



Beating the Clock: From Concept to Protocol in Under a Week

How Veridix Helped a Clinical-Stage Biopharma Company Developing Novel Therapies for Infectious Diseases Beat the Clock on Protocol Development

Infectious disease trials don't wait. When the transmission season closes, so does the opportunity, and for a biopharma company racing to initiate a clinical study before that window shut, every day on the calendar carried real-world consequences.

To begin site feasibility and study initiation in the countries where the disease is active, the client needed a fully developed, submission-ready protocol in hand well before the season started. There was no room to absorb a traditional 8–10-week protocol development timeline. Missing the deadline didn't mean a delay. It meant losing the study year entirely. **This is what made speed not a preference, but a necessity.**

The Challenge

For this biopharma company, **the pressure wasn't just internal. It came from the disease itself.**

The indication under study is seasonal, active only during specific months, only in certain countries. Protocol development had to be completed early enough to allow site feasibility, country selection, and study startup to happen before that window opened. Traditional timelines simply couldn't accommodate that sequence.

Layered on top of this deadline were the usual complexities of protocol development

Literature reviews, synopsis drafting, and full protocol writing are each resource-intensive in isolation, doing them in sequence compounds the time pressure



Regulatory and compliance requirements don't show-off for urgency, every document still needs to meet the same standard of traceability, scientific rigor, and auditability

Cross-functional collaboration and iterative revisions create bottlenecks even under normal timelines

Additional subject matter expert input was needed at key stages, adding further coordination overhead

The question wasn't just how to go faster. It was how to go faster without cutting corners, with a hard, seasonal deadline that couldn't be negotiated.

The Solution

Veridix deployed VeriScribe™, its AI-powered document authoring agent, under a managed service model, giving the client an end-to-end, governed environment to move from study concept to finalized protocol without the traditional bottlenecks.

VeriScribe handled the heavy lifting across every stage of the process



Automated literature search: surfacing and synthesizing relevant evidence in real time, eliminating weeks of manual research



Synopsis generation: producing a structured, source-linked synopsis as the foundation for full protocol development



AI-assisted protocol drafting: generating a robust initial draft that immediately addressed the core scientific and regulatory requirements



Human-in-the-loop review: keeping expert oversight embedded throughout, ensuring accuracy, compliance, and explainability at every step



Revision workflows within a single platform: enabling rapid iteration without version chaos or collaboration delays

The result was a process where AI took on the repetitive, time-consuming work, and the company stayed focused on the decisions that required human judgment.

What would have taken 8–10 weeks under a traditional model was completed in 5 days.

The full scope, literature search, protocol synopsis, AI-generated draft, and document review, was wrapped up in under a week, giving the client the runway it needed to begin site feasibility ahead of the seasonal window.

The timeline wasn't just a speed achievement. It was what made the study possible at all.

What the Client Said

This biopharma company's experience with the protocol drafting process reflected what VeriScribe is designed to deliver- clarity, structure, and momentum from day one.

From the outset, expectations and responsibilities were clearly communicated, giving the client confidence in the process and a shared understanding of how the engagement would unfold. The quality of the initial draft stood out immediately, robust enough to address the core requirements and move the document meaningfully forward without multiple rounds of foundational rework.

“For a team working against a hard seasonal deadline, reaching 80% of the protocol in a fraction of the traditional timeline wasn't just efficient, it was what kept the study on track.”



For additional information on VeriScribe™, please visit:
<https://www.theemmesgroup.com/veridix/document-authoring>