CASE STUDY
February 2020

VANTAGE BIOTRIALS

Successful Clinical Trial Enrollment 12 Months Ahead of Schedule: Utilizing Quality by Design and Risk-Mitigation Strategies

Post Marketing Observational Epidemiological Study: Assessing Sponsor Drug's Real-life Effectiveness and Impact on Rare Dermatological Indication™ Burden of Illness and Health Care Resources Utilization

Vantage BioTrials was appointed by its Pharmaceutical Sponsor to manage their Phase IV Post Market Observational Epidemiological clinical trial in a rare dermatological disease. The set enrollment expectation by the Pharmaceutical Sponsor was to recruit 145 patients across 30 Canadian sites within 24 months. This target was set as a realistic expectation given the complexity and challenge of finding patients with the disease, as well as finding health care providers and dermatologists with sufficient understanding of the rare condition. Vantage BioTrials was mandated to fully manage the study (including site management, project management, clinical monitoring, and vendor management).

Vantage BioTrials efficiently completed the study and obtained the results necessary to answer the study's research questions and objectives, namely (1) to assess the Sponsor's drug for real-life effectiveness in the management of dermatological manifestations of the rare dermatological condition; (2) describe the profile and regional variations in terms of demographics, disease parameters, comorbidities, concurrent diseases, concomitant medication use, clinical course of the rare dermatological condition, and management by dermatologists of Canadian patients with the disease; (3) describe the burden of illness of the disease in Canada and estimate the impact of the Sponsor's drug on the patients in terms of physical and psychological quality of life, work productivity, health care resource utilization, and cost. Here's how we achieved and surpassed our Sponsor's expectations:

The anticipated 24-month enrollment time frame was **accelerated by twelve (12) full months**, allowing our Sponsor to include additional patients in their statistical analysis, and resulting in an *unprecedented 9-month early study completion.*

Quality by Design Strategies: Overcoming Key Challenges

Using an evaluation model called CMO (Context + Mechanism = Outcome), Vantage BioTrials' key factors to successfully implementing and managing this trial began with:

Context (i.e. the "what")

1. Our team focused on the Patient Journey and experiences by implementing a holistic approach to patient care.
2. A "fit for purpose" training was provided to all study staff to enhance skills and competencies.
3. We encouraged a working ethos that functions within a Lean Operational Model.
4. Site Engagement and Relationship Management strategies were implemented.

Mechanism (i.e. the "how")

Understand the Patient's Experience

- Our Project Manager identified and analyzed Key Risk Indicators (KRIs) related to patient recruitment and retention and put in place strategies to mitigate those risks.
- We gained understanding of the burden of disease and its co-morbidities through literature searches, team training with medical advisors, and educational forums with study coordinators and PIs.
- When possible, we interacted with and gained insights from patient advocacy groups regarding the disease in question. We also implemented those insights into the study's design/concept.

Training to Enhance Skills & Competencies

- We used knowledge from disciplines of psychology and behavioral science to provide tips on how to manage patients with the rare dermatological condition, especially since most suffer from related co-morbidities that lead to mental health issues.
- We set-up webinar Lunch'n'Learns to share best practices and to involve/engage study coordinators from across all sites.

Lean Operational Model

A centralized governance model is ideal which allows for a synergistic relationship to develop, and can introduce innovative approaches into the Sponsor-CRO relationship, increased trust and collaboration, joint investment to support performance improvement, and the ability to more easily share risk and commit to a long term relationship.

Site Engagement & Relationship Management

- We encouraged direct, timely and respectful communication with sites.
- Continuous and balanced amount of Site support, respecting and taking into consideration each site's workload and availability to answer queries/questions.
- Development of high-quality, professional-style Newsletters and e-blasts.
- Soliciting support from Sponsor's upper management & frequent communications.
- Use of existing resources/processes from the Sponsor's pool of experts.
- Recruited new and clinical research-naïve sites and provided close support to carry them through the burdensome process of running a clinical trial.

Outcome (i.e. the "wow")

By implementing the above CMO model and Quality by Design methods, Vantage BioTrials met the enrollment goal 12 months ahead of schedule. The transparent communication and honest collaboration between all stakeholders also played a key role in the successful completion of this project. Through effective relationship management, the sites received sufficient support to alleviate unforeseen hurdles, which enabled them the ease of conducting the trial and in-turn achieve their enrollment milestones.

About us

Vantage BioTrials, Inc. is a leading Canadian Contract Research Organization (CRO) that provides Phase I-IV clinical trial management services to international biopharmaceutical, biotechnology, generic pharma and medical device companies within North America and Europe.

We are experts in implementing Risk-Based Management through the use of Quality by Design (QbD) methodologies, which helps accelerate the conduct of a study and reduces overall risk.

To learn more about how we can add value to your clinical trials, please feel free to contact us at info@vantagebiotrials.com or visit us at www.vantagebiotrials.com.

[Ŧ] *Due to the rarity of the disease condition within Canada, the specific dermatological condition has been redacted to protect the identity & confidentiality rights of Vantage BioTrials' Pharmaceutical Sponsor.*