CASE STUDY

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™

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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