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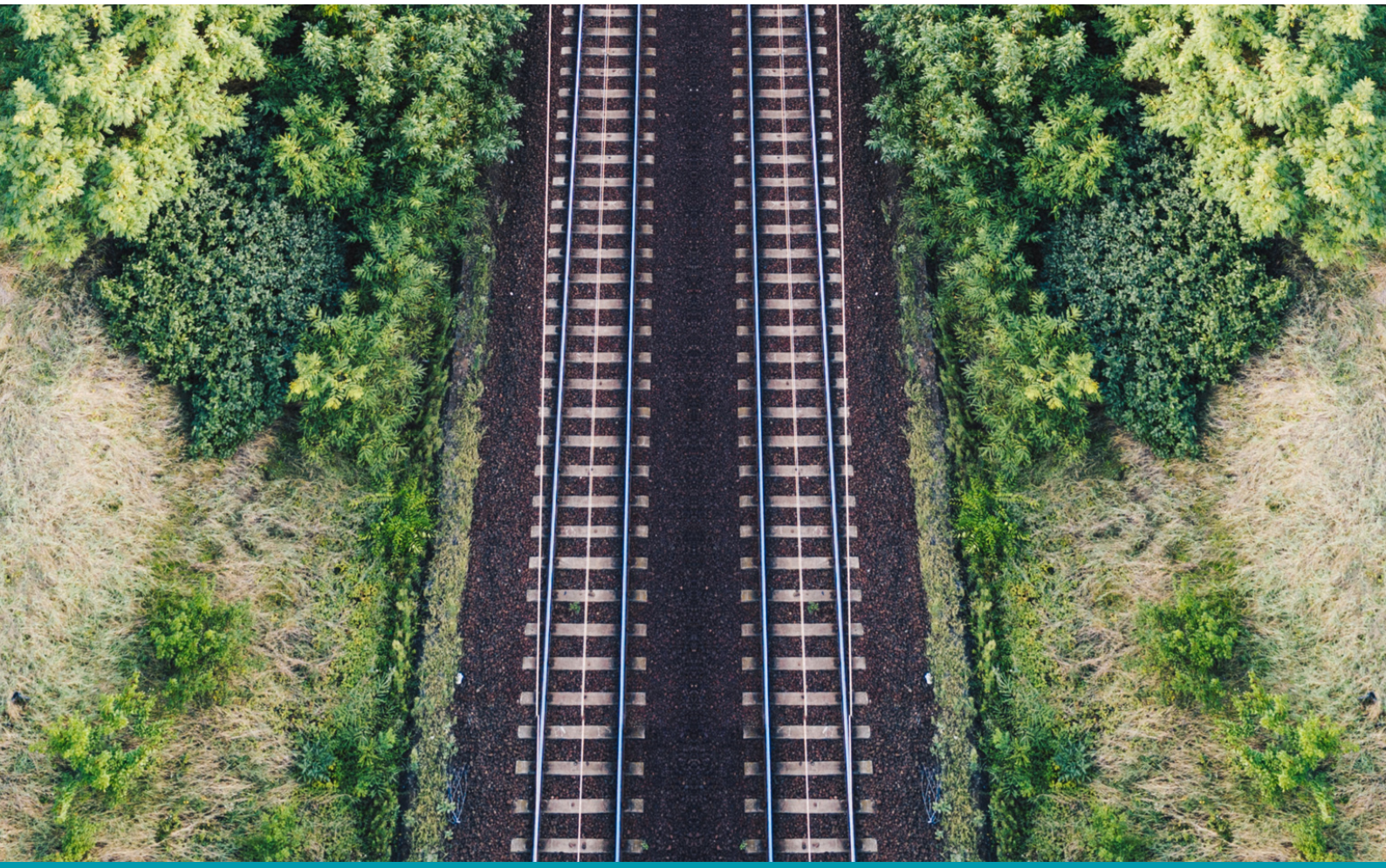
Clinical Trial Document Exchange - Opportunities and Challenges

Minding the gap between ISF and eTMF



In this series we take a look at the challenges associated with exchanging documents between ISF and eTMF and the opportunities for delivering greater efficiency and eTMF quality.

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Executive Summary

Electronic Trial Master File (eTMF) quality relies on the timely collection and filing of regulatory documents during a clinical trial.

Whether sites use paper, hybrid, or fully electronic Investigator Site Files (ISF), the physical and functional gaps between an ISF and eTMF generally mean that some form of manual handling is required to exchange documents between systems. Managing the document exchange process is essential to retaining a state of audit readiness.

In this series we will look at the challenges associated with exchanging documents between ISFs and eTMF and the opportunities for delivering greater efficiency and eTMF quality.

We start by looking at the challenges associated with managing paper documents in the eTMF era.

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The gap between the ISF and eTMF

The uptake of digital technology by clinical operations teams has sharply increased over the past 5 years, with most (78%) Sponsor and Contract Research Organisations now using electronic Trial Master Files (eTMF) [1], compared with just 23% in 2016 [2].

By contrast, the majority of clinical trial sites (estimated 75%) are still using either paper or hybrid Investigator Site Files (ISF) [3].

This technology gap is significant for the trial teams tasked with maintaining an eTMF, as integrating paper documents into an eTMF is both time consuming and prone to error.

eTMF quality is dependent upon site documents being filed appropriately in the eTMF in a timely manner [4-6]. That means:

- Digitizing and importing documents quickly
- Ensuring documents are correctly indexed, and
- Ensuring documents are clearly and consistently labelled for ready retrieval.

Failure to effectively manage these processes results not only in poor quality eTMFs but also poor study visibility and sponsor oversight.

Drive efficiency by reducing redundant, manual tasks

eTMF Quality Failures

In the 2020 Veeva survey, 53% of respondents cited misfiled and/or missing documents as one of the biggest challenges in information exchange; the other challenges being manual processes (64%), document tracking (67%) and duplicate data entry (43%) [1].

With the typical TMF having somewhere in the order of 100,000 documents [7], it is not surprising that some documents are missed or misfiled amid a busy clinical trial. Yet such broad industry experience points to a more deeply rooted issue.

Multiple Points of Failure

When digitizing and filing paper documents in an eTMF, there are multiple points at which the process can fail: documents must be digitally captured in a form which is clear and complete, the documents must find their way to the correct eTMF in a timely manner and be correctly classified and clearly and consistently labelled for future retrieval.

Manual Workarounds are Inefficient

Processes have remained surprisingly manual despite improvements in eTMF technology.

In the main, paper-based site documents are still photocopied and physically collected by study monitors. Photocopies are scanned on local machines or get batched and transported to scanning facilities to be digitized. The digitized documents are then uploaded to the eTMF after which interim photocopies are simply destroyed.

Multiple handoffs are managed with tracking processes that require the repetitive entry of study, site, and document details.

These time and resource intensive processes create a lag in documents reaching the file and so impact eTMF timeliness, study visibility and oversight.

Misfiled & missing documents are one of the biggest challenges in information exchange.

2020 Veeva Unified Clinical Operations Survey.

Minimize decision points to improve quality

Indexing is Error Prone
The indexing process involves classifying and labelling documents so they can be readily found by other users, including inspectors. Inconsistent and erroneous indexing results in lost and misfiled documents.

The indexing process is complex due to the large number and type of documents being filed and the varied requirements of different studies, sponsors, and eTMF vendors. It is made more difficult because of inherent experiential biases across global teams, and because the process remains highly manual.

Each user must first understand how the document should be classified for the specific study, sponsor, and vendor before navigating to the appropriate section of the eTMF and correctly applying the relevant details.

The process is routinely managed with training and quality control measures, yet errors are still occurring.

The risk of errors and inconsistencies is greatly increased by the manual nature of the classification and labelling process. Minimizing these errors is the key to reducing missing and misfiled documents.

Error prone, manual touch points increase the risk of error and inconsistency.

Automate to minimize lost and misfiled documents

The Opportunity to Automate

Streamlining the process by reducing manual and redundant tasks and enabling the rapid flow of correctly indexed documents into the eTMF has the potential to:

- Drive efficiencies by reducing document handling times
- Improve eTMF quality by increasing file timeliness and accuracy, and
- Promote greater visibility by reducing the number of missing and misfiled documents.

Document handling time can be significantly reduced by technologies that facilitate the digitization process. Several eTMF vendors offer vendor specific mobile scanning applications to help speed document collection but require indexing and metadata to be applied within the eTMF itself.

The Need for Automated Indexing

Automated indexing technology has the potential to reduce errors from manual data entry and minimize lost and misfiled documents, however, for greatest impact it needs to be introduced early in the process, ideally at the point of document capture, to reduce redundancy and rework.

Looking Towards a Solution

A robust and ideally mobile technology that minimizes error prone touch points is required to help collect and index documents, particularly when those documents are paper based.

There are three key challenges in delivering such a solution:

1. Addressing regulatory and security requirements
2. Controlling application of the appropriate index and metadata, and
3. Maintaining ease of use in an inherently complex process

Stay tuned for the rest of this series as we look more closely at these challenges and at potential opportunities for delivering greater efficiency and eTMF quality.

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In our next article in this series we take a look at regulatory requirements and expectations.

About trialwiseSCAN

trialwiseSCAN is a CFR part 11 compliant, vendor agnostic document scanning application, that delivers on-device document indexing for faster filing with greater accuracy

About Trialwise Pty Ltd

Trialwise Pty Ltd is an Australian based company, established in 2014. We develop innovative technology for the clinical research industry with the aim of making things more efficient, containing costs and improving quality

www.trialwise.com.au