# Remote Monitoring and Clinical Quality Management: 5 Keys for Success

*By Ken Lownie, Head of North American Operations, Agatha*

It appears that the time has arrived to get real about remote monitoring for virtual and remote clinical trials.

At the recent Virtual Clinical Trials conference, I gave a talk on the role of emerging technologies in enabling virtual clinical trials. I was stunned at the response. I have never had so many people reach out and want to continue the conversation we started during the session.

The reason is the Covid-19 pandemic, which acts as a catalyst in two ways:

- The first is a tsunami of clinical trials directly focused on Covid-19, which have a life and death urgency about them. With 2000 or more people dying in the US every day, there has never been a situation that demands urgent trials of new therapies and vaccines.
- The second reason for the newfound focus is that no one can travel right now, so doing traditional monitoring and inspections is not possible. Without a way to conduct these activities with technologies that can connect monitors, inspectors, and clinical sites, the whole clinical trial ecosystem breaks down, and trials come to a halt.

The good news is that, as I said in my talk, the fact that remote monitoring and clinical quality management is more of a goal than reality is NOT because of a gap in the technology. As they say, “we have the technology.”

My own company, Agatha, as well as other vendors, can provide a cloud-based, fully compliant space for monitors, inspectors, and sites to share documents and coordinate actions, communicate findings, and agree on required actions.

These applications allow site staff to upload the content of the investigator site file (ISF) — the binder if you will – to a shared space that is fully HIPAA and 21 CFR Part 11 compliant. In turn, CRAs and monitors can review the content, document observations, and findings and share those back with the site, which can then document the changes and actions they take in response. These remote sharing capabilities are all available and in use today by lots of Agatha customers.

But it is also true that the adoption of remote monitoring and quality management is not yet widespread in the industry. And that’s because there are behavioral, process, and cultural factors, especially at the site level, that slow down the adoption of virtual clinical trial techniques.

From our work with a number of sponsors, CRO and site organizations, there are five key things you need to do at the site level to ensure success when transitioning to remote monitoring and Clinical Trial Management.

## 1. Educate all stakeholders about compliance in a remote monitoring model.

In almost every conversation I have had with organizations contemplating remote monitoring and quality management (RMQM), stakeholders express serious concerns about compliance. Sites ask if they are "allowed to" share patient data in a cloud-based system. Sponsors and CROs worry about 21 CFR Part 11. Paper-based binders are familiar and comforting, and change is scary.

Education is the key to addressing these concerns. Sites need to hear authoritatively, from the sponsor, the CRO, and the FDA that storing digital documents and patient data is completely compliant if they use a system that is validated and proven. Agatha and other vendors have white papers that directly address the issue, and companies already down the road of remote monitoring can reassure those considering the transition.

The key is to not take it for granted that everyone knows that remote monitoring and quality management are a reality today and that you can implement it in a completely compliant way. Address it head-on.

## 2. Ensure that the systems adopted at the site level are easy and efficient to use.

Usability a very valid concern. If you ask a Site to upload documents and the process is not extremely fast and easy, they will reject the solution.

Make sure that any remote monitoring and quality management application:

- Has a distinct and separate login for site staff,
- Is optimized to make it easy to add files, and
- Has a modern, sleek, and intuituve interface that makes adding new documents straightforward (so simple that nothing more than a quick video is needed to train site-based users).

It is equally critical for the system to allow the easy upload of a batch of documents, including documents exported from another system or stored on a local network drive. Sites are very busy places, and their top concern is with their patients, so the work to upload content into an application that enables remote monitoring and quality management has to be efficient and straightforward to use.

## 3. Provide a single remote monitoring application for site staff that works with other systems they use.

If a site is working on multiple trials, and each asks them to add documents to a different system, with a separate login and interface, it creates a considerable challenge in terms of user training. There is no simple response to this today, but there are approaches that can reduce the problem.

I think the key is for the site to have a single electronic site file solution that they use for all studies, and NOT to be asked to use multiple sponsor systems. That site file system can then export or exchange files and content with another system dictated by a CRO or Sponsor, or a patient records system. As an example, Agatha enables a one-click export of data in a format that

## 4. Create incentives to drive changes in behavior.

Behavioral economics is a powerful lens to look through when managing change. Fundamentally, it insists that we answer the question "What's in it for me?" when we look at implementing changes in the way people act – in this case, in their jobs. And when you think about site staff, that's a tough question. What do they have to gain from shifting from paper to the electronic systems needed for remote monitoring and quality management?

There are two paths available here. One is to make the costs of NOT using a new system high, and the other is to increase the benefits (or the awareness of the benefits) of adopting the system.

Increasing the costs of not adopting a new process or behavior is relatively easy. You can mandate the new process and make the costs of non-compliance explicit through traditional performance management mechanisms such as documented goals and periodic appraisals.

The other side of the coin – aligning positive incentives — is a more significant challenge mostly because different people have different motivators.

For that reason, we need to make sure different types of benefits that result from using a new shared system are made very clear. For those motivated by approval, this includes strong sponsorship from leadership and recognition of the team members who move to the new system first.

For more altruistic team members, it may mean communicating and emphasizing that remote trials have the potential to accelerate the speed with which drugs can get to the patients who need them, as well as reduce the costs to their organization, allowing growth and success to all the team members.

## 5. Reduce costs for sites and recognize their economic realities.

Software systems that address document sharing and management are traditionally costly, with prices into and beyond the $100,000 range. That amount of cost is simply not possible for most clinical sites. The cost to a clinical site for a system that enables remote monitoring and quality management needs to be far less or have no out-of-pocket cost at all.

One path forward is that the sponsor or CRO pays the subscription cost for the software since it is the sponsor or CRO that stand to gain the most from the shift away from on-site, in-person visits. But this creates the problem mentioned above, which is that a single site engaged with multiple studies are asked to use different systems for storing site files electronically.

An alternative is for vendors of software applications to provide their solutions at a significantly lower cost for sites than they would for sponsors and CROs.

At Agatha, we are experimenting with a variety of licensing models as we all work together to sort out the best approach to ensure that sites can access and afford applications like Agatha as part of the shift to remote monitoring and quality management.

## Final Thoughts

With the technology to enable remote monitoring and quality management readily available, it is clear that the remaining obstacles are cultural, regulatory, and economic. We all need to work together to drive this change from on-site, in-person visits to a remote model because it can accelerate and reduce the costs of trials, which today is more critical than ever.

Hopefully, the five factors I've talked about above will help you think through your own transition. If you have comments or questions, please reach out to me at ken.lownie@agathalife.com. I feel this is one of the most important issues in front of the clinical operations community today and would love to get your thoughts.

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