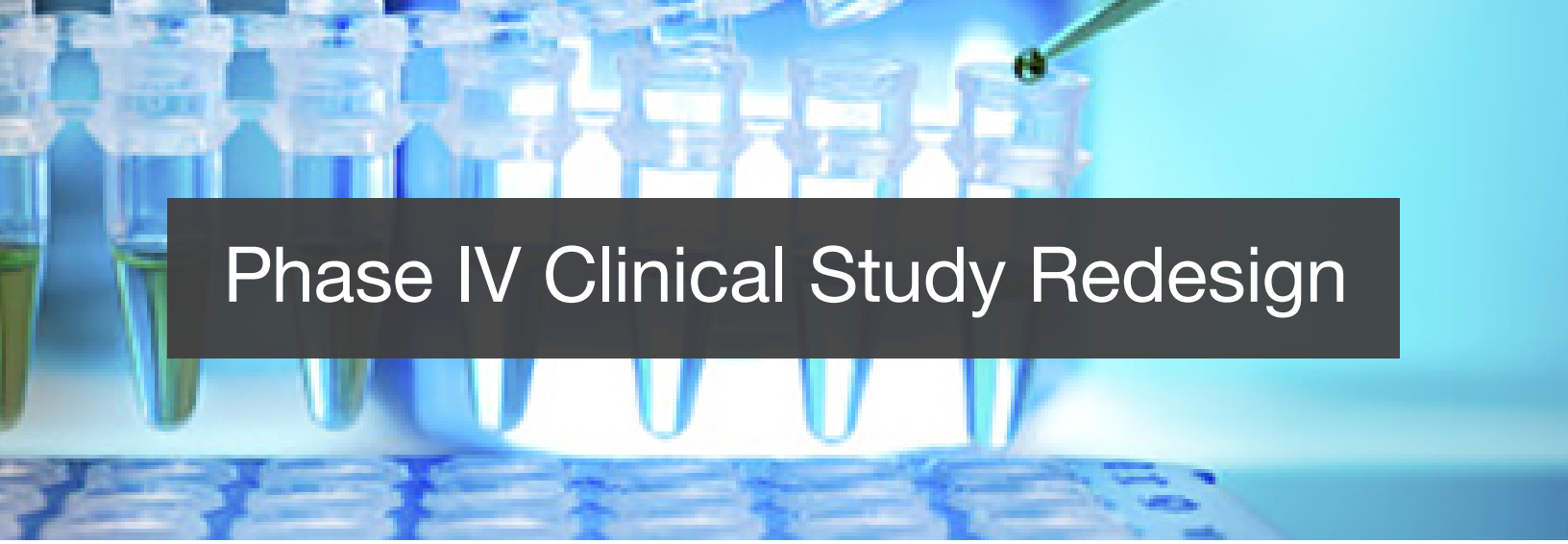

Phase IV Clinical Study Redesign

A major Pharmaceutical company needed assistance in the design, implementation and management of a phase IV clinical study involving a major hormone replacement therapy (HRT).

The Challenge

One of the major challenges was insufficient patient enrollment in the current studies. The enrollment of new patients was challenging because the side effect profile of HRT is still relatively ambiguous; the benefits versus risks is currently a hot topic of debate, making it difficult to obtain patient referrals. Wability collaborated with this client in the development of a comprehensive phase IV program. The program included the redesign and management of several studies in order to support the product claims and enhance market share.

Our Solution

Two studies were designed in order to allow patients who completed the initial study the opportunity to participate in a rollover open label extension. This was done to enhance both patient and investigator interest, as well as capitalize on the already established relationships with key OB/GYN centers around the country. Wability also recruited top investigators and sites to participate in these studies. Wability developed a comprehensive multi-tier strategy including news flashes, recruitment packages, investigator slide packs, recruitment of investigator-advocates, targeted teleconferences, Internet listings, and networking sites. “Thought leader” meetings were also employed to enhance program awareness and facilitate increased patient enrollment. Additionally, an incentive program was established in order further encourage patient participation. The introduction of open-labeled extensions meant that all patients, regardless of the initial randomization arm, (e.g., active or control) eventually received the therapy. The new study designs were extremely effective in getting out the message about the benefits of HRT, and educating the medical community about the availability, safety and efficacy of the product. Wability was able to maintain the integrity of the program, while significantly enhancing enrollment. Prior to the implementation of the study extension design, patient enrollment occurred at a rate of (2) patients per month, with twelve months projected to complete the study. The revised study design, and the new multi-tier approach employed to support the study, resulted in enhanced enrollment at a rate of (20) patients per month. Patient enrollment was complete two weeks before the date of closing enrollment.

The Results

As a result of Wability’s assistance in employing more attractive study design as well as opening up access to top OB/GYN centers around the country, we were able to rapidly accelerate patient enrollment in this large, multiphase national Phase IV program, exceeding our client’s expectations.

Contact us today to discuss your consulting needs:
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