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™

Company Overview

Pearl Pathways is obsessed with accelerating life science product development for our clients. We are an extension of our clients' teams; partnering with the clinical team, in-house regulatory experts, the quality compliance specialists, the quality auditors, and the senior leadership team to get life-saving diagnostics and therapeutics on the market sooner. Our talented staff is focused on getting critical research done, ensuring high quality and efficient manufacturing of products, accelerating global product registrations, and keeping our clients up to date on current regulatory and quality compliance best practices for life science product development.

Pearl IRB: Protecting human subjects and driving improved value and efficiency in protocol reviews and study implementation

Pearl ReGXP: Providing regulatory & quality consulting, and auditing services

Pearl IDEAS: Offering strategic product development assistance through our life science consulting practice

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