



For more information,
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DRS Proactive OverSight

LOOKING OVER EVERYTHING
OVERLOOKING NOTHING

Problem

Without GDP, RBM and DRS an eTMF alone cannot ensure and/or remedy:

- **Correctness** -- Missing pages, image rotation, pages out of order, poor image quality and missing translations
- **Duplicate Identification** -- How to ID duplicates with different names
- **Submission Difficulty** -- Dependent on many to submit & file docs singularly
- **End of Study TMF Cleanup**

Solution

DRS eTMF has the application and services to have a great eTMF

- Structure that allows GDP disciplines
- Quality documents
- Complete TMF
- Standardized structure incorporating both sponsor and DIA guidelines
- Rapid rollout
- Agile CR and SR process
- Ability to incorporate Services as required to manage and review TMF
- New tools can be incorporated to manage collection

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 over 30 years' document management expertise particularly in the areas of collection, indexing and the QC of extraordinarily large numbers of documents utilizing Risk Based Monitoring.

Proactive OverSight

GAP Analysis

Metric Analysis

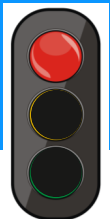
Dashboard Reports

Risk Based QA

Inspection Ready

Results

- Installed DRS's eTMF software and services that monitor GDP disciplines
- Standardized structure incorporating both sponsor and DIA guidelines
- Quality Document collection and Risk Based TMF assessment
- Analysis of metrics through *Audit Reviews* to correct GDP issues and retrain
- Reducing risk with *Metrics* that measure overall TMF health
- *Proactively* mitigating GAPS in the study as they occur
- *Inspection Ready* state throughout the study life



TMF
NOT
READY

Don't ignore the warning signs.

Contact us today for a no obligation demonstration.