# Case Study

## Healthcare & Insurance

# A Major Healthcare and Life Sciences Services Company Enhances the Capabilities of eTMF with Intelligent Automation

eTMF (Electronic Trial Master File) is a specialized content management system to manage documents across the lifecycle of a clinical trial. It is a fully digital 'single record of truth' of all documents that are generated and shared over the course of a trial. Despite of it being beneficial at many levels, there are limitations like it cannot classify documents automatically or extract metadata. This leads to huge manual effort, an extended quality check process and a lost opportunity to cut millions of dollars in expense.

## About the Client:

Our client is a global Clinical Research Organization, a world leader in providing end-to-end solutions in conducting clinical trials for biotech companies, medical device companies and pharmaceuticals. It is one of the largest players in the industry with a focus on Phase II-IV trials, having revenue of over USD 11 Billion.

The client conducts clinical studies across multiple sites, regions and countries for a long duration, resulting in huge volumes of semi-structured and unstructured documents with varied templates and information. The studies involve tons of paperwork, globally spread out sites, hundreds of collaborators, multiple versions of same documents and compliance to extremely stringent protocols.

## Business Challenges:

- Huge manual effort required to read, classify documents, perform quality checks and upload to eTMF system; requires 15-25 minutes per document
- High number of backlogs and errors in classifying and processing the documents
- Increased overhead costs in hiring additional SMEs with specific expertise to handle new types of documents
- Inability to meet safety reporting timelines
- More time required in interacting and harmonizing activities among geographically separated sites

## What was the client looking for?

The client wanted to automate the manual processes and achieve a flexible eTMF process.

**The new solution was expected to:**

Classify the documents as per the TMF reference model

Perform QC and extract metadata information present in the documents and upload in the eTMF system.

## Solution:

We partnered with the client in building and deploying an AI-driven automation solution with machine learning capabilities to automate the manual processes of classification and QC, thereby improving performance of the overall eTMF process.

## Key highlights of our solution:

- Cognitive OCR (optical character recognition) converts the scanned documents into text format and pre-processes them with segmentation and noise-reduction. Also extracts spatial information of the fields.
- Detects the language, interprets the text in the documents and classifies them according to the 4000+ categories, leveraging machine learning. Also extracts the metadata information about the configured fields present in the documents. The classification and extraction results are displayed to the end user with confidence level calculated based on statistical models.
- Delivers real-time visibility on trial documentation quality and status across the organization.
- Reads and classifies 143 document classes which cover 80% volume of total TMF filings.
- The user-based learning capability of the solution continuously learns and updates through feedback loop from corrections performed by the end users.

## Business Benefits:

We delivered a solution that empowered the client on all critical fronts, namely scalability, profitability, customer experience and performance.
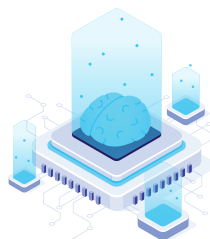
**Our solution ensured the following:**

**90%**
increase in document accuracy

Capability to process up to
**3000** documents in **69** minutes

Savings of up to
**80%** time per quality check

Enabled classification of the imported documents based on **machine learning algorithm** with no manual effort

**Eliminated** process inefficiencies

**Naming convention** in the beginning, based on the DIA TMF Reference Model

## Conclusion:

The Intelligent eTMF solution automated manual processes, reduced total TMF review time, increased team efficiency, enhanced security and reduced overall costs. With end-to-end solutions for conducting eTMF implementation and a global delivery model, we can help your business also achieve strategic goals.

## About Hexaware

Hexaware is the fastest growing next-generation provider of IT, BPO and Consulting services. Our focus lies on taking a leadership position in helping our clients attain customer intimacy as their competitive advantage. Our digital offerings have helped our clients achieve operational excellence and customer delight. We are now on a journey of metamorphosing the experiences of our customer's customers by leveraging our industry-leading delivery and execution model, built around the strategy— 'Automate Everything™, Cloudify Everything™, Transform Customer Experiences™.' Hexaware services customers in over two dozen languages, from every major time zone and every major regulatory zone. Our goal is to be the first IT services company in the world to have a 50% digital workforce.

Learn more about Hexaware at http://www.hexaware.com

**NA Headquarters**
Metro 101, Suite 600,101
Wood Avenue South, Iselin,
New Jersey - 08830
Tel: +001-609-409-6950
Fax: +001-609-409-6910

**India Headquarters**
152, Sector – 3
Millennium Business Park
'A' Block, TTC Industrial Area
Mahape, Navi Mumbai – 400 710
Tel : +91-22-67919595
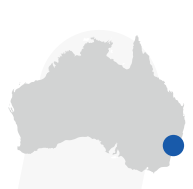Fax : +91-22-67919500

**EU Headquarters**
Level 19, 40 Bank Street,
Canary Wharf,
London - E14 5NR
Tel: +44-020-77154100
Fax: +44-020-77154101

**APAC Headquarters**
180 Cecil Street,
#11-02, Bangkok Bank
Building, Singapore - 069546
Tel : +65-63253020
Fax : +65-6222728

**Australia Headquarters**
Level 26, #44, Market
Street Sydney,
NSW 2000, Australia
Tel : +61 2 9089 8959
Fax : +61 2 9089 8989