A Data Reduction Systems White Paper by James Peters, Director of Professional Services

The DRS TMF Audit

Proactively monitoring studies residing in your system using a risk-based approach to ensure 24/7 eTMF Inspection Readiness

November 20, 2017 -- *Capturing essential study documents during the conduct of a study and into a centralized eTMF offers opportunities never before possible. Like improved filing capabilities not available in the days of paper files. Or currently in systems where CROs maintain sponsor TMFs with limited visibility. It is a widely-accepted fact that accumulating and reviewing the TMF at the end of a study results in a significant effort shouldered by sponsors and their CRO partners. Today, centralized eTMFs have virtually put an end to this process. However, to ensure collections and overall quality, ongoing eTMF status audits are highly recommended. At studies where systems are not ongoing-audit capable, DRS monitors full end-to-end TMF auditing designed to uncover collection problems, attribution and filing of the study documents, ensuring that all gaps are resolved prior to inspections.*

Study Collection Background

In the past, systems were managed with paper filing methods that made it difficult to accurately track the documents that were placed in the TMF. Not only were the systems cumbersome but it was difficult to track the ongoing volume of work that came in from multiple studies, countries and sites. Even more problematic was the reliance on CRO partners to complete the collection and filing of the documents throughout the conduct of the study without an easy means of identifying gaps in the manual system.

It was difficult to objectively 'scorecard' the performance of the third party vendor or the internal staff responsible for the collection of documents.

Proactive Monitoring

Today with the emergence of eTMF, the critical nature of tracking the ongoing collection and filing of study documents has become even more important. Quite often, the issue at hand is the lack of time and resources to complete an examination of the TMF while it is still in progress.

In addition, because it is quite common for CROs to use dissimilar software and/or TMF document collection methods, it can become difficult for sponsors to be absolutely certain that a proactive monitoring process is actually in place.

Proactive Tools

- Review your processes for document collection and attribution with all study staff and partners. Make absolutely sure that everyone is 'on the same page' with all study instructions

Proactive Tools (cont'd)

- Measure the effectiveness of document collection and processes to make sure timely submission of site level documents is being done
- Complete oversight of the quality of the documents and associated metadata to ensure compliance with study instructions
- Conduct trainings and update processes and applicable SOPs with CRO partners to proactively address issues and observations based on findings, inclusive of staff performance guidelines
- Have the ability to identify items for mitigation of GAPS prior to site closing or study completion

DRS eTMF
TOTAL TRIAL MASTER FILE SOLUTIONS

The DRS TMF Audit service offering works toward providing a full inspection-ready system for your TMF

Problem Statement

Auditing of the records following completion of the study does not allow for an efficient means of finding missing records or identifying the documents that are not properly attributed. In 'drop and drag' systems, records are often deposited in the wrong folders and may be lost forever.

One of the biggest known concerns is the attribution of the study records as they are being collected.

We have all been part of studies when an audit is conducted and it appears that there are not common rules used in the collection and indexing of records. Unfortunately, these tools are not always applied proactively throughout the study and human error comes into play when documents are submitted.

Problem Statement (cont'd)

It is the typical problem of missing, misfiled or duplicate records that can become a source of frustration for Regulatory Authorities during inspections. They want to audit the conduct of the study, not the quality of the TMF.

Many times quality of the TMF is a matter of training and using consistent methods when collecting documents and submitting them to the system.

If this ongoing oversight cannot be conducted by CRO partners using defined attribution naming conventions, then the responsibility falls on the shoulders of the sponsor to identify gaps and remediate them as soon as possible to avoid further delays and inaccurate collection.

This is not something that anyone wants to find out at the end of the study or during an inspection.

DRS Inspection-Ready Benefits

- DRS provides the business process expertise, involvement, documentation, and participation required for a comprehensive TMF Audit
- For any eTMF system you are using, DRS provides an overall Risk Based Assessment of the TMF as to the condition, completeness, and accuracy of the filed documents in the TMF. Access to the system is all we require.
- DRS reviews the TMF completeness, ability to locate essential study documents easily, and quality of the TMF overall
- DRS reduces the amount of internal staff required to complete a full QC check of the study
- DRS presents findings as to status and summarizes deficiencies as to risk
  - ⇒ Performance of collection and document submitters
  - ⇒ Performance of document filing and attribution
- DRS presents options for mitigation that remain to put the file in *Inspection Ready Status and* provides mitigation services with direct contact to sponsor partners for open issue resolution and collection of any outstanding records

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