Winning the Biosimilar Race: Trastuzumab Biosimilar Phase III Breast Cancer Study

Sponsor Challenges

Speed and cost are key for biosimilar development, but development is not necessarily less complex than for a reference biologic. It requires state-of-the-art manufacturing expertise to ensure the biosimilar is "highly similar" with no significant clinical differences in safety profile, efficacy, and potency. Competition for patients against other studies with novel therapeutics often amplifies these challenges.

For PSI's transition of a global Phase 3 study of a trastuzumab biosimilar in HER2+ early breast cancer patients, it was critical to understand the patient flow from surgery to chemotherapy and back. An additional challenge was that the sponsor's previous CRO had placed the study primarily in Western countries, where higher standards of care and availability of trastuzumab are common.

At a glance

A sponsor of a global Phase 3 study of a trastuzumab biosimilar came to PSI after falling behind schedule with their current CRO. Drawing on PSI's biosimilar experience going back to the first such product ever approved by the FDA, we supported the sponsor in recruiting the required 800 patients in just over a year, leading to an EMA approval. Before getting there, though, we had to navigate additional challenges, including an unexpected delay that led to late site activation – just before the summer slow-down.

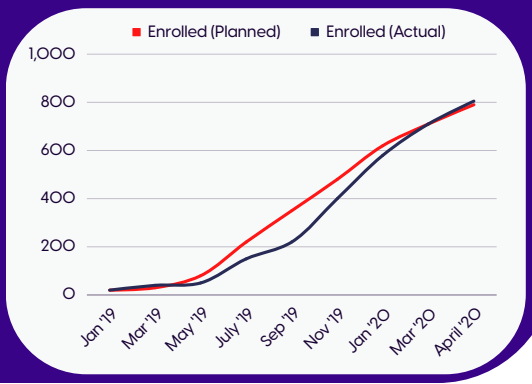
Key Metrics

1050
Screened Patients

800
Enrolled Patients

100
Trial Sites

10
Countries



How our team made a difference

- **Understanding the landscape:** PSI started by thoroughly assessing the country landscape and the product's reception by sites from our vast oncology network. We selected 100 sites in 10 countries in Eastern Europe, Asia-Pacific, Latin America, and South Africa. The US was also included due to prior expectations from the FDA. The data from other countries was perfectly acceptable.
- **Ready for the green light:** Our startup roadmap had to be adjusted when the sponsor put the study on hold for internal reasons, leading to almost half a year of delay in site activation. While waiting for the go-ahead to resume activation, the PSI team prepared contracts ahead of time and had vendors and sites in standby mode. The preparation paid off: as soon as PSI was notified, our teams activated the remaining sites almost simultaneously.
- **Relentless focus on patient enrollment:** Because of the delay, site activation occurred just before the summer break, leading to a slow start to patient enrollment. PSI and the sponsor decided to implement several enrollment-boosting measures and organized local investigator meetings for open discussion. A common concern we heard from sites was time and resources, so we optimized site processes to make their work more efficient and focused on the personal relationships of our CRAs and Medical Monitors with investigators and site staff. By optimizing our SDV strategy, close cost control, and the implementation of a blinding system that allowed us to perform drug accountability without the need for a whole unblinded team, we obtained important cost efficiencies.

Program Successes and Outcomes

- 800 patients enrolled in just over a year
- Last patient enrolled only 2 months later than initial goal, despite 6-month startup delay
- Successful FDA inspection and EMA approval