms, electronic data systems and technology-supported models of care to improve access, efficiency and clinical decision-making. Initiatives such as SMART health demonstrate how digital tools and community-based healthcare

workers can help improve the prevention and management of chronic diseases, especially in rural and underserved areas.

Health equity is central to the Institute's mission. It recognises that health outcomes are shaped by poverty, gender, geographical location, access to services and the strength of healthcare systems. Therefore, communities and patients are often involved in identifying priorities and designing interventions. By combining scientific research, clinical expertise, technology and policy engagement, The George Institute for Global Health India works towards improving treatments, strengthening healthcare delivery and building healthier and more equitable societies.

Acknowledgements

The past six months has been incredibly intense and full of experience and reflecting on this I would like to extend my gratitude to the people who have guided me to end up with this completion day. This internship would not have been possible without the contribution of the following people.

First, I would like to express my gratitude towards IIHMR DELHI for providing me with the opportunity to work with The George Institute for Global Health India and my mentor **Dr. Shikha Bassi ma'am** for incessantly guiding me.

I extend my sincere thanks to **Mr. Abhinav Bassi (Leads Operations); Dr. Aishwarya Nair (Project Manager) and Niranjana Gangadharan (Associate Project Manager)** and all my fellow colleagues for their unwavering guidance and support throughout the internship have been instrumental in shaping my understanding of the industry. Their expertise and encouragement not only facilitated my learning but also helped me contribute meaningfully to the ongoing projects and have been instrumental in my development as a budding professional.

I would also like to extend my sincere thanks to **Anshul Kumar (CRA)** for her support in my internship project. A special thanks to my family for supporting me.

Their collaborative spirit, patience, and willingness to involve me in meaningful projects have truly made a difference in my learning experience. I am grateful for their trust and the opportunities they provided me to contribute to the team's objectives. The positive work environment fostered a sense of belonging and made every day an enjoyable and productive one.

I would also like to extend my appreciation to my fellow colleagues, with whom I had the pleasure of collaborating. Their enthusiasm and dedication made the internship experience even more enjoyable, and I am thankful for the knowledge exchange we had.

I look forward to utilizing this experience as a foundation for my future endeavours in the field public health.

Thank you

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List of Abbreviations

Abbreviation	Full Form
CRA	Clinical Research Associate
CRC	Clinical Research Coordinator
CRO	Contract Research Organization
CTM	Clinical Trial Manager
EDC	Electronic Data Capture
EMR	Electronic Medical Record
GCP	Good Clinical Practice
ICH	International Council for Harmonisation
RBM	Risk-Based Monitoring
SOP	Standard Operating Procedure

Research Project

CHAPTER 1: INTRODUCTION

1.1 Background of the Study

Traditionally, the monitoring of a clinical trial was generally considered an activity at the trial site.

This was primarily because source notes, regulatory binders, pharmacy records and investigator files were paper based. A monitor had to look at these records in person and a monitor had to see how the study was actually run. As EDC, eTMF and other electronic systems become more mainstream, some monitoring aspects are no longer restricted to physical site visits.

The change has not been the same in all experimental settings. While some sites have made the transition to electronic documents and digital processes easily, many others are still relying on paper files and manual tracking. This difference is important because remote monitoring is not just a technological shift. It also changes the way in which monitors, project teams, investigators and coordinators communicate, break down work and follow-up pending issues. Clinical trials are central part of medical research. They are used to study the safety and effectiveness of medicines, vaccines, devices, diagnostic tools and treatment approaches before these are used more widely in patients. Since human participants are involved, clinical trials require careful ethical, scientific and regulatory oversight. Participant safety, data integrity, protocol compliance and Good Clinical Practice remain essential to the credibility of clinical trial data (1).

Monitoring is one of the main quality control activities in a clinical trial. It helps confirm that participants are protected, the approved protocol is followed, trial data are entered correctly and the information recorded in trial systems can be supported by source documents. Traditionally, this work was performed through on-site visits, where monitors reviewed files, verified data and discussed open issues with site teams.

Clinical research operations have changed with the wider use of electronic data capture systems, electronic trial master files, clinical trial management systems, electronic medical records and virtual communication platforms. Now thanks to these tools several monitoring activities can be done remotely. In this dissertation remote monitoring means monitoring and follow-up activities that are performed without the monitor being physically present at the site, e.g. EDC review, query follow-up, review of essential documents, virtual meetings and remote source review where permitted.

The COVID-19 pandemic brought even more attention to remote and hybrid monitoring

as travel restrictions and limited access to hospitals disrupted routine site visits (4,5). Many organisations continued to include remote review as a planned component of monitoring beyond that period. This is especially true in India, where trial sites vary in digital maturity, internet access, documentation practices and staff availability. Learning how professionals experience remote monitoring can thus contribute to making remote.

1.1 Overview of Clinical Trial Monitoring

Monitoring has a supportive role, not just a checking role. In day-to-day trial work, monitors advise sites on protocol requirements, documentation, query responses and reporting timelines. They often help catch the little things before they become big compliance findings. So, in that sense, monitoring also contributes to both the quality culture of the site and data verification.

Today monitoring is closely linked with data management, medical review, safety review and project oversight in clinical trials. The findings of the monitoring are therefore not seen in isolation. If data is missing repeatedly, adverse events are documented late or there are many queries, this may indicate that a site needs more training or support. Used correctly, electronic systems can help to identify such patterns early through remote monitoring.

Clinical trial monitoring is a systematic process for overseeing progress, conduct and quality of a trial

. It helps ensure the study is being conducted in accordance with the protocol, SOPs, GCP and applicable regulatory requirements. The CRA or monitor is a vital link between the sponsor, CRO, investigator and site team.

Typical monitoring activities include review of informed consent, eligibility checks, source data verification, safety reporting review, regulatory file review, investigational product accountability, protocol deviation follow-up, query management and closeout activities. Such activities enable the trial team to detect errors or compliance issues in sufficient time to take corrective and preventive action.

Monitoring has moved from a largely on-site model to a more mixed model with centralised, remote, risk-based and hybrid approaches. This change is in response to the need to maintain trial quality and use monitoring resources more sensibly and focus attention on critical data and processes.

1.2 Traditional On-Site Monitoring in Clinical Trials

In traditional on-site monitoring, a monitor physically visits the investigational site. During such visits, the monitor may review source documents, meet with the investigator and coordinator, review study files, and observe site level processes. This

method is still valuable as it offers direct observation of documentation practices, pharmacy processes, investigational product storage and staff coordination.

In addition, monitoring on the ground can be a time consuming and resource intensive activity. It depends on travel, scheduling and availability of site staff. The need to travel repeatedly to other sites in multicentre studies can increase costs and delay resolution of problems. There ’s also on-site visits for periodic oversight , not continuous review . Such constraints have pushed organisations to mix

on-site visits with remote and risk-based approaches.

1.3 Remote Monitoring in Clinical Trials

The practical benefit of remote monitoring is that review can occur between scheduled site visits. CRAs can review EDC entries and observe missing information and can contact sites shortly after

data are entered, thus monitoring is more continuous. This can help to reduce the pile-up of open queries and enable faster follow-up.

Careful documentation is also needed for remote monitoring. In the absence of the monitor being physically present, then records such as email trails, monitoring notes, access logs, query histories and follow-up letters become important evidence that oversight was in fact carried out. Clear documentation also enables other team members to understand what has been reviewed and what needs to be done.

Remote monitoring uses digital technology and communication systems to carry out selected monitoring activities from a distance, away from the site. It is generally appropriate for EDC review, query follow-up, critical document review, recruitment tracking, virtual site meetings and central data review.

Remote monitoring does not replace monitoring on the spot. Instead, it provides trial teams with flexibility to carry out appropriate activities remotely while retaining the ability to conduct on-site visits for activities requiring physical verification. It reduces travel, enhances communication, provides continuity in the face of disruptions and enables more frequent data review.

Remote monitoring can be effective, though, if there are basic support systems in place. Secure access, clear rules, trained staff, reliable internet and disciplined documentation are necessary. Remote review should be planned taking into account factors like access to the source, confidentiality, data privacy and cybersecurity.

Table 1.1: Key Differences Between On-Site and Remote Monitoring

Basis	On-Site Monitoring	Remote Monitoring
Physical presence	Monitor physically visits the investigational site.	Monitor reviews data and documents remotely.
Main activities	Source verification, pharmacy review, site file review, direct discussion.	EDC review, query management, virtual meetings, document follow-up.
Strength	Allows direct observation and physical verification.	Provides flexibility, faster follow-up, and reduced travel.
Dependency	Less dependent on digital infrastructure.	Highly dependent on internet, platforms, and secure access.
Limitations	Costly, time-consuming, and affected by travel restrictions.	Limited physical observation and source access concerns.
Best use	High-risk activities and physical verification.	Routine data review and follow-up activities.
Modern role	Used selectively in hybrid monitoring.	Used with centralized and risk-based monitoring.

1.4 Remote Monitoring in the Indian Clinical Research Context

In India, remote monitoring has to be seen in a very mixed context of health care and research. Some trial sites are large tertiary hospitals with better digital systems while others are smaller centres where documentation is still very much paper based. Such variability means that a single remote monitoring process will not be equally effective at all sites.

Another important factor is the workload of site staff in the Indian context. Clinical Research

Coordinators often manage the patient visit, data entry, query response, ethics submission, filing and sponsor interaction. While remote monitoring may reduce travel for the monitor it may increase workload for the coordinator if documents have to be scanned, uploaded, redacted or explained again and again. Thus, when planning monitoring, the burden on the site must be taken into account.

With a large pool of patients, experienced investigators, growing hospital network and the presence of sponsors and CROs, India is an important destination for clinical research. Trial sites also vary in terms of infrastructure, documentation systems, availability of staff, internet connectivity and use of EMRs.

These differences have a direct effect on remote monitoring. Larger urban sites may be more comfortable with electronic review while smaller or less experienced sites may use paper files and manual preparation. Remote monitoring may reduce the travel between geographically dispersed sites and improve communication, but may increase the workload to prepare documents at site.

But in this context, regulatory and ethical expectations matter. Remote monitoring needs to maintain participant confidentiality, protect data integrity and ensure sites are ready for inspection. Hence a practical hybrid approach is more realistic in India where remote monitoring can be done for appropriate review activities and on-site visits for activities which require physical verification.

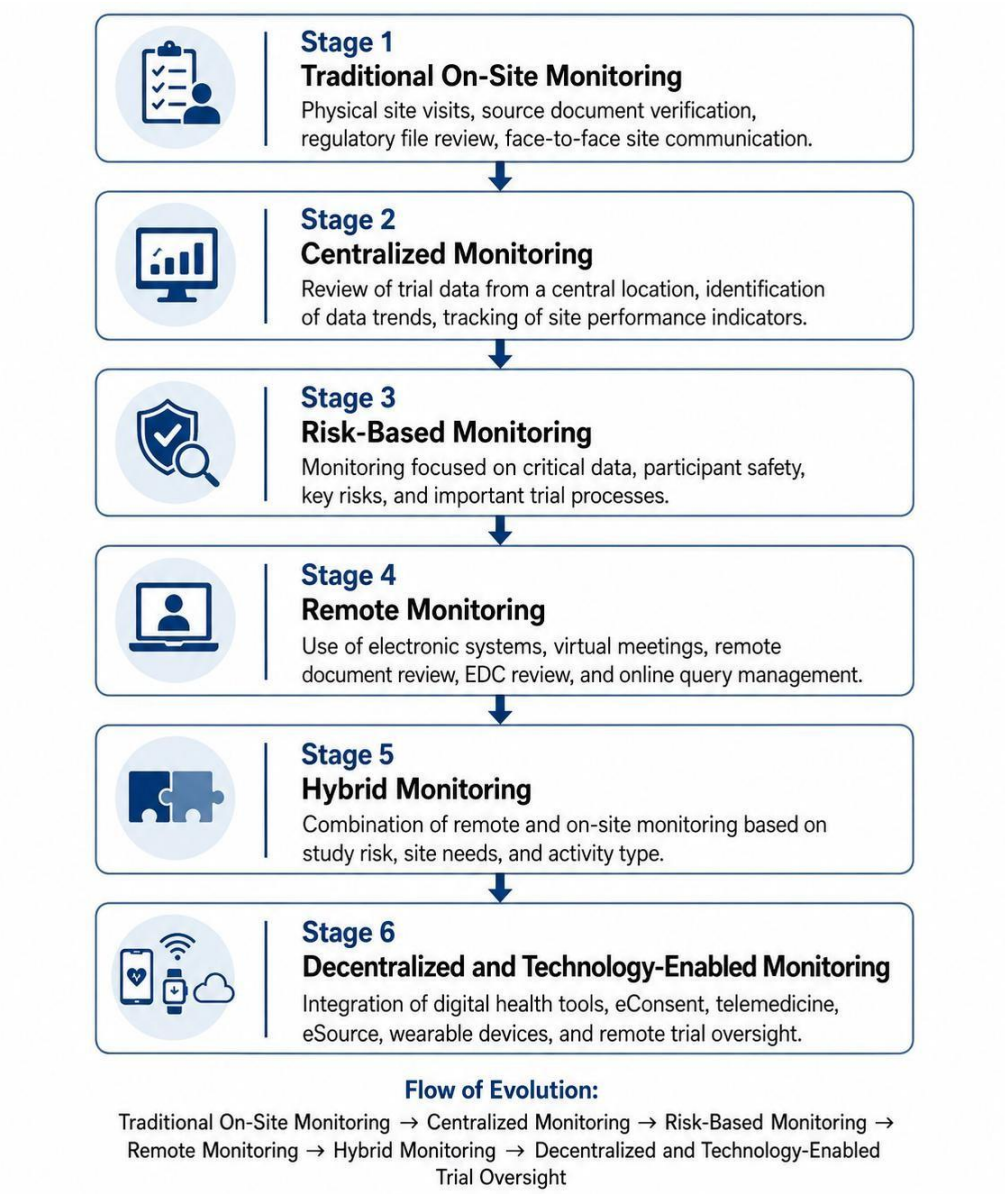


Figure 1.1: Evolution of Clinical Trial Monitoring Approaches

1.5 Rationale / Need for the Study

Remote monitoring increasingly being used in clinical trial operations, but whether it works depends on local realities such as sites readiness, digital infrastructure, training, source access and sponsor or CRO processes. Much of the evidence available from international settings and may not be fully representative of the Indian trial environment. These processes are directly experienced by clinical research professionals in their work. CRAs, CRCs, project managers, investigators and quality professionals can talk about what works well, where problems exist and what can be improved. Therefore their views are useful in making

1.6 Problem Statement

Remote monitoring is being increasingly implemented in clinical trials but qualitative evidence on how clinical research professionals in India perceive and understand it is still scarce. This study aims to bridge that gap by examining the practical experiences, challenges, facilitators, regulatory concerns and future expectations of remote monitoring in Indian clinical trials.

1.7 Scope of the Study

This study is intended for clinical research professionals in India who are involved in monitoring, site coordination, project management, investigation and related trial activities. It examines their experiences with remote, on-site and hybrid monitoring, including barriers, facilitators, training needs, privacy concerns and recommendations. This study does not assess trial outcomes, nor compare specific sponsors, CROs, therapeutic areas or protocols.

1.8 Aim of the Study

To explore the perceptions, experiences, challenges, facilitators and future applicability of remote monitoring in clinical trials from the perspective of clinical research professionals working in India.

1.9 Objective

Primary Objective

To explore how clinical research professionals in India experience and perceive remote monitoring in clinical trials.

Secondary Objectives

1. To determine how remote monitoring is used in different clinical trial settings.
2. To investigate barriers and facilitators to the practice of remote monitoring.
3. To understand stakeholder perspectives on remote, on-site and hybrid monitoring.
4. To understand infrastructure, training, competency and regulatory considerations for remote monitoring.
5. To make recommendations for improvement of remote monitoring practices in India.

1.10 Research Questions

1. What are the experiences of clinical research professionals with remote monitoring in India?
2. How do professionals compare remote monitoring with on-site monitoring?

3. Which monitoring activities are suitable for remote review and which require on-site presence?
4. What barriers and facilitators influence remote monitoring?
5. What recommendations can improve remote and hybrid monitoring practices in India?

CHAPTER 2: REVIEW OF LITERATURE

2.1 Clinical Trial Monitoring and Good Clinical Practice

Good Clinical Practice provides the base for any monitoring model. Whether monitoring is done on-site or remotely, the essential expectations remain the same: participants must be protected, consent must be documented properly, protocol deviations must be identified, safety information must be reported and data must be traceable. Remote monitoring does not reduce these responsibilities; it changes the way they are managed. GCP also makes sponsor oversight important. In remote monitoring, this oversight may be shown through monitoring plans, risk assessment documents, review logs, query reports, escalation records and documented follow-up. Planning and documentation therefore become especially important. If remote review is carried out without clear procedures, audit readiness may be weak even when data have been reviewed.

Clinical trial monitoring is a quality management activity that supports participant safety, protocol compliance, reliable data and adherence to regulatory requirements. GCP is an accepted standard for designing, conducting, recording and reporting clinical trials. It places responsibility on sponsors to implement appropriate monitoring and oversight to protect participants and data quality (1). In India, clinical trials are also guided by national requirements, including the New Drugs and Clinical Trials Rules, 2019 (2).

2.2 Traditional Monitoring Practices in Clinical Trials

On-site monitoring is most useful when the monitor needs to understand how a site works in practice. Physical presence allows the monitor to observe how records are maintained, how investigational products are managed, how staff interact with each other, and whether the processes described are being followed. Not all of these observations are electronically represented at times.

At the same time, traditional monitoring may be inefficient when applied to all activities disregarding the risk. There is a lot of routine data that is available electronically and repeated travel for EDC review might not be the best use of time or resources. This is why many organisations today are using on-site visits more selectively, and supplementing them with remote review.

Traditional monitoring typically includes site visits to investigational sites. During these visits the monitors review consent forms, source documents, regulatory files, investigational product accountability, protocol deviations and safety documentation. On-site monitoring is important for high risk activities, allowing for direct observation, but is also costly, travel dependent and periodic. Such constraints have led to more flexible monitoring models.

2.3 Emergence of Remote Monitoring

The rise of remote monitoring is closely related to the availability of electronic trial data. Authorised monitors can review case report form entries and queries from a remote location with EDC systems. eTMF systems allow the review of key documents and virtual meeting tools facilitate regular contact with site teams. Together these tools make remote oversight operationally possible.

But with these tools, the quality of remote monitoring still depends a lot on the process behind it. When access is delayed, or the documents are incomplete, or the site team is not responsive, remote review is difficult. Hence remote monitoring has to be a structured process with planning, training and clear responsibilities – not a digital version of a site visit.

Remote monitoring increased with the adoption of EDC systems, eTMF, CTMS, electronic medical records, secure portals and virtual communication tools. It allows monitors to review data, follow up on queries, communicate with sites and review documents without being physically onsite. In most practical cases it is used as part of a hybrid approach, rather than as a complete substitute for on-site visits.

2.4 Risk-Based Monitoring and Centralized Monitoring

Risk-based monitoring has changed the way organisations think about the intensity of their monitoring. Rather than checking all data in the same manner, study teams are encouraged to identify critical data and critical processes. This facilitates directing monitoring resources to the areas most likely to impact participant safety or data integrity. This approach is supported by remote monitoring, because electronic data can be reviewed more frequently and risks detected earlier

Centralized monitoring may also improve consistency across sites. If trial data are subject to central monitoring, the study team may identify patterns such as late data entry, unusually low reporting of adverse events, or repeated deviations from the protocol. These patterns can then drive whether a site needs remote follow-up, retraining or an on-site visit.

Risk-based monitoring focuses oversight on the most critical data and processes to ensure participant safety and study integrity (3). Centralised monitoring uses data available centrally to flag missing data, unusual patterns and site level risks. Remote monitoring enables both, as it allows for earlier follow-up and more frequent review.

Recent developments in GCP also support a proportionate and technology aware approach to trial oversight. ICH E6(R3) features more focus on quality by design, critical thinking, fit-for-purpose systems and proportionate conduct, all of which are directly relevant to remote and hybrid monitoring

(13). This implies that in this study remote monitoring should not be regarded as a shortcut. It should be risk based and planned based on data criticality and site capability.

2.5 Remote Monitoring During and After COVID-19

The COVID-19 pandemic influenced the conduct of clinical trials because of travel restrictions, limited access to hospitals and concerns about the safety of participants. Regulatory agencies have issued guidance to allow trials to continue while maintaining participant safety and data integrity (4,5). In this period remote monitoring became a necessity and later remained as part of hybrid monitoring models

2.6 Decentralized and Hybrid Clinical Trial Models

Decentralised and hybrid clinical trials use tools like telemedicine, eConsent, remote visits, and electronic data collection to reduce the burden on participants and sites. In these models, remote monitoring is essential, because some trial activities are being conducted outside the traditional site, and still requires oversight. Hybrid monitoring, often a possibility in variable infrastructure environments, combines remote review with

targeted on-site verification (9).

Regulators and industry have discussed decentralised trial elements, indicating that some trial activities can be conducted outside of traditional sites while maintaining safety, data quality and oversight (14,15). This is in line with the perspective that remote monitoring is one aspect of a wider move towards flexible trial conduct. However, decentralisation still needs to be applied selectively depending on the activity, participant population, technology and local operational conditions. (16)

Table 2.2: Benefits and Challenges of Remote Monitoring Identified in Literature

Area	Benefits	Challenges
Operational efficiency	Flexible scheduling and faster follow-up.	Requires coordination across stakeholders.

Area	Benefits	Challenges
Cost and resources	Reduces travel and improves resource use.	Needs secure platforms and training.
Data review	Supports EDC review and query management.	Source access may be limited.
Communication	Enables virtual meetings and frequent contact.	Responses may be delayed.
Site workload	Reduces disruption from physical visits.	May increase scanning and upload burden.
Privacy	Can use controlled platforms and audit trails.	Confidentiality risks if poorly managed.
Future applicability	Supports hybrid and risk-based models.	Needs standardization and clear guidance.

2.7 Data Privacy, Cybersecurity, and Source Document Access

Data privacy in remote monitoring is a regulatory requirement as well as a day-to-day operational concern. When source documents are reviewed remotely, trial teams will need to determine what access is permitted, for how long open access will be available and whether documents can be downloaded and how the access will be recorded. Without these decisions, sites and monitors may do things differently.

Cybersecurity protections are important because clinical trial records may contain sensitive health information. Secure logins, role-based permissions, controlled document access, audit trails and

restricted downloads can mitigate risk. But technology alone won't do it. Monitoring staff and site staff both need privacy training so that they know how to handle data correctly.

Remote monitoring may include access to sensitive trial data and, sometimes, source information about the patient. As a result, it is necessary to have secure platforms, role-based access, audit trails, restricted downloads and confidentiality safeguards. Source review should only be undertaken where allowed and in a way that protects the identity of the participants and the integrity of the data (1).

Guidance on decentralised elements also underpins careful data governance, particularly where electronic systems, remote visits, eConsent or digitally collected data are applied (14,15). Recent discussions on operations of decentralised trials also mention the need to look at completeness, accountability, privacy and consistency across sites for remote data collection and oversight (17).

2.8 Regulatory and Ethical Considerations

Monitoring remains ethically important and participant protection central, even if remote. Remote tools should not increase the risk to the confidentiality of the participants. Where remote source review is planned, the process should be appropriate to the approved study documents, site policies and ethics committee expectations, particularly where identifiers are contained within medical records.

From a functional perspective, compliance is very document-dependent. Monitoring teams should record what they reviewed remotely, what they were unable to review, limitations and what follow-up actions were agreed. This transparency shows that sponsor oversight was performed even if monitoring was not physically conducted on site.

Remote monitoring must also comply with GCP, regulatory expectations, ethics committee requirements and institutional policies. Regardless of the mode of

monitoring, consent, confidentiality, protocol compliance and accurate documentation are mandatory (1,2). Hence, monitoring reports, communication, query logs and access trails are important for audit readiness.

2.9 Remote Monitoring in India and Emerging Economies

Remote monitoring may increase oversight of emerging economies without increasing travel burdens. This is particularly the case for multicentre studies with sites from different regions. But the model has to be adapted locally. Within one study you might have a digitally mature metropolitan hospital and a smaller paper-based site and you may want to monitor them differently.

Trust between stakeholders is emphasised in the Indian context too. Sites may be reluctant to share documents remotely, and sponsors may vary in their comfort with remote source review. Trust is built through clear privacy safeguards, transparent processes and consistent communication between sponsors, CROs and site teams.

In India and similar settings, remote monitoring is driven by infrastructure, digital maturity, site workload, internet connectivity, and institutional policies. Some sites have electronic systems, and some still use paper files. So while a fully remote model may not work everywhere, a hybrid and risk-based approach can be tailored to site capability.

2.10 Experiences and Perspectives of Clinical Research Professionals

Clinical research professionals are the backbone of remote monitoring. CRAs experience this through site data review and communication. That's what CRCs experience when they prepare documents and respond to enquiries. For project managers it's timelines and sponsor expectations; for

investigators it's oversight and the safety of the participants. These different views are necessary for practical recommendations.

2.11 Research Gap

The existing literature discusses remote monitoring, risk-based monitoring and decentralised trials but there is limited qualitative evidence on the experiences of clinical research professionals in India. The discussion is largely operational or regulatory. This study seeks to fill this gap by exploring professional perspectives from both CRO and site roles.

The gap is also related to quality management. ICH E8(R1) notes that clinical trials should be designed around quality attributes critical to participant protection, reliable

results, and meaningful conduct (18). The professional experiences in this dissertation are used to underscore the most visible quality factors as monitoring shifts from primarily on-site work to remote or hybrid models

2.12 Conceptual Framework

Conceptual framework adopted in this study Factors influencing adoption of remote monitoring in India include technology infrastructure, internet connectivity, EMR access, access to source documents, site readiness, training, communication, sponsor/CRO processes and regulatory requirements </jats:sec> These factors affect professional experiences and result in outcomes like flexibility, faster query handling, workload challenges, privacy concerns, and preference for hybrid monitoring.

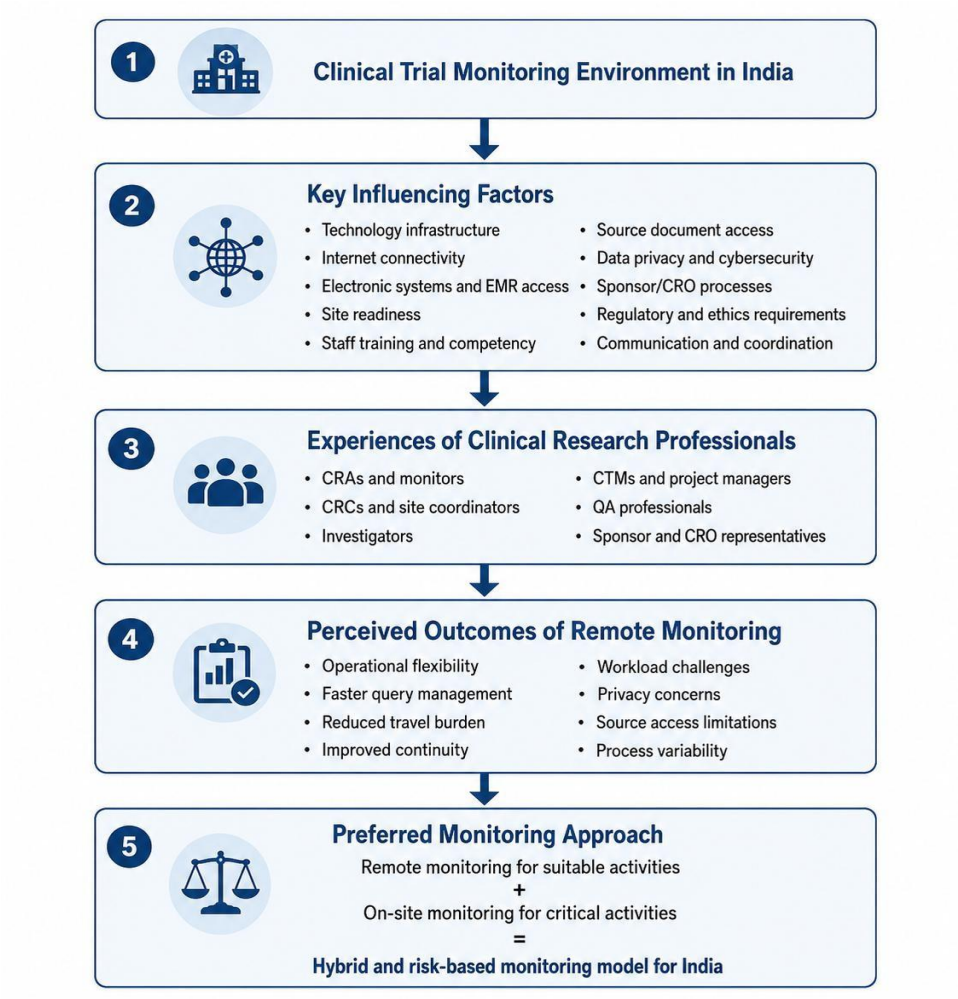


Figure 2.1: Conceptual Framework for Remote Monitoring Adoption in India Table 2.1: Summary of Literature Review

Sr. No.	Source	Focus Area	Key Findings	Relevance
1	ICH E6(R2)	GCP and monitoring	Defines monitoring responsibilities and emphasizes participant safety and data integrity.	Forms the quality framework for the study.
2	MoHFW, India 2019	Indian clinical trial rules	Provides regulatory framework for clinical trials in India.	Supports Indian context.
3	TransCelerate RBM guidance	Risk-based monitoring	Emphasizes targeted, risk-focused monitoring.	Explains RBM linkage with remote monitoring.

Sr. No.	Source	Focus Area	Key Findings	Relevance
4	FDA guidance 2023	Trial conduct during disruptions	Supports alternative approaches during public health emergencies.	Explains COVID-related remote monitoring adoption.
5	EMA COVID-19 guidance	Pandemic trial management	Addresses continuity and safety during pandemic disruptions.	Supports remote monitoring during COVID-19.
6	Duley et al. 2023	Trial conduct and monitoring survey	Reports pandemic impact on trial conduct and monitoring.	Supports operational changes.
7	Fu et al. 2023	Hybrid monitoring efficiency	Reports efficiency and cost-related benefits of hybrid monitoring.	Supports benefits of hybrid monitoring.
8	Mahajan and Gupta 2023	Emerging economies	Discusses RBM and remote monitoring in emerging contexts.	Relevant to India.
9	Benda et al. 2024	Decentralized trials	Highlights opportunities and challenges of digital trial models.	Supports future context.
10	ICH E6(R3), 2025	Modern GCP and quality by design	Emphasizes proportionate conduct, critical thinking, technology use, and risk-based quality management.	Supports the need for planned and documented remote monitoring.
11	FDA Decentralized Clinical Trials Guidance, 2023	Decentralized trial conduct	Discusses remote and local trial activities while maintaining oversight, safety, and data integrity.	Supports remote oversight within flexible trial models.
12	European Commission / EMA / HMA, 2022	Decentralized elements	Provides recommendations on decentralized clinical trial elements and operational safeguards.	Supports discussion of hybrid and remote trial procedures.

Sr. No.	Source	Focus Area	Key Findings	Relevance
13	ACRO, 2020	Decentralizing clinical trials	Recommends evaluating which elements of a trial can be decentralized rather than assuming fully virtual trials.	Supports selective and activity-based remote monitoring.
14	Chen et al., 2024	Decentralized trials and real-world evidence	Highlights statistical, operational, privacy, and oversight issues in decentralized trial designs.	Supports discussion on data quality and consistency.
15	ICH E8(R1), 2021	General considerations for clinical studies	Emphasizes quality factors critical to participant protection and reliable results.	Supports the quality-focused interpretation of study findings.

Table 2.2: Benefits and Challenges of Remote Monitoring Identified in Literature

Area	Benefits	Challenges
Operational efficiency	Flexible scheduling and faster follow-up.	Requires coordination across stakeholders.
Cost and resources	Reduces travel and improves resource use.	Needs secure platforms and training.
Data review	Supports EDC review and query management.	Source access may be limited.
Communication	Enables virtual meetings and frequent contact.	Responses may be delayed.
Site workload	Reduces disruption from physical visits.	May increase scanning and upload burden.
Privacy	Can use controlled platforms and audit trails.	Confidentiality risks if poorly managed.
Future applicability	Supports hybrid and risk-based models.	Needs standardization and clear guidance.

CHAPTER 3: RESEARCH METHODOLOGY

3.1 Study Design

The qualitative exploratory design was useful to capture everyday language and practical concerns of the participants. Rather than imposing answers on pre-defined categories, it allowed participants to define what remote monitoring meant to their own work. This was useful as remote monitoring is experienced differently by role, type of organization and site capability.

The study was not designed to statistically test the effectiveness of remote monitoring. It aimed to develop a rich description of experiences and to identify patterns that could inform recommendations. This makes the design appropriate for a subject which is still evolving in routine clinical trial practice.

The study was a qualitative exploratory design as the aim was to understand experiences, perceptions, challenges and recommendations rather than numerical outcomes. This way participants could define remote monitoring in their own words.

3.2 Study Setting

The study was conducted virtually in India using Zoom, Google Meet, Microsoft Teams and Telephonic interviews. Given that the participants were in different locations and the topic was about remote and digital clinical trial activities, a virtual setting was appropriate.

3.3 Study Population

The study population comprised clinical research professionals involved in monitoring, coordination, project management, investigation and other related activities in clinical trials in India. Participants were CRAs, a Junior CRA, Senior CRA, Clinical Research Coordinators, Project Managers, Associate Project Manager and Investigator.

3.4 Sampling Technique

Purposeful sampling with maximum variation was used. Participants were chosen for their first-hand experience with remote or hybrid monitoring. Roles for both CRO and site included to capture different practical perspectives.

3.5 Sample Size

The study involved eight in-depth interviews. In qualitative research the sample size is dictated by the depth of information and repetition of themes rather than statistical calculation. The sample selected gave useful insights from the CRO and the site perspective.

3.6 Inclusion Criteria

Clinical research professionals working in India, with at least 2 years of clinical research experience, exposure to remote or hybrid monitoring, directly involved in trial operations, and provided informed consent.

3.7 Exclusion Criteria

Individuals were excluded if they had less than 2 years of clinical research experience, had no meaningful exposure to remote or hybrid monitoring, were not directly involved in clinical trial conduct or oversight, or did not consent to participation.

Table 3.1: Inclusion and Exclusion Criteria

Type	Criteria
Inclusion	Clinical research professionals working in India.
Inclusion	Minimum two years of clinical research experience.
Inclusion	Experience with remote or hybrid monitoring.
Inclusion	Direct involvement in clinical trial operations or oversight.
Inclusion	Willingness to provide informed consent.
Exclusion	Less than two years of clinical research experience.
Exclusion	No meaningful exposure to remote or hybrid monitoring.
Exclusion	Not involved in clinical trial conduct or oversight.
Exclusion	Unwilling to provide informed consent.

3.8 Data Collection Method

Data were gathered through semi-structured in-depth interviews. The interviews explored experiences of remote monitoring, views on different monitoring approaches, facilitators, barriers, data privacy concerns, training needs and future recommendations.

3.9 Data Collection Procedure

Participants were recruited through industry contacts and professional networks. Once the study was explained and consent was obtained, interviews were arranged at times convenient for participants. The interviews were held online or by telephone and notes were taken for analysis.

3.10 Study Tool / Instrument

Data were collected using a semi-structured interview guide. It included open-ended questions on experience, perception, facilitators, challenges, regulatory issues and future directions.

3.11 Data Analysis Plan

During the coding of the participant statements, the meaning was checked. Statements that reflected experiences, challenges, facilitators or recommendations were given short codes. Codes of a similar nature were pooled. For example, comments about internet problems, EMR availability and secure platforms were combined under technology and infrastructure related ideas.

The development of themes was an iterative process. Codes were reviewed multiple times to check whether each theme had a meaningful pattern in the data. We selected representative quotes that best articulated the theme. Lastly, the themes were linked back to the research questions and study aims.

The data were analysed using Braun and Clarke's six-phase thematic analysis framework. Transcripts and notes were read repeatedly, initial codes were developed, related codes were grouped into themes and the themes were refined and interpreted. Manual coding was organized in Microsoft Excel.

3.12 Ensuring Rigor and Trustworthiness

Trustworthiness was supported through systematic coding, verbatim notes, an audit trail, reflexive note-taking and the use of representative quotes. Maximum variation across roles added richness to the findings.

3.13 Researcher Reflexivity

The researcher acknowledged that prior exposure to the clinical research field could influence interpretation. Reflexive notes were maintained to reduce personal bias and

keep the themes grounded in participant responses

Ethical Considerations

Participation was voluntary. Informed consent was taken before the interviews. Participants were anonymized using codes such as P01 and P08. No patient-identifiable information or organization-specific confidential details were collected. The data were used only for academic purposes.

3.14 Limitations of the Methodology

The study used a small purposive sample, so the findings cannot be statistically generalized. Responses were self-reported and may reflect individual role-based experiences. Virtual interviews may also limit observation of non-verbal cues. However, the approach was suitable for exploring professional perspectives in depth.

Table 3.2: Interview Domains and Purpose

Interview Domain	Purpose
Introductory questions	To understand participant role and clinical research experience.
Experiences with remote monitoring	To explore current remote monitoring activities and practical experiences.
Perceptions of monitoring approaches	To compare remote, on-site, and hybrid monitoring.
Facilitators	To identify factors supporting successful remote monitoring.
Challenges	To identify operational, technical, privacy, and communication barriers.
Regulatory and future direction	To explore compliance issues and recommendations.

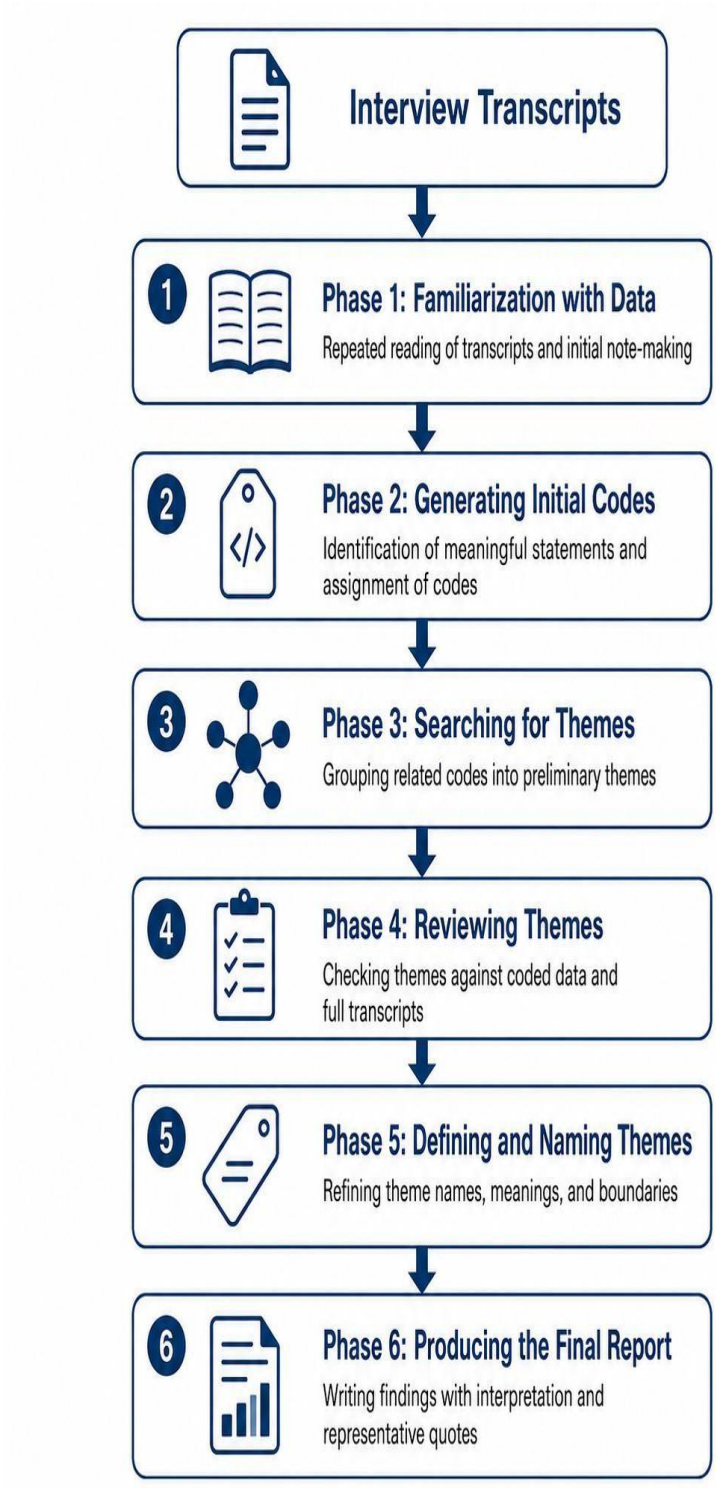


Figure 3.1: Braun and Clarke's Six-Phase Thematic Analysis Process

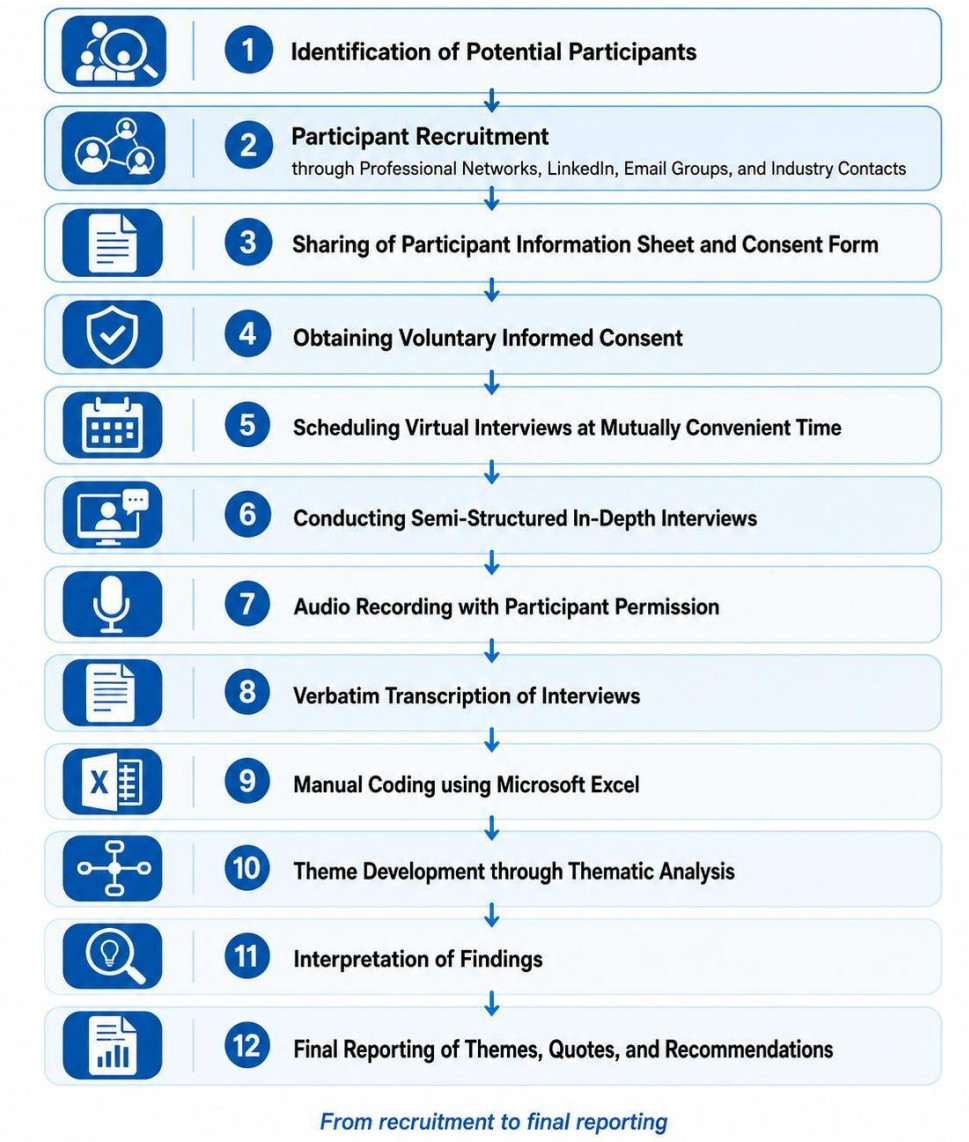


Figure 3.2: Data Collection and Analysis Flow

CHAPTER 4: RESULTS AND THEMATIC ANALYSIS

4.1 Participant Profile

The participants represented both CRO and site perspectives. The sample included CRAs, a Junior CRA, a Senior CRA, clinical research coordinators, project management professionals and an investigator. All participants had experience with remote or hybrid monitoring.

Table 4.1: Participant Profile

Participant ID	Designation / Role	Years of Experience	Organization Type	Remote / Hybrid Experience	Mode	Duration
P01	Clinical Research Associate	3 years	CRO	Yes	Online	25 minutes
P02	Associate Project Manager	5 years	CRO	Yes	Online	36 minutes
P03	Clinical Research Coordinator	2 years	Site	Yes	Online	31 minutes
P04	Investigator	22 years	Site	Yes	Telephone	22 minutes
P05	Senior Clinical Research Associate	6 years	CRO	Yes	Online	29 minutes
P06	Clinical Research Coordinator	2 years	Site	Yes	Online	36 minutes
P07	Project Manager	12 years	CRO	Yes	Online	41 minutes
P08	Junior Clinical Research Associate	2.5 years	CRO	Yes	Online	28 minutes

4.2 Overview of Themes

Themes suggest influence of technical and human factors on remote monitoring. Technology makes remote access possible, but it is people and process that determine if remote review really works. Responsiveness, communication, documentation, training, clarity of expectations were all repeatedly mentioned by participants.

The themes also demonstrate that remote monitoring is not a one-time activity. Participants clearly differentiated between remote activities (e.g., EDC review and query management) and those that required the participant to be on site (e.g., pharmacy review and direct observation). This difference justifies the selection of hybrid

monitoring.

The analysis found remote monitoring is now well known in trial operations, but its effectiveness depends on people, process, technology and compliance-related factors. The codes were grouped into six themes as shown in the table below.

Table 4.2: Codes and Theme Development

Theme	Codes / Sub-Themes	Description
Theme 1: Experiences and Current Utilization	Routine remote monitoring, EDC review, query management, virtual meetings, remote document review	Captures how remote monitoring is used in daily trial operations.
Theme 2: Perceptions of Monitoring Approaches	Remote flexibility, on-site value, hybrid preference, risk-based approach	Explores comparison of remote, on-site, and hybrid models.
Theme 3: Facilitators	Site readiness, responsiveness, digital maturity, communication, training	Identifies factors that support successful remote monitoring.
Theme 4: Challenges and Barriers	Source access, connectivity, workload, scheduling, privacy, process variability	Describes practical barriers experienced by participants.
Theme 5: Regulatory and Operational Considerations	GCP compliance, audit readiness, sponsor expectations, documentation standards	Captures compliance and operational requirements.
Theme 6: Future Directions and Recommendations	Standardization, infrastructure, capacity building, guidance, flexible hybrid model	Reflects participant views on future improvement.

4.3 Theme 1: Experiences and Current Utilization of Remote Monitoring

Participants said remote monitoring was especially useful for routine data work. EDC review, checking missing data, creation of queries and following up on action items can be done without waiting for the next site visit. It also allows for more continuous monitoring and easier tracking of progress for project teams.

Virtual site meetings were also considered useful as they offer more frequent increased contact between monitors and site teams. Participants said virtual communication works best with clarity on roles, timelines and expectations. Without that clarity it can take a lot of time to chase up again and again.

Participants said remote monitoring is now routine in clinical trials. “It’s become a normal part of the job now,” a CRA said. This means that remote monitoring is no longer just a stop-gap measure during disruptions, but now a part of normal monitoring workflows.

The most frequently identified activities suitable for remote monitoring were EDC review, query management, document review, and virtual site meetings. “The EDC review is mostly done

remotely,” said a Senior CRA. At the project level, participants also reported increased use of Teams and similar platforms for site connectivity.

4.4 Theme 2: Perceptions of Remote, On-Site, and Hybrid Monitoring Approaches

Hybrid monitoring is the preferred option for realistic understanding of trial operations. Participants didn't reject remote monitoring, but they also didn't overstate what it can do. They realised that some tasks could be done remotely, and others required the monitor to review records, facilities or storage of investigational product on site.

This is a balanced view and more so true in India where site infrastructure is uneven. This hybrid model allows trial teams to customise monitoring based on study risk, site experience and data availability. It can reduce unnecessary visits, but still retain the value of direct observation where it is needed.

Participants appreciated the flexibility of remote monitoring but did not view it as a complete replacement of on-site monitoring. One CRA said, “We can review data and handle queries

remotely,” but the investigator said some activities still require a physical presence.

The majority view was that hybrid monitoring is the most practical solution. “The most pragmatic

way is probably hybrid,” said the associate project manager. Participants also stated

their support for risk-based selection ie the monitoring mode should be based on study risk and type of activity.

4.5 Theme 3: Facilitators of Successful Remote Monitoring

Key enablers included site readiness, responsive coordinators, digital maturity, robust internet, effective communication and training. Experienced coordinators "make it easy" for remote monitoring by organising documents, coordinating calls and answering questions, according to site-level participants.

Both site and CRO participants mentioned training. “When you have had proper training as a junior CRA, it is a lot easier to manage remote review,” said the junior CRA. This suggests that training may be especially important for new monitors and site staff who are learning remote processes.

4.6 Theme 4: Challenges and Barriers to Remote Monitoring

Access to source documents was strongly related to privacy issues. While participants identified the need to monitor reviews, they also highlighted the need to protect the patient records. So clear procedures for access to sources must be established before remote monitoring can start. Without pre-planning remote monitoring can be limited to EDC and document follow up.

workload was another big problem. Remote monitoring can seem efficient from the sponsor or monitor perspective, but it does involve some tasks being done by the site. Coordinators might need to prepare documents, upload files, respond to messages and coordinate availabilities of investigators. That is why remote monitoring needs to be designed with site burden in mind.

The key challenges identified were: access to source documents, connectivity issues, workload, scheduling difficulty, privacy concerns and variability in sponsor process. Some sites are not comfortable sharing source documents remotely, in part due to concerns about confidentiality and institutional policy, a CRA said.

At site level, participants reported problems with internet and workload pressure. "Remote follow-up can take longer when monitors depend on responses from sites," said the Junior CRA. This suggests that remote monitoring may reduce travel for monitors, but could still pose coordination problems.

4.7 Theme 5: Regulatory and Operational Considerations

The participants agreed on the importance of being GCP compliant and inspection ready with remote monitoring. “Remote monitoring must comply with GCP requirements,” one Senior CRA explained. Documentation was seen as critical because remote

reviewing is so dependent on records of what was reviewed, what was pending and how issues were resolved.

Another aspect was the sponsor's expectations. Participants noted variation in procedures with sponsors being more or less comfortable to review remotely. Perceptions about audit readiness included clear SOPs, access logs, monitoring reports and communication records.

4.8 Theme 6: Future Directions and Recommendations for Remote Monitoring

Participants felt that remote monitoring would still be useful but require further standardisation. Standardisation does not imply that all studies follow the same process. Instead, there must be clear definitions around the core expectations of source access, documentation, communication, privacy and escalation.

The future direction participants describe as a flexible model. Where remote review improves efficiency it should be used, where on-site monitoring adds quality value it should be used. This is in line with the principles of risk based monitoring and ground realities of Indian clinical trial sites.

Participants felt remote monitoring would be part of clinical trial operations but not a replacement for site visits. The preferred model for the future was flexible, hybrid and risk-oriented. One participant

summed this up as, “Remote where it adds efficiency and on-site where it adds value. Recommendations included standardisation of core processes, improvements to infrastructure, structured training and clearer guidance. Such changes were viewed as enhancing consistency and lessening the burden on monitors and sites.

Table 4.3: Themes, Sub-Themes, and Representative Quotes

Theme	Sub-Themes / Codes	Representative Quote	Participant
Theme 1: Experiences and Current Utilization of Remote Monitoring	Routine use of remote monitoring	“It has become a normal part of the job now.”	P01, Clinical Research Associate
Theme 1: Experiences and Current Utilization of Remote Monitoring	EDC review	“EDC review happens remotely most of the time.”	P05, Senior CRA
Theme 1: Experiences and Current Utilization of Remote Monitoring	Virtual site meetings	“We connect with sites more frequently through Teams meetings.”	P07, Project Manager
Theme 1: Experiences and Current Utilization of Remote Monitoring	Monitoring workflow integration	“Remote review is now built into the monitoring plan.”	P02, Associate Project Manager
Theme 2: Perceptions of Remote, On-Site, and Hybrid Monitoring Approaches	Suitability for remote monitoring	“Data review and query management can happen remotely.”	P01, CRA
Theme 2: Perceptions of Remote, On-Site, and Hybrid Monitoring Approaches	Continued value of on-site monitoring	“Certain activities still require physical presence.”	P04, Investigator
Theme 2: Perceptions of Remote, On-Site, and Hybrid Monitoring Approaches	Hybrid monitoring preference	“Hybrid is probably the most practical approach.”	P02, Associate Project Manager
Theme 2: Perceptions of Remote, On-Site, and Hybrid Monitoring Approaches	Risk-based monitoring	“The monitoring strategy should depend on study risk.”	P07, Project Manager
Theme 3: Facilitators of Successful Remote Monitoring	Site readiness	“Experienced coordinators make the process smoother.”	P03, CRC
Theme 3: Facilitators of Successful Remote Monitoring	Site responsiveness	“If the coordinator is responsive, half the problem is solved.”	P01, CRA

Theme	Sub-Themes / Codes	Representative Quote	Participant
Theme 3: Facilitators of Successful Remote Monitoring	Digital maturity	“Sites with EMR systems adapt much more easily.”	P02, Associate Project Manager

Theme	Sub-Themes / Codes	Representative Quote	Participant
Theme 3: Facilitators of Successful Remote Monitoring	Training needs	“Training is important for both site staff and monitors.”	P06, CRC
Theme 3: Facilitators of Successful Remote Monitoring	Training support for new monitors	“As a junior CRA, proper training makes remote review much easier to handle.”	P08, Junior CRA
Theme 4: Challenges and Barriers to Remote Monitoring	Source document access	“Not every site is comfortable sharing source documents remotely.”	P01, CRA
Theme 4: Challenges and Barriers to Remote Monitoring	Connectivity challenges	“Internet issues are still common at smaller sites.”	P03, CRC
Theme 4: Challenges and Barriers to Remote Monitoring	Workload constraints	“Site staff are already handling multiple responsibilities.”	P06, CRC
Theme 4: Challenges and Barriers to Remote Monitoring	Dependency on site response	“Sometimes follow-up takes longer remotely because we depend on site responses.”	P08, Junior CRA
Theme 4: Challenges and Barriers to Remote Monitoring	Data privacy concerns	“Patient confidentiality is always a concern.”	P05, Senior CRA
Theme 4: Challenges and Barriers to Remote Monitoring	Process variability	“Every sponsor follows a slightly different process.”	P02, Associate Project Manager
Theme 5: Regulatory and Operational Considerations	GCP compliance	“Remote monitoring must still comply with GCP requirements.”	P05, Senior CRA
Theme 5: Regulatory and Operational Considerations	Audit readiness	“You have to remain inspection ready regardless of the model.”	P04, Investigator
Theme 5: Regulatory and Operational Considerations	Documentation standards	“Documentation becomes even more important remotely.”	P05, Senior CRA
Theme 5: Regulatory and Operational Considerations	Documentation clarity	“Clear documentation helps juniors understand what has been reviewed and what is pending.”	P08, Junior CRA
Theme 6: Future Directions and Recommendations for Remote Monitoring	Standardization	“More standardized approaches would help everyone.”	P07, Project Manager

Theme	Sub-Themes / Codes	Representative Quote	Participant
Theme 6: Future Directions and Recommendations for Remote Monitoring	Infrastructure improvement	“Some sites still need infrastructure upgrades.”	P03, CRC

Theme	Sub-Themes / Codes	Representative Quote	Participant
Theme 6: Future Directions and Recommendations for Remote Monitoring	Structured training	“More structured training programs are required.”	P06, CRC
Theme 6: Future Directions and Recommendations for Remote Monitoring	Balanced hybrid model	“Remote where it adds efficiency and on-site where it adds value.”	P02, Associate Project Manager
Theme 6: Future Directions and Recommendations for Remote Monitoring	Regulatory guidance	“Clearer guidance would improve consistency.”	P05, Senior CRA

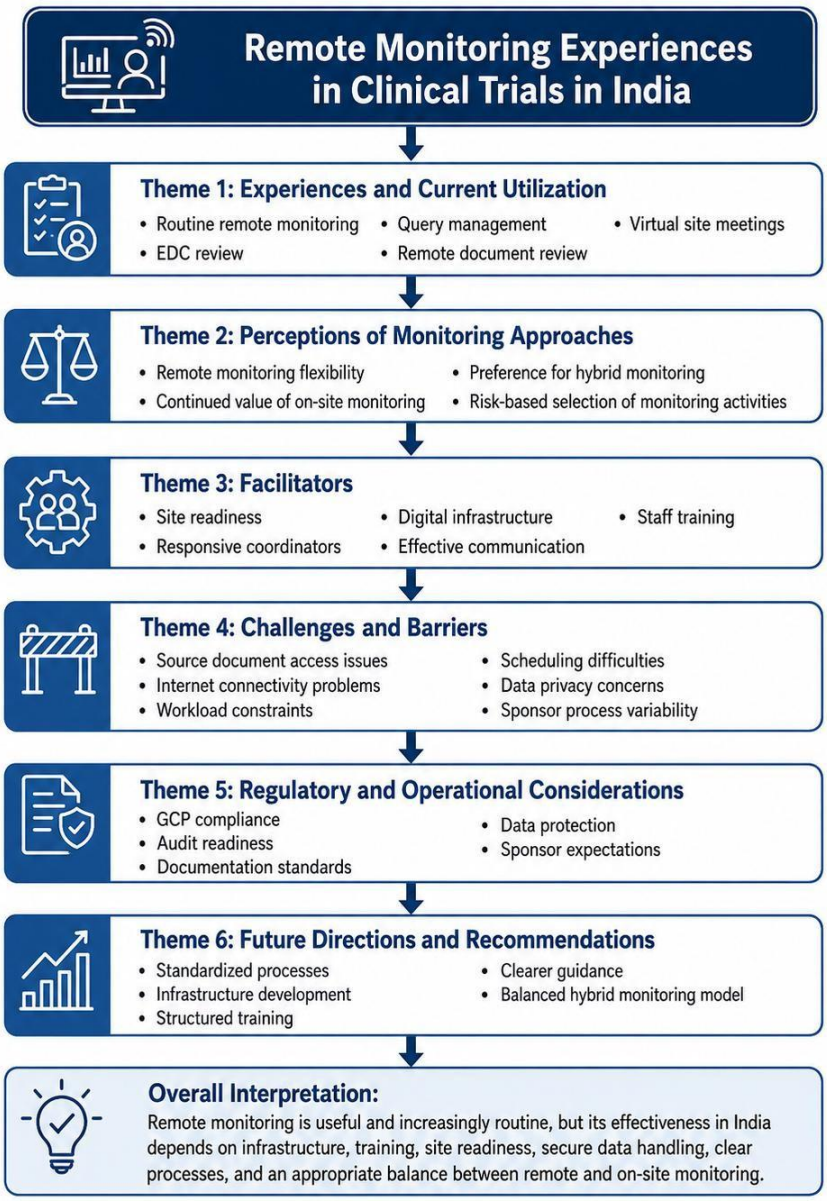


Figure 4.1: Thematic Map of Remote Monitoring Experiences

4.9 Summary of Key Findings

The most common message in the interviews was remote monitoring is accepted when it is practical, safe and clearly organised. Participants did not characterise it as a complete replacement for site visits. Instead they viewed it as a useful tool of surveillance to be tailored to the activity under review. This suggests that professional acceptance is a matter of having realistic expectations.

The participant profile impacted the findings. The CRO-based participants were more focused on monitoring plans, EDC review, sponsor expectations and standardisation. Site based participants focused on workload, document preparation, coordination and infrastructure. The investigator

stressed oversight and inspection readiness. “Training and clear documentation were key,” said junior CRA. Taken together, these views reveal the differential impacts of remote monitoring on various stakeholders.

Remote monitoring was viewed as useful and increasingly routine overall, but effectiveness depends on site readiness, digital infrastructure, communication, training, source access, privacy safeguards and clear processes. Participants preferred a hybrid, risk-based approach using remote monitoring for appropriate activities and on-site monitoring for critical physical verification.

CHAPTER 5: DISCUSSION

5.1 Remote Monitoring as a Routine Part of Clinical Trial Operations

Remote monitoring becoming routine is a sign of changing professional expectations. Monitors need to be at ease with electronic systems, virtual communication, remote follow up and review of data trends. Site teams are also expected to answer questions remotely and submit documents that can be reviewed remotely.

This change changes the pace of the monitoring work. Instead of one review during a site visit, there are now more frequent and smaller remote interactions to monitor. It can lead to better oversight, but it does require careful tracking of outstanding issues and action items.

The findings indicate that remote monitoring has transitioned from an emergency response to a standard operational practice. EDC review, query management, document follow-up and virtual meetings were some of the tasks that participants reported now routinely being done remotely. This is consistent with the literature describing increased use of remote monitoring post COVID-19 (4,5).

5.2 Comparison of Remote, On-Site, and Hybrid Monitoring

Remote monitoring was perceived as flexible and efficient but not appropriate for all activities. On-site monitoring is still important for physical verification, pharmacy review, investigational product accountability and direct observation. For that reason, hybrid monitoring was found to be the most practical model.

5.3 Role of Site Readiness and Digital Infrastructure

Site readiness and digital infrastructure were major factors in remote monitoring. Sites with responsive coordinators, organised documents and stable internet and EMR systems were more flexible. In India, where the capability varies from site to site, remote monitoring should be planned according to the preparedness of each site.

5.4 Operational Challenges in the Indian Context

The operational challenges were related to getting access to source documents, scheduling, workload, connectivity and process variability. Remote monitoring may decrease travel for monitors but may increase the work of site coordinators through scanning, uploading, meeting coordination and query responses.

5.5 Data Privacy, Documentation, and GCP Compliance

Data privacy was not just a technical issue; it was a professional one. Participants acknowledged that even with a platform in place, document sharing, access, downloading and storage need to be controlled. This makes training and SOPs a must-have.

The documentation shows remote supervision. When the monitor is not physically present, the results of the monitoring report and communication records should clearly reflect what was reviewed and what could not be reviewed, what issues were found and how follow-up was completed. This is essential for audit readiness.

The participants stressed that there are no different requirements for remote monitoring in GCP. Confidentiality, secure access, audit trails and documentation are still important. You need clear processes and secure platforms to comply with remote monitoring.

5.6 Training and Competency Requirements

Training was one of the most needed." Training for Monitors, junior CRAs and site staff on remote review, documentation, privacy, system use and communication Structured training may improve confidence and reduce inconsistency.

5.7 Future of Hybrid and Risk-Based Monitoring in India

Hybrid monitoring should remain relevant for its flexibility without sacrificing the value of site visits. Risk-based hybrid models can help sponsors and CROs decide when the remote review is enough versus when an onsite visit is necessary. Routine EDC review can be done remotely, but pharmacy review or repeated deviations might require site presence.

What enables India to do this is the diversity of site capabilities. Good EMR access and trained staff may allow more remote activities. A paper based site may require more on site support.

The future of monitoring in India is likely to be hybrid and risk based. Some appropriate review activities can be carried out remotely, while high-risk or physically verifiable activities should be conducted on-site. Such an even-handed approach might boost efficiency without sacrificing oversight.

The results are consistent with the literature that indicates remote monitoring is useful for flexibility, continuity and efficient use of resources. They also support risk based monitoring principles where monitoring effort is focused on critical data and processes. The insights also provide India-specific understandings by exposing the workload of sites, source access and digital readiness.

5.9 Practical Implications for Clinical Research Stakeholders

Sponsors need to establish the scope of remote monitoring and offer secure platforms. Monitors and site support need to be trained by CROs. Be prepared in advance with documents and communicate in a timely manner. Investigators should remain involved

in oversight and QA teams should be prepared for audits protect data and ensure SOP compliance

Table 5.1: Comparison of Study Findings with Existing Literature

Area	Findings from Present Study	Support from Literature
Routine use	Remote monitoring is common for EDC review and query follow-up.	Literature shows increased use after digitalization and COVID-19 (4,5).
Hybrid preference	Participants preferred a combination of remote and on-site monitoring.	Hybrid models are reported to support efficiency and oversight (7).
Risk-based approach	Monitoring should depend on study risk and activity type.	RBM guidance emphasizes critical data and processes (3).
Site readiness	Responsive sites and digital maturity support remote monitoring.	Literature highlights site preparedness in remote trials (9).
Privacy and compliance	Confidentiality, GCP, and documentation remain essential.	GCP and regulations emphasize participant protection and data integrity (1,2).
Training	Both monitors and site staff require structured training.	Training and process clarity are repeatedly identified as requirements (3,9).

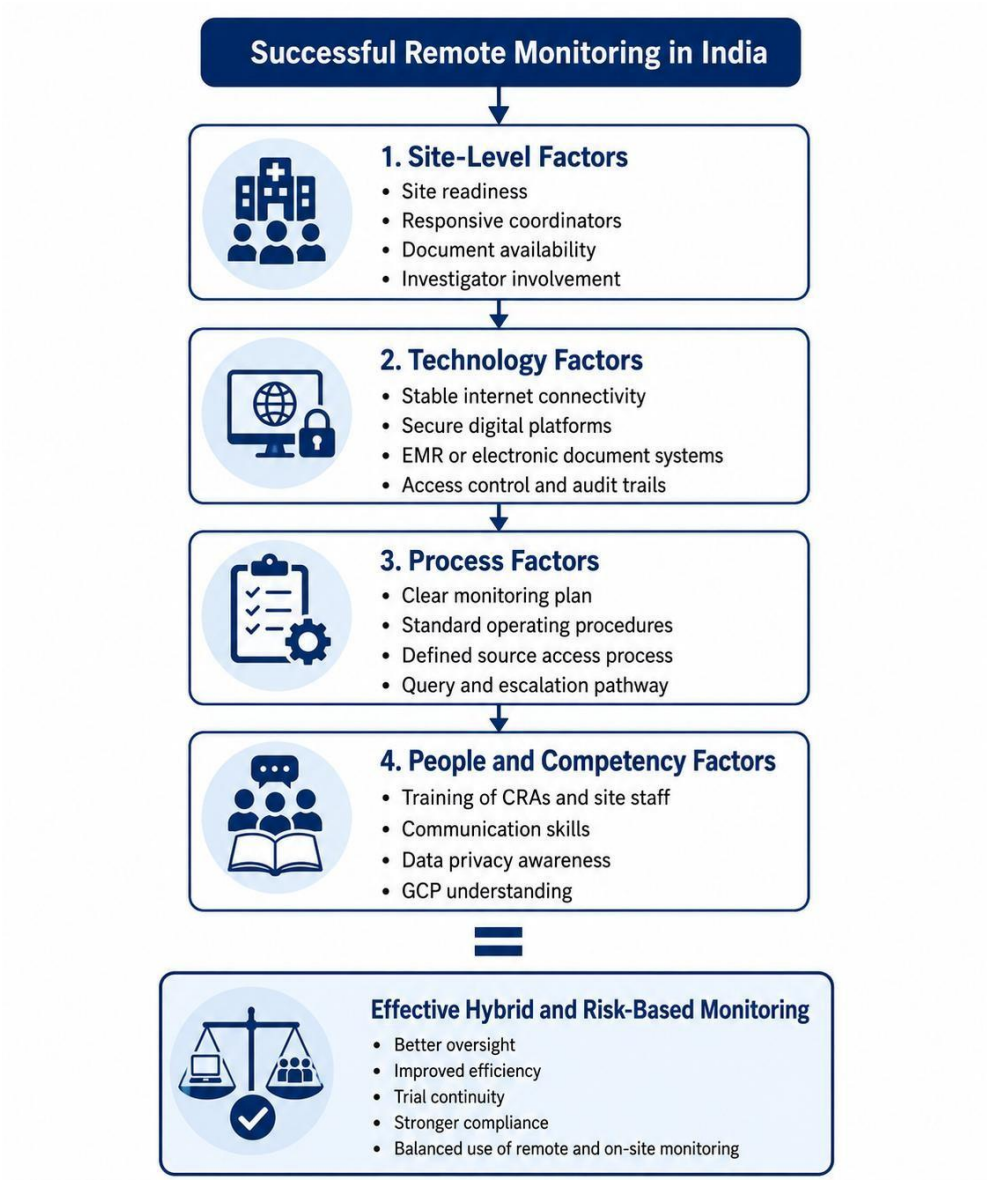


Figure 5.1: Practical Factors Influencing Remote Monitoring Success

CHAPTER 6: RECOMMENDATIONS

Table 6.1: Stakeholder-Wise Recommendations

Stakeholder	Recommendations
Sponsors	Develop clear remote monitoring plans, classify remote and on-site activities, provide secure platforms, and align processes with GCP.
CROs	Train CRAs, standardize reporting, support sites, and maintain escalation pathways.
CRAs / Monitors	Use risk-based review, communicate regularly, document activities, and respect site policies.
Clinical Trial Sites	Maintain document readiness, assign responsible staff, respond to queries promptly, and ensure secure document sharing where permitted.
Investigators	Remain involved in oversight, participant safety, protocol compliance, and resolution of clinical queries.
CRCs / Site Coordinators	Organize documents, coordinate virtual meetings, manage data entry, and protect confidentiality.
Quality Assurance Teams	Develop SOPs, review audit trails, support data protection, and conduct periodic quality checks.
Ethics Committees / Regulators	Provide clearer expectations for remote source access, confidentiality, documentation, and hybrid monitoring.
Technology Teams	Provide secure, user-friendly, access-controlled platforms with audit trails and technical support.

6.1 Suggested Remote Monitoring Framework for India

The proposed framework is intended to be used as a planning tool and not a strict checklist. It begins with study and site readiness because remote monitoring isn't suitable in the same way for every site or study. Activities for reviewing low risk data can be done remotely, while reviewing high risk data may still require a visit to the site. Continuous review is important because remote monitoring processes may need to be adjusted over the course of the study. Feedback from CRAs, CRCs, investigators and project managers can help to address recurring problems and improve the process over time.

A practical remote monitoring framework for India should start with study and site readiness assessment and end with documentation and continuous improvement. The ultimate aim is a hybrid monitoring model that is efficient, compliant, secure and contextual.

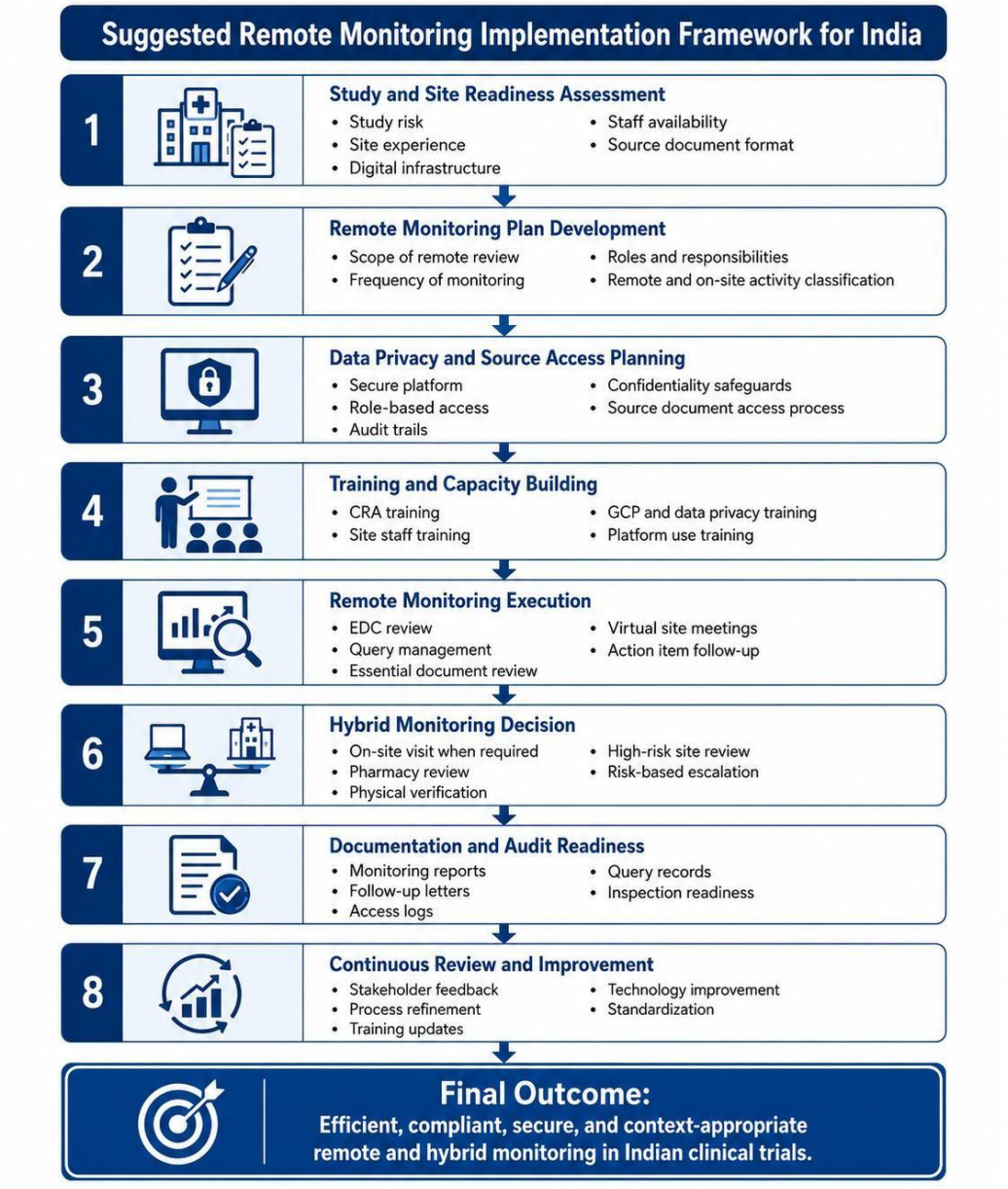


Figure 6.1: Suggested Remote Monitoring Implementation Framework for India

CHAPTER 7: CONCLUSION

7.1 Overall Conclusion

This study explored the experiences and views of clinical research professionals on remote monitoring in clinical trials in India. The findings suggest that remote monitoring has become a part of routine clinical trial operations, especially for EDC review, query management, document follow-up and virtual site communication. But study also shows that remote monitoring is not a complete substitute for on-site monitoring.

7.2 Key Takeaways from the Study

The study found that remote monitoring is flexible, reduces travel, allows for faster communication and helps to maintain continuity. However, physical verification, direct observation, pharmacy review and investigational product accountability require site visits. Remote monitoring success depends on site preparedness, digital infrastructure, training, source accessibility, privacy safeguards and defined processes.

7.3 Contribution of the Study

This study gives qualitative insights into remote monitoring from the perspective of Indian clinical research professionals. It shares the insights of remote monitoring of CRO based and site based professionals and discusses the practical aspects that influence the success of remote monitoring. Findings can help sponsors, CROs, sites, investigators and QA teams to design better remote and hybrid monitoring processes

7.4 Future Scope of Research

Further research can investigate economic and operational implications of remote monitoring in India.

Studies can quantify query resolution time, monitoring cost, protocol deviations and inspection readiness for remote, on-site and hybrid models.

Technology readiness is another avenue for future research. Studies can assess the impact of EMR systems, eSource, eConsent, secure portals and artificial intelligence tools on monitoring quality, site workload and data protection.

Future studies may involve larger sample sizes across different regions of India, and compare sponsor, CRO, and site perspectives. Also in cases involving remote access to source documents or decentralised trial components, insights from patients and ethics committees could be investigated.

SUPPLEMENTARY SECTION

Appendix A: Participant Information Sheet Study Title

Experiences and Perspectives of Clinical Research Professionals on Remote Monitoring in Clinical Trials in India: A Qualitative Exploratory Study

Introduction

You are invited to take part in a study of a postgraduate dissertation. The study examines the experience of clinical research professionals in India regarding remote monitoring in clinical trials, covering its benefits, limitations, challenges and future applications.

Purpose of the Study

This study seeks to explore the experiences and views of clinical research professionals on remote monitoring. The study also aims to identify barriers, facilitators, training needs, privacy concerns and recommendations to improve remote and hybrid monitoring practices in India.

What Participation Will Involve

Participation involves a semi-structured interview of 30-45 minutes. The interview will be conducted online/on phone as per the convenience of the participant. The interview can be recorded with permission to ensure correct transcription and analysis.

Confidentiality

All responses will be confidential. Names, organisations, sponsors, sites and patient-identifiable data will not be reported. Participants will be identified by codes, e.g. P01, P02. Data will be used solely for academic purposes.

Appendix B: Informed Consent Form

"Hello. I am Piyush Dutt, a postgraduate student at IIHMR Delhi. I am conducting this interview for my dissertation titled 'Experiences and Perspectives of Clinical Research Professionals on Remote Monitoring in Clinical Trials in India.' The interview will take approximately 30–45 minutes.

Your participation is completely voluntary. You may choose not to answer any question or withdraw from the interview at any time without any consequence.

All information shared by you will remain confidential. Your name, organization, sponsor, site, and any personal or patient-related information will not be disclosed. Your responses will be used only for academic purposes and will be reported using a participant code.

With your permission, I would also like to audio-record this interview only for transcription and research analysis.

Do you voluntarily agree to participate in this interview? Do you also consent to audio recording of this interview?" Participant Response: □ Yes □ No

Audio Recording Consent: □ Yes □ No

Appendix C: Semi-Structured Interview Guide

Interview Guide

Domain	Questions
Introductory Questions	Please describe your role and experience in clinical research. How long have you been involved in clinical trial activities? Can you describe your experience with remote monitoring?
Experiences with Remote Monitoring	What types of remote monitoring activities have you been involved in? How is remote monitoring conducted in your organization? Can you describe a situation where it worked well or was challenging?
Perceptions of Monitoring Approaches	How do you compare remote monitoring with on-site monitoring? What activities are suitable for remote review? What are your views on hybrid monitoring?
Facilitators	What factors support remote monitoring? What role do site readiness, infrastructure, communication, and training play?
Challenges	What challenges have you faced in remote monitoring? How do connectivity, source access, workload, and privacy affect the process?
Regulatory and Future Direction	What compliance issues influence remote monitoring? What improvements are needed in India? What recommendations would you give to sponsors, CROs, sites, and regulators?

Appendix D: Participant Profile Format

Participant ID	Designation / Role	Years of Experience	Organization Type	Remote / Hybrid Experience	Mode of Interview	Duration
P01	Clinical Research	3 years	CRO	Yes	Online	25 minutes

Participant ID	Designation / Role	Years of Experience	Organization Type	Remote / Hybrid Experience	Mode of Interview	Duration
	Associate					

Participant ID	Designation / Role	Years of Experience	Organization Type	Remote / Hybrid Experience	Mode of Interview	Duration
P02	Associate Project Manager	5 years	CRO	Yes	Online	36 minutes
P03	Clinical Research Coordinator	2 years	Site	Yes	Online	31 minutes
P04	Investigator	22 years	Site	Yes	Telephone	22 minutes
P05	Senior Clinical Research Associate	6 years	CRO	Yes	Online	36 minutes
P06	Clinical Research Coordinator	2 years	Site	Yes	Online	39 minutes
P07	Project Manager	12 years	CRO	Yes	Online	41 minutes
P08	Junior Clinical Research Associate	2.5 years	CRO	Yes	Online	28 minutes

Appendix E: Coding Framework

Interview ID	Respondent Role	Respondent Statement	Initial Code
P01	Clinical Research Associate	"It has become a normal part of the job now."	Routine remote monitoring
P01	Clinical Research Associate	"Most activities happen remotely before or after the site visit."	Integration of remote monitoring
P05	Senior Clinical Research Associate	"EDC review happens remotely most of the time."	Remote data review
P07	Project Manager	"We connect with sites more frequently through Teams meetings."	Virtual site communication
P02	Associate Project Manager	"Remote review is now built into the monitoring plan."	Monitoring workflow integration
P01	Clinical Research Associate	"Data review and query management can happen remotely."	Suitability for remote monitoring

Interview ID	Respondent Role	Respondent Statement	Initial Code
P05	Senior Clinical Research Associate	"Document review is easier to conduct remotely."	Remote document review
P04	Investigator	"Certain activities still require physical presence."	Need for on-site monitoring
P01	Clinical Research Associate	"You notice things when you are physically present at the site."	Value of direct observation

Interview ID	Respondent Role	Respondent Statement	Initial Code
P02	Associate Project Manager	"Hybrid is probably the most practical approach."	Hybrid monitoring preference
P07	Project Manager	"The monitoring strategy should depend on study risk."	Risk-based monitoring
P03	Clinical Research Coordinator	"Experienced coordinators make the process smoother."	Site readiness
P01	Clinical Research Associate	"If the coordinator is responsive, half the problem is solved."	Site responsiveness
P04	Investigator	"Good communication helps resolve issues faster."	Effective communication
P02	Associate Project Manager	"Sites with EMR systems adapt much more easily."	Digital maturity
P01	Clinical Research Associate	"Stable internet is probably the most important thing."	Internet connectivity
P06	Clinical Research Coordinator	"Training is important for both site staff and monitors."	Training needs
P08	Junior Clinical Research Associate	"As a junior CRA, proper training makes remote review much easier to handle."	Training support for new monitors
P05	Senior Clinical Research Associate	"People need to understand data handling requirements."	Regulatory competency
P01	Clinical Research Associate	"Not every site is comfortable sharing source documents remotely."	Source document access challenges
P03	Clinical Research Coordinator	"Internet issues are still common at smaller sites."	Connectivity challenges
P07	Project Manager	"Aligning schedules for everyone can be difficult."	Scheduling challenges
P06	Clinical Research Coordinator	"Site staff are already handling multiple responsibilities."	Workload constraints
P08	Junior Clinical Research Associate	"Sometimes follow-up takes longer remotely because we depend on site responses."	Dependency on site response
P05	Senior Clinical Research Associate	"Patient confidentiality is always a concern."	Data privacy concerns

Interview ID	Respondent Role	Respondent Statement	Initial Code
P02	Associate Project Manager	"Every sponsor follows a slightly different process."	Process variability
P01	Clinical Research Associate	"Most challenges are actually around people and processes."	Operational barriers
P05	Senior Clinical Research Associate	"Remote monitoring must still comply with GCP requirements."	GCP compliance
P04	Investigator	"You have to remain inspection ready regardless of the model."	Audit readiness

Interview ID	Respondent Role	Respondent Statement	Initial Code
P02	Associate Project Manager	"Different sponsors have different comfort levels."	Sponsor expectations
P05	Senior Clinical Research Associate	"Documentation becomes even more important remotely."	Documentation standards
P08	Junior Clinical Research Associate	"Clear documentation helps juniors understand what has been reviewed and what is pending."	Documentation clarity
P07	Project Manager	"More standardized approaches would help everyone."	Need for standardization
P03	Clinical Research Coordinator	"Some sites still need infrastructure upgrades."	Infrastructure improvement
P06	Clinical Research Coordinator	"More structured training programs are required."	Capacity building
P01	Clinical Research Associate	"I do not think remote monitoring will completely replace site visits."	Continued role of on-site monitoring
P02	Associate Project Manager	"Remote where it adds efficiency and on-site where it adds value."	Balanced monitoring model
P05	Senior Clinical Research Associate	"Clearer guidance would improve consistency."	Regulatory guidance
P04	Investigator	"Future monitoring approaches should remain flexible."	Flexible monitoring strategies

Appendix F: Theme and Quote Matrix

Theme	Sub-Themes / Codes	Representative Quote	Participant
Theme 1: Experiences and Current Utilization of Remote Monitoring	Routine use of remote monitoring	"It has become a normal part of the job now."	P01, Clinical Research Associate

Theme	Sub-Themes / Codes	Representative Quote	Participant
Theme 1: Experiences and Current Utilization of Remote Monitoring	EDC review	“EDC review happens remotely most of the time.”	P05, Senior CRA
Theme 1: Experiences and Current Utilization of Remote Monitoring	Virtual site meetings	“We connect with sites more frequently through Teams meetings.”	P07, Project Manager
Theme 1: Experiences and Current Utilization of Remote Monitoring	Monitoring workflow integration	“Remote review is now built into the monitoring plan.”	P02, Associate Project Manager

Theme	Sub-Themes / Codes	Representative Quote	Participant
Theme 2: Perceptions of Remote, On-Site, and Hybrid Monitoring Approaches	Suitability for remote monitoring	“Data review and query management can happen remotely.”	P01, CRA
Theme 2: Perceptions of Remote, On-Site, and Hybrid Monitoring Approaches	Continued value of on-site monitoring	“Certain activities still require physical presence.”	P04, Investigator
Theme 2: Perceptions of Remote, On-Site, and Hybrid Monitoring Approaches	Hybrid monitoring preference	“Hybrid is probably the most practical approach.”	P02, Associate Project Manager
Theme 2: Perceptions of Remote, On-Site, and Hybrid Monitoring Approaches	Risk-based monitoring	“The monitoring strategy should depend on study risk.”	P07, Project Manager
Theme 3: Facilitators of Successful Remote Monitoring	Site readiness	“Experienced coordinators make the process smoother.”	P03, CRC
Theme 3: Facilitators of Successful Remote Monitoring	Site responsiveness	“If the coordinator is responsive, half the problem is solved.”	P01, CRA
Theme 3: Facilitators of Successful Remote Monitoring	Digital maturity	“Sites with EMR systems adapt much more easily.”	P02, Associate Project Manager
Theme 3: Facilitators of Successful Remote Monitoring	Training needs	“Training is important for both site staff and monitors.”	P06, CRC

Theme	Sub-Themes / Codes	Representative Quote	Participant
Theme 3: Facilitators of Successful Remote Monitoring	Training support for new monitors	"As a junior CRA, proper training makes remote review much easier to handle."	P08, Junior CRA
Theme 4: Challenges and Barriers to Remote Monitoring	Source document access	"Not every site is comfortable sharing source documents remotely."	P01, CRA
Theme 4: Challenges and Barriers to Remote Monitoring	Connectivity challenges	"Internet issues are still common at smaller sites."	P03, CRC
Theme 4: Challenges and Barriers to Remote Monitoring	Workload constraints	"Site staff are already handling multiple responsibilities."	P06, CRC
Theme 4: Challenges and Barriers to Remote Monitoring	Dependency on site response	"Sometimes follow-up takes longer remotely because we depend on site responses."	P08, Junior CRA

Theme	Sub-Themes / Codes	Representative Quote	Participant
Theme 4: Challenges and Barriers to Remote Monitoring	Data privacy concerns	“Patient confidentiality is always a concern.”	P05, Senior CRA
Theme 4: Challenges and Barriers to Remote Monitoring	Process variability	“Every sponsor follows a slightly different process.”	P02, Associate Project Manager
Theme 5: Regulatory and Operational Considerations	GCP compliance	“Remote monitoring must still comply with GCP requirements.”	P05, Senior CRA
Theme 5: Regulatory and Operational Considerations	Audit readiness	“You have to remain inspection ready regardless of the model.”	P04, Investigator
Theme 5: Regulatory and Operational Considerations	Documentation standards	“Documentation becomes even more important remotely.”	P05, Senior CRA
Theme 5: Regulatory and Operational Considerations	Documentation clarity	“Clear documentation helps juniors understand what has been reviewed and what is pending.”	P08, Junior CRA
Theme 6: Future Directions and Recommendations for Remote Monitoring	Standardization	“More standardized approaches would help everyone.”	P07, Project Manager
Theme 6: Future Directions and Recommendations for Remote Monitoring	Infrastructure improvement	“Some sites still need infrastructure upgrades.”	P03, CRC
Theme 6: Future Directions and Recommendations for Remote Monitoring	Structured training	“More structured training programs are required.”	P06, CRC
Theme 6: Future Directions and Recommendations for Remote Monitoring	Balanced hybrid model	“Remote where it adds efficiency and on-site where it adds value.”	P02, Associate Project Manager
Theme 6: Future Directions and Recommendations for Remote Monitoring	Regulatory guidance	“Clearer guidance would improve consistency.”	P05, Senior CRA

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