

Case Study

VISIONAL™

AI/ML-powered Insights for your next trial



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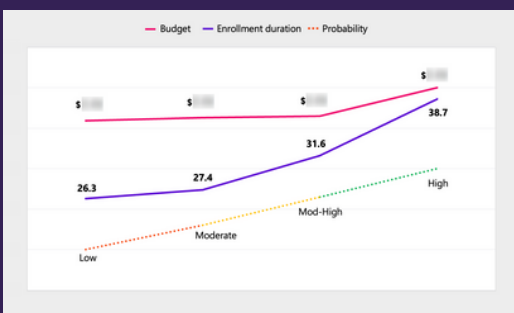
Sponsor Challenges

The study targeted patients pretreated with recently approved drugs. Our key criteria for country and site selection included local standards of care, historical performance in the indication, and current competition. After the initial planning had begun, the sponsor also requested 20% of patients from Latin America.

At a glance

A sponsor of a challenging breast cancer study needed to identify the optimal mix of countries and sites with similar experience and access to a hard-to-recruit subpopulation of breast cancer. Using internal and external data sources, PSI's VISIONAL™ platform compared thousands of feasible country-site combinations and recommended the optimal enrollment scenario to meet the sponsor's timelines and cost constraints.

Key Metrics



How VISIONAL™ Helps Make Strategic Decisions

Working with internal and external data sources and KOLs, PSI feasibility team quickly pulled all available data on standards of care, site performance, and historical enrollment rates, carefully curated for similarity. The dataset included 40+ countries in North America, South America, Europe, Asia-Pacific, and Africa. Using this trove of data, VISIONAL™ compared hundreds of country/site combinations, taking into account study costs and probability of success.



Customizable



Data-Driven



Predictive

We were able to easily adjust the constraints for regional patient quotas as well as additional requirements from the FDA and EMA after two rounds of protocol review.

Results

1

Optimal Enrollment Scenario

VISIONAL recommended the most optimal combination of sites, countries, and timelines based on the current landscape and historical benchmarks, while taking into account all constraints set by the sponsor and the FDA.

2

Cost vs. Speed

The system recommended the fastest and most cost-efficient scenario within the sponsor's budget range and timelines. We were also able to quickly evaluate alternative options:

- Faster scenarios with an acceptable risk level
- Longer but less expensive scenarios
- Scenarios that buffer for unexpected delays

3

Customizable and Adaptive Reports

The initial work done during the planning stage also provided the sponsor with peace of mind during the study launch with the ability to rapidly model new scenarios based on additional constraints/new requirements.