propharma

CASE STUDY

Obesity – Accelerated Timelines

Challenge

Customer: Mid-Size Biotech Company Therapeutic Area & Development

Stage: Phase 2 / Metabolic (Obesity)

Background: A new entrant into the US Market for an obesity investigational product needed to achieve rapid site activation and recruitment with 300+ patients enrolled within 3 months of the first patient visit.

Key Challenges:

- Accelerated Site Identification and Activation: Identification of all sites with expedited activation timelines.
- Rapid Enrollment Timeline: This is a compressed timeline in a US-only study. The sponsor increased the sample size by ~10% without extending the enrollment timeline. Sites need to be engaged for rapid recruitment.
- Patient Retention: Ensuring that patients, particularly those not experiencing the benefits of the investigational product, continue to participate in the study.
- Self-Administration of Investigational Product: Patients should be able to accurately administer the investigational product at home without supervision to prevent errors in administration.

Solution

- Streamlined Decision Making for Cross- functional Team: Utilizing highly skilled team members with deep therapeutic expertise to ensure project success. Providing unified leadership and oversight for efficient decision-making and maintaining focus on objectives.
- Accelerate the feasibility process: Develop streamlined feasibility strategies to support accelerated timelines. Select sites with a proven track record of recruiting in this disease.
- Incorporate Site Networks: Site networks utilize centralized systems for regulatory submissions, contract negotiations, and training, which can expedite these processes by minimizing redundancy and ensuring consistency across sites.
- Leverage augmented staff strategy through ProPharma Patient Services: Deployed ProPharma employee nurses for individualized outreach for patients to enhance compliance with the protocol and increase retention.
- Design Site / Patient training for Investigational Product Administration: A robust training for at-home administration of the IP using various media tools (video, printed images, slides, hands-on test-injections, etc.).

Results

Achieved high-quality results in a fast-paced, highly competitive study in the obesity therapeutic space with a multifaceted approach.

ProPharma has created a more streamlined process for feasibility and activation, and the team's dedication to strengthening relationships with sponsors and sites fosters the acceleration of the program.

- First site activated in less than 3 months from contract execution. ProPharma activated all 20 sites within 30 days.
- Surpassed recruitment target: ProPharma completed enrollment, including the increased sample size, within the 3-month timeline.
- The results of ProPharma's work led to the successful and compliant self-administration of the drug at home.

Contact us to learn how our experienced team can help ensure successful outcomes throughout the product lifecycle.

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