CASE STUDY

Study Startup in the U.S. for a European Sponsor

Client: CRO for a European Pharmaceutical Company

SITUATION

An EU-based CRO was working with a sponsor to set up a trial in Europe when the sponsor expressed interest in expanding the trial into Australia and the United States. This was a particularly ambitious expansion due to several factors: regulatory requirements and logistical realities associated with performing clinical research in the U.S., the proposed timelines and recruitment goals, and the fact that some of the U.S. sites the sponsor was hoping to work with were known to be challenging to quickly engage and activate.

Because these factors meant the expansion into the U.S. would create additional challenges, the CRO identified the need to secure a partner experienced in managing clinical research in the U.S. This led the CRO's team to reach out to Pearl for assistance with selecting and onboarding the U.S. sites and navigating FDA requirements on behalf of the sponsor.

SOLUTION

The Pearl team's overarching approach was a commitment to communication, and the team took the time at every turn to inform and advise the sponsor with clear and detailed guidance. Specific tasks included managing the process of securing the required IND, interfacing with the IRB, serving as an intermediary with sites and principal investigators, identifying and qualifying viable sites, and facilitating progress as sites moved toward activation and startup. Pearl also provided general advice and guidance regarding the U.S. process.

If one piece of the puzzle encountered a delay, the team swiftly moved other pieces into place, never allowing a moment to be wasted—always keeping the sponsor's goals and timeline top of mind.

RESULT

Drawing on its depth and range of experience, the Pearl team was able to guide the sponsor to select, well-qualified sites that were eager to participate in the trial and able to accommodate the aggressive timeline. Beyond this, Pearl helped the sponsor overcome numerous challenges and obstacles with confidence and successfully secure all the elements it needed to conduct its ambitious trial in the U.S.

Pearl Pathways™

Pearl Pathways is a comprehensive life science product development services company. Every day we strive to provide our customers top quality service, unyielding ethics, and efficient services through our team of experts. Pearl Pathways supports biopharmaceutical, medical device, and diagnostic companies as well as life science service providers with clinical, regulatory, and quality compliance needs. Our full-service central IRB supports all aspects of human research.

Clinical: Pearl Pathways' expertise in medical practice, science, ethics, and clinical research supports all phases of clinical development. Our expert consultants help implement customized solutions that drive efficient clinical research programs.

Regulatory (drug): Our consultants draw on over 20 years of scientific, industry, and FDA experience to translate your data into strategic drug development pathways, providing guidance from molecule to market while navigating a complex regulatory environment.

Regulatory (device): Delivering superior end-to-end product development and commercialization strategies, our consultants provide regulatory guidance that adds decades of industry and FDA regulatory expertise to your team, helping you balance risk, cost, and time to market.

Quality: From risk-based quality system development to gap analysis and remediation, our partnership helps reduce operational burdens, manufacturing impacts, regulatory agency warnings, and costly recalls—allowing you to focus on ongoing product quality assurance.

IRB: Our accredited independent review board ensures quality research, unyielding ethics, and human subject protection with individualized Expedited and Full Board reviews.

29 E McCarty Street, Suite 100
Indianapolis, IN

317.899.9341 ph
317.602.6554 fax

www.pearlpathways.com
www.pearlirb.com