CITELINE
REGULATORY

Use Case

Streamlining the Clinical Trial Workflow from Protocol Design to Regulatory Submission

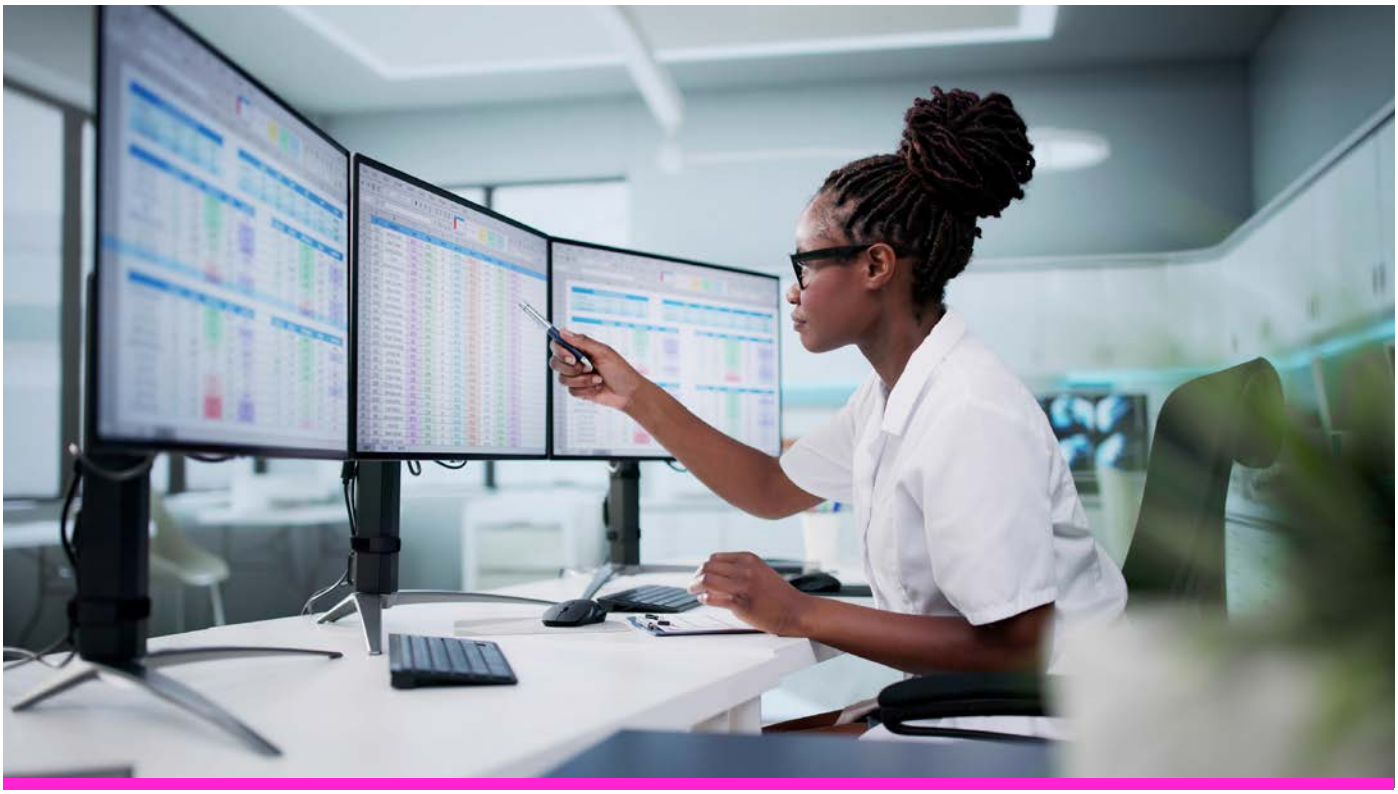
January 2026

The situation

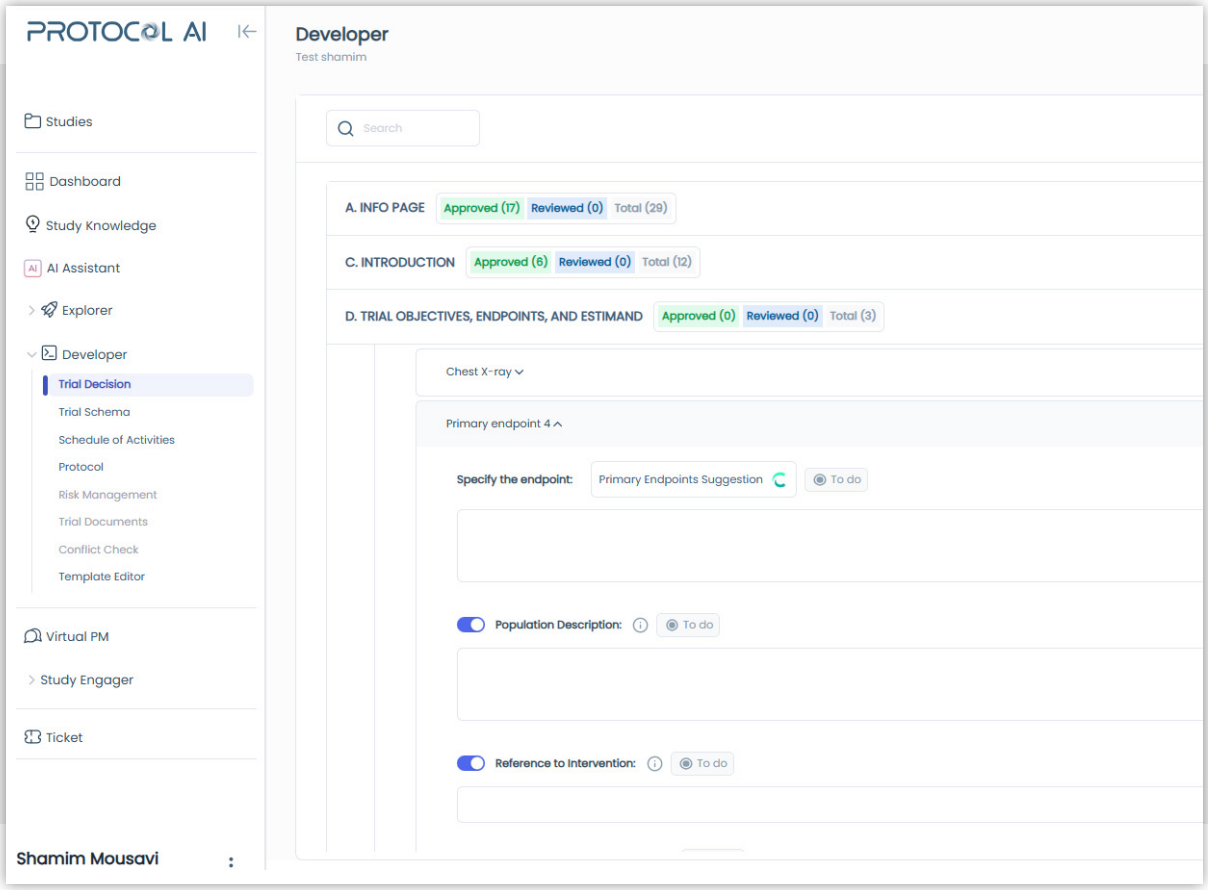
A sponsor in the early stages of planning a breast cancer clinical trial wanted to address potential stumbling blocks from the start. Its main concerns were costly protocol amendments and clinical trial regulatory submission, two areas at either end of the clinical trial life cycle that could threaten to disrupt the study's aggressive timeline.

Our approach

For many pharmaceutical companies, clinical operations and clinical disclosure teams typically work in silos. That's why this sponsor turned to Citeline, whose solutions span the R&D spectrum, from clinical trial design to patient engagement/recruitment to clinical trial disclosure.

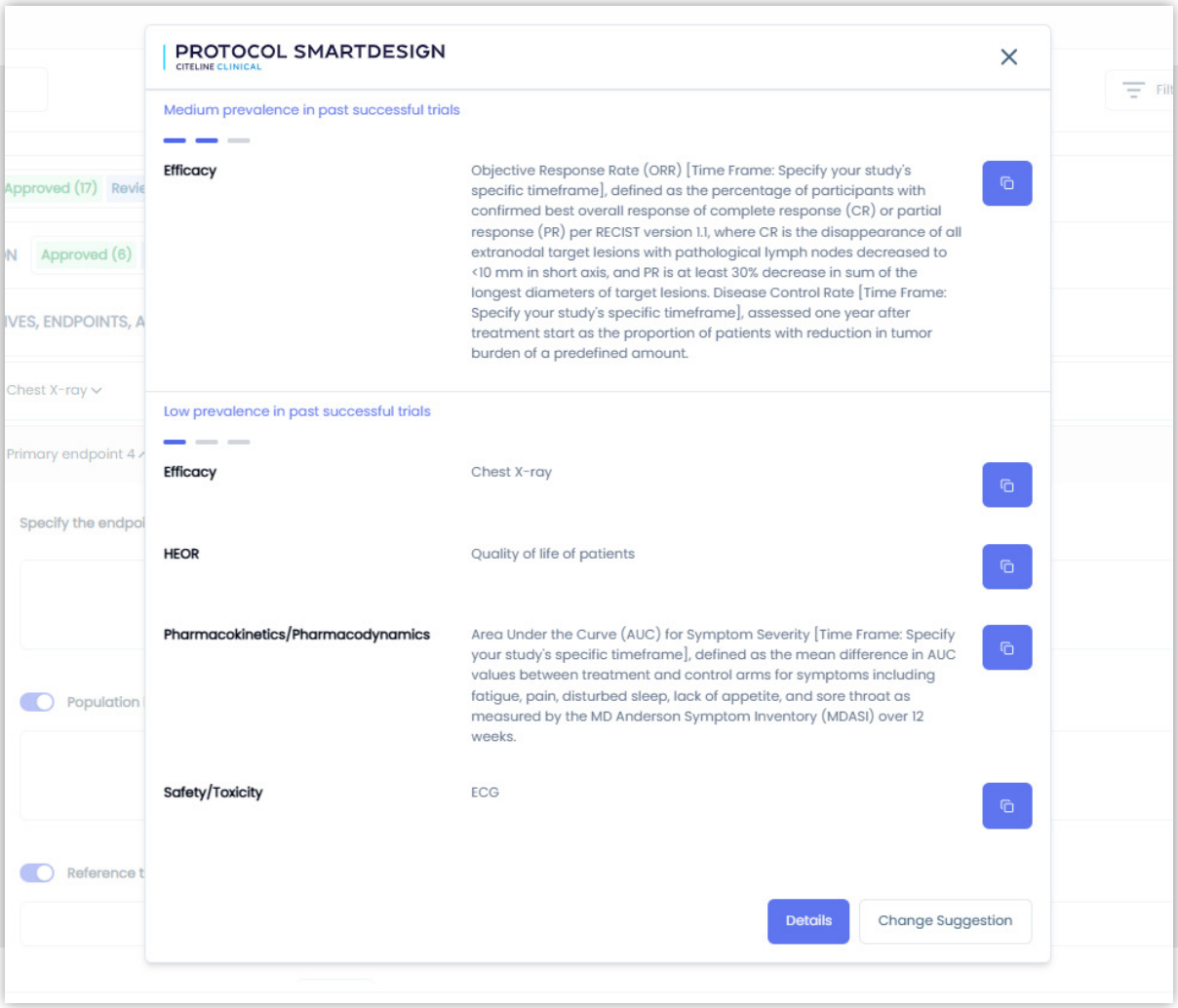


The process

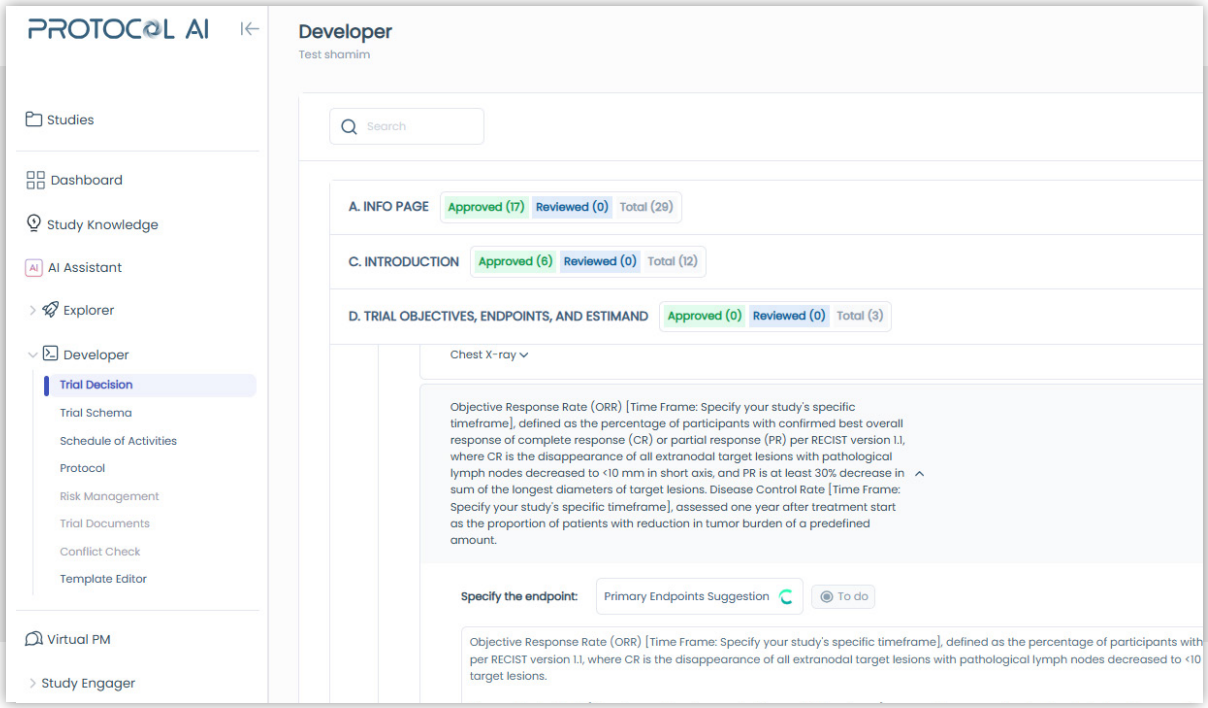


The Citeline-Risklick partnership gives this sponsor gets the best of both worlds. Both Citeline and Risklick harness the power of AI to refine the protocol design process.

Protocol SmartDesign mines Citeline's Trialtrove and Sitetrove data for successful trials similar to the sponsor's. It then instantly generates primary endpoints and inclusion/exclusion criteria for the sponsor's trial. **Risklick's AI platform** uses these recommendations to rapidly design a high-quality protocol.



But the efficiencies don't end there. When the sponsor is ready to submit its protocol to regulatory agencies, the AI Importer feature of **TrialScope Disclose** takes over. **AI Importer** does more than simply import the protocol into TrialScope Disclose — it automatically maps relevant data to the corresponding fields in the submission form.



And, with the **Global Disclosure Form** in TrialScope Disclose, the sponsor can prepare, approve, and submit to multiple registries all in one unified platform.

The difference

Unlike many other clinical trial disclosure solutions, which only offer a clinical trial management system (CTMS), Citeline offers sponsors the clinical component. By creating a direct line from clinical planning/protocol design to clinical trial disclosure, Citeline helps sponsors optimize the entire process.

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The benefits

Thanks to Citeline's holistic approach, the sponsor can realize efficiencies from start to finish.

50% reduction
in protocol development time

20% reduction
in protocol amendments

up to 85% reduction
in time to prepare clinical trial disclosure submissions

What this means for the sponsor:

- Accelerates the entire clinical planning process
- Reduces burden on staff
- Avoids costly, time-consuming protocol amendments
- Improves communication between ClinOps and Disclosure teams
- Promotes consistency and minimizes error in regulatory submissions
- Boosts likelihood of clinical success

Discover how TrialScope Disclose takes the tedium out of regulatory submissions.

LEARN MORE

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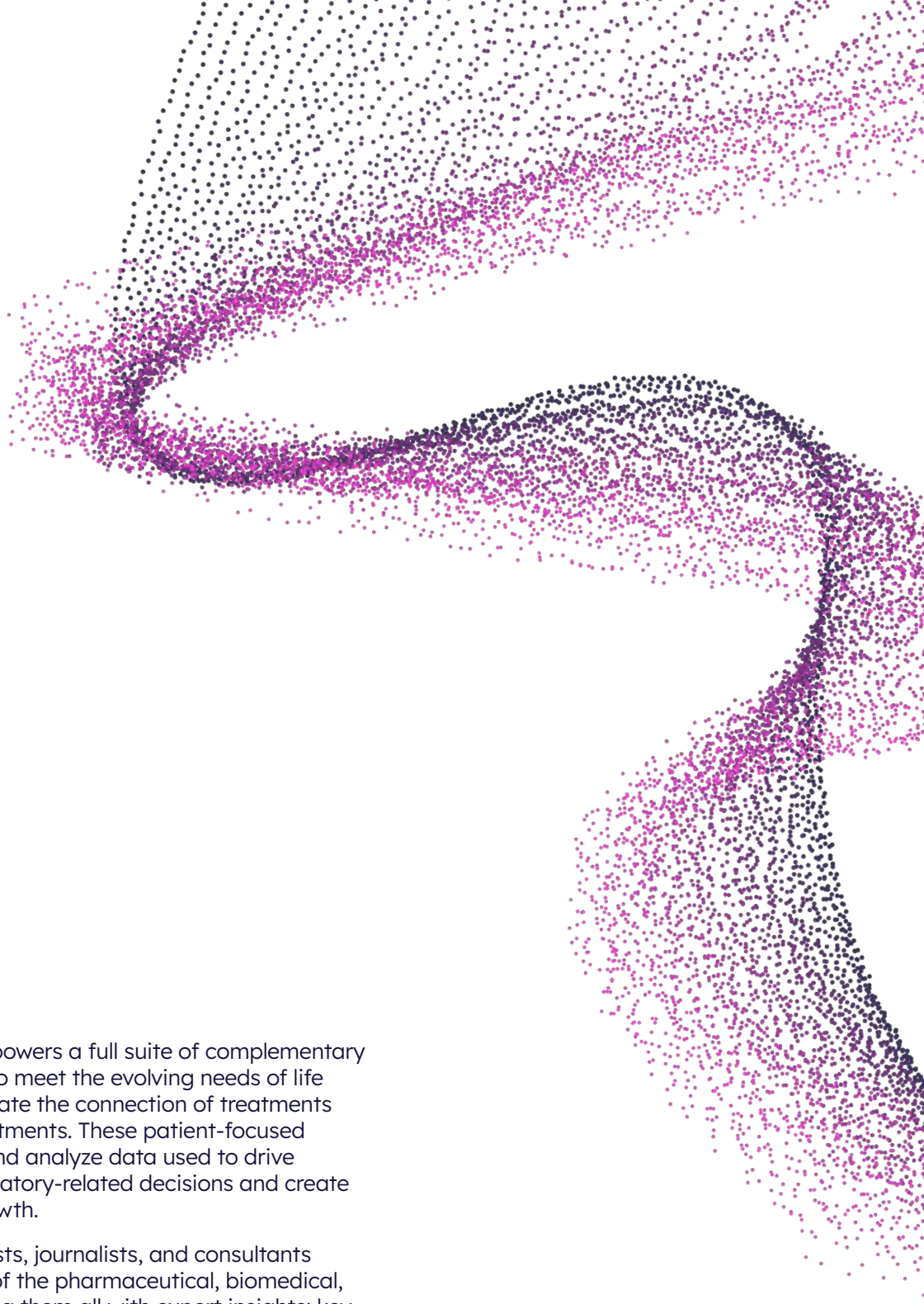

About Citeline

Citeline, a Norstella company, powers a full suite of complementary business intelligence offerings to meet the evolving needs of life science professionals to accelerate the connection of treatments to patients and patients to treatments. These patient-focused solutions and services deliver and analyze data used to drive clinical,- commercial-, and regulatory-related decisions and create real-world opportunities for growth.

Citeline's global teams of analysts, journalists, and consultants keep their fingers on the pulse of the pharmaceutical, biomedical, and medtech industries, covering them all with expert insights: key diseases, clinical trials, drug R&D and approvals, market forecasts, and more. For more information on one of the world's most trusted health science partners, visit Citeline and follow on LinkedIn and X.
