Case Study:

THE POWER OF PARTNERSHIP: HOW EARLY ENGAGEMENT DRIVES RAPID ACTIVATION & ENROLLMENT SUCCESS IN WOMEN'S HEALTH TRIAL

Women's health clinical development has long been under-resourced relative to its impact. As a result, women's health programs operate with minimal buffer for inefficiency or delay—just as the R&D environment has grown more complex, with intensified competition for site capacity, tougher recruitment, and gaps in cross-therapeutic-area expertise. **Against this backdrop, this case study shows how early, strategic engagement mitigated these constraints, enabling rapid site activation and accelerated enrollment, culminating in a successful study launch.**

SERVICES PROVIDED

- Regulatory Services
- Study Start-Up
- Clinical Trial Management
- Vendor Management
- Clinical Packaging & Supplies
- Patient Recruitment & Retention
- Data Management
- Medical Monitoring
- Pharmacovigilance
- Medical Writing
- Quality Assurance
- Integrated Services
  - Central Lab
  - Microbiology Lab:
    - Microscopy Guide Development

CHALLENGES

Experience and Bandwidth

- Company experienced in women's health indications with limited research and development background, requiring additional operational guidance and scientific expertise to maintain targeted study momentum.
- Site personnel also with limited niche-specific research experience, necessitating proactive support and tailored training.

Study Design and Patient Participation

- Longer treatment period than available options coupled with multiple follow-up visits presented challenges for capturing patient interest and ability to participate.
- A condensed screening window required rapid coordination across assessments and lab result timelines.

Operational and Logistical Coordination

- Alignment between specialty lab result processing timeline and site screening readiness is critical to maintain enrollment pace.
- Variability in local site equipment nuances and practices introduced additional complexity in implementing standardizing procedures.

THE SOLUTIONS

Early and Continuous Engagement

- Initiated collaboration early in the development process by supporting protocol design, synopsis development, and regulatory submissions.
- Maintained open and consistent and continuous communication with Sponsor and sites to ensure alignment from study start-up through execution.
- Data Integrity Unity: Critical ongoing analysis of study endpoints to result in early identification of issues and risks allowing Medpace to intervene.

Site Empowering and Training

- Implemented a combination of practice guideline refreshers with regulatory strategies to align all parties and ensure readiness prior to first patient.
- Provided targeted tools and resources, including patient selection and specimen collection guidance, to streamline study procedures.

Strategic Oversight and Support

- Leveraged centralized oversight and early data review to identify and resolve site-level challenges to alleviate impacting timelines.
- Reinforced adherence to scientific and regulatory standards to promote consistent, high-quality data collection across regions.

Site Discovery Conversations

- Highly granular conversations with sites to explore and uncover site-specific challenges in a collbaorative fashion.

RESULTS

Rapid Enrollment:
Enrollment rates met or exceeded projected/ contracted timelines due to strong early engagement and preparation.

Scalable Success:
During peak enrollment all sites were fully activated within 24 hours of investigational product (IP) arrival, driving enrollment rates beyond projections and accelerating overall study progress.

Sustained Collaboration:
Early partnership followed by continuous, collaborative, and supportive communication contributed to efficient execution and long-term study stability.