

CASE STUDY

The “Easy” button for eTMF classification

Using AI to Streamline Classification of
Clinical Trial Documents

| EXECUTIVE SUMMARY

A growing CRO recognized that the amount of time spent to ingest documents from multiple clinical sites over multiple trials significantly increased costs and project delays. As the number of trials expanded, the increase in costs and delays became even more troubling. The problem was compounded by a dwindling number of CRAs who possessed knowledge to classify these documents due to workforce challenges. The CRO set out to find a solution to more effectively utilize the people within the company.

| ABOUT THE CLIENT

The client is a growing CRO with a specialty in the CNS therapeutic area. To support their rapid growth the CRO sought to hire more people. But it was proving difficult to find enough clinical staff with the experience and knowledge to classify the documents accurately for import into the DIA eTMF reference model.

| THE CHALLENGES

The first challenge was to ensure that the personnel reviewing the documents from the clinical sites were able to process those documents. Often, multiple documents were combined, scanned, saved in a single PDF and emailed to the CRAs. Extracting, separating, and determining what to do with each document was a very manual effort. CRAs needed to manually break up large files into several individual documents. After the documents were separated, CRAs needed to apply a standard naming convention.

Often clinical sites provided files with non-conforming file names. Once renamed, each document was filed into the appropriate location in the DIA eTMF file/folder structure. This labor-intensive process required knowledge of the overall eTMF structure and for the CRAs to read each document and determine the appropriate folder to store the document based on the content within.

| THE SOLUTION

The solution provided by Court Square Group & Adlib Software used the RegDocs365™ eTMF platform, integrated with Adlib 7 content processing software. The combined solution was able to intelligently identify and assign the meta-data, automatically classify the documents, and to file the documents to the appropriate locations within the eTMF structure.

Based on client preference the system used a pre-defined naming structure to rename the files to make them more meaningful and representative of the originating location. Once the files were broken up into separate documents the system applied a standard naming convention and put each document into the appropriate location into the DIA eTMF file/folder structure. This required knowledge of both the overall eTMF structure and an AI analysis of each documents' content to determine where they should be placed.

| THE RESULTS

The combined solution provided by Court Square Group & Adlib Software was able to replace the manual effort that required 7-9 minutes per document of manual processing time to less than five minutes to review the *entire* results of the classification engine and accepting the recommendations from the system.

The solutions delivered approximately **75% savings** in time from manual effort and an **increase in the accuracy** in the classification of the documents based on their content. In addition to the time and accuracy improvements, the solution freed-up CRA resources since they only needed to review the and accept the system's recommendations rather than opening, reading, and manually manipulating documents.

Once the recommendations were accepted, the documents were stored and classified in the appropriate locations within the eTMF structure for easy review and retrieval by clinical personnel.

| CALL TO ACTION

Implementing the solution provided by Adlib and Court Square will improve your resource allocation. Enable staff to save time and focus their efforts on more meaningful tasks to help drive better results for all clinical trials.

| ABOUT ADLIB

Adlib is a document conversion and transformation platform that delivers unsurpassed accuracy, automation, and third-party integration. Companies trust Adlib to access and convert multiple file types from multiple sources, automate manual data entry processes, and generate submission-ready, technically-compliant documents of record.

| ABOUT COURT SQUARE GROUP

Court Square Group is a leading managed services technology company dedicated to empowering those who change lives. Our Audit Ready, Compliant Cloud™ (ARCC) infrastructure provides Life Science companies with the highest level of data integrity from pre-clinical to clinical and regulatory approval through manufacturing. We manage the 21 CFR Part 11 validated infrastructure so you can focus on secure Clinical Collaboration & Content Management.



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