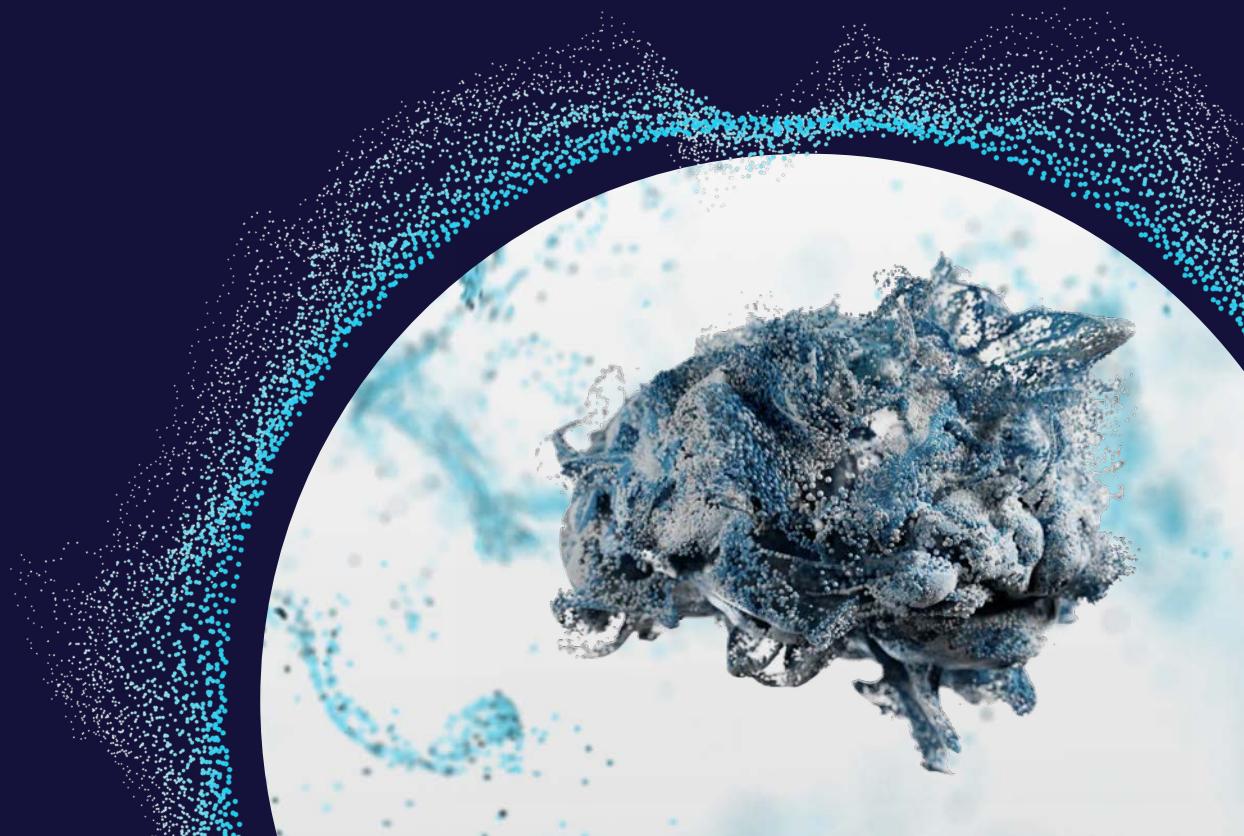


USE CASE

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.

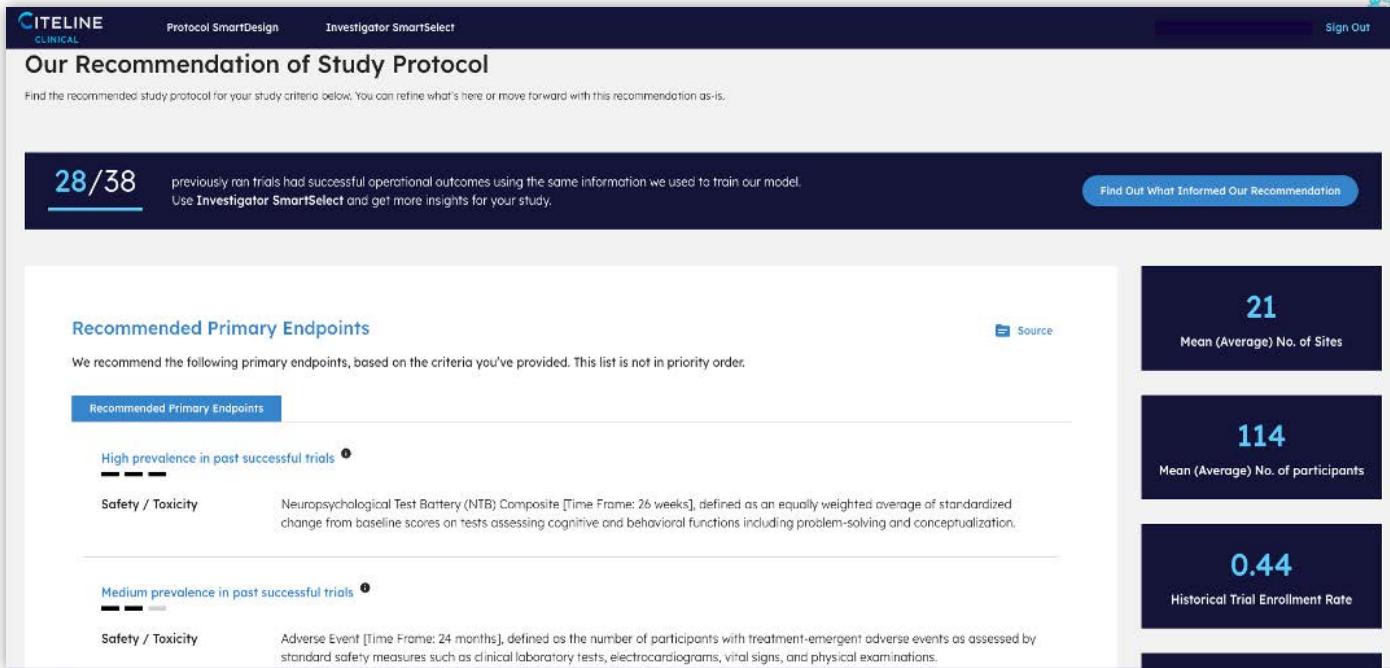


Use Case | Optimizing a Breast Cancer Clinical Trial with Data-Driven Solutions

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.



The screenshot shows the CiteLine Clinical interface for Protocol SmartDesign. At the top, there are navigation links for 'Protocol SmartDesign', 'Investigator SmartSelect', and 'Sign Out'. Below this, a section titled 'Our Recommendation of Study Protocol' is displayed. It includes a sub-section for 'Recommended Primary Endpoints' and a summary of previous trials. On the right side, there are three summary boxes: 'Mean (Average) No. of Sites' (21), 'Mean (Average) No. of participants' (114), and 'Historical Trial Enrollment Rate' (0.44).

Protocol SmartDesign | **Investigator SmartSelect** | **Sign Out**

Our Recommendation of Study Protocol

Find the recommended study protocol for your study criteria below. You can refine what's here or move forward with this recommendation as-is.

28/38 previously ran trials had successful operational outcomes using the same information we used to train our model. Use **Investigator SmartSelect** and get more insights for your study.

Find Out What Informed Our Recommendation

Recommended Primary Endpoints

We recommend the following primary endpoints, based on the criteria you've provided. This list is not in priority order.

Recommended Primary Endpoints

High prevalence in past successful trials

Safety / Toxicity Neuropsychological Test Battery (NTB) Composite [Time Frame: 26 weeks], defined as an equally weighted average of standardized change from baseline scores on tests assessing cognitive and behavioral functions including problem-solving and conceptualization.

Medium prevalence in past successful trials

Safety / Toxicity Adverse Event [Time Frame: 24 months], defined as the number of participants with treatment-emergent adverse events as assessed by standard safety measures such as clinical laboratory tests, electrocardiograms, vital signs, and physical examinations.

21
Mean (Average) No. of Sites

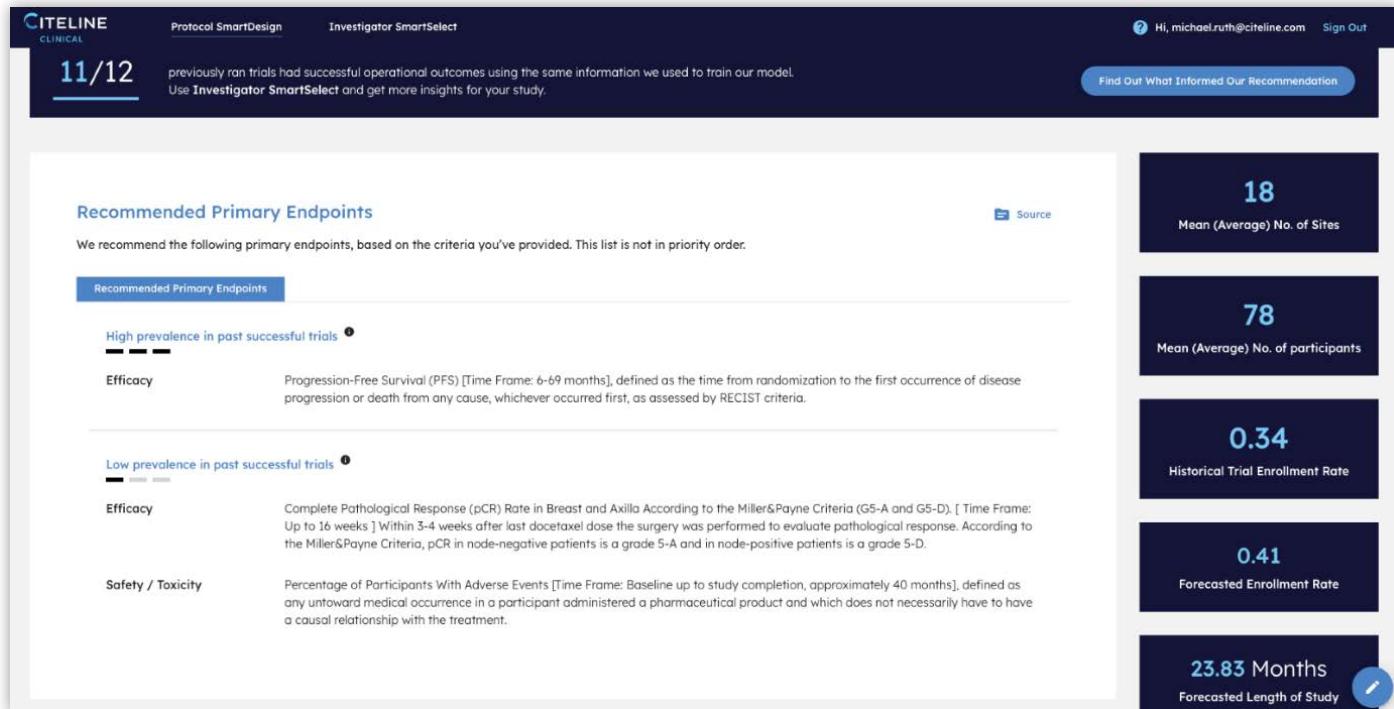
114
Mean (Average) No. of participants

0.44
Historical Trial Enrollment Rate

Use Case | Optimizing a Breast Cancer Clinical Trial with Data-Driven Solutions

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.



The screenshot shows the Citelene Clinical Protocol SmartDesign interface. At the top, it displays '11/12' and a message: 'previously ran trials had successful operational outcomes using the same information we used to train our model. Use **Investigator SmartSelect** and get more insights for your study.' On the right, there are five dark blue boxes with white text: '18 Mean (Average) No. of Sites', '78 Mean (Average) No. of participants', '0.34 Historical Trial Enrollment Rate', '0.41 Forecasted Enrollment Rate', and '23.83 Months Forecasted Length of Study' (with a blue edit icon).

Recommended Primary Endpoints

We recommend the following primary endpoints, based on the criteria you've provided. This list is not in priority order.

High prevalence in past successful trials

Efficacy Progression-Free Survival (PFS) [Time Frame: 6-69 months], defined as the time from randomization to the first occurrence of disease progression or death from any cause, whichever occurred first, as assessed by RECIST criteria.

Low prevalence in past successful trials

Efficacy Complete Pathological Response (pCR) Rate in Breast and Axilla According to the Miller&Payne Criteria (G5-A and G5-D). [Time Frame: Up to 16 weeks] Within 3-4 weeks after last docetaxel dose the surgery was performed to evaluate pathological response. According to the Miller&Payne Criteria, pCR in node-negative patients is a grade 5-A and in node-positive patients is a grade 5-D.

Safety / Toxicity Percentage of Participants With Adverse Events [Time Frame: Baseline up to study completion, approximately 40 months], defined as any untoward medical occurrence in a participant administered a pharmaceutical product and which does not necessarily have to have a causal relationship with the treatment.

Use Case | Optimizing a Breast Cancer Clinical Trial with Data-Driven Solutions

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.

Recommended Investigators

You requested recommendation for 150 investigators based on the criteria you provided above

Recommended Investigators Historical Investigators Selected Investigators (0)

Out of our extensive pool of 8254 we can only recommend 3549 investigators based on our model's analysis, presenting here the top 149 choices for your consideration. To see a description of the data in each column, hover over the column name.

Filters

Investigator	Trial Load	Specialties	Country/State/City	Primary Organization	Total Matching Trials	Total Ongoing Matching Trials	Total Ongoing Trials	Patient Count	Organic Patient
Contact Info	High	Internal Medicine/Oncology	United States California Duarte	City of Hope-Beckman Research Institute	9	0	10	774	2
Contact Info	High	Internal Medicine/Oncology	United States Minnesota Minneapolis	Allina Health - Piper Breast Center - Minneapolis	5	1	7	577	1
Contact Info	High	Hematology/Internal Medicine/Oncology	South Korea Seoul Seoul	Seoul National University Hospital (SNUH) - Breast Care Center	14	1	36	-	1
Contact Info	Medium	Hematology/Internal Medicine/Oncology	United States Pennsylvania Pittsburgh	University of Pittsburgh Medical Center (UPMC) - Passavant - McCandless	12	1	7	67	2
Contact Info	High	Hematology/Internal Medicine/Oncology	United States Arizona Phoenix	Cancer Treatment Centers of America (CTCA) - Outpatient Care Center - North Phoenix	2	0	2	263	8

Use Case | Optimizing a Breast Cancer Clinical Trial with Data-Driven Solutions

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.

CITELINE
CLINICAL

Protocol SmartDesign Investigator SmartSelect Sign Out

Recommended Investigators

Leveraging intelligence on investigator activity, performance, availability, industry experience, competitive landscape, and regulatory status, we've recommended the most suitable investigators who meet your study criteria.

[RECOMMENDATIONS](#) [STUDY ANALYTICS](#)

Forecasted Enrollment Rate

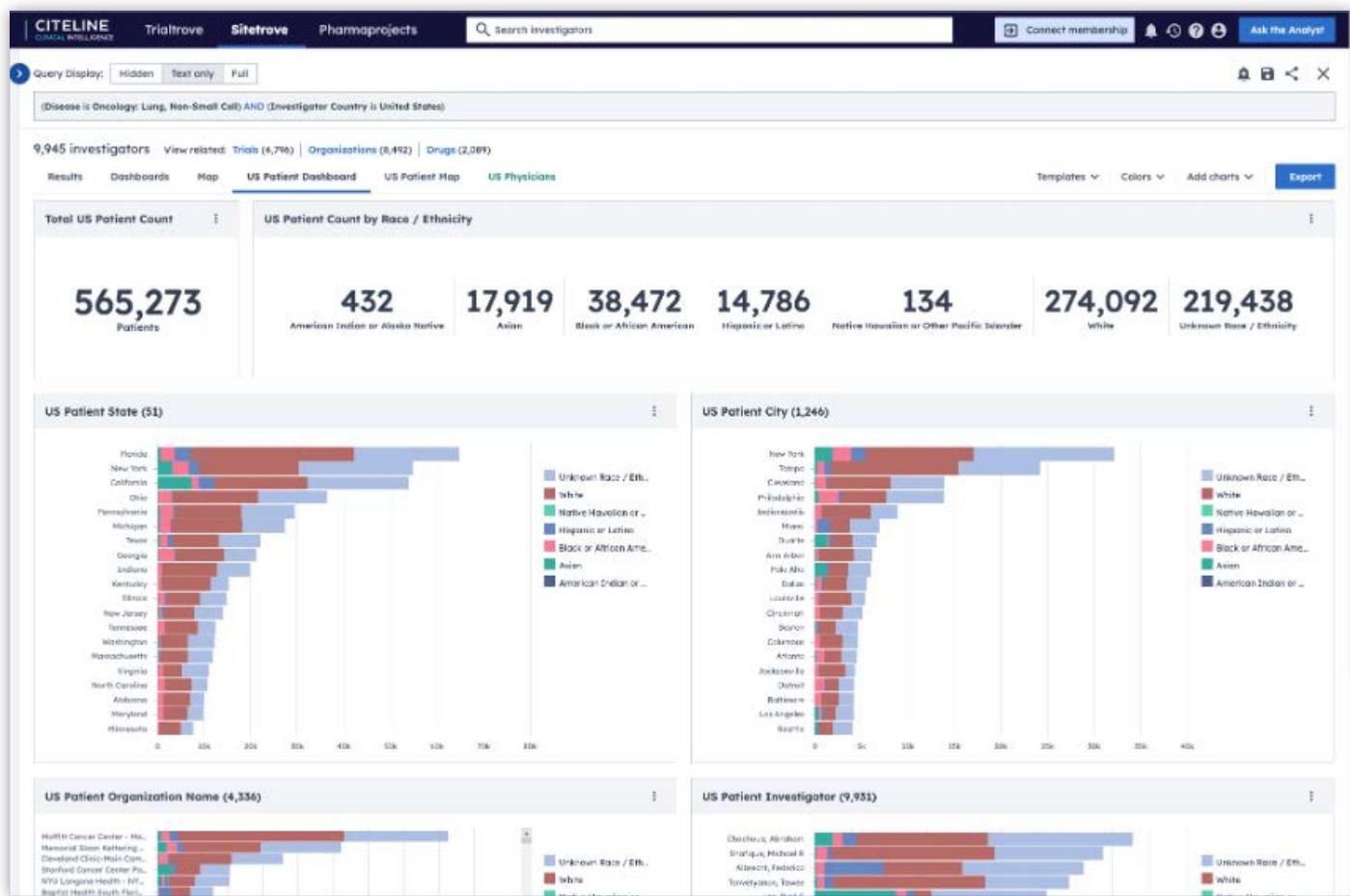
The Forecasted Enrollment Rates vary depending on the countries chosen in the Input Form, those recommended by our model, and the Investigators selected from the Recommendation table. We provide historically informed allocation percentages for both the selected and recommended countries. [View More Info](#)

Our Model's Suggested Countries			Based On The Investigators You Have Selected		
0.28 Forecasted Enrollment Rate	0.13 Historical Trial Enrollment Rate		0.3 Forecasted Enrollment Rate	0.13 Historical Trial Enrollment Rate	
38 Forecasted Trial Duration (Months)	6 Total Countries	19 Total Investigators	40 Forecasted Trial Duration (Months)	6 Total Countries	17 Total Investigators

Use Case | Optimizing a Breast Cancer Clinical Trial with Data-Driven Solutions

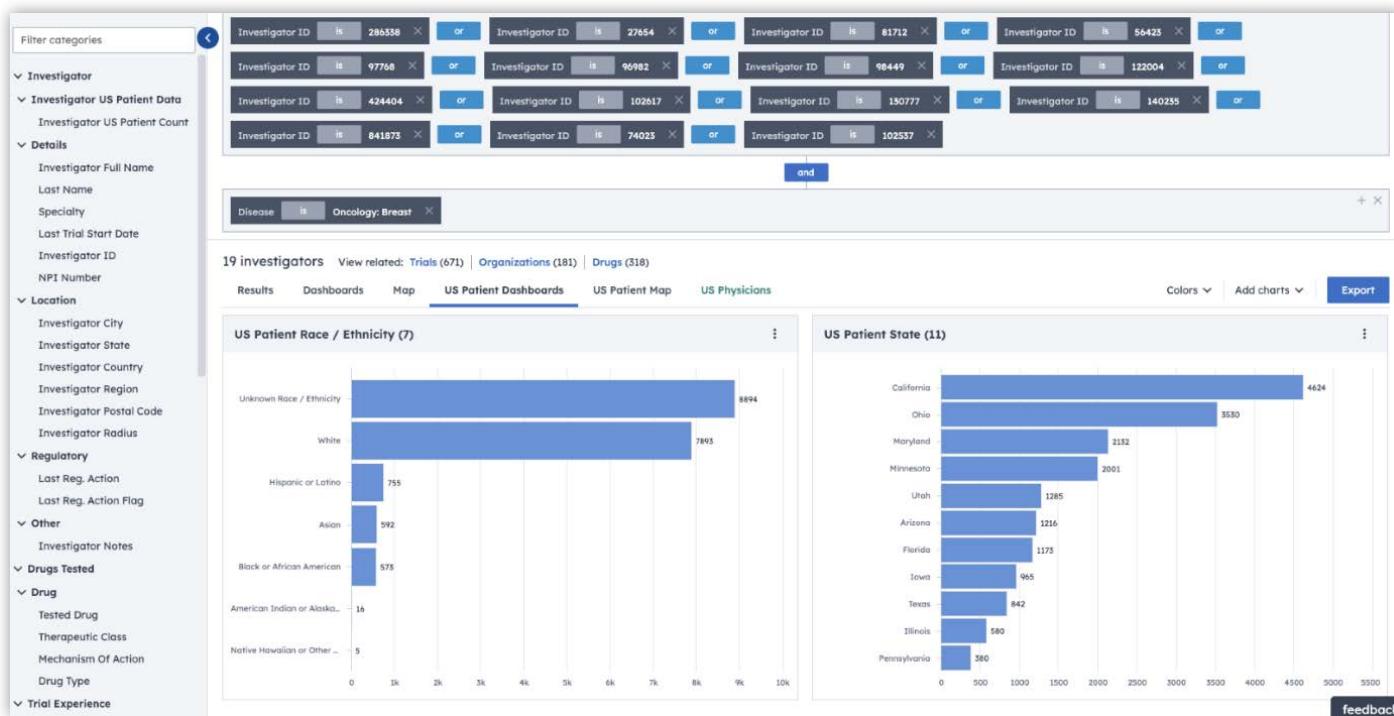
Step 4: Investigating Patient Populations and Diversity Goals

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



Use Case | Optimizing a Breast Cancer Clinical Trial with Data-Driven Solutions

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.



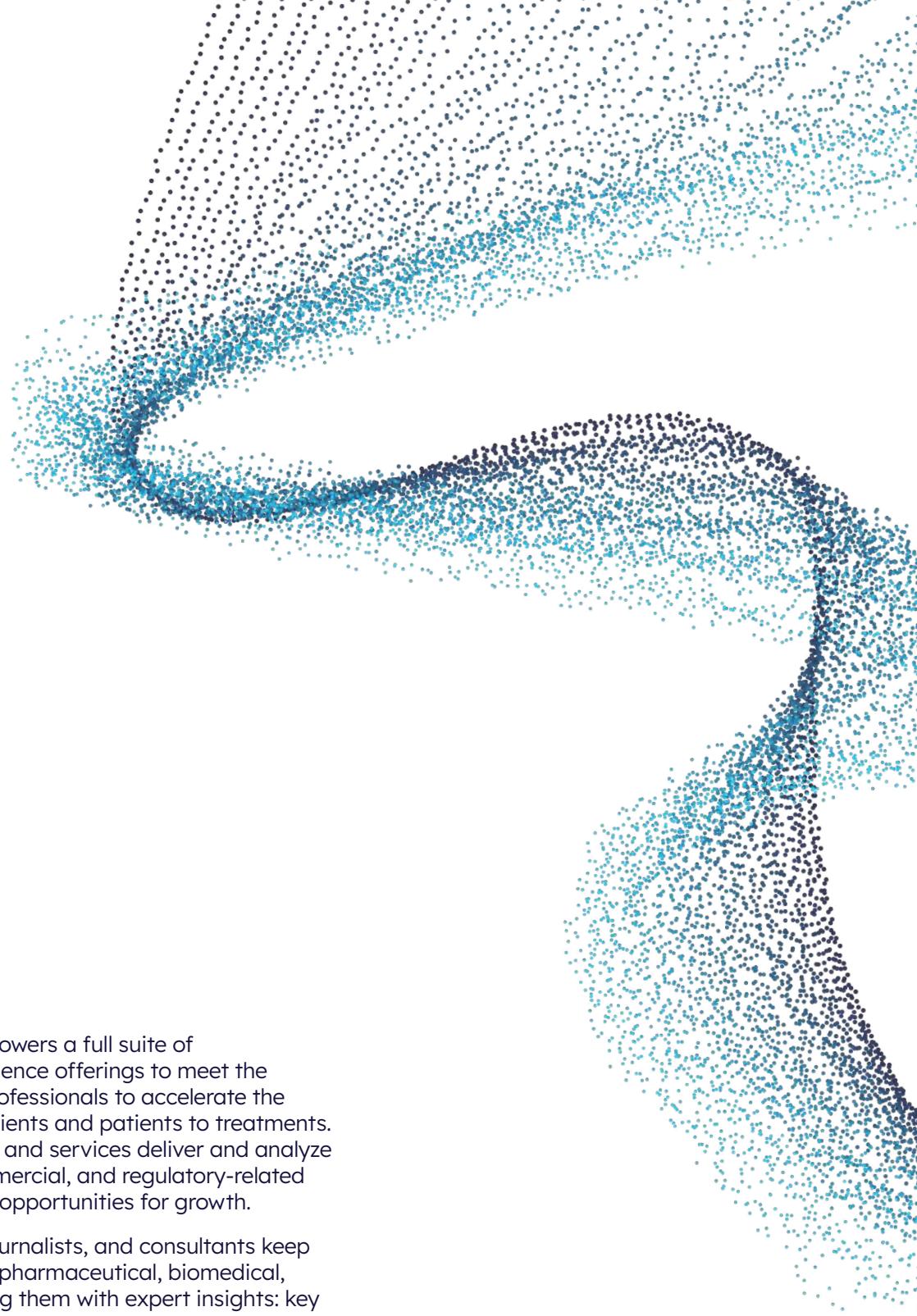
Step 5: Finalizing the Trial Plan

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 successfully 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.

[LEARN MORE](#)



About Citeline

Citeline, a [Norstellia](#) 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](#).