



# Veridix Document Authoring Agent

## AI-Powered Authoring for Protocols, SAPs, CSRs and Other Clinical Trial Documents

Veridix Document Authoring Agent is an AI-enabled copilot purpose-built to streamline clinical trial document development. Designed for regulatory-grade use, it rapidly generates and refines complex trial documents – including protocols, statistical analysis plans (SAPs), and clinical study reports (CSRs) – by drawing on curated clinical knowledge, historical documents, and study metadata. By automating first drafts, redlines, and quality reviews, the Document Authoring Agent reduces manual effort, shortens cycle times, and improves consistency across studies and teams.

## Document Authoring Features

- **Rapid First-Draft Generation** – Generates full protocol, SAP, or CSR drafts in 3–5 days based on structured inputs such as indication, study phase, and endpoints.
- **Trained on Clinical-Grade Content** – Built on a foundation model trained using thousands of real-world protocols and statistical documents to ensure scientifically sound outputs.
- **Semantic Referencing & Template Reuse** – Accesses curated libraries of prior studies, regulatory guidance, and internal templates to inform and enhance generated content.
- **Smart Metadata Linking** – Connects to study metadata and structured data inputs (e.g., arms, endpoints, populations) for dynamic content generation and auto-updating.
- **In-Line Editing & Redline Support** – Offers collaborative review with tracked changes, rationale for edits, and versioned document history.
- **Consistency Checks & Quality Flags** – Scans for discrepancies across sections (e.g., mismatched objectives, endpoint inconsistencies) and flags outdated or missing content.

### What Sets Veridix Apart?

100+

Integrations

1K+

Studies

8K+

Sites

60K+

Users

1M+

Participants

300M+

Records



# Document Authoring Benefits

## Accelerates Trial Timelines

Reduces protocol authoring time by over 60% and enables teams to meet aggressive study startup deadlines.

## Improves Consistency Across Documents

Applies standardized language, structure, and regulatory references to ensure uniformity and reduce rework.

## Reduces Manual Workload

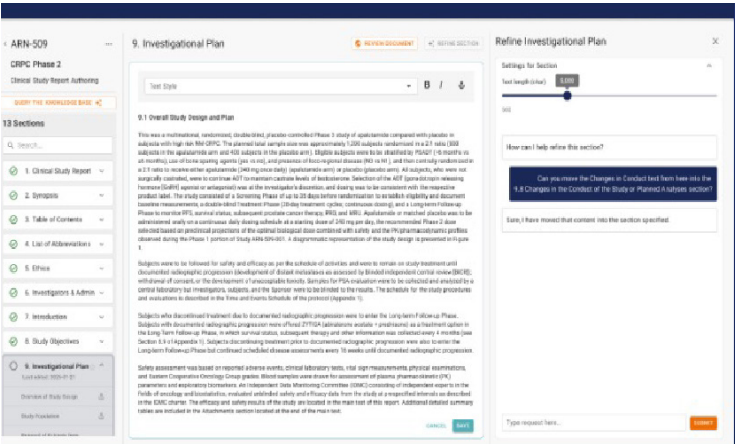
Shifts effort from drafting to reviewing, freeing medical writers and statisticians to focus on scientific oversight.

## Enhances Collaboration

Enables medical, regulatory, and biostatistics teams to work from a single source of truth with clear edit histories and approval workflows.

## Supports Audit Readiness

Provides full traceability of AI-generated content and version history to meet regulatory compliance needs.



Document Authoring Interface – Protocol Drafting Example

Accelerated  
Drafting With  
AI-Powered Precision

Reduced  
Review and  
Revision Burden

Trained by and  
Oversight from Emmes  
Domain Experts

# Why Choose Veridix Document Authoring?



## Purpose-Built for Clinical Research

Designed specifically for trial authoring, not retrofitted from general-purpose AI. Reflects domain-specific workflows and regulatory demands.

## Trained on Verified Historical Documents

Leverages prior protocols, SAPs, and CSRs to generate accurate, relevant content aligned with your organization's standards.



## Integrated with Study Systems

Seamlessly connects with metadata repositories and trial design platforms to streamline data-to-document workflows.

## Explainable and Transparent AI

Delivers outputs with source traceability, version control, and rationales for edits to maintain trust and auditability.



## Validated Across Sponsors and Therapeutic Areas

Proven in real-world use across vaccine, oncology, CNS, and rare disease trials.

# Document Authoring Use Cases:

- ✓ Protocol drafting for new studies
- ✓ Statistical analysis plan (SAP) creation
- ✓ Clinical study report (CSR) generation
- ✓ Automatic document updates from metadata changes
- ✓ Cross-checking documents for content consistency
- ✓ Redline support during review cycles

