

TMF Professional Services

Proactively monitoring clinical studies residing in your system (or in ours) using a risk-based approach to ensure 24/7 eTMF Inspection Readiness.

DRS TMF Professional Services not only completes DRS eTMF OneSource - our full circle suite of eTMF solutions - it has become an indispensable service for our clients and their quest to maintain Inspection Readiness throughout the term of the study.

With over 30 years of document management experience, a successful history serving the life sciences and an internal culture rooted in compliance, DRS developed DRS eTMF OneSource, a suite of exemplary software and audit services for all your eTMF needs.

To ensure collections and overall quality, ongoing eTMF status audits are highly recommended...using your software or ours. At studies where systems are not ongoing-audit capable, DRS reviews the end-to-end TMF to uncover collection problems, attribution and filing of the study ensuring that all gaps are resolved prior to inspections.

DRS provides the business process expertise, involvement, documentation, and participation required for a comprehensive TMF Inspection.

- For any eTMF system you're 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 TMF completeness, ability to locate essential study documents easily, and quality of the TMF overall
- DRS reduces the number of internal study staff required to complete a full QC check
- DRS presents status findings and summarizes risk deficiencies

DRS presents mitigation options to make the file Inspection Ready and provides mitigation services with direct contact to sponsor partners for open issue resolution and collection of any outstanding records.

For our Software and Professional Services Clients.

DRS eTMF was developed with built-in mechanisms to capture and report on poor document submissions and to assist sponsors with vendor reporting. It is a system based on more than three decades of document management expertise particularly in the areas of collection, indexing and the QC of extraordinarily large numbers of documents utilizing Risk-Based Monitoring.

Documents, for example, must still be carefully reviewed to make certain they are collected, complete and correct. Good Document Practices (GDP) requires every document filed in an eTMF to be reviewed for completeness and correctness. The eTMF should (a) produce reports which clearly identify duplicate and/or missing documents and (b) provide a mitigation process for remediating documents with issues.

The DRS TMF Professional Services Group ensures that document management disciplines are applied to the studies' Trial Master File. Dedicated Clinical Research Analysts (CRAs) manage all clinical study documentation with in-depth knowledge of the DIA File Structure and Clinical Study Document Flow.

DRS CRAs are trained on each client's specific documented processes. The regimen includes collection, attribution, mitigation, quality assurance (QA), and the electronic and paper filing of documents with accuracy and expediency in anticipation of internal and external inspections.

DRS can safely ensure that documents in the TMF are (a) collected in a timely manner, (b) complete and attributed, and (c) filed correctly. From the sponsors viewpoint, there are generally three inspection perspectives:

- 1. External** -- Adherence to regulations mandated by authorities like the FDA, EU, MHRA and others...
- 2. Internal** -- Adherence to regulations mandated by the sponsors own auditors, and...
- 3. Departmental** -- Adherence to self-guided regulations mandated by the sponsors' staff and their auditing functions which includes monitoring the performance of CROs.

The bottom line is no sponsor wants to fail any inspection (regulatory or internal) or fall short of a milestone due to bad or missing documents. With DRS, the Professional Service Group ensures that inspection readiness is maintained daily, allowing you to keep a watchful eye on all audit perspectives including your CRO's collection performance.

DRS TMF Professional Services in combination with the DRS eTMF application protect and provide the optimal inspection ready solution.