Guide to Implementing Remote Monitoring

For Clinical Research Sites

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Introduction

Since 2013, the Food and Drug Administration (FDA) has encouraged the use of centralized or remote monitoring due to evidence showing improvements in data quality, access, and monitoring effectiveness.

> *… increasing use of electronic systems and records … can improve the quality and efficiency of sponsor oversight of clinical investigations. FDA encourages sponsors to develop monitoring plans that manage important risks to human subjects and data quality and address the challenges of oversight in part by taking advantage of the innovations in modern clinical trials.*[1]
>
> **-- FDA, 2013**

Despite encouragement from regulators, clinical research sites and sponsors have been hesitant to adopt remote monitoring practices due to change management concerns, access to technology, lack of clear expectations, patient privacy concerns, budgetary restrictions, and the administrative work required to update operations and policies within clinical research sites.[2]

However, in early 2020, global circumstances impacted the industry's ability to carry out clinical trials, forcing sites and sponsors to reevaluate monitoring practices. As a result, health officials renewed their support for using remote monitoring practices to maintain oversight of clinical studies.[3]

This guide is intended to arm research sites with the knowledge and resources needed to be successful when implementing remote monitoring practices today and in the long term.

Developed by former clinical research professionals, this guide includes resources that sites can start using today, including:

- Best practices for implementing remote monitoring
- SOP (Standard Operating Procedure) template to manage remote monitoring activities
- Tips to ensure regulatory compliance and protect patient privacy
- Template to outline study-specific source generation and review plans
- Considerations for implementing purpose-built software solutions
- Lists of regulations and resources for ongoing reference

Regulations must not hold the industry back from implementing remote monitoring. Now is the time for clinical research sites to ready themselves to implement remote monitoring to improve clinical trials and get new treatments to patients faster.

Navigating this Guide

This guide is organized into four key steps or phases:

1. **Plan**: provides guidance to identify goals, incorporate process tracking tools, and prioritize studies
2. **Assess**: evaluate resources and approaches for generating source documents
3. **Update**: promotes best practices for facilitating source document review and revising existing policies and documentation to support remote monitoring
4. **Implement**: ensures alignment with study sponsors, outlines the need for study-specific source plans, and promotes effective communication when changes impact study participants

Quick Tips

Communicate
Research sites should communicate their intention to implement remote monitoring with their sponsors, CROs, and central and supporting offices in advance. Sites often wait to communicate until a detailed, well-defined plan is in place; however, this can lead to many downstream inefficiencies. As a best practice, sites should set up consistent, recurring appointments to connect with their sponsors, CROs, central and supporting offices and vendors when initially implementing remote monitoring.

Stay Focused
Block time to focus on building your remote monitoring plan and understand that there will be iterations. Do not allow yourself to get distracted by an unexpected request before determining how it ranks in priority compared to your current to-do list. Keep in mind that others do not know how their request measures up against requests you are also receiving for other studies. Take control of your schedule and priorities with confidence so you can stay focused on building and executing your plan.

Think Long Term
Keep the long term benefits in mind when implementing a remote monitoring plan. Consider how quality can be impacted when we operate outside of standard operating practices and procedures. Look for opportunities to identify long term efficiencies gained from incorporating new technology, revisiting and updating outdated policies, creating more efficient methods for communicating with study monitors, and proactively implementing ways to reduce monitoring costs - both remotely and on-site.

How to Establish Remote Monitoring at your Site

Plan

Sites should first identify their overall goals, then select or develop a tool that tracks the process of implementing remote monitoring, and incorporate a consistent method to prioritize the order in which remote monitoring practices are incorporated across studies.

Identify goals

Developing clear goals is the first step when updating traditional monitoring practices to support remote monitoring. For some organizations, remote monitoring may require significant change management strategies and resources. Stakeholders will benefit from aligning early on in the process. Goals should be revisited to encourage success as decisions are made.

When identifying organizational goals, consider the following example goals as a starting point:

- Sustain health and provide patients with access to novel therapies
- Maintain patient trust
- Protect the safety of study participants
- Ensure the safety of site staff and healthcare workers
- Improve study quality
- Demonstrate innovation
- Use resources more efficiently
- Improve partnership with sponsors and CROs

Once defined, sites should consider sharing goals to drive awareness and adoption of remote monitoring.

Incorporate process tracking tools

Implementing updates to policies, practices, and systems across studies requires organization. Sites should track activities and study progress to improve efficiency, reduce the need to redundantly document activities, organize tasks, and determine what tasks should take priority.

Sites should document and track the following activities:

- **Sponsor / CRO communication**: track the communication and approvals required from sponsors / CROs when updating remote monitoring practices
- **Study classification**: track methods for classifying the priority (high, medium, and low) of implementing remote monitoring for your studies
- **Approaches for source collection and review**: assess and determine what monitoring methods (remote and on-site) can be adopted for your studies

- **Individual study source plans**: identify approved methods for generating source documents and providing monitor access to source documents on an individual study basis
- **Policy and document updates**: organize the review and, when required, amendment process for updating policies and agreements to facilitate various remote monitoring practices
- **Communication with study participants**: document the process to inform study participants, when applicable, about changes related to the creation of or sharing of their source data

Tip: Download the **Remote Monitoring Tracking Template** to support the implementation process of remote monitoring across your studies. Consider storing this document in an environment where it can be version controlled, is accessible to multiple parties, and where cloud-based collaborative authoring is supported.

Overtime, elements from the Remote Monitoring Tracking Template can be embedded into the routine study startup process. Consider incorporating standards to categorize studies based on their clinical and business implications, ensure appropriate approvals are in place to support remote monitoring, and outline individual study plans to collect and share source documentation. Routinely capturing operational data needed to facilitate remote monitoring as part of standard working practice will allow research sites to be better prepared to operate remotely and more efficiently in the future.

Classify studies by level of priority

Sites need a method to prioritize their studies to become remote monitoring capable. The below study characteristics should be considered:

- Studies with upcoming participant visits
- Studies offering investigational treatment to participants
- Studies that offer direct benefits to patients
- Studies that have a high volume of enrolled participants
- Historical studies that are still predominantly on paper
- Studies supported by coordinators that are supportive of new processes that can provide feedback as remote monitoring practices are initially introduced
- Studies that offer a direct benefit to the research site's business
- Studies that are active but have not yet enrolled a participant

Awareness of how sponsors and CROs are prioritizing their studies is key. Sites should not burden themselves with prioritizing a study if the sponsor is not also prioritizing it.

Figure 1 below shows a simple example of a study prioritization decision tree. This example method has been incorporated into the 'Studies Overview' tab on the Remote Monitoring Tracking Template.

To access the full guide and templates, click here ⟩⟩