TRIAL INTERACTIVE

Implementing Remote Trial Management:

Proven Approaches for a Quick and Effective Launch

Summary

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In response to COVID-19, the clinical trials industry has had to shift many on-site activities and procedures to a virtual environment. While managing clinical trials without direct access to sites has presented unique challenges, this shift also presents opportunities to enhance the accuracy and efficiency of clinical trials with new technology and processes.

If you're in the midst of looking at remote trial management solutions, it's important to look for technology that is easily accessible, scales with your organization's needs, and will be ready to launch quickly. Implementing a new remote trial management solution requires a combination of the right technology and processes to help you facilitate a successful clinical trial without the ability to physically go to your sites. Every process and piece of data associated with an on-site visit must have a corresponding remote process and documented data source. Before beginning your search for the perfect remote trial management solution, answer these questions:

How would you monitor a trial if you did everything remotely?

How would you access your data?

How would you access your essential documents?

Don't forget to consider how you'll avoid some of the most common clinical trial site failures as you shift to a remote trial management approach. According to the FDA, these are the top five clinical trial site failures found during audits:

- Failure to follow the investigational plan
- Inadequate records (including source records)
- Inadequate IP oversight
- Inadequate Informed Consent
- Inadequate safety reporting

In this whitepaper, we'll show you how to choose a vendor that can provide you with the right solution to not only ensure your clinical trials maintain accuracy and compliance as they go virtual, but also help you innovate your approach to clinical trial management.

Choosing a vendor for your remote trial management solution is not just your IT department's responsibility. As a clinical researcher, you're in the driver's seat for making this decision. Your inspectors may ask you how you chose your vendor. Be prepared to answer this question by executing these steps:

- Develop your vendor requirements.
- Understand how to get the most out of vendor demos.
- Conduct a thorough evaluation of a vendor.
- Conduct a thorough audit of a vendor.

Developing Vendor Requirements

Starting with a clear set of vendor requirements will be your foundation for selecting the right remote trial management solution. This is when you'll establish everything your software needs to accomplish.

USABILITY

Will your sites be able to use the software easily and quickly to access what they need? How intuitive is it, and can the site personnel get what they need without hours of training? How many steps will the study sites need to do their job? Do all users at the site have access, and is the security set up so sites only see their information, any required study training, and study reference information? How easy is the system to set up? Can you do it yourself, or do you need the vendor to do the set up? Are all the central study vendors listed with contacts, so sites can easily log in to the various portals and reach main contacts without needing seven different usernames and passwords per study?

DATA EXPORTS

Electronic data capture (EDC) systems are designed to capture data but not to analyze and review data. How are you going to review your data? In what formats can your data be exported? For instance, CDISC ODM is the standard for EDC but is not user friendly. SAS Transport files are another format that can be used more easily, but they do not include as much metadata as CDISC ODM. One area that is critical to consider is how quickly exports will be available after systems go live. Is the data something you can easily extract automatically, or does your data have to be extracted manually? If your data is extracted in a report format, is that report going to include everything you need to determine you have all your documents? Will you be able to identify missing documents as well? Focusing on these questions and understanding whether you can do an automated review are very important.

AUDIT TRAILS

When a team makes any kind of change in your system, is there an audit trail showing this change, and is it in a readable format? This is an absolute requirement based on 21 CFR Part 11. Does your system have the ability to produce an audit trail of any action a person takes in your system?

REPORTING

Older clinical trial management systems sometimes offer reports that only contain a component of what you need, which requires you to get more reports with additional information and then merge reports together. Even when vendors tell you they have reporting capabilities, make sure every piece of data you need for your review comes in one report.

PROTECTED HEALTH INFORMATION (PHI)

Technology systems use role-based access to not only store regulatory documents but also store subject source. Being able to identify missing documents—especially source documents—is a significant component. When you have a system with powerful role-based access, you can make sure that your protected documents are only available to the site and the monitor. Make sure your system meets protections and requirements, so people can't download the data and take it elsewhere. Some systems are also good about protecting documents in the system, but if you decide to provide an archive to each of your sites, you need to make sure that protection is in your archive as well. Lastly, make sure your system online can funnel documents to your research sites only; these documents should not go to your TMF.

eSOURCE

Evaluate whether you'll need to access your remote trial management solution from a tablet, a web application, or both. If you are using a tablet, ask how a vendor manages upgrades or changes in versions, because software goes through continual improvements and enhancements. Will this require your vendor to download a new version and do a lot of manipulation to set it up? If there is no internet access at the sites where you're conducting a study, you will need to go through these permutations. If your sites do have internet access, it may be easier to use a web application, since upgrades automatically will go into effect.

Once you define your vendor requirements, develop a specifications document to send to multiple vendors. This will be an instrumental tool for showing inspectors how you chose your vendor and what requirements you expected your vendor to meet. The specification document also will serve as your guide at every subsequent step in your vendor selection process.

Getting the Most from Vendor Demos

Once you have narrowed your search down to a few vendors, it's time to see their demos. This is the time to make sure vendors show you exactly how their system meets your requirements.

Your most important takeaway from a demo should be an understanding of how the vendor's system will work for your study. Here are the most important questions vendors should be able to answer during a demo:

- What does a data export from this vendor's system look like? Ask for examples of data reports.
- Who will set up the system? Will you have to set it up, or will the vendor do it?
- Who will perform user acceptance testing (UAT)? As a user, you are required to accept the system. Thoroughly test the vendor's system and make sure it works for your specific needs.
- What type of support does this vendor offer? Will the vendor be easy to work with? How will this team get to a solution that fits your needs?
- Does this vendor have the same goals as you do for your systems and technology? Remember that your relationship with your vendor could potentially be long-term, depending on whether you want to use this vendor for a study or establish a five-year technology partnership. Make sure this vendor understands and believes in your organization's trajectory and will help you accomplish your goals.
- Will this vendor be able to add enhancements as you work with them? Will this vendor help you with adding new features and functions to address any requirements the software does not already meet? Perhaps a vendor's software doesn't cover 5 percent of what you do. Can the vendor adapt and configure the software to create a solution or process to cover what's missing?

Remember, the demo is for you. Don't hesitate to ask every question you need to understand how a vendor's system will address all your requirements and deliver the remote trial management solution you need to conduct successful clinical trials.

Auditing the Vendor

Auditing a technology vendor is different than auditing a clinical research organization (CRO). The goal of this audit is to understand how a vendor develops their software and releases product updates. You can conduct a thorough audit of your vendors remotely and learn a lot about their processes. Here are the key factors to include in your audit checklist:

- **Know** about the vendor's infrastructure and security. If the vendor has cloud-based services, what platform are they using (e.g., AWS, Azure, Google Cloud Platform)? Does the vendor host its own servers? How does this vendor approach security? How does the vendor approach core product development, and what artifacts go with that? We recommend doing a small product release to make sure the vendor has all the documents and processes in place for software development.

- **Understand** the vendor's organizational structure. You want to make sure software developers are in a different organizational line than the quality team. This way, you won't need to worry whether the head of software development could pressure the quality group into accepting a release that may not be right. An independent quality group ensures you get a product that works properly.

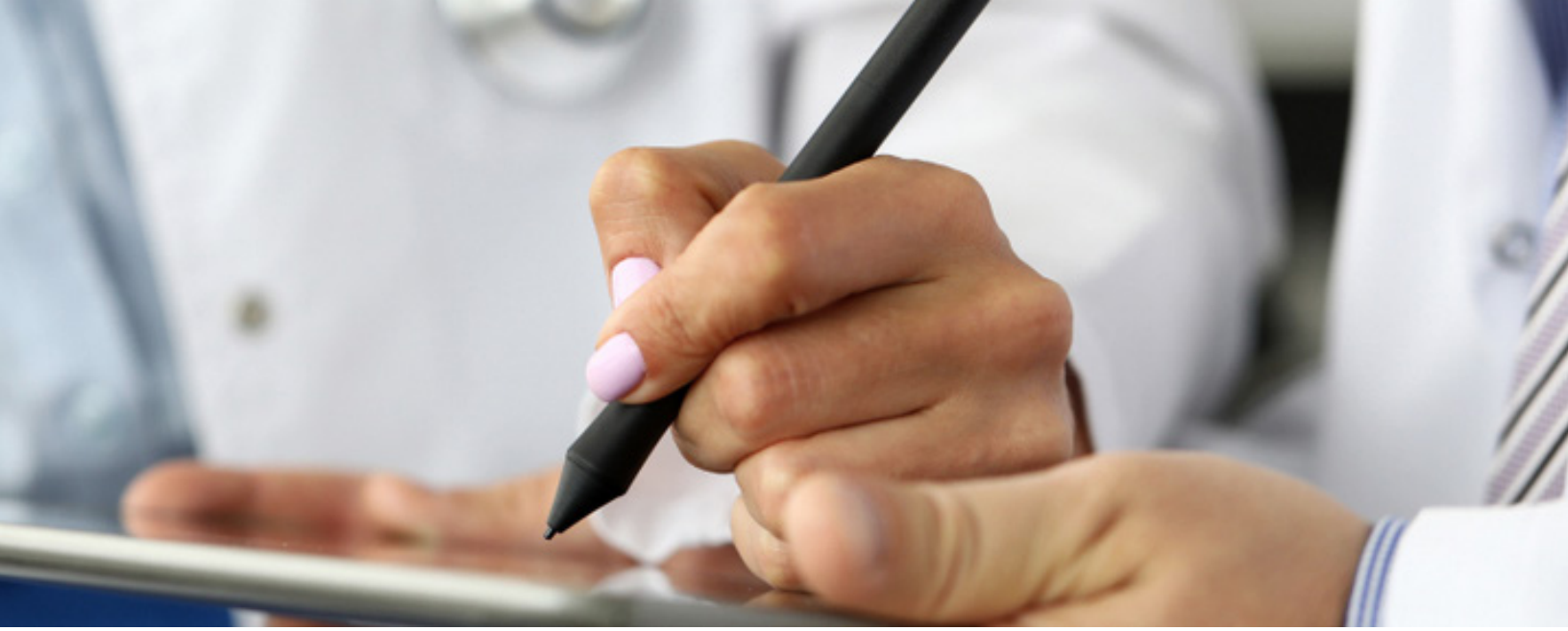
- If you're a European client, make sure you can host the system in Europe or Asia-Pacific.

- If your vendor offers a platform with different pieces, make sure the platform pieces are developed and released in the same way.

- **Consider** how to handle change control. Make sure that when your vendor makes a change, it will not affect anything else you have already changed in your system. Establish risk-based monitoring as an ongoing practice—don't just think about what can go wrong only when you're evaluating vendors. Continually check this even after you've put your remote monitoring solution in place.

- **Make** sure the vendor can implement system role-based access or can help you implement a specific process for role-based access. A vendor may have defined system role-based access, which you can test up front and then assign each team member to a specific role. Or, you can put a process in place if your system doesn't include this kind of role-based access. Make sure role-based access covers not only the study but the data export, too.

After you create your audit checklist, make sure you have it on file. If you are inspected by a regulatory agency, the checklist offers documentation that you inspected your vendor and ensured it offers suitable technology to help you execute your clinical programs.



21 CFR Part 11 Compliance

Taking 21 CFR Part 11 compliance into account when choosing your vendor is critical. 21 CFR Part 11 establishes compliance regulations for eSignatures, audit trails, and the conversion of documents to certified electronic copies. Remember that 21 CFR Part 11, unlike FDA guidance, is a law and you must be able to show evidence that your remote trial management system meets the requirements.

New technology vendors who work in the clinical trial industry may not be familiar with this law. Other vendors may say that they're 21 CFR Part 11 certified. This is a red flag—there is no stamp or certification from the FDA for this law because 21 CFR Part 11 compliance requires a combination of technology and processes.

If a company is using eSignatures for the first time, it must send a letter notifying the FDA. This letter needs to be on paper with a wet signature. All users of eSignatures also must understand that their electronic signature on any document is equivalent to their handwritten signature. The signer is accountable and responsible for all actions initiated under the eSignature and must not share their unique username and password for email or any other electronic system with anyone else. The following is a list of facts to keep in mind about compliant eSignatures:

- In some vendor systems, you will not be able to customize attestation language (e.g., "By signing this, I am certifying…."). Being able to modify this language is especially helpful when you start certifying electronic documents.
- A signer is required to have two forms of identification in the system. Username and password are the most common forms.
- Your system's audit trail needs to show the user who signed each document requiring an eSignature. If you only see a drawn signature and don't have an audit trail, you do not have a true eSignature.
- Make sure you have multiple users who can access eSignature functionality. Your principal investigator (PI) should not be the only user who can access this. Make sure your study coordinators and other study team members can execute eSignatures as well.

Certified Electronic Copies

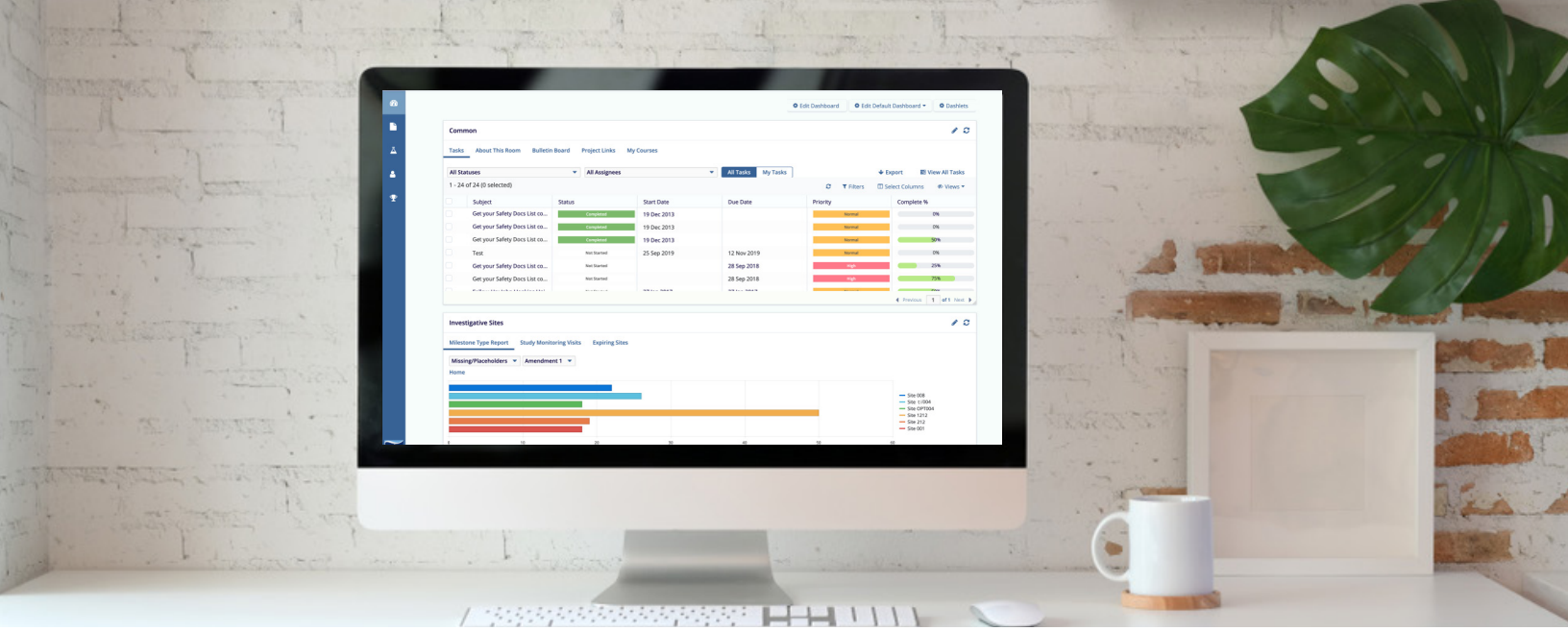
Under 21 CFR Part 11, any paper document or any other format can be converted to a certified electronic copy that is considered exactly the same as the original. This has been especially helpful for medical record information, because electronic medical records (EMRs) are not 21 CFR Part 11 compliant. You can download the appropriate information you need for your trial from an EMR and make a certified electronic copy with an audit trail that shows when your documents became certified copies. This provides you with a full record for your electronic investigator site file. Depending on your standards of procedure (SOPs), you can destroy your original document once you have your certified copy and use it for all of your references. Certified electronic copies also are helpful for expediting the subject consent process as well. With a certified electronic copy, you can perform a consent review within five days of a subject's visit instead of waiting weeks or months to complete a review.

For a document to be converted to a certified electronic copy, the attestation language for your eSignature must state the person who uploaded and reviewed the document confirms the electronic copy is the same: All pages are present, legible, and in the right order. You also can develop a certification process that doesn't require an eSignature. No matter your process, make sure you have an audit trail to prove what has been signed and who signed it.

Ease of Use for Sites

When you think about how you want your remote trial management system to operate, keep ease of use for your sites top of mind. Each of your sites works with many different studies, sponsors, and technologies, so the easier you can make it for a site to access information, the better. One of the biggest challenges for sites is knowing where to find information, so it's best to do everything you can to reduce their administrative burden and help them increase efficiency.

Ultimately, you'll need to choose a remote trial management solution based on how your site personnel work. If site personnel prefer to do their work on tablets or phones, consider how you can make your system easy to navigate on an Android or iOS device. At the end of the day, this is about managing your trials in a way that speaks to the way your site works, even when you can't be there in person.



Conclusion

Enabling remote trial management is more accessible and more necessary in today's environment and for the future of clinical trials than ever. With available technology solutions, as well as sponsors, CROs, sites, and vendors who have tested and refined implementations, there now exists precedent, best practices, and tactical know-how to effectively deliver these solutions. Study teams can be confident in moving forward with a vision for more flexibility in their operations and spend less time on unnecessary and administrative tasks. Remote trial management has often appeared to be a luxury for larger companies, but this is not the case. Study teams of all sizes can implement scalable solutions to get started on the path to remote capability. Remote-enabled operations are now critical to the continuity and execution of any ongoing or new clinical trial in the current world of clinical trials. Are you and your company ready?

For help exploring remote capabilities such as eISF, remote monitoring, eTMF, LMS, document management, CTMS, and more, contact us at **info@trialinteractive.com**.

To speak with MANA RBM, email **info@manarbm.com**.