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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

Proactive OverSight

GAP Analysis

Metric Analysis

Dashboard Reports

Risk Based QA

Inspection Ready

% Optimized

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.

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.