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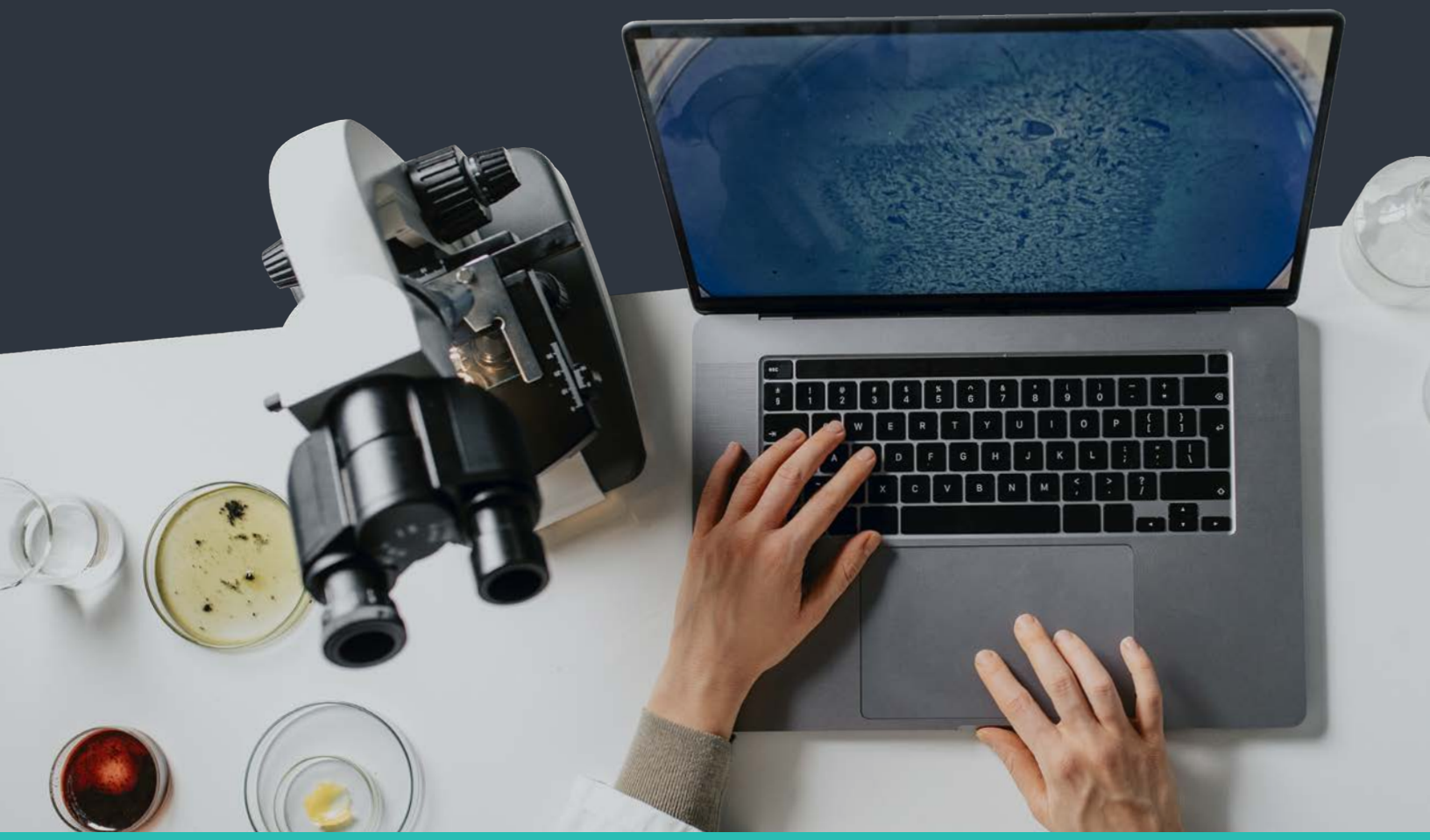
Investing in an eTMF?

Here's What You Need to Know.



The eClinical revolution has provided a host of electronic solutions to reduce paper usage and increase efficiency in clinical trials.

Electronic Data Capture (EDC), electronic Patient-Reported Outcomes (ePRO), electronic Clinical Outcome Assessment (eCOA), and other technologies all have specialized uses in the collection and management of clinical data. But it's the electronic Trial Master File (eTMF) that ultimately serves as the central data repository across your trial's life cycle.

Clinical trials are complex undertakings, with many junctions in which even a small misstep can compromise your data integrity, compliance, or timeline. The best eTMFs are those that don't simply provide electronic alternatives to paper-based processes, but also the functionality to make sure data collection is easy, data security is formidable, and audit trails are ready when regulators need to examine them. This is especially – but not exclusively – true for life science professionals coming into their first hands-on role in a clinical trial.

The success of your trial, then, may well be determined by two factors:

01. Choosing the right eTMF
02. Understanding how each stakeholder will use the system

This guide will explore the differences between traditional and cutting-edge eTMF technology, and share best practices for getting the most out of your eTMF.

Getting ready for your eTMF journey

Regardless of which eTMF vendor you partner with, there are certain steps you'll need to take before implementing your solution.

Step 1: Define the needs of your team

With so much data from so many sources stored in your system, using an eTMF is a group effort. Different members of your team will have different roles to play. The more of a head start you get on defining these roles, the faster you'll be able to implement your system.

Step 2: Establish your goals

There's more than one way to use an eTMF, and how you use yours will depend on what you hope to accomplish, what other resources you have in place, and other factors. For example, some teams use their eTMF to collect data at the point of entry, while others use it simply for centralized storage of data previously collected in an EDC platform.

Step 3: Evangelize

If your team includes those with a long career in clinical research, there may be some resistance to implementing a new system. This challenge also comes into play when working with external partners, such as site staff, who have their own way of doing things. The good news is that you can catalyze user adoption by keeping your lines of communication open, providing ample training resources throughout the lifecycle of your study, and demonstrating the benefits of using an eTMF: Better data integrity, simpler processes, stronger compliance, and more.

Determine, in advance, the person or people on your team who are best equipped to:

- Handle the upfront configuration of the system
- Migrate data from your previous system – or, if this is your first time going electronic, from paper documents.
- Access the eTMF data for analysis
- Archive the eTMF data for future analysis
- Management of data entry

What to look for in your eTMF

A key fact to keep in mind when embarking on your eTMF journey is that an eTMF is more than just a data entry tool. Your eTMF is an always-auditable, single source of truth for the data collected, how it was collected, and who collected it. After all, if all you needed was an electronic repository for your data, a spreadsheet and hard drive would more or less suffice.

When evaluating a vendor, it's essential to learn how well that vendor performs in critically important areas beyond simple data entry – areas like GxP compliance, access and permissions, inter-site communication, controlling for quality and consistency, and more. The best eTMFs today have features bolstered by AI and machine learning (ML) to prevent critical lapses and shortcomings in these areas.

Here are some of the key elements of a clinical trial that your eTMF should enable you to easily address.

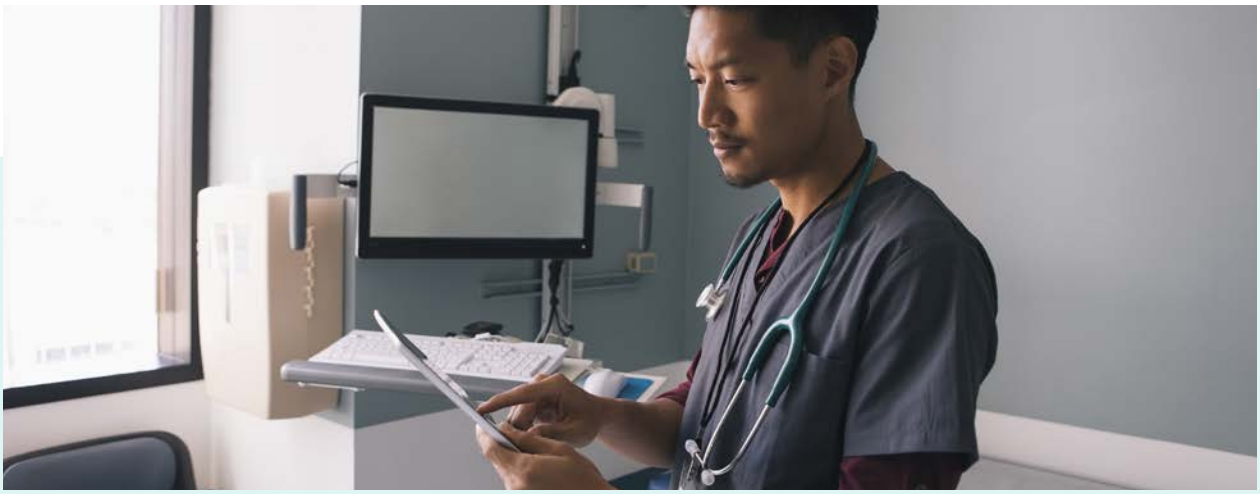
Data Governance

Clinical trials typically involve millions of data points, every one of which is subject to potential human error. If even one error goes uncorrected, it can have downstream effects that can compromise your trial. An EDC platform may have range check functionality that reduces the risk of data being entered incorrectly. But when it comes to eTMF, you'll need to go beyond data entry and also consider storage, permissions, and other factors that impact data integrity.

For example, documents are placed in the wrong folder where certain individuals are erroneously granted access to data they shouldn't be permitted to view. Look for an eTMF with AI and ML that can process the type and content of your files, use that information to alert you to errors like these, and help you correct them.

Consistency

Similarly, you'll want a system you can use to establish standards around the processes and formats your team uses. Harmonizing your team's practices for collecting, storing, and organizing data can prevent the kind of confusion, later on, that can lead to costly trial delays.



GxP Compliance

If you've got little to no firsthand experience in clinical trials, you may be inclined to collect your data using general file-sharing services, or some other platform with which you're already familiar. While these platforms may be capable of storing your data, they lack one particular feature that any eTMF will have and that is absolutely critical for regulatory compliance: an audit trail. A key safeguard of data integrity, your audit trail provides a window into valuable information around each data point, such as:

- Who entered the data point?
- What changes have been made to it?
- Who made these changes, and when?

The good news is that if you have data stored in Box (or another file repository), you don't necessarily have to throw it away and start from scratch. Instead, look for an eTMF that can seamlessly pull in data from these other systems and centralize it. Once that happens, the data will be subject to your system's audit trail and thus provide the kind of visibility that regulatory bodies demand.

Collaboration

In a clinical trial, there's an array of stakeholders who need access to data and documentation, including sites, sponsors, CROs, vendors, and others. They're often widely dispersed – especially at a time when decentralized trials have become so common. Your eTMF should make it seamless for all stakeholders in all locations to find, view, enter, and modify data as needed.

But be careful: Not every stakeholder should have access to every piece of data. The ideal eTMF has permissions functionality that is granular enough both to promote collaboration and to regulate it so that everyone has all the access they need – but not more.

Easy Access and Organization

All the remote access and granular permissions functionality in the world won't be enough if your data and documents are all but impossible to locate. With such a massive volume of multifaceted data from such a wide array of sources, your eTMF should offer structured document storage with quick search and filter functionality for easy document retrieval.

Security

Look for a solution that offers encryption, backups, and other security methods and is easy to implement such as a cloud solution. Across the clinical research industry, there is the belief that data is more secure when stored locally, either via on-premise software or on paper locked away in filing cabinets.

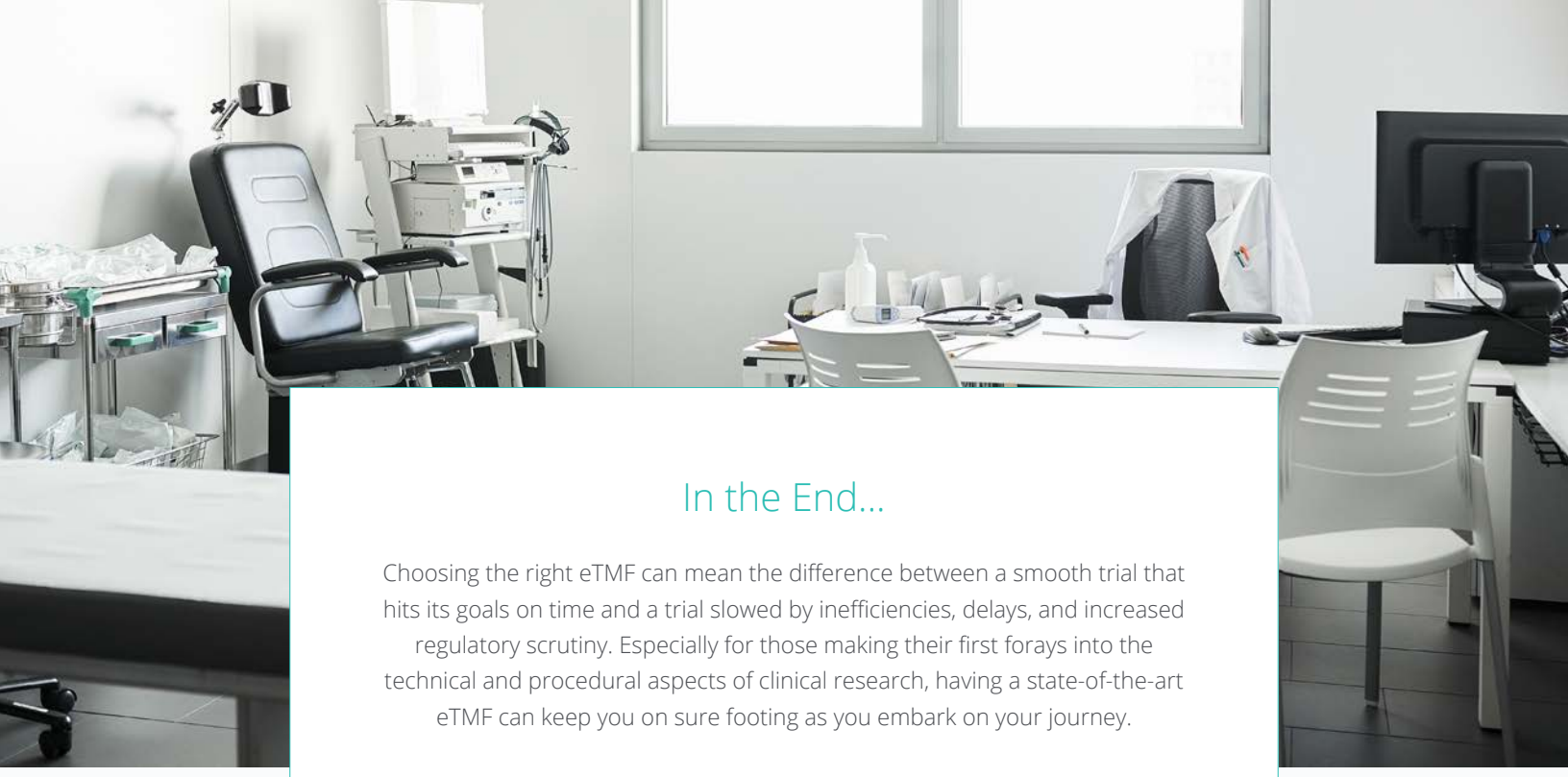
But today, a cloud solution can offer a secure framework that ensures data protection and confidentiality while also enabling large storage capability and ease of collaboration across sites.

Archiving

Though your trials will end, your data will live on – usually for quite a long time. It's often necessary for clinical trial data to be preserved for 10, 15, or even 20 years after the trial is finished. The previous generation of clinical researchers stored their files on CDs and floppy drives; today, those formats are all but inaccessible. How do the vendors you're evaluating ensure that your data will be available in the long term?

Costs

Any eTMF will enable you to avoid many of the costs associated with paper processes – costs like physical document storage, ink, and managing the paper itself. Once you decide to go electronic, though, your next decision will be whether to go with a cloud-based software-as-a-service (SaaS) platform or an on-premise one. On-premise solutions often involve ancillary costs like on-site installation, making SaaS generally more cost-effective. Moreover, many of the measures outlined above will help you avoid the kinds of snags and delays that can ultimately expand the cost of your trial.



In the End...

Choosing the right eTMF can mean the difference between a smooth trial that hits its goals on time and a trial slowed by inefficiencies, delays, and increased regulatory scrutiny. Especially for those making their first forays into the technical and procedural aspects of clinical research, having a state-of-the-art eTMF can keep you on sure footing as you embark on your journey.

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