CASE STUDY

Clinical Trial Protocol Writing & IRB Review

Client: Small Medical Device Company

SITUATION

A small medical startup device company submitted a 510k for a class II diagnostic device with strong established predicates. The existing five predicates were not required by the FDA to do clinical research studies in order to gain market clearance; however, FDA required this startup to execute a clinical trial. The diagnostic device technology included hardware, IT software, and mobile technologies. The client contacted Pearl for assistance with protocol writing and IRB review.

SOLUTION

Pearl assembled a team consisting of a medical writer and a biostatistician. They worked with other consultants and the internal client team. Early on, Pearl Pathways recognized that the regulatory strategy had not yet been agreed upon and, therefore, the protocol design was not set. Pearl worked diligently with the team to product a protocol that met FDA rigor and also produced meaningful data for post commercialization. Pearl also offered advice on clinical trial execution including requirements for the principal investigator and site qualifications throughout the engagement. The Pearl biostatistician designed a statistical analysis plan for the data, based on a sample size dictated by FDA.

RESULT

Pearl Pathways not only delivered the protocol to the client, but added value via their regulatory expertise and clinical design capabilities. This was the device company's first experience with a clinical trial, so it valued Pearl's staff's experience and leadership in the project. Lastly, this study qualified expedited review requirements and was reviewed and approved by members of Pearl IRB's board.

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.

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