

Are you facing challenges in getting your arms around the vast documentation required for the FDA drug review process? Revolutionize your document processing and regulatory compliance with eTMF autoclassification powered by Court Square Group's RegDocs365 in collaboration with Docxonomy.

# **COMPLETENESS, QUALITY, & TIMELINESS: eTMF & eCTD AutoClassification**



Despite technology advancements, the clinical documentation process largely remains a human-centric activity. Today, Docxonomy's intuitive AI technology bridges the gap, automating collection, classification, formatting, and metadata extraction with human-like intelligence. And the results speak for themselves.

Manual Effort Reduction

This solution minimizes manual processing time by **75%**, allowing efficient review of classification engine results.

Enhance Accuracy

Reduce human error using AI and Machine Learning (ML) utilizing multiple Large Language Models (LLMs).

Accelerate Decision-Making

Transform large volumes of unstructured documentation into well-organized content in a fraction of the time.

Refuse-to-File Actions

In the face of rising regulatory standards, it's crucial to eliminate misclassifications and missing metadata to avoid RTFs.

Streamline FDA Submissions

Create a unified and organized Electronic Trial Master File (eTMF) to ensure TMF completeness - ensuring more efficient FDA submissions.

#### **Core Features of Court Square Group's AutoClassification Solution**

- ★ 21 CFR Part 11 audit trail
- ★ DIA TMF Reference Model/CDISC standard alignment
- ★ Built-in quality control checks for high quality output
- ★ Document collection and synchronization
- ★ Unstructured content transformation after completely combing content databases
- ★ Automatic OCR for content extraction
- ★ Al capabilities for timely data extractiont

#### THE BENEFITS SPEAK FOR THEMSELVES

Up to 90% reduction in RTF actions & up to 100% efficiency gain within six months.

### **MEET COURT SQUARE GROUP**



As a leading managed services technology company dedicated to empowering those who change lives in the pharmaceutical and life sciences space, Court Square partners with the market's most innovative AI technology companies to provide platforms and point solutions that accelerate decision-making, reduce operational costs, and improve company-wide productivity levels. Our partnership with RegDocs365 and Docxonomy provides our clients and partners with technology that is private, secure, and regulatory compliant so they can move to market quickly.

## **Simplify The Process**

