Migration services *for every requirement* from active study transfers to acquired and archive-ready studies and *from any TMF system or software*

Executive Summary *- New drug approvals are on the rise thus far this year and while this bodes well for the industry, the uptick is creating new demands at the clinical studies level. Study managers, for example, are taking on more and broader responsibilities, e.g., ensuring that multi-sourced, multi-type studies are properly migrated and integrated into their eTMF -- regardless of type or complexity. Many have turned to outside resources for help -- often with mixed results. This white paper underscores the importance of having study migrations and systems integrations conducted only by experienced special-ists. That position is supported by three real-world client examples detailed on the reverse side.*

Background

Over the past dozen or so years, it has become common industry practice to collect paper TMF documents and migrate them to electronic format. Doing so has yielded benefits, but the e-file structures, although similar, are different enough to keep things interesting. For example, what is considered "essential" and where should they be filed?

As technologies advanced and clinical study management partnerships developed, collected TMF documents and ownership spread over a larger landscape.

Think about it... CROs and sponsors alike collect documents in paper format as well as in a wide variety of electronic systems.

Multiple TMF file structure SOPs are often employed as well as electronic storage strategies -- from network applications to cloud- based eTMF.

Perhaps most problematic is not all of the solutions offer software validation and document visibility.

Problem Description

And so, as solutions become better defined and multiple partnerships continue to grow and conduct studies, it is becoming increasingly more difficult for sponsors to oversee numerous studies with multiple structures, TMF applications, document collection organizations collecting documents and simultaneously ensuring a complete, correct, and current TMF.

With multiple sponsor partnerships for each study, a single SOP that defines the organization's TMF structure, collection practices, oversight and expectations filing, a single process often falls by the wayside.

And in addition to clinical study teams, sponsors have QA and Audit responsibilities to ensure that all studies are managed properly and in their best interest. With multiple file structures and systems, oversight beyond the clinical study team can become a real challenge with in-place multiple structures, systems, quality processes and solutions all contributing to the possibility of an incomplete TMF .

High-Level Solution

The bottom line? It is clearly in the best interest of sponsors to have an eTMF that offers a single application, process and structure definition for the collection of their TMF documents.

A single application ensures visibility for all required parties. A single TMF allows a standard file structure to be followed across the entire organization. And, a single application enables document QA reviews and filing quality processes to be accurately followed.

Oversight of the condition, collection and status of the TMF by the sponsors' QA teams then becomes a process that can be measured across the entire organization.

Management tools, from reporting to analytics, can then be put in place to present an ongoing view of process and TMF condition. Deficiencies can be identified and remedied to keep the TMF in good condition.

A standard TMF structure and process in a validated application generating appropriate clinical study condition measurement reports of all activities minimizes risk and is obviously of incalculable value.

DRS TMF OneSource

Thorough evaluations specific to client needs are made prior to plan development to help ensure successful outcomes

Special treatment for special studies

Solution Details

Client Example #1

Multinational pharmaceutical and chemical company, primarily a producer of blood plasma-based products, a field in which it is the European leader.

As customer satisfaction levels increased over the four years of our association with this worldwide pharmaceutical company, so have the number of projects and responsibilities. Starting out as an active user of DRS software and services for existing studies, the company has recently added a live migration of six new studies into DRS eTMF Ver. 2.0 software. They are also an active user of DRS OverSight -- services for all studies reporting on GAPS, issues, and the overall State of the TMF.

As another show of confidence in DRS, they are now moving responsibilities and studies away from their CRO and loading data into the DRS eTMF platform.

Recently, at the conclusion of a full audit of a large paper study that DRS ran for them and reported on all gaps, DRS was awarded with a blanket contract covering all audit services for all studies.

In that capacity, DRS will conduct more in depth, ongoing tracking of their live study progress in which trending is reported as well as performance of the document collection and missing items not in the study.

Client Example #2

Diversified biopharmaceutical company whose core purpose is to create medicines that help improve the lives of patients suffering from serious illnesses.

A DRS eTMF client using our software and services for all current 6 studies. Over the next quarter, they will be moving to version 2.0. And they will be migrating thirteen existing 'closed' studies into the DRS eTMF for archiving. As a result, all studies -- current and closed -- will then be on a common platform.

Client Example #3

A leading science and technology organization founded by physician-scientists delivering life-transforming medicines for serious diseases.

This client originally purchased software from a well-known vendor and required DRS migration services to bring all of the current studies into the new eTMF system.

These studies resided in various formats within the system. Since several of the studies were maintained in paper, they required DRS services to scan, attribute, and ultimately provide them with a file structure that could be imported into the new software system.

DRS services were utilized to MAP the fields from other eTMF platforms into the software system referencing a spreadsheet provided by the client.

At most recent count, this is now the fourth time the client has turned to DRS for this type of project – over 250,000 line items!

Summary

When clinical studies managers acquire eTMF software, more and more they turn to the DRS eTMF service professionals to migrate and verify TMF content. The integration then proceeds efficiently, reliably and at the required quality levels. Working with sponsors, the DRS team identifies and reports on GAPS and filing integrity issues for immediate rectification.

"DRS made a big difference. With Team DRS as our TMF service partner, migration and training times were completed faster and more accurately increasing speed-to-implementation."

For more information, please contact Richard McQuade, Business Development rickm@drscorp.com

908.622.9240

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www.drscorp.com