CASE STUDY

Clinical Research Compliance Remediation

Client: Large Academic Hospital Institution

SITUATION

A large academic hospital institution approached Pearl to assist with remediation of an oncology clinical research department. The hospital's clinical trial enrollment had been suspended for a number of studies due to lack of GCP compliance.

SOLUTION

Pearl assembled a team of multiple individuals to assist with identifying issues and providing remediation. The team reviewed historical source data, case report forms, consent forms and all study documentation to close gaps. They filed correspondence with the IRB and wrote notes to file. Pearl was able to assist their client in just a few weeks to lift the suspension. Meanwhile, a second project need arose with the client. The effort for remediation activities across the institution impacted internal resource availability for the compliance department. As a result, Pearl was asked to provide two experienced GCP auditors to supplement the hospital's internal audit program. This action was needed in order to meet committed internal deadlines. Further, additional GCP compliance issues were discovered in another department. Pearl was asked to provide experts to review the documents, close gaps in the system, and remediate all study files.

RESULT

As a result of Pearls efforts, the suspension of clinical trial enrollment was lifted. The client was so pleased with the results of the oncology project; they engaged Pearl in two additional projects. The oncology department is activity enrolling and the institution has hired qualified individuals to keep the research moving. The compliance department is currently on target and on schedule with their internal audit program. Remediation efforts by Pearl continue for the last department, but are on track to conclude within 60 days.

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