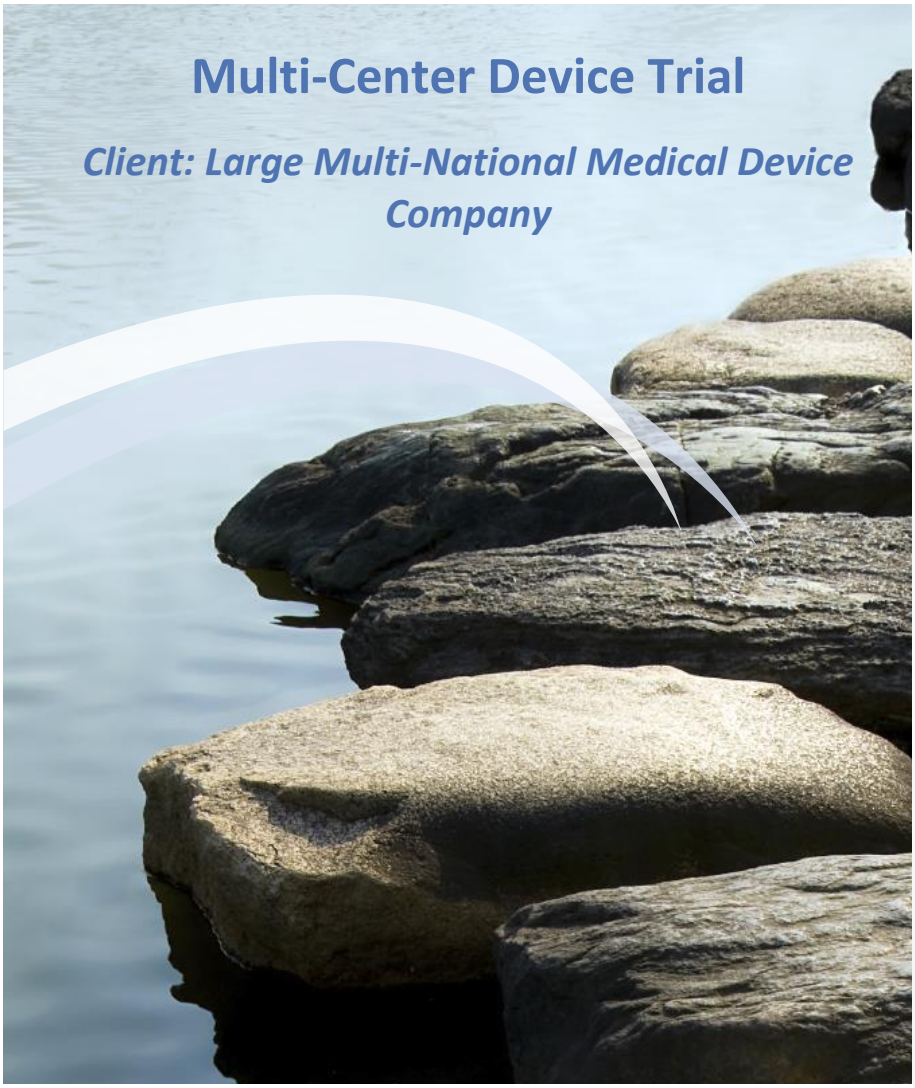
Multi-Center Device Trial

Client: Large Multi-National Medical Device Company



Situation:

A large medical device company contacted Pearl IRB to assist them with a post-marketing surveillance study for an implantable device. The scope of the study was to follow patients post-surgery for ten years tracking outcomes and safety. Pearl staff have noticed a trend of increased post-marketing surveillance studies for implantable devices across the board somewhat driven by pressures from FDA, as well as the market.

Solution:

The Pearl IRB Review Board reviewed the study protocol and template informed consent document (ICD).

Result:

Pearl IRB delivered an initial review in eight (8) business days. Reviews and all follow-up correspondence were performed in a professional and timely fashion. Further, Pearl ReGXP staff has been able to provide expert advice on several regulatory issues and ongoing FDA discussions poised by the sponsor.

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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