CASE STUDY

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™

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.

29 E McCarty Street, Suite 100
Indianapolis, IN

317.899.9341 ph
317.602.6554 fax

www.pearlpathways.com
www.pearlirb.com