



Mobile eTMF: Once a “Would-Be-Nice”.
Now a “Must-Have”!

“Work today is done on the move. Managers expect it. Employees demand it. Mobile devices are critical to business performance and ubiquitous across the enterprise, wherever and whenever the job gets done. Simply put, most people need mobile phones to do their jobs as well as possible.”⁽¹⁾

EXECUTIVE SUMMARY

Mobile devices, and the apps that live on them, have become as attached to us as our purses and wallets. While there will always be a debate about when, where, and how much time people should spend on their phones, there is no debate to be had about how easy they can make accessing information and accomplishing tasks on the go. Every day people pull up their navigation application to get from point A to point B, log in to their bank account to scan and cash a check, look up a piece of trivia on their mobile browser, jot down a world-changing idea in their favorite note-taking app, manage personal tasks with a task manager, shop conveniently, set reminders, manage their schedule, send emails, chat, text, take pictures... simply put, we use our mobiles to do just about everything!

Mobile applications are streamlined, simplified extensions of the things we already do—both personally and professionally. In the world of business software, these mobile extensions are all about placing important insights and processes at the user’s fingertips. These micro experiences demonstrate an ability to distill all of the power of a platform down to a focused

set of data and features that are the most advantageous to have available at any time. Just as a copywriter is tasked with developing a deep understanding of the business to summarize a brand in a single tagline, product teams must similarly shrink the exhaustive capabilities of enterprise business software down to the most practical features for a mobile use case, based on the needs of their users. Companies vetting software should not overlook the extent to which a mobile experience can illustrate real empathy and understanding for their business needs. Moreover, there is no longer any reason for a platform not to offer a mobile experience to lend convenience and efficiency to users; we are far enough into the rise of mobile that it should now be expected.



Sponsors and CROs evaluating e-clinical software should arrive at the discovery process with the above assertions as hard parameters. Can my vendor demonstrate real understanding of the needs of my CRAs through a mobile experience? Is my vendor meeting the expectation that mobile has to be an option for my team? The benefits of offering a mobile experience are simply too great to ignore.

BUSINESS CASE

The document processes for maintaining a healthy TMF were once (and in many cases, still are) manual and on paper, but eTMF technologies have since been introduced to help organizations streamline and digitize these processes. Now, we can push the optimization of these processes even further with the help of mobile applications, and the timing couldn't be better. According to RCRWireless, there are now more mobile devices in circulation than the global population of people, with mobile internet use exceeding desktops. Further, it is estimated that by 2020, the workforce will be comprised of five different generations and more than 70% will be millennials by 2025. This means that the majority of the workforce will come from an age where technology adoption is the norm, with the younger generations holding an innate expectation that their essential processes will be supported with accessible, user-friendly technology.⁽ⁱⁱ⁾

Currently, regulatory binders or ISF for investigative sites are still very much a paper process. Offices and basements are filled with boxes of binders, all of which need to be mailed, transported to scanning facilities, or moved to long-term archive facilities. The associated costs add up quickly. CRAs visiting sites have to review the regulatory binder at each site visit, which can be every 4-6 weeks (depending, of

course, on the type of study) as subjects come in throughout the study.

Bottlenecks emerge quickly when CRAs are faced with limited (or non-existent) scanners and copiers at each site, as well as password problems and other technical issues when trying to scan and email documents. They also can face limited access to on-site computers to access the eTMF in a timely fashion. CRAs carrying laptops can face frequent wifi connectivity challenges as well, and troubleshooting these issues are further time sucks. Some CRAs flat out dislike being tied to a computer at all. Moreover, many CRAs are mainly focused on getting documents into the eTMF and do not need all of the features available with the full eTMF experience. These logistical and technical hurdles lead to personnel interruptions and time management challenges that have a rippling effect on overall performance. The "solutions" that are employed really add more problems. Some CRAs lug around portable scanners that are cumbersome, annoying to set up, and tend to yield subpar scanning quality. Even worse, word on the street is that CRAs—out of desperation—will download non-validated scanning applications to their devices to scan documents and then save to non-compliant and non-secure cloud environments. Others simply use their device camera to take pictures, store locally on the device, and then attach the images to emails, significantly impacting confidentiality. These practices are regulatory **no-nos!**



"Consumers are now multiplatform and access digital experiences across devices (desktop, tablet, mobile)."⁽ⁱⁱⁱ⁾

EMBRACE A MOBILE WORLD WITH PREDICTABLE ROI

A Future of Practical, Convenient Benefits for Clinical Teams



MOBILE APPS



SAVE TIME



REDUCE COSTS



INCREASE PRODUCTIVITY

Tablets, wearables, and ultrabooks are expected to be the primary work devices by **2020**.^{iv}

The mobile workforce will grow to **1.87 billion** people, globally. That means, **42.5%** will be mobile by **2022**.^v

Mobile users find value in taking work-relevant pictures, accessing data, and collaboration (conferencing and chat/text).^{vi}



80%

OF EMPLOYEES feel they cannot perform effectively without their phone.^{vii}

75%

OF EMPLOYEES could continue work if interrupted through the use of mobile applications.^{viii}

25%

OF KNOWLEDGE worker-centric professionals are out of the office at any given time.^{ix}

35-45%

PRODUCTIVITY GAINS in remote workers of several Fortune 500 companies.^x

Clinical teams are seeing similar performance gains through e-clinical mobile apps.
Time to go mobile!



73%

of senior executives see their mobile devices as critical to business communications.^{xi}



Small businesses are ultimately saving almost

5-6 HOURS

weekly by using mobile applications.^{xii}



Users spent 2x more time on mobile than desktop across

9 GLOBAL MARKETS^{xiii}



UNITED STATES



CANADA



UNITED KINGDOM



SPAIN



ITALY



BRAZIL



MEXICO



CHINA



INDONESIA

TMF ADVANTAGES FOR CRAs

Business processes in clinical studies are specific and nuanced, but they are ultimately not so unlike business processes in other industries that have seen the above benefits from mobile apps. Scanning a document is just capturing an image of a document, like a banking app captures an image of a check to make a mobile deposit. To-do lists are ubiquitous in business, and while the associated deliverables may vary, the logic behind a to-do list is pretty consistent. Document processes in any business are a series of steps that need to be accomplished to consider a document process complete. Again, the logic is similar, regardless of the industry. The devil is in the details, which is why you would not use a one-size-fits-all software for your study. Rather, you should select the e-clinical platform that best suits your needs. The point remains, mobile benefits are as accessible to study teams as they are to any other business.

HERE IS WHAT THOSE BENEFITS LOOK LIKE IN PRACTICE:



No more non-validated apps and non-compliant cloud storage

Remember when we discussed CRAs using their own, non-validated scanning apps? A mobile app provides the convenience of mobile scanning with none of the compliance risk. Documents are submitted directly to the eTMF and are not stored on the device or in an unsecure cloud hosting environment. Make sure any app you use is 21 CFR Part 11 compliant! Your Quality Assurance department will back you up to eliminate regulatory risk.



Reduce transport expenses for scanning and be nicer to the environment

All those binders and boxes are much easier to process. Less paper transport is required when you can just pull out your phone and begin scanning. Your suitcase and back will thank you!



Reduce scanner availability challenges and technical issues that waste time

Gone are the days of chasing down available scanners when your phone now serves that exact purpose. Technical obstacles are reduced when all that is needed is launching an application from your phone or tablet. Quick and easy.



Get rid of clunky, outdated portable scanners

Your personal or company-issued device replaces the clunky portable scanner. With the use of modern phone cameras and application features that detect documents and correct perspective, the image quality is fantastic—and enables review prior to a safe, secure, and easy submission to the eTMF.



Get the features you need, when and where you need them

A mobile application means ultimate accessibility to CRAs, as they will no longer require a desktop/laptop in order to work, and can enjoy a streamlined experience that provides only the features they really need to get their work done. This accessibility removes many of the bottlenecks that slow down document processing.



No more disparate systems and passwords

Logging into the system is no hassle when you can use your own fingerprint or face to get access using a biometric login such as Face ID® or Touch ID®.



Save time by being able to perform key processes, where and when you want

Reviewing, scanning, uploading, and applying metadata to documents live to the eTMF anytime, anywhere makes for massive time savings when these activities might otherwise be delayed. Similarly, oversight is available at a glance.



No more struggling with wifi connectivity when you can work offline

Mobile applications allow for secure, temporary local data storage. This means an application can facilitate your essential processes even when you can't get access to a reliable connection. When connectivity is restored, this data is immediately transferred directly to the eTMF.



Manage the TMF proactively with real-time information

With quick TMF health views and less time spent on manual scanning, shipment, delivery, and processing, there is more time to focus on TMF oversight.



TMF completeness can be easily monitored and maintained

Quality, document statuses, and options to resolve queries are all capabilities within a mobile experience that can help you maintain a complete eTMF.

CONCLUSION

According to the Worldwide Semiannual Mobility Spending Guide from International Data Corporation (IDC) in 2018, spending on mobility solutions is forecasted to grow 3.2% globally year over year, and to surpass \$1.7 trillion in 2021.^(xiv)

"Organizations of all sizes and from all industries are enjoying the benefits of mobile solution, [...] In industries further along the adoption curve, mobility projects incorporate other transformational elements such as IoT, cloud and big data to challenge—and change—the status quo. Even smaller scale mobility solutions are expanding from their initial single-function footprint to empower and enable workers across the enterprise. So long as organizations strive to gain efficiencies and deliver a superior customer experience, we expect to see continued interest, adoption, spending, and growth of mobility solutions."^(xv)

- Jessica Goepfert, Program Vice President, Customer Insights & Analysis

E-clinical technologies have become essential to supporting clinical operations and it has become vital that we strive for the most user-friendly, accessible, and practical experiences. In the case of eTMF, the fundamental data and work processes are available and ready to be further streamlined, extending the experience and removing unnecessary obstacles that impact TMF health and overall compliance.

Paper in clinical trials is becoming increasingly obsolete. Meanwhile, real-time transparency into clinical documentation and associated processes is becoming even more important to regulatory authorities worldwide. A mobile experience can speed up the review process by 30-60 days. That means even quicker review and approval.

The reasons for considering a mobile eTMF experience essential to your e-clinical investment can be boiled down to two concepts:

1 A well-functioning mobile experience demonstrates that the product team understands your business needs to the

extent that they can reduce a platform to the most practical functions to have available on the go.

2 The benefits of making business process and data insights available via mobile are too many to ignore.

Early adopters of eTMF mobile applications will not only improve the lives of CRAs, but they will also be industry influencers. With a large section of the industry still using paper, the organizations that are incorporating cross-platform e-clinical capabilities will set the bar for how to conduct studies with the most effectively streamlined clinical operations.

WHY TRIAL INTERACTIVE?

Our specialized, integrated innovation speeds processes and improves quality across site identification, site selection, site activation, compliance training, document collaboration, eTMF management, closeout, and more.



Cloud-Based
E-Clinical Platform:
Go Paperless!



Secure
Document Transfer
and Hosting



Easy to Use,
Comprehensive
Workflows, Mobile eTMF



Saves Time and
Money, and Reduces
Compliance Risks



21 CFR Part 11,
Annex 11, ERES, GxP,
and GDPR Compliant



Flexible and
Configurable to
Requirements



Expedites Site
Activation and Document
Work Streams



Fast Implementation
and User Onboarding/
Adoption



Multilingual Interface
with Global Language
Services



24/7 Global
Customer
Support

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