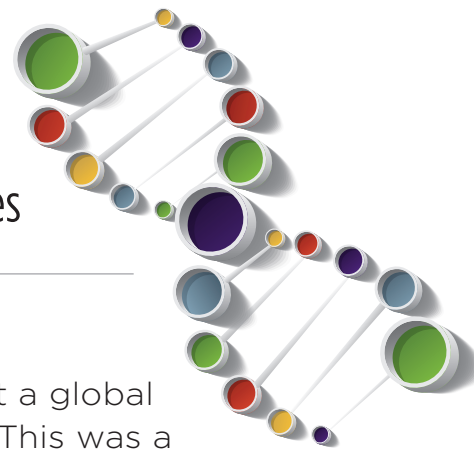


Accelerating Breast Cancer Study Enrollment

Innovative and Flexible Approach to Find Patients and Engage Sites



BACKGROUND

A small biotech company contracted PPD Biotech to conduct a global Phase III trial, which was already underway, for its sole asset. This was a metastatic breast cancer study, facing significant recruitment challenges and delays.



OBJECTIVE

PPD Biotech was tasked with bringing recruitment back on target in North America, South America and Japan.



CHALLENGES

Because this was a study in patients with metastatic breast cancer who had been through chemotherapy and surgery, yet were still progressing and still considered healthy, it was extremely difficult to find and enroll patients. The screen-fail rate was nearly 50 percent.

By the time we were brought on to rescue this study, recruitment had been lagging to the point where last patient in (LPI) was projected to be one year past target. Additionally, because this was a small company, they did not yet have the team nor the reputation to sufficiently encourage sites to step up recruitment. Also, many sites were unconvinced the potential treatment side effects (in this case, diarrhea) would be remedied by the trial.

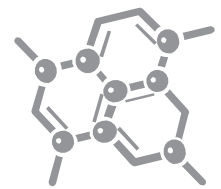


STRATEGY

Having scoured traditional methods of identifying new patients but not finding enough to move the needle, we realized that we would have to get creative. With the aim of developing innovative ways to find patients and increasing the percentage of actively enrolling sites, our strategy took two main forms.

New Pre-screening Methodology

We needed to be ready for immediate screening and enrollment of patients when they met the right criteria for the study. To make sure no time was lost or opportunities were missed, we transformed the



small biotech with

**one
ASSET**



**200+
PATIENTS**

across all countries
in a challenging
population



**ADAPTIVE
STRATEGY TO
MEET SMALL
BIOTECH NEEDS**

Accelerating Breast Cancer Study Enrollment

pre-screen database to understand and follow patients step-by-step through earlier lines of therapy, collecting valuable data including past therapy regimens and date of next disease assessment.

Close Site Engagement

Given this biotech company's limited ability to engage with investigators, PPD Biotech became the voice of the client with study sites. We leveraged site management calls to:

- Build rapport and keep investigators engaged.
- Offer one-on-one time for the client to meet with investigators to talk about the drug, its future potential and patient success stories.
- Counteract the negative "buzz" around the potential for diarrhea in patients by re-clarifying that the client was providing an effective prophylactic treatment for all patients.

In our pre-screen database, we also tracked site engagement, allowing our team to understand what has been communicated to sites and how sites responded. This provided our client with a data source they used to inform their management and investors of recruitment progress, as well as investigator perspectives on the treatment.

To move the needle with enrollment and better engage investigators, PPD Biotech became the voice of the client with sites and converted nearly all ambivalent sites to actively enrolling sites.

PPD[®] Biotech

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THE RESULTS

Our flexible approach and strategic focus delivered excellent results for the client.

- Within the first year, we doubled the percentage of actively enrolling sites, from 48 percent to 98 percent.
- Not only did we hit the original LPI milestone (projected to be delayed by more than one year when we took over the study), we exceeded it by 1.5 months.

The client was extremely satisfied and is currently on track to complete database lock on time.



100%
INCREASE
in active sites



Enrollment targets exceeded by

1.5
MONTHS