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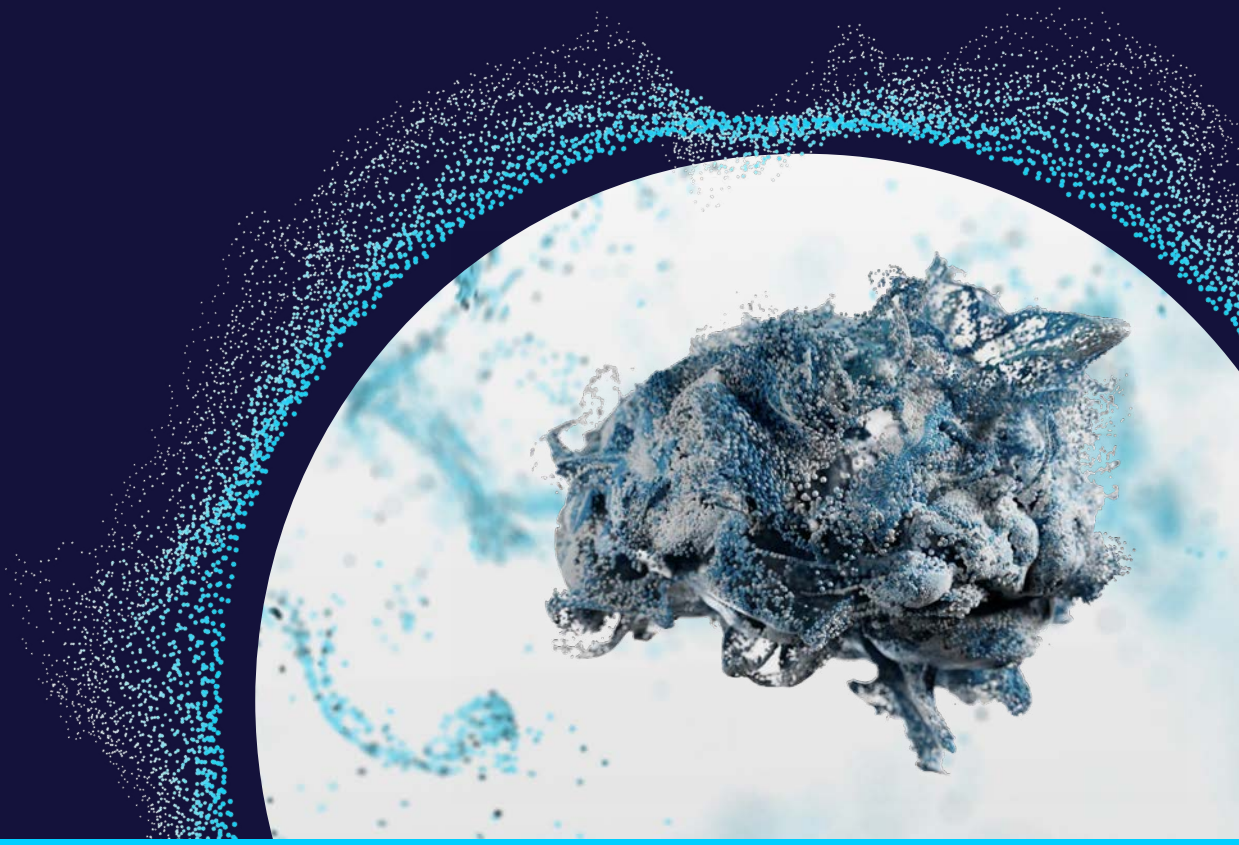
USE CASE

Optimizing a Breast Cancer Clinical Trial with Data-Driven Solutions

A global pharmaceutical company is preparing to conduct a clinical trial for a novel breast cancer treatment. The company uses a suite of Citeline solutions to accelerate trial planning and study start-up to ensure a data-driven and efficient approach. These solutions provide instant recommendations on key trial parameters — based on the gold standard in clinical trial data in Trialtrove and Sitetrove, which the pharmaceutical company has relied on for years for protocol development and investigator and site selection.



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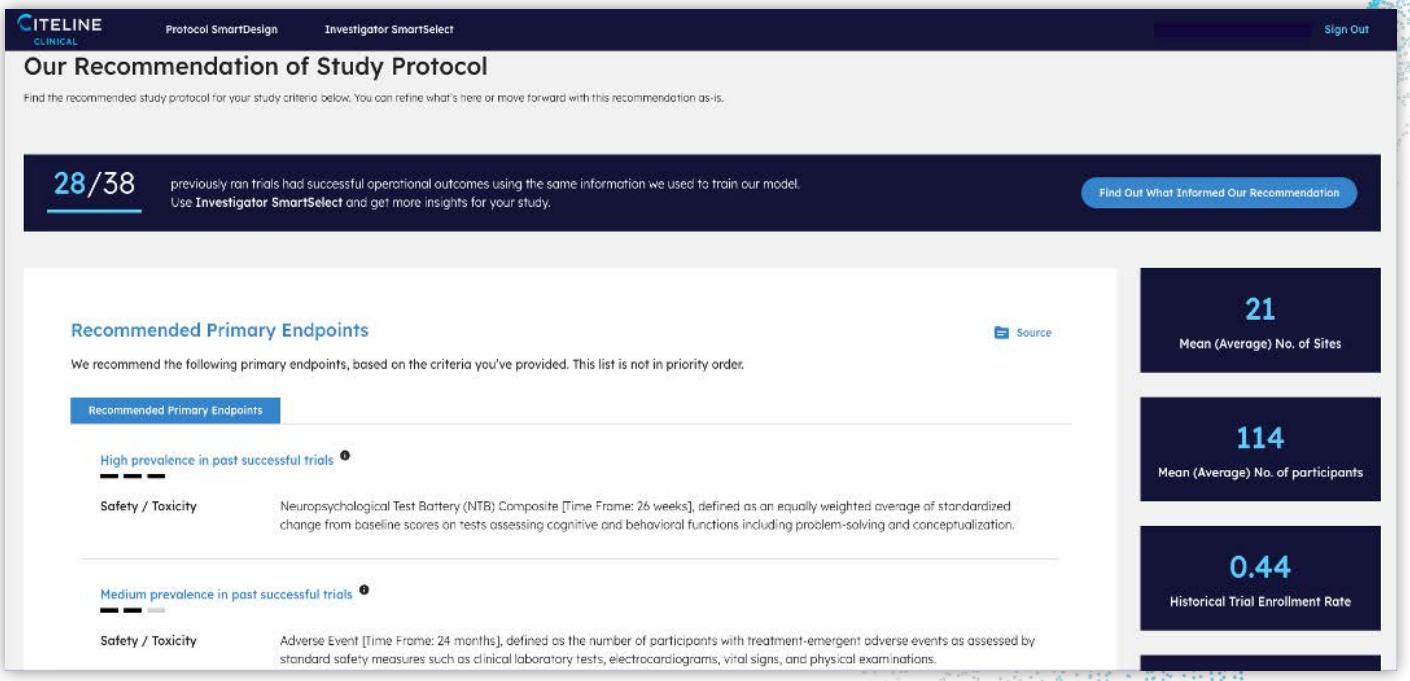
Step 1:
Determining Primary Endpoints & I/E Criteria

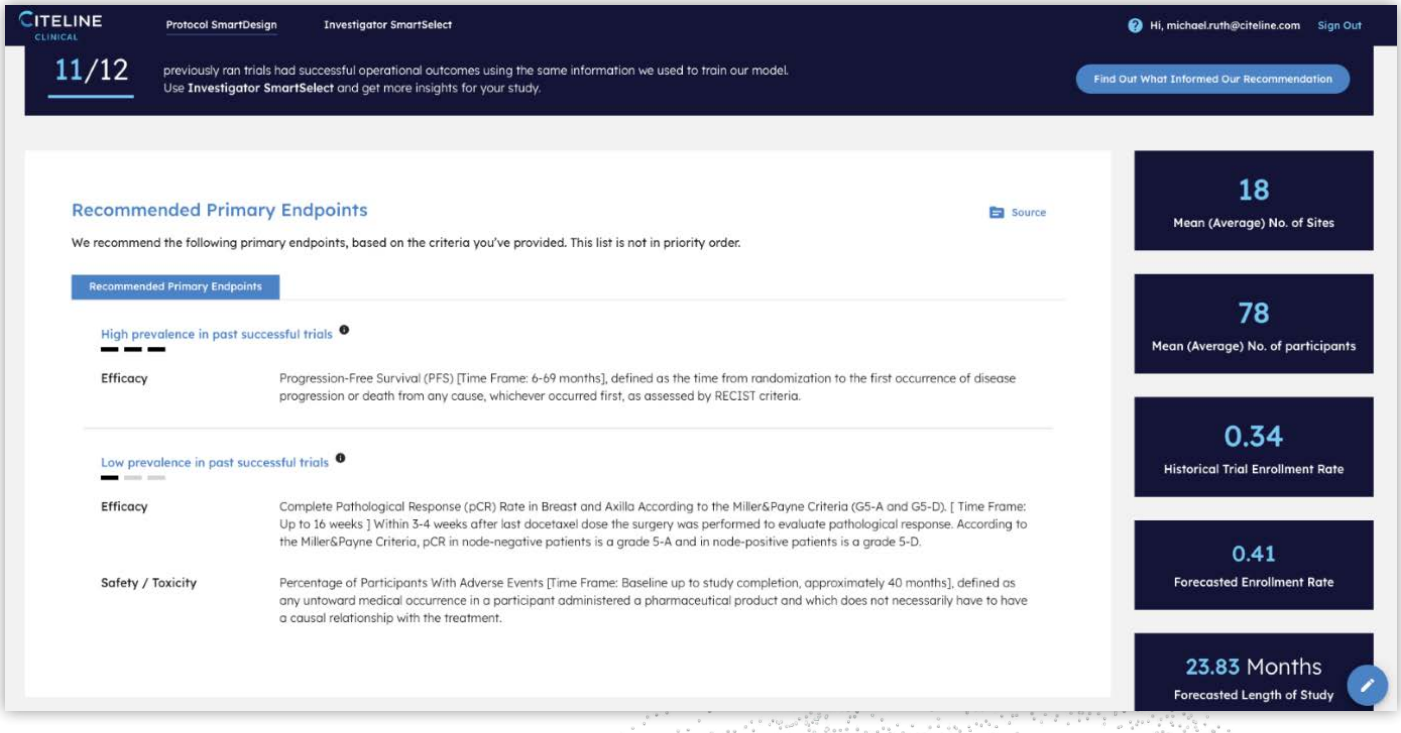
The company defines the type of breast cancer trial they need to run in Protocol SmartDesign, which provides recommendations for primary endpoints. These suggestions are tailored to the specific subtype of breast cancer being targeted, such as HER2-positive, triple-negative, or hormone receptor-positive breast cancer.

Protocol SmartDesign also suggests inclusion/exclusion (I/E) criteria, which factor in key patient characteristics such as age, tumor stage, previous treatments, and genetic markers. After reviewing the suggestions, the company modifies the I/E criteria slightly to align with their study's focus on patients with a specific mutation. The platform updates the projected study duration in real-time, ensuring the company is aware of how these adjustments affect the trial timeline.



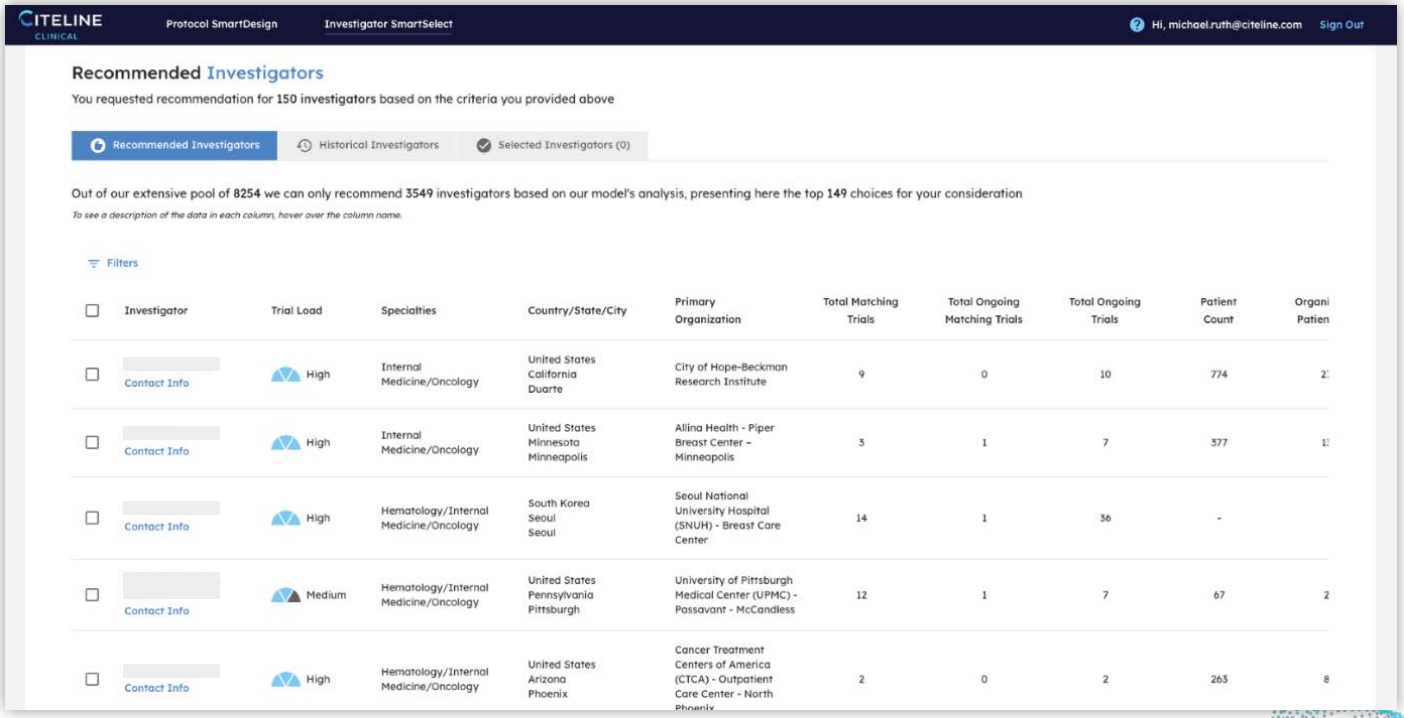
Step 2:
Forecasting Length of Study

By refining the I/E criteria, the company immediately sees how their changes impact the forecasted enrollment duration. This dynamic feedback enables the team to balance the scientific rigor of the criteria with the practical considerations of recruiting breast cancer patients who meet their specific trial parameters. Protocol SmartDesign ensures that the trial is designed to meet both scientific and operational needs.



Step 3:
Selecting Countries and Investigators

The company then moves to select the best countries and investigators to run the trial. Investigator SmartSelect generates a list of recommended investigators account with a strong history of success in breast cancer trials, considering factors such as investigator expertise in treating the specific subtype of breast cancer and their capacity to run a new study. The platform will also recommend countries and investigator allocation.



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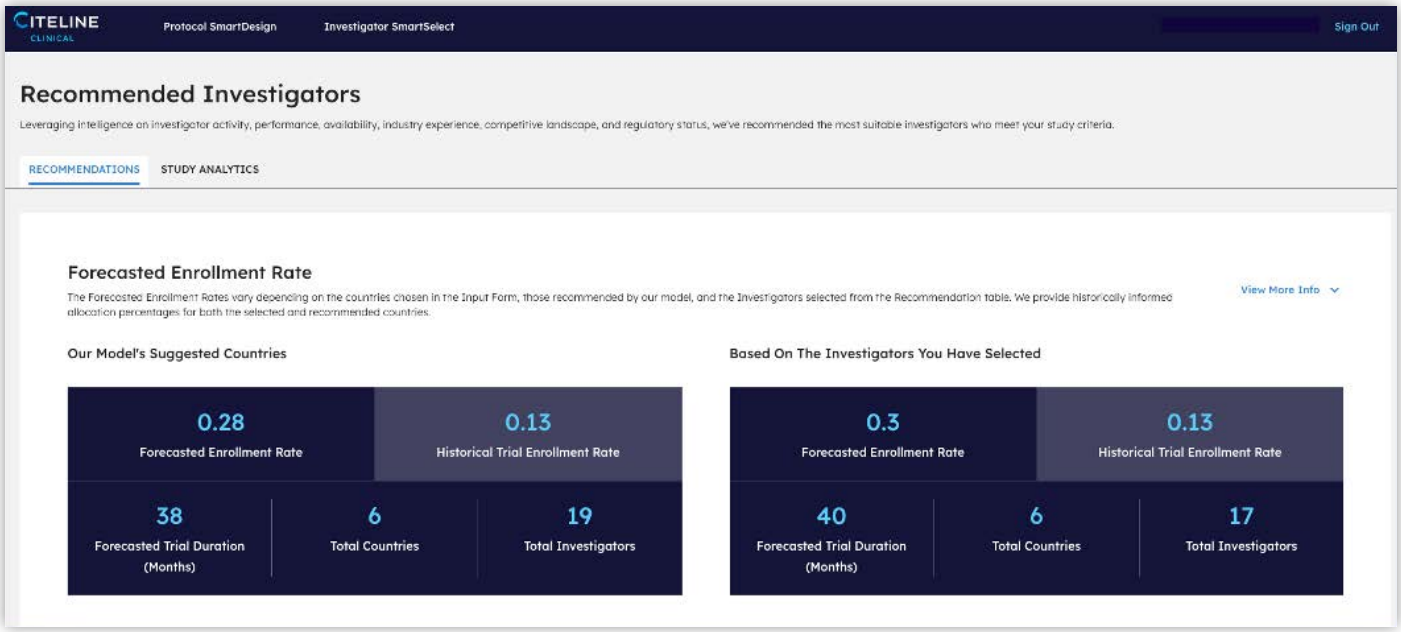
The company can see forecasted enrollment rates, allowing them to fine-tune the selection of countries and investigators until the trial's timeline is optimal. Adjusting the mix of countries and investigators ensures they can hit enrollment targets within the desired timeframe.



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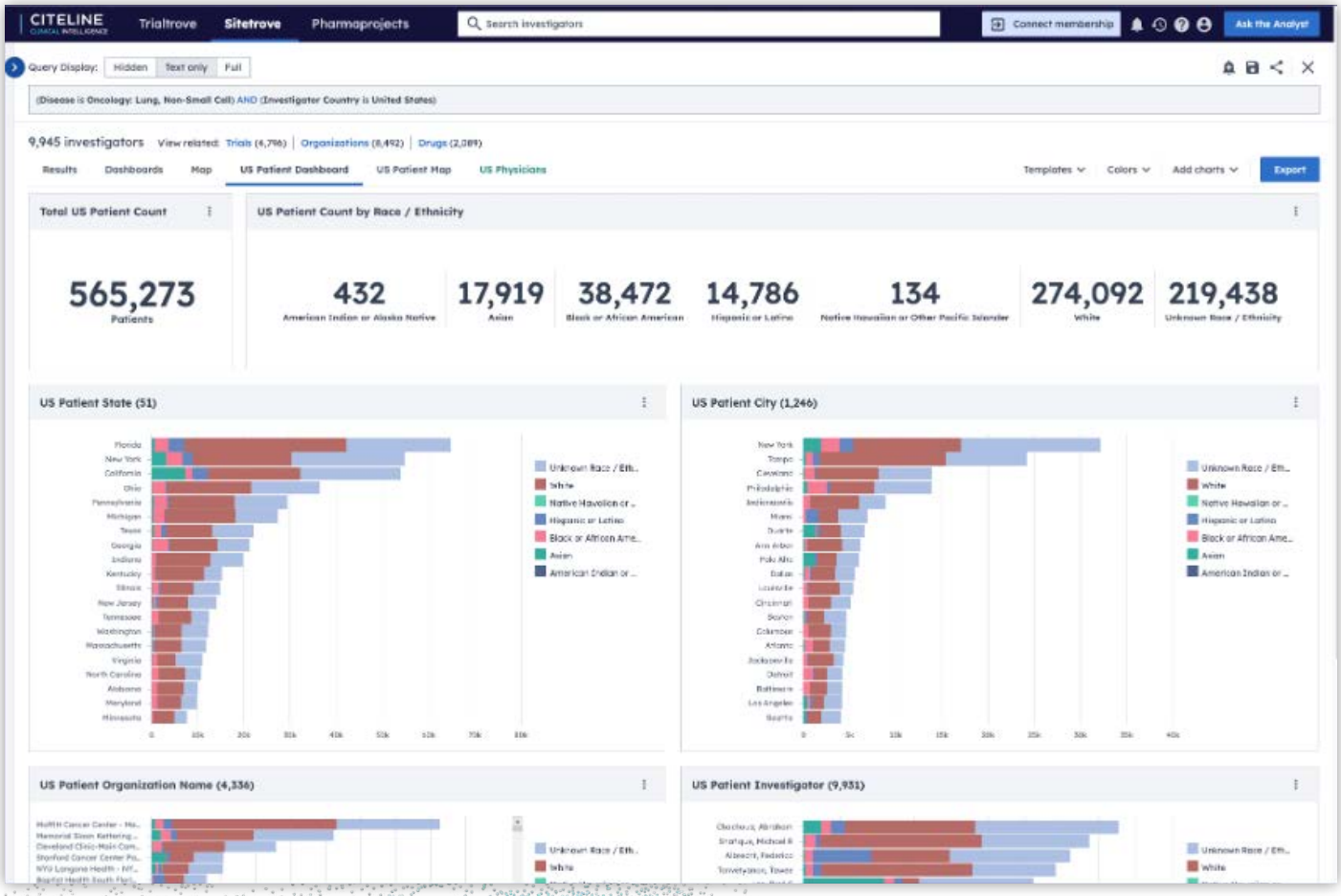
Step 4:
Investigating Patient Populations and Diversity Goals

Once the investigators are selected, the team leverages Sitetrove's Global Patient Insights to explore patient populations at the selected sites.



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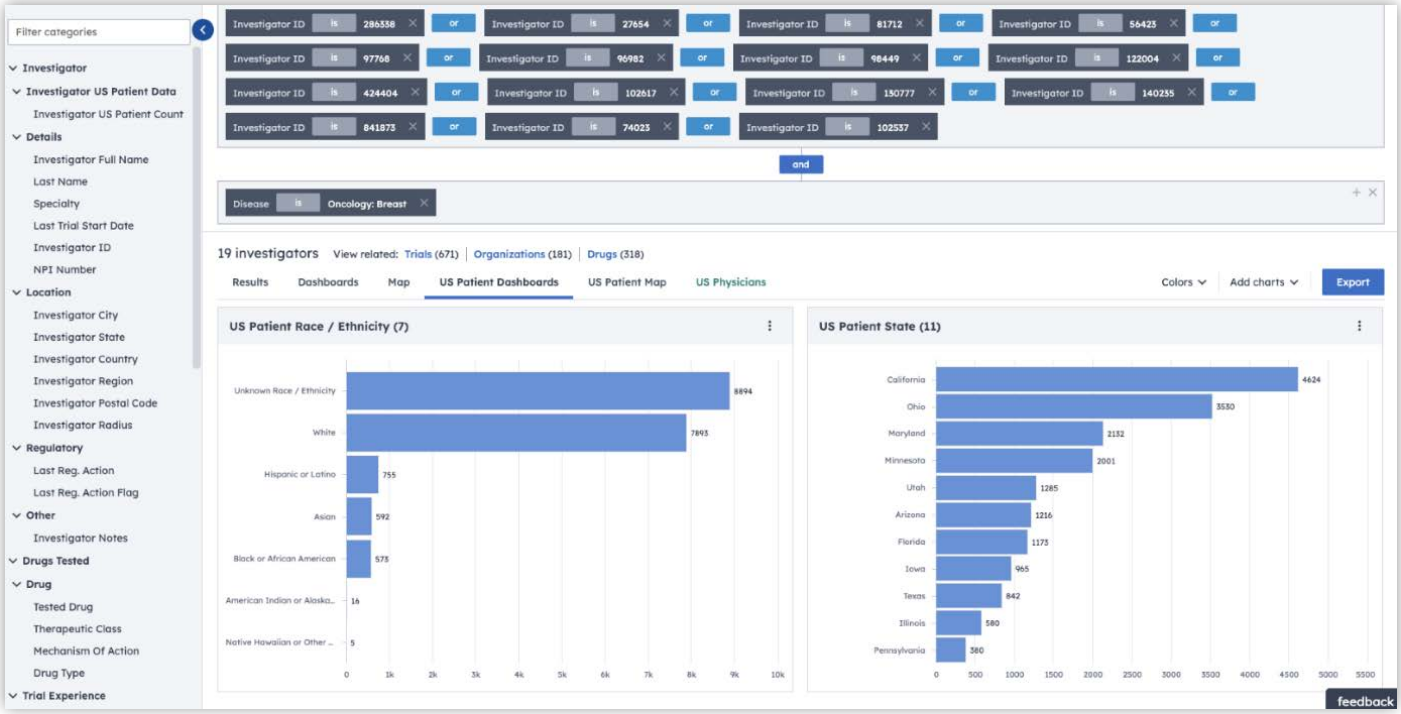
This feature allows them to analyze whether there are enough eligible breast cancer patients available in the targeted regions. Importantly, they also confirm that the selected sites can meet all diversity goals, ensuring representation across race, ethnicity, and age groups, which is critical for breast cancer trials where specific populations may have higher risks or respond differently to treatments.



Step 5:
Finalizing the Trial Plan

With a breast cancer trial design that has been optimized for both patient recruitment and trial timeline, the pharmaceutical company is ready to move forward confidently. By leveraging real-time data and predictive analytics, they've created a trial that not only meets scientific objectives but also ensures a diverse and representative patient population, critical to the study of breast cancer treatment outcomes.

Leveraging the power of Citeline SmartSolutions, Trialtrove, Sitetrove and Global Patient Insights, this company produced a protocol that had limited amendments, investigators who could successful run and recruit for the trial, allowing them to hit enrollment goals and complete the study on time and on budget.

Learn how Citeline can help you optimize and accelerate clinical trial planning and site selection.

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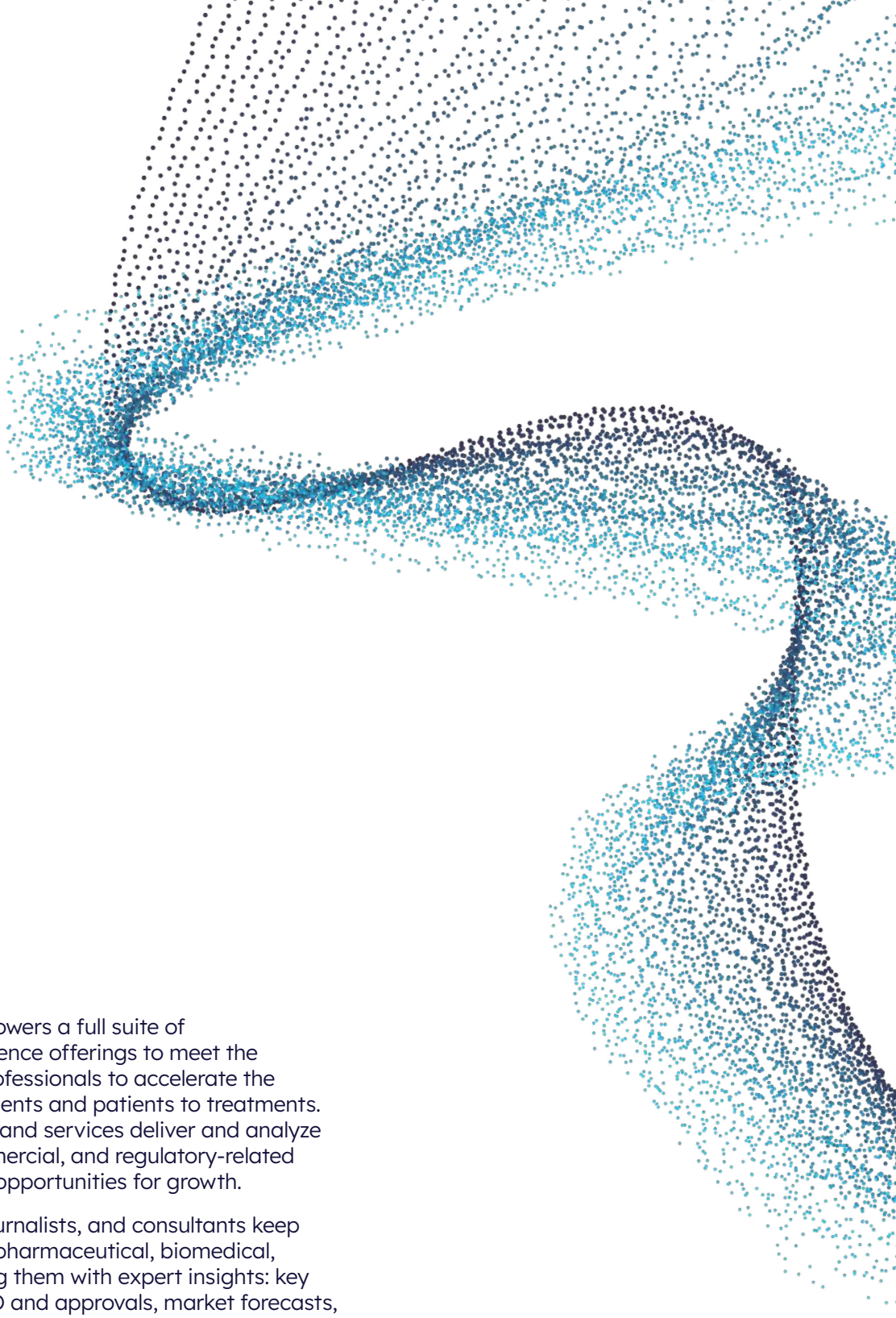

About Citeline

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.

Our global teams of analysts, journalists, and consultants keep their fingers on the pulse of the pharmaceutical, biomedical, and medtech industries, covering them 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 life science partners, visit Citeline and follow on LinkedIn and X.