

HEXAWARE

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

Boosting Clinical Trials with AI

Case study



Client

- | Client
- Challenge
- Solution
- Benefits
- Summary

Our client, a global Clinical Research Organization, stands at the forefront of clinical trial solutions for biotech, medical device, and pharmaceutical companies. With revenues surpassing USD 11 Billion, they specialize in Phase II-IV trials, conducting extensive studies across multiple sites, regions, and countries.



Challenge

Client

Challenge

Solution

Benefits

Summary

The Burden of Manual Effort

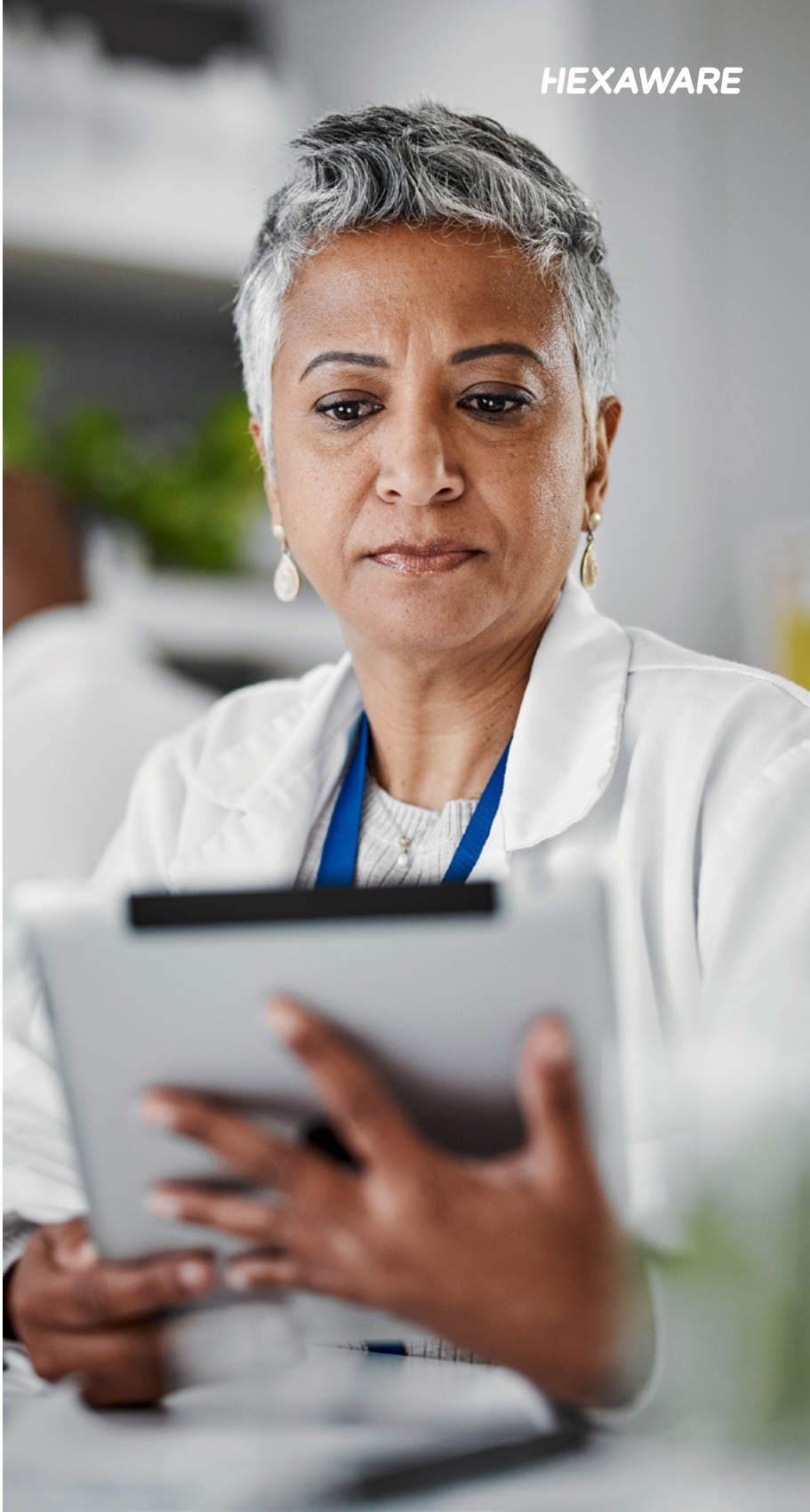
For our client, managing clinical trial documentation became a laborious process. With an Electronic Trial Master File (eTMF) system in place, their expectations were high, but limitations became evident. The system lacked the ability to automatically classify documents or extract metadata, leading to significant manual effort and an extended quality check process. As a result, valuable time was wasted, and expenses continued to escalate. Challenges included:

- Extensive manual effort for document reading, classification, and quality checks, taking 15-25 minutes per document.
- High number of backlogs and errors in classifying and processing documents.
- Increased overhead costs due to hiring additional SMEs with specific expertise to handle new document types.
- Inability to meet safety reporting timelines.
- Need for more time to interact and harmonize activities among geographically separated sites.

The Quest for Automation

Seeking to eliminate manual inefficiencies, the client aimed to implement an automated eTMF process that would:

- Classify documents according to the TMF reference model.
- Perform quality checks and extract metadata information.
- Improve compliance and safety reporting timelines.
- Enhance coordination among dispersed sites.



Solution

- Client
- Challenge
- Solution**
- Benefits
- Summary

We collaborated with the client to create and implement an advanced AI-driven automation solution equipped with machine learning capabilities, streamlining the labor-intensive classification and quality control processes within the eTMF system. The key components of our solution included:

- Cognitive Optical Character Recognition (OCR), converting scanned documents into text format and pre-processing them to enhance segmentation and noise reduction, as well as spatial data extraction.
- Document language detection and text interpretation, enabling classification into over 4,000 categories, driven by machine learning and metadata extraction from document fields.
- Classification and extraction of results, presented to end users with confidence levels calculated through statistical models.
- Real-time monitoring of trial documentation quality and status throughout the organization.
- Classification and categorization of 143 document classes, encompassing 80% of the total TMF filings.
- A user-based learning mechanism, continuously adapting and improving through feedback loops based on corrections made by end users.



Benefits

- Client
- Challenge
- Solution
- Benefits**
- Summary

Our solution propelled the client to excel in pivotal areas, encompassing scalability, profitability, customer experience, and performance. The achievements included:

- 90% enhancement in document accuracy
- 3,000 documents processed in just 69 minutes
- Up to 80% savings in time per quality check

The seamless classification of imported documents based on an **efficient machine learning algorithm** entirely eliminated manual effort.



Summary

- Client
 - Challenge
 - Solution
 - Benefits
- Our client, a leading Clinical Research Organization generating USD 11 Billion in revenue, faced document management challenges due to eTMF limitations. Collaborating with us, they deployed an AI-driven solution, reducing manual effort and boosting document accuracy by 90%, transforming their clinical trial management for more efficient and compliant operations.

| Summary



About Hexaware

Hexaware is a global technology and business process services company. Our 27,000 Hexawarians wake up every day with a singular purpose; to create smiles through great people and technology. With this purpose gaining momentum, we are well on our way to realizing our vision of being the most loved digital transformation partner in the world. We also seek to protect the planet and build a better tomorrow for our customers, employees, partners, investors, and the communities in which we operate.

With 40+ offices in 19 countries, we empower enterprises worldwide to realize digital transformation at scale and speed by partnering with them to build, transform, run, and optimize their technology and business processes.

Learn more about Hexaware at www.hexaware.com.

Get in touch