

Healthcare and life sciences (HLS) organizations face challenges with inefficient document workflows that lead to operational ineffectiveness, errors, and compliance problems.

To address these issues WinWire built an intelligent clinical document automation solution that can greatly enhance the quality of medical documentation to meet regulatory standards and guidelines.

WinWire's Clinical Document Automation Solution

WinWire's Clinical Document Automation Solution leverages Generative AI and natural language generation (NLG) to revolutionize drug development. By streamlining the creation and review of clinical trial documents, our platform speeds up time-to-market for new drugs and significantly reduces the risk of human error.

The solution generates documents like informed consent forms and clinical study reports that comply with regulatory standards set by the FDA, EMA, and ICH, ensuring that users meet regulatory requirements.

WinCDA - Clinical Document Automation



Preclinical Research

 IND (Investigational new drug) application generation



Clinical Research

- Clinical trial protocols generation
- Protocol summarization
- Protocol review
- Site contracts
- Informed Consent Form (ICF)
- Nonclinical IND summary documents
- Draft Investigators Brochures
- Generate safety patient narratives
- Clinical study report
- Document Compare



New Drug Application

- NDA (New drug application)
- NDA/BLA modules



Post-Market Safety Monitoring

- Phase IV study protocol and study reports
- Generate patient safety narrative

Key Features

Faster Review Cycles & Time Savings

Improves efficiency leads to shorter lead times for launching clinical trials & bringing new drugs to market.

Enhanced Accuracy and Compliance Assurance

Detects errors, inconsistencies, and deviations from regulatory standards



Improved Risk Mitigation & Patient Safety

Identifies potential safety concerns or ethical issues within clinical trial protocols & can cross-reference historical data & adverse event reports

Faster Approvals

Minimize review cycles with automation that generates formatted documents.

Business Value



Clinical Study Report (CSR)

Reduces the time required for CSR report writing, allowing for faster & more efficient documentation processes.



Protocol Summarization

Achieve comprehensive & precise summaries effortlessly, saving time and ensuring consistency.



Clinical Trial Narrative

Effortlessly generate tables and narratives for patient safety, enhancing accuracy & efficiency.



Summary Clinical Safety

Automate the creation of module summaries, ensuring consistent & precise safety data reporting.

Customer Story



WinWire empowered a genomics-based drug discovery company to expedite the analysis of clinical trial protocol documents for various personas by leveraging WinWire's Clinical Document Automation Solution. As a result, the company was able to significantly reduce the time needed for document review.

For more information, visit us at www.winwire.com









