IDENTIFY. RECRUIT. RESULTS. AN ONCOLOGY CASE STUDY

A large, multi-national pharmaceutical company was conducting a randomized Phase II study in patients with HER2-positive metastatic breast cancer. Another CRO had started the study a year earlier, but patient recruitment was significantly behind schedule. Of 116 initiated sites, only 42 were active and only 77 patients had been randomized in 15 months, so Covance was called upon to rescue the study.

Understanding the Challenge

- Ensuring a smooth, efficient and effective hand-over of the project
- Performing a thorough analysis of current sites
- Identifying new sites through a feasibility analysis to improve recruitment rates and patient randomization

Exceeding Expectations by Making Solutions Real

After project initiation, we cross-referenced all participating sites with our Xcellerate® Clinical Trial Optimization® tool. Xcellerate is a unique, proprietary approach to forecasting, investigator and site selection, and clinical trial management that is designed to improve quality, reduce waste, decrease timelines and increase clinical return on investment. Accordingly, by using this tool, we were able to identify those sites in the study that, based on historical performance metrics, were not optimal for recruitment of breast cancer patients. Conversely, the tool enabled our team to identify historically high-performing sites that were not included in the study. Thus, using our insights gleaned from Xcellerate combined with our past experience in oncology trials, we proposed closing 31 non-performing sites and adding 51 new sites in both existing and new countries. This would allow our client to hone in on optimized sites for recruitment.

To facilitate open communication surrounding the project transfer, we conducted a series of face-to-face meetings with our client and the outgoing CRO. Clear status trackers were implemented to ensure that each stage of the handover was adequately monitored with defined responsibilities. In addition, we agreed to a risk management strategy that used a risk register to capture and score risks and to document mitigation activities. Furthermore, on-site handover meetings were arranged to ensure site staff were introduced to the new CRA. This demonstrated our commitment, both to the sites for a smooth transition and continued support, and to our client, as our myriad solutions were all designed to set them up for success.

In the end, 661 patients were screened – 33% at new sites and 452 patients randomized – 35% of which were at the new sites. These results closely reflected our projections, detailed at rescue, demonstrating the accuracy of Xcellerate®. Furthermore, the average recruitment rate increased dramatically: from 0.12 patients/site/month to 0.22 patients/site/month. Because of these solid

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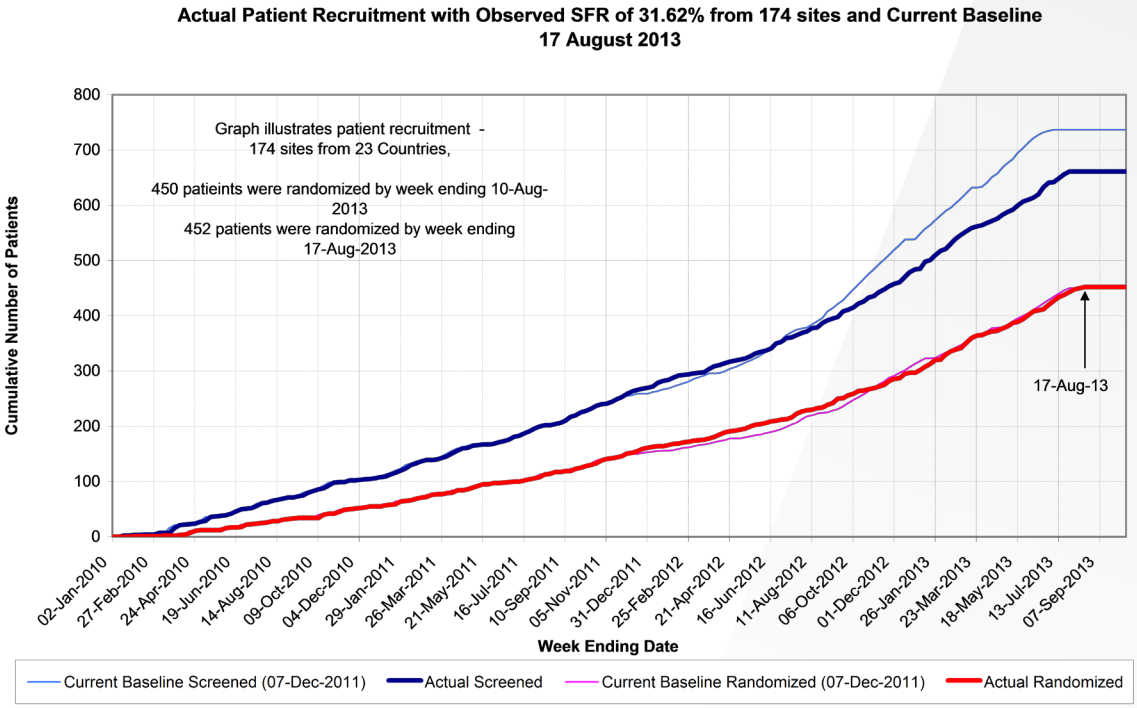
improvements, the project team was confident moving forward and planning future milestones including LPLV, interim and final database locks and regulatory filing dates.

Huge global trials can be complex and challenging. Let us be your partner and together, we can navigate the best path toward completion.



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