

Use Case

Biotech Vets CROs with Trifecta of Data, AI, and Study Savvy

Global Expansion Demands On-point Strategy

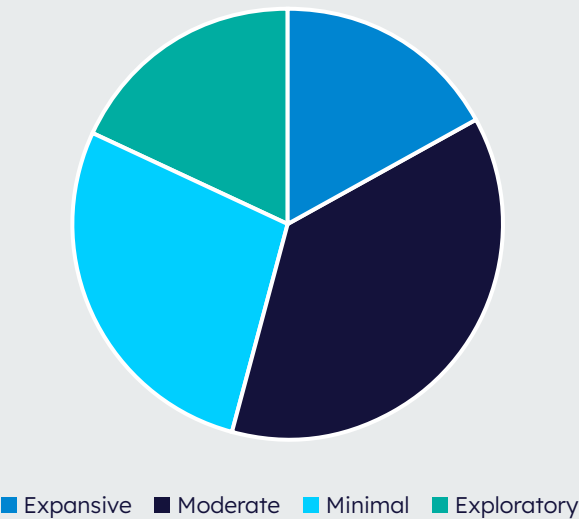
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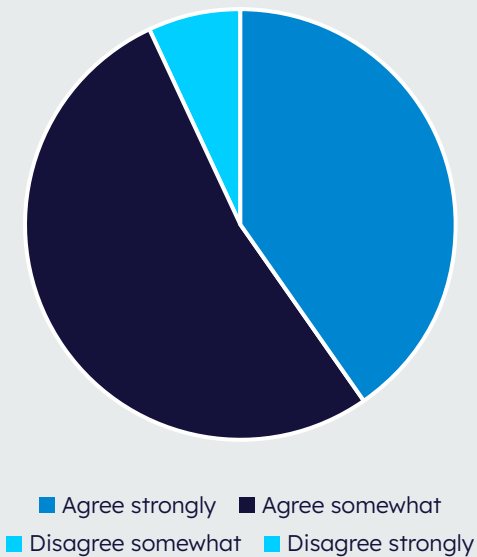
Executive summary

According to a recent survey of biopharma executives by TriNetX, a partner of Citeline’s parent company Norstellla, more than half of the respondents are embracing AI in the context of RWD. A substantial majority (93%) said they thought AI technologies could make RWD more accessible and actionable in drug development.

How biopharma leaders describe their application of AI to RWD



“AI technologies have the potential to make RWD more accessible and actionable in drug development.”



Source: TriNetX

At Citeline, we’re harnessing AI to tease out the most relevant insights from our massive datasets. One area benefitting greatly from this marriage of AI and RWD is clinical trial recruitment. Here, our proprietary AI algorithm uses site and investigator performance metrics to predict a study’s feasibility, as well as help us identify patients who need to fit into often tightly defined inclusion/exclusion (I/E) criteria. Read on to see how we’ve combined AI with RWD to help a biotech plan for, select, and better manage the CRO relationship.

The challenge

A biopharma company specializing in the treatment of mood disorders completed early phase work and was preparing to expand to global studies. This necessitated contracting with a CRO.

This biotech focused on a single asset and, while its small team was extremely knowledgeable about the science behind the drug, it was less adept at clinical operations and thus would need to rely heavily on its CRO. Because all its eggs were in one basket, so to speak, the sponsor was understandably cautious and wanted an expert, unbiased review of prospective CROs and their recommendations. The client sought to vet the CROs based on data, not just on the relationships the CROs have with their own sites.

The sponsor sought:



Help with protocol development/writing



Input on study feasibility



Strategic guidance on working with a CRO



The approach

As with all clients, Citeline met with key stakeholders to determine their unique requirements, establish timelines, and develop the best path forward. Citeline quickly discovered that the biotech wanted answers to specific questions, including:

-  What should our protocol entail?
-  What protocol design elements are more associated with successful recent trials?
-  How can we determine the study's feasibility?
-  What should our country and site strategy be?
-  How will various strategies perform vis-a-vis forecasted recruitment durations and rates?

With that in mind, Citeline scheduled two workshops: one on the study protocol, and one on feasibility. To ensure client participation in the process, Citeline collaboratively created the two scenarios with the help of its AI-powered SmartSolutions products, Protocol SmartDesign and Investigator SmartSelect, both of which incorporate proprietary RWD. This transparent approach enabled the client to observe live manipulation of the datasets — which also included curated data from both public and proprietary sources across Trialtrove+, Sitetrove+, and Global Patient Insights — and view the subsequent output.

Knowing that some smaller biotechs require more handholding along the way, the Citeline team walked the client through the process, explaining what datasets would be involved and how they would be used. Biotechs like this one appreciate the fact that Citeline does not merely serve up data, it enriches that data and provides guidance. That advice is based on fact, backed by historical data, and it provides strategic direction to make the data actionable.

The outcome

The client realized both short- and long-term benefits through its partnership with Citeline.



Short-term value:

- As a smaller sponsor whose team members wear many hats — such as procurement and regulatory — it was quicker and more cost-effective to have Citeline to use the data tools instead of having to be trained to use them.
- Entering the CRO selection process, the client was in a much stronger position.
- The client maintained control of its strategy, relying on the CRO to simply execute against it, not run the show.

Long-term value:

- After conducting a feasibility assessment and establishing a sound strategy, the client was set up for a greater probability of success.
- The protocol was developed expeditiously, balancing medical and operational elements to help avoid amendments down the road, and saving associated downtime and costs.
- The client found in Citeline a vendor it could trust, knowing that its Consulting & Analytics services could be scaled up or down as priorities shift.





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](#).

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