Regulatory Consulting & Clinical Study Support

Client: Startup Medical Device Company

Situation:

Prior to engaging Pearl Pathways, a small startup medical device company filed a 510k for their imaging device. During 510k negotiations, FDA requested additional data and for the company to design and execute a clinical study. At this point, the client reached out to Pearl to ask for their assistance with regulatory strategy, expertise in developing and executing a clinical study, and for support of ongoing FDA correspondence and meetings.

Solution:

Pearl's staff analyzed past FDA correspondence and existing clinical data then offered several different regulatory approaches for the client to consider. After the best fit path was chosen, Pearl worked closely with the client team to assemble the best data and resources required to prepare for a pre-IDE (Investigational Device Exemption) meeting. In addition, a Pearl medical writer led the efforts to take the clinical study designed and translated it to a usable protocol. Client will also use the Pearl IRB board as the Central IRB to review the protocol once FDA agrees to design.

Result:

The team is pleased with the progress to date. Pearl and the client have worked together to develop the proposed protocol and are in the middle of FDA discussions leading up to the pre-IDE meeting. In the meantime, clinical sites have been recruited, and the entire client management is aligned around the current approach.

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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