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ACCELERATE CLINICAL TRIAL START-UP
—BEGINNING WITH THE PROTOCOL

Deloitte helped AstraZeneca use Anthropic Claude powered Generative AI to write first drafts of clinical study protocols faster, and with shorter review cycles with scientists reviewing every step and every claim with clinical evidence.

Developing a new medicine involves a great deal of paperwork and approvals. One of the most important documents is the Clinical Study Protocol (CSP), the blueprint that sets out how a clinical trial will be designed and run.

AstraZeneca set out to compress CSP drafting and review cycles while maintaining scientific rigor and compliance expectations. Deloitte delivered Intelligent Protocol, an AI-assisted authoring capability powered by Claude models and designed with evidence-backed, human-in-the-loop controls to help teams research, draft and refine protocol content in standard, traceable ways.

By removing friction from a critical early step in trial start-up, teams can initiate studies sooner and spend more time on science and delivery—helping accelerate the journey from research to patient impact.

THE CHALLENGE

CSP authoring is traditionally manual, resource intensive and highly iterative—often spanning months as teams gather disconnected inputs, reconcile cross-functional feedback and merge study-specific narrative with required template language.

AstraZeneca faced three persistent challenges:

1 *Disconnected inputs*

Authors spent significant time tracking down prior protocols, reference materials and published literature without a unified starting point.

2 *Inconsistent standardization*

Protocols often varied across study teams, complicating reuse and increasing rework.

3 *Long iteration cycles*

Open-ended scientific narrative sections required repeated "search, draft, review, revise" loops across functions—creating pressure to move faster without compromising quality or compliance.

THE SOLUTION

Deloitte built a writing process in which AI agents do the heavy lifting and people stay in charge. It grounds its work in real science, reuses approved content, and lets writers draft interactively. The tool is powered by Claude, implemented on AWS/Bedrock and securely integrated into AstraZeneca's existing AWS technology environment. Claude drafts long scientific sections, answers questions about the source documents, and refines drafts; Deloitte designed the overall process, the step-by-step guidance, and the built-in review controls so it works for everyday use, with writers firmly in control.

HOW IT WORKS, END-TO-END:

1 *Research and gather*

The tool can rapidly identify and extract relevant content from prior protocols and scientific literature, while filtering and drilling down to the most pertinent sources for a current study.

2 *Synthesis and authoring*

The tool can help teams draft open-ended narrative sections and merge them with standard protocol language to produce a high-quality first draft faster.

3 *Iterate with functions*

The tool supports collaborative authoring and review, enabling quicker iteration cycles through AI-assisted research, drafting and quality checks—while keeping authors in control.

KEY CAPABILITIES:

- **Evidence-backed drafting (traceable):** Pull from prior protocols and scientific literature with inline citations to speed review and strengthen defensibility.
- **Reusable structure and from-scratch drafting:** Use pre-approved templates or libraries as a foundation, then add custom-written sections—this maintains the required structure while producing tailored content faster.
- **Guided, consistent authoring:** Section-level guidance and prompts help improve consistency across authors and protocol sections.
- **Interactive refinement:** Ask questions of source documents and iteratively edit drafts to validate assumptions and refine language.
- **Quality and governance built in:** Human-in-the-loop controls and agent-led quality checks help reduce avoidable rework before broader reviews.
- **Works with your existing tools:** Takes in rich content like tables and figures in many formats, and exports to the platforms teams already use for collaboration and approvals.

THE IMPACT

AstraZeneca has used the protocol authoring capability to develop two protocols for new studies, with six additional studies planned soon. The effort achieved approximately 50% time savings for Clinical Scientists and Medical Writers, while producing "clinically coherent and scientifically accurate" narrative outputs consistent with manually authored drafts.

WHAT'S NEXT

AstraZeneca plans to use the tool for more studies. Building on this foundation, there is potential to extend the same agentic authoring pattern—research, synthesis, collaborative iteration—to additional templates and document types across the clinical trials.

Contact to learn more:

GINA SCHAEFER
ANTHROPIC ALLIANCE LEADER
Deloitte Consulting LLP
gschaefer@deloitte.com

SUBADHRA PARTHASARATHY
MANAGING DIRECTOR
Deloitte Consulting LLP
suparthasarathy@deloitte.com