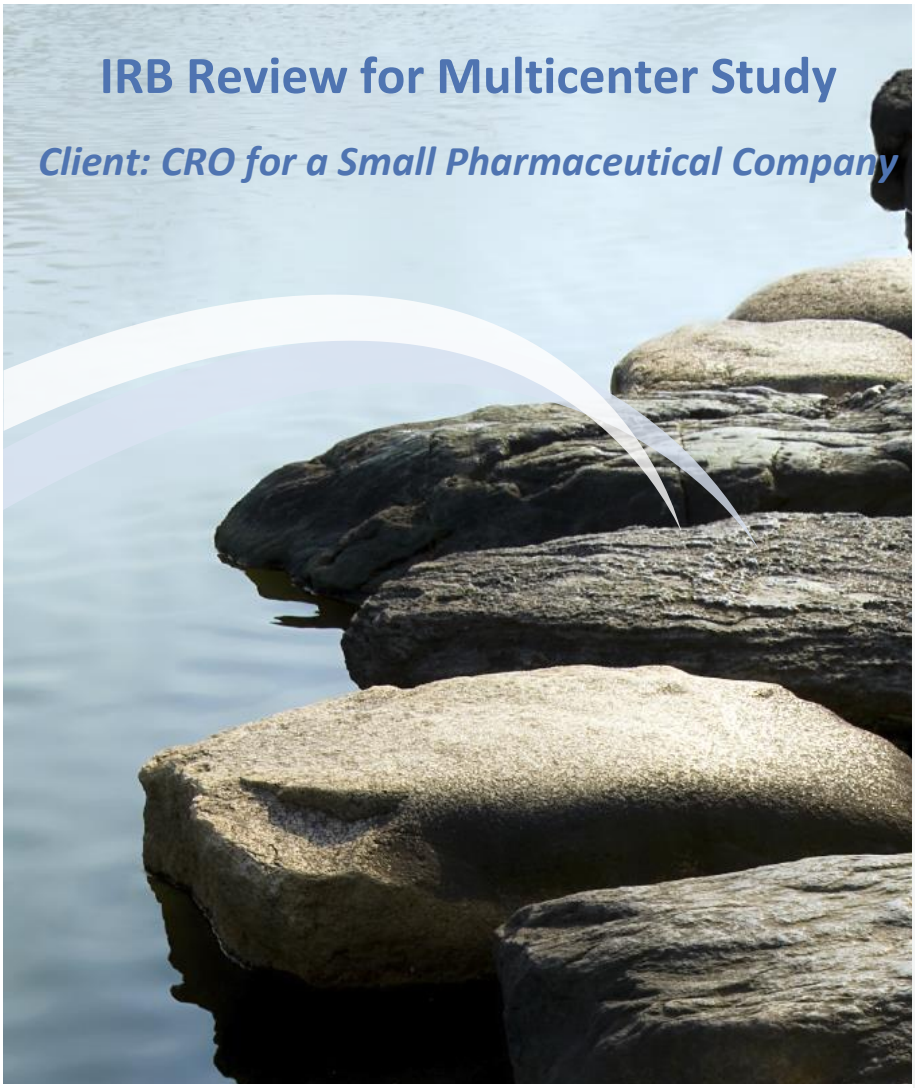
IRB Review for Multicenter Study

Client: CRO for a Small Pharmaceutical Company



Situation:

A small-tier pharmaceutical company and their CRO approached Pearl IRB with an urgent need for an IRB review for a multi-site Phase III registration study for their oncology drug. Client personnel had contacted another commercial IRB who had told them that it would be over a month before they could review their protocol.

Solution:

Pearl quickly slotted the study into the next IRB board meeting and committed to an eight day review process. While the timeline slipped one week due to client contract processes, Pearl IRB staff was able to easily move the study to the following board meeting.

Result:

Pearl demonstrated agility and flexibility in working through this with the sponsor and the CRO. From first day of contact, Board review was under fifteen days. The Board co-chair followed up with some requested information and changes, and the client was responsive resulting in a rapid study kick off.

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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