

Available online on 15.08.2023 at <http://ajprd.com>

# Asian Journal of Pharmaceutical Research and Development

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Review Article

## Remote Monitoring In Clinical Trial – A Guide for Healthcare Professionals

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### ABSTRACT

Remote monitoring is a key step in clinical research that produces reliable, high-quality, and scientifically sound data from clinical studies. According to ICH-GCP, the sponsor has the responsibility for preserving the monitoring of data for the continuing trials. Due to the development of remote monitoring, the monitoring of the trials has become fairly simple for the CRA (a person assigned by the sponsor to monitor the ongoing trials). The primary benefit of remote monitoring is that it speeds up the on-time completion of work by reducing the time required for final trial reports output. It significantly lowers the sponsor's travel costs. Reducing the time between site monitoring enhances the accuracy and timeliness of study data and increases the safety of human subjects participating in a clinical trial. By using the secure off-site electronic health records access is currently utilized for clinical care, and also used to validate the source documentation. This article provides an overview of the offsite monitoring processes involved and standards adopted in remote monitoring.

**Key Words:** Clinical Trial Monitoring, Electronic Medical Records, Good Clinical Practice, Remote Monitoring.

**ARTICLE INFO:** Received 2023; Review Complete 2023; Accepted 2023; Available online 15 August 2023



#### Cite this article as:

Pachiappan S, Gnanasambandam A, Samundi S P, Parameshwaran SP, Hassan AAF, Saravanan PP, Remote Monitoring In Clinical Trial – A Guide For Healthcare Professionals, Asian Journal of Pharmaceutical Research and Development. 2023; 11(4):139-142.  
DOI: <http://dx.doi.org/10.22270/ajprd.v11i4.1300>

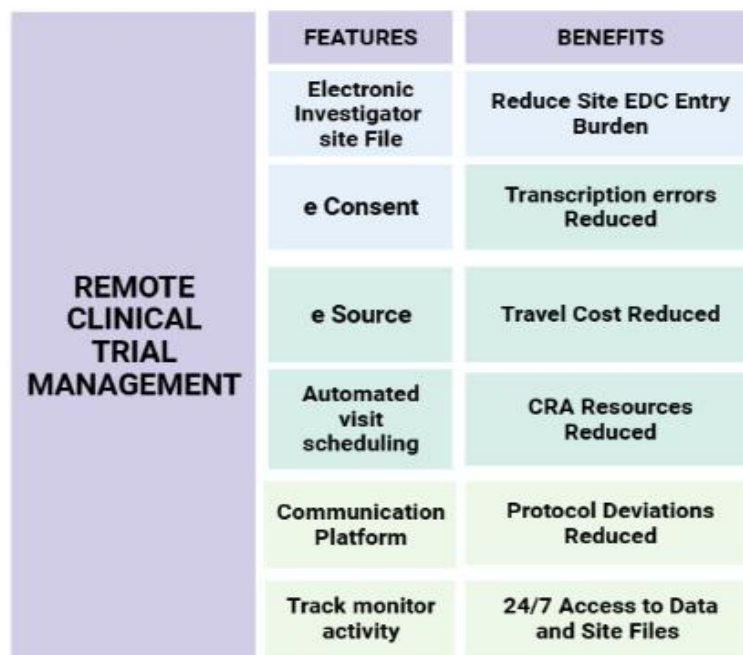
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### INTRODUCTION

Safeguarding the health of the people" is the main goal of the medical profession. According to this principle, clinical trials should be planned and carried out ethically and scientifically. To ensure the effectiveness and safety of the intervention, human clinical trials are a necessity in the development of novel medications or medical devices <sup>(1)</sup>. An essential component of conducting clinical trials is monitoring. It is the process of observing a clinical trial being conducted to make sure that it is documented, reported on, and carried out in compliance with the protocol, SOPs, GCP, and other essential regulatory requirements <sup>(2)</sup>. The goal of monitoring is to ensure that human subjects' rights and welfare are upheld and that the trial data published are true, accurate, and able to be independently verified from the source <sup>(3)</sup>. A new implementing strategy in the clinical trial is remote monitoring. Just as it sounds, remote monitoring doesn't

involve any travel <sup>(4)</sup>. Most of the monitoring activities may be completed without visiting the site from a distance. This keeps costs down and cuts down on the amount of time needed for monitoring operations <sup>(5)</sup>. In a remote monitoring system, a clinical research associate (CRA) assesses the data through secure online workplaces and other related platforms instead of physically visiting the study site to conduct monitoring visits <sup>(6)</sup>. Uploading all the source documents, lab results, medical histories, consent forms, and other relevant documents to the secure virtual workstation, makes them instantly accessible to the CRA. Once the documents for a specific visit are available within the virtual workspace, the CRA conducts a "monitoring visit" by comparing the source documents to the knowledge that was entered within the eCRF. Because the monitor completes the source data verification remotely, this monitoring strategy is usually mentioned as "remote monitoring" (Figure 1) <sup>(7)</sup>.



**Figure 1:** Overall Management of the Remote Clinical Trial Process

It is challenging to carry out on-site clinical trial monitoring since travel, expenses, and associated risks, many clinical studies are terminated. Remote monitoring has always made sense since it allows Clinical Research Organizations (CROs) and research sponsors/stakeholders to access data from any location<sup>(8)</sup>. Due to advancements in technology that allow Source Data Verification (SDV) to be carried out without requiring site visits, remote monitoring has become a standard approach to clinical trial oversight. However, remote monitoring often changes the workflow of the clinical trial site staff<sup>(9)</sup>. In this review, we reviewed the overall benefits, processes, and software used for remote clinical trial monitoring.

### PURPOSE OF REMOTE MONITORING

To maintain the confidentiality of clinical trials, the Food and Drug Administration (FDA) recommends that all the sponsors should monitor and validate their activities. This is utilized to mean a tone of work for sponsors and CROs. The FDA revised its regulations in 2011 to promote remote processes at a lower cost. Whenever a sponsor conducts a monitoring visit, the site coordinators and research assistants usually set up an opportunity to be ready for the visit as well as time to respond to queries and worries while the monitor is there. The monitor will make sure the site complies with the sponsor-written protocol during a visit and compare the data entered into the electronic data capture (EDC) system with the source data. By reducing the number of site visits along with travel expenses, remote monitoring favors the sponsor<sup>(10)</sup>.

### CHALLENGES TO REMOTE MONITORING

The goal of remote monitoring should be activities that can be evaluated and observed remotely, such as data completeness, consistency checking, identifying high error rates, and protocol violations. Source data that are included in the case report form (CRF) or electronic records which are added to an electronic trial master file (eTMF) can be viewed and therefore examined remotely. In addition to reducing the scope and frequency of on-site monitoring, remote monitoring can help differentiate

between reliable and incorrect data<sup>(9)</sup>. The following are some challenges of using remote monitoring:

- Need to create unique procedures and guidelines
- Audit issues
- Less accountability than on-site.

Health officials provide more guidance to ensure that systems that track remotely support clinical site authority and participant safety. Sponsors should think about making the best use of central and remote monitoring activities to maintain up-to-date clinical sites if scheduled on-site monitoring visits are no longer feasible<sup>(11)</sup>.

### COMMON PROCEDURE FOR REMOTE MONITORING

#### Email, Fax, and File Sharing

Delivering source documents via fax and email adds additional workload on highly overworked workers<sup>(12)</sup>. The amount of time it takes for sites to identify, transmit, recover, scan, and link documents to email are limited. In the same way, monitors must focus their attention on when sites require support for document collection and organization<sup>(13)</sup>.

#### Access to the Electronic Medical Record

Direct access to an electronic medical record (EMR) to monitor is possible with the right consents and agreements in place. Because most EMR systems lack restrictions to limit views for study monitors, research institutions should put into effect comprehensive guidelines before providing direct EMR access to monitors<sup>(14)</sup>.

### PREPARATION FOR REMOTE MONITORING

Preparation for remote monitoring in clinical trials may include the following activities:

1. Verify the correct version of the informed consent and a revised version of the consent form.

2. Review Screening Logs monthly – verify the number of patients screened and screen failure rates as expected.
3. Review Delegation and Training Logs monthly – verify they are current and tasks delegated appropriately.
4. Once electronic CRFs are available, check entries/reports for completeness of data.
5. Review maintenance of the trial master file (TMF) for the site.
6. Maintain relationship with site staff with regular discussions via telephone or e-mail to follow up on study progress or to answer questions.
7. Analyze reports on safety under the protocol's requirements for safety monitoring, and submit results to the relevant parties under at National Health and Medical Research Council (NHMRC) Guidance <sup>(15)</sup>.

### IMPACT OF REMOTE MONITORING ON CRA

Remote monitoring and digital research continue expanding at a rapid rate as their long-term advantages become more evident. Although they are responsible for overseeing and maintaining clinical research sites, CRA belongs to clinical trial professions that have been most significantly impacted <sup>(16)</sup>. Sponsors and CROs will gain advantages from quicker study timelines and more effective go-to-market strategies if they can capitalize on the opportunity of changes to remote links to research locations and be innovators. The part begins with a look at the variation between current and upcoming CRA monitoring responsibilities <sup>(17, 18)</sup>. Traditional CRA tasks are performed locally and in person. They include:

- Drug reconciliation
- Source Data Verification (SDV)
- Essential document inspection
- Risk detection and query development

However, as their duties evolve, CRAs will need to oversee automated processes and conduct these tasks remotely. The following CRA tasks will be completed in the future:

- Remote SDV using EDC software
- Site contact frequency increased by 200% over the previous period while still using phone calls and emails
- Differently focused onsite visits that are less frequent: In contrast to traditional inventory and document review tasks, more time will be spent onsite developing connections, promoting GCP, and assisting with process knowledge
- Working with a separate monitoring team that is only in charge of data evaluation, eliminating the CRA's responsibility for SDV and key document responsibilities <sup>(19)</sup>.

How Remote Monitoring is Impacting CRAs are:

- CRAs identify and fix regulatory and performance issues at study sites faster

- Study sites and higher-quality documents in the eTMF are faster
- CRAs can easily replace an outgoing CRA, reducing any disruptions to operations
- CRAs are changing how they manage and work with study sites <sup>(20, 21)</sup>.

### REASON TO UTILIZE REMOTE MONITORING

Remote monitoring is a subset of clinical trials where the monitor or clinical research associate (CRA) reviews the data using secure online workspaces or other platforms without physically visiting the study site. Some of the reasons to utilize remote monitoring clinical trials are:

- Remote monitoring refers to an off-site assessment conducted by the monitor away from where the clinical study is being carried out
- Tracking the development of the trial's outcome serves as one of the numerous benefits of remote clinical trial monitoring.
- Sponsors and CROs are having a hard time trying to blend new technology like Artificial Intelligence (AI) with existing platforms <sup>(22, 23)</sup>.

### SOFTWARE USED FOR REMOTE MONITORING

Clinical Trial Remote Management Systems (CTRMS) is a group of software applications used for remote monitoring. It is essential to manage the enormous volume of data in multicenter trials. A few open-source tools are also accessible, however, most remote management systems used by the pharmaceutical industry are commercial <sup>(24)</sup>. Tools like eClinical Suite, MACRO, RAVE, and Oracle Clinical are frequently utilized. These software tools are functionally comparable and neither system provides a clear advantage over the other. These software tools are expensive and require a high-end IT infrastructure to operate <sup>(25)</sup>.

### BENEFITS OF REMOTE MONITORING OVER ON-SITE MONITORING

Future clinical trials will be more accurate and specific. Regulatory agencies are pushing for remote monitoring and promoting it <sup>(26)</sup>. Digitizing and simplifying the clinical trial process offers significant benefits.

#### 1. Reduced Trial Costs

Clinical trials can be expensive to execute however Remote Clinical Trial Monitoring (RCTM) offers several cost-saving advantages, such as:

- **Lowering on-site visits:** Reduces travel time as well as expenses for both participants and clinical trial staff <sup>(27)</sup>.
- **Less time is used for site visits:** Fewer efforts are needed for on-site visits, which increases staff productivity and lowers labor expenses <sup>(28)</sup>.
- **Decreased need for clinical trial personnel:** The majority of the data collection and evaluation can perform by remote monitoring facilities, which lowers labor expenses <sup>(29)</sup>.



## 2. Accelerated Clinical Trial Timelines

RCTM provides many approaches for shortening clinical trial schedules, including:

- **Random site visits:** By eliminating site visits, the clinical trial procedure is streamlined and travel time is reduced<sup>(30)</sup>.
- **Improved data collection:** Remote collection and analysis of data lowers the possibility of human error and increases the accuracy of the data<sup>(31)</sup>.

## 3. Advancement of Cures

The advantages of RCTM also aid in the development of novel therapies, such as:

- **Increased patient safety:** Regular monitoring of patient data lowers the possibility of unfavorable outcomes and assures security.
- **Better data quality:** Data accuracy and dependability are increased by remote collection and processing.
- **Streamlined processes:** Reduced travel and increased efficiency streamline the clinical trial process<sup>(32)</sup>.

## CONCLUSION

In conclusion, more intense source data verification assures higher-quality data, and these techniques are economical, decrease exposure, deal with resource shortages, and offer safety to the investigators while achieving patient satisfaction for the majority of patients. A fascinating, quickly evolving, as well as challenging aspect in the delivery of healthcare is remote monitoring. It is important to remember that remote monitoring serves a variety of functions related to trial design, conduct, process, and outcome. As a result, remote monitoring will produce high-quality data and ensure compliance. And also, the method of offsite monitoring can assure that study participants are being protected and the data provided are accurate.

## ACKNOWLEDGEMENT

The authors express their gratitude to the management of Swamy Vivekanandha College of Pharmacy, Elayampalayam, Namakkal, Tamil Nadu, for acquiring the necessary assistance for completing this article.

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