



SOLUTION OVERVIEW


Clinical Data Intelligence for Life Sciences

Intelligently classify, analyze, categorize and extract clinical data to speed regulatory approval



 **Streamline data collection** with a single point of capture

 **Easily search and find** results data

 **Extract context** from structured and unstructured trial documentation

 **Support FDA audit and reporting** requirements

While documentation is often captured within electronic trial master file (eTMF) solutions using electronic data capture (EDC) technology, Life Sciences organizations are left managing millions of records with little insight or intelligence into content and context. Yet maintaining quality metadata, combined with accurate classification of clinical trial documents, is invaluable to Life Sciences companies. By leveraging AI-augmented intelligent capture and data analytics, trial data is automatically classified, categorized, and analyzed, streamlining clinical trial processes and improving the trial-sponsored experience.

Clinical Data Intelligence for Life Sciences from OpenText™ automates classification and data extraction so trial documents can be accurately filed into any eTMF system. The addition of AI and natural language processing enhances metadata and text extraction used for self-training of exceptions, further automating and improving the classification of trial data. As a result of adding efficiency, automation and accuracy to the document-intensive clinical trial process, organizations accelerate regulatory filing for new medical entities to bring therapies more quickly and efficiently to market.

OpenText Professional Services: AI & Analytics Services

The OpenText™ Magellan™ Professional Services team includes data scientist and Life Sciences experts on application machine learning, text mining and algorithms in data analytics scenarios.

Use Case

A Life Sciences company wanted to improve the quality and efficiency of classification for clinical trial documents. With Clinical Data Intelligence, the company can now take advantage of capture and AI technology to improve data quality, expedite inspection readiness for validation and get to market faster.

Streamline data collection with a single point of capture

Clinical trials are often global in nature, resulting in content in various languages and document formats. Intelligent capture technology validates, captures and classifies data in an intelligent and consistent way, maintaining data integrity. With integrated machine learning, semi-structured and un-structured trial data is read, analyzed and automatically categorized to reduce discrepancies. The more documents that are added, the more intelligent the classification, further improving processes over time. Plus, information is routed directly to lead systems with simple-to-use workflows to eliminate the need for complex and costly system integrations.

Easily search and find results data

Classify and route clinical trial content, from mobile images to paper-based case report forms, without additional steps. When content enters a Contract Research Organization (CRO) or sponsor organization, key information is automatically extracted, such as trial identification numbers, patient identification numbers, signature identification (manually signed and labeled) and duplicity check. The solution automatically adds the content in the right place in the metadata, intelligently organizing and classifying the content to save valuable time. It determines where the content should go based on context and priority and makes it easy to find and readily accessible to meet "data lock-downs," filing deadlines and requirements. The addition of AI-augmented metadata and classification within Clinical Data Intelligence not only reduces time-consuming, manual tasks, but makes searching and finding results data easy.

Extract context from structured and unstructured trial documentation

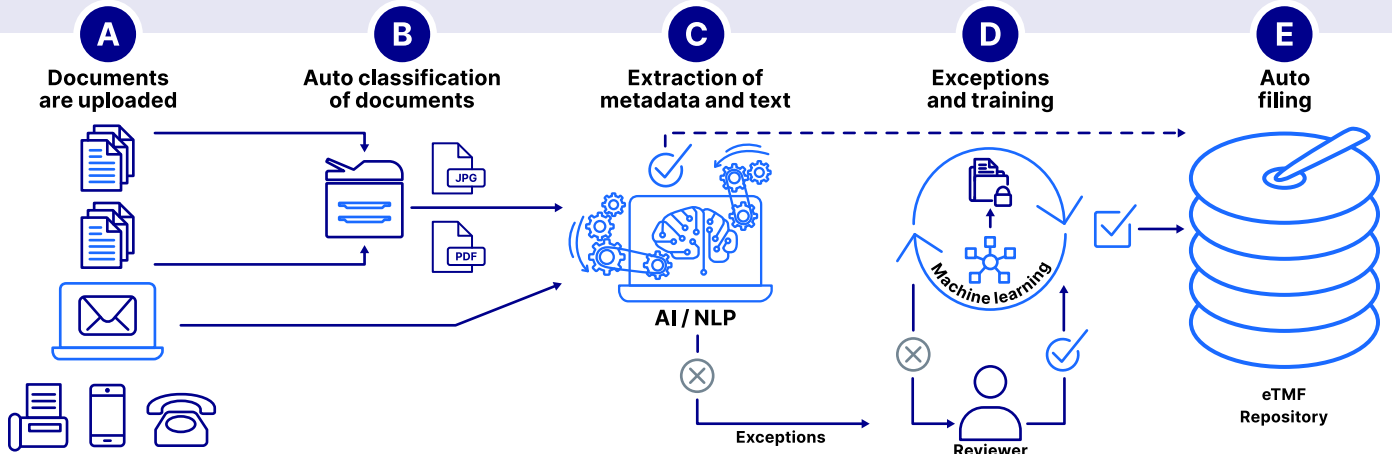
Easily and accurately extract text, from among millions of pages, to classify essential clinical trial documentation. Analytics and text mining tools go beyond simply tagging content, identifying key concepts, context, meaning and entities from vast amounts of unstructured content to harness its full potential for more complete trial outcomes. In addition, organizations can facilitate the identification of facts, trends, events and other relationships within large document collections to understand root causes in near real-time.

Support FDA audit and reporting requirements

Taking advantage of clinical trial management software introduces efficiency throughout the trial process, allowing organizations to establish and maintain Good Clinical Practices (GCP) to meet international ethical and scientific quality standards for trial design, performance, recording and reporting. Automatically classify trial content as it enters the organization to ensure that incoming content, including paper and email attachments, are properly identified based on all types of security and compliance tags, such as Personally Identifying Information (PII), geo-location and contracts. In addition, organizations can intelligently index and enrich archives to identify content that needs to be retained, archived or shared for more reliable information governance and regulatory compliance.

Clinical Data Intelligence for Life Sciences by OpenText

The solution provides an automated classification with data extraction mechanism to accurately and correctly file clinical trial documents into any eTMF system. By adding AI/NLP, it further enhances metadata and text extraction used for self-training of exceptions in automating classification of trial data.



Product	Solution
OpenText™ Intelligent Capture	Automate process initiation across departments with a single platform.
OpenText™ Magellan™ Content Analytics Suite	Leverage integrated text mining and natural language processing to make sense of text, millions of pages at a time.
OpenText™ Magellan™ Analytics Platform	Augment data-driven decision making and accelerate business with advanced artificial intelligence in a pre-built machine learning and big data analytics platform.
OpenText™ Artificial Intelligent & Analytics Services	Take advantage of Professional Services support from data scientists and experts on application machine learning, text mining and algorithms in data analytics scenarios.

About OpenText

OpenText, The Information Company, enables organizations to gain insight through market leading information management solutions, on-premises or in the cloud. For more information about OpenText (NASDAQ: OTEX, TSX: OTEX) visit: [opentext.com](https://www.opentext.com).

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