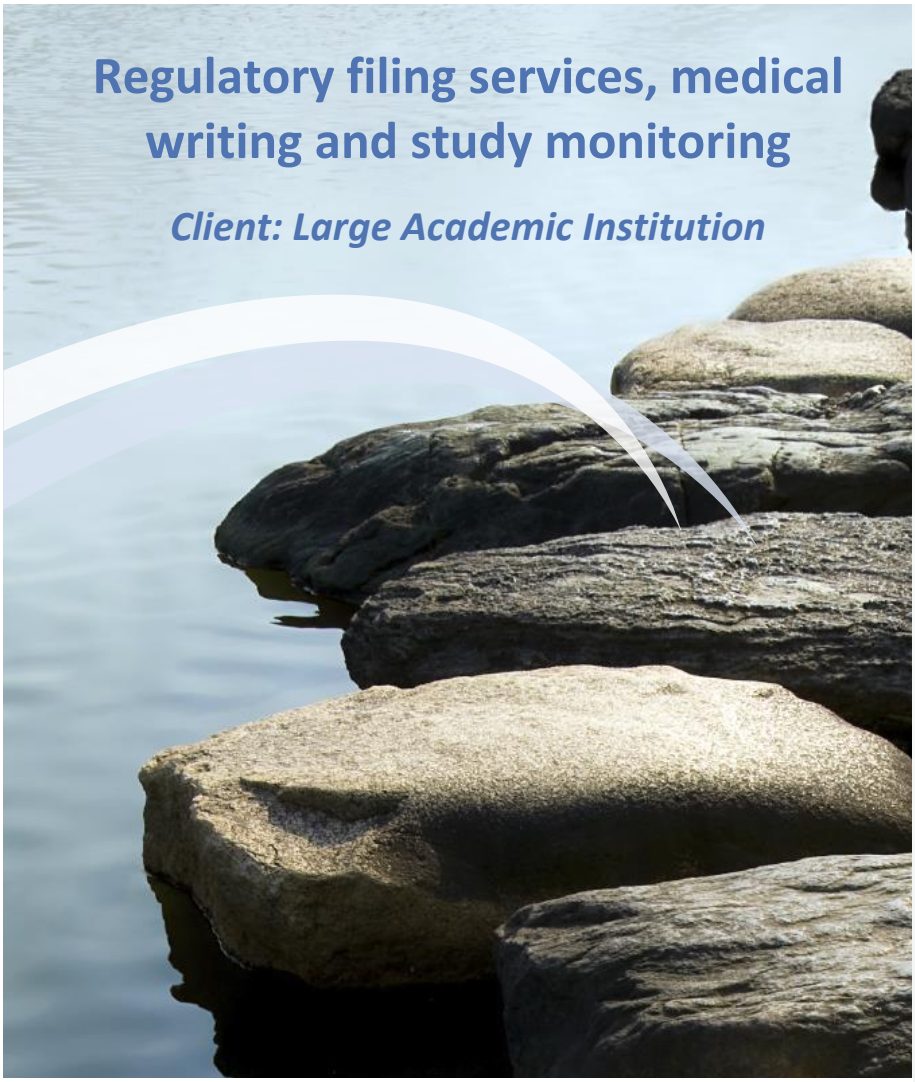
Regulatory filing services, medical writing and study monitoring

Client: Large Academic Institution



Situation:

One of the country's largest academic research institutions contacted Pearl Pathways asking for assistance with a clinical study and regulatory filing for a cardiac medical device.

Solution:

The scope of services Pearl was able to deliver included assistance in writing a protocol for an Investigator Initiated Trial (IIT), leading the filing of an Investigational Device Exemption (IDE) with FDA, and providing clinical study monitoring services. Pearl first worked with a protocol implemented in Europe and adapted it to meet the needs of the investigator implementing the IIT. Pearl also created informed consent documents, CRFs (case report forms), and will assist with the study report creation once the study is complete. Pearl provided a total of three staff members to support the various needs of this engagement. These included specialists in regulatory device strategy and filing, a medical writer, and an experienced clinical study monitor.

Result:

The client is pleased with project process but it is early. The team is on track to receive the IDE and implement the clinical study in under 90 days. Stay tuned and come back for more information!

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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