Clinion | ePROTOCOL

Solution Sheet

From Synopsis to **Protocol-Draft** in **Hours**

Clinion eProtocol uses AI to turn a synopsis into a structured, compliant protocol draft in hours, while medical writers retain full control over all final decisions and content approval.

80%

FFaster protocol development

Generate up to 80% of a protocol draft in hours not weeks.

100%

Compliant by design

Aligned with ICH M11, TransCelerate or Sponsor templates from the first draft.

60%

Cost and time savings

Accelerate protocol development while reducing resource requirements.

THE PROBLEM

Protocol authoring is still driven by fragmented, document-based processes

Developing a protocol often involves working across multiple documents, templates, reference materials, and stakeholder inputs. Medical writers must coordinate content, maintain consistency across sections, and manage multiple review cycles. As protocols evolve, updates need to be reflected throughout the document, creating rework, increasing the risk of inconsistencies, and extending development timelines.

THE SOLUTION

Empower medical writers with AI-assisted protocol authoring

Clinion eProtocol transforms a synopsis and supporting documents into a structured protocol draft aligned with **ICH M11, TransCelerate, and sponsor** requirements. Rather than replacing the medical writer, it **removes manual drafting effort** so teams can focus on scientific judgment, review, and protocol refinement.

HOW ePROTOCOL WORKS

Four steps from Synopsis to Export

1

Upload your synopsis.

Add a summary and reference documents. AI extracts the key study details in the backend.

2

Generate a compliant draft.

AI creates a structured protocol in line with ICH or TransCelerate guidelines.

3

Collaborate and review.

Authors and Reviewers collaborate online with full version tracking.

4

Finalize and export.

Complete protocol authoring online and export a publication-ready protocol in Word document.

Purpose-built AI for Protocol Authoring

eProtocol is powered by specialized AI agents that automate key protocol development tasks while maintaining traceability and keeping critical decisions with the medical writing team.

Section Applicability Agent

Identifies required protocol sections based on the synopsis. You can approve or modify each recommendation.

Authoring Agent

Generates structured content with consistent terminology across the protocol.

Reviewing Agent

Reviews content against protocol-writing and regulatory standards, with a complete audit trail.

Impact Analysis Agent

Flags changes that may affect other sections before inconsistencies occur.

Regeneration Impact Agent

Detects downstream impacts when content is regenerated from edits or source documents.

Citation Agent

Creates clickable, traceable references in the exported protocol.

Nothing is finalized without human review

Protocol drafts are generated faster with AI assistance, while medical writers maintain oversight of the content and make all final decisions.

Why Clinion

- Faster Protocol Generation
- Built-In Quality Checks
- Evidence-Driven Authoring
- Empowering Medical Writers

About Clinion

Clinion

Clinion's AI-enabled eClinical platform brings together **EDC**, **RTSM**, **CTMS**, **eConsent**, **ePRO**, **eSource**, **eProtocol Automation**, **CSR Automation**, and **eTMF** in a unified ecosystem for clinical trials.

300k+	650+	150+	70+	20+
Patients	Clinical Trials	FDA Studies	Clients	Countries

Learn more at **www.clinion.com**